Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

QUARON PAA family

Product types 2, 3 and 4

Peracetic acid

Case Number in R4BP: BC-MM034284-34

Evaluating Competent Authority: BE

Date: [10/08/2020]

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1 CONCLUSION

Application type	refMS/eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
NA-ADC	*BE*	BC-GJ082995-21	xx.xx.xxxx	Change in the name or address of the authorisation holder, which remains in the EEA: QUARON SAS becomes STOCKMEIER FRANCE SAS. Change in the name of the manufacturer of active substance QUARON SAS becomes STOCKMEIER FRANCE SAS.	Chapter 2.1.1

The biocidal product family is based on the equilibrium peracetic acid – hydrogen peroxide, in presence of acetic acid, as defined in the CAR of the active substance. The formulation of the whole family is liquid concentrate (SL).

Quaron PAA BPF is composed by 6 meta-SPC, each of them containing one biocidal product.

All products of the family are colourless translucent liquids with vinegar-like odour. Combined application with another product is not recommended or foreseen. The dilution stability tests have demonstrated no separated material for all products. The shelflife of the meta-SPCs 1, 2, 3, and 5 is set to 18 months, based on accelerated storage tests and ambient temperature storage tests. The shelflife of the meta-SPCs 4 and 6 is set to 12 months, based on efficacy tests on aged products. The mentions "Store at temperature no greater than 30°C" and "Protect from frost" are to be indicated on the label. For more details on physico-chemical parameters of the family, please refer to the corresponding section of the PAR.

The products of the *QUARON BPF* are intended to be used as disinfectants (Group 1) for PT2 (*Disinfectants and algaecides not intended for direct applications to humans or animals*); PT3 (*Veterinary Hygiene*) & PT4 (*Food & feed Area*) applications, divided into 6 Meta SPCs. The use in PT 5 is not granted at this stage, due to the efficacy assessment.

Target organisms include bacteria (also as biofilms), mycobacteria, fungi, viruses, phages, bacterial spores, and algae, relevant to the products' areas of use and in-use conditions.

Detailed function, field of use (including areas) and application rates of the products is described in the Efficacy part of the PAR and described in the section *# 2.1.4." Authorized use(s)*".

The BPF is intended to be used by professional user. The use of the products are safe pending particular conditions. For more details, please see the part risk assessement for human health**.**

Based on this risk assessment and on available data, an unacceptable risk to the STP and the aquatic compartment has been identified for the meta-SPC 3 (INDAL PAA 5) and meta-SPC 4 (INDAL PAA 15), when applied for disinfection of waste water and leachates in private sewage treatment plants, and for disinfection of small equipment by dipping and closed circulation circuits by cleaning-in-place in sewage treatment plants. The considered RMM are not considered as sufficient to mitigate risks to acceptable levels. Therefore, the uses #3-2, #3-4, #3-5 and #4-1 are not authorised.

Based on the existing knowledge and the data provided by the applicant, there is no indication of concern regarding the ED properties of the substances used in the biocidal product family QUARON PAA. If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product/family authorisation will be revised according to CAMarch18.Doc.7.b-final, section 2.3 (47).

2 ASSESSMENT REPORT

2.1 SUMMARY OF THE PRODUCT ASSESSMENT

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	**Country (if relevant)**
QUARON PAA Family	Belgium

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	QUARON SAS
	Address	3 rue de la Buhotière – Saint-Jacques de la Lande BP 89 152 35 091 Rennes CEDEX 9 France
Authorisation number	BE2020-0011-00-00	
Date of the authorisation	10/08/20	
Expiry date of the authorisation	10/08/30	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	QUARON SAS		
Address of manufacturer	3 rue de la Buhotière – Saint-Jacques de la Lande BP 89 152 35 091 Rennes CEDEX 9 France		
Location of manufacturing sites	QUARON SAS 3 rue de la Buhotière 35136 Saint-Jacques de la Lande France	QUARON SAS Rue des Criquiers 60 220 Formerie France	OQEMA s.r.o. Tovární 2093, 356 80 Sokolov Česka republika

2.1.1.4 Manufacturer(s) of the active substance(s)[1]

Active substance	Peracetic acid
Name of manufacturer	QUARON SAS
Address of manufacturer	3 rue de la Buhotière – Saint-Jacques de la Lande BP 89 152

[1] As stated in the CAR of a.s. the PAA is generated from AA and H2O2/water, and is not manufactured as such. Therefore it the manufacturing plant of PAA is in fact manufacturing plant of "starting materials".

	35 091 Rennes CEDEX 9 France	
Location of manufacturing sites	QUARON SAS 3 rue de la Buhotière 35136 Saint-Jacques de la Lande France	QUARON SAS Rue des Criquiers 60 220 Formerie France

2.1.2 Family composition and formulation

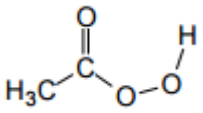
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐

No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Peracetic acid
IUPAC or EC name	Peroxyethanoic Acid
EC number	201-186-8
CAS number	79-21-0
Index number in Annex VI of CLP	607-094-00-8
Minimum purity / content	-
Structural formula	

2.1.2.2 Candidate(s) for substitution

The active substance Peracetic Acid contained in the biocidal formulations of the biocidal products family «QUARON PAA family» is not candidate for substitution in accordance with Article 10 of BPR.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family

The biocidal product family is based on the equilibrium peracetic acid – hydrogen peroxide, in presence of acetic acid, as defined in the CAR of the active substance. The formulation of the whole family is liquid concentrate (SL). The composition with ranges of concentration is explained in the table below.

Common name	IUPAC name	Function	CAS number	EC number	Content (%w/w)	
					Min	Max
Peracetic acid	Peroxyethanoic acid	Active substance	79-21-0	201-186-8	1.2	15.8
Hydrogen peroxide	Hydrogen peroxide	Active substance precursor	7722-84-1	231-765-0	13.0	35.5
Acetic acid	Acetic acid	Active substance precursor	64-19-7	200-580-7	2.2	13.8
Sulfuric acid	Sulfuric acid	Non-active substance	7664-93-9	231-639-5	0.0	13.5
Alcohol C10 ethoxylated	Decan-1-ol, ethoxylated	Non-active substance	26183-52-8	500-046-6	0.0	3.0
For the full composition, please refer to the Confidential Annex						

2.1.2.4 Qualitative and quantitative information on the composition of the biocidal products in the family

The biocidal family is composed by 6 meta-SPC, each of them containing one biocidal product. The composition of each meta-SPC, and, each product (2nd and 3rd level) are summarized below.

Meta SPC 1 :

Product "INDAL PAA 3.5" :

Common name	IUPAC name	Function	CAS number	EC number	Content (%w/w)
Peracetic acid	Peroxyethanoic acid	Active substance	79-21-0	201-186-8	2.6
Hydrogen peroxide	Hydrogen peroxide	Active substance precursor	7722-84-1	231-765-0	25.0
Acetic acid	Acetic acid	Active substance precursor	64-19-7	200-580-7	5.0
Sulfuric acid	Sulfuric acid	Non-active substance	7664-93-9	231-639-5	0.96
For the full composition, please refer to the Confidential Annex					

Meta SPC 2 :

Product "INDAL PAA 2.5":

Common name	IUPAC name	Function	CAS number	EC number	Content (%w/w)
Peracetic acid	Peroxyethanoic acid	Active substance	79-21-0	201-186-8	2.0
Hydrogen peroxide	Hydrogen peroxide	Active substance precursor	7722-84-1	231-765-0	35.5
Acetic acid	Acetic acid	Active substance precursor	64-19-7	200-580-7	2.2
Sulfuric acid	Sulfuric acid	Non-active substance	7664-93-9	231-639-5	0.3
For the full composition, please refer to the Confidential Annex					

Meta SPC 3 :

Product "INDAL PAA 5"[2]:

Common name	IUPAC name	Function	CAS number	EC number	Content (%w/w)
Peracetic acid	Peroxyethanoic acid	Active substance	79-21-0	201-186-8	5.3
Hydrogen peroxide	Hydrogen peroxide	Active substance precursor	7722-84-1	231-765-0	25.5
Acetic acid	Acetic acid	Active substance precursor	64-19-7	200-580-7	8.2
Sulfuric acid	Sulfuric acid	Non-active substance	7664-93-9	231-639-5	0.96
For the full composition, please refer to the Confidential Annex					

Meta SPC 4 :

Product "INDAL PAA 15"[3]:

2 This product is the "theoretical product 1" of the a.s. CAR
3 This product is the "theoretical product 2" of the a.s. CAR

Common name	IUPAC name	Function	CAS number	EC number	Content (%w/w)
Peracetic acid	Peroxyethanoic acid	Active substance	79-21-0	201-186-8	15.8
Hydrogen peroxide	Hydrogen peroxide	Active substance precursor	7722-84-1	231-765-0	25.0
Acetic acid	Acetic acid	Active substance precursor	64-19-7	200-580-7	13.8
For the full composition, please refer to the Confidential Annex					

Meta SPC 5 :
Product "INDAL OXY MOUSS":

Common name	IUPAC name	Function	CAS number	EC number	Content (%w/w)
Peracetic acid	Peroxyethanoic acid	Active substance	79-21-0	201-186-8	1.2
Hydrogen peroxide	Hydrogen peroxide	Active substance precursor	7722-84-1	231-765-0	13.0
Acetic acid	Acetic acid	Active substance precursor	64-19-7	200-580-7	5.75
Sulfuric acid	Sulfuric acid	Non-active substance	7664-93-9	231-639-5	0.5
Alcohol C10 ethoxylated	Decan-1-ol, ethoxylated	Non-active substance	26183-52-8	500-046-6	3.0
For the full composition, please refer to the Confidential Annex					

Meta SPC 6 :
Product "INDAL TAP 5":

Common name	IUPAC name	Function	CAS number	EC number	Content (%w/w)
Peracetic acid	Peroxyethanoic acid	Active substance	79-21-0	201-186-8	5.0

Common name	IUPAC name	Function	CAS number	EC number	Content (%w/w)
Hydrogen peroxide	Hydrogen peroxide	Active substance precursor	7722-84-1	231-765-0	21.0
Acetic acid	Acetic acid	Active substance precursor	64-19-7	200-580-7	5.95
Sulfuric acid	Sulfuric acid	Non-active substance	7664-93-9	231-639-5	13.5
For the full composition, please refer to the Confidential Annex					

For the complete qualitative and quantitative information on final composition of the whole biocidal product family and its biocidal products, please refer to the confidential annex of this document.

2.1.2.5 Information on technical equivalence

Not relevant.

2.1.2.6 Information on the substance(s) of concern

Please see Table 2.2.6.2: Substances of concerns analysed in the "QUARON PAA family" for more details.

The BPF contains 2 substances of concern: sulphuric acid and ethoxylated alcohol.

Sulphuric acid is identified as SOC because of its reference on the list of European Community workplace limit. Ethoxylated alcohol (Decan-1-ol, ethoxylated) is identified as a SOC because this ingredient contributes to the concentrate product classification of the meta-SPC 5 (product: INDAL OXY MOUSS) as Skin corrosion 1A, and more specifically as Eye damage 1.

Please note that Acetic Acid and Hydrogen Peroxide are considered as being part of the active substance PAA (as it is defined in the CAR of PAA). An assessment for Hydrogen Peroxide is nonetheless performed.

2.1.2.7 Type of formulation

SL: liquid concentrate

2.1.3 Hazard and precautionary statements

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Meta SPC 1: Biocidal product INDAL PAA 3.5

Classification	
Hazard category	Met. Corr. 1 Org. Perox. G Ox. Liq. 2 Skin corr. 1 STOT SE 3 Acute Tox. 4 (Oral) Acute Tox. 4 (Inhalation: dust, mist) Aquatic Chronic 1
Hazard statement	H290: May be corrosive to metals H272: May intensify fire; oxidiser H314: Causes severe skin burns and eye damage H335: May cause respiratory irritation H302: Harmful if swallowed H332: Harmful if inhaled H410: Very toxic to aquatic life with long lasting effects EUH071: Corrosive to the respiratory tract
Labelling	
Signal words	Danger GHS03 GHS05 GHS07 GHS09
Hazard statements	H290: May be corrosive to metals H272: May intensify fire; oxidiser H314: Causes severe skin burns and eye damage H302+H332: Harmful if swallowed or if inhaled H410: Very toxic to aquatic life with long lasting effects EUH071: Corrosive to the respiratory tract
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P220: Keep away from clothing and other combustible materials. P234: Keep only in original packaging P260: Do not breathe vapours P270: Do not eat, drink or smoke when using this product P271: Use only outdoors or in a well-ventilates area P273: Avoid release to the environment P280: Wear protective equipement P301+P312: IF SWALLOWED: Call a POISON Center or doctor/physician if you feel unwell. P301+P330+P331: If SWALLOWED: Rinse mouth. Do NOT induce vomiting P303+P361+P353: If ON SKIN: Remove immediately all contaminated clothing. Rinse skin with water P304+P340: If INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing P305+P351+P338:If IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P312: call a POISON CENTER or doctor/physician if you feel unwell P330: Rinse mouth P370 + P378: In case of fire: Use … for extinction. P390: Absorb spillage to prevent material damage P391: Collect spillage P403+P233 Store in a well-ventilates place P405: Store locked up P501: Dispose of contents/container in accordance with national/regional regulations

Note	Please, refer to Risk mitigation measures related to this Meta SPC to have specifications related to the conclusion of the Human Health Risk Assessment regarding P280.

Meta SPC 2: Biocidal product INDAL PAA 2.5

Classification	
Hazard category	Met. Corr. 1 Org. Perox. G Ox. Liq. 2 Skin corr. 1 STOT SE 3 Acute Tox. 4 (Oral) Acute Tox. 4 (Inhalation: dust, mist) Aquatic Chronic 2
Hazard statement	H290: May be corrosive to metals H272: May intensify fire; oxidiser H314: Causes severe skin burns and eye damage H335: May cause respiratory irritation H302: Harmful if swallowed H332: Harmful if inhaled H411: Toxic to aquatic life with long lasting effects EUH071: Corrosive to the respiratory tract
Labelling	
Signal words	Danger GHS03 GHS05 GHS07 GHS09
Hazard statements	H290: May be corrosive to metals H272: May intensify fire; oxidiser H314: Causes severe skin burns and eye damage H302+H332: Harmful if swallowed or if inhaled H411: Toxic to aquatic life with long lasting effects EUH071: Corrosive to the respiratory tract
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking P220: Keep away from clothing and other combustible materials P234: Keep only in original packaging. P260: Do not breathe vapours P270: Do not eat, drink or smoke when using this product P271: Use only outdoors or in a well-ventilates area P273: Avoid release to the environment P280: Wear protective equipement P301+P312: IF SWALLOWED: Call a POISON Center or doctor/physician if you feel unwell. P301+P330+P331: If SWALLOWED: Rinse mouth. Do NOT induce vomiting P303+P361+P353: If ON SKIN: Remove immediately all contaminated clothing. Rinse skin with water P304+P340: If INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing P305+P351+P338:If IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P312: call a POISON CENTER or doctor/physician if you feel unwell P330: Rinse mouth P370 + P378: In case of fire: Use … for extinction. P390: Absorb spillage to prevent material damage P391: Collect spillage P403+P233 Store in a well-ventilates place P405: Store locked up P501: Dispose of contents/container in accordance with national/regional regulations

Note	Please, refer to Risk mitigation measures related to this Meta SPC to have specifications related to the conclusion of the Human Health Risk Assessment regarding P280.

Meta SPC 3: Biocidal product INDAL PAA 5

Classification	
Hazard category	Met. Corr. 1 Org. Perox. F Skin corr. 1 STOT SE 3 Acute Tox. 4 (Oral) Acute Tox. 4 (Inhalation: dust, mist) Acute Tox 4 (dermal) Aquatic Chronic 1
Hazard statement	H290: May be corrosive to metals H242: Heating may cause a fire H314: Causes severe skin burns and eye damage H335: May cause respiratory irritation H302: Harmful if swallowed H332: Harmful if inhaled H312: Harmful in contact with skin H410: Very toxic to aquatic life with long lasting effects EUH071: Corrosive to the respiratory tract
Labelling	
Signal words	Danger GHS02 GHS05 GHS07 GHS09
Hazard statements	H290: May be corrosive to metals H242: Heating may cause a fire H314: Causes severe skin burns and eye damage H302+H312+H332: Harmful if swallowed, if in contact with skin or if inhaled H410: Very toxic to aquatic life with long lasting effects EUH071: Corrosive to the respiratory tract

Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking P220: Keep/Store away from combustible materials P234: Keep only in original packaging P260: Do not breathe vapours P270: Do not eat, drink or smoke when using this product P271: Use only outdoors or in a well-ventilates area P273: Avoid release to the environment P280: Wear protective equipement P301+P312: IF SWALLOWED: Call a POISON Center or doctor/physician if you feel unwell. P301+P330+P331: If SWALLOWED: Rinse mouth. Do NOT induce vomiting P303+P361+P353: If ON SKIN: Remove immediately all contaminated clothing. Rinse skin with water P304+P340: If INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing P305+P351+P338:If IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P312: call a POISON CENTER or doctor/physician if you feel unwell P330: Rinse mouth P370 + P378: In case of fire: Use … for extinction. P390: Absorb spillage to prevent material damage P391: Collect spillage P403+P235: Store in a well-ventilated place. Keep cool. P405: Store locked up P411: Store at temperatures not exceeding …º C. P420: Store separately. P501: Dispose of contents/container in accordance with national/regional regulations
Note	Please, refer to Risk mitigation measures related to this Meta SPC to have specifications related to the conclusion of the Human Health Risk Assessment regarding P280.

Meta SPC 4: Biocidal product INDAL PAA 15

Classification	
Hazard category	Met. Corr. 1 Org. Perox. E Skin corr. 1 STOT SE 3 Acute Tox. 4 (Oral) Acute Tox. 4 (Inhalation: dust, mist) Acute Tox. 3 (Dermal) Aquatic Chronic 1
Hazard statement	H290: May be corrosive to metals H242: Heating may cause a fire H314: Causes severe skin burns and eye damage H335: May cause respiratory irritation H302: Harmful if swallowed H332: Harmful if inhaled H311: Toxic in contact with skin H410: Very toxic to aquatic life with long lasting effects EUH071: Corrosive to the respiratory tract
Labelling	
Signal words	Danger GHS02 GHS05 GHS06 GHS09
Hazard statements	H290: May be corrosive to metals H242: Heating may cause a fire H314: Causes severe skin burns and eye damage H302 +H332: Harmful if swallowed or if inhaled H311: Toxic in contact with skin H410: Very toxic to aquatic life with long lasting effects EUH071: Corrosive to the respiratory tract
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P234: Keep only in original packaging. P260: Do not breathe vapours P264: Wash … thoroughly after handling P270: Do not eat, drink, or smoke when using this product P271: Use only outdoors or in a well-ventilated area P280: Wear protective equipment P301+P312: IF SWALLOWED: Call a POISON Center or doctor/physician if you feel unwell P301+P330+P331: If SWALLOWED: Rinse mouth. Do NOT induce vomiting P302+P352: IF ON SKIN: Wash with plenty of soap and water P303+P361+P353: If ON SKIN: Remove immediately all contaminated clothing. Rinse skin with water P304+P340: If INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing P305+P351+P338: If IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310: Immediately call a POISON Center or doctor/physician P330: Rinse mouth P363: Wash contaminated clothing before reuse P370+P378: In case of fire: Use … for extinction P273: Avoid release to the environnement P390: Absorb spillage to prevent material damage P391: Collect spillage P403+P235: Store in a well-ventilated place. Keep cool

	P405: Store locked up P411: Store at temperatures not exceeding …º C P420: Store separately P501: Dispose of contents/container in accordance with national/regional regulations
Note	Please, refer to Risk mitigation measures related to this Meta SPC to have specifications related to the conclusion of the Human Health Risk Assessment regarding P280.

Meta SPC 5: Biocidal product INDAL OXY MOUSS

Classification	
Hazard category	Met. Corr. 1 Org. Perox. G Ox. Liq. 2 Skin corr. 1 STOT SE 3 Acute Tox. 4 (Oral) Acute Tox 4 (Dermal) Aquatic Chronic 2
Hazard statement	H290: May be corrosive to metals H272: May intensify fire; oxidiser H335: May cause respiratory irritation H312: Harmful in contact with skin H314: Causes severe skin burns and eye damage H302: Harmful if swallowed H411: Toxic to aquatic life with long lasting effects EUH071: Corrosive to the respiratory tract
Labelling	
Signal words	Danger GHS03 GHS05 GHS07 GHS09
Hazard statements	H290: May be corrosive to metals H272: May intensify fire; oxidiser H314: Causes severe skin burns and eye damage H302+H312: Harmful if swallowed or if in contact with skin H411: Toxic to aquatic life with long lasting effects EUH071: Corrosive to the respiratory tract
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking P220: Keep away from clothing and other combustible materials P234: Keep only in original packaging. P260: Do not breathe vapours P264: Wash … thoroughly after handling P270: Do not eat, drink, or smoke when using this product P271: Use only outdoors or in a well-ventilated area P273: Avoid release to the environnement P280: Wear protective equipment P301+P312: IF SWALLOWED: Call a POISON Center or doctor/physician if you feel unwell P301+P330+P331: If SWALLOWED: Rinse mouth. Do NOT induce vomiting P303+P361+P353: If ON SKIN: Remove immediately all contaminated clothing. Rinse skin with water P304+P340: If INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing P305+P351+P338: If IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310: Immediately call a POISON Center or doctor/physician P330: Rinse mouth P363: Wash contaminated clothing before reuse P370 + P378: In case of fire: Use … for extinction. P390: Absorb spillage to prevent material damage P391: Collect spillage P403+P235: Store in a well-ventilated place. Keep cool P405: Store locked up P501: Dispose of contents/container in accordance with national/regional regulations

Note	Please, refer to Risk mitigation measures related to this Meta SPC to have specifications related to the conclusion of the Human Health Risk Assessment regarding P280.

Meta SPC 6: Biocidal product INDAL TAP 5

Classification	
Hazard category	Met. Corr. 1 Org. Perox. G Ox. Liq. 2 Skin corr. 1 STOT SE 3 Acute Tox. 4 (Oral) Acute Tox. 4 (Inhalation: dust, mist) Acute Tox. 4 (Dermal) Aquatic Chronic 1
Hazard statement	H290: May be corrosive to metals H272: May intensify fire; oxidiser H335: May cause respiratory irritation H314: Causes severe skin burns and eye damage. H302: Harmful if swallowed H312: Harmful in contact with skin H332: Harmful if inhaled H410: Very toxic to aquatic life with long lasting effects EUH071: Corrosive to the respiratory tract
Labelling	
Signal words	Danger GHS03 GHS05 GHS07 GHS09
Hazard statements	H290: May be corrosive to metals H272: May intensify fire; oxidiser H314: Causes severe skin burns and eye damage. H302+H312+H332: Harmful if swallowed, inhaled or in contact with skin H410: Very toxic to aquatic life with long lasting effects EUH071: Corrosive to the respiratory tract

Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P220: Keep away from clothing and other combustible materials. P234: Keep only in original packaging. P260: Do not breathe vapours P264: Wash … thoroughly after handling P270: Do not eat, drink, or smoke when using this product P271: Use only outdoors or in a well-ventilated area P273: Avoid release to the environnement P280: Wear protective equipment P301+P312: IF SWALLOWED: Call a POISON Center or doctor/physician if you feel unwell P302+P352: IF ON SKIN: Wash with plenty of soap and water P304+P340: If INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing P305+P351+P338: If IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310: Immediately call a POISON Center or doctor/physician P330: Rinse mouth P363: Wash contaminated clothing before reuse P370 + P378: In case of fire: Use … for extinction. P390: Absorb spillage to prevent material damage P391: Collect spillage P403+P235: Store in a well-ventilated place. Keep cool P405: Store locked up P501: Dispose of contents/container in accordance with national/regional regulations
Note	Please, refer to Risk mitigation measures related to this Meta SPC to have specifications related to the conclusion of the Human Health Risk Assessment regarding P280.

2.1.4 Authorised use(s)

In order to facilitate the understanding of every biocidal product contained in each Meta SPC but also, every use related to these Meta SPC, a table summarizing all the uses of the QUARON PAA family is presented here below. Please, refer to detailed information on authorized uses in the following points of the "Authorised uses" to have more information on each use number shown in the table related to its Meta SPC.

Biocidal Product Family	Meta SPC	Biocidal Product (Trade Name)	Product Type	Use #
QUARON PAA Family	Meta SPC 1 – INDAL PAA 3.5	INDAL PAA 3.5	PT 2	Use #1-1 Use #1-2
			PT 4	Use #1-3 Use #1-4 Use #1-5 Use #1-6
	Meta SPC 2 - INDAL PAA 2.5	INDAL PAA 2.5	PT 2	Use #2-1 Use #2-2 Use #2-3
	Meta SPC 3 - INDAL PAA 5	INDAL PAA 5	PT 2	Use #3-1 Use #3-2 Use #3-3 Use #3-4 Use #3-5 Use #3-6

Biocidal Product Family	Meta SPC	Biocidal Product (Trade Name)	Product Type	Use #
				Use #3-7
			PT 3	Use #3-8 Use #3-9 Use #3-10 Use #3-11 Use #3-12 Use #3-13
			PT 4	Use #3-14 Use #3-15 Use #3-16 Use #3-17
			PT 5	Use #3-18
	Meta SPC 4 - INDAL PAA 15	INDAL PAA 15	PT 2	Use #4-1 Use #4-2
			PT 4	Use #4-3 Use #4-4
	Meta SPC 5 - INDAL OXY MOUSS	INDAL OXY MOUSS	PT 3	Use #5-1
			PT 4	Use #5-2
	Meta SPC 6 - INDAL TAP 5	INDAL TAP 5	PT 4	Use #6-1

2.1.4.1 Use description

Meta SPC 1 :

Table 1. Use #1-1 – Disinfection of wasted water, leachates and liquid laboratory waste in closed systems in medical biology laboratories

Use #1-1: Disinfection of wasted water, leachates and liquid laboratory waste in closed systems in medical biology laboratories	
Product Type	2
Where relevant, an exact description of the authorised use	Waste water that can be biologically contaminated by activities in medical biology laboratories (anatomopathology, molecular biology microbiology services), in dialysis services, in mortuary services, etc. cannot be discharged in common waste water without being inactivated by "appropriated means" according to French regulation (arrêté du 16/07/2007). The effluents of the medical analysis machines are discharged in the equipment placed under laboratory bench: 1st compartment is a storage one, and when a sufficient level of liquid is reached, waste water is automatically transferred for a batch treatment in the 2nd compartment. During 30 min after automatic injection v/v of the disinfectant, the waste water is mixed: at the end of the treatment, inactivated waste water is then discharge in common waste water. Process is automatically controlled and managed by captors / probes / microprocessors.

Target organism (including development stage)	Bacteria (including mycobacteria) Yeasts Fungi Viruses
Field of use	Indoor & outdoor disinfection of wasted water (including leachates and liquid laboratory waste) in medical biology laboratories - In closed systems
Application method(s)	The concentrated product solution is automatically diluted in the waste water via a proportional automatic dosage system or a venture system according to use instructions of the proper application equipment. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	Under dirty conditions, at +20°C with a 30 min contact time: - For an effect on bacteria (including Legionella pneumophila, Salmonella typhimurium & Listeria monocytogenes) and on yeasts : 0.5 % - For an effect on fungi : 2% - For an effect on mycobacteria : 1.5% - For an effect on viruses : 1.5%
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 2. Use #1-2 – Disinfection of closed circulation circuits for cleaning in place in private and public pharmaceutical and cosmetic industries and institutions

Use #1-2: Disinfection of closed circulation circuits for cleaning in place in private and public pharmaceutical and cosmetic industries and institutions	
Product Type	2
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria (including spore-forming bacteria and mycobacteria) Yeasts Fungi Viruses Bacteriophages

Field of use	Indoors disinfection of closed circulation circuits for cleaning in place pharmaceutical and cosmetic industries and institutions.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system*. The product is then applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	Under clean conditions, at +20°C: Thoroughly clean & rinse the surfaces before disinfection. - For an effect on bacteria (including Salmonella typhimurium & Listeria monocytogenes) and on yeasts : 0.6% in a 5 min contact time - For an effect on fungi and on spore-forming bacteria : 2% in a 15 min contact time - For an effect on mycobacteria and on viruses : 1.5% in a 30 min contact time - For an effect on bacteriophages : 0,2% in a 15 min contact time
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

** Automatic system works with electric power and venturi system works only with fluid mechanics as water circulate rapidly in the pump and create a depression and then the product is aspired through a suction strainer. In terms of mix and loading and exposure, both systems are identical.*

Table 3. Use #1-3 – Surface disinfection by manual spraying in agri-food industry

Use #1-3: Surface disinfection by manual spraying in agri-food industry	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria (including spore-forming bacteria) Yeasts Fungi Viruses Bacteriophages

	Biofilms
Field of use	Indoors disinfection of open surfaces, materials or equipments, walls or floors by manual spraying in agri-food industry.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The product is then applied manually by spraying on surfaces. Device to be used for spraying: low-medium pressure (4 to 7 bars). After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	On hard non-porous surfaces with prior cleaning, at +20°C : Thoroughly clean & rinse the surfaces before disinfection. Make sure to wet surfaces completely. The application dose is 20mL/m². - For an effect on bacteria (including Salmonella typhimurium, Listeria monocytogenes & Legionella pneumophila) and on yeasts : 0.6% in a 5 min contact time - For an effect on fungi and on spore-forming bacteria : 2% in a 15 min contact time - For an effect on viruses: 1.5% in a 30 min contact time - For an effect on bacteriophages : 0,2% in a 15 min contact time - For an effect to remove biofilms : 0.4% in a 5 min contact time
Category(ies) of users	professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 4. Use #1-4 – Disinfection of closed circulation circuits for cleaning in place in agri food industry.

Use #1-4: Disinfection of closed circulation circuits for cleaning in place (with circulation) in agri food industry	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria (including spore-forming bacteria) Yeasts

	Fungi Viruses Bacteriophages Biofilms
Field of use	Indoors disinfection of closed circulation circuits for cleaning in place in agri-food industry.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The product is then applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	Under clean conditions, at +20°C : Thoroughly clean & rinse the surfaces before disinfection. - For an effect on bacteria (including Salmonella typhimurium, Listeria monocytogenes & Legionella pneumophila) and on yeasts : 0.6% in a 5 min contact time - For an effect on fungi and on spore-forming bacteria : 2% in a 15 min contact time - For an effect on viruses: 1.5% in a 30 min contact time - For an effect on bacteriophages : 0,2% in a 15 min contact time - For an effect to remove biofilms : 0.1% in a 15 min contact time
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 5. Use #1-5 – Surfaces disinfection by manual dipping in agri-food industry.

Use #1-5: Surfaces disinfection by manual dipping in agri-food industry.	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria (including spore-forming bacteria) Yeasts Fungi

	Viruses Bacteriophages Biofilms
Field of use	Indoor disinfection of surfaces by manual dipping in agri-food industry.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The product is then applied manually by dipping on surfaces. No heating takes places during dipping bathes. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	On hard non-porous surfaces with prior cleaning, at +20°C : Thoroughly clean & rinse the surfaces before disinfection. - For an effect on bacteria (including *Salmonella typhimurium, Listeria monocytogenes & Legionella pneumophila*) and on yeasts : 0.6% in a 5 min contact time - For an effect on fungi and on spore-forming bacteria : 2% in a 15 min contact time - For an effect on viruses : 1.5% in a 30 min contact time - For an effect on bacteriophages : 0.2% in a 15 min contact time - For an effect to remove biofilms : 0.1% in a 15 min contact time The dipping solution must be replaced by a fresh solution when it becomes visually polluted, and in all cases daily.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 6. Use #1-6 – Disinfection by automated spraying in closed professional washing machines in agri food industry and institutions, and institutional kitchens.

USE NOT GRANTED (for more details, see the efficacy assessment).

2.1.4.2 Use-specific instructions for use

Please refer to description of application method related to each use.

2.1.4.3 Use-specific risk mitigation measures

1) For Automatic pumping/mixing and loading applications for PT2 and 4: gloves, a protective coverall are required for professional users. General public is not allowed to enter areas where the biocidal product is connected manually to automatic mixing and loading systems. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

2) For manual spraying for PT 4 applications in agri-food industries: gloves, a protective coverall and a half-mask are required. General public is not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC

3) For manual dipping for all PT 4 applications: gloves and a protectiove coverall are required. No respiratory protective equipment (RPE) is necessary.

4) For all spraying application: "The treated surface is not allowed to get dry prior to rinsing."

5) For manual rinsing and manual draining for PT 2 and PT 4 applications: no personal protective equipment (PPE) and RPE is required.

6) The process of dilution has to be carried out using an automatic dosing system.

7) For all dipping applications: "No heating takes places during dipping. The room need to be sufficiently well ventilated with 10 air changes per hour.

8) After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.

9) Provide adequate ventilation before the general public re-enter treated areas.

10) The general public is not allowed to enter the outdoor application site and an area 20 m around during spraying and until the surface is rinsed.

11) The process of dilution has to be carried out using an automatic dosing system

12) For all M&L steps and for all spraying application: The room need to be sufficiently well ventilated with 10 air changes per hour.

13) For all spraying area: immediately leave the room after application.

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Likely direct or indirect effects:

- May be corrosive to metals.
- Harmful if swallowed or inhaled.
- Causes severe skin burns and eye damage.
- May cause respiratory irritation.
- Very toxic to aquatic life with long lasting effects.

First aid instructions:

- IF SWALLOWED : Rinse mouth. DO NOT induce vomiting.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- in case of skin contact, eye contact, inhalation and ingestion: "Get medical attention immediately".

Emergency measures to protect the environment:

- Avoid release to the environment
- Keep only in original container

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

Please refer to general directions for uses of the «QUARON PAA family» biocidal product family

2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

The shelflife of the meta-SPCs is set to 18 months.

The mentions "Store at temperature no greater than 30°C" and "Protect from frost" are to be indicated on the label.

Protect from light

Meta SPC 2 :

Table 1. Use #2-1 – Disinfection of water in private and public swimming pool, in balneotherapy basin and in private ponds

USE NOT GRANTED (for more details, see the efficacy assessment).

Table 2. Use #2-2 – Surfaces disinfection by manual spraying in private and public swimming pool, in balneotherapy basin and in private ponds

USE NOT GRANTED (for more details, see the Human Health Assessment assessment)

Table 3. Use #2-3 – Disinfection of closed circulation circuits for cleaning-in-place in private and public swimming pool, in balneotherapy basin, in private ponds and in sanitary hot water network.

Use #2-3: Disinfection of closed circulation circuits for cleaning-in-place in private and public swimming pool, in balneotherapy basin, in private ponds and in sanitary hot water network.	
Product Type	2
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses Unicellular green algae & blue-green algae (cyanobacteria)
Field of use	Indoors and outdoors disinfection of closed circulation circuits for cleaning-in-place in private and public swimming pool, in balneotherapy basin, in private ponds and in sanitary water network (radiators).
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The diluted product is applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	Under clean conditions, at +20°C : Thoroughly clean & rinse the surfaces before disinfection. - For an effect on bacteria (including Legionella pneumophila), on yeasts and on viruses (including Human rotavirus) : 0.4% in a 60 min contact time - For an effect on fungi : 2% in a 60 min contact time

	- For an effect on unicellular green algae & blue-green algae (cyanobacteria) : 2% in a 48h contact time
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

2.1.4.7 Use-specific instructions for use

Please refer to description of application method related to each use.

2.1.4.8 Use-specific risk mitigation measures

1) For manual mixing and loading for PT2 applications: gloves, a protective coverall, a face shield are required..

2) For Automatic pumping/mixing and loading applications for PT2: gloves, a protective coverall are required. General public is not allowed to enter areas where the biocidal product is connected manually to automatic mixing and loading systems. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

3) After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.

4) The general public is not allowed to enter the outdoor application site and an area 20 m around during application and until the surface is rinsed.

5) The process of dilution has to be carried out using an automatic dosing system, except for the use 2.3

6) For all M&L steps: The room need to be sufficiently well ventilated with 10 air changes per hour.

2.1.4.9 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Likely direct or indirect effects:

- May be corrosive to metals.
- Harmful if swallowed or if inhaled.
- Causes severe skin burns and eye damage.
- May cause respiratory irritation.
- Toxic to aquatic life with long lasting effects.

First aid instructions:

- IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- in case of skin contact, eye contact, inhalation and ingestion: "Get medical attention immediately".

Emergency measures to protect the environment:

- Avoid release to the environment
- Keep only in original container

2.1.4.10 Where specific to the use, the instructions for safe disposal of the product and its packaging

Please refer to general directions for uses of the «QUARON PAA family» biocidal product family

2.1.4.11 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

The shelflife is set to 18 months.

The mentions "Store at temperature no greater than 30°C" and "Protect from frost" are to be indicated on the label.

Protect from light

Meta SPC 3 :

Table 1. Use #3-1 – Surfaces disinfection by manual spraying in industrial areas

Use #3-1: Surfaces disinfection by manual spraying in industrial areas	
Product Type	2

Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria (including tuberculo-bacteria & spore-forming bacteria) Yeasts Fungi Viruses Bacteriophages Biofilms unicellular green algae & blue-green algae (cyanobacteria)
Field of use	Indoors disinfection of open surfaces, materials or equipments, walls or floors by manual spraying in industrial areas.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The product is then applied manually by spraying on surfaces. Device to be used for spraying: low-medium pressure (4 to 7 bars) in industrial areas. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	On hard non-porous surfaces with prior cleaning, at +20°C : Thoroughly clean & rinse the surfaces before disinfection. Make sure to wet surfaces completely. The application dose is 20 ml/m². - For an effect on bacteria (including Salmonella typhimurium, Listeria monocytogenes, Enterobacter cloacae, Lactobacillus brevis, Campylobacter jejuni & Legionella pneumophila) and on yeasts (including Dekkera bruxellensis & Saccharomyces cerevisae) : 0.5% in a 5 min contact time - For an effect on fungi (including Mucor racemosus) : 3.5% in a 5 min contact time - For an effect on tuberculo-bacteria : 0.5% in a 15 min contact time - For an effect on viruses : 1.5% in a 15 min contact time - For an effect on bacteriophages : 0.1% in a 15 min contact time - For an effect on spore-forming bacteria (including Bacillus cereus & Clostridium sporogenes) : 1% in a 15 min contact time - For an effect to remove biofilms : 0.2% in a 5 min contact time

	- For an effect on unicellular green algae : 1.2% in a 24 h contact time
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 2. Use #3-2 – Disinfection of closed circulation circuits by cleaning-in-place in sewage treatment plant. USE NOT AUTHORISED (for more details, see the environmental assessment).

Table 3. Use #3-3 – Disinfection of closed circulation circuits for cleaning in place in private and public pharmaceutical and cosmetic industries and institutions

Use #3-3: Disinfection of closed circulation circuits for cleaning in place in private and public pharmaceutical and cosmetic industries and institutions	
Product Type	2
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria (including tuberculo-bacteria) Yeasts Fungi Viruses Bacteriophages Biofilms Unicellular green algae & blue-green algae (cyanobacteria)
Field of use	Indoor disinfection of closed circulation circuits for cleaning in place in private and public pharmaceutical and cosmetic industries and institutions
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The product is then applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	Under clean conditions, at +20°C : Thoroughly clean & rinse the surfaces before disinfection. - For an effect on bacteria & on yeasts: 0.2% in a 5 min contact time

	- For an effect on fungi : 3.5% in a 5 min contact time - For an effect on tuberculo-bacteria: 0.5% in a 15 min contact time - For an effect on viruses : 1.5 % in a 15 min contact time - For an effect on bacteriophages : 0.1% in a 15 min contact time - For an effect to remove biofilms :0.2% in a 5 min contact time - For an effect on unicellular green algae & blue-green algae (cyanobacteria) : 1.2% in a 72h contact time
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 4. Use #3-4 – Surfaces disinfection by manual dipping of small equipment in an industrial sewage treatment plant :USE NOT AUTHORISED (for more details, see the environmental assessment).

Table 5. Use #3-5 – Disinfection of waste water and leachates in private sewage treatment plant:USE NOT AUTHORISED (for more details, see the environmental assessment).

Table 6. Use #3-6 – Disinfection of wasted water, leachates and liquid laboratory waste in closed systems in medical biology laboratories

Use #3-6: Disinfection of wasted water, leachates and liquid laboratory waste in closed systems in medical biology laboratories	
Product Type	2
Where relevant, an exact description of the authorised use	Waste water that can be biologically contaminated by activities in medical biology laboratories (anatomopathology, molecular biology microbiology services), in dialysis services, in mortuary services, etc. cannot be discharged in common waste water without being inactivated by "appropriated means" according to French regulation (arrêté du 16/07/2007). The effluents of the medical analysis machines are discharged in the equipment placed under laboratory bench: 1st compartment is a storage one, and when a sufficient level of liquid is reached, waste water is automatically transferred for a batch treatment in the 2nd compartment. During 30 min after automatic injection v/v of the disinfectant, the waste water is mixed: at the end of the treatment, inactivated waste water is then discharge in common waste water. Process is automatically controlled and managed by captors / probes / microprocessors.

Target organism (including development stage)	Bacteria (including mycobacteria) Yeasts Fungi Viruses
Field of use	Indoors disinfection of wasted water, leachates and liquid laboratory waste in closed systems in medical biology laboratories.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. No heating takes place during dipping bathes. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	In dirty conditions, at +20°C in a 30 min contact time : - For an effect on bacteria (including *Legionella pneumophila, E. faecium, E. coli K12, Salmonella typhimurium & Listeria monocytogenes*) & on yeasts : 0.5% - For an effect on fungi : 2% - For an effect on mycobacteria : 1% - For an effect on viruses (including Parvovirus) : 0.75 %
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 7. Use #3-7 – Laundry disinfection in professional laundry and washing machine USE NOT GRANTED (for more details, see the efficacy assessment).

Table 8. Use #3-8 – Milking claws shape disinfection

Use #3-8: Milking claws shape disinfection	
Product Type	3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts Viruses
Field of use	Indoors surface disinfection of milking parlour systems by manual spraying.

Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The milking claws are sprayed with the diluted product, using a semi-automatic low pressure spraying system. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	Thoroughly clean & rinse the surfaces before disinfection. Make sure to wet surfaces completely. The application dose is 20 ml/m. On hard non-porous surfaces with prior cleaning, at +20°C : - For an effect on bacteria & on yeasts: 0.6% in a 15 min contact time - For an effect on viruses: 0.5 % in a 5 min contact time
Category(ies) of users	Professionals users
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 9. Use #3-9 – Surface disinfection by manual dipping in fish farming industry

Use #3-9: Surface disinfection by manual dipping in fish farming industry	
Product Type	3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria (including mycobacteria) Yeasts Fungi Viruses Unicellular green algae & blue-green algae (cyanobacteria)
Field of use	Outdoors and indoors disinfection of surfaces by manual dipping in fish farming industry.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The diluted product is applied automatically and continuously to containers during the time of treatment. No heating takes place during dipping bathes. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.

Application rate(s) and frequency	On hard non-porous surfaces with prior cleaning, at +20°C : Thoroughly clean & rinse the surfaces before disinfection. - For an effect on bacteria & on yeasts: 0.6% in a 15 min contact time - For an effect on fungi : 2% in a 15 min contact time - For an effect on mycobacteria : 2% in a 30 min contact time - For an effect on viruses : 0.1 % in a 15 min contact time - For an effect on unicellular green algae : 1.2% in a 24h contact time The dipping solution must be replaced by a fresh solution when it becomes visually polluted, and in all cases daily.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 10. Use #3-10 – Disinfection of closed circulation circuits by cleaning-in-place in fish farming industry

Use #3-10: Disinfection of closed circulation circuits by cleaning-in-place in fish farming industry	
Product Type	3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses Unicellular green algae & blue-green algae (cyanobacteria)
Field of use	Outdoors and indoors disinfection of surfaces in closed circulation circuits by cleaning-in-place in fish farming industry.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The diluted product is applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	In clean conditions, at +10°C :

	Thoroughly clean & rinse the surfaces before disinfection. - For an effect on bacteria & on yeasts: 0.6% in a 15 min contact time - For an effect on fungi : 2% in a 15 min contact time - For an effect on viruses : 0.1 % in a 15 min contact time - For an effect on unicellular green algae & blue-green algae (cyanobacteria) : 1.2% in a 72h contact time
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 11. Use #3-11 – Surfaces disinfection by manual dipping of small equipment in livestock housing

Use #3-11: Surfaces disinfection by manual dipping of small equipment **in livestock housing**	
Product Type	3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria (including mycobacteria) Yeasts Fungi Viruses Unicellular green algae & blue-green algae (cyanobacteria)
Field of use	Indoors disinfection of surfaces by manual dipping of small equipment in livestock housing.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The diluted product is applied by manual dipping of surfaces. No heating takes place during dipping bathes. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	On hard non-porous surfaces with prior cleaning, at +20°C : Thoroughly clean & rinse the surfaces before disinfection. - For an effect on bacteria & on yeasts: 0.6% in a 15 min contact time - For an effect on fungi : 2% in a 15 min contact time - For an effect on mycobacteria : 2% in a 30 min contact time - For an effect on viruses : 0.1 % in a 15 min contact time

	- For an effect on unicellular green algae : 1.2% in a 72h contact time The dipping solution must be replaced by a fresh solution when it becomes visually polluted, and in all cases daily.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 12. Use #3-12 – Surfaces disinfection by manual spraying in livestock housing

Use #3-12: Surfaces disinfection by manual spraying in livestock housing	
Product Type	3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria (including mycobacteria) Yeasts Fungi Viruses unicellular green algae
Field of use	Indoors disinfection of surfaces by manual spraying in livestock housing.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The diluted product is applied manually by spraying on surfaces. Device to be used for spraying: low-medium pressure (4 to 7 bars). After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	On hard non-porous surfaces with prior cleaning, at +20°C : Thoroughly clean & rinse the surfaces before disinfection. Make sure to wet surfaces completely. The application dose of diluted product is 20 ml/m². - For an effect on bacteria & on yeasts: 0.6% in a 15 min contact time - For an effect on fungi : 2% in a 15 min contact time - For an effect on mycobacteria : 2% in a 30 min contact time - For an effect on viruses : 0.1 % in a 15 min contact time

	- For an effect on unicellular green algae : 1.2% in a 24h contact time
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 13. Use #3-13 – Disinfection of closed circulation circuits (drinking water and feed) by cleaning-in-place in livestock housing

Use #3-13: Disinfection of closed circulation circuits (drinking water and feed) by cleaning-in-place in livestock housing	
Product Type	3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses unicellular green algae & blue-green algae (cyanobacteria)
Field of use	Indoors surface disinfection in closed circulation circuits by cleaning-in-place in livestock housing.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The diluted product is then applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	In clean conditions, at +10°C : Thoroughly clean & rinse the surfaces before disinfection. - For an effect on bacteria & on yeasts: 0.6% in a 15 min contact time - For an effect on fungi : 2% in a 15 min contact time - For an effect on viruses : 0.1 % in a 15 min contact time - For an effect on unicellular green algae & blue-green algae (cyanobacteria) : 1.2% in a 72h contact time
Category(ies) of users	. professionals

Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 14. Use #3-14 – Surfaces disinfection by manual spraying in agri-food industry

Use #3-14: Surfaces disinfection by manual spraying in agri-food industry	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria (including spore-forming bacteria) Yeasts Fungi Viruses Bacteriophages Biofilms
Field of use	Indoors disinfection surfaces by manual spraying in agri-food industry.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The product is then applied manually by spraying on surfaces. Device to be used for spraying: low-medium pressure (4 to 7 bars). After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	On hard non-porous surfaces with prior cleaning, at +20°C : Make sure to wet surfaces completely. Thoroughly clean & rinse the surfaces before disinfection. The application dose is 20 ml/m². - For an effect on bacteria (including *Salmonella typhimurium, Listeria monocytogenes, Enterobacter cloacae, Lactobacillus brevis, Campylobacter jejuni & Legionella pneumophila*) and on yeasts (including *Dekkera bruxellensis & Saccharomyces cerevisae*) : 0.5% in a 5 min contact time - For an effect on fungi (including *Mucor racemosus*) : 3.5% in a 5 min contact time - For an effect on viruses : 1.5% in a 15 min contact time - For an effect on bacteriophages : 0.1% in a 15 min contact time - For an effect on spore-forming bacteria (including *Bacillus cereus & Clostridium sporogenes*) : 1% in a 15 min contact time

	- For an effect to remove biofilms0.2% in a 5 min contact time
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 15. Use #3-15 – Disinfection of closed circulation circuits by cleaning-in-place in agri-food industry

Use #3-15: Disinfection of closed circulation circuits by cleaning-in-place in agri-food industry	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria (including spore-forming bacteria) Yeasts Fungi Viruses Bacteriophages Biofilms
Field of use	Indoors surfaces disinfection in closed circulation circuits by cleaning-in-place in agri-food industry.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The product is then applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	Under clean conditions, at +20°C : Thoroughly clean & rinse the surfaces before disinfection. - For an effect on bacteria & on yeasts: 0.2% in a 5 min contact time - For an effect on fungi : 3.5% in a 5 min contact time - For an effect on spore-forming bacteria (including Bacillus cereus & Clostridium sporogenes) : 1% in a 15 min contact time - For an effect on viruses : 1.5 % in a 15 min contact time - For an effect on bacteriophages : 0.1% in a 15 min contact time - For an effect to remove biofilms: 0.2% in a 5 min contact time

Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 16. Use #3-16– Surfaces disinfection by manual dipping of small equipment in agri-food industry

Use #3-16: Surfaces disinfection by manual dipping of small equipment in agri-food industry	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria (including spore-forming bacteria) Yeasts Fungi Viruses Bacteriophages Biofilms
Field of use	Indoors disinfection of surfaces in contact with food and water for animals by manual dipping of small equipment in agri-food industry.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The product is then applied by manual dipping in containers. No heating takes place during dipping bathes. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	On hard non-porous surfaces with prior cleaning, at +20°C : Make sure to wet surfaces completely. Thoroughly clean & rinse the surfaces before disinfection. - For an effect on bacteria (including *Salmonella typhimurium, Listeria monocytogenes, Enterobacter cloacae, Lactobacillus brevis, Campylobacter jejuni & Legionella pneumophila*) and on yeasts (including *Dekkera bruxellensis & Saccharomyces cerevisae*) : 0.5% in a 5 min contact time - For an effect on fungi (including *Mucor racemosus*) : 3.5% in a 5 min contact time - For an effect on viruses : 1.5% in a 15 min contact time - For an effect on bacteriophages : 0.1% in a 15 min contact time

	- For an effect on spore-forming bacteria (including *Bacillus cereus & Clostridium sporogenes*) : 1% in a 15 min contact time - For an effect to remove biofilms: 0.2% in a 5 min contact time The dipping solution must be replaced by a fresh solution when it becomes visually polluted, and in all cases daily.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 17. Use #3-17 – Disinfection by automated spraying in closed professional washing machines in agri food industry and institutions, and institutional kitchens

USE NOT GRANTED (for more details, see the efficacy assessment).

Table 18. Use #3-18 – Drinking water disinfection for animals in farms

USE NOT GRANTED (for more details, see the efficacy assessment).

2.1.4.12 Use-specific instructions for use

Please refer to description of application method related to each use.

2.1.4.13 Use-specific risk mitigation measures

1) For Automatic pumping/mixing and loading applications for PT2, 3 and 4: gloves, a protective coverallare required. General public is not allowed to enter areas where the biocidal product is connected manually to automatic mixing and loading systems. 2) For manual spraying for PT 2 applications in industries: gloves, a protective coverall are required. General public not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC. At least a powered air purifying respirator with helmet/hood/mask (TH3/TM3) with combination filter gas/P3 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information) 3) For manual spraying for PT 3 applications in animal houses, as well as for manual dipping in aquaculture plants: gloves, a protective coverall are required. General public not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC. Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory. At least a powered air purifying respirator with helmet/hood/mask

(TH3/TM3) with combination filter gas/P3 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

4) For manual spraying for PT 4 applications, as well as for manual dipping for PT 3 applications in animal housing except in aquaculture plants and for PT 4 applications: gloves, a protective coverall are required. At least a powered air purifying respirator with helmet/hood/mask (TH3/TM3) with combination filter gas/P3 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information)

5) For all spraying application: "The treated surface is not allowed to get dry prior to rinsing."

6) For manual rinsing and manual draining for PT 2, 3 and 4 applications: no personal protective equipment (PPE) and no RPE is required.

7) The process of dilution has to be carried out using an automatic dosing system.

8) For manual spraying for PT 3 applications for disinfection of milking parlour system in farms, no specific PPE or RPE are required.

9) For All dipping applications: No heating takes place during dipping bathes and the room need to be sufficiently well ventilated with 10 air changes per hour.

10) After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.

11) Provide adequate ventilation before the general public re-enter treated areas.

12) The general public is not allowed to enter the outdoor application site and an area 20 m around during spraying and until the surface is rinsed.

13) For all M&L steps and for all spraying application: The room need to be sufficiently well ventilated with 10 air changes per hour.

14) For all spraying area: immediately leave the room after application.

2.1.4.14 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Likely direct or indirect effects:

- May be corrosive to metals.
- Harmful if swallowed or inhaled.
- Causes severe skin burns and eye damage.
- May cause respiratory irritation
- Very toxic to aquatic life with long lasting effects.

First aid instructions:

- IF SWALLOWED : Rinse mouth. DO NOT induce vomiting.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- in case of skin contact, eye contact, inhalation and ingestion: "Get medical attention immediately".

Emergency measures to protect the environment:

- Avoid release to the environment
- Keep only in original container

2.1.4.15 Where specific to the use, the instructions for safe disposal of the product and its packaging

Please refer to general directions for uses of the «QUARON PAA family» biocidal product family

2.1.4.16 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

The shelflife is set to 18 months.

The mentions "Store at temperature no greater than 30°C" and "Protect from frost" are to be indicated on the label.

Protect from light

Meta SPC 4:

Table 1. Use #4-1 – Disinfection of waste water and leachates in private sewage treatment plant: USE NOT AUTHORISED (for more details, see the environmental assessment).

Table 2. Use #4-2 – Laundry disinfection in professional laundry and washing machine

Use #4-2: Laundry disinfection in professional laundry and washing machine	
Product Type	2
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria (including tuberculo-bacteria) Yeasts

Field of use	Indoors laundry disinfection in professional laundry and washing machine.
Application method(s)	The diluted product is applied automatically and continuously to water during the rinsing step.
Application rate(s) and frequency	On clean textiles, at +40°C in a 15 min contact time with 1 (laundry):4 (water) ratio: - For an effect on bacteria, yeasts and tuberculobacteria : 2 mL/L
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 3. Use #4-3 – Disinfection of closed circulation circuits by cleaning-in-place in agri-food industry

Use #4-3: Disinfection of closed circulation circuits by cleaning-in-place in agri-food industry	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria (including spore-forming bacteria) Yeasts Fungi Viruses Bacteriophages
Field of use	Indoors disinfection of closed circulation circuits by cleaning-in-place in agri-food industry.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The product is then applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	Under clean conditions, at +20°C in a 15 min contact time: Thoroughly clean & rinse the surfaces before disinfection.

	- For an effect on bacteria (including *Salmonella typhimurium, Enterobacter cloacae, Lactobacillus brevis, Listeria monocytogenes*) & on yeasts: 0.15% - For an effect on fungi : 0.8% - For an effect on viruses : 0.6 % - For an effect on bacteriophages : 0.05% - For an effect on spore-forming bacteria : 0.4%
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 4. Use #4-4 – Surfaces disinfection by manual dipping

Use #4-4: Surfaces disinfection by manual dipping.	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria (including spore-forming bacteria) Yeasts Fungi Viruses Bacteriophages
Field of use	Indoors disinfection of containers or surfaces by manual dipping in agri-food industry.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The product is then applied by manual dipping in containers. No heating takes place during dipping bathes. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	On hard non-porous surfaces with prior cleaning, at +20°C in a 15 min contact time: Thoroughly clean & rinse the surfaces before disinfection. - For an effect on bacteria & on yeasts: 0.15% - For an effect on fungi : 0.8% - For an effect on viruses : 0.6 % - For an effect on bacteriophages : 0.05% - For an effect on spore-forming bacteria : 1.5%

	The dipping solution must be replaced by a fresh solution when it becomes visually polluted, and in all cases daily.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

2.1.4.17 Use-specific instructions for use

For all meta-SPCs, please refer to description of application method related to each use.

2.1.4.18 Use-specific risk mitigation measures

1) For Automatic pumping/mixing and loading applications for PT2 and PT 4: gloves, a protective coverall are required.

General public is not allowed to enter areas where the biocidal product is connected manually to automatic mixing and loading systems. Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH3/TM3) with combination filter gas/P3 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

2) For manual dipping for PT 4 applications in industries: gloves and a protective coverall are required. But no RPE is necessary.
3) The process of dilution has to be carried out using an automatic dosing system.

4) No manual Mixing and Loading or manual pouring is approved for products from the meta-SPC 4 (Indal PAA 14). Please only proceed with automatic steps.

5) For all dipping applications: No heating takes place during dipping bathes and the room need to be sufficiently well ventilated with 10 air changes per hour.

6) After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.

7) Provide adequate ventilation before the general public re-enter treated areas.

8) The general public is not allowed to enter the outdoor application site and an area 20 m around during spraying and until the surface is rinsed. For all M&L steps, a ventilation rate of 10/hour is required.

9) For all spraying area: immediately leave the room after application.

2.1.4.19 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Likely direct or indirect effects:

- Heating may cause a fire.
- May be corrosive to metals.
- Harmful if swallowed, in contact with skin or inhaled.
- Causes severe skin burns and eye damage.
- May cause respiratory irritation.
- Very toxic to aquatic life with long lasting effects.

First aid instructions:

- IF SWALLOWED : Rinse mouth. DO NOT induce vomiting.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- in case of skin contact, eye contact, inhalation and ingestion: "Get medical attention immediately".

Emergency measures to protect the environment:

- Avoid release to the environment
- Keep only in original container

2.1.4.20 Where specific to the use, the instructions for safe disposal of the product and its packaging

Please refer to general directions for uses of the «QUARON PAA family» biocidal product family

2.1.4.21 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

The shelflife is set to 12 months.

The mentions "Store at temperature no greater than 30°C" and "Protect from frost" are to be indicated on the label.

Protect from light

Meta SPC 5:

Table 1. Use #5-1 – Surfaces disinfection by manual foam spraying in livestock industry

Use #5-1: Surfaces disinfection by manual foam spraying in livestock industry	
Product Type	3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria (including mycobacteria) Yeasts Fungi Viruses
Field of use	Indoors disinfection of open surfaces, materials or equipments, walls, floors or vehicles transport by manual foam spraying in livestock industry.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system & then applied foam by manual spraying on surfaces with a foam generator. Device to be used for spraying: low-medium pressure (4 to 7 bars). After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	On hard non-porous surfaces with prior cleaning, at +10°C in a 30 min contact time: Make sure to wet surfaces completely. Thoroughly clean & rinse the surfaces before disinfection. The application dose is 50 mL/m². - For an effect on bacteria (including *Salmonella typhimurium and Listeria monocytogenes*) & on yeasts: 2% - For an effect on fungi (including *Aspergilus fumigatus*) : 5% - For an effect on mycobacteria : 2% - For an effect on viruses (including H5N1 & H1N1; FMDV; Gumboro, Newcastle, Aujeszky virus) : 0.5% - Active against Porcine Enterovirus : 1% - Active against Classical swine fever : 2% On hard porous surfaces with prior cleaning, at +10°C in 30 min : Make sure to wet surfaces completely. - For an effect on bacteria (including Salmonella typhimurium and Listeria monocytogenes) & on yeasts: 4%

Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

Table 2. Use #5-2 – Large scale surfaces disinfection by manual foam spraying in agri-food industry

Use #5-2: Large scale surfaces disinfection by manual foam spraying in agri-food industry	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses Bacteriophages Biofilms
Field of use	Indoors disinfection of open surfaces, walls and floors by manual foam spraying in agri-food industry.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system & then applied foam by manual spraying on surfaces with a foam generator. Device to be used for spraying: low-medium pressure (4 to 7 bars). After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	Make sure to wet surfaces completely On hard non-porous surfaces with prior cleaning, at +20°C: Thoroughly clean & rinse the surfaces before disinfection. Make sure to wet surfaces completely. - For an effect on bacteria (including *including Salmonella typhimurium, Listeria monocytogenes, Enterobacter cloacae, Lactobacillus brevis, Campylobacter jejuni & Legionella pneumophila*) & on yeasts: 1% in a 15 min contact time - For an effect on fungi : 4% in a 15 min contact time - For an effect on viruses : 3% in a 30 min contact time

	- For an effect on bacteriophages: 0.55% in a 15 min contact time - For an effect to remove biofilms : 1% in a 15 min contact time
Category(ies) of users	Professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

2.1.4.22 Use-specific instructions for use

Please refer to description of application method related to each use.

2.1.4.23 Use-specific risk mitigation measures

1) For Automatic pumping/mixing and loading applications for PT 3 and PT 4: gloves, a protective coverall are required.
   General public is not allowed to enter areas where the biocidal product is connected manually to automatic mixing and loading systems. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter vapour /P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

2) For manual spraying for PT 3 applications in animal houses: no personal protective equipment (PPE) is required. But RPE are necessary. General public is not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC. Use of respiratory protective equipment (RPE). At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter vapour/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

3) For all Spraying applications: "The treated surface is not allowed to get dry prior to rinsing."

4) For manual rinsing and manual draining for PT 2, 3 and 4 applications: no personal protective equipment (PPE) and no RPE is required.

5) The process of dilution has to be carried out using an automatic dosing system.

6) After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.

7) Provide adequate ventilation before the general public re-enter treated areas.

8) The general public is not allowed to enter the outdoor application site and an area 20 m around during spraying and until the surface is rinsed.

9) For all M&L steps and spraying application: The room need to be sufficiently well ventilated with 10 air changes per hour.

10) For all spraying area: immediately leave the room after application.

2.1.4.24 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Likely direct or indirect effects:

- May be corrosive to metals.
- Harmful if swallowed or if in contact with skin.
- Causes severe skin burns and eye damage.
- May cause respiratory irritation.
- Toxic to aquatic life with long lasting effects.

First aid instructions:

- IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- in case of skin contact, eye contact, inhalation and ingestion: "Get medical attention immediately".

Emergency measures to protect the environment:

- Avoid release to the environment
- Keep only in original container

2.1.4.25 Where specific to the use, the instructions for safe disposal of the product and its packaging

Please refer to general directions for uses of the «QUARON PAA family» biocidal product family

2.1.4.26 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

The shelflife is set to 18 months. The mentions "Store at temperature no greater than 30°C" and "Protect from frost" are to be indicated on the label. Protect from light

Meta SPC 6:

Table 1. Use #6-1 – Disinfection of closed circulation circuits by cleaning-in-place in agri-food industry

Use #6-1: Disinfection of closed circulation circuits by cleaning-in-place in agri-food industry	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria (including spore-forming bacteria) Yeasts Fungi Viruses Bacteriophages
Field of use	Indoors disinfection in closed circulation circuits by cleaning-in-place in agri-food industry.
Application method(s)	The concentrated product solution is diluted via a proportional automatic dosage system or a venturi system. The product is then applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	Under clean conditions, at +20°C: Thoroughly clean & rinse the surfaces before disinfection. - For an effect on bacteria & on yeasts: 0.4% in a 15 min contact time - For an effect on fungi : 2% % in a 15 min contact time - For an effect on viruses : 1.5 %% in a 30 min contact time - For an effect on bacteriophages : 0.2% % in a 15 min contact time

	- For an effect on spore-forming bacteria : 1 % % in a 15 min contact time
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section 2.1.7

2.1.4.27 Use-specific instructions for use

Please refer to description of application method related to each use.

2.1.4.28 Use-specific risk mitigation measures

For Automatic pumping/mixing and loading applications for PT 4: gloves, a protective coverall are required.
General public is not allowed to enter areas where the biocidal product is connected manually to automatic mixing and loading systems. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).
The process of dilution has to be carried out using an automatic dosing system.
After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.

Provide adequate ventilation before the general public re-enter treated areas.

The general public is not allowed to enter the application site and an area 20 m around during spraying and until the surface is rinsed.

For all M&L steps , a ventilation rate of 10/hour is needed.

2.1.4.29 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Likely direct or indirect effects:

- May be corrosive to metals.
- Harmful if swallowed or inhaled.
- Causes severe skin burns and eye damage.
- May cause respiratory irritation.
- Very toxic to aquatic life with long lasting effects.

First aid instructions:

- IF SWALLOWED : Rinse mouth. DO NOT induce vomiting.

- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- in case of skin contact, eye contact, inhalation and ingestion: "Get medical attention immediately".

Emergency measures to protect the environment:

- Avoid release to the environment
- Keep only in original container

2.1.4.30 Where specific to the use, the instructions for safe disposal of the product and its packaging

Please refer to general directions for uses of the «QUARON PAA family» biocidal product family.

2.1.4.31 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

The shelflife is set to 12 months.

The mentions "Store at temperature no greater than 30°C" and "Protect from frost" are to be indicated on the label.

Protect from light

2.1.5 General directions for use

2.1.5.1 Instructions for use

Please refer to Use-specific instructions for uses given in point 2.1.4.2 of the Authorized uses 2.1.4 above.

2.1.5.2 Risk mitigation measures

Please refer to Use-Specific risk mitigation measures

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Please refer to Use-Specific particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

2.1.5.4 Instructions for safe disposal of the product and its packaging

- Avoid release to the environment
- Keep only in original container

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Please refer to use-specifi conditions of storage and shelf-life of the product under normal conditions of storage

2.1.6 Other information

-

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)	Remark
Bottle	0.25 to 1L	HDPE	Degassing cap (HDPE screw cap with microporous PTFE membrane)	Professional	Yes	For all uses and used for manual mixing and loading
Jerrycan	5L to 20L	HDPE		Professional	Yes	For all uses and used for manual mixing and loading
Drum	60 to 220 L	HDPE		Professional	Yes	For all uses but not for manual mixing and loading
Bulk container	1000L	HDPE		Professional	Yes	For all uses but not for manual mixing and loading

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

The whole list of the submitted studies is summarized in the Annex 1.

2.1.8.2 Access to documentation

As member of the task force PAR "Peracetic Acid Registration group" within CEFIC, QUARON SAS, which submitted a complete dossier on peracetic acid for PT1-6, is considered as an official active substance supplier of peracetic acid.

2.2 ASSESSMENT OF THE BIOCIDAL PRODUCT (FAMILY)

2.2.1 Intended use(s) as applied for by the applicant

Meta SPC 1 :

Table 1. Use #1-1 – Disinfection of wasted water, leachates and liquid laboratory waste in closed systems in medical biology laboratories

Use #1-1: Disinfection of wasted water, leachates and liquid laboratory waste in closed systems in medical biology laboratories	
Product Type	2
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, mycobacteria and viruses
Field of use	Indoors disinfection of wasted water, leachates and liquid laboratory waste in closed systems in medical biology laboratories.
Application method(s)	The concentrate solution is automatically diluted in the waste water to treat at 0.1% to 3.0% (v/v) via a proportional automatic dosage system or a venture system according to use instructions of the proper application equipment. The product is applied at ambient temperature with a contact time with liquid waste and surfaces of 30 minutes. The product can be applied on dirty surfaces of the equipment to disinfect them. The treated surfaces are rinsed with drinking water after the indicated contact time. The treated liquid waste, and the rinse water are discharged to be treated in a STEP. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year. The application is continuous during the time of treatment.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 2. Use #1-2 – Disinfection of closed circulation circuits for cleaning in place in private and public pharmaceutical and cosmetic industries and institutions

Use #1-2: Disinfection of closed circulation circuits for cleaning in place in private and public pharmaceutical and cosmetic industries and institutions

Product Type	2
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi and viruses
Field of use	Indoors and outdoors disinfection of closed circulation circuits for cleaning in place pharmaceutical and cosmetic industries and institutions.
Application method(s)	The concentrate solution is diluted in tap water from 0.1% to 2% (v/v), via a proportional automatic dosage system or a venturi system. The product is then applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. The diluted product is applied at ambient temperature with a contact time with surfaces of 5 to 30 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year. The application is continuous during the time of treatment.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 3. Use #1-3 – Surface disinfection by manual spraying in agri-food industry

Use #1-3: Surface disinfection by manual spraying in agri-food industry	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, spores, biofilms and viruses.
Field of use	Indoors disinfection of open surfaces, materials or equipments, walls or floors by manual spraying in agri-food industry.
Application method(s)	The concentrate solution is diluted in tap water from 0.4% to 2% (v/v), via a proportional automatic dosage system or a

	venturi system and then applied manually by spraying on surfaces. Device to be used for spraying: low-medium pressure (4 to 7 bars) The diluted product is then applied at ambient temperature with a contact time with surfaces of 5 to 30 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year. The application dose is 20mL/m².
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 4. Use #1-4 – Disinfection of closed circulation circuits for cleaning in place in agri food industry.

Use #1-4: Disinfection of closed circulation circuits for cleaning in place in agri-food industry.	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, spores, biofilms and viruses.
Field of use	Indoors disinfection of closed circulation circuits for cleaning in place in agri-food industry.
Application method(s)	The concentrate solution is diluted in tap water from 0.1% to 2% (v/v), via a proportional automatic dosage system or a venturi systen. The product is then applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. The diluted product is applied at ambient temperature with a contact time with surfaces of 5 to 30 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.

Application rate(s) and frequency	The product is used once a day, 220 days per year. The application is continuous during the time of treatment.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 5. Use #1-5 – Surfaces disinfection by manual dipping in agri-food industry.

Use #1-5: Surfaces disinfection by manual dipping in agri-food industry.	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, spores, biofilms and viruses
Field of use	Indoors disinfection of surfaces by manual dipping in agri-food industry. This use also includes a foot bath disinfection.
Application method(s)	The concentrate solution is diluted in tap water from 0.4% to 2% (v/v), via a proportional automatic dosage system or a venturi system and then applied manually by dipping on surfaces. The diluted product is applied at ambient temperature with a contact time with surfaces of 5 to 30 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. No heating takes place during dipping bathes. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 6. Use #1-6 – Disinfection by automated spraying in closed professional washing machines in agri food industry and institutions, and institutional kitchens.

Use #1-6: Disinfection by automated spraying in closed professionnal washing machines in agri-food industry and institutions, and institutional kitchens.

Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, spores, biofilms and viruses
Field of use	Indoors disinfection of materials and small equipments in closed professionnal washing machines in agri-food industry and institutions, and institutional kitchens.
Application method(s)	The concentrate solution is diluted in tap water from 0.4% to 2% (v/v), via a proportional automatic dosage system or a venturi system. The product is then applied automatically and continuously during the time of treatment in closed professional washing machines. The diluted product is applied at ambient temperature with a contact time with surfaces of 5 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year. The application is continuous during the time of treatment.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Meta SPC 2 :

Table 2. Use #2-1 – Disinfection of water in private and public swimming pool, in balneotherapy basin and in private ponds

Use #2-1: Disinfection of water in private and public swimming pool, in balneotherapy basin and in private ponds	
Product Type	2
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, algae and virus

Field of use	1a. Indoors and outdoors disinfection of water in private and public swimming pool, in balneotherapy basin and in private ponds before water discharging. 1b. Indoors and outdoors shock disinfection of water in private and public swimming pool, in balneotherapy basin and in private ponds.
Application method(s)	The concentrate solution is automatically diluted in the water to treat at 0.15 to 0.6% (v/v), via a proportional automatic dosage system, a venturi system, or is applied directly to the water to disinfect by a manual mixing and loading. The product is applied in dirty conditions in order to proceed to a curative disinfection that can take place for more than 12 hours. The treated surfaces are rinsed with drinking water after the indicated contact time only when the water is discharged. For shock disinfection, the product is applied in the water with a 60 minutes contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once or twice a year (occasional use) during the sanitary emptying or 2 to 5 times a year if there is a contamination and a shock treatment is required.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 2. Use #2-2 – Surfaces disinfection by manual spraying in private and public swimming pool, in balneotherapy basin and in private ponds

Use #2-2: Surfaces disinfection by manual spraying in private and public swimming pool, in balneotherapy basin and in private ponds	
Product Type	2
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, algae and viruses
Field of use	Indoors and outdoors disinfection of open surfaces, materials or equipments, walls or floors by manual spraying in private and public swimming pool, in balneotherapy basin and in private ponds.
Application method(s)	The concentrate solution is diluted in tap water from 0.3% to 4% (v/v), via a proportional automatic dosage system or a

	venturi system. The product is then applied manually by spraying on surfaces. Device to be used for spraying: low-medium pressure (4 to 7 bars) The diluted product is applied at ambient temperature with a contact time with surfaces of 60 minutes. The product can be applied on dirty surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year. The application dose is 20mL/m².
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 3. Use #2-3 – Disinfection of closed circulation circuits for cleaning-in-place in private and public swimming pool, in balneotherapy basin, in private ponds and in sanitary hot water network.

Use #2-3: Disinfection of closed circulation circuits for cleaning-in-place in private and public swimming pool, in balneotherapy basin, in private ponds and in sanitary hot water network.	
Product Type	2
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, algae and viruses
Field of use	Indoors and outdoors disinfection of closed circulation circuits for cleaning-in-place in private and public swimming pool, in balneotherapy basin, in private ponds and in sanitary water network (radiators).
Application method(s)	The concentrate solution is diluted in tap water from 0.15 to 2% (v/v), via a proportional automatic dosage system or a venturi system. The diluted product is applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. The diluted product is applied at ambient temperature with a contact time with surfaces of 60 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time.time.

	After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Meta SPC 3 :

Table 1. Use #3-1 – Surfaces disinfection by manual spraying in private, public, and industrial areas and in other areas for professional activities

Use #3-1: Surfaces disinfection by manual spraying in private, public, and industrial areas and in other areas for professional activities	
Product Type	2
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, algae, viruses, mycobacteria and biofilms
Field of use	Indoors and outdoors disinfection of open surfaces, materials or equipments, walls or floors by manual spraying in private, public, and industrial areas and in other areas for professional activities.
Application method(s)	The concentrate solution is diluted in tap water from 0.2 to 1.5% (v/v), via a proportional automatic dosage system or a venturi system and then applied manually by spraying on surfaces. Device to be used for spraying: low-medium pressure (4 to 7 bars) The diluted product is applied at ambient temperature with a contact time with surfaces of 1 to 15 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year. The application dose is 20 ml/m².
Category(ies) of users	. professionals

Pack sizes and packaging material	Please see the relevant section.

Table 2. Use #3-2 – Disinfection of closed circulation circuits by cleaning-in-place in sewage treatment plant.

Use #3-2: Disinfection of closed circulation circuits by cleaning-in-place in sewage treatment plant.	
Product Type	2
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, biofilms, spored, algae, mycobacteria and viruses.
Field of use	Outdoors disinfection of closed circulation circuits by cleaning-in-place in sewage treatment plant.
Application method(s)	The concentrate solution is diluted in tap water from 0.05 to 1.5% (v/v), via a proportional automatic dosage system or a venturi system. The product is then applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. The diluted product is applied at ambient temperature with a contact time with surfaces of 5 to 60 minutes. The product can be applied on dirty surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 20 days per year.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 3. Use #3-3 – Disinfection of closed circulation circuits for cleaning in place in private and public pharmaceutical and cosmetic industries and institutions

Use #3-3: Disinfection of closed circulation circuits for cleaning in place in private and public pharmaceutical and cosmetic industries and institutions	
Product Type	2

Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, spores, biofilms, mycobacteria and viruses
Field of use	Indoors and outdoors disinfection of closed circulation circuits for cleaning in place pharmaceutical and cosmetic industries and institutions.
Application method(s)	The concentrate solution is diluted in tap water from 0.05 to 1.5% (v/v), via a proportional automatic dosage system or a venturi syste. The product is then applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. The diluted product is applied at ambient temperature with a contact time with surfaces of 5 to 15 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used 220 days per year. The application is continuous during the time of treatment.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 4. Use #3-4 – Surfaces disinfection by manual dipping.

Use #3-4: Surfaces disinfection by manual dipping.	
Product Type	2
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, spores, mycobacteria, biofilms and viruses
Field of use	Outdoors and indoors disinfection of surfaces by manual dipping in sewage treatment plant and in waste processing industries.
Application method(s)	The concentrate solution is diluted in tap water from 0.2% to 1.5% (v/v), via a proportional automatic dosage system or a venturi system.

	The diluted product is applied manually by dipping in containers during the time of treatment. The diluted product can be applied on dirty surfaces at ambient temperature with a contact time with surfaces of 1 to 15 minutes. The treated surfaces are then rinsed with drinking water after the indicated contact time. No heating takes place during dipping bathes. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 5. Use #3-5 – Disinfection of waste water and leachates in private and public sewage treatment plant.

Use #3-5: Disinfection of waste water and leachates in private and public sewage treatment plant.	
Product Type	2
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, mycobacteria and viruses
Field of use	Outdoors disinfection of waste water and leachates in private and public sewage treatment plant.
Application method(s)	The concentrate solution is continuously added in used waters so as to reach a concentration of 0.1 to 2% (v/v), via a proportional automatic dosage system or a venturi system. The product is applied at ambient temperature with a contact time from 5 to 30 minutes. The product is continuously applied in dirty conditions. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used daily and continuously.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 6. Use #3-6 – Disinfection of wasted water, leachates and liquid laboratory waste in closed systems in medical biology laboratories

Use #3-6: Disinfection of wasted water, leachates and liquid laboratory waste in closed systems in medical biology laboratories	
Product Type	2
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, mycobacteria and viruses
Field of use	Indoors disinfection of wasted water, leachates and liquid laboratory waste in closed systems in medical biology laboratories.
Application method(s)	The concentrate solution is continuously added in waste waters so as to reach a concentration of 0.1 to 2% (v/v), via a proportional automatic dosage system or a venturi system. The product is applied at ambient temperature with a contact time with surfaces from 5 to 30 minutes. The product is applied in dirty conditions. The treated surfaces are rinsed with drinking water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used daily. The application is continuous during the time of treatment.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 7. Use #3-7 – Laundry disinfection in professional laundry and washing machine

Use #3-7: Laundry disinfection in professional laundry and washing machine	
Product Type	2
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, mycobacteria and viruses

Field of use	Indoors laundry disinfection in closed circulation circuits in professional laundry and washing machine of agri-food industries.
Application method(s)	The concentrate solution is continuously diluted in tap water to reach a concentration of 0.6% v/v (24 ml/kg laundry, 4 litres of water/kg laundry), via a proportional automatic dosage system with a membrane pump integrated into the washing machine.The diluted product is then applied automatically and continuously to water during cleaning cycle. The diluted product is directly applied at a temperature of 40°C to the tap water in order to obtain a washing solution. The contact time with surfaces is 15 minutes. The product is applied on clean surfaces. The treated surfaces are then rinsed with tap water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used daily, 220 days per year. The applied dose of concentrate is 24 ml/kg of laundry.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 8. Use #3-8 – **Milking Claws shape disinfection**

Use #3-8: Milking Claws shape disinfection	
Product Type	3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts and viruses.
Field of use	Indoors surface disinfection of milking parlour systems by manual spraying.
Application method(s)	The concentrate solution is diluted in tap water from 0.5 – 1% (v/v), via a proportional automatic dosage system or a venturi system. The milking claws are sprayed with the diluted product at ambient temperature with a contact time with surfaces of 5 minutes. The product can be applied on dirty surfaces.

	The treated surfaces are rinsed with drinking water after the indicated contact time. The product is applied using a semi-automatic low pressure spraying system. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 365 days per year, for about 2 hours a day. The application dose is 20 ml/m².
Category(ies) of users	Professional users
Pack sizes and packaging material	Please see the relevant section.

Table 9. Use #3-9 – Surface disinfection by manual dipping in fish farming industry

Use #3-9: Surface disinfection by manual dipping in fish farming industry	
Product Type	3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, mycobacteria, algae and viruses
Field of use	Outdoors and indoors disinfection of surfaces by manual dipping in fish farming industry.
Application method(s)	The concentrate solution is diluted in tap water from 0.1% to 1% (v/v), via a proportional automatic dosage system or a venturi system. The diluted product is applied automatically and continuously to containers during the time of treatment. The diluted product is applied at 20°C with a contact time with surfaces of 60 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. No heating takes place during dipping bathes. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 200 days per year.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 10. Use #3-10 – Disinfection of closed circulation circuits by cleaning-in-place in fish farming industry

Use #3-10: Disinfection of closed circulation circuits by cleaning-in-place in fish farming industry	
Product Type	3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, mycobacteria, virus and algae
Field of use	Outdoors and indoors disinfection of surfaces in closed circulation circuits by cleaning-in-place in fish farming industry.
Application method(s)	The concentrate solution is diluted in tap water from 0.1% to 2% (v/v), via a proportional automatic dosage system or a venturi system. The diluted product is applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. The diluted product is applied at a temperature of 20°C with a contact time with surfaces from 15 to 60 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 200 days per year.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 11. Use #3-11 – Surfaces disinfection by manual dipping in livestock housing

Use #3-11: Surfaces disinfection by manual dipping in livestock housing	
Product Type	3
Where relevant, an exact description of the authorised use	-

Target organism (including development stage)	Bacteria, yeasts, fungi, viruses, mycobacteria and biofilms
Field of use	Indoors disinfection of surfaces by manual dipping in livestock housing.
Application method(s)	The concentrate solution is diluted in tap water from 0.1% to 1% (v/v), via a proportional automatic dosage system or a venturi system and then applied by manual dipping of surfaces. The diluted product is applied at a temperature of 20°C with a contact time with surfaces of 15 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. No heating takes place during dipping bathes. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 12. Use #3-12 – Surfaces disinfection by manual spraying in livestock housing

Use #3-12: Surfaces disinfection by manual spraying in livestock housing	
Product Type	3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, viruses, mycabacteria and biofilms
Field of use	Indoors disinfection of surfaces by manual spraying in livestock housing.
Application method(s)	The concentrate solution is diluted in tap water from 0.1% to 1% (v/v), via a proportional automatic dosage system or a venturi system and then applied manually by spraying on surfaces. Device to be used for spraying: low-medium pressure (4 to 7 bars)

	The diluted product is applied at a temperature of 20°C with a contact time with surfaces of 15 minutes. The product should be applied on clean surfaces. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year. The application dose of diluted product is 20 ml/m².
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 13. Use #3-13 – Disinfection of closed circulation circuits (drinking water and feed) by cleaning-in-place in livestock housing

Use #3-13: Disinfection of closed circulation circuits (drinking water and feed) by cleaning-in-place in livestock housing	
Product Type	3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, viruses, mycabacteria and biofilms
Field of use	Indoors surface disinfection in closed circulation circuits by cleaning-in-place in livestock housing.
Application method(s)	The concentrate solution is diluted in tap water from 0.1% to 2% (v/v), via a proportional automatic dosage system or a venturi system. The diluted product is then applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. The diluted product is applied at ambient temperature with a contact time with surfaces of 15 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year.
Category(ies) of users	. professionals

Pack sizes and packaging material	Please see the relevant section.

Table 14. Use #3-14 – Surfaces disinfection by manual spraying in agri-food industry

Use #3-14: Surfaces disinfection by manual spraying in agri-food industry	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, viruses, spores and biofilms
Field of use	Indoors disinfection surfaces by manual spraying in agri-food industry.
Application method(s)	The concentrate solution is diluted in tap water from 0.2% to 1.5% (v/v), via a proportional automatic dosage system or a venturi system. The product is then applied by manual spraying on surfaces. Device to be used for spraying: low-medium pressure (4 to 7 bars) The diluted product is applied at ambient temperature with a contact time with surfaces of 1 to 15 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year. The application dose is 20 ml/m².
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 15. Use #3-15 – Disinfection of closed circulation circuits by cleaning-in-place in agri-food industry

Use #3-15: Disinfection of closed circulation circuits by cleaning-in-place in agri-food industry	
Product Type	4
Where relevant, an exact description of the authorised use	-

Target organism (including development stage)	Bacteria, yeasts, fungi, viruses, spores and biofilms
Field of use	Indoors surfaces disinfection in closed circulation circuits by cleaning-in-place in agri-food industry.
Application method(s)	The concentrate solution is diluted in tap water from 0.05% to 1.5% (v/v), via a proportional automatic dosage system or a venturi system. The diluted product is then applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. The diluted product is applied at ambient temperature with a contact time with surfaces of 5 to 15 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 16. Use #3-16– Surfaces disinfection by manual dipping in agri-food industry

Use #3-16: Surfaces disinfection by manual dipping in agri-food industry	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, viruses, spores and biofilms
Field of use	Indoors disinfection of surfaces in contact with food and water for animals by manual dipping in agri-food industry.
Application method(s)	The concentrate solution is diluted in tap water from 0.2% to 1.5% (v/v), via a proportional automatic dosage system or a venturi system. The product is then applied by manual dipping in containers. The diluted product is applied at ambient temperature with a contact time with surfaces of 1 to 15 minutes.

	The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. No heating takes place during dipping bathes. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 17. Use #3-17 – Disinfection by automated spraying in closed professional washing machines in agri food industry and institutions, and institutional kitchens

Use #3-17: Disinfection by automated spraying in closed professionnal washing machines in agri-food industry or institutions, and institutional kitchens	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, viruses, spores and biofilms
Field of use	Indoors disinfection of materials and small equipments in closed professionnal washing machines in agri-food industry and institutions, and institutional kitchens.
Application method(s)	The concentrate solution is diluted in tap water from 0.2% to 1.5% (v/v), via a proportional automatic dosage system or a venturi system. The product is then applied automatically and continuously during the time of treatment in closed professionnal washing machines. The diluted product is applied at ambient temperature with a contact time with surfaces of 1 to 15 minutes.The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year. The application is continuous during the time of treatment.
Category(ies) of users	. professionals

Pack sizes and packaging material	Please see the relevant section.

Table 18. Use #3-18 – Drinking water disinfection for animals in farms

Use #3-18: Drinking water disinfection for animals in farms	
Product Type	5
Where relevant, an exact description of the authorised use	-
&Target organism (including development stage)	Bacteria and viruses
Field of use	Outdoors and indoors disinfection of drinking water for animals in farms.
Application method(s)	The concentrate solution is continuously diluted in drinking water at ambient temperature via a proportional automatic dosage system in order to obtain a final concentration of 0.07% v/v (PAA content of 42 ppm), and stored in an intermediate tank during 60 minutes. The treated water is then distributed to the animals. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used daily and continuously.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Meta SPC 4:

Table 1. Use #4-1 – Disinfection of waste water and leachates in private and public sewage treatment plant

Use #4-1: Disinfection of waste water and leachates in private and public sewage treatment plant	
Product Type	2
Where relevant, an exact description of the authorised use	-

Target organism (including development stage)	Bacteria, yeasts, fungi, mycobacteria and viruses
Field of use	Outdoors disinfection of waste water and leachates in private and public sewage treatment plant.
Application method(s)	The concentrate solution is continuously added in used waters to reach a concentration of 0.8% (v/v), via a proportional automatic dosage system or a venturi system. The product is applied automatically and continuously to waste water during the time of treatment. The product is applied at ambient temperature with a contact time with surfaces of 30 minutes. The product is continuously applied in dirty conditions. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used daily and continuously.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 2. Use #4-2 – Laundry disinfection in professional laundry and washing machine

Use #4-2: Laundry disinfection in professional laundry and washing machine	
Product Type	2
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, viruses and mycobacteria
Field of use	Indoors laundry disinfection in professional laundry and washing machine.
Application method(s)	The concentrate solution is continuously diluted in tap water to reach a concentration of 0.2% v/v (8 ml/kg laundry, 4 litres of water/kg laundry), via a proportional automatic dosage system with a membrane pump integrated into the washing machine. The diluted product is then applied automatically and continuously to water during cleaning cycle (rinsing step). The diluted product is directly applied at a temperature of 40°C to the tap water in order to obtain a disinfecting solution. The contact time with surfaces (textiles) is 15 minutes.

	The product is applied on clean textiles. The treated textiles are then rinsed with tap water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used daily. The applied dose of concentrate is 8 ml/kg of laundry.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 3. Use #4-3 – Disinfection of closed circulation circuits by cleaning-in-place in agri-food industry

Use #4-3: Disinfection of closed circulation circuits by cleaning-in-place in agri-food industry	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, spores and viruses
Field of use	Indoors disinfection of closed circulation circuits by cleaning-in-place in agri-food industry.
Application method(s)	The concentrate solution is diluted in tap water from 0.04 to 0.8% (v/v), via a proportional automatic dosage system or a venturi system. The product is then applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. The diluted product is applied at ambient temperature with a contact time with surfaces of 5 to 15 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 4. Use #4-4 – Surfaces disinfection by manual dipping

Use #4-4: Surfaces disinfection by manual dipping.	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, spores and viruses
Field of use	Indoors disinfection of containers or surfaces by manual dipping in agri-food industry.
Application method(s)	The concentrate solution is diluted in tap water from 0.08% to 0.6% (v/v), via a proportional automatic dosage system or a venturi system. The diluted product is applied by manual dipping in containers during the time of treatment. The product should be applied on clean surfaces at ambient temperature with a contact time with surfaces of 5 to 15 minutes.The treated surfaces are rinsed with drinking water after the indicated contact time. No heating takes place during dipping bathes. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year.
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Meta SPC 5:

Table 1. Use #5-1 – Surfaces disinfection by manual foam spraying in livestock industry

Use #5-1: Surfaces disinfection by manual foam spraying in livestock industry	
Product Type	3
Where relevant, an exact description of the authorised use	-

Target organism (including development stage)	Bacteria, yeasts, fungi, mycobacteria, viruses and biofilms
Field of use	Outdoors and indoors disinfection of open surfaces, materials or equipments, walls, floors or vehicles transport by manual foam spraying in livestock industry.
Application method(s)	The concentrated solution is diluted in tap water from 0.5% to 5% (v/v), via a proportional automatic dosage system or a venturi system and then applied foam by manual spraying on surfaces with a foam generator. Device to be used for spraying: low-medium pressure (4 to 7 bars). The diluted product is applied in low-level of dirty conditions, at a temperature of 20°C with a contact time with surfaces of 30 minutes minimum. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year. The application dose is 50 mL/m².
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Table 2. Use #5-2 – Surfaces disinfection by manual foam spraying in agri-food industry

Use #5-2: Surfaces disinfection by manual foam spraying in agri-food industry	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, virus and biofilms
Field of use	Indoors disinfection of open surfaces, materials or equipments, walls and floors by manual foam spraying in agri-food industry.
Application method(s)	The concentrated solution is diluted in tap water from 0.5 % to 4% (v/v), via a proportional automatic dosage system or a venturi system and then applied foam manually by spraying on surfaces with a foam generator. Device to be used for spraying: low-medium pressure (4 to 7 bars). The diluted product is applied at ambient temperature with a contact time with surfaces of 5 to 30 minutes. The product should be applied on clean surfaces. The treated surfaces

	are rinsed with drinking water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year. The application dose is 50 mL/m².
Category(ies) of users	. professionals
Pack sizes and packaging material	Please see the relevant section.

Meta SPC 6:

Table 1. Use #6-1 – Disinfection of closed circulation circuits by cleaning-in-place in agri-food industry

Use #6-1: Disinfection of closed circulation circuits by cleaning-in-place in agri-food industry	
Product Type	4
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi, algae, spores and viruses
Field of use	Indoors disinfection of closed circulation circuits by cleaning-in-place in agri-food industry.
Application method(s)	The concentrate solution is diluted in tap water from 0.3% to 4% (v/v), via a proportional automatic dosage system or a venturi system. The product is then applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. The diluted product is applied at ambient temperature with a contact time with surfaces of 5 to 30 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.
Application rate(s) and frequency	The product is used once a day, 220 days per year.
Category(ies) of users	. professionals

Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

The applicant has submitted data for determination of physical, chemical and technical properties for all products (one product by meta SPC). The parameters are summarized in the table below.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
- Physical state at 20 °C and 101.3 kPa - Colour at 20 °C and 101.3 kPa - Odour at 20 °C and 101.3 kPa	Organoleptic observations	INDAL PAA 3.5 (meta-SPC 1) - 2.6% PAA - Batch QUA-JCF-P35S	Colourless translucent liquid with pungent vinegar-like odour	Report study number 16-35-077-ES: Physical-chemical properties, stability and shelflife of Indal PAA 3.5. Part 1 : Physical-chemical properties upon receipt and after accelerated storage, E. Servajean, September 2017
		INDAL PAA 2.5 (meta-SPC 2) - 2.0% PAA - Batch QUA-JCF-HD10427		Report study number 16-35-076-ES: Physical-chemical properties, stability and shelflife of Indal PAA 2.5. Part 1 : Physical-chemical properties upon receipt and after accelerated storage, E. Servajean, September 2017
		INDAL PAA 5 (Meta-SPC 3) - 5.3% PAA - Batch QUA-JCF-F8-PER50		Report study number 16-35-078-ES: Physical-chemical properties, stability and shelflife of Indal PAA 5. Part 1 : Physical-chemical properties upon receipt and after accelerated storage, E. Servajean, September 2017
		INDAL PAA 15 (Meta-SPC 4) - 15.8% PAA - Batch QUA-JCF-F1-HD10778		Report study number 16-35-079-ES: Physical-chemical properties, stability and shelflife of Indal PAA 15. Part 1 : Physical-chemical properties upon receipt and after accelerated storage, E. Servajean, September 2017
		INDAL OXY MOUSS (meta-SPC 5) - 1.2% PAA - Batch QUA-JCF-F8-HD10350		Report study number 16-35-080-ES: Physical-chemical properties, stability and shelflife of Indal Oxy Mouss. Part 1 : Physical-chemical properties upon receipt and after accelerated storage, E. Servajean, September 2017

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		INDAL TAP 5 (Meta-SPC 6) - 5.0% PAA - Batch QUA-JCF-HD10390		Report study number 16-35-081-ES: Physical-chemical properties, stability and shelflife of Indal Tap 5. Part 1 : Physical-chemical properties upon receipt and after accelerated storage, E. Servajean, September 2017
Acidity / alkalinity	CIPAC method MT 191 for free acidity Deviation from the study plan: sample weight was decreased (10g normally used), due to high acidity: - INDAL PAA 3.5: 3g. - INDAL PAA 2.5: 5g. - INDAL PAA 5: 1g. - INDAL PAA 15: 1-2g. - INDAL OXY MOUSS: 2g. - INDAL TAP 5: 0.5-1g. CIPAC method MT 75.3 for pH determination (undiluted and 1% dilution)	INDAL PAA 3.5 (meta-SPC 1) - 2.6% PAA - Batch QUA-JCF-P35S	pH: neat: 0.76 1% dilution: 3.03 Free acidity: 4.49% w/w H_2SO_4	Report study number 16-35-077-ES[4]
		INDAL PAA 2.5 (Meta-SPC 2) - 2.0% PAA - Batch QUA-JCF-HD10427	pH: neat: 0.43 1% dilution: 3.33 Free acidity: 1.99% w/w H_2SO_4	Report study number 16-35-076-ES
		INDAL PAA 5 (Meta-SPC 3) - 5.3% PAA - Batch QUA-JCF-F8-PER50	pH: neat: 0.24 1% dilution: 2.64 Free acidity: 7.60% w/w H_2SO_4	Report study number 16-35-078-ES
		INDAL PAA 15(Meta-SPC 4) - 15.8% PAA - Batch QUA-JCF-F1-HD10778	pH: neat: -0.19 1% dilution: 2.63 Free acidity: 13.11% w/w H_2SO_4	Report study number 16-35-079-ES
		INDAL OXY MOUSS (Meta-SPC 5) - 1.2% PAA	pH: neat: 1.07 1% dilution: 2.93	Report study number 16-35-080-ES

[4] For the sake of clarity and better understanding only the short description of the test is indicated here. The complete name of the studies can be found in the first row of the table.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		- Batch QUA-JCF-F8-HD10350	Free acidity: 6.77% w/w H_2SO_4	
		INDAL TAP 5 (Meta-SPC 6) - 5.0% PAA - Batch QUA-JCF-HD10390	pH: neat: -0.31 1% dilution: 1.59 Free acidity: 19.64% w/w H_2SO_4	Report study number 16-35-081-ES
Relative density / bulk density	OECD 109	INDAL PAA 3.5 (Meta-SPC 1) - 2.6% PAA - Batch QUA-JCF-P35S	D^{20}_4 =1.114	Report study number 16-35-077-ES
		INDAL PAA 2.5 (Meta-SPC 2) - 2.0% PAA - Batch QUA-JCF-HD10427	D^{20}_4 = 1.141	Report study number 16-35-076-ES
		INDAL PAA 5 (Meta-SPC 3) - 5.3% PAA - Batch QUA-JCF-F8-PER50	D^{20}_4 = 1.123	Report study number 16-35-078-ES
		INDAL PAA 15 (Meta-SPC 4) - 15.8% PAA - Batch QUA-JCF-F1-HD10778	D^{20}_4 = 1.155	Report study number 16-35-079-ES
		INDAL OXY MOUSS (Meta-SPC 5) - 1.2% PAA - Batch QUA-JCF-F8-HD10350	D^{20}_4 = 1.065	Report study number 16-35-080-ES
		INDAL TAP 5 (Meta-SPC 6) - 5.0% PAA - Batch QUA-JCF-HD10390	D^{20}_4 = 1.207	Report study number 16-35-081-ES
Storage stability test – **accelerated storage**	CIPAC MT 46.3 18 weeks at 30°C+- 2°C	INDAL PAA 3.5 (meta-SPC 1) - 2.6% PAA	$[PAA]t_0$ = 2.8% w/w $[PAA]t_{18w}$ = 2.6% w/w	Report study number 16-35-077-ES: Physical-

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	(Deviation from the study plan: temperature conditions decreased down to 18.3°C for successive 3 days during week 14.) HEDP packaging The method is the one validated in section 2.2.4	- Batch QUA-JCF-P35S	Variation: 7% $[H_2O_2]t_0$ = 25.9% w/w $[H_2O_2]t_{18w}$ = 23.6% w/w Variation: 8.9% $[AA]t_0$ = 4.5% w/w $[AA]t_{18w}$ = 4.3% w/w Variation: 4.4% $Weight_{t0}$ = 1070.24 g $Weight_{18w}$ = 1061.29 g Loss of 0.8 % Neat: pH_{t0} = 0.76 pH_{18w} = 0.87 1% dilution: pH_{t0} = 3.03 pH_{18w} = 3.03 No change in appearance of product, no alteration of the packaging	chemical properties, stability and shelflife of Indal PAA 3.5. Part 1 : Physical-chemical properties upon receipt and after accelerated storage, E. Servajean, September 2017
		INDAL PAA 2.5 (Meta-SPC 2) - 2.0% PAA - Batch QUA-JCF-HD10427	$[PAA]t_0$ = 2.1% w/w $[PAA]t_{18w}$ = 1.8% w/w Variation: 14.3% $[H_2O_2]t_0$ = 33.9% w/w	Report study number 16-35-076-ES: Physical-chemical properties, stability and shelflife of Indal PAA 2.5. Part 1 :

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			$[H_2O_2]t_{18w}$ = 30.7% w/w Variation: 9.4% $[AA]t_0$ = 2.2% w/w $[AA]t_{18w}$ = 1.6% w/w Variation: 27.3% $Weight_{t0}$ = 1067.81 g $Weight_{18w}$ = 1051.7 g Loss of 1.5 % Neat: pH_{t0} = 0.43 pH_{18w} = 0.58 1% dilution: pH_{t0} = 3.33 pH_{18w} = 3.23 No change in appearance of product, no alteration of the packaging	Physical-chemical properties upon receipt and after accelerated storage, E. Servajean, September 2017
		INDAL PAA 5 (Meta-SPC 3) - 5.3% PAA - Batch QUA-JCF-F8-PER50	$[PAA]t_0$ = 5.8% w/w $[PAA]t_{18w}$ = 4.9% w/w Variation: 15.5% $[H_2O_2]t_0$ = 25.9% w/w $[H_2O_2]t_{18w}$ = 22.7% w/w Variation: 12.4% $[AA]t_0$ = 7.3% w/w $[AA]t_{18w}$ = 7.6% w/w	Report study number 16-35-078-ES: Physical-chemical properties, stability and shelflife of Indal PAA 5. Part 1 : Physical-chemical properties upon receipt and after accelerated storage, E.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Variation: 4.1% $Weight_{t0}$ = 1069.56 g $Weight_{18w}$ = 1056.39 g Loss of 1.2% Neat: pH_{t0} = 0.24 pH_{18w} = 0.39 1% dilution: pH_{t0} = 2.64 pH_{18w} = 2.80 No change in appearance of product, no alteration of the packaging	Servajean, September 2017
		INDAL PAA 15 (Meta-SPC 4) - 15.8% PAA - Batch QUA-JCF-F1-HD10778	$[PAA]t_0$ = 16.8% w/w $[PAA]t_{18w}$ = 13.7% w/w Variation: 18.5% $[H_2O_2]t_0$ = 24.3% w/w $[H_2O_2]t_{18w}$ = 21.6% w/w Variation: 11.1% $[AA]t_0$ = 12.4% w/w $[AA]t_{18w}$ = 14.8% w/w Variation: 19.4%	Report study number 16-35-079-ES: Physical-chemical properties, stability and shelflife of Indal PAA 15. Part 1 : Physical-chemical properties upon receipt and after accelerated storage, E. Servajean, September 2017

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			$Weight_{t0}$ = 1068.62 g $Weight_{18w}$ = 1038.48 g Loss of 2.8% Neat: pH_{t0} = -0.194 pH_{18w} = 0.13 1% dilution: pH_{t0} = 2.63 pH_{18w} = 2.74 No change in appearance of product, no alteration of the packaging	
		INDAL OXY MOUSS (Meta-SPC 5) - 1.2% PAA - Batch QUA-JCF-F8-HD10350	$[PAA]t_0$ = 1.2% w/w $[PAA]t_{18w}$ = 1.1% w/w Variation: 8.3% $[H_2O_2]t_0$ = 12.8% w/w $[H_2O_2]t_{18w}$ = 11.5% w/w Variation: 10.2% $[AA]t_0$ = 5.7% w/w $[AA]t_{18w}$ = 5.7% w/w No variation $Weight_{t0}$ = 1069.44 g $Weight_{18w}$ = 1064.02 g	Report study number 16-35-080-ES: Physical-chemical properties, stability and shelflife of Indal Oxy Mouss. Part 1 : Physical-chemical properties upon receipt and after accelerated storage, E. Servajean, September 2017

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Loss of 0.5 % Neat: pH_{t0} = 1.07 pH_{18w} = 1.06 1% dilution: pH_{t0} = 2.93 pH_{18w} = 2.89 No change in appearance of product, no alteration of the packaging Foaming after 1 min: - 0.5% dilution rate: 2% of foam for fresh sample (4 ml), 4% for aged sample (8 ml) - 10% dilution rate: 27% of foam for fresh sample (54 ml), 44% for aged sample (88 ml) Foaming after 12 min: - 0.5% dilution rate: 1% of foam for fresh sample (2 ml), 3% for	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			aged sample (6 ml) - 10% dilution rate: 25% of foam for fresh sample (50 ml), 20% for aged sample (40 ml)	
		INDAL TAP 5 (Meta-SPC 6) - 5.0% PAA - Batch QUA-JCF-HD10390	$[PAA]t_0$ = 5.2% w/w $[PAA]t_{18w}$ = 3.9% w/w Variation: 25% $[H_2O_2]t_0$ = 19.5% w/w $[H_2O_2]t_{18w}$ = 13.5% w/w Variation: 30.8% $[AA]t_0$ = 5.6% w/w $[AA]t_{18w}$ = 6.4% w/w Variation: 14.3% $Weight_{t0}$ = 1073.02 g $Weight_{18w}$ = 1038.97 g Loss of 3.2% Neat: pH_{t0} = -0.31 pH_{18w} = -0.21 1% dilution: pH_{t0} = 1.59 pH_{18w} = 1.76	Report study number 16-35-081-ES: Physical-chemical properties, stability and shelflife of Indal Tap 5. Part 1 : Physical-chemical properties upon receipt and after accelerated storage, E. Servajean, September 2017

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			No change in appearance of product, no alteration of the packaging	
Storage stability test – **long term storage at ambient temperature**	Ambiant temperature, intermediate results available at 3 – 6 – 9 – 12-18 -24 months. HEDP packaging The method is the one validated in section 2.2.4	INDAL PAA 3.5 (Meta-SPC 1) - 2.6% PAA - Batch QUA-JCF-P35S	$[PAA]t_0$ = 2.83% w/w $[PAA]t_{24m}$ = 2.56% w/w Variation: 9.5% $[H_2O_2]t_0$ = 26.0% w/w $[H_2O_2]t_{24m}$ = 23.72% w/w Variation: 8.8% $[AA]t_0$ = 4.51% w/w $[AA]t_{24m}$ = 5.68% w/w Variation: 25.9% $[AA]t_0$ = 4.51% w/w $[AA]t_{18m}$ = 4.9% w/w Variation: 8.6% $Weight_{t0}$ = 1069.32 g $Weight_{24m}$ = 1055.41 g Loss of 1.30% Neat: pH_{t0} = 0.71 pH_{24m} = 0.74 1% dilution: pH_{t0} = 2.99 pH_{24m} = 2.92	Study 16-35-077-ES: Final report Physical- chemical properties, stability and shelf-life of Indal PAA 3.5, Part 2: shelf-life, Servajean, June 2019

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			No change in appearance of product, no alteration of the packaging	
		INDAL PAA 2.5 (Meta-SPC 2) - 2.0% PAA - Batch QUA-JCF-HD10427	$[PAA]t_0$ = 2.08% w/w $[PAA]t_{24m}$ = 1.63% w/w Variation: 21.63% $[PAA]t_0$ = 2.08% w/w $[PAA]t_{18m}$ = 1.91% w/w Variation: 8.17% $[H_2O_2]t_0$ = 33.94% w/w $[H_2O_2]t_{18m}$ = 31.48% w/w $[H_2O_2]t_{24m}$ = 31.99% w/w Variation: 5.7% $[AA]t_0$ = 2.20% w/w $[AA]t_{18m}$ = 1.98% w/w $[AA]t_{24m}$ = 2.11% w/w Variation: 4.09% $Weight_{t0}$ = 1065.51 g $Weight_{24m}$ = 1044.50 g Loss of 1.97% Neat: pH_{t0} = 0.43 pH_{24m} = 0.46	Study 16-35-076-ES: Final report Physical- chemical properties, stability and shelf-life of Indal PAA 2.5, Part 2: shelf-life, Servajean, June 2019

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			1% dilution: pH_{t0} = 3.33 pH_{24m} = 3.21 No change in appearance of product, no alteration of the packaging	
		INDAL PAA 5 (Meta-SPC 3) - 5.3% PAA - Batch QUA-JCF-F8-PER50	$[PAA]t_0$ = 5.76% w/w $[PAA]t_{24m}$ = 5.13% w/w Variation: 10.9% $[PAA]t_0$ = 5.76% w/w $[PAA]t_{18m}$ = 5.21% w/w Variation: 9.55% $[H_2O_2]t_0$ = 25.87% w/w $[H_2O_2]t_{24m}$ = 23.00% w/w Variation: 11.09% $[H_2O_2]t_0$ = 25.87% w/w $[H_2O_2]t_{18m}$ = 23.16% w/w Variation: 10.48% $[H_2O_2]t_0$ = 25.87% w/w $[H_2O_2]t_{12m}$ = 23.46% w/w Variation: 9.32% $[AA]t_0$ = 7.29% w/w $[AA]t_{24m}$ = 10.07% w/w	Study 16-35-078-ES: Final report Physical- chemical properties, stability and shelf-life of Indal PAA 5, Part 2: shelf-life, Servajean, June 2019

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Variation: 38.13% $[AA]t_0$ = 7.29% w/w $[AA]t_{18m}$ = 7.72% w/w Variation: 5.9% $Weight_{t0}$ = 1072.01 g $Weight_{24m}$ = 1057.58 g Loss of 1.35% Neat: pH_{t0} = 0.24 pH_{24m} = 0.27 1% dilution: pH_{t0} = 2.64 pH_{24m} = 2.74 No change in appearance of product, no alteration of the packaging	
		INDAL PAA 15 (Meta-SPC 4) - 15.8% PAA - Batch QUA-JCF-F1-HD10778	$[PAA]t_0$ = 16.8% w/w $[PAA]t_{12m}$ = 15.09% w/w Variation: 10.2% $[PAA]t_0$ = 16.8% w/w $[PAA]t_{9m}$ = 15.30% w/w Variation: 8.9% $[H_2O_2]t_0$ = 24.3% w/w $[H_2O_2]t_{12m}$ = 21.48% w/w Variation: 11.6%	Report study number 16-35-079-ES: Physical-chemical properties, stability and shelflife of Indal PAA 15. Part 2 : shelf-life, Servajean, June 2018

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			$[H_2O_2]t_0$ = 24.3% w/w $[H_2O_2]t_{9m}$ = 22.04% w/w Variation: 9.3% $[AA]t_0$ = 12.4% w/w $[AA]t_{12m}$ = 14.89% w/w Variation: 20.1% $[AA]t_0$ = 12.4% w/w $[AA]t_{9m}$ = 12.79% w/w Variation: 3.15% $Weight_{t0}$ = 1069.12 g $Weight_{12m}$ = 1052.98 g Loss of 1.51% Neat: pH_{t0} = -0.194 pH_{12m} = 0.5 1% dilution: pH_{t0} = 2.63 pH_{12m} = 2.9 No change in appearance of product, no alteration of the packaging	
		INDALOXY MOUSS (Meta-SPC 5) - 1.2% PAA - Batch QUA-JCF-F8-HD10350	$[PAA]t_0$ = 1.19% w/w $[PAA]t_{24m}$ = 0.94% w/w Variation: 21.00% $[PAA]t_0$ = 1.19% w/w	Report study number 16-35-080-ES: Physical-chemical properties,

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			$[PAA]t_{18m}$ = 1.09% w/w Variation: 8.40% $[H_2O_2]t_0$ = 12.81% w/w $[H_2O_2]t_{24m}$ = 12.06% w/w Variation: 5.85% $[AA]t_0$ = 5.72% w/w $[AA]t_{24m}$ = 5.55% w/w Variation: 2.97% $Weight_{t0}$ = 1067.22 g $Weight_{24m}$ = 1057.58 g Loss of 0.9% Neat: pH_{t0} = 1.07 pH_{24m} = 1.07 1% dilution: pH_{t0} = 2.93 pH_{24m} = 2.88 Persistent foaming at 0.5% $_{t0}$ =2% at 1 min, 1% at 12 min Persistent foaming at 0.5% $_{t24m}$ = 8% (16 ml) at 1 min, 5% at 12 min (10 ml)	stability and shelflife of Indal Oxy Mouss. Part 2 : shelf-life, Servajean, June 2019

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Persistent foaming at 10% $_{t0}$ =27% at 1 min, 25% at 12 min Persistent foaming at 10% $_{t24m}$ = 19% (38 ml) at 1 min, 18% (36 ml) at 12 min No change in appearance of product, no alteration of the packaging	
		INDAL TAP 5 (Meta-SPC 6) - 5.0% PAA - Batch QUA-JCF-HD10390	$[PAA]t_0$ = 5.2% w/w $[PAA]t_{12m}$ = 4.21% w/w Variation: 19.3% $[PAA]t_0$ = 5.2% w/w $[PAA]t_{6m}$ = 4.69% w/w Variation: 9.8% $[H_2O_2]t_0$ = 19.5% w/w $[H_2O_2]t_{12m}$ = 15.32% w/w Variation: 21.4% $[H_2O_2]t_0$ = 19.5% w/w $[H_2O_2]t_{6m}$ = 17.51% w/w Variation: 10.2% $[AA]t_0$ = 5.6% w/w $[AA]t_{12m}$ = 6.8% w/w Variation: 21.4% $[AA]t_0$ = 5.6% w/w $[AA]t_{6m}$ = 5.84% w/w Variation: 4.3%	Report study number 16-35-081-ES: Physical-chemical properties, stability and shelflife of Indal Tap 5. Part 2 : Shelf-life, E. Servajean, July 2018

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			$Weight_{t0}$ = 1066.71 g $Weight_{12m}$ = 1036.14 g Loss of 2.87% Neat: pH_{t0} = -0.31 pH_{12m} = 0.25 1% dilution: pH_{t0} = 1.59 pH_{12m} = 1.97 No change in appearance of product, no alteration of the packaging	
Storage stability test – **low temperature stability test for liquids**		INDAL PAA 3.5 (Meta-SPC 1)	The products are not intended to be exposed to low temperatures. The mention "Protect from frost" is intended to be indicated on the label.	
		INDAL PAA 2.5 (Meta-SPC 2)		
		INDAL PAA 5 (Meta-SPC 3)		
		INDAL PAA 15 (Meta-SPC 4)		
		INDAL OXY MOUSS (Meta-SPC 5)		
		INDAL TAP 5 (Meta-SPC 6)		
Effects on content of the active substance and technical characteristics of the biocidal product - **ligh**t	Statement	QUARON PAA Family, on the six products	All products will be sold in opaque packages. Thus, the light sensitivity during storage was not addressed. The risk mitigation measure: "protect form light" is to be added.	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Statement	QUARON PAA Family, on the six products	Effect of higher temperature than recommended storage temperature is addressed in accelerated storage. Effect of humidity is not applicable for the concerned type of formulation and packaging.	
Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material	-	QUARON PAA Family, on the six products	The commercial packaging is intact at the end of long-term stability tests.	
Wettability	n.a.	Irrelevant for the formulation type of the products		
Suspensibility, spontaneity and dispersion stability	n.a.	Irrelevant for the formulation type of the products		
Wet sieve analysis and dry sieve test	n.a.	Irrelevant for the formulation type of the products		
Emulsifiability, re-emulsifiability and emulsion stability	n.a.	Irrelevant for the formulation type of the products		
Disintegration time	n.a.	Irrelevant for the formulation type of the products		
Particle size distribution, content of dust/fines, attrition, friability	Waived	This technical parameter has only a consequence on the inhalation absorption of aerosol droplets. So, even if this MMAD is not measured, the following justification can be made. The exposure assessment of the human health risk assessment was conducted considering two possible physical states of the substances (active substance and substances of concern) contained in the different formulations: 1) The exposure to aerosol generated during the applications of the products which was assessed by the TNsG 2002 Spraying model 2, 2) The exposure to the vapours of the substances during the application by spraying assessed by the Evaporation model of ConsExpo. Taking into account this approach, the following analysis can be made: The conducted exposure to vapour scenario of ConsExpo considers 100% of the applied product will evaporate and generate vapours to which the user is directly exposed, considering a mass transfer coefficient. This coefficient is supposed to be a worst-case as now the Thibodeau's method is not applied anymore in the exposure assessment (cfr updated Cleaning products factsheet of RIVM from February 2018). In addition, the exposure to aerosol droplets is summed up to the exposure to vapours assessed by ConsExpo. That means the exposure assessment overestimate the real inhalation exposure. Indeed, it considers all the substances assessed in the HHRA		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		will turn to vapour and will be directly inhalated by the user. To this exposure, is added the inhalable aerosol. So, it can be concluded the inhalation exposure assessed in the HHRA takes into account all the possible states of the product. Furthermore, the MMAD would only be useful in the case this parameter would be directly used in the exposure assessment. But it is not the case in this dossier. In these terms, there is no indication to measure the MMAD. Besides the HHRA aspects, the products applied by manual spraying are used in a large possible range of sprayers, from which it would be not possible to determine a worst-case for the testing. And as already stated above, even if it could be measured, this parameter will not have any impact in the dossier as all the potential exposure triggered by the inhalable droplets is already taken into account in the Exposure assessment and risk characterization of the human health risk assessment.		
Persistent foaming	CIPAC method MT 47.3 Measures at 10 sec, 1min, 3 min & 12 min.	INDAL PAA 3.5 (Meta-SPC 1) - 2.6% PAA - Batch QUA-JCF-P35S *Performed on both lowest (0.1% w/w) and highest (5.0% w/w) in use*	No foam (no foaming observed after accelerated storage testing)	Report study number 16-35-077-ES
		INDAL PAA 2.5 (Meta-SPC 2) - 2.0% PAA - Batch QUA-JCF-HD10427 *Performed on both lowest (0.1% w/w) and highest (5.0% w/w) in use*	No foam (no foaming observed after accelerated storage testing)	Report study number 16-35-076-ES
		INDAL PAA 5 (Meta-SPC 3) - 5.3% PAA - Batch QUA-JCF-F8-PER50	No foam (no foaming observed after accelerated storage testing)	Report study number 16-35-078-ES

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		Performed on both lowest (0.1% w/w) and highest (5.0% w/w) in use		
		INDAL PAA 15 (Meta-SPC 4) - 15.8% PAA - Batch QUA-JCF-F1-HD1077 *Performed on both lowest (0.1% w/w) and highest (3.0% w/w) in use*	No foam (no foaming observed after accelerated storage testing)	Report study number 16-35-079-ES
		INDAL OXY MOUSS (Meta-SPC 5) - 1.2% PAA - Batch QUA-JCF-F8-HD10350 *Performed on both lowest (0.5% w/w) and highest (10.0% w/w) in use*	Product supplied as a foam	
		INDAL TAP 5 (Meta-SPC 6) - 5.0% PAA - Batch QUA-JCF-HD10390 *Performed on both lowest (0.1% w/w) and highest (5.0% w/w) in use*	No foam (no foaming observed after accelerated storage testing)	Report study number 16-35-081-ES
Flowability/Pourability/Dustability	n.a.	Irrelevant for the formulation type of the products		
Burning rate — smoke generators	n.a.	Irrelevant for the formulation type of the products		
Burning completeness — smoke generators	n.a.	Irrelevant for the formulation type of the products		
Composition of smoke — smoke generators	n.a.	Irrelevant for the formulation type of the products		
Spraying pattern — aerosols	n.a.	Irrelevant for the formulation type of the products		
Physical compatibility Chemical compatibility	Statement	QUARON PAA Family, on the six products	This parameter is not required as a combined application with another product is not recommended or foreseen by the applicant	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Degree of dissolution and **dilution stability**	CIPAC method MT 41.1. 24 hours of standing Performed on highest and lowest in use concentrations of each product	INDAL PAA 3.5 (Meta-SPC 1) - 2.6% PAA - Batch QUA-JCF-P35S	No separated material (no separated material on products after accelerated and long-term ambiant temperature storage testing)	Report study number 16-35-077-ES
		INDAL PAA 2.5 (Meta-SPC 2) - 2.0% PAA - Batch QUA-JCF-HD10427		Report study number 16-35-076-ES
		INDAL PAA 5 (Meta-SPC 3) - 5.3% PAA - Batch QUA-JCF-F8-PER50		Report study number 16-35-078-ES
		INDAL PAA 15 (Meta-SPC 4) - 15.8% PAA - Batch QUA-JCF-F1-HD10778		Report study number 16-35-079-ES
		INDAL OXY MOUSS (Meta-SPC 5) - 1.2% PAA - Batch QUA-JCF-F8-HD10350		Report study number 16-35-080-ES
		INDAL TAP 5 (Meta-SPC 6) - 5.0% PAA - Batch QUA-JCF-HD10390		Report study number 16-35-081-ES
Surface tension	OECD method 115 T° = 20°C Deviation from the study plan: measure performed on the neat item instead of highest in use concentration.	INDAL PAA 3.5 (Meta-SPC 1) - 2.6% PAA - Batch QUA-JCF-P35S	55.2 mN/m	Report study number 16-35-077-ES
		INDAL PAA 2.5 (Meta-SPC 2) - 2.0% PAA - Batch QUA-JCF-HD10427	49.0 mN/m	Report study number 16-35-076-ES

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	We are of opinion that these tests are still acceptable, since the results show that for all products except INDAL OXY MOUSS, the wetting potential of products is low. It will be lower once the products are diluted. For INDAL OXY MOUSS, the only tension-actif product, the measure was permformed for both neat and diluted product.	INDAL PAA 5 (Meta-SPC 3) - 5.3% PAA - Batch QUA-JCF-F8-PER50	54.0 mN/m	Report study number 16-35-078-ES
		INDAL PAA 15 (Meta-SPC 4) - 15.8% PAA - Batch QUA-JCF-F1-HD10778	47.1 mN/m	Report study number 16-35-079-ES
		INDAL OXY MOUSS (Meta-SPC 5) - 1.2% PAA - Batch QUA-JCF-F8-HD10350	30.7 mN/m for the neat product 27.4 mN/m for the dilution at 10g/L	Report study number 16-35-080-ES
		INDAL TAP 5 (Meta-SPC 6) - 5.0% PAA - Batch QUA-JCF-HD10390	53.7 mN/m	Report study number 16-35-081-ES
Viscosity	OECD method 114 T_1°: 20.1°C T_2°: 40.0°C	INDAL PAA 3.5 (Meta-SPC 1) - 2.6% PAA - Batch QUA-JCF-P35S	At 20.0°C: 0.89 mm²/s At 40.1°C: 0.59 mm²/s	Report study number 16-35-077-ES
		INDAL PAA 2.5 (Meta-SPC 2) - 2.0% PAA - Batch QUA-JCF-HD10427	At 20.1°C: 0.83 mm²/s At 40.0°C: 0.56 mm²/s	Report study number 16-35-076-ES
		INDAL PAA 5 (Meta-SPC 3) - 5.3% PAA - Batch QUA-JCF-F8-PER50	At 20.1°C: 0.97 mm²/s At 40.0°C: 0.63 mm²/s	Report study number 16-35-078-ES
		INDAL PAA 15 (Meta-SPC 4) - 15.8% PAA - Batch QUA-JCF-F1-HD10778	At 20.1°C: 1.21 mm²/s At 40.0°C: 0.76 mm²/s	Report study number 16-35-079-ES

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		INDAL OXY MOUSS (Meta-SPC 5) - 1.2% PAA - Batch QUA-JCF-F8-HD10350	At 20.1°C: 1.06 mm²/s At 40.0°C: 0.71 mm²/s	Report study number 16-35-080-ES
		INDAL TAP 5 (Meta-SPC 6) - 5.0% PAA - Batch QUA-JCF-HD10390	At 20.1°C: 1.26 mm²/s At 40.0°C: 0.85 mm²/s	Report study number 16-35-081-ES

For the stability, please find below the summarising table and the accepted shelf-life and restriction to be indicated on the label:

Meta-SPC/product	Results of accelerated storage test (if concentration variation is below 10%: OK. On the contrary: NOK)	Results of ambient temperature storage test (if concentration variation is below 10%: OK. On the contrary: NOK)	Accepted shelf life and justification	Restriction to indicate on the label – related to temperature of storage
Meta-SPC 1/ INDAL PAA 3.5	PAA OK H_2O_2 OK AA OK Other parameters OK	<u>24 months</u> PAA OK H_2O_2 OK AA NOK Other parameters OK <u>18 months</u> PAA OK H_2O_2 OK AA OK Other parameters OK	18 months Both a.s. and precursors show variation within 10% after a storage of 18 months at ambient temperature	Do not store at temperatures below 0°C Store at temperature no greater than 30°C

Meta-SPC 2/ INDAL PAA 2.5	PAA OK H_2O_2 OK AA NOK Other parameters OK	<u>24 months</u> PAA NOK H_2O_2 OK AA OK Other parameters OK <u>18 months</u> PAA OK H_2O_2 OK AA OK Other parameters OK	18 months Both a.s. and precursors show variation within 10% after a storage of 18 months at ambient temperature	Do not store at temperatures below 0°C Store at temperature no greater than 30°C
Meta-SPC 3/ INDAL PAA 5	PAA NOK H_2O_2 NOK AA OK Other parameters OK	<u>24 months</u> PAA NOK H_2O_2 NOK AA NOK Other parameters OK <u>18 months</u> PAA OK H_2O_2 NOK (slightly higher than 10%) AA OK Other parameters OK <u>12 months</u> PAA OK H_2O_2 OK AA OK Other parameters OK	18 months Both a.s. and precursor are not stable under accelerated storage conditions, meaning that the storage at 30°C must be excluded. One precursor shows variation around 10% after a storage of 18 months at ambient temperature Both a.s. and precursors show variation within 10% after a storage of 12 months at ambient temperature	Do not store at temperatures below 0°C Store at temperature no greater than 30°C

Meta-SPC 4/ INDAL PAA 15	PAA NOK H_2O_2 NOK AA NOK Other parameters OK	<u>12 months</u> PAA OK H_2O_2 NOK AA NOK Other parameters stable <u>6 months</u> PAA OK H_2O_2 OK AA OK Other parameters stable	12 months The variation of the products equilibrium components is greater than 10%, but the variation of the active substance itself, *i.e.* peracetic acid, does not exceed 10%. A shelf-life of one year is therefore justified, as no increase in the hazard caused by the product can be expected, and the product can be foreseen to still show sufficient efficacy after one year of storage, as the variation of PAA (a.s.) is lower than 10% and therefore should not adversely affect the efficacy and risk assessment of the product. Since the variation is within the range, there is no need to address the efficacy after 1 year... The absence of additional danger rests on the following elements: - The decrease in hydrogen peroxide content is explained by the well-known phenomenon of dissociation of H_2O_2 into water and dioxygen. - This decrease in hydrogen peroxide modifies the equilibrium state of the product and leads to the formation of acetic acid from peracetic acid, as can be seen from the parallel increase in acetic acid and decrease in peracetic acid. Indeed, based on the molecular weight of both substances, a	Do not store at temperatures below 0°C Store at temperature no greater than 30°C

			decrease of 1 g/kg of peracetic acid should lead to an increase of 0.79 g/kg of acetic acid. The acetic acid content found being greater than what could be expected from this ratio and from the decreased concentration in peracetic acid, it means that the whole lost content in peracetic acid can be explained by the increase of acetic acid. Since the only possible source of acetic acid in the formulation is peracetic acid, the greater-than-expected increase in acetic acid is considered to be due to experimental errors. The decrease in hydrogen peroxide and in peracetic acid diminishes the hazard caused by the product, while the formation of water and dioxygen does not increase it. Regarding the raise in the acetic acid concentration, it could be argued that it brings additional danger. However, since an increase in acetic acid is only possible from a decrease in peracetic acid, which is a more dangerous compound, it can be concluded that no additional danger is expected from the aged product compared with the product assessed at its initial concentrations. BE eCA agrees with the explanation of the	

			applicant: the PAA concentration remains in the acceptable variation in order to guarantee enough efficacy. The two other partners of the equilibrium vary indeed, but the degradation compounds are well known: water and acetic acid.	
Meta-SPC 5/ INDAL OXY MOUSS	PAA OK H_2O_2 OK AA OK Other parameters OK	<u>24 months</u> PAA NOK H_2O_2 OK AA OK Other parameters OK <u>18 months</u> PAA OK H_2O_2 OK AA OK Other parameters OK	18 months Both a.s. and precursors show variation within 10% after a storage of 18 months at ambient temperature	Do not store at temperatures below 0°C Store at temperature no greater than 30°C
Meta-SPC 6/ INDAL TAP 5	PAA NOK H_2O_2 NOK AA NOK Other parameters OK	<u>12 months</u> PAA NOK H_2O_2 NOK AA NOK Other parameters stable <u>9 months</u> PAA OK H_2O_2 OK	12 months The stability results after 12 months of storage at ambient temperature are as follows: • Loss of 20.1% of peracetic acid, equivalent to a loss of 10.6 g/kg. • Loss of 21.6% of hydrogen peroxide, equivalent to a loss of 42.2 g/kg.	Do not store at temperatures below 0°C Store at temperature no greater than 30°C

		AA OK Other parameters stable	• Increase of 20.7% of acetic acid, equivalent to an increase of 11.6 g/kg. The variations of the three equilibrium constituents are greater than 10%. Yet, in this case also, sufficient elements exist to justify a shelf-life of one year. First, efficacy results are available to show that the product will still be sufficiently efficacious after one year of storage. These results are summarised in section 2.2.5, and are also briefly discussed below. Then, no additional danger can be expected following the change in composition during storage. Indeed, as explained for INDAL PAA 15, hydrogen peroxide naturally turns into water and oxygen, leading to a decrease in the hazard caused by the product as oxygen and water are less dangerous than H2O2. Also, the loss of peracetic acid is explained by the gain in acetic acid since its increase is greater than 79% of the decrease in peracetic acid. The greater-than-expected increase in acetic acid is considered to come from experimental errors. As the acetic acid increase is balanced by a peracetic acid loss, the aged product does not cause any additional risk compared with the unaged formulation.	

			According to report MERIEUX 18/000031718 (EN1276) and according to report MIDAC RE-17-203-1 (EN1650), it can be concluded that under clean conditions, INDAL TAP 5 has: • bactericidal and yeasticidal efficacies when used at 0.3% (basic requirements / EFF guidance), under clean conditions, at +20°C in 15 min, • Bactericidal, yeasticidal/fungicidal efficacies when used at 2%, under clean conditions, at +20°C in 15 min. A sample of INDAL TAP 5 was taken from those used for the PHYTOSAFE long-term storage study and tested according to EN1276 and EN1650, after more than 12 months due to laboratories constraints (manufactured on 13/02/2017, tested from 17/09/2018 to 27/09/2018, which means after 19 months). According to report MERIEUX 18/000462974 (EN1276), this aged INDAL TAP 5 sample has shown a bactericidal efficacy under clean conditions, at 20°C in 5 minutes when used at 0.4%. In this test, INDAL TAP 5 has bactericidal activity (log R ≥ 5) at 0.25% against Pseudomonas aeruginosa, Escherichia coli and Enterococcus hirae strains, but Staphylococcus aureus is the limiting strain. With the 0.3% concentration of INDAL TAP 5, the bactericidal activity is nearly reached (log R = 4,88) against Staphylococcus aureus in 5	

			minutes, so it is quite sure than with a 15 minutes contact time, a bactericidal activity with log R ≥ 5 would be achieved also against this strain. According to report MERIEUX 18/000462979 (EN1650), this aged INDAL TAP 5 sample has shown a yeasticidal efficacy under clean conditions, at 20°C in 15 minutes when used at 0.3%, and a fungicidal efficacy when used at 2%. From these two tests, it can be concluded that an aged INDAL TAP 5 (more than 12 months) has the same efficacy than a new made one: • bactericidal and yeasticidal efficacies when used at 0.3% (basic requirements / EFF guidance), under clean conditions, at +20°C in 15 min, • Bactericidal, yeasticidal/fungicidal efficacies when used at 2%, under clean conditions, at +20°C in 15 min.	

Conclusion on the physical, chemical and technical properties of the product
All products of the family are colourless translucent liquids with vinegar-like odour. The pH for the family is between -0.31 and 1.07 for the neat product, and between 1.59 and 3.33 for the 1% dilutions. The relative density for the family is between 1.065 and 1.207. All products are to be protected from light. Combined application with another product is not recommended or foreseen. **No persistent foaming is detected for all products except the one intended to be for foam application. The dilution stability tests have demonstrated no separated material for all products. The surface tension of the products is ranged between 30.7 mN/m and 54 mN/m. The viscosity at 20°C is in the range 0.83 – 1.26 mm²/s and 0.56 – 0.85 mm²/s for 40°C.** **The shelflife of the meta-SPCs 1, 2, 3, and 5 is set to 18 months, based on accelerated storage tests and ambient temperature storage tests. The shelflife of the meta-SPCs 4 and 6 is set to 12 months, based on efficacy tests on aged products. The mentions "Store at temperature no greater than 30°C" and "Protect from frost" are to be indicated on the label.**

2.2.3 Physical hazards and respective characteristics

All physical hazards characteristics were determined on the formulation as commercialized.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	This hazard is covered by "Organic peroxide hazard"			
Flammable gases	n.a.	Irrelevant for the formulation type of the products		
Flammable aerosols	n.a.	Irrelevant for the formulation type of the products		
Oxidising gases	n.a.	Irrelevant for the formulation type of the products		
Gases under pressure	n.a.	Irrelevant for the formulation type of the products		
Flammable liquids	EEC A9, The measurement was operated according to the equilibrium method, using a closed-cup Setaflash tester Series 3 (Stanhope SETA Ltd)	INDAL PAA 3.5 (Meta-SPC 1) - 2.6% PAA - Batch QUA-JCF-P35S	Flash point = 84°C	Report study number 16-35-077-ES
		INDAL PAA 2.5 (Meta-SPC 2) - 2.0% PAA - Batch QUA-JCF-HD10427	Flash point >90°C (at 90°C: greenish deposit, supposed degradation of a.s.)	Report study number 16-35-076-ES
		INDAL PAA 5 (Meta-SPC 3) - 5.3% PAA Batch QUA-JCF-F8-PER50	Flash point >105°C (at 90°C: greenish deposit, supposed degradation of a.s.)	Report study number 16-35-078-ES
		INDAL PAA 15 (Meta-SPC 4) - 15.8% PAA	Flash point = 80°C	Report study number 16-35-079-ES

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		- Batch QUA-JCF-F1-HD10778		
		INDAL OXY MOUSS (Meta-SPC 5) - 1.2% PAA - Batch QUA-JCF-F8-HD10350	Flash point >105°C (at 90°C: greenish deposit, supposed degradation of a.s.)	Report study number 16-35-080-ES
		INDAL TAP 5 (Meta-SPC 6) - 5.0% PAA - Batch QUA-JCF-HD10390	Flash point >110°C (at 90°C: greenish deposit, supposed degradation of a.s.)	Report study number 16-35-081-ES
Flammable solids	n.a.	Irrelevant for the formulation type of the products		
Self-reactive substances and mixtures	The formulation is predominantly composed of water. In addition, the mixture is not classified as an oxidizer. Furthermore, this hazard is covered by the hazard "Organic peroxide".			
Pyrophoric liquids	Experience in manufacture or handling shows that the liquid does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the liquid is known to be stable at room temperature for prolonged periods of time (days)). Thus, based on the guidance on the application of the CLP criteria (Guidance to Regulation (EC) No 1272/2008, 2015, version 4.1), this classification can be excluded without further testing.			
Pyrophoric solids	n.a.	Irrelevant for the formulation type of the products		
Self-heating substances and mixtures	n.a.	Irrelevant for the formulation type of the products		
Substances and mixtures which in contact with water emit flammable gases	Experience in handling and use shows that the mixture does not react with water. The formulation contains water and can be mixed with water to form a stable mixture. Thus, based on the guidance on the application of the CLP criteria (Guidance to Regulation (EC) No 1272/2008, 2015, version 4.1), this classification can be excluded without further testing			
Oxidising liquids	Please see the explanation concerning organic peroxides below this table			
Oxidising solids	n.a.	Irrelevant for the formulation type of the products		
Organic peroxides	Please see the explanation below		TNO report : Transport classification of two peroxyacetic acid formulations (INDAL PAA 15 (Meta-SPC 4) and INDAL OXY MOUSS (Meta-SPC 5)), April 2019, W. Mak Essais sur les preparations INDAL PAA 3.5 et INDAL PAA 5 Epreuves ONU E.1 et ONU F.2 INERIS DRA-18-175073-06829A, 2019, P. Vicot TESTS ON A PREPARATION OF PERACETIC ACID _ INDAL PAA 2.5 INERIS DRA-19-177201-00330A, 2019, P. Vicot	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			TESTS ON A PREPARATION OF PERACETIC ACID _ INDAL PAA 5 INERIS DRA-19-177201-00659A, 2019, P. Vicot UN TEST F2 ON A PREPARATION OF PERACETIC ACID_INDAL TAP 5 DRA-19-181008-4788A, 2019, P. Vicot	
Corrosive to metals	Experience in handling and use shows that the mixtures are corrosive to metals. Thus, based on the guidance on the application of the CLP criteria (Guidance to Regulation (EC) No 1272/2008, 2015, version 4.1), this classification can be applied without further testing. Each product of the "QUARON PAA family" is thus classified as **Met. Corr. 1, H290**			
Auto-ignition temperatures of products (liquids and gases)	n.a.	Irrelevant for organic peroxide		
Relative self-ignition temperature for solids	n.a.	Irrelevant for the formulation type of the products		
Dust explosion hazard	n.a.	Irrelevant for the formulation type of the products		

Organic peroxide hazard:

Because of the presence of peracetic acid and hydrogen peroxide, the products of this BPF are classified as organic peroxide, on basis of the chemical structure of these substances.

In general, the worst case is defined as formulation containing the highest amount of PAA. However, it is important to note that the contents of hydrogen peroxide and peracetic acid have also effects on physical hazards/classification. In this family, a worst case regarding organic peroxide hazard can be reasonably defined as the formulation INDAL PAA 15, fully tested in the test submitted by the applicant.

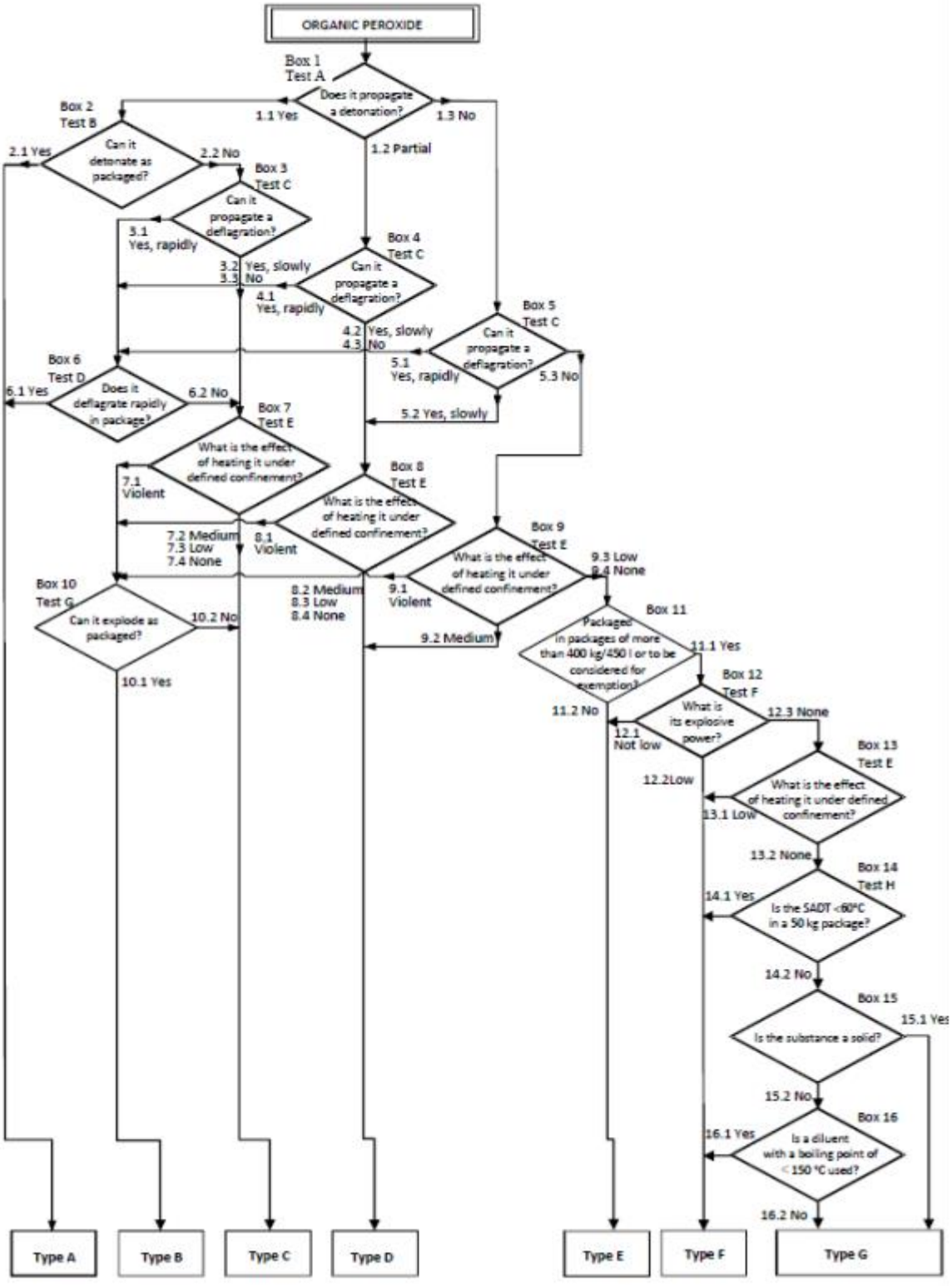
For the meta-SPCs 4 (INDAL PAA 15 product), the applicant has submitted a set of tests:

- UN detonation test (A.6): detonative properties;
- time/pressure test (C.1) and deflagration test (C.2) : deflagrative properties:;
- Koenen test (E.1) and Dutch pressure vessel test (E.2): sensitivity to heating under confinement;
- modified Trauzl test (F.4): explosive power

Additionally, the self-accelerating decomposition temperature (SADT) has been determined using the isothermal storage test (H.3).

All tests are performed according to the procedures laid down in the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, sixth revised edition.

Here is the results of these tests, following the decision logical tree.



Does it propagate a detonation? → NO → Can it propagates a deflagration? → YES, slowly (C.1) & NO (C.2) → What is the effect of heating it under defined confinement? → LOW (E.1 & E.2) → Packaged in packages of more than 400 kg/ 450 l or to be considered for exemption? → YES → What is its explosive power? → NOT LOW → **Type E**.

The self-accelerated temperature of decomposition is 50°C for INDAL PAA 15 product.
The product containing 15 % PAA is thus classified as **Org. Perox. E**, **H242**.

As said previously, the worst case was fully tested. For the rest of the products the applicant has performed a partial testing with some read across to the worst case: Because the peracetic acid and hydrogen peroxide concentration are lower in the other formulations than in INDAL PAA 15, the results of series (A.6 ; C.1 ; C.2) from INDAL PAA 15 can be used for all formulations.

Also because of the lower concentration of :

- INDAL PAA 3.5 compared to INDAL PAA 5, the result of SADT and Dutch pressure vessel test (VPVT) of INDAL PAA 5 can be used for INDAL PAA 3.5;
- INDAL OXY MOUSS compared to INDAL TAP 5, the result of SADT of INDAL TAP 5 can be used for INDAL OXY MOUSS. The strategy and the results are the following:

Test/ series	INDAL PAA 15 Meta-SPC 4		INDAL PAA 2.5 Meta-SPC 2		INDAL PAA 5 Meta-SPC 3		INDAL PAA 3.5 Meta-SPC 1		INDAL OXY MOUSS Meta-SPC 5		INDAL TAP 5 Meta- SPC 6	
	Remark	Result	Remark	Result	Remark	Result	Remark	Result	Remark	Result	Remark	Result
UN detonation test	A.6	No	According to UN MTC Section 21.2.2: A test of UN Test Series A need not be performed if: (a) A "No" result is obtained from the explosive power test (any test of series F except test F.5 for peroxides); and (b) A "No" or "Low" result is obtained from test E.2 and either test E.1 or E.3.									
detonation (series A)	No		No									
time/pressure test	C.1	Yes, slowly	Conclusion, that the test result from INDAL PAA 15 is considered to be valid in relation to the composition of the formulations and no further tests are needed									
deflagration test	C.2	No										
deflagration (series C)	No		No									
Koenen test	E.1	Low	E.1	No	E.1	No	E.1	No	E.1	No	E.1	No
Dutch pressure vessel test (DPVT)	E.2	Low	E.2	No	E.2	No	In relation to the composition of INDAL PAA 5 the result of E.2 is expected to be "No".		E.2	No	E.2	No
heating under confinement (series E)	Low		No		No		No		No		No	
modified Trauzl test (F.4)	F.4	Not low	F.2	No	F.2	No	F.2	No	F.4	No	F.2	No
explosive power (series F)	Not low		No		No		No		No		No	
SADT (typical 50-kg package)	H.3	50°C	ARST calorimeter	135° C	ARST calorimeter	129° C	In relation to the composition of INDAL PAA 5 the SADT is expected to be > 100 °C.		In relation to the composition of INDAL TAP 5 the SADT is expected to be > 70 °C.		H.3	70°C

classification (organic peroxide type) from the tests	E	F	F	F	F	F

Based on the classification criteria/ procedure of organic peroxides, the Meta-SPCs 1, 2, 3, 5 and 6 should in principle be classified as an organic peroxide type F, since the very last point of the decisional tree includes the boiling point of the solvent, water for the BPF.

However, the Guidance on the application of the CLP Criteria describes a*n exceptional case in this respect is a peroxyacetic acid formulation, as currently classified in the UN RTDG Model Regulations under UN 3149, with the following description: HYDROGEN PEROXIDE AND PEROXYACETIC ACID MIXTURE with acid(s), water and not more than 5 % peroxyacetic acid, STABILISED. In the classification procedure for organic peroxides, see decision logic in Section 2.15.4.4, this formulation will be assigned to organic peroxide Type G, and consequently no label elements are allocated. In view of the above, this formulation can be classified, also in accordance with CLP, as an Oxidising liquid, Category 2.*

Based on the content in PAA, this exceptional case could be applied to the meta-SPCs 1, 2, 5 and 6. The **meta-SPC 3** contains 5.3 % of PAA, and thus remains classified as **organic peroxide F**.

Based on this exemption, the Meta-SPCs 1, 2 and 5, are proposed to be classified as **oxidising liquid category 2** (UN 3149), and shall be labelled according the CLP as an **organic peroxide type G** (although it is a type F) to avoid duplicate labelling as oxidising liquid and organic peroxide.

Meta SPC 6 contains a higher amount of sulfuric acid than in the rest of the BPF, so the application of the exceptional provision UN3149 has to be considered with precaution. The special provision 196 of the UN regulation indicates the following: *Formulations which in laboratory testing neither detonate in the cavitated state nor deflagrate, which show no effect when heated under confinement and which exhibit no explosive power may be transported under this entry. The formulation must also be thermally stable (i.e. the SADT is 60°C or higher for a 50 kg packaging).*

The SADT for this product has been tested experimentally and is 70°C, that confirms that the formulation is thermally stable. A ballistic mortar test has also been performed (F.2), with the results "no", showing no explosive properties of the formulation. The effect when heated under confinement (E.1) has also been investgated, and the result is "no". The rest of the tests haven't been performed on this particular formulation but a read across was proposed from the worst case: meta-SPC 4, indicating that no detonation and deflagration are observed. In view of this, and the experimentally obtained SADT, we propose to also classify the meta-SPC 6 as **oxidising liquid category 2** (UN 3149). It shall be labelled according the CLP as an **organic peroxide type G** (although it is a type F) to avoid duplicate labelling as oxidising liquid.

The resulting classification is summarized in the table below:

	Classification	Hazard statements	Pictograms and signal word

Meta-SPC 1	Org. Perox. G (theoric F)[5]	Type G has no hazard communication elements assigned	-
	Ox. Liq. 2	H272: May intensify fire; oxidiser	GHS03, Danger
	Met. Corr. 1	H290: May be corrosive to metals	GHS05, Warning
Meta-SPC 2	Org. Perox. G (theoric F)	Type G has no hazard communication elements assigned	-
	Ox. Liq. 2	H272: May intensify fire; oxidiser	GHS03, Danger
	Met. Corr. 1	H290: May be corrosive to metals	GHS05, Warning
Meta-SPC 3	Org. Perox. F	H242: Heating may cause a fire	GHS02, Warning
	Met. Corr. 1	H290: May be corrosive to metals	GHS05, Warning
Meta-SPC 4	Org. Perox. E	H242: Heating may cause a fire	GHS02, Warning
	Met. Corr. 1	H290: May be corrosive to metals	GHS05, Warning
Meta-SPC 5	Org. Perox. G (theoric F)	Type G has no hazard communication elements assigned	-
	Ox. Liq. 2	H272: May intensify fire; oxidiser	GHS03, Danger
	Met. Corr. 1	H290: May be corrosive to metals	GHS05, Warning
Meta-SPC 6	Org. Perox. G (theoric F)	Type G has no hazard communication elements assigned	-
	Ox. Liq. 2	H272: May intensify fire; oxidiser	GHS03, Danger
	Met. Corr. 1	H290: May be corrosive to metals	GHS05, Warning

Conclusion on the physical hazards and respective characteristics of the product
The flash point for products INDAL PAA 3.5 (Meta-SPC 1) and INDAL PAA 15 (Meta-SPC 4) is, respectively, 80°C and 84°C. For all other products, the degradation occurs before flashing. **The products of the biocidal family present physical hazard classification:** - **All products are classified as Met. Corr. 1, H290.** - **Meta-SPCs 1, 2, 5, 6 are classified as Org. Perox. G and Ox. Liq. 2, H272** - **Meta-SPC 3 is classified as Org. Perox. F, H242**

[5] (theoric F) means if classification as oxidising liquids category 2 is not wanted or the formulation does not fulfil the requirements of the exemption (UN 3149), the product shall be classified as organic peroxide type F.

- **Meta-SPC 4 is classified as Org. Perox. E, H242**

2.2.4 Methods for detection and identification

The applicant has provided validated analytical methods for each product of the biocidal family, all species involved in the equilibrium: peracetic acid, acetic acid and hydrogen peroxide.

The applicant has also provided information on validation parameters of analytical method for detection of SOCs: decyl alcohol ethoxylated and sulphuric acid. The results are indicated in the corresponding tables.

Analytical methods for the analysis of the product INDAL PAA 3.5 (Meta SPC 1) as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Peracetic acid (active substance)	HPLC-UV Parameters: *Mobile phase:* *95% acetonitrile with 0.04% pentafluoropropionic acid* *5% N-formate 50 mM in Water* *Flow: 1.0 ml/min* *T°: 5°C* *Detection: 210 nm* Retention times: Peracetic acid: 4 min Acetic acid: 4.5 min Hydrogen peroxide: 5 min	Linearity: 10 calibration solutions Precision: 6 stock solutions Accuracy: 1 spiking level	Range: 16.4 – 1640.7 mg/L R^2=0.9999	The analytical method was considered as specific and selective on the basis of the retention time and peak shape for peracetic acid.	102.1 to 102.4 %	102.25%	0.21 %	16.4 mg/L	Dr E. Servajean, 2017, Report 16-35-077-ES Part 1
Hydrogen Peroxide		Linearity: 9 calibration solutions Precision: 6 stock solutions	Range: 39.5 – 1973.1 mg/L R^2=0.998	The analytical method was considered as specific and selectiv	99.0 to 101.9 %	100.45%	2.04 %	39.5 mg/L	Dr E. Servajean, 2017, Report 16-35-077-ES Part 1

Analytical methods for the analysis of the product INDAL PAA 3.5 (Meta SPC 1) as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
		Accuracy: 1 spiking level		e on the basis of the retention time and peak shape for hydrogen peroxide.					
Acetic acid		Linearity: 7 calibration solutions Precision:6 stock solutions Accuracy: 1 spiking level	Range: 489.1 - 16303.7 mg/L R^2=0.9999	The analytical method was considered as specific and selective on the basis of the retention time and peak shape for acetic acid.	100.7 to 102.4 %	101.55%	1.18 %	489.1 mg/L	Dr E. Servajean, 2017, Report 16-35-077-ES Part 1

Analytical methods for the analysis of the product INDAL PAA 2.5 (Meta SPC 2) as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Peracetic acid (active	HPLC-UV	Linearity: 10	Range: 16.4 –	The analytical	99.6 to	100.75%	1.61 %	16.4 mg/L	Dr E. Servajean,

Analytical methods for the analysis of the product INDAL PAA 2.5 (Meta SPC 2) as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
substance)	Parameters: *Mobile phase:* *95% acetonitrile with 0.04% pentafluoropropionic acid* *5% N-formate 50 mM in Water* *Flow: 1.0 ml/min* *T°: 5°C* *Detection: 210 nm* Retention times: Peracetic acid: 4 min Acetic acid: 4.5 min Hydrogen peroxide: 5 min	calibration solutions Precision: 6 stock solutions Accuracy: 1 spiking level	1640.7 mg/L R^2=0.9999	method was considered as specific and selective on the basis of the retention time and peak shape for peracetic acid.	101.9 %				2017, Report 16-35-076-ES Part 1
Hydrogen Peroxide		Linearity: 9 calibration solutions Precision: 6 stock solutions Accuracy: 1 spiking level	Range: 39.5 – 1973.1 mg/L R^2=0.9998	The analytical method was considered as specific and selective on the basis of the retention time and peak shape for hydrogen peroxide.	99.0 to 99.2 %	99.1%	0.14 %	39.5 mg/L	Dr E. Servajean, 2017, Report 16-35-076-ES Part 1
Acetic acid		Linearity: 7 calibration solutions Precision:6 stock solutions	Range: 489.1 - 16303.7 mg/L R^2=0.9999	The analytical method was considered as specific and selective on the	98.5 to 100.5 %	99.5%	1.42 %	489.1 mg/L	Dr E. Servajean, 2017, Report 16-35-076-ES Part 1

Analytical methods for the analysis of the product INDAL PAA 2.5 (Meta SPC 2) as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
		Accuracy: 1 spiking level		basis of the retention time and peak shape for acetic acid.					

Analytical methods for the analysis of the product INDAL PAA 5 (Meta SPC 3) as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Peracetic acid (active substance)	HPLC-UV Parameters: *Mobile phase:* *95% acetonitrile with 0.04% pentafluoropropionic acid* *5% N-formate 50 mM in Water* *Flow: 1.0 ml/min* *T°: 5°C* *Detection: 210 nm* Retention times: Peracetic acid: 4 min Acetic acid: 4.5 min	Linearity: 10 calibration solutions Precision: 6 stock solutions Accuracy: 1 spiking level	Range: 16.4 – 1640.7 mg/L R^2=0.9999	The analytical method was considered as specific and selective on the basis of the retention time and peak shape for peracetic acid.	99.7 to 101.5 %	100.6 %	1.27 %	16.4 mg/L	Dr E. Servajean, 2017, Report 16-35-078-ES Part 1
Hydrogen Peroxide		Linearity: 9 calibration solutions	Range: 39.5 – 1973.1 mg/L	The analytical method was consider	97.9 to 98.9 %	98.4 %	0.72 %	39.5 mg/L	Dr E. Servajean, 2017, Report 16-35-

Analytical methods for the analysis of the product INDAL PAA 5 (Meta SPC 3) as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
	Hydrogen peroxide: 5 min	Precision: 6 stock solutions Accuracy: 1 spiking level	R^2=0.9998	ed as specific and selective on the basis of the retention time and peak shape for hydrogen peroxide.					078-ES Part 1
Acetic acid		Linearity: 7 calibration solutions Precision:6 stock solutions Accuracy: 1 spiking level	Range: 489.1 - 16303.7 mg/L R^2=0.9999	The analytical method was considered as specific and selective on the basis of the retention time and peak shape for acetic acid.	99.1 to 99.2 %	99.15 %	0.07 %	489.1 mg/L	Dr E. Servajean, 2017, Report 16-35-078-ES Part 1

Analytical methods for the analysis of the product INDAL PAA 15 (Meta SPC 4) as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Peracetic acid (active substance)	HPLC-UV Parameters: *Mobile phase:* *95% acetonitrile with 0.04% pentafluoropropionic acid* *5% N-formate 50 mM in Water* *Flow: 1.0 ml/min* *T°: 5°C* *Detection: 210 nm* Retention times: Peracetic acid: 4 min Acetic acid: 4.5 min Hydrogen peroxide: 5 min	Linearity: 10 calibration solutions Precision: 6 stock solutions Accuracy: 1 spiking level	Range: 16.4 – 1640.7 mg/L R^2=0.9999	The analytical method was considered as specific and selective on the basis of the retention time and peak shape for peracetic acid..	100.7 to 101.1 %	100.9 %	0.28 %	16.4 mg/L	Dr E. Servajean, 2017, Report 16-35-079-ES Part 1
Hydrogen Peroxide		Linearity: 9 calibration solutions Precision: 6 stock solutions Accuracy: 1 spiking level	Range: 39.5 – 1973.1 mg/L R^2=0.998	The analytical method was considered as specific and selective on the basis of the retention time and peak shape for hydrogen peroxide.	99.0 to 99.4 %	99.2 %	0.29 %	39.5 mg/L	Dr E. Servajean, 2017, Report 16-35-079-ES Part 1
Acetic acid		Linearity: 7 calibration solutions Precision:6 stock solutions	Range: 489.1 - 16303.7 mg/L R^2=0.999	The analytical method was considered as specific	99.0 to 102.4 %	100.7 %	2.39 %	489.1 mg/L	Dr E. Servajean, 2017, Report 16-35-079-ES Part 1

Analytical methods for the analysis of the product INDAL PAA 15 (Meta SPC 4) as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
		Accuracy: 1 spiking level		and selective on the basis of the retention time and peak shape for acetic acid.					

Analytical methods for the analysis of the product INDAL OXY MOUSS (Meta SPC 5) as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Peracetic acid (active substance)	HPLC-UV Parameters: *Mobile phase:* *95% acetonitrile with 0.04% pentafluoropropionic acid* *5% N-formate 50 mM in Water* *Flow: 1.0 ml/min* *T°: 5°C* *Detection: 210 nm* Retention times: Peracetic acid: 4 min Acetic acid: 4.5 min	Linearity: 10 calibration solutions Precision: 6 stock solutions Accuracy: 1 spiking level	Range: 16.4 – 1640.7 mg/L R^2=0.9999	The analytical method was considered as specific and selective on the basis of the retention time and peak shape for peracetic acid.	100.7 to 100.9 %	100.8 %	0.14 %	16.4 mg/L	Dr E. Servajean, 2017, Report 16-35-080-ES Part 1
Hydrogen Peroxide		Linearity: 9 calibration solutions	Range: 39.5 – 1973.1 mg/L	The analytical method was consider	97.9 to 101.2 %	99.55 %	2.34 %	39.5 mg/L	Dr E. Servajean, 2017, Report 16-35-

Analytical methods for the analysis of the product INDAL OXY MOUSS (Meta SPC 5) as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
	Hydrogen peroxide: 5 min	Precision: 6 stock solutions Accuracy: 1 spiking level	R^2=0.9998	ed as specific and selective on the basis of the retention time and peak shape for hydrogen peroxide.					080-ES Part 1
Acetic acid		Linearity: 7 calibration solutions Precision:6 stock solutions Accuracy: 1 spiking level	Range: 489.1 - 16303.7 mg/L R^2=0.9999	The analytical method was considered as specific and selective on the basis of the retention time and peak shape for acetic acid.	99.6 to 102.1 %	100.85%	1.75 %	489.1 mg/L	Dr E. Servajean, 2017, Report 16-35-080-ES Part 1

Analytical methods for the analysis of the product INDAL TAP 5 (Meta SPC 6) as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Peracetic acid (active substance)	HPLC-UV Parameters: *Mobile phase:* *95% acetonitrile with 0.04% pentafluoropropionic acid* *5% N-formate 50 mM in Water* *Flow: 1.0 ml/min* *T°: 5°C* *Detection: 210 nm* Retention times: Peracetic acid: 4 min Acetic acid: 4.5 min Hydrogen peroxide: 5 min	Linearity: 10 calibration solutions Precision: 6 stock solutions Accuracy: 1 spiking level	Range: 16.4 – 1640.7 mg/L R^2=0.9999	The analytical method was considered as specific and selective on the basis of the retention time and peak shape for peracetic acid.	100.8 to 100.9 %	100.85%	0.07 %	16.4 mg/L	Dr E. Servajean, 2017, Report 16-35-081-ES Part 1
Hydrogen Peroxide		Linearity: 9 calibration solutions Precision: 6 stock solutions Accuracy: 1 spiking level	Range: 39.5 – 1973.1 mg/L R^2=0.998	The analytical method was considered as specific and selective on the basis of the retention time and peak shape for hydrogen peroxide.	100.8 to 102.1 %	101.45%	0.91 %	39.5 mg/L	Dr E. Servajean, 2017, Report 16-35-081-ES Part 1
Acetic acid		Linearity: 7 calibration solutions Precision:6 stock solutions	Range: 489.1 - 16303.7 mg/L R^2=0.999	The analytical method was considered as specific	98.5 to 101.3 %	99.9%	1.98 %	489.1 mg/L	Dr E. Servajean, 2017, Report 16-35-081-ES Part 1

Analytical methods for the analysis of the product INDAL TAP 5 (Meta SPC 6) as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
		Accuracy: 1 spiking level		and selective on the basis of the retention time and peak shape for acetic acid.					

Analytical methods for the analysis of the SOC *decyl alcohol ethoxylated*									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Decyl alcohol ethoxylated (CAS: 26183-52-8): *SOC*	HPLC-MS/MS Parameters: *Mobile phase:* *50% acetonitrile with 0.2% pentafluoropropionic acid* *20% Isopropanol with 0.5% formic acid* *30% water with 50 mM NH4-formate + 0.5% formic acid* *Flow: 0.8 ml/min* *T°: 55°C* *Detection: ESI +* m/z: 352.1, 396.1, 440.1, 484.1, 528.1, 572.1, 616.1, 660.1	Linearity: 7 calibration solutions Precision: 2 analytical series – 6 samples	Range: 97.0 – 3231.9 ug/L r^2=0.9990 The lowest point (32.3 ug/L) is excluded due to the relative error on the linear regression higher than 6%.	The analytical method was considered as specific and selective on the basis of the retention time and m/z of the SOC analyte.	97 to 103%	101.23%	<2.3%	LOQ = 97.0 ug/L LOD = 32.3 ug/L	Report study number 16-35-080-ES: Physical-chemical properties, stability and shelflife of Indal Oxy Mouss. Part 1 : Physical-chemical properties upon receipt and after accelerated storage, E. Servajean, September 2017

Analytical methods for the analysis of the SOC *sulphuric acid*									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Sulphuric acid (CAS: 7664-93-9): *SOC*	IC Parameters: *Mobile phase:* *Na_2CO_3 5 mM* *Flow: 1.0 ml/min* *T°: room temperature* Retention time: 12.9 min	Linearity: 7 calibration solutions Precision: 2 analytical series – 6 replicates	Range: 1.5 – 147.9 mg/L r^2=0.9996 Two lowest point (0.3 and 0.9 mg/L) are excluded due to the relative error on the linear regression higher than 6%.	The analytical method was considered as specific and selective on the basis of the retention time and peak shape of the SOC analyte.	98.4 to 99.5%	99%	0.67%	LOQ = 1.48 mg/L LOD = 0.30 mg/L	Report study number 16-35-081-ES: Physical-chemical properties, stability and shelflife of Indal Tap 5. Part 1 : Physical-chemical properties upon receipt and after accelerated storage, E. Servajean, September 2017

Analytical methods for monitoring purposes including recovery rates and the limits of determination of active substance in soil, air, water and animal and human body fluids and tissues were determined in the active substance dossiers.

Conclusion on the methods for detection and identification of the product
The method for quantification of substances involved in the equilibrium: peracetic acid, acetic acid and hydrogen peroxide was validated. These substances are detected using HPLC – UV method. The method is selective and accurate. The recovery rates are within authorised variation regarding the concentrations. The LOQ for peracetic acid, acetic acid and H_2O_2 are, respectively, 16.4 mg/L, 489.1 mg/L and 39.5 mg/L. The method of quantification for substances of concern decyl alcohol ethoxylated and sulfuric acid was also validated. Decyl alcohol ethoxylated is detected by HPLC-MS/MS method. The method is is specific and accurate. LOQ is 97.0 ug/L. Sulfuric acid is detected via IC method. The method is selective and accurate. LOQ is 1.48 mg/L.

2.2.5 Efficacy against target organisms

2.2.5.1 Function (organisms to be controlled) and field of use (products/objects to be protected)

The products of the ***QUARON BPF*** are intended to be used as disinfectants (Group 1) for PT2 (*Disinfectants and algaecides not intended for direct applications to humans or animals*); PT3 (*Veterinary Hygiene*) & PT4 (*Food & feed Area*) applications, divided into 6 Meta SPCs.

Please find below a table summarizing all the uses of the ***QUARON PAA*** family.

Meta SPC	Biocidal Product	PT	Use #	Use Description	Target organisms claimed by the Applicant
1	INDAL PAA 3.5	PT 2	Use #1 Use #2	- Waste water disinfection in medical bio labs - Inner surface disinfection by CIP procedures (with circulation)	B - F/Y - MycoB – V B - F/Y – Sp - MycoB - V
		PT 4	Use #3 Use #4 Use #5 Use #6	- Surface disinfection by spraying procedure - Inner surface disinfection by CIP procedures (with circulation) - Surface disinfection by dipping procedures (only for containers) - Disinfection in washing machines in agri-food industry and institutions (dish-washers and crates-washers)	B - F/Y – Sp – BF - V
2	INDAL PAA 2.5	PT 2	Use #1 Use #2 Use #3	- Disinfection of water from swimming pools, balneotherapy & private ponds - Surface disinfection by spraying procedures in swimming pools, balneotherapy & ponds - CIP procedures (with circulation) in swimming pools, balneotherapy & private ponds	B - F/Y – Alg - V
3	INDAL PAA 5	PT 2	Use #1 Use #2 Use #3 Use #4 Use #5 Use #6 Use #7	- Surface disinfection by manual spraying procedures - CIP (with circulation) procedures in STP - CIP (with circulation) procedures in private & public industries and in institutions - Surface disinfection by manual dipping procedures - Waste water disinfection in public/private STP - Waste water disinfection in medical biology labs - Linen disinfection	B - F/Y – Sp - MycoB – V – Alg – BF B - F/Y – MycoB – V – Alg – BF B - F/Y – MycoB – V – Alg – BF B - F/Y – Sp - MycoB – V – Alg – BF B - F/Y – MycoB – V B - F/Y – MycoB – V B - F/Y – MycoB – V
		PT 3	Use #8 Use #9 Use #10 Use #11 Use #12 Use #13	- Surface disinfection by manual spraying procedures of milking parlour systems - Surface disinfection by manual spraying procedures in fish farming industry - CIP (with circulation) procedures in fish farming industry - Surface disinfection by manual dipping procedures in livestock housing - Surface disinfection by manual spraying procedures in livestock housing - CIP procedures (with circulation) in livestock housing	B - Y – V B - F/Y - MycoB – V – Alg B - F/Y – V – Alg - BF B - F/Y – MycoB – V – Alg B - F/Y – MycoB – V – Alg B - F/Y – V – Alg - BF
		PT 4	Use #14 Use #15 Use #16 Use #17	- Surface disinfection by manual spraying procedures - CIP (with circulation) procedures - Surface disinfection by manual dipping procedures - Disinfection in washing machines	B - F/Y – Sp – BF - V
		~~PT 5~~	~~Use #18~~	~~- Drinking water disinfection for animals in farms~~	~~B – V~~
4	INDAL PAA 15	PT 2	Use #1 Use #2	- Waste water/leachates disinfection in public/private STP - Linen disinfection	B - F/Y - MycoB – V
		PT 4	Use #3 Use #4	- CIP (with circulation) procedures - Surface disinfection by dipping procedures	B - F/Y – Sp - V

Meta SPC	Biocidal Product	PT	Use #	Use Description	Target organisms claimed by the Applicant
5	INDAL OXY MOUSS	PT 3	Use #1	- Surface disinfection by foam-spraying procedures	B - F/Y - MycoB – V
		PT 4	Use #2	- Surface disinfection by foam-spraying procedures in livestock industries	B - F/Y – BF - V
6	INDAL TAP 5	PT 4	Use #1	- Disinfection of inner surfaces by CIP procedures (with circulation)	B - F/Y – Sp – V

Detailed function and field of use (including areas) of the products is described in the section *2.1.4. Authorized use(s)*.

Target organisms include bacteria (also as biofilsm), mycobacteria, fungi, viruses, phages, bacterial spores, and algae, relevant to the products' areas of use and in-use conditions.

2.2.5.2 Mode of action and effects on target organisms, including unacceptable suffering

The active substance is peracetic acid in an aqueous solution containing acetic acid, hydrogen peroxide and water.

Peracetic acid has a toxic effect on microorganisms. Its mode of action is very unspecific.

Regarding suffering, this aspect is not relevant in regards to the organisms to be controlled.

2.2.5.3 Efficacy data

Efficacy data was generated to support the efficacy claims of the products of the Quaron BPF.

Studies were carried out for each of the 6 products in the family.

Please note that Phase 1 efficacy studies were also carried out with the ingredient "sulfuric acid" of the product ***INDAL TAP 5*** (Meta SCP 6) to verify that this acid does not have biocidal properties in the conditions of use of this product.

The efficacy data is listed in the following tables, and is referenced according to each Meta SPC of the family.

Meta SPC-1 : *INDAL PAA 3.5 (2.5% PAA)* **Experimental data on the efficacy of the biocidal product against target organisms**		
Field of use envisaged	**PT2**	Use #1 : Waste water disinfection in medical bio labs Use #2 : Inner surface disinfection by CIP procedures (with circulation)
	PT4	Use #3 : Surface disinfection by spraying procedures Use #4 : Inner surface disinfection by CIP procedures (with circulation) Use #5: Surface disinfection by dipping procedures (only for containers) Use #6: Disinfection in washing machines in agri-food industry and institutions (dish-washers and crates-washers)

Test product	Function & Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results : effects	Reference & R.I.
INDAL PAA 3.5 (2.5% PAA)	**Bactericidal activity** Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus* Additional test organisms: *Salmonella typhimurium* *Listeria monocytogenes*	**EN 1276 (2009 + EC1 2011)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.05 - 0.1 – 0.2 – 0.3 – 0.4 % • I.S. : 0.3g/L BSA (clean conditions)	Bactericidal activity (including *Salmonella typhimurium* and *Listeria monocytogenes*) at 0.1% in 5 min at +20°C in clean conditions.	**Doc. 1** : *Meta SPC 1_INDAL PAA 3.5_EN1276_bacteria_0.1%_5 min_20°C_clean_MERIEUX 17-000310627*. **Reliability 1** **Key study**
INDAL PAA 3.5 (2.5% PAA)	**Fungicidal/yeasticidal activity** Obligatory test organisms: *Candida albicans* *Aspergillus brasiliensis*	**EN 1650 + A1 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.1 – 0.2 – 0.4 – 0.6 – 0.8 % (Y) 0.1 – 1 – 2 – 3 – 4 % (F) • I.S. : 0.3g/L BSA (clean conditions)	Yeasticidal activity at 0.6% in 15 min at +20°C in clean conditions. Fungicidal activity at 2% in 15 min at +20°C in clean conditions.	**Doc. 5** : *INDAL PAA 3.5 HD10354 EN1650 fongicide 2% 15min 20°C propréte MIDAC RE17-196-3 2017-08-31*. **Reliability 1** **Key study**
INDAL PAA 3.5 (2.5% PAA)	**Bactericidal activity** Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus* Additional test organisms:	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +18-25 ± 1°C • Contact time : 5 min • Concentrations tested : 0.1 – 0.2 – 0.4 – 0.6 – 0.8 % • I.S. :	Bactericidal activity (including *Salmonella typhimurium* and *Listeria monocytogenes*) at 0.4% in 5 min at +20°C on hard/non-porous surfaces with prior cleaning.	**Doc. 3** : *Meta SPC 1_INDAL PAA 3.5_EN13697_bacteria_0.4%_5min_20°C_clean_MERIEUX 17-000310627* **Reliability 1** **Key study**

	Salmonella typhimurium *Listeria monocytogenes*	0.3g/L BSA (clean conditions)		
INDAL PAA 3.5 (2.5% PAA)	**Fungicidal/yeasticidal activity** Obligatory test organisms: *Candida albicans* *Aspergillus brasiliensis*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +18-25 ± 1°C • Contact time : 15 min • Concentrations tested : 0.1 – 0.2 – 0.4 – 0.6 – 0.8 % (Y) 0.1 – 1 - 1.5 - 2 – 3 – 4 – 5 – 6% (F) • I.S. : 0.3g/L BSA (clean conditions)	Yeasticidal activity at 0.2% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning. Fungicidal activity at 1% in 15 min at +20°C in on hard/non-porous surfaces with prior cleaning.	**Doc. 4** : *Meta SPC 1_INDAL PAA 3.5_EN13697_fungi_1%_15min_20°C_clean_MIDAC R-E17-177-1* **Reliability 1** **Key study**
INDAL PAA 3.5 (2.5% PAA)	**Virucidal activity** Phages P001 & P008 (lytic for *Lactococcus lactis subspecies lactis*)	**EN 13610 (2003)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.1 – 0.2 – 0.4 – 0.8 – 1.2 % • I.S. : 1% Acid whey	Virucidal activity towards bacteriophages at 0.2% in 15 min at +20°C in presence of 1% Acid whey.	**Doc. 2** : *Meta SPC 1_INDAL PAA 3.5_EN13610_bacteriophage_0.2%_15min_20°C_1% acid whey_LMH-4554-1* **Reliability 1** **Key study**
INDAL PAA 3.5 (2.5% PAA)	**Sporicidal activity** *Bacillus subtilis*	**EN 13704 (2002)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.1 – 0.5 – 1 – 2 - 3% • I.S. : 0.3g/L BSA (clean conditions)	Sporicidal activity at 2% in 15 min at +20°C in clean conditions.	**Doc. 6** : *INDAL PAA 3.5 HD10354 EN13704 sporicide 2% 15min 20°C proprete MIDAC RE-17-206-2 2017-09-13* **Reliability 1** **Key study**

INDAL PAA 3.5 (2.5% PAA)	**Fungicidal/yeasticidal activity** *Candida albicans*	**EN 1650 + A1 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.01– 0.1 – 0.2– 0.4 – 0.6 % I.S. : 0.3g/L BSA (clean conditions)	Yeasticidal activity at 0.6% in 5 min at +20°C on clean conditions	Doc. « INDAL PAA 3.5 HD10354 EN1650 levuricide 0.6% 5min 20°C proprete MERIEUX 19.501679.0001_19_000327202 2018-06-04 » **Reliability 1** **Key study**
INDAL PAA 3.5 (2.5% PAA)	**Fungicidal/yeasticidal activity** *Candida albicans*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +18-25 ± 1°C • Contact time : 5 min • Concentrations tested : 0.01% - 0.1% - 0.2% - 0.4% - 0.6% I.S. : 0.3g/L BSA (clean conditions)	Yeasticidal activity at 0.4% in 5 min at +20°C on hard/non-porous surfaces with prior cleaning.	Doc. « INDAL PAA 3.5 HD10354 EN13697 levuricide 0.4% 5min 20°C proprete MERIEUX 19.501679.0001_19_000327202 2019-06-14 » **Reliability 1** **Key study**
INDAL PAA 3.5 (2.5% PAA)	**Sporicidal activity** *Bacillus subtilis*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +18-25 ± 1°C • Contact time : 15 min • Concentrations tested : 0.1 – 0.5 - 1 % I.S. : 0.3g/L BSA (clean conditions)	Sporicidal activity at 1% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning.	Doc. « INDAL PAA 3.5 HD10354 EN13697 sporicide Bs 1% 15min 20°C proprete MERIEUX 19.501679.0001_19_000327202 2019-02-14 » **Reliability 2**
INDAL PAA 3.5 (2.5% PAA)	**Bactericidal activity** ***Obligatory test organisms :***	**EN 13727** Quantitative suspension test • Temperature :	Bactericidal activity (including *Salmonella typhimurium* and *Listeria monocytogenes*) at 0.5% in 30 min at +20°C in dirty conditions.	Doc. "INDAL PAA 3.5 HD10354 EN13727 bactericide 0.5% 30min 20°C salete

	Enterococcus hirae *Pseudomonas aeruginosa* *Staphylococcus aureus* ***Additional test organisms:*** *Escherichia coli* *Listeria monocytogenes* *Salmonella typhimurium*	+18-25 ± 1°C • Contact time : 30 min • Concentrations tested : 0.1 – 0.2 – 0.5 % I.S. : 3g/L BSA + 3ml/L erythrocytes (dirty conditions)		MERIEUX 19.501679.0001_19_000327202 2018-06-04" **Reliability 1** **Key study**
INDAL PAA 3.5 (2.5% PAA)	**Bactericidal activity** ***Obligatory test organisms :*** *Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus* ***Additional test organisms:*** *Escherichia coli* *Listeria monocytogenes* *Salmonella typhimurium*	**EN 14561** Quantitative carrier test – hard & non-porous surfaces • Temperature : +18-25 ± 1°C • Contact time : 30 min • Concentrations tested : 0.1 – 0.5 – 1.0 % I.S. : 3g/L BSA + 3ml/L erythrocytes (dirty conditions)	Bactericidal activity (including *Salmonella typhimurium* and *Listeria monocytogenes*) at 0.5% in 30 min at +20°C in dirty conditions.	Doc. "INDAL PAA 3.5 HD10354 EN14561 bactericide 0.5% 30min 20°C salete MERIEUX 19.501679.0001_19_000327202 2018-06-04" **Reliability 1** **Key study**
INDAL PAA 3.5 (2.5% PAA)	**Bactericidal activity** ***Obligatory test organisms:*** *Legionella pneumophila*	**EN 13623** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 30 min • Concentrations tested : 0.01 – 0.2 – 0.4 % I.S. : 3g/L BSA + 3ml/L erythrocytes (dirty conditions)	Active *Legionella pneumophila* against at 0.2% in 30 min at +20°C in dirty conditions.	Doc. "INDAL PAA 3.5 HD10354 EN13623 Legionella 0.2% 30min 20°C salete MERIEUX 19.501679.0001_19_000327202 2019-06-14" **Reliability 1** **Key study**
INDAL PAA 3.5 (2.5% PAA)	**Bactericidal activity** ***Obligatory test organisms:***	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature :	Active *Legionella pneumophila* against at 0.2% in 30 min at +20°C on hard/non-porous surfaces wo prior cleaning.	Doc. "INDAL PAA 3.5 HD10354 EN13697 Legionella 0.2% 30min 20°C salete

	Legionella pneumophila	+18-25 ± 1°C • Contact time : 30 min • Concentrations tested : 0.01 – 0.2 – 0.4 % I.S. : 3g/L BSA + 3ml/L erythrocytes (dirty conditions)		MERIEUX 19.501679.0001_19_000327202 2019-06-14" **Reliability 1** **Key study**
INDAL PAA 3.5 (2.5% PAA)	**Fungicidal/yeasticidal activity** ***Obligatory test organisms:*** *Aspergillus brasiliensis* *Candida albicans*	**EN 13624** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 30 min • Concentrations tested : 0.1- 0.5 – 1.0% (Y) 1.0 – 2.0 – 3.0 % (F) I.S. : 3g/L BSA + 3ml/L erythrocytes (dirty conditions)	Yeasticidal activity at 0.5% in 30 min at +20°C in dirty conditions Fungicidal activity at 2% in 30 min at +20°C in in dirty conditions	Doc. "INDAL PAA 3.5 HD10354 EN13624 fongicide 2% 30min 20°C salete MERIEUX 19.501679.0001_19_000327202 2019-06-04" **Reliability 1** **Key study**
INDAL PAA 3.5 (2.5% PAA)	**Fungicidal/yeasticidal activity** ***Obligatory test organisms:*** *Aspergillus brasiliensis* *Candida albicans*	**EN 14562** Quantitative carrier test – hard & non-porous surfaces • Temperature : +18-25 ± 1°C • Contact time : 30 min • Concentrations tested : 0.1- 0.5 – 1.0% (Y) 1.0 – 2.0 – 3.0 % (F) I.S. : 3g/L BSA + 3ml/L erythrocytes (dirty conditions)	Yeasticidal activity at 0.5% in 30 min at +20°C in dirty conditions Fungicidal activity at 2% in 30 min at +20°C in in dirty conditions	Doc. "INDAL PAA 3.5 HD10354 EN14562 fongicide 2% 30min 20°C salete MERIEUX 19.501679.0001_19_000327202 2019-06-04" **Reliability 1** **Key study**
INDAL PAA 3.5 (2.5% PAA)	**Virucidal activity** ***Obligatory test organisms:*** *Poliovirus type 1,* *Adénovirus type 5* *Norovirus murin,*	**EN 14476** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 30 min • Concentrations	Full virucidal activity at 1.5% in 30 min at +20°C in in dirty conditions	Doc. "INDAL PAA 3.5 HD10354 EN14476 virucide 1.5% 30min 20°C salete IRM RE1035-0119 2019-06-17"

		tested : 0.01- 0.2 – 0.4% I.S. : 3g/L BSA + 3ml/L erythrocytes (dirty conditions)		**Reliability 1** **Key study**
INDAL PAA 3.5 (2.5% PAA)	**Virucidal activity** ***Obligatory test organisms:*** *Adénovirus type 5* *Norovirus murin,*	**pr EN 16777 (2018)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +18-25 ± 1°C • Contact time : 30 min • Concentrations tested : 0.01- 0.2 – 0.4% I.S. : 3g/L BSA + 3ml/L sheep erythrocytes (dirty conditions)	Full virucidal activity at 0.4% in 30 min at +20°C in in dirty conditions	Doc. "INDAL PAA 3.5 HD10354 EN16777 virucide 0.4% 30min 20°C salete IRM 1036-0119 2019-08-02" **Reliability 1** **Key study**
INDAL PAA 3.5 (2.5% PAA	**Mycobactericidal activity** ***Obligatory test organisms:*** *Mycobacterium terrae* ***Additional test organism*** *Mycobacterium avium*	**EN 14348** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 30 min • Concentrations tested : 0.1- 0.5 – 1.0 – 1.5 – 2 – 2.5% I.S.: 3g/L BSA + 3ml/L sheep erythrocytes (dirty conditions)	Tuberculocidal activity at 1% in 30 min at +20°C in in dirty conditions Mycobactericidal activity at 1.5% in 30 min at +20°C in in dirty conditions	Doc. "INDAL PAA 3.5 HD10354 EN14348 tuberculocide 1% 30min 20°C salete MERIEUX 19.501679.0001_19_000327202 2019-07-15 Inefficacite Ma" Doc. "INDAL PAA 3.5 HD10354 EN14348,mycobactéricidie 1.5% 30min 20°C saleté MERIEUX 19.016569.0001_19_000403047" **Reliability 1** **Key study**
INDAL PAA 3.5 (2.5% PAA	**Mycobactericidal activity** *Mycobacterium terrae* *Mycobacterium avium*	**EN 14563** Quantitative carrier test – hard & non-porous surfaces • Temperature : +18-25 ± 1°C • Contact time : 30 min	Mycobactericidal activity at 1% in 30 min at +20°C in in dirty conditions	Doc. "INDAL PAA 3.5 HD10354 EN14563 mycobactericide 1% 30min 20°C salete MERIEUX 19.501679.0001_19_000327202 2019-07-15"

		• Concentrations tested : 0.1 – 1.0 - 2.0% I.S. : 3g/L BSA + 3ml/L sheep erythrocytes (dirty conditions)		**Reliability 1** **Key study**
INDAL PAA 3.5 (2.5% PAA	**Bactericidal activity** *Pseudomonas aeruginosa* *Staphylococcus aureus*	**CEN ISO/TS 15883-5:2005 Annex F.** Biofilm simulated test • Temperature : +18-25 ± 1°C • Contact time : 5 min • Concentrations tested : 0.1 – 0.2% - 0.5% I.S. : 0.3g/L BSA	*Pseudomonas aeruginosa :* In static contact at 0.4% (Log↓ > 5.7) in 5 min at +20°C *Staphylococcus aureus :* In static contact at 0.4% (Log↓ > 5.7) in 5 min at +20°C	Doc. "INDAL PAA 3.5 HD10354 ISO 15883-5 bactericide biofilm Pseudomonas 0.4% 5min 20°C proprete IPL 190247-01 2019-02-25 English" Doc. "INDAL PAA 3.5 HD10354 ISO 15883-5 bactericide biofilm Staphylococcus 0.4% 5min 20°C proprete IPL 190247-02 2019-03-19 English" **Reliability 1** **Key study**

Meta SPC1

Conclusions on the efficacy of the representative product *INDAL PAA 3.5 (2.5% PAA) & Label claims*

Please note that, since required by other MSs, for surface disinfection by spraying/mopping or immersion, P2S1 and all P2S2 tests are mandatory and must be taken into account and therefore the higher concentration required is the limiting one and thus be set up as the necessary concentration.
Please note that, to stay in line with the decision made for other dossiers, specific organisms mentioned in the efficacy conclusions of the PAR should not be included in the SPC.

PT2 - Use #1 : Disinfection of wasted water, leachates and liquid laboratory waste in closed systems in medical biology laboratories

Under dirty conditions, at +20°C in 30 min, the product **INDAL PAA 3.5** (2.5% PAA) is :

- Bactericidal (including Legionella pneumophila, Salmonella typhimurium & Listeria monocytogenes) & yeasticidal when used at 0.5%
- Fungicidal when used at 2%
- Mycobactericidal when used at 1.5%
- Virucidal when used at 1.5%

PT2 - Use #2 : Inner surface disinfection by CIP procedures (with circulation)

The representative product for the **Meta SPC1** i.e. ***INDAL PAA 3.5*** (2.5% PAA) is :
Under clean conditions, at +20°C :

- Bactericidal (including *Salmonella typhimurium* & *Listeria monocytogenes*) and yeasticidal when used at 0.6% in 5 min
- Fungicidal & sporicidal when used at 2% in 15 min
- Mycobactericidal and Virucidal when used at 1.5% in 30 min
- Active against bacteriophages when used at 0.2% in 15 min

REMARK(S) :

- About the mycobacteria & virus activities, all the efficacy tests provided by the Applicant have been performed under dirty conditions. Then, since the product is intended to be used under clean conditions, a read-across is acceptable.

PT4 - Use #3 : Surface disinfection by spraying procedures
PT4 - Use #5: Surface disinfection by dipping procedures (only for containers)

The representative product for the **Meta SPC1** i.e. ***INDAL PAA 3.5*** (2.5% PAA) is :

On hard non-porous surfaces with prior cleaning, at +20°C :
Make sure to wet surfaces completely.
Thoroughly clean & rinse the surfaces before disinfection.

- Bactericidal (including *Salmonella typhimurium, Listeria monocytogenes& Legionella pneumophila*) and yeasticidal when used at 0.6% in 5 min
- Fungicidal & sporicidal when used at 2% in 15 min
- Virucidal when used at 1.5% in 30 min
- Active against bacteriophages when used at 0.2% in 15 min
- Active to remove biofilms when used at 1% in 15 min

REMARK(S) :

- About the virus activity, all the efficacy tests provided by the Applicant have been performed under dirty conditions. Then, since the product is intended to be used under clean conditions, a read-across is acceptable.

- Biofilm activity – read-across from Meta SPC5 : About the representative product for Meta SPC 5 (with 1.2% PAA), the Applicant has provided 3 simulated-use tests (duly supported by P2S1 tests) with one for each species mentioned in the guidance i.e. *P. aeruginosa, S. aureus* and *L. pneumophila* with effectivity at 1% in 15 min. The BE eCA is then of the opinion to use this study as a read-across.

- Relevance of the additional target organisms *L.pneumophila* for diping in agri-food industry (Applicant justification) : As L. pneumophila is a relevant organism to test the efficacy of disinfectants for curative treatments against biofilms, it is also relevant to test them on surfaces and circuits before these bacteria can form a biofilm. As L. pneumophila is found in natural hydro-telluric environments and in water systems, it can be found in agri-food industries where large amount of potable water is needed, sometime provided by a drilling. As for example, large amounts of water are used by soaking and dipping, spraying and/or nebulizing in fresh fruits and vegetables industries to clean them before package, freeze or transform them. The disinfection of the materials, surfaces and circuits / pumps / tanks of these industrial equipment against L. pneumophila is relevant to avoid survival of

bacteria and to protect workers from contaminations by aerosols or splashes from water in contact of them.

PT4 - Use #4 : Disinfection of closed circulation circuits for cleaning in place **(with circulation)** in agri food industry

The representative product for the **Meta SPC1** i.e. ***INDAL PAA 3.5*** (2.5% PAA) is :
Under clean conditions, at +20°C :

- Bactericidal (including *Salmonella typhimurium, Listeria monocytogenes & Legionella pneumophila*) and yeasticidal when used at 0.6% in 5 min
- Fungicidal & sporicidal when used at 2% in 15 min
- Virucidal when used at 1.5% in 30 min
- Active against bacteriophages when used at 0.2% in 15 min
- Active to remove biofilms when used at 1% in 15 min

REMARK(S) :

- Biofilm activity – read-across from Meta SPC5 : About the representative product for Meta SPC 5 (with 1.2% PAA), the Applicant has provided 3 simulated-use tests (duly supported by P2S1 tests) with one for each species mentioned in the guidance i.e. *P. aeruginosa, S. aureus* and *L. pneumophila* with effectivity at 1% in 15 min. The BE eCA is then of the opinion to use this study as a read-across.

- Relevance of the additional target organisms *L.pneumophila* for diping in agri-food industry (Applicant justification) : As L. pneumophila is a relevant organism to test the efficacy of disinfectants for curative treatments against biofilms, it is also relevant to test them on surfaces and circuits before these bacteria can form a biofilm. As L. pneumophila is found in natural hydro-telluric environments and in water systems, it can be found in agri-food industries where large amount of potable water is needed, sometime provided by a drilling. As for example, large amounts of water are used by soaking and dipping, spraying and/or nebulizing in fresh fruits and vegetables industries to clean them before package, freeze or transform them. The disinfection of the materials, surfaces and circuits / pumps / tanks of these industrial equipment against L. pneumophila is relevant to avoid survival of bacteria and to protect workers from contaminations by aerosols or splashes from water in contact of them.

PT4 - Use #6: Disinfection in washing machines in agri-food industry and institutions (dish-washers and crates-washers)

Not proven enough : Efficacy tests performed according to DIN SPEC 10534 standard not provided
=> **USE NOT GRANTED**

Meta SPC-2 : *INDAL PAA 2.5 (2.0% PAA)*

Experimental data on the efficacy of the biocidal product against target organisms

Field of use envisaged	***PT2***	Use #1 : Disinfection of water from swimming pools, balneotherapy & private ponds Use #2 : Surface disinfection by spraying procedures in swimming pools, balneotherapy & ponds Use #3 : CIP procedures (with circulation) in swimming pools, balneotherapy & private ponds

Test product	**Function & Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results : effects**	**Reference & R.I.**

INDAL PAA 2.5 (2.0% PAA)	**Bactericidal activity** *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1276 (2009 + EC1 2011)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 60 min • Concentrations tested : 0.025 – 0.05 - 0.1 – 0.15 –0.2 % • I.S. : 3g/L BSA (dirty conditions)	Bactericidal activity at 0.15% in 60 min at +20°C in dirty conditions.	**Doc. 7** : *INDAL PAA 2.5 HD10427 EN1276 efficacite bactericide 0.15% 60min 20°C salete MERIEUX 17-597238-0002 2017-07-27* **Reliability 1** **Key study**
INDAL PAA 2.5 (2.0% PAA)	**Bactericidal activity** *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1276 (2009 + EC1 2011)** Quantitative suspension test • Temperature : +10 ± 1°C • Contact time : 12 h • Concentrations tested : 0.005 – 0.01 - 0.025 – 0.05 – 0.1 % • I.S. : 3g/L BSA (dirty conditions)	Bactericidal activity at 0.1% (highest concentration tested) in 12h at +10°C in dirty conditions not proven.	**Doc. 8** : *INDAL PAA 2.5 HD10427 EN1276 efficacite bactericide Gram- 0.1% 12h 10°C salete MERIEUX 17-597238-0002 2017-12-01* **Reliability 3: efficacy not proven considering the test conditions**
INDAL PAA 2.5 (2.0% PAA)	**Bactericidal activity** *Enterococcus hirae* *Staphylococcus aureus*	**EN 1276 (2009 + EC1 2011)** Quantitative suspension test • Temperature : +10 ± 1°C • Contact time : 12 h • Concentrations tested : 0.1 – 0.125 – 0.15 – 0.2 – 0.25 % • I.S. : 3g/L BSA (dirty conditions)	At 0.2% in 12h at +10°C in dirty conditions, the product is active against *Enterococcus hirae* & *Staphylococcus aureus* (most resistant for the product). Taking into account the result of the test just above (test performed under the same conditions), the product has a bactericidal activity at 0.2% in 12h at +10°C in dirty conditions.	**Doc. 9** : *INDAL PAA 2.5 HD10427 EN1276 efficacite bactericide Gram+ 0.25% 12h 10°C salete MERIEUX 17-597238-0003 2018-02-14* **Reliability 3: contact time not in the range allowed by**

				the standard
INDAL PAA 2.5 (2.0% PAA)	**Fungicidal/yeasticidal activity** Obligatory test organisms: *Candida albicans* *Aspergillus brasiliensis*	**EN 1650+A1 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 60 min • Concentrations tested : 0.05 - 0.1 - 0.2 – 0.3 – 0.4% (Y) 0.5 – 1 – 2 – 3 – 4 % (F) • I.S. : 3g/L BSA (dirty conditions)	Yeasticidal activity at 0.4% in 60 min at +20°C in dirty conditions. Fungicidal activity at 2% in 60 min at +20°C in dirty conditions.	**Doc. 10** : *INDAL PAA 2.5 HD10427 EN1650 fongicide 2% 60min 20°C salete MIDAC-17-197-1 2017-09-13* **Reliability 1** **Key study**
INDAL PAA 2.5 (2.0% PAA)	**Bactericidal activity** *Legionella pneumophila*	**EN 13623 (2010)** Quantitative suspension test • Temperature : +10 ± 1°C • Contact time : 12 h • Concentrations tested : 0.005 – 0.01 – 0.025 – 0.05 – 0.1 % • I.S. : 3g/L BSA	Active against *Legionella pneumophila* at 0.025% in 12h at +10°C	**Doc. 11** : *INDAL PAA 2.5 HD10427 EN13623 efficacite contre Legionella 0.025% 12h 10°C salete MERIEUX 17-597238-0002 2017-12-01* **Reliability 1** **Key study**
INDAL PAA 2.5 (2.0% PAA)	**Bactericidal activity** Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +18-25 ± 1°C • Contact time : 60 min • Concentrations tested : 0.05 – 0.1 – 0.2 – 0.3 – 0.4% • I.S. : 3g/L BSA (dirty conditions)	Bactericidal activity at 0.3% in 60 min at +20°C on hard/non-porous surfaces wo prior cleaning.	**Doc. 12** : *INDAL PAA 2.5 HD10427 EN13697 efficacite bactericide 0.3% 60min 20°C salete MERIEUX 17-597238-0002 2017-07-27* **Reliability 1** **Key study**
INDAL PAA 2.5 (2.0% PAA)	**Fungicidal/yeasticidal activity**	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces	Yeasticidal activity at 0.3% in 60 min at +20°C on hard/non-	**Doc. 13** : *INDAL PAA 2.5 HD10427*

	Obligatory test organisms: *Candida albicans* *Aspergillus brasiliensis*	• Temperature : +18-25 ± 1°C • Contact time : 60 min • Concentrations tested : 0.05 – 0.1 – 0.2 – 0.3 – 0.4% (Y) 0.5 – 1 – 2 – 3 – 4% (F) • I.S. : 3g/L BSA (dirty conditions)	porous surfaces wo prior cleaning. Fungicidal activity at 1% in 60 min at +20°C on hard/non-porous surfaces wo prior cleaning.	*EN13697 fongicide 2% 60min 20°C salete MIDAC-17-198-1 2017-08-31* **Reliability 1** **Key study**
INDAL PAA 2.5 (2.0% PAA)	**Virucidal activity** Poliovirus Adenovirus Murine Norovirus Rotavirus	**EN 14476 + A1 (2015)** Quantitative suspension test • Temperature : +20°C • Contact time : 60 min • Concentrations tested : 0.05 – 0.1 – 0.2 – 0.4 – 0.6% • I.S. : 3g/L BSA	Virucidal activity (including Rotavirus) at 0.4% in 60 min at +20°C wo prior cleaning.	**Doc. 14** : *INDAL PAA 2.5 HD10427 EN14476 virucide 0.6% 60min 20°C salete MERIEUX 17-597238-0003 2017-11-06* Doc. « INDAL PAA 2.5 HD10427 EN14476 virucide 0.4% 60min 20°C salete IRM 1216-0619 2019-08-19 » **Reliability 1** **Key study**
INDAL PAA 2.5 (2.0% PAA)	**Bactericidal activity** Legionella pneumophila	**EN 13623 (2010)** Quantitative suspension test • Temperature : +20°C • Contact time : 60 min • Concentrations tested : 0.01 – 0.05 – 0.1% • I.S. : 3g/L BSA (dirty conditions)	Active against Legionella pneumophila at 0.05% in 60 min at +20°C in dirty conditions.	Doc. "INDAL PAA 2.5 HD10427 EN13623 Legionella 0.05% 60min 20°C salete MERIEUX 19.501679.0003_19_000174751 2019-03-16" **Reliability 1**

INDAL PAA 2.5 (2.0% PAA)	**Bactericidal activity** Legionella pneumophila	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20°C • Contact time : 60 min • Concentrations tested : 0.01 – 0.1 – 0.2% • I.S. : 3g/L BSA (dirty conditions)	Active against Legionella pneumophila at 0.2% in 60 min at +20°C on surfaces wo prior cleaning.	Doc. "INDAL PAA 2.5 HD10427 EN13697 Legionella 0.2% 60min 20°C salete MERIEUX 19.501679.0003_19_000174751 2019-03-16" **Reliability 1**
INDAL PAA 2.5 (2.0% PAA)	**Virucidal activity** <u>Obligatory test organisms</u>: Adenovirus type 5, Murine Norovirus	**pr EN 16777 (2018)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +18-25 ±1°C • Contact time : 60 min • Concentrations tested : 0.05 – 0.4 – 0.6% I.S. : 3g/L BSA (dirty conditions)	Non-active against Adenovirus at 0.6% in 60 min at +20°C (Log↓ ≥ 3.48) on surfaces wo prior cleaning. Non-active against MNV at 0.6% in 60 min at +20°C (Log↓ ≥ 3.32) on surfaces wo prior cleaning.	Doc. "INDAL PAA 2.5 HD10427 EN16777 virucide 0.4% 60min 20°C salete IRM 1034-0119 2019-07-31" **Reliability 3: efficacy not proven considering the test conditions.**
INDAL PAA 2.5 (2.0% PAA)	**Algicidal activity** *Chlorella vulgaris* *Nostoc sp.* *Chlamydomonas sp.*	**ASTM 645-13** Quantitative suspension test • Temperature : +10°C • Contact time : 6 and 12 h • Concentrations tested : 0.01 – 0.05 – 0.1% I.S. : 3g/L BSA + 3ml/L erythrocytes	Algaecidal activity (with R >=90%) at 0.05% in 6 and 12 hours at +10°C wo prior cleaning	**Doc. 15:** *INDAL PAA 2.5 HD10427* *ASTM 645-13 algicide 0.05% 6h 10°C, APEX 185D11-2017-02 2018-06-30* **Reliability 1** **Key study**
INDAL PAA 2.5 (2.0% PAA)	**Algicidal activity** *Stichococcus bacillaris*	**Protocole CONIDIA** Quantitative suspension test / carrier test – hard & non-porous surfaces	*Stichococcus bacillaris :* • Suspension : ↓ = 90% 2% within 48h at +10°C	Doc. "CONIDIA rapport final INDAL PAA

	Nostoc commune	• Temperature : +10°C • Contact time : 4 – 24 -48 – 72 – 144 h • Concentrations tested : 0.4 – 2 – 5 % I.S. : 3g/L BSA	• Surfaces : ↓ = 99% at 5% (with 200 mL/m^3) in 48h at +10°C wo prior cleaning *Nostoc commune* : • Suspension : ↓ = 95% 2% within 48h at +10°C • Surfaces : ↓ = 62% at 5% (with 200 mL/m^3) in 144h at +10°C wo prior cleaning	2.5 essai algicide" **Reliability 2: home-made test (not a standard test)**

Meta SPC2

Conclusions on the efficacy of the representative product *INDAL PAA 2.5 (2.0% PAA) & Label claims*

Please note that, since required by other MSs, for surface disinfection by spraying/mopping or immersion, P2S1 and all P2S2 tests are mandatory and must be taken into account and therefore the higher concentration required is the limiting one and thus be set up as the necessary concentration.

Please note that, to stay in line with the decision made for other dossiers, specific organisms mentioned in the efficacy conclusions of the PAR should not be include in the SPC.

PT2 - Use #1 : Disinfection of water from swimming pools, balneotherapy & private ponds

Simulated-use tests not provided => **USE NOT GRANTED**

PT2 - Use #2 : Surface disinfection by spraying procedures in swimming pools, balneotherapy & ponds

The representative product for the **Meta SPC2** i.e. ***INDAL PAA 2.5 (2.0% PAA)*** is :

On hard non-porous surfaces without prior cleaning, at +20°C :

Make sure to wet surfaces completely.

- Bactericidal (including *Legionella pneumophila*), yeasticidal and virucidal (including Human rotavirus) when used at 0.4% in 60 min
- Fungicidal when used at 2% in 60 min

REMARK(S) :

- Acticity against algae :

Since the intended uses are all related to surface disinfection by spraying or/and dipping, results from CONIDIA tests (on surfaces) with 48 & 144h contact time are the more relevant, to stay in line with other requirements for surface disinfection.

Due to the lack of a harmonised/endorsed EFF guidance about algae (level of efficacy/pass criteria) and according to our expert judgment and to all the comments received from cMS,

a contact time higher than 12-24h for surface disinfection by spraying seems unrealistic and unpractical.

As the conlusion, the activity against algae is not granted.

- About intended uses by soaking procedures, since no efficacy tests performed according to EN 14561 & EN 14562 standards have been provided (according to the Annex IV of the ECHA Eff guidances) : **USES NOT GRANTED**

PT2 - Use #3 : CIP procedures (with circulation) in swimming pools, balneotherapy & private ponds

The representative product for the **Meta SPC2** i.e. ***INDAL PAA 2.5 (2.0% PAA)*** is :

Under clean conditions, at +20°C :

- Bactericidal (including *Legionella pneumophila*), yeasticidal and virucidal (including Human rotavirus) when used at 0.4% in 60 min
- Fungicidal when used at 2% in 60 min

For an effect on unicellular green algae & blue-green algae (cyanobacteria): 2% in a 48h min contact time

REMARK(S) :

- Since all the efficacy tests provided by the Applicant have been performed under dirty conditions, a read-across for intended uses in clean conditions is acceptable.

Meta SPC-3 : *INDAL PAA 5 (5% PAA)* **Experimental data on the efficacy of the biocidal product against target organisms**		
Field of use envisaged	**PT2**	Use #1 : Surface disinfection by manual spraying procedures Use #2 : CIP (with circulation) procedures in STP Use #3 : CIP (with circulation) procedures in private & public industries and in institutions Use #4 : Surface disinfection by manual dipping procedures Use #5 : Waste water disinfection in public/private STP Use #6 : Waste water disinfection in medical biology labs Use #7 : Linen disinfection
	PT3	Use #8 : Surface disinfection by manual spraying procedures of milking parlour systems Use #9 : Surface disinfection by manual spraying procedures in fish farming industry Use #10 : CIP (with circulation) procedures in fish farming industry Use #11 : Surface disinfection by manual dipping procedures in livestock housing Use #12 : Surface disinfection by manual spraying procedures in livestock housing Use #13 : CIP procedures (with circulation) in livestock housing
	PT4	Use #14 : Surface disinfection by manual spraying procedures Use #15 : CIP (with circulation) procedures Use #16 : Surface disinfection by manual dipping procedures Use #17 : Disinfection in washing machines
	~~**PT5**~~	~~Use #18 : Drinking water disinfection for animals in farms~~

Test product	**Function & Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results : effects**	**Reference & R.I.**
***INDAL PAA 5* (5% PAA)**	**Bactericidal activity** *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus* <u>Additional test organisms :</u> *Salmonella typhimurium* *Listeria monocytogenes* *Enterobacter cloacae* *Lactobacillus brevis* *Acinetobacter baumanii* *Pediococcus damnosus* *Campylobacter jejuni*	**EN 1276 (2009 + EC1 2011)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.01 - 0.05 – 0.1 – 0.15 – 0.2 % • I.S. : 0.3g/L BSA (clean conditions)	Bactericidal activity (including *Salmonella typhimurium, Listeria monocytogenes* *Acinetobacter baumanii, Enterobacter cloacae, Lactobacillus brevis, Pediococcus damnosus* and *Campylobacter jejuni*) at 0.15% in 5 min at +20°C in clean conditions.	**Doc. 65** : *INDAL PAA 5 HD10357 EN1276 bactericide 0.15% 5min 20°C proprete MERIEUX RF 17-597231-0007 2018-01-22* **Reliability 1** **Key study**

***INDAL PAA 5* (5% PAA)**	**Bactericidal activity** *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus* <u>Additional test organisms :</u> *Salmonella typhimurium* *Listeria monocytogenes* *Enterobacter cloacae*	**EN 1276 (2009 + EC1 2011)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 60 min • Concentrations tested : 0.005 - 0.01 – 0.02 – 0.03 – 0.04 % • I.S. : 0.3g/L BSA (clean conditions)	Non-bactericidal activity at 0.04% in 60 min at +20°C in clean conditions.	**Doc. 63** : *INDAL PAA 5 HD10357 EN1276 bactericide partielle 0.04% 60min 20°C proprete MERIEUX RF 17-597231-0007 2017-10-19* **Reliability 3 : efficacy not proven considering the test conditions**
***INDAL PAA 5* (5% PAA)**	**Bactericidal activity** *Enterococcus hirae*	**EN 1276 (2009 + EC1 2011)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 60 min • Concentrations tested : 0.04 - 0.05 – 0.06 – 0.07 – 0.08 % • I.S. : 0.3g/L BSA (clean conditions)	Active against *Enterococcus hirae* at 0.07% in 60 min at +20°C in clean conditions. ⇨ *Bactericidal activity (including Salmonella typhimurium, Listeria monocytogenes Enterobacter cloacae) at 0.07% in 60 min at +20°C in clean conditions.*	**Doc. 64** : *INDAL PAA 5 HD10357 EN1276 bactericide Enterococcus 0.07% 60min 20°C proprete MERIEUX RF 17-597231-0007 2017-10-19* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Bactericidal activity** *Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus* <u>Additional test organisms :</u> *Enterococcus faecium* *E. coli K12* *Salmonella typhimurium* *Listeria monocytogenes*	**EN 13727 (2015)** Quantitative suspension test • Temperature : +45 ± 1°C • Contact time : 15 min • Concentrations tested : 0.01 - 0.02 – 0.03 – 0.04 – 0.05 % • I.S. : 0.3g/L BSA (clean conditions)	Bactericidal activity (including E. faecium, E. coliK12, *Salmonella typhimurium & Listeria monocytogenes*) for instrument disinfection at 0.05% in 15 min at +45°C in clean conditions.	**Doc. 35** : *INDAL PAA 5 HD10357 EN13727 bactericide 0.05% 15min 45°C proprete MERIEUX RF 17-597231-0007 2017-08-14* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Bactericidal activity** *Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus* <u>Additional test organisms :</u> *Enterococcus faecium* *E. coli K12*	**EN 13727 (2015)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 30 min • Concentrations tested : 0.1 - 0.2 – 0.4 – 0.6 – 0.8 % • I.S. :	Bactericidal activity (*including E. faecium, E. coli* K12, *Salmonella typhimurium & Listeria monocytogenes*) for instrument disinfection at 0.1% in 30 min at +20°C in dirty conditions.	**Doc. 36** : *INDAL PAA 5 HD10357 EN13727 bactericide 0.1% 30min 20°C salete MERIEUX RF 17-597231-0007 2017-08-14* **Reliability 2: Representati**

	Salmonella typhimurium *Listeria monocytogenes*	3g/L BSA + 3 mL/L sheep RBC (dirty conditions)		**ve bacteria not tested.**
***INDAL PAA 5* (5% PAA)**	**Fungicidal/yeasticidal activity** *Aspergillus brasiliensis*	**EN 1650 + A1 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 1 – 2 – 2.5 – 3 – 3.5% • I.S. : 0.3g/L BSA (clean conditions)	Active against *Aspergillus brasiliensis* at 2 % in 15 min at +20°C in clean conditions.	**Doc. 62** : *INDAL PAA 5 HD10357 EN1650 fongicide 2% 15min 20°C proprete MIDAC RE-17-187-2 2017-11-21* **Reliability 2 : C. albicans not tested**
***INDAL PAA 5* (5% PAA)**	**Fungicidal/yeasticidal activity** *Aspergillus brasiliensis* *Candida albicans*	**EN 1650 + A1 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.1 – 0.2 – 0.3 – 0.4 – 0.5 (Y) 2 – 2.5 – 3 – 3.5 - 4 (F) • I.S. : 0.3g/L BSA (clean conditions)	Yeasticidal activity at 0.2% in 5 min at +20°C in clean conditions. Fungicidal activity at 3.5% in 5 min at +20°C in clean conditions.	**Doc. 61** : *INDAL PAA 5 HD10357 EN1650 fongicide 3.5% 5min 20°C proprete MIDAC RE-17-188-2 2017-10-06* **Reliability 1 Key study**
***INDAL PAA 5* (5% PAA)**	**Fungicidal/yeasticidal activity** *Mucor racemosus*	**EN 1650 + A1 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.1 – 0.2 – 0.5 – 1 – 1.5% • I.S. : 0.3g/L BSA (clean conditions)	Active against *Mucor racemosus* at 0.5 % in 5 min at +20°C in clean conditions.	**Doc. 60** : *INDAL PAA 5 HD10357 EN1650 fongicide Mucor 0.5% 5min 20°C proprete MIDAC RE-17-188-5 2017-10-09* **Reliability 2: Representative fungi/yeasts not tested**
***INDAL PAA 5* (5% PAA)**	**Fungicidal/yeasticidal activity** *Dekkera bruxellensis*	**EN 1650 + A1 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.1 – 0.2 – 0.5 – 1 – 1.5% • I.S. :	Active against *Dekkera bruxellensis* at 0.1 % in 5 min at +20°C in clean conditions.	**Doc. 59** : *INDAL PAA 5 HD10357 EN1650 levuricide Dekkera 0.1% 5min 20°C proprete MIDAC RE 17-188-3 2017-10-06* **Reliability 2:**

		0.3g/L BSA (clean conditions)		**Representative fungi/yeasts not tested**
***INDAL PAA 5* (5% PAA)**	**Fungicidal/yeasticidal activity** *Saccharomyces cerevisae*	**EN 1650 + A1 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.1 – 0.2 – 0.5 – 1 – 1.5% • I.S. : 0.3g/L BSA (clean conditions)	Active against *Saccharomyces cerevisae* at 0.5 % in 5 min at +20°C in clean conditions.	**Doc. 58** : *INDAL PAA 5 HD10357 EN1650 levuricide Saccharomyces 0.5% 5min 20°C proprete MIDAC RE 17-188-4 2017-10-06* **Reliability 2:** **Representative fungi/yeasts not tested**
***INDAL PAA 5* (5% PAA)**	**Fungicidal/yeasticidal activity** *Candida albicans*	**EN 13624 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.1 – 0.15 – 0.2 – 0.25 – 0.3 % • I.S. : 0.3g/L BSA (clean conditions)	Yeasticidal activity at 0.3% in 5 min at +20°C in clean conditions.	**Doc. 50** : *INDAL PAA 5 HD10357 EN13624 levuricide 0.3% 5min 20°C proprete MIDAC RE 17-480-1 2018-01-30* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Fungicidal/yeasticidal activity** *Aspergillus brasiliensis*	**EN 13624 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 1 – 1.5 – 2 – 2.5 – 3 % • I.S. : 0.3g/L BSA (clean conditions)	Active against *Aspergillus brasiliensis* at 1.5 % in 5 min at +20°C in clean conditions. ⇨ Fungicidal activity at 1.5% in 5 min at +20°C in clean conditions.	**Doc. 51** : INDAL PAA 5 HD10357 EN13624 fongicide Aspergillus 1.5% 5min 20°C proprete MIDAC RE 18-071-1 2018-02-26 **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Fungicidal/yeasticidal activity** *Aspergillus brasiliensis* *Candida albicans*	**EN 13624 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 30 min • Concentrations tested : 0.1 – 0.2 – 0.5 – 1 – 1.5% (Y) 0.1 – 0.5 – 1 – 2 – 3% (F)	Yeasticidal activity at 0.5% in 30 min at +20°C in dirty conditions. Fungicidal activity at 2% in 30 min at +20°C in dirty conditions.	**Doc. 52** : INDAL PAA 5 HD10357 EN13624 fongicide 2% 30min 20°C salete MIDAC RE 17-191-3 2017-08-31 **Reliability 1** **Key study**

		• I.S. : 3g/L BSA + 3 mL/L sheep RBC (dirty conditions)		
***INDAL PAA 5* (5% PAA)**	**Fungicidal/yeasticidal activity** *Aspergillus brasiliensis* *Candida albicans*	**EN 13624 (2013)** Quantitative suspension test • Temperature : +45 ± 1°C • Contact time : 15 min • Concentrations tested : 0.1 – 0.2 – 0.3 – 0.4 - 0.5 % (Y) 0.4 – 0.6 – 0.8 – 1 -2% (F) • I.S. : 0.3g/L BSA (clean conditions)	Yeasticidal activity at 0.2% in 15 min at +45°C in clean conditions. Fungicidal activity at 0.6% in 15 min at +45°C in clean conditions.	**Doc. 53** : INDAL PAA 5 HD10357 EN13624 fongicide 0.6% 15min 45°C proprete MIDAC RE 17-193-3 2017-09-04 **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Virucidal activity** Poliovirus Adenovirus Murine Norovirus	**EN 14476 + A1 (2015)** Quantitative suspension test • Temperature : +20°C • Contact time : 15 min • Concentrations tested : 0.05 – 0.1 - 0.2 – 0.4 – 0.6 % + 0.7 – 0.8 – 0.9 – 1 – 1.25 – 1.5 – 2 – 2.5% (Poliovirus) • I.S. : 0.3g/L BSA (clean conditions)	Virucidal activity at 1.5% in 15 min at +20°C in clean conditions.	**Doc. 28** : *INDAL PAA 5 HD10357 EN14476 virucide 1.5% 15min 20°C proprete MERIEUX 17-597231-0007 2018-02-02* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Virucidal activity** Adenovirus Murine Norovirus Murine parvovirus	**EN 14476 + A1 (2015)** Quantitative suspension test • Temperature : +20°C • Contact time : 30 min • Concentrations tested : 0.1 – 0.25 – 0.5 – 0.75 – 1% • I.S. : 3g/L BSA + 3 mL/L sheep RBC (dirty conditions)	Virucidal activity at 0.75% in 30 min at +20°C in dirty conditions. Active against murine parvovirus at 0.4% in 15 min at +45°C in clean conditions.	**Doc. 29** : *INDAL PAA 5 HD10357 EN14476 virucide 0.75% 30min 20°C salete MERIEUX 17-597231-0007 2017-11-06* *Doc. « INDAL PAA 5 HD10357 EN14476 Adenovirus Norovirus 0.05% 60min 25°C proprete IRM 1038-0119 2019-05-27 »* *Doc. « INDAL PAA 5 HD10357 EN14476 virucide 0.4% 15min 45°C proprete IRM*

				1215-0619 2019-08-19 » **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Virucidal activity** Phages P001 & P008 (lytic for *Lactococcus lactis subspecies lactis*)	**EN 13610 (2003)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.05 – 0.1 – 0.2 – 0.4 – 0.6 % • I.S. : 1% Acid whey	Virucidal activity against bacteriophages at 0.1% in 15 min at +20°C in presence of 1% Acid whey.	**Doc. 15** : *Meta SPC 3_INDAL PAA 5_EN13610_bacteriophage_0.1%_15min_20°C_ 1% acid whey_LMH-4583-1* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Mycobactericidal activity** *Mycobacterium terrae* *Mycobacterium avium*	**EN 14348 (2005)** Quantitative suspension test (additional conditions) • Temperature : +20 ± 1°C • Contact time : 30 min • Concentrations tested : 0.1 – 0.5 – 1 – 1.5 – 2% % • I.S. : 3g/L BSA + 3 mL/L sheep RBC (dirty conditions)	Mycobactericidal activity at 0.5% in 30 min at +20°C in dirty conditions.	**Doc. 32** : *INDAL PAA 5 HD10357 EN14348 mycobactericide 0.5% 30min 20°C salete APEX 143D08-2017-03 2017-10-25* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Mycobactericidal activity** *Mycobacterium terrae* *Mycobacterium avium*	**EN 14348 (2005)** Quantitative suspension test (additional conditions) • Temperature : +45 ± 1°C • Contact time : 15 min • Concentrations tested : 0.1 – 0.5 – 1 – 1.5 – 2% % • I.S. : 0.3g/L BSA (clean conditions)	Mycobactericidal activity at 0.5% in 15 min +45°C in clean conditions.	**Doc. 33** : *INDAL PAA 5 HD10357 EN14348 mycobactericide 0.5% 15min 45°C proprete APEX 143D08-2017-05 2017-10-25* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Mycobactericidal activity** *Mycobacterium terrae*	**EN 14348 (2005)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.1 – 0.5 – 1 – 1.5 – 2% % • I.S. :	Tuberculocidal activity at 0.5% in 15 min at +20°C in clean conditions.	**Doc. 34** : *INDAL PAA 5 HD10357 EN14348 mycobactericide 0.5% 15min 20°C proprete APEX 143D08-2017-01 2017-10-25* **Reliability 1** **Key study**

		0.3g/L BSA (clean conditions)		
***INDAL PAA 5* (5% PAA)**	**Sporicidal activity** *Bacillus subtilis* *Clostridium sporogenes* *Bacillus cereus*	**EN 13704 (2002)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.1 – 0.5 – 1 – 2 – 3% • I.S. : 0.3g/L BSA (clean conditions)	Sporicidal activity at 1% in 15 min at +20°C in clean conditions. Active against *Clostridium sporogenes* at 0.5% in 15 min at +20°C in clean conditions. Active against *Bacillus cereus* at 0.5% in 15 min at +20°C in clean conditions.	**Doc.38** : *INDAL PAA 5 HD10357 EN13704 sporicide B subtilis 1% 15min 20°C proprete MIDAC RE 17-204-3 2017-10-23* **Reliability 1** **Key study** **Doc. 37** : *INDAL PAA 5 HD10357 EN13704 sporicide Clostridium 0.5% 15min 20°C proprete MIDAC RE 17-204-5 2017-10-23* **Reliability 2:** **Representative spore-forming bacteria not tested** **Doc. 39** : *INDAL PAA 5 HD10357 EN13704 sporicide B cereus 0.5% 15min 20°C proprete MIDAC RE 17-204-4 2017-10-23* **Reliability 2:** **Representative spore-forming bacteria not tested**
***INDAL PAA 5* (5% PAA)**	**Bactericidal activity** *Legionella pneumophila*	**EN 13623 (2010)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations	Active against *Legionella pneumophila* at 0.05% in 5 min at +20°C	**Doc. 54** : *INDAL PAA 5 HD10357 EN13623 Legionella 0.05% 5min 20°C 0.05 gL albumine MERIEUX 17-*

		tested : 0.01 – 0.05 – 0.1 – 0.2 – 0.25% • I.S. : 0.05 g/L BSA		*597231-0002 2017-08-17* **Reliability 1**
***INDAL PAA 5* (5% PAA)**	**Bactericidal activity** *Legionella pneumophila*	**EN 13623 (2010)** Quantitative suspension test • Temperature : +10 ± 1°C • Contact time : 5 min • Concentrations tested : 0.05 – 0.1– 0.25 – 0.4 – 0.5 % • I.S. : 3g/L BSA + 3 mL/L sheep RBC (dirty conditions)	Active against *Legionella pneumophila* at 0.1% in 5 min at +10°C.	**Doc. 55** : *INDAL PAA 5 HD10357 EN13623 Legionella 0.1% 5min 10°C 3 gL albumine + erythrocytes MERIEUX 17-597231-0010 2018-01-04* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Bactericidal activity** *Legionella pneumophila*	**Field test for validation of a chemical treatment against *Legionella pneumophila* in the leachate of a Ultimate Waste Storage Center**	Active against *Legionella pneumophila* at 0.1% for a shock treatment in 4h at +20°C Active against *Legionella pneumophila* at 0.02% for a continuous treatment at ambient temperature	**Doc. 16** : *Meta SPC 3_INDAL PAA 5_phase 3_legionnella_ NUCLEOXY 5.5* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Mycobactericidal activity** *Mycobacterium terrae* *Mycobacterium avium*	**EN 14563 (2009)** Quantitative carrier test – Instruments • Temperature : +10 ± 1°C +20 ± 1°C • Contact time : 15 - 30 min • Concentrations tested : 0.1 – 0.5 – 1 – 1.5 - 2% 0.2 – 0.4 – 0.6 – 0.8 – 1% • I.S. : 3g/L BSA (dirty conditions) 3g/L BSA + 3 mL/L sheep RBC (dirty conditions)	Tuberculocidal activity at 1% in 15 min at +20°C in clean conditions. Mycobactericidal activity at 1% in 30 min at +20°C in dirty conditions. Active against *Mycobacterium avium* at 1% in 15 min at +10°C in dirty conditions.	**Doc. 24** : *INDAL PAA 5 HD10357 EN14563 mycobactericide 1% 30min 20°C salete APEX 143D08-2017-04 2017-10-25* **Doc. 25** : *INDAL PAA 5 HD10357 EN14563 mycobactericide 1% 15min 20°C proprete APEX 143D08-2017-02 2017-10-25* *Dco. « INDAL PAA 5 HD10357 EN14563 mycobactericide 0.8% 15min 10°C salete BN MERIEUX 19.0501679.0002_19_00017 4560 2019-03-16 »*

				Reliability 1 **Key study**
***INDAL PAA 5* (5% PAA)**	**Fungicidal/yeasticidal activity** *Candida albicans* *Aspergillus brasiliensis*	**EN 14562 (2006)** Quantitative carrier test – Instruments • Temperature : +20 ± 1°C • Contact time : 30 min • Concentrations tested : 0.1 – 0.2 - 0.5 – 1 – 1.5 % (Y) 0.1 – 0.5 – 1 – 2 – 3% (F) • I.S. : 3g/L BSA + 3 mL/L sheep RBC (dirty conditions)	Yeasticidal activity at 0.2% in 30 min at +20°C in dirty conditions. Fungicidal activity at 2% in 30 min at +20°C in dirty conditions.	**Doc. 26** : *INDAL PAA 5 HD10357 EN14562 fongicide 2% 30min 20°C salete MIDAC RE 17-192-2 2017-11-06* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Bactericidal activity** *Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus* <u>Additional test organisms :</u> *E. coli K12* *Salmonella typhimurium* *Listeria monocytogenes*	**EN 14561 (2006)** Quantitative carrier test – Instruments • Temperature : +20 ± 1°C • Contact time : 30 min • Concentrations tested : 0.1 - 0.5 – 1 – 1.5 - 2% • I.S. : 3g/L BSA + 3 mL/L sheep RBC (dirty conditions)	Bactericidal activity (including E. coli K12, *Salmonella typhimurium* and *Listeria monocytogenes*) at 0.5% in 30 min at +20°C in dirty conditions.	**Doc. 27** : *INDAL PAA 5 HD10357 EN14561 bactericide 0.5% 30min 20°C salete MERIEUX 17-597231-0006 2017-09-05* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Bactericidal activity** *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus* <u>Additional test organisms :</u> *Salmonella typhimurium* *Listeria monocytogenes* *Enterobacter cloacae* *Lactobacillus brevis* *Acinetobacter baumanii* *Pediococcus damnosus* *Campylobacter jejuni*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +18-25 ± 1°C • Contact time : 5 min • Concentrations tested : 0.1 – 0.2 – 0.3 – 0.4 – 0.5 % • I.S. : 0.3g/L BSA (clean conditions)	Bactericidal activity (including *Salmonella typhimurium, Listeria monocytogenes* *Acinetobacter baumanii, Enterobacter cloacae, Lactobacillus brevis, Pediococcus damnosus* and *Campylobacter jejuni*) at 0.2% in 5 min at +20°C on hard/non-porous surfaces with prior cleaning.	**Doc. 49** : *INDAL PAA 5 HD10357 EN13697 bactericide 0.2% 5min 20°C proprete MERIEUX RF 17-597231-0007 2018-01-22* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Bactericidal activity** *Enterococcus hirae*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces	Bactericidal activity at 0.4% in 1 min at +20°C on hard/non-porous surfaces with prior cleaning.	**Doc. 48** : *INDAL PAA 5 HD10357 EN13697 bactericide*

	E.coli *Pseudomonas aeruginosa* *Staphylococcus aureus*	• Temperature : +18-25 ± 1°C • Contact time : 1 min • Concentrations tested : 0.2 – 0.3 – 0.4 – 0.5 – 0.6 % • I.S. : 0.3g/L BSA (clean conditions)		*0.4% 1min 20°C proprete MERIEUX RF 17-597231-0007 2017-07-29* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Fungicidal/yeasticidal activity** *Candida albicans* *Aspergillus brasiliensis*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.1 – 0.2 – 0.5 – 1 – 1.5 % • I.S. : 0.3g/L BSA (clean conditions)	Yeasticidal activity at 0.2% in 5 min at +20°C on hard/non-porous surfaces with prior cleaning. Fungicidal activity at 1% in 5 min at +20°C on hard/non-porous surfaces with prior cleaning.	**Doc. 47** : *INDAL PAA 5 HD10357 EN13697 fongicide 1% 5min 20°C proprete MIDAC RE 17-190-2 2017-09-25* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Fungicidal/yeasticidal activity** *Aspergillus brasiliensis*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +18-25 ± 1°C • Contact time : 15 min • Concentrations tested : 0.1 – 0.5 – 0.8 – 1 – 2 % • I.S. : 0.3g/L BSA (clean conditions)	Active against *Aspergillus brasiliensis* at 0.8 % in 15 min at +20°C in clean conditions.	**Doc. 46** : *INDAL PAA 5 HD10357 EN13697 fongicide Aspergillus 0.8% 15min 20°C proprete MIDAC RE-17-189-1 2017-08-31* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Fungicidal/yeasticidal activity** *Mucor racemosus*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.1 – 0.2 – 0.5 – 1 – 1.5% • I.S. : 0.3g/L BSA (clean conditions)	Active against *Mucor racemosus* at 0.2 % in 5 min at +20°C in clean conditions.	**Doc. 45** : *INDAL PAA 5 HD10357 EN13697 fongicide Mucor 0.2% 5min 20°C proprete MIDAC RE 17-190-5 2017-10-05* **Reliability 2**
***INDAL PAA 5* (5% PAA)**	**Fungicidal/yeasticidal activity** *Dekkera bruxellensis*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time :	Active against *Dekkera bruxellensis* at 0.1 % in 5 min at +20°C in clean conditions.	**Doc. 44** : *INDAL PAA 5 HD10357 EN13697 levuricide Dekkera 0.1% 5min 20°C proprete MIDAC RE 17-*

		5 min • Concentrations tested : 0.1 – 0.2 – 0.5 – 1 – 1.5% • I.S. : 0.3g/L BSA (clean conditions)		*190-3 2017-09-25* **Reliability 2:** **Representative fungi/yeasts not tested**
***INDAL PAA 5* (5% PAA)**	**Fungicidal/yeasticidal activity** *Saccharomyces cerevisae*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.1 – 0.2 – 0.5 – 1 – 1.5% • I.S. : 0.3g/L BSA (clean conditions)	Active against *Saccharomyces cerevisae* at 0.1% in 5 min at +20°C in clean conditions.	**Doc. 43** : *INDAL PAA 5 HD10357 EN13697 levuricide Saccharomyces 0.1% 5min 20°C proprete MIDAC RE 17-190-4 2017-09-25* **Reliability 2:** **Representative fungi/yeasts not tested**
***INDAL PAA 5* (5% PAA)**	**Sporicidal activity** *Bacillus subtilis* *Clostridium sporogenes* *Bacillus cereus*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.1 – 0.5 – 1 – 2 – 3% • I.S. : 0.3g/L BSA (clean conditions)	Sporicidal activity at 0.5% (with > Log3 reduction) in 15 min at +20°C in clean conditions. Active against *Bacillus cereus* at 0.5% (with > Log4 reduction) in 15 min at +20°C in clean conditions. Active against *Clostridium sporogenes* at 0.5% (with > Log4 reduction) in 15 min at +20°C in clean conditions.	**Doc. 42** : *INDAL PAA 5 HD10357 EN13697 sporicide B cereus 0.1% 15min 20°C proprete MIDAC RE 17-205-5 2017-12-15* **Reliability 2:** **Representative spore-forming bacteria not tested** **Doc.41** : *INDAL PAA 5 HD10357 EN13697 sporicide B subtilis 0.5% 15min 20°C proprete MIDAC RE17-205-4 2017-12-14* **Reliability 1** **Key study** **Doc. 40** : *INDAL PAA 5 HD10357*

				EN13697 sporicide Clostridium 0.1% 15min 20°C proprete MIDAC RE 17-205-6 2017-12-15 **Reliability 2:** **Representative spore-forming bacteria not tested**
***INDAL PAA 5* (5% PAA)**	**Bactericidal activity** *Staphylococcus aureus*	**Protocol from the Institut Pasteur de Lille** BIOFILM - Simulated-use test Biofilm formation according to the method described in the annex F of the ISO/TS 15883-5 standard (from 2005) i.e. via circulation (3 mL/min) of a liquid growth medium contaminated with *Staphylococcus aureus* (10^6 UFC/mL) in a hosepipe during 3-4 days kept at +30°C. Disinfection test by dipping of the hosepipes in the disinfectant (in presence of 0.3g/L BSA) during 5 min. • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0 – 0.1 – 0.2 – 0.4 % • I.S. : 0.3g/L BSA (clean conditions)	Active against a *Staphylococcus aureus* biofilm at 0.1% (with > Log7 reduction) in 5 min at +20°C in clean conditions.	**Doc. 17** : INDAL PAA 5 HD10357 ISO 15883-5 bactericide biofilm Staphylococcus 0.1% 5min 20°C proprete IPL 170178-01b 2017-12-18 **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Bactericidal activity** *Pseudomonas aeruginosa*	**Protocol from the Institut Pasteur de Lille** BIOFILM - Simulated-use test Biofilm formation according to the method described in the annex F of the ISO/TS 15883-5 standard (from 2005) i.e. via circulation (3 mL/min) of a liquid growth medium contaminated with *Pseudomonas aeruginosa* (10^6 UFC/mL) in a hosepipe during 3-4 days kept at +30°C. Disinfection test by dipping of the hosepipes in the	Active against a *Pseudomonas aeruginosa* biofilm at 0.2% (with > Log7 reduction) in 5 min at +20°C in clean conditions.	**Doc. 18** : INDAL PAA 5 HD10357 ISO 15883-5 bactericide biofilm Pseudomonas 0.2% 5min 20°C proprete IPL 170178-02b 2017-12-18 **Reliability 1** **Key study**

		disinfectant (in presence of 0.3g/L BSA) during 5 min. • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0 – 0.1 – 0.2 – 0.4 % • I.S. : 0.3g/L BSA (clean conditions)		
***INDAL PAA 5* (5% PAA)**	**Bactericidal activity** *Legionella pneumophila*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces •Temperature : +20 ± 1°C •Contact time : 5 – 30 min •Concentrations tested : 0.1 - 0.15 – 0.2 % •I.S. : 0.3g/L BSA (clean conditions) 3g/L BSA + 3ml/L erythrocytes (dirty conditions)	Active against *Legionella pneumophila* at 0.15% in 5 min at +20°C in clean conditions. Active against *Legionella pneumophila* at 0.15% in 30 min at +20°C on hard/non-porous surfaces wo prior cleaning.	Doc. « INDAL PAA 5 HD10357 EN13697 Legionella 0.15% 5min 20°C proprete MERIEUX RF 19.501679.0002_19_000309164 2019-07-15 » Doc. « INDAL PAA 5 HD10357 EN13697 Legionella 0.15% 30min 20°C salete MERIEUX RF 19.501679.0002_19_000309164 2019-07-15 » **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Bactericidal activity** *Pseudomonas aeruginosa* *Staphylococcus aureus* *Legionella pneumophila*	**Protocol from the Institut Pasteur de Lille** BIOFILM - Simulated-use test •Temperature : +20 ± 1°C •Contact time : 5 min •Concentrations tested : 0.1 – 0.2 – 0.4% •I.S. : 0.3g/L BSA (clean conditions)	In static contact, active against *Legionella pneumophila* biofilms (Log ↓ > 2.6) at 0.1% in 5 min at +20°C in clean conditions.	Doc. "INDAL PAA 5 HD10357 ISO 15883-5 bactericide biofilm Legionella 0.1% 5min 20°C proprete IPL 170178-03 2018-05-23" **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Virucidal activity** *Adénovirus type 5* *Norovirus murin*	**prEN 16777 (2018)** Quantitative carrier test – hard & non-porous surfaces •Temperature : +20 ± 1°C •Contact time : 15 min	Virucidal activity at 0.2% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning	Doc. "INDAL PAA 5 HD10357 EN16777 virucide 0.2% 15min 20°C proprete IRM RE1039-0119 2019-08-14"

		•Concentrations tested : 0.01 – 0.1 – 0.2% (A) 0.01 – 0.2 – 0.4% (N) •I.S. : 0.3g/L BSA (clean conditions)		**Reliability 1** **Key study**
INDAL PAA 5 **(5% PAA)**	**Bactericidal activity** *Enterococcus hirae* *Staphylococcus aureus* **Yeasticidal activity** *Candida albicans* **Tuberculocidal activity** *Mycobacterium terrae*	**EN 16616 (2014)** Quantitative carrier test – hard & non-porous surfaces •Temperature: +45 ± 1°C •Contact time: 15 min •Concentrations tested: 6 – 7 – 8 mL/L •I.S. : 12.5 ml sterile defibrinated sheep blood / kg of linen Control wo product but with detergent.	Partial results : Bactericidal, yeasticidal & tuberculocidal activity at 8 mL/L in 15 min at +45°C. **BUT** 1- *Pseudomonas aeruginosa , E. coli K12 and Aspergillus brasiliensis* not tested.	Doc. "INDAL PAA 5 HD10357 EN16616 partielle 8ml 15min 45°C salete HYGIENE NORD PB191446.VI version 1 2019-10-09" Doc. "INDAL PAA 5 HD10357 EN16616 screening 6 & 7ml 15min 45°C proprete HYGIENE NORD 2019-08-30" **Reliability 3 : Representative organisms bacteria not tested**
INDAL PAA 5 **(5% PAA)**	**Bactericidal activity** *Enterococcus hirae* *Proteus vulgaris* *Pseudomonas aeruginosa* *Staphylococcus aureus* *+ E.coli* *Salmonella typhimurium* *Listeria monocytogenes*	**EN 1656 (2010)** Quantitative suspension test • Temperature : +10 ± 1°C • Contact time : 15 min • Concentrations tested : 0.05 – 0.1 – 0.2 – 0.3 – 0.4% • I.S. : 3g/L BSA (clean conditions)	Bactericidal activity (+ *E.coli* *Salmonella typhimurium* & *Listeria monocytogenes*) at 0.3% in 15 min at +10°C in clean conditions.	**Doc. 57** : INDAL PAA 5 HD10357 EN1656 bactericide 0.3% 15min 10°C salete bas niveau MERIEUX RF 17-597231-0007 2017-08-14 **Reliability 1** **Key study**
INDAL PAA 5 **(5% PAA)**	**Fungicidal/yeasticidal activity** *Candida albicans* *Aspergillus brasiliensis*	**EN 1657 (2016)** Quantitative suspension test • Temperature : +10 ± 1°C • Contact time : 15 min • Concentrations tested : 0.2 – 0.4 – 0.6 – 0.8 – 1% (Y) 0.1 – 1 – 1.5 – 2 – 3% (F)	Yeasticidal activity at 0.6% in 15 min at +10°C in clean conditions. Fungicidal activity at 2% in 15 min at +10°C in in clean conditions.	**Doc. 56** : *INDAL PAA 5 HD10357 EN1657 fongicide 2% 15min 10°C salete bas niveau MIDAC RE-17-184-4 2017-10-17* **Reliability 1** **Key study**

		• I.S. : 3g/L BSA (clean conditions)		
***INDAL PAA 5* (5% PAA)**	**Bactericidal activity** *Enterococcus hirae* *Proteus vulgaris* *Pseudomonas aeruginosa* *Staphylococcus aureus* *+ E.coli* *Salmonella typhimurium* *Listeria monocytogenes*	**EN 14349 (2013)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +10 ± 1°C • Contact time : 15 min • Concentrations tested : 0.01 – 0.2 – 0.4 – 0.6 – 0.8 % • I.S. : 3g/L BSA (clean conditions)	Bactericidal activity (+ *E.coli* *Salmonella typhimurium* & *Listeria monocytogenes*) at 0.4% in 15 min at +10°C on hard/non-porous surfaces with prior cleaning.	**Doc. 31** : INDAL PAA 5 HD10357 EN14349 bactericide 0.4% 15min 10°C salete bas niveau MERIEUX 17-597231-0001 2017-09-05 **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Bactericidal activity** *Enterococcus hirae* *Proteus vulgaris* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 14349 (2013)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +10 ± 1°C • Contact time : 3 min • Concentrations tested : 0.01 – 0.5 – 1 – 1.5 – 2% • I.S. : 10.0 g/L Skimmed Milk	Bactericidal activity at 0.6% in 3 min at +10°C on hard/non-porous surfaces in presence of milk.	**Doc. 30** : INDAL PAA 5 HD10357 EN14349 bactericide 0.6% 3min 10°C 10 gL lait MERIEUX 17-605077-0001 18-000109287 2018-03-19 **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Fungicidal/yeasticidal activity** *Candida albicans*	**EN 16438 (2014)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +10 ± 1°C • Contact time : 1min • Concentrations tested : 0.01 – 0.2 – 0.5 – 1 -2% • I.S. : 10.0 g/L Skimmed Milk	Yeasticidal activity at 1 % in 1 min at +10°C on hard/non-porous surfaces in presence of milk.	**Doc. 19** : *INDAL PAA 5 HD10357 EN16438 levuricide 1% 1min 10°C 1 gL lait MIDAC RE 17-195-1 2017-10-12* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Fungicidal/yeasticidal activity** *Candida albicans* *Aspergillus brasiliensis*	**EN 16438 (2014)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +10 ± 1°C • Contact time : 15 min • Concentrations tested : 0.1 – 0.4 – 0.6 – 0.8 - 1% (Y) 0.5 – 1 – 2 – 3 – 4% (F) • I.S. :	Yeasticidal activity at 0.2 % in 15 min at +10°C on hard/non-porous surfaces with prior cleaning. Fungicidal activity at 1 % in 15 min at +10°C on hard/non-porous surfaces with prior cleaning.	**Doc. 20** : *INDAL PAA 5 HD10357 EN16438 fongicide 1% 15min 10°C salete bas niveau MIDAC RE 17-194-2 2017-11-02* **Reliability 1** **Key study**

		3g/L BSA (clean conditions)		
***INDAL PAA 5* (5% PAA)**	**Virucidal activity** Vaccinia virus	**EN 14675 (2015)** Quantitative suspension test • Temperature : +10°C ± 1°C • Contact time : 5 min • Concentrations tested : 0.01 – 0.1 – 0.5 – 1 – 1.5 – 2% • I.S. : 10.0 g/L Skimmed Milk	Active against Vaccinia virus at 0.1% in 5 min at +10°C in presence of milk.	**Doc. 21** : *INDAL PAA 5 HD10357 EN14675 virus vaccine 0.1% 5min 10°C 10 gL lait VIRHEALTH R-LVQUA004 2017-10-30* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Virucidal activity** Bovine enterovirus (ECBO)	**EN 14675 (2015)** Quantitative suspension test • Temperature : +10°C ± 1°C • Contact time : 5 min • Concentrations tested : 0.01 – 0.1 – 0.5 – 1 – 1.5 – 2% • I.S. : 10.0 g/L Skimmed Milk	Virucidal activity at 0.5% in 5 min at +10°C in presence of milk.	**Doc. 22** : *INDAL PAA 5 HD10357 EN14675 virus ECBO 0.5% 5min 10°C 10 gL lait VIRHEALTH R-LVQUA005 2017-11-06* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Virucidal activity** Bovine enterovirus (ECBO)	**EN 14675 (2015)** Quantitative suspension test • Temperature : +10°C ± 1°C • Contact time : 15 min • Concentrations tested : 0.01 – 0.1 – 0.2 – 0.4 – 0.6 – 0.8 % • I.S. : 3g/L BSA (clean conditions)	Virucidal activity at 0.1% in 15 min at +10°C in in clean conditions.	**Doc. 23** : *INDAL PAA 5 HD10357 EN14675 virucide 0.1% 15min 10°C salete bas niveau VIRHEALTH R-LVQUA002 2017-10-16* **Reliability 1** **Key study**
***INDAL PAA 5* (5% PAA)**	**Algicidal activity** *Chlorella vulgaris* *Nostoc sp.* *Chlamydomonas sp.*	**ASTM 645-13** Quantitative suspension test • Temperature : +10°C • Contact time : 6 and 12 h • Concentrations tested : 0.004 - 0.01 – 0.02 – 0.04 - 0.05 % I.S. : 3g/L BSA + 3ml/L erythrocytes	Algaecidal activity (with R ≥ 90%) at 0.02% in 6 hours at +10°C wo prior cleaning Algaecidal activity (with R ≥ 90%) at 0.01% in 12 hours at +10°C wo prior cleaning	**Doc.** *"INDAL PAA 5 HD10357 ASTM E645-13 algicide 0.2% 6h et 0.1% 12h 10°C salete APEX 185D11-2017-01 2018"* **Reliability 1** **Key study**

***INDAL PAA 5* (5% PAA)**	**Algicidal activity** *Stichococcus bacillaris* *Nostoc commune*	**Protocole CONIDIA** Quantitative suspension test / carrier test – hard & non-porous surfaces • Temperature : +10°C • Contact time : 4 – 24 -48 – 72 – 144 h • Concentrations tested : 0.4 – 2 – 5 % I.S. : 3g/L BSA	*Stichococcus bacillaris :* • Suspension : Log↓ = 95% at 1.2% within 72h at +10°C • Surfaces : ↓ = 99% at 1.2% (with 100 mL/m^2) in 24h at +10°C wo prior cleaning *Nostoc commune* : • Suspension : Log↓ = 95% at 0.8% within 48h at +10°C • Surfaces : ↓ = 60% at 5% (with 200 mL/m^2) in 144h at +10°C wo prior cleaning	Doc. "CONIDIA rapport final INDAL PAA 5 essai algicide" **Reliability 1** **Key study**

Meta SPC3

Conclusions on the efficacy of the representative product *INDAL PAA 5 (5% PAA)* & *Label claims*

Please note that, since required by other MSs, for surface disinfection by spraying/mopping or immersion, P2S1 and all P2S2 tests are mandatory and must be taken into account and therefore the higher concentration required is the limiting one and thus be set up as the necessary concentration.

Please note that, to stay in line with the decision made for other dossiers, specific organisms mentioned in the efficacy conclusions of the PAR should not be include in the SPC.

PT2 - Use #1 : Surface disinfection by manual spraying procedures

The representative product for the ***Meta SPC3*** i.e. ***INDAL PAA 5*** (5% PAA) intended to be used for surface disinfection by manual spraying procedures is:

On hard non-porous surfaces with prior cleaning, at +20°C :

Make sure to wet surfaces completely.

- Bactericidal (including *Salmonella typhimurium, Listeria monocytogenes, Enterobacter cloacae, Lactobacillus brevis, Campylobacter jejuni & Legionella pneumophila*) and yeasticidal (including *Dekkera bruxellensis & Saccharomyces cerevisae*) when used at 0.5% in 5 min
- Fungicidal (including *Mucor racemosus*) when used at 3.5% in 5 min
- Tuberculocidal when used at 0.5% in 15 min
- Virucidal when used at 1.5% in 15 min
- Active against bacteriophages when used at 0.1% in 15 min
- Sporicidal (including *Bacillus cereus & Clostridium sporogenes*) when used at 1% in 15 min
- Active to remove biofilms when used at 0.2% in 5 min
- Active against unicellular green algae when used at 1.2% in 24h

In medical areas – for disinfection of frequently touched surfaces :

- For an effect on bacteria (including Salmonella typhimurium, Listeria monocytogenes, Enterobacter cloacae, Lactobacillus brevis, Campylobacter jejuni & Legionella pneumophila) and on yeasts (including Dekkera bruxellensis & Saccharomyces cerevisae) : 0.5% in a 5 min contact time

- For an effect on fungi (including Mucor racemosus) : 3.5% in a 5 min contact time

REMARK:

Since the product is used for surface disinfection, the efficient concentration should be deduced from the surface tests and not the suspension tests. Since efficacy against cyanobacteria is not proven in the surface tests (60% efficacy at 5% within 144H), only an efficacy against green algae (1.2% in 24h) should be validated.

PT2 - Use #2 : CIP (with circulation) procedures in STP

The representative product for the ***Meta SPC3*** i.e. ***INDAL PAA 5*** (5% PAA) intended to be used CIP (with circulation) procedures in STP is :

Under dirty conditions, at +20°C :

- Bactericidal (including *Legionella pneumophila, E. faecium, E. coli K12, Salmonella typhimurium & Listeria monocytogenes*) and yeasticidal when used at 0.5% in 30 min
- Fungicidal when used at 2% in 30 min
- Mycobactericidal when used at 0.5% in 30 min
- Virucidal when used at 0.75% in 30 min
- Active against unicellular green algae & blue-green algae (cyanobacteria) when used at 1.2% in 72h

REMARK(S) :

- Efficacy against biofilms, not proven under dirty conditions.

- Relevance of the additional target organisms *L.pneumophila* for diping in agri-food industry (Applicant justification) : As L. pneumophila is a relevant organism to test the efficacy of disinfectants for curative treatments against biofilms, it is also relevant to test them on surfaces and circuits before these bacteria can form a biofilm. As L. pneumophila is found in natural hydro-telluric environments and in water systems, it can be found in agri-food industries where large amount of potable water is needed, sometime provided by a drilling. As for example, large amounts of water are used by soaking and dipping, spraying and/or nebulizing in fresh fruits and vegetables industries to clean them before package, freeze or transform them. The disinfection of the materials, surfaces and circuits / pumps / tanks of these industrial equipment against L. pneumophila is relevant to avoid survival of bacteria and to protect workers from contaminations by aerosols or splashes from water in contact of them.

PT2 - Use #3 : CIP (with circulation) procedures in private & public industries and in institutions

The representative product for the ***Meta SPC3*** i.e. ***INDAL PAA 5*** (5% PAA) intended to be used CIP (with circulation) procedures in private & public industries is :

Under clean conditions, at +20°C :

- Bactericidal and yeasticidal when used at 0.2% in 5 min
- Fungicidal when used at 3.5% in 5 min
- Tuberculocidal when used at 0.5% in 15 min
- Virucidal when used at 1.5 % in 15 min
- Active against bacteriophages when used at 0.1% in 15 min
- Active to remove biofilms) when used at 0.2% in 5 min
- Active against unicellular green algae & blue-green algae (cyanobacteria) when used at 1.2% in 72h

REMARK(S) :

About the algicidal activity, since the efficacy has been performed at +10°C, the efficacy against algae at +20°C is proven enough.

- Relevance of the additional target organisms *L.pneumophila* for diping in agri-food industry (Applicant justification) : As L. pneumophila is a relevant organism to test the efficacy of disinfectants for curative treatments against biofilms, it is also relevant to test them on surfaces and circuits before these bacteria can form a biofilm. As L. pneumophila is found in natural hydro-telluric environments and in water systems, it can be found in agri-food industries where large amount of potable water is needed, sometime provided by a drilling. As for example, large amounts of water are used by soaking and dipping, spraying and/or

nebulizing in fresh fruits and vegetables industries to clean them before package, freeze or transform them. The disinfection of the materials, surfaces and circuits / pumps / tanks of these industrial equipment against L. pneumophila is relevant to avoid survival of bacteria and to protect workers from contaminations by aerosols or splashes from water in contact of them.

PT2 - Use #4 : Surface disinfection by manual dipping procedures

The representative product for the ***Meta SPC3*** i.e. ***INDAL PAA 5*** (5% PAA) intended to be used for surfaces disinfection during dipping procedures is :

On hard non-porous surfaces without prior cleaning, at +20°C :

- Bactericidal, yeasticidal and virucidal (including Parvovirus) when used at 0.75% in 30 min
- Fungicidal when used at 3.5% in 30 min
- Mycobactericidal when used at 1% in 30 min
- Active to remove biofilms when used at 0.2% in 5 min
- Active against unicellular green algae when used at 1.2% in 24h

REMARK(S) :

- About the algicidal activity, since the efficacy has been performed at +10°C, the efficacy against algae at +20°C is proven enough.

- About the mycobacteria activity, use conditions validated from a read-across with Meta SPC1

- Applicant clarification about the relevance of additionnal target organisms and algae in the frame of disinfection of closed circulation circuits : see as an example the DOC 16 "Field test for validation of a chemical treatment against *Legionella pneumophila* in the leachate of a Ultimate Waste Storage Center". Development of algae in equipment used to concentrate leachate leads to reduce the efficacy of the process and increase energy consumption.

REMARK:

Since the product is used for surface disinfection, the efficient concentration should be deduced from the surface tests and not the suspension tests. Since efficacy against cyanobacteria is not proven in the surface tests (60% efficacy at 5% within 144H), only an efficacy against green algae (1.2% in 24h) should be validated.

PT2 - Use #5 : Waste water disinfection in public/private STP
PT2 - Use #6 : Waste water disinfection in medical biology labs

The representative product for the ***Meta SPC3*** i.e. ***INDAL PAA 5*** (5% PAA) is :

In dirty conditions, at +20°C in 30 min :

- Bactericidal (including *Legionella pneumophila, E. faecium, E. coli K12, Salmonella typhimurium & Listeria monocytogenes*) and yeasticidal when used at 0.5%
- Fungicidal when used at 2%
- Mycobactericidal when used at 1%
- Virucidal (including Parvovirus) when used at 0.75 %

REMARK about Use #3.5 : WWSTP disinfection

Please note first of all that, due to the dossier submission in 2017, the requirements discussed and defined during the WG 2018 are not of application.

1) About relevant target organisms, considering the conclusion of the WGVI2018 meeting, "*The EFF WG agreed that efficacy against bacteria is mandatory, efficacy against other organisms should only be demonstrated if claimed*".

According to the eff studies submitted and validated, the product is efficacious against bacteria (including mycobacteria) but also against fungi/yeasts and viruses (poliovirus, adenovirus & norovirus including parvovirus) under dirty conditions with 0.5% PB (with 5% PAA) ⇔ 0.025 % PAA ⇔ 250 mg/L PAA in 30 min.

From relevant scientific literature reporting field tests, *E. coli* is the most important strain to be controlled in WWTP and a dose of 25 mg/L provided about 5 Log reductions for both *E. coli* and *S. faecalis* with 10 min of contact time.

PT2 - Use #7 : Linen disinfection
Not proven enough : Efficacy tests performed according to EN 16616 standard not acceptable (please see comments in the table above) => **USE NOT GRANTED**

PT3 - Use #8 : Surface disinfection by manual spraying procedures of milking parlour systems

The representative product for the ***Meta SPC3*** i.e. ***INDAL PAA 5*** (5% PAA) intended to be used for surface disinfection by manual spraying procedures of milking parlors systems is :

On hard non-porous surfaces with prior cleaning, at +20°C :

- Bactericidal and yeasticidal when used at 0.6% in 15 min
- Virucidal when used at 0.5 % in 5 min

PT3 - Use #9 : Surface disinfection by manual dipping procedures in fish farming industry
PT3 - Use #11 : Surface disinfection by manual dipping procedures in livestock housing

The representative product for the ***Meta SPC3*** i.e. ***INDAL PAA 5*** (5% PAA) intended to be used for surface disinfection by manual dipping procedures in fish farming industry is :

On hard non-porous surfaces with prior cleaning, at +10°C :

- Bactericidal and yeasticidal when used at 0.6% in 15 min
- Fungicidal when used at 2% in 15 min
- Mycobactericidal when used at 2% in 30 min
- Virucidal when used at 0.1 % in 15 min
- Active against unicellular green algae when used at 1.2% in 24h

REMARK(S) :

- About the mycobacteria activity, use conditions validated from a read-across with Meta SPC5

- Since the product is used for surface disinfection, the efficient concentration should be deduced from the surface tests and not the suspension tests. Since efficacy against cyanobacteria is not proven in the surface tests (60% efficacy at 5% within 144H), only an efficacy against green algae (1.2% in 24h) should be validated.

PT3 - Use #10 : CIP (with circulation) procedures in fish farming industry
PT3 - Use #13 : CIP procedures (with circulation) in livestock housing

The representative product for the ***Meta SPC3*** i.e. ***INDAL PAA 5*** (5% PAA) is :

In clean conditions, at +10°C :

- Bactericidal and yeasticidal when used at 0.6% in 15 min
- Fungicidal when used at 2% in 15 min
- Virucidal when used at 0.1 % in 15 min
- Active against unicellular green algae & blue-green algae (cyanobacteria) when used at 1.2% in 72h

REMARK(S) :

- Efficacy against biofilms, not proven at +10°C.

- About the use #3.13 : it should be mentioned that, according to the ECHA EFF guidance, this use should be considered as PT4.

The EFF expert duly follows the guidance as much as possible, but in the case presented here, considering that Risk Assessment & residus for which used scenario are more relevant, we made the decision to let this use in PT3, **as an exception**.

This use in PT3 has been duly demonstrated and does duly fulfill the conditions mentioned in Art. 19 of the BPR.

PT3 - Use #12 : Surface disinfection by manual spraying procedures in livestock housing

The representative product for the ***Meta SPC3*** i.e. ***INDAL PAA 5*** (5% PAA) intended to be used for surface disinfection by manual spraying procedures in livestock housing is :

On hard non-porous surfaces with prior cleaning, at +10°C :

Make sure to wet surfaces completely.

- Bactericidal and yeasticidal when used at 0.6% in 15 min
- Fungicidal when used at 2% in 15 min
- Mycobactericidal when used at 2% in 30 min
- Virucidal when used at 0.1 % in 15 min
- Active against unicellular green algae when used at 1.2% in 24h

REMARK:

- About the mycobacteria activity, use conditions validated from a read-across with Meta SPC5

- Since the product is used for surface disinfection, the efficient concentration should be deduced from the surface tests and not the suspension tests. Since efficacy against cyanobacteria is not proven in the surface tests (60% efficacy at 5% within 144H), only an efficacy against green algae (1.2% in 24h) should be validated.

PT4 - Use #14 : Surface disinfection by manual spraying procedures

The representative product for the ***Meta SPC3*** i.e. ***INDAL PAA 5*** (5% PAA) intended to be used for surface disinfection by manual spraying procedures is :

On hard non-porous surfaces with prior cleaning, at +20°C :

Make sure to wet surfaces completely.

- Bactericidal (including *Salmonella typhimurium, Listeria monocytogenes, Enterobacter cloacae, Lactobacillus brevis, Campylobacter jejuni & Legionella pneumophila*) and yeasticidal (including *Dekkera bruxellensis & Saccharomyces cerevisae*) when used at 0.5% in 5 min
- Fungicidal (including *Mucor racemosus*) when used at 3.5% in 5 min
- Virucidal when used at 1.5% in 15 min
- Active against bacteriophages when used at 0.1% in 15 min
- Sporicidal (including *Bacillus cereus & Clostridium sporogenes*) when used at 1% in 15 min
- Active to remove biofilms when used at 0.2% in 5 min

PT4 - Use #15 : CIP (with circulation) procedures

The representative product for the ***Meta SPC3*** i.e. ***INDAL PAA 5*** (5% PAA) intended to be used CIP procedures (with circulation) is :

Under clean conditions, at +20°C :

- Bactericidal and yeasticidal when used at 0.2% in 5 min
- Fungicidal when used at 3.5% in 5 min
- Sporicidal (including *Bacillus cereus & Clostridium sporogenes*) when used at 1% in 15 min
- Virucidal when used at 1.5 % in 15 min
- Active against bacteriophages when used at 0.1% in 15 min
- Active to remove biofilms when used at 0.2% in 5 min

PT4 - Use #16 : Surface disinfection by manual dipping procedures

The representative product for the ***Meta SPC3*** i.e. ***INDAL PAA 5*** (5% PAA) intended to be used for surfaces disinfection during dipping procedures is :

On hard non-porous surfaces with prior cleaning, at +20°C :

- Bactericidal (including *Salmonella typhimurium, Listeria monocytogenes, Enterobacter cloacae, Lactobacillus brevis, Campylobacter jejuni & Legionella pneumophila*) and yeasticidal (including *Dekkera bruxellensis & Saccharomyces cerevisae*) when used at 0.5% in 5 min
- Fungicidal (including *Mucor racemosus*) when used at 3.5% in 5 min

• Virucidal when used at 1.5% in 15 min • Active against bacteriophages when used at 0.1% in 15 min • Sporicidal (including *Bacillus cereus & Clostridium sporogenes*) when used at 1% in 15 min • Active to remove biofilms when used at 0.2% in 5 min
PT4 - Use #17 : Disinfection in washing machines Not proven enough : Efficacy tests performed according to DIN SPEC 10534 standard not provided **=> USE NOT GRANTED**
PT5 - Use #18 : Drinking water disinfection for animals in farms Not proven enough : simulated-use (or P3) tests for bacteria still missing **=> USE NOT GRANTED**

Meta SPC-4 : INDAL PAA 15 (15% PAA) **Experimental data on the efficacy of the biocidal product against target organisms**		
Field of use envisaged	**PT2**	- Waste water/leachates disinfection in public/private STP - Linen disinfection
	PT4	- CIP (with circulation) procedures - Surface disinfection by dipping procedures

Test substance	**Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results : effects**	**Reference & R.I.**
***INDAL PAA 15* (15% PAA)**	**Bactericidal activity** Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus* Additional test organisms: *Salmonella typhimurium* *Enterobacter cloacae* *Lactobacillus brevis* *Listeria monocytogenes*	**EN 1276 (2009 + EC1 2011)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.01 - 0.02 – 0.03 – 0.04 – 0.05 % • I.S. : 0.3g/L BSA (clean conditions)	Bactericidal activity (including *Salmonella typhimurium, Enterobacter cloacae, Lactobacillus brevis* and *Listeria monocytogenes*) at 0.04% in 5 min at +20°C in clean conditions.	**Doc. 67** : *INDAL PAA 15 HD10778 EN1276 bactericide 8 souches 0.04% 5min 20°C proprete MERIEUX 17 600588 0002_18_ 00000619 3 2018-01-05* **Reliability 1** **Key study**
***INDAL PAA 15* (15% PAA)**	**Fungicidal/yeasticidal activity** *Aspergillus brasiliensis*	**EN 1650 + A1 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.6 – 0.7 – 0.8 – 0.9 – 1% • I.S. : 0.3g/L BSA (clean conditions)	Active against *Aspergillus brasiliensis* at 0.8 % in 15 min at +20°C in clean conditions.	**Doc. 68** : *INDAL PAA 15 HD10778 EN1650 0.8% 15min 20°C proprete MIDAC-17-317-1 2017-10-11* **Reliability 2:** **C. albicans not tested**

***INDAL PAA 15* (15% PAA)**	**Fungicidal/yeasticidal activity** *Aspergillus brasiliensis* *Candida albicans*	**EN 1650 + A1 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.03 – 0.06 – 0.12 – 0.15 – 0.2 % (Y) 0.3 – 0.6 – 1.2 – 1.5 – 2% (F) • I.S. : 0.3g/L BSA (clean conditions)	Yeasticidal activity at 0.15% in 15 min at +20°C in clean conditions. Fungicidal activity at 1.2% in 15 min at +20°C in clean conditions.	**Doc. 69** : *INDAL PAA 15 HD10778 EN1650 1.2% 15min 20°C proprete MIDAC-17-199-1 2017-08-29* **Reliability 1** **Key study**
***INDAL PAA 15* (15% PAA)**	**Fungicidal/yeasticidal activity** *Aspergillus brasiliensis* *Candida albicans*	**EN 13624 (2013)** Quantitative suspension test • Temperature : +45 ± 1°C (OK for instrument disinfection) • Contact time : 15 min • Concentrations tested : 0.05 – 0.1 – 0.2 – 0.3 – 0.4% (Y) 0.2 – 0.4 – 0.8 – 1.2 – 1.6 % (F) • I.S. : 0.3g/L BSA (clean conditions)	Yeasticidal activity at 0.2% in 15 min at +45°C in clean conditions. Fungicidal activity at 0.4% in 15 min at +45°C in clean conditions.	**Doc. 70** : *INDAL PAA 15 HD10778 EN13624 0.4% 15min 45°C proprete MIDAC-17-201-1 2017-09-08* **Reliability 1** **Key study**
***INDAL PAA 15* (15% PAA)**	**Fungicidal/yeasticidal activity** *Aspergillus brasiliensis* *Candida albicans*	**EN 13624 (2013)** Quantitative suspension test • Temperature : +10 ± 1°C (OK for surface disinfection) • Contact time : 30 min • Concentrations tested : 0.03 – 0.06 – 0.12 – 0.15 – 0.2 % (Y) 0.1 – 0.3 – 0.6 – 1.2 – 1.5 % (F) • I.S. : 3g/L BSA + 3mL/L sheep RBC (dirty conditions)	Yeasticidal activity at 0.12% in 30 min at +10°C in dirty conditions. Fungicidal activity at 1.2 % in 30 min at +10°C in dirty conditions.	**Doc. 71** : *INDAL PAA 15 HD10778 EN13624 1.2% 30min 10°C salete MIDAC-17-200-1 2017-09-08* **Reliability 1** **Key study**
INDAL PAA 15	**Fungicidal/yeasticidal activity**	**EN 13624 (2013)**	Active against *Aspergillus*	**Doc. 72** : *INDAL PAA*

(15% PAA)	*Aspergillus brasiliensis*	Quantitative suspension test • Temperature : +10 ± 1°C (OK for surface disinfection) • Contact time : 30 min (OK for surface disinfection, not in medical areas / too long contact time) • Concentrations tested : 0.8 – 1 – 1.2 % • I.S. : 3g/L BSA + 3mL/L sheep RBC (dirty conditions)	*brasiliensis* at 0.8 % in 30 min at +10°C in dirty conditions.	*15 HD10778 EN13624 Aspergillus 0.8% 30min 10°C salete MIDAC-17-318-1 2017-10-03* **Reliability 1** **Key study**
INDAL PAA 15 **(15% PAA)**	**Fungicidal/yeasticidal activity** *Candida albicans* *Aspergillus brasiliensis*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.01 – 0.03 – 0.06 – 0.12 – 0.15 % (Y) 0.1 – 0.2 – 0.4 – 0.6 – 0.8 % (F) • I.S. : 0.3g/L BSA (clean conditions)	Yeasticidal activity at 0.12% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning. Fungicidal activity at 0.6% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning.	**Doc. 73** : *INDAL PAA 15 HD10778 EN13697 0.6% 15min 20°C proprete MIDAC-17-341-1 2017-11-06* **Reliability 1** **Key study**
INDAL PAA 15 **(15% PAA)**	**Bactericidal activity** <u>Obligatory test organisms</u>: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus* <u>Additional test organisms:</u> *Salmonella typhimurium* *Enterobacter cloacae* *Lactobacillus brevis* *Listeria monocytogenes*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +18-25 ± 1°C • Contact time : 5 min • Concentrations tested : 0.01 – 0.04 – 0.06 – 0.08 – 0.1% • I.S. : 0.3g/L BSA (clean conditions)	Bactericidal activity (including *Salmonella typhimurium, Enterobacter cloacae, Lactobacillus brevis* and *Listeria monocytogenes*) at 0.08% in 5 min at +20°C on hard/non-porous surfaces with prior cleaning.	**Doc. 74** : *INDAL PAA 15 HD10778 EN13697 bactericide 8 souches 0.08% 5min 20°C proprete MERIEUX 17 600588 0002_18_ 00000619 3 2018-01-05* **Reliability 1** **Key study**

***INDAL PAA 15* (15% PAA)**	**Virucidal activity** Phages P001 & P008 (lytic for *Lactococcus lactis subspecies lactis*)	**EN 13610 (2003)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.01 – 0.05 – 0.1 – 0.2 – 0.3 % • I.S. : 1% Acid whey	Virucidal activity against bacteriophages at 0.05% in 15 min at +20°C in presence of 1% Acid whey.	**Doc. 66** : *Meta SPC 4_INDAL PAA 15_EN13610_0.05%_15min_20°C_ 1% acid whey_LMH-4552-1* **Reliability 1** **Key study**
***INDAL PAA 15* (15% PAA)**	**Sporicidal activity** *Bacillus cereus*	**EN 13704 (2002)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.2 – 0.2 – 0.4 – 0.6 – 0.8% • I.S. : 0.3g/L BSA (clean conditions)	Active against *Bacillus cereus* at 0.1% in 15 min at +20°C in clean conditions.	**Doc. 75** : *INDAL PAA 15 HD10778 EN13704 B. cereus 0.1% 15min 20°C proprete MIDAC-17-207-3 2017-10-23* **Reliability 2:** **Representative spore-forming bacteria not tested**
***INDAL PAA 15* (15% PAA)**	**Sporicidal activity** *Bacillus subtilis*	**EN 13704 (2002)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.1 – 0.2 – 0.4 – 0.6 – 0.8% • I.S. : 0.3g/L BSA (clean conditions)	Sporicidal activity at 0.4% in 15 min at +20°C in clean conditions.	**Doc. 76** : *INDAL PAA 15 HD10778 EN13704 B. subtilis 0.4% 15min 20°C proprete MIDAC-17-207-1 2017-10-05* **Reliability 1**

				Key study
***INDAL PAA 15* (15% PAA)**	**Sporicidal activity** *Clostridium sporogenes*	**EN 13704 (2002)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.1 – 0.2 – 0.4 – 0.6 – 0.8% • I.S. : 0.3g/L BSA (clean conditions)	Active against *Clostridium sporogenes* at 0.4% in 15 min at +20°C in clean conditions.	**Doc. 77** : *INDAL PAA 15 HD10778 EN13704 Clostridium 0.4% 15min 20°C proprete MIDAC-17-207-2 2017-10-05* **Reliability 1** **Key study**
***INDAL PAA 15* (15% PAA)**	**Bactericidal activity** Obligatory test organisms: *Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus* Additional test organisms: *Salmonella typhimurium* *E. coli K12* *Listeria monocytogenes*	**EN 13727 (2015)** Quantitative suspension test • Temperature : +10 ± 1°C • Contact time : 30 min • Concentrations tested : 0.01 - 0.05 – 0.1 – 0.15 – 0.2 % • I.S. : 3g/L BSA + 3mL/L sheep RBC (dirty conditions)	Bactericidal activity (including *Salmonella typhimurium, E. coli K12* and *Listeria monocytogenes*) at 0.05% in 30 min at +10°C in dirty conditions.	**Doc. 78** : *INDAL PAA 15 HD10778 EN13727 bactericide 6 souches 0.05% 30min 10°C proprete MERIEUX 17 600588 0002_18_ 00000619 3 2018-01-05* **Reliability 1** **Key study**
***INDAL PAA 15* (15% PAA)**	**Bactericidal activity** Obligatory test organisms: *Enterococcus faecium* Additional test organisms: *Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 13727 (2015)** Quantitative suspension test • Temperature : +45 ± 1°C • Contact time : 15 min • Concentrations tested : 0.005 - 0.01 – 0.02 – 0.03 – 0.04 % • I.S. : 0.3g/L BSA (clean conditions)	Bactericidal activity (including *Enterococcus faecium, Salmonella typhimurium, E. coli K12* and *Listeria monocytogenes*) at 0.03% in 15 min at +45°C in clean conditions.	**Doc. 79** : *INDAL PAA 15 HD10778 EN13727 bactericide 7 souches 0.03% 15min 45°C proprete MERIEUX 17 600588 0002_18_ 00000619 3 2018-01-05*

	Salmonella typhimurium *E. coli K12* *Listeria monocytogenes*			**Reliability 1** **Key study**
***INDAL PAA 15* (15% PAA)**	**Mycobactericidal activity** *Mycobacterium terrae* *Mycobacterium avium*	**EN 14348 (2005)** Quantitative suspension test • Temperature : +45 ± 1°C • Contact time : 15 min • Concentrations tested : 0.01 – 0.1 - 0.2 – 0.4 – 0.8 % • I.S. : 0.3g/L BSA (clean conditions)	Mycobactericidal activity at 0.2% in 15 min at +45°C in clean conditions.	**Doc. 80** : *INDAL PAA 15 HD10778 EN14348 mycobactericide 0.2% 15min 45°C proprete APEX 143D08-2017-08 2017-10-25* **Reliability 1** **Key study**
***INDAL PAA 15* (15% PAA)**	**Virucidal activity** Poliovirus Adenovirus Murine Norovirus	**EN 14476 + A1 (2015)** Quantitative suspension test • Temperature : +10°C (OK for surface disinfection) • Contact time : 30 min • Concentrations tested : 0.1 – 0.05 – 0.1 - 0.2 – 0.3 % + 0.4 – 0.5 – 0.6 – 0.7 – 0.8 % (Poliovirus) • I.S. : 3g/L BSA or 3g/L BSA + 3mL/L sheep RBC (dirty conditions)	Virucidal activity at 0.4% in 30 min at +10°C in dirty conditions.	**Doc. 81** : *INDAL PAA 15 HD10778 EN14476 virucide 0.4% 30min 10°C salete MERIEUX 17 600588 0002_18_ 00000619 3 2018-01-05* **Reliability 1** **Key study**
***INDAL PAA 15* (15% PAA)**	**Virucidal activity** Poliovirus Adenovirus Murine Norovirus Murine Parvovirus	**EN 14476 + A1 (2015)** Quantitative suspension test • Temperature : +20°C + 45°C • Contact time : 15 min (OK for instrument disinfection in medical areas; for surface disinfection not in medical areas)	Virucidal activity at 0.6% in 15 min at +20°C in clean conditions. Active against Murine Parvovirus at 0.2% in 15 min at +45°C in clean conditions.	**Doc. 82** : *INDAL PAA 15 HD10778 EN14476 virucide 0.6% 15min 20°C proprete MERIEUX 17 600588 0002_18_*

		• Concentrations tested : 0.1 – 0.05 – 0.1 - 0.15 – 0.2 % + 0.2 – 0.3 - 0.4 – 0.5 – 0.6 % (Poliovirus) • I.S. : 0.3g/L BSA (clean conditions)		*00000619 3 2018-01-05* *Doc. « INDAL PAA 15 HD10778 EN14476 Parvovirus 0.2% 15min 45°C proprete IRM 1032-0119 2019-04-08 »* **Reliability 1** **Key study**
***INDAL PAA 15* (15% PAA)**	**Virucidal activity** **Obligatory test organisms :** Adénovirus type 5, Norovirus murin,	**pr EN 16777** Quantitative carrier test – hard & non-porous surfaces •Temperature : +20 ± 1°C •Contact time : 15 min •Concentrations tested : 0.001 – 0.1 - 0.2 % •I.S. : 0.3g/L BSA (clean conditions)	Virucidal activity at 0.1% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning.	Doc. « INDAL PAA 15 HD10778 EN16777 virucide 0.1% 15min 20°C proprete IRM 1033-0119 2019-07-26 » **Reliability 1** **Key study**
INDAL PAA 15 (15% PAA)	**Sporicidal activity** **Obligatory test organisms:** *Bacillus subtilis* **additional test organisms:** *Bacillus cereus* *Clostridium sporogenes*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces •Temperature : +20 ± 1°C •Contact time : 15 min •Concentrations tested: 0.1 – 0.4 - 0.6 – 1 -1.25 -1.5 % •I.S. : 0.3g/L BSA (clean conditions)	Sporicidal activity (including *Clostridium sporogenes*) at 0.4% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning. Sporicidal activity (including *Bacillus cereus* & *Clostridium sporogenes*) at 1.5% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning.	Doc. "INDAL PAA 15 HD10778 EN13697 sporicide 0.6% 15min 20°C proprete MERIEUX 19.501679 .0004_19_ 00017476 5 2019-03-16 Inefficacit e Bc"

				Doc. "INDAL PAA 15 EN13697 sporicide B. cereus 1.5% 15min 20°C proprete MERIEUX 19.016570 .0002_19_ 00035783 6 2019-09-02" **Reliability 1** **Key study**
INDAL PAA 15 (15% PAA)	**Mycobactericidal activity** Mycobacterium terrae Mycobacterium avium	**EN 14348 (2006)** Quantitative suspension test •Temperature : +10 ± 1°C •Contact time : 30 min •Concentrations tested : 0.4 – 0.5 – 0.6 – 0.7 – 0.8 – 0.9 % •I.S. : 3g/L BSA + 3ml erythrocytes (dirty conditions)	Tuberculocidal activity at 0.5% in 30 min at +10°C on dirty conditions. Mycobactericidal activity at 0.9% in 30 min at +10°C on dirty conditions.	Doc. "INDAL PAA 15 HD10778 EN14348 tuberculocide 0.5% 30min 10°C salete MERIEUX 19.501679 .0004_19_ 00032724 8 2019-07-15 Inefficacite Ma" Doc. "INDAL PAA 15 HD10778 EN14348 mycobactericidie 0.9% 30min 20°C saleté MERIEUX 19.016570 .0001_19_ 00040304 8" **Reliability 1**

<table>
<tr><td></td><td></td><td></td><td></td><td>Key study</td></tr>
<tr><td>INDAL PAA 15 (15% PAA)</td><td>Bactericidal activity
Enterococcus hirae
Staphylococcus aureus
E. coli
Pseudomonas aeruginosa

Fungicidal & Yeasticidal activity
Candida albicans
Aspergillus brasiliensis

Tuberculocidal activity
Mycobacterium terrae</td><td>EN 16616 (2015)
Quantitative carrier test (chemical textile disinfection)

• Temperature:
+40 ± 1°C (8 min needed to achieve the process T°C)
• Contact time: 15 min
• Concentrations tested: 2 mL/L
• I.S. :
12.5 mL sterile defibrinated sheep blood / kg of linen
using an 1(laundry) : 4 (water) ratio.

On blended fabric (65% PE + 35% Cotton)
With 1 cm x 1 cm cotton carriers (quality defined by DIN 53919).

Tests in triplicates.

With controls.
No detergent since the product is intended to be used on clean textiles during the rinsing step.</td><td><table><tr><td></td><td colspan="2">Mean Log↓</td></tr><tr><td></td><td>With PB</td><td>WO PB</td></tr><tr><td>S.a.</td><td>8.38</td><td>2.60</td></tr><tr><td>E.h.</td><td>7.81</td><td>2.83</td></tr><tr><td>P.a.</td><td>8.38</td><td>2.90</td></tr><tr><td>E.c.</td><td>7.19</td><td>3.19</td></tr><tr><td>C.a.</td><td>7.41</td><td>2.89</td></tr><tr><td>A.b.</td><td>3.71</td><td>2.54</td></tr><tr><td>T.t.</td><td>8.2</td><td>1.95</td></tr></table>Bactericidal, yeasticidal & tuberculocidal activity of the product INDAL PAA 15 (15% PAA) when used at 2 mL/L during rinsing step on clean textiles at +40°C.</td><td>Doc. " INDAL PAA 15 HD10778 EN16616 bactericide levuricide mycobacteri cide 2 ml-L15min 40°C salete HYGIENE"

Reliability 1
Key study</td></tr>
</table>

Meta SPC4

Conclusions on the efficacy of the representative product INDAL PAA 15 (15% PAA) & claims

Please note that, since required by other MSs, for surface disinfection by spraying/mopping or immersion, P2S1 and all P2S2 tests are mandatory and must be taken into account and therefore the higher concentration required is the limiting one and thus be set up as the necessary concentration.

Please note that, to stay in line with the decision made for other dossiers, specific organisms mentioned in the efficacy conclusions of the PAR should not be include in the SPC.

PT2 - Use #1 : Waste water/leachates disinfection in public/private STP

The representative product for the **Meta SPC4** i.e. ***INDAL PAA 15*** (15% PAA) intended to be used for waste water/leachates disinfection in public/private STP is:

Under dirty conditions, at +10°C in 30 min :

- Bactericidal (including *Salmonella typhimurium, E. coli K12* and *Listeria monocytogenes*) & yeasticidal when used at 0.12%
- Fungicidal when used at 0.8%
- Virucidal when used at 0.4%
- Mycobactericidal when used at 0.9%

REMARK about Use #4.1 : WWSTP disinfection

Please note first of all that, due to the dossier submission in 2017, the requirements discussed and defined during the WG 2018 are not of application.

1) About relevant target organisms, considering the conclusion of the WGVI2018 meeting, "*The EFF WG agreed that efficacy against bacteria is mandatory, efficacy against other organisms should only be demonstrated if claimed*".

According to the eff studies submitted and validated, the product is efficacious against bacteria (including mycobacteria) but also against fungi/yeasts and viruses (poliovirus, adenovirus & norovirus including parvovirus) under dirty conditions with 0.12% PB (with 5% PAA) ⇔ 0.018 % PAA ⇔ 180 mg/L PAA in 30 min.

From relevant scientific literature reporting field tests, *E. coli* is the most important strain to be controlled in WWTP and a dose of 25 mg/L provided about 5 Log reductions for both *E. coli* and *S. faecalis* with 10 min of contact time.

2) In addition, the last conclusion is "the EFF WG agreed with the proposal of the eCA under condition that if the phase 2, step 1 test is failed, the simulated use test or field test may overrule the laboratory test", meaning on our part that results from P2S1 tests may be taken into account if passed and may be sufficient to set an application rate up.

PT2 - Use #2 : Linen disinfection

The representative product for the Meta SPC4 i.e. INDAL PAA 15 (15% PAA) intended to be used for textile disinfection is:

Bactericidal, yeasticidal & tuberculocidal when used at 2 mL/L during rinsing step on clean textiles at +40°C using an 1(laundry) : 4 (water) ratio.

PT4 - Use #1 : CIP (with circulation) procedures

The representative product for the **Meta SPC4** i.e. ***INDAL PAA 15*** (15% PAA) intended to be used for inner surfaces disinfection by CIP (with circulation) is:

Under clean conditions, at +20°C in 15 min :

- Bactericidal (including *Salmonella typhimurium, Enterobacter cloacae, Lactobacillus brevis, Listeria monocytogenes*) & yeasticidal when used at 0.15%
- Fungicidal when used at 0.8%
- Sporicidal when used at 0.4%
- Virucidal when used at 0.6%
- Active against bacteriophages when used at 0.05%

PT4 - Use #2 : Surface disinfection by dipping procedures

The representative product for the **Meta SPC4** i.e. ***INDAL PAA 15*** (15% PAA) intended to be used for surface disinfection by soaking procedures is:

Under clean conditions, at +20°C in 15 min :

- Bactericidal (including *Salmonella typhimurium, Enterobacter cloacae, Lactobacillus brevis, Listeria monocytogenes*) & yeasticidal when used at 0.15%
- Fungicidal when used at 0.8%
- Sporicidal when used at 1.5%
- Virucidal when used at 0.6%
- Active against bacteriophages when used at 0.05%

Meta SPC-5 : *INDAL OXY MOUSS (1.2% PAA)* **Experimental data on the efficacy of the biocidal product against target organisms**		
Field of use envisaged	**PT4**	- Surface disinfection by foam-spraying procedures
	PT3	- Surface disinfection by foam-spraying procedures in livestock industries

Test product	**Function & Test organism(s)**	**Test method /Test system / concentrations applied / exposure time**	**Test results : effects**	**Reference & R.I.**
INDAL OXY MOUSS (1.2% PAA)	**Bactericidal activity** *E.coli* *Pseudomonas aeruginosa*	**EN 1276 (2009 + EC1 2011)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.12 - 0.25 – 0.5 – 1 - 2 % • I.S. : 0.3g/L BSA (clean conditions)	Active against *E.coli* at 0.25% in 5 min at +20°C in clean conditions. Active against *Pseudomonas aeruginosa* at 0.5% in 5 min at +20°C in clean conditions.	**Doc. 86** : *Meta SPC 5_INDAL OXY MOUSS_EN1276_0,5%_5min_20°_clean_LDA67-131022-006156-03* **Reliability 2** **2 representative bacteria not tested**
INDAL OXY MOUSS (1.2% PAA)	**Bactericidal activity** *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1276** **(2009 + EC1 2011)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.125 - 0.25 – 0.5 – 1 - 2 % • I.S. : 0.3g/L BSA (clean conditions)	Bactericidal activity at 1% in 5 min at +20°C in clean conditions.	**Doc. 87** : *Meta SPC 5_INDAL OXY MOUSS_EN1276_1%_5min_20°_clean_LDA67-131017-006038-04* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Bactericidal activity** <u>Additional test organisms ONLY:</u> *Salmonella typhimurium* *Listeria monocytogenes* *Enterobacter cloacae* *Lactobacillus brevis* *Campylobacter jejuni*	**EN 1276** **(2009 + EC1 2011)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.1 - 0.4 – 0.6 – 0.8 - 1 % • I.S. : 0.3g/L BSA (clean conditions)	Active against *Salmonella typhimurium*, *Listeria monocytogenes*, *Enterobacter cloacae*, *Lactobacillus brevis* and *Campylobacter jejuni* at 0.6% in 5 min at +20°C in clean conditions. Representative bacteria not tested.	**Doc. 95** : *INDAL OXY MOUSS HD10350 EN1276 souches complementaires 0,6% 5min 20°C proprete MERIEUX 17-597223-0003 18-000099098 2018-03-12* **Reliability2** **Representative bacteria not tested.**

INDAL OXY MOUSS (1.2% PAA)	**Fungicidal/yeasticidal activity** *Aspergillus brasiliensis*	**EN 1650+ A1 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.5 – 1 – 2 – 3 – 4 % • I.S. : 0.3g/L BSA (clean conditions)	Active against *Aspergillus brasiliensis* at 4% in 15 min at +20°C in clean conditions.	**Doc. 88** : *Meta SPC 5_INDAL OXY MOUSS_EN1650_fungi_4%_15min_20°_clean_LDA67-131017-006038-03* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Fungicidal/yeasticidal activity** *Candida albicans*	**EN 1650+ A1 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.125 – 0.25 – 0.5 – 1 – 2 % • I.S. : 0.3g/L BSA (clean conditions)	Yeasticidal activity at 1% in 15 min at +20°C in clean conditions.	**Doc. 89** : *Meta SPC 5_INDAL OXY MOUSS_EN1650_yeast_1%_15min_20°_clean_LDA67-131017-006038-05* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Virucidal activity** <u>Obligatory test organisms</u>: Poliovirus Adenovirus Murine Norovirus	**EN 14476 (2015)** Quantitative suspension test • Temperature : +20°C ± 1°C • Contact time : 15 min + 30 min (Poliovirus) • Concentrations tested : 0.5 – 1 – 1.5 – 2 – 2.5 % + 2 – 3 – 4 – 5 - 6% (Poliovirus) • I.S. : 0.3g/L BSA (clean conditions)	Virucidal activity at 3% in 30 min at +20°C in clean conditions.	**Doc. 103** : *INDAL OXY MOUSS HD10350 EN14476 3% 30 min 20°C proprete MERIEUX 17-597223-0003 18-000099098 2018-03-12* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Virucidal activity** Phages P001 & P008 (lytic for *Lactococcus lactis subspecies lactis*)	**EN 13610 (2003)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.05 – 0.2 – 0.3 – 0.4 – 0.5 – 1 – 1.5 – 2 – 2.5% • I.S. : 1% Acid whey	Virucidal activity against bacteriophages at 0.5% in 15 min at +20°C in presence of 1% Acid whey.	**Doc. 92** : *Meta SPC 5_INDAL OXY MOUSS_EN13610_bacteriophage_0.5%_15 min_20°C_1% acid whey_LMH-4553-1* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Fungicidal/yeasticidal activity**	**EN 13697 (2015)** Quantitative carrier test • Temperature :	Yeasticidal activity at 0.2% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning.	**Doc. 98** : *INDAL OXY MOUSS HD10350 EN13697*

	Candida albicans *Aspergillus brasiliensis*	+18-25 ± 1°C • Contact time : 15 min • Concentrations tested : 0.2 – 0.2 – 0.4 – 0.6 – 0.8 % (Y) 0.1 – 1 – 1.5 – 2 – 3% (F) • I.S. : 0.3g/L BSA (clean conditions)	Fungicidal activity at 2% in 15 min at +20°C in on hard/non-porous surfaces with prior cleaning.	*fongicide 2% 15min 20°C proprete MIDAC 17-178-3 2017-08-31* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Bactericidal activity** *Legionella pneumophila*	**EN 13697 (2015)** Quantitative carrier test • Temperature : +18-25 ± 1°C • Contact time : 5 min • Concentrations tested : 0.1 – 0.2 – 0.4 – 0.6 – 0.8 % • I.S. : 0.05g/L BSA (clean conditions)	Active against *Legionella pneumophila* at 0.8% in 5 min at +20°C in clean conditions.	**Doc. 99** : *INDAL OXY MOUSS HD10350 EN13697 Legionella 0,8% 5min 20°C proprete MERIEUX 17-597223-0003 18-000099098 2018-03-12* **Reliability 2: from a standard test adapted**
INDAL OXY MOUSS (1.2% PAA)	**Bactericidal activity** <u>Obligatory test organisms</u>: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus* <u>Additional test organisms:</u> *Salmonella typhimurium* *Listeria monocytogenes* *Enterobacter cloacae* *Lactobacillus brevis* *Campylobacter jejuni*	**EN 13697 (2015)** Quantitative carrier test • Temperature : +18-25 ± 1°C • Contact time : 5 min • Concentrations tested : 0.1 – 0.2 – 0.4 – 0.6 – 0.8 % • I.S. : 0.3g/L BSA (clean conditions)	Bactericidal activity (including *Salmonella typhimurium*, *Listeria monocytogenes*, *Enterobacter cloacae*, *Lactobacillus brevis* and *Campylobacter jejuni*) at 0.8% in 5 min at +20°C on hard/non-porous surfaces with prior cleaning.	**Doc. 100** : *INDAL OXY MOUSS HD10350 EN13697 souches 0,8% 5min 20°C proprete MERIEUX 17-597223-0003 18-000099098 2018-03-12* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Bactericidal activity** *Pseudomonas aeruginosa*	**Protocol from the Institut Pasteur de Lille** Simulated-use test Biofilm formation according to the method described in the annex F of the ISO/TS 15883-5 standard (from 2005) i.e. via circulation (3 mL/min) of a liquid growth	Active against a *Pseudomonas aeruginosa* biofilm at 1% in 15 min at +20°C in clean conditions (↓Log 7).	**Doc. 84** : *Meta SPC 5_INDAL OXY MOUSS_biofilm_Pseudomonas aeruginosa_IPL-160140-02*

		medium contaminated with *Pseudomonas aeruginosa* (10^6 UFC/mL) in a hosepipe during 3-4 days kept at +30°C. Disinfection test by dipping of the hosepipes in the disinfectant (in presence of 0.3g/L BSA) during 15 min. • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0 - 1 – 3 – 5 % • I.S. : 0.3g/L BSA (clean conditions)		**Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Bactericidal activity** *Staphylococcus aureus*	**Protocol from the Institut Pasteur de Lille** Simulated-use test Biofilm formation according to the method described in the annex F of the ISO/TS 15883-5 standard (from 2005) i.e. via circulation (3 mL/min) of a liquid growth medium contaminated with *Staphylococcus aureus* (10^6 UFC/mL) in a hosepipe during 3-4 days kept at +30°C. Disinfection test by dipping of the hosepipes in the disinfectant (in presence of 0.3g/L BSA) during 15 min. • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0 - 1 – 3 – 5 % • I.S. : 0.3g/L BSA (clean conditions)	Active against a *Staphylococcus aureus* biofilm at 1% in 15 min at +20°C in clean conditions (↓Log 7).	**Doc. 85** : *Meta SPC 5_INDAL OXY MOUSS_biofilm_Staphylococcus aureus_IPL-160140-01* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Bactericidal activity** *Legionella pneumophila*	**Protocol from the Institut Pasteur de Lille** Simulated-use test Biofilm formation according to the method described in the annex F of the ISO/TS 15883-5 standard (from 2005) i.e. via circulation (3 mL/min) of a liquid growth medium contaminated with *Legionella pneumophila* (10^6 UFC/mL) in a hosepipe during 3-4 days kept at +30°C. With pre-culture.	Active against a *Legionella pneumophila* biofilm at 1% in 15 min at +20°C in clean conditions (↓Log 3).	**Doc. 83** : *Meta SPC 5_INDAL OXY MOUSS_biofilm_Legionella pneumophila_IPL-160140-03* **Reliability 1** **Key study**

		Disinfection test by dipping of the hosepipes in the disinfectant (in presence of 0.3g/L BSA) during 15 min. • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0 - 1 – 3 – 5 % • I.S. : 0.3g/L BSA (clean conditions)		
INDAL OXY MOUSS (1.2% PAA)	**Virucidal activity** *Adénovirus type 5,* *Norovirus murin,*	**PrEN16777(2018)** Quantitative carrier test •Temperature : +18-25 ± 1°C •Contact time : 15 min •Concentrations tested : 0.1 – 0.5 – 1.0 – 2.0% •I.S. : 0.3g/L BSA (clean conditions)	Non-active against Adenovirus at 2% in 15 min at +20°C in clean conditions (Log↓ ≥ 3.95). Active against MNV at 1% in 15 min at +20°C in clean conditions.	**Doc.** "*INDAL OXY MOUSS EN16777 virucidie IRM 10400119"* **Reliability 3:** **No effective concentration validated**
INDAL OXY MOUSS (1.2% PAA)	**Bactericidal activity** *Enterococcus hirae* *Proteus vulgaris* *Pseudomonas aeruginosa Staphylococcus aureus*	**EN 1656 (2010)** Quantitative suspension test • Temperature : +10 ± 1°C • Contact time : 30 min • Concentrations tested : 30.01 – 0.5 – 1% • I.S. : 3g/L BSA (clean conditions)	Bactericidal activity at 0.5% in 30 min at +10°C in clean conditions.	**Doc. 90** : *Meta SPC 5_INDAL OXY MOUSS_EN1656_0,5%_30 min_ 10°_low level soiling_IRM-176-0316-2* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Bactericidal activity** *E.coli* *Salmonella typhimurium* *Listeria monocytogenes*	**EN 1656 (2010)** Quantitative suspension test • Temperature : +10 ± 1°C • Contact time : 30 min • Concentrations tested : 30.01 – 0.4 – 0.6 – 0.8 – 1% • I.S. : 3g/L BSA (clean conditions)	Active against E. coli, *Salmonella typhimurium* and *Listeria monocytogenes* at 0.4% in 5 min at +20°C in clean conditions.	**Doc. 96** : *INDAL OXY MOUSS HD10350 EN1656 souches complementaires 0,4% 30min 10°C salete bas niveau MERIEUX 18-000099098 2018-03-12* **Reliability 2: Representative bacteria not tested.**

INDAL OXY MOUSS (1.2% PAA)	**Fungicidal/yeasticidal activity** *Aspergillus fumigatus*	**EN 1657 (2006)** Quantitative suspension test • Temperature : +10 ± 1°C • Contact time : 30 min • Concentrations tested : 30 – 2 – 3% • I.S. : 3g/L BSA (clean conditions)	Active against *Aspergillus fumigatus* at 2% in 30 min at +10°C in clean conditions.	**Doc. 91** : *Meta SPC 5_INDAL OXY MOUSS_EN1657_fungi_2%_30 min_10°_low level soiling_IRM-1173-0916-2* **Reliability 2** **C. albicans not tested.**
INDAL OXY MOUSS (1.2% PAA)	**Fungicidal/yeasticidal activity** *Candida albicans* *Aspergillus brasiliensis*	**EN 1657 (2006)** Quantitative suspension test • Temperature : +10 ± 1°C • Contact time : 30 min • Concentrations tested : 0.1 – 0.2 – 0.5 – 1 – 1.5% (Y) 0.1 – 1 – 2 – 3 – 4% (F) • I.S. : 3g/L BSA (clean conditions)	Yeasticidal activity at 1.5% in 30 min at +10°C in clean conditions. Fungicidal activity at 3% in 30 min at +10°C in clean conditions.	**Doc. 97** : *INDAL OXY MOUSS HD10350 EN1657 fongicide 3% 30min 10°C salete bas niveau MIDAC 17-183-1 2017-08-31* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Bactericidal activity** *Enterococcus hirae* *Proteus vulgaris* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 14349 (2012)** Quantitative carrier test • Temperature : +10 ± 1°C • Contact time : 30 min • Concentrations tested : 30.01 – 0.5 – 1 – 2% • I.S. : 3g/L BSA (clean conditions)	Bactericidal activity at 2% in 30 min at +10°C on hard/non-porous surfaces with prior cleaning.	**Doc. 93** : *Meta SPC 5_INDAL OXY MOUSS_EN14349_bacteria_2%_30 min_10°_low level soiling_IRM-176-0316-6* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Bactericidal activity** *E.coli* *Salmonella typhimurium* *Listeria monocytogenes*	**EN 14349 (2012)** Quantitative carrier test • Temperature : +10 ± 1°C • Contact time : 30 min • Concentrations tested : 0.5 – 1 – 1.5 – 2 – 2.5% • I.S. : 3g/L BSA (clean conditions)	Active against E. coli, *Salmonella typhimurium* and *Listeria monocytogenes* at 1% in 30 min at +10°C on hard/non-porous surfaces with prior cleaning.	**Doc. 102** : *INDAL OXY MOUSS HD10350 EN14349 bactericide 1% 30min 10°C salete bas niveau MERIEUX 17-597226-0001 2017-09-05* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Fungicidal/yeasticidal activity**	**EN 16438 (2014)** Quantitative carrier test • Temperature :	Active against *Aspergillus brasiliensis* at 2% in 30 min at +10°C on	**Doc. 94** : *Meta SPC 5_INDAL OXY MOUSS_EN16438_fungi_2%_*

	Aspergillus brasiliensis (ATCC 1022)	+10 ± 1°C • Contact time : 30 min • Concentrations tested : 30 – 2 – 4% • I.S. : 3g/L BSA (clean conditions)	hard/non-porous surfaces with prior cleaning.	*30 min_10°_low level soiling_IRM-1174-0916-2* **Reliability 2: C. albicans not tested.**
INDAL OXY MOUSS (1.2% PAA)	**Fungicidal/yeasticidal activity** *Candida albicans*	**EN 16438 (2014)** Quantitative carrier test • Temperature : +10 ± 1°C • Contact time : 15 min • Concentrations tested : 30.01 – 0.5 – 1 – 1.5 – 2% • I.S. : 3g/L BSA (clean conditions)	Yeasticidal activity at 1 % in 15 min at +10°C on hard/non-porous surfaces with prior cleaning.	**Doc. 111** : *INDAL OXY MOUSS HD10350 EN16438 levuricidie 1% 15 min 10° salete bas niveau MIDAC 17-202-4 2017-11-02* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Fungicidal/yeasticidal activity** *Aspergillus brasiliensis*	**EN 16438 (2014)** Quantitative carrier test • Temperature : +10 ± 1°C • Contact time : 30 min • Concentrations tested : 3 – 4 – 5 – 6 – 7% • I.S. : 3g/L BSA (clean conditions)	Active against Aspergillus brasiliensis at 5% in 30 min at +10°C on hard/non-porous surfaces with prior cleaning.	**Doc. 110** : *INDAL OXY MOUSS HD10350 EN16438 fongicide 5% 30min 10°C salete bas niveau MIDAC 17-422-1 2017-12-27* **Reliability 2: C. albicans not tested**
INDAL OXY MOUSS (1.2% PAA)	**Bactericidal activity** *Enterococcus hirae* *Proteus vulgaris* *Pseudomonas aeruginosa* *Staphylococcus aureus* + *E.coli* *Salmonella typhimurium* *Listeria monocytogenes*	**EN 16437 (2014)** Quantitative carrier test • Temperature : +10 ± 1°C • Contact time : 30 min • Concentrations tested : 0.5 – 1 – 1.5 – 2 – 2.5 % • I.S. : 3g/L BSA (clean conditions)	Non-bactericidal activity (Enterococcus hirae & Salmonella typhimurium not killed at 2.5%) at 2.5% in 30 min at +10°C on porous surfaces with prior cleaning.	**Doc. 109** : *INDAL OXY MOUSS HD10350 EN16437 efficacite bactericide partielle 2.5% 30min 10°C salete bn MERIEUX 17-597226-0002 2017-10-04* **Reliability 3 :** **No effective concentration**
INDAL OXY MOUSS (1.2% PAA)	**Bactericidal activity** *Enterococcus hirae*	**EN 16437 (2014)** Quantitative carrier test • Temperature :	Additional % tested / study presented in Doc. 19 just above : ➔ Bactericidal activity at 4% in 30 min at +10°C	**Doc. 108** : *INDAL OXY MOUSS HD10350 EN16437 bactericide*

	+ *Salmonella typhimurium*	+10 ± 1°C • Contact time : 30 min • Concentrations tested : 2.5 – 3 – 3.5 – 4 – 5% • I.S. : 3g/L BSA (clean conditions)	on porous surfaces with prior cleaning.	*Ent. & salm. 4% 30min 10°C salete bas niveau MERIEUX 17-610317-0001 2017-12-21* **Reliability 2:** **Not all the representative bacteria tested**
INDAL OXY MOUSS (1.2% PAA)	**Mycobactericidal activity** Obligatory test organisms: *Mycobacterium terrae Mycobacterium avium*	**EN 14563 (2009)** Quantitative carrier test • Temperature : +10 ± 1°C • Contact time : 30 min • Concentrations tested : 30.01 – 0.5 – 1 – 1.5 – 2% • I.S. : 3g/L BSA (clean conditions for veterinary areas)	Mycobactericidal activity at 2% in 30 min at +10°C in clean conditions.	**Doc. 104** : *INDAL OXY MOUSS HD10350 EN14563 mycobactericidie 2% 30 min 10° salete bas niveau APEX 143D08-2017-07 2017-10-25* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Mycobactericidal activity** Obligatory test organisms: *Mycobacterium terrae Mycobacterium avium*	**EN 14204 (2012)** Quantitative suspension test • Temperature : +10 ± 1°C • Contact time : 30 min • Concentrations tested : 30 – 2 – 4 – 6 – 8% • I.S. : 3g/L BSA (clean conditions for veterinary areas)	Mycobactericidal activity at 2% in 30 min at +10°C in clean conditions.	**Doc. 101** : *INDAL OXY MOUSS HD10350 EN14204 mycobactericidie 2% 30 min 10° salete bas niveau APEX 143D08-2017-06 2017-12-07* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Virucidal activity** Bovine enterovirus (ECBO)	**EN 14675 (2015)** Quantitative suspension test • Temperature : +10°C ± 1°C • Contact time : 30 min • Concentrations tested : 30.01 – 0.1 – 0.5 – 1 – 1.5 – 2% • I.S. : 3g/L BSA (clean conditions)	Virucidal activity at 0.5% in 30 min at +10°C in clean conditions.	**Doc. 105** : *INDAL OXY MOUSS HD10350 EN14675 virucidie ECBO 0,5% 30 min 10°C salete bas niveau VIRHEALTH R-LVQUA007 2018-02-20* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Virucidal activity** Porcine enterovirus (PEV-9)	**EN 14675 (2015)** Quantitative suspension test • Temperature : +10°C ± 1°C • Contact time :	Active against the porcine enterovirus at 1% in 30 min at +10°C in clean conditions.	**Doc. 106** : *INDAL OXY MOUSS HD10350 EN14675 virucidie enterovirus*

		30 min • Concentrations tested : 30.01 – 0.1 – 0.5 – 1 – 1.5 – 2% • I.S. : 3g/L BSA (clean conditions)		*porcin 1% 30 min 10°C salete bas niveau VIRHEALTH R-LVQUA008 2018-03-15* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Virucidal activity** Avian influenza virus (type H5).	**EN 14675 (2015)** Quantitative suspension test • Temperature : +10°C ± 1°C • Contact time : 30 min • Concentrations tested : 30.01 – 0.1 – 0.5 – 1 – 1.5 – 2% • I.S. : 3g/L BSA (clean conditions)	Active against the avian influenza virus (type H5) at 0.1% in 30 min at +10°C in clean conditions.	**Doc. 107** : *INDAL OXY MOUSS HD10350 EN14675 virucidie grippe aviaire H5 0,1% 30 min 10°C salete bas niveau VIRHEALTH R-LVQUA006 2017-12-05* **Reliability 1** **Key study**
INDAL OXY MOUSS (1.2% PAA)	**Virucidal activity** FMDV virus	**BDTL-SOP-2 Suspension Test for the Disinfectant Efficacy against FMDV and SVDV** Quantitative suspension test • Temperature : +4°C • Contact time : 30 min • Concentrations tested : 1/1000 – 1/200 – 1/100 – 1/50 – 1/33 • I.S. : 1% BSA	Active against the FMDV virus at 1/1000 in 30 min at +4°C	**Doc. 112** : *INDAL OXY MOUSS HD10350 virucidie fievre aphteuse 0,001% 30 min 4°C 1% BSA PIRBRIGHT INSTITUTE PRI0118 FMDV 2018-04-19* **Reliability 2:** **ECBO not tested in parallel**
INDAL OXY MOUSS (1.2% PAA)	**Virucidal activity** **Aujeszky** **Grippe humaine H1N1** **Gumboro** **Newcastle** **Classical Swine Fever's disease virus**	**EN 14675 (2015)** Quantitative suspension test •Temperature : +10°C •Contact time : 30 min •Concentrations tested : 0.01 -- 2% • I.S. : 3g/L BSA (clean conditions)	Active against the Aujeszky's virus at 0.25% in 30 min at +10°C in clean conditions. Active against the H1N1 virus at 0.1% in 30 min at +10°C in clean conditions. Active against the Gumboro's disease virus at 0.5% in 30 min at +10°C in clean conditions. Active against the NewCastle disease virus at 0.5% in 30 min at	Doc. "INDAL OXY MOUSS HD10350 EN14675 virucidie grippe H1N1 0.1% et Aujeszky 0,25% 30 min 10°C salete bas niveau MERIEUX 17-597223-0001 2018-02-28" "INDAL OXY MOUSS HD10350 EN14675 virucidie Gumboro 0.5% 30 min 10°C salete

			+10°C in clean conditions. Active against the Classical Swine Fever's disease virus at 2% in 30 min at +10°C in clean conditions	bas niveau LABOCEA ù247464 2019-02-26" "INDAL OXY MOUSS HD10350 EN14675 virucidie Peste porcine 2% 30 min 10°C saleté bas niveau LABOCEA %247460 2019-06-24" **Reliability 2 :** **ECBO not tested in paralle**

Meta SPC5

Conclusions on the efficacy of the representative product *INDAL OXY MOUSS (1.2% PAA)* & claims

Please note that, since required by other MSs, for surface disinfection by spraying/mopping or immersion, P2S1 and all P2S2 tests are mandatory and must be taken into account and therefore the higher concentration required is the limiting one and thus be set up as the necessary concentration.

Please note that, to stay in line with the decision made for other dossiers, specific organisms mentioned in the efficacy conclusions of the PAR should not be included in the SPC.

PT3 - Use #1: Surface disinfection by foam-spraying procedures in livestock industries

The representative product for the **Meta SPC5** i.e. ***INDAL OXY MOUSS (1.2% PAA)*** intended to be used for surface disinfection by foam-spraying procedures in livestock industries is:

<u>On hard non-porous surfaces with prior cleaning, at +10°C in 30 min :</u>

- bactericidal (including *Salmonella typhimurium, Listeria monocytogenes)* & yeasticidal activities when used at 2%
- Fungicidal activity (including *Aspergillus fumigatus*) when used at 5%
- Virucidal activity (including H5N1 & H1N1; FMDV; Gumboro; Newcastle & Aujeszky virus) when used at 0.5%
- Active against Porcine Enterovirus when used at 1%
- Active against Classical swine fever when used at 2%
- Mycobactericidal activity when used at 2%

<u>On hard porous surfaces with prior cleaning, at +10°C in 30 min :</u>

- bactericidal (including *Salmonella typhimurium, Listeria monocytogenes)* & yeasticidal activities when used at 4%

PT4 - Use #1 : Surface disinfection by foam-spraying procedures

The representative product for the **Meta SPC5** i.e. ***INDAL OXY MOUSS (1.2% PAA)*** intended to be used for surface disinfection by foam-spraying procedures is:

On hard non-porous surfaces with prior cleaning, at +20°C:

- Bactericidal (including *Salmonella typhimurium, Listeria monocytogenes, Enterobacter cloacae, Lactobacillus brevis, Campylobacter jejuni* & *Legionella pneumophila*) & yeasticidal activities when used at 1% in 15 min
- Fungicidal activity when used at 4% in 15 min
- Full virucidal activity when used at 3% in 30 min
- Active against bacteriophages when used at 0.5% in 15 min
- Active to remove biofilms when used at 1% in 15 min

Meta SPC-6 : *INDAL TAP5 (5% PAA)*

Experimental data on the efficacy of the biocidal product against target organisms

Field of use envisaged	**PT4**	- Disinfection of inner surfaces by CIP procedures (with circulation)

Test product	**Function & Test organism(s)**	**Test method/ Test system / concentrations applied / exposure time**	**Test results : effects**	**Reference & R.I.**
Sulphuric Acid aqueous solution at 13.4% w/w	**Bactericidal activity** *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1040 (2006)** Quantitative suspension (P1) test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.1 – 0.5 – 1 – 1.5 – 2%	Non-bactericidal activity at 2% (i.e. 0.268% Sulphuric Acid ⇔ 2% from 13.4%) in 5 min at +20°C.	**Doc. 113** : *ACIDE SULFURIQUE solution 13,5% EN1040 inefficacite bactericide 2% 5min 20°C MERIEUX 17-597215-0001 2017-10-17* **Reliability 1** **Key study**
Sulphuric Acid aqueous solution at 13.4% w/w	**Fungicidal/yeasticidal activity** *Aspergillus brasiliensis* *Candida albicans*	**EN 1275 (2006)** Quantitative suspension (P1) test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 1 – 2 – 3 – 4 – 5%	Non-yeasticidal activity at 5% (i.e. 0.648% Sulphuric Acid) in 15 min at +20°C. Non-fungicidal activity at 5% (i.e. 0.648% Sulphuric Acid) in 15 min at +20°C.	**Doc. 114** : *ACIDE SULFURIQUE solution 13,5% EN1275 inefficacite fongicide 5% 15min 20°C MIDAC RE 17-229-1 2017-08-30* **Reliability 1** **Key study**
Sulphuric Acid aqueous solution at	**Sporicidal activity** *Bacillus subtilis*	**EN 14347 (2005)** Quantitative suspension (P1) test	Non-sporicidal activity at 2% (i.e. 0.2592% Sulphuric Acid) in 30 min at +20°C.	**Doc. 115** : *ACIDE SULFURIQUE solution 13,5% EN1275 inefficacite*

13.4% w/w		• Temperature : +20 ± 1°C • Contact time : 30 min • Concentrations tested : 0.1 – 0.25 – 0.5 – 1 - 2 %		*sporicide 2% 30min 20°C MIDAC RE 17-263-1 2017-11-17* **Reliability 1** **Key study**
INDAL TAP5 (5% PAA)	**Bactericidal activity** *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1276 (2009 + EC1 2011)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.01 – 0.05 – 0.1 – 0.15 – 0.2 % + 0.25 – 0.3 – 0.4 – 0.5 % (*E. hirae*) • I.S. : 0.3g/L BSA (clean conditions)	Bactericidal activity at 0.25% in 5 min at +20°C in clean conditions.	**Doc. 116** : *INDAL TAP 5 HD10390 EN1276 bactericide 0.25% 5min 20°C proprete MERIEUX RF 17 600588 0001 2018-01-25* **Reliability 1** **Key study**
INDAL TAP5 (5% PAA)	**Fungicidal/yeasticidal activity** *Aspergillus brasiliensis* *Candida albicans*	**EN 1650 + A1 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.1 - 0.2 – 0.3 – 0.4 – 0.5 % (Y) 0.1 – 0.5 – 1 – 2 – 3% (F) • I.S. : 0.3g/L BSA (clean conditions)	Yeasticidal activity at 0.3% in 15 min at +20°C in clean conditions. Fungicidal activity at 2% in 15 min at +20°C in clean conditions.	**Doc. 117** : *INDAL TAP 5 HD10390 EN1650 fongicide 2% 15min 20°C proprete MIDAC RE-17-203-1 2017-08-31* **Reliability 1** **Key study**
INDAL TAP5 (5% PAA)	**Sporicidal activity** *Bacillus subtilis*	**EN 13704 (2002)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.3 – 0.25 – 0.5 - 1 – 2% • I.S. :	Sporicidal activity at 1% in 15 min at +20°C in clean conditions.	**Doc. 118** : *INDAL TAP 5 HD10390 EN13704 sporicide 1% 15min 20°C proprete MIDAC RE-17-208-2 2017-09-08* **Reliability 1** **Key study**

		0.3g/L BSA (clean conditions)		
INDAL TAP5 (5% PAA) Aged samples at 15 months	**Bactericidal activity** *Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1276 (2009 + EC1 2011)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.01 – 0.1 – 0.25 – 0.3 – 0.4 % • I.S. : 0.3g/L BSA (clean conditions)	Bactericidal activity at 0.4% in 5 min at +20°C in clean conditions.	*INDAL TAP 5 QUA-JCF-HD10390 EN1276 bactericide 0.4% 5 min 20°C proprete MERIEUX RF 18 070643-0001 18-000462974 – 2018-10-24* **Reliability 1** **Key study**
INDAL TAP5 (5% PAA) Aged samples at 15 months	**Fungicidal/yeasticidal activity** *Aspergillus brasiliensis* *Candida albicans*	**EN 1650 + A1 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.1 - 0.5 - 1 – 2 - 3 % (F) 0.1 - 0.2 - 0.3 - 0.4 - 0.5% (Y) • I.S. : 0.3g/L BSA (clean conditions)	Yeasticidal activity at 0.3% in 15 min at +20°C in clean conditions. Fungicidal activity at 2% in 15 min at +20°C in clean conditions.	*INDAL TAP 5 QUA-JCF-HD10390 EN1650 fungicide 2% levuricide 0.3% 15 min 20°C proprete MERIEUX RF 18 070643 0002_18_000462979 2018-10-24* **Reliability 1** **Key study**

Meta SPC6

Conclusions on the efficacy of the representative product INDAL TAP5 (5% PAA) & claims

PT4 - Use #1 : Disinfection of inner surfaces by CIP procedures (with circulation)

The representative product for the **Meta SPC6 : INDAL TAP5 (5% PAA)** intended to be used for disinfection of inner surfaces by CIP procedures (with circulation) & stored up to 15 months is :

Under clean conditions, at +20°C:

- Bactericidal & yeasticidal when used at 0.4% in 15 min
- Fungicidal when used at 2% in 15 min
- Virucidal when used at 1.5% in 30 min
- Active against bacteriophages when used at 0.2% in 15 min
- Sporicidal when used at 1% in 15 min

REMARK(S) :

- About the virucidal activity (including bacteriophages), use conditions validated from a read-across with Meta SPC1.

- Impact of Sulphuric Acid on the efficiency of the representative product for the Meta SPC6 i.e. INDAL TAP5 (5% PAA) *:

To demonstrate the impact of Sulphuric Acid on the efficiency of the product, the efficacy of a Sulphuric Acid aqueous solution at 13.4% w/w was determined via Phase 1 (EN 1040, EN 1275 & 14347 standards) efficacy tests with bacteria (including spore-forming bacteria) & yeast/fungi. According to the results of the tests, a Sulphuric Acid aqueous solution (at 13.4% w/w) used at 2% doesn't possess a bactericidal activity. As the conclusion, Sulphuric Acid has no impact on the efficiency of the product.

** Please note that the discussion about the impact of co-formulants on efficacy has started in 2017. The conclusions and the final decision (with cut-off) have been added in the 1.3 version of the T.A.B. from August 2017 and will only become applicable in Sept. 2019. Since this NA-APP was submitted in April 2018, the BE eCA does consider that the submitted information is clear, robust and sufficient enough to address the point.*

2.2.5.4 Occurrence of resistance and resistance management

Since the mode of action of peracetic acid is very unspecific, it is very unlikely that resistance to peracetic acid can develop. The development of specific resistance management strategies for the use of peracetic acid does not seem to be an urgent task. Nevertheless, the general principle of alternating use of disinfectants with different modes of action is recommended.

2.2.5.5 Known limitations

There are no known limitations to the products of the ***QUARON BPF***.

2.2.5.6 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

Not applicable, as the products of the ***QUARON BPF*** are not intended for use with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

(I) Skin corrosion and irritation

Data waiving	
Information requirement	No study is available and submitted for this effect on human health for any member of the Quaron Biocidal Product Family. pH of all biocidal products of the assessed Quaron PAA family: pH <2.
Justification	Study scientifically unjustified. Mixtures with extreme pH, pH-based assessment.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Causes severe burns
Justification for the value/conclusion	Mixtures with an extreme pH: pH<2.
Classification of the products according to CLP and DSD	Meta SPC 1: Indal PPA 3,5: Skin Corr. 1B, H314 Meta SPC 2: Indal PPA 2,5: Skin Corr. 1A, H314 Meta SPC 3: Indal PPA 5: Skin Corr. 1A, H314 Meta SPC 4: Indal PPA 15: Skin Corr. 1A, H314 Meta SPC 5: Indal oxy Mouss: Skin Corr. 1A, H314 Meta SPC 6: Indal TAP 5: Skin Corr. 1A, H314

(II) Eye Irritation

Data waiving	
Information requirement	No study is available and submitted for this effect on human health for any member of the Quaron Biocidal Product Family. pH of all biocidal products of the assessed Quaron PAA family: pH <2.
Justification	Study scientifically unjustified. Mixtures with extreme pH, pH-based assessment.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Cause severe burns
Justification for the value/conclusion	Mixtures with an extreme pH: pH<2.

Classification of the product according to CLP and DSD	Meta SPC 1: Indal PPA 3,5: Skin Corr. 1B, H314 Meta SPC 2: Indal PPA 2,5: Skin Corr. 1A, H314 Meta SPC 3: Indal PPA 5: Skin Corr. 1A, H314 Meta SPC 4: Indal PPA 15: Skin Corr. 1A, H314 Meta SPC 5: Indal oxy Mouss: Skin Corr. 1A, H314 Meta SPC 6: Indal TAP 5: Skin Corr. 1A, H314

(III) Respiratory tract irritation

Data waiving	
Information requirement	No study is available and submitted for this effect on human health for any member of the Quaron Biocidal Product Family. pH of all biocidal products of the assessed Quaron PAA family: pH <2.
Justification	Study scientifically unjustified. Mixtures with extreme pH. Hazard is estimated by the calculation method. In order to avoid unnecessary animal experiments, no respiratory tract irritation toxicity study was conducted with the product according to the following arguments: 1° According to Regulation (EC) No.1272/2008 (CLP) and ECHA Recommendations (2014), at present, recognized and validated animal models for the testing of respiratory irritation are not available. Therefore, no study on respiratory tract irritation has been conducted on the product. 2° In line with Regulation (EU) No.528/2012, testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Regulation (EC) No.1272/2008 (CLP), and synergistic effects between any of the components are not expected. 3° In the formulated products, some of the components are toxicologically relevant for respiratory tract irritation: these components are classified with STOT-SE 3 which are present at a concentration higher or below the specific concentration limits or general concentration limit.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Causes respiratory tract irritation. All biocidal products evaluated have a Peracetic acid concentration ≥ 1%
Classification of the product according to CLP and DSD	Since there are valid data available to allow classification of the mixtures and since synergistic effects between any of the components are not expected, according to the criteria of Annex I to Regulation (EC) No.1272/2008, the proposed classification is:

	Meta SPC 1: Indal PPA 3,5: STOT SE3, H335, EUH071 Meta SPC 2: Indal PPA 2,5: STOT SE3, H335, EUH071 Meta SPC 3: Indal PPA 5: STOT SE3, H335, EUH071 Meta SPC 4: Indal PPA 15: STOT SE3, H335, EUH071 Meta SPC 5: Indal oxy Mouss: STOT SE3, H335, EUH071 Meta SPC 6: Indal TAP 5: STOT SE3, H335, EUH071

(IV) Skin sensitization

Data waiving	
Information requirement	No study is available and submitted for this effect on human health. pH of all biocidal products of the assessed Quaron PAA family: pH <2.
Justification	Study scientifically unjustified. Mixtures with extreme pH. Hazard is estimated by the calculation method.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Non sensitising
Justification for the value/conclusion	None of the ingredients of the members of the Quaron Biocidal Product Family under evaluation is classified as skin sensitizer, which would trigger a classification for the formulations. However evaluation of the ingredients (other than the active substance Peracetic acid which is not sensitizing) is only based on information from the MSDS and consultation of the ECHA dissemination web page. There are no reactions know between the components that would result in a sensitizer.
Classification of the products according to CLP and DSD	No classification needed Meta SPC 1: Indal PPA 3,5: No classification Meta SPC 2: Indal PPA 2,5: No classification Meta SPC 3: Indal PPA 5: No classification Meta SPC 4: Indal PPA 15: No classification Meta SPC 5: Indal oxy Mouss: No classification Meta SPC 6: Indal TAP 5: No classification

(V) Respiratory sensitization (ADS)

Data waiving	
Information requirement	No study is available and submitted for this effect on human health for any member of the Quaron Biocidal Product Family. pH of all biocidal products of the assessed Quaron PAA family: pH <2.
Justification	Study scientifically unjustified. Mixtures with extreme pH. Hazard is estimated by the calculation method. In order to avoid unnecessary animal experiments, no respiratory sensitization study was conducted with the product according to the following arguments: 1° According to Regulation (EC) No.1272/2008 (CLP) and ECHA Recommendations (2014), at present, recognized and validated animal models for the testing of respiratory sensitization are not available. Therefore, no study on respiratory sensitization has been conducted on the product. 2° In line with Regulation (EU) No.528/2012, testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Regulation (EC) No.1272/2008 (CLP), and synergistic effects between any of the components are not expected. 3° In the formulated products, none of the components are toxicologically relevant for respiratory sensitization.

Ingredient		**Classification**	**Concentration triggering classification of a mixture**	**Concentration (% w/w)**
Name	**Cas N°**			
According to the harmonized classification and labelling of the active substance peracetic acid, peracetic acid is not a respiratory sensitizer. None of the other ingredients have respiratory sensitization properties.				

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising No studies are available but the product is not expected to cause any respiratory sensitisation.
Justification for the value/conclusion	According to the harmonized classification and labelling of the active substance peracetic acid, peracetic acid is not a respiratory sensitizer. None of the other ingredients have respiratory sensitization properties.
Classification of the product according to CLP and DSD	No classification needed Meta SPC 1: Indal PPA 3,5: No classification Meta SPC 2: Indal PPA 2,5: No classification

	Meta SPC 3: Indal PPA 5: No classification Meta SPC 4: Indal PPA 15: No classification Meta SPC 5: Indal oxy Mouss: No classification Meta SPC 6: Indal TAP 5: No classification

(VI) Acute toxicity

a. Acute toxicity by oral route

Data waiving	
Information requirement	No data is available and submitted for this effect on human health. Study scientifically unjustified.
Justification	In order to avoid unnecessary animal experiments, no acute oral toxicity study was conducted on the products according to the following argument: In line with Directive 98/8/EC and with Regulation (EU) No.528/2012, testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Regulation (EC) No.1272/2008 (CLP), and synergistic effects between any of the components are not expected. The ATE for the oral route of the Quaron PAA family is determined using the following formula: $ATE_{mix} = \frac{100}{\Sigma_n \frac{Ci}{ATE_i}}$ where: Ci = concentration of ingredient i (% w/w) i = individual ingredient from 1 to n n = number of ingredients ATEi = Acute Toxicity Estimate of ingredient i. Therefore, since there are valid data available to allow classification of the mixture and since synergistic effects between any of the components are not expected, according to the criteria of Annex I to Regulation (EC) No.1272/2008, the proposed classification of the biocidal products from the Quaron PAA family evaluated in this dossier is: acutely toxic *via* oral route category 4.

Value used in the Risk Assessment – Acute oral toxicity	
Value	Cat 4: 300 < ATE ≤2000 For all evaluated meta SPC/biocidal products

Justification for the selected value	As the mixture itself has not been tested to determine its acute oral toxicity properties and as there is no data on similar mixtures to adequately characterise the hazards of the mixture, the classification of the mixture has to be done by assessment on the basis of ingredient information (additivity formula).
Classification of the product according to CLP and DSD	Meta SPC 1: Indal PPA 3,5: Acute Tox. 4, oral, H302 Meta SPC 2: Indal PPA 2,5: Acute Tox. 4, oral, H302 Meta SPC 3: Indal PPA 5: Acute Tox. 4, oral, H302 Meta SPC 4: Indal PPA 15: Acute Tox. 4, oral, H302 Meta SPC 5: Indal oxy Mouss: Acute Tox. 4, oral, H302 Meta SPC 6: Indal TAP 5: Acute Tox. 4, oral, H302

b. Acute toxicity by inhalation

Data waiving	
Information requirement	No data is available and submitted for this effect on human health. Study scientifically unjustified.
Justification	In order to avoid unnecessary animal experiments, no acute inhalation toxicity study was conducted on the products according to the following argument: In line with Directive 98/8/EC and with Regulation (EU) No.528/2012, testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Regulation (EC) No.1272/2008 (CLP), and synergistic effects between any of the components are not expected. The ATE for the inhalation route of the Quaron PAA family is determined using the following formula: $ATE_{mix} = \frac{100}{\Sigma_n \frac{Ci}{ATE_i}}$ where: Ci = concentration of ingredient i (% w/w) i = individual ingredient from 1 to n n = number of ingredients ATEi = Acute Toxicity Estimate of ingredient i. Therefore, since there are valid data available to allow classification of the mixture and since synergistic effects between any of the components are not expected, according to the criteria of Annex I to Regulation (EC) No.1272/2008, the proposed classification of most of the biocidal products from the Quaron PAA family evaluated in this dossier is: acutely toxic *via* inhalation route category 4.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Cat 4 dusts/mists (mg/l, 4h): 1.0 < ATE ≤ 5.0 For most of the evaluated meta SPC/biocidal products
Justification for the selected value	As the mixture itself has not been tested to determine its acute inhalation toxicity properties and as there is no data on similar mixtures to adequately characterise the hazards of the mixture, the classification of the mixture has to be done by assessment on the basis of ingredient information (additivity formula).
Classification of the product	Meta SPC 1: Indal PPA 3,5: Acute Tox. 4, inhalation, H332 Meta SPC 2: Indal PPA 2,5: Acute Tox. 4, inhalation, H332

according to CLP and DSD	Meta SPC 3: Indal PPA 5: Acute Tox. 4, inhalation, H332 Meta SPC 4: Indal PPA 15: Acute Tox. 4, inhalation, H332 Meta SPC 5: Indal oxy Mouss: no classification Meta SPC 6: Indal TAP 5: Acute Tox. 4, inhalation, H332

c. Acute toxicity by dermal route

Data waiving	
Information requirement	No data is available and submitted for this effect on human health. Study scientifically unjustified.
Justification	In order to avoid unnecessary animal experiments, no acute dermal toxicity study was conducted on the products according to the following argument: In line with Directive 98/8/EC and with Regulation (EU) No.528/2012, testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Regulation (EC) No.1272/2008 (CLP), and synergistic effects between any of the components are not expected. The ATE for the dermal route of the Quaron PAA family is determined using the following formula: $ATE_{mix} = \frac{100}{\Sigma_n \frac{Ci}{ATE_i}}$ where: Ci = concentration of ingredient i (% w/w) i = individual ingredient from 1 to n n = number of ingredients ATEi = Acute Toxicity Estimate of ingredient i. Therefore, since there are valid data available to allow classification of the mixture and since synergistic effects between any of the components are not expected, according to the criteria of Annex I to Regulation (EC) No.1272/2008, the proposed classification of some of the biocidal products from the Quaron PAA family evaluated in this dossier is: acutely toxic *via* dermal route category 4.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Cat 4: 1000 < ATE ≤2000 For the evaluated meta SPC 4 and meta SPC 6 biocidal products
Justification for the selected value	As the mixture itself has not been tested to determine its acute inhalation toxicity properties and as there is no data on similar mixtures to adequately characterise the hazards of the mixture, the

	classification of the mixture has to be done by assessment on the basis of ingredient information (additivity formula).
Classification of the product according to CLP and DSD	Meta SPC 1: Indal PPA 3,5: no classification Meta SPC 2: Indal PPA 2,5: no classification Meta SPC 3: Indal PPA 5: no classification Meta SPC 4: Indal PPA 15: Acute Tox. 4, dermal, H312 Meta SPC 5: Indal oxy Mouss: no classification Meta SPC 6: Indal TAP 5: Acute Tox. 4, dermal, H312

(VII)Information on dermal absorption

Data waiving	
Information requirement	No study is available and submitted for dermal absorption.
Justification	No standard dermal penetration studies with aqueous peracetic acid have been successfully conducted. Because of the absence of clear systemic effects of the active substance, peracetic acid, no dermal penetration parameter is needed in order to conclude on human health risks from the presented uses. The biocidal products based on peracetic acid only induce local effects at the first site of contact. In conclusion, it is acceptable to 'waive' the dermal absorption studies.

(VIII) Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

According to Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, Assessment Report **Peracetic acid** (PT1, 2, 3, 4, 5, 6) November 2015, Finland.

Peracetic acid in aqueous solution is composed of **peracetic acid**, **hydrogen peroxide**, **acetic acid** and water. After application of equilibrium peracetic acid in the intended uses, all three ingredients contribute to the human health effects and the subsequent risks, and have to be taken into account in the overall risk characterisation. The toxicity tests have been performed with the aqueous solution. Hence, the results also inherently contain the effects of each ingredient. In practice, both peracetic acid and hydrogen peroxide are highly reactive and degrade rapidly at the site of first contact with organic material. Acetic acid is also metabolised relatively quickly. Based on the evaluated information, peracetic acid is the most critical ingredient of solutions with regard to possible health risks and the conclusions of the risk assessment of peracetic acid are driven by effect data on peracetic acid itself and the exposure estimates for each intended use.

The adverse effects of peracetic acid in humans are limited to local effects at the site of first contact with the body. No clear systemic effects from equilibrium PAA were observed which is plausible in the light of the mode of action, i.e. direct chemical reactivity leading to rapid degradation of peracetic acid. Corrosion and/or irritation of the skin and mucous membranes are the most prominent observations in the variety of animal studies. These effects are concentration dependent with no or only minor dependence from exposure duration.

Besides the direct chemical reactivity underlying the irritation and corrosion related lesions, peracetic acid causes sensory irritation. This phenomenon is also clearly concentration dependent and the symptoms manifest soon after start of exposure.

Absorption, distribution, metabolism and excretion in mammals	
Rate and extent of oral absorption:	Not determined, 100% as a default.
Rate and extent of dermal absorption for the active substance:	Not determined, 100% as a default.
Rate and extent of dermal absorption for the representative product(s):	Not determined, 100% as a default.
Distribution:	20 % of radio-activity tissue-bound with highest levels found in liver, gastro-intestinal tract and exposed skin
Potential for accumulation:	No evidence for bioaccumulation
Rate and extent of excretion:	- approx. 30 – 60 % of the applied dose recovered as CO_2 after 72 hours with the majority formed after 24 hours; an initial lag phase of approx. 1 hour evident - about 17 % of given radioactivity excreted via the urine after 72 hours; majority of urinary excretion occurred after 24 hours - about 4 - 5 % of given radioactivity excreted via the faeces and 17 % via urine after 72 hours; majority of faecal excretion occurred after 24 hours
Toxicologically significant metabolite(s)	None

Acute toxicity	
Rat LD_{50} oral	1020 mg/kg; (Acute Tox. 4 *, H302; Xn, R22) 85 mg/kg (100% PAA) (Acute Tox. 3; H301)
Rabbit LD_{50} dermal	1147 mg/kg; (Acute Tox. 4 *, H312; Xn, R21) 56.1 mg/kg (100% PAA) (Acute Tox. 2; H310)
Rat LC_{50} inhalation	1 mg/L ≤ LC50 ≤ 5 mg/L; (Acute Tox.4 *, H332; Xn, R20) LC50 0.204 mg/l (100% PAA) (Acute Tox. 2; H330)
Skin irritation	Corrosive; (Skin Corr. 1A, H314; C, R35)
Eye irritation	Corrosive (severe damage to the eyes) ; (Skin Corr. 1A H314; Xi, R41)
Skin sensitization (test method used and result)	Non-sensitising (GPMT)

Repeated dose toxicity	
Species/ target / critical effect	Rat (oral): local irritation in stomach/gastro-intestinal-tract, no systemic effects
Lowest relevant oral NOAEL / LOAEL	90-days gavage study in rats NOAEL 15 mg/kg bw/day corresponding to 0.055% PAA
Lowest relevant dermal NOAEL / LOAEL	Not established
Lowest relevant inhalation NOAEL / LOAEL	No study required for this endpoint for animal welfare reasons and owing to the intrinsic properties of PAA (primary local irritation/corrosion at the site of first contact and absence of systemic effects/systemic availability)

Genotoxicity	*In vitro*: Positive results in *in vitro* cytogenetic assay (chromosome aberrations) in human lymphocytes. Negative results in Ames test, gene mutation assay in mammalian cells, negative/equivocal *in vitro* chromosome aberration assay with Chinese hamster lung fibroblasts *In vivo*: Equivocal in three micronucleus tests and *in vivo* UDS. The biological meaning of any result from the *in vivo* studies is questionable in view of uncertainty of the availability of the test substance in the target organ. Weight of evidence indicates no concern of mutagenic / genotoxic potential

Carcinogenicity	
Species/type of tumour	No study required for this endpoint for animal welfare reasons and owing to the intrinsic properties of PAA (primary local irritation/corrosion at the site of first contact and absence of systemic effects/systemic availability) No concern of mutagenic / genotoxic potential. Site of contact carcinogenicity not tested.
Lowest dose with tumours	n.a.

Reproductive toxicity	
Species/ Reproduction target / critical effect	No indication of reproductive toxicity in 90-days oral and continuous breeding studies

	In the absence of both teratogenic effect and findings on reproductive organs in repeated dose toxicity studies, no study is required for this particular endpoint for animal welfare reasons and owing to the intrinsic properties of PAA (primary local irritation/corrosion at the site of first contact and absence of systemic effects/systemic availability)
Lowest relevant reproductive NOAEL / LOAEL	n.a.
Species/Developmental target / critical effect	Rat: maternal effects: reductions in body weight, body weight gain developmental effects: impairment of ossification (bones missing or poor/hypertrophic ossification)
Developmental toxicity	
Lowest relevant developmental NOAEL / LOAEL	Maternal: 12.5 mg PAA/kg bw/d Developmental: 12.5 mg PAA/kg bw/d

Neurotoxicity / Delayed neurotoxicity	
Species/ target/critical effect	No indicative signs from acute and repeated dose studies; no structural alerts
Lowest relevant developmental NOAEL / LOAEL.	n.a.

Other toxicological studies	
Toxic effects on livestock and pets	Not required since the mode of action of PAA is known, i.e. the primary toxicological effect (local irritation/corrosion) which is not specific to any particular mammalian species or organ/tissue but is limited to the site of first contact. PAA is not systemically available in the body beyond the site of first contact due to rapid breakdown to the physiological metabolites hydrogen peroxide, water, oxygen and acetic acid The toxicity of Peracetic acid has been investigated and it has been shown not to be mutagenic or teratogenic. In the summary report of the Committee for Veterinary Medicinal Products (CVMP) on Peracetic acid (EMEA/MRL/060/96-FINAL, Doc. No. 983-001), PAA is admitted for use in livestock animals and that there is no need to establish an MRL for PAA.

Studies related to the exposure of the a.s. to humans	Not required since the mode of action of PAA is known, i.e. the primary toxicological effect (local irritation/corrosion) which is not specific to any particular mammalian species or organ/tissue but is limited to the site of first contact. PAA is not systemically available in the body beyond the site of first contact due to rapid breakdown to the physiological metabolites hydrogen peroxide, water, oxygen and acetic acid. These degradation products will form in any species and no other pathways of degradation occur. No degradation pathways other than those known from animal studies are expected to occur. Thus, PAA will not be transformed to further substances which were not observed and assessed in the available mammalian toxicity studies.
Food and feeding stuffs	Peracetic acid (PAA) is not intended to be used in or on food or feeding stuff. In uses, however, where residues on food stuff packaging material cannot be excluded, no safety concern for does exist since PAA is rapidly degraded to the physiological metabolites hydrogen peroxide, oxygen and acetic acid. Based on the evaluation of and the conclusions made by the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food, possible residues of PAA on food and feeding stuff are not considered to be associated with a safety concern.
Other tests related to exposure of the a.s. to human considered to be necessary	No other tests related to the exposure of the active substance to humans for the purpose of performing reliable human health risk assessments studies necessary. The proposed biocidal products are sufficiently covered by the aforementioned tests. There are no endpoints of concern which would require further testing.
Tests to assess toxic effects from metabolites of treated plants	Peracetic acid is not used in products for action against plants. Therefore, no tests to assess toxic effects of metabolites from treated plants are required.

Mechanistic studies	Based upon the known mode of action of peracetic acid, no mechanistic studies are required. The toxicity of PAA is due to its locally irritating properties, i.e. decomposition to hydrogen peroxide, oxygen and acetic acid. After contact with organs and tissues, hydrogen peroxide will undergo decomposition into water and oxygen. The primary toxicological effect (local irritation) is not specific to any particular mammalian species or organ/tissue but is limited to the site of first contact. PAA is not systemically available in the body beyond the site of first contact due to rapid breakdown to the physiological metabolites hydrogen peroxide, water, oxygen and acetic acid. Acetic acid is introduced in the C2-pool or further metabolised via physiological pathways to carbon dioxide and water. All occurring metabolites are rapidly eliminated and do not bioaccumulate.
Further human health related studies	In view of the known mode of action and considering results of available mammalian toxicity studies, no further human health-related studies are required.

Medical data	
Medical surveillance data on manufacturing plant personnel	No data available
Direct observations, e.g. clinical cases, poisoning incidents	1: The cytotoxic and irritating potential of peracetic acid in humans used as a disinfectant for hand washing procedures applied by surgeons was investigated. Three of 15 surgeons developed immediately erythema and 6 of 15 surgeons developed dermatosis of the hands after 7 days following daily soaping, brushing and disinfection of skin with PAA at a concentration of 0.5 %. PAA applied as Wofasteril caused dermal irritation reactions in a third of health care workers. 2: Several recommendations were made to allow a safe handling with concentrated PAA solutions: - wearing protective gloves and protective glasses for diluting concentrated PAA - dilutions should be made in a ventilated room - for spray application of dilutions for

	disinfection purposes a respirator should be used. 3: Effects of diluted PAA solutions used as an aerosol (0.8 % PAA) as a disinfectant for human skin (0.08 or 0.2 % PAA) and for the treatment of a recurrent, pruritic epidermitis (0.1 % PAA): - irritation of the respiratory tract, lachrimation, salivation, increased nasal discharge and partly temporal loss of olfactory senses (0.8 % PAA) - slight skin desquamation after 1 or 2 days without hypersensitivity (0.2 % PAA) - daily skin disinfection for 3 years using solutions of 0.2 % PAA mixed with alcohol did not cause any adverse effects - temporarily reduced skin roughness after 1 day. The hands appeared slippery when wet, smooth and well-manicured (0.2 % PAA) - treatment of a recurrent, pruritic epidermitis using a 0.1 % PAA successful - Concentrations of 0.2 % peracetic acid can be considered as non to only slightly irritating to skin. 4: After a Patch test with dilutions of 1:33 (1500 mg/L PAA), 1:20 (2500 mg/L PAA) and 1:15 (3500 mg/L according to publication, correct value should be 3300 mg/L) it was concluded that up to 2500 mg/L PAA (corresponding to an about 0.25 % solution) is non-irritant. At 3300 mg/L PAA (corresponding to an about 0.33 % solution) is a mild irritant.
Health records, both form industry and any other sources	The Persteril dilution containing 0.2 % PAA was well tolerated by the 20 volunteers. The concentration of 0.2 % PAA is sufficient for eradication of pyogenic staphylococci and 97 % reduction of residual flora on the hand within 3 minutes. PAA does not have a residual effect. Solutions of PAA with concentrations of 0.2 % do not damage the skin.
Epidemiological studies on the general population	No data available
Diagnosis of poisoning including specific signs of poisoning and clinical tests	No data available

Sensitization/allergenicity observations	The cases of two subjects who developed cough wheezing and shortness of breath after being exposed to PAA-hydrogen peroxide (PAA-HP) vapours are investigated. The main symptoms observed were rhinorrhoea, conjunctivitis, continuous cough, breathlessness and chest tightness appeared after several hours of exposure to PAA-HP vapours and improved after removal from exposure. It was concluded that symptoms in these subjects were generated by an irritant mechanism and occupational prolonged exposure to vapours of PAA-HP mixtures caused symptoms which were the consequence of a sustained irritation process rather than a real asthmatic reaction.
Specific treatment in case of an accident or poisoning: first aid measures and medical treatment	Basic aid: decontamination and symptomatic treatment is warranted. No specific antidote is known. Eyes: In case of contact with eyes rinse thoroughly with water. Contact a physician immediately. Skin: Remove contaminated clothes. Wash affected body areas carefully with plenty of water and soap. Ingestion: Rinse out mouth and give plenty of water to drink. Do not induce vomiting. Inhalation: Ensure supply of fresh air. Contact a physician as necessary.
Prognosis following poisoning	Depending on severity of effects

Summary	Value	Study	Safety factor
Peracetic acid:			
ADI (acceptable daily intake, external long-term reference dose)	n.a.; PAA does not cause systemic effects	-	-
AEL short-term/medium-term/long-term	n.a.; PAA does not cause systemic effects	-	-
NOAEC dermal	0.2% for short/medium term	Human volunteer study	-
	0.1% for long-term	rabbit one year study	2
AEC inhalation	0.5 mg/m^3 (0.16 ppm)	Human data (NOAEC 0.5 ppm)	3.16

ArfD (acute reference dose)	n.a.; PAA does not cause systemic effects	-	-
Reference value for inhalation (proposed OEL)	-	-	-
Reference value for dermal absorption concerning the active substance:	100% as a default	-	-
Reference value for dermal absorption concerning the representative product(s)[4]:	100% as a default	-	-

Hydrogen peroxide:

Skin irritating threshold	35%	classification limit for irritation	-
AEC inhalation	1.25 mg/m^3	NOAEC in 90-day inhalation rat study	8

(IX) Available toxicological data relating to a mixture

Peracetic acid in aqueous solution is composed of **peracetic acid**, **hydrogen peroxide**, **acetic acid** and water. After application of equilibrium peracetic acid in the intended uses, all three ingredients contribute to the human health effects and the subsequent risks, and have to be taken into account in the overall risk characterisation. The toxicity tests have been performed with the aqueous solution. Hence, the results also inherently contain the effects of each ingredient. In practice, both peracetic acid and hydrogen peroxide are highly reactive and degrade rapidly at the site of first contact with organic material. Acetic acid is also metabolised relatively quickly. Based on the evaluated information, peracetic acid is the most critical ingredient of solutions with regard to possible health risks and the conclusions of the risk assessment of peracetic acid are driven by effect data on peracetic acid itself and the exposure estimates for each intended use.

Besides the exposure assessment to PAA and H_2O_2, other substances have been identified as substances of concern. These ingredients and the reasons why they are analysed as SOCs are described in the table below. These substances have been identified following the finalized document of the CA meeting (CA-Nov14-Doc.5.11 - SoC guidance_final.doc).

Substances of concerns analysed in the "QUARON PAA family"

Substances of concern: Summary table				
Name and CAS od the identified SOC	**Reason(s) for identification**	**Consequences on the Human Risk assessment**	**Community workplace exposure limit (if needed)**	**Vapour pressure**
Sulfuric Acid – CAS 7664-93-9	Substances for which there are Community workplace exposure limits.	Fully quantitative risk assessment by using EU IOELVs (when available), AECs or other reference values (e.g. AELs, AECs)	Long-term (8 hours): 0.05 mg/m³ Short-term (15 minutes): No limit specified	0.1 Pa
Decan-1-ol, ethoxylated– CAS 26183-52-8	Contribution to the CLP classification of the biocidal product as "Eye Dam. 1".	Application of P statements normally associated with concerned H statements.	-	negligible

The exposure to these substances of concern is also assessed. Please note that Hydrogen Peroxide and Acetic Acid are also discussed below, even if they are not to be considered as substances of concern, given that they are part of the active substance (as described in the CAR of PAA°. This was done in order to place all relevant information of substances that needed an assessment in the same place for ease of use. Please note that neither Hydrogne peroxide nor Acetic Acid have thus to be considered as substance of concern.

HYDROGEN PEROXIDE

According to Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, Assessment Report **Hydrogen peroxide** (PT1, 2, 3, 4, 5, 6) March 2015, Finland.

The adverse effects of hydrogen peroxide in humans are limited to local effects at the site of first contact with the body and to embolism in some cases. No clear systemic effects were observed which is plausible in the light of the mode of action, i.e. direct chemical reactivity leading to rapid degradation. Corrosion and/or irritation of the skin and mucous membranes are the most prominent observations in the variety of animal studies. These effects are concentration dependent with no or only minor dependence from exposure duration.
Besides the direct chemical reactivity underlying the irritation and corrosion related lesions, hydrogen peroxide causes sensory irritation. This phenomenon is also concentration dependent and the symptoms manifest soon after start of exposure. There is no human data available specifically on sensory irritation. In a mouse test of sensory irritation, an RD_{50}

value of 113 ppm has been determined. The data allows extrapolation of an RD_{10} of approximately 12 ppm. In order to extrapolate the animal data to humans an assessment factor of 2.5 and an intraspecies assessment factor of 3.2 for the remaining uncertainty is considered sufficient to derive an AEC value (ca. 1.5 ppm). This value was not used for risk characterization, but could be used in later refinements.

Indicative dermal reference value

No dermal irritation was noted after application of 10% hydrogen peroxide. The 35 % hydrogen peroxide caused slight to moderate reversible erythema and edema in a skin irritation study. However, irreversible desquamation of skin triggers classification of Skin irritation 2, H315: "Causes skin irritation". (Xi; R38 "Irritating to skin"). In view of the absence of systemic effects after exposure to hydrogen peroxide, only external exposure limits are relevant to account for the potential local effects of hydrogen peroxide. Since in the intended use(s) the in-use concentration of hydrogen peroxide is below a skin irritating threshold (concentration limit for classification as skin irritating is 35%), only the inhalation route of exposure has been identified to be relevant in the quantitative exposure and risk assessment. In the absence of more accurate data, potential exposure in the different use scenarios should be compared to the thresholds set for classification. In mixing and loading exposure to undiluted products may occur.

Serious eye damage/eye irritation: Hydrogen peroxide causes concentration dependent eye lesions. At higher concentrations, severe and irreversible damage to the rabbit eye has been demonstrated. The results support the current classification with Eye irritation 2, H319: "Causes serious eye irritation" for 5 % ≤ hydrogen peroxide < 8 % (Xi; R36 "Irritating to eyes), and for for 8% ≤ hydrogen peroxide < 50% classification with Eye damage 1, H318 (Xi; R41 "Risk of serious damage to eyes").

Inhalation reference values

The following **AEC for inhalation exposure** is proposed for hydrogen peroxide: For acute, medium-term and long-term exposure: 1.25. mg/m_3 based on the NOAEC in 90-day inhalation rat study with the overall assessment factor of 8. This value is reasonably well in line with human data, where a level of no symptoms at 0.5 to 0.7 mg/m_3 (0.36−0.5 ml/m_3; 8-hour mean values, no higher peak exposures) could be determined.

Summary

	Value	Study	Safety factor
AEC inhalation$_{long\text{-}term}$	1.25 mg/m^3	NOAEC in 90-day inhalation study (rat)	8

AEC inhalation$_{medium-term}$	1.25 mg/m^3	NOAEC in 90-day inhalation study (rat)	8
AEC inhalation$_{acute}$	1.25 mg/m^3	NOAEC in 90-day inhalation study (rat)	8
ADI[2]	ADI not established, the substance is not systemically available. The agreed acceptable max concentration is 0.1 mg/L in human drinking water. In the main use in PT 5, drinking water of chicken, max concentration: 5 mg/L		
ARfD	not established		

MRLs

Relevant commodities	-

Reference value for groundwater

According to BPR Annex VI, point 68	-

Dermal absorption

Study (*in vitro/vivo*), species tested	not feasible, not assessed
Formulation (formulation type and including concentration(s) tested, vehicle)	-
Dermal absorption values used in risk assessment	100 % as default

ACETIC ACID

According to Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, Assessment Report **Peracetic acid** (PT1, 2, 3, 4, 5, 6) DocIIB, November 2015, Finland.

Toxicokinetics/Metabolism

A) Absorption, Distribution & Excretion

Acetic acid is absorbed from the GI tract and through the lung [Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. John Wiley & Sons. New York, N.Y. (2001), p. V5 701].

B) Metabolism

Acetic acid is readily metabolized by most tissues and may give rise to the production of ketone bodies as intermediates. In vitro, acetate is incorporated into phospholipids, neutral lipids, steroids, sterols, and

saturated and unsaturated fatty acids in a variety of human and animal tissue preparations. Metabolism of 14C acetate in mice results in radioactivity associated with the protein fractions of plasma and most major tissues [Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. John Wiley & Sons. New York, N.Y. (2001)., p. V5 701].

In the body, acetic acid is partially converted into formic acid [Sheftel, V.O.; Indirect Food Additives and Polymers. Migration and Toxicology. Lewis Publishers, Boca Raton, FL. 2000., p. 650].

When dogs were administered large doses (1 – 2 g/kg ip or sc) of sodium acetate, only small amounts appeared in the urine, which is evidence of the rapid utilization of acetic acid [Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. John Wiley & Sons. New York, N.Y. (2001)., p. V5 701].

Acute Oral Toxicity

The LD50 of acetic acid was determined to be 3310 - 3530 mg/kg bw in rats, 4960 mg/kg bw in mice and 600 – 1200 mg/kg bw in rabbits.

Acute Dermal Toxicity
The acute dermal toxicity (LD50) of acetic acid in rabbits was found to be 1060 mg/kg bw. In guinea pigs the dermal LD50 was 20 mL/kg bw for a 5 % solution of acetic acid and 3.2 mL/kg bw for a 28 % solution, respectively.

Acute Inhalation Toxicity
The acute inhalation toxicity of acetic acid was determined in rats and mice:
- LD50 rat, inhalation: 11.4 mg/L after 4 hours of exposure
- LD50 mouse, inhalation: 5620 ppm after 1 hour of exposure

Skin/Eye Irritation
The dermal irritation of acetic acid was tested in guinea pigs and rabbits by application of acetic acid solutions to intact or abraded skin patches. Concentrations from 80 % to glacial produced severe burns to guinea pig skin, concentrations from 50 - 80% produced moderate to severe burns, and concentrations of 5 -15 % caused slight to moderate irritation of the skin.
Concentrated acetic acid (90 %) was corrosive to rabbit skin whereas concentrations from 35 – 50 % caused irritations.
Acetic acid was shown to be highly irritating when applied to rabbit eyes. Concentrations of 5 % caused severe irritation but the damage was reversible following a 14-day recovery. Acetic acid solutions > 10 % caused irreversible, permanent corneal damage.

Skin Sensitisation

No studies on the skin sensitisation potential of acetic acid are available. However, as acetic acid is a physiologically essential element and nutrient, no skin sensitising potential is implied.

Genotoxicity
Acetic acid has shown no evidence of mutagenic activity with or without metabolic activation using Ames Salmonella typhimurium strains TA 98, TA 100, TA 1535, TA 97 and TA 1537 at concentrations of 100, 333, 1000, 3333, 6666, and 10000 µg/plate.
Acetic acid (sodium salt) elicited no mutagenic response in the Ames Salmonella typhimurium assay or in Saccharomyces cerevisiae with or without liver preparations from mouse, rat, or monkey.
The potential of acetic acid to induce structural chromosome aberrations was assessed in cultured Chinese hamster ovary K1 cells. It was concluded that acetic acid was not clastogenic at concentrations close to those that showed cytotoxicity up to 16 mM. Although chromosomal aberrations could be induced at these high concentrations, they were shown to be artefacts due to acidification of the culture medium and could be eliminated by neutralizing the medium or enhancing its buffering ability.

Short-Term Repeated Dose Toxicity
Treatment of rats with 3 % acetic acid administered intragastrically for 6 months resulted in chronic inflammation of the oesophageal mucosa.
Female mice (strain: CD-1 (ICR) BR) were dermally treated on the shaven interscapular region with 50 µL of a 6, 9 or 12 % solution of acetic acid, respectively, over a period of 3 months (once per day at 5 days per week). At the highest dose level clinical skin changes were observed at 9 out of 10 animals with 5 animals showing scab formation and ulceration. At the medium level, 5 out of 10 animals showed skin defects and eschar formation. At the lowest dose level eschar formation was observed in 3 out of 10 animals. It was concluded that acetic acid concentrations need to be < 6% to be considered non-irritating.
Rats that inhaled acetic acid vapours at a concentration of 75 mg/m³ for 35 days showed damages of kidneys and hemosiderosis in spleen.

Male mice (strain: Swiss) that inhaled acetic acid at concentrations of 55 or 160 ppm (10 animals per group, respectively) for 4, 9 or 14 days, respectively, at a frequency of 6 hours per day and 5 days per week, showed no substance related mortality. Histopathological changes of the olfactory epithelium were observed whereby the effects were strongest after 4 days of exposure and less strong after 14 days of exposure.

Long-Term Repeated Dose Toxicity and Carcinogenicity
Nine out bred white male rats were given either N-nitrosarcosin ethyl ester (NSEE) alone, NSEE with acetic acid solution, or acetic acid solution alone. Doses (0.5 mL of 3 % water solution of acetic acid corresponding to about 60 mg/kg bw/treatment) were given by intubation into the esophagus 3 times per week. Animals were killed by ether inhalation after 8 months of experiments and autopsied. As expected, rats treated with the carcinogen NSEE had high incidences of pre-neoplastic lesions of the esophagus and forestomach, as well as benign tumours, carcinomas and squamous cell cancer. Prolonged administration of acetic acid in combination with NSEE resulted in an increase in the number of benign and malignant tumours and carcinomas in the esophagus. Prolonged administration of acetic acid alone did not induce tumours. All nine of these rats, however, did experience hyperplasia in the esophagus and forestomach.

The potency of acetic acid in the tumour progression phase of the mouse skin model of chemical carcinogenesis and the role of cytotoxicity in carcinogenesis was investigated. Mice were initiated with a topical application of 7,12-dimethylbenzanthracene and two weeks later promoted with 12-O-tetradecanoylphosbol-13-acetate, twice weekly for 16 weeks. Four weeks later, topical treatment with 40 mg glacial acetic acid in 200 µL acetone twice weekly was started and continued for 30 weeks. Prior to treatment with acetic acid, each group of mice had approximately the same number of papillomas at the

exposure site. After 30 weeks of treatment, mice treated with acetic acid had a 55 % greater conversion of skin papillomas to carcinomas than vehicle treated mice. Papilloma regression was not significantly altered in the acetic acid group, compared to the acetone group. Histological examination revealed no significant differences in the cancers formed.

Reproductive and Developmental Toxicity/Teratogenicity
Suckling rats were exposed to 5 x 10-3 M acetic acid from parturition until the pups were 18 days old. Male offspring from dams on acetic acid demonstrated above normal pre-weaning body weights and were significantly less active than normal in the open field by day 44.

Following mating, adult female albino CD-1 mice were dosed daily at concentrations of 0 (control), 16, 74, 345, and 1600 g/kg bw/day by oral intubation beginning on day 6 of gestation. Animals were observed daily and body weights recorded for 10 days. On day 17, Caesarian sections were performed on all dams and the number of implantation sites, resorption sites, and live and dead fetuses was recorded. General external and internal examinations were also made of the dams. No effects on nidation or on maternal or fetal survival were observed at doses up to 1600 g/kg bw/day. The number of abnormalities seen in either soft or skeletal tissues of the test groups did not differ from the number occurring in the controls.

Conclusion
There is no need to calculate specific reference values for acetic acid (decided in TM IV 2013).

Acetic acid is of no concern for systemic toxicity after dermal exposure and, thus, does not require establishment of reference values for systemic effects. No systemic reference values have been set for the substance under other regimes (PPP, REACH) either. Regarding local risk characterisation the equilibrium solution should be considered as an entity rather than considering e.g. the irritation potential of acetic acid separately. There is no exposure to

acetic acid alone and for the local risk characterisation the whole equilibrium solution has been taken into account in the risk characterisation. The representative products contain approx. 1-15% acetic acid and the toxicity studies were performed with solutions containing up to 36% acetic acid. The proposed AECinhalation of the equilibrium solution is two times lower than the corresponding AEC value established for acetic acid under PPP (0.5 mg/m3 vs. 1 mg/m3). The risks from acetic acid are adequately covered in this CAR and no systemic reference values are needed.

(X) Available toxicological data relating to a mixture

No toxicological data related to the mixtures contained in the QUARON PAA family is submitted and available. Indeed, all the required data and conclusions are used and assessed in the Human Health Risk Assessment here below.

2.2.6.2 Exposure assessment

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

The biocidal product family "QUARON PAA family" contains 6 Meta SPC of which each include one biocidal product.

These products are part of the Main Group 1: disinfectants products from PT2 to PT 5 applications and are only intended for professional use.

Since this biocidal product family has a high number of uses, all the applications are summarized for each Meta SPC in the table below. The coloured/marked fields mean the use applies to the Meta SPC. The related use number is also specified in the box.

Table 2.2.6.1: Uses and scenarios summary developed in the exposure assessment

Product type	**Uses**	**Scenarios**	**Meta SPC 1**	**Meta SPC 2**	**Meta SPC 3**	**Meta SPC 4**	**Meta SPC 5**	**Meta SPC 6**
PT 2	Swimming pool disinfection	Automatic dosing in piped water – Automatic mixing and loasing		*Meta SPC 2 – Use #1*				
		Manual mixing and loading in the pool		*Meta SPC 2 – Use #1*				
	Manual spraying on open surfaces to treat	Automatic dosing- Automatic mixing and loading		*Meta SPC 2- Use #2*	*Meta SPC 3- Use#1*			
		Manual spraying with a low-						

Product type	Uses	Scenarios	Meta SPC 1	Meta SPC 2	Meta SPC 3	Meta SPC 4	Meta SPC 5	Meta SPC 6
		medium pressure sprayer						
	Cleaning in Place disinfection	Automatic dosing-Automatic mixing and loading	Meta SPC 1 – Use #2	*Meta SPC 2 – Use #3*	Meta SPC 3 – Use #3			
	STEP disinfection	Automatic dosing-Automatic mixing and loading			Meta SPC 3 – Use #2			
	Disinfection of container and material	Automatic dosing-Automatic mixing and loading			Meta SPC 3 – Use #4			
		Manual Dipping						
	Waste water disinfection	Automatic dosing-Automatic mixing and loading	Meta SPC 1 – Use #1		Meta SPC 3 – Uses #5 and #6	Meta SPC 4 – Use #1		
	Laundry disinfection	Automatic dosing-Automatic mixing and loading			*Meta SPC 3 – Use #7*	Meta SPC 4 – Use #2		
PT 3	Milking Claw shape disinfection	Automatic dosing-Automatic mixing and loading			Meta SPC 3 – Use #8			
		Manual spraying						
	Disinfection of container and material	Automatic dosing-Automatic mixing and loading			Meta SPC 3 – Uses #9 and #11			
		Manual Dipping						
	Cleaning in Place disinfection	Automatic dosing-Automatic mixing and loading			Meta SPC 3 – Uses #10 and #13			
	Manual spraying on open	Automatic dosing-Automatic mixing and loading			Meta SPC 3 –		Meta SPC 5 – Use #1	

Product type	Uses	Scenarios	Meta SPC 1	Meta SPC 2	Meta SPC 3	Meta SPC 4	Meta SPC 5	Meta SPC 6
	surfaces to treat	Manual spraying with a low-medium pressure sprayer			Use #12			
PT 4	Manual spraying on open surfaces to treat	Automatic dosing-Automatic mixing and loading	Meta SPC 1 – Use #3		Meta SPC 3 – Use #14		Meta SPC 5 – Use #2	
		Manual spraying with a low-medium pressure sprayer						
	Cleaning in Place disinfection	Automatic dosing-Automatic mixing and loading	Meta SPC 1 – Use #4		Meta SPC 3 – Use #15	Meta SPC 4 – Use #3		Meta SPC 6 – Use #1
	Disinfection of container and material	Automatic dosing-Automatic mixing and loading	Meta SPC 1 – Use #5		Meta SPC 3 – Use #16	Meta SPC 4 – Use #4		
		Manual Dipping						
	Automated spraying in closed systems	Automatic dosing-Automatic mixing and loading	Meta SPC 1 – Use #6		Meta SPC 3 – Use #17			
PT5	Drinking water disinfection but only intended for animals	Automatic dosing-Automatic mixing and loading			Meta SPC 3 – Use #18			

The relevant paths of human exposure that apply to the "QUARON PAA family" are also described here below. This analysis is made taking into account the active substance characteristics, but also the physical and chemical properties of an important ingredient that takes part of the equilibrium reaction that produces peracetic acid, hydrogen peroxide.

These two substances have both local effects at the site of first contact. The skin and eyes exposures are assessed by a concentration comparison of these substances to each threshold concentration that triggers effects to the eyes or/and to the skin.

To assess the inhalation exposure, local effects to the respiratory tract are assessed for both substances by quantitative estimation of the exposure to aerosols, but also to vapour.

Indeed, peracetic acid (PAA) and hydrogen peroxide (H_2O_2) are two highly volatile substance since their vapour pressures > 0.1 Pa, 1410 Pa for PAA and 214 Pa for H_2O_2.

That is the reason why the inhalation exposure to aerosol and vapour are assessed for each substance. Then, a combined exposure to aerosol and vapour of those two substances is also estimated since they are part of the equilibrium and both have effects on humans.

The oral exposure route is not assessed in this risk assessment. Indeed, all the products are used by professionals. So, this user category is not supposed to be exposed orally.

Besides the exposure assessment to PAA and H_2O_2, other substances have been identified as substances of concern. These ingredients and the reasons why they are analysed as SOCs are described in the table below. These substances have been identified following the finalized document of the CA meeting (CA-Nov14-Doc.5.11 - SoC guidance_final.doc). Please, note that hydrogen peroxide also appears in the following table. Indeed, this ingredient is also referred as a substance of concern in the dossier, even if it is assessed at the same level than the active substance in the human health risk assessment that is conducted here after, for the reasons described in the previous paragraphs.

Table 2.2.6.2: Substances of concerns analysed in the "QUARON PAA family"

Substances of concern: Summary table				
Name and CAS od the identified SOC	**Reason(s) for identification**	**Relation to band**	**Consequences on the Human Risk assessment**	**Community workplace exposure limit (if needed)**
Sulfuric Acid – CAS 7664-93-9	Substances for which there are Community workplace exposure limits.	Band C	Fully quantitative risk assessment by using EU IOELVs (when available), AECs or other reference values (e.g. AELs, AECs)	Long-term (8 hours): 0.05 mg/m³ Short-term (15 minutes): No limit specified
Decan-1-ol, ethoxylated– CAS 26183-52-8	Contribution to the CLP classification of the biocidal product as "STOT S3 resp.".	Band A	Application of P statements normally associated with concerned H statements.	-

The exposure to these substances of concern is also assessed.

Two of them, acetic acid and sulphuric acid are identified as SOCs because of their reference on the list of European Community workplace limit. So, only the inhalation exposure is assessed for these ingredients.

As for PAA and H_2O_2, acetic acid is also part of the equilibrium reaction. Furthermore, due to its high vapour pressure (2079 Pa), the respiratory exposure to this substance is quantified for exposures to aerosol and vapour.

For sulphuric acid, only the inhalation exposure to aerosol is quantified. Indeed, this substance is only slightly volatile as its vapour pressure is 0.1 Pa. And a substance is defined as volatile only if its vapour pressure is higher than 0.1Pa (RIVM, Consexpo General fact sheet)[6].

The last ingredient that is identified as a SOC is the ethoxylated alcohol (Decan-1-ol, ethoxylated). This ingredient only contributes to the concentrate product classification of the INDAL OXY MOUSS included in the Meta SPC 4 as Skin corrosion 1A, and more specifically as Eye damage 1. So, for this product and substance, the only think to consider is to check if the P phrases related to the statement H318 "Cases serious eye damage" well applies to the product during its use to guarantee a safe use during its handling.

6 J.D. te Biesebeek et al. National Inistitute for Public Health and the Environment. *Ministry of Health, Welfare and Sport.* RIVM report 090013003, 2014.

Since the SOCs that need to be assessed quantitatively have only effects on respiratory tract, only their local effects are also assessed.

Taking into account local effects rather than systemic effects means that exposure and related risk are assessed for each application separately and are not be summed up for all applications for a same user.

Indeed, it is stated in the CAR[7] of PAA that *"Based on the absence of systemic effects after exposure towards peracetic acid, it is important to note in this context that the inhalation AEC values are not time-dependent and relate to the concentrations of peracetic acid in the air, which do not cause sensory irritation or corrosive effects. For this reason, only the highest inhalation exposure level is relevant and the addition of exposure levels and the calculation of a combined inhalation exposure during the different tasks are not relevant".*

Furthermore, due to the high volatility of PAA, H_2O_2 and acetic acid assessed, all the risk assessment is conducted only considering the **primary exposure**. Indeed, it is assumed that all the substances react with organic matter, are evaporated and are not present anymore on the treated surface after application. So, for post-application scenario as rinsing the treated surface or draining a diluted solution present in a container after dipping application, no exposure to volatile substances is assumed to occur. So, these exposures are not assessed here. In the same way, no secondary exposure to volatile substances occurs here.

Secondary exposure will be qualitatively assessed only for the shock treatment of swimming pool water to explain that no exposure to the product occurs. Secondary exposure is also developed for bystanders and general public for which inhalation exposure might happen during the different application of the products when they are present in the same room.

The only substance for which exposure during post-application is developed is sulphuric acid as this substance is only slightly volatile.

There is also no **exposure via food**. Indeed, even if the products of the "QUARON PAA family" are applied in food industries, PAA and H_2O_2 highly react with organic matter. Furthermore, all the treated surfaces, included those which could be in contact with food, are rinsed with tap water after disinfection.

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	Yes	Yes	n.a.	n.a.	Yes	Yes	n.a.
Dermal	Yes	Yes	n.a.	n.a.	n.a.	n.a.	n.a.
Oral	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

[7] Assessment Report Peracetic acid Product-types 1-6. Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. Finland. Novembre 2015

The inhalation exposure is quantitatively assessed by considering exposure to aerosol and also exposure to vapour.

To assess the skin and eye exposures to PAA and H_2O_2, a qualitative approach is conducted.

In the assessment report of PAA[8], the NOAEC for dermal exposure is 0.2% for short/medium term exposure and 0.1% for long-term exposure. It is described that "*approx. 0.2% PAA concentration seems to be non-irritating in human volunteers. It is considered that the human evidence comes from a sufficiently large number of people to be used as a starting point for risk characterisation. Instead, in the absence of adequate information from human use for longer periods, data from animals is chosen as the starting point for the dose descriptor for long-term exposure scenarios. Based on animal data from the dermal one year study (LOAEC 0.2%) with an uncertainty factor of 2 is proposed to be used for risk characterisation. This study was considered as a supplementary information due to its short comings as a chronic study but that did not compromise the dermal effects observed.*

In conclusion, based on the effects in humans 0.2% peracetic acid is proposed to be used as a dermal NOAEC for short-term and medium-term exposure scenarios and 0.1% for long-term exposure scenarios."

In the assessment report of H_2O_2, it is described that "*no dermal irritation was noted after application of 10% hydrogen peroxide. The 35% hydrogen peroxide caused slight to moderate reversible erythema and edema in a skin irritation study. However, irreversible desquamation of skin triggers classification Skin irritation 2, H315. In view of the absence of systemic effect after exposure to hydrogen peroxide, only external exposure limits are relevant to account for potential local effects of H_2O_2. When in-use concentration of hydrogen peroxide in a biocidal product is below the skin irritating threshold (concentration limit for classification for skin irritation 2 is 35%), only the inhalation route of exposure has been identified to be relevant in the quantitative exposure and risk assessment*."

In addition, H_2O_2 causes concentration dependent eye lesions. At higher concentrations, severe and irreversible damage to rabbit eye has been showed. The results support the current classification with Eye irritation 2, H319 for 5% ≤ hydrogen peroxide ≤ 8% and Eye damage 1, H318 for 8% ≤ hydrogen peroxide ≤50%.

For each of the listed scenario, the PAA and H_2O_2 concentrations of the used products are compared to the concentrations that trigger skin corrosion, skin irritation and eye damage or eye irritation effects. The consequences for the user are described for each use of each product. In the present report, this skin and eye exposures assessment is developed before the inhalation quantitative assessment.

The following paragraphs contains a more detailed presentation of the calculation for the ATE. Note that for hydrogen peroxide, an ATE = 11 mg/L was used:

If we base the classification calculation on hydrogen peroxide being inhaled as vapour, then the following toxicity values can be considered:

- Peracetic acid: ATE = 0.204 mg/L (mist).
- Hydrogen peroxide: ATE = 11 mg/L (vapour).

8 Assessment Report Peracetic acid Product-types 1-6.Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. Finland. Novembre 2015

The gives the following Meta SPC-specific values:

Peracetic acid		Hydrogen peroxide	
Conc. (%)	Conc/100/ATE	Conc. (%)	Conc/100/ATE
Meta SPC 1			
2.6	0.13	25	0.023
Meta SPC 2			
2.0	0.10	35.5	0.032
Meta SPC 3			
5.3	0.26	25.5	0.023
Meta SPC 4			
15.8	0.77	25.0	0.023
Meta SPC 5			
1.2	0.06	13.0	0.012
Meta SPC 6			
5.0	0.25	21.0	0.019

If we assess whether the Meta SPCs should be classified as H332 (Acute Tox. 4), it gives the following results:

	Σ (limit / ATE) x conc./100
Meta SPC 1	1.09
Meta SPC 2	1.14
Meta SPC 3	1.76
Meta SPC 4	4.33
Meta SPC 5	0.53
Meta SPC 6	1.61

This shows that all Meta SPCs should be classified at least in category 4 of the acute inhalation toxicity hazard, except for Meta SPC 5 which does not need to be classified.

If we assess whether the Meta SPCs should be classified as H331 (Acute Tox. 3), it gives the following results:

	Σ (limit / ATE) x conc./100
Meta SPC 1	0.35
Meta SPC 2	0.42
Meta SPC 3	0.49
Meta SPC 4	1.00

Meta SPC 6	0.18

This shows that no Meta SPC needs to be classified in the category 3 of the acute inhalation toxicity hazard, except, it would seem, for Meta SPC 4.

Nevertheless, we are in the opinion that Meta SPC 4 should not be classified as H331. Indeed, the results of the sum of the fractions is barely above the threshold of 1. Moreover, this value is an overestimation because the toxicity result of 0.204 mg/L is not representative of pure peracetic acid. It was defined based on results obtained on a 5% PAA solution (LC_{50} = 4.08 mg/L) extrapolated to assess the toxicity of pure PAA. However, the 5% solution used for the test already contains hydrogen peroxide, which means that the LC_{50} of 4.08 mg/L is relevant for a solution of 5% PAA + X% H_2O_2. When using the 0.204 mg/L ATE value in the classification calculations and summing the toxicity of PAA and H_2O_2, it is therefore as if hydrogen peroxide was counted twice. Taking this into account, it can be considered that the actual ATE of pure peracetic acid is > 0.204 mg/L, hence the ∑ (limit / ATE) x conc./100 of Meta SPC 4 is < 1 and this Meta SPC does not need to be classified as H331. Another way to view this would be to extrapolate the result obtained on the 5% PAA solution, 4.08 mg/L, to a 15% solution, which gives an LC_{50} of 1.36, resulting in the acute inhalation category 4 classification. The expected LC_{50} of a 15% solution would actually be > 1.36 as formulations containing 5% of PAA usually contain more than the third of hydrogen peroxide as 15% PAA formulations.

In conclusion, Meta SPCs 1, 2, 3, 4 and 6 need to be classified as H332 (Acute Tox. 4). Meta SPC 5 does not need to be classified for the acute inhalation hazard.

(I) List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Manual mixing and loading	**Primary exposure** Exposure during handling to dilute the concentrate for ready-to-use product applied in several systems and for several type of applications. *Scenarios 1.1 for PT 2 applications*	. professionals
2.	Automatic mixing and loading	**Primary exposure** Automated pumping and transfer of concentrate solution *Scenarios 2.1 for PT 2 applications* *Scenarios 2.2 for PT 3 applications* *Scenarios 2.3 for PT 4 applications* *Scenarios 2.4 for PT 5 applications*	. professionals
3.	Manual spraying	**Primary exposure** Manual spraying of the diluted solution to treat open surfaces *Scenarios 3.1 for PT 2 applications* *Scenarios 3.2 for PT 3 applications* *Scenarios 3.3 for PT 4 applications*	. professionals
4.	Manual dipping	**Primary exposure** Manual dipping of containers or material/equipment in diluted solution in open spaces *Scenarios 4.1 for PT 2 applications* *Scenarios 4.2 for PT 3 applications* *Scenarios 4.3 for PT 4 applications*	. professionals
5.	Rinsing	**Primary exposure** Manual rinsing of the treated surface with tap water *Scenarios 5.1 for PT 2 applications* *Scenarios 5.2 for PT 3 applications* *Scenarios 5.3 for PT 4 applications*	. professionals
6.	Draining	**Primary exposure** Manual draining of the diluted solution used to treat container, waste water or material after dipping applications *Scenarios 6.1 for PT 2 applications* *Scenarios 6.2 for PT 3 applications* *Scenarios 6.3 for PT 4 applications*	. professionals

7.	Swimming	**Secondary exposure** Swimming into treated water after shock treatment (Meta SPC 2 Use #1b. *Statement*	Swimmers

Meta-SPC n°	Meta-SPC/Product Name	Concentration of the product	PT	Scenario	In-Use concentration	Description
1	INDAL PAA 3.5	**2.6**	**2**	**2**	**2.6**	Automatic M&L
			4	**2**	**2.6**	Automatic M&L
				3.3	**0.104**	Manual Spraying on open surfaces
				4.3	**0.104**	Manual Dipping
				5	**-**	Manual rinsing
				6	**-**	Manual draining
2	INDAL PAA 2.5	**2.0**	**2**	**1**	**2**	Manual M&L
				2	**2**	Automatic M&L
				5	**-**	Manual rinsing
				6	**-**	Manual draining
3	INDAL PAA 5	**5.3**	**2**	**2**	**5.3**	Automatic M&L
				3.1 (except 3.1.4)	**0.186**	Manual Spraying on open surfaces
				3.1.4	**0.0636**	Manual Spraying on open surfaces (with algae)
				4.1	**0.265**	Manual Dipping
				5	**-**	Manual rinsing
				6	**-**	Manual draining
				7	**-**	Secondary exposure of swimmers
			3	**2**	**5.3**	Automatic M&L
				3.2	**0.106**	Manual Spraying on open surfaces
				4.2	**0.265**	Manual Dipping
				5	**-**	Manual rinsing
				6	**-**	Manual draining

4	INDAL PAA 15	**15.8**	**4**	**2**	**5.3**	Automatic M&L
				3.3	**0.86**	Manual Spraying on open surfaces
				4.3	**0.186**	Manual Dipping
				5	**-**	Manual rinsing
				6	**-**	Manual draining
			5	**2**	**5.3**	Automatic M&L
			2	**2**	**15.8**	Automatic M&L
			4	**2**	**15.8**	Automatic M&L
				4.3	**0.2528**	Manual Dipping
5	INDAL OXY MOUSSE	**1.2**	**3**	**2**	**1.2**	Automatic M&L
				3.1	**0.06**	Manual Spraying on open surfaces
				5	**-**	Manual rinsing
			4	**3.3**	**0.65**	Manual Spraying on open surfaces
				5	**-**	Manual rinsing
6	INDAL TAP 5	**5.0**	**4**	**2**	**5.0**	Automatic M&L

The different exposures to vapour related to each scenario are all developed for each product concerned by the use and also for each volatile substance of concern contained in the product. Each parameter and its justification or reference, as well as each input is explained for each scenario in the tables here after.

The Exposure assessments related to each developed scenario in ConsExpo web are given in the Annexes.

But, these assessments are only given for one product and the active substance of each scenario in order to keep this document to a reasonable size.

However, all the data used to assess the exposure for the other products and/or other substances are summarized in the tables below and have led to the exposure assessment values given for each scenario.

(II) Industrial and professional exposure

Please note that there is a high level of uncertainty for human health risk assessment for all application by spraying.

Scenario 1: Manual mixing and loading

The product is mixed and loaded manually to dilute it. This manual application occurs before each use as a pre-application step and only with packaging from 5 to 20 liters. Indeed, with higher volume packaging, only automatic pumping and transfer is feasible. After application of the biocidal product rinse treated surfaces, equipment, pipework or

installations with drinking water. Provide adequate ventilation before the general public re-enter treated areas. The general public is not allowed to enter the outdoor application site and an area 20 m around during spraying and until the surface is rinsed.

Dermal exposure

To assess the skin exposure to PAA and H_2O_2, a qualitative approach was performed, as indicated in the introduction.

For the biocidal product contained in the Meta SPC 2, the PAA and H_2O_2 concentrations are 2% w/w and 35.5% w/w, respectively.

This means that its PAA content is higher than the skin irritation threshold of 0.2% for the short-term exposure and 0.1% for the long-term exposure.

For the H_2O_2 content, the 35.5% w/w concentration is higher than the skin irritation threshold of 35% w/w and is also in the range of concentrations that triggers an Eye damage 1 classification. Indeed, 35.5% w/w is well in the range of 8% w/w to 50% w/w.

Therefore, local skin irritation and eye damage effects are expected when the products from Meta-SPC 2 (like INDAL PAA 2.5) are used as concentrate product and are handled during manual mixing and loading application. To protect the user, the risk related to dermal and eye exposures is only acceptable with the wearing of chemical-resistant gloves, of a protective coverall but also of a face shield during this application.

Inhalation exposure

For local effects to respiratory tract, exposure to aerosol is taken into account. But, the exposure to vapour is also considered for the highly volatile substances (PAA, H_2O_2 and acetic acid).

To assess the exposure to aerosol, the Mixing and Loading model 7, pouring liquid from TNsG 2002[9], with an indicative value of 0.94 mg/m³ for inhalation exposure is used. This inhalation indicative value is in accordance with ECHA recommendation N°6 (updated version of February 2017- version 3)[10].

9 Working Group. Technical notes for guidance. Human exposure to biocidal products – Guidance on exposure estimation. June 2002

10 BPC Ad hoc Working Group on Human Exposure. ECHA Recommandation N°6 – Methods and models to assess exposure to biocidal products in different product types versio 3. 2017

Description of Scenario 1: Manual Mixing and loading – Exposure to aerosol
This scenario applies for the next uses: 1) Meta SPC 2 (INDAL PAA2.5)– Use #1 for PT2 application: PAA exposure : 0.02*0.94 = 0.01974 mg/m³ H2O2 exposure : 0.355*0.94 =0.3337 mg/m³ Acetic acid exposure: 0.0220*0.94 = 0.02068 mg/m³ Sulphuric acid exposure: 0.003*0.94 = 0.00282 mg/m³

To assess the exposure to vapour, the model "Exposure to vapour – Evaporation" of the scenario "Mixing and loading" of the "Disinfectant products fact sheet" of the online program ConsExpo Web is applied[11].

[11] L.C.H. Prud'homme de Lodder, H.J. Bremmer, S.M.G.J. Pelgrom, M.V.D.Z. Park, J.G.M. van Engelen. Disinfectant Products Fact Sheet to assess the risks fort he consumer. RIVM report 320005003/2006, 2006. P22.

Description of Scenario 1: Manual Mixing and loading – Exposure to vapour			
This scenario applies for the next uses: 1) Meta SPC 2 – Use #1 Since it is an exposure assessment for local effects on respiratory tract, the frequence of application does not play a role in the model.			
	Parameters	**Value**	**Reference**
Tier 1	Exposure duration	10 minutes	This is the default exposure for mixing and loading application duration that is used according to the CAR on PAA PT1-6.
	Product amount	Worst-case packaging volume for manual application: 20L (density: 1.14 for INDAL PAA 2.5): For INDAL PAA 2.5 - meta-SPC 2: 10 000*1.14 = 11 400 g	Applicant's information. But, it is considered as a default value that the user is exposed to the half of the packaging content during inhalation exposure: evaporation from constant surface of the mixing and loading applications of a liquid (Default value from ConsExpo, Disinfectant products fact sheet).
	Weight fraction substance	For INDAL PAA 2.5 (meta-SPC 2): a) PAA: 0.02 b) H2O2: 0.355 c) CH3COOH: 0.022	Applicant's information. Worst-case in-use dilution is 4%.
	Room volume	1 m³	Personal volume, default value from ConsExpo, Disinfectant products fact sheet used for phase liquid
	Ventilation rate	0.6/hour	Default value for non-specified room (ConsExpo, Disinfectant products fact sheet, mixing and loading of e liquid, p 22)

	Inhalation rate	1.37 m³/hr	Default inhalation rate for an adult during light exercise (ConsExpo).
	Vapour pressure	For PAA: 1410 Pa For H2O2: 214 Pa For CH3COOH: 2079 Pa	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: information taken on the ingredient's suppliers (please refer to SDS documents provided in the dossier)
	Application temperature	20°C	Application temperature given by the applicant (ambient temperature)
	Molecular weight	For PAA: 76.05 g/mol For H2O2: 34.01 g/mol For CH3COOH: 60.05 g/mol	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: no information in the SDS or in the REACH dossier. So the value was calculated based on the molecular formula.
	Mass transfer coefficient	For PAA: 18.6 m/hour For H2O2: 24.3 m/hour For CH3COOH: 20.1 m/hour	Esimated with the Thibodeau's method as the products are aqueous solutions
	Release area mode: Release area Emission duration	20 cm² 10 min	Default value from the opening of the packaging given in the ConsExpo Disinfectant products fact sheet. Indeed, it is considered that the liquid evaporates from a bottle with a circular opening of 5 cm diameter or 20 cm². Here, the emission duration is the same than the exposure duration.
	Molecular weight matrix	18.1 g/mol	ConsExpo information[12]. The parameter 'molecular weight matrix' is the molecular

12 Bremmer, H.J., M.P. van Veen, 2000 Paint Fact Sheet. Bilthoven, the Netherlands: National Institute for Public Health and the Environment (RIVM). Report no. 612810010 (in Dutch)

			weight of the 'other' components in the product. The molecular weight of the matrix is: Molecular weight of the substance/fraction other components
Tier 2	Room volume	80 m³	Room volume default value given for PT2/PT4 applications, according the Biocides Human Health Exposure Methodology for uses in PT2/PT4 (p. 105) [13]and in line with the HEAdhoc Recommendation no. 9 (2016) - "Hand disinfection in hospitals by professionals – Inhalation and dermal exposure during hand disinfection"[14] and considered a realistic scenario for manual M/L tasks.
	Ventilation rate	1.5/hour	Default value for hospital rooms according to HEAdhoc Recommendation no. 9, 2016) and 3/h (best case assumption for well ventilated rooms) is observed, probably due to the short application and exposure duration. Furthermore, ventilation rate is assumed to be at least 2 air change per hour in Recommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfection Recommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfection[15] that gives air change rates in typical rooms and building. Thus, this worst-case ventilation rate of 1.5/h is considered for the exposure assessments.

Combined inhalation exposure to aerosol and vapour during manual mixing and loading application for each substance and product

Exposure type	Substances	Exposure to Meta-SPC 2 (INDAL PAA 2.5) [mg/m³]
Exposure to aerosol	Peracetic acid	0.0197
	Hydrogen peroxide	0.3337
	Acetic acid	0.0207
	Sulphuric acid	0.0028
Exposure to vapour	Peracetic acid	0.032
	Hydrogen peroxide	0.064
	Acetic acid	0.045
	Sulphuric acid	n.a.
Total exposure to aerosol and vapour	Peracetic acid	0.0517
	Hydrogen peroxide	0.3977
	Acetic acid	0.0648
	Sulphuric acid	0.0028

n.a. Not applicable because sulphuric acid is slightly volatile

Combined risk related to total inhalation exposure during manual mixing and loading application for each product

TIER 2 APPROACH	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 2.5 (meta-SPC 2)	0.0517	0.3977	0.0648	0.0028
AEC for local effects to repiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 2.5 (meta-SPC 2)	0.1034	0.3182	0.0026	0.056

13 Biocides Human Health Exposure Methodology. First edition, 2015. P105

14 Recommendatioon no. 9 of the BPC Ad hoc Working Group on Human Exposure. Hand disinfection in hospitals. Revision agreed at the Human Health Working Group I. January 2017.

15 Resources, Tools and Basic Information for Engineering and Design of Technical Applications. The Enineering ToolBox http://www.engineeringtoolbox.com/, August 2017.

	Combined risk due to equilibrium reaction [mg/m³]		
INDAL PAA 2.5 (meta-SPC 2)	0.4216	0.0026	0.056
• **Risk acceptable or non acceptable?**	Acceptable	Acceptable	Acceptable

Conclusions to the primary exposure during manual mixing and loading of the user

During manual mixing and loading, risk related to dermal exposure is acceptable if the user wears chemical-resistant gloves, a protective coverall and a face shield due to classification as Skin corrosions 1 and eye damage 1 of the meta-SPC 2 (product INDAL PAA 2.5) (pH <2), related to high concentration in peracetic acid and hydrogen peroxide.

During this application, no respiratory protective equipment is required. Indeed, the risk related to inhalation exposure to aerosol and vapour is acceptable without any personal protective equipment.

As there is no systemic toxicity known for peracetic acid and hydrogen peroxide, and that they present risk mainly as corrosive substances, combining exposure makes little sense, and the major risk is presented by the undiluted product used during the M&L step. If the different RMM put in place, including PPE and RPE, can be considered as enough protection during M&L, the diluted product is not seen as problematic.

Scenario 2: Automated mixing and loading by pumping of concentrates

The product is mixed and loaded automatically to dilute it. Since this application occurs in closed systems, and connecting the packaging to the automated system has a negligible duration, only the exposure to aerosol is considered here below. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water. Provide adequate ventilation before the general public re-enter treated areas. The general public is not allowed to enter the outdoor application site and an area 20 m around during spraying and until the surface is rinsed.

Dermal exposure

To assess the skin exposure to PAA and H_2O_2, a qualitative approach was performed, as indicated in the introduction.

For the biocidal product contained in the Meta SPC 1

The PAA and H_2O_2 concentrations are 2.6% w/w and 25% w/w, respectively.

This means that its PAA content is higher than the skin irritation threshold of 0.2% for the short-term exposure and 0.1% for the long-term exposure.

For the H_2O_2, the 25% w/w concentration is below the skin irritating threshold of 35% w/w and included in the range that triggers an eye damage 1 classification: 25% w/w is well in the range of 8% w/w to 50% w/w.

Therefore, local skin irritation and eye damage effects are expected when the products from Meta-SPC 1 (such as INDAL PAA 3.5), used as concentrate product are handled during manual connecting for automatic mixing and loading application. To protect the user, the risk related to dermal and eye exposures is only acceptable with the wearing of chemical-resistant gloves, of a protective coverall but also of a face shield during this application.

For the biocidal product contained in the Meta SPC 2

The PAA and H_2O_2 concentrations are 2% w/w and 35.5% w/w, respectively.

This means that its PAA content is higher than the skin irritation threshold of 0.2% for the short-term exposure and 0.1% for the long-term exposure.

For the H_2O_2 content, the 35.5% w/w concentration is higher than the skin irritation threshold of 35% w/w and is also in the range of concentrations that triggers an eye damage 1 classification: 35.5% w/w is well in the range of 8% w/w to 50% w/w.

Therefore, local skin irritation and eye damage effects are expected when the products from Meta-SPC 2 (such as INDAL PAA 2.5) are used as concentrate product and are handled during manual connecting for automatic mixing and loading application. To protect the user, the risk related to dermal and eye exposures is only acceptable with the wearing of chemical-resistant gloves, of a protective coverall but also of a face shield during this application.

For the biocidal product contained in the Meta SPC 3

The PAA and H_2O_2 concentrations are 5.3% w/w and 25.5% w/w, respectively.

This means that its PAA content is higher than the skin irritation threshold of 0.2% for the short-term exposure and 0.1% for the long-term exposure.

For the H_2O_2, the 25.5% w/w concentration is below the skin irritating threshold of 35% w/w and included in the range that triggers an eye damage 1 classification: 25.5% w/w is well in the range of 8% w/w to 50% w/w.

Therefore, local skin irritation and eye damage effects are expected when the products from Meta-SPC 3 (such as INDAL PAA 5) are used as concentrate product and are handled during manual connecting for automatic mixing and loading application. To protect the user, the risk related to dermal and eye exposures is only acceptable with the wearing of chemical-resistant gloves, of a protective coverall but also of a face shield during this application.

For the biocidal product contained in the Meta SPC 4

The PAA and H_2O_2 concentrations are 15.8% w/w and 25% w/w, respectively.

This means that its PAA content is higher than the skin irritation threshold of 0.2% for the short-term exposure and 0.1% for the long-term exposure.

For the H_2O_2, the 25% w/w concentration is below the skin irritating threshold of 35% w/w and included in the range that triggers an eye damage 1 classification: 25% w/w is well in the range of 8% w/w to 50% w/w.

Therefore, local skin irritation and eye damage effects are expected when the products from Meta-SPC 4 (such as INDAL PAA 15) are used as concentrate product and are handled during manual connecting for automatic mixing and loading application. To protect the user, the risk related to dermal and eye exposures is only acceptable with the wearing of chemical-resistant gloves, of a protective coverall but also of a face shield during this application.

For the biocidal product contained in the Meta SPC 5

The PAA and H_2O_2 concentrations are 1.2% w/w and 13% w/w, respectively.

This means that its PAA content is higher than the skin irritation threshold of 0.2% for the short-term exposure and 0.1% for the long-term exposure.

For the H_2O_2, the 13% w/w concentration is below the skin irritating threshold of 35% w/w and included in the range that triggers an eye damage 1 classification: 13% w/w is in the range of 8% w/w to 50% w/w.

Therefore, local skin irritation and eye damage effects are expected when the products from Meta-SPC 5 (such as INDAL OXY MOUSS) are used as concentrate product and are handled during manual connecting for automatic mixing and loading application. To protect the user, the risk related to dermal and eye exposures is only acceptable with the wearing of chemical-resistant gloves, of a protective coverall but also of a face shield during this application.

For the biocidal product contained in the Meta SPC 6

The PAA and H_2O_2 concentrations are 5.0% w/w and 21.0% w/w, respectively.

This means that its PAA content is higher than the skin irritation threshold of 0.2% for the short-term exposure and 0.1% for the long-term exposure.

For the H_2O_2, the 21% w/w concentration is below the skin irritating threshold of 35% w/w and included in the range that triggers an eye damage 1 classification: 21% w/w is well in the range of 8% w/w to 50% w/w.

Therefore, local skin irritation and eye damage effects are expected when the products from Meta-SPC 6 (such as INDAL TAP 5) are used as concentrate product and are handled during manual connecting for automatic mixing and loading application. To protect the user, the risk related to dermal and eye exposures is only acceptable with the wearing of chemical-resistant gloves, of a protective coverall but also of a face shield during this application.

Inhalation exposure

For local effects to respiratory tract, only the exposure to aerosol is taken into account.

No exposure to vapour is assessed because:

- 1° the dosing systems for all applications occur in closed systems
- 2° the exposure duration is assumed to be negligeable

As a worst-case approach, only the exposure to aerosol, assessed by the Mixing and loading model 7, liquid pumping from the HEEG Opinion 1[16], with an indicative value of 22 mg/m³, for inhalation exposure is used.

Description of Scenario 2: Automatic Mixing and loading – Exposure to aerosol
This scenario applies for the next uses: 1) For PT 2 applications: ○ Meta SPC 1 - Uses #1 and #2 for Meta-SPC 1 (the product INDAL PAA 3.5):

16 HEEG Opinion on the use of available data and models fort he assessment oft he exposure of operators during the loading of products into vessels or systems in industrial scale. Mixing & loading model 7; TNsG part 2 p.142 (corrected) 2008. P 7-8

PAA exposure : 0.026*22 = 0.572 mg/m³
H2O2 exposure : 0.25*22 =5.5 mg/m³
Acetic acid exposure: 0.05*22 = 1.1 mg/m³
Sulphuric acid exposure: 0.0096*22 = 0.2112 mg/m³

- Meta SPC 2 – Uses #1, #2 and #3 for the Meta-SPC 2 (product INDAL PAA 2.5):
  PAA exposure : 0.02*22 = 0.44 mg/m³
  H2O2 exposure : 0.355*22 = 7.81 mg/m³
  Acetic acid exposure: 0.022*22 = 0.484 mg/m³
  Sulphuric acid exposure: 0.003*22 = 0.066 mg/m³

- Meta SPC3 – Uses #1, #2, #3, #4, #5, #6 and #7 for the Meta-SPC 3 (product INDAL PAA 5):
  PAA exposure : 0.053*22 = 1.166 mg/m³
  H2O2 exposure : 0.255*22 =5.61 mg/m³
  Acetic acid exposure: 0.082*22 = 1.804 mg/m³
  Sulphuric acid exposure: 0.0096*22 = 0.2112 mg/m³

- Meta SPC 4 – Uses #1 and #2 for the Meta-SPC 4 (product INDAL PAA 15):
  PAA exposure : 0.158*22 = 3.476 mg/m³
  H2O2 exposure : 0.25*22 =5.5 mg/m³
  Acetic acid exposure: 0.138*22 = 3.036 mg/m³
  Sulphuric acid exposure: no sulphuric acid is contained in this formulation

2) For PT 3 applications:
   - Meta SPC 3 – Uses #8, #9, #10, #11, #12 and #13 for the Meta-SPC 3 (product INDAL PAA 5):
     PAA exposure : 0.053*22 = 1.166 mg/m³
     H2O2 exposure : 0.255*22 =5.61 mg/m³
     Acetic acid exposure: 0.082*22 = 1.804 mg/m³
     Sulphuric acid exposure: 0.0096*22 = 0.2112 mg/m³

   - Meta SPC 5 - Use #1 for the Meta-SPC 5 (product INDAL OXY MOUSS):
     PAA exposure : 0.012*22 = 0.264 mg/m³
     H2O2 exposure : 0.13*22 =2.86 mg/m³
     Acetic acid exposure: 0.0575*22 = 1.265 mg/m³
     Sulphuric acid exposure: 0.005*22 = 0.11 mg/m³

3) For PT 4 applications:

- Meta SPC 1 - Uses #3, #4, #5 and #6 for the Meta-SPC 1 (product INDAL PAA 3.5):
  PAA exposure : 0.026*22 = 0.572 mg/m³
  H2O2 exposure : 0.25*22 =5.5 mg/m³
  Acetic acid exposure: 0.05*22 = 1.1 mg/m³
  Sulphuric acid exposure: 0.0096*22 = 0.2112 mg/m³

- Meta SPC 3 – Uses #14, #15, #16, and #17 for the Meta-SPC 3 (product INDAL PAA 5):
  PAA exposure : 0.053*22 = 1.166 mg/m³
  H2O2 exposure : 0.255*22 =5.61 mg/m³
  Acetic acid exposure: 0.082*22 = 1.804 mg/m³
  Sulphuric acid exposure: 0.0096*22 = 0.2112 mg/m³

- Meta SPC 4 – Uses #3 and #4 for the Meta-SPC4 (product INDAL PAA 15):
  PAA exposure : 0.158*22 = 3.476 mg/m³
  H2O2 exposure : 0.25*22 =5.5 mg/m³
  Acetic acid exposure: 0.138*22 = 3.036 mg/m³
  Sulphuric acid exposure: no sulphuric acid is contained in this formulation

- Meta SPC 5 - Use #2 for the Meta-SPC 5 (product INDAL OXY MOUSS):
  PAA exposure : 0.012*22 = 0.264 mg/m³
  H2O2 exposure : 0.13*22 =2.86 mg/m³
  Acetic acid exposure: 0.0575*22 = 1.265 mg/m³
  Sulphuric acid exposure: 0.005*22 = 0.11 mg/m³

- Meta SPC 6 – Use #1 for the Meta-SPC 6 (product INDAL TAP 5):
  PAA exposure : 0.05*22 = 1.1 mg/m³
  H2O2 exposure : 0.21*22 =4.62 mg/m³
  Acetic acid exposure: 0.0595*22 = 1.309 mg/m³
  Sulphuric acid exposure: 0.135*22 = 2.97 mg/m³

Inhalation exposure to aerosol during automatic mixing and loading application for each substance and product

Product	**Substances**	**Exposure type: aerosol [mg/m³]**
INDAL PAA 3.5 (Meta-SPC 1)	Peracetic acid	0.572
	Hydrogen peroxide	5.5
	Acetic acid	1.1

	Sulphuric acid	0.2112
INDAL PAA 2.5 (Meta-SPC 2)	Peracetic acid	0.44
	Hydrogen peroxide	7.81
	Acetic acid	0.484
	Sulphuric acid	0.066
INDAL PAA 5 (Meta-SPC 3)	Peracetic acid	1.166
	Hydrogen peroxide	5.61
	Acetic acid	1.804
	Sulphuric acid	0.2112
INDAL PAA 15 (Meta-SPC 4)	Peracetic acid	3.476
	Hydrogen peroxide	5.5
	Acetic acid	3.036
	Sulphuric acid	-
INDAL OXY MOUSS (Meta-SPC 5)	Peracetic acid	0.264
	Hydrogen peroxide	2.86
	Acetic acid	1.265
	Sulphuric acid	0.11
INDAL TAP 5 (Meta-SPC 6)	Peracetic acid	1.1
	Hydrogen peroxide	4.62
	Acetic acid	1.309
	Sulphuric acid	2.97

Combined risk related to total inhalation exposure to aerosol for each product

	Exposure to aerosol [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.572	5.1	1.1	0.2112
Meta-SPC 2 (INDAL PAA 2.5)	0.44	7.81	0.484	0.066
Meta-SPC 3 (INDAL PAA 5)	1.166	5.61	1.804	0.2112
Meta-SPC 4 (INDAL PAA 15)	3.476	5.5	3.036	n.a.
Meta-SPC 5 (INDAL OXY MOUSS)	0.264	2.86	1.265	0.11

Meta-SPC 6 (INDAL TAP 5)	1.1	5.62	1.309	2.97
AEC for local effects to repiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol (Exposure/AEC) [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	1.144	4.08	0.044	4.224
Meta-SPC 2 (INDAL PAA 2.5)	0.88	6.248	0.0194	1.32
Meta-SPC 3 (INDAL PAA 5)	2.332	4.488	0.0722	4.224
Meta-SPC 4 (INDAL PAA 15)	6.952	4.4	0.1214	n.a.
Meta-SPC 5 (INDAL OXY MOUSS)	0.528	2.288	0.0506	2.2
Meta-SPC 6 (INDAL TAP 5)	2.2	4.496	0.0524	59.4
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 1: Meta-SPC 1 (INDAL PAA 3.5)	5.224		0.044	4.224
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Non acceptable
• **TIER 2: Ventilation rate from 1.5 /h to 10/h**	– 0.78		/	– 0.634
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 1: Meta-SPC 2 (INDAL PAA 2.5)	7.128		0.0194	1.32
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Non acceptable
• **TIER 2: Ventilation rate from 1.5 /h to 10/h**	– 1,07		/	– 0.198
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 1: Meta-SPC 3 (INDAL PAA 5)	6.82		0.0722	4.224
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Non acceptable
• **TIER 2: Ventilation rate from 1.5 /h to 10/h and face mask P1 filter**	0.256		/	– 0.159
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

Tier 1: Meta-SPC 4 (INDAL PAA 15)	11.352	0.11214	n.a.
• **Risk acceptable or non acceptable?**	Non acceptable	Acceptable	n.a.
• **TIER 2: Ventilation rate from 1.5 /h to 10/h and face mask P1 filter**	– 0.426	/	n.a.
• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	n.a.
Meta-SPC 5 (INDAL OXY MOUSS)	2.816	0.0506	2.2
• **Risk acceptable or non acceptable?**	Non acceptable	Acceptable	Non acceptable
• **TIER 2: Ventilation rate from 1.5 /h to 10/h**	– 0.422	/	– 0.33
• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	Acceptable
Tier 1: Meta-SPC 6 (INDAL TAP 5)	6.696	0.0524	59.4
• **Risk acceptable or non acceptable?**	Non acceptable	Acceptable	Non acceptable
• **TIER 2: Ventilation rate from 1.5 /h to 10/h and face mask P2 filter**	– 0.101	/	– 0.892
• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	Acceptable .

n.a. Not applicable because INDAL PAA 15 does not contain sulphuric acid in its formulation.

Conclusions to the primary exposure during manual connecting for automatic mixing and loading system

During manual connecting to automated dosing systems, the risk related to dermal exposure is acceptable if the user wears chemical-resistant gloves, a protective coverall and a face shield due to classification as Skin corrosive and Eye damage of all the concentrated products (pH<2), related to high concentration in peracetic acid and hydrogen peroxide in concentrates.

During this application, all products requires the wearing of a respiratory protective equipment (RPE). Full masks are proposed to also protect the eyes due to the damaging effects to eyes of the biocidal products.

However, different kind of RPE are required, depending on the product.

- For INDAL PAA 3.5 (Meta-SPC 1), INDAL PAA 2.5 (Meta-SPC 2) and INDAL OXY MOUSS (Meta-SPC 5), a ventilation rate of 10 per hour should be used (technical Risk mitigation measures have to be used before PPE;
- For the products INDAL PAA 5 (Meta-SPC 3) and INDAL PAA 15 (Meta-SPC 4), a ventilation rate of 10 per hour and amask with a P1 filter are required to have an acceptable level of exposure and related risk for the user;
- For the product INDAL TAP 5 (Meta-SPC 6)a ventilation rate of 10 and a face mask with a P2 filter are required to have an acceptable level of exposure and related risk for the user.

As there is no systemic toxicity known for peracetic acid and hydrogen peroxide, and that they present risk mainly as corrosive substances, combining exposure makes little sense, and the major risk is presented by the undiluted product used during the M&L step. If the different RMM put in place, including PPE and RPE, can be considered as enough protection during M&L, the diluted product is not seen as problematic.

Scenario 3: Manual spraying on open surfaces for all Meta SPC except Meta SPC4 (INDAL PAA 15) and Meta SPC 6 (INDAL TAP 5)

Please note that there is a high level of uncertainty for all human risk assessment for application by spraying.

The product is sprayed manually with a low-pressure sprayer. This manual application takes place on open surfaces in several industrial/professional sectors.

Please, note that all products for which a manual spraying application takes place, a pre-application dilution step is conducted before. The related exposures to these applications are developed in the scenario 2.

All exposure assessments for manual spraying are conducted with the in-use concentrations to which the user is directly exposed.

After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.

Device to be used for spraying: low-medium pressure (4 to 7 bars) (except spraying on milking claw, with low pressure sprayer with 2 bars).

Please note that the treated surface is not allowed to get dry prior to rinsing.

Provide adequate ventilation before the general public re-enter treated areas. The general public is not allowed to enter the outdoor application site and an area 20 m around during spraying and until the surface is rinsed.

A ventilation rate of 10/hours is required for all applications.

Dermal exposure

To assess the skin exposure to PAA and H_2O_2, a qualitative approach was performed, as indicated in the introduction.

For the biocidal product contained in the Meta SPC 1 (only for PT4 applications)

The PAA and H_2O_2 in-use concentrations are 0.104% w/w and 1.0% w/w, respectively when INDAL PAA 3.5 is used at the maximum efficacy concentration of 4% v/v.

This means that its PAA content is below the skin irritation threshold of 0.2% for the short-term exposure and above 0.1% for the long-term exposure.

For the H_2O_2, the 1.0% w/w concentration is also below the skin irritating threshold of 35% w/w and out of the range that triggers an eye damage 1 ($8\% < C \leq 50\%$) or eye irritation ($5\% < C \leq 8\%$) classification.

Therefore, local eye damage or eye irritating effects are not expected when the INDAL PAA 3.5 (Meta-SPC 1) in-use product is handled during manual spraying application. But local skin irritation is expected. Indeed, manual spraying application can be considered as long-term application.

To protect the user, the risk related to dermal and eye exposures is acceptable with the wearing of chemical-resistant gloves and a protective coverall during the spraying.

For the biocidal product contained in the Meta SPC 2 (only for PT2 applications without activity on algae)

The PAA and H_2O_2 in-use concentrations are 0.08% w/w and 1.42% w/w, respectively when INDAL PAA 2.5 is used at the maximum efficacy concentration of 4% v/v.

This means that its PAA content is below the skin irritation threshold of 0.2% for the short-term exposure and 0.1% for the long-term exposure.

For the H_2O_2, the 1.42% w/w concentration is also below the skin irritating threshold of 35% w/w and out of the range that triggers an eye damage 1 (8%<C≤50%) or eye irritation (5%<C≤8%) classification.

Therefore, local skin irritation, eye damage or eye irritating effects are not expected when the INDAL PAA 2.5 in-use product is handled during manual spraying application.

To protect the user: the risk related to dermal and eye exposures is acceptable without any personal protective equipment.

For the biocidal product contained in the Meta SPC 2 (only for PT2 applications on algae)

The PAA and H2O2 in use concentrations should be 0.024% w/w and 0.3% w/w, respectively when INDAL PAA 2.5 is used at the maximum efficacy concentration of 1.2% v/v.

This means that its PAA content is below the skin irritation threshold of 0.2% for the short-term exposure but above the skin irritation threshold of 0.1% for the long-term exposure.

For the H_2O_2, the 1.775% w/w concentration is also below the skin irritating threshold of 35% w/w and out of the range that triggers an eye damage 1 (8%<C≤50%) or eye irritation (5%<C≤8%) classification.

Therefore, local skin irritation is expected when the INDAL PAA 2.5 in-use product is handled during manual spraying application.

To protect the user: the risk related to dermal and eye exposures is acceptable with the wearing of chemical-resistant gloves and a protective coverall during the spraying.

For the biocidal product contained in the Meta SPC 3 (for PT2 except for activity on algae and PT4 applications)

The PAA and H_2O_2 concentrations are 0.186% w/w and 0.893% w/w, respectively, when INDAL PAA 5 is used at the maximum efficacy concentration of 3.5% v/v, except for disinfection of contaminated milking parlour systems for which the concentrations of both ingredients are 0.0265% w/w and 0.1275% w/w, respectively, when INDAL PAA 5 is used at the concentration of 0,5% v/v.

This means that its PAA content is below the skin irritation threshold of 0.2% for the short-term exposure and above 0.1% for the long-term exposure when used at the maximum efficacy concentration of 3% v/v.

For the H_2O_2, the 1.0% w/w concentration is also below the skin irritating threshold of 35% w/w and out of the range that triggers an eye damage 1 (8%<C≤50%) or eye irritation (5%<C≤8%) classification.

Therefore, local eye damage or eye irritating effects are not expected when the INDAL PAA 5 in-use product is handled during manual spraying application at the maximum efficacy concentration of 3% v/v. But local skin irritation is expected. Indeed, manual spraying application can be considered as long-term application.

To protect the user, the risk related to dermal and eye exposures is acceptable with the wearing of chemical-resistant gloves and a protective coverall during the spraying.

For disinfection of contaminated milking parlour systems, local skin irritation, eye damage or eye irritating effects are not expected when the INDAL PAA 5 in-use product is handled during manual spraying application at the concentration of 0.5% v/v. The risk related to dermal and eye exposures is acceptable without any personal protective equipment.

For the biocidal product contained in the Meta SPC 3 (for PT2 activity on algae and PT3 applications)

The PAA and H2O2 concentrations are 0.0636% w/w and 0.306% w/w, respectively, when INDAL PAA 5 is used at the maximum efficacy concentration of 1.2% v/v, against algae (PT2) and are 0.106% w/w 0.51% w/w respectively when used at the maximum efficacy concentration of 2% (see use 3.12) except for disinfection of contaminated milking parlour systems for which the concentrations of both ingredients are 0.0318% w/w and 0.153% w/w, respectively, when INDAL PAA 5 is used at the concentration of 0,6% v/v.

This means that its PAA content is above the skin irritation threshold of 0.2% for the short-term exposure and the 0.1% threshold for the long-term exposure when used at the maximum efficacy concentration of 5% v/v.

For the H2O2, the 1.275% w/w concentration is also below the skin irritating threshold of 35% w/w and out of the range that triggers an eye damage 1 (8%<C≤50%) or eye irritation (5%<C≤8%) classification.

Therefore, local eye damage or eye irritating effects are not expected when the INDAL PAA 5 in-use product is handled during manual spraying application at the maximum efficacy concentration of 5% v/v. But local skin irritation is expected. Indeed, manual spraying application can be considered as long-term application.

To protect the user, the risk related to dermal and eye exposures is acceptable with the wearing of chemical-resistant gloves and a protective coverall during the spraying.

For disinfection of contaminated milking parlour systems, local skin irritation, eye damage or eye irritating effects are not expected when the INDAL PAA 5 in-use product is handled during manual spraying application at the concentration of 0.5% v/v. The risk related to dermal and eye exposures is acceptable without any personal protective equipment.

For the biocidal product contained in the Meta SPC 5 (for PT 3 and PT 4 applications)

The PAA and H_2O_2 concentrations are 0.06% w/w and 0.65% w/w, respectively for PT 3 and PT4 applications, when INDAL OXY MOUSS is used at the maximum efficacy concentration of 5% v/v.

This means that its PAA content is below the skin irritation threshold of 0.2% for the short-term exposure and 0.1% for the long-term exposure.

For the H_2O_2, the 0.65% w/w concentration is also below the skin irritating threshold of 35% w/w and out of the range that triggers an eye damage 1 (8%<C≤50%) or eye irritation (5%<C≤8%) classification.

Therefore, local skin irritation, eye damage or eye irritating effects are not expected when the INDAL OXY MOUSS in-use product is handled during manual spraying application.

To protect the user: the risk related to dermal and eye exposures is acceptable without any personal protective equipment.

Inhalation exposure

For local effects to respiratory tract, exposure to aerosol is taken into account. But, the exposure to vapour is also considered for the highly volatile substances (PAA, H_2O_2 and acetic acid).

To assess the exposure to **aerosol**, the Spraying Model 2 TNsG 2002 with an indicative value of 76 mg/m³ for inhalation exposure was used. This inhalation indicative value is in accordance with ECHA recommendation N°6 (updated version of February 2017- version 3)[17].

Description of Scenario 3: Manual spraying – Exposure to aerosol

This scenario applies for the next uses:

1) For PT 2 applications:
   - Meta SPC 2 – Use #2 (not for application on algae) for the Meta-SPC 1 (product INDAL PAA 2.5):

     PAA exposure : 0.0008*76 = 0.0608 mg/m³

     H2O2 exposure : 0.0142*76 = 1.0792 mg/m³

     Acetic acid exposure: 0.00088*76 = 0.0669 mg/m³

     Sulphuric acid exposure: 0.00012*76 = 0.00912 mg/m³

   - Meta SPC 2 – Use #2 (for application on algae) for the Meta-SPC 2 (product INDAL PAA 2.5):

     PAA exposure : 0.001*76 = 0.076 mg/m³

     H2O2 exposure : 0.0178*76 = 1.353 mg/m³

     Acetic acid exposure: 0.0011*76 = 0.0836 mg/m³

     Sulphuric acid exposure: 0.00015*76 = 0.0114 mg/m³

   - Meta SPC3 – Use #1 (not for application on algae) for the Meta-SPC 3 (product INDAL PAA 5):

     PAA exposure : 0.00159*76 = 0.1208 mg/m³

     H2O2 exposure : 0.00765*76 =0.5814 mg/m³

     Acetic acid exposure: 0.00246*76 = 0.187 mg/m³

     Sulphuric acid exposure: 0.000288*76 = 0.0219 mg/m³

   - Meta SPC3 – Use #1 (for application on algae) for the Meta-SPC 3 (product INDAL PAA 5):

     PAA exposure : 0.00265*76 = 0.2014 mg/m³

     H2O2 exposure : 0.01275*76 =0.969 mg/m³

     Acetic acid exposure: 0.0041*76 = 0.3116 mg/m³

     Sulphuric acid exposure: 0.00048*76 = 0.03648 mg/m³

[17] BPC Ad hoc Working Group on Human Exposure. ECHA Recommandation N°6 – Methods and models to assess exposure to biocidal products in different product types versio 3. 2017

2) For PT 3 applications:
   - Meta SPC3 – Use #12 for the Meta-SPC 3 (product INDAL PAA 5):
     PAA exposure : 0.00265*76 = 0.2014 mg/m³
     H2O2 exposure : 0.01275*76 =0.969 mg/m³
     Acetic acid exposure: 0.0041*76 = 0.3116 mg/m³
     Sulphuric acid exposure: 0.00048*76 = 0.03648 mg/m³

   - Meta SPC 3 - Use #8 for the Meta-SPC 3 (product INDAL PAA 5):
     PAA exposure : 0.000265*76 = 0.02014 mg/m³
     H2O2 exposure : 0.001275*76 =0.0969 mg/m³
     Acetic acid exposure: 0.00041*76 = 0.03116 mg/m³
     Sulphuric acid exposure: 0.000048*76 = 0.0036 mg/m³

   - Meta SPC 5 - Use #1 for the Meta-SPC 5 (product INDAL OXY MOUSS):
     PAA exposure : 0.0006*76 = 0.0456mg/m³
     H2O2 exposure : 0.0065*76 = 0.494 mg/m³
     Acetic acid exposure: 0.002875*76 = 0.2185 mg/m³
     Sulphuric acid exposure: 0.00025*76 = 0.019 mg/m³

3) For PT 4 applications:
   - Meta SPC 1 - Use #3 for the Meta-SPC 1 (product INDAL PAA 3.5):
     PAA exposure : 0.00104*76 = 0.079 mg/m³
     H2O2 exposure : 0.01*76 = 0.76 mg/m³
     Acetic acid exposure: 0.002*76 = 0.152 mg/m³
     Sulphuric acid exposure: 0.000384*76 = 0.0292 mg/m³

   - Meta SPC 3 – Use #14 for the Meta-SPC 3 (product INDAL PAA 5):
     PAA exposure : 0.00159*76 = 0.1208 mg/m³
     H2O2 exposure : 0.00765*76 =0.5814 mg/m³
     Acetic acid exposure: 0.00246*76 = 0.187 mg/m³
     Sulphuric acid exposure: 0.000288*76 = 0.0219 mg/m³

   - Meta SPC 5 - Use #2 for the Meta-SPC 5 (product INDAL OXY MOUSS):
     PAA exposure : 0.0006*76 = 0.0456mg/m³
     H2O2 exposure : 0.0065*76 = 0.494 mg/m³
     Acetic acid exposure: 0.002875*76 = 0.2185 mg/m³
     Sulphuric acid exposure: 0.00025*76 = 0.019 mg/m³

To assess the exposure to **Vapour** for **PT 2** applications, the model "Exposure to vapour – Evaporation" of the "Disinfectant products fact sheet" of the online program ConsExpo Web[18] was applied.

The private area is related to application of the product in Swimming pool of an hostel of in a balneotherapy of an hostel, or a fitness.

As stated in the HEAd hoc recommendation 15 for small-scale disinfection for PT2, the health-care situation represents a worst-case here in terms of combination room volume-ventilation rate.

Please note the worst-case scenario of the complete human health risk assessment related to the exposure to the product applied in institutions by spraying to treat algae i.e. Scenario 3.1.4 was re-simulated with the default room value for health care institutions (80 m^3) and the ventilation rate of 1.5/hour as stated in HEAd hoc recommendation 15 , i.e. Scenario 3.1.4.

The obtained combined risk values to peracetic acid and hydrogen peroxide, i.e. 25.2344 and 39.978, respectively do not change the conclusions of the exposure and a Respiratory protective equipment with a P3 filter can still be proposed.

So, it can be assumed the use of 80 m^3 and 1.5/hour would not have any impact on the proposed risk mitigation measures, the user being already sufficiently protected.

18 L.C.H. Prud'homme de Lodder, H.J. Bremmer, S.M.G.J. Pelgrom, M.V.D.Z. Park, J.G.M. van Engelen. Disinfectant Products Fact Sheet to assess the risks fort he consumer. RIVM report 320005003/2006, 2006. P 21, P27-28.

Description of Scenario 3.1: Manual spraying on open surfaces for PT2 applications – Exposure to vapour

This scenario applies for the next uses:

a) The products INDAL PAA 2.5 (Meta-SPC 2) and INDAL PAA 5 (Meta-SPC 3) are used in industrial buildings to disinfect open surfaces, materials, the walls, the floor, furniture.
   - All these surfaces are considered as large scale surfaces

b) The products INDAL PAA 2.5 (Meta-SPC 2) and INDAL PAA 5 (meta-SPC 3) are used in industries to disinfect equipment
   - This is considered as a small scale disinfection that takes place in the industries directly

c) The product INDAL PAA 2.5 (Meta-SPC 2) and INDAL PAA 5 (meta-SPC 3) are used by spraying in industrial areas and in other areas for professional activities in order to treat the surfaces against algae.
   - For this application a separate model is developed taking into account the disinfection of small-scale surfaces in institutions as this area is considered as the worst-case if exposure related to uses a, b and c are compared (please refer to the expoisure assessment developed here below)

So, scenario 3.1 is declined in three separated scenarios:

- one for the large scale spraying application on floor, walls and ceilings in large scale industries: scenario 3.1.1
- one for the small scale spraying disinfection of equipment in large scale industries, scenario 3.1.2.
- one for the small scale spraying disinfection of floor, walls, ceilings and equipment in small scale institutions, scenario 3.1.2.

Description of Scenario 3.1.1: Manual spraying for PT2-large scale disinfection in industries – Exposure to vapour			
Since it is an exposure assessment for local effects on respiratory tract, the frequency of application does not play a role in the model.			
	Parameters	**Value**	**Reference**
Tier 1	Exposure duration	480 minutes	In the RIVM factsheet the application speed is derived because 5000 mL is applied in 16,7 min, based on the application rate of 300 mL/m2. Regarding this BPF, as described in each scenario the application rate is 20 mL/m2, meaning that a user can treat 250 m2 (5000 mL/20 ml/m2) in 16,7 min. This is equal to the application speed of ca 15 m2/min. This should normally lead to a reduced treatment time, of 66 minutes. In order to take into account the possibility that multiple warehouse and/or surfaces are being treated, a normal duration of 480 minutes is chosen.
	Product amount	1) <u>For INDAL PAA 2.5 (Meta-SPC 2):</u> 20 000 mL*1.14 = 22 800 g 2) <u>For INDAL PAA 5 (Meta-SPC 3):</u> 20 000 mL*1.122 = 22 440 g	Applicant's information The application rate is 20 mL/m², the treated surface is 1000 m² and the product density is 1.14 for INDAL PAA 2.5 and 1.122 for INDAL PAA 5.

	Weight fraction substance	1) <u>For INDAL PAA 2.5 (Meta-SPC 2):</u> PAA: 0.0008 H2O2: 0.0142 CH3COOH: 0.00088 2) <u>For INDAL PAA 5 (Meta-SPC 3):</u> PAA: 0.00159 H2O2: 0.00765 CH3COOH: 0.00246	Applicant's information. Worst-case dilution at 4% for INDAL PAA 2.5 and at 3% for INDAL PAA 5
	Room volume	900 m³	Expert's judgement as no default value stated. Estimated considering a room with a cuboid shape. If the total surface of the room including the ceiling, the walls and the floor is 1000 m² and the height of the walls is 2.5 m (default value for a non-specified room, ConsExpo, general fact sheet), the report volume per surface is 0.9. So, the room volume is 0.9*1000 = 900 m³[19].

19 http://www.toutcalculer.com/geometrie/volume-surface-parallelepipede-rectangle.php august 2017

	Ventilation rate	1.5/hour	Default value for hospital rooms according to HEAdhoc Recommendation no. 9, 2016)[20] and 3/h (best case assumption for well ventilated rooms) is observed, probably due to the short application and exposure duration. Furthermore, ventilation rate is assumed to be at least 2 air change per hour in "Recommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfectionRecommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfection" that gives air change rates in typical rooms and building. Thus, this worst case ventilation rate of 1.5/h is considered for the exposure assessments.
	Inhalation rate	1.37 m^3/hr	Default inhalation rate for an adult during light exercise (ConsExpo).
	Vapour pressure	For PAA: 1410 Pa For H2O2: 214 Pa For CH3COOH: 2079 Pa	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: information taken on the ingredient's suppliers (please refer to SDS documents provided in the dossier)
	Application temperature	20°C	Application temperature given by the applicant (ambient temperature)

20 Recommendatioon no. 9 of the BPC Ad hoc Working Group on Human Exposure. Hand disinfection in hospitals. Revision agreed at the Human Health Working Group I. January 2017.

	Molecular weight	For PAA: 76.05 g/mol For H2O2: 34.01 g/mol For CH3COOH: 60.05 g/mol	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: no information in the SDS or in the REACH dossier. So the value was calculated based on the molecular formula.
	Mass transfer coefficient	10 m/hour	Estimated with the Thibodeau's
	Release area mode, increasing: Release area Application duration	1000 m² 120 min	The treated surface is increasing over the time. The total treated surface is 1000 m² and the application duration is 668 minutes, as already mentioned above.
	Molecular weight matrix	18 g/mol	Since the disinfection of surfaces is performed with a diluted solution of the product, the default value of 18 g/mol for water-based products is considered for the input parameter.
Tier 2	Exposure and application duration	120 minutes	A professional works a maximum of 8 hours a day. So, the maximum exposure and application durations of a single worker is 480 minutes.
	Release area	718.6 m²	If the maximum exposure and application duration for a single user is 480 minutes, the maximum treated surface is 480 / (16.7/25) = 718.6 m², by extrapolation of the default value from ConsExpo disinfectant products factsheet.

	Product amount	1) For INDAL PAA 2.5 (Meta-SPC 2): 16384 g 2) For INDAL PAA 5 (Meta-SPC 3): 16125.4 g	Applicant's information. The application rate is 20 mL/m², the treated surface is 718.6 m² and the product density is 1.14 for INDAL PAA 2.5 and 1.122 for INDAL PAA 5.
	Ventilation rate	10/hour	As decided by discussion during the referral.

Combined inhalation exposure to aerosol and vapour during manual spraying for PT2 large scale disinfection in industries for each substance and product

Exposure type	**Substances**	**Exposure to INDAL PAA 2.5 (Meta-SPC 2) [mg/m³]**	**Exposure to INDAL PAA 5 (meta-SPC 3) [mg/m³]**
Exposure to aerosol	Peracetic acid	0.0608	0.1208
	Hydrogen peroxide	1.0792	0.5814
	Acetic acid	0.0669	0.187
	Sulphuric acid	0.00912	0.0219
Exposure to vapour	Peracetic acid	0.75	1.5
	Hydrogen peroxide	8.2	4.4
	Acetic acid	0.76	2.4
	Sulphuric acid	n.a.	n.a.
Total exposure to aerosol and vapour	Peracetic acid	0.8108	1.6208
	Hydrogen peroxide	9.2792	4.9814
	Acetic acid	0.8269	2.587
	Sulphuric acid	0.00912	0.0219

n.a. Not applicable because sulphuric acid is slightly volatile

Combined risk related to total inhalation exposure during manual spraying for PT2 large scale disinfection in industries for each product

Please note that, as all Tier 1 scenario were above the limit, only values for tier 2 and tier 3 (RPE) are provided

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 2 (INDAL PAA 2.5)	0.71	6.8	0.79	0.00051
Meta-SPC 3 (INDAL PAA 5)	1.6	4.2	2.5	0.0014
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 2 (INDAL PAA 2.5)	1.42	5.44	0.0316	0.0102
Meta-SPC 3 (INDAL PAA 5)	3.2	3.36	0.10	0.028
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 2 (INDAL PAA 2.5)	6.86		0.0316	0.0102
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P2 filter to protect respiratory tract – 0.686		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 3 (INDAL PAA 5)	6.56		0.1035	0.438
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P2 filter to protect respiratory tract – 0.656		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

Description of Scenario 3.1.2: Manual spraying for PT2-small scale disinfection in industries – Exposure to vapour			
Since it is an exposure assessment for local effects on respiratory tract, the frequency of application does not play a role in the model.			
	Parameters	**Value**	**Reference**
Tier 1	Exposure duration	120 minutes	Default value from ConsExpo, Disinfectant products fact sheet. Indeed, for knapsack application[21], exposure and application durations are 16.7 minutes for a surface of 25 m². Here, for small scale disinfection for PT2, the total treated surface is 100 m² (from Supplement to the ESD for PT2: Emission scenarios for private and public health area disinfectants and other biocidal products, JRC Scientific and Technical Reports, 2011, p11)[22]. The exposure and application durations are: 120 minutes, as default.
	Product amount	1) <u>For INDAL PAA 2.5 (Meta-SPC 2):</u> 2000 mL*1.14 = 2280 g 2) <u>For INDAL PAA 5 (Meta-SPC 3):</u> 2000 mL*1.122 = 2244 g	Applicant's information The application rate is 20 mL/m², the treated surface is 100 m² and the product density is 1.14 for INDAL PAA 2.5 and 1.122 for INDAL PAA 5.

21 L.C.H. Prud'homme de Lodder, H.J. Bremmer, S.M.G.J. Pelgrom, M.V.D.Z. Park, J.G.M. van Engelen. Disinfectant Products Fact Sheet to assess the risks fort he consumer. RIVM report 320005003/2006, 2006. pp35.

22 Drafted by Scientific Consulting Company (SCC) GmbH Revised by the Biocides Technical Meeting Endorsed by the Biocides Competent Authorities Meeting Edited by B. Raffael and E. van de Plassche. Emission Scenario Document for Product type 2. Private and public health aera disinfectantcs and other biocidal products. JRC Scientific and Technical Reports, 2011. p11

	Weight fraction substance	1) <u>For INDAL PAA 2.5 (Meta-SPC 2):</u> PAA: 0.0008 H2O2: 0.0142 CH3COOH: 0.00088 2) <u>For INDAL PAA 5 (Meta-SPC 3):</u> PAA: 0.00186 H2O2: 0.00893 CH3COOH: 0.00287	Applicant's information. Worst-case dilution at 4% for INDAL PAA 2.5 and at 3.5% for INDAL PAA 5
	Room volume	900 m³	Expert's judgement as no default value stated. Estimated considering a room with a cuboid shape. If the total surface of the room including the ceiling, the walls and the floor is 1000 m² and the height of the walls is 2.5 m (default value for a non-specified room, ConsExpo, general fact sheet), the report volume per surface is 0.9. So, the room volume is 0.9*1000 = 900 m³.[23]

23 http://www.toutcalculer.com/geometrie/volume-surface-parallelepipede-rectangle.php august 2017

	Ventilation rate	1.5/hour	Default value for hospital rooms according to HEAdhoc Recommendation no. 9, 2016)[24] and 3/h (best case assumption for well ventilated rooms) is observed, probably due to the short application and exposure duration. Furthermore, ventilation rate is assumed to be at least 2 air change per hour in "Recommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfection" that gives air change rates in typical rooms and building. Thus, this worst case ventilation rate of 1.5/h is considered for the exposure assessments.
	Inhalation rate	1.37 m³/hr	Default inhalation rate for an adult during light exercise (ConsExpo).
	Vapour pressure	For PAA: 1410 Pa For H2O2: 214 Pa For CH3COOH: 2079 Pa	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: information taken on the ingredient's suppliers (please refer to SDS documents provided in the dossier)
	Application temperature	20°C	Application temperature given by the applicant (ambient temperature)

24 Recommendatioon no. 9 of the BPC Ad hoc Working Group on Human Exposure. Hand disinfection in hospitals. Revision agreed at the Human Health Working Group I. January 2017.

	Molecular weight	For PAA: 76.05 g/mol For H2O2: 34.01 g/mol For CH3COOH: 60.05 g/mol	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: no information in the SDS or in the REACH dossier. So the value was calculated based on the molecular formula.
	Mass transfer coefficient	10 m/hour	with the Thibodeau's
	Release aera mode, increasing: Release area Application duration	100 m² 120 min	The treated surface is increasing over the time. The total treated surface is 100 m² .
	Molecular weight matrix	18 g/mol	Since the disinfection of surfaces is performed with a diluted solution of the product, the default value of 18 g/mol for water-based products is considered for the input parameter.
Tier 2	Ventilation rate	10/hour	As decided during referal

<u>Combined inhalation exposure to aerosol and vapour during manual spraying for PT2 small scale disinfection in industries for each substance and product</u>

Exposure type	**Substances**	**Exposure to INDAL PAA 2.5 (Meta-SPC 2) [mg/m³]**	**Exposure to INDAL PAA 5 (Meta-SPC 3) [mg/m³]**
Exposure to aerosol	Peracetic acid	0.0608	0.1208
	Hydrogen peroxide	1.0792	0.5814
	Acetic acid	0.0669	0.187
	Sulphuric acid	0.00912	0.0219
Exposure to vapour	Peracetic acid	0.43	0.84
	Hydrogen peroxide	3.6	1.9

	Acetic acid	0.51	1.4
	Sulphuric acid	n.a.	n.a.
Total exposure to aerosol and vapour	Peracetic acid	0.4908	0.9608
	Hydrogen peroxide	4.6792	2.4814
	Acetic acid	0.5769	1.587
	Sulphuric acid	0.00912	0.0219

n.a. Not applicable because sulphuric acid is slightly volatile

Combined risk related to total inhalation exposure during manual spraying for PT2 small scale disinfection in industries for each product

As all Tier 1 scenario were above the AEC, only values for tier 2 and tier 3 (RPE) are provided below.

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 2 (INDAL PAA 2.5)	0.099	1.8	0.11	0.00011
Meta-SPC 3 (INDAL PAA 5)	0.23	0.78	0.35	0.00031
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 2 (INDAL PAA 2.5)	0.198	1.44	0.0044	0.0.0022
Meta-SPC 3 (INDAL PAA 5)	0.46	0.624	0.014	0.0062
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 2 (INDAL PAA 2.5)	1.638		0.0044	0.0022
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.4095		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 3 (INDAL PAA 5)	1.084		0.014	0.0062
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable

• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.271	/	/
• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	Acceptable

n.a. Not applicable because sulphuric acid is slightly volatile

ng manual.

Description of Scenario 3.2: Manual spraying of on open surfaces for PT3 applications – Exposure to vapour

This scenario applies for the next uses:

1) The Meta-SPC 3 (product INDAL PAA 5) and Meta-SPC 5 (INDAL OXY MOUSS) are used in animal husbandry to disinfect open surfaces, walls, ceiling
   - This is a large scale disinfection that is developed for poultry and pig houses. These two animal houses have the worst-case large scale surface disinfection and covers other animal housing uses.

2) The Meta-SPC 3 (productsINDAL PAA 5) and Meta-SPC 5 (product INDAL OXY MOUSS) are used in animal husbandry to disinfect materials and furniture
   - This is a small scale disinfection that is developed for poultry and pig houses. These two animal houses have the worst-case large scale surface disinfection and covers other animal housing uses.

3) The product INDAL OXY MOUSS from Meta-SPC 5 is also used for the disinfection of vehicles for animal transport.

4) The product INDAL PAA 5 from Meta-SPC 3 is used to disinfect milking parlour by spraying. The exposure is only assessed for the treatment of one system as the user is only exposed to the product for its local effects. So, the exposure is assumed to be exactly the same for each disinfection and as these treatments occur separately in the time, they are not summed up.

So, scenario 3.2 is declined in four separated scenarios:

- one for the large scale spraying application on floor, walls and ceilings: scenario 3.2.1-a and 3.2.1-b (for poultry and pig houses respectively)
- one for the small scale spraying disinfection of equipment in animal house, scenario 3.2.2-a and 3.2.2-b (for poultry and pig houses respectively)
- one for the small scale spraying disinfection of vehicles used for animal transport, scenario 3.2.3.
- one for the spraying disinfection of contaminated milking parlour systems, scenario 3.2.4.

Description of Scenario 3.2.1: Manual spraying for PT3-large scale disinfection in animal houses – Exposure to vapour			
a) In poultry houses b) In pig houses Since it is an exposure assessment for local effects on respiratory tract, the frequency of application does not play a role in the model.			
	Parameters	**Value**	**Reference**

Tier 1	Exposure duration	a) 536 minutes b) (146.6) minutes	Default value from ConsExpo, Disinfectant products fact sheet. Indeed, for knapsack application[25], exposure and application durations are 16.7 minutes for a surface of 25 m². Here, however, for large scale disinfection for PT3, the total treated surface is The disinfection is performed with a low-medium pressure spraying device (4-7 bars), with an application speed of 15 m^2/min: a) 8040 m² for the worst-case poultry housing (walls, roof, floor and other area), that is for Turkey poultry from ESD for PT3 (Emission scenarios for veterinary hygiene biocidal products, JRC Scientific and Technical Reports, 2011, p51)[26]. The exposure and application durations are: 8040/15 = 536 minutes b) 2220 m² for the worst-case poultry housing (walls, roof, floor, slatted area and other area), that is for sows in group from ESD for PT3 (Emission scenarios for veterinary hygiene biocidal products, JRC Scientific and Technical Reports, 2011, p51)[27]. The exposure and application durations are: 2200/15 = 146.6 minutes. As a full day of work is at 480 minutes, and that it is possible that more than one warehouse is treated, we use 480 minutes as a worst case.

25 L.C.H. Prud'homme de Lodder, H.J. Bremmer, S.M.G.J. Pelgrom, M.V.D.Z. Park, J.G.M. van Engelen. Disinfectant Products Fact Sheet to assess the risks fort he consumer. RIVM report 320005003/2006, 2006. p35.

26 Drafted by Scientific Consulting Company (SCC) GmbH Revised by the Biocides Technical Meeting Endorsed by the Biocides Competent Authorities Meeting Edited by B. Raffael and E. van de Plassche. Emission Scenario Document for Product Type 3. Veterinary hygiene biocidal products. JRC Scientific and Technical Reports. 2011. p51

27 Cfr Reference 39

	Product amount	<u>For INDAL PAA 5 (Meta-SPC 3):</u> a) 1 608 000 mL*1.122 = 1 804 176 g b) 440 000 mL*1.122 = 49 3 680 g <u>For INDAL OXY MOUSS (Meta-SPC 5):</u> a) 402 000 mL*1.064 = 427 728 g b) 110 000 mL*1.064 = 117 040 g	Applicant's information. For <u>INDAL PAA 5</u>, the application rate is 200 mL/m². a) the treated surface is 8040 m² and the product density is 1.122 b) the treated surface is 2200 m² and the product density is 1.122. For <u>INDAL OXY MOUSS, t</u>he application rate is 50 mL/m². a) the treated surface is 8040 m² and the product density is 1.064. b) the treated surface is 2200 m² and the product density is 1.064.
	Weight fraction substance	<u>For INDAL PAA 5 (Meta-SPC 3):</u> PAA: 0.00265 H2O2: 0.01275 CH3COOH: 0.0041 <u>For INDAL OXY MOUSS (Meta-SPC 5):</u> PAA: 0.0006 H2O2: 0.0065 CH3COOH: 0.002875	Applicant's information Worst-case dilution: 5% for INDAL PAA 5 5 % for INDAL OXY MOUSS.

	Room volume	a) 7182 m³ b) 1683 m³	Expert's judgement as no default value is referenced. Estimated considering a room with a cuboid shape. If the total surface of the room including the ceiling, the walls and the floor is a) 7980 m² and b) 1870 m² and the height of the walls is 2.5 m (default value for a non-specified room, ConsExpo, general fact sheet), the report volume per surface is 0.9[28]. So, the room volume is a) 0.9*7980 = 7182 m³ b) 0.9*1870 = 1683 m³
	Ventilation rate	1.5/hour	Default value for hospital rooms according to HEAdhoc Recommendation no. 9, 2016)[29] and 3/h (best case assumption for well ventilated rooms) is observed, probably due to the short application and exposure duration. Furthermore, ventilation rate is assumed to be at least 2 air change per hour in "Recommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfection" that gives air change rates in typical rooms and building. Thus, this worst case ventilation rate of 1.5/h is considered for the exposure assessments.
	Inhalation rate	1.37 m³/hr	Default inhalation rate for an adult during light exercise (ConsExpo).

28 http://www.toutcalculer.com/geometrie/volume-surface-parallelepipede-rectangle.php

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29 Recommendatioon no. 9 of the BPC Ad hoc Working Group on Human Exposure. Hand disinfection in hospitals. Revision agreed at the Human Health Working Group I. January 2017.

	Vapour pressure	For PAA: 1410 Pa For H2O2: 214 Pa For CH3COOH: 2079 Pa	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: information taken on the ingredient's suppliers (please refer to SDS documents provided in the dossier)
	Application temperature	20°C	Application temperature given by the applicant
	Molecular weight	For PAA: 76.05 g/mol For H2O2: 34.01 g/mol For CH3COOH: 60.05 g/mol	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: no information in the SDS or in the REACH dossier. So the value was calculated based on the molecular formula.
	Mass transfer coefficient	10 m/hour	Estimated with the Thibodeau's method
	Release aera mode, increasing: Release area Application duration	a) 8040 m² and 536 min b) 2200 m² and 146.6 min	The treated surface is increasing over the time. The total treated surface is: a) 8040 m² and the application duration is 536 minutes, as already mentioned above for poultry. b) 2200 m² and the application duration is 146.6 minutes, as already mentioned above for poultry.
	Molecular weight matrix	18 g/mol	Since the disinfection of surfaces is performed with a diluted solution of the product, the default value of 18 g/mol for water-based products is considered for the input parameter.

Tier 2	Exposure and application duration	120 minutes	As discussed during the Referral
	Release area	a) and b) 718.6 m²	If the maximum exposure and application duration for a single user is 480 minutes, the maximum treated surface is 480 / (16.7/25) = 718.6 m², by extrapolation of the default value from ConsExpo disinfectant factsheet.
	Product amount	a) and b) For INDAL PAA 5 (Meta-SPC 3): 161 254 g For INDAL OXY MOUSS (Meta-SPC 5): 38 229.5 g	Applicant's information. The treated surface is 718.6 m². INDAL PAA 5, the application rate is 200 mL/m² and the density is 1.122. INDAL OXY MOUSS, the application rate is 50 mL/m² and the density is 1.064.
	Ventilation rate	a) and b) 10/hour	As decided during the referral.

Combined inhalation exposure to aerosol and vapour during manual spraying for PT3 large scale disinfection in animal houses for each substance and product

Poultry houses			
Exposure type	**Substances**	**Exposure to Meta-SPC 3 (INDAL PAA 5) [mg/m³]**	**Exposure to Meta-SPC 5 (INDAL OXY MOUSS) [mg/m³]**
Exposure to aerosol	Peracetic acid	0.3021	0.0684
	Hydrogen peroxide	1.4535	0.741
	Acetic acid	0.4674	0.32775
	Sulphuric acid	0.05472	0.0285
Exposure to vapour	Peracetic acid	1.278	0.093
	Hydrogen peroxide	5.58	0.825

	Acetic acid	1.98	0.45
	Sulphuric acid	n.a.	n.a.
Total exposure to aerosol and vapour	Peracetic acid	1.5801	0.1614
	Hydrogen peroxide	7.0335	1.566
	Acetic acid	2.4474	0.7778
	Sulphuric acid	0.05472	0.0285
Pig houses			
Exposure type	**Substances**	**Exposure to Meta-SPC 3 (INDAL PAA 5) [mg/m³]**	**Exposure to Meta-SPC 5 (INDAL OXY MOUSS) [mg/m³]**
Exposure to aerosol	Peracetic acid	0.3021	0.0684
	Hydrogen peroxide	1.4535	0.741
	Acetic acid	0.4674	0.32775
	Sulphuric acid	0.05472	0.0285
Exposure to vapour	Peracetic acid	5.4	0.39
	Hydrogen peroxide	21.6	3.0
	Acetic acid	8.46	1.95
	Sulphuric acid	n.a.	n.a.
Total exposure to aerosol and vapour	Peracetic acid	5.7021	0.4584
	Hydrogen peroxide	23.0535	3.741
	Acetic acid	8.9274	2.27775
	Sulphuric acid	0.05472	0.0285

n.a. Not applicable because sulphuric acid is slightly volatile

<u>Combined risk related to total inhalation exposure during manual spraying for PT3 large scale disinfection in animal houses for each product</u>

Since all Tier 1 value were above AEC, only Tier 2 and Tier 3 (RPE) values are proposed here:

Poultry houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 3 (INDAL PAA 5)	1.6	1.7	3.2	0.00041

Meta-SPC 5 (INDAL OXY MOUSS)	0.15	0.7	0.75	0.00021
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	3.2	1.36	0.128	0.0082
Meta-SPC 5 (INDAL OXY MOUSS)	0.3	0.56	0.0.03	0.0042
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	4.56		0.128	0.0082
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P2 filter to protect respiratory tract – 0.456		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	0.86		0.0.03	0.0042
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
•				
•				
Pig houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**

Tier 2: Meta-SPC 3 (INDAL PAA 5)	5.9	5.6	12	0.00140
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	0.62	2.4	3.1	0.00071
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	11.8	4.48	0.48	0.028
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	1.24	1.92	0.124	0.0142
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	16.28		0.48	0.028
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.407		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	3.16		0.124	0.028
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.79		/	/
• **Risk acceptable**	Acceptable		Acceptable	Acceptable

of non acceptable?			

Worst Case approach

As the conditions stated above were deemed not worst case enough, (especially due to the dimension of the room chosen), it was decided to proceed with a worst case assessment with the smallest room dimension possible: parent boilers.

The conditions applied for this worst case assessment can be found below:

Description of Scenario 3.2.1: Manual spraying for PT3-large scale disinfection in animal houses – Exposure to vapour – Worst Case approach

The worst case approach is identified with the following conditions:

- Room size: smaller surface possible (the link between volume and surface makes it so that a smaller room will lead to a higher concentration.
- Ventilation rate: 1.5/h
- Exposure duration: 480 min (one working day)

Since it is an exposure assessment for local effects on respiratory tract, the frequency of application does not play a role in the model.

	Parameters	**Value**	**Reference**
Tier 1	Exposure duration	480 minutes	The disinfection is performed with a low-medium pressure spraying device (4-7 bars), with an application speed of 15 m^2/min and for a surface of 1290 m^3 The exposure and application durations are: 1290/15 = 86 minutes. However, as a full day of work is at 480 minutes, and that it is possible that more than one warehouse is treated, we use 480 minutes as a worst case.
	Product amount	For INDAL PAA 5 (Meta-SPC 3): 258 000 mL*1.122 = 1 289 476 g For INDAL OXY MOUSS (Meta-SPC 5): 64 500 mL*1.064 = 68 628 g	Applicant's information. For INDAL PAA 5, the application rate is 200 mL/m². the treated surface is 1290 m² and the product density is 1.122 For INDAL OXY MOUSS, the application rate is 50 mL/m². the treated surface is 1290 m² and the product density is 1.064.

	Weight fraction substance	<u>For INDAL PAA 5 (Meta-SPC 3):</u> PAA: 0.00265 H2O2: 0.01275 CH3COOH: 0.0041 <u>For INDAL OXY MOUSS (Meta-SPC 5):</u> PAA: 0.0006 H2O2: 0.0065 CH3COOH: 0.002875	Applicant's information Worst-case dilution: 5% for INDAL PAA 5 5 % for INDAL OXY MOUSS.
	Room volume	1161 m³	Expert's judgement as no default value is referenced. Estimated considering a room with a cuboid shape. If the total surface of the room including the ceiling, the walls, slatted area and the floor is 1290 m² and the height of the walls is 2.5 m (default value for a non-specified room, ConsExpo, general fact sheet), the report volume per surface is 0.9[30]. So, the room volume is 0.9*1290 = 1161 m³

30 http://www.toutcalculer.com/geometrie/volume-surface-parallelepipede-rectangle.php August 2017

	Ventilation rate	1.5/hour	Default value for hospital rooms according to HEAdhoc Recommendation no. 9, 2016)[31] and 3/h (best case assumption for well ventilated rooms) is observed, probably due to the short application and exposure duration. Furthermore, ventilation rate is assumed to be at least 2 air change per hour in "Recommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfection" that gives air change rates in typical rooms and building. Thus, this worst case ventilation rate of 1.5/h is considered for the exposure assessments.
	Inhalation rate	1.37 m³/hr	Default inhalation rate for an adult during light exercise (ConsExpo).
	Vapour pressure	For PAA: 1410 Pa For H2O2: 214 Pa For CH3COOH: 2079 Pa	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: information taken on the ingredient's suppliers (please refer to SDS documents provided in the dossier)
	Application temperature	20°C	Application temperature given by the applicant

31 Recommendatioon no. 9 of the BPC Ad hoc Working Group on Human Exposure. Hand disinfection in hospitals. Revision agreed at the Human Health Working Group I. January 2017.

	Molecular weight	For PAA: 76.05 g/mol For H2O2: 34.01 g/mol For CH3COOH: 60.05 g/mol	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: no information in the SDS or in the REACH dossier. So the value was calculated based on the molecular formula.
	Mass transfer coefficient	10 m/hour	Estimated with the Thibodeau's method
	Molecular weight matrix	18 g/mol	Since the disinfection of surfaces is performed with a diluted solution of the product, the default value of 18 g/mol for water-based products is considered for the input parameter.
Tier 2	Exposure and application duration	120 minutes	As discussed during the referal.
	Release area	1290 m^2	Surface of one warehouse
	Ventilation rate	10/hour	As agreed during the referal

Parent Boiler				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Tier 2: Meta-SPC 3 (INDAL PAA 5)	10	7.5	22	0.0017
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	1.3	3.5	7.1	0.00091
AEC for local effects to respiratory	0.5	1.25	25	0.05

tract [mg/m³]				
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	20	6	0.88	0.034
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	2.6	2.8	0.284	0.0182
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	26		0.88	0.034
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	acceptable
• **TIER 3: Type of RPE and risk with RPE**	full face mask with a P3 filter to protect respiratory tract – 0.65		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	5.4		0.284	0.0182
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P2 filter to protect respiratory tract – 0.54		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

Conclusion from the worst case approach and justification for refinements:

a. Worst case approach:

A ventilation rate of 1.5/h and an exposure duration of 480 lead to unacceptable uses, and it is therefore necessary to increase the ventilation rate to 4/h and limit the disinfection to one parent boilers a day (exposure duration: 86 minutes). Even with those restriction, RPE are required:

- For Meta-SPC 3, a full face mask with P3 filters
- For Meta-SPC 5, a half face mask with a P1 filter.

The worst case approach thus proves that safe uses are possible, provided that some precaution are taken: a ventilation rate of 4/h and RPE.

b. Justification for refinements:

In order to provide a realistic worst case approach with acceptable uses, several refinement were performed. Here is the lsit of the refinements and their justification:

- The exposure duration has been switched from 480 minutes to 86 minutes. This is deemed acceptable for the following reason: most installation only present a few warehouse, and they are usually not all treated the same day, because of housing capacities for the animal. Additionnally, a proposing the limitation of one disinfection a day is proposed.
- A ventilation rate of 4/h is proposed, this is in accordance with the worst-case ventilation rate from the Recommandation of the AdHoc Working Group on Human Exposure n°13.
-

Description of Scenario 3.2.2: Manual spraying for PT3-small scale disinfection in animal houses – Exposure to vapour

a) <u>In poultry houses</u>

Since in the TAB (Technical Agreements for Biocides) the small scale surfaces are referred to be 10% of the total large scale surface default values used for PT2 and PT4, we can assume that the treated small scale surfaces in animal housing are 10% of the total large-scale surface used for poultry (Turkey as a worst-case) houses. So, if the small scale surface in poultry houses is 10% of 8040, this means that the total small scale surface is 804 m². But, as previously mentioned, a user works 8 hours a day. This means that the maximum exposure and application durations for a single user is 480 min for a surface disinfection of 718.6 m². So, to assess the exposure during the small scale disinfection in poultry houses, please refer to the TIER 2 of the scenario 3.2.1. a. The exposure is identical. Indeed, it is assumed that this application takes place in the same room volume.

So please, note that the exposure of the user during manual spraying for small scale disinfection in poultry house is not developed here below.

b) <u>In pig houses</u>

Since in the TAB (Technical Agreements for Biocides)[32] the small scale surfaces are referred to be 10% of the total large scale surface default values used for PT2 and PT4, we can assume that the treated small scale surfaces in animal housing are 10% of the total large-scale surface used for pigs (sows in group as a worst-case) houses. So, if the small scale surface in pig houses is 10% of 2200, this means that the total small scale surface is 220 m². This scenario is developed here below.

Since it is an exposure assessment for local effects on respiratory tract, the frequency of application does not play a role in the model.

	Parameters	**Value**	**Reference**

32 European Chemicals Agency. Technical Agreements for Biocides (TAB) version 1.3. ECHA-17-R-19-EN. August 2017. Pp 28.

Tier 1	Exposure duration	120 minutes	Default value from ConsExpo, Disinfectant products fact sheet. Indeed, for knapsack application[33], exposure and application durations are 16.7 minutes for a surface of 25 m². Here, for large scale disinfection for PT3, the total treated surface is 220 m² for the worst-case poultry housing (walls, roof, floor, slatted area and other area), that is for sows in group from ESD for PT3 (Emission scenarios for veterinary hygiene biocidal products, JRC Scientific and Technical Reports, 2011, p51)[34]. The disinfection is perfomed with a low-medium pressure spraying device (4-7 bar).
	Product amount	For INDAL PAA 5 (Meta-SPC 3): 44 000 mL*1.122 = 49 368 g For INDAL OXY MOUSS (Meta-SPC 5): 11 000 mL*1.064 = 11 704 g	Applicant's information The application rate is 200 mL/m² for the product INDAL PAA 5 and 50 mL/m² for the product INDAL OXY MOUSS The treated surface is 220 m² and the product density is 1.122 for INDAL PAA 5 and 1.064 for INDAL OXY MOUSS
	Weight fraction substance	For INDAL PAA 5 (Meta-SPC 3): PAA: 0.00265 H2O2: 0.01275 CH3COOH: 0.0041 For INDAL OXY MOUSS (Meta-SPC 5): PAA: 0.0006 H2O2: 0.0065 CH3COOH: 0.002875	Applicant's information Worst-case dilution is 5% for INDAL PAA 5 and 5 % for INDAL OXY MOUSS.

[33] L.C.H. Prud'homme de Lodder, H.J. Bremmer, S.M.G.J. Pelgrom, M.V.D.Z. Park, J.G.M. van Engelen. Disinfectant Products Fact Sheet to assess the risks fort he consumer. RIVM report 320005003/2006, 2006. p35.

[34] Drafted by Scientific Consulting Company (SCC) GmbH Revised by the Biocides Technical Meeting Endorsed by the Biocides Competent Authorities Meeting Edited by B. Raffael and E. van de Plassche. Emission Scenario Document for Product Type 3. Veterinary hygiene biocidal products. JRC Scientific and Technical Reports. 2011. p51

	Room volume	1683 m³	it is assumed that this application takes place in the same room volume than during large scale manual spraying described in the previous scenario 3.2.1 b.
	Ventilation rate	1.5/hour	Default value for hospital rooms according to HEAdhoc Recommendation no. 9, 2016)[35] and 3/h (best case assumption for well ventilated rooms) is observed, probably due to the short application and exposure duration. Furthermore, ventilation rate is assumed to be at least 2 air change per hour in "Recommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfection" that gives air change rates in typical rooms and building. Thus, this worst case ventilation rate of 1.5/h is considered for the exposure assessments.
	Inhalation rate	1.37 m³/hr	Default inhalation rate for an adult during light exercise (ConsExpo).
	Vapour pressure	For PAA: 1410 Pa For H2O2: 214 Pa For CH3COOH: 2079 Pa	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: information taken on the ingredient's suppliers (please refer to SDS documents provided in the dossier)
	Application temperature	20°C	Application temperature given by the applicant

	Molecular weight	For PAA: 76.05 g/mol For H2O2: 34.01 g/mol For CH3COOH: 60.05 g/mol	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: no information in the SDS or in the REACH dossier. So the value was calculated based on the molecular formula.
	Mass transfer coefficient	10 m/hour	Estimated with the Thibodeau's method
	Release aera mode, increasing: Release area Application duration	220 m² and 146,96 min	The treated surface is increasing over the time. The total treated surface is: 220 m² and the application duration is 146.96 minutes, as already mentioned above.
	Molecular weight matrix	18 g/mol	Since the disinfection of surfaces is performed with a diluted solution of the product, the default value of 18 g/mol for water-based products is considered for the input parameter.
Tier 2	Ventilation rate	10/hour	Worst-case ventilation rate from the Recommandation of the AdHoc Working Group on Human Exposure n°13for any animal house (pig houses). As it is difficult to prove that a higher ventilation rate would be realistic for all application presented here, a higher ventilation rate is not proposed here.

Combined inhalation exposure to aerosol and vapour during manual spraying for PT3 small scale disinfection in animal houses for each substance and product

35 Recommendatioon no. 9 of the BPC Ad hoc Working Group on Human Exposure. Hand disinfection in hospitals. Revision agreed at the Human Health Working Group I. January 2017.

Pig houses			
Exposure type	**Substances**	**Exposure to Meta-SPC 3 (INDAL PAA 5) [mg/m³]**	**Exposure to Meta-SPC 5 (INDAL OXY MOUSS) [mg/m³]**
Exposure to aerosol	Peracetic acid	0.3021	0.0684
	Hydrogen peroxide	1.4535	0.741
	Acetic acid	0.4674	0.32775
	Sulphuric acid	0.05472	0.0285
Exposure to vapour	Peracetic acid	5.04	0.33
	Hydrogen peroxide	17.46	1.95
	Acetic acid	7.92	1.65
	Sulphuric acid	n.a.	n.a.
Total exposure to aerosol and vapour	Peracetic acid	5.3421	0.3984
	Hydrogen peroxide	18.9135	2.691
	Acetic acid	8.3874	1.97775
	Sulphuric acid	0.05472	0.0285

n.a. Not applicable because sulphuric acid is slightly volatile

Combined risk related to total inhalation exposure during manual spraying for PT3 small scale disinfection in animal houses for each product

As all Tier 1 values were above the AEC, only Tier 2 and Tier 3 (RPE) values are presented below

Pig houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Tier 2: Meta-SPC 3 (INDAL PAA 5)	2.1	2.1	4.1	0.00052
Meta-SPC 5 (INDAL OXY MOUSS)	0.2	0.89	0.98	0.00027
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05

	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	4.2	1.68	0.164	0.0104
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	4	0.712	0.0392	0.0054
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	5.88		0.164	1.0104
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P2 filter to protect respiratory tract – 0.588		/	
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	4.712		0.0392	0.0054
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P2 filter to protect respiratory tract – 0.471		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

Worst Case approach and justification for refinements

a. Worst case approach

As this is an application for small scale disinfection only, the surface treated is lower than the one considered for the worst case approach in scenario 3.2.1. It is thus considered that scenario 3.2.2 is already the worst case situation.

b. Justification for refinements:

In order to provide a realistic worst case approach with acceptable uses, several refinement were performed. Here is the list of the refinements and their justification:

- A ventilation rate of 4/h is proposed, this is in accordance with the worst-case ventilation rate from the Recommandation of the AdHoc Working Group on Human Exposure n°13.

Description of Scenario 3.2.4: Manual spraying for PT3- Milking claws shape disinfection – Exposure to vapour

- In dairy cattle houses

Since it is an exposure assessment for local effects on respiratory tract, the frequency of application (2 times per day)does not play a role in the model.

It is expected that claws are disinfected in order to avoid cross-contamination from an infected animal to a healthy animal. Considering a herd of 100 cows and a lactation period of 300 days per year, 82 claws will be treated per event.

Spraying takes place with a semi-automatic trigger spray using network water pressure (2 bars) comprising two functions (a) disinfection, (b) flushing which the operator can control either with his index finger. Firstly b to eliminate milk residue, secondly a to disinfect, and then b to rinse after the contact time.

The head of the trigger spray is oriented towards the inside of the claws and the spray is activated by the trigger.

It is important to consider no room size default values exist in the Recommendation 6, neither in the BPR guidance on Human health.

The only provided room volumes are those for evaporation from hoof bath disinfection, in the ECHA Recommendation 6, which seems not appropriate for spraying application and to cover all the animal housing application of the QUARON PAA Family.

That is the reason why the smallest and largest surfaces of animal housing stated in the ESD for PT3 were selected. The lowest is for sows and the biggest is for poultry if all the surfaces stated in the table 8 of the ESD for PT 3 are summed up for each animal category.

In the scenario 3.2.4, the room volume was estimated based on the surface of the floor, and of the walls stated in the table 8 of the ESD PT03 as well as the default room height of 2.5 m stated as a general default value in ConsExpo. The shape of the room was considered as cuboïc and an expert judgement of the room volume was extrapolated from those stated surfaces.

	Parameters	**Value**	**Reference**
Tier 1	Exposure duration	90 min (expert judgement: 55 min for the disinfection followed by 35 min for rinsing	The HEADhoc Recommendation 13 specifies that 82 animals are treated at each milking. The duration determined is thus based on the timing necessary for the disinfection of the milking claws (55 min) and the rinsing (35 min).

	Product amount	For INDAL PAA 5 (Meta-SPC 3): 20 mL/m²*0.075m²/claw*82claws/event = 123 ml	Applicant's information. For INDAL PAA 5, the application rate is 20 mL/m². The total treated surface of the claws is estimated to be 750 cm². Indeed, there are 4 claws and each is a cylinder of +/- 3 cm diameter and a height of 20 cm (applicant's data). So the total surface is 4*3/2cm*2*π*20 ~750 cm²=0.075 m². The treated surface of all 82 claws is 82*0.075 m²=6.15.
	Weight fraction substance	For INDAL PAA 5 (Meta-SPC 3): PAA: 0.0003568 H2O2: 0.001717 CH3COOH: 0.000552	Applicant's information Worst-case dilution is 0.6%.
	Room volume	2556 m³	Estimated considering a room with a cuboid shape. If the total surface of the room including the ceiling, the walls and the floor is 1170 m² + 1670 m² (ESD for PT3, 2011, dairy cattle)[36] and the Height of the walls is 2.5 m (default value for a non-specified room, ConsExpo, general fact sheet), the report volume per surface is 0.9. So, the room volume is: 0.9*2840 m² = 2556 m³

[36] Drafted by Scientific Consulting Company (SCC) GmbH Revised by the Biocides Technical Meeting Endorsed by the Biocides Competent Authorities Meeting Edited by B. Raffael and E. van de Plassche. Emission Scenario Document for Product Type 3. Veterinary hygiene biocidal products. JRC Scientific and Technical Reports. 2011. p51

	Ventilation rate	10/hour	Default value for hospital rooms according to HEAdhoc Recommendation no. 9, 2016)[37] and 3/h (best case assumption for well ventilated rooms) is observed, probably due to the short application and exposure duration. Furthermore, ventilation rate is assumed to be at least 2 air change per hour in "Recommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfection" that gives air change rates in typical rooms and building. Thus, this worst case ventilation rate of 1.5/h is considered for the exposure assessments.
	Inhalation rate	1.37 m³/hr	Default inhalation rate for an adult during light exercise (ConsExpo).
	Vapour pressure	For PAA: 1410 Pa For H2O2: 214 Pa For CH3COOH: 2079 Pa	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: information taken on the ingredient's suppliers (please refer to SDS documents provided in the dossier)
	Application temperature	20°C	Application temperature given by the applicant (ambient temperature).

37 Recommendatioon no. 9 of the BPC Ad hoc Working Group on Human Exposure. Hand disinfection in hospitals. Revision agreed at the Human Health Working Group I. January 2017.

	Molecular weight	For PAA: 76.05 g/mol For H2O2: 34.01 g/mol For CH3COOH: 60.05 g/mol	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: no information in the SDS or in the REACH dossier. So the value was calculated based on the molecular formula.
	Mass transfer coefficient	10 m/hour	Default value given in Consexpo
	Release aera mode, increasing: Release area Application duration	0.075 m^2/claw*82 claws/event = 6.15 m^2	The treated surface is increasing over the time.
	Molecular weight matrix	18 g/mol	Since the disinfection of surfaces is performed with a diluted solution of the product, the default value of 18 g/mol for water-based products is considered for the input parameter.

Combined inhalation exposure to aerosol and vapour during manual spraying of contaminated milking parlour for each substance and product

Exposure type	**Substances**	**Exposure to INDAL PAA 5 (Meta-SPC 3) [mg/m³]**
Exposure to aerosol	Peracetic acid	0.0464
	Hydrogen peroxide	0.2232
	Acetic acid	0.0718
	Sulphuric acid	0.00829
Exposure to vapour	Peracetic acid	0.0081
	Hydrogen peroxide	0.0202
	Acetic acid	0.0131
	Sulphuric acid	n.a.

Total exposure to aerosol and vapour	Peracetic acid	0.0545
	Hydrogen peroxide	0.2434
	Acetic acid	0.0849
	Sulphuric acid	0.00829

n.a. Not applicable because sulphuric acid is slightly volatile

Combined risk related to total inhalation exposure during manual spraying of contaminated milking parlour for each product

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 3 (INDAL PAA 5)	0.0545	0.2434	0.0849	0.00829
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	0.109	0.19472	0.003396	0.1658
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 1: Meta-SPC 3 (INDAL PAA 5)	0.3037		0.0034	0.1658
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

Worst Case approach

As this is an application for milking claw disinfection only, the surface treated is very low compared to the volume of the room were the treatment is taking place. Establishing a realistic worst case seems not relevant.

Conclusions to the exposure during all PT3 manual spraying application

During manual spraying applications the risk related to dermal and eye exposures are acceptable for Meta-SPC 5 (INDAL OXY MOUSS) without wearing personal protective equipment when diluted to a 5% use concentration and only with chemical-resistant gloves and a protective coverall for the use of the Meta-SPC 3 (product: INDAL PAA 5) when diluted to a 3% use concentration.

During these manual spraying applications, both products INDAL PAA 5 and INDAL OXY MOUSS, require the wearing of a respiratory protective equipment (RPE), except for 1 application. Only half masks are proposed since no protection to eyes is required.

However, different kind of RPE are required, depending on the use of the products:

- The product INDAL PAA 5 requires a half mask with a P3 filter to have an acceptable level of exposure and related risk for the user during large scale and small scale manual spraying animal houses.

- The product INDAL OXY MOUSS requires a half mask with a P2 filter to have an acceptable level of exposure and related risk for the user during the disinfection of vehicles for animal transport.

For the use of INDAL PAA 5 when diluted to a 0,5% use concentration during manual spraying disinfection of milking claws in farms, no respiratory protective equipment is required for the user that is safely exposed to the product only by wearing gloves and a protective coat.

To assess the exposure to **Vapour** for **PT4** applications, the model "Exposure to vapour – Evaporation" of the scenario "Spraying" of the "Disinfectant products fact sheet" of the online program ConsExpo Web[38] was applied.

Provide adequate ventilation before the general public re-enter treated areas. The general public is not allowed to enter the outdoor application site and an area 20 m around during spraying and until the surface is rinsed.

Description of Scenario 3.3: Manual spraying on open surfaces for PT4 applications – Exposure to vapour

This scenario applies for the next uses:

- The products INDAL PAA 3.5 (Meta-SPC 1), INDAL PAA 5 (Meta-SPC 3) and INDAL OXY MOUSS (Meta-SPC 5) are used in all agri-food industries and institutional kitchens for the disinfection of large scale open surfaces.
    - A large scale disinfection is developed for agri-food industries and institutional kitchen.

      To cover all kind of agri-food industries

      a) the worst-case parent Broiler was chosen because of its smaller volume for this kind of application
      b) Besides the slaughter houses, to cover all the agri-food sector, the scenario is also assessed for the institutional kitchen.

      In large-scale application, it is considered that floor, ceiling and walls are disinfected.

So, scenario 3.3 is further devided in two sub scenarios:

- Scenario 3.3.1-a for the large scale manual spraying application on floor, walls and ceilings in slaughter houses,

38 L.C.H. Prud'homme de Lodder, H.J. Bremmer, S.M.G.J. Pelgrom, M.V.D.Z. Park, J.G.M. van Engelen. Disinfectant Products Fact Sheet to assess the risks fort he consumer. RIVM report 320005003/2006, 2006. P 21, P27-28.

- Scenario 3.3.1-b for the large scale manual spraying application on floor, walls and ceilings in institutional kitchen,
-

Description of Scenario 3.3.1: Manual spraying for PT4-large scale disinfection– Exposure to vapour			
a) Slaughter houses b) Institutional kitchen Since it is an exposure assessment for local effects on respiratory tract, the frequency of application does not play a role in the model.			
	Parameters	**Value**	**Reference**
Tier 1	Exposure duration	a) 666 minutes b) 133 minutes	Default value from ConsExpo, Disinfectant products fact sheet. Indeed, for knapsack application[39], exposure and application durations are normally 16.7 minutes for a surface of 25 m². However, here he disinfection is performed with a low-medium pressure spraying device (4-7 bars), with an application speed of 15 m^2/min: : a) 10 000 m² for slaughter houses (Emission scenarios for disinfectants used in food and feed areas, JRC Scientific and Technical Reports, 2011, p20)[40]. So, the exposure and application durations are10000/15 = 666 minutes b) 2000 m² for institutional kitchen (Emission scenarios for disinfectants used in food and feed areas, JRC Scientific and Technical Reports, 2011, p21)[41]. The exposure and application durations are: 2000/15 = 133 minutes

39 L.C.H. Prud'homme de Lodder, H.J. Bremmer, S.M.G.J. Pelgrom, M.V.D.Z. Park, J.G.M. van Engelen. Disinfectant Products Fact Sheet to assess the risks fort he consumer. RIVM report 320005003/2006, 2006. p35.

40 Drafted by Scientific Consulting Company (SCC) GmbH Revised by the Biocides Technical Meeting Endorsed by the Biocides Competent Authorities Meeting Edited by B. Raffael and E. van de Plassche. Emission Scenario

Document for Product Type 4. Disinfectants used in food and feed ares. JRC Scientific and Technical Reports. 2011. p20

41 Please refer to reference 67.

	Product amount	<u>For INDAL PAA 3.5 (Meta-SPC 1):</u> a) 200 000mL*1.113 = 222 600 g b) 40 000mL*1.113 = 44520 g <u>For INDAL PAA 5 (Meta-SPC 3):</u> a) 200 000mL*1.122 = 224 400 g b) 40 000mL*1.122 = 44880 g <u>For INDAL OXY MOUSS (Meta-SPC 5):</u> a) 500 000 mL*1.064 = 532 000 g b) 100 000 mL*1.064 = 106 400 g	Applicant's information. a) the treated surface is 10000 m² b) the treated surface is 2000 m² <u>For INDAL PAA 3.5:</u> The application rate is 20 mL/m² and the density is 1.113. <u>For INDAL PAA 5:</u> The application rate is 20 mL/m² and the density is 1.122. <u>For INDAL OXY MOUSS:</u> The application rate is 50 mL/m² and the density is 1.064.
	Weight fraction substance	<u>For INDAL PAA 3.5 (Meta-SPC 1):</u> PAA: 0.00104 H2O2: 0.01 CH3COOH: 0.002 <u>For INDAL PAA 5 (Meta-SPC 3):</u> PAA: 0.00159 H2O2: 0.00765 CH3COOH: 0.00246 <u>For INDAL OXY MOUSS (Meta-SPC 5):</u> PAA: 0.0006 H2O2: 0.0065 CH3COOH: 0.002875	Applicant's information The worst-case dilution is: - 4% for INDAL PAA 3.5 - 3% for INDAL PAA 5 - 5% for INDAL OXY MOUSS

	Room volume	a) 50 000 m³ b) 6 000 m³	a) Slaughter house: 50,000 m³: assuming a surface area of 10,000 m2 multiplied by a room height of 5 m (reference for room height: http://www.fao.org/docrep/003/x6509f/X6509E01.htm page 3 and Annex 1) (Technical agreement for Biocides, December 2016)[42] b) Large kitchen: 6,000 m³: assuming a surface area of 2,000 m² multiplied by a room height of 3 m (Technical agreement for Biocides, December 2016)[43]
	Ventilation rate	1.5/hour	Default value for hospital rooms according to HEAdhoc Recommendation no. 9, 2016)[44] and 3/h (best case assumption for well ventilated rooms) is observed, probably due to the short application and exposure duration. Furthermore, ventilation rate is assumed to be at least 2 air change per hour in "Recommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfection" that gives air change rates in typical rooms and building. Thus, this worst case ventilation rate of 1.5/h is considered for the exposure assessments.
	Inhalation rate	1.37 m³/hr	Default inhalation rate for an adult during light exercise (ConsExpo).

42 European Chemicals Agency. Technical Agreements for Biocides (TAB) version 1.3. ECHA-17-R-19-EN. August 2017. p 28.

43 Please refer to reference 69

44 Recommendatioon no. 9 of the BPC Ad hoc Working Group on Human Exposure. Hand disinfection in hospitals. Revision agreed at the Human Health Working Group I. January 2017.

	Vapour pressure	For PAA: 1410 Pa For H2O2: 214 Pa For CH3COOH: 2079 Pa	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: information taken on the ingredient's suppliers (please refer to SDS documents provided in the dossier)
	Application temperature	20°C	Application temperature given by the applicant (ambient temperature).
	Molecular weight	For PAA: 76.05 g/mol For H2O2: 34.01 g/mol For CH3COOH: 60.05 g/mol	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: no information in the SDS or in the REACH dossier. So the value was calculated based on the molecular formula.
	Mass transfer coefficient	For PAA: 18.6 m/hour For H2O2: 24.3 m/hour For CH3COOH: 20.1 m/hour	Estimated with the Thibodeau's method as the products are aqueous solutions.
	Release aera mode, increasing: Release area Application duration	a) 10 000 m² and 666 min b) 2000 m² and 133 min	The treated surface is increasing over the time. The total treated surface is: a) 10 000 m² and the application duration is 666 minutes, as already mentioned above for slaughter houses. b) 2000 m² and the application duration is 133 minutes, as already mentioned above for institutional kitchen.

	Molecular weight matrix	18 g/mol	Since the disinfection of surfaces is performed with a diluted solution of the product, the default value of 18 g/mol for water-based products is considered for the input parameter.
Tier 2	Exposure and application duration	b) c) 120 minutes	HEADhoc 6, gives an application duration of 120 min for this task
	Release area	a) 718.6 m²	If the maximum exposure and application duration for a single user is 480 minutes, the maximum treated surface is 480 / (16.7/25) = 718.6 m², by extrapolation of the default value from ConsExpo disinfectant factsheet.
	Product amount	<u>For INDAL PAA 3.5 (Meta-SPC 1):</u> a) and b) 15996.04 g <u>For INDAL PAA 5 (Meta-SPC 3):</u> a) and b) 16125.4 g <u>For INDAL OXY MOUSS (Meta-SPC 5):</u> a) and b) 38229.5 g	Applicant's information. The treated surface is 718.6 m² <u>For INDAL PAA 3.5:</u> The application rate is 20 mL/m² and the density is 1.113. <u>For INDAL PAA 5:</u> The application rate is 20 mL/m² and the density is 1.122. <u>For INDAL OXY MOUSS:</u> The application rate is 50 mL/m² and the density is 1.064.

	Ventilation rate	a) 10/hour	For b) Worst-case ventilation rate from the Recommandation of the AdHoc Working Group on Human Exposure n°6 for small kitchen. Indeed, the ventilation rate for large kitchen is higher. As it is difficult to prove that a higher ventilation rate would be realistic for all application presented here, a higher ventilation rate is not proposed here.

Combined inhalation exposure to aerosol and vapour during manual spraying for PT4 large scale disinfection for each substance and product

Slaughter houses				
Exposure type	**Substances**	**Exposure to Meta-SPC 1 (INDAL PAA 3.5) [mg/m³]**	**Exposure to Meta-SPC 3 (INDAL PAA 5) [mg/m³]**	**Exposure to Meta-SPC 5 (INDAL OXY MOUSS) [mg/m³]**
Exposure to aerosol	Peracetic acid	0.079	0.1208	0.0456
	Hydrogen peroxide	0.76	0.5814	0.494
	Acetic acid	0.152	0.187	0.2185
	Sulphuric acid	0.0292	0.0219	0.019
Exposure to vapour	Peracetic acid	0.025	0.038	0.033
	Hydrogen peroxide	0.22	0.17	0.3
	Acetic acid	0.048	0.06	0.16
	Sulphuric acid	n.a.	n.a.	n.a.
Total exposure to aerosol and vapour	Peracetic acid	0.104	0.1588	0.0786
	Hydrogen peroxide	0.98	0.7514	0.794
	Acetic acid	0.2	0.247	0.3785
	Sulphuric acid	0.0292	0.0219	0.019
Institutional kitchen				

Exposure type	Substances	Exposure to Meta-SPC 1 (INDAL PAA 3.5) [mg/m³]	Exposure to Meta-SPC 3 (INDAL PAA 5) [mg/m³]	Exposure to Meta-SPC 5 (INDAL OXY MOUSS) [mg/m³]
Exposure to aerosol	Peracetic acid	0.079	0.1208	0.0456
	Hydrogen peroxide	0.76	0.5814	0.494
	Acetic acid	0.152	0.187	0.2185
	Sulphuric acid	0.0292	0.0219	0.019
Exposure to vapour	Peracetic acid	0.033	0.052	0.045
	Hydrogen peroxide	0.3	0.23	0.4
	Acetic acid	0.065	0.08	0.22
	Sulphuric acid	n.a.	n.a.	n.a.
Total exposure to aerosol and vapour	Peracetic acid	0.112	0.1728	0.0906
	Hydrogen peroxide	1.06	0.8114	0.894
	Acetic acid	0.217	0.267	0.4385
	Sulphuric acid	0.0292	0.0219	0.019

n.a. Not applicable because sulphuric acid is slightly volatile

Combined risk related to total inhalation exposure during manual spraying for PT4 large scale disinfection for each product

Slaughter houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.104	0.98	0.2	0.0292
Meta-SPC 3 (INDAL PAA 5)	0.1588	0.7514	0.247	0.0219
Meta-SPC 5 (INDAL OXY MOUSS)	0.0786	0.794	0.3785	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05

	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	0.208	0.784	0.008	0.584
Meta-SPC 3 (INDAL PAA 5)	0.3176	0.6011	0.0099	0.438
Meta-SPC 5 (INDAL OXY MOUSS)	0.1572	0.6352	0.0151	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 1 (INDAL PAA 3.5)	0.992		0.008	0.584
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 3 (INDAL PAA 5)	0.9187		0.0099	0.438
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	0.7924		0.0151	0.38
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Institutional Kitchen				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.112	1.06	0.217	0.0292
Meta-SPC 3 (INDAL PAA 5)	0.1728	0.8114	0.267	0.0219
Meta-SPC 5 (INDAL OXY MOUSS)	0.0906	0.894	0.4385	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AC) [mg/m³]			
Tier 2: Meta-SPC 1 (INDAL PAA 3.5)	0.0495	0.236	0.00241	0.162
Tier 2: Meta-SPC 3 (INDAL PAA 5)	0.0906	0.180	0.00297	0.121

Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	0.0502	0.0.198	0.00975	0.211
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 1 (INDAL PAA 3.5)	0.297		0.00241	0.162
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 3 (INDAL PAA 5)	0.276		0.00297	0.121
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	0.249		0.00975	0.211
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

Worst case approach and refinement justification:

a. Worst case approach

As the conditions stated above were deemed not worst case enough, (especially due to the dimension of the room chosen), it was decided to proceed with a worst case assessment with the smallest room dimension possible: parent boilers.

The conditions applied for this worst case assessment can be found below:

b. Refinement justification

In order to provide a realistic worst case, several refinement have been performed. Here is the lsit with their justification:

- The exposure duration was changed to 480 min and 133 minutes respectively. The 480 duration seems realistic as it is related to the normal timing of a working day. The second value is linked to the time necessary to clean a warehouse of the corresponding size.
- Release area and product amount: as the application time has decreased, this also implies a decrease in the quantity of product used
- Ventilation rate pushed to 10/h (for industrial kitchen only):_Worst-case ventilation rate from the Recommandation of the AdHoc Working Group on Human Exposure n°6 for small kitchen. Indeed, the ventilation rate for large kitchen is higher

Description of Scenario 3.3.1: Manual spraying for PT4-large scale disinfection– Exposure to vapour			
Parent Boilers Since it is an exposure assessment for local effects on respiratory tract, the frequency of application does not play a role in the model.			
	Parameters	**Value**	**Reference**
Tier 1	Exposure duration	480 minutes	The disinfection is performed with a low-medium pressure spraying device (4-7 bars), with an application speed of 15 m^2/min and for a surface of 1290 m^3 The exposure and application durations are: 1290/15 = 86 minutes. However, as a full day of work is at 480 minutes, and that it is possible that more than one warehouse is treated, we use 480 minutes as a worst case.
	Product amount	<u>For INDAL PAA 3.5 (Meta-SPC 1):</u> c) 25 800 mL*1.113 = 28 715 g <u>For INDAL PAA 5 (Meta-SPC 3):</u> 258 000 mL*1.122 = 1 289 476 g <u>For INDAL OXY MOUSS (Meta-SPC 5):</u> 64 500 mL*1.064 = 68 628 g	<u>For INDAL PAA 3.5:</u> The application rate is 20 mL/m² and the density is 1.113. For <u>INDAL PAA 5</u>, the application rate is 200 mL/m². the treated surface is 1290 m² and the product density is 1.122 For <u>INDAL OXY MOUSS, t</u>he application rate is 50 mL/m². the treated surface is 1290 m² and the product density is 1.064.

	Weight fraction substance	<u>For INDAL PAA 3.5 (Meta-SPC 1):</u> PAA: 0.00104 H2O2: 0.01 CH3COOH: 0.002 <u>For INDAL PAA 5 (Meta-SPC 3):</u> PAA: 0.00186 H2O2: 0.00893 CH3COOH: 0.00287 <u>For INDAL OXY MOUSS (Meta-SPC 5):</u> PAA: 0.0006 H2O2: 0.0065 CH3COOH: 0.002875	Applicant's information The worst-case dilution is: - 2% for INDAL PAA 3.5 - 3.5% for INDAL PAA 5 - 5% for INDAL OXY MOUSS
	Room volume	1161	Expert's judgement as no default value is referenced. Estimated considering a room with a cuboid shape. If the total surface of the room including the ceiling, the walls, slatted area and the floor is 1290 m² and the height of the walls is 2.5 m (default value for a non-specified room, ConsExpo, general fact sheet), the report volume per surface is 0.9[45]. So, the room volume is 0.9*1290 = 1161 m³

45 http://www.toutcalculer.com/geometrie/volume-surface-parallelepipede-rectangle.php August 2017

	Ventilation rate	1.5/hour	Default value for hospital rooms according to HEAdhoc Recommendation no. 9, 2016)[46] and 3/h (best case assumption for well ventilated rooms) is observed, probably due to the short application and exposure duration. Furthermore, ventilation rate is assumed to be at least 2 air change per hour in "Recommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfection" that gives air change rates in typical rooms and building. Thus, this worst case ventilation rate of 1.5/h is considered for the exposure assessments.
	Inhalation rate	1.37 m³/hr	Default inhalation rate for an adult during light exercise (ConsExpo).
	Vapour pressure	For PAA: 1410 Pa For H2O2: 214 Pa For CH3COOH: 2079 Pa	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: information taken on the ingredient's suppliers (please refer to SDS documents provided in the dossier)
	Application temperature	20°C	Application temperature given by the applicant (ambient temperature).

46 Recommendatioon no. 9 of the BPC Ad hoc Working Group on Human Exposure. Hand disinfection in hospitals. Revision agreed at the Human Health Working Group I. January 2017.

	Molecular weight	For PAA: 76.05 g/mol For H2O2: 34.01 g/mol For CH3COOH: 60.05 g/mol	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: no information in the SDS or in the REACH dossier. So the value was calculated based on the molecular formula.
	Mass transfer coefficient	For PAA: 18.6 m/hour For H2O2: 24.3 m/hour For CH3COOH: 20.1 m/hour	Estimated with the Thibodeau's method as the products are aqueous solutions.
	Molecular weight matrix	18 g/mol	Since the disinfection of surfaces is performed with a diluted solution of the product, the default value of 18 g/mol for water-based products is considered for the input parameter.
Tier 2	Exposure and application duration	120 minutes	As the cleaning of one warehouse takes 86 minutes, and if the limit is given to not clean more than one per day.
	Release area	1290 m^2	If the maximum exposure and application duration for a single user is 480 minutes, the maximum treated surface is 480 / (16.7/25) = 718.6 m², by extrapolation of the default value from ConsExpo disinfectant factsheet.
	Ventilation rate	10/h	

Parent Boiler				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**

Tier 2: Meta-SPC 3 (INDAL PAA 5)	9.5	7.2	21	0.0017
Meta-SPC 1 (INDAL PAA 3.5)	1.2	2.9	2.4	0.00097
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	1.4	4.6	7.7	0.0013
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	19	5.76	0.84	0.034
Meta-SPC 1 (INDAL PAA 3.5)	2.4	2.32	0.096	0.0194
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	2.8	3.68	0.308	0.026
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	24.76		0.84	0.034
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	acceptable
• **TIER 3: Type of RPE and risk with RPE**	full face mask with a P3 filter to protect respiratory tract – 0.619		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 1 (INDAL PAA 3.5)	4.72		0.096	0.0194
• **Risk acceptable or non acceptable?**	Non Acceptable		Acceptable	Acceptable

• **TIER 3: Type of RPE and risk with RPE**	full face mask with a P2 filter to protect respiratory tract – 0.472	/	/
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	6.48	0.308	0.026
• **Risk acceptable or non acceptable?**	Non acceptable	Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P2 filter to protect respiratory tract – 0.648	/	/
• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	Acceptable

Conclusion from the worst case approach:

a. Worst case approach

A ventilation rate of 1.5/h and an exposure duration of 480 lead to unacceptable uses, and it is therefore necessary to increase the ventilation rate to 10/h and limit the disinfection to one parent boilers a day (exposure duration: 86 minutes). Even with those restriction, RPE are required:

- For Meta-SPC 1, a half mask with a P2 filter.
- For Meta-SPC 3, a full face mask with P3 filter
- For Meta-SPC 5, a half face mask with a P2 filter.

The worst case approach thus proves that safe uses are possible, provided that some precaution are taken: a ventilation rate of 4/h and RPE.

b. Justification for refinements:

In order to provide a realistic worst case approach with acceptable uses, several refinement were performed. Here is the lsit of the refinements and their justification:

- The exposure duration has been switched from 480 minutes to 120 minutes. This is deemed acceptable for the following reason: most installation only present a few warehouse, and they are usually not all treated the same day, because of housing capacities for the animal. Additionnally, a proposing the limitation of one disinfection a day is proposed.
- A ventilation rate of 4/h is proposed, this is in accordance with the worst-case ventilation rate from the Recommandation of the AdHoc Working Group on Human Exposure n°13.

Conclusions to the exposure during all PT4 manual spraying application

During manual spraying applications the risk related to dermal and eye exposures are acceptable for Meta-SPC 5 (INDAL OXY MOUSS) without wearing personal protective equipment. The risk related to dermal and eye exposures are only acceptable with the use

of chemical-resistant gloves and a protective coverall for the Meta-SPC 1 and 3 (products INDAL PAA 3.5 and INDAL PAA 5, respectively).

During these applications, the product INDAL PAA 3.5 requires the wearing of a respiratory protective equipment (RPE). Only half masks are proposed since no protection to eyes is required.

- The product INDAL PAA 3.5 requires a half mask with a P1 filter to have an acceptable level of exposure and related risk for the user during large scale and small scale manual spraying disinfection in an institutional kitchen.

For the use of INDAL PAA 5, as well as of INDAL OXY MOUSS, no respiratory protective equipment is required for the manual spraying disinfection in all agri-food industries.

Provide adequate ventilation before the general public re-enter treated areas. The general public is not allowed to enter the outdoor application site and an area 20 m around during spraying and until the surface is rinsed.

Scenario 4: Manual dipping of material and/or containers for the Meta SPC 1, Meta SPC 3, Meta SPC 4

The product is applied manually or automatically to a recipient or a container, to disinfect it or to dip material to be disinfected. This manual dipping takes place in open space in several industrial or institutional sectors.

Note that all products for which a manual dipping application takes place, a pre-application dilution step is conducted before. The related exposures to these applications are developed in the scenarios 1 and 2. All the exposure assessments for manual dipping are conducted with the in-use concentrations to which the user is directly exposed.

Note that for all dipping application, no heating takes place during dipping bathes and the room need to be sufficiently well ventilated with 10 air changes per hour.

Dermal exposure

The dermal exposure is assessed for each Meta SPC/biocidal product characterized by a manual dipping use. To assess the skin exposure to PAA and H_2O_2, a qualitative approach is performed.

After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.

Provide adequate ventilation before the general public re-enter treated areas. The general public is not allowed to enter the outdoor application site and an area 20 m around during spraying and until the surface is rinsed.

For the biocidal product contained in the Meta SPC 1 (only for PT4 applications)

The PAA and H_2O_2 in-use concentrations are 0.104% w/w and 1.0 % w/w, respectively when INDAL PAA 3.5 is used at the maximum efficacy concentration of 4% v/v.

This means that its PAA content is below the skin irritation threshold of 0.2% for the short-term exposure and above the threshold of 0.1% for the long-term exposure.

For the H_2O_2, the 1.0% w/w concentration is also below the skin irritating threshold of 35% w/w and out of the range that triggers an eye damage 1 (8%<C≤50%) or eye irritation (5%<C≤8%) classification.

Therefore, local eye damage or eye irritating effects are not expected when the INDAL PAA 3.5 in-use product is handled during the manual dipping application. But, local skin irritation is expected. Indeed, manual dipping can be considered as long-term application.

To protect the user, the risk related to dermal and eye exposures is acceptable with the wearing of chemical-resistant gloves and a protective coverall during manual dipping PT4 applications. The wearing of a face shield or goggles is not required.

For the biocidal product contained in the Meta SPC 3 (for PT2 an PT3 applications)

The PAA and H_2O_2 concentrations are 0.265% w/w and 1.275% w/w for PT2 applications, when INDAL PAA 5 is used at the maximum efficacy concentration of 5% v/v.

This means that its PAA content is above the skin irritation threshold of 0.2% and 0.1% for the short-term and long-terme exposures, respectively.

For the H_2O_2, the 1.275% w/w concentration is also below the skin irritating threshold of 35% w/w and out of the range that triggers an eye damage 1 (8%<C≤50%) or eye irritation (5%<C≤8%) classification.

Therefore, local eye damage or eye irritating effects are not expected when the INDAL PAA 5 in-use product is handled during the manual dipping application at the maximum efficacy concentration of 5% v/v. But, local skin irritation is expected.

To protect the user, the risk related to dermal and eye exposures is acceptable with the wearing of chemical-resistant gloves and a protective coverall during manual dipping PT2 and PT3 applications. The wearing of a face shield or goggles is not required.

For the biocidal product contained in the Meta SPC 3 (for PT4 applications)

The PAA and H_2O_2 concentrations are 0.159% w/w and 0.765% w/w, respectively for PT3 and PT4 applications, when INDAL PAA 5 is used at the maximum efficacy concentration of 3% v/v.

This means that its PAA content is below the skin irritation threshold of 0.2% for the short-term exposure and above 0.1% for the long-term exposure.

For the H_2O_2, the 0.765% w/w concentration is also below the skin irritating threshold of 35% w/w and out of the range that triggers an eye damage 1 (8%<C≤50%) or eye irritation (5%<C≤8%) classification.

Therefore, local eye damage or eye irritating effects are not expected when the INDAL PAA 5 in-use product is handled during the manual dipping application at the maximum efficacy concentration of 3% w/w. But, local skin irritation is expected. Indeed, manual dipping can be considered as long-term application.

To protect the user, the risk related to dermal and eye exposures is acceptable with the wearing of chemical-resistant gloves and a protective coverall during manual dipping PT3 and PT4 applications. The wearing of a face shield or goggles is not required.

For the biocidal product contained in the Meta SPC 4 (only for PT4 applications)

The PAA and H_2O_2 concentrations are 0.2528% w/w and 0.4% w/w, respectively when INDAL PAA 15 is used at the maximum efficacy concentration of 1.6% v/v.

This means that its PAA content is above the skin irritation threshold of 0.2% for the short-term exposure and above the threshold of 0.1% for the long-term exposure.

For the H_2O_2, the 0.4% w/w concentration is below the skin irritating threshold of 35% w/w and out of the range that triggers an eye damage 1 (8%<C≤50%) or eye irritation (5%<C≤8%) classification.

Therefore, local eye damage or eye irritating effects are not expected when the INDAL PAA 15 in-use product is handled during the manual dipping application. But, local skin irritation is expected.

To protect the user, the risk related to dermal and eye exposures is acceptable with the wearing of chemical-resistant gloves and a protective coverall during manual dipping PT4 applications. The wearing of a face shield or goggles is not required.

Inhalation exposure

The inhalation exposure assessment is developed taking into account specific use characteristics related to a specific product type. The inhalation exposure is shown for each product type in which specificities that trigger exposure features for the user are also assessed.

For local effects to respiratory tract, exposure to aerosol is taken into account. But, the exposure to vapour is also considered for highly volatile substances (PAA, H_2O_2 and acetic acid).

To assess the exposure to **aerosol**, the Dipping Model 4 TNsG 2002 with an indicative value of 0.2 mg/m³ for inhalation exposure was used. This inhalation indicative value is in accordance with ECHA recommendation N°6 (updated version of February 2017- version 3)[47].

Description of Scenario 4: Manual dipping – Exposure to aerosol

This scenario applies for the next uses:

1) For PT 2 applications:
   - Meta SPC 3 – Use #4 for the product INDAL PAA 5:

     PAA exposure : 0.00265*0.2 = 0.00053 mg/m³

     H2O2 exposure : 0.01275*0.2 = 0.00255 mg/m³

     Acetic acid exposure: 0.0041*0.2 = 0.00082 mg/m³

     Sulphuric acid exposure: 0.00048*0.2 = 0.000096 mg/m³

2) For PT 3 applications:
   - Meta SPC 3 – Uses #9 and #11 for the product INDAL PAA 5:

     PAA exposure : 0.00265*0.2 = 0.00053 mg/m³

     H2O2 exposure : 0.01275*0.2 = 0.00255 mg/m³

     Acetic acid exposure: 0.0041*0.2 = 0.00082 mg/m³

     Sulphuric acid exposure: 0.00048*0.2 = 0.000096 mg/m³

3) For PT 4 applications:
   - Meta SPC 1 – Uses #3 for the product INDAL PAA 3.5:

     PAA exposure : 0.00104*0.2 = 0.0002 mg/m³

[47] BPC Ad hoc Working Group on Human Exposure. ECHA Recommandation N°6 – Methods and models to assess exposure to biocidal products in different product types versio 3. 2017

H2O2 exposure : 0.01*0.2 = 0.002 mg/m³
Acetic acid exposure: 0.002*0.2 = 0.0004 mg/m³
Sulphuric acid exposure: 0.0384*0.2 = 0.0077 mg/m³

- Meta SPC 3 – Uses #13 for the product INDAL PAA 5:
PAA exposure : 0.00159*0.2 = 0.0003 mg/m³
H2O2 exposure : 0.00765*0.2 = 0.0015 mg/m³
Acetic acid exposure: 0.00246*0.2 = 0.0005 mg/m³
Sulphuric acid exposure: 0.000288*0.2 = 0.00006 mg/m³

- Meta SPC 4 – Use #4 for the product INDAL PAA 15:
PAA exposure : 0.002528*0.2 = 0.0005 mg/m³
H2O2 exposure : 0.004*0.2 = 0.0008 mg/m³
Acetic acid exposure: 0.002208*0.2 = 0.0004 mg/m³
Sulphuric acid exposure: -

To assess the exposure to **Vapour** for **PT 2** dipping applications, the model "Exposure to vapour – Evaporation" of the scenario "Application for hand washing cleaning products" of the "Cleaning products fact sheet" of the online program ConsExpo Web[48] was applied. Reasoning: in the RIVM "Disinfectant products fact sheet" no dipping model is developed and available.

Description of Scenario 4.1: Manual dipping of surfaces for PT2 applications – Exposure to vapour

This scenario applies for the next uses:

a) The Meta-SPC 3 (product INDAL PAA 5) is used in industrial buildings, swimming pool building (public or private) to disinfect open surfaces, material, equipment and container by dipping application.
   - All these institutions and surfaces are considered as large scale surfaces

b) The Meta-SPC 3 (product INDAL PAA 5) is also used in public institution buildings to disinfect open surfaces, furniture equipment.
   - All these institutions and surfaces are considered as small scale surfaces compared to other applications

So, scenario 4.1 is declined in two separated scenarios:

- one for dipping application in industries: scenario 4.1.1
- one for dipping application in institutions, scenario 4.1.2.

48 L.C.H. Prud'homme de Lodder, H.J. Bremmer, S.M.G.J. Pelgrom, M.V.D.Z. Park, J.G.M. van Engelen. Cleaning Products Fact Sheet to assess the risks fort he consumer. RIVM report 320104003/2006, 2006. p47-49.

Description of Scenario 4.1.1: Manual dipping for PT2- disinfection in industries – Exposure to vapour

Since it is an exposure assessment for local effects on respiratory tract, the frequency of application does not play a role in the model.

For this assessment, the Cleaning products fact sheet from ConsExpo is used. Here, the Hand dishwashing liquid scenario is chosen because it is the closest to the manual dipping application.

Besides this scenario, the ECHA Recommendation n°6 of the BPC Ad hoc Working Group on Human Exposure[49] was used in which the proposed model 8 for Dipping application for PT2, PT3 and PT4 indicates the reference to the document HEEG Opinion 8 for the defaults and appropriate models to assess human exposure for dipping processes[50]. This HEEG opinion clearly advises experts to use the evaporation model in ConsExpo, in case inhalation exposure has to be assessed.

That is the reason why this model is chosen and developed here below.

	Parameters	**Value**	**Reference**
Tier 1	Exposure duration	60 minutes	Default value from ConsExpo, Cleaning products fact sheet, Hand dishwashing liquid scenario.
	Product amount	<u>For INDAL PAA 5:</u> 2500L * 1.122 = 2 805 000 g	Applicant's information Containers with a volume of 2500L are usually disinfected by dipping. Of course, these volumes can be lower. So, 2500L is a worst-case volume for dipping application for PT 2 industries. Indeed, when equipment or material is treated by dipping, the volume of product is lower than 2500L.
	Weight fraction substance	<u>For INDAL PAA 5:</u> PAA: 0.00265 H2O2: 0.01275 CH3COOH: 0.0041	Applicant's information. The worst-case dilution is 5% for this product.

49 BPC Ad hoc Working Group on Human Exposure. ECHA Recommandation N°6 – Methods and models to assess exposure to biocidal products in different product types versio 3. 2017

50 EUROPEAN COMMISSION JOINT RESEARCH CENTRE Institute for Health and Consumer Protection. Chemical Assessment and Testing. HEEG Opinion 8-Defaults and appropriate models to assess human exposure for dipping processes (PT8). 2009.

	Room volume	900 m³	Here, for large scale disinfection for PT2, the total treated surface is 1000 m² from Supplement to the ESD for PT2 (Emission scenarios for private and public health area disinfectants and other biocidal products, JRC Scientific and Technical Reports, 2011, p11)[51]. So, if a cuboid shape is considered for the room with a total surface of the room including the ceiling, the walls and the floor is 1000 m² and the Height of the walls is 2.5 m (default value for a non-specified room, ConsExpo, general fact sheet), the report volume per surface is 0.9[52]. So, the room volume is 0.9*1000 = 900 m³.

51 Drafted by Scientific Consulting Company (SCC) GmbH Revised by the Biocides Technical Meeting Endorsed by the Biocides Competent Authorities Meeting Edited by B. Raffael and E. van de Plassche. Emission Scenario Document for Product type 2. Private and public health aera disinfectantcs and other biocidal products. JRC Scientific and Technical Reports, 2011. p11

52 http://www.toutcalculer.com/geometrie/volume-surface-parallelepipede-rectangle.php august 2017

	Ventilation rate	~~1.5/hour~~ 10/h	~~Default value for hospital rooms according to HEAdhoc Recommendation no. 9, 2016)[53] and 3/h (best case assumption for well ventilated rooms) is observed, probably due to the short application and exposure duration. Furthermore, ventilation rate is assumed to be at least 2 air change per hour in "Recommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfection" that gives air change rates in typical rooms and building.~~ ~~Thus, this worst case ventilation rate of 1.5/h is considered for the exposure assessments.~~ As a conclusion from the referral, it has been decided that the RMM: "The room needs to be sufficiently ventilated with a ventilation rate of 10/h" was to be implemented. All subsequent calculation were thus remade with that value.
	Inhalation rate	1.37 m³/hr	Default inhalation rate for an adult during light exercise (ConsExpo).

53 Recommendatioon no. 9 of the BPC Ad hoc Working Group on Human Exposure. Hand disinfection in hospitals. Revision agreed at the Human Health Working Group I. January 2017.

	Vapour pressure	For PAA: 1410 Pa For H2O2: 214 Pa For CH3COOH: 2079 Pa	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: information taken on the ingredient's suppliers (please refer to SDS documents provided in the dossier)
	Application temperature	20°C	Ambient temperature
	Molecular weight	For PAA: 76.05 g/mol For H2O2: 34.01 g/mol For CH3COOH: 60.05 g/mol	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: no information in the SDS or in the REACH dossier. So the value was calculated based on the molecular formula.
	Mass transfer coefficient	For PAA: 18.6 m/hour For H2O2: 24.3 m/hour For CH3COOH: 20.1 m/hour	Estimated with the Thibodeau's method as the products are aqueous solutions.
	Release area mode, increasing: Release area Emission duration	4m² 30 min	The release area is constant over the time. The size of a 2500L container[54] is standard most of the time and is estimated to be: Height: 1.505 m Length: 2.245 m Width: 1.7 m So the surface from which the product evaporates is 2.245*1.7 = 3.8165 m² ~4.0 m² <u>Emission duration:</u> The HEEG Opinion 8[55] also agreed to maintain the duration of 30 minutes as the default.

	Molecular weight matrix	18 g/mol	Since the disinfection of surfaces is performed with a diluted solution of the product, the default value of 18 g/mol for water-based products is considered for the input parameter.

Combined inhalation exposure to aerosol and vapour during manual dipping for PT2 disinfection in industries for each substance and product

Exposure type	**Substances**	**Exposure to Meta-SPC 3 (INDAL PAA 5) [mg/m³]**
Exposure to aerosol	Peracetic acid	0.00053
	Hydrogen peroxide	0.00255
	Acetic acid	0.00082
	Sulphuric acid	0.000096
Exposure to vapour	Peracetic acid	0.501
	Hydrogen peroxide	0.4676
	Acetic acid	1.2358
	Sulphuric acid	n.a.
Total exposure to aerosol and vapour	Peracetic acid	0.5015
	Hydrogen peroxide	0.4702
	Acetic acid	1.2366
	Sulphuric acid	0.000096

n.a. Not applicable because sulphuric acid is slightly volatile

Combined risk related to total inhalation exposure during manual dipping for PT2 disinfection in industries for each product

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**

54 SUEZBELGIUM website, https://suezbelgium.be/fr/professionnel/afval-inzamelen/nos-conteneurs/conteneur-mobile-de-2-500-litres, September 2017

55 EUROPEAN COMMISSION JOINT RESEARCH CENTRE Institute for Health and Consumer Protection. Chemical Assessment and Testing. HEEG Opinion 8-Defaults and appropriate models to assess human exposure for dipping processes (PT8). 2009.

Meta-SPC 3 (INDAL PAA 5)	0.0753	0.070	0.186	0.000016
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	0.151	0.0565	0.00743	0.000288
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	0.207		0.00743	0.000288
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

Worst Case approach:

This was solved during discussion on the referral, were it was considered that enforcing a ventilation rate of 10/h on top of the conditions already put in place would provide a reasonable safe use for all dipping application.

Description of Scenario 4.1.2: Manual dipping for PT2- disinfection in institutions – Exposure to vapour			
Since it is an exposure assessment for local effects on respiratory tract, the frequency of application does not play a role in the model. For this assessment, the Cleaning products fact sheet from ConsExpo is used. Here, the Hand dishwashing liquid scenario is chosen because it is the closest to the application. Besides this scenario, the ECHA Recommendation n°6 of the BPC Ad hoc Working Group on Human Exposure[56] was used in which the proposed model 8 for Dipping application for PT2, PT3 and PT4 indicates the reference to the document HEEG Opinion 8 for the defaults and appropriate models to assess human exposure for dipping processes[57]. This HEEG opinion clearly advises experts to use the evaporation model in ConsExpo, in case inhalation exposure has to be assessed. That is the reason why this model is chosen and developed here below.			
	Parameters	**Value**	**Reference**
Tier 1	Exposure duration	60 minutes	Default value from ConsExpo, Cleaning products fact sheet, Hand dishwashing liquid scenario.
	Product amount	<u>For INDAL PAA 5:</u> 120 000 mL*1.122 = 134 640 g	Applicant's information Containers with a volume of 120L are usually disinfected by dipping. Of course, these volumes can be lower. So, 120L is a worst-case volume for dipping application for PT 2 institutions. Indeed, when equipment or material is treated by dipping, the volume of product is lower than 120L.
	Weight fraction substance	<u>For INDAL PAA 5:</u> PAA: 0.00265 H2O2: 0.01275 CH3COOH: 0.0041	Applicant's information. The product is diluted at 5% to obtain the in-use concentration for this application.

56 BPC Ad hoc Working Group on Human Exposure. ECHA Recommandation N°6 – Methods and models to assess exposure to biocidal products in different product types versio 3. 2017

57 EUROPEAN COMMISSION JOINT RESEARCH CENTRE Institute for Health and Consumer Protection. Chemical Assessment and Testing. HEEG Opinion 8-Defaults and appropriate models to assess human exposure for dipping processes (PT8). 2009.

	Room volume	90 m³	Here, for large scale disinfection for PT2, the total small-scale treated surface is 100 m² from Supplement to the ESD for PT2 (Emission scenarios for private and public health area disinfectants and other biocidal products, JRC Scientific and Technical Reports, 2011, p11)[58]. So, if a cuboid shape is considered for the room with a total surface of the room including the ceiling, the walls and the floor is 100 m² and the Height of the walls is 2.5 m (default value for a non-specified room, ConsExpo, general fact sheet), the report volume per surface is 0.9[59]. So, the room volume is 0.9*100 = 90 m³.
	Ventilation rate	1.5/hour	Default value for hospital rooms according to HEAdhoc Recommendation no. 9, 2016) and 3/h (best case assumption for well ventilated rooms) is observed, probably due to the short application and exposure duration. Furthermore, ventilation rate is assumed to be at least 2 air change per hour in "Recommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfection"that gives air change rates in typical rooms and building. Thus, this worst case ventilation rate of 1.5/h is considered for the exposure assessments.
	Inhalation rate	1.37 m³/hr	Default inhalation rate for an adult during light exercise (ConsExpo).

58 Drafted by Scientific Consulting Company (SCC) GmbH Revised by the Biocides Technical Meeting Endorsed by the Biocides Competent Authorities Meeting Edited by B. Raffael and E. van de Plassche. Emission Scenario Document for Product type 2. Private and public health aera disinfectantcs and other biocidal products. JRC Scientific and Technical Reports, 2011. p11

59 http://www.toutcalculer.com/geometrie/volume-surface-parallelepipede-rectangle.php august 2017

	Vapour pressure	For PAA: 1410 Pa For H2O2: 214 Pa For CH3COOH: 2079 Pa	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: information taken on the ingredient's suppliers (please refer to SDS documents provided in the dossier)
	Application temperature	20°C	Ambient temperature
	Molecular weight	For PAA: 76.05 g/mol For H2O2: 34.01 g/mol For CH3COOH: 60.05 g/mol	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: no information in the SDS or in the REACH dossier. So the value was calculated based on the molecular formula.
	Mass transfer coefficient	For PAA: 18.6 m/hour For H2O2: 24.3 m/hour For CH3COOH: 20.1 m/hour	Estimated with the Thibodeau's method as the products are aqueous solutions.
	Release area mode, increasing: Release area Emission duration	0.6 m² 30 min	The release area is constant over the time. The size of a 120L container is standard most of the time and is estimated to be: Height: 0.96 m Length: 0.55 m Width: 0.48 m So the worst-case surface from which the product evaporates is 0.55*0.96 = 0.528 m² ~0.6 m² Emission duration: The HEEG Opinion 8[60] also agreed to maintain the duration of 30 minutes as the default.

60 EUROPEAN COMMISSION JOINT RESEARCH CENTRE Institute for Health and Consumer Protection. Chemical Assessment and Testing. HEEG Opinion 8-Defaults and appropriate models to assess human exposure for dipping processes (PT8). 2009.

	Molecular weight matrix	18 g/mol	Since the disinfection of surfaces is performed with a diluted solution of the product, the default value of 18 g/mol for water-based products is considered for the input parameter.
Tier 2	Ventilation rate	~~3/hour~~ 10/h	~~Default value for hospital rooms according to HEAdhoc Recommendation no. 9, 2016)[61] and 3/h (best case assumption for well ventilated rooms) is observed, probably due to the short application and exposure duration.~~ ~~Furthermore, Recommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfection gives a ventilation rate of 4 changes per hour for all spaces in general. So, the value of 3/hour can be used.~~ It was decided during referral that dipping could only happen in room with ventilation of 10/h. this value is thus used in the Tier 2 refinement.

<u>Combined inhalation exposure to aerosol and vapour during manual dipping for PT2 large scale disinfection in istitutions for each substance and product</u>

Exposure type	**Substances**	**Exposure to Meta-SPC 3 (INDAL PAA 5) [mg/m³]**
Exposure to aerosol	Peracetic acid	0.00053
	Hydrogen peroxide	0.00255
	Acetic acid	0.00082
	Sulphuric acid	0.000096
Exposure to vapour	Peracetic acid	0.4843

61 Recommendatioon no. 9 of the BPC Ad hoc Working Group on Human Exposure. Hand disinfection in hospitals. Revision agreed at the Human Health Working Group I. January 2017.

	Hydrogen peroxide	0.4676
	Acetic acid	1.2191
	Sulphuric acid	n.a.
Total exposure to aerosol and vapour	Peracetic acid	0.4848
	Hydrogen peroxide	0.4702
	Acetic acid	1.2199
	Sulphuric acid	0.000096

n.a. Not applicable because sulphuric acid is slightly volatile

Combined risk related to total inhalation exposure during manual spraying for PT2 small scale disinfection in industries

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 3 (INDAL PAA 5)	0.1616	0.141	0.366	0.0000288
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	0.291	0.1130	0.0146	0.000577
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	0.4041		0.0146	0.000577
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

Worst Case approach:

This was solved during discussion on the referral, were it was considered that enforcing a ventilation rate of 10/h on top of the conditions already put in place would provide a reasonable safe use for all dipping application.

Conclusions to the exposure during all PT2 manual dipping applications

During manual dipping applications with the maximum use concentration of 5%, the risk related to dermal exposure is acceptable for Meta-SPC 3 (INDAL PAA 5) with the wearing of chemical-resistant gloves and a protective coverall to guarantee sufficient skin protection for the user. No eye protection is required. A ventilation rate of 10/h is required.

To assess the exposure to **Vapour** for **PT3** dipping applications, the model "Exposure to vapour – Evaporation" of the scenario "Application for hand washing cleaning products" of the "Cleaning products fact sheet" of the online program ConsExpo Web[62] was applied. Indeed, in the RIVM "Disinfectant products fact sheet" no dipping model is developed and available.

Description of Scenario 4.2: Manual dipping of open surfaces for PT3 applications – Exposure to vapour

This scenario applies for the next uses:

1) The product INDAL PAA 5 (Meta-SPC 3) is used in animal husbandry to disinfect the open surfaces, material, equipment and containers by dipping application.
    - This is a large scale disinfection that is developed for poultry and pig houses. These two animal houses have the worst-case large scale surface disinfection and covers other animal housing uses.

2) The product INDAL PAA 5 (Meta-SPC 3) is also used in aquaculture plant to disinfect the open surfaces, material, equipment and recirculating aquaculture systems by dipping application.

So, scenario 4.2 is declined in two separated scenarios:

- one for the disinfection by dipping application for poultry and pig houses, scenarios 4.2.1-a and 4.2.1-b, respectively
- one for the disinfection by dipping application in aquaculture farms, scenario 4.2.2

62 L.C.H. Prud'homme de Lodder, H.J. Bremmer, S.M.G.J. Pelgrom, M.V.D.Z. Park, J.G.M. van Engelen. Cleaning Products Fact Sheet to assess the risks fort he consumer. RIVM report 320104003/2006, 2006. p47-49.

Description of Scenario 4.2.1: Manual dipping for PT3- disinfection in animal houses – Exposure to vapour

a) In poultry houses
b) In pig houses

Since it is an exposure assessment for local effects on respiratory tract, the frequency of application does not play a role in the model.

For this assessment, the Cleaning products fact sheet from ConsExpo is used. The Hand dishwashing liquid scenario is chosen because it is the closest to the manual dipping application.

Besides this scenario, the ECHA Recommendation n°6 of the BPC Ad hoc Working Group on Human Exposure was used in which the proposed model 8 for Dipping application[63] for PT2, PT3 and PT4 indicates the reference to the document HEEG Opinion 8 for the defaults and appropriate models to assess human exposure for dipping processes[64]. This HEEG opinion clearly advises experts to use evaporation model in ConsExpo, in case inhalation exposure has to be assessed.

That is the reason why this model is chosen and developed here below.

	Parameters	**Value**	**Reference**
Tier 1	Exposure duration	60 minutes	Default value from ConsExpo, Cleaning products fact sheet, Hand dishwashing liquid scenario.
	Product amount	For INDAL PAA 5 (Meta-SPC 3): 500 000 mL*1.122 = 561 000 g	Applicant's information Containers with a volume of 500L are usually disinfected by dipping. Of course, these volumes can be lower. So, 500L is a worst-case volume for dipping application for PT 3 animal houses. Indeed, when equipment or material is treated by dipping, the volume of product is lower than 500L.
	Weight fraction substance	For INDAL PAA 5 (Meta-SPC 3): PAA: 0.00265 H2O2: 0.01275 CH3COOH: 0.0041	Applicant's information. The product is diluted at 5% to obtain the in-use concentration for this application.

63 BPC Ad hoc Working Group on Human Exposure. ECHA Recommandation N°6 – Methods and models to assess exposure to biocidal products in different product types versio 3. 2017

64 EUROPEAN COMMISSION JOINT RESEARCH CENTRE Institute for Health and Consumer Protection. Chemical Assessment and Testing. HEEG Opinion 8-Defaults and appropriate models to assess human exposure for dipping processes (PT8). 2009.

	Room volume	a) 7182 m³ b) 1683 m³	Here, for disinfection for PT3, the total treated surface is : a) 8040 m² for the worst-case poultry housing (walls, roof, floor and other area), that is for Turkey poultry from ESD for PT3 (Emission scenarios for veterinary hygiene biocidal products, JRC Scientific and Technical Reports, 2011, p51)[65]. b) 2220 m² for the worst-case pig housing (walls, roof, floor, slatted area and other area), that is for sows in group from ESD for PT3 (Emission scenarios for veterinary hygiene biocidal products, JRC Scientific and Technical Reports, 2011, p51)[66]. So, the room volume is estimated considering a room with a cuboid shape. As indicated in the ESD for PT3, the total surface of the room including the ceiling, the walls and the floor is a) 7980 m² and b) 1870 m² and the height of the walls is 2.5 m (default value for a non-specified room, ConsExpo, general fact sheet), the report volume per surface is 0.9. So, the room volume is c) 0.9*7980 = 7182 m³ d) 0.9*1870 = 1683 m³

65 Drafted by Scientific Consulting Company (SCC) GmbH Revised by the Biocides Technical Meeting Endorsed by the Biocides Competent Authorities Meeting Edited by B. Raffael and E. van de Plassche. Emission Scenario Document for Product Type 3. Veterinary hygiene biocidal products. JRC Scientific and Technical Reports. 2011. p51

66 Please refer to the reference 100.

	Ventilation rate	~~1.5/hour~~ 10/h	~~Default value for hospital rooms according to HEAdhoc Recommendation no. 9, 2016)[67] and 3/h (best case assumption for well ventilated rooms) is observed, probably due to the short application and exposure duration. Furthermore, ventilation rate is assumed to be at least 2 air change per hour in "Recommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfection" that gives air change rates in typical rooms and building.~~ ~~Thus, this worst case ventilation rate of 1.5/h is considered for the exposure assessments.~~ A ventilation rate of 10/h was decided as RMM during the referral. All calculation have thus been remade with this new ventilation rate.
	Inhalation rate	1.37 m³/hr	Default inhalation rate for an adult during light exercise (ConsExpo).
	Vapour pressure	For PAA: 1410 Pa For H2O2: 214 Pa For CH3COOH: 2079 Pa	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: information taken on the ingredient's suppliers (please refer to SDS documents provided in the dossier)
	Application temperature	20°C	Ambient temperature

67 Recommendatioon no. 9 of the BPC Ad hoc Working Group on Human Exposure. Hand disinfection in hospitals. Revision agreed at the Human Health Working Group I. January 2017.

	Molecular weight	For PAA: 76.05 g/mol For H2O2: 34.01 g/mol For CH3COOH: 60.05 g/mol	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: no information in the SDS or in the REACH dossier. So the value was calculated based on the molecular formula.
	Mass transfer coefficient	For PAA: 18.6 m/hour For H2O2: 24.3 m/hour For CH3COOH: 20.1 m/hour	Estimated with the Thibodeau's method as the products are aqueous solutions.
	Release area mode, increasing: Release area Application duration	0.8 m² 30 min	The release area is constant over the time. The size of a 500L container is standard most of the time and is estimated to be: Height: 1.1 m Length: 1.2 m Width: 0.655 So the surface from which the product evaporates is 1.2*0.655 = 0.786 m² ~0.8 m² Emission duration: The HEEG Opinion 8[68] also agreed to maintain the duration of 30 minutes as the default.
	Molecular weight matrix	18 g/mol	Since the disinfection of surfaces is performed with a diluted solution of the product, the default value of 18 g/mol for water-based products is considered for the input parameter.

Combined inhalation exposure to aerosol and vapour during Manual dipping for PT3- disinfection in animal houses for each substance and product

68 EUROPEAN COMMISSION JOINT RESEARCH CENTRE Institute for Health and Consumer Protection. Chemical Assessment and Testing. HEEG Opinion 8-Defaults and appropriate models to assess human exposure for dipping processes (PT8). 2009.

Poultry houses		
Exposure type	**Substances**	**Exposure to Meta-SPC 3 (INDAL PAA 5) [mg/m³]**
Exposure to aerosol	Peracetic acid	0.00053
	Hydrogen peroxide	0.00255
	Acetic acid	0.00082
	Sulphuric acid	0.000096
Exposure to vapour	Peracetic acid	0.0132
	Hydrogen peroxide	0.0125
	Acetic acid	0.0317
	Sulphuric acid	n.a.
Total exposure to aerosol and vapour	Peracetic acid	0.0137
	Hydrogen peroxide	0.0151
	Acetic acid	0.0325
	Sulphuric acid	0.000096
Pig houses		
Exposure type	**Substances**	**Exposure to Meta-SPC 3 (INDAL PAA 5) [mg/m³]**
Exposure to aerosol	Peracetic acid	0.00053
	Hydrogen peroxide	0.00255
	Acetic acid	0.00082
	Sulphuric acid	0.000096
Exposure to vapour	Peracetic acid	0.0568
	Hydrogen peroxide	0.0534
	Acetic acid	0.1386
	Sulphuric acid	n.a.
Total exposure to aerosol and vapour	Peracetic acid	0.0573
	Hydrogen peroxide	0.056
	Acetic acid	0.1394
	Sulphuric acid	0.000096

n.a. Not applicable because sulphuric acid is slightly volatile

Combined risk related to total inhalation exposure during manual dipping for PT3- disinfection in animal houses for each product

Poultry houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 3 (INDAL PAA 5)	0.00206	0.00227	0.00488	0.000016
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	0.00411	0.00182	0.000195	0.000288
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 1 :Meta-SPC 3 (INDAL PAA 5)	0.00593		0.000195	0.000288
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Pig houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Tier 1: Meta-SPC 3 (INDAL PAA 5)	0.0086	0.0084	0.0209	0.000016
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	0.0172	0.00672	0.000840	0.000288
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 1: Meta-SPC 3 (INDAL PAA 5)	0.0239		0.000840	0.000288
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

Worst Case approach:

This was solved during discussion on the referral, were it was considered that enforcing a ventilation rate of 10/h on top of the conditions already put in place would provide a reasonable safe use for all dipping application.

Description of Scenario 4.2.2: Manual dipping for PT3- disinfection in aquaculture plants – Exposure to vapour

Since it is an exposure assessment for local effects on respiratory tract, the frequency of application does not play a role in the model.

For this assessment, the Cleaning products fact sheet from ConsExpo is used. Here, the Hand dishwashing liquid scenario is chosen because it is the closest to the application.

Besides this scenario, the ECHA Recommendation n°6 of the BPC Ad hoc Working Group on Human Exposure[69] was used in which the 8th proposed model for Dipping application for PT2, PT3 and PT4 indicates the reference to the document HEEG Opinion 8 for the defaults and appropriate models to assess human exposure for dipping processes[70]. This HEEG opinion clearly advises experts to use evaporation model in ConsExpo, in case inhalation exposure has to be assessed.

That is the reason why this model is chosen and developed here below.

	Parameters	**Value**	**Reference**
Tier 1	Exposure duration	60 minutes	Default value from ConsExpo, Cleaning products fact sheet, Hand dishwashing liquid scenario.
	Product amount	For INDAL PAA 5 (Meta-SPC 3): 20000 L*1.122 = 22 440 000 g	Applicant's information Tanks with a volume of 20 m³ are usually disinfected by dipping. Of course, these volumes can be lower. So, 20000L is a worst-case volume for dipping application for PT 3 in aquaculture plants. Indeed, when equipment or material is treated by dipping, the volume of product is lower than 500L.
	Weight fraction substance	For INDAL PAA 5 (Meta-SPC 3): PAA: 0.00265 H2O2: 0.01275 CH3COOH: 0.0041	Applicant's information. The product is diluted at 5% to obtain the in-use concentration for this application.

69 BPC Ad hoc Working Group on Human Exposure. ECHA Recommandation N°6 – Methods and models to assess exposure to biocidal products in different product types versio 3. 2017

70 EUROPEAN COMMISSION JOINT RESEARCH CENTRE Institute for Health and Consumer Protection. Chemical Assessment and Testing. HEEG Opinion 8-Defaults and appropriate models to assess human exposure for dipping processes (PT8). 2009.

	Room volume	635.04 m^3	Recirculating aquaculture system are circular tanks with a 20 m^3 volume and a height of 1m. The surface of the basis is 20m^2. The diameter of the tank is 5.04 m. Indeed, $\pi r^2 = 20$ and $d=2r$. This kind of farming can have rooms with 10 aquaculture systems per room (Applicant's data). Considering we can have 10 same tanks with a diameter of 5.04m in a room, the room volume can be estimated as following: Length of the room = 5 tanks Width of the room = 2 tanks So, the room is 25.2 m * 10.08 m= 254.016 m^2. The height of the walls is 2.5 m (default value for a non-specified room, ConsExpo, general fact sheet). So, the room volume is estimated to be: 2.5 * 254.016 = 635.04 m^2

	Ventilation rate	1.5/hour	Default value for hospital rooms according to HEAdhoc Recommendation no. 9, 2016)[71] and 3/h (best case assumption for well ventilated rooms) is observed, probably due to the short application and exposure duration. Furthermore, ventilation rate is assumed to be at least 2 air change per hour in "Recommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfection" that gives air change rates in typical rooms and building. Thus, this worst case ventilation rate of 1.5/h is considered for the exposure assessments.
	Inhalation rate	1.37 m³/hr	Default inhalation rate for an adult during light exercise (ConsExpo).
	Vapour pressure	For PAA: 1410 Pa For H2O2: 214 Pa For CH3COOH: 2079 Pa	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: information taken on the ingredient's suppliers (please refer to SDS documents provided in the dossier)
	Application temperature	20°C	Ambient temperature

71 Recommendatioon no. 9 of the BPC Ad hoc Working Group on Human Exposure. Hand disinfection in hospitals. Revision agreed at the Human Health Working Group I. January 2017.

	Molecular weight	For PAA: 76.05 g/mol For H2O2: 34.01 g/mol For CH3COOH: 60.05 g/mol	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: no information in the SDS or in the REACH dossier. So the value was calculated based on the molecular formula.
	Mass transfer coefficient	For PAA: 18.6 m/hour For H2O2: 24.3 m/hour For CH3COOH: 20.1 m/hour	Estimated with the Thibodeau's method as the products are aqueous solutions.
	Release area mode, increasing: Release area Application duration	20 m² 30 min	The release area is constant over the time. The volume of the tank is 20 m³ and the height is 1m. So, the surface from which the product directly evaporates is 20m². Emission duration: The HEEG Opinion 8[72] also agreed to maintain the duration of 30 minutes as the default.
	Molecular weight matrix	18 g/mol	Since the disinfection of surfaces is performed with a diluted solution of the product, the default value of 18 g/mol for water-based products is considered for the input parameter.
Tier 2	Ventilation rate	~~4/hour~~ 10/h	~~Worst-case ventilation rate from the Recommandation of the AdHoc Working Group on Human Exposure n°6 that list the air change rates in typical rooms and buildings for public institutions.~~ It was decided during the referral that all dipping application are required to happen with a ventilation rate of 10/h. This value is thus used for the Tier 2.

Combined inhalation exposure to aerosol and vapour during manual dipping for PT3 disinfection in aquaculture plants for each substance and product

Aquaculture plants		
Exposure type	**Substances**	**Exposure to Meta-SPC 3 (INDAL PAA 5) [mg/m³]**
Exposure to aerosol	Peracetic acid	0.00053
	Hydrogen peroxide	0.00255
	Acetic acid	0.00082
	Sulphuric acid	0.000096
Exposure to vapour	Peracetic acid	1.837
	Hydrogen peroxide	1.6667
	Acetic acid	4.509
	Sulphuric acid	n.a.
Total exposure to aerosol and vapour	Peracetic acid	1.8375
	Hydrogen peroxide	1.6693
	Acetic acid	4.5098
	Sulphuric acid	0.000096

n.a. Not applicable because sulphuric acid is slightly volatile

Combined risk related to total inhalation exposure during manual dipping for PT3 disinfection in aquaculture plants for each product

Aquaculture plants				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Tier 2: Meta-SPC 3 (INDAL PAA 5)	0.735	0.6677	1,804	0.0000384
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05

72 EUROPEAN COMMISSION JOINT RESEARCH CENTRE Institute for Health and Consumer Protection. Chemical Assessment and Testing. HEEG Opinion 8-Defaults and appropriate models to assess human exposure for dipping processes (PT8). 2009.

	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	1.47	0,534	0.07216	0.000768
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	2.0042		0.07216	0.000768
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	face mask with a P1 filter respiratory tract – 0.501		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

Worst Case approach:

This was solved during discussion on the referral, were it was considered that enforcing a ventilation rate of 10/h on top of the conditions already put in place would provide a reasonable safe use for all dipping application.

Conclusions to the exposure during all PT3 manual dipping application

During manual dipping applications with the maximum use concentration of 5%, the risk related to dermal exposure is acceptable for Meta-SPC 3(INDAL PAA 5) with the wearing of chemical-resistant gloves and a protective coverall to guarantee sufficient skin protection for the user. No eye protection is required.

To protect the respiratory tract, the wearing of a respiratory protection equipment (P1 type) is required for the professional use of INDAL PAA 5 with the maximum use concentration of 5% for PT 3 dipping applications in aquaculture plants. For the professional use of INDAL PAA 5 with the maximum use concentration of 5%, no respiratory protective equipment (RPE) is required for the manual dipping applications in other animal houses (poultry houses, pig houses as worst case).

In order to protect the respiratory tract, for all dipping application, the following instructions have to be followed: No heating takes place during dipping bathes and the room need to be sufficiently well ventilated with 10 air changes per hour.

Provide adequate ventilation before the general public re-enter treated areas. The general public is not allowed to enter the outdoor application site and an area 20 m around during spraying and until the surface is rinsed.

To assess the exposure to **Vapour** for **PT4** dipping applications, the model "Exposure to vapour – Evaporation" of the scenario "Application for hand washing cleaning products" of the "Cleaning products fact sheet" of the online program ConsExpo Web[73] was applied.

73 L.C.H. Prud'homme de Lodder, H.J. Bremmer, S.M.G.J. Pelgrom, M.V.D.Z. Park, J.G.M. van Engelen. Cleaning Products Fact Sheet to assess the risks fort he consumer. RIVM report 320104003/2006, 2006. p47-49.

Indeed, in the RIVM "Disinfectant products fact sheet" no dipping model is developed and available.

Description of Scenario 4.3: Manual dipping on open surfaces for PT4 applications – Exposure to vapour

This scenario applies for the next uses:

1) The products INDAL PAA 3.5 (Meta-SPC 1), INDAL PAA 5 (Meta-SPC 3) and INDAL PAA 15 (Meta-SPC 4) are used in all agri-food industries and institutional kitchens to disinfect the open surfaces, material, equipment and containers by dipping application.
    - The scenarios are developed for agri-food industries and institutional kitchen.

      To cover all kind of agri-food industries

      a) the worst-case slaughter houses was chosen because of its worst-case surface to treat from ESD for PT4 (Emission scenarios for disinfectants used in food and feed areas, JRC Scientific and Technical Reports, 2011, p20)[74].
      b) Besides these industries, the scenario is also assessed for the institutional kitchen to cover all agri-food industries.
2) The products INDAL PAA 3.5, INDAL PAA 5 and INDAL PAA 15 are used in all agri-food industries to disinfect boots by dipping application with a foot bath.

So, scenario 4.3 is declined in the next separated scenarios:

- Scenario 4.3.1-a for the manual dipping application in slaughter houses,
- Scenario 4.3.1-b for the manual dipping application in institutional kitchen,
- Scenario 4.3.2-a for the foot bath disinfection application in agri-food industries.

74 Drafted by Scientific Consulting Company (SCC) GmbH Revised by the Biocides Technical Meeting Endorsed by the Biocides Competent Authorities Meeting Edited by B. Raffael and E. van de Plassche. Emission Scenario Document for Product Type 4. Disinfectants used in food and feed ares. JRC Scientific and Technical Reports. 2011. p20

Description of Scenario 4.3.1: Manual dipping for PT4 disinfection– Exposure to vapour

a) In slaughter houses
b) In institutional kitchens

Since it is an exposure assessment for local effects on respiratory tract, the frequency of application does not play a role in the model.

For this assessment, the Cleaning products fact sheet from ConsExpo is used. The Hand dishwashing liquid scenario is chosen because it is the closest to the application.

Besides this scenario, the ECHA Recommendation n°6 of the BPC Ad hoc Working Group on Human Exposure[75] was used in which the 8th proposed model for Dipping application for PT2, PT3 and PT4 indicates the reference to the document HEEG Opinion 8 for the defaults and appropriate models to assess human exposure for dipping processes[76]. This HEEG opinion clearly advises experts to use evaporation model in ConsExpo, in case inhalation exposure has to be assessed.

That is the reason why this model is chosen and developed here below.

	Parameters	**Value**	**Reference**
Tier 1	Exposure duration	a) 60 minutes	Default value from ConsExpo, Cleaning products fact sheet, Hand dishwashing liquid scenario.
	Product amount	<u>For INDAL PAA 3.5 (Meta-SPC 1):</u> 2500L * 1.113 = 2 782 500 g <u>For INDAL PAA 5 ((Meta-SPC 3):</u> 2500L * 1.122 = 2 805 000 g <u>For INDAL PAA 15 (Meta-SPC 4):</u> 2500L * 1.154 = 2 885 000 g	Applicant's information Containers with a volume of 2500L are usually disinfected by dipping. Of course, these volumes can be lower. So, 2500L is a worst-case volume for PT 4 dipping application. Indeed, when equipment or material is treated by dipping, the volume of product is lower than 2500L.

75 BPC Ad hoc Working Group on Human Exposure. ECHA Recommandation N°6 – Methods and models to assess exposure to biocidal products in different product types versio 3. 2017

76 EUROPEAN COMMISSION JOINT RESEARCH CENTRE Institute for Health and Consumer Protection. Chemical Assessment and Testing. HEEG Opinion 8-Defaults and appropriate models to assess human exposure for dipping processes (PT8). 2009.

	Weight fraction substance	For INDAL PAA 3.5 (Meta-SPC 1): PAA: 0.00104 H2O2: 0.01 CH3COOH: 0.002 For INDAL PAA 5 (Meta-SPC 3): PAA: 0.00159 H2O2: 0.00765 CH3COOH: 0.00246 For INDAL PAA 15 (Meta-SPC 4): PAA: 0.002528 H2O2: 0.004 CH3COOH: 0.002208	Applicant's information. The product is diluted at: - 4% to obtain the in-use concentration for this application for INDAL PAA 3.5 - 3% to obtain the in-use concentration for this application for INDAL PAA 5 - 1.6% to obtain the in-use concentration for this application for INDAL PAA 15
	Room volume	a) 50000 m³ b) 6000 m³	c) Slaughter house: 50,000 m³: assuming a surface area of 10,000 m2 multiplied by a room height of 5 m (reference for room height: http://www.fao.org/docrep/003/x6509f/X6509E01.htm page 3 and Annex 1) (Technical agreement for Biocides, December 2016)[77] d) Large kitchen: 6,000 m³: assuming a surface area of 2,000 m² multiplied by a room height of 3 m (Technical agreement for Biocides, December 2016)[78]

77 European Chemicals Agency. Technical Agreements for Biocides (TAB) version 1.3. ECHA-17-R-19-EN. August 2017. p 28.

78 Please refer to reference 116.

	Ventilation rate	~~1.5/hour~~ 10/h	~~Default value for hospital rooms according to HEAdhoc Recommendation no. 9, 2016)[79] and 3/h (best case assumption for well ventilated rooms) is observed, probably due to the short application and exposure duration. Furthermore, ventilation rate is assumed to be at least 2 air change per hour in "Recommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfection" that gives air change rates in typical rooms and building.~~ ~~Thus, this worst case ventilation rate of 1.5/h is considered for the exposure assessments.~~ It was decided at the referral that all dipping application had to be performed with a required ventilation of 10/h.
	Inhalation rate	1.37 m³/hr	Default inhalation rate for an adult during light exercise (ConsExpo).
	Vapour pressure	For PAA: 1410 Pa For H2O2: 214 Pa For CH3COOH: 2079 Pa	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: information taken on the ingredient's suppliers (please refer to SDS documents provided in the dossier)
	Application temperature	20°C	Ambient temperature

79 Recommendatioon no. 9 of the BPC Ad hoc Working Group on Human Exposure. Hand disinfection in hospitals. Revision agreed at the Human Health Working Group I. January 2017.

	Molecular weight	For PAA: 76.05 g/mol For H2O2: 34.01 g/mol For CH3COOH: 60.05 g/mol	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: no information in the SDS or in the REACH dossier. So the value was calculated based on the molecular formula.
	Mass transfer coefficient	For PAA: 18.6 m/hour For H2O2: 24.3 m/hour For CH3COOH: 20.1 m/hour	Estimated with the Thibodeau's method as the products are aqueous solutions.
	Release area mode, increasing: Release area Application duration	4 m² 30 min	The release area is constant over the time. The size of a 2500L container[80] is standard most of the time and is estimated to be: Height: 1.505 m Length: 2.245 m Width: 1.7 m So the surface from which the product evaporates is 2.245*1.7 = 3.8165 m² ~4.0 m² Emission duration: The HEEG Opinion 8[81] also agreed to maintain the duration of 30 minutes as the default.
	Molecular weight matrix	18 g/mol	Since the disinfection of surfaces is performed with a diluted solution of the product, the default value of 18 g/mol for water-based products is considered for the input parameter.

80 SUEZ BELGIUM website, https://suezbelgium.be/fr/professionnel/afval-inzamelen/nos-conteneurs/conteneur-mobile-de-2-500-litres, September 2017

81 EUROPEAN COMMISSION JOINT RESEARCH CENTRE Institute for Health and Consumer Protection. Chemical Assessment and Testing. HEEG Opinion 8-Defaults and appropriate models to assess human exposure for dipping processes (PT8). 2009.

Combined inhalation exposure to aerosol and vapour during manual dipping for PT4 disinfection for each substance and product

Slaughter houses				
Exposure type	**Substances**	**Exposure to Meta-SPC 1 (INDAL PAA 3.5) [mg/m³]**	**Exposure to Meta-SPC 3 (INDAL PAA 5) [mg/m³]**	**Exposure to Meta-SPC 4 (INDAL PAA 15) [mg/m³]**
Exposure to aerosol	Peracetic acid	0.0002	0.0003	0.0005
	Hydrogen peroxide	0.002	0.0015	0.0008
	Acetic acid	0.0004	0.0005	0.0004
	Sulphuric acid	0.0077	0.00006	n.a.
Exposure to vapour	Peracetic acid	0.0036	0.0055	0.0087
	Hydrogen peroxide	0.0068	0.0052	0.0027
	Acetic acid	0.011	0.013	0.012
	Sulphuric acid	n.a.	n.a.	n.a.
Total exposure to aerosol and vapour	Peracetic acid	0.0038	0.0058	0.0092
	Hydrogen peroxide	0.0088	0.0067	0.0035
	Acetic acid	0.0114	0.0135	0.0124
	Sulphuric acid	0.0077	0.00006	n.a.
Institutional kitchen				
Exposure type	**Substances**	**Exposure to Meta-SPC 1 (INDAL PAA 3.5) [mg/m³]**	**Exposure to Meta-SPC 3 (INDAL PAA 5) [mg/m³]**	**Exposure to Meta-SPC 4 (INDAL PAA 15) [mg/m³]**
Exposure to aerosol	Peracetic acid	0.0002	0.0003	0.0005
	Hydrogen peroxide	0.002	0.0015	0.0008
	Acetic acid	0.0004	0.0005	0.0004
	Sulphuric acid	0.0077	0.00006	n.a.
Exposure to vapour	Peracetic acid	0.03	0.045	0.072
	Hydrogen peroxide	0.057	0.043	0.023
	Acetic acid	0.091	0.11	0.1
	Sulphuric acid	n.a.	n.a.	n.a.

Total exposure to aerosol and vapour	Peracetic acid	0.0302	0.0453	0.0725
	Hydrogen peroxide	0.059	0.0445	0.0238
	Acetic acid	0.0914	0.1105	0.1204
	Sulphuric acid	0.0077	0.00006	n.a.

n.a. Not applicable because sulphuric acid is slightly volatile

Combined risk related to total inhalation exposure during manual dipping for PT4 disinfection for each product

Slaughter houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Tier 1 :Meta-SPC 1 (INDAL PAA 3.5)	0.000570	0.00132	0.00171	0.001157
Tier 1: Meta-SPC 3 (INDAL PAA 5)	0.000870	0.0011	0.00202	0.000009
Tier 1: Meta-SPC 4 (INDAL PAA 15)	0.00138	0.000525	0.00186	n.a.
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Tier 1: Meta-SPC 1 (INDAL PAA 3.5)	0.001141	0.0011	0.000075	0.0231
Tier 1: Meta-SPC 3 (INDAL PAA 5)	0.00174	0.00081	0.000075	0.000180
Tier 1: Meta-SPC 4 (INDAL PAA 15)	0.00276	0.000420	0.000075	n.a.
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 1: Meta-SPC 1 (INDAL PAA 3.5)	0.00219		0.000075	0.0231
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 1: Meta-SPC 3 (INDAL PAA 5)	0.00255		0.000075	0.000180
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

Tier 1: Meta-SPC 4 (INDAL PAA 15)	0.020318		0.000075	n.a.
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Institutional Kitchen				
	Exposure to aerosol [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Tier 1: Meta-SPC 1 (INDAL PAA 3.5)	0.00453	0.00885	0.0137	0.0011
Tier 1: Meta-SPC 3 (INDAL PAA 5)	0.0068	0.00668	0.0165	0.000001
Tier 1: Meta-SPC 4 (INDAL PAA 15)	0.01088	0.0357	0.0180	n.a.
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Tier 1: Meta-SPC 1 (INDAL PAA 3.5)	0.00906	0.00708	0.00055	0.0231
Tier 1: Meta-SPC 3 (INDAL PAA 5)	0.0136	0.00534	0.000660	0.00018
Tier 1: Meta-SPC 4 (INDAL PAA 15)	0.0217	0.00285	0.00072	n.a.
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 1: Meta-SPC 1 (INDAL PAA 3.5)	0.016		0.00055	0.0231
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 1: Meta-SPC 3 (INDAL PAA 5)	0.0189		0.00066	0.00018
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 1: Meta-SPC 4 (INDAL PAA 15)	0.0246		0.00072	n.a.
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

Worst Case approach:

This was solved during discussion on the referral, were it was considered that enforcing a ventilation rate of 10/h on top of the conditions already put in place would provide a reasonable safe use for all dipping application.

Description of Scenario 4.3.2: Foot bath dipping for PT4 disinfection– Exposure to vapour

Since it is an exposure assessment for local effects on respiratory tract, the frequency of application does not play a role in the model.

For this assessment, the Cleaning products fact sheet from ConsExpo is used. Here, the Hand dishwashing liquid scenario is chosen because it is the closest to the application.

Besides this scenario, the ECHA Recommendation n°6 of the BPC Ad hoc Working Group on Human Exposure[82] was used in which the 8th proposed model for Dipping application for PT2, PT3 and PT4 indicates the reference to the document HEEG Opinion 8 for the defaults and appropriate models to assess human exposure for dipping processes[83]. This HEEG opinion clearly advises experts to use evaporation model in ConsExpo, in case inhalation exposure has to be assessed.

That is the reason why this model is chosen and developed here below.

	Parameters	**Value**	**Reference**
	Exposure duration	30 seconds	Default value from ECHA Recommendation n°6[84], disinfection foot bath for rubber boots. There is no other default value available in guidances (human toxicology as well as environment toxicology) for exposure duration for foot bath application.
	Product amount	<u>For INDAL PAA 3.5 (Meta-SPC 1):</u> 100 000 mL*1.113 = 111 300 g	The only foot bath volume given is 10L to 100L for PT 3 applications in ECHA Recommendations n°6. So, a volume of 100L is used as a worst-case value extrapolated for disinfection in agri-food industries.
	Weight fraction substance	<u>For INDAL PAA 3.5 (Meta-SPC 1):</u> PAA: 0.00104 H2O2: 0.01 CH3COOH: 0.002	Applicant's information. The product is diluted at: 4% to obtain the in-use concentration for this application for INDAL PAA 3.5

82 BPC Ad hoc Working Group on Human Exposure. ECHA Recommandation N°6 – Methods and models to assess exposure to biocidal products in different product types versio 3. 2017

83 EUROPEAN COMMISSION JOINT RESEARCH CENTRE Institute for Health and Consumer Protection. Chemical Assessment and Testing. HEEG Opinion 8-Defaults and appropriate models to assess human exposure for dipping processes (PT8). 2009.

84 Please refer to reference 121.

	Room volume	6000 m³	The worst-case room volume is chosen, the room volume of a large kitchen. Indeed, assuming a surface area of 2,000 m² multiplied by a room height of 3 m (Technical agreement for Biocides, December 2016)[85].
	Ventilation rate	~~1.5/hour~~ 10/h	~~Default value for hospital rooms according to HEAdhoc Recommendation no. 9, 2016)[86] and 3/h (best case assumption for well ventilated rooms) is observed, probably due to the short application and exposure duration. Furthermore, ventilation rate is assumed to be at least 2 air change per hour in "Recommandation of the AdHoc Working Group on Human Exposure n°6, for application such as hoof bath disinfection" that gives air change rates in typical rooms and building.~~ ~~Thus, this worst case ventilation rate of 1.5/h is considered for the exposure assessments.~~ It was decided during the referral that all dipping application could only take place with a mandatory ventilation rate of at least 10/h. This value is thus used for all calculation.
	Inhalation rate	1.37 m³/hr	Default inhalation rate for an adult during light exercise

85 European Chemicals Agency. Technical Agreements for Biocides (TAB) version 1.3. ECHA-17-R-19-EN. August 2017. p 28.

86 Recommendatioon no. 9 of the BPC Ad hoc Working Group on Human Exposure. Hand disinfection in hospitals. Revision agreed at the Human Health Working Group I. January 2017.

	Vapour pressure	For PAA: 1410 Pa For H2O2: 214 Pa For CH3COOH: 2079 Pa	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: information taken on the ingredient's suppliers (please refer to SDS documents provided in the dossier)
	Application temperature	20°C	Ambient temperature
	Molecular weight	For PAA: 76.05 g/mol For H2O2: 34.01 g/mol For CH3COOH: 60.05 g/mol	PAA and H2O2 (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: no information in the SDS or in the REACH dossier. So the value was calculated based on the molecular formula.
	Mass transfer coefficient	For PAA: 18.6 m/hour For H2O2: 24.3 m/hour For CH3COOH: 20.1 m/hour	Estimated with the Thibodeau's method as the products are aqueous solutions.

	Release area mode, constant: Release area Application duration	3 m² 30 sec	The release area is constant over the time. Default value used to assess inhalation exposure for application for volatile compounds by ConsExpo (evaporation-area of release constant. This information is indicated in the ECHA recommendation n°6, for the hoof bath disinfection. This scenario can be compared to foot bath application, even if it is normally for animals. There is no other default value available in guidances (human toxicology as well as environment toxicology) for release area for foot bath application. Furthermore, release area for hoof bath is considered to be a worst-case value as it is given for cattle that are bigger than humans. Emission duration: Default value from ECHA Recommendation n°6[87], disinfection foot bath for rubber boots.
	Molecular weight matrix	18 g/mol	Since the disinfection of surfaces is performed with a diluted solution of the product, the default value of 18 g/mol for water-based products is considered for the input parameter.

Combined inhalation exposure to aerosol and vapour during foot bath dipping for PT4 disinfection for each substance and product

Exposure type	**Substances**	**Exposure to Meta-SPC 1 (INDAL PAA 3.5) [mg/m³]**

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Exposure to aerosol	Peracetic acid	0.0002
	Hydrogen peroxide	0.002
	Acetic acid	0.0004
	Sulphuric acid	0.0077
Exposure to vapour	Peracetic acid	0.0004
	Hydrogen peroxide	0.0008
	Acetic acid	0.0013
	Sulphuric acid	n.a.
Total exposure to aerosol and vapour	Peracetic acid	0.0006
	Hydrogen peroxide	0.0028
	Acetic acid	0.0017
	Sulphuric acid	0.0077

n.a. Not applicable because sulphuric acid is slightly volatile

Combined risk related to total inhalation exposure during foot bath dipping for PT4 disinfection for each product

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Tier 1: Meta-SPC 1 (INDAL PAA 3.5)	0.0001	0.00042	0.00025	0.001156
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Tier 1: Meta-SPC 1 (INDAL PAA 3.5)	0.00018	0.00033	0.000015	0.0231
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 1: Meta-SPC 1 (INDAL PAA 3.5)	0.00051		0.000015	0.0231
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

Worst Case approach:

This was solved during discussion on the referral, were it was considered that enforcing a ventilation rate of 10/h on top of the conditions already put in place would provide a reasonable safe use for all dipping application.

Conclusions to the exposure during all PT4 manual dipping application

During manual dipping applications the risks related to dermal and eye exposures are only acceptable with the use of chemical-resistant gloves and a protective coverall for the products INDAL PAA 3.5 (Meta-SPC 1), INDAL PAA 5 (Meta-SPC 3), and INDAL PAA 15 (Meta-SPC 4). No protection of eyes is required.

During the manual dipping applications making use of INDAL PAA 3.5, INDAL PAA 5, and INDAL PAA 15, the professional user can proceed the manual dipping without any respiratory protective equipment in all agri-food industries, as well as for foot bath disinfection.

In order to protect the respiratory tract, the following instructions have to be applied for all dipping application: No heating takes place during dipping bathes and the room needs to be sufficiently well ventilated with 10 air changes per hour.

Provide adequate ventilation before the general public re-enter treated areas. The general public is not allowed to enter the outdoor application site and an area 20 m around during spraying and until the surface is rinsed.

Scenario 5: Manual rinsing of open surfaces for the Meta SPC 1, Meta SPC 2, Meta SPC 3, Meta SPC 5

The product is rinsed manually after manual spraying application. This manual application takes place on open surfaces in several industrial sectors. During rinsing of equipment and treated surfaces with water, possible residues on equipment and treated surfaces are highly diluted with water. Possible dermal exposure is therefore considered to be negligible and far below the exposure determined during spray application of the disinfection solution (assumed dilution by a factor of 100).

This exposure is only developed for sulphuric acid. Sulphuric acid is the only substance with a slightly volatility property because of its vapour pressure that is not higher than 0.1Pa (= 0.1 Pa). So, it is assumed that the substances react with organic matter, and that the volatile substances (peracetic acid, hydrogen peroxide, acetic acid) are evaporated after manual spraying and the only substance that is still present on the treated surface is sulphuric acid. The exposure to aerosol is only developed for this chemical to assess the user exposure during this manual rinsing post-application scenario.

No dermal exposure needs to be assessed for sulphuric acid. This ingredient is analysed as a Substance of concern only because it is an element of the list of the European workplace limit that references this chemical for its inhalation exposure characteristics, and not its skin exposure.

The inhalation exposure is developed taking into account specific use characteristics related to a specific product type. The inhalation exposure is shown for each product type in which specificities that trigger exposure features for the user are also assessed.

Note that all products for which a manual rinsing application takes place, a manual spraying application step was conducted before. The related exposures to these spraying applications are assessed in scenarios 3. Please note that for all low-medium spraying application, the treated surface is not allowed to get dry prior to rinsing.

Inhalation exposure

To assess the exposure to **aerosol**, the Spraying Model 2 TNsG 2002 with an indicative value of 76 mg/m³ for inhalation exposure was used. This inhalation indicative value is in accordance with ECHA recommendation N°6 (updated version of February 2017- version 3)[88] and is also referred in the CAR[89] to assess exposure during rinsing post-application.

Description of Scenario 5: Manual rinsing – Exposure to aerosol
This scenario applies for the next uses: 1) For PT 2 applications: ○ Meta SPC 2 – Use #2 for the product INDAL PAA 2.5: Sulphuric acid exposure: 0.00015*76 = 0.0114 mg/m³ ○ Meta SPC3 – Use #1 for the product INDAL PAA 5: Sulphuric acid exposure: 0.00048*76 = 0.03648 mg/m³ 2) For PT 3 applications: ○ Meta SPC 3 - Use #8 for the product INDAL PAA 5: Sulphuric acid exposure: 0.000048*76 = 0.0036 mg/m³ ○ Meta SPC 3 – Use #12 for the product INDAL PAA 5: Sulphuric acid exposure: 0.00048*76 = 0.03648 mg/m³ ○ Meta SPC 5 – Use #1 in vehicle transport for the product INDAL OXY MOUSS: Sulphuric acid exposure: 0.00025*76 = 0.019 mg/m³ 3) For PT 4 applications: ○ Meta SPC 1 - Use #3 for the product INDAL PAA 3.5: Sulphuric acid exposure: 0.000384*76 = 0.0292 mg/m³ ○ Meta SPC 3 – Use #14 for the product INDAL PAA 5: Sulphuric acid exposure: 0.000288*76 = 0.0219 mg/m³ ○ Meta SPC 5 - Use #2 for the product INDAL OXY MOUSS: Sulphuric acid exposure: 0.00025*76 = 0.019 mg/m³

88 BPC Ad hoc Working Group on Human Exposure. ECHA Recommandation N°6 – Methods and models to assess exposure to biocidal products in different product types versio 3. 2017

89 Assessment Report Peracetic acid Product-types 1-6.Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. Finland. Novembre 2015

Risk related to total inhalation exposure during manual rinsing

	Exposure to aerosol [mg/m³]
Substance	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.0292
Meta-SPC 2 (INDAL PAA 2.5)	0.0114
Meta-SPC 3 (INDAL PAA 5) - disinfection in public institutions against algae	0.03648
Meta-SPC 3 (INDAL PAA 5) - disinfection of of animal houses, animal transport vehicles	0.03648
Meta-SPC 3 (INDAL PAA 5) - disinfection of milking parlour	0.0036
Meta-SPC 3 (INDAL PAA 5) - disinfection of agri-food industries	0.0219
Meta-SPC 5 (INDAL PAA OXY MOUSS) - disinfection of animal houses, animal transport vehicles	0.019
Meta-SPC 5 (INDAL PAA OXY MOUSS) - disinfection of agri-food industries	0.019
AEC for local effects to repiratory tract [mg/m³]	0.05
	Risk related to exposure to aerosol (Exposure/AEC) [mg/m³]
Meta-SPC 1 (INDAL PAA 3.5)	0.584
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 2 (INDAL PAA 2.5)	0.228
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 3 (INDAL PAA 5) - disinfection in public institutions against algae	0.7269
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 3 (INDAL PAA 5) - disinfection of of animal houses, animal transport vehicles	0.7269
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 3 (INDAL PAA 5) - disinfection of milking parlour	0.072
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 3 (INDAL PAA 5) - disinfection of agri-food industries	0.438

• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 5 (INDAL PAA OXY MOUSS) - disinfection of animal houses, animal transport vehicles	0.38
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 5 (INDAL PAA OXY MOUSS) - disinfection of agri-food industries	0.38
• **Risk acceptable or non acceptable?**	Acceptable

Conclusions to the exposure during manual rinsing application

During the manual rinsing application, no dermal personal protective equipment or respiratory protective equipment is required for the user that can safely rinse off the diluted biocidal products of the "QUARON PAA family" from treated surfaces, equipment, material, ...

Provide adequate ventilation before the general public re-enter treated areas. The general public is not allowed to enter the outdoor application site and an area 20 m around during spraying and until the surface is rinsed.

Scenario 6: Manual draining of solution contained in recipient or container after dipping applications for Meta SPC 1, Meta SPC 2, Meta SPC 3

The product is drained manually after the manual dipping applications. This manual application takes place after manual dipping material or containers in several industrial sectors.

This exposure is only developed for sulphuric acid. Sulphuric acid is the only substance with a slightly volatility property because of its vapour pressure that is not higher than 0.1Pa (= 0.1 Pa). So, it is assumed that the substances react with organic matter, and that the volatile substances (peracetic acid, hydrogen peroxide, acetic acid) are evaporated after manual dipping and the only substance that is still present on the treated surface is sulphuric acid. The exposure to aerosol is only developed for this chemical to assess the user exposure during this manual draining post-application scenario.

No dermal exposure needs to be assessed for sulphuric acid. Indeed, this ingredient is analysed as a Substance of concern only because it is an element of the European workplace limit that references this chemical for its inhalation exposure characteristics, and not its skin exposure.

The inhalation exposure is assessed taking into account specific use characteristics related to a specific product type. The inhalation exposure is shown for each product type in which specificities that trigger exposure features for the user are also assessed.

Note that all products for which a draining application takes place, a manual dipping application step or only a manual or automated mixing and loading was conducted before. The related exposures to these applications are developed in the scenarios 1, 2, or 4, depending on the use.

Inhalation exposure

To assess the exposure to **aerosol**, the Dipping Model 4 TNsG 2002 with an indicative value of 0.2 mg/m³ for inhalation exposure was used. This inhalation indicative value is in accordance with ECHA recommendation N°6 (updated version of February 2017- version 3)[90] and is also referred in the CAR[91] to assess exposure during rinsing post-application.

Description of Scenario 6: Manual draining – Exposure to aerosol
This scenario applies for the next uses: 1) For PT 2 applications: ○ Meta SPC 2 – Use #1 and 2 for the product INDAL PAA 2.5: Sulphuric acid exposure: 0.00015*0.2 = 0.00003 mg/m³ ○ Meta SPC3 – Use #4 for the product INDAL PAA 5: Sulphuric acid exposure: 0.00048*0.2 = 0.000096 mg/m³ 2) For PT 3 applications: ○ Meta SPC 3 – Uses #9 and #11 for the product INDAL PAA 5: Sulphuric acid exposure: 0.00048*0.2 = 0.000096 mg/m³ 3) For PT 4 applications: ○ Meta SPC 1 - Use #3 for the product INDAL PAA 3.5: Sulphuric acid exposure: 0.000384*0.2 = 0.0001 mg/m³ ○ Meta SPC 3 – Use #16 for the product INDAL PAA 5: Sulphuric acid exposure: 0.000288*0.2 = 0.0001 mg/m³

Risk related to total inhalation exposure during manual draining

	Exposure to aerosol [mg/m³]
Substance	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.0001
Meta-SPC 2 (INDAL PAA 2.5)	0.00003
Meta-SPC 3 (INDAL PAA 5) for PT2 and PT4 applications	0.0001
Meta-SPC 3 (INDAL PAA 5) for PT3 applications	0.0001

90 BPC Ad hoc Working Group on Human Exposure. ECHA Recommandation N°6 – Methods and models to assess exposure to biocidal products in different product types versio 3. 2017

91 Assessment Report Peracetic acid Product-types 1-6.Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. Finland. Novembre 2015

AEC for local effects to repiratory tract [mg/m³]	0.05
	Risk related to exposure to aerosol (Exposure/AEC) [mg/m³]
Meta-SPC 1 (INDAL PAA 3.5)	0.002
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 2 (INDAL PAA 2.5)	0.0006
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 3 (INDAL PAA 5) for PT2 and PT4 applications	0.002
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 3 (INDAL PAA 5) for PT3 applications	0.002
• **Risk acceptable or non acceptable?**	Acceptable

Conclusions to the exposure during manual draining application

During manual draining application, no dermal personal protective equipment or respiratory protective equipment is required for the user that safely drain the diluted biocidal products of the "QUARON PAA family".

Provide adequate ventilation before the general public re-enter treated areas. The general public is not allowed to enter the outdoor application site and an area 20 m around during spraying and until the surface is rinsed.

Combined scenarios

Dermal exposure

Worst case approach since local effects at the site of first contact (and absence of a systemic availability of peracetic acid and hydrogen peroxide), only the highest concentration (= undiluted) of the biocidal products of the „QUARON PAA family" is relevant for exposure/risk assessment purposes and no calculations of a combined dermal exposure during the different tasks for a same user is required.

Worst case: mixing and loading

	Dermal exposure			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	2.6%	25%	5%	0.96%
Meta-SPC 2 (INDAL PAA 2.5)	2%	35.5%	2.2%	0.3%
Meta-SPC 3 (INDAL PAA 5)	5.3%	25.5%	8.2%	0.96%

Meta-SPC 4 (INDAL PAA 15)	15.8%	25%	13.8%	-
Meta-SPC 5 (INDAL OXY MOUSS)	1.2%	13.0%	5.75%	0.5%
Meta-SPC 6 (INDAL TAP 5)	5%	21%	5.95%	13.5%
NOAEC local dermal effects or Skin irritating threshold	0.2% (short) 0.1% (long)	35% (eye dam 8%<C≤50%) (eye irrit 5%<C≤8%)	10%	5%
	Risk related to dermal exposure (comparing to dermal NOAEC or skin irritating threshold)			
Meta-SPC 1 (INDAL PAA 3.5)	higher skin protection needed	Skin: lower Eye: higher eye protection needed	lower	lower
PPE	Gloves, coverall, face shield			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
Meta-SPC 2 (INDAL PAA 2.5)	higher skin protection needed	higher skin protection needed	lower	lower
PPE	Gloves, coverall, face shield			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	higher skin protection needed	Skin: lower Eye: higher eye protection needed	lower	lower
PPE	Gloves, coverall, face shield			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
Meta-SPC 4 (INDAL PAA 15)	higher skin protection needed	Skin: lower Eye: higher eye protection needed	higher skin protection needed	n.a.
PPE	Gloves, coverall, face shield			

Risk acceptable or non acceptable?	Acceptable			n.a.
Meta-SPC 5 (INDAL OXY MOUSS)	higher skin protection needed	Skin: lower Eye: higher eye protection needed	lower	lower
PPE	Gloves, coverall, face shield			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
Meta-SPC 6 (INDAL TAP 5)	higher skin protection needed	Skin: lower Eye: higher eye protection needed	lower	higher
PPE	Gloves, coverall, face shield			
Risk acceptable or non acceptable?	Acceptable	Acceptable	Acceptable	Acceptable

Inhalation exposure

Worst case approach since local effects at the site of first contact (and absence of a systemic availability of peracetic acid and hydrogen peroxide), only the highest exposure level in air of the biocidal products of the „QUARON PAA family" is relevant for exposure/risk assessment purposes and no addition of exposure levels and no calculations of a combined inhalation exposure during the different tasks for a same user is required.

(III) Non-professional exposure

No applications related to non-professional use were identified. The biocidal products of the „QUARON PAA family" are not available for non-professional use.

(IV) Exposure of the general public

Local effects

Secondary exposure

Dermal

Secondary exposure scenarios of humans and a systemic exposure following dermal contact with treated areas, surfaces, material, or equipment is considered to be not relevant. It is assumed that the substances react with organic matter, are evaporated (high volatility of peracetic acid, hydrogen peroxide and acetic acid) and are not present anymore on the treated surface after application and post-application rinsing/draining after

spraying/dipping. Indeed, because of the rinsing, the products are further diluted. Therefore, no skin damage occurs or is expected after dermal contact with treated surfaces, material, equipment.

Furthermore (refere to Document IIB Peracetic acid PT1-6, section 8.2.3 Secondary exposure, final CAR 2015, Finland),

-Owing to the chemical properties of peracetic acid and considering the mechanism of action as well as its function as a strong oxidant, peracetic acid is highly unstable and will rapidly degrade at the site of first contact, i.e. on treated surfaces or equipment. This mode of action applies also to hydrogen peroxide. Even in the case, that higher concentrated peracetic acid solutions might cross the skin barrier as a consequence of skin damage, peracetic acid will not become systemically available or will be systemically distributed in the organism due to its instantaneous degradation in the blood. Thus, in light of the known high reactivity of peracetic acid and hydrogen peroxide, systemic exposure towards peracetic acid and hydrogen peroxide after dermal contact is not likely to occur and the substance will not become systemically available as a consequence thereof.

- Hydrogen peroxide solutions below skin irritating concentrations as well do not penetrate the skin, since it reacts rapidly at the site of first contact and degrades to form water and oxygen. In the unlikely case that hydrogen peroxide penetrates skin, it will not become systemically available as it is enzymatically degraded within the body (catalase, glutathione peroxidase). Therefore, systemic exposure towards hydrogen peroxide is not likely to occur after dermal contact since it will not become systemically available.

Inhalation

Certain situations do exist in which a secondary exposure of humans *via* the inhalation route cannot be excluded. For instance, after application of peracetic acid solutions for disinfection of surfaces in industrial, public and health care areas (PT2) or following spraying of animal houses, animal transport vehicles (PT3), or following disinfection of surfaces in the agri-food industry (PT4), people walking by or entering treated premises may be potentially exposed to airborne peracetic acid and hydrogen peroxide for a short period of time. The exposure of the general public is considered to be of short duration and to occur under conditions related to an acute exposure scenario only.

Refering to the exposure assessment for the industrial and professional user:

***Scenario 1**: Manual mixing and loading*

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 2 (INDAL PAA 2.5)	0.0517	0.3977	0.0648	0.0028
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 2 (INDAL PAA 2.5)	0.1034	0.3182	0.0026	0.056
	Combined risk due to equilibrium reaction [mg/m³]			

Meta-SPC 2 (INDAL PAA 2.5)	0.4216	0.0026	0.056
• **Risk acceptable or non acceptable?**	Acceptable	Acceptable	Acceptable

Conclusions to the primary exposure during manual mixing and loading of the user:

During this application, no respiratory protective equipment is required. Indeed, the risk related to inhalation exposure to aerosol and vapour is acceptable without any personal protective equipment.

Conclusions to the secondary exposure manual mixing and loading of the general public:

The risk related to inhalation exposure to aerosol and vapour is acceptable as no respiratory protective equipment is required.

***Scenario 2**: Automated mixing and loading by pumping of concentrates*

Inhalation **Exposure to aerosol [mg/m³]**				
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.572	5.1	1.1	0.2112
Meta-SPC 2 (INDAL PAA 2.5)	0.44	7.81	0.484	0.066
Meta-SPC 3 (INDAL PAA 5)	1.166	5.61	1.804	0.2112
Meta-SPC 4 (INDAL PAA 15)	3.476	5.5	3.036	n.a.
Meta-SPC 5 (INDAL OXY MOUSS)	0.264	2.86	1.265	0.11
Meta-SPC 6 (INDAL TAP 5)	1.1	5.62	1.309	2.97
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol (Exposure/AEC) [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	1.144	4.08	0.044	4.224
Meta-SPC 2 (INDAL PAA 2.5)	0.88	6.248	0.0194	1.32
Meta-SPC 3 (INDAL PAA 5)	2.332	4.488	0.0722	4.224
Meta-SPC 4 (INDAL PAA 15)	6.952	4.4	0.1214	n.a.

Meta-SPC 5 (INDAL OXY MOUSS)	0.528	2.288	0.0506	2.2
Meta-SPC 6 (INDAL TAP 5)	2.2	4.496	0.0524	59.4
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5-	5.224		0.044	4.224
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Non acceptable
Meta-SPC 2 (INDAL PAA 2.5)	7.128		0.0194	1.32
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Non acceptable
Meta-SPC 3 (INDAL PAA 5)	6.82		0.0722	4.224
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Non acceptable
Meta-SPC 4 (INDAL PAA 15)	11.352		0.11214	n.a.
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	n.a.
Meta-SPC 5 (INDAL OXY MOUSS)	2.816		0.0506	2.2
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Non acceptable
Meta-SPC 6 (INDAL TAP 5)	6.696		0.0524	59.4
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Non acceptable

n.a. Not applicable because INDAL PAA 15 does not contain sulphuric acid in its formulation.

Conclusions to the primary exposure during manual connecting for automatic mixing and loading system of the user:

During this application, all products requires the wearing of a respiratory protective equipment (RPE). Full masks are proposed to also protect the eyes due to the damaging effects to eyes of the biocidal products.

Conclusions to the secondary exposure manual connecting for automatic mixing and loading system of the general public:

The risk related to inhalation exposure to aerosol and vapour is not acceptable as the wearing of respiratory protective equipment is required. Any bystander should be protected in this way and general public should not be allowed to enter places where biocidal products of the Quaron PAA family are connected manually for automatic mixing and loading system.

***Scenario 3**: Manual spraying on open surfaces for all Meta SPC exepted Meta SPC 4 (INDAL PAA 15) and Meta SPC 6 (INDAL TAP 5)*

3.1 PT2 Manual spraying

3.1.1 Inhalation exposure: large scale disinfection in industries

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 2 (INDAL PAA 2.5)	0.8108	9.2792	0.8269	0.00912
Meta-SPC 3 (INDAL PAA 5)	1.6208	4.9814	2.587	0.0219
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 2 (INDAL PAA 2.5)	1.6216	7.4234	0.0331	0.1824
Meta-SPC 3 (INDAL PAA 5)	3.2416	3.9851	0.1035	0.438
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 2 (INDAL PAA 2.5)	9.045		0.0331	0.1824
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	7.2267		0.1035	0.438
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable

3.1.2 Inhalation exposure: small scale disinfection in industries

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 2 (INDAL PAA 2.5)	0.4908	4.6792	0.5769	0.00912
Meta-SPC 3 (INDAL PAA 5)	0.9608	2.4814	1.587	0.0219
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 2 (INDAL PAA 2.5)	0.9816	3.7434	0.0231	0.1824
Meta-SPC 3 (INDAL PAA 5)	1.9216	1.9851	0.0635	0.438

	Combined risk due to equilibrium reaction [mg/m³]		
Meta-SPC 2 (INDAL PAA 2.5)	4.725	0.0231	0.1824
• **Risk acceptable or non acceptable?**	Non acceptable	Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	3.9067	0.0635	0.438
• **Risk acceptable or non acceptable?**	Non acceptable	Acceptable	Acceptable

3.1.3 Inhalation exposure: small scale disinfection in institutions

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 2 (INDAL PAA 2.5)	2.7608	14.0792	3.6669	0.00912
Meta-SPC 3 (INDAL PAA 5)	5.4208	7.6814	10.087	0.0219
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 2 (INDAL PAA 2.5)	5.5216	11.2634	0.1467	0.1824
Meta-SPC 3 (INDAL PAA 5)	10.8416	6.1451	0.4035	0.438
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 2 (INDAL PAA 2.5)	16.785		0.1467	0.1824
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	16.9867		0.4035	0.438
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable

3.1.4 Inhalation exposure: small scale disinfection in swimming pool and balneotherapy and other institutions against algae

Since all Tier 1 approach were above the AEC, only Tier 2 and Tier 3 values are presented below

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**

Tier 2: Meta-SPC 2 (INDAL PAA 2.5)	5.076	16.353	7.9836	0.0114
Tier 2: Meta-SPC 3 (INDAL PAA 5)	13.2014	10.969	30.3116	0.03648
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Tier 2: Meta-SPC 2 (INDAL PAA 2.5)	10.152	13.0824	0.3193	0.228
Tier 2: Meta-SPC 3 (INDAL PAA 5)	26.4028	8.7752	1.2125	0.7296
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 2 (INDAL PAA 2.5)	23.2344		0.3193	0.228
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.5809		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 3 (INDAL PAA 5)	35.178		1.2125	0.7296
• **Risk acceptable or non acceptable?**	Non acceptable		Non acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.8795		Half face mask with a P1 filter to protect respiratory tract – 0.3031	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

3.2 PT3 Manual spraying

3.2.1 Inhalation exposure: large scale disinfection in animal houses

Since Tier 1 values were above AEC, only Tier 2 and Tier 3 values are presented below

Poultry houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**

Tier 2: Meta-SPC 3 (INDAL PAA 5)	1.0534	4.689	1.6316	0.03648
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	0.1076	1.044	0.5185	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Tier2: Meta-SPC 3 (INDAL PAA 5)	2.106	3.7512	0.06526	0.7296
Tier2: Meta-SPC 5 (INDAL OXY MOUSS)	0.2152	0.8352	0.0207	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	5.8572		0.06526	0.7296
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P2 filter to protect respiratory tract – 0.5857		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	1.0504		0.0242	0.38
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.2626		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Pig houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Tier 2: Meta-SPC 3 (INDAL PAA 5)	3.8014	15.369	5.9516	0.03648

Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	0.3056	2.494	1.5185	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	7.6028	12.2952	0.2381	0.7296
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	0.6112	1.9952	0.0607	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	19.898		0.0263	0.38
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.4975		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	2.6064		0.0607	0.38
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.6516		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

3.2.2 Inhalation exposure: small scale disinfection in animal houses

Poultry houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**

Tier 2: Meta-SPC 3 (INDAL PAA 5)	1.0534	4.689	1.6316	0.03648
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	0.1076	1.044	0.5185	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	2.106	3.7512	0.06526	0.7296
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	0.2152	0.8352	0.0207	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	19.898		0.06526	0.7296
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.4975		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	1.0504		0.0242	0.38
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.2626		/	/
• **Risk acceptable**	Acceptable		Acceptable	Acceptable

of non acceptable?				
Pig houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Tier 2: Meta-SPC 3 (INDAL PAA 5)	3.5614	12.609	5.5916	0.03648
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	0.2656	1.794	1.3185	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	7.122	10.0872	0.2237	0.7296
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	0.5312	1.4352	0.0527	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	17.2092		0.2237	0.7296
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.4302		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	1.9664		0.0527	0.38
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable

• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.4916	/	/
• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	Acceptable

3.2.3 Inhalation exposure: disinfection of vehicles for animal transport

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	1.7456	5.794	10.2185	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	3.4912	4.6352	0.4087	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	8.1264		0.4087	0.38
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable

3.2.4 Inhalation exposure: disinfection of milking parlour systems in farms

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Tier 2: Meta-SPC 3 (INDAL PAA 5)	0.0201	0.0969	0.0312	0.0036
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Tier 2: Meta-SPC 3 (INDAL PAA 5)	0.0402	0.0775	0.0012	0.072
	Combined risk due to equilibrium reaction [mg/m³]			

Tier 2: Meta-SPC 3 (INDAL PAA 5)	0.1177	0.0012	0.072
• **Risk acceptable or non acceptable?**	Acceptable	Acceptable	Acceptable

3.3 PT4 Manual spraying

3.3.1 Inhalation exposure: large scale disinfection

Slaughter houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.104	0.98	0.2	0.0292
Meta-SPC 3 (INDAL PAA 5)	0.1588	0.7514	0.247	0.0219
Meta-SPC 5 (INDAL OXY MOUSS)	0.0786	0.794	0.3785	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	0.208	0.784	0.008	0.584
Meta-SPC 3 (INDAL PAA 5)	0.3176	0.6011	0.0099	0.438
Meta-SPC 5 (INDAL OXY MOUSS)	0.1572	0.6352	0.0151	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 1 (INDAL PAA 3.5)	0.992		0.008	0.584
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 3 (INDAL PAA 5)	0.9187		0.0099	0.438
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	0.7924		0.0151	0.38
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Institutional Kitchen				
	Total exposure to aerosol and vapour [mg/m³]			

Substances	Peracetic acid	Hydrogen peroxide	Acetic acid	Sulphuric acid
Tier 2: Meta-SPC 1 (INDAL PAA 3.5)	0.112	1.06	0.217	0.0292
Tier 2: Meta-SPC 3 (INDAL PAA 5)	0.1728	0.8114	0.267	0.0219
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	0.0906	0.894	0.4385	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Tier 2: Meta-SPC 1 (INDAL PAA 3.5)	0.224	0.848	0.0087	0.584
Tier 2: Meta-SPC 3 (INDAL PAA 5)	0.3456	0.6491	0.0107	0.438
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	0.1812	0.7152	0.0351	0.76
	Combined risk due to equilibrium reaction [mg/m³]			
Tier 2: Meta-SPC 1 (INDAL PAA 3.5)	1.072		0.0087	0.584
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 3 (INDAL PAA 5)	0.9947		0.0107	0.438
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Tier 2: Meta-SPC 5 (INDAL OXY MOUSS)	0.8964		0.0351	0.76
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

3.3.2 Inhalation exposure: small scale disinfection

Slaughter houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.104	0.98	0.2	0.0292

Meta-SPC 3 (INDAL PAA 5)	0.1588	0.7514	0.247	0.0219
Meta-SPC 5 (INDAL OXY MOUSS)	0.0786	0.794	0.3785	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	0.208	0.784	0.008	0.584
Meta-SPC 3 (INDAL PAA 5)	0.3176	0.6011	0.0099	0.438
Meta-SPC 5 (INDAL OXY MOUSS)	0.1572	0.6352	0.0151	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	0.992		0.008	0.584
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	0.9187		0.0099	0.438
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 5 (INDAL OXY MOUSS)	0.7924		0.0151	0.38
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Institutional Kitchen				
	Exposure to aerosol [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.11	0.99	0.213	0.0292
Meta-SPC 3 (INDAL PAA 5)	0.1688	0.7614	0.263	0.0219
Meta-SPC 5 (INDAL PAA OXY MOUSS)	0.0846	0.724	0.4185	0.019
AEC for local effects to repiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			

Meta-SPC 1 (INDAL PAA 3.5)	0.22	0.792	0.0085	0.584
Meta-SPC 3 (INDAL PAA 5)	0.3376	0.6091	0.0105	0.438
Meta-SPC 5 (INDAL PAA OXY MOUSS)	0.1692	0.5792	0.0167	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	1.012		0.0085	0.584
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	0.9467		0.0105	0.438
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 5 (INDAL PAA OXY MOUSS)	0.7484		0.0167	0.38
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

Conclusions to the primary exposure during all **PT2** manual spraying applications of the user:

During this application, both products INDAL PAA2.5 (Meta-SPC 2) and INDAL PAA 5 (Meta-SPC 3), require the wearing of a respiratory protective equipment (RPE). Only half masks are proposed since no protection to eyes is required.

Conclusions to the secondary exposure for all PT2 manual spraying applications of the general public:

The risk related to inhalation exposure to aerosol and vapour is not acceptable as the wearing of respiratory protective equipment is required. General public should not be allowed to enter places where spraying activities with the biocidal products INDAL PAA 2.5 and INDAL PAA 5 (respectively from Meta-SPC 2 and 3) of the Quaron PAA family are taking place. The general public is only allowed to re-enter these places when these places are well ventilated and the concentration of peracetic acid and hydrogen peroxide in the air is lower than the AEC for local effects to respiratory tract.

Conclusions to the primary exposure during all **PT3** manual spraying applications of the user:

During these manual spraying applications, both products INDAL PAA 5 and INDAL OXY MOUSS (from Meta-SPC 5), require the wearing of a respiratory protective equipment (RPE), except for 1 application. Only half masks are proposed since no protection to eyes is required.

For the use of INDAL PAA 5 when diluted to a 0.5% use concentration during manual spraying disinfection of milking claws in farms, no respiratory protective equipment is required for the user.

Conclusions to the secondary exposure for all PT3 manual spraying applications of the general public:

The risk related to inhalation exposure to aerosol and vapour is not acceptable as the wearing of respiratory protective equipment is required except for the use of INDAL PAA 5

when diluted to a 0.5% use concentration during manual spraying disinfection of milking claws in farms. General public should not be allowed to enter places where spraying activities with the biocidal products INDAL PAA 5 and INDAL OXY MOUSS of the Quaron PAA family are taking place. The general public is only allowed to re-enter these places when these places are well ventilated and the concentration of peracetic acid and hydrogen peroxide in the air is lower than the AEC for local effects to respiratory tract. There is no inhalation risk for the general public for the manual spraying disinfection of milking claws in farms with INDAL PAA 5 at a use concentration of 0.5%.

Conclusions to the primary exposure during all **PT4** manual spraying applications of the user:

During these applications, the product INDAL PAA 3.5 requires the wearing of a respiratory protective equipment (RPE). Only half masks is proposed since no protection to eyes is required.

For the use of INDAL PAA 5, as well as of INDAL OXY MOUSS, no respiratory protective equipment is required for the manual spraying disinfection in all agri-food industries.

Conclusions to the secondary exposure for all PT4 manual spraying applications of the general public:

The risk related to inhalation exposure to aerosol and vapour is not acceptable for the product INDAL PAA 3.5 (Meta-SPC 1) as the wearing of respiratory protective equipment is required. For the use of INDAL PAA 5 (Meta-SPC 3) and INDAL OXY MOUSS (Meta-SPC 5), no respiratory protective equipment is required for the manual spraying disinfection in all agri-food industries.

General public should not be allowed to enter places where spraying activities with the biocidal product INDAL PAA 3.5 of the Quaron PAA family are taking place. The general public is only allowed to re-enter these places when these places are well ventilated and the concentration of peracetic acid and hydrogen peroxide in the air is lower than the AEC for local effects to respiratory tract. There is no inhalation risk for the general public for the manual spraying disinfection in all agri-food industries with INDAL PAA 5 and INDAL OXY MOUSS.

After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.

Scenario 4: *Manual dipping of material and/or containers for the Meta SPC 1, Meta SPC 3, Meta SPC 4*

4.1 PT2 Manual dipping

4.1.1 Inhalation exposure: large scale disinfection in industries

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 3 (INDAL PAA 5)	0.5015	0.4702	1.2366	0.000096
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05

	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	1.003	0.3762	0.04946	0.00192
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	1.3792		0.04946	0.00192
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.3448		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

4.1.2 Inhalation exposure: small scale disinfection in institutions

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 3 (INDAL PAA 5)	0.4848	0.4702	1.2199	0.000096
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	0.9696	0.3762	0.0488	0.00192
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	1.3458		0.0488	0.00192
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.3365		/	/
• **Risk acceptable of**	Acceptable		Acceptable	Acceptable

non acceptable?			

4.2 PT3 Manual dipping

4.2.1 Inhalation exposure: large scale disinfection in animal housing

Poultry houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 3 (INDAL PAA 5)	0.0137	0.0151	0.0325	0.000096
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	0.0274	0.0121	0.0013	0.00192
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	0.0395		0.0013	0.00192
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Pig houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 3 (INDAL PAA 5)	0.0573	0.056	0.1394	0.000096
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	0.1146	0.0448	0.0056	0.00192
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	0.1594		0.0056	0.00192
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

4.2.2 Inhalation exposure: disinfection in aquaculture farms

Aquaculture plants				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 3 (INDAL PAA 5)	1.8375	1.6693	4.5098	0.000096
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	3.675	1.3354	0.1804	0.00192
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	5.0104		0.1804	0.00192
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P2 filter respiratory tract – 0.501		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

4.3 PT4 Manual dipping

4.3.1 Inhalation exposure: large scale disinfection in agri-food industries

Slaughter houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.0038	0.0088	0.0114	0.0077
Meta-SPC 3 (INDAL PAA 5)	0.0058	0.0067	0.0135	0.00006
Meta-SPC 4 (INDAL PAA 15)	0.0092	0.0035	0.0124	n.a.

AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	0.0076	0.007	0.0005	0.154
Meta-SPC 3 (INDAL PAA 5)	0.0116	0.0054	0.0005	0.0012
Meta-SPC 4 (INDAL PAA 15)	0.0184	0.0028	0.0005	n.a.
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	0.0146		0.0005	0.154
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	0.017		0.0005	0.0012
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 4 (INDAL PAA 15)	0.0212		0.0005	n.a.
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Institutional Kitchen				
	Exposure to aerosol [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.0302	0.059	0.0914	0.0077
Meta-SPC 3 (INDAL PAA 5)	0.0453	0.0445	0.1105	0.00006
Meta-SPC 4 (INDAL PAA 15)	0.0725	0.0238	0.1204	n.a.
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	0.0604	0.0472	0.0037	0.154
Meta-SPC 3 (INDAL PAA 5)	0.0906	0.0356	0.0044	0.0012

Meta-SPC 4 (INDAL PAA 15)	0.145	0.019	0.0048	n.a.
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	0.1076		0.0037	0.154
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	0.1262		0.0044	0.0012
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 4 (INDAL PAA 15)	0.164		0.0048	n.a.
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

4.3.2 Inhalation exposure: foot bath disinfection in agri-food industries

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.0006	0.0028	0.0017	0.0077
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	0.0012	0.0022	0.0001	0.154
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	0.0034		0.0001	0.154
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

Conclusions to the primary exposure during all **PT2** manual dipping applications of the user:

For the professional use of INDAL PAA 5 (Meta-SPC 3) with the maximum use concentration of 5%, a

a respiratory protective equipment (RPE) and especially a half face mask with a P1 filter to protect respiratory tract is required for the manual dipping applications in industries as well as in institutions.

Conclusions to the secondary exposure for all PT2 manual dipping applications of the general public:

The risk related to inhalation exposure to aerosol and vapour is not acceptable as the wearing of respiratory protective equipment is required. General public should not be allowed to enter places where dipping activities with the biocidal products INDAL PAA 5 (Meta-SPC 3) and of the Quaron PAA family are taking place. The general public is only allowed to re-enter these places when these places are well ventilated and the concentration of peracetic acid and hydrogen peroxide in the air is lower than the AEC for local effects to respiratory tract.

Conclusions to the primary exposure during all **PT3** manual dipping applications of the user:

To protect the respiratory tract, the wearing of a respiratory protection equipment (P2 type) is required for the professional use of INDAL PAA 5 with the maximum use concentration of 5% for PT 3 dipping applications in aquaculture plants. For the professional use of INDAL PAA 5 with the maximum use concentration of 5%, no respiratory protective equipment (RPE) is required for the manual dipping applications in other animal houses (poultry houses, pig houses as worst case).

Conclusions to the secondary exposure for all PT3 manual dipping applications of the general public:

Aquaculture plants: The risk related to inhalation exposure to aerosol and vapour is not acceptable for the product INDAL PAA 5 (Meta-SPC 3)as the wearing of respiratory protective equipment is required. General public should not be allowed to enter places where spraying activities with the biocidal product INDAL PAA 5 of the Quaron PAA family are taking place. The general public is only allowed to re-enter these places when these places are well ventilated and the concentration of peracetic acid and hydrogen peroxide in the air is lower than the AEC for local effects to respiratory tract.

Other animal housing: The risk related to inhalation exposure to aerosol and vapour is acceptable as no respiratory protective equipment is required. The general public can enter the treated animal housing with INDAL PAA 5 without risk related to inhalation exposure.

Conclusions to the primary exposure during all **PT4** manual dipping applications of the user:

During the manual dipping applications making use of INDAL PAA 3.5, INDAL PAA 5, and INDAL PAA 15, the professional user can proceed the manual dipping without any respiratory protective equipment in all agri-food industries, as well as for foot bath disinfection.

Conclusions to the secondary exposure for all PT4 manual dipping applications of the general public:

The risk related to inhalation exposure to aerosol and vapour is acceptable as no respiratory protective equipment is required. The general public can enter the treated areas of the agri-food industries with INDAL PAA 3.5 (Meta-SPC 1), INDAL PAA 5 (Meta-SPC 3), INDAL PAA 15 (Meta-SPC 4) without risk related to inhalation exposure.

***Scenario 5**: Manual rinsing of open surfaces for the Meta SPC 1, Meta SPC 2, Meta SPC 3, Meta SPC 5*

	Exposure to aerosol [mg/m³]
Substance	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.0292

Meta-SPC 2 (INDAL PAA 2.5)	0.0114
Meta-SPC 3 (INDAL PAA 5) - disinfection in public institutions against algae	0.03648
Meta-SPC 3 (INDAL PAA 5) - disinfection of of animal houses, animal transport vehicles	0.03648
Meta-SPC 3 (INDAL PAA 5) - disinfection of milking parlour	0.0036
Meta-SPC 3 (INDAL PAA 5) - disinfection of agri-food industries	0.0219
Meta-SPC 5 (INDAL PAA OXY MOUSS) - disinfection of animal houses, animal transport vehicles	0.019
Meta-SPC 5 (INDAL PAA OXY MOUSS) - disinfection of agri-food industries	0.019
AEC for local effects to repiratory tract [mg/m³]	0.05
	Risk related to exposure to aerosol (Exposure/AEC) [mg/m³]
Meta-SPC 1(INDAL PAA 3.5)	0.584
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 2 (INDAL PAA 2.5)	0.228
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 3 (INDAL PAA 5) - disinfection in public institutions against algae	0.7269
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 3 (INDAL PAA 5) - disinfection of of animal houses, animal transport vehicles	0.7269
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 3 (INDAL PAA 5) - disinfection of milking parlour	0.072
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 3 (INDAL PAA 5) - disinfection of agri-food industries	0.438
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 5 (INDAL PAA OXY MOUSS) - disinfection of animal houses, animal transport vehicles	0.38
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 5 (INDAL PAA OXY MOUSS) - disinfection of agri-food industries	0.38
• **Risk acceptable or non acceptable?**	Acceptable

Conclusions to the primary exposure during manual rinsing application of the user:

During the manual rinsing application, no dermal personal protective equipment or respiratory protective equipment is required for the user that can safely rinse off the diluted biocidal products of the "QUARON PAA family" from treated surfaces, equipment, material, ...

For all low-medium pressure application, the treated surface is not allowed to get dry prior to rinsing.

Conclusions to the secondary exposure for manual rinsing application of the general public:

The risk related to inhalation exposure to aerosol and vapour is acceptable as no respiratory protective equipment is required. The general public can enter the rinsed areas without risk related to inhalation exposure.

Nevertheless, it has to be kept in mind that before the rinsing the spraying application (scenario 3) was performed by the industrial/professional user. We refer to the combined exposure of the industrial/professional user: the highest exposure level in air of the biocidal products of the „QUARON PAA family" is relevant for exposure/risk assessment purposes.

The general public is only allowed to re-enter the treated (sprayed) and rinsed areas when these areas are well ventilated and the concentration of peracetic acid and hydrogen peroxide in the air is lower than the AEC for local effects to respiratory tract (more specified: see scenario 3).

***Scenario 6**: Manual draining of solution contained in recipient or container after dipping applications for Meta SPC 1, Meta SPC 2, Meta SPC 3*

	Exposure to aerosol [mg/m³]
Substance	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.0001
Meta-SPC 2 (INDAL PAA 2.5)	0.00003
Meta-SPC 3 (INDAL PAA 5) for PT2 and PT4 applications	0.0001
Meta-SPC 3 (INDAL PAA 5) for PT3 applications	0.0001
AEC for local effects to repiratory tract [mg/m³]	0.05
	Risk related to exposure to aerosol (Exposure/AEC) [mg/m³]
Meta-SPC 1 (INDAL PAA 3.5)	0.002
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 2 (INDAL PAA 2.5)	0.0006
• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 3 (INDAL PAA 5) for PT2 and PT4 applications	0.002

• **Risk acceptable or non acceptable?**	Acceptable
Meta-SPC 3 (INDAL PAA 5) for PT3 applications	0.002
• **Risk acceptable or non acceptable?**	Acceptable

Conclusions to the primary exposure during manual draining application of the user:

During manual draining application, no dermal personal protective equipment or respiratory protective equipment is required for the user that safely drain the diluted biocidal products of the "QUARON PAA family".

Conclusions to the secondary exposure for the manual draining application of the general public:

The risk related to inhalation exposure to aerosol and vapour is acceptable as no respiratory protective equipment is required. The general public can enter the areas where the diluted products are drained without risk related to inhalation exposure.

Nevertheless, it has to be kept in mind that before the draining of the diluted product the dipping application (scenario 4) or automated M&L was performed by the industrial/professional user. We refer to the combined exposure of the industrial/professional user: the highest exposure level in air of the biocidal products of the „QUARON PAA family" is relevant for exposure/risk assessment purposes.

The general public is only allowed to re-enter the treated and drained areas in the aquaculture farms when these areas are well ventilated and the concentration of peracetic acid and hydrogen peroxide in the air is lower than the AEC for local effects to respiratory tract.

In addition, secondary exposure will be qualitatively assessed for the shock treatment of swimming pool balneotherapy basin and private ponds water.

Scenario 7: Potential exposure of swimmers after shock treatment with Meta SPC 1 (INDAL PPA 2.5) at a maximum dilution of 0.5% for Use #1b

The product INDAL PAA 2.5 of the Meta SPC 1 of the "QUARON PAA family" is used for shock treatment of swimming water at a maximum dilution of 0.5 %.

Exposure to skin and eyes:

Regarding the low in-use concentration of the active substance peracetic acid (0.013% w/w) as well as of hydrogen peroxide (0.1775% w/w), acetic acid (0.011% w/w), and sulphuric acid acid (0.0015% w/w), no risks from skin or eyes damage is expected as the concentrations applied are below the skin-irritating/eye irritating concentrations.

Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 2 (INDAL PAA 2.5)	0.01%	0.1775%	0.011%	0.0015%
NOAEC local dermal effects or	0.2% (short) 0.1% (long)	35% (eye dam 8%<C≤50%)	10%	5%

Skin irritating threshold		(eye irrit 5%<C≤8%)		
	Risk related to dermal exposure (comparing to dermal NOAEC or skin irritating threshold)			
Meta-SPC 2 (INDAL PAA 2.5)	lower	lower	lower	lower
PPE				
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable

Exposure to respiratory tract:

Considering the high volatility of peracetic acid, hydrogen peroxide and acetic acid, as well as the high reactivity of peracetic acid and hydrogen peroxide with organic matter, it is assumed that no exposure occurs to swimmers for these three substances. Furthermore, this treatment generally takes place during the night. So, general public can only access to the swimming pool or the balneotheraphy basin after about 12 hours. After this time, all the volatile substances as well as the slightly volatile ingredient (sulphuric acid) are not present anymore in the water in a chemical form that could trigger an inhalation exposure. Furthermore, swimming pools and balneotherapy basin are well-ventilated.

Anyhow, sulphuric acid is only characterized as a substance of concern when it is in the form of mist as it clearly appears in the Community workplace exposure defined in the European Commission directive 2009/161/EU (Annex, L338/89). So, after 12 hours, the aqueous solution containing ions that come from sulphuric acid do not trigger any inhalation exposure.

To conclude, no skin, eyes or inhalation exposures are expected due to high volatility and reactivity of the substances, but also to the time between the treatment and the access to the treated water that is assumed to only contain substances at a physical and chemical form that do not induce any inhalation exposure of the secondary user.

(V) Dietary exposure

There is no exposure via food.

In applications of peracetic acid solutions as a disinfectant in food and feeding areas, treated equipment, pipework or installations are rinsed with water prior to further operations. Therefore, secondary human exposure to peracetic acid and hydrogen peroxide *via* food etc. is not considered to be relevant as both peracetic acid and hydrogen peroxide highly react with organic matter and as such degrade rapidly following application. Furthermore, peracetic acid and hydrogen peroxide will be rapidly degraded by the efficient detoxification mechanism of the organism even in the unlikely case that residues of both substances would be orally ingested. No residues are expected in foodstuffs (CAR[92] of PAA).

The Meta SPC 3 of the "QUARON PAA family" is used to disinfect tap water for animals in farms. The in-use concentration of this product is 25 ppm, 0.0025% of PAA and 0.012% H_2O_2.

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The CAR[93] of PAA states the following for this specific use:

"In the application of peracetic acid as a disinfectant of animal drinking water, chronic exposure of farm animals via treated water is possible. Based on the comparison of the concentrations of peracetic acid administered to experimental animals via the drinking water at concentrations ranging from 0.02 – 0.03 % peracetic acid (200 – 300 ppm or 200 – 300 mg peracetic acid/L) with the concentration in disinfected drinking water within PT5 (0.0025 %), no health risk for farm animals including their offspring is expected as concentrations applied for the disinfection of animal drinking water within PT5 are well below the no-adverse effect levels derived from available animal studies and the margin of safety for farm animals is considered to be sufficient. Similarly, drinking water studies performed with hydrogen peroxide in rats identified a NOAEL ranging from 0.1% to 0.6% in drinking water which provides also a sufficient margin of safety with respect to the hydrogen peroxide concentrations of 0.0042% applied for the disinfection of drinking water of farm animals. Council Dir 2011/84/EU allows use of hydrogen peroxide in oral products sold directly to consumers up to a maximum concentration of 0.1%. Products containing greater than 0.1% and up to 6% hydrogen peroxide must be applied under the supervision of a dental practitioner. Most importantly, the concentration of peracetic acid and hydrogen peroxide in drinking water causing no adverse effects in the offspring of a rat teratology study is also much higher than the concentration in drinking water for the intended use within PT5 thereby substantiating a sufficient margin of safety for a more sensitive segment of the animal population as well. In addition, the residual concentrations in the drinking water are much lower than the applied concentrations as rapid degradation happens."

The oral uptake of peracetic acid by farm animals via disinfected water corresponds to about 1/10 of the NOAEC determined in studies with experimental animals.

The oral updtake of hydrogen peroxide by farm animals via disinfected drinking water corresponds to about 0.88% of the NOAEC determined in studies with experimental animals.

Long-term secondary exposure farm animals:

Exposure scenario	**Exposure route**	**Species**	**In-use concentration (% w/w)**	**%NO(A)EC**	**Exposure**	
					Inhalation (mg/m³)	**Oral (mg/kg bw/day)**
PT5: disinfection of animal drinking water	oral	Farm animals	PAA: 0.0025 H2O2: 0.012	PAA: ~10 H2O2: ~1	Not relevant	PAA: ~1/10 of NOAEC H2O2: ~1/100 of NOAEC

Residue definitions

No residue is expected due to the properties of peracetic acid that is highly unstable and rapidly reacts upon contact with organic matter[94].

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Estimating Livestock Exposure to Active Substances used in Biocidal Products

The Meta SPC 3 of the "QUARON PAA family" is used to disinfect tap water for animals in farms. The in-use concentration of this product is 25 ppm, 0.0025% of PAA and 0.012% H_2O_2.

The CAR[95] of PAA states the following for this specific use:

"In the application of peracetic acid as a disinfectant of animal drinking water, chronic exposure of farm animals via treated water is possible. Based on the comparison of the concentrations of peracetic acid administered to experimental animals via the drinking water at concentrations ranging from 0.02 – 0.03 % peracetic acid (200 – 300 ppm or 200 – 300 mg peracetic acid/L) with the concentration in disinfected drinking water within PT5 (0.0025 %), no health risk for farm animals including their offspring is expected as concentrations applied for the disinfection of animal drinking water within PT5 are well below the no-adverse effect levels derived from available animal studies and the margin of safety for farm animals is considered to be sufficient. Similarly, drinking water studies performed with hydrogen peroxide in rats identified a NOAEL ranging from 0.1% to 0.6% in drinking water which provides also a sufficient margin of safety with respect to the hydrogen peroxide concentrations of 0.0042% applied for the disinfection of drinking water of farm animals. Council Dir 2011/84/EU allows use of hydrogen peroxide in oral products sold directly to consumers up to a maximum concentration of 0.1%. Products containing greater than 0.1% and up to 6% hydrogen peroxide must be applied under the supervision of a dental practitioner. Most importantly, the concentration of peracetic acid and hydrogen peroxide in drinking water causing no adverse effects in the offspring of a rat teratology study is also much higher than the concentration in drinking water for the intended use within PT5 thereby substantiating a sufficient margin of safety for a more sensitive segment of the animal population as well. In addition, the residual concentrations in the drinking water are much lower than the applied concentrations as rapid degradation happens."

The oral uptake of peracetic acid by farm animals via disinfected water corresponds to about 1/10 of the NOAEC determined in studies with experimental animals.

The oral uptake of hydrogen peroxide by farm animals via disinfected drinking water corresponds to about 0.88% of the NOAEC determined in studies with experimental animals.

Long-term secondary exposure farm animals:

Exposure scenario	**Exposure route**	**Species**	**In-use concentration (% w/w)**	**%NO(A)EC**	**Exposure**	
					Inhalation (mg/m³)	**Oral (mg/kg bw/day)**
PT5: disinfection of animal drinking water	oral	Farm animals	PAA: 0.0025 H2O2: 0.012	PAA: ~10 H2O2: ~1	Not relevant	PAA: ~1/10 of NOAEC H2O2: ~1/100 of NOAEC

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The "QUARON PAA family" does not include biocidal product that leads to a livestock exposure to active substances used in the biocidal poducts. Indeed, the disinfection occurs without the presence of animals. Furthermore, no residue is expected due to the properties of peracetic acid and hydrogen peroxyde that are highly unstable and rapidly react upon contact with organic matter[96] and as such degrade rapidly after application. But also to the high volatility of these substances and of the substances of concern that the biocidal products family contains. Furthermore, peracetic acid and hydrogen peroxide will be rapidly degraded by the efficient detoxification mechanism of the organism even in the unlikely case that residues of both substances would be orally ingested.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

No transfer of biocidal active substance into food can occur since there is a rinsing post-application step for every biocidal products used in PT3/PT4 applications.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

The biocidal products of the "QUARON PAA family" are only used by professionals.

(VI) Summary of exposure assessment

Primary exposure

Exposed group: industrial/professional user					
Scenario or Use	**Product Type**	**Product**	**Dermal exposure (%)**	**Inhalation exposure (mg/m³)**	**Conclusions for an acceptable risk for the user (PPE and RPE)**
1° Manual mixing and loading	PT 2	INDAL PAA 2.5 (meta-SPC 2)	PAA: 2 HP: 35.5 AA: 2.2 SA: 0.3	PAA: 0.0517 HP: 0.3977 AA: 0.0648 SA: 0.0028	- Gloves, face shield or goggles and a protective coverall. - No RPE
2° Automatic pumping/mixing and loading	PT 2 and PT 4	INDAL PAA 3.5 (meta-SPC 1)	PAA: 2.6 HP: 25 AA: 5 SA: 0.96	PAA: 0.572 HP: 5.1 AA: 1.1 SA: 0.2112	- Gloves, face shield or goggles and a protective coverall. - RPE: full-mask type P2
	PT 2	INDAL PAA 2.5 (meta-SPC 2)	PAA: 2 HP: 35.5 AA: 2.2 SA: 0.3	PAA: 0.44 HP: 7.81 AA: 0.484 SA: 0.066	
	PT 2, PT 3, PT 4 and PT 5	INDAL PAA 5 (meta-SPC 3)	PAA: 5.3 HP: 25.5 AA: 8.2 SA: 0.96	PAA: 1.166 HP: 5.61 AA: 1.804 SA: 0.2112	
	PT 2 and PT 4	INDAL PAA 15 (meta-SPC 4)	PAA: 15.8 HP: 25 AA: 13.8 SA: -	PAA: 3.476 HP: 5.5 AA: 3.036 SA: -	- Gloves, face shield or goggles and a protective coverall. - RPE: full-mask type P3

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Exposed group: industrial/professional user					
Scenario or Use	**Product Type**	**Product**	**Dermal exposure (%)**	**Inhalation exposure (mg/m^3)**	**Conclusions for an acceptable risk for the user (PPE and RPE)**
	PT 4	INDAL TAP 5 (meta-SPC 6)	PAA: 5 HP: 21 AA: 5.95 SA: 13.5	PAA:1.1 HP: 5.62 AA: 1.309 SA: 2.97	
	PT 3 and PT 4	INDAL OXY MOUSS (meta-SPC 5)	PAA: 1.2 HP: 13 AA: 5.75 SA: 0.5	PAA: 0.264 HP: 2.86 AA: 1.265 SA: 0.11	- Gloves, face shield or goggles and a protective coverall. - RPE: full-mask type P1
3° Manual spraying	PT 2	INDAL PAA 2.5 (meta-SPC 2)	PAA: 0.08 HP: 1.42 AA: 0.088 SA: 0.012	Industries, large scale PAA: 0.8108 HP: 9.2792 AA: 0.8269 SA: 0.00912 Industries, small scale PAA: 0.4908 HP: 4.6792 AA: 0.5769 SA: 0.00912 Institutions, small scale PAA: 2.7608 HP: 14.0792 AA: 3.6669 SA: 0.00912 Swimming pool and balneotherapy institutions against algae PAA: 5.076 HP: 16.353 AA: 7.9836 SA: 0.0114	- No PPE required for all application except against algae in swimming pool and balneotherapy institutions - Gloves and a protective coverall for application in swimming pool and balneotherapy institutions against algae - RPE: half-mask type P2 for industries - RPE: half-mask type P3 for institutions - RPE: half-mask type P3 for swimming pool and balneotherapy and other institutions against algae
		INDAL PAA 5 (meta-SPC 3)	PAA: 0.159 HP: 0.765 AA: 0.246 SA: 0.0288	Industries, large scale PAA: 1.6208 HP: 4.9814 AA: 2.587 SA: 0.0219 Industries, small scale PAA: 0.9608 HP: 2.4814 AA: 1.587 SA: 0.0219 Institutions, small scale PAA: 5.4208 HP: 7.6814 AA: 10.087 SA: 0.0219 Public institutions against algae PAA: 13.2014 HP: 10.969 AA: 30.3116	- Gloves and a protective coverall - RPE: half-mask type P2 for industries - RPE: half-mask type P3 for institutions - RPE: half-mask type P3 for public institutions against algae

Exposed group: industrial/professional user					
Scenario or Use	**Product Type**	**Product**	**Dermal exposure (%)**	**Inhalation exposure (mg/m^3)**	**Conclusions for an acceptable risk for the user (PPE and RPE)**
				SA: 0.03648	
	PT 3	INDAL PAA 5 (meta-SPC 3)	PAA: 0.159 HP: 0.765 AA: 0.246 SA: 0.0288	Large scale poultry house PAA: 1.053 HP: 4.689 AA: 1.6316 SA: 0.03648 Large scale pig house PAA: 3.801 HP: 15.369 AA: 5.9516 SA: 0.03648 Small scale poultry house PAA: 1.053 HP: 4.689 AA: 1.6316 SA: 0.03648 Small scale pig house PAA: 3.561 HP: 12.609 AA: 5.591 SA: 0.03648 Milking parlour PAA: 0.0201 HP: 0.0969 AA: 0.0312 SA: 0.0036	- Gloves and a protective coverall - RPE: half-mask type P3 for animal houses disinfection - No RPE for milking parlour systems disinfection
		INDAL OXY MOUSS (meta-SPC 5)	PAA: 0.06 HP: 0.65 AA: 0.2875 SA: 0.025	Large scale poultry house PAA: 0.1076 HP: 1.044 AA: 0.5185 SA: 0.019 Large scale pig house PAA: 0.3056 HP: 2.494 AA: 1.5185 SA: 0.019 Small scale poultry house PAA: 0.1076 HP: 1.044 AA: 0.5185 SA: 0.019 Small scale pig house PAA: 0.2656 HP: 1.794 AA: 1.3185 SA: 0.019 Vehicles for animal transport PAA: 1.7456 HP: 5.794 AA: 10.2185 SA: 0.019	- No PPE required - RPE: half-mask type P1 for animal houses disinfection - RPE: half-mask type P2 for vehicles disinfection for animal transport

Exposed group: industrial/professional user					
Scenario or Use	**Product Type**	**Product**	**Dermal exposure (%)**	**Inhalation exposure (mg/m^3)**	**Conclusions for an acceptable risk for the user (PPE and RPE)**
	PT 4	INDAL PAA 3.5 (meta-SPC 1)	PAA: 0.104 HP: 1.0 AA: 0.2 SA: 0.0384	Large scale Slaughter house PAA: 0.104 HP: 0.98 AA: 0.2 SA: 0.0292 Institutional kitchen PAA: 0.122 HP: 1.06 AA: 0.217 SA: 0.0292 Small scale Slaughter house PAA: 0.104 HP: 0.98 AA: 0.2 SA: 0.0292 Institutional kitchen PAA: 0.11 HP: 0.99 AA: 0.213 SA: 0.0292	- Gloves and a protective coverall. - RPE: half-mask type P1 for Kitchens - No RPE for slaughterhouses
		INDAL PAA 5 (meta-SPC 3)	PAA: 0.159 HP: 0.765 AA: 0.246 SA: 0.0288	Large scale Slaughter house PAA: 0.1588 HP: 0.7514 AA: 0.247 SA: 0.0219 Institutional kitchen PAA: 0.1728 HP: 0.8114 AA: 0.267 SA: 0.0219 Small scale Slaughter house PAA: 0.1588 HP: 0.7514 AA: 0.247 SA: 0.0219 Institutional kitchen PAA: 0.1688 HP: 0.7614 AA: 0.263 SA: 0.0219	- Gloves and a protective coverall - No RPE
		INDAL OXY MOUSS (meta-SPC 5)	PAA: 0.06 HP: 0.65 AA: 0.2875 SA: 0.025	Large scale Slaughter house PAA: 0.0786 HP: 0.794 AA: 0.3785 SA: 0.019 Institutional kitchen	- No PPE - No RPE

Exposed group: industrial/professional user					
Scenario or Use	**Product Type**	**Product**	**Dermal exposure (%)**	**Inhalation exposure (mg/m^3)**	**Conclusions for an acceptable risk for the user (PPE and RPE)**
				PAA: 0.0906 HP: 0.894 AA: 0.4385 SA: 0.019 Small scale Slaughter house PAA: 0.0786 HP: 0.794 AA: 0.3785 SA: 0.019 Institutional kitchen PAA: 0.0846 HP: 0.724 AA: 0.4185 SA: 0.019	
4° Manual dipping	PT 2	INDAL PAA 5 (meta-SPC 3)	PAA: 0.159 HP: 0.765 AA: 0.246 SA: 0.0288	Large scale industrial PAA: 0.5015 HP: 0.4702 AA: 1.2366 SA: 0.000096 Small scale industrial PAA: 0.4848 HP: 0.4702 AA: 1.2199 SA: 0.000096	- Gloves and a protective coverall. - RPE: half-mask type P1 - No heating takes place during dipping bathes - The room needs to be sufficiently ventilated with 10 air changes per hour.
	PT 3	INDAL PAA 5 (meta-SPC 3)	PAA: 0.159 HP: 0.765 AA: 0.246 SA: 0.0288	Large scale Poultry house PAA: 0.0137 HP: 0.0151 AA: 0.0325 SA: 0.000096 Large scale Pig house PAA: 0.0573 HP: 0.056 AA: 0.139 SA: 0.000096 Aquaculture farms PAA: 1.8375 HP: 1.6693 AA: 4.5098 SA: 0.000096	- Gloves and a protective coverall. - RPE: half-mask type P2 for disinfection in aquaculture plants - No RPE for dipping disinfection in other animal houses - No heating takes place during dipping bathes - The room needs to be sufficiently ventilated with 10 air changes per hour.
	PT 4	INDAL PAA 3.5 (meta-SPC 1)	PAA: 0.104 HP: 1.0 AA: 0.2 SA: 0.0384	Large scale Slaughter house PAA: 0.0038 HP: 0.0088 AA: 0.0114 SA: 0.0077 Industrial kitchen PAA: 0.0302 HP: 0.059 AA: 0.0914 SA: 0.0077 Foot bath	- Gloves and a protective coverall. - No RPE - No heating takes place during dipping bathes - The room needs to be sufficiently ventilated with 10 air changes per hour.

Exposed group: industrial/professional user					
Scenario or Use	**Product Type**	**Product**	**Dermal exposure (%)**	**Inhalation exposure (mg/m^3)**	**Conclusions for an acceptable risk for the user (PPE and RPE)**
				PAA: 0.0006 HP: 0.0028 AA: 0.0017 SA: 0.0077	
		INDAL PAA 5 (meta-SPC 3)	PAA: 0.159 HP: 0.765 AA: 0.246 SA: 0.0288	Large scale Slaughter house PAA: 0.0058 HP: 0.0067 AA: 0.0135 SA: 0.00006 Industrial kitchen PAA: 0.0453 HP: 0.0445 AA: 0.1105 SA: 0.00006	
		INDAL PAA 15 (meta-SPC 4)	PAA:0.2528 HP: 0.4 AA: 0.2208 SA: -	Large scale Slaughter house PAA: 0.0092 HP: 0.0035 AA: 0.0124 SA: - Industrial kitchen PAA: 0.0725 HP: 0.0238 AA: 0.1204 SA: -	
5° Manual rinsing	PT 2 and PT 4	INDAL PAA 3.5 (meta-SPC 1)	Negligible	SA: 0.0292	- No PPE - No RPE
	PT 2	INDAL PAA 2.5 (meta-SPC 2)	Negligible	SA: 0.0114	
	PT 2, PT 3 and PT 4	INDAL PAA 5 (meta-SPC 3)	Negligible	SA: milking parlour: 0.0036; TP 4: 0.0219 all other: 0.03648	
	PT 3 and PT 4	INDAL OXY MOUSS (meta-SPC 5)	Negligible	SA: 0.019	
6° Manual draining	PT 4	INDAL PAA 3.5 (meta-SPC 1)	Negligible	SA: 0.0001	- No PPE - No RPE
	PT 2	INDAL PAA 2.5 (meta-SPC 2)	Negligible	SA: 0.00003	
	PT 2, PT 3 and PT 4	INDAL PAA 5 (meta-SPC 3)	Negligible	SA: PT2/PT4: 0.0001 PT3: 0.0001	

Secondary exposure

Exposed group: General public			
Scenario or Use	**Product Type**	**Product**	**Conclusions for an acceptable risk**
1° Manual mixing and loading	PT 2	INDAL PAA 2.5 (meta-SPC 2)	- Inhalation: No RPE, acceptable. General public can access to the room during manual mixing and loading applications.
2° Automatic pumping/mixing and loading	PT 2 and PT 4	INDAL PAA 3.5 (meta-SPC 1)	- RPE: full-mask type P2 for user. General public not allowed to enter areas where the biocidal product is connected manually to automatic mixing and loading systems.
	PT 2	INDAL PAA 2.5 (meta-SPC 2)	
	PT 2, PT 3, PT 4 and PT 5	INDAL PAA 5 (meta-SPC 3)	
	PT 2 and PT 4	INDAL PAA 15 (meta-SPC 4)	- RPE: full-mask type P3 for user. General public not allowed to enter areas where the biocidal product is connected manually to automatic mixing and loading systems..
	PT 4	INDAL TAP 5 (meta-SPC 6)	
	PT 3 and PT 4	INDAL OXY MOUSS (meta-SPC 5)	- RPE: full-mask type P1 for user. General public not allowed to enter areas where the biocidal product is connected manually to automatic mixing and loading systems.
3° Manual spraying	PT 2	INDAL PAA 2.5 (meta-SPC 2)	- RPE: half-mask type P2 for industries. - RPE: half-mask type P3 for institutions - RPE: half-mask type P3 for swimming pool and balneotherapy institutions against algae General public not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC
		INDAL PAA 5 (meta-SPC 3)	- RPE: half-mask type P2 for industries - RPE: half-mask type P3 for institutions - RPE: half-mask type P3 for public institutions against algae General public not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC
	PT 3	INDAL PAA 5 (meta-SPC 3)	- RPE: half-mask type P3 for animal houses disinfection General public not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC - No RPE for milking parlour systems disinfection General public is allowed to enter areas where milking parlour systems disinfection takes place

Exposed group: General public			
Scenario or Use	**Product Type**	**Product**	**Conclusions for an acceptable risk**
		INDAL OXY MOUSS (meta-SPC 5)	- RPE: half-mask type P1 for animal houses disinfection - RPE: half-mask type P2 for vehicles disinfection for animal transport General public not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC
	PT 4	INDAL PAA 3.5 (meta-SPC 1)	- RPE: half-mask type P1 for Kitchens General public not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC - No RPE for slaughterhouse sprayer. Inhalation exposure is acceptable for general public. General public can enter the treated areas and can access to the room during spraying applications.
		INDAL PAA 5 (meta-SPC 3)	- No RPE for sprayer Inhalation exposure is acceptable for general public. General public can enter the treated areas and can access to the room during spraying applications.
		INDAL OXY MOUSS	- No RPE for sprayer Inhalation exposure is acceptable for general public. General public can enter the treated areas and can access to the room during spraying applications.
4° Manual dipping	PT 2	INDAL PAA 5 (meta-SPC 3)	- RPE: half-mask type P1 for user General public not allowed to enter areas during dipping. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC - No heating takes place during dipping bathes The room needs to be sufficiently ventilated with 10 air changes per hour.
	PT 3	INDAL PAA 5 (meta-SPC 3)	- RPE: half-mask type P2 for disinfection in aquaculture plants General public not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC - No RPE for dipping disinfection in other animal houses General public not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC - No heating takes place during dipping bathes

Exposed group: General public			
Scenario or Use	**Product Type**	**Product**	**Conclusions for an acceptable risk**
			- The room needs to be sufficiently ventilated with 10 air changes per hour.
	PT 4	INDAL PAA 3.5 (meta-SPC 1)	- No RPE for user Inhalation exposure is acceptable for general public. General public can enter the treated areas and can access to the room during dipping applications. - No heating takes place during dipping bathes - The room needs to be sufficiently ventilated with 10 air changes per hour.
		INDAL PAA 5 (meta-SPC 3)	
		INDAL PAA 15 (meta-SPC 4)	
5° Manual rinsing	PT 2 and PT 4	INDAL PAA 3.5 (meta-SPC 1)	- No RPE for user Inhalation exposure is acceptable for general public. General public can enter the areas where rinsing took place. For all low-medium pressure spraying application, the treated surface is not allowed to get dry prior to rinsing.
	PT 2	INDAL PAA 2.5 (meta-SPC 2)	
	PT 2, PT 3 and PT 4	INDAL PAA 5 (meta-SPC 3)	
	PT 3 and PT 4	INDAL OXY MOUSS	
6° Manual draining	PT 4	INDAL PAA 3.5 (meta-SPC 1)	- No RPE for user Inhalation exposure is acceptable for general public. General public can enter the areas where draining took place.
	PT 2	INDAL PAA 2.5 (meta-SPC 2)	
	PT 2, PT 3 and PT 4	INDAL PAA 5 (meta-SPC 3)	
7° Swimming	PT 2	INDAL PAA 2.5 (meta-SPC 2)	- Dermal: PAA: 0.01 HP: 0.1775 AA: 0.011 SA: 0.0015 No PPE, acceptable for swimmer - Inhalation: The general public can access the swimming pool and balneotherapy bassin after about 12 hours.

Dietary exposure

There is no exposure via food.

2.2.6.3 Risk characterisation for human health

The derivation of systemic AELs is considered inappropriate. Risk assessment is focused on risk for local effects.

Reference values to be used in Risk Characterisation

Reference	Study	NOAEC	AF	Value
Peracetic acid				

Dermal NOAEC short/medium term	Human volunteer study	0.2%	-	0.2%
Dermal NOAEC long term	Rabbit one year study	0.2%	2	0.1%
Inhalation AEC short/medium/ long-term	Human data	0.5 ppm	3.16	0.5 mg/m^3 (0.16 ppm)
Hydrogen peroxide				
Dermal Skin irritating threshold	Classification limit for irritation	-	-	35%
Inhalation AEC short/medium/ long-term	90-day inhalation rat study	10 mg/m^3	8	1.25 mg/m^3
Acetic acid				
Dermal Skin irritating threshold	Classification limit for irritation	-	-	10%
Inhalation AEC (8h, long-term)	-	-	-	25 mg/m^3
Sulphuric acid				
Dermal Skin irritating threshold	Classification limit for irritation	-	-	5%
Inhalation AEC (8h, long-term)	-	-	-	0.05 mg/m^3

Maximum residue limits or equivalent

Not relevant

Specific reference value for groundwater

Not relevant

(VII)Risk for industrial and professional users

Local effects

Scenario 1: Manual mixing and loading

	Dermal exposure			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 2 (INDAL PAA 2.5)	2%	35.5%	2.2%	0.3%
NOAEC local dermal effects or Skin irritating threshold	0.2% (short) 0.1% (long)	35%	10%	5%
	Risk related to dermal exposure			

	(comparing to dermal NOAEC or skin irritating threshold)			
Meta-SPC 2 (INDAL PAA 2.5)	higher skin protection needed	Higher skin protection needed	lower	lower
PPE	Gloves, coverall, face shield			
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 2 (INDAL PAA 2.5)	0.0517	0.3977	0.0648	0.0028
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 2 (INDAL PAA 2.5)	0.1034	0.3182	0.0026	0.056
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 2 (INDAL PAA 2.5)	0.4216		0.0026	0.056
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

Conclusions to the primary exposure during manual mixing and loading of the user

During manual mixing and loading, risk related to dermal exposure is acceptable if the user wears chemical-resistant gloves, a protective coverall and a face shield due to classification as Skin corrosions 1 and eye damage 1 of the product INDAL PAA 2.5 (Meta-SPC 2) (pH <2), related to high concentration in peracetic acid and hydrogen peroxide.

During this application, no respiratory protective equipment is required. Indeed, the risk related to inhalation exposure to aerosol and vapour is acceptable without any personal protective equipment.

Scenario 2: Automated mixing and loading by pumping of concentrates

	Dermal exposure

Substances	Peracetic acid	Hydrogen peroxide	Acetic acid	Sulphuric acid
Meta-SPC 1 (INDAL PAA 3.5)	2.6%	25%	5%	0.96%
Meta-SPC 2 (INDAL PAA 2.5)	2%	35.5%	2.2%	0.3%
Meta-SPC 3 (INDAL PAA 5)	5.3%	25.5%	8.2%	0.96%
Meta-SPC 4 (INDAL PAA 15)	15.8%	25%	13.8%	-
Meta-SPC 5 (INDAL OXY MOUSS)	1.2%	13.0%	5.75%	0.5%
Meta-SPC 6 (INDAL TAP 5)	5%	21%	5.95%	13.5%
NOAEC local dermal effects or Skin irritating threshold	0.2% (short) 0.1% (long)	35% (eye dam 8%<C≤50%) (eye irrit 5%<C≤8%)	10%	5%
	Risk related to dermal exposure (comparing to dermal NOAEC or skin irritating threshold)			
Meta-SPC 1 (INDAL PAA 3.5)	higher skin protection needed	Skin: lower Eye: higher eye protection needed	lower	lower
PPE	Gloves, coverall, face shield			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
Meta-SPC 2 (INDAL PAA 2.5)	higher skin protection needed	higher skin protection needed	lower	lower
PPE	Gloves, coverall, face shield			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	higher skin protection needed	Skin: lower Eye: higher eye protection needed	lower	lower
PPE	Gloves, coverall, face shield			

Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
Meta-SPC 4 (INDAL PAA 15)	higher skin protection needed	Skin: lower Eye: higher eye protection needed	higher skin protection needed	n.a.
PPE	Gloves, coverall, face shield			
Risk acceptable or non acceptable?	Acceptable			n.a.
Meta-SPC 5 (INDAL OXY MOUSS)	higher skin protection needed	Skin: lower Eye: higher eye protection needed	lower	lower
PPE	Gloves, coverall, face shield			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
Meta-SPC 6 (INDAL TAP 5)	higher skin protection needed	Skin: lower Eye: higher eye protection needed	lower	higher
PPE	Gloves, coverall, face shield			
Risk acceptable or non acceptable?	Acceptable	Acceptable	Acceptable	Acceptable

Inhalation **Exposure to aerosol [mg/m³]**				
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.572	5.1	1.1	0.2112
Meta-SPC 2 (INDAL PAA 2.5)	0.44	7.81	0.484	0.066
Meta-SPC 3 (INDAL PAA 5)	1.166	5.61	1.804	0.2112
Meta-SPC 4 (INDAL PAA 15)	3.476	5.5	3.036	n.a.
Meta-SPC 5 (INDAL OXY MOUSS)	0.264	2.86	1.265	0.11
Meta-SPC 6 (INDAL TAP 5)	1.1	5.62	1.309	2.97

AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol (Exposure/AEC) [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	1.144	4.08	0.044	4.224
Meta-SPC 2 (INDAL PAA 2.5)	0.88	6.248	0.0194	1.32
Meta-SPC 3 (INDAL PAA 5)	2.332	4.488	0.0722	4.224
Meta-SPC 4 (INDAL PAA 15)	6.952	4.4	0.1214	n.a.
Meta-SPC 5 (INDAL OXY MOUSS)	0.528	2.288	0.0506	2.2
Meta-SPC 6 (INDAL TAP 5)	2.2	4.496	0.0524	59.4
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	5.224		0.044	4.224
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Non acceptable
• **TIER 2: Type of RPE and risk with RPE**	full face mask with a P2 filter to protect eyes and respiratory tract – 0.5224		/	full face mask with a P2 filter to protect eyes and respiratory tract – 0.4224
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 2 (INDAL PAA 2.5)	7.128		0.0194	1.32
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Non acceptable
• **TIER 2: Type of RPE and risk with RPE**	full face mask with a P2 filter to protect eyes and respiratory tract – 0.7128		/	full face mask with a P2 filter to protect eyes and respiratory tract – 0.33
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	6.82		0.0722	4.224
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Non acceptable
• **TIER 2: Type of RPE and risk with RPE**	full face mask with a P2 filter to protect eyes and respiratory tract – 0.682		/	full face mask with a P2 filter to protect eyes

			and respiratory tract – 0.4224
• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	Acceptable
Meta-SPC 4 (INDAL PAA 15)	11.352	0.11214	n.a.
• **Risk acceptable or non acceptable?**	Non acceptable	Acceptable	n.a.
• **TIER 2: Type of RPE and risk with RPE**	full face mask with a P3 filter to protect eyes and respiratory tract – 0.2838	/	n.a.
• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	n.a.
Meta-SPC 5 (INDAL OXY MOUSS)	2.816	0.0506	2.2
• **Risk acceptable or non acceptable?**	Non acceptable	Acceptable	Non acceptable
• **TIER 2: Type of RPE and risk with RPE**	full face mask with a P1 filter to protect eyes and respiratory tract – 0.704	/	full face mask with a P1 filter to protect eyes and respiratory tract – 0.55
• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	Acceptable
Meta-SPC 6 (INDAL TAP 5)	6.696	0.0524	59.4
• **Risk acceptable or non acceptable?**	Non acceptable	Acceptable	Non acceptable
• **TIER 2: Type of RPE and risk with RPE**	full face mask with a P2 filter to protect eyes and respiratory tract – 0.6696	/	full face mask with a P3 filter to protect eyes and respiratory tract – 1.485
• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	Acceptable due to the very short time of exposure during connecting pipes. One can assume that if the user wear a full mask with a P3 filter, the protection will be sufficient.

n.a. Not applicable because INDAL PAA 15 does not contain sulphuric acid in its formulation.

Conclusions to the primary exposure during manual connecting for automatic mixing and loading system

During manual connecting to automated dosing systems, the risk related to dermal exposure is acceptable if the user wears chemical-resistant gloves, a protective coverall and a face shield due to classification as Skin corrosive and Eye damage of all the concentrated products (pH<2), related to high concentration in peracetic acid and hydrogen peroxide in concentrates.

During this application, all products requires the wearing of a respiratory protective equipment (RPE). Full masks are proposed to also protect the eyes due to the damaging effects to eyes of the biocidal products.

However, different kind of RPE are required, depending of the product.

- For INDAL OXY MOUSS (Meta-SPC 5), a full mask with a P1 filter is required to have an acceptable level of exposure and related risk for the user;
- For the products INDAL PAA 3.5 (Meta-SPC 1), INDAL PAA 2.5 (Meta-SPC 2) and INDAL PAA 5 (Meta-SPC 3), a full mask with a P2 filter is required to have an acceptable level of exposure and related risk for the user;
- For the products INDAL PAA 15 (Meta-SPC 4) and INDAL TAP 5 (Meta-SPC 6) a full mask with a P3 filter is required to have an acceptable level of exposure and related risk for the user.

Scenario 3: Manual spraying on open surfaces for all Meta SPC exepted Meta SPC 4 (INDAL PAA 15) and Meta SPC 6 (INDAL TAP 5)

Dermal

	Dermal exposure			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.104%	1.0%	0.2%	0.0384%
Meta-SPC 2 (INDAL PAA 2.5)	0.08%	1.42%	0.088%	0.012%
Meta-SPC 2 (INDAL PAA 2.5) (swimming pool and balneotherapy against algae)	0.1%	1.775%	0.11%	0.015%
Meta-SPC 3 (INDAL PAA 5)	0.159%	0.765%	0.246%	0.0288%
Meta-SPC 3 (INDAL PAA 5) (PT2 in public institutions against	0.265%	1.275%	0.41%	0.048%

algae and PT3 applications)				
Meta-SPC 5 (INDAL OXY MOUSS)	0.06%	0.65%	0.2875%	0.025%
NOAEC local dermal effects or Skin irritating threshold	0.2% (short) 0.1% (long)	35% (eye dam 8%<C≤50%) (eye irrit 5%<C≤8%)	10%	5%
	Risk related to dermal exposure (comparing to dermal NOAEC or skin irritating threshold)			
Meta-SPC 1 (INDAL PAA 3.5)	higher skin protection needed	Skin: lower Eye: lower	lower	lower
PPE	Gloves, coverall			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
Meta-SPC 2 (INDAL PAA 2.5)	lower	Skin: lower Eye: lower	lower	lower
PPE	Not required			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
Meta-SPC 2 (INDAL PAA 2.5) (swimming pool and balneotherapy institutions against algae)	higher skin protection needed	Skin: lower Eye: lower	lower	lower
PPE	Gloves, coverall			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	higher skin protection needed	Skin: lower Eye: lower	lower	lower
PPE	Gloves, coverall			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5) (PT2 in public institutions against	higher	skin protection needed	lower	lower

algae and PT3 applications)				
PPE	Gloves, coverall			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
Meta-SPC 5 (INDAL OXY MOUSS)	lower	Skin: lower Eye: lower	lower	lower
PPE	Not required			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable

Inhalation

3.1 PT2 Manual spraying

Meta SPC 2 (INDAL PAA 2.5) and SPC 3 (INDAL PAA 5)

3.1.1 Inhalation exposure: large scale disinfection in industries

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 2 (INDAL PAA 2.5)	0.8108	9.2792	0.8269	0.00912
Meta-SPC 3 (INDAL PAA 5)	1.6208	4.9814	2.587	0.0219
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 2 (INDAL PAA 2.5)	1.6216	7.4234	0.0331	0.1824
Meta-SPC 3 (INDAL PAA 5)	3.2416	3.9851	0.1035	0.438
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 2 (INDAL PAA 2.5)	9.045		0.0331	0.1824
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P2 filter to protect respiratory tract – 0.9045		/	/

• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	7.2267	0.1035	0.438
• **Risk acceptable or non acceptable?**	Non acceptable	Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P2 filter to protect respiratory tract – 0.7227	/	/
• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	Acceptable

3.1.2 Inhalation exposure: small scale disinfection in industries

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 2 (INDAL PAA 2.5)	0.4908	4.6792	0.5769	0.00912
Meta-SPC 3 (INDAL PAA 5)	0.9608	2.4814	1.587	0.0219
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 1 (INDAL PAA 2.5)	0.9816	3.7434	0.0231	0.1824
Meta-SPC 3 (INDAL PAA 5)	1.9216	1.9851	0.0635	0.438
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 2 (INDAL PAA 2.5)	4.725		0.0231	0.1824
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P2 filter to protect respiratory tract – 0.4725		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	3.9067		0.0635	0.438
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.9767		/	/

• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	Acceptable

3.1.3 Inhalation exposure: small scale disinfection in institutions

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 2 (INDAL PAA 2.5)	2.7608	14.0792	3.6669	0.00912
Meta-SPC 3 (INDAL PAA 5)	5.4208	7.6814	10.087	0.0219
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 2 (INDAL PAA 2.5)	5.5216	11.2634	0.1467	0.1824
Meta-SPC 3 (INDAL PAA 5)	10.8416	6.1451	0.4035	0.438
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 2 (INDAL PAA 2.5)	16.785		0.1467	0.1824
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.4196		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	16.9867		0.4035	0.438
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.4247		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

3.1.4 Inhalation exposure: small scale disinfection in swimming pool and balneotherapy and other institutions against algae

	Total exposure to aerosol and vapour [mg/m³]

Substances	Peracetic acid	Hydrogen peroxide	Acetic acid	Sulphuric acid
Meta-SPC 2 (INDAL PAA 2.5)	5.076	16.353	7.9836	0.0114
Meta-SPC 3 (INDAL PAA 5)	13.2014	10.969	30.3116	0.03648
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 2 (INDAL PAA 2.5)	10.152	13.0824	0.3193	0.228
Meta-SPC 3 (INDAL PAA 5)	26.4028	8.7752	1.2125	0.7296
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 2 (INDAL PAA 2.5)	23.2344		0.3193	0.228
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.5809		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	35.178		1.2125	0.7296
• **Risk acceptable or non acceptable?**	Non acceptable		Non acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.8795		Half face mask with a P1 filter to protect respiratory tract – 0.3031	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

3.2 PT3 Manual spraying

Meta SPC 3 (INDAL PAA 5) and Meta SPC 5 (INDAL OXY MOUSS)

3.2.1 Inhalation exposure: large scale disinfection in animal houses

Poultry houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 3 (INDAL PAA 5)	1.0534	4.689	1.6316	0.03648
Meta-SPC 5 (INDAL OXY MOUSS)	0.1076	1.044	0.5185	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	2.106	3.7512	0.06526	0.7296
INDAL OXY MOUSS	0.2152	0.8352	0.0207	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	5.8572		0.06526	0.7296
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P2 filter to protect respiratory tract – 0.5857		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 5 (INDAL OXY MOUSS)	1.0504		0.0242	0.38
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.2626		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Pig houses				
	Total exposure to aerosol and vapour [mg/m³]			

Substances	Peracetic acid	Hydrogen peroxide	Acetic acid	Sulphuric acid
Meta-SPC 3 (INDAL PAA 5)	3.8014	15.369	5.9516	0.03648
Meta-SPC 5 (INDAL OXY MOUSS)	0.3056	2.494	1.5185	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	7.6028	12.2952	0.2381	0.7296
Meta-SPC 5 (INDAL OXY MOUSS)	0.6112	1.9952	0.0607	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	19.898		0.0263	0.38
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.4975		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 5 (INDAL OXY MOUSS)	2.6064		0.0607	0.38
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.6516		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

3.2.2 Inhalation exposure: small scale disinfection in animal houses

Poultry houses

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 3 (INDAL PAA 5)	1.0534	4.689	1.6316	0.03648
Meta-SPC 5 (INDAL OXY MOUSS)	0.1076	1.044	0.5185	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	2.106	3.7512	0.06526	0.7296
Meta-SPC 5 (INDAL OXY MOUSS)	0.2152	0.8352	0.0207	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	19.898		0.06526	0.7296
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.4975		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 5 (INDAL OXY MOUSS)	1.0504		0.0242	0.38
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and**	Half face mask with a P1 filter to protect respiratory tract – 0.2626		/	/

risk with RPE				
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Pig houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 3 (INDAL PAA 5)	3.5614	12.609	5.5916	0.03648
Meta-SPC 5 (INDAL OXY MOUSS)	0.2656	1.794	1.3185	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	7.122	10.0872	0.2237	0.7296
Meta-SPC 5 (INDAL OXY MOUSS)	0.5312	1.4352	0.0527	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	17.2092		0.2237	0.7296
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.4302		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 5 (INDAL OXY MOUSS)	1.9664		0.0527	0.38

• **Risk acceptable or non acceptable?**	Non acceptable	Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.4916	/	/
• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	Acceptable

3.2.3 Inhalation exposure: disinfection of vehicles for animal transport

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 5 (INDAL OXY MOUSS)	1.7456	5.794	10.2185	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 5 (INDAL OXY MOUSS)	3.4912	4.6352	0.4087	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 5 (INDAL OXY MOUSS)	8.1264		0.4087	0.38
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P2 filter to protect respiratory tract – 0.8126		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

3.2.4 Inhalation exposure: disinfection of milking parlour systems in farms

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 3 (INDAL PAA 5)	0.0201	0.0969	0.0312	0.0036

AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	0.0402	0.0775	0.0012	0.072
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 3 (INDAL PAA 5)	0.1177		0.0012	0.072
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

3.3 PT4 Manual spraying

Meta SPC 1 (INDAL PAA 3.5), Meta SPC 3 (INDAL PAA 5) and Meta SPC 5 (INDAL OXY MOUSS)

3.3.1 Inhalation exposure: large scale disinfection

Slaughter houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.104	0.98	0.2	0.0292
Meta-SPC 3 (INDAL PAA 5)	0.1588	0.7514	0.247	0.0219
Meta-SPC 5 (INDAL OXY MOUSS)	0.0786	0.794	0.3785	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	0.208	0.784	0.008	0.584
Meta-SPC 3 (INDAL PAA 5)	0.3176	0.6011	0.0099	0.438
Meta-SPC 5 (INDAL OXY MOUSS)	0.1572	0.6352	0.0151	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	0.992		0.008	0.584

• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	0.9187		0.0099	0.438
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 5 (INDAL OXY MOUSS)	0.7924		0.0151	0.38
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Institutional Kitchen				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.112	1.06	0.217	0.0292
Meta-SPC 3 (INDAL PAA 5)	0.1728	0.8114	0.267	0.0219
Meta-SPC 5 (INDAL OXY MOUSS)	0.0906	0.894	0.4385	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	0.224	0.848	0.0087	0.584
Meta-SPC 3 (INDAL PAA 5)	0.3456	0.6491	0.0107	0.438
Meta-SPC 5 (INDAL OXY MOUSS)	0.1812	0.7152	0.0351	0.76
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	1.072		0.0087	0.584
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.268		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	0.9947		0.0107	0.438
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

Meta-SPC 5 (INDAL OXY MOUSS)	0.8964	0.0351	0.76
• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	Acceptable

3.3.2 Inhalation exposure: small scale disinfection

Slaughter houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
Meta-SPC 1 (INDAL PAA 3.5)	0.104	0.98	0.2	0.0292
Meta-SPC 3 (INDAL PAA 5)	0.1588	0.7514	0.247	0.0219
Meta-SPC 5 (INDAL OXY MOUSS)	0.0786	0.794	0.3785	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	0.208	0.784	0.008	0.584
Meta-SPC 3 (INDAL PAA 5)	0.3176	0.6011	0.0099	0.438
Meta-SPC 5 (INDAL OXY MOUSS)	0.1572	0.6352	0.0151	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	0.992		0.008	0.584
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	0.9187		0.0099	0.438
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 5 (INDAL OXY MOUSS)	0.7924		0.0151	0.38
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Institutional Kitchen				
	Exposure to aerosol [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**

Meta-SPC 1 (INDAL PAA 3.5)	0.11	0.99	0.213	0.0292
Meta-SPC 3 (INDAL PAA 5)	0.1688	0.7614	0.263	0.0219
Meta-SPC 5 (INDAL PAA OXY MOUSS)	0.0846	0.724	0.4185	0.019
AEC for local effects to repiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	0.22	0.792	0.0085	0.584
Meta-SPC 3 (INDAL PAA 5)	0.3376	0.6091	0.0105	0.438
Meta-SPC 5 (INDAL PAA OXY MOUSS)	0.1692	0.5792	0.0167	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
Meta-SPC 1 (INDAL PAA 3.5)	1.012		0.0085	0.584
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.253		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 3 (INDAL PAA 5)	0.9467		0.0105	0.438
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Meta-SPC 5 (INDAL PAA OXY MOUSS)	0.7484		0.0167	0.38
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

Conclusions to the primary exposure during all PT2 manual spraying applications:

During manual spraying applications the risk related to dermal and eye exposures are acceptable for INDAL PAA 2.5 (Meta-SPC 2) without wearing personal protective equipment and only with chemical-resistant gloves and a protective coverall for the use of the product INDAL PAA 5 (Meta-SPC 3).

During this application, both products INDAL PAA2.5 and INDAL PAA 5, require the wearing of a respiratory protective equipment (RPE). Only half masks are proposed since no protection to eyes is required.

After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.

However, different kind of RPE are required, depending on the use of the products:

- The products INDAL PAA 2.5 and PAA 5 require a half mask with a P2 filter to have an acceptable level of exposure and related risk for the user during large scale and small scale manual spraying in industries.
- Both products, INDAL PAA 2.5 and PAA 5, require a half mask with a P3 filter to have an acceptable level of exposure and related risk for the user during small scale disinfection in institutions (including swimming pool, balneotherapy and other institutions for application on algae);

Conclusions to the primary exposure during all PT3 manual spraying applications:

During manual spraying applications the risk related to dermal and eye exposures are acceptable for INDAL OXY MOUSS (Meta-SPC 5) without wearing personal protective equipment when diluted to a 5% use concentration and only with chemical-resistant gloves and a protective coverall for the use of the product INDAL PAA 5 (Meta-SPC 3) when diluted to a 3% use concentration.

After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.

During these manual spraying applications, both products INDAL PAA 5 (Meta-SPC 3) and INDAL OXY MOUSS (Meta-SPC 5), require the wearing of a respiratory protective equipment (RPE), except for 1 application. Only half masks are proposed since no protection to eyes is required.

However, different kind of RPE are required, depending on the use of the products:

- The product INDAL PAA 5 requires a half mask with a P3 filter to have an acceptable level of exposure and related risk for the user during large scale and small scale manual spraying animal houses.
-
- The product INDAL OXY MOUSS requires a half mask with a P1 filter to have an acceptable level of exposure and related risk for the user during large scale and small scale manual spraying animal houses.The product INDAL OXY MOUSS requires a half mask with a P2 filter to have an acceptable level of exposure and related risk for the user during the disinfection of vehicles for animal transport.

For the use of INDAL PAA 5 when diluted to a 0,5% use concentration during manual spraying disinfection of milking claws in farms, no respiratory protective equipment is required for the user that is safely exposed to the product only by wearing gloves and a protective coat.

Conclusions to the primary exposure during all PT4 manual spraying applications:

During manual spraying applications the risk related to dermal and eye exposures are acceptable for INDAL OXY MOUSS (Meta-SPC 5) without wearing personal protective equipment. The risk related to dermal and eye exposures are only acceptable with the use of chemical-resistant gloves and a protective coverall for the products INDAL PAA 3.5 (Meta-SPC 1) and INDAL PAA 5 (Meta-SPC 3).

After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.

During these applications, the product INDAL PAA 3.5 requires the wearing of a respiratory protective equipment (RPE). Only half mask is proposed since no protection to eyes is required.

- The product INDAL PAA 3.5 requires a half mask with a P1 filter to have an acceptable level of exposure and related risk for the user during large scale and small scale manual spraying disinfection in an institutional kitchen.

For the use of INDAL PAA 5, as well as of INDAL OXY MOUSS, no respiratory protective equipment is required for the manual spraying disinfection in all agri-food industries.

Scenario 4: Manual dipping of material and/or containers for the Meta SPC 1, Meta SPC 3, Meta SPC 4

Dermal

	Dermal exposure			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 3.5 ((Meta-SPC 1)	0.104%	1.0%	0.2%	0.0384%
INDAL PAA 5 (Meta-SPC **3) for PT2 and PT3 applications**	0.265%	1.275%	0.41%	0.048%
INDAL PAA 5 (Meta-SPC **3) for PT4 applications**	0.159%	0.765%	0.246%	0.0288%
INDAL PAA 15 (Meta-SPC 4)	0.2528	0.4	0.2208	-
NOAEC local dermal effects or Skin irritating threshold	0.2% (short) 0.1% (long)	35% (eye dam 8%<C≤50%) (eye irrit 5%<C≤8%)	10%	5%
	Risk related to dermal exposure (comparing to dermal NOAEC or skin irritating threshold)			
INDAL PAA 3.5 ((Meta-SPC 1)	higher skin protection needed	Skin: lower Eye: lower	lower	lower
PPE	Gloves, coverall			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
INDAL PAA 5 (Meta-SPC 3) **for PT2 and PT3 applications**	Higher skin protection needed	Skin: lower Eye: lower	lower	lower

PPE	Gloves, coverall			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
INDAL PAA 5 (Meta-SPC 3) **for PT4 applications**	higher skin protection needed	Skin: lower Eye: lower	lower	lower
PPE	Gloves, coverall			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
INDAL PAA 15 (Meta-SPC 4)	higher skin protection needed	Skin: lower Eye: lower	lower	n.a.
PPE	Gloves, coverall			n.a.
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable

Inhalation

4.1 PT2 Manual dipping

Meta SPC 3 (INDAL PAA 5)

4.1.1 Inhalation exposure: large scale disinfection in industries

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 5 (Meta-SPC 3)	0.5015	0.4702	1.2366	0.000096
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	1.003	0.3762	0.04946	0.00192
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	1.3792		0.04946	0.00192
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable

• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.3448	/	/
• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	Acceptable

4.1.2 Inhalation exposure: small scale disinfection in institutions

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 5 (Meta-SPC 3)	0.4848	0.4702	1.2199	0.000096
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	0.9696	0.3762	0.0488	0.00192
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	1.3458		0.0488	0.00192
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.3365		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

4.2 PT3 Manual dipping

SPC 3 (INDAL PAA 5)

4.2.1 Inhalation exposure: large scale disinfection in animal housing

Poultry houses

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 5 (Meta-SPC 3)	0.0137	0.0151	0.0325	0.000096
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	0.0274	0.0121	0.0013	0.00192
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	0.0395		0.0013	0.00192
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Pig houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 5 (Meta-SPC 3)	0.0573	0.056	0.1394	0.000096
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	0.1146	0.0448	0.0056	0.00192
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	0.1594		0.0056	0.00192
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

4.2.2 Inhalation exposure: disinfection in aquaculture farms

Aquaculture plants	
	Total exposure to aerosol and vapour [mg/m³]

Substances	Peracetic acid	Hydrogen peroxide	Acetic acid	Sulphuric acid
INDAL PAA 5 (Meta-SPC 3)	1.8375	1.6693	4.5098	0.000096
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	3.675	1.3354	0.1804	0.00192
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	5.0104		0.1804	0.00192
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P2 filter respiratory tract – 0.501		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

4.3 PT4 Manual dipping

Meta SPC 1 (INDAL PAA 3.5), Meta SPC 3 (INDAL PAA 5), and Meta SPC 4 (INDAL PAA 15)

4.3.1 Inhalation exposure: large scale disinfection in agri-food industries

Slaughter houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 3.5 (Meta-SPC 1)	0.0038	0.0088	0.0114	0.0077
INDAL PAA 5 (Meta-SPC 3)	0.0058	0.0067	0.0135	0.00006
INDAL PAA 15 (Meta-SPC 4)	0.0092	0.0035	0.0124	n.a.
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			

INDAL PAA 3.5 (Meta-SPC 1)	0.0076	0.007	0.0005	0.154
INDAL PAA 5 (Meta-SPC 3)	0.0116	0.0054	0.0005	0.0012
INDAL PAA 15 (Meta-SPC 4)	0.0184	0.0028	0.0005	n.a.
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	0.0146		0.0005	0.154
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
INDAL PAA 5 (Meta-SPC 3)	0.017		0.0005	0.0012
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
INDAL PAA 15 (Meta-SPC 4)	0.0212		0.0005	n.a.
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Institutional Kitchen				
	Exposure to aerosol [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 3.5 (Meta-SPC 1)	0.0302	0.059	0.0914	0.0077
INDAL PAA 5 (Meta-SPC 3)	0.0453	0.0445	0.1105	0.00006
INDAL PAA 15 (Meta-SPC 4)	0.0725	0.0238	0.1204	n.a.
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	0.0604	0.0472	0.0037	0.154
INDAL PAA 5 (Meta-SPC 3)	0.0906	0.0356	0.0044	0.0012
INDAL PAA 15 (Meta-SPC 4)	0.145	0.019	0.0048	n.a.
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	0.1076		0.0037	0.154

• **Risk acceptable or non acceptable?**	Acceptable	Acceptable	Acceptable
INDAL PAA 5 (Meta-SPC 1)	0.1262	0.0044	0.0012
• **Risk acceptable or non acceptable?**	Acceptable	Acceptable	Acceptable
INDAL PAA 15 (Meta-SPC 4)	0.164	0.0048	n.a.
• **Risk acceptable or non acceptable?**	Acceptable	Acceptable	Acceptable

4.3.2 Inhalation exposure: foot bath disinfection in agri-food industries

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 3.5 (Meta-SPC 1)	0.0006	0.0028	0.0017	0.0077
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	0.0012	0.0022	0.0001	0.154
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	0.0034		0.0001	0.154
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

Conclusions to the primary exposure during all PT2 manual dipping applications:

During manual dipping applications with the maximum use concentration of 5%, the risk related to dermal exposure is acceptable for INDAL PAA 5 (Meta-SPC 3)with the wearing of chemical-resistant gloves and a protective coverall to guarantee sufficient skin protection for the user. No eye protection is required.

For the professional use of INDAL PAA 5 with the maximum use concentration of 5%, a respiratory protective equipment (RPE) and especially a half face mask with a P1 filter to protect respiratory tract is required for the manual dipping applications in industries as well as in institutions. No heating takes place during dipping bathes. The room needs to be sufficiently well ventilated with 10 air changes per hour. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.

Conclusions to the primary exposure during all PT3 manual dipping applications:

During manual dipping applications with the maximum use concentration of 5%, the risk related to dermal exposure is acceptable for INDAL PAA 5 (Meta-SPC 3) with the wearing of

chemical-resistant gloves and a protective coverall to guarantee sufficient skin protection for the user. No eye protection is required.

To protect the respiratory tract, the wearing of a respiratory protection equipment (P2 type) is required for the professional use of INDAL PAA 5 with the maximum use concentration of 5% for PT 3 dipping applications in aquaculture plants. For the professional use of INDAL PAA 5 with the maximum use concentration of 5%, no respiratory protective equipment (RPE) is required for the manual dipping applications in other animal houses (poultry houses, pig houses as worst case). No heating takes place during dipping bathes. The room needs to be sufficiently well ventilated with 10 air changes per hour. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.

Conclusions to the primary exposure during all PT4 manual dipping applications:

During manual dipping applications the risks related to dermal and eye exposures are only acceptable with the use of chemical-resistant gloves and a protective coverall for the products INDAL PAA 3.5 (Meta-SPC 1), INDAL PAA 5 (Meta-SPC 3), and INDAL PAA 15 (Meta-SPC 4). No protection of eyes is required.

During the manual dipping applications making use of INDAL PAA 3.5, INDAL PAA 5, and INDAL PAA 15, the professional user can proceed the manual dipping without any respiratory protective equipment in all agri-food industries, as well as for foot bath disinfection. No heating takes place during dipping bathes. The room needs to be sufficiently well ventilated with 10 air changes per hour. After application of the biocidal product rinse treated surfaces, equipment, pipework or installations with drinking water.

Scenario 5: Manual rinsing of open surfaces for the Meta SPC 1, Meta SPC 2, Meta SPC 3, Meta SPC 5

Dermal

Dermal exposure is considered to be negligible.

Inhalation

	Exposure to aerosol [mg/m³]
Substance	**Sulphuric acid**
INDAL PAA 3.5 (Meta-SPC 1)	0.0292
INDAL PAA 2.5 (Meta-SPC 2)	0.0114
INDAL PAA 5 (Meta-SPC 3) **-** disinfection in public insitutions against algae	0.03648
INDAL PAA 5 (Meta-SPC **3)-** disinfection of of animal houses, animal transport vehicles	0.03648
INDAL PAA 5 (Meta-SPC **3)-** disinfection of milking parlour	0.0036
INDAL PAA 5 (Meta-SPC 3) **-** disinfection of agri-food industries	0.0219

INDAL PAA OXY MOUSS (Meta-SPC 5) **-** disinfection of animal houses, animal transport vehicles	0.019
INDAL PAA OXY MOUSS (Meta-SPC 5) **-** disinfection of agri-food industries	0.019
AEC for local effects to repiratory tract [mg/m³]	0.05
	Risk related to exposure to aerosol (Exposure/AEC) [mg/m³]
INDAL PAA 3.5 (Meta-SPC 1)	0.584
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA 2.5 (Meta-SPC 2)	0.228
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA 5 (Meta-SPC 3) **-** disinfection in public insitutions against algae	0.7269
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA 5 (Meta-SPC 3) **-** disinfection of of animal houses, animal transport vehicles	0.7269
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA 5 (Meta-SPC 3) **-** disinfection of milking parlour	0.072
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA 5 (Meta-SPC 3) **-** disinfection of agri-food industries	0.438
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA OXY MOUSS (Meta-SPC 5) **-** disinfection of animal houses, animal transport vehicles	0.38
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA OXY MOUSS (Meta-SPC 5) **-** disinfection of agri-food industries	0.38
• **Risk acceptable or non acceptable?**	Acceptable

Conclusions to the exposure during manual rinsing application:

During the manual rinsing application, no dermal personal protective equipment or respiratory protective equipment is required for the user that can safely rinse off the diluted biocidal products of the "QUARON PAA family" from treated surfaces, equipment, material, ...

Scenario 6: Manual draining of solution contained in recipient or container after dipping applications for Meta SPC 1, Meta SPC 2, Meta SPC 3

Dermal

Dermal exposure is considered to be negligible.

Inhalation

	Exposure to aerosol [mg/m³]
Substance	**Sulphuric acid**
INDAL PAA 3.5 (Meta-SPC 1)	0.0001
INDAL PAA 2.5 (Meta-SPC 2)	0.00003
INDAL PAA 5 (Meta-SPC 3) for PT2 and PT4 applications	0.0001
INDAL PAA 5 (Meta-SPC 3) for PT3 applications	0.0001
AEC for local effects to repiratory tract [mg/m³]	0.05
	Risk related to exposure to aerosol (Exposure/AEC) [mg/m³]
INDAL PAA 3.5 (Meta-SPC 1)	0.002
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA 2.5 (Meta-SPC 2)	0.0006
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA 5 (Meta-SPC 3) for PT2 and PT4 applications	0.002
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA 5 (Meta-SPC 3) for PT3 applications	0.002
• **Risk acceptable or non acceptable?**	Acceptable

Conclusions to the exposure during manual draining application:

During manual draining application, no dermal personal protective equipment or respiratory protective equipment is required for the user that safely drain the diluted biocidal products of the "QUARON PAA family".

Combined scenarios

Dermal exposure

Worst case approach since local effects at the side of first contact (and absence of a systemic availability of peracetic acid and hydrogen peroxide), only the highest concentration (= undiluted) of the biocidal products of the „QUARON PAA family" is

relevant for exposure/risk assessment purposes and no calculations of a combined dermal exposure during the different tasks for a same user is required.

Worst case: mixing and loading

	Dermal exposure			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 3.5 (Meta-SPC 1)	2.6%	25%	5%	0.96%
INDAL PAA 2.5 (Meta-SPC 2)	2%	35.5%	2.2%	0.3%
INDAL PAA 5 (Meta-SPC 3)	5.3%	25.5%	8.2%	0.96%
INDAL PAA 15 (Meta-SPC 4)	15.8%	25%	13.8%	-
INDAL OXY MOUSS (Meta-SPC 5)	1.2%	13.0%	5.75%	0.5%
INDAL TAP 5 (Meta-SPC 6)	5%	21%	5.95%	13.5%
NOAEC local dermal effects or Skin irritating threshold	0.2% (short) 0.1% (long)	35% (eye dam 8%<C≤50%) (eye irrit 5%<C≤8%)	10%	5%
	Risk related to dermal exposure (comparing to dermal NOAEC or skin irritating threshold)			
INDAL PAA 3.5 (Meta-SPC 1)	higher skin protection needed	Skin: lower Eye: higher eye protection needed	lower	lower
PPE	Gloves, coverall, face shield			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
INDAL PAA 2.5 (Meta-SPC 2)	higher skin protection needed	higher skin protection needed	lower	lower
PPE	Gloves, coverall, face shield			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
INDAL PAA 5 (Meta-SPC 3)	higher	Skin: lower Eye: higher	lower	lower

	skin protection needed	eye protection needed		
PPE	Gloves, coverall, face shield			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
INDAL PAA 15 (Meta-SPC 4)	higher skin protection needed	Skin: lower Eye: higher eye protection needed	higher skin protection needed	n.a.
PPE	Gloves, coverall, face shield			
Risk acceptable or non acceptable?	Acceptable			n.a.
INDAL OXY MOUSS (Meta-SPC 5)	higher skin protection needed	Skin: lower Eye: higher eye protection needed	lower	lower
PPE	Gloves, coverall, face shield			
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable
INDAL TAP 5 (Meta-SPC 6)	higher skin protection needed	Skin: lower Eye: higher eye protection needed	lower	higher
PPE	Gloves, coverall, face shield			
Risk acceptable or non acceptable?	Acceptable	Acceptable	Acceptable	Acceptable

Inhalation exposure

Worst case approach since local effects at the side of first contact (and absence of a systemic availability of peracetic acid and hydrogen peroxide), only the highest exposure level in air of the biocidal products of the „QUARON PAA family" is relevant for exposure/risk assessment purposes and no addition of exposure levels and no calculations of a combined inhalation exposure during the different tasks for a same user is required.

Conclusions for all the uses and scenarios of the "QUARON PAA Family"

Scenario or Use	Product Type	Product	Conclusions for an acceptable risk for the user (PPE and RPE)
Manual mixing and loading	PT 2	INDAL PAA 2.5 (Meta-SPC 2)	- Gloves, face shield or goggles and a protective coverall. - No RPE
Automatic pumping/mixing and loading	PT 2 and PT 4	INDAL PAA 3.5 (Meta-SPC 1)	- Gloves, face shield or goggles and a protective coverall. - RPE: full-mask type P2
	PT 2	INDAL PAA 2.5 (Meta-SPC 2)	
	PT 2, PT 3, PT 4 and PT 5	INDAL PAA 5 (Meta-SPC 3)	
	PT 2 and PT 4	INDAL PAA 15 (Meta-SPC 4)	- Gloves, face shield or goggles and a protective coverall. - RPE: full-mask type P3
	PT 4	INDAL TAP 5 (Meta-SPC 6)	
	PT 3 and PT 4	INDAL OXY MOUSS (Meta-SPC 5)	- Gloves, face shield or goggles and a protective coverall. - RPE: full-mask type P1
Manual spraying	PT 2	INDAL PAA 2.5 (Meta-SPC 2)	- No PPE required for all application except against algae in swimming pool and balneotherapy institutions - Gloves and a protective coverall for application in swimming pools and balneotherapy against algae - RPE: half-mask type P2 for industries - RPE: half-mask type P3 for institutions - RPE: half-mask type P3 for swimming pool and balneotherapy against algae
		INDAL PAA 5 (Meta-SPC 3)	- Gloves and a protective coverall - RPE: half-mask type P2 for industries - RPE: half-mask type P3 for institutions - RPE: half-mask type P3 for public institutions against algae
	PT 3	INDAL PAA 5 (Meta-SPC 3)	- Gloves and a protective coverall

Scenario or Use	Product Type	Product	Conclusions for an acceptable risk for the user (PPE and RPE)
			- RPE: half-mask type P3 for animal houses disinfection - No RPE for miliking parlour systems disinfection
		INDAL OXY MOUSS (Meta-SPC 5)	- No PPE - RPE: half-mask type P1 for animal houses disinfection - RPE: half-mask type P2 for vehicles disinfection for animal transport
	PT 4	INDAL PAA 3.5 (Meta-SPC 1)	- Gloves and a protective coverall. - RPE: half-mask type P1 for Kitchens - No RPE for slaughterhouses
		INDAL PAA 5 (Meta-SPC 3)	- Gloves and a protective coverall. - No RPE
		INDAL OXY MOUSS (Meta-SPC 5)	- No PPE - No RPE
Manual dipping	PT 2	INDAL PAA 5 (Meta-SPC 3)	- Gloves and a protective coverall. - RPE: half-mask type P1
	PT 3	INDAL PAA 5 (Meta-SPC 3)	- Gloves and a protective coverall. - RPE: half-mask type P2 for disinfection in aquaculture plants - No RPE for dipping disinfection in other animal houses - No heating takes place during dipping bathes. - The room needs to be sufficiently well ventilated with 10 air changes per hour.
	PT 4	INDAL PAA 3.5 (Meta-SPC 1)	- Gloves and a protective coverall. - No RPE - No heating takes place during dipping bathes. - The room needs to be sufficiently well ventilated with 10 air changes per hour.
		INDAL PAA 5 (Meta-SPC 3)	
		INDAL PAA 15 (Meta-SPC 4)	
Manual rinsing	PT 2 and PT 4	INDAL PAA 3.5 (Meta-SPC 1)	- No PPE - No RPE

Scenario or Use	Product Type	Product	Conclusions for an acceptable risk for the user (PPE and RPE)
	PT 2	INDAL PAA 2.5 (Meta-SPC 2)	- For all low-medium pressure spraying application, the treated surface is not allowed to get dry prior to rinsing.
	PT 2, PT 3 and PT 4	INDAL PAA 5 (Meta-SPC 3)	
	PT 3 and PT 4	INDAL OXY MOUSS (Meta-SPC 5)	
Manual draining	PT 4	INDAL PAA 3.5 (Meta-SPC 1)	- No PPE - No RPE
	PT 2	INDAL PAA 2.5 (Meta-SPC 2)	
	PT 2, PT 3 and PT 4	INDAL PAA 5 (Meta-SPC 3)	

(VIII) Risk for non-professional users

No applications related to non-professional use were identified. The biocidal products of the „QUARON PAA family" are not available for non-professional use.

(IX) Risk for the general public

Local effects

Dermal

Secondary exposure scenarios of humans and a systemic exposure following dermal contact with treated areas, surfaces, material, or equipment is considered to be not relevant.

Inhalation

The exposure of the general public is considered to be of short duration and to occur under conditions related to an acute exposure scenario only.

Refering to the exposure assessment for the industrial and professional user:

***Scenario 1**: Manual mixing and loading*

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 2.5 (Meta-SPC 2)	0.0517	0.3977	0.0648	0.0028

AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 2.5 (Meta-SPC 2)	0.1034	0.3182	0.0026	0.056
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 2.5 (Meta-SPC 2)	0.4216		0.0026	0.056
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

Conclusions to the secondary exposure manual mixing and loading of the general public:
The risk related to inhalation exposure to aerosol and vapour is acceptable as no respiratory protective equipment is required.

***Scenario 2**: Automated mixing and loading by pumping of concentrates*

Inhalation **Exposure to aerosol [mg/m³]**				
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 3.5 (Meta-SPC 1)	0.572	5.1	1.1	0.2112
INDAL PAA 2.5 (Meta-SPC 2)	0.44	7.81	0.484	0.066
INDAL PAA 5 (Meta-SPC 3)	1.166	5.61	1.804	0.2112
INDAL PAA 15 (Meta-SPC 4)	3.476	5.5	3.036	n.a.
INDAL OXY MOUSS (Meta-SPC 5)	0.264	2.86	1.265	0.11
INDAL TAP 5 (Meta-SPC 6)	1.1	5.62	1.309	2.97
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol (Exposure/AEC) [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	1.144	4.08	0.044	4.224
INDAL PAA 2.5 (Meta-SPC 2)	0.88	6.248	0.0194	1.32

INDAL PAA 5 (Meta-SPC 3)	2.332	4.488	0.0722	4.224
INDAL PAA 15 (Meta-SPC 4)	6.952	4.4	0.1214	n.a.
INDAL OXY MOUSS (Meta-SPC 5)	0.528	2.288	0.0506	2.2
INDAL TAP 5 (Meta-SPC 6)	2.2	4.496	0.0524	59.4
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	5.224		0.044	4.224
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Non acceptable
INDAL PAA 2.5 (Meta-SPC 2)	7.128		0.0194	1.32
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Non acceptable
INDAL PAA 5 (Meta-SPC 3)	6.82		0.0722	4.224
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Non acceptable
INDAL PAA 15 (Meta-SPC 4)	11.352		0.11214	n.a.
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	n.a.
INDAL OXY MOUSS (Meta-SPC 5)	2.816		0.0506	2.2
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Non acceptable
INDAL TAP 5 (Meta-SPC 6)	6.696		0.0524	59.4
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Non acceptable

n.a. Not applicable because INDAL PAA 15 does not contain sulphuric acid in its formulation.

Conclusions to the secondary exposure manual connecting for automatic mixing and loading system of the general public:

The risk related to inhalation exposure to aerosol and vapour is not acceptable as the wearing of respiratory protective equipment is required. General public should not be allowed to enter places where biocidal products of the Quaron PAA family are connected manually for automatic mixing and loading system.

***Scenario 3**: Manual spraying on open surfaces for all Meta SPC exepted Meta SPC 4 (INDAL PAA 15) and META 6 (INDAL TAP 5)*

3.1 PT2 Manual spraying

3.1.1 Inhalation exposure: large scale disinfection in industries

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 2.5 (Meta-SPC 2)	0.8108	9.2792	0.8269	0.00912
INDAL PAA 5 (Meta-SPC 3)	1.6208	4.9814	2.587	0.0219
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 2.5 (Meta-SPC 2)	1.6216	7.4234	0.0331	0.1824
INDAL PAA 5 (Meta-SPC 3)	3.2416	3.9851	0.1035	0.438
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 2.5 (Meta-SPC 2)	9.045		0.0331	0.1824
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
INDAL PAA 5 (Meta-SPC 3)	7.2267		0.1035	0.438
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable

3.1.2 Inhalation exposure: small scale disinfection in industries

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 2.5 (Meta-SPC 2)	0.4908	4.6792	0.5769	0.00912
INDAL PAA 5 (Meta-SPC 3)	0.9608	2.4814	1.587	0.0219
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 2.5 (Meta-SPC 2)	0.9816	3.7434	0.0231	0.1824
INDAL PAA 5 (Meta-SPC 3)	1.9216	1.9851	0.0635	0.438

	Combined risk due to equilibrium reaction [mg/m³]		
INDAL PAA 2.5 (Meta-SPC 2)	4.725	0.0231	0.1824
• **Risk acceptable or non acceptable?**	Non acceptable	Acceptable	Acceptable
INDAL PAA 5 (Meta-SPC 3)	3.9067	0.0635	0.438
• **Risk acceptable or non acceptable?**	Non acceptable	Acceptable	Acceptable

3.1.3 Inhalation exposure: small scale disinfection in institutions

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 2.5 (Meta-SPC 2)	2.7608	14.0792	3.6669	0.00912
INDAL PAA 5 (Meta-SPC 3)	5.4208	7.6814	10.087	0.0219
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 2.5 (Meta-SPC 2)	5.5216	11.2634	0.1467	0.1824
INDAL PAA 5 (Meta-SPC 3)	10.8416	6.1451	0.4035	0.438
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 2.5 (Meta-SPC 2)	16.785		0.1467	0.1824
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
INDAL PAA 5 (Meta-SPC 3)	16.9867		0.4035	0.438
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable

3.1.4 Inhalation exposure: small scale disinfection in swimming pools and balneotherapy institutions against algae

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**

INDAL PAA 2.5 (Meta-SPC 2)	5.076	16.353	7.9836	0.0114
INDAL PAA 5 (Meta-SPC 3)	13.2014	10.969	30.3116	0.03648
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/Aec) [mg/m³]			
INDAL PAA 2.5 (Meta-SPC 2)	10.152	13.0824	0.3193	0.228
INDAL PAA 5 (Meta-SPC 3)	26.4028	8.7752	1.2125	0.7296
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 2.5 (Meta-SPC 2)	23.2344		0.3193	0.228
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.5809		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
INDAL PAA 5 (Meta-SPC 3)	35.178		1.2125	0.7296
• **Risk acceptable or non acceptable?**	Non acceptable		Non acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.8795		Half face mask with a P1 filter to protect respiratory tract – 0.3031	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

3.2 PT3 Manual spraying

3.2.1 Inhalation exposure: large scale disinfection in animal houses

Poultry houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**

INDAL PAA 5 (Meta-SPC 3)	1.0534	4.689	1.6316	0.03648
INDAL OXY MOUSS (Meta-SPC 5)	0.1076	1.044	0.5185	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	2.106	3.7512	0.06526	0.7296
INDAL OXY MOUSS (Meta-SPC 5)	0.2152	0.8352	0.0207	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	5.8572		0.06526	0.7296
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P2 filter to protect respiratory tract – 0.5857		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
INDAL OXY MOUSS (Meta-SPC 5)	1.0504		0.0242	0.38
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.2626		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Pig houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 5 (Meta-SPC 3)	3.8014	15.369	5.9516	0.03648

INDAL OXY MOUSS (Meta-SPC 5)	0.3056	2.494	1.5185	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	7.6028	12.2952	0.2381	0.7296
INDAL OXY MOUSS (Meta-SPC 5)	0.6112	1.9952	0.0607	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	19.898		0.0263	0.38
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.4975		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
INDAL OXY MOUSS (Meta-SPC 5)	2.6064		0.0607	0.38
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.6516		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

3.2.2 Inhalation exposure: small scale disinfection in animal houses

Poultry houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**

INDAL PAA 5 (Meta-SPC 3)	1.0534	4.689	1.6316	0.03648
INDAL OXY MOUSS (Meta-SPC 5)	0.1076	1.044	0.5185	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	2.106	3.7512	0.06526	0.7296
INDAL OXY MOUSS (Meta-SPC 5)	0.2152	0.8352	0.0207	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	19.898		0.06526	0.7296
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.4975		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
INDAL OXY MOUSS (Meta-SPC 5)	1.0504		0.0242	0.38
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.2626		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
Pig houses				

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 5 (Meta-SPC 3)	3.5614	12.609	5.5916	0.03648
INDAL OXY MOUSS (Meta-SPC 5)	0.2656	1.794	1.3185	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	7.122	10.0872	0.2237	0.7296
INDAL OXY MOUSS (Meta-SPC 5)	0.5312	1.4352	0.0527	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 5 (Meta-SPC 3	17.2092		0.2237	0.7296
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P3 filter to protect respiratory tract – 0.4302		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable
INDAL OXY MOUSS (Meta-SPC 5)	1.9664		0.0527	0.38
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.4916		/	/
• **Risk acceptable**	Acceptable		Acceptable	Acceptable

of non acceptable?			

3.2.3 Inhalation exposure: disinfection of vehicles for animal transport

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL OXY MOUSS (Meta-SPC 5)	1.7456	5.794	10.2185	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL OXY MOUSS (Meta-SPC 5)	3.4912	4.6352	0.4087	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL OXY MOUSS (Meta-SPC 5)	8.1264		0.4087	0.38
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable

3.2.4 Inhalation exposure: disinfection of milking parlour systems in farms

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 5 (Meta-SPC 3)	0.0201	0.0969	0.0312	0.0036
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	0.0402	0.0775	0.0012	0.072
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	0.1177		0.0012	0.072
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

3.3 PT4 Manual spraying

3.3.1 Inhalation exposure: large scale disinfection

Slaughter houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 3.5 (Meta-SPC 1)	0.104	0.98	0.2	0.0292
INDAL PAA 5 (Meta-SPC 3)	0.1588	0.7514	0.247	0.0219
INDAL OXY MOUSS (Meta-SPC 5)	0.0786	0.794	0.3785	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	0.208	0.784	0.008	0.584
INDAL PAA 5 (Meta-SPC 3)	0.3176	0.6011	0.0099	0.438
INDAL OXY MOUSS (Meta-SPC 5)	0.1572	0.6352	0.0151	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	0.992		0.008	0.584
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
INDAL PAA 5 (Meta-SPC 3)	0.9187		0.0099	0.438
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
INDAL OXY MOUSS (Meta-SPC 5)	0.7924		0.0151	0.38
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Institutional Kitchen				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 3.5 (Meta-SPC 1)	0.112	1.06	0.217	0.0292
INDAL PAA 5 (Meta-SPC3)	0.1728	0.8114	0.267	0.0219

INDAL OXY MOUSS (Meta-SPC 5)	0.0906	0.894	0.4385	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	0.224	0.848	0.0087	0.584
INDAL PAA 5 (Meta-SPC 3)	0.3456	0.6491	0.0107	0.438
INDAL OXY MOUSS (Meta-SPC 5)	0.1812	0.7152	0.0351	0.76
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	1.072		0.0087	0.584
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
INDAL PAA 5 (Meta-SPC 3)	0.9947		0.0107	0.438
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
INDAL OXY MOUSS (Meta-SPC 5)	0.8964		0.0351	0.76
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

3.3.2 Inhalation exposure: small scale disinfection

Slaughter houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 3.5 (Meta-SPC 1)	0.104	0.98	0.2	0.0292
INDAL PAA 5 (Meta-SPC 3)	0.1588	0.7514	0.247	0.0219
INDAL OXY MOUSS (Meta-SPC 5)	0.0786	0.794	0.3785	0.019
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			

INDAL PAA 3.5 (Meta-SPC 1)	0.208	0.784	0.008	0.584
INDAL PAA 5 (Meta-SPC 3)	0.3176	0.6011	0.0099	0.438
INDAL OXY MOUSS (Meta-SPC 5)	0.1572	0.6352	0.0151	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	0.992		0.008	0.584
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
INDAL PAA 5 (Meta-SPC 3)	0.9187		0.0099	0.438
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
INDAL OXY MOUSS (Meta-SPC 5)	0.7924		0.0151	0.38
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Institutional Kitchen				
	Exposure to aerosol [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 3.5 (Meta-SPC 1)	0.11	0.99	0.213	0.0292
INDAL PAA 5 (Meta-SPC 3)	0.1688	0.7614	0.263	0.0219
INDAL PAA OXY MOUSS (Meta-SPC 5)	0.0846	0.724	0.4185	0.019
AEC for local effects to repiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	0.22	0.792	0.0085	0.584
INDAL PAA 5 (Meta-SPC 3)	0.3376	0.6091	0.0105	0.438
INDAL PAA OXY MOUSS (Meta-SPC 5)	0.1692	0.5792	0.0167	0.38
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	1.012		0.0085	0.584

• **Risk acceptable or non acceptable?**	Non acceptable	Acceptable	Acceptable
INDAL PAA 5 (Meta-SPC 3)	0.9467	0.0105	0.438
• **Risk acceptable or non acceptable?**	Acceptable	Acceptable	Acceptable
INDAL PAA OXY MOUSS (Meta-SPC 5)	0.7484	0.0167	0.38
• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	Acceptable

Conclusions to the secondary exposure for all PT2 manual spraying applications of the general public:

The risk related to inhalation exposure to aerosol and vapour is not acceptable as the wearing of respiratory protective equipment is required. General public should not be allowed to enter places where spraying activities with the biocidal products INDAL PAA2.5 (Meta-SPC 2)and INDAL PAA 5 (Meta-SPC 3) of the Quaron PAA family are taking place. The general public is only allowed to re-enter these places when these places are well ventilated and the concentration of peracetic acid and hydrogen peroxide in the air is lower than the AEC for local effects to respiratory tract.

Conclusions to the secondary exposure for all PT3 manual spraying applications of the general public:

The risk related to inhalation exposure to aerosol and vapour is not acceptable as the wearing of respiratory protective equipment is required except for the use of INDAL PAA 5 (Meta-SPC 3) when diluted to a 0.5% use concentration during manual spraying disinfection of milking claws in farms. General public should not be allowed to enter places where spraying activities with the biocidal products INDAL PAA 5 and INDAL OXY MOUSS (Meta-SPC 5) of the Quaron PAA family are taking place. The general public is only allowed to re-enter these places when these places are well ventilated and the concentration of peracetic acid and hydrogen peroxide in the air is lower than the AEC for local effects to respiratory tract. There is no inhalation risk for the general public for the manual spraying disinfection of milking claws in farms with INDAL PAA 5 at a use concentration of 0.5%

Conclusions to the secondary exposure for all PT4 manual spraying applications of the general public:

The risk related to inhalation exposure to aerosol and vapour is not acceptable for the product INDAL PAA 3.5 (Meta-SPC 1)as the wearing of respiratory protective equipment is required. For the use of INDAL PAA 5 (Meta-SPC 3)and INDAL OXY MOUSS (Meta-SPC 5), no respiratory protective equipment is required for the manual spraying disinfection in all agri-food industries.

General public should not be allowed to enter places where spraying activities with the biocidal product INDAL PAA 3.5 of the Quaron PAA family are taking place. The general public is only allowed to re-enter these places when these places are well ventilated and the concentration of peracetic acid and hydrogen peroxide in the air is lower than the AEC for local effects to respiratory tract. There is no inhalation risk for the general public for the manual spraying disinfection in all agri-food industries with INDAL PAA 5 and INDAL OXY MOUSS.

Scenario 4: *Manual dipping of material and/or containers for the Meta SPC 1, Meta SPC 3, Meta SPC 4*

4.1 PT2 Manual dipping

4.1.1 Inhalation exposure: large scale disinfection in industries

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 5 (Meta-SPC 3)	0.5015	0.4702	1.2366	0.000096
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	1.003	0.3762	0.04946	0.00192
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	1.3792		0.04946	0.00192
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.3448		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

4.1.2 Inhalation exposure: small scale disinfection in institutions

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 5 (Meta-SPC 3)	0.4848	0.4702	1.2199	0.000096
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05

	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	0.9696	0.3762	0.0488	0.00192
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	1.3458		0.0488	0.00192
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P1 filter to protect respiratory tract – 0.3365		/	/
• **Risk acceptable of non acceptable?**	Acceptable		Acceptable	Acceptable

4.2 PT3 Manual dipping

4.2.1 Inhalation exposure: large scale disinfection in animal housing

Poultry houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 5 (Meta-SPC 3)	0.0137	0.0151	0.0325	0.000096
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	0.0274	0.0121	0.0013	0.00192
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	0.0395		0.0013	0.00192
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Pig houses				
	Total exposure to aerosol and vapour [mg/m³]			

Substances	Peracetic acid	Hydrogen peroxide	Acetic acid	Sulphuric acid
INDAL PAA 5 (Meta-SPC 3)	0.0573	0.056	0.1394	0.000096
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	0.1146	0.0448	0.0056	0.00192
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	0.1594		0.0056	0.00192
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

4.2.2 Inhalation exposure: disinfection in aquaculture farms

Aquaculture plants				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 5 (Meta-SPC 3)	1.8375	1.6693	4.5098	0.000096
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	3.675	1.3354	0.1804	0.00192
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 5 (Meta-SPC 3)	5.0104		0.1804	0.00192
• **Risk acceptable or non acceptable?**	Non acceptable		Acceptable	Acceptable
• **TIER 3: Type of RPE and risk with RPE**	Half face mask with a P2 filter respiratory tract – 0.501		/	/

• **Risk acceptable of non acceptable?**	Acceptable	Acceptable	Acceptable

4.3 PT4 Manual dipping

4.3.1 Inhalation exposure: large scale disinfection in agri-food industries

Slaughter houses				
	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 3.5 (Meta-SPC 1)	0.0038	0.0088	0.0114	0.0077
INDAL PAA 5 (Meta-SPC 3)	0.0058	0.0067	0.0135	0.00006
INDAL PAA 15 (Meta-SPC 4)	0.0092	0.0035	0.0124	n.a.
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	0.0076	0.007	0.0005	0.154
INDAL PAA 5 (Meta-SPC 3)	0.0116	0.0054	0.0005	0.0012
INDAL PAA 15 (Meta-SPC 4)	0.0184	0.0028	0.0005	n.a.
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	0.0146		0.0005	0.154
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
INDAL PAA 5 (Meta-SPC 3)	0.017		0.0005	0.0012
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
INDAL PAA 15 (Meta-SPC 4)	0.0212		0.0005	n.a.
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
Institutional Kitchen				
	Exposure to aerosol [mg/m³]			

Substances	Peracetic acid	Hydrogen peroxide	Acetic acid	Sulphuric acid
INDAL PAA 3.5 (Meta-SPC 1)	0.0302	0.059	0.0914	0.0077
INDAL PAA 5 (Meta-SPC 3)	0.0453	0.0445	0.1105	0.00006
INDAL PAA 15 (Meta-SPC 4)	0.0725	0.0238	0.1204	n.a.
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	0.0604	0.0472	0.0037	0.154
INDAL PAA 5 (Meta-SPC 3)	0.0906	0.0356	0.0044	0.0012
INDAL PAA 15 (Meta-SPC 4)	0.145	0.019	0.0048	n.a.
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	0.1076		0.0037	0.154
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
INDAL PAA 5 (Meta-SPC 3)	0.1262		0.0044	0.0012
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable
INDAL PAA 15 (Meta-SPC 4)	0.164		0.0048	n.a.
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

4.3.2 Inhalation exposure: foot bath disinfection in agri-food industries

	Total exposure to aerosol and vapour [mg/m³]			
Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 3.5 (Meta-SPC 1)	0.0006	0.0028	0.0017	0.0077
AEC for local effects to respiratory tract [mg/m³]	0.5	1.25	25	0.05
	Risk related to total exposure to aerosol and vapour (Exposure/AEC) [mg/m³]			

INDAL PAA 3.5 (Meta-SPC 1)	0.0012	0.0022	0.0001	0.154
	Combined risk due to equilibrium reaction [mg/m³]			
INDAL PAA 3.5 (Meta-SPC 1)	0.0034		0.0001	0.154
• **Risk acceptable or non acceptable?**	Acceptable		Acceptable	Acceptable

Conclusions to the secondary exposure for all PT2 manual dipping applications of the general public:

The risk related to inhalation exposure to aerosol and vapour is not acceptable as the wearing of respiratory protective equipment is required. General public should not be allowed to enter places where dipping activities with the biocidal products INDAL PAA 5 ((Meta-SPC 3) and of the Quaron PAA family are taking place. The general public is only allowed to re-enter these places when these places are well ventilated and the concentration of peracetic acid and hydrogen peroxide in the air is lower than the AEC for local effects to respiratory tract.

Conclusions to the secondary exposure for all PT3 manual dipping applications of the general public:

Aquaculture plants: The risk related to inhalation exposure to aerosol and vapour is not acceptable for the product INDAL PAA 5 (Meta-SPC 3) as the wearing of respiratory protective equipment is required. General public should not be allowed to enter places where spraying activities with the biocidal product INDAL PAA 5 of the Quaron PAA family are taking place. The general public is only allowed to re-enter these places when these places are well ventilated and the concentration of peracetic acid and hydrogen peroxide in the air is lower than the AEC for local effects to respiratory tract.

Other animal housing: The risk related to inhalation exposure to aerosol and vapour is acceptable as no respiratory protective equipment is required. The general public can enter the treated animal housing with INDAL PAA 5 without risk related to inhalation exposure.

Conclusions to the secondary exposure for all PT4 manual dipping applications of the general public:

The risk related to inhalation exposure to aerosol and vapour is acceptable as no respiratory protective equipment is required. The general public can enter the treated areas of the agri-food industries with INDAL PAA 3.5 (Meta-SPC1) , INDAL PAA 5 (Meta-SPC 3), INDAL PAA 15 (Meta-SPC 4) without risk related to inhalation exposure.

***Scenario 5**: Manual rinsing of open surfaces for the Meta SPC 1, Meta SPC 2, Meta SPC 3, Meta SPC 5*

	Exposure to aerosol [mg/m³]
Substance	**Sulphuric acid**
INDAL PAA 3.5 (Meta-SPC 1)	0.0292
INDAL PAA 2.5 (Meta-SPC 2)	0.0114

INDAL PAA 5 (Meta-SPC **3)-** disinfection in public insitutions against algae	0.03648
INDAL PAA 5 (Meta-SPC 3) **-** disinfection of of animal houses, animal transport vehicles	0.03648
INDAL PAA 5 (Meta-SPC 3) **-** disinfection of milking parlour	0.0036
INDAL PAA 5 (Meta-SPC 3) **-** disinfection of agri-food industries	0.0219
INDAL PAA OXY MOUSS (Meta-SPC 5) **-** disinfection of animal houses, animal transport vehicles	0.019
INDAL PAA OXY MOUSS (Meta-SPC 5) **-** disinfection of agri-food industries	0.019
AEC for local effects to repiratory tract [mg/m³]	0.05
	Risk related to exposure to aerosol (Exposure/AEC) [mg/m³]
INDAL PAA 3.5 (Meta-SPC 1)	0.584
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA 2.5 (Meta-SPC 2)	0.228
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA 5 (Meta-SPC 3) **-** disinfection in public insitutions against algae	0.7269
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA 5 (Meta-SPC 3) **-** disinfection of of animal houses, animal transport vehicles	0.7269
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA 5 (Meta-SPC 3) **-** disinfection of milking parlour	0.072
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA 5 (Meta-SPC 3) **-** disinfection of agri-food industries	0.438
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA OXY MOUSS (Meta-SPC 5) **-** disinfection of animal houses, animal transport vehicles	0.38
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA OXY MOUSS (Meta-SPC 5) **-** disinfection of agri-food industries	0.38
• **Risk acceptable or non acceptable?**	Acceptable

Conclusions to the secondary exposure for manual rinsing application of the general public:

The risk related to inhalation exposure to aerosol and vapour is acceptable as no respiratory protective equipment is required. The general public can enter the the rinsed areas without risk related to inhalation exposure.

Nevertheless, it has to be kept in mind that before the rinsing the spraying application (scenario 3) was performed by the industrial/professional user. We refer to the combined exposure of the industrial/professional user: the highest exposure level in air of the biocidal products of the „QUARON PAA family" is relevant for exposure/risk assessment purposes.

For all low-medium pressure spraying application, the treated surface is not allowed to get dry prior to rinsing.

The general public is only allowed to re-enter the treated (sprayed) and rinsed areas when these areas are well ventilated and the concentration of peracetic acid and hydrogen peroxide in the air is lower than the AEC for local effects to respiratory tract (more specified: see scenario 3).

***Scenario 6**: Manual draining of solution contained in recipient or container after dipping applications for Meta SPC 1, Meta SPC 2, Meta SPC 3*

	Exposure to aerosol [mg/m³]
Substance	**Sulphuric acid**
INDAL PAA 3.5 (Meta-SPC 1)	0.0001
INDAL PAA 2.5 (Meta-SPC 2)	0.00003
INDAL PAA 5 (Meta-SPC 3) for PT2 and PT4 applications	0.0001
INDAL PAA 5 (Meta-SPC 3) for PT3 applications	0.0001
AEC for local effects to repiratory tract [mg/m³]	0.05
	Risk related to exposure to aerosol (Exposure/AEC) [mg/m³]
INDAL PAA 3.5 (Meta-SPC 1)	0.002
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA 2.5 (Meta-SPC 2)	0.0006
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA 5 (Meta-SPC 1)for PT2 and PT4 applications	0.002
• **Risk acceptable or non acceptable?**	Acceptable
INDAL PAA 5 (Meta-SPC 3) for PT3 applications	0.002
• **Risk acceptable or non acceptable?**	Acceptable

Conclusions to the secondary exposure for the manual draining application of the general public:

The risk related to inhalation exposure to aerosol and vapour is acceptable as no respiratory protective equipment is required. The general public can enter the areas where the diluted products are drained without risk related to inhalation exposure.

Nevertheless, it has to be kept in mind that before the draining of the diluted product the dipping application (scenario 4) or automated M&L was performed by the industrial/professional user. We refer to the combined exposure of the industrial/professional user: the highest exposure level in air of the biocidal products of the „QUARON PAA family" is relevant for exposure/risk assessment purposes.

The general public is only allowed to re-enter the treated and drained areas in the aquaculture farms when these areas are well ventilated and the concentration of peracetic acid and hydrogen peroxide in the air is lower than the AEC for local effects to respiratory tract.

In addition, secondary exposure will be qualitatively assessed for the shock treatment of swimming pool water.

Scenario 7: Potential exposure of swimmers after shock treatment with Meta SPC 1 (INDAL PPA 2.5) at a maximum dilution of 0.5% for Use #1b

Dermal:

Regarding the low in-use concentration of the active substance peracetic acid (0.013% w/w) as well as of hydrogen peroxide (0.1775% w/w), acetic acid (0.011% w/w), and sulphuric acid acid (0.0015% w/w), no risks from skin or eyes damage is expected as the concentrations applied are below the skin-irritating/eye irritating concentrations.

Substances	**Peracetic acid**	**Hydrogen peroxide**	**Acetic acid**	**Sulphuric acid**
INDAL PAA 2.5 (Meta-SPC 2)	0.01%	0.1775%	0.011%	0.0015%
NOAEC local dermal effects or Skin irritating threshold	0.2% (short) 0.1% (long)	35% (eye dam 8%<C≤50%) (eye irrit 5%<C≤8%)	10%	5%
	Risk related to dermal exposure (comparing to dermal NOAEC or skin irritating threshold)			
INDAL PAA 2.5 (Meta-SPC 2)	lower	lower	lower	lower
PPE				
Risk acceptable or non acceptable?	Acceptable		Acceptable	Acceptable

Inhalation:

Considering the high volatility of peracetic acid, hydrogen peroxide and acetic acid, as well as the high reactivity of peracetic acid and hydrogen peroxide with organic matter, it is

assumed that no exposure occurs to swimmers for these three substances. Furthermore, this treatment generally takes place during the night. So, general public can only access to the swimming pool after about 12 hours. After this time, all the volatile substances as well as the slightly volatile ingredient (sulphuric acid) are not present anymore in the water in a chemical form that could trigger an inhalation exposure. Furthermore, swimming pools are well-ventilated.

Anyhow, sulphuric acid is only characterized as a substance of concern when it is in the form of mist as it clearly appears in the Community workplace exposure defined in the European Commission directive 2009/161/EU (Annex, L338/89). So, after 12 hours, the aquous solution containing ions that come from sulphuric acid do not trigger any inhalation exposure.

Conclusions to the secondary exposure of swimmers after shock treatment:

To conclude, no skin, eyes or inhalation exposures are expected due to high volatility and reactivity of the substances, but also to the time between the treatment and the access to the treated water that is assumed to only contain substances at a physical and chemical form that do not induce any inhalation secondary exposure.

Conclusions for all the uses and scenarios of the "QUARON PAA Family"

Exposed group: General public			
Scenario or Use	**Product Type**	**Product**	**Conclusions for an acceptable risk**
1° Manual mixing and loading	PT 2	INDAL PAA 2.5 (Meta-SPC 2)	- Inhalation: No RPE, acceptable. General public can access to the room during manual mixing and loading applications.
2° Automatic pumping/mixing and loading	PT 2 and PT 4	INDAL PAA 3.5 (Meta-SPC 1)	- RPE: full-mask type P2 for user. General public not allowed to enter areas where the biocidal product is connected manually to automatic mixing and loading systems.
	PT 2	INDAL PAA 2.5 (Meta-SPC 2)	
	PT 2, PT 3, PT 4 and PT 5	INDAL PAA 5 (Meta-SPC 3)	
	PT 2 and PT 4	INDAL PAA 15 (Meta-SPC 4)	- RPE: full-mask type P3 for user. General public not allowed to enter areas where the biocidal product is connected manually to automatic mixing and loading systems..
	PT 4	INDAL TAP 5 (Meta-SPC 6)	
	PT 3 and PT 4	INDAL OXY MOUSS (Meta-SPC 5)	- RPE: full-mask type P1 for user. General public not allowed to enter areas where the biocidal product is connected manually to automatic mixing and loading systems.
3° Manual spraying	PT 2	INDAL PAA 2.5 (Meta-SPC 2)	- RPE: half-mask type P2 for industries. - RPE: half-mask type P3 for institutions - RPE: half-mask type P3 for swimming pool and balneotherapy institutions against algae General public not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the /AEC

Exposed group: General public			
Scenario or Use	**Product Type**	**Product**	**Conclusions for an acceptable risk**
		INDAL PAA 5 (Meta-SPC 3)	- RPE: half-mask type P2 for industries - RPE: half-mask type P3 for institutions - RPE: half-mask type P3 for public institutions against algae General public not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC
	PT 3	INDAL PAA 5 (Meta-SPC 3)	- RPE: half-mask type P3 for animal houses disinfection General public not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC - No RPE for milking parlour systems disinfection General public is allowed to enter areas where milking parlour systems disinfection takes place
		INDAL OXY MOUSS (Meta-SPC 5)	- RPE: half-mask type P1 for animal houses disinfection - RPE: half-mask type P2 for vehicles disinfection for animal transport General public not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC
	PT 4	INDAL PAA 3.5 (Meta-SPC 1)	- RPE: half-mask type P1 for Kitchens General public not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC - No RPE for slaughterhouse sprayer. Inhalation exposure is acceptable for general public. General public can enter the treated areas and can access to the room during spraying applications.
		INDAL PAA 5 (Meta-SPC 3)	- No RPE for sprayer Inhalation exposure is acceptable for general public. General public can enter the treated areas and can access to the room during spraying applications.
		INDAL OXY MOUSS (Meta-SPC 5)	- No RPE for sprayer Inhalation exposure is acceptable for general public. General public can enter the treated areas and can access to the room during spraying applications.
4° Manual dipping	PT 2	INDAL PAA 5 (Meta-SPC 3)	- RPE: half-mask type P1 for user General public not allowed to enter areas during dipping. Re-entry is only allowed after ventilation and when the

Exposed group: General public			
Scenario or Use	**Product Type**	**Product**	**Conclusions for an acceptable risk**
			concentrations in the air are lower than the AEC - No heating takes place during dipping bathes. - The room needs to be sufficiently well ventilated with 10 air changes per hour.
	PT 3	INDAL PAA 5 (Meta-SPC 3)	- RPE: half-mask type P2 for disinfection in aquaculture plants General public not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC - No RPE for dipping disinfection in other animal houses General public not allowed to enter areas during spraying. Re-entry is only allowed after ventilation and when the concentrations in the air are lower than the AEC - - No heating takes place during dipping bathes. - - The room needs to be sufficiently well ventilated with 10 air changes per hour.
	PT 4	INDAL PAA 3.5 (Meta-SPC 1) INDAL PAA 5 (Meta-SPC 3) INDAL PAA 15 (Meta-SPC 4)	- No RPE for user Inhalation exposure is acceptable for general public. General public can enter the treated areas and can access to the room during dipping applications. - - No heating takes place during dipping bathes. - The room needs to be sufficiently well ventilated with 10 air changes per hour.
5° Manual rinsing	PT 2 and PT 4	INDAL PAA 3.5 (Meta-SPC 1)	- No RPE for user Inhalation exposure is acceptable for general public. For all low-medium pressure application, the treated surface is not allowed to get dry prior to rinsing. General public can enter the areas after rinsing took place.
	PT 2	INDAL PAA 2.5 (Meta-SPC 2)	
	PT 2, PT 3 and PT 4	INDAL PAA 5 (Meta-SPC 3)	
	PT 3 and PT 4	INDAL OXY MOUSS (Meta-SPC 5)	
6° Manual draining	PT 4	INDAL PAA 3.5 (Meta-SPC 1)	- No RPE for user Inhalation exposure is acceptable for general public. General public can enter the areas where draining took place.
	PT 2	INDAL PAA 2.5 (Meta-SPC 2)	
	PT 2, PT 3 and PT 4	INDAL PAA 5 (Meta-SPC 3)	
7° Swimming	PT 2	INDAL PAA 2.5 (Meta-SPC 2)	- Dermal: PAA: 0.01 HP: 0.1775 AA: 0.011 SA: 0.0015

Exposed group: General public			
Scenario or Use	**Product Type**	**Product**	**Conclusions for an acceptable risk**
			No PPE, acceptable for swimmer - Inhalation: The general public can access the swimming pool or balneotherapy basin after about 12 hours.

Maximum In use concentration

Scenario	Meta-SPC & Use	PAA concentration (% W/W)	H2O2 concentration (% W/W)
Scenario 1 – Manual Mixing and Loading	Meta-SPC 2 – use 1	2	35.5
Scenario 2 – Automatic Mixing and Loading	Meta-SPC 1 – Use 1	2.6	25
	Meta-SPC 2 – use 2 & 3	2	35.5
	Meta-SPC 3 – use 1	5.3	25.5
	Meta-SPC 4– Use 1 & 2	15.8	25
	Meta-SPC 5 – Use 1 & 2	1.2	13
	Meta-SPC 6 - Use 1	5	21
Scenario 3 – Manual Spraying	Meta-SPC 1 – use 3	0.104	1.0
	Meta-SPC 2 – Use 2	0.1	1.775
	Meta-SPC 3 – Use 12 & 8	0.265	1.275
	Meta-SPC 5 – Use 1	0.06	0.65
Scenario 4 – Manual Dipping	Meta-SPC 1 – use 5	0.104	1.0
	Meta-SPC 3 – uses 4, 9 & 11	0.265	1.275
	Meta-SPC 4 – use 4	0.2528	0.4

Note that Scenario 5 and 6 are not mentioned in this table since they represent, respectively, rinsing and draining of products used in scenario 3 and 4. The maximum in use concentration for those scenario is thus not relevant, since they are cleaning steps. Scenario 7 is also not present, since it represent secondary exposure to the product. An in-use concentration would thus be meaningless.

It is to be noted that some uses are present more than once in the table. This is due, to the presence of multiple steps in one use (such as M&L and spraying). Max in-use concentration for all M&L scenario are of course the concentration of the products undiluted.

(X) Risk for consumers via residues in food

There is no exposure via food.

In applications of peracetic acid solutions as a disinfectant in food and feeding areas, treated equipment, pipework or installations are rinsed with water prior to further operations. Therefore, secondary human exposure to peracetic acid and hydrogen peroxide *via* food etc. is not considered to be relevant as both peracetic acid and hydrogen peroxide highly react with organic matter and as such degrade rapidly following application. Furthermore, peracetic acid and hydrogen peroxide will be rapidly degraded by the efficient detoxification mechanism of the organism even in the unlikely case that residues of both substances would be orally ingested.

No residue are expected due to the properties of peracetic acid that is highly unstable and rapidly reacts upon contact with organic matter[97]. No residues are expected in foodstuffs (CAR[98] of PAA).

2.2.7 Risk assessment for animal health

The Meta SPC 3 of the "QUARON PAA family" is used to disinfect tap water for animals in farms. The in-use concentration of this product is 25 ppm, 0.0025% of PAA and 0.012% H_2O_2.

The CAR[99] of PAA states the following for this specific use:

"In the application of peracetic acid as a disinfectant of animal drinking water, chronic exposure of farm animals via treated water is possible. Based on the comparison of the concentrations of peracetic acid administered to experimental animals via the drinking water at concentrations ranging from 0.02 – 0.03 % peracetic acid (200 – 300 ppm or 200 – 300 mg peracetic acid/L) with the concentration in disinfected drinking water within PT5 (0.0025 %), no health risk for farm animals including their offspring is expected as concentrations applied for the disinfection of animal drinking water within PT5 are well below the no-adverse effect levels derived from available animal studies and the margin of safety for farm animals is considered to be sufficient. Similarly, drinking water studies performed with hydrogen peroxide in rats identified a NOAEL ranging from 0.1% to 0.6% in drinking water which provides also a sufficient margin of safety with respect to the hydrogen peroxide concentrations of 0.0042% applied for the disinfection of drinking water of farm animals. Council Dir 2011/84/EU allows use of hydrogen peroxide in oral products sold directly to consumers up to a maximum concentration of 0.1%. Products containing greater than 0.1% and up to 6% hydrogen peroxide must be applied under the supervision of a dental practitioner. Most importantly, the concentration of peracetic acid and hydrogen peroxide in drinking water causing no adverse effects in the offspring of a rat teratology study is also much higher than the concentration in drinking water for the intended use within PT5 thereby substantiating a sufficient margin of safety for a more sensitive segment of the animal population as well. In addition, the residual concentrations in the drinking water are much lower than the applied concentrations as rapid degradation happens."

97 Assessment Report Peracetic acid Product-types 1-6.Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. Finland. Novembre 2015

98 Assessment Report Peracetic acid Product-types 1-6.Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. Finland. Novembre 2015

99 Assessment Report Peracetic acid Product-types 1-6.Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. Finland. Novembre 2015

The oral uptake of peracetic acid by farm animals via disinfected water corresponds to about 1/10 of the NOAEC determined in studies with experimental animals.

The oral uptake of hydrogen peroxide by farm animals via disinfected drinking water corresponds to about 0.88% of the NOAEC determined in studies with experimental animals.

Long-term secondary exposure farm animals:

Exposure scenario	**Exposure route**	**Species**	**In-use concentration (% w/w)**	**%NO(A)EC**	**Exposure**	
					Inhalation (mg/m³)	**Oral (mg/kg bw/day)**
PT5: disinfection of animal drinking water	oral	Farm animals	PAA: 0.0025 H2O2: 0.012	PAA: ~10 H2O2: ~1	Not relevant	PAA: ~1/10 of NOAEC H2O2: ~1/100 of NOAEC

The "QUARON PAA family" does not include biocidal product that leads to a livestock exposure to active substances used in the biocidal poducts. Indeed, the disinfection occurs without the presence of animals. Furthermore, no residue are expected due to the properties of peracetic acid and hydrogen peroxyde that are highly unstable and rapidly react upon contact with organic matter[100] and as such degrade rapidly after application. But also to the high volatility of these substances and of the substances of concern that the biocidal products family contains. Furthermore, peracetic acid and hydrogen peroxide will be rapidly degraded by the efficient detoxification mechanism of the organism even in the unlikely case that residues of both substances would be orally ingested.

No transfer of biocidal active substance into food can occur since there is a rinsing post-application step for every biocidal product used in PT3 applications.

2.2.8 Risk assessment for the environment

The Quaron PAA family contains 6 products based on the active substance equilibrium of peracetic acid (CAS 79-21-0), hydrogen peroxide (CAS 7722-84-1) and acetic acid (CA 64-19-7). The content of peracetic acid in the products ranges from 1.20% w/w to 15.80% w/w, that of hydrogen peroxide ranges from 13.00% w/w to 35.50% w/w, and that of acetic acid ranges from 2.2% w/w to 13.8% w/w.

The products of the Quaron PAA family are applied as PT2, PT3, PT4 and PT5 disinfectants. Specific product uses are detailed in the section *2.1.4 Authorized use(s)*. As the specific uses and/or in-use concentrations of the products are not all covered by the peracetic acid and the hydrogen peroxide assessment reports, a quantitative risk assessment for the environment was carried out for the products of the family and is detailed hereafter.

100 Assessment Report Peracetic acid Product-types 1-6.Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. Finland. Novembre 2015

This risk assessment focuses on the substance peracetic acid, which is the active substance, and on the substances hydrogen peroxide and acetic acid, which are considered as parts of the active substance equilibrium mixture. According to WGIV2019_ENV_6.3, it was agreed not to consider acetic acid as a substance of concern. Peracetic acid and hydrogen peroxide are evaluated quantitatively. Apart from these substances, the products within the Quaron PAA family do not contain any other environmental SOCs that would need to be addressed in a risk evaluation for the environment and no other relevant metabolites are formed in the environment.

2.2.8.1 Effects assessment on the environment

No new environmental studies have been carried out with the products of the Quaron PAA family. All data pertaining to the active substance is therefore derived from the peracetic acid and hydrogen peroxide assessment reports.

Peracetic acid:

Ecotoxicological studies on the active substance peracetic acid were carried out for aquatic organisms, activated sewage sludge and terrestrial organisms. The measured endpoints are summarized in the following table.

Summary table of ecotoxicological studies for peracectic acid			
Species	**Time-scale**	**Endpoint**	**Toxicity**
Fish			
Lepomis macrochirus (bluegill sunfish)	96 h	Mortality	*LC50 = 1.1 mg a.s./L*
Danio rerio (zebra fish)	33 d	Post hatch success / overall survival	*NOEC = 0.00069 mg a.s./L*
Invertebrates			
Daphnia magna	48 h	Immobility	*EC50 = 0.73 mg a.s./L*
Daphnia magna	21 d	Reproduction	*NOEC = 0.0121 mg a.s./L*
Algae			
Selenastrum capricornutum	72 h	Growth inhibition rate	*EC50 = 0.16 mg a.s./L* *NOEC = 0.061 mg a.s./L*
Microorganisms			

Activated sludge	3 h	Respiration rate	EC50 = 5.1 mg a.s./l
Earthworms			
Earthworm	14 d	LC50	LC50 > 1000 mg a.s./kg dry soil, equals > 885 mg a.s./kg wet soil
Terrestrial plants			
Brassica napus	21 d	Seedling emergence reduction	EC50 = 320 mg a.s./kg dry soil, equals 282 mg a.s./kg wet soil
Soil microorganisms			
Nitrogen mineralization	28 d	EC50	EC50 > 933.6 mg a.s./kg dry soil, equals 826.2 mg a.s./kg wet soil
Carbon mineralization	28 d	EC50	EC50 = 933.6 mg a.s./kg dry soil, equals 826.2 mg a.s./kg wet soil

The corresponding PNEC values for each environmental compartment are shown in the following table.

Summary table on PNEC values							
$PNEC_{STP}$	**$PNEC_{water}$**	**$PNEC_{sed}$**	**$PNEC_{seawater}$**	**$PNEC_{seased}$**	**$PNEC_{soil}$**	**Trigger value $_{GW}$**	**$PNEC_{air}$**
[mg/l]	[µg/l]	[µg/kg_{wwt}]	[µg/l]	[µg/kg_{wwt}]	[mg/ kg_{wwt}]	[µg/l]	[mg/m^3]
0.051	0.069	0.0562	0.0069	0.00562	0.282	0.1	-

For the STP, aquatic and soil compartments, PNEC values were derived from the ecotoxicological endpoints reported in the peracetic acid assessment report. PNEC values for sediment dwelling organisms were derived through equilibrium partitioning.

The 0.1 µg/L trigger value for pesticides was applied for the groundwater compartment, as indicated in the Guidance on the BPR. Vol. IV Part B Risk Assessment (2015).

The physico-chemical properties of PAA suggest that it will not pose a risk to the atmospheric environment. Therefore, no PNEC was calculated for the air compartment.

No data is derived for primary poisoning as product use is not expected to lead to direct exposure of birds and mammals. No secondary poisoning is expected for peracetic acid either. The log K_{ow} is -0.60 at pH 7, indicating that peracetic acid has a negligible potential

for bioconcentration in biota. Furthermore, peracetic acid dissipates rapidly in the environment. No accumulation of peracetic acid in the foodchain is therefore expected.

Hydrogen peroxide:

Ecotoxicological studies on the active substance hydrogen peroxide were carried out for aquatic organisms and activated sewage sludge. The measured endpoints are summarized in the following table.

Summary table of ecotoxicological studies from the hydrogen peroxide assessment report			
Species	**Time-scale**	**Endpoint**	**Toxicity**
Fish			
Pimephales promelas	96 h, semi-static	Mortality, LC50	*16.4 mg a.s./L*
Invertebrates			
Daphnia pulex (crustaceans)	48 h, semi-static	Immobility, EC50	*2.34 mg a.s./L*
Daphnia magna (crustaceans)	21 d, flow-through	Reproduction, NOEC	*0.63 mg a.s./L*
Algae			
Skeletonema costatum (marine diatom)	72 h, static	Growth rate, NOEC	*1.69 mg a.s./L*
Microorganisms			
Activated sewage sludge from sewage treatment plant	0.5 hours and 3 hours, static	Respiration inhibition, EC50	466 mg a.s./l

Corresponding PNEC values for each environmental compartment are indicated in the table below.

Summary table on PNEC values							
$PNEC_{STP}$	**$PNEC_{water}$**	**$PNEC_{sed}$**	**$PNEC_{seawater}$**	**$PNEC_{seased}$**	**$PNEC_{soil}$**	**Trigger value $_{GW}$**	**$PNEC_{air}$**
[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg/ kg_{wwt}]	[µg/l]	[mg/m^3]
4.66	0.0126	0.0103	0.00126	0.00103	0.00184	0.1	-

For the STP and aquatic compartments, PNEC values were derived from the ecotoxicological endpoints reported in the hydrogen peroxide assessment report.

No ecotoxicological data was generated for sediment dewelling and soil organisms as the physico-chemical properties of hydrogen peroxide do not point towards a risk for their corresponding environmental compartments. PNEC values for both these compartments were therefore derived through equilibrium partitioning.

The 0.1 µg/L trigger value for pesticides was applied for the groundwater compartment, as indicated in the Guidance on the BPR. Vol. IV Part B Risk Assessment (2015).

The physico-chemical properties of hydrogen peroxide suggest that it will not pose a risk to the atmospheric environment. Therefore, no PNEC was calculated for the air compartment.

No data is derived for primary poisoning as product use is not expected to lead to direct exposure of birds and mammals. No secondary poisoning is expected for hydrogen peroxide either. The log K_{ow} is -1.57, indicating that hydrogen peroxide has a negligible potiential for bioconcentration in biota. The BCFs for fish and earthworms are 1.4 and 0.84 respectively, indicating that the risk of secondary poisoning for aquatic and terrestrial predators will be negligible. No accumulation of hydrogen peroxide in the foodchain is therefore expected.

Acetic acid

According to WGIV2019_ENV, acetic acid is not considered as a SoC. As acetic acid is included in Annex I, and toxicity to both aquatic and terrestrial life is low, it can be assumed that acetic acid will not pose a significant ecotoxicological risk. Therefore, acetic acid will not be further assessed in this risk evaluation.

(I) Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

No further data are available.

(II) Further Ecotoxicological studies

No further data are available.

(III) Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No further data are available.

(IV) Supervised trials to assess risks to non-target organisms under field conditions

No further data are available.

(V) Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No data are available.

(VI) Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Not relevant.

(VII) Foreseeable routes of entry into the environment on the basis of the use envisaged

See section fate and distribution in exposed environmental compartments.

(VIII) Further studies on fate and behaviour in the environment (ADS)

No further data available.

(IX) Leaching behaviour (ADS)

No data are available.

(X) Testing for distribution and dissipation in soil (ADS)

No further data are available.

(XI) Testing for distribution and dissipation in water and sediment (ADS)

No further data are available.

(XII)Testing for distribution and dissipation in air (ADS)

No further data are available.

(XIII) If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not relevant.

(XIV) If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not relevant.

2.2.8.2 Exposure assessment

(I) General information

The products of the Quaron PAA family are applied as PT2, PT3, PT4 and PT5 disinfectants. The choice of emission scenarios applied to assess each specific product use, as well as the selection of worst-case products, are detailed hereafter.

In the table on the following pages, all product uses are summarised, along with the granted maximal in-use concentrations for each use. For uses that where not granted, the maximal requested in-use concentration is used. The scenario's mentioned in the table will be detailed further in this document

PT2: Disinfectants and algaecides not intended for direct application to humans or animals

PT2 surface disinfection by spraying:

The products INDAL PAA 2.5 (Meta-SPC 2) and INDAL PAA 5 (Meta-SPC 3) are applied by spraying on PT2 type surfaces. The product INDAL PAA 2.5 is applied with a manual sprayer on surfaces in pool resorts. The product INDAL PAA 5 is applied with a manual sprayer on surfaces in industrial and institutional areas, such as the cosmetic field, locker rooms in gyms and pool resorts, furniture, etc. All product emissions occur to the STP.

The disinfection of surfaces in industrial, public and health care areas was assessed in the peracetic acid assessment report. The in-use concentration for hydrogen peroxide for INDAL PAA 2.5 and INDAL PAA 5 is lower than the in-use concentration reported in the peracetic acid assessment report.

A risk assessment was still carried out with this product. The scenarios used to calculate the emissions to the STP are "Disinfection of surfaces in industrial premises (ESD PT2, 2011, table 2, p.12)", "Disinfection of surfaces in institutional areas (ESD PT2, 2011, table 4, p.16)".

PT2 disinfection of medical laboratory wastes:

The products INDAL PAA 3.5 (Meta-SPC 1) and INDAL PAA 5 (Meta-SPC 3) are used for the disinfection of liquid waste of medical biology laboratories. No specific scenario exists for this use, but we consider it is covered by the scenario's for "industrial premises" and "institutional areas".

PT2 disinfection by CIP:

The product INDAL PAA 2.5 (Meta-SPC 2) is used for the disinfection by CIP of pipework in pool resorts, while the products INDAL PAA 3.5 (Meta-SPC 1) and INDAL PAA 5 (Meta-SPC 3) are used for disinfection by CIP in the pharmaceutical and cosmetic industries. Product emissions take place to the STP. No emission scenario is available to cover these product uses. However, disinfection by CIP is also assessed for the product application in the food industry.

The volume of peracetic acid and hydrogen peroxide applied in an industrial food plant is higher than the amount that will be used for pipework disinfection in a pool resort, and is assumed to be similar to the volume that is applied in a pharmaceutical or cosmetic industrial plant. It is therefore considered that the emissions caused by PT2 pipework disinfection by CIP is covered by the emissions caused by PT4 CIP disinfection in the food industry, similarly to the approach used in the PAA CAR.

PT2 STP disinfection:

The product INDAL PAA 5 (Meta-SPC 3) is used on waste water treatment plants for the disinfection of small equipment by dipping, for the disinfection of pipework by CIP and for the disinfection of liquid waste at the treatment plant. The product INDAL PAA 15 (Meta-SPC 4) is used for the disinfection of liquid waste on waste water treatment plants. The products are expected to be used 4-5 times/year, for a maximum of a few days each time.

These different product uses are not completely covered by the peracetic acid and hydrogen peroxide assessment reports. The risk for the environment was therefore evaluated for the products of the Quaron PAA family. Calculations were carried out by considering an overall worst case, based on applicant information.

PT2 laundry disinfection:

The products INDAL PAA 5 (Meta-SPC 3) and INDAL PAA 15 (Meta-SPC 4) are applied in industrial washing machines (tumbler machines as well as washing streets) for the disinfection of laundry. The products are automatically injected in the washing machines during the washing cycle. All product emissions occur to the STP.

For this use, the same scenario as in the CAR ("Emission scenario for calculating the release of disinfectants used for doing biologically contaminated laundry from hospitals in washing streets (ESD PT2, 2001, table 3.9, p.29)") was used to calculate the emissions to the STP, as the emissions resulting from the use in washing streets is a worst case compared to tumbler machines.

PT2 disinfection of swimming pools:

The applicant requested the use of product INDAL PAA 2.5 (Meta SPC 2) for the disinfection of swimming pool waters (Use #1). Even when this use was not granted, the possible risks have been assessed.

The product can be applied for a shock disinfection, following for example the malfunction of a chlorine feeding pump. In this case, the pool water is not drained after product application, and swimmers can re-enter the pool after 24 to 48 hours. This means that no environmental emissions occur following this use.

The product INDAL PAA 2.5 can also be applied before the pool waters are emptied during a maintenance event, a sanitary draining, before wintering, and after wintering in the case of outdoor pools. Emissions are directed towards the STP.

Product application to pool waters was not considered in the peracetic acid assessment report. An environmental risk assessment for this use was therefore carried out with the product INDAL PAA 2.5. The disinfection before drainage is considered as a worst case scenario, as the emission of the pool waters to the STP will take place in a shorter time frame than the shock disinfection, leaving less time for the active substance to be degraded at the contact of organic matter present in the pool.

For disinfection of private pools, emissions to the environment were calculated following the emissions scenario described in the TAB p.15 (Dec. 2016). For the disinfection of public pools, emisisons to the environment were calculated according to the scenario described in the RIVM report 601450009 *Emission Scenario Document for Biocides* p.40 (2001).

PT3: Veterinary hygiene

PT3 disinfection of aquaculture systems:

The product INDAL PAA 5 (Meta-SPC 3) is used for the disinfection of aquaculture systems. The product can be applied by CIP for the disinfection of the system's pipework. It can also be applied to the tank water when the tanks are completely drained.

The disinfection of aquaculture systems was not considered in the active substances assessment reports. The risk for the environment was therefore evaluated for the product INDAL PAA 5 (Meta-SPC 3) by considering a worst case application, based on information from the applicant.

PT3 disinfection of animal housing (Use 3.12; Use 5.1):

The product INDAL PAA 5 (Meta-SPC 3) is used for disinfection of surfaces in animal housing. The product INDAL OXY MOUSS (Meta-SPC 5) is used for the disinfection of animal housing, for any type of animal husbandry. The products are applied onto the surfaces by manual spraying or with a foam generator.

PT3 disinfection of animal feeders and watering troughs (Use 3.13):

The product INDAL PAA 5 (Meta-SPC 3) is also used for the disinfection of feeders and water troughs in animal housing. The product can be applied by spraying, or by CIP in watering and feeding pipework.

This product use was not mentioned in the peracetic acid assessment report. However, it can be assumed that the volume of peracetic acid and hydrogen peroxide that is applied for the disinfection of feeders and water troughs only will be considerably lower than the volume used to disinfect complete animal housings. Consequently, this use is covered by the assessment of disinfection of animal housing. We don't consider a further exposure calculation needed.

PT3 disinfection of small equipment in dipping baths (Use 3.11):

The product INDAL PAA 5 (Meta-SPC 3) is used for the disinfection of small PT3 equipment in dipping baths. This product use was evaluated in the peracetic acid assessment report. However, the in-use concentrations of the product INDAL PAA 5 (Meta-SPC 3) are higher than those reported in the peracetic assessment report for the corresponding use.

In-use concentrations are higher for INDAL PAA 5 than for the reference product. The risk for the environment was therefore calculated for the product INDAL PAA 5. The calculation of product emissions was based on the scenario "Emission scenario for the disinfection of footwear and animal's feet (ESD PT3, 2011, table 4a, p.28)", adapted for the disinfection of small equipment in dipping baths similarly as in the peracetic acid CAR.

PT3 disinfection of milking claws (Use 3.8):

The product INDAL PAA 5 (Meta-SPC 3) is used for the disinfection of the outer surface of milking claws during milking events to avoid cross-contamination from an infected animal to a healthy animal. The product is applied by spraying onto the claws and is rinced afterwards.

The disinfection of milking claws was not covered by the active substance CAR, so the risk for the environment was evaluated for the product INDAL PAA 5. The calculation of emissions to the environment was based on information provided by the applicant.

Only emissions to the STP are considered relevant. Following the same reasoning as for the disinfection of animal housing, we consider risks resulting from emissions to manure/slurry as negligible.

PT3 disinfection of vehicles used for animal transport (Use 5.2):

The product INDAL OXY MOUSS (Meta-SPC 5) can be used for the disinfection of vehicles used for animal transport. The product is applied to the surfaces by spraying or by foaming. Product emissions occur to the STP.

The disinfection of vehicles used for animal transport is not a use that was considered in the peracetic acid assessment report. The risk for the environment was therefore assessed with

the product INDAL OXY MOUSS. The scenario used to calculate product emissions to the environment is the "Emission scenario for the disinfection of vehicles used for animal transport (ESD PT3, 2011, Table 2, p.21)".

PT4: Food and feed area

PT4 surface disinfection by spraying, foaming, dipping, CIP:

Products of the Quaron PAA family can be used for the disinfection of surfaces in the food and feed sector. Disinfection can take place by spraying (INDAL PAA 3.5 (Meta-SPC 1), INDAL PAA 5 (Meta-SPC 3), INDAL OXY MOUSS (Meta-SPC 5)), by CIP (INDAL PAA 3.5, INDAL PAA 5, INDAL PAA 15, INDAL TAP 5 (Meta-SPC 6)), and by dipping of equipment in dipping baths (INDAL PAA 3.5, INDAL PAA 5, INDAL PAA 15 (Meta-SPC 4)).

Disinfection of surfaces in the food and feed sector was considered in the peracetic acid assessment report. Emissions to the environment were calculated with scenario "Emission scenario for calculating the releases of disinfectants used in large scale catering kitchens, canteens, slaughterhouses and butcheries (ESD PT4, 2011, table 10, p.24)" for product applications by low pressure manual spraying, with scenario "Emission scenario: assessment of entire plants (ESD PT4, 2011, table 5, p.15)" for product applications by automated spraying, immersion and CIP, and with scenario "Emission scenario for the disinfection of milking parlour systems (ESD PT4, 2011, table 11, p.26)".

Risks for the Quaron PAA Family were calculated for the same 3 scenario's.

In-use concentrations of the active substances are higher for the products of the Quaron PAA family than the in-use concentrations of the reference products, but application rates are considerably lower.

PT5: Drinking water

PT5 disinfection of animal drinking water (Use 3.18):

The product INDAL PAA 5 (Meta-SPC 3) is used for the disinfection of livestock drinking water via automated dosing into the water stream. Emissions from this product use will occur when water is spilled by drinking animals. These emissions are directed to the manure/slurry.

No emission scenario is available to assess product emissions that occur from the disinfection of animal drinking water. However, following the same approach that was taken in the peracetic assessment report, it can be assumed that emissions occurring from this product use are covered by those occurring from animal housing disinfection. Indeed, the emission pathway is identical for both these uses and taking into account the rapid degradation of peracetic acid and hydrogen peroxide in contact with organic matter, the amount of these active substances in the manure/slurry or in the waste water, resulting from spilled water will be much lower than that resulting from housing disinfection. For this reason, it is considered not necessary to further assess this scenario.

The following table gives an overview of all the scenarios that will be assessed in this document.

General information

Assessed PT	PT 2, PT3, PT4, PT5
Assessed scenarios	PT2: Disinfectants and algaecides not intended for direct application to humans or animals • Scenario 1: Emission scenario for calculating the releases of disinfectants used in industrial areas (ESD PT2, 2011, table 2, p.12) • Scenario 2: Emission scenario for calculating the releases of disinfectants used for sanitary purposes based on average consumption (ESD PT2, 2011, table 4, p.16) • Scenario 3: Disinfection occurring on sewage treatment plants • Scenario 4: Emission scenario for calculating the release of disinfectants used for doing biologically contaminated laundry from hospitals in washing streets (ESD PT2, 2001, table 3.9, p.29) • Scenario 5: Private pools, peak emission: releases to wastewater due to the preparation for wintering (TAB, Dec. 2016) • Scenario 6: Discharge of swimming water by public swimming pools for the acute situation (RIVM, 2001) PT3: Veterinary hygiene • Scenario 7: Emissions occurring from the disinfection of PT3 aquaculture systems • Scenario 8: Emission scenario for the disinfection of footwear and animal's feet (ESD PT3, 2011, table 4a, p.28), adapted for the disinfection of equipment in dipping baths • Scenario 9: Disinfection of milking claws by spraying • Scenario 10: Emission scenario for the disinfection of vehicles used for animal transport (ESD PT3, 2011, Table 2, p.21) • Scenario 11: Emission scenario for calculating the release of disinfectants used for the disinfection of animal housings (ESD PT3, 2011, table 1, p.14) PT4: Food and feed area • Scenario 12: Emission scenario: assessment of entire plants (ESD PT4, 2011, table 5, p.15) • Scenario 13: Emission scenario for calculating the releases of disinfectants used in large scale catering kitchens, canteens, slaughterhouses and butcheries (ESD PT4, 2011, table 10, p.24) • Scenario 14: Emission scenario for the disinfection of milking parlour systems (ESD PT4, 2011, table 11, p.26) PT5: Drinking water -

ESD(s) used	• P. van der Poel, Emission Scenarios Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), 2001 • B. Raffael and E. van de Plassche, Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products, 2011 • B. Raffael and E. van de Plassche, Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, 2011 • B. Raffael and E. van de Plassche, Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas, 2011
Approach	Average consumption
Distribution in the environment	Estimated according to : • Guidance on the Biocidal Products Regulation, Vol. IV. Env., Part B Risk Assessment (active substances), April 2015. • Technical Agreements for Biocides, December 2016 • Assessment report: Peracetic acid, Product-types 1-6, November 2015 • Assessment report: Hydrogen peroxide, Product-types 1-6, March 2015.
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Product use
Remarks	/

For clarity purposes, all product uses are summarised in the table below, along with the scenarios that allow to cover their emissions to the environment and the maximal in-use concentrations from the approved uses. Uses marked with an asterisk have not been granted because of a negative efficacy evaluation, for those uses, the applicant's maximal requested in-use concentration was used.

Use	Use title	PT	Covered by scenario(s)	Max. in-use dilution (% v/v)	Max. PAA conc. (g/L)	Max. HP conc. (g/L)
Meta SPC 1 (INDAL PAA 3.5) 2.6% w/w PAA; 25.0% w/w HP; density = 1.113 g/mL						
1	Disinfection of wasted water, leachates and liquid laboratory waste in closed systems in medical biology laboratories	2	Scenario 1 Scenario 2	2.0	0.579	5.565
2	Disinfection of closed circulation circuits for cleaning in place in private and public pharmaceutical and cosmetic industries and institutions	2	Scenario 1 Scenario 2 Scenario 12	2.0	0.579	5.565
3	Surface disinfection by manual spraying in agri-food industry	4	Scenario 12 Scenario 13	2.0	0.579	5.565
4	Disinfection of closed circulation circuits for cleaning in place in agri food industry	4	Scenario 12 Scenario 14	2.0	0.579	5.565
5	Surfaces disinfection by manual dipping in agri-food industry	4	Scenario 12	2.0	0.579	5.565
6*	Disinfection by automated spraying in closed professional washing machines in agri food industry and institutions, and institutional kitchens	4	Scenario 12 Scenario 13	1.0	0.289	2.782
Meta SPC 2 – 2.0% w/w PAA; 35.5% w/w HP; density = 1.14 g/mL						
1*	Disinfection of water in private and public swimming pool, in balneotherapy basin and in private ponds	2	**Scenario 5** **Scenario 6**	2.0	**0.456**	**8.094**
2	Surfaces disinfection by manual spraying and soaking in private and public swimming pool, in balneotherapy basin and in private ponds	2	Scenario 2	2.0	0.456	8.094
3	Disinfection of closed circulation circuits for cleaning-in-place in private and public swimming pool, in balneotherapy basin, in private ponds and in sanitary hot water network	2	Scenario 2 Scenario 12	2.0	0.456	8.094
Meta SPC 3 – 5.3% w/w PAA; 25.5% w/w HP; density = 1.122 g/mL						
1	Surfaces disinfection by manual spraying in private, public, and industrial areas and in other areas for professional activities	2	**Scenario 1** **Scenario 2**	3.5	**2.081**	**10.014**

2	Disinfection of closed circulation circuits by cleaning-in-place in sewage treatment plant	2	**Scenario 3a/3b**	2.0	1.189	**5.722**
3	Disinfection of closed circulation circuits for cleaning in place in private and public pharmaceutical and cosmetic industries and institutions	2	**Scenario 1** **Scenario 2** Scenario 12	3.5	**2.081**	**10.014**
4	Surfaces disinfection by manual dipping in sewage treatment plants	2	Scenario 3a	3.5	**2.081**	**10.014**
5	Disinfection of waste water and leachates in private and public sewage treatment plant	2	**Scenario 3a/3b**	2.0	1.189	**5.722**
6	Disinfection of wasted water, leachates and liquid laboratory waste in closed systems in medical biology laboratories	2	Scenario 1 Scenario 2	2.0	1.189	5.722
7*	Laundry disinfection in professional laundry and washing machine	2	**Scenario 4**	0.8	**0.476**	**2.289**
8	Surface disinfection of milking parlour systems by manual spraying	3	**Scenario 9**	1.0	**0.595**	**2.861**
9	Surface disinfection by manual dipping in fish farming industry	3	**Scenario 7**	2.0	**1.189**	**5.722**
10	Disinfection of closed circulation circuits by cleaning-in-place in fish farming industry	3	**Scenario 7**	2.0	**1.189**	**5.722**
11	Surfaces disinfection by manual dipping in livestock housing	3	**Scenario 8**	2.0	**1.189**	**5.722**
12	Surfaces disinfection by manual spraying in livestock housing	3	**Scenario 11**	2.0	**1.189**	**5.722**
13	Disinfection of closed circulation circuits (drinking water and feed) by cleaning-in-place in livestock housing	3	**Scenario 11**	2.0	**1.189**	**5.722**
14	Surfaces disinfection by manual spraying in agri-food industry	4	**Scenario 12** **Scenario 13**	3.5	2.081	**10.014**
15	Disinfection of closed circulation circuits by cleaning-in-place in agri-food industry	4	**Scenario 12** **Scenario 14**	3.5	2.081	**10.014**
16	Surfaces disinfection by manual dipping in agri-food industry	4	**Scenario 12**	3.5	2.081	**10.014**

17*	Disinfection by automated spraying in closed professional washing machines in agri food industry and institutions, and institutional kitchens	4	Scenario 12 Scenario 13	1.5	0.892	4.29
18*	Drinking water disinfection for animals in farms	5	Scenario 11	0.07	0.0416	0.20
Meta SPC 4 (INDAL PAA 15) – 15.8% w/w PAA; 25.0% w/w HP; density = 1.154 g/mL						
1	Disinfection of waste water and leachates in private and public sewage treatment plant	2	**Scenario 3a/3b**	0.9	**1.641**	2.597
2	Laundry disinfection in professional laundry and washing machine	2	Scenario 4	0.2	0.365	0.577
3	Disinfection of closed circulation circuits by cleaning-in-place in agri-food industry	4	Scenario 12 Scenario 14	0.8	1.459	2.308
4	Surfaces disinfection by manual dipping	4	**Scenario 12**	1.5	**2.735**	4.328
Meta SPC 5 (INDAL OXY MOUSS) – 1.2% w/w PAA; 13.0% w/w HP; density = 1.064 g/mL						
1	Surfaces disinfection by manual foam spraying in livestock industry	3	**Scenario 10** Scenario 11	5.0	**0.638**	**6.916**
2	Surfaces disinfection by manual foam spraying in agri-food industry	4	Scenario 12 Scenario 13	4.0	0.511	5.533
Meta SPC 6 (INDAL TAP 5) – 5.0% w/w PAA; 21.0% w/w HP; density = 1.206 g/mL						
1	Disinfection of closed circulation circuits by cleaning-in-place in agri-food industry	4	Scenario 12 Scenario 14	2.0	1.206	5.065

Values in bold represent the worst-case in-use concentrations for a specific scenario. When relevant, the application rate (mL/m²) of the product was also considered for identification of the worst-case.

(II) Emission estimation

Fate and distribution in exposed environmental compartments

Depending on the scenario, the primary receiving compartment will be the STP via waste water or the soil via application of either manure or STP sludge. After entering the environment, the active substances will then distribute to the different environmental compartments. The fate and distribution of peracetic acid and hydrogen peroxide in the exposed environmental compartments were calculated according to the Guidance on the Biocidal Products Regulation, Vol. IV. Env., Part B Risk Assessment (active substances), October 2017.

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	+	+	-	-	++	+	+	+	
Scenario 2	+	+	-	-	++	+	+	+	
Scenario 3	++	++	-	-	-	-	-	-	
Scenario 4	+	+	-	-	++	+	+	+	
Scenario 5	+	+	-	-	++	+	+	+	
Scenario 6	+	+	-	-	++	+	+	+	
Scenario 7	+	+	-	-	++	+	+	+	
Scenario 8	+	+	-	-	++	+	++	+	
Scenario 9	+	+	-	-	++	+	+	+	
Scenario 10	+	+	-	-	++	++	+	+	
Scenario 11	+	+	-	-	++	+	+	+	
Scenario 12	+	+	-	-	++	+	+	+	
Scenario 13	+	+	-	-	++	+	+	+	
Scenario 14	+	+	-	-	++	+	+	+	

++: direct exposure +: indirect exposure -: no exposure

Even while air is exposed directly or indirectly in most scenarios, the exposure assessment in the CAR showed that the emission to air is negligible for all pathways. Consequently, air is not considered an environmental compartment of concern, and not assessed quantitatively.

As discussed in the ENV WG, no groundwater assessment is needed for the rapidly reacting substances PAA and hydrogen peroxide.

Environmental risks to the soil compartment are considered negligible as well: due to the high reactivity of PAA and hydrogen peroxide, and the high organic matter content of both STP sludge and liquid manure, PAA and HP are not expected to persist in relevant concentrations until the sludge or the manure are applied to agricultural soil. A further quantitative assessment is not deemed necessary.

Input parameters for calculating the fate and distribution of PAA and HP in the environment were selected from the LoEP for the respective substance. They are detailed in the following tables

Input parameters for calculating the fate and distribution in the environment				
Input	**PAA**	**HP**	**Unit**	**Remarks**
Molecular weight	76.05	34.01	g/mol	
Melting point	0	-0.43	°C	
Boiling point	105	150.2	°C	
Vapour pressure	1410	214	Pa	At 20°C
Water solubility	Completely miscible	Completely miscible	mg/l	
Log Octanol/water partition coefficient	-0.6	-1.57	Log 10	At pH 7
Organic carbon/water partition coefficient (Koc)	1.46	1.598	l/kg	
Henry's Law Constant	0.217 (25°C)	7.5×10^{-4} (20°C)	Pa/m³/mol	
Biodegradability	Ready biodegradable	Ready biodegradable		
DT_{50} for biodegradation in surface water	-	5	days	
DT_{50} for hydrolysis in surface water	89.7	-	Hour	At 12ºC
DT_{50} for degradation in soil	12	12	Hour	
DT_{50} for degradation in air	95.26	24	Hour	
DT_{50} for STP	<3	<2	Min	At 20°C
k for STP	13.86	20.79	h^{-1}	At 20°C
DT_{50} for biodegradation in effluent stream	<< 9.5	169	Min	At 12°C

k for biodegradation in effluent stream	4.38	0.25	h^{-1}	At 12°C
DT_{50} for biodegradation in sewer	<< 9.5	11.4	Min	At 12°C
k for biodegradation in sewer	4.38	3.65	Min	At 12°C
DT_{50} for biodegradation in liquid manure	<< 9.5	11.4	Min	At 12°C
k for biodegradation in liquid manure	4.38	3.65	Min	At 12°C

Calculated fate and distribution in the STP *(calculated with Simple Treat 4.0)*		
Compartment	**Percentage PAA [%]**	**Percentage HP [%]**
Air	0.04657	0.0001568
Water	0.9891	0.6631
Sludge	0.0132	0.01445
Degraded in STP	98.95	99.32

Scenario 1: Emission scenario for calculating the release of disinfectants used in industrial areas (ESD PT2, 2011, table 2, p.12)

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Scenario 1: Emission scenario for calculating the release of disinfectants used in industrial areas (ESD PT2, 2011, table 2, p.12)				
Application rate of biocidal products	*Vform*	0.02	l/m²	The product INDAL PAA 5 is applied at a rate of 20 ml/m².
Concentration of active substance in the product	Cform	PAA: 2.081 HP: 10.014	g/l	Maximum application rate for INDAL PAA 5
Surface area to be disinfected	AREAsurface	1000	m²	Default value (ESD PT2, 2011)
Number of applications per day	Nappl	1	d^{-1}	Default value (ESD PT2, 2011)
Fraction of substance disintegrated during or after application (before release to the sewer system)	Fdis	0	-	Default value (ESD PT2, 2011)
Fraction released to wastewater	Fwater	1	-	Default value (ESD PT2, 2011)

Calculations for Scenario 1

Local emissions to waste water ($Elocal_{ww}$):

$Elocal_{ww}$ = Vform * Cform * AREAsurface * Nappl * (1 – Fdis) * Fwater / 1000
= 0.0416 kg/d PAA
= 0.200 kg/d HP

Active substance degradation in the sewer system:

Following the approach taken in the peracetic acid CAR, it is considered that the active substances peracetic acid and hydrogen peroxide will undergo rapid degradation in the sewer system before reaching and entering the STP. This degradation in the sewer system was therefore taken into account in the emissions calculations, following the same method that was applied during the active substance evaluation.

Following a residence time of 1 hour in the sewer system, the amounts of active substances that are actually emitted to the STP are calculated according to the following equation:

$M_{t1} = M_{t0} * \exp^{(- k * t1)}$

where M_{t1} = total amount of substances present at t1 (kg)
M_{t0} = total amount of substance at t0 (kg)
k = rate constant (ln2 / DT_{50})
t1 = time (h) = 1 hour residence time in the sewer system

The degradation rates in the sewer systems applied to the equation are the half-lives that were measured for each substance in the STP effluent. This is considered a worst-case approach as the organic load causing peracetic acid and hydrogen peroxide degradation is higher in raw sewage than in the effluent stream. As discussed in the ENV WG, the degradation half-life values for PAA and HP in the sewer system used were 9.5 min and 11.4 min respectively, resulting in a rate constant k = 4.38 h^{-1} for peracetic acid and k = 3.65 h^{-1} for hydrogen peroxide.

Considering the degradation of the active substances in the sewer system, the local emission to waste water is refined in the following manner:

M_{t1} = $M_{t0} * \exp^{(- k * t1)}$
= $0.0416 * \exp^{(- 4.38 * 1)}$ = $0.200 * \exp^{(- 3.65 * 1)}$
= 5.22×10^{-4} kg/d PAA = 5.21×10^{-3} kg/d HP

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	PAA: 5.22×10^{-4} kg/d HP: 5.21×10^{-3} kg/d	These values take into account a degradation of the active substances during their stay in the sewer system.

Scenario 2: Emission scenario for calculating the release of disinfectants used for sanitary purposes based on average consumption (ESD PT2, 2011, table 4, p.16)

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Scenario 2: Emission scenario for calculating the release of disinfectants used for sanitary purposes based on average consumption (ESD PT2, 2011, table 4, p.16)				
Number of inhabitants feeding one STP	*Nlocal*	10000	cap	Default value (ESD PT2, 2011)
Fraction released to waste water	*Fwater*	1	-	Default value (ESD PT2, 2011)
Concentration of active substance in biocidal product	*Cform*	PAA: 2.081 HP: 10.014	g/l	Maximum application rate for INDAL PAA 5
Comsumption per capita: - general purpose (tiles, floors, sinks) - lavatory	*Vform*	 0.005 0.002	l/cap/d	Default value (ESD PT2, 2011). Both values were summed to consider a worst case value of 0.007 l/cap.d.
Fraction of substance disintegrated during or after application (before release to the sewer system)	*Fdis*	0	-	Default value (ESD PT2, 2011)
Penetration factor of disinfectant	*Fpenetr*	0.5	-	Default value (ESD PT2, 2011)

Calculations for Scenario 2

Local emissions to waste water ($Elocal_{ww}$):

$Elocal_{ww}$ = Nlocal * Vform * Cform * Fpenetr * (1 – Fdis) * Fwater / 1000
= 0.0728 kg/d PAA
= 0.350 kg/d HP

After active substance degradation in the sewer system (as detailed for scenario 1), this results in the following emissions:

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	PAA: 9.14×10^{-4} kg/d HP: 9.11×10^{-3} kg/d	These values take into account a degradation of the active substances during their stay in the sewer system.

Scenario 3: Emission scenario for calculating the release of disinfectants used for STP disinfection

Scenario 3a:

No scenario is available to estimate the active substances emissions caused by the product uses in the STP. Calculations were therefore carried out by considering an overall worst case situation.

Based on applicant information, the disinfection for a volume of 20 m³ (20 000 l) in a day is considered to cover product use for disinfection of liquid waste, small equipment by dipping and pipework by CIP on a waste water treatment plant.

Worst-case, the disinfected water is considered to be released directly into the effluent. The total volume of treated water in the STP is considered to be 2000 m³/day, corresponding to an additional dilution of the treated water with a factor of 100.

Scenario 3b:

According to the use descriptions, the products are used to disinfect waste water itself as well, in private sewage treatment plants. The volumes treated are estimated at 2000 m³ (2×10^6 l) per day.

The worst case in-use concentration of each active substance was selected, corresponding to 1.641 g/l PAA and 5.722 g/l HP. Worst-case, the product is considered to be added in these concentrations to the effluent.

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Scenario 3: Disinfection of waste water effluent				
Application rate of the active substance	*C(0)*	3a: PAA: 2081 HP: 10014 3b: PAA: 1641 HP: 5722	mg/l	Application rate for Indal 5 Maximum application rate for Indal PAA 15 for PAA and INDAL PAA 5 for HP.

Total retention time of the disinfected effluent in the STP	*t*	0	minutes	
Half-life of the active substance in effluent at 12°C	DT_{50}	PAA: 9.5 HP: 169	Minutes	
Ditlution factor of disinfected effluent in surface water	*DIL*	3a: 1000 3b: 10	[-]	Additional dilution factor of 100 for 3a.

Calculations for Scenario 3a

Local concentrations in surface waterdue to disinfection of liquid waste, small equipment and pipework:

$Clocal_{ww}$ = 2081 / 1000 = 10014 / 1000
= 2.081 mg/l PAA = 10.014 mg/l kg/d HP

Resulting local emission to relevant environmental compartments		
Compartment	**Local concentration ($Clocal_{compartment}$) [mg/l]**	**Remarks**
Surface water	PAA: 2.081 mg/l HP: 10.014 mg/l	-

Calculations for Scenario 3b

$Clocal_{ww}$ = 1641 / 10 = 5722 / 10
= 164.1 mg/l kg/d PAA = 572.2 mg/l HP

Resulting local emission to relevant environmental compartments		
Compartment	**Local concentration ($Clocal_{compartment}$) [mg/l]**	**Remarks**
Surface water	PAA: 164.1 mg/l HP: 572.2 mg/l	-

Scenario 4: Emission scenario for calculating the release of disinfectants used for doing biologically contaminated laundry from hospitals in washing streets (ESD PT2, 2001, table 3.9, p.29)

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Scenario 4: Emission scenario for calculating the release of disinfectants used for doing biologically contaminated laundry from hospitals in washing streets (ESD PT2, 2001, table 3.9, p.29)				
Number of washing tubes	Nm	3	-	Default value (ESD PT2, 2001)
Capacity of washing tube (laundry)	Cap	8000	kg/d	Default value (ESD PT2, 2001)
Amount of disinfectant for laundry: - INDAL PAA 5 - INDAL PAA 15	Vproduct	 0.032 0.008	l/kg	The product INDAL PAA 5 is applied at a dose of 8 ml product/l water. The product INDAL PAA 15 is applied at a dose of 2 ml product/l water. 4 litres of water are needed for the disinfection of 1 kg of dry laundry.
Concentration of active substance in disinfectant - INDAL PAA 5 - INDAL PAA 15	Cdisinf	 PAA: 0.0594 HP: 0.286 PAA: 0.182 HP: 0.288	kg/l	
Concentration reduction in washing process	Fred	PAA: 0.9967 HP: 0.9906	-	Based on data generated in the peracetic acid assessment report (Van de Velde, 2005), a reduction of 0.9967 for PAA and 0.9906 for HP are applied to take into account a.s. degradation during the washing process.

Calculations for Scenario 4

Local emissions to waste water ($Elocal_{ww}$):

For INDAL PAA 5:

$Elocal_{ww}$ = Nm * Cap * Vproduct * Cdisinf * (1 – Fred)

= 0.151 kg/d PAA

= 2.065 kg/d HP

For INDAL PAA 15:

$Elocal_{ww}$ = 0.116 kg/d PAA

= 0.521 kg/d HP

The worst-case for PAA is 0.151 kg/d.

The worst-case for HP is 2.07 kg/d.

Active substance degradation in the sewer system (as detailed for scenario 1) results in:

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	PAA: 0.00189 kg/d HP: 0.0537 kg/d	These values take into account a degradation of the active substances during their stay in the sewer system.

Scenario 5: Private pools – Peak emission: releases to wastewater due to the preparation for wintering (TAB, December 2016)

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Scenario 5: Private pools – Peak emission: releases to wastewater due to the preparation for wintering (TAB, December 2016)				
Private pool volume	*Vpool*	48	m^3	Default value (TAB, dec 2016)
Number of private pools with releases by day: Southern country Northern country	*Npool*	 10 2	d^{-1}	Default value (TAB, dec 2016). The worst-case value of 10 pool releases was selected.
Fraction acutely released to STP	*Facute*	0.33	d^{-1}	Default value (TAB, dec 2016)
Efficient dose rate of active substance in the pool water	*Qappl*	PAA: 0.456 HP: 8.094	g/l	Maximum application rate of INDAL PAA 2.5
Fraction of active substance released to wastewater	*Fwater*	1	-	Default value (TAB, dec 2016)
Market share	*Fmarket*	0.5	-	Default value (TAB, dec 2016)

Calculations for Scenario 5

Number of treated private pools with releases:

Npool_acute = Npool * Fmarket
= 10 * 0.5
= 5

Local emissions to waste water ($Elocal_{ww}$):

$Elocal_{ww}$ = Vpool * Npool_acute * Fwater * Facute * Qappl
= 48 * 5 * 1 * 0.33 * 0.1368 = 48 * 5 * 1 * 0.33 * 2.43
= 36.12 kg/d PAA = 641 kg/d HP

After active substance degradation in the sewer system (as detailed for scenario 1):

Considering the degradation of the active substances in the sewer system, the local emission to waste water is refined in the following manner:

$M_{t1} = M_{t0} * \exp^{(-k * t1)}$
$= 36.12 * \exp^{(-4.38 * 1)} = 641 * \exp^{(-3.65 * 1)}$
= 0.453 kg/d PAA = 16.7 kg/d HP

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	PAA: 0.453 kg/d HP: 16.7 kg/d	These values take into account a degradation of the active substances during their stay in the sewer system.

Scenario 6: Discharge of swimming water by public swimming pools for the acute situation (RIVM, 2001 – TAB_2.0 Aug. 2018)

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Scenario 6: Discharge of swimming water by public swimming pools for the acute situation (				
Water surface	$AREA_{swim}$	440	m^2	D
Average depth of water	$DEPTH_{swim}$	1.8	m	D
Fraction released to STP	F_{rel}	1	-	D
Concentration in swimming water	C_{prod}	PAA: 0.456 HP: 8.094	g/l	Maximum application rate of INDAL PAA 2.5
Emission period	*Ep*	3	D	D

Calculations for Scenario 6

Local emissions to waste water ($Elocal_{ww}$):

$Elocal_{ww}$ = $(AREA_{swim} * DEPTH_{swim} * C_{prod} * F_{rel})/Ep$

= 120 kg/d PAA = 2136 kg/d HP

Active substance degradation in the sewer system (as detailed for scenario 1):

Considering the degradation of the active substances in the sewer system, the local emission to waste water is refined in the following manner:

$M_{t1} = M_{t0} * \exp^{(-k * t1)}$

$= 36.17 * e^{(-4.38 * 1)}$ $= 642 * e^{(-0.25 * 1)}$

= 1.51 kg/d PAA = 55.5 kg/d

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	PAA: 1.51 kg/d HP: 55.5 kg/d	These values take into account a degradation of the active substances during their stay in the sewer system.

Scenario 7: Emissions occurring from the disinfection of PT3 aquaculture systems

The product INDAL PAA 5 is used for the disinfection of aquaculture systems. The product can be applied by CIP for the disinfection of the system's pipework. It can also be applied to the tank water when the tanks are completely drained. Application of the product INDAL PAA 5 takes place at a maximum concentration of 1.123 g/l PAA and 5.727 g/l HP.

No emission scenario is available for the use of disinfectants in aquaculture systems. Emissions to the environment were therefore calculated based on information provided by the applicant.

As a worst-case situation, it is considered that 10 basins of 20 m³ (20 000 l) can be drained simultaneously. This volume will also include the use of the disinfectant by CIP in the system's pipework. Given that the requested use is limited to CIP and manual dipping, this approach is very worst-case. Based on this information, a worst-case daily emission can be calculated for each active substance.

Calculations for Scenario 7

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Scenario 7: Discharge of disinfected aquaculture tanks				
Volume of aquaculture tank	V_{tank}	20	m^3	D
Number of aquaculture tank	N_{tank}	10	m	D
Concentration	C_{prod}	PAA: 1.189 HP: 5.722	g/l	Maximum in-use concentration of INDAL PAA 5

Local emissions to waste water ($Elocal_{ww}$):

$Elocal_{ww}$ = Vtank * Ntank * Cprod
= 20 * 10 * 1.19 = 20 * 10 * 5.727
= 237.8 kg/d PAA = 1144 kg/d HP

Active substance degradation in the sewer system (as detailed for scenario 1):

Considering the degradation of the active substances in the sewer system, the local emission to waste water is refined in the following manner:

$M_{t1} = M_{t0} * \exp^{(-k * t1)}$
$= 237.8 * e^{(-4.38 * 1)}$ = 2.99 kg/d PAA
$= 1144 * e^{(-3.65 * 1)}$ = 29.7 kg/d HP

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	PAA: 2.99 kg/d HP: 29.7 kg/d	These values take into account a degradation of the active substances during their stay in the sewer system.

Scenario 8: Emission scenario for the disinfection of footwear and animal's feet (ESD PT3, 2011, table 4a, p.28) – adapted for the disinfection of PT3 equipment in dipping baths

The scenario "Emission scenario for the disinfection of footwear and animal's feet (ESD PT3, 2011, table 4a, p.28)" was adapted to represent the specific product use of the PAA biocidal

products family. The product INDAL PAA 5 is used for the disinfection of PT3 equipment in dipping baths.

Based on the indications given in the Technical Agreements for Biocides (Dec. 2016), a reservoir volume of 100 l is considered for the disinfection of small items of equipment in livestock farming environment.

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Scenario 8: Emission scenario for the disinfection of footwear and animal's feet (ESD PT3, 2011, table 4a, p.28) – adapted for the disinfection of PT3 equipment in dipping baths				
Content of the active ingredient at the in-use concentration (diluted solution)	Fbioc	PAA: 1.189 HP: 5.722	g/l	Maximum in-use concentration for INDAL PAA 5
Volume of the reservoir (tub)	*Vreserv*	100	l	A realistic worst-case of 100 l is considered for the disinfection of small items of equipment in livestock farming environment (TAB, dec. 2016)
Fraction of the active ingredient released to waste water	Fstp	1	-	Default value (ESD PT3, 2011)
Fraction of the active ingredients released to slurry/manure	$F_{slurry/manure}$	1		Default value (ESD PT3, 2011)

Calculations for Scenario 8

Local emissions to slurry/manure are a possible pathway for this scenario. However, due to the high reactivity of PAA and HP with organic matter, no significant concentrations are expected for slurry or manure applied on agricultural lanc. This pathway will therefore not be considered quantitatively.

Local emissions to waste water ($Elocal_{ww}$):

$Elocal_{ww} = 10^{-3} * Vreserv * Fbioc * Fstp$

$= 10^{-3} * 100 * 1.189 * 1 = 10^{-3} * 100 * 5.722 * 1$

$= 0.1189$ kg/d PAA $= 0.5722$ kg/d HP

Active substance degradation in the sewer system (as detailed for scenario 1):

Considering the degradation of the active substances in the sewer system, the local emission to waste water is refined in the following manner:

M_{t1} = M_{t0} * exp $^{(- k * t1)}$

= 0.1189 * exp $^{(- 4.38 * 1)}$ = 0.5722 * exp $^{(- 3.65 * 1)}$

= 1.49 x10^{-3} kg/d PAA = 0.0149 kg/d HP

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	PAA: 1.49 x 10^{-3} kg/d HP: 0.0149 kg/d	These values take into account a degradation of the active substances during their stay in the sewer system.

Scenario 9: Emission scenario for the disinfection of milking claws by spraying (based on information from the applicant)

The emissions resulting from milking claws disinfection were calculated based on information from the applicant. The product INDAL PAA 5 is applied to milking claws in order to avoid cross-contamination from an infected animal to a healthy animal. The product is applied by spraying onto the claws and is rinced afterwards.

It is considered that 10% of a default sized herd (100 milking cows) will present infections requirering a subsequent disinfection of the milking claws during a milking event. However, from a worst-case approach, it is considered that all milking claws used will be treated. Considering a total surface of the milking claws of 750 cm², it is therefore possible to calculate a total amount of product applied in a day.

As described in the ESD for PT4 (2011), "the tendency [in milking parlours] is definitely to separate the waste water stream coming from the milking parlours from the manure storage system since a certain amount of water is used for cleaning, disinfection and subsequent flushing of the milking equipment which leads to a high water contribution to the manure storage tank. Based on this information, it is assumed that the waste water from the milking parlour system is mainly released to the sewer system". Following this approach, the emissions resulting from the disinfection of milking claws are assumed to be mostly directed towards the STP. Emission to manure can still be considered as a possible (albeit less likely) pathway. However, due to the high reactivity of PAA and HP with organic matter, no significant concentrations are expected to remain in manure that is applied on agricultural land. Therefore, the pathway to slurry/manure is not further considered quantitatively.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 9: Emission scenario for the disinfection of milking claws by spraying (based on information from the applicant)			

Content of the active ingredient at the in-use concentration (diluted solution)	Fbioc	PAA: 0.595 HP: 2.861	g/l	Maximum in-use concentration for INDAL PAA 5
Application rate of the biocide	*Appl*	0.020	l/m²	The product INDAL PAA 5 is applied at a rate of 20 ml/m².
Treated surface	*Surf*	0.0750	m²	The surface of the milking claw to be disinfected is calculated as the following : 4 claws of 1.5 cm radius and 20 cm height. This amounts to a total surface of 4 x 2 x 1.5 x 3.14 x 20 = 750 cm².
Number of disinfection events taking place in a day	*Napp*	2	d^{-1}	The product is only applied post-milking, and is meant for application after manual milking.
Number of milk producing animals per day	N_{mp_animal}	82	-	Based on a herd of 100 cows, corrected for a lactation period of 300 days, cfr. TAB ENV63.
Fraction of the active ingredient released	Fstp Fslurry/manure	1 1	-	Based on the indications in the ESD for PT4 (2011), it is assumed that emissions occurring from a milking parlour are released to the STP.

Calculations for Scenario 9

Local emissions to waste water ($Elocal_{ww}$):

$Elocal_{ww} = 10^{-3} * Fbioc * Appl * Surf * Napp * N_{mp\_animal} * Fstp$

$= 10^{-3} * 0.595 * 0.02 * 0.075 * 2*82 * 1$

$= 1.46 \times 10^{-4}$ kg/d PAA

$= 10^{-3} * 0.861 * 0.02 * 0.075 * 2*82 * 1$

$= 7.04 \times 10^{-4}$ kg/d HP

Active substance degradation in the sewer system (as detailed in scenario 1):

Considering the degradation of the active substances in the sewer system, the local emission to waste water is refined in the following manner:

$M_{t1} = M_{t0} * \exp^{(-k * t1)}$

$= 1.469 \times 10^{-4} * \exp^{(-4.38 * 1)}$ $= 7.04 \times 10^{-4} * \exp^{(-3.65 * 1)}$

$= 1.84 \times 10^{-6}$ kg/d PAA $= 1.83 \times 10^{-5}$ kg/d HP

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	PAA: 2.24 x 10^{-7} kg/d HP: 2.23 x 10^{-6} kg/d	These values take into account a degradation of the active substances during their stay in the sewer system.

Scenario 10: Emission scenario for the disinfection of vehicles used for animal transport (ESD PT3, 2011, table 2, p.21)

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Scenario 10: Emission scenario for the disinfection of vehicles used for animal transport (ESD PT3, 2011, table 2, p.21)				
Mammal transports: - area of trucks Poultry transports: - area of trucks - area of containers	 *AREAmam* *AREApoul* *AREAcont*	 4546 1120 3355	m²	Default values (ESD PT3, 2011). The worst-case value of 4546 m² is selected.
Content of active ingredient in formulation (product)	*Fbioc*	PAA: 12.8 HP: 138	g/l	The product INDAL OXY MOUSS has an a.s. content of 12.8 g/l PAA and 138 g/l HP.
Amount of (undiluted) product prescribed to be used per m²	*Vprod*	0.05	l/m²	The product INDAL OXY MOUSS is applied at a rate of 50 ml/m².
Dilution factor (for preparation of the working solution from the formulation (product))	*Fdil*	0.05	-	The product INDAL OXY MOUSS is diluted at maximum 5% before application.
Fraction released to air	*Fair*	0.1	-	Default value (ESD PT3, 2011)
Fraction released to waste water	*Fstp*	1 – *Fair*	-	

Calculations for Scenario 10

Amount of active ingredient to be used for one application:

Qai-prescr = 10^{-3} * Fbioc * Vprod * Fdil * AREAmam
= 10^{-3} * 12.8 * 0.05 * 0.05 * 4546
= 0.1454 kg PAA

$= 10^{-3} * 138.3 * 0.05 * 0.05 * 4546$
$= 1.571$ kg HP

Local emissions to waste water ($Elocal_{ww}$)

$Elocal_{ww}$ = Qai-prescr * Fstp
= 0.1454 * 0.9 = 1.571 * 0.9
= 0.131 kg/d PAA = 1.415 kg/d HP

Active substance degradation in the sewer system (as detailed in scenario 1):

Considering the degradation of the active substances in the sewer system, the local emission to waste water is refined in the following manner:

$M_{t1} = M_{t0} * \exp^{(-k * t1)}$
$= 0.1308 * \exp^{(-4.38 * 1)}$ $= 1.413 * \exp^{(-3.65 * 1)}$
= 0.00164 kg/d PAA = 0.0368 kg/d HP

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	PAA: 0.00164 kg/d HP: 0.0368 kg/d	These values take into account a degradation of the active substances during their stay in the sewer system.

Scenario 11: Emission scenario calculating the release of disinfectants used for disinfection of animal housings (ESD PT3, 2011, table 1a, p.14)

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Scenario 11: Emission scenario calculating the release of disinfectants used for disinfection of animal housings (ESD PT3, 2011, table 1a, p.14)				
Area of the housing for application	*AREA*	*	m^2	* The area of application varies according to the animal type, and is detailed in the following table. Following the indications in the TAB (dec. 2016), all surfaces in the respective animal housing, provided in Table 8 of the ESD for PT3 (p. 51), are considered.

Content of the active ingredient	Fbioc	PAA: 1.189 HP: 5.722	g/l	The product INDAL PAA 5 is applied at a maximum a.s. concentration of 1.189 g/l PAA and 5.722 g/l HP.
Amount of product prescribed to be used per m²	Vprod	0.2	l/m²	The product INDAL PAA 5 is applied at a rate of up to 200 ml/m².
Fraction of the active ingredient released	Fstp	*	-	* The fraction of the active ingredient released to STP and slurry/manure varies according to the animal type, and is detailed in the following table.

Emissions were calculated for each of the 18 animal types referenced in the ESD for PT3 (2011). Input values that are specific to each housing type are listed in the following table.

Input parameters applied according to the animal housing type		
Animal type	AREA [m²]	Fstp [-]
1. Dairy cattle	3230	-
2. Beef cattle	1750	-
3. Veal calves	650	-
4. Sows, individual	1930	-
5. Sows, group	2200	-
6. Fattening pigs	2020	-
7. Laying hens, battery, no treatment	4410	-
8. Laying hens, battery, belt trying	4410	0.2
9. Laying hens, battery, deep pit	3810	-
10. Laying hens, battery, compact	3510	-
11. Laying hens, free range, litter floor	4610	0.2
12. Broilers, litter floor	2730	0.2
13. Laying hens, grating floor	4992	-
14. Parent broilers, grating floor	1290	-
15. Parent broilers in rearing, grating floor	1640	-
16. Turkey, litter floor	8040	0.2
17. Ducks, litter floor	4880	0.2
18. Geese, litter floor	6060	0.2

As only emissions to waste water are considered, only housing types 8, 11, 12, 16, 17 and 18 are relevant. Type 16 (Turkey, litter floor) represents the worst case.

Calculations for Scenario 11

Amount of active ingredient to be released to STP for 1 application:

$Elocal_{ww}$ = 10^{-3} * Fbioc * Vprod * AREA * F_{STP}
= 10^{-3} * 1.189 * 0.2 * 8040 * 0.2
= 0.382 kg/d PAA

= 10^{-3} * 5.722 * 0.2 * 8040 * 0.2
= 1.84 kg/d HP

Active substance degradation in the sewer system (as detailed for scenario 1):

Considering the degradation of the active substances in the sewer system, the local emission to waste water is refined in the following manner:

M_{t1} = M_{t0} * exp $^{(- k * t1)}$
= 0.382 * exp $^{(- 4.38 * 1)}$ = 1.84 * exp $^{(- 3.65 * 1)}$
= 0.00480 kg/d PAA = 0.0478 kg/d HP

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	PAA: 0.00480 kg/d HP: 0.0478 kg/d	The worst case values of the 18 animal types were selected as input values. These values take into account a degradation of the active substances during their stay in the sewer system.

Scenario 12: Emission scenario: assessment of entire plants in drink and beverage industry (ESD PT4, 2011, table 5, p.15)

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 12: Emission scenario: assessment of entire plants (ESD PT4, 2011, table 5, p.15)			

Amount of biocidal active substance used per year in the local plant	*Qai*	PAA: 407 HP: 4409	kg/y	Peracetic acid: The default value for PAA is 407 kg PAA/y (ESD PT4, 2011). Hydrogen peroxide: Based on a value of 407 kg PAA/y, the corresponding worst-case amount of hydrogen peroxide used per year in the local plant is 4409 kg HP/y, which corresponds to the product INDAL OXY MOUSS (the product with the highest ratio HP to PAA).
Number of emission days per year	*Temission*	220	d/y	Based on information by applicant
Fraction released to waste water	*Fwater*	1	-	Default value (ESD PT4, 2011)
Fraction of substance eliminated due to on-site pre-treatment of the plant waste water	*Felim*	0	-	Default value (ESD PT4, 2011)
Fraction of substance disintegrated during or after application (before release to the sewer system)	*Fdis*	0	-	Default value (ESD PT4, 2011)

Calculations for Scenario 12

Local release to waste water ($Elocal_{ww}$):

$Elocal_{ww}$ = (Qai / Temission) * Fwater * (1 – Fdis) * (1 – Felim)
= 1.85 kg/d = 20.04 kg/d HP

Active substance degradation in the sewer system (as detailed for scenario 1):

Considering the degradation of the active substances in the sewer system, the local emission to waste water is refined in the following manner:

$M_{t1} = M_{t0} * \exp^{(- k * t1)}$
$= 1.85 * \exp^{(- 4.38 * 1)}$ $= 20.04 * \exp^{(- 3.65 * 1)}$
= 0.0232 kg/d PAA = 0.521 kg/d HP

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	PAA: 0.0232 kg/d HP: 0.521 kg/d	These values take into account a degradation of the active substances during their stay in the sewer system.

Scenario 13: Emission scenario for calculating the releases of disinfectants used in large scale catering kitchens, canteens, slaughterhouses and butcheries (ESD PT4, 2011, table 10, p.24)

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Scenario 13: Emission scenario for calculating the releases of disinfectants used in large scale catering kitchens, canteens, slaughterhouses and butcheries (ESD PT4, 2011, table 10, p.24)				
Application rate of the active substance	*Qai*	PAA: 0.0416 HP: 0.277	g/m²	The worst-case product was selected for each a.s. The product INDAL PAA 3.5 is applied at a maximum a.s. concentration of 0.579 g/l PAA and 5.57 g/l HP, at a rate of 20 ml/m². The product INDAL PAA 5 is applied at a maximal a.s. concentration of 2.081 g/l PAA and 10.014 g/l at a rate of 20 ml/m². The product INDAL OXY MOUSS is applied at a maximum a.s. concentration of 0.511 g/l PAA and 5.533 g/l HP at a rate of 50 ml/m².
Surface area to be disinfected: - slaughterhouses - large scale catering kitchens	*AREAsurface*	 10 000 2000	m²	Default values (ESD PT4, 2011). The worst-case value of 10 000 m² is selected.
Number of applications per day	*Nappl*	1	d^{-1}	Default value (ESD PT4, 2011)
Fraction of substance disintegrated during or after application (before release to the sewer system)	*Fdis*	0	-	Default value (ESD PT4, 2011)
Fraction of substance eliminated due to on-site pre-treatment of waste water	*Felim*	0	-	Default value (ESD PT4, 2011)
Fraction released to waste water	*Fwater*	1	-	Default value (ESD PT4, 2011)

Calculations for Scenario 13

Local release to waste water ($Elocal_{ww}$):

$Elocal_{ww}$ = Qai * AREAsurface * Nappl * (1 – Fdis) * (1 – Felim) * Fwater / 1000
= 0.0416 * 10 000 * 1 / 1000 = 0.277 * 10 000 * 1 / 1000
= 0.416 kg/d PAA = 2.77 kg/d HP

Active substance degradation in the sewer system (as detailed for scenario 1):

Considering the degradation of the active substances in the sewer system, the local emission to waste water is refined in the following manner:

$M_{t1} = M_{t0} * \exp^{(- k * t1)}$
$= 0.416 * \exp^{(- 4.38 * 1)}$ $= 2.77 * \exp^{(- 3.65 * 1)}$
= 0.00522 kg/d PAA = 0.0719 kg/d HP

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	PAA: 0.00522 kg/d HP: 0.0719 kg/d	These values take into account a degradation of the active substances during their stay in the sewer system.

Scenario 14: Emission scenario for the disinfection of milking parlour systems (ESD PT4, 2011, table 11, p.26)

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Scenario 14: Emission scenario for the disinfection of milking parlour systems (ESD PT4, 2011, table 11, p.26)				
Concentration of active ingredient	*Cform*	PAA: 2.081 HP: 10.014	g/l	Maximum in-use concentration for INDAL PAA 15
Amount of disinfectant used for cleaning of the milking installation	*Vform-inst*	130	l/d	Default value (ESD PT4, 2011)
Amount of disinfectant used for cleaning of the milk storage tank	*Vform-tank*	45	l/d	Default value (ESD PT4, 2011)

Fraction of substance disintegrated during or after application (before release to the sewer system)	*Fdis*	0	-	Default value (ESD PT4, 2011)
Fraction of the emission to waste water	*Fwater*	1	-	Default value (ESD PT4, 2011)

Calculations for Scenario 14

Local emission to waste water ($Elocal_{ww}$):

$Elocal_{ww}$ = Cform * (Vform-inst + Vform-tank) * (1 – Fdis) * Fwater / 1000
= 0.364 kg/d PAA = 1.752 kg/d HP

Active substance degradation in the sewer system (as detailed for scenario 1):

Considering the degradation of the active substances in the sewer system, the local emission to waste water is refined in the following manner:

$M_{t1} = M_{t0} * \exp^{(-k * t1)}$
$= 0.364 * \exp^{(-4.38 * 1)}$ $= 1.752 * \exp^{(-3.65 * 1)}$
= 0.00457 kg/d PAA = 0.0455 kg/d HP

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	PAA: 0.00457 kg/d HP: 0.0455 kg/d	These values take into account a degradation of the active substances during their stay in the sewer system.

Calculated PEC values

PEC values were only calculated for the STP and surface water. Seawater is not considered a relevant compartment. Risks to air, soil and GW are considered as negligible. As the PNEC values for sediment were calculated by the equilibrium partitioning method, PEC/PNEC ratio's will be equal for surface water and sediment.

Summary table on calculated PEC values				
	PEC_{STP}		**PEC_{water}**	
	[mg/l]		[mg/l]	
	PAA	HP	PAA	HP
Scenario 1+2	7.11×10^{-6}	4.75×10^{-5}	7.11×10^{-7}	4.75×10^{-6}

Scenario 3a	n.a.	n.a.	2.08	10
Scenario 3b	n.a.	n.a.	164	572
Scenario 4	7.17×10^{-6}	4.49×10^{-5}	7.17×10^{-7}	4.49×10^{-5}
Scenario 5	2.24×10^{-3}	0.0552	2.24×10^{-4}	5.52×10^{-3}
Scenario 6	7.47×10^{-3}	0.184	7.47×10^{-4}	0.0184
Scenario 7	0.0148	0.0986	1.48×10^{-3}	9.86×10^{-3}
Scenario 8	7.38×10^{-6}	4.93×10^{-5}	7.38×10^{-7}	4.93×10^{-6}
Scenario 9	9.09×10^{-9}	6.06×10^{-8}	9.09×10^{-10}	6.06×10^{-9}
Scenario 10	8.11×10^{-6}	1.22×10^{-4}	8.11×10^{-7}	1.22×10^{-5}
Scenario 11	2.37×10^{-5}	1.59×10^{-4}	2.37×10^{-6}	1.59×10^{-5}
Scenario 12	1.15×10^{-4}	1.73×10^{-3}	1.15×10^{-5}	1.73×10^{-4}
Scenario 13	2.58×10^{-5}	2.38×10^{-4}	2.58×10^{-6}	2.59×10^{-5}
Scenario 14	2.26×10^{-5}	1.51×10^{-4}	2.26×10^{-6}	1.51×10^{-5}

(III) Primary and secondary poisoning

Primary poisoning

The use of products from the Quaron PAA family is not likely to lead to primary poisoning. No direct exposure of birds or mammals is expected.

Secondary poisoning

No secondary poisoning is expected for peracetic acid. The log K_{ow} is -0.60, indicating that peracetic acid has a negligible potential for bioconcentration in biota. Furthermore, peracetic acid dissipates rapidly in the environment. No accumulation of peracetic acid in the foodchain is therefore expected.

No secondary poisoning is expected for hydrogen peroxide either. The log K_{ow} is -1.57, indicating that hydrogen peroxide has a negligible potiential for bioconcentration in biota. The BCFs for fish and earthworms are 1.4 and 0.84 respectively, indicating that the risk of secondary poisoning for aquatic and terrestrial predators will be negligible. No accumulation of hydrogen peroxide in the foodchain is therefore expected.

2.2.8.3 Risk characterisation

Summary table on calculated PEC/PNEC ratio's						
	STP			**Surface water**		
	PAA	HP	Σ PAA, HP	PAA	HP	Σ PAA, HP
Scenario 1+2	1.39×10^{-4}	1.02×10^{-5}	1.50×10^{-4}	0.0103	3.77×10^{-4}	0.0107
Scenario 3a	n.a.	n.a.	n.a.	**30 159**	**794**	**30 954**
Scenario 3b	n.a.	n.a.	n.a.	**2.38×10^{6}**	**45 413**	**2.42×10^{6}**

Scenario 4	1.41×10^{-4}	9.63×10^{-6}	1.50×10^{-4}	0.0104	3.56×10^{-4}	0.0108
Scenario 5	0.0440	0.0118	0.0559	**3.25**	0.438	**3.69**
Scenario 6	0.147	0.0396	0.186	**10.8**	**1.46**	**12.3**
Scenario 7	0.290	0.0211	0.311	**21.4**	**0.783**	**22.2**
Scenario 8	1.45×10^{-4}	1.06×10^{-5}	1.55×10^{-4}	0.0107	3.91×10^{-4}	0.0111
Scenario 9	1.78×10^{-7}	1.30×10^{-8}	1.91×10^{-7}	1.32×10^{-5}	4.81×10^{-7}	1.37×10^{-5}
Scenario 10	1.59×10^{-4}	2.62×10^{-5}	1.85×10^{-4}	0.0118	9.68×10^{-4}	0.0127
Scenario 11	4.66×10^{-4}	3.40×10^{-5}	5.00×10^{-4}	0.0344	1.26×10^{-3}	0.0357
Scenario 12	2.25×10^{-3}	3.71×10^{-4}	2.63×10^{-3}	0.166	0.0137	0.180
Scenario 13	5.07×10^{-4}	5.12×10^{-5}	5.58×10^{-4}	0.0374	1.89×10^{-3}	0.0393
Scenario 14	4.43×10^{-4}	3.24×10^{-5}	4.76×10^{-4}	0.0328	1.20×10^{-3}	0.0340

(I) Atmosphere

Risks due to PAA or HP in the atmosphere are considered to be negligible.

(II) Sewage treatment plant (STP)

Only in the scenario's for STP disinfection are PEC/PNEC ratio's higher than 1 calculated.

(III) Aquatic compartment

Unacceptable risks area calculated for scenario 3a and 3b (disinfection of STP), scenario 5 and 6 (disinfection of private and public pools) and for scenario 7 (disinfection of aquaculture systems). For the other scenario's, no unacceptable risks are expected.

For scenario's 5, 6 and 7, the calculated risks in the aquatic compartment are probably a significant overestimation of the actual risks:

- No degradation was taken into account in the pool water and aquaculture basins. As especially the aquaculture basins contain a quite high concentration of organic matter, degradation of PAA and HP will already start before release to the sewer system.
- No degradation was taken into account for the residence time in the primary settler of the STP (estimated at 2 hours). This residence time, combined with the degradation rate used in the sewer, would reduce the concentrations of PAA by a further factor of ~6300 and HP by a factor of ~1500. Therefore, further degradation in the primary settler is expected to be more than sufficient to further reduce the PEC/PNEC ratio below 1.
- Additionally, the DT50 of 5 minutes for the degradation of PAA in the sewer system (9.5 minutes at 12°C) is already a worst-case approach, as the degradation test observed a decrease in concentration in effluent from 2 mg/l to below 0.1 mg/l in 5 minutes.
- Swimming pools and aquaculture basins will only be drained periodically. Emission could therefore be considered as intermittent.

Based on this reasoning, we can consider the risks for scenario's 5, 6 and 7 as acceptable.

Furthermore, the use related to scenarios 5 and 6 (use 2.1) was not granted for efficacy reasons.

For the disinfection in STP's (scenarios 3a and 3b), additional reaction time is probably limited, and calculated risks are much higher. We expect that these risks will persist. To mitigate this risk, the applicant proposed to make a neutralisation with sodium thiosulfate mandatory for disinfection in the STP.

A document detailing this neutralization process has been attached to the IUCLID dossier *section 13*. According to the applicant, the reactions are quick and complete, which would mean that it can be expected that no hydrogen peroxide or peracetic acid will be present in the wastewater sent to the sewer system when a sufficient dose of thiosulfate is added.

However, we are concerned about the correct dosing of the thiosulfate powder. Even when toxicity of thiosulfate and the reaction products is low, over-dosing could cause de-oxygenation of the STP effluent and consequently of the receiving surface water. Therefore, we are not in favour of using this technique to neutralize the water from pools and aquaculture basins (scenarios 5, 6 and 7), especially since risks for these scenarios are considered to be acceptable.

Risks are expected to be a lot higher for disinfection in the STP. For this use, it might be necessary to use additional RMM like adding thiosulfate. Because of the concerns on overdosing after use of the biocidal products in an STP, the applicant proposes to further complete the risk mitigation measure by adding: "The quantity of thiosulfate to be added to the medium in order to neutralize the excess of substances should be determined by consultation with the biocidal product supplier."

The aim of this addition is for the users to contact the applicant so that they can define together (for instance by measuring the peracetic acid and hydrogen peroxide concentrations in the treated water) the precise quantity of thiosulfate to be used in order to avoid using an excess of substance. According to the applicant, such contacts between the users and the supplier are standard procedure, the applicant always offers technical assistance to their customers.

Further RMM considered were the obligatory presence of a retention system (e.g. buffer tank or labyrinth) to allow for further contact time, and an automatic monitoring and dosing system for the thiosulfate.

However, a retention system allowing for a contact time of e.g. 30 minutes is only expected to mitigate risks by a factor of ~10. In this case, vast amounts of neutralizing agent would still be needed. No quantitative data on the exact efficiency of the neutralizing process are available, and uncertainties on the exact application of both product and neutralizing agent remain. In any case the thiosulfate will lead to very high concentrations of sodium- and sulfate based substances in the receiving surface water. Furthermore, unknown by-products could possibly be formed, and a risk on under- or overdosing will remain.

Therefore, adding thiosulfate as a neutralizing agent is not accepted as a feasible and sufficiently reliable measure to reduce the risks to acceptable levels. The uses related to scenarios 3a and 3b (uses #3-2, #3-4, #3-5 and #4-1) can therefore not be authorised.

(IV) Terrestrial compartment and groundwater

Based on the high reactivity of both peracetic acid and hydrogen peroxide, and the high organic matter content of manure, slurry and STP sludge, risks for soil and groundwater are expected to be negligible.

(V) Primary and secondary poisoning

a) Primary poisoning

No risks are expected.

b) Secondary poisoning

No secondary poisoning is expected.

(VI) Mixture toxicity

The RCRs for peracetic acid and hydrogen peroxide were already added together. The environmental risks for acetic acid are considered as negligible. No further environmental SoC's are present in the product.

(VII)Aggregated exposure (combined for relevant emmission sources)

Calculating the aggregated exposure more in detail for all scenario's combined, is not considered needed. Due to the high reactivity of both peracetic acid and hydrogen peroxide, the aggregated risks will in practice be limited.

Overall conclusion on the risk assessment for the environment of the product
Based on this risk assessment and on available data, an unacceptable risk to the aquatic compartment has been identified for the products INDAL PAA 5 and INDAL PAA 15, when applied for disinfection of waste water and leachates in private and public sewage treatment plants, and for disinfection of small equipment by dipping and closed circulation circuits by cleaning-in-place in sewage treatment plants (uses #3-2, #3-4, #3-5 and #4-1). For all other uses, no unacceptable risk to the different environmental compartments is expected.

2.2.9 Assessment of endocrine disrupting properties

A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the ED properties of the substances in biocidal product family QUARON PAA:

1. Assessment of the ED properties of the active substances in QUARON PAA family:

- According to section 2.1.1 of the final CA document, the assessment of ED properties of the active substances that have already been evaluated and approved will be coordinated at EU level. Hence, the rMS should not evaluate the ED properties of these substances nor request additional data on the ED properties in the context of product authorisation procedures. As peracetic acid is not part of the list2 of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review.

- Therefore, BE eCA considers that there are no concerns regarding ED properties of peracetic acid.

2. Assessment of the ED properties of non-active substances (co-formulants) in QUARON PAA family:

- After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex - ED assessment), none of the co-formulants has been identified as having ED properties or are subject to an on-going evaluation or a decision regarding their ED properties. Based on the available information, BE eCA considers that there is no concern regarding the ED properties of these co-formulants.

Overall conclusion on the biocidal product/family regarding ED properties:

Based on the existing knowledge and the data provided by the applicant, there is no indication of concern regarding the ED properties of the substances used in the biocidal product family QUARON PAA.

If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product/family authorisation will be revised according to CAMarch18.Doc.7.b-final, section 2.3 (47).

2.2.10 Measures to protect man, animals and the environment

For the disinfection of water in sewage treatment plants: "In water treatment plant, before discharge to the environment, the treated water should be neutralized with thiosulfate. The quantity of thiosulfate to be added to the medium in order to neutralize the excess of substances should be determined by consultation with the biocidal product supplier."

2.2.11 Assessment of a combination of biocidal products

Quaron PAA Biocidal products are not intended to be used in combination with other biocidal product.

2.2.12 Comparative assessment

Not relevant.

3 ANNEXES

3.1 LIST OF STUDIES FOR THE BIOCIDAL PRODUCT (FAMILY)

Section No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data Protection (Yes/No)	Owner
3, 4 & 5	Dr E. Servajean	2017	Physical-chemical properties, stability and shelf-life of Indal Oxy Mouss Part 1: Physical-chemical properties upon receipt and after accelerated storage Phytosafe s.a.r.l. 16-35-080-ES GLP; Unpublished	Yes	QUARON s.a.s.
3, 4 & 5	Dr. E. Servajean	2017	Physical-chemical properties, stability and shelf-life of Indal PAA 15 Part 1 : Physical-chemical properties upon receipt and after accelerated storage Phytosafe s.a.r.l. 16-35-079-ES GLP; Unpublished	Yes	QUARON s.a.s.
3, 4 & 5	Dr. E. Servajean	2017	Physical-chemical properties, stability and shelf-life of Indal PAA 2.5 Part 1: Physical-chemical properties upon receipt and after accelerated storage Phytosafe s.a.r.l. 16-35-076-ES GLP; Unpublished	Yes	QUARON s.a.s.
3, 4 & 5	Dr. E. Servajean	2017	Physical-chemical properties, stability and shelf-life of Indal PAA 3.5 Part 1 : Physical-chemical properties upon receipt and after accelerated storage Phytosafe s.a.r.l. 16-35-077-ES GLP; Unpublished	Yes	QUARON s.a.s.
3, 4 & 5	Dr. E. Servajean	2017	Physical-chemical properties, stability and	Yes	QUARON s.a.s.

			shelf-life of Indal PAA 5 Part 1 : Physical-chemical properties upon receipt and after accelerated storage Phytosafe s.a.r.l. 16-35-078-ES GLP; Unpublished		
3, 4 & 5	Dr. E. Servajean	2017	Physical-chemical properties, stability and shelf-life of Indal Tap 5 Part 1 : Physical-chemical properties upon receipt and after accelerated storage Phytosafe s.a.r.l. 16-35-081-ES GLP; Unpublished	Yes	QUARON s.a.s.
3	Dr. E. Servajean	2018	Physical-chemical properties, stability and shelf-life of Indal PAA 15 Part 2 : Shelf-life Phytosafe s.a.r.l. 16-35-079-ES GLP; Unpublished	Yes	QUARON s.a.s.
3	Dr. E. Servajean	2018	Physical-chemical properties, stability and shelf-life of Indal Tap 5 Part 2 : Shelf-life Phytosafe s.a.r.l. 16-35-081-ES GLP; Unpublished	Yes	QUARON s.a.s.
3	Dr. E Servajean	2019	Physical-chemical properties, stability and shelf-life of Indal PAA 3.5 Part 2 : Shelf-life Phytosafe s.a.r.l. 16-35-077-ES GLP; Unpublished	Yes	QUARON s.a.s.
3	Dr. E Servajean	2019	Physical-chemical properties, stability and shelf-life of Indal PAA 2.5 Part 2 : Shelf-life Phytosafe s.a.r.l. 16-35-076-ES GLP; Unpublished	Yes	QUARON s.a.s.
3	Dr. E Servajean	2019	Physical-chemical properties, stability and shelf-life of Indal PAA 5 Part 2 : Shelf-life Phytosafe s.a.r.l.	Yes	QUARON s.a.s.

			16-35-078-ES GLP; Unpublished		
3	Dr. E Servajean	2019	Physical-chemical properties, stability and shelf-life of Indal OXY MOUSS Part 2 : Shelf-life Phytosafe s.a.r.l. 16-35-080-ES GLP; Unpublished	Yes	QUARON s.a.s.
4	P. Vicot	2018	Essais sur les preparations INDAL PAA 3.5 et INDAL PAA 5 Epreuves ONU E.1 et ONU F.2 INERIS DRA-18-175073-06829A, Non GLP ; Unpublished	Yes	QUARON s.a.s.
4	P. Vicot	2019	TESTS ON A PREPARATION OF PERACETIC ACID _ INDAL PAA 2.5 INERIS DRA-19-177201-00330A Non GLP; Unpublished	Yes	QUARON s.a.s.
4	P. Vicot	2019	TESTS ON A PREPARATION OF PERACETIC ACID _ INDAL PAA 5 INERIS DRA-19-177201-00659A Non GLP; Unpublished	Yes	QUARON s.a.s.
4	W. A. Mak	2019	Transport classification of two peroxyacetic acid formulations (INDAL PAA 15 and INDAL OXY MOUSS) TNO innovation for life Draft Non GLP; Unpublished	Yes	QUARON s.a.s.
4	P. VICOT	2019	UN TEST F2 ON A PREPARATION OF PERACETIC ACID_INDAL TAP 5 DRA-19-181008-4788A Non GLP; Unpublished	Yes	Quaron s.a.s.
4	P. VICOT	2020	UN TEST E1 ON A PREPARATION OF PERACETIC ACID: "Quaron Family PAA META SPC 6" Ineris-202786-2341284-v2.0	Yes	Quaron s.a.s.

			Non GLP		
6	C. Rubrecht	2017	Fungicidal activity according to the NF EN 13697 : 2015 standard RE-17-177-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the sporocodal activity according to the protocol of the NF EN 13704 : 2002 standard RE 17-206-2 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	A-F. Gabillet, M. Sesques	2017	Efficacy test for virucidal activity towards bacteriophages according to the standard EN 13610 (2003) - INDAL PAA 3.5 LMH Laboratoire de Microbiologie et Hygiène 4554-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	F. Cattapan, S. Moulard	2018	INDAL PAA 2.5 - Evaluation of bactericidal activity according to UNI EN 1276:2009 / EC1:2011 18/000081330 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	F. Cattapan, S. Moulard	2018	INDAL PAA 2.5 - Evaluation of bactericidal activity according to UNI EN 1276:2009 / EC1:2011 18/000081330 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	F. Cattapan, S. Moulard	2018	INDAL PAA 2.5 - Evaluation of bactericidal activity according to UNI EN 1276:2009 / EC1:2011 18/000081367 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	F. Cattapan, S. Moulard	2018	INDAL PAA 2.5 - Evaluation of bactericidal activity according to UNI EN 13697:2015 18/000081330 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	F. Cattapan, S. Moulard	2018	INDAL PAA 2.5 - Evaluation of bactericidal activity against Legionella according to UNI EN 13623:2010	Yes	QUARON s.a.s.

			18/000081330 Non GLP; Unpublished		
6	P. Lemaitre	2017	Evaluation of the fungicidal activity according to the protocol of the NF EN 1650 + A1 : 2013 standard RE 17-197-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Fungicidal activity according to the protocol of the NF EN 13697 : 2015 standard RE 17198-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	F. Cattapan, S. Moulard	2018	UNI EN 14476+A1:2015 - Chemical disinfectants and antiseptics Quantitative suspension test for the evaluation of virucidal activity in the medical area (phase 2, step 1) 18/000081330 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2018	INDAL PAA 5 - Evaluation of bactericidal activity according to UNI EN 1276:2009 / EC1:2011 18/000061341 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2018	INDAL PAA 5 - Evaluation of bactericidal activity according to UNI EN 13697:2015 18/000061341 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2017	INDAL PAA 5 - Evaluation of bactericidal activity according to UNI EN 13697:2015 18/000061341 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2017	Evaluation of bactericidal activity against Legionella on INDAL PAA 5 according to UNI EN 13623:2010 17/597231.0002 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	A. Pinon	2017	Evaluation de l'efficacité de l'INDAL PAA 5 à 0.1%, 0.2% et 0.4% avec le temps de contact de 5 minutes pour	Yes	QUARON s.a.s.

			l'élimination de biofilm mono-espèce de Staphylococcus aureus en conditions de laboratoire 170178-01b Non GLP; Unpublished		
6	A. Pinon	2017	Evaluation de l'efficacité de l'INDAL PAA 5 à 0.1%, 0.2% et 0.4% avec temps de contact de 5 minutes pour l'élimination de biofilm mono-espèce de Pseudomonas aeruginosa en conditions de laboratoire 170178-02b Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the fungicidal activity according to the NF EN 1650+A1:2013 standard RE-17-188-2 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the yeasticidal activity according to the NF EN 1650+A1:2013 standard RE-17-188-3 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the yeasticidal activity according to the NF EN 1650+A1:2013 standard RE-17-188-4 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the fungicidal activity according to the NF EN 1650+A1:2013 standard RE-17-188-5 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the fungicidal activity according to the NF EN 13697:2015 standard - Product INDAL PAA 5 batch QUA-JCF-F8-PER50 RE-17-190-2 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the yeasticidal activity according to the NF EN 13697:2015 standard RE-17-190-3 Non GLP; Unpublished	Yes	QUARON s.a.s.

6	P. Lemaitre	2017	Evaluation of the yeasticidal activity according to the NF EN 13697:2015 standard RE-17-190-4 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the fungicidal activity according to the NF EN 13697:2015 standard RE-17-190-5 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2018	Evaluation of the yeasticidal activity according to the NF EN 13624:2013 standard RE-17-480-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2018	Evaluation of the fungicidal activity according to the NF EN 13624:2013 standard RE-18-071-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the fungicidal activity according to the NF EN 1650+A1:2013 standard RE-17-187-2 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Fungicidal activity according to the NF EN 13697:2015 standard - Product INDAL PAA 5 batch QUA-JCF-F8-PER50 du 13/02/2017 RE-17-189-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	A-F. Gabillet, M. Sesques	2017	Efficacy test for virucidal activity towards bacteriophages according to the standard EN 13610 (July 2003) - INDAL PAA 5 4583-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	F. Cattapan, S. Moulard	2018	UNI EN 14476+A1:2015 - Chemical disinfectants and antispetics - Quantitative suspension test for the evaluation of virucidal activity in the medical area 18/000061341 Non GLP; Unpublished	Yes	QUARON s.a.s.

6	P. Lemaitre	2017	Evaluation of the sporicidal activity according to the NF EN 13704:2002 standard RE-17-204-3 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the sporicidal activity according to the NF EN 13704:2002 standard RE-17-204-4 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the sporicidal activity according to the NF EN 13704:2002 standard RE-17-204-5 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the sporicidal activity according to the protocol of the NF EN 13697:2015 standard RE-17-205-4 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the sporicidal activity according to the protocol of the NF EN 13697:2015 standard RE-17-205-4 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the sporicidal activity according to the protocol of the NF EN 13697:2015 standard RE-17-205-3 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	S. Morot-Bizot, G. Herbein	2017	Mycobactericidal and tuberculocidal activity of the INDAL PAA 5 product according to the EN 14348 standard 143D08-2017-01 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	S. Morot-Bizot, G. Herbein	2017	Mycobactericidal and tuberculocidal activity of the INDAL PAA 5 product according to the EN 14563 standard 143D08-2017-02 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2017	INDAL PAA 5 - Evaluation of bactericidal activity	Yes	QUARON s.a.s.

			according to UNI EN 13727:2015 18/000061341 Non GLP; Unpublished		
6	G. Zilio	2017	Evaluation of bactericidal activity on INDAL PAA 5 according to UNI EN 14561:2006 - Quantitative carrier test 17.597231.0006 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2017	INDAL PAA 5 - Evaluation of bactericidal activity against Legionella according to UNI EN 13623:2010 18/000034410 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the fungicidal activity according to the NF EN 13624:2013 standard RE-17-191-3 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the fungicidal activty according to the NF EN 14562:2006 standard RE-17-192-2 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	F. Cattapan, S. Moulard	2018	UNI EN 14476+A1:2015 - Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area (phase 2, step 1) 18/000061341 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	S. Morot-Bizot, G. Herbein	2017	Mycobactericidal and tuberculocidal activity of the INDAL PAA 5 product according to the EN 1438 standard 143D08-2017-03 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	S. Morot-Bizot, G. Herbein	2017	Mycobactericidal and tuberculocidal activity of the INDAL PAA 5 product according to the EN 14563 standard 143D08-2017-4 Non GLP; Unpublished	Yes	QUARON s.a.s.

6	M. Revel, J-L. Rebstock	2013	Nucleos - Etude de faisabilité du traitement chimique des légionelles dans les lixiviats d'un CET DRC-12045-EI Non GLP; Unpublished	Yes	Nucleos
6	G. Zilio	2017	INDAL PAA 5 - Evaluation of bactericidal activity according to UNI EN 13727:2015 18/000061341 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the fungicidal activity according to the NF EN 13624:2013 standard RE-17-193-3 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	S. Morot-Bizot, G. Herbein	2017	Mycobactericidal and tuberculocidal activity of the INDAL PAA 5 product according to the EN 14348 standard 143D08-2017-05 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2017	INDAL PAA 5 - Evaluation of bactericidal activity according to UNI EN 1656:2010 18/000061341 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2017	Evaluation of bactericidal activity on INDAL PAA 5 according to UNI EN 14349:2013 - Quantitative non-porous surface test 17.597231.0001 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the fungicidal activity according to the NF EN 1657 : 2016 standard RE 17-184-4 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the fungicidal activity to the NF EN 16438:2014 standard RE-17-194-2 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	A. Proust	2017	Determination of virucidal activity of INDAL PAA 5 on	Yes	QUARON s.a.s.

			bovine enterovirus with 3 g/l of BSA - Quantitative suspension test according to NF EN 14675 standard (veterinary area, phase 2 step 1, 2015) R-LVQUA002 Non GLP; Unpublished		
6	G. Zilio	2018	INDAL PAA 5 - Evaluation of bactericidal activity according to UNI EN 14349:2013 18/000109287 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the yeasticidal activity according to the NF EN 16438:2014 standard RE-17-195-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	A. Proust	2017	Determination of virucidal activity of INDAL PAA 5 on Modified Vaccinia Virus Ankara (MVA) with 10 g/l of skimmed milk - Quantitative suspension test according to NF EN 14675 standard (veterinary area, phase 2 step 1, 2015) R-LVQUA004 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	A. Proust	2017	Determination of virucidal activity of INDAL PAA 5 on bovine enterovirus with 10 g/l of skimmed milk - Quantitative suspension test according to NF EN 14675 standard (veterinary area, phase 2 step 1, 2015) R-LVQUA005 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2017	INDAL PAA 5 - Evaluation of bactericidal activity according to UNI EN 1276:2009 18/000061341 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2017	INDAL PAA 5 - Evaluation of bactericidal activity according to UNI EN 1276:2009 18/000061341	Yes	QUARON s.a.s.

			Non GLP; Unpublished		
6	G. Zilio	2017	INDAL PAA 15 - Evaluation of bactericidal activity according to UNI EN 13727:2015 18/000006193 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the fungicidal activity according to the protocol of the NF EN 13624:2013 standard RE-17-200-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	C. Rubrecht	2017	Evaluation of the fungicidal activity according to the NF EN 13624:2013 standard RE-17-318-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	F. Cattapan, S. Moulard	2018	UNI EN 14476+A1:2015 - Chemical disinfectants and antiseptics: quantitative suspension test for the evaluation of virucidal activity in the medical area (phase 2, step 1) 18/000006193 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2017	INDAL PAA 15 - Evaluation of bactericidal activity according to UNI EN 13727:2015 18/000006193 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2017	INDAL PAA 15 - Evaluation of bactericidal activity according to UNI EN 13727:2015 18/000006193 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the fungicidal activity according to the protocol of the NF EN 13624:2013 standard RE-17-201-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	S. Morot-Bizot, G. Herbein	2017	Mycobactericidal and tuberculocidal activity of the INDAL PAA 15 product according to the EN 14348 standard	Yes	QUARON s.a.s.

			143D08-2017-08 Non GLP; Unpublished		
6	G. Zilio	2017	INDAL PAA 15 - Evaluation of bactericidal activity according to UNI EN 1276:2009 / EC1:2011 18/000006193 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2017	INDAL PAA 15 - Evaluation of bactericidal activity according to UNI EN 13697:2015 18/000006193 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	R. Dugué	2017	Evaluation of the fungicidal activity according to the NF EN 1650 + A1 : 2013 standard RE-17-199-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the fungicidal activity according to the NF EN1650+A1:2013 standard RE-17-317-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the fungicidal activity according to the NF EN13697:2015 standard RE-17-341-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the sporicidal activity according to the NF EN 13704:2002 standard RE-17-207-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the sporicidal activity according to the NF EN 13704:2002 standard RE-17-207-2 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the sporicidal activity according to the protocol of the NF EN 13704:2002 standard RE-17-207-3 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	F. Cattapan, S. Moulard	2017	UNI EN14476+A1:2015 - Chemical disinfectants and antiseptics: quantitative	Yes	QUARON s.a.s.

			suspension test for the evaluation of virucidal activity in the medical area (phase 2, step 1) 18/000006193 Non GLP; Unpublished		
6	A-F. Gabillet, M. Sesques	2017	Efficacy test for virucidal activity towards bacteriophages according to the standard EN 13610 (July 2003) - INDAL PAA 15 4552-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	A. Carré, P. Strohl	2016	Rapport d'essai n°176/0316-2 176-0316-2 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2017	INDAL OXY MOUSS - Evaluation of bactericidal activity according to UNI EN 1656:2010 18/000099098 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	A. Carré, P. Strohl	2016	Rapport d'essai n°176/0316-6 176-0316-6 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2017	Evaluation of bactericidal activity on INDAL OXY MOUSS according to UNI EN 14349:2013 17.597226.0001 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2017	Evaluation of bactericidal activity on INDAL OXY MOUSS according to UNI EN 16437:2014 - Quantitative porous surface test 17.597226.0002 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2017	Evaluation of bactericidal activity on INDAL OXY MOUSS according to UNI EN 16437:2014 - Quantitative porous surface test 17.610317.0001 Non GLP; Unpublished	Yes	QUARON s.a.s.

6	P. Lemaitre	2017	Evaluation of the fongicidal activity according to the NF EN 1657 : 2006 standard RE 17-183-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	A. Carré, P. Strohl	2016	Rapport d'essai n°RE-1173/0916-2 1173-0916-2 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the yeasticidal activity according to the NF EN 16438:2014 standard RE-17-202-4 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the yeasticidal activity according to the NF EN 16438 : 2014 standard RE 17-422-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	A. Carré, P. Strohl	2016	Rapport d'essai n°RE-1174/0916-2 1174-0916-2 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	A. Proust	2017	Determination of virucidal activity of INDAL OXY MOUSS on avian influenza virus with 3 g/l of BSA - Quantitative suspension test according to NF EN 14675 standard (veterinary area, phase 2 step 1, 2015) R-LVQUA006 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	A. Proust	2018	Determination of virucidal activity of INDAL OXY MOUSS on bovine enterovirus with 3 g/l of BSA - Quantitative suspension test according to NF EN14675 standard (veterinary area, phase 2 step 1, 2015) R-LVQUA007 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	V. Moules	2018	Determination of virucidal activity of INDAL OXY MOUSS on porcine enterovirus with 3 g/l of BSA - Quantitative	Yes	QUARON s.a.s.

			suspension test according to NF EN 14675 standard R-LVQUA008 Non GLP; Unpublished		
6	I. Stokes	2018	Testing the efficacy of disinfectants against FMDV PRI0118 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	S. Morot-Bizot, G. Herbein	2017	Mycobactericidal and tuberculocidal activity of the INDAL OXY MOUSS product according to the EN14204 standard 143D08-2017-06 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	S. Morot-Bizot, G. Herbein	2017	Mycobactericidal and tuberculocidal activity of the INDAL OXY MOUSS product according to the EN 14563 standard 143D08-2017-07 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	F. Paté	2013	Recherche(s) demandée(s) Evaluation de l'activité bactéricide selon NF EN1276 (Mars 2010) LDA67-131017-006038-04 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	F. Paté	2013	Recherche(s) demandée(s): Evaluation de l'activité selon NF EN 1276 (Mars 2010) LDA67-131022-006156-03 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2018	INDAL OXY MOUSS - Evaluation of bactericidal activity according to UNI EN 1276:2009 / EC1:2011 18/000099098 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2018	INDAL OXY MOUSS - Evaluation of bactericidal activity according to UNI EN 13697:2015 18/000099098 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2017	INDAL OXY MOUSS - Evaluation of bactericidal activity against Legionella	Yes	QUARON s.a.s.

			according to UNI EN 13697:2015 18/000099098 Non GLP; Unpublished		
6	A. Pinon	2017	Rapport d'essais Quaron n°160140-01 - exemplaire n°1 160140-01 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	A. Pinon	2017	Rapport d'essais Quaron n°160140-02 - Exemplaire n°1 160140-02 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	A. Pinon	2017	Rapport d'essais Quaron n°160140-03 - Exemplaire n°1 160140-03 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	F. Paté	2013	Recherche(s) demandée(s): Evaluation de l'activité levuricide selon NF EN 1650 + A1 (Juillet 2013) LDA67 - 131017-006038-05 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	F. Paté	2013	Recherche(s) demandée(s): Evaluation de l'activité selon NF EN 1650 + A1 (Juillet 2013) LDA67-131017-006038-03 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Fungicidal activity according to the NF EN 13697 : 2015 standard RE 17-178-3 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	F. Cattapan, S. Moulard	2018	UNI EN 14476+A1:2015 - Chemical disinfectants and antiseptics: Quantitative suspension test for the evaluation of virucidal activity in the medical area (phase 2, step 1) 18/000099098 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	A-F. Gabillet, M. Sesques	2017	Efficacy test for virucidal activity towards bacteriophages according to	Yes	QUARON s.a.s.

			the standard EN 13610 (July 2003) 4553-1 Non GLP; Unpublished		
6	G. Zilio	2017	INDAL TAP 5 - Evaluation of bactericidal activity according to UNI EN 1276:2009/EC:2011 18/000031718 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the fungicidal activity according to the NF EN 1650+A1:2013 standard RE-17-203-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the sporicidal activity according to the protocol of the NF EN 13704:2002 standard RE-17-208-2 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	G. Zilio	2017	Evaluation of basic bactericidal activity on SULPHURIC ACID AQUEOUS SOLUTION 13.4% w/w according to UNI EN 1040:2006 17.597215.0001 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	R. Dugué	2017	Evaluation of the fungicidal activity according to the NF EN 1275:2006 RE-17-229-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	P. Lemaitre	2017	Evaluation of the basic sporicidal activity according to the NF EN 14347:2005 standard RE-17-263-1 Non GLP; Unpublished	Yes	QUARON s.a.s.
6	S. Morot-Bizot	2018	DETERMINATION OF ALGICIDAL ACTIVITY OF INDAL PAA 2,5 PRODUCT ACCORDING TO A DERIVATED PROTOCOL OF THE ASTM 645-13 STANDARD 85D11-2017-02 Non GLP; Unpublished	Yes	Quaron s.a.s.

6	S. Morot-Bizot	2018	DETERMINATION OF ALGICIDAL ACTIVITY OF INDAL PAA 5 PRODUCT ACCORDING TO A DERIVATED PROTOCOL OF THE ASTM 645-13 STANDARD 185D11-2017-01 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	T. Koburger-Janssen	2018	Test Report A 18205-1 INDAL PAA 15 - Chemical-Thermal Textile Disinfection (EN 16616) 40°C A 18205-1 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Giulio Zilio	2018	INDAL TAP 5 Evaluation of bactericidal activity according to UNI EN 1276:2009 / EC1:2011 18/000462974 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Giulio Zilio	2018	INDAL TAP 5 Evaluation of fungicidal activity according to UNI EN 1650:2013 18/000462979 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Ana CEPEDA	2019	INDAL OXY MOUSS Determination of virucidal activity of antiseptics and chemicals disinfectants used in the veterinary area adapted from NF EN 14675 Standard (Mai 2015) LABOCEA $247459 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Ana CEPEDA	2019	INDAL OXY MOUSS Determination of virucidal activity of antiseptics and chemicals disinfectants used I nthe veterinary area according from NF EN 14675 Standard (Mai 2015) LABOCEA $247464 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Ana CEPEDA	2019	INDAL OXY MOUSS Determination of virucidal activity of antiseptics and chemicals disinfectants used in the veterinary area	Yes	Quaron s.a.s.

			according from NF EN 14675 Standard (Mai 2015) LABOCEA $247460 Non GLP; Unpublished		
6	G. Bazza	2018	INDAL OXY MOUSS Evaluation of virucidal activity on INDAL OXY MOUSS, batch n° QUA-JCF-F8-HD10350 according to UNI EN 14675:2015: Quantitative suspension test for the evaluation of virucidal activity in the veterinary area (phase 2/step 1) MERIEUX 17-597223-0001 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Federica Cattapan and Sébastien Moulard	2019	INDAL PAA 2.5 Evaluation of bactericidal activity against Legionelle according to UNI EN 13623:2010 MERIEUX 19/000174751 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Federica Cattapan and Sébastien Moulard	2019	INDAL PAA 2.5 Evaluation of bactericidal activity against Legionella according to UNI EN 13697:2015 MERIEUX 19/000174751 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Amandine CARRE	2019	INDAL PAA 3.5 Test: In accordance with the procedures of EUROPEAN STANDARD NF EN 14476+A1 (October 2015) - chemical disinfectants and antiseptics - virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine IRM RE-1035-0119 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Amandine CARRE	2019	INDAL PAA 5 In accordance with the procedures of EUROPEAN STANDARD NF EN 14476 + A1 (October 2015) - chemical disinfectants and antiseptics - virucidal	Yes	Quaron s.a.s.

			quantitative suspension test for chemical disinfectants and antiseptics used in human medicine IRM RE-1038/0119 Non GLP; Unpublished		
6	Amandine CARRE	2019	INDAL PAA 15 European Standard NF EN 14476 + A1 (October 2015) - chemical disinfectants and antiseptics - virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine IRM RE-1032/0119 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Giulio Zilio	2019	INDAL PAA 3.5 Evaluation of yeasticidal activity according to UNI EN 1650:2013 N. 19/000327202 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Giulio Zilio	2019	INDAL PAA 3.5 Evaluation of fungicidal activity for instrument/surface disinfection according to BS EN 13624:2013 N. 19/000327202 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Giulio Zilio	2019	INDAL PAA 3.5 Evaluation of yeasticidal activity according to UNI EN 13697:2015 N. 19/000327202 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Giulio Zilio	2019	INDAL PAA 3.5 Evaluation of bactericidal activity for instrument/surface disinfection according to UNI EN 13727:2015 N. 19/000327202 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Giulio Zilio	2019	INDAL PAA 3.5 Evaluation of bactericidal activity for instruments according to UNI EN 14561:2006 N. 19/000327202 Non GLP; Unpublished	Yes	Quaron s.a.s.

6	Giulio Zilio	2019	INDAL PAA 3.5 Evaluation of fungicidal activity for instruments according to UNI EN 14562:2006 N. 19/000327202 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Giulio Zilio	2019	INDAL PAA 3.5 Evaluation of bactericidal activity against Legionella according to UNI EN 13623:2010 N. 19/000327202 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Giulio Zilio	2019	INDAL PAA 3.5 Evaluation of sporicidal activity on non-porous surfaces without mechanical action (UNI EN 13697:2015) N. 19/000327202 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Giulio Zilio	2019	INDAL PAA 3.5 Evaluation of bactericidal activity against Legionella according to UNI EN 13697:2015 N. 19/000327202 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Giulio Zilio	2019	INDAL PAA 3.5 Evaluation of mycobactericidal activity according to UNI EN 14348:2005 N. 19/000327202 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Giulio Zilio	2019	INDAL PAA 3.5 Evaluation of mycobactericidal activity for instrument disinfection according to UNI EN 14563:2009 N. 19/000327202 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	S. Pasquinelli	2019	INDAL PAA 5 Evaluation of bactericidal activity against Legionella according to UNI EN 13697:2015 19/000309164 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	S. Pasquinelli	2019	INDAL PAA 5 Evaluation of bactericidal activity against Legionella according to UNI EN 13697:2015 19/000309164	Yes	Quaron s.a.s.

			Non GLP; Unpublished		
6	S. Pasquinelli	2019	INDAL PAA 15 Evaluation of mycobactericidal activity according to UNI EN 14348:2005 19/000327248 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Giulio Zilio	2019	INDAL PAA 15 Evaluation of sporicidal activity on non-porous surfaces without mechanical action EN 13697 19/000174765 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Amandine CARRE	2019	INDAL PAA 3.5 - Test: European standard NF EN 16777 (December 2018) Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area RE-1036/0119 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Amandine CARRE	2019	INDAL PAA 2.5 - Test: In accordance with the methodology of the EUROPEAN STANARD NF EN 16777 (December 2018) IRM RE-1034/0119 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Amandine CARRE	2019	INDAL OXY MOUSS - Test: EUROPEAN STANDARD NF EN 16777 (December 2018) IRM RE-1040/0119 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Amandine CARRE	2019	INDAL PAA 15 - TEST: EUROPEAN STANDARD NF EN 16777 (December 2018) IRM RE-1033/0119 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	A. Pinon	2019	INDAL PAA 3.5-EN-Efficiency of INDAL PAA 3.5 at 0.1%, 0.4%, and 0.6% with contact time 5 minutes for removal of single-species Pseudomonas aeruginosa	Yes	Quaron s.a.s.

			biofilm in laboratory conditions. IPL N° 190247-01 Non GLP; Unpublished		
6	A. Pinon		INDAL PAA 3.5 - Efficiency of INDAL PAA 3.5 at 0.1%, 0.4%, and 0.6% with contact time 5 minutes for removal of single-species Staphylococcus aureus biofilm in laboratory conditions. IPL N° 190247-02 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Amandine CARRE	2019	INDAL PAA 2.5 - In accordance with the procedures of the European standard NF EN 14476 + A1 (October 2015) - chemical disinfectans and antispetics - virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine RE - 1216/0619 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Amandine CARRE	2019	INDAL PAA 5 - In accordance with the procedures of the European Standard NF EN 14476 + A1 (October 2015) - chemical disinfectants and antiseptics - virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine RE - 1215/0619 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	Giulio Zilio	2019	INDAL PAA 5 - Evaluation of mycobactericidal activity for instrument disinfection according to UNI EN 14563:2009 19/000174560 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	T. Koburger-Janssen	2019	INDAL PAA 5 - Chemical - Thermal Textile Disinfection (EN16616) 45°C - Screening Test 191242.V1 Non GLP; Unpublished	Yes	Quaron s.a.s.

6	A. Pinon	2019	INDAL PAA 5 - Évaluation de l'efficacité de l'INDAL PAA 5 à 0,1%, 0,2% et 0,4% avec temps de contact de 5 minutes pour l'élimination de biofilm mono-espèce de Legionella pneumophila en conditions de laboratoire. 170178-03 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	I. Masetto	2019	INDAL PAA 15: Evaluation of sporicidal activity on non-porous surfaces without mechanical action (UNI EN 13697:2015) 19/000357836 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	P. Strohl	2019	INDAL PAA 5 - European Standard NF EN 16777 (December 2018) Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in medical area RE 1039-0119 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	V. Maire	2019	Rapport d'essais: Travaux de laboratorie pour valider l'activité algicide du produit INDAL PAA 2.5 en suspension et sur support. n°0619-010_1 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	V. Maire	2019	Rapport d'essais: Travaux de laboratoire pour valider l'activité algicide du produit INDAL PAA 5 en suspension et sur support. n°0619-010_1 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	S. Pasquinelli	2019	INDAL PAA 3.5 Evaluation of mycobactericidal activity according to UNI EN 14348:2005 19/000403047 Non GLP; Unpublished	Yes	Quaron s.a.s.

6	S. Pasquinelli	2019	INDAL PAA 15 Evaluation of mycobactericidal activity according to UNI EN 14348:2005 19/000403048 Non GLP; Unpublished	Yes	Quaron s.a.s.
6	T. Koburger-Janssen	2019	INDAL PAA 5 – Chemical – Thermal Textile Disinfection (EN16616) 45°C – Screening Test 191446.VI Non GLP; Unpublished	Yes	Quaron s.a.s.

3.2 OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS

3.2.1 Output tables from Human Health Exposure Assessment

Please, find the output tables from the scenarios assessed on ConsExpoweb.
The following outputs are only given for one product for each assessed scenario for which an assessment to vapour exposure is conducted, and only for the active substance. All the data used as input for these assessments performed for the other products and substances characterized in each related scenario are given in the Human Health Risk assessment (point 2.2.6 of this document), as well as the exposure assessment results related to all these data. Please, also note the output result selected is each time the „Mean event concentration" which estimates local inhalation exposure to vapour in mg/m³. This result appears in bold in the output tables.
Finaly, only the results oft he TIER 2 approach is given here below, when it is necessary. If no TIER 2 approach is conducted, only the TIER 1 is shown.

So, for each scenario the exposure assessment results fort he following product is presented below:

1) For the manual mixing and loading application (scenarios 1 in the HHRA): INDAL PAA 2.5 – Meta-SPC 2
2) For the manual spraying for PT 2, PT 3 and PT 4 applications (scenarios 3 in the HHRA): INDAL PAA 5 - Meta-SPC 3
    a. Except for vehicle disinfection by manual spraying that is only conducted for the product INDAL OXY MOUSS - Meta-SPC 5
3) For the manual dipping for PT 2, PT 3 and PT 4 applications (scenario 4 in the HHRA): INDAL PAA 5 – Meta-SPC 3
    a. Except for foot bath disinfection that is only conducted for the product INDAL PAA 3.5 - Meta-SPC 1

3.2.1.1 Output tables for the Scenario 1: Manual mixing and loading application (INDAL PAA 2.5) – Meta-SPC 2:

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance	
Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log
Product	
Name	INDAL PAA 2.5
Weight fraction substance	–
Population	
Name	Adults_professionals

Body weight	60 kg

Scenario Manual Mixing and Loading TIER 2

Frequency	1 per day
Description	

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	10 minute
Product amount	11400 g
Weight fraction substance	0.02
Room volume	80 m^3
Ventilation rate	1.5 per hour
Inhalation rate	1.37 m^3/hr
Application temperature	20 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Constant
Release area	20 cm^2
Emission duration	10 minute
Product in pure form	No
Molecular weight matrix	77.6 g/mol
Absorption model	n.a.

Results for scenario Manual Mixing and Loading TIER 2

Inhalation

Mean event concentration	3.2×10^{-2} mg/m^3
Mean concentration on day of exposure	2.2×10^{-4} mg/m^3
Year average concentration	2.2×10^{-4} mg/m^3
External event dose	1.2×10^{-4} mg/kg bw

External dose on day of exposure **2.2** **× 10^{-4} MG/KG BW**

3.2.1.2 Output tables for the Scenario 3: Manual spraying applications (INDAL PAA 5 for PT 2, PT 3 and PT 4 applications and INDAL OXY MOUSS for PT 3 vehicle transport disinfection), respectively Meta-SPC 3 and Meta-SPC 5:

Report for assessment QUARON PAA Family

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Substance	
Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log
Product	
Name	INDAL PAA 5
Weight fraction substance	–
Population	
Name	Adults_professionals
Body weight	60 kg

Scenario Manual spraying_TP2_large scale_TIER 2

Frequency 365 per year

Description

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	480 minute
Product amount	16100 g
Weight fraction substance	0.00159
Room volume	900 m^3
Ventilation rate	2 per hour

Inhalation rate	1.37 m³/hr
Application temperature	20 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Increasing
Release area	719 m²
Application duration	480 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Manual spraying_TP2_large scale_TIER 2

Inhalation

Mean event concentration	1.5 mg/m³
Mean concentration on day of exposure	4.9×10^{-1} mg/m³
Year average concentration	4.9×10^{-1} mg/m³
External event dose	2.7×10^{-1} mg/kg bw
External dose on day of exposure	2.7×10^{-1} mg/kg bw

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance

Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log

Product

Name	INDAL PAA 5
Weight fraction substance	–

Population

Name	Adults_professionals
Body weight	60 kg

Scenario Manual spraying_TP2_small scale_TIER 2

Frequency	365 per year
Description	

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	66.8 minute
Product amount	2240 g
Weight fraction substance	0.00159
Room volume	900 m³
Ventilation rate	2 per hour
Inhalation rate	1.37 m³/hr
Application temperature	20 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Increasing
Release area	100 m²
Application duration	66.8 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Manual spraying_TP2_small scale_TIER 2

Inhalation

Mean event concentration	8.4×10^{-1} mg/m³
Mean concentration on day of exposure	3.9×10^{-2} mg/m³

Year average concentration	3.9×10^{-2} mg/m³
External event dose	2.1×10^{-2} mg/kg bw
External dose on day of exposure	2.1×10^{-2} mg/kg bw

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance	
Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log
Product	
Name	INDAL PAA 5
Weight fraction substance	–
Population	
Name	Adults_professionals
Body weight	60 kg

Scenario Man. Spraying_TP2_small scale room_TIER2

Frequency 365 per year

Description

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	66.8 minute
Product amount	2244 g
Weight fraction substance	0.00159
Room volume	90 m³
Ventilation rate	2 per hour

Inhalation rate	1.37 m³/hr
Application temperature	20 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Increasing
Release area	100 m²
Application duration	66.8 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Man. Spraying_TP2_small scale room_TIER2

Inhalation

Mean event concentration	5.3 mg/m³
Mean concentration on day of exposure	2.5×10^{-1} mg/m³
Year average concentration	2.5×10^{-1} mg/m³
External event dose	1.4×10^{-1} mg/kg bw
External dose on day of exposure	1.4×10^{-1} mg/kg bw

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance

Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log

Product

Name	INDAL PAA 5

Weight fraction substance –

Population	
Name	Adults_professionals
Body weight	60 kg

Scenario Man. spraying_TP3_large scale_TIER 2_Poultry

Frequency	365 per year
Description	

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	480 minute
Product amount	16125.4 g
Weight fraction substance	0.00159
Room volume	7180 m³
Ventilation rate	6 per hour
Inhalation rate	1.37 m³/hr
Application temperature	10 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Increasing
Release area	719 m²
Application duration	480 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Man. spraying_TP3_large scale_TIER 2_Poultry

Inhalation

Mean event concentration	7.1×10^{-2} mg/m³

Mean concentration on day of exposure	2.4×10^{-2} mg/m³
Year average concentration	2.4×10^{-2} mg/m³
External event dose	1.3×10^{-2} mg/kg bw
External dose on day of exposure	1.3×10^{-2} mg/kg bw

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance	
Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log
Product	
Name	INDAL PAA 5
Weight fraction substance	–
Population	
Name	Adults_professionals
Body weight	60 kg

Scenario Man. spraying_TP3_large scale_TIER 2_Pig

Frequency	365 per year
Description	

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	480 minute
Product amount	16100 g
Weight fraction substance	0.00159
Room volume	1680 m³
Ventilation rate	6 per hour
Inhalation rate	1.37 m³/hr

Application temperature	10 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Increasing
Release area	719 m²
Application duration	480 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Man. spraying_TP3_large scale_TIER 2_Pig

Inhalation

Mean event concentration	3.0×10^{-1} mg/m³
Mean concentration on day of exposure	10.0×10^{-2} mg/m³
Year average concentration	10.0×10^{-2} mg/m³
External event dose	5.5×10^{-2} mg/kg bw
External dose on day of exposure	5.5×10^{-2} mg/kg bw

Scenario Manual spraying_TP3_small scale_TIER 2 for poultry

For the exposure assessment during small scale manual spraying application in poultry houses, please, refer to the scenario for Large scale manual spraying disinfection in poultry houses here above.

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance	
Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log
Product	

Name	INDAL PAA 5
Weight fraction substance	–
Population	
Name	Adults_professionals
Body weight	60 kg

Scenario Manual spraying_TP3_small scale_TIER 2 (pig)

Frequency	365 per year
Description	

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	147 minute
Product amount	11700 g
Weight fraction substance	0.0006
Room volume	1680 m³
Ventilation rate	6 per hour
Inhalation rate	1.37 m³/hr
Application temperature	10 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Increasing
Release area	220 m²
Application duration	147 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Manual spraying_TP3_small scale_TIER 2

Inhalation

Mean event concentration	2.2×10^{-1} mg/m³
Mean concentration on day of exposure	2.3×10^{-2} mg/m³
Year average concentration	2.3×10^{-2} mg/m³
External event dose	1.3×10^{-2} mg/kg bw
External dose on day of exposure	1.3×10^{-2} mg/kg bw

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance

Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log

Product

Name	INDAL OXY MOUSS
Weight fraction substance	–

Population

Name	Adults_professionals
Body weight	60 kg

Scenario Manual spraying_TP3_vehicles_TIER 2

Frequency 365 per year

Description

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	93.5 minute
Product amount	7450 g
Weight fraction substance	0.0006
Room volume	84 m³
Ventilation rate	10 per hour

Inhalation rate	1.37 m³/hr
Application temperature	10 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Increasing
Release area	140 m²
Application duration	93.5 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Manual spraying_TP3_vehicles_TIER 2

Inhalation

Mean event concentration	1.7 mg/m³
Mean concentration on day of exposure	1.1×10^{-1} mg/m³
Year average concentration	1.1×10^{-1} mg/m³
External event dose	6.2×10^{-2} mg/kg bw
External dose on day of exposure	6.2×10^{-2} mg/kg bw

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance	
Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log
Product	
Name	INDAL PAA 5
Weight fraction substance	–
Population	

Name	Adults_professionals
Body weight	60 kg

Scenario Manual spraying_TP 3_milking parlour

Frequency	365 per year
Description	

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	0.0668 minute
Product amount	2.24 mg
Weight fraction substance	0.000265
Room volume	2560 m³
Ventilation rate	1.5 per hour
Inhalation rate	1.37 m³/hr
Application temperature	20 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Constant
Release area	1000 cm²
Emission duration	0.0668 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Manual spraying_TP 3_milking parlour

Inhalation

Mean event concentration	2.1×10^{-7} mg/m³
Mean concentration on day of exposure	9.9×10^{-12} mg/m³

Year average concentration	9.9×10^{-12} mg/m³
External event dose	5.4×10^{-12} mg/kg bw
External dose on day of exposure	5.4×10^{-12} mg/kg bw

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance

Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log

Product

Name	INDAL PAA 5
Weight fraction substance	–

Population

Name	Adults_professionals
Body weight	60 kg

Scenario Spraying_TP4_large scale_Slaughter_TIER2

Frequency 365 per year

Description

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	480 minute
Product amount	16125.4 g
Weight fraction substance	0.00159
Room volume	50000 m³
Ventilation rate	1.5 per hour

Inhalation rate	1.37 m³/hr
Application temperature	20 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Increasing
Release area	719 m²
Application duration	480 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Spraying_TP4_large scale_Slaughter_TIER2

Inhalation

Mean event concentration	3.8×10^{-2} mg/m³
Mean concentration on day of exposure	1.3×10^{-2} mg/m³
Year average concentration	1.3×10^{-2} mg/m³
External event dose	7.0×10^{-3} mg/kg bw
External dose on day of exposure	7.0×10^{-3} mg/kg bw

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance

Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log

Product

Name	INDAL PAA 5
Weight fraction substance	–

Population

Name	Adults_professionals
Body weight	60 kg

Scenario Spraying_TP4_large scale_Kitchen_TIER 2

Frequency	365 per year
Description	

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	480 minute
Product amount	16125.4 g
Weight fraction substance	0.00159
Room volume	6000 m³
Ventilation rate	10 per hour
Inhalation rate	1.37 m³/hr
Application temperature	20 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Increasing
Release area	719 m²
Application duration	480 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Spraying_TP4_large scale_Kitchen_TIER 2

Inhalation

Mean event concentration	5.2×10^{-2} mg/m³
Mean concentration on day of exposure	1.7×10^{-2} mg/m³

Year average concentration	1.7×10^{-2} mg/m³
External event dose	9.4×10^{-3} mg/kg bw
External dose on day of exposure	9.4×10^{-3} mg/kg bw

Scenario Spraying_TP4_large scale_Slaughter_TIER2

For the exposure assessment during small scale manual spraying application in slaughter houses, please, refer to the scenario for Large scale manual spraying disinfection in slaughter houses here above.

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance	
Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log
Product	
Name	INDAL PAA 5
Weight fraction substance	–
Population	
Name	Adults_professionals
Body weight	60 kg

Scenario Spraying_TP4_small scale_Kitchen_TIER 2

Frequency	365 per year
Description	

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	134 minute
Product amount	4490 g
Weight fraction substance	0.00159

Room volume	6000 m³
Ventilation rate	10 per hour
Inhalation rate	1.37 m³/hr
Application temperature	20 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Increasing
Release area	200 m²
Application duration	134 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Spraying_TP4_small scale_Kitchen_TIER 2

Inhalation

Mean event concentration	4.8×10^{-2} mg/m³
Mean concentration on day of exposure	4.4×10^{-3} mg/m³
Year average concentration	4.4×10^{-3} mg/m³
External event dose	2.4×10^{-3} mg/kg bw
External dose on day of exposure	2.4×10^{-3} mg/kg bw

3.2.1.3 Output tables for the Scenario 4: Manual dipping applications (INDAL PAA 5 for PT 2, PT 3 and PT 4 applications and INDAL PAA 3.5 for PT 4 foot bath disinfection) - respectively Meta-SPC 3 and meta-SPC 1

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance	
Name	Peracetic acid

Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log
Product	
Name	INDAL PAA 5
Weight fraction substance	–
Population	
Name	Adults_professionals
Body weight	60 kg

Scenario Dipping_TP2_L&S Scale_industries

Frequency	365 per year
Description	

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	60 minute
Product amount	2810000 g
Weight fraction substance	0.00159
Room volume	900 m^3
Ventilation rate	1.5 per hour
Inhalation rate	22.9 l/min
Application temperature	20 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Constant
Release area	4 m^2
Emission duration	30 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Dipping_TP2_L&S Scale_industries

Inhalation

Mean event concentration	3.0×10^{-1} mg/m³
Mean concentration on day of exposure	1.2×10^{-2} mg/m³
Year average concentration	1.2×10^{-2} mg/m³
External event dose	6.8×10^{-3} mg/kg bw
External dose on day of exposure	6.8×10^{-3} mg/kg bw

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance	
Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log
Product	
Name	INDAL PAA 5
Weight fraction substance	–
Population	
Name	Adults_professionals
Body weight	60 kg

Scenario Dipping_TP2_S.scale_institution

Frequency	365 per year
Description	

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	60 minute
Product amount	135000 g

Weight fraction substance	0.00159
Room volume	90 m³
Ventilation rate	3 per hour
Inhalation rate	22.9 l/min
Application temperature	20 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Constant
Release area	0.6 m²
Emission duration	30 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Dipping_TP2_S.scale_institution

Inhalation

Mean event concentration	2.9×10^{-1} mg/m³
Mean concentration on day of exposure	1.2×10^{-2} mg/m³
Year average concentration	1.2×10^{-2} mg/m³
External event dose	6.7×10^{-3} mg/kg bw
External dose on day of exposure	6.7×10^{-3} mg/kg bw

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance

Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log

Product

Name	INDAL PAA 5
Weight fraction substance	–

Population

Name	Adults_professionals
Body weight	60 kg

Scenario Dipping_TP3_Poultry

Frequency 365 per year

Description

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	60 minute
Product amount	561000 g
Weight fraction substance	0.00159
Room volume	7180 m³
Ventilation rate	1.5 per hour
Inhalation rate	22.9 l/min
Application temperature	10 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Constant
Release area	0.8 m²
Emission duration	30 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Dipping_TP3_Poultry

Inhalation

Mean event concentration	7.9×10^{-3} mg/m³
Mean concentration on day of exposure	3.3×10^{-4} mg/m³
Year average concentration	3.3×10^{-4} mg/m³
External event dose	1.8×10^{-4} mg/kg bw
External dose on day of exposure	1.8×10^{-4} mg/kg bw

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance	
Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log
Product	
Name	INDAL PAA 5
Weight fraction substance	–
Population	
Name	Adults_professionals
Body weight	60 kg

Scenario Dipping_TP3_pig

Frequency 365 per year

Description

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	60 minute
Product amount	561000 g
Weight fraction substance	0.00159
Room volume	1680 m³
Ventilation rate	1.5 per hour

Inhalation rate	22.9 l/min
Application temperature	10 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Constant
Release area	0.8 m²
Emission duration	30 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Dipping_TP3_pig

Inhalation

Mean event concentration	3.4×10^{-2} mg/m³
Mean concentration on day of exposure	1.4×10^{-3} mg/m³
Year average concentration	1.4×10^{-3} mg/m³
External event dose	7.7×10^{-4} mg/kg bw
External dose on day of exposure	7.7×10^{-4} mg/kg bw

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance

Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log

Product

Name	INDAL PAA 5
Weight fraction substance	–

Population

Name	Adults_professionals
Body weight	60 kg

Scenario Dipping_TP3_Aquaculture

Frequency	365 per year
Description	

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	60 minute
Product amount	22400000 g
Weight fraction substance	0.00159
Room volume	635 m³
Ventilation rate	4 per hour
Inhalation rate	22.9 l/min
Application temperature	10 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Constant
Release area	20 m²
Emission duration	30 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Dipping_TP3_Aquaculture

Inhalation

Mean event concentration	1.1 mg/m³
Mean concentration on day of exposure	4.5×10^{-2} mg/m³

Year average concentration	4.5×10^{-2} mg/m³
External event dose	2.5×10^{-2} mg/kg bw
External dose on day of exposure	2.5×10^{-2} mg/kg bw

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance	
Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log
Product	
Name	INDAL PAA 5
Weight fraction substance	–
Population	
Name	Adults_professionals
Body weight	60 kg

Scenario Dipping_TP4_slaughterhouses

Frequency 365 per year

Description

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	60 minute
Product amount	2810000 g
Weight fraction substance	0.00159
Room volume	50000 m³
Ventilation rate	1.5 per hour
Inhalation rate	22.9 l/min

Application temperature	20 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Constant
Release area	4 m²
Emission duration	30 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Dipping_TP4_slaughterhouses

Inhalation

Mean event concentration	5.5×10^{-3} mg/m³
Mean concentration on day of exposure	2.3×10^{-4} mg/m³
Year average concentration	2.3×10^{-4} mg/m³
External event dose	1.2×10^{-4} mg/kg bw
External dose on day of exposure	1.2×10^{-4} mg/kg bw

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance	
Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log
Product	
Name	INDAL PAA 5
Weight fraction substance	–
Population	

Name	Adults_professionals
Body weight	60 kg

Scenario Dipping_TP4_Industrial kitchen

Frequency	365 per year
Description	

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	60 minute
Product amount	2810000 g
Weight fraction substance	0.00159
Room volume	6000 m³
Ventilation rate	1.5 per hour
Inhalation rate	22.9 l/min
Application temperature	20 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Constant
Release area	4 m²
Emission duration	30 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Results for scenario Dipping_TP4_Industrial kitchen

Inhalation

Mean event concentration	4.5×10^{-2} mg/m³
Mean concentration on day of exposure	1.9×10^{-3} mg/m³

Year average concentration	1.9×10^{-3} mg/m³
External event dose	1.0×10^{-3} mg/kg bw
External dose on day of exposure	1.0×10^{-3} mg/kg bw

Report for assessment QUARON PAA Family

ConsExpo Web - Thu Sep 14 2017

Substance	
Name	Peracetic acid
Molecular weight	76.1 g/mol
K_{OW}	-0.23 10Log
Product	
Name	INDAL PAA 3.5
Weight fraction substance	–
Population	
Name	Adults_professionals
Body weight	60 kg

Scenario Dipping_TP4_ foot bath disinfection

Frequency 365 per year

Description

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	0.5 minute
Product amount	111000 g
Weight fraction substance	0.00104
Room volume	6000 m³
Ventilation rate	1.5 per hour
Inhalation rate	22.9 l/min
Application temperature	20 °C

Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	18.6 m/hr
Release area mode	Constant
Release area	3 m²
Emission duration	0.5 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

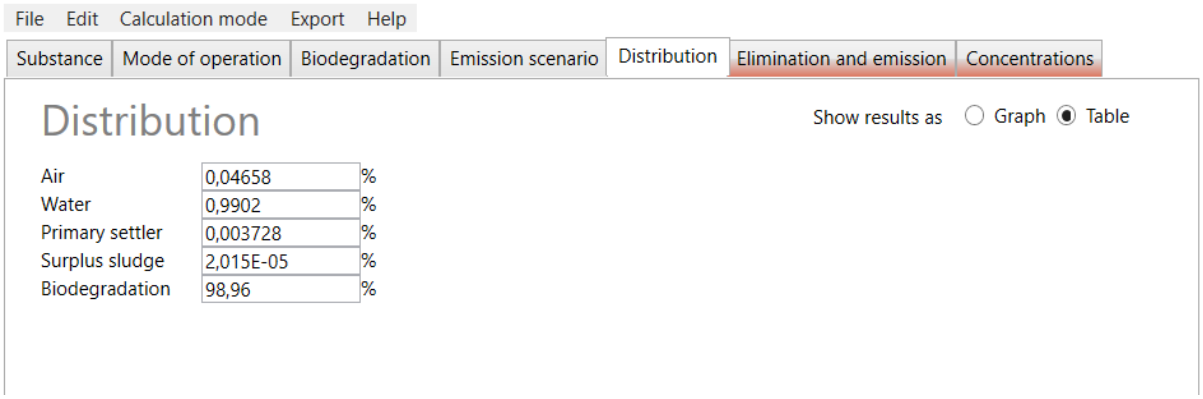
Results for scenario Dipping_TP4_ foot bath disinfection

Inhalation

Mean event concentration	4.2×10^{-4} mg/m³
Mean concentration on day of exposure	1.5×10^{-7} mg/m³
Year average concentration	1.5×10^{-7} mg/m³
External event dose	8.0×10^{-8} mg/kg bw
External dose on day of exposure	8×10^{-8} mg/kg bw

3.2.2 Output tables from Environmental Exposure Assessment

3.3



SimpleTreat 4.0 - Simple Treat Quaron PAA

File Edit Calculation mode Export Help

Substance | Mode of operation | Biodegradation | Emission scenario | Distribution | Elimination and emission | Concentrations

Chemical class

Acid

	User value	Default value	Unit		
Molecular weight	76,05	-	g mole^{-1}		
Octanol-water particion coefficient (Kow)	0,251	-	-		
Aparent Kow of a base at actual pH (Dow)			-		
Vapour pressure (Vp)	1410	-	Pa	at 293,15	K
Solubility (S)	1000000	-	mg l^{-1}	at 293,15	K
pKa	8,24	-	-		
Henry coefficient (H)	**0,217**	0,0762689849097478	Pa m^3 mole^{-1}	at 293,15	K
Organic carbon partition coefficient (Koc)	**1,46**	6,44428497508356	l kg^{-1}		
Partition coefficient in raw sewage (Kp_S)		0,438	l kg^{-1}		
Partition coefficient in activated sludge (Kp_{AS})		0,5402	l kg^{-1}		

SimpleTreat 4.0 - Simple Treat Quaron PAA

File Edit Calculation mode Export Help

Substance | Mode of operation | Biodegradation | Emission scenario | Distribution | Elimination and emission | Concentrations

Facility type

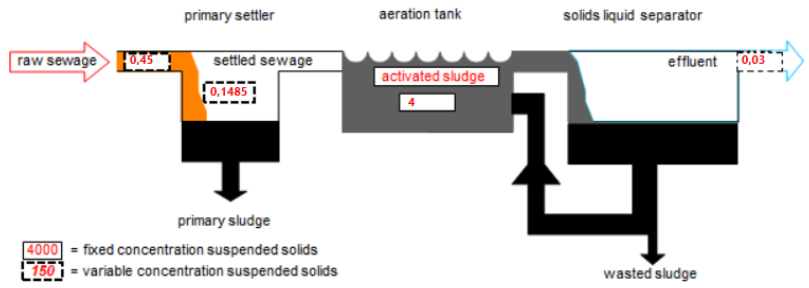
(•) Municipal ( ) Industrial

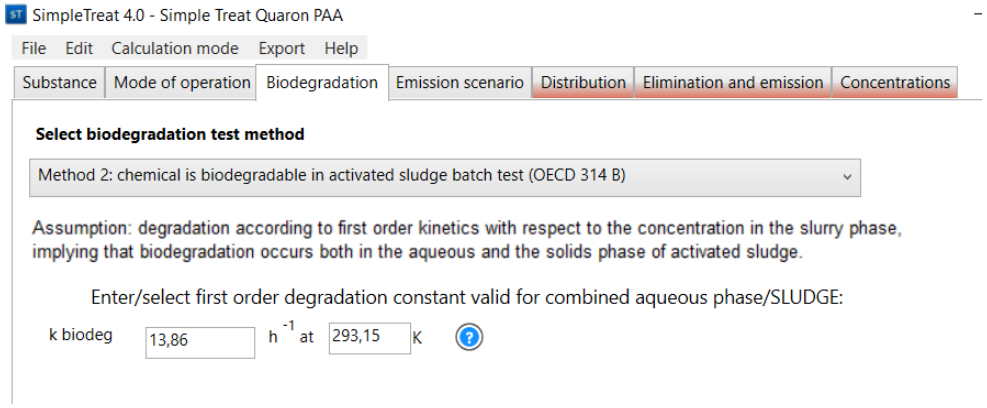
Operation mode

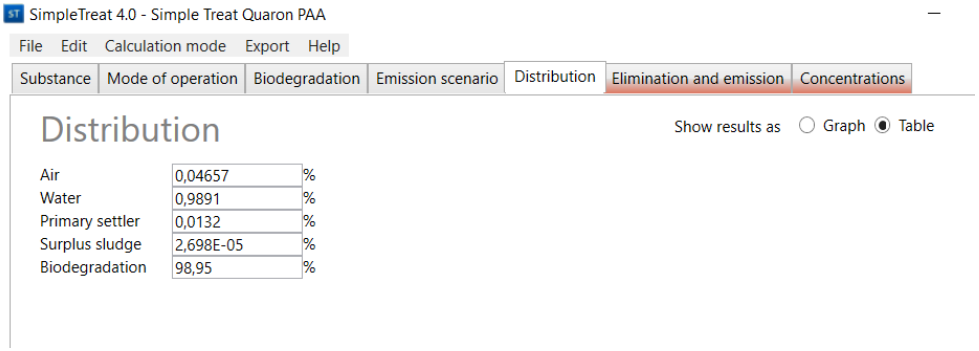
(•) Include primary solids removal (default) ( ) No primary solids removal

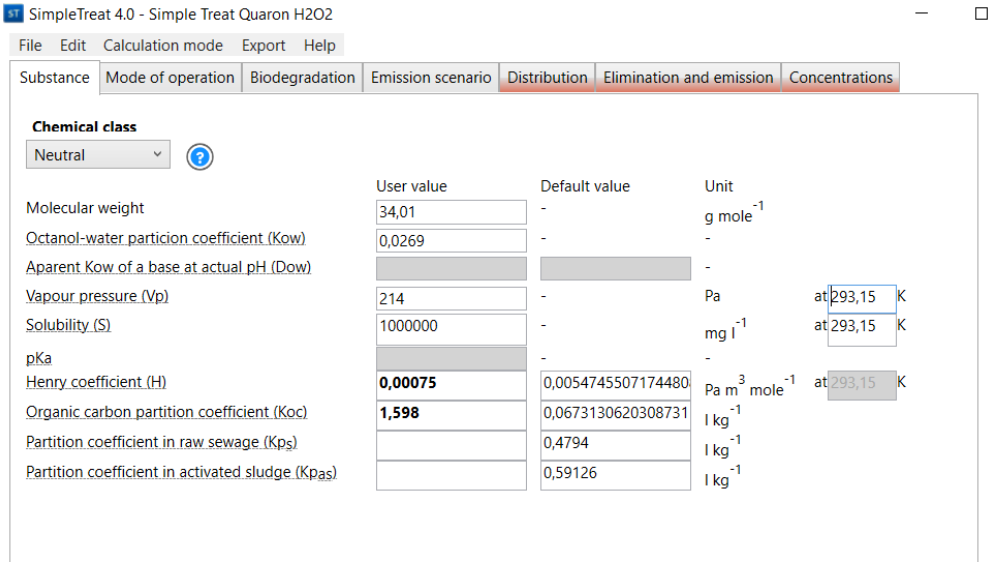
Sewage flow (Q)	0,2	m^3 d^{-1} PE^{-1}
Mass of sewage solids (SO)	0,09	kg d^{-1} PE^{-1}
Mass of O2 binding material in sewage (BOD)	60	g O_2 d^{-1} PE^{-1}
Fraction of BOD in sewage solids (FB)	0,5417	-
Fraction of sewage solids removed by primary sedimentation (FS)	0,67	-
Sludge loading rate (kslr)	0,1	-
pH	7	-
Concentration suspended solids effluent	0,03	kg m^{-3}

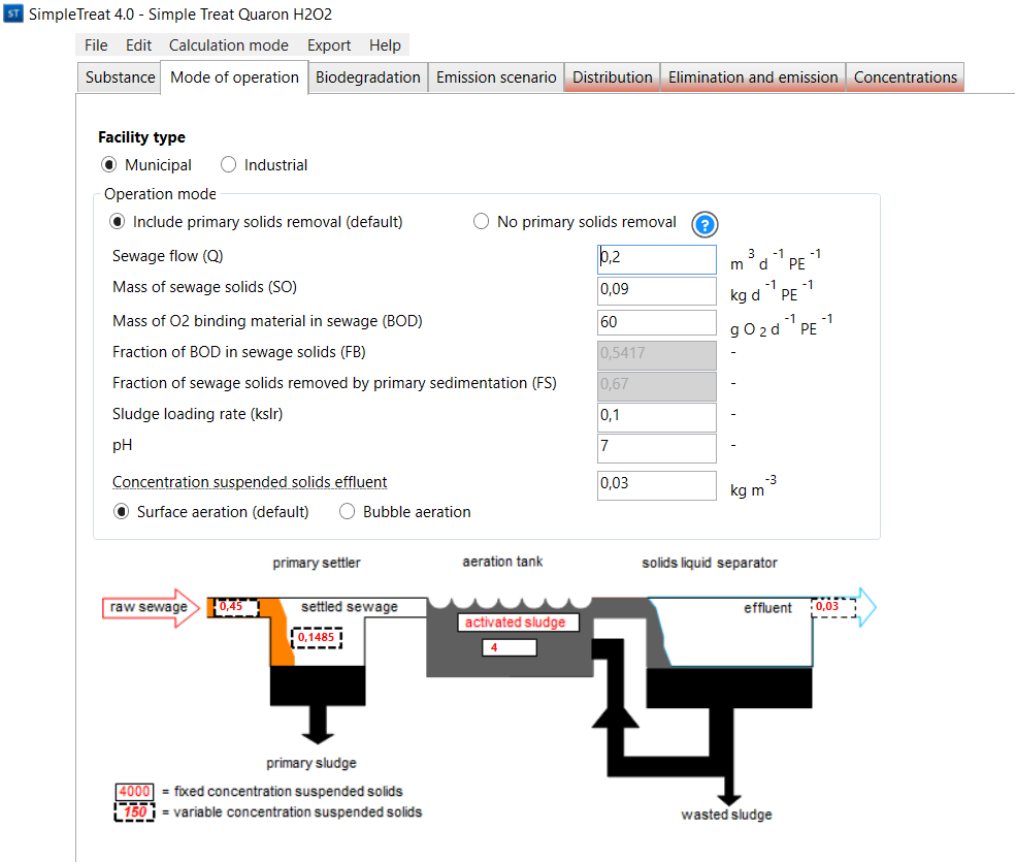
(•) Surface aeration (default) ( ) Bubble aeration

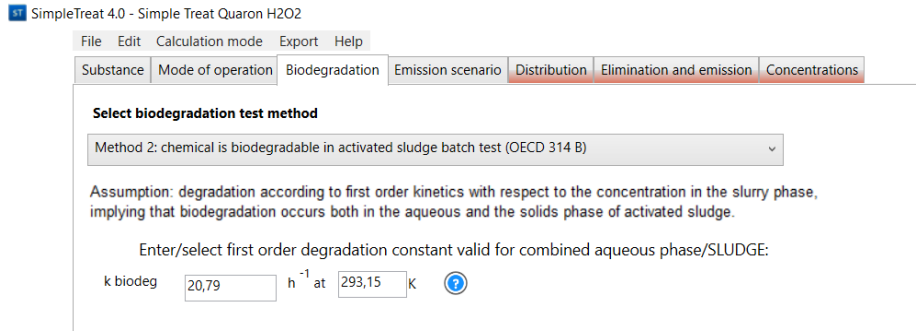


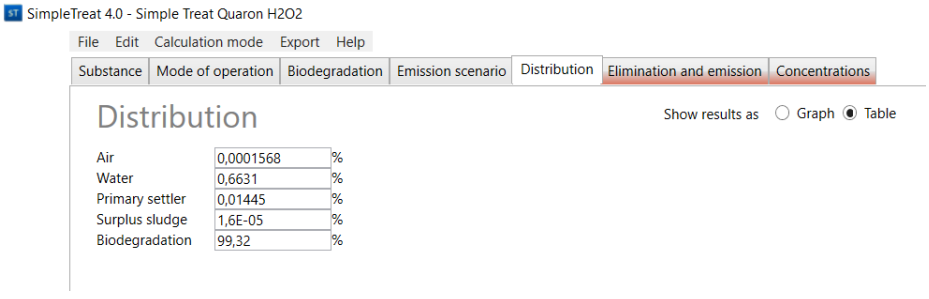

SimpleTreat 4.0 - Simple Treat Quaron PAA
File Edit Calculation mode Export Help
Substance Mode of operation Biodegradation Emission scenario Distribution Elimination and emission Concentrations
Select biodegradation test method
Method 2: chemical is biodegradable in activated sludge batch test (OECD 314 B)
Assumption: degradation according to first order kinetics with respect to the concentration in the slurry phase, implying that biodegradation occurs both in the aqueous and the solids phase of activated sludge.
Enter/select first order degradation constant valid for combined aqueous phase/SLUDGE:
k biodeg 13,86 h -1 at 293,15 K


SimpleTreat 4.0 - Simple Treat Quaron PAA
File Edit Calculation mode Export Help
Substance Mode of operation Biodegradation Emission scenario Distribution Elimination and emission Concentrations
Distribution
Show results as Graph Table
Air 0,04657 %
Water 0,9891 %
Primary settler 0,0132 %
Surplus sludge 2,698E-05 %
Biodegradation 98,95 %


SimpleTreat 4.0 - Simple Treat Quaron H2O2
File Edit Calculation mode Export Help
Substance Mode of operation Biodegradation Emission scenario Distribution Elimination and emission Concentrations
Chemical class
Neutral
User value Default value Unit
Molecular weight 34,01 - g mole -1
Octanol-water particion coefficient (Kow) 0,0269 - -
Aparent Kow of a base at actual pH (Dow) - -
Vapour pressure (Vp) 214 - Pa at 293,15 K
Solubility (S) 1000000 - mg l -1 at 293,15 K
pKa - -
Henry coefficient (H) 0,00075 0,0054745507174480 Pa m 3 mole -1 at 293,15 K
Organic carbon partition coefficient (Koc) 1,598 0,0673130620308731 l kg -1
Partition coefficient in raw sewage (Kps) 0,4794 l kg -1
Partition coefficient in activated sludge (Kpas) 0,59126 l kg -1







3.4 NEW INFORMATION ON THE ACTIVE SUBSTANCE

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3.5 RESIDUE BEHAVIOUR

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3.6 SUMMARIES OF THE EFFICACY STUDIES (B.5.10.1-XX)

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3.7 CONFIDENTIAL ANNEX

Please see separate document

3.8 OTHER

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