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

PRODUCT ASSESSMENT REPORT OF A FAMILY FOR UNION AUTHORISATION APPLICATIONS

SOPUROXID

Product types 2; 3 & 4

with Peracetic acid as A.I.

Case Number in R4BP: BC-KV033704-17

eCA : Belgium

Date: 17 June 2021 – **Version 3**

Table of Contents

1 ASSESSMENT REPORT

1.1 Summary of the product assessment

1.1.1 Administrative information

1.1.1.1 Identifier of *SOPUROXID*

Identifier	**Country (if relevant)**
SOPUROXID	Union Authorisation – eCA Belgium

1.1.1.2 Authorisation holder

<table>
<tr><td rowspan="2">Name and address of the authorisation holder</td><td>Name</td><td>SOPURA</td></tr>
<tr><td>Address</td><td>Rue de Trazegnies 199,
BE-6180 COURCELLES
Belgium</td></tr>
<tr><td>Pre-submission phase started on</td><td colspan="2">22nd of March 2016 (communication number: D(2016)2192)</td></tr>
<tr><td>Pre-submission phase concluded on</td><td colspan="2">30th of June 2016</td></tr>
<tr><td>Authorisation number</td><td colspan="2">To be completed upon completion of authorisation process</td></tr>
<tr><td>Date of the authorisation</td><td colspan="2">To be completed upon completion of authorisation process</td></tr>
<tr><td>Expiry date of the authorisation</td><td colspan="2">To be completed upon completion of authorisation process</td></tr>
</table>

1.1.1.3 Manufacturer(s) of the products of *SOPUROXID*

Name of manufacturers	SOPURA SOPURA Química HYPRED SAS – KERSIA Group
Address of manufacturers	- SOPURA Rue de Trazegnies 199, 6180 COURCELLES - BELGIUM - SOPURA Quimica Pol. Ind. " La Canaleta " Avinguda Júpiter n° 7 25300 TARREGA (LLEIDA) - SPAIN - HYPRED SAS – KERSIA Group 55, Boulevard Jules Verger (BP 10180) 35803 DINARD Cedex - FRANCE
Location of manufacturing sites	- SOPURA Rue de Trazegnies 199, BE-6180 COURCELLES BELGIUM - SOPURA Quimica Pol. Ind. " La Canaleta " Avinguda Júpiter n° 7

	25300 TARREGA (LLEIDA) SPAIN - HYPRED SAS – KERSIA Group 55, Boulevard Jules Verger (BP 10180) 35803 DINARD Cedex - FRANCE - KERSIA Polska Sp. z o.o. Niepruszewo, ul. Kasztanowa 64-320 Buk - POLAND

1.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	Peracetic acid
Name of manufacturer	SOPURA SOPURA Química HYPRED SAS – KERSIA Group
Address of manufacturer	- SOPURA Rue de Trazegnies 199, 6180 COURCELLES - BELGIUM - SOPURA Quimica Pol. Ind. " La Canaleta " Avinguda Júpiter n° 7 25300 TARREGA (LLEIDA) - SPAIN - HYPRED SAS – KERSIA Group 55, Boulevard Jules Verger (BP 10180) 35803 DINARD Cedex - FRANCE
Location of manufacturing sites	- SOPURA Rue de Trazegnies 199, BE-6180 COURCELLES BELGIUM - SOPURA Quimica Pol. Ind. " La Canaleta " Avinguda Júpiter n° 7 25300 TARREGA (LLEIDA) SPAIN - HYPRED SAS – KERSIA Group 55, Boulevard Jules Verger (BP 10180) 35803 DINARD Cedex - FRANCE - KERSIA Polska Sp. z o.o. Niepruszewo, ul. Kasztanowa 64-320 Buk - POLAND

Status of hydrogen peroxide

The Biocidal Products Committee (BPC) agreed during the meeting on 27 April 2017[1] that hydrogen peroxide should not be regarded as a second active substance in the case of a biocidal product based on the active substance peracetic acid. Therefore, the manufacturers of hydrogen peroxide are not listed here.

Note however that, for the exposure and risk assessment, hydrogen peroxide is considered.

1.1.2 *SOPUROXID* - Family composition and formulation

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

SOPUROXID is a family composed of 4 meta-SPC : Meta-SPC 1 and Meta-SPC 4 present similar uses, but with different concentrations (5% PAA and 15% PAA respectively). Meta-SPC 2 covers uses and disinfection by fogging. Meta-SPC 3 covers application by foaming. This means that uses in Meta-SPC 2 and 3 have dedicated scenario while, for most uses in Meta-SPC 1 & 4, the same scenario can be used, with an adaptation for the difference in concentration.

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 ☒

Yes & No as SOPUROXID contains two products which are identical to the products that were evaluated in connection with the approval for listing of the active substance (Sopuroxid 5 and Sopuroxid 15), but SOPUROXID also contains 4 new products.

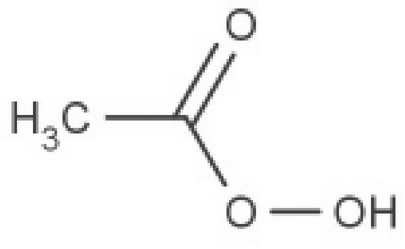
In total, 4 META SPC's were defined for this SOPUROXID family according to following principles:

(1) Similar composition
(2) Similar uses and common set of RMM's
(3) Similar levels of risk and hence same classification and labelling
(4) Similar levels of efficacy

1.1.2.1 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	-

[1] Minutes of the 20th meeting of the Biocidal Products Committee (BPC) held on 27 April 2017. BPC-M-20-2017. 16 June 2017.

Structural formula	

Peracetic acid is produced by reacting hydrogen peroxide (H_2O_2) with acetic acid in aqueous solution. In this process, peracetic acid is obtained in the form of aqueous solutions containing peracetic acid, acetic acid, hydrogen peroxide and water.
The specifications are based on the starting materials acetic acid and hydrogen peroxide. The specification of (starting material) acetic acid is as in accordance to Regulation 231/2012. The minimum purity of acetic acid is >99.8%
For (starting material) hydrogen peroxide the specification is as in the hydrogen peroxide CAR in PTs 1-6, and the purity/contents in aqueous solution is 35 - 69.9%, as in Regulation (EU) 2015/1730.

1.1.2.2 Candidate(s) for substitution

The active substances relevant to products of SOPUROXIDare not identified as candidates for substitution.

1.1.2.3 Qualitative and quantitative information on the composition of the *SOPUROXID* Family

SOPUROXID is based on the equilibrium peracetic acid – hydrogen peroxide, in presence of acetic acid, as defined in the CAR of the active substance.

The substances listed in the table below are limited to Active Ingredients, substances being part of the active substance equilibrium and those substances identified as SoCs. It should be noted that the concentrations indicated here are those obtained once the equilibrium is established.

<table>
<tr><th rowspan="2">Common name</th><th rowspan="2">IUPAC name</th><th rowspan="2">Function</th><th rowspan="2">CAS number</th><th rowspan="2">EC number</th><th colspan="2">Content (%)</th></tr>
<tr><th>Min</th><th>Max</th></tr>
<tr><td>Peracetic Acid[2]</td><td>Peracetic Acid</td><td>Active substance</td><td>79-21-0</td><td>201-186-8</td><td>3.2</td><td>15</td></tr>
<tr><td>Hydrogen peroxide</td><td>Hydrogen peroxide</td><td>part of active substance equilibrium</td><td>7722-84-1</td><td>231-765-0</td><td>16.5</td><td>23.5</td></tr>
<tr><td>Acetic acid</td><td>Acetic acid</td><td>part of active substance equilibrium</td><td>64-19-7</td><td>200-580-7</td><td>5.5</td><td>16.7</td></tr>
<tr><td rowspan="2">Sulfuric acid</td><td rowspan="2">Sulfuric acid</td><td>Non-active substance : Supporting acid as catalyser</td><td rowspan="2">7664-93-9</td><td rowspan="2">231-639-5</td><td>0.2</td><td>0.8</td></tr>
<tr><td>Non-active substance : Conductivity co-formulant</td><td>0.0</td><td>23.24</td></tr>
<tr><td>Other co-formulants</td><td colspan="6">Please see Confidential Annex</td></tr>
</table>

1.1.2.4 Qualitative and quantitative information on the composition of SOPUROXID and its Meta SPC

Please see Confidential Annex.

[2] It has to be noted that the concentration of peracetic acid indicated here is the pure concentration at equilibrium. A substance, as defined by the Article 3(2) of the BPR referring to Regulation (EC) No 1970/2006 (REACH) includes any additive necessary to preserve its stability and any impurity deriving from the process used. As a consequence, when referring to the content of the AS, it is not possible to consider solely the content of the main constituent of the AS ("pure" active substance) on its own without impurities. However, in this precise exceptional case, the peracetic acid active substance is produced from the acetic acid and hydrogen peroxide directly during the equilibrium establishment, and thus is, by definition, containing no impurities.

1.1.2.5 Information on technical equivalence

The sources of the active substance are the same as the ones evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation No. 528/2012. Therefore, an assessment of technical equivalence of the active substance is not required.

1.1.2.6 Information on the substance(s) of concern

The active substance peracetic acid is an equilibrium between PAA, Acetic Acid, H_2O_2 and water. Only PAA is considered to bring the biocidal action.
Acetic Acid and H_2O_2 are considered as being part of the active substance PAA (as it is defined in the CAR of PAA) and influences the equilibrium and the content of PAA.

The main intrinsic properties of PAA and H_2O_2 are described by the harmonised classification and labelling (incl. certain specific concentration limits) specified in Annex VI of the CLP Regulation.
Within the risk assessment both substances (PAA and H_2O_2) are described and evaluated for their exposure and risk.

H_2O_2 and Acetic Acid are not considered as SoCs.

Sulfuric acid is the single SoC but only for Meta-SPC 1, whose risk assessment is fully covered in the local risk assessment of the active substance.

Common name	IUPAC name	Function	CAS number	EC number	Content (%)		Risk Assessment	Information	Covered
					Min	Max			
Peracetic acid	ethaneperoxoic acid	Active Substance	79-21-0	201-186-8	3.2	15	HH	Active Substance	YES Biocidal active substance
							ENV	Harmonized classification	
Hydrogen peroxide	Hydrogen peroxide	Part of active substance equilibrium	7722-84-1	231-765-0	16.5	23.5	HH	Part of active substance equilibrium, but not determined as “active substance” as such as described in the minutes of the 20th BPC meeting (2017)	YES Part of active substance equilibrium
							ENV		
Sulfuric acid	Sulfuric acid	Non-Active Substance - Supporting acid (catalyser) / Conductivity co-formulant	7664-93-9	231-639-5	0.2	24.04	HH	Product that is used has a concentration > 24%. This is represented with a classification as Skin Corr. 1A (H314), as per harmonized classification (SCL). $OEL_{long-term}$ = 0.05 mg/m^3 As the products of SOPUROXID are already classified as Skin Corr. 1A, this hazardous property of this substance will not influence the risk assessment of SOPUROXID, therefore no further assessments were performed	**YES** but only considered relevant for meta SPC1 and more specifically Sopuroxid 5C where the max. concentration is 24.04%. In all other meta SPC the max. concentration is 1% which is below the concentration limit for classification. **Substance of Concern for HH**
Other co-formulants		Please see Confidential Annex							

1.1.2.7 Type of formulation

SL - Soluble concentrate

1.1.3 Hazard and precautionary statements

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

Meta-SPC 1

Classification	
Hazard category	Ox Liq 2 Org Perox G Met Corr 1 Skin corrosion cat. 1A Eye Damage cat. 1 Acute tox 4 (oral, dermal and inhalation) STOT SE 3 Aquatic Chronic 1
Hazard statement	H272: May intensify fire; oxidizer H290 : May be corrosive to metals H314: Causes severe skin burns and eye damage H318: Causes serious eye damage H302: Harmful if swallowed. H312: Harmful in contact with skin. H332: Harmful if inhaled. H335: May cause respiratory irritation. H410 : Very toxic to aquatic life with long-lasting effects)
Labelling	
Signal words	DANGER
Hazard statements	H272: May intensify fire; oxidizer H290 : May be corrosive to metals H314: Causes severe skin burns and eye damage H302: Harmful if swallowed. H312: Harmful in contact with skin. H332: Harmful if inhaled. H335: May cause respiratory irritation. H410 : Very toxic to aquatic life with long-lasting effects)

Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P221: Take any precaution to avoid mixing with combustibles. P235 : Keep cool. P280: Wear protective gloves/protective clothing/eye protection/face protection P260: Do not breathe vapours/spray. P261: Avoid breathing vapours/spray. P264: Wash hands 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 environment. P310: Immediately call a POISON CENTER/doctor. P321: Specific treatment P330: Rinse mouth. P363: Wash contaminated clothing before reuse. P301+312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P301+330+331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting P302+352: IF ON SKIN: Wash with plenty of water. P303+361+353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower. P304+340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. P361+364: Take off immediately all contaminated clothing and wash it before reuse. P391: Collect spillage. P405: Store locked up. P403+233: Store in a well ventilated place. Keep container tightly closed. P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

GHS Pictogram	GHS03:  GHS05:  GHS07:  GHS09: 

Meta-SPC 2

Classification	
Hazard category	Ox Liq 2 Org Perox G Met Corr 1 Skin corrosion cat. 1A Eye Damage cat. 1 Acute tox 4 (dermal and inhalation) STOT SE 3 Aquatic Chronic 1
Hazard statement	H272: May intensify fire; oxidizer H290 : May be corrosive to metals H314: Causes severe skin burns and eye damage H318: Causes serious eye damage H302: Harmful if swallowed. H312: Harmful in contact with skin. H332: Harmful if inhaled. H335: May cause respiratory irritation. H410 : Very toxic to aquatic life with long-lasting effects)
Labelling	
Signal words	DANGER
Hazard statements	H272: May intensify fire; oxidizer H290 : May be corrosive to metals H314: Causes severe skin burns and eye damage H302: Harmful if swallowed. H312: Harmful in contact with skin. H332: Harmful if inhaled. H335: May cause respiratory irritation. H410 : Very toxic to aquatic life with long-lasting effects)

Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P221: Take any precaution to avoid mixing with combustibles. P235 : Keep cool. P280: Wear protective gloves/protective clothing/eye protection/face protection P260: Do not breathe vapours/spray. P261: Avoid breathing vapours/spray. P264: Wash hands 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 environment. P310: Immediately call a POISON CENTER/doctor. P321: Specific treatment P330: Rinse mouth. P363: Wash contaminated clothing before reuse. P301+312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P301+330+331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting P302+352: IF ON SKIN: Wash with plenty of water. P303+361+353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower. P304+340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. P361+364: Take off immediately all contaminated clothing and wash it before reuse. P391: Collect spillage. P405: Store locked up. P403+233: Store in a well ventilated place. Keep container tightly closed. P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

GHS Pictogram	GHS03:  GHS05:  GHS07:  GHS09: 

Meta-SPC 3

Classification	
Hazard category	Ox Liq 2 Org Perox G Met Corr 1 Skin corrosion cat. 1A Eye Damage cat. 1 Acute tox 4 (dermal and inhalation) STOT SE 3 Aquatic Chronic 1
Hazard statement	H272: May intensify fire; oxidizer H290 : May be corrosive to metals H314: Causes severe skin burns and eye damage H318: Causes serious eye damage H302: Harmful if swallowed. H312: Harmful in contact with skin. H332: Harmful if inhaled. H335: May cause respiratory irritation. H410 : Very toxic to aquatic life with long-lasting effects)
Labelling	
Signal words	DANGER
Hazard statements	H272: May intensify fire; oxidizer H290 : May be corrosive to metals H314: Causes severe skin burns and eye damage H302: Harmful if swallowed. H312: Harmful in contact with skin. H332: Harmful if inhaled. H335: May cause respiratory irritation. H410 : Very toxic to aquatic life with long-lasting effects)

Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P221: Take any precaution to avoid mixing with combustibles. P235 : Keep cool. P280: Wear protective gloves/protective clothing/eye protection/face protection P260: Do not breathe vapours/spray. P261: Avoid breathing vapours/spray. P264: Wash hands 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 environment. P310: Immediately call a POISON CENTER/doctor. P321: Specific treatment P330: Rinse mouth. P363: Wash contaminated clothing before reuse. P301+312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P301+330+331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting P302+352: IF ON SKIN: Wash with plenty of water. P303+361+353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower. P304+340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. P361+364: Take off immediately all contaminated clothing and wash it before reuse. P310: Immediately call a POISON CENTER/doctor. P391: Collect spillage. P405: Store locked up. P403+233: Store in a well ventilated place. Keep container tightly closed. P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

GHS Pictogram	GHS03:  GHS05:  GHS07:  GHS09: 

Meta-SPC 4

Classification	
Hazard category	Flam Liq 3 Org Perox F Met Corr 1 Skin corrosion cat. 1A Eye Damage cat. 1 Acute tox 4 (oral and inhalation) Acute Tox 3 (Dermal) STOT SE 3 Aquatic Chronic 1
Hazard statement	H226: Flammable liquid and vapour H242: Heating may cause a fire H290; May be corrosive to metals H311: Toxic in contact with skin H314: Causes severe skin burns and eye damage H318: Causes serious eye damage H302: Harmful if swallowed. H332: Harmful if inhaled. H335: May cause respiratory irritation. H410 : Very toxic to aquatic life with long-lasting effects)
Labelling	
Signal words	DANGER

Hazard statements	H226: Flammable liquid and vapour H242: Heating may cause a fire H290; May be corrosive to metals H311: Toxic in contact with skin H314: Causes severe skin burns and eye damage H302: Harmful if swallowed. H332: Harmful if inhaled. H335: May cause respiratory irritation. H410 : Very toxic to aquatic life with long-lasting effects)
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P221: Take any precaution to avoid mixing with combustibles. P234 – Keep only in original packaging P235 : Keep cool. P280: Wear protective gloves/protective clothing/eye protection/face protection P260: Do not breathe vapours/spray. P261: Avoid breathing vapours/spray. P264: Wash hands 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 environment. P310: Immediately call a POISON CENTER/doctor. P321: Specific treatment P330: Rinse mouth. P363: Wash contaminated clothing before reuse. P301+312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P301+330+331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting P302+352: IF ON SKIN: Wash with plenty of water. P303+361+353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower. P304+340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. P361+364: Take off immediately all contaminated clothing and wash it before reuse. P391: Collect spillage. P405: Store locked up. P403+235: Store in a well ventilated place. Keep cool. P403+233: Store in a well ventilated place. Keep container tightly closed. P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

GHS Pictogram	 GHS02, Warning :  GHS05, Danger:  GHS07, Warning:  GHS09, Warning:

1.1.4 Authorised use(s)

Meta SPC1

PT2 - Use #1.1 : Disinfection of surfaces in industrial, public and ~~**HEALTHCARE / non-medical areas**~~ non-medical healthcare areas - manual treatment (mopping)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor - In Industrial, public and healthcare/non-medical areas : Disinfection of hard/non-porous surfaces by manual treatment (mopping) with prior cleaning
Application method(s)	Diluted product is applied by mopping with the appropriate tool (e.g. flat mops or cleaning cloths). After application, the diluted product is drained.
Application rate(s) and frequency	Against bacteria and yeasts : ~~**HEALTHCARE / non-medical areas**~~ **Non-medical healthcare areas** With 0.048% PAA (Dilution of the product at 0.96 % ⇔ 960 mL / 100 L) at Room Temperature in 5 min contact time. Application rate : 20 mL/m².

	Use other that in HEALTHCARE With 0.048% PAA (Dilution of the product at 0.96 % ⬄ 960 mL / 100 L) in 15 min contact time, efficient use temperature from +4°C up to Room Temperature. Application rate : 30 mL/m².
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

Items to be disinfected by mopping have to stay sufficiently wet during the required contact time to allow optimal disinfection

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing and loading. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Re-entry is only permitted once the air concentrations of peracetic acid and hydrogen peroxide have dropped below the respective reference values (AEC). After the application, the room must be ventilated, preferably by mechanical ventilation. The duration of the ventilation period has to be established by measurement with suitable measurement equipment (specified by applicant). Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #1.2 : Disinfection of surfaces in industrial, public and ~~HEALTHCARE / non-medical areas~~ non-medical healthcare areas - manual treatment (spraying)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In Industrial, public and and healthcare/non-medical areas : Disinfection of hard/non-porous surfaces by manual treatment (spraying) with prior cleaning
Application method(s)	Diluted product is applied by spraying using a small spraying can.
Application rate(s) and frequency	Against bacteria and yeasts : ~~**HEALTHCARE / non-medical areas**~~ **Non-medical healthcare areas** With 0.048% PAA (Dilution of the product at 0.96 % ⬄ 960 mL / 100 L) at Room Temperature in 5 min contact time. Application rate : 20 mL/m². **Use other that in HEALTHCARE** With 0.048% PAA (Dilution of the product at 0.96 % ⬄ 960 mL / 100 L) in 15 min contact time, efficient use temperature from +4°C up to Room Temperature. Application rate : 30 mL/m².
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance.

"The treated surface should not be allowed to dry prior to rinsing. Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #1.3 : CIP in the pharmaceutical and cosmetic industry

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor - In pharmaceutical and cosmetic industry : Disinfection of hard/non-porous surfaces by CIP procedures (with circulation) with prior cleaning
Application method(s)	Diluted product does automatically circulate from the CIP holding tanks through closed pipework and installations. After the disinfection procedure, the vessels (pipework and tanks) are drained and rinsed with water under closed system conditions.
Application rate(s) and frequency	Against bacteria and yeasts : With 0.032% PAA (Dilution of the product at 0.64 % ⇔ 640 mL / 100 L) in 15 min contact time, efficient use temperature from +4°C up to Room Temperature.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing & loading phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading. Rinse the pump and disconnect it from the installation before maintenance”

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #1.4 : Surface disinfection in greenhouses via spraying by user with personal enclosure (in absence of plants - for general hygiene purpose only)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In greenhouses : Disinfection of hard/non-porous surfaces by spraying
Application method(s)	Diluted product is automatically applied in all directions via a spraying device The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device)
Application rate(s) and frequency	Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.96 % ⇔ 960 mL / 100 L) in 60 min contact time. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use[3]

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing & loading phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading and application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning The application should only take place with the user in a personal enclosure and no other person is present. Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing". Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #1.5 : Surface disinfection in greenhouses via spraying by user without personal enclosure (in absence of plants - for general hygiene purpose only)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In greenhouses :

3 Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

	Disinfection of hard/non-porous surfaces by spraying
Application method(s)	Diluted product is automatically applied in all directions via a spraying device.
Application rate(s) and frequency	Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.96 % ⇔ 960 mL / 100 L) in 60 min contact time. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance "The treated surface should not be allowed to dry prior to rinsing". Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #1.6 : Disinfection of agriculture & horticulture equipment by soaking (in absence of plants - for general hygiene purpose only)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In agriculture/horticulture areas : Disinfection of hard/non-porous surfaces/equipment (small parts such as equipment, spare parts, tools, valves, hoses, ...) by immersion in soaking baths with prior cleaning
Application method(s)	The concentrated product is pumped in a soaking bath and diluted to the desired use concentration, before immersion of items to be disinfected
Application rate(s) and frequency	Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.96 % ⇔ 960 mL / 100 L) in 60 min contact time.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the application phase. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the post-application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance”

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #1.7 : Disinfection of surfaces and agriculture/horticulture equipment by spraying - manually (in absence of plants - for general hygiene purpose only)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In agriculture/horticulture areas : Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	The diluted solution is manually sprayed on the equipment using spraying equipment. Spraying is only applied downwards and in a horizontal direction.
Application rate(s) and frequency	Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.96 % ⇔ 960 mL / 100 L) in 60 min contact time. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target

organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing".

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #1.8 : Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (in absence of plants - for general hygiene purpose only)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In agriculture/horticulture areas : Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	Diluted product is applied by spraying in an automated way Spraying is only applied downwards and in a horizontal direction.
Application rate(s) and frequency	Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.96 % ⇔ 960 mL / 100 L) in 60 min contact time
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning The application is automatic and should only take place when no one is present in the treated area. Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing".

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #1.9 : Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (closed room) (in absence of plants - for general hygiene purpose only)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In agriculture/horticulture areas : Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	Diluted product is applied by spraying in an automated way without any user being present.
Application rate(s) and frequency	Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.96 % ⇔ 960 mL / 100 L) in 60 min contact time.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging	HDPE with screw and venting caps (weight depends on

material	density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing & loading. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning The application is automatic and should only take place when no one is present in the treated area. Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing".

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT3 - Use #1.10 : Disinfection of animal housing – via low-pressure spraying by user with personal enclosure

Product Type(s)	3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Viruses
Field of use	Indoor – In animal housing: Disinfection of hard/non-porous surfaces by spraying with prior cleaning
Application method(s)	Diluted product is automatically applied in all directions by low-pressure manual spraying via a spraying device

	The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device)
Application rate(s) and frequency	Against bacteria, yeasts and viruses : With 0.064% PAA (Dilution of the product at 1.28 % ⇔ 1280 mL / 100 L) in 60 min contact time. Application rate between 20 and 300 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

It has to be assured that animals are not present when treatment takes place.

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading and application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning The application should only take place with the user in a personal enclosure and no other person is present. Rinse the pump and disconnect it from the installation before maintenance” “The treated surface should not be allowed to dry prior to rinsing”. Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT3 - Use #1.11 : Disinfection of animal housing via low-pressure manual spraying by user without personal enclosure

Product Type(s)	3

Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Viruses
Field of use	Indoor – In animal housing : Disinfection of hard/non-porous surfaces by spraying with prior cleaning
Application method(s)	Diluted product is automatically applied in all directions by low-pressure automatic spraying via a spraying device
Application rate(s) and frequency	Against bacteria, yeasts and viruses : With 0.064% PAA (Dilution of the product at 1.28 % ⇔1280 mL / 100 L) in 60 min contact time. Application rate between 20 and 300 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

It has to be assured that animals are not present when treatment takes place.

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance” “The treated surface should not be allowed to dry prior to rinsing”. Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT3 - Use #1.12 : Disinfection of boots in footbaths in animal housing/husbandries

Product Type(s)	3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Viruses
Field of use	Indoor – in animal housing/husbandries : Disinfection of boots by dipping (not for walk-through) with prior cleaning.
Application method(s)	Diluted product is put in the footbath No rinse needed
Application rate(s) and frequency	Against bacteria, yeasts and viruses : With 0.064% PAA (Dilution of the product at 1.28 % ⇔ 1280 mL / 100 L) in 60 min contact time.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the application phase. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the post-application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance. Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT3 - Use #1.13 : Disinfection of equipment by dipping

Product Type(s)	3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Viruses
Field of use	Indoor Disinfection of hard/non-porous surfaces/equipment (small parts such as equipment, spare parts, tools, valves, hoses, ...) by immersion in soaking baths with prior cleaning
Application method(s)	The concentrated product is pumped in a soaking bath and diluted to the desired use concentration, before immersion of items to be disinfected
Application rate(s) and frequency	Against bacteria, yeasts and viruses : With 0.064% PAA (Dilution of the product at 1.28 % ⬄ 1280 mL / 100 L) in 60 min contact time.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is

mandatory during the application phase. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the post-application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance”

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #1.14 : Disinfection in Aseptic Filling Lines (crown corks, cheese moulds and food crates) - Automated spraying closed systems

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts bacterial spores Viruses Bacteriophages
Field of use	Indoor – In food and beverage industry : Disinfection of hard/non-porous surfaces by spraying with prior cleaning
Application method(s)	Diluted product is sprayed on the surfaces in an automated way without any user being present.
Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.96% ⇔ 960 mL / 100 L) in 15 min contact time , efficient use temperature from +4°C up to Room Temperature. - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 1.28 % ⇔ 1280 mL / 100 L) in 60 min contact time, efficient use temperature from +4°C up to Room Temperature. For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning The application is automatic and should only take place when no one is present in the treated area. Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing".

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #1.15 : Disinfection of equipment in the food and beverage industry by immersion

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts bacterial spores Viruses Bacteriophages

Field of use	Indoor – In food and beverage industry : Disinfection of hard/non-porous surfaces (small parts such as equipment, spare parts, tools, valves, hoses, ...) by immersion in soaking baths with prior cleaning
Application method(s)	The concentrated product is pumped in a soaking bath and diluted to the desired use concentration, before immersion of items to be disinfected
Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.96% ⇔ 960 mL / 100 L) in 15 min contact time , efficient use temperature from +4°C up to Room Temperature. - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 1.28 % ⇔ 1280 mL / 100 L) in 60 min contact time, efficient use temperature from +4°C up to Room Temperature. For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the application phase. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the post-application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance. Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #1.16 : Disinfection of heat and ion exchangers, membrane filters and glass and PET bottles – CIP procedures

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts bacterial spores Viruses Bacteriophages
Field of use	Indoor – In food and beverage industry : Disinfection of hard/non-porous surfaces by CIP procedures (with circulation) with prior cleaning
Application method(s)	Diluted product does automatically circulate from the CIP holding tanks through closed pipework and installations. After the disinfection procedure, the vessels (pipework and tanks) are drained and rinsed with water under closed system conditions.
Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.96% ⇔ 960 mL / 100 L) in 15 min contact time , efficient use temperature from +4°C up to Room Temperature. - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 1.28 % ⇔ 1280 mL / 100 L) in 60 min contact time, efficient use temperature from +4°C up to Room Temperature. For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing & loading. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading. Rinse the pump and disconnect it from the installation before maintenance”

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #1.17 : Disinfection of surfaces and equipment by low pressure spraying – spraying with personal enclosure

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts bacterial spores Viruses Bacteriophages
Field of use	Indoor – In food industry : Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	Diluted product is automatically applied in all directions by low-pressure spraying via a spraying device The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device).
Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.96% ⇔ 960 mL / 100 L) in 15 min contact time , efficient use temperature from +4°C up to Room Temperature. - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 1.28 % ⇔ 1280 mL / 100 L) in 60 min contact time, efficient use temperature from +4°C up to Room Temperature.

	For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading and application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning. The application should only take place with the user in a personal enclosure and no other person is present. Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing".

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #1.18 : Disinfection of surfaces and equipment by low pressure spraying – spraying without personal enclosure

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant

Target organism (including development stage)	Bacteria Yeasts bacterial spores Viruses Bacteriophages
Field of use	Indoor – In food industry : Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	Diluted product is automatically applied in all directions by low-pressure spraying via a spraying device.
Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.96% ⇔ 960 mL / 100 L) in 15 min contact time , efficient use temperature from +4°C up to Room Temperature. - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 1.28 % ⇔ 1280 mL / 100 L) in 60 min contact time, efficient use temperature from +4°C up to Room Temperature. For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning. Rinse the pump and disconnect it from the installation before maintenance” “The treated surface should not be allowed to dry prior to rinsing”.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #1.19 : Disinfection of surfaces and equipment by low pressure spraying, manually

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts bacterial spores Viruses Bacteriophages
Field of use	Indoor – In food industry : Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	Diluted product is manually applied by low-pressure spraying, only downwards and horizontal.
Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.96% ⇔ 960 mL / 100 L) in 15 min contact time , efficient use temperature from +4°C up to Room Temperature. - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 1.28 % ⇔ 1280 mL / 100 L) in 60 min contact time, efficient use temperature from +4°C up to Room Temperature. For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing".

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #1.20 : Disinfection of surfaces and equipment by low pressure spraying, automatically

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts bacterial spores Viruses Bacteriophages
Field of use	Indoor – In food industry : Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	The diluted product is sprayed on the equipment, on conveyor belt, automatically. The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming

	device). Spraying is only applied downwards and in a horizontal direction.
Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.96% ⇔ 960 mL / 100 L) in 15 min contact time , efficient use temperature from +4°C up to Room Temperature. - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 1.28 % ⇔ 1280 mL / 100 L) in 60 min contact time, efficient use temperature from +4°C up to Room Temperature. For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. RPE are not mandatory during the application phase, on the condition that the user remains in the control room and do not enter the treated area. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning The application is automatic and should only take place when no one is present in the treated area. Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing".

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #1.21 : Disinfection of surfaces and equipment by low pressure spraying – automatic spraying (closed room)

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts bacterial spores Viruses Bacteriophages
Field of use	Indoor – In food industry : Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	The diluted solution is sprayed on the surfaces in an automated way without any user being present.
Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.96% ⇔ 960 mL / 100 L) in 15 min contact time , efficient use temperature from +4°C up to Room Temperature. - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 1.28 % ⇔ 1280 mL / 100 L) in 60 min contact time, efficient use temperature from +4°C up to Room Temperature. For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) is not mandatory during the application phase, on condition that the user do not enter the treated area and remains in the control room. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing".

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #1.22 : Disinfection of inner surfaces (pipelines, tanks, vessels, …) by CIP

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts bacterial spores Viruses Bacteriophages
Field of use	Indoor – In food industry : Disinfection of hard/non-porous surfaces by CIP procedures (with circulation) with prior cleaning
Application method(s)	Diluted product does automatically circulate from the CIP holding tanks through closed pipework and installations. After the disinfection procedure, the vessels (pipework and tanks) are drained and rinsed with water under closed system conditions.
Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.96% ⇔ 960

	mL / 100 L) in 15 min contact time , efficient use temperature from +4°C up to Room Temperature. - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 1.28 % ⇔ 1280 mL / 100 L) in 60 min contact time, efficient use temperature from +4°C up to Room Temperature. For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing & loading phase. **Respiratory protection:**. Rinse the pump and disconnect it from the installation before maintenance" Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #1.23 : Disinfection of water used for rinsing of recycled items during the washing process

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts

Field of use	Indoor – In food industry : Disinfection of water (in clean conditions) used for rinsing of recycled items = Water from drinking water quality shortly stored in tanks until use to rinse items such as bottles. The water should be disinfected to avoid recontamination and in a extent to avoid cross-contamination of inner bottle surfaces
Application method(s)	Concentrated product will be pumped into a reservoir from which it is continuously dosed into the water stream. Dilution of the product to the intended in-use concentration occurs in the water stream. This application is a closed, automated process.
Application rate(s) and frequency	Against bacteria and yeasts : With 0.008% PAA (Dilution of the product at 0.16 % ⬄ 160 mL / 100 L) at Room Temperature in 15 min contact time.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:** Not mandatory. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning. Rinse the pump and disconnect it from the installation before maintenance”

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

Meta SPC2

PT2 - Use #2.1 : Room Disinfection by fogging - In industrial, public and healthcare/non-medical areas (pharmaceutical and cosmetic industry)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts bacterial spores
Field of use	Indoor – In industrial, public and healthcare/non-medical areas : Disinfection of hard/non-porous surfaces by fogging ~~without prior cleaning~~
Application method(s)	By fogging with the diluted product
Application rate(s) and frequency	Active against bacteria (including bacterial spores) and yeasts : With 5.6 mL/m^3 (Dilution of the product at 40% ⬄ 40 L / 100 L ⬄ 1.28% PAA) at Room Temperature in 2h contact time (after diffusion)
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance. Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #2.2 : Room Disinfection by fogging - In agriculture & horticulture areas (in absence of plants - for general hygiene purpose only)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In agriculture/horticulture areas : Disinfection of hard/non-porous surfaces by fogging with prior cleaning
Application method(s)	By fogging with the diluted product
Application rate(s) and frequency	Against bacteria and yeasts : With 5.6 mL/m^3 (Dilution of the product at 40% ⇔ 40 L / 100 L ⇔ 1.28% PAA) at Room Temperature in 2h contact time (after diffusion)
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing & loading. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance. Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT3 - Use #2.3 : Room Disinfection by fogging – In animal housing

Product Type(s)	3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In animal housing : Disinfection of hard/non-porous surfaces by fogging with prior cleaning
Application method(s)	By fogging with the diluted product
Application rate(s) and frequency	Against bacteria and yeasts : With 5.6 mL/m^3 (Dilution of the product at 40% ⬄ 40 L / 100 L ⬄ 1.28% PAA) at Room Temperature in 2h contact time (after diffusion)
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing & loading. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken

in case of poisoning Rinse the pump and disconnect it from the installation before maintenance. Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #2.4 : Room Disinfection by fogging – In storage rooms with special device in storage cellar or room

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts bacterial spores
Field of use	Indoor - In food/feed areas (storage rooms) : Disinfection of hard/non-porous surfaces by fogging ~~without prior cleaning~~
Application method(s)	By fogging with the diluted product
Application rate(s) and frequency	Active against bacteria (including bacterial spores) and yeasts With 5.6 mL/m^3 (Dilution of the product at 40% ⇔ 40 L / 100 L ⇔ 1.28% PAA) at Room Temperature in 2h contact time (after diffusion)
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing & loading.

Respiratory protection:. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance. Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

Meta SPC3

PT2 - Use #3.1 : Disinfection of surfaces in industrial, public and healthcare/non-medical areas – foam application on surfaces

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor - In industrial, public and healthcare/non-medical areas : Disinfection of hard/non-porous surfaces by foaming with prior cleaning
Application method(s)	By foaming via a small foaming can with the diluted product
Application rate(s) and frequency	Against bacteria and yeasts : **HEALTHCARE /non-medical areas** With 0.048% PAA (Dilution of the product at 1.5 % ⬄ 1500 mL / 100 L) at Room Temperature in 5 min contact time. Application rate : 20 mL/m² **Use other that in HEALTHCARE** With 0.048% PAA (Dilution of the product at 1.5 % ⬄ 1500 mL / 100 L) in 15 min contact time, efficient use temperature from +4°C up to Room Temperature.

	Application rate : 30 mL/m²
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance” “The treated surface should not be allowed to dry prior to rinsing”. Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #3.2 : Disinfection of surfaces and agriculture/horticulture equipment by foaming, manually (in absence of plants - for general hygiene purpose only)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development	Bacteria Yeasts

stage)	
Field of use	Indoor – In agriculture/horticulture areas : Disinfection of hard/non-porous surfaces/equipment by foaming with prior cleaning
Application method(s)	By foaming via a small foaming can with the diluted product Foaming is only applied downwards and in a horizontal direction.
Application rate(s) and frequency	Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 1.5 % ⇔ 1500 mL / 100 L) in 60 min contact time. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection:
Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.
Respiratory protection:.
Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.
Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase.
When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning
Rinse the pump and disconnect it from the installation before maintenance”
“The treated surface should not be allowed to dry prior to rinsing”.
Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #3.3 : Disinfection of surfaces and agriculture/horticulture equipment by automatic foaming (in absence of plants - for general hygiene purpose only)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In agriculture/horticulture areas : Disinfection of hard/non-porous surfaces/equipment by automatic foaming with prior cleaning
Application method(s)	The diluted product is foamed on the equipment in an automated way while the user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device). Foaming is only applied downwards and in a horizontal direction.
Application rate(s) and frequency	Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 1.5 % ⇔ 1500 mL / 100 L) in 60 min contact time.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing & loading. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning The application is automatic and should only take place when no one is present in the treated area. Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing".

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #3.4 : Disinfection of surfaces and agriculture/horticulture equipment by automatic foaming (closed rooms) (in absence of plants - for general hygiene purpose only)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In agriculture/horticulture areas : Disinfection of hard/non-porous surfaces/equipment by automatic foaming with prior cleaning
Application method(s)	The diluted product is foamed on the surfaces in an automated way without any user being present.
Application rate(s) and frequency	Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 1.5 % ⬄ 1500 mL / 100 L) in 60 min contact time.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing & loading. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target

organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning The application is automatic and should only take place when no one is present in the treated area. Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing".

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT3 - Use #3.5 : Disinfection of animal housing by foaming – foaming with personal enclosure

Product Type(s)	3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Viruses
Field of use	Indoor – In animal housing Disinfection of hard/non-porous surfaces by foaming with prior cleaning
Application method(s)	The diluted product is automatically foamed in all directions on the surfaces / walls, via a foaming device. The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device)
Application rate(s) and frequency	Against bacteria, yeasts and viruses : With 0.064% PAA (Dilution of the product at 2 % ⬄ 2000 mL / 100 L) in 60 min contact time.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

It has to be assured that animals are not present when treatment takes place.

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading and of a factor of 10 during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken The application should only take place with the user in a personal enclosure and no other person is present. Rinse the pump and disconnect it from the installation before maintenance” “The treated surface should not be allowed to dry prior to rinsing”. Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT3 - Use #3.6 : Disinfection of animal housing by foaming – foaming without personal enclosure

Product Type(s)	3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Viruses
Field of use	Indoor – In animal housing Disinfection of hard/non-porous surfaces by foaming with prior cleaning
Application method(s)	The diluted product is automatically foamed on the surfaces / walls, in all directions, via a foaming device.
Application rate(s) and frequency	Against bacteria, yeasts and viruses : With 0.064% PAA (Dilution of the product at 2 % ⇔ 2000 mL / 100 L) in 60 min contact time.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging	HDPE with screw and venting caps (weight depends on

material	density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

It has to be assured that animals are not present when treatment takes place.

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing". Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #3.7 : Disinfection of surfaces by foaming with personal enclosure

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts bacterial spores Virus Bacteriophages
Field of use	Indoor – In food industry :

	Disinfection of hard/non-porous surfaces by foaming with prior cleaning
Application method(s)	The diluted product is automatically foamed on the surfaces / walls, in all directions, via a foaming device. The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device)
Application rate(s) and frequency	Against bacteria & yeasts : With 0.048% PAA (Dilution of the product at 1.5% ⇔ 1500 mL / 100 L) in 15 min contact time, efficient use temperature from +4°C up to Room Temperature. Against bacteria (including bacterial spores), yeasts and viruses (including bacteriophages): With 0.064% PAA (Dilution of the product at 2 % ⇔ 2000 mL / 100 L) at Room Temperature in 60 min contact time. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading. Respiratory protection with an APF of 10 is required during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning The application should only take place with the user in a personal enclosure and no other person is present. Rinse the pump and disconnect it from the installation before maintenance” “The treated surface should not be allowed to dry prior to rinsing”. Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #3.8 : Disinfection of surfaces by foaming without personal enclosure

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Bacterial spores Virus Bacteriophages
Field of use	Indoor – In food industry : Disinfection of hard/non-porous surfaces by foaming with prior cleaning
Application method(s)	The diluted product is automatically foamed on the surfaces / walls, in all directions, via a foaming device.
Application rate(s) and frequency	Against bacteria & yeasts : With 0.048% PAA (Dilution of the product at 1.5% ⇔ 1500 mL / 100 L) in 15 min contact time, efficient use temperature from +4°C up to Room Temperature. Against bacteria (including bacterial spores), yeasts and viruses (including bacteriophages): With 0.064% PAA (Dilution of the product at 2 % ⇔ 2000 mL / 100 L) at Room Temperature in 60 min contact time. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**.

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing". Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

Meta SPC4

PT2 - Use #4.1 : Disinfection of surfaces in industrial, public and ~~HEALTHCARE / non-medical areas~~ non-medical healthcare areas - manual treatment (mopping)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor - In Industrial, public and healthcare/non-medical areas : Disinfection of hard/non-porous surfaces by manual treatment (mopping) with prior cleaning
Application method(s)	Diluted product is applied by mopping with the appropriate tool (e.g. flat mops or cleaning cloths). After application, the diluted product is drained.
Application rate(s) and frequency	Against bacteria and yeasts : **~~HEALTHCARE / non-medical areas~~** **Non-medical healthcare areas** With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) at Room Temperature in 5 min contact time. Application rate : 20 mL/m².

	Use other that in HEALTHCARE With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) ~~at minimum +4°C (and above, up to +20-25°C)~~ in 15 min contact time, efficient use temperature from +4°C up to Room Temperature. Applcation rate : 30 mL/m².
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

Items to be disinfected by mopping have to stay sufficiently wet during the required contact time to allow optimal disinfection.

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance” Re-entry is only permitted once the air concentrations of peracetic acid and hydrogen peroxide have dropped below the respective reference values (AEC). After the application, the room must be ventilated, preferably by mechanical ventilation. The duration of the ventilation period has to be established by measurement with suitable measurement equipment (specified by applicant). Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #4.2 : Disinfection of surfaces in industrial, public and ~~HEALTHCARE / non-medical areas~~ non-medical healthcare areas - manual treatment (spraying)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In Industrial, public and healthcare/non-medical areas : Disinfection of hard/non-porous surfaces by manual treatment (spraying) with prior cleaning
Application method(s)	Diluted product is applied by spraying using a small spraying can.
Application rate(s) and frequency	Against bacteria and yeasts : **~~HEALTHCARE / non-medical areas~~** **Non-medical healthcare areas** With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) at Room Temperature in 5 min contact time. Application rate : 20 mL/m². **Use other that in HEALTHCARE** With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) ~~at minimum +4°C (and above, up to +20-25°C)~~ in 15 min contact time, efficient use temperature from +4°C up to Room Temperature. Application rate : 30 mL/m².
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target

organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing". Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #4.3 : CIP in the pharmaceutical and cosmetic industry

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor - In pharmaceutical and cosmetic industry : Disinfection of hard/non-porous surfaces by CIP procedures (with circulation) with prior cleaning
Application method(s)	Diluted product does automatically circulate from the CIP holding tanks through closed pipework and installations. After the disinfection procedure, the vessels (pipework and tanks) are drained and rinsed with water under closed system conditions.
Application rate(s) and frequency	Against bacteria & yeasts : With 0.032% PAA (Dilution of the product at 0.2133 % <=> 213.33 mL / 100 L) in 15 min contact time, efficient use temperature from +4°C up to Room Temperature
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading. Rinse the pump and disconnect it from the installation before maintenance”

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #4.4 : Surface disinfection in greenhouses via spraying by user with personal enclosure (in absence of plants - for general hygiene purpose only)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In greenhouses : Disinfection of hard/non-porous surfaces by spraying with prior cleaning
Application method(s)	Diluted product is automatically applied in all directions by spraying via a spraying device The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device)
Application rate(s) and frequency	Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) in 60 min contact time. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading and the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning The application should only take place with the user in a personal enclosure and no other person is present. Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing". Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #4.5 : Surface disinfection in greenhouses via spraying by user without personal enclosure (in absence of plants - for general hygiene purpose only)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In greenhouses : Disinfection of hard/non-porous surfaces by spraying with prior cleaning
Application method(s)	Diluted product is automatically applied in all directions by spraying via a spraying device.

Application rate(s) and frequency	Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) in 60 min contact time. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance” “The treated surface should not be allowed to dry prior to rinsing”. Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #4.6 : Disinfection of agriculture & horticulture equipment by soaking (in absence of plants - for general hygiene purpose only)

Product Type(s)	2
Where relevant, an exact description of the	Not relevant

authorised use	
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In agriculture/horticulture areas : Disinfection of hard/non-porous surfaces/equipement (small parts such as equipment, spare parts, tools, valves, hoses, ...) by immersion in soaking baths with prior cleaning
Application method(s)	The concentrated product is pumped in a soaking bath and diluted to the desired use concentration, before immersion of items to be disinfected
Application rate(s) and frequency	Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) in 60 min contact time.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the application phase. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the post-application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance”

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #4.7 : Disinfection of surfaces and agriculture/horticulture equipment by spraying (in absence of plants - for general hygiene purpose only)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In agriculture/horticulture areas : Disinfection of hard/non-porous surfaces/equipement by spraying with prior cleaning
Application method(s)	The diluted solution is manually sprayed on the equipment using spraying equipment. Spraying is only applied downwards and in a horizontal direction.
Application rate(s) and frequency	Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) in 60 min contact time. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance "The treated surface should not be allowed to dry prior to rinsing".

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #4.8 : Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (in absence of plants - for general hygiene purpose only)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In agriculture/horticulture areas : Disinfection of hard/non-porous surfaces/equipement by spraying with prior cleaning
Application method(s)	Diluted product is applied by spraying in an automated way Spraying is only applied downwards and in a horizontal direction.
Application rate(s) and frequency	Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) in 60 min contact time.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning The application is automatic and should only take place when no one is present in the treated area. Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing".

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT2 - Use #4.9 : Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (closed room) (in absence of plants - for general hygiene purpose only)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In agriculture/horticulture areas : Disinfection of hard/non-porous surfaces/equipement by spraying with prior cleaning
Application method(s)	Diluted product is applied by spraying in an automated way without any user being present.
Application rate(s) and frequency	Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) in 60 min contact time.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning The application is automatic and should only take place when no one is present in the treated area. Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing".

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT3 – Use #4.10 : Disinfection of animal housing via low-pressure spraying by user with personal enclosure

Product Type(s)	3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Viruses
Field of use	Indoor – In animal housing : Disinfection of hard/non-porous surfaces by spraying with prior cleaning
Application method(s)	Diluted product is automatically applied in all directions by low-pressure manual spraying via a spraying device. The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device)
Application rate(s) and frequency	Against bacteria, yeasts and viruses : With 0.064% PAA (Dilution of the product at 0.42 % <=> 426.6 mL / 100 L) in 60 min contact time. Application rate between 20 and 300 mL/m^2

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

It has to be assured that animals are not present when treatment takes place.

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading and the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning The application is automatic and should only take place when no one is present in the treated area. Rinse the pump and disconnect it from the installation before maintenance” “The treated surface should not be allowed to dry prior to rinsing”. Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT3 – Use #4.11 : Disinfection of animal housing via low-pressure manual spraying by user without personal enclosure

Product Type(s)	3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Viruses

Field of use	Indoor – In animal housing : Disinfection of hard/non-porous surfaces by spraying with prior cleaning
Application method(s)	Diluted product is automatically applied in all directions by low-pressure automatic spraying via a spraying device.
Application rate(s) and frequency	Against bacteria, yeasts and viruses : With 0.064% PAA (Dilution of the product at 0.42 % <=> 426.6 mL / 100 L) in 60 min contact time. Application rate between 20 and 300 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

It has to be assured that animals are not present when treatment takes place.

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing". Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT3 – Use #4.12 : Disinfection of boots in footbaths in animal housing/husbandries

Product Type(s)	3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Viruses
Field of use	Indoor – in animal housing/husbandries : Disinfection of boots by dipping (not for walk-through) with prior cleaning.
Application method(s)	Diluted product is put in the footbath No rinse needed
Application rate(s) and frequency	Against bacteria, yeasts and viruses : With 0.064% PAA (Dilution of the product at 0.42 % <=> 426.6 mL / 100 L) in 60 min contact time.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the application phase. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the post-application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance". Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT3 – Use #4.13 : Disinfection of equipment by dipping

Product Type(s)	3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Viruses
Field of use	Indoor Disinfection of hard/non-porous surfaces/equipement (small parts such as equipment, spare parts, tools, valves, hoses, ...) by immersion in soaking baths with prior cleaning
Application method(s)	The concentrated product is pumped in a soaking bath and diluted to the desired use concentration, before immersion of items to be disinfected
Application rate(s) and frequency	Against bacteria, yeasts and viruses : With 0.064% PAA (Dilution of the product at 0.42 % <=> 426.6 mL / 100 L) in 60 min contact time.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the application phase. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the post-application phase. When the product is being used in areas accesible to the public, mark treated areas

during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance”

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #4.14 : Disinfection in Aseptic Filling Lines (crown corks, cheese moulds and food crates) - Automated spraying closed systems

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts bacterial spores Viruses Bacteriophages
Field of use	Indoor – In food and beverage industry : Disinfection of hard/non-porous surfaces by spraying with prior cleaning
Application method(s)	Diluted product is sprayed on the surfaces in an automated way without any user being present.
Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) in 15 min contact time, efficient use temperature from +4°C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 0.42 % <=> 426.6 mL / 100 L) in 60 min contact time, efficient use temperature from +4°C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):

	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning The application is automatic and should only take place when no one is present in the treated area. Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing".

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #4.15 : Disinfection of equipment in the food and beverage industry by immersion

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Bacterial spores Viruses Bacteriophages
Field of use	Indoor – In food and beverage industry : Disinfection of hard/non-porous surfaces/equipment (small parts such as equipment, spare parts, tools, valves, hoses, ...) by immersion in soaking baths with prior cleaning

Application method(s)	The concentrated product is pumped in a soaking bath and diluted to the desired use concentration, before immersion of items to be disinfected
Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) in 15 min contact time, efficient use temperature from +4°C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 0.42 % <=> 426.6 mL / 100 L) in 60 min contact time, efficient use temperature from +4°C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the application phase. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the post-application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance” Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #4.16 : Disinfection of heat and ion exchangers, membrane filters and glass and PET bottles – CIP procedures

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Bacterial spores Viruses Bacteriophages
Field of use	Indoor – In food and beverage industry : Disinfection of hard/non-porous surfaces by CIP procedures (with circulation) with prior cleaning
Application method(s)	Diluted product does automatically circulate from the CIP holding tanks through closed pipework and installations. After the disinfection procedure, the vessels (pipework and tanks) are drained and rinsed with water under closed system conditions.
Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) in 15 min contact time, efficient use temperature from +4°C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 0.42 % <=> 426.6 mL / 100 L) in 60 min contact time, efficient use temperature from +4°C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing & loading. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is

mandatory during mixing and loading. Rinse the pump and disconnect it from the installation before maintenance”

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #4.17 : Disinfection of surfaces and equipment by low pressure spraying – spraying with personal enclosure

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Bacterial spore Viruses Bacteriophages
Field of use	Indoor – In food industry : Disinfection of hard/non-porous surfaces/equipement by spraying with prior cleaning
Application method(s)	Diluted product is automatically applied in all directions by low-pressure spraying via a spraying device The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device)
Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) in 15 min contact time, efficient use temperature from +4°C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 0.42 % <=> 426.6 mL / 100 L) in 60 min contact time, efficient use temperature from +4°C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users

Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading and the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning The application should only take place with the user in a personal enclosure and no other person is present. Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing". Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #4.18 : Disinfection of surfaces and equipment by low pressure spraying – spraying without personal enclosure

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Bacterial spores Viruses Bacteriophages

Field of use	Indoor – In food industry : Disinfection of hard/non-porous surfaces/equipement by spraying with prior cleaning
Application method(s)	Diluted product is automatically applied in all directions by low-pressure spraying via a spraying device.
Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) in 15 min contact time, efficient use temperature from +4°C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 0.42 % <=> 426.6 mL / 100 L) in 60 min contact time, efficient use temperature from +4°C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning Rinse the pump and disconnect it from the installation before maintenance” “The treated surface should not be allowed to dry prior to rinsing”. Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #4.19 : Disinfection of surfaces and equipment by low pressure spraying, manually

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Bacterial spores Viruses Bacteriophages
Field of use	Indoor – In food industry : Disinfection of hard/non-porous surfaces/equipement by low-pressure spraying with prior cleaning
Application method(s)	Diluted product is manually applied by low-pressure spraying, only downwards and horizontal.
Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) in 15 min contact time, efficient use temperature from +4°C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 0.42 % <=> 426.6 mL / 100 L) in 60 min contact time, efficient use temperature from +4°C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing, loading & application phase. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory during the application phase. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning. Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing". Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #4.20 : Disinfection of surfaces and equipment by low pressure spraying, automatically

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Bacterial spores Viruses Bacteriophages
Field of use	Indoor – In food industry : Disinfection of hard/non-porous surfaces/equipement by low-pressure spraying with prior cleaning
Application method(s)	The diluted product is sprayed on the equipment The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device). Spraying is only applied downwards and in a horizontal direction.

Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) in 15 min contact time, efficient use temperature from +4°C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 0.42 % <=> 426.6 mL / 100 L) in 60 min contact time, efficient use temperature from +4°C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing & loading. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. RPE are not mandatory during the application phase, on the condition that the user remains in the control room and do not enter the treated area. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning. The application is automatic and should only take place when no one is present in the treated area. Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing". Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #4.21 : Disinfection of surfaces and equipment by low pressure spraying – automatic spraying (closed room)

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Bacterial spores Viruses Bacteriophages
Field of use	Indoor – In food industry : Disinfection of hard/non-porous surfaces/equipement by low-pressure spraying with prior cleaning
Application method(s)	The diluted solution is sprayed on the surfaces in an automated way without any user being present.
Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) in 15 min contact time, efficient use temperature from +4°C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 0.42 % <=> 426.6 mL / 100 L) in 60 min contact time, efficient use temperature from +4°C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature. Application rate between 20 and 200 mL/m^2
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing & loading. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is

mandatory during mixing and loading. RPE are not mandatory during the application phase, on the condition that the user remains in the control room and do not enter the treated area. When the product is being used in areas accesible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning. Rinse the pump and disconnect it from the installation before maintenance" "The treated surface should not be allowed to dry prior to rinsing". Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #4.22 : Disinfection of inner surfaces (pipelines, tanks, vessels, …) by CIP

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Bacterial spores Viruses Bacteriophages
Field of use	Indoor – In food industry : Disinfection of hard/non-porous surfaces by CIP procedures (with circulation) with prior cleaning
Application method(s)	Diluted product does automatically circulate from the CIP holding tanks through closed pipework and installations. After the disinfection procedure, the vessels (pipework and tanks) are drained and rinsed with water under closed system conditions.
Application rate(s) and frequency	- Against bacteria and yeasts : With 0.048% PAA (Dilution of the product at 0.32 % <=> 320 mL / 100 L) in 15 min contact time, efficient use temperature from +4°C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts : With 0.064% PAA (Dilution of the product at 0.42 % <=> 426.6 mL / 100 L) in 60 min contact time, efficient use

	temperature from +4°C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing & loading. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading. Rinse the pump and disconnect it from the installation before maintenance”

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

PT4 - Use #4.23 : Disinfection of water used for rinsing of recycled items during the washing process

Product Type(s)	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In food industry : Disinfection of water (in clean conditions) used for rinsing of recycled items = Water from drinking water quality shortly stored in tanks until use to rinse items such as bottles. The water should be disinfected to avoid recontamination and in a extent to avoid cross-contamination of inner bottle surfaces

Application method(s)	Concentrated product will be pumped into a reservoir from which it is continuously dosed into the water stream. Dilution of the product to the intended in-use concentration occurs in the water stream. This application is a closed, automated process.
Application rate(s) and frequency	Against bacteria and yeasts : With 0.008% PAA (Dilution of the product at 0.0533 % <=> 53.3 mL/100L) at Room Temperature in 15 min contact time.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

Use-specific instructions for use

See general directions for use

Use-specific risk mitigation measures

Dermal protection: Use appropriate safety glasses and/or face shield during the mixing & loading. **Respiratory protection:**. Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading. When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning. Rinse the pump and disconnect it from the installation before maintenance”

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

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

No use specific instructions: see section on general directions for use.

1.1.5 General directions for use

1.1.5.1 Instructions for use

1) All the surfaces to be disinfected must be cleaned before the disinfection procedure.
Then, the user should thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected.

2) Disinfection cycle :
   - Products must be diluted in potable water before use.
   - Dilution rate & contact time depends on the use considered. Please refer to the description of application method related to each use.
   - Final rinsing (with potable water) is mandatory : after the disinfection procedure, treated surfaces are rinsed with water and the water is drained into the sewer system.
     For exceptions, please refer to the description of application method related to each use.

Meta SPC 1 & 4 :
Only for use in areas that are inaccessible to the general public and companion animals. No access for the general public during treatment.

- Disinfection procedures **by CIP** - Final rinsing step (with potable water). After the disinfection procedure, CIP vessels (pipework and tanks) are drained and rinsed with water under closed system conditions

- Disinfection procedures **by dipping** : The bath is not intended to be re-used. Use the bath only once a day after work replace it by a fresh solution daily.

- Disinfection procedures **by spraying** : the surfaces to be disinfected must be wet enough in order to keep them wet during the required contact time for optimal disinfection. Then, the user should pay attention to wet surfaces completely with the disinfectant solution.

  The Application Rate for spraying of diluted product must be between 20 and 30 mL/m²

Meta SPC2 : Disinfection procedures **by fogging**
The product ***SOPUROXID 3.2*** is a liquid disinfectant to be applied (after dilution at 40%) by fogging for airborne surface disinfection and to be used indoor by professional users only.
Always check compatibility of the products with the hard/non-porous surfaces to be disinfected.

~~The product ***SOPUROXID 3.2*** has been developed and demonstrated as efficacious (via efficacy studies performed according to the NF T 72 281 standard), using one device HYSPRAY, for rooms with a volume between 30 & 150 m^3 with a flow rate of 0.047 mL/min/m^3 (volume per application and per device).~~
The product ***SOPUROXID 3.2*** has been developed and demonstrated as efficacious (via efficacy studies performed according to the NF T 72 281 standard), using one device HYSPRAY, for rooms with a volume between 30 & 150 m^3 (volume per application and per device) with a flow rate of 0,047 mL/min/m^3.

The use of other devices is possible. They must be designed to work with PAA-based products and to ensure a fog production able to stay suspended in the air and provided that these devices meet following characteristics these devices meet following characteristics :

1) Particle (medium droplet) size : between 1 and 15 µm
2) Flow rate : 0.047 mL/min/m^3 ~~(volume per application and per device)~~
3) Application rate : 5.6 mL/m^3

4) Room volume between 30 and 150 m^3 per application and per device (i.e. diffusion time between 5 and 30 min) - Airborne disinfection should be done only after thorough cleaning and rinsing. The surfaces to be disinfected should be dried before the disinfection procedure. Please pay attention to open the cupboard doors. Please check the temperature and the relative room humidity (to be set between 40 and 80%) to obtain an optimal level for the product efficiency. - The room where the fogging activity takes place is tightly sealed during fogging, no user is present : Before the start of the disinfection cycle by fogging, the treated room is sealed. All the safety tasks for the implementation of decontamination are entrusted to an user who has completed the necessary training. Among them, first step is shutting down the air handling units and closing the air intake and return, so the product is not spread in the other rooms. The door or doors to the outside of the area are then locked and, if the joints are not tight enough, they are taped to seal. An orange tape, or bright color, is preferably chosen to attract attention and a sign *"Access ban, room disinfection in progress"* is put on. Only for use in areas that are inaccessible to the general public and companion animals". - The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable *"standard room"*, if applicable) with the devices to be used, after which a protocol for disinfection of these rooms can be made and used thereafter. Each device or specific installation is systematically validated when it is set up. **Meta SPC 3** : Disinfection procedures **by foaming** Only for use in areas that are inaccessible to the general public and companion animals. No access for the general public during treatment. The surfaces to be disinfection must be wet enough in order to keep them wet during the required contact time for optimal disinfection. Wet surfaces completely.

1.1.5.2 Risk mitigation measures

Dermal protection : Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information). + Additional specific RMM for **fogging** applications : Only for use in areas that are inaccessible to the general public and companion animals. - After disinfection product's application by fogging & required contact time for optimal disinfection (2h), the room must be ventilated, preferably by mechanical ventilation at least for 60 min. The duration of the ventilation period has to be established by measurement with suitable measurement equipment (specified by the authorisation holder within the product information). - After ventilation, re-entry in the disinfected area is only permitted after the air

concentrations of peracetic acid and hydrogen peroxide have been checked and seen as dropped below the respective reference values (AEC) :
• The air concentration of PAA must have dropped to 0.5 mg/m^3.
• The air concentration of HP must have dropped to 1.25 mg/m^3.

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

Indirect effects
The two products are oxidising agents and reactive. In case of thermal decomposition steam and oxygen will be released as decomposition products. The release of oxygen may support combustion.
Also, contact with impurities, decomposition catalysts, metallic salts, alkalis, reducing agents may lead to self-accelerated, exothermic decomposition and the formation of oxygen.
In case of decomposition of the products in confined spaces and pipers, there is a risk of overpressure and burst.

First aid measures

- **General advice**

Move out of dangerous area.
Take care of your own personal safety.
Take off immediately all contaminated clothing.

- **Inhalation**

Take affected persons out into the fresh air.
Possible discomfort: Irritates skin and mucous linings of the eyes and respiratory tract and cough.
If breathing difficulties occur (e.g. severe continual coughing): Keep patient half sitting with upper body raised; keep warm and in a quiet place; call a physician immediately.

- **Skin contact**

After contact with skin, wash immediately with plenty of water.
Consult a physician.
Take off immediately all contaminated clothing.
Immediately rinse contaminated or saturated clothing with water.

- **Eye contact**

With eye held open, thoroughly rinse immediately with plenty of water for at least 10 minutes.
Protect unharmed eye.
Continue rinsing process with eye rinsing solution.
Call ambulance (caustic burn of the eyes)
Immediate further treatment in ophthalmic hospital/ophthalmologist.
Continue rinsing eye until arrival at ophthalmic hospital.

- **Ingestion**

Do not induce vomiting.
Danger of penetration of the lungs (danger to breathing) when swallowed or vomited, due to gas evolution and foam formation.
Only when patient fully conscious: have the mouth rinsed with water; have the patient drink plenty of water in small sips; keep patient warm and at rest.
Notify ambulance immediately (key word: acid burn).

- **Notes to physician**

Therapy as for chemical burn.
<u>Following inhalation:</u>
Formation of a toxic lung oedema is possible if product continues to be inhaled despite

acute irritative effect (e.g. if it is not possible to leave the danger area).
Prophylaxis of a toxic lung oedema with inhalative steroids (dosing spray, e.g. auxilosone).
If substance has been swallowed:
Aspiration hazard.
Risk of gaseous embolisms.
In case of excessive strain on the stomach due to gas evolution, insert siphon tube.
Early endoscopy in order to assess mucosa lesions in the oesophagus and stomach which may appear.
If necessary, suck away leftover substance.
Do not administer activated charcoal, since risk of release of large amounts of gas from hydrogen peroxide.

Emergency measures to protect the environment
Observe regulations on prevention of water pollution (collect, dam up, cover up).
Do not allow to run into water channels, surface water or into the ground.

- **Methods for cleaning up**

Clean contaminated surface thoroughly; recommended cleaning agent is water.
In case of small spills, dilute product with lots of water and rinse away or absorb product with liquid-binding material, e.g. chemi-sorption, diatomaceous earth, universal binder. Do not use textiles, saw dust, combustible substances. After binding, pick up mechanically and collect in suitable containers. Dispose of absorbed material in accordance with the regulations.

- **Additional advice**

Make safe or remove all sources of ignition.
Isolate defective containers immediately, if possible and safe to do.
Shut off leak, if possible and safe to do.
Place defective containers in waste receptacle (waste packaging receptacle) made of plastic (not metal).
Do not seal defective containers or waste receptacles airtight (danger of bursting due to product decomposition).
Product taken out should not be returned into container.
Never return spilled product into its original container for re-use (risk of decomposition).

1.1.5.4 Instructions for safe disposal of the product and its packaging

The biocidal product must be stored at temperatures below +30°C.
Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains
Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

Keep only in the original packaging tightly closed in a cool and well-ventilated place
Keep products away from direct sunlight, source of heat and ignition

~~The shelf life is 6 months for all the products in all the meta-SPCs.~~
The shelf life of the biocidal product is 6 months.
In addition, the following RMM is :

- For meta-SPCs 1, 2 and 3: "do not store at temperatures higher than +30°C". - For Meta-SPC 4 : "store at Ambient Temperature".

1.1.6 Other information

Reference values of peracetic acid and hydrogen peroxide used for the risk assessment : **PAA** : AEC_{inhal} = 0.5 mg/m^3 **HP** : AEC_{inhal} = 1.25 mg/m^3

1.1.7 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)
Bottle	1 L	HDPE	Screw and venting caps	Professional	Yes
Jerry cans	10 to 20 L	HDPE	Screw and venting caps	Professional	Yes
Drums	200 L	HDPE	Screw and venting caps	Professional	Yes
IBC	1000 L	HDPE	Screw and venting caps	Professional	Yes

1.1.8 Documentation

1.1.8.1 Data submitted in relation to product application

No new data on the active substance has been generated since the active substance approval.

1.1.8.2 Access to documentation

The active substance dossier on Peracetic acid was submitted by the Peracetic Acid Registration Group (PAR), a sector group of Cefic. Sopura is one of the co-operating companies within that group and therefore has access to the all the data available in the active substance dossier. The statement of membership of the Peracetic Acid Registration Group is available in Annex 3.7.

1.1.8.3 Similar conditions of use

Extract from outcome of pre-submission consultation (Communication number: D(2016)2192: ***"SOPUROXID is deemed eligible for Union authorisation"***

Reasons
Based on the information provided by the applicant it appears that the application could meet the basic requirement of Article 42(1) of the Biocidal Products Regulation.
No objections were raised from either the Commission or the Member States Competent Authorities (MSCAs) as regards the eligibility of the prospective application for Union authorisation on the grounds that SOPUROXID falls outside of the scope of the BPR, or

had been attributed the wrong product type, or that it would have non-similar conditions of use across the Union. "
For detailed comments reference is made to the Annex of the original document received as outcome of the pre-submission session.

1.2 Assessment of the biocidal product (family)

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

In the tables below an overview of all the uses linked to their respective exposure scenario and META SPC is given.
As the difference between META SPC 1 and 4 is only related to the fact that they respectively contain 5 and 15% PAA solution products but not to any other differences in operational conditions and/or risk management measures these uses are further on in this section presented together.

PLEASE NOTE that, during the peer review, due to insufficient data to confirm their efficacy, the uses in META-SPC 5 and 6 have been removed from the draft PAR and SPC and, consequently, have not been discussed further by the BPC WGs.

PT 2	**Disinfectants and algaecides not intended for direct application to humans or animals**	**Link to scenario**	**META SPC**					
Use			1	2	3	4	5	6
1	Disinfection of surfaces in industrial, public and health care areas – manual treatment	1	X			X		
2	Disinfection of surfaces in industrial, public and health care areas – spraying on small surfaces	4f	X			X		
3	Disinfection of surfaces in industrial, public and health care areas – foam application on small surfaces	6f			X			
4	Disinfection of surfaces and/or equipment in industrial, public and health care areas (pharmaceutical and cosmetic industry) - fogging	7		X				
5	CIP in the pharmaceutical and cosmetic industry	2	X			X		
6	Disinfection by spraying (e.g. greenhouses) – spraying with personal enclosure	4a	X			X		
7	Disinfection by spraying (e.g. greenhouses) – spraying without personal enclosure	4b	X			X		
8	Disinfection of equipment by soaking (e.g. agriculture & horticulture)	5	X			X		
9	Disinfection of equipment by spraying (e.g. agriculture & horticulture equipment) – spraying of equipment, on conveyor belt,	4c	X			X		

	manually							
10	Disinfection of equipment by spraying (e.g. agriculture & horticulture) – spraying of equipment, on conveyor belt, automatically	4d	X			X		
11	Disinfection of equipment by spraying (e.g. agriculture & horticulture equipment) – automatic spraying (closed room)	4e	X			X		
12	Disinfection of equipment by foaming (e.g. agriculture & horticulture equipment) – foaming of equipment, on conveyor belt, manually	6c			X			
13	Disinfection of equipment by foaming (e.g. agriculture & horticulture equipment) – foaming of equipment, on conveyor belt, automatically	6d			X			
14	Disinfection of equipment by foaming (e.g. agriculture & horticulture equipment) – automatic foaming (closed room)	6e			X			
15	Disinfection of surfaces and/or equipment by fogging (e.g. agriculture & horticulture equipment)	7		X				

PT 3	**Veterinary hygiene**	**Link to scenario**	**META SPC**					
Use			1	2	3	4	5	6
1	Disinfection of animal houses by low-pressure manual spraying – spraying with personal enclosure	4a	X			X		
2	Disinfection of animal houses by low-pressure manual spraying – spraying without personal enclosure	4b	X			X		
3	Disinfection of animal houses by foaming – foaming with personal enclosure	6a			X			
4	Disinfection of animal houses by foaming – foaming without personal enclosure	6b			X			
5	Disinfection of animal houses by fogging	7		X				
6	Disinfection of boots in footbaths in animal productions	5	X			X		
7	Disinfection of equipment by dipping	5	X			X		

PT 4	**Food and feed area**	**Link to scenario**	**META SPC**					
Use			1	2	3	4	5	6
1	Automated spraying closed systems (aseptic filling and sterilization of crown corks,	4e	X			X		

	cheese moulds and food crates in the food and beverage industry) – automatic spraying (closed room)							
2	Disinfection of equipment in the food and beverage industry by dipping and immersion	5	X			X		
3	CIP and disinfection of heat and ion exchangers, membrane filters and returnable and non-returnable glass and PET bottles in the food and beverage industry	2	X			X		
4	Disinfection of surfaces and equipment by low pressure spraying – spraying with personal enclosure	4a	X			X		
5	Disinfection of surfaces and equipment by low pressure spraying – spraying without personal enclosure	4b	X			X		
6	Disinfection of surfaces and equipment by low pressure spraying – spraying of equipment, on conveyor belt, manually	4c	X			X		
7	Disinfection of surfaces and equipment by low pressure spraying – spraying of equipment, on conveyor belt, automatically	4d	X			X		
8	Disinfection of surfaces and equipment by low pressure spraying – automatic spraying (closed room)	4e	X			X		
9	Disinfection of surfaces by foaming – foaming with personal enclosure	6a			X			
10	Disinfection of surfaces by foaming – foaming without personal enclosure	6b			X			
11	Disinfection of inner surfaces of pipelines, tanks, vessels, … in milking parlours (only by CIP procedures)	2	X			X		
12	Micropreservation of water used for final rinse	3	X			X		
13	Disinfection of storage rooms with special device in storage cellar or room	7		X				

PT 5	**Drinking water**	**Link to scenario**	**META SPC**					
Use			1	2	3	4	5	6
1	Disinfection animal drinking water – closed system	3					X	X

META SPC 1 & META SPC 4:

As already indicated, as the difference between META SPC 1 and 4 is only related to the fact that they respectively contain 5 and 15% PAA solution products but not to any other difference in operational conditions and/or risk management measures these uses are further on in this section presented together.

Table 1. Intended use # PT2-1 – Disinfection of surfaces in industrial, public and health care areas - manual treatment

Product Type(s)	2
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection by applying the product by wiping of hard surfaces with flat mops or cleaning cloths.
Target organism (including development stage)	- Bacteria - Yeast
Field of use	PT 2: Industrial, public and health care areas
Application method(s)	Main steps: - Pre-rinsing & cleaning: the surface to be disinfected will be rinsed prior to disinfection - Disinfection cycle: the concentrated product is diluted to use concentrations before use. Apply the diluted solution with the appropriate tool e.g. flat mops or cleaning cloths on hard surfaces. After application, the recipient containing the solution is drained. - Final rinsing: rinse surface after use.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C) - Yeast o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 2. Intended use # PT2-2 : Disinfection of surfaces in industrial, public and health care areas - manual treatment (spraying)

Product Type(s)	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor (Industrial, public and health care areas) Surface disinfection by applying the product by spraying of hard surfaces with a small spraying can.

Application method(s)	Manual treatment (spraying) <u>Main steps</u> : - Surface to be disinfected should be cleaned before the disinfection procedure - Disinfection procedure : products should be diluted before and then by spraying using a small spraying can. - Surface disinfected should be rinsed after the disinfection procedure
Application rate(s) and frequency	On hard non-porous surfaces with prior cleaning. Against bacteria and yeasts : **In HEALTHCARE** With 0.048% PAA (⇔ 1% PB) at +20°C in 5 min contact time. **Out HEALTHCARE** With 0.048% PAA (⇔ 1% PB) at minimum +4°C (and above, up to +20-25°C) in 15 min contact time.
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery. Weight depends on density of BP.

Table 3. Intended use # PT2-5 – CIP in the pharmaceutical and cosmetic industry

Product Type(s)	2
Where relevant, an exact description of the authorised use	For CIP-procedures, the biocidal product is automatically circulated from the CIP holding tanks through closed pipework and installations during application of the product. After cleaning/disinfection are completed, pipework and tanks are rinsed with water, which is done under closed system conditions as well.
Target organism (including development stage)	- Bacteria - Yeast
Field of use	PT 2: Industrial, public and health care areas
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the CIP installation to be disinfected will be rinsed prior to disinfection - Disinfection cycle: the concentrated product is diluted to use concentrations before use. The diluted product is used within the CIP. After application, the CIP vessel is drained. - Final rinsing: rinse CIP vessel after use.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C) - Yeast o Use concentration of 0.016% PAA, 15 min at

	+4°C (and above, up to +20-25°C)
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 4. Intended use # PT2-6 – Disinfection by spraying (e.g. of greenhouses) – spraying with personal enclosure

Product Type(s)	2
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection surfaces, for example in greenhouses. The diluted solution is sprayed on the surface via a spraying device. The application of the disinfectant is done automatically using of spraying equipment. The worker or operator is present but in a personal enclosure. Spraying is done in all directions.
Target organism (including development stage)	- Bacteria - Yeast
Field of use	PT 2: Industrial, public and health care areas
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the greenhouse surfaces to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and sprayed on the surfaces that are to be treated via a spraying device. - Final rinsing: after the disinfection procedure is completed, surfaces and equipment are rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C) - Yeast o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 52. Intended use # PT2-7 – Disinfection by spraying (e.g. greenhouses) – spraying without personal enclosure

Product Type(s)	2
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection surfaces, for example in greenhouses. The diluted solution is sprayed on the surface, either manually or via a spraying device. The worker or operator is not present within a personal enclosure (e.g. cabin). Spraying is done in all directions.

Target organism (including development stage)	- Bacteria - Yeast
Field of use	PT 2: Industrial, public and health care areas
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the greenhouse surfaces to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and sprayed on the surfaces that are to be treated manually or via a spraying device. - Final rinsing: after the disinfection procedure is completed, surfaces and equipment are rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C) - Yeast o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 63. Intended use # PT2-8 – Disinfection of equipment by soaking (e.g. agriculture & horticulture equipment)

Product Type(s)	2
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of small parts (equipment, spare parts, tools, valves, hoses,…). The equipment is submerged in soaking baths containing the biocidal solution.
Target organism (including development stage)	- Bacteria - Yeast
Field of use	PT 2: Industrial, public and health care areas
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the equipment to be disinfected is rinsed prior to disinfection. - Disinfection cycle: the concentrated product is pumped in a soaking bath and diluted to the desired use concentration. The equipment is dipped into the soaking bath. - Final rinsing: after the disinfection procedure is completed, equipment or small parts are rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria

	○ Use concentration of 0.025% PAA, 60 min at +4°C (and above, up to +20-25°C) - Yeast ○ Use concentration of 0.012% PAA, 60 min at +4°C (and above, up to +20-25°C)
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 7. Intended use # PT2-9 – Disinfection of equipment by spraying (e.g. agriculture & horticulture equipment) – spraying of equipment, on conveyor belt, manually

Product Type(s)	2
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of equipment. The diluted solution is manually sprayed on the equipment using spraying equipment. Spraying is only applied downwards and in a horizontal direction.
Target organism (including development stage)	- Bacteria - Yeast
Field of use	PT 2: Industrial, public and health care areas
Application method(s)	Main steps: - Pre-rinsing & cleaning: the equipment to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and sprayed on the equipment that are to be treated. - Final rinsing: after the disinfection procedure is completed, equipment is rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria ○ Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C) - Yeast ○ Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 8. Intended use # PT2-10 – Disinfection of equipment by spraying (e.g. agriculture & horticulture) – spraying of equipment, on conveyor belt, automatically

Product Type(s)	2
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of equipment. The diluted solution is sprayed on the equipment in an automated way while the operator is present within a

	personal enclosed area. Spraying is only applied downwards and in a horizontal direction.
Target organism (including development stage)	- Bacteria - Yeast
Field of use	PT 2: Industrial, public and health care areas
Application method(s)	Main steps: - Pre-rinsing & cleaning: the equipment to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and sprayed on the equipment that are to be treated. - Final rinsing: after the disinfection procedure is completed, equipment is rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C) - Yeast o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 9. Intended use # PT2-11 – Disinfection of equipment by spraying (e.g. agriculture & horticulture) – automatic spraying (closed room)

Product Type(s)	2
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of a specific area (room). The diluted solution is sprayed on the surfaces in an automated way without any operator being present.
Target organism (including development stage)	- Bacteria - Yeast
Field of use	PT 2: Industrial, public and health care areas
Application method(s)	Main steps: - Pre-rinsing & cleaning: the surfaces to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and sprayed on the surfaces (within the room) that are to be treated. - Final rinsing: after the disinfection procedure is completed, equipment is rinsed with water and the water is drained into the sewer system.
Application rate(s) and	Application rates are expressed in concentration active

frequency	substance:
	- Bacteria
	  o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Yeast
	  o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 104. Intended use # PT3-1 – Disinfection of animal houses by low-pressure manual spraying – spraying with personal enclosure

Product Type(s)	3
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of animal house surfaces. The diluted solution is sprayed on the surface via a spraying device. The application of the disinfectant is done automatically using of spraying equipment. The worker or operator is present but in a personal enclosure. Spraying is done in all directions.
Target organism (including development stage)	- Bacteria - Yeast - Viruses
Field of use	PT 3: Veterinary use
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the greenhouse surfaces to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and sprayed on the surfaces that are to be treated via a spraying device. - Final rinsing: after the disinfection procedure is completed, surfaces and equipment are rinsed with water and the water is drained into the sewer system.

Application rate(s) and frequency	Application rates are expressed in concentration active substance:
	- Bacteria
	  o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Yeast
	  o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Viruses
	  o Use concentration of 0.048% PAA, 30 min at +10°C

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 11. Intended use # PT3-2 – Disinfection of animal houses by low-pressure manual spraying – spraying without personal enclosure

Product Type(s)	3
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of surfaces in animal houses. The diluted solution is sprayed on the surface, either manually or via a spraying device. The worker or operator is not present within a personal enclosure (e.g. cabin). Spraying is done in all directions.
Target organism (including development stage)	- Bacteria - Yeast - Viruses
Field of use	PT 3: Veterinary use
Application method(s)	Main steps: - Pre-rinsing & cleaning: the greenhouse surfaces to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and sprayed on the surfaces that are to be treated manually or via a spraying device. - Final rinsing: after the disinfection procedure is completed, surfaces and equipment are rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C) - Yeast o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C) - Viruses o Use concentration of 0.048% PAA, 30 min at +10°C
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 5. Intended use # PT3-6 – Disinfection of boots in footbaths in animal productions

Product Type(s)	3
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of boots in footbaths in animal production sites. The boots are first rinsed off and then submerged in soaking baths containing the biocidal solution (i.e. the worker walks through the soaking bath).
Target organism (including development stage)	- Bacteria - Yeast - Viruses
Field of use	PT 3: Veterinary use
Application method(s)	Main steps:

	- Pre-rinsing & cleaning: the equipment to be disinfected is rinsed prior to disinfection. - Disinfection cycle: the concentrated product is pumped in a soaking bath and diluted to the desired use concentration. The equipment is dipped into the soaking bath. - Final rinsing: after the disinfection procedure is completed, equipment or small parts are rinsed with water and the water is drained into the sewer system.

Application rate(s) and frequency	Application rates are expressed in concentration active substance:
	- Bacteria
	  o Use concentration of 0.025% PAA, 60 min at +10°C (and above, up to +20-25°C)
	- Yeast
	  o Use concentration of 0.096% PAA, 60 min at +10°C (and above, up to +20-25°C)
	- Viruses
	  o Use concentration of 0.048% PAA, 30 min at +10°C

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 63. Intended use # PT3-7 – Disinfection of equipment by dipping

Product Type(s)	3
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of small parts (equipment, spare parts, tools, valves, hoses,…). The equipment is submerged in soaking baths containing the biocidal solution.
Target organism (including development stage)	- Bacteria - Yeast - Viruses
Field of use	PT 3: Veterinary use
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the equipment to be disinfected is rinsed prior to disinfection. - Disinfection cycle: the concentrated product is pumped in a soaking bath and diluted to the desired use concentration. The equipment is dipped into the soaking bath. - Final rinsing: after the disinfection procedure is completed, equipment or small parts are rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria o Use concentration of 0.025% PAA, 60 min at +4°C (and above, up to +20-25°C)

	- Yeast
	  o Use concentration of 0.012% PAA, 60 min at +4°C (and above, up to +20-25°C)
	- Viruses
	  o Use concentration of 0.048% PAA, 30 min at +10°C

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 14. Intended use # PT4-1 – Automated spraying closed systems (aseptic filling and sterilization of crown corks, cheese moulds and food crates in the food and beverage industry) – automatic spraying (closed room)

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of a specific area (room). The diluted solution is sprayed on the surfaces in an automated way without any operator being present.
Target organism (including development stage)	- Bacteria - Yeast - Spores - Bacteriophages
Field of use	PT 4: Food and Feed area
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the surfaces to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and sprayed on the surfaces (within the room) that are to be treated. - Final rinsing: after the disinfection procedure is completed, equipment is rinsed with water and the water is drained into the sewer system.

Application rate(s) and frequency	Application rates are expressed in concentration active substance:
	- Bacteria
	  o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Yeast
	  o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Spores
	  o Use concentration of 0.064% PAA, 60 min at +4°C (and above, up to +20-25°C)
	- Bacteriophage
	  o Use concentration of 0.064% PAA, 60 min at +20°C

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 15. Intended use # PT4-2 – Disinfection of equipment in the food and beverage industry by dipping and immersion

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of small parts (equipment, spare parts, tools, valves, hoses,…). The equipment is submerged in soaking baths containing the biocidal solution.
Target organism (including development stage)	- Bacteria - Yeast - Spores - Bacteriophages
Field of use	PT 4: Food and Feed area
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the equipment to be disinfected is rinsed prior to disinfection. - Disinfection cycle: the concentrated product is pumped in a soaking bath and diluted to the desired use concentration. The equipment is dipped into the soaking bath. - Final rinsing: after the disinfection procedure is completed, equipment or small parts are rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria o Use concentration of 0.025% PAA, 60 min at +4°C (and above, up to +20-25°C) - Yeast o Use concentration of 0.012% PAA, 60 min at +4°C (and above, up to +20-25°C) - Spores o Use concentration of 0.025% PAA, 120 min at +4°C (and above, up to +20-25°C) - Bacteriophage o Use concentration of 0.064% PAA, 60 min at +20°C
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 16. Intended use # PT4-3 – CIP and disinfection of heat and ion exchangers, membrane filters and returnable and non-returnable glass and PET bottles in the food and beverage industry

Product Type(s)	4
Where relevant, an exact description of the authorised use	For CIP-procedures, the biocidal product is automatically circulated from the CIP holding tanks through closed pipework and installations during application of the product.

	After cleaning/disinfection are completed, pipework and tanks are rinsed with water, which is done under closed system conditions as well.
Target organism (including development stage)	- Bacteria - Yeast - Spores - Bacteriophages
Field of use	PT 4: Food and Feed areas
Application method(s)	Main steps: - Pre-rinsing & cleaning: the CIP installation to be disinfected will be rinsed prior to disinfection - Disinfection cycle: the concentrated product is diluted to use concentrations before use. The diluted product is used within the CIP. After application, the CIP vessel is drained. - Final rinsing: rinse CIP vessel after use.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C) - Yeast o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C) - Spores o Use concentration of 0.064% PAA, 60 min at +4°C (and above, up to +20-25°C) - Bacteriophage o Use concentration of 0.064% PAA, 60 min at +20°C
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 7. Intended use # PT4-4 – Disinfection of surfaces and equipment by low pressure spraying – spraying with personal enclosure

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of surfaces and equipment. The diluted solution is sprayed on the surface via a spraying device. The application of the disinfectant is done automatically using of spraying equipment. The worker or operator is present but in a personal enclosure. Spraying is done in all directions.
Target organism (including development stage)	- Bacteria - Yeast - Spores - Bacteriophages
Field of use	PT 4: Food and Feed area

Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the surfaces and equipment to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and sprayed on the surfaces that are to be treated via a spraying device. - Final rinsing: after the disinfection procedure is completed, surfaces and equipment are rinsed with water and the water is drained into the sewer system.

Application rate(s) and frequency	Application rates are expressed in concentration active substance:
	- Bacteria
	  o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Yeast
	  o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Spores
	  o Use concentration of 0.064% PAA, 60 min at +4°C (and above, up to +20-25°C)
	- Bacteriophage
	  o Use concentration of 0.064% PAA, 60 min at +20°C

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 18. Intended use # PT4-5 – Disinfection of surfaces and equipment by low pressure spraying – spraying without personal enclosure

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of surfaces and equipment. The diluted solution is sprayed on the surface, either manually or via a spraying device. The worker or operator is not present within a personal enclosure (e.g. cabin). Spraying is done in all directions.
Target organism (including development stage)	- Bacteria - Yeast - Spores - Bacteriophages
Field of use	PT 4: Food and Feed area
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the surfaces and equipment to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and sprayed on the surfaces that are to be treated manually or via a spraying device. - Final rinsing: after the disinfection procedure is completed, surfaces and equipment are rinsed with water and the water is drained into the sewer system.

Application rate(s) and frequency	Application rates are expressed in concentration active substance:
	- Bacteria
	  o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Yeast
	  o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Spores
	  o Use concentration of 0.064% PAA, 60 min at +4°C (and above, up to +20-25°C)
	- Bacteriophage
	  o Use concentration of 0.064% PAA, 60 min at +20°C

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 19. Intended use # PT4-6 – Disinfection of surfaces and equipment by low pressure spraying – spraying of equipment, on conveyor belt, manually

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of equipment. The diluted solution is manually sprayed on the surface using spraying equipment. Spraying is only applied downwards and in a horizontal direction.
Target organism (including development stage)	- Bacteria - Yeast - Spores - Bacteriophages
Field of use	PT 4: Food and Feed areas
Application method(s)	Main steps: - Pre-rinsing & cleaning: the equipment to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and sprayed on the equipment that are to be treated. - Final rinsing: after the disinfection procedure is completed, equipment is rinsed with water and the water is drained into the sewer system.

Application rate(s) and frequency	Application rates are expressed in concentration active substance:
	- Bacteria
	  o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Yeast
	  o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Spores
	  o Use concentration of 0.064% PAA, 60 min at

	+4°C (and above, up to +20-25°C) - Bacteriophage o Use concentration of 0.064% PAA, 60 min at +20°C
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 20. Intended use # PT4-7 – Disinfection of surfaces and equipment by low pressure spraying – spraying of equipment, on conveyor belt, automatically

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of equipment. The diluted solution is sprayed on the equipment in an automated way while the operator is present within a personal enclosed area. Spraying is only applied downwards and in a horizontal direction.
Target organism (including development stage)	- Bacteria - Yeast - Spores - Bacteriophages
Field of use	PT 4: Food and Feed areas
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the equipment to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and sprayed on the equipment that are to be treated. - Final rinsing: after the disinfection procedure is completed, equipment is rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C) - Yeast o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C) - Spores o Use concentration of 0.064% PAA, 60 min at +4°C (and above, up to +20-25°C) - Bacteriophage o Use concentration of 0.064% PAA, 60 min at +20°C
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 21. Intended use # PT4-8 – Disinfection of surfaces and equipment by low pressure spraying – automatic spraying (closed room)

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of a specific area (room). The diluted solution is sprayed on the surfaces in an automated way without any operator being present.
Target organism (including development stage)	- Bacteria - Yeast - Spores - Bacteriophages
Field of use	PT 4: Food and Feed areas
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the surfaces to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and sprayed on the surfaces (within the room) that are to be treated. - Final rinsing: after the disinfection procedure is completed, equipment is rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C) - Yeast o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C) - Spores o Use concentration of 0.064% PAA, 60 min at +4°C (and above, up to +20-25°C) - Bacteriophage o Use concentration of 0.064% PAA, 60 min at +20°C
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 8. Intended use # PT4-11 – Disinfection of inner surfaces of pipelines, tanks, vessels, … in milking parlours (only by CIP procedures)

Product Type(s)	4
Where relevant, an exact description of the authorised use	For CIP-procedures, the biocidal product is automatically circulated from the CIP holding tanks through closed pipework and installations during application of the product. After cleaning/disinfection are completed, pipework and tanks are rinsed with water, which is done under closed system conditions as well.

Target organism (including development stage)	- Bacteria - Yeast - Spores - Bacteriophages
Field of use	PT 4: Food and Feed areas
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the CIP installation to be disinfected will be rinsed prior to disinfection - Disinfection cycle: the concentrated product is diluted to use concentrations before use. The diluted product is used within the CIP. After application, the CIP vessel is drained. - Final rinsing: rinse CIP vessel after use.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C) - Yeast o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C) - Spores o Use concentration of 0.064% PAA, 60 min at +4°C (and above, up to +20-25°C) - Bacteriophage o Use concentration of 0.064% PAA, 60 min at +20°C
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 23. Intended use # PT4-12 – Micropreservation of water used for final rinse

Product Type(s)	4
Where relevant, an exact description of the authorised use	Concentrated product will be pumped into a reservoir from which it is continuously dosed into the water stream. Dilution of the product to the intended in-use concentration occurs in the water stream. This application is a closed, automated process.
Target organism (including development stage)	- Bacteria - Yeast
Field of use	PT 4: Food and Feed areas
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: not applicable. - Disinfection cycle: the concentrated product is diluted to use concentrations via continous dosing into the water stream. Consequently, there is no real dilution step before use. - Final rinsing: not applicable.

Application rate(s) and frequency	Application rates are expressed in concentration active substance:
	- Bacteria
	  o Use concentration of 0.005% PAA, 15 min at +20°C
	- Yeast
	  o Use concentration of 0.005% PAA, 15 min at +20°C

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

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Table 24. Intended use # PT2-4 – Disinfection of surfaces and/or equipment in industrial, public and health care areas (pharmaceutical and cosmetic industry) – fogging

Product Type(s)	2
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of equipment and/or surfaces within the pharmaceutical and cosmetic industry. The diluted solution is applied on the surfaces and/or equipment that is to be disinfected by fogging. The room where the fogging activity takes place is tightly sealed during fogging. Entrance in the room is allowed after verification of the concentrations.
Target organism (including development stage)	- Bacteria - Yeast
Field of use	PT 2: Industrial, public and health care areas
Application method(s)	Main steps: - Disinfection cycle: the product is diluted to use concentrations and applied on the surfaces and/or equipment that are to be treated by fogging.

Application rate(s) and frequency	Application rates are expressed in concentration active substance:
	- Bacteria
	  o Use concentration of 0.100% PAA, 60 min at +4°C (and above, up to +20-25°C)
	- Yeast
	  o Use concentration of 0.100% PAA, 60 min at +4°C (and above, up to +20-25°C)

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 95. Intended use # PT2-15 – Disinfection of equipment by fogging (e.g. agriculture & horticulture equipment)

Product Type(s)	2
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of equipment and/or surfaces. The diluted solution is applied on the equipment that is to be disinfected by fogging. The room where the fogging activity takes place is tightly sealed during fogging. Entrance in the room is allowed after verification of the concentrations.
Target organism (including development stage)	- Bacteria - Yeast
Field of use	PT 2: Industrial, public and health care areas
Application method(s)	Main steps: - Disinfection cycle: the product is diluted to use concentrations and applied on the equipment that are to be treated by fogging.

Application rate(s) and frequency	Application rates are expressed in concentration active substance:
	- Bacteria
	  o Use concentration of 0.100% PAA, 60 min at +4°C (and above, up to +20-25°C)
	- Yeast
	  o Use concentration of 0.100% PAA, 60 min at +4°C (and above, up to +20-25°C)

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 10. Intended use # PT3-5 – Disinfection of animal houses by fogging

Product Type(s)	3
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of animal houses. The diluted solution is applied on the surfaces within the animal house which is to be disinfected by fogging. The room where the fogging activity takes place is tightly sealed during fogging. Entrance in the room is allowed after verification of the concentrations.
Target organism (including development stage)	- Bacteria - Yeast - Viruses
Field of use	PT 3: Veterinary use
Application method(s)	Main steps: - Disinfection cycle: the product is diluted to use concentrations and applied on the surfaces that are to be treated by fogging.
Application rate(s) and frequency	Application rates are expressed in concentration active substance:

	- Bacteria
	  - Use concentration of 0.100% PAA, 60 min at +4°C (and above, up to +20-25°C)
	- Yeast
	  - Use concentration of 0.100% PAA, 60 min at +4°C (and above, up to +20-25°C)
	- Viruses
	  - Use concentration of 0.100% PAA, 60 min at +4°C (and above, up to +20-25°C)

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 117 Intended use # PT4-13 – Disinfection of storage rooms with special device in storage cellar or room

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of storage rooms. The diluted solution is applied on the surfaces within the storage rooms which are to be disinfected by fogging. The room where the fogging activity takes place is tightly sealed during fogging. Entrance in the room is allowed after verification of the concentrations.
Target organism (including development stage)	- Bacteria - Yeast - Spores - Bacteriophages
Field of use	PT 4: Food and Feed areas
Application method(s)	<u>Main steps:</u> - Disinfection cycle: the product is diluted to use concentrations and applied on the surfaces that are to be treated by fogging.

Application rate(s) and frequency	Application rates are expressed in concentration active substance:
	- Bacteria
	  - Use concentration of 0.100% PAA, 60 min at +4°C (and above, up to +20-25°C)
	- Yeast
	  - Use concentration of 0.100% PAA, 60 min at +4°C (and above, up to +20-25°C)
	- Spores
	  - Use concentration of 0.100% PAA, 60 min at +4°C (and above, up to +20-25°C)
	- Bacteriophage
	  - Use concentration of 0.100% PAA, 60 min at +4°C

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

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Table 28. Intended use # PT2-3 – Disinfection of surfaces in industrial, public and health care areas – foam application on small surfaces

Product Type(s)	2
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of small hard surfaces by applying the product by foam application using a small foaming can.
Target organism (including development stage)	- Bacteria - Yeast
Field of use	PT 2: Industrial, public and health care areas
Application method(s)	Main steps: - Pre-rinsing & cleaning: the surface to be disinfected will be rinsed prior to disinfection - Disinfection cycle: the concentrated product is diluted to use concentrations before use. Apply the diluted solution by foaming using a small foaming can. - Final rinsing: rinse surface after use.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C) - Yeast o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 129. Intended use # PT2-12 – Disinfection of equipment by foaming (e.g. agriculture & horticulture equipment) – foaming of equipment, on conveyor belt, manually

Product Type(s)	2
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of equipment. The diluted solution is manually foamed on the surface using foaming equipment. Foaming is only applied downwards and in a horizontal direction.
Target organism (including development stage)	- Bacteria - Yeast
Field of use	PT 2: Industrial, public and health care areas
Application method(s)	Main steps: - Pre-rinsing & cleaning: the equipment to be

	disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and foamed on the equipment that are to be treated. - Final rinsing: after the disinfection procedure is completed, equipment is rinsed with water and the water is drained into the sewer system.

Application rate(s) and frequency	Application rates are expressed in concentration active substance:
	- Bacteria
	  o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Yeast
	  o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 30. Intended use # PT2-13 – Disinfection of equipment by foaming (e.g. agriculture & horticulture equipment) – foaming of equipment, on conveyor belt, automatically

Product Type(s)	2
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of equipment. The diluted solution is foamed on the equipment in an automated way while the operator is present within a personal enclosed area. Foaming is only applied downwards and in a horizontal direction.
Target organism (including development stage)	- Bacteria - Yeast
Field of use	PT 2: Industrial, public and health care areas
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the equipment to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and foamed on the equipment that are to be treated. - Final rinsing: after the disinfection procedure is completed, equipment is rinsed with water and the water is drained into the sewer system.

Application rate(s) and frequency	Application rates are expressed in concentration active substance:
	- Bacteria
	  o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Yeast
	  o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 13. Intended use # PT2-14 – Disinfection of equipment by foaming (e.g. agriculture & horticulture equipment) – automatic foaming (closed room)

Product Type(s)	2
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of a specific area (room). The diluted solution is foamed on the surfaces in an automated way without any operator being present.
Target organism (including development stage)	- Bacteria - Yeast
Field of use	PT 2: Industrial, public and health care areas
Application method(s)	Main steps: - Pre-rinsing & cleaning: the surfaces to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and foamed on the surfaces (within the room) that are to be treated. - Final rinsing: after the disinfection procedure is completed, equipment is rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C) - Yeast o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 32. Intended use # PT3-3 – Disinfection of animal houses by foaming – foaming with personal enclosure

Product Type(s)	3
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of animal houses. The diluted solution is foamed on the surfaces / walls via a foaming device. The application of the disinfectant is done automatically using of foaming equipment. The worker or operator is present but in a personal enclosure. Foaming is done in all directions.
Target organism	- Bacteria

(including development stage)	- Yeast - Spores - Viruses
Field of use	PT 3: Veterinary use
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the animal houses surfaces to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and foaming takes place on surfaces that are to be treated via a foaming device. - Final rinsing: after the disinfection procedure is completed, surfaces and equipment are rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C) - Yeast o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C) - Spores o Use concentration of 0.064% PAA, 60 min at +4°C (and above, up to +20-25°C) - Viruses o Use concentration of 0.048% PAA, 30 min at +4°C (and above, up to +20-25°C)
Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 33. Intended use # PT3-4 – Disinfection of animal houses by foaming – foaming without personal enclosure

Product Type(s)	3
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of animal houses. The diluted solution is foamed on the surfaces/walls, either manually or via a spraying device. The worker or operator is not present within a personal enclosure (e.g. cabin). Spraying is done in all directions.
Target organism (including development stage)	- Bacteria - Yeast - Spores - Viruses
Field of use	PT 3: Veterinary use
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the animal house surfaces to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and foamed on the surfaces that are to

	be treated manually or via a spraying device. - Final rinsing: after the disinfection procedure is completed, surfaces and equipment are rinsed with water and the water is drained into the sewer system.

Application rate(s) and frequency	Application rates are expressed in concentration active substance:
	- Bacteria
	  o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Yeast
	  o Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Spores
	  o Use concentration of 0.064% PAA, 60 min at +4°C (and above, up to +20-25°C)
	- Viruses
	  o Use concentration of 0.048% PAA, 30 min at +4°C (and above, up to +20-25°C)

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 145. Intended use # PT4-9 – Disinfection of surfaces by foaming – foaming with personal enclosure

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of animal houses. The diluted solution is foamed on the surfaces / walls via a foaming device. The application of the disinfectant is done automatically using of foaming equipment. The worker or operator is present but in a personal enclosure. Foaming is done in all directions.
Target organism (including development stage)	- Bacteria - Yeast - Spores
Field of use	PT 4: Food and Feed areas
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the animal houses surfaces to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and foaming takes place on surfaces that are to be treated via a foaming device. - Final rinsing: after the disinfection procedure is completed, surfaces and equipment are rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	Application rates are expressed in concentration active substance: - Bacteria o Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C)

	- Yeast
	  - Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Spores
	  - Use concentration of 0.064% PAA, 60 min at +4°C (and above, up to +20-25°C)

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

Table 15 Intended use # PT4-10 – Disinfection of surfaces by foaming – foaming without personal enclosure

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of surfaces. The diluted solution is foamed on the surfaces, either manually or via a spraying device. The worker or operator is not present within a personal enclosure (e.g. cabin). Spraying is done in all directions.
Target organism (including development stage)	- Bacteria - Yeast - Spores
Field of use	PT 4: Food and Feed areas
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: the surfaces to be disinfected will be rinsed prior to disinfection. - Disinfection cycle: the product is diluted to use concentrations and foamed on the surfaces that are to be treated manually or via a spraying device. - Final rinsing: after the disinfection procedure is completed, surfaces and equipment are rinsed with water and the water is drained into the sewer system.

Application rate(s) and frequency	Application rates are expressed in concentration active substance:
	- Bacteria
	  - Use concentration of 0.048% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Yeast
	  - Use concentration of 0.016% PAA, 15 min at +4°C (and above, up to +20-25°C)
	- Spores
	  - Use concentration of 0.064% PAA, 60 min at +4°C (and above, up to +20-25°C)

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

<u>**META SPC 5 & META SPC 6**</u>

PLEASE NOTE that, during the peer review, due to insufficient data to confirm their efficacy, the uses in META-SPC 5 and 6 have been removed from the draft PAR and SPC and, consequently, have not been discussed further by the BPC WGs.

Table 36. Intended use # PT5-1 – Disinfection of drinking water – closed system

Product Type(s)	5
Where relevant, an exact description of the authorised use	Concentrated product will be pumped into a reservoir from which it is continuously dosed into the water stream. Dilution of the product to the intended in-use concentration occurs in the water stream. This application is a closed, automated process.
Target organism (including development stage)	- Bacteria - Yeast
Field of use	PT 5: Drinking water
Application method(s)	<u>Main steps:</u> - Pre-rinsing & cleaning: not applicable. - Disinfection cycle: the concentrated product is diluted to use concentrations via continous dosing into the water stream. Consequently, there is no real dilution step before use. - Final rinsing: not applicable.

Application rate(s) and frequency	Application rates are expressed in concentration active substance:
	- Bacteria
	  ○ Use concentration of 0.004% PAA, 60 min at +4°C (and above, up to +20-25°C)
	- Yeast
	  ○ Use concentration of 0.002% PAA, 60 min at +4°C (and above, up to +20-25°C)

Category(ies) of user(s)	Industrial or professional users
Pack sizes and packaging material	Jerry cans (20 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), bulk delivery. Weight depends on density of BP.

1.2.2 Physical, chemical and technical properties

The applicant has submitted data for determination of physical, chemical and technical properties for all products. The parameters are summarized in the table below.

- The product **Sopuroxid 5 and Sopuroxid 5C** are the representative products for physchemical parameters for meta–SPC 1 (containing products Sopuroxid 5 et Sopuroxid 5C).
- The product **Sopuroxid 3.2** is the representative product for physchemical parameters for meta-SPC 2 (containing product Sopuroxid 3.2)
- The product **Acidofoam CF** is the representative product for physchemical parameters for meta-SPC 3 (containing product Acidofoam CF)
- The products **Sopuroxid 15 and Oxypur CS** are the representative product for physchemical parameters for meta-SPC 4 (containing product Sopuroxid 15 and Oxypur CS).

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
- Physical state - Colour - Odour at 20 °C and 101.3 kPa	Organoleptic observation	All products	For all products: Limpid colourless liquid with vinegar odour	Test report: Physico-chemical characteristics of SOPUROXID 5, 03/08/2016 Test report REGU012-F: Physico-chemical characteristics of SOPUROXID 5C, 06/10/2016 Test report REGU015-F: Physico-chemical characteristics of SOPUROXID 3.2, 03/08/2016 Test report REGU002-F: Physico-chemical characteristics of ACIDOFOAM CF, 03/08/2016 Test report REGU011-F: Physico-chemical characteristics of SOPUROXID 15, 03/08/2016 Test report REGU013-F: Physico-chemical characteristics of OXYPUR CS, 03/08/2016
Acidity / alkalinity	OECD 122 20°C	All products	Sopuroxid 5: pH = 0.7 Acidity = 8.3 %w/w H_2SO_4 Sopuroxid 5C: pH = 0.5 Acidity = 60.7 %w/w H_2SO_4	Test report REGU010-F: Physico-chemical characteristics of SOPUROXID 5, 03/08/2016 Test report REGU012-F: Physico-chemical characteristics of SOPUROXID 5C, 06/10/2016

			Sopuroxid 3.2: pH = 1 Acidity = 8.6 %w/w H_2SO_4 Acidofoam CF: pH = 1 Acidity = 8.6 %w/w H_2SO_4 Sopuroxid 15: pH = 0.7 Acidity = 14.7 %w/w H_2SO_4 Oxypur CS: pH = 1 Acidity = 16 %w/w H_2SO_4	Test report REGU015-F: Physico-chemical characteristics of SOPUROXID 3.2, 03/08/2016 Test report REGU002-F: Physico-chemical characteristics of ACIDOFOAM CF, 03/08/2016 Test report REGU011-F: Physico-chemical characteristics of SOPUROXID 15, 03/08/2016 Test report REGU013-F: Physico-chemical characteristics of OXYPUR CS, 03/08/2016 Refinement of the pH values for the products of the SOPUROXID BPF, 03/11/20
Relative density / bulk density	OECD109 20°C	All products	Sopuroxid 5: 1.123 g/ml Sopuroxid 5C: 1.235 g/ml Sopuroxid 3.2: 1.108 g/ml Acidofoam CF: 1.108 g/ml Sopuroxid 15: 1.144 g/ml	Test report REGU010-F: Physico-chemical characteristics of SOPUROXID 5, 03/08/2016 Test report REGU012-F: Physico-chemical characteristics of SOPUROXID 5C, 06/10/2016 Test report REGU015-F: Physico-chemical characteristics of SOPUROXID 3.2, 03/08/2016 Test report REGU002-F: Physico-chemical characteristics of ACIDOFOAM CF, 03/08/2016

			Oxypur CS: 1.155 g/ml	Test report REGU011-F: Physico-chemical characteristics of SOPUROXID 15, 03/08/2016 Test report REGU013-F: Physico-chemical characteristics of OXYPUR CS, 03/08/2016
Storage stability test – **accelerated storage**	OECD 223 MT 41 For more details, please see the overview below this table	Sopuroxid 5 40°C during 12 weeks (Analysis during this test were performed at 0, 3, 6 and 12 weeks. The usual 8 weeks for this temperature of storage is lacking. However, because of the analysis at 12 weeks, we accept this deviation) 1 L plastic bottle HDPE with venting caps	$[PAA]_{t0}$ = 5.39 % w/w $[PAA]_{t12w}$ = 5.07 % w/w Variation: 5.9% $[H_2O_2]_{t0}$ = 24.02 % w/w $[H_2O_2]_{t12w}$ = 22.17 % w/w Variation: 7.7% Appearance remains conform Packaging appearance remains conforme	Test report REGU010-B: Stability study in accelerated conditions (40°C) SOPUROXID 5, 03/08/2016

		Sopuroxid 5C 30°C during 18 weeks 250 ml bottle HDPE with venting caps	$[PAA]_{t0}$ = 5.40 % w/w $[PAA]_{t18w}$ = 4.89 % w/w Variation: 9.4% $[H_2O_2]_{t0}$ = 16.03 % w/w $[H_2O_2]_{t12w}$ = 14.73 % w/w Variation $_{t12w}$: 8.1% $[H_2O_2]_{t18w}$ = 13.73 % w/w Variation $_{t18w}$: 14.4% Appearance remains conform Packaging appearance remains conform In view of the very high variability of concentrations during the accelerated storage test the applicant had submitted biocidal efficacy test on the aged sample. However, the efficacy is not enough demonstrated . Please see the long-term storage test for more information on shelf-life	Test report REGU013-162-ACCEL: Stability study in accelerated conditions SOPUROXID 5C, 23/07/2019
		Sopuroxid 3.2 30°C during 18 weeks 250 ml bottle HDPE with venting caps	$[PAA]_{t0}$ = 3.48 % w/w $[PAA]_{t18w}$ = 3.22 % w/w Variation: 7.5% $[H_2O_2]_{t0}$ = 23.13 % w/w $[H_2O_2]_{t18w}$ = 22.17 % w/w Variation: 4.2%	Test report REGU013-1692-ACCEL: Stability study in accelerated conditions SOPUROXID 3.2, 19/07/2019

			Appearance remains conform Packaging appearance remains conforme	
		Acidofoam CF 30°C during 18 weeks 250 ml bottle HDPE with venting caps	$[PAA]_{t0}$ = 3.17 % w/w $[PAA]_{t18w}$ = 2.93 % w/w Variation: 7.6 % $[H_2O_2]_{t0}$ = 23.80 % w/w $[H_2O_2]_{t18w}$ = 22.10 % w/w Variation: 7.7% Appearance remains conform Packaging appearance remains conform	Test report REGU013-1448-ACCEL: Stability study in accelerated conditions Acidofoam CF, 22/07/2019
		Sopuroxid 15 30°C during 18 weeks 1 L plastic bottle HDPE with venting caps	$[PAA]_{t0}$ = 15.09 % w/w $[PAA]_{t18w}$ = 13.86 % w/w Variation: 8.2 % $[H_2O_2]_{t0}$ = 22.84 % w/w $[H_2O_2]_{t18w}$ = 20.99 % w/w Variation: 8.1% Appearance remains conform Packaging appearance remains conform	Test report REGU013-152-ACCEL: Stability study in accelerated conditions SOPUROXID 15, 19/07/2019

		OXYPUR CS 30°C during 18 weeks 1 L plastic bottle HDPE with venting caps	$[PAA]_{t0}$ = 15.02 % w/w $[PAA]_{t12w}$ = 13.53 % w/w Variation $_{t12w}$: 9.9 % $[PAA]_{t18w}$ = 12.93 % w/w Variation $_{t18w}$: 13.9 % $[H_2O_2]_{t0}$ = 22.43 % w/w $[H_2O_2]_{t12w}$ = 20.71 % w/w Variation $_{t12w}$: 7.7% $[H_2O_2]_{t18w}$ = 19.81 % w/w Variation $_{t18w}$: 11.7% Appearance remains conform Packaging appearance remains conform	Test report REGU013-751-ACCEL: Stability study in accelerated conditions OXYPUR CS, 04/07/2019
Storage stability test – **long term storage at ambient temperature**	20°C OECD 223 & MT41 For more details, please see the	***Sopuroxid 5*** Packaging: 1L HDPE with venting caps	$[PAA]_{t0}$ = 5.39 % w/w $[PAA]_{t6m}$ = 5.46 % w/w Variation: 1.3% $[H_2O_2]_{t0}$ = 24.02 % w/w $[H_2O_2]_{t6m}$ = 22.79 % w/w Variation: 5.1% Appearance remains conform	Test report REGU010-A: Stability study in normal storage conditions (20°C) SOPUROXID 5, 03/08/2016 SOPUROXID BIOCIDE PRODUCT FAMILY, Stability study in normal conditions (20°C). Additional test parameters, 30/10/20

	overview below this table	***Sopuroxid 5C*** Packaging: 1L HDPE with venting caps	Packaging appearance remains conform. No data on pH stability, dilution stability and weight change of the packaging has been provided. However, this data requirement are covered by the data on Sopuroxid 5C, the second representative product of the meta-SPC. $[PAA]_{t0}$ = 5.40 % w/w $[PAA]_{t6m}$ = 4.94 % w/w Variation: 8.5% $[H_2O_2]_{t0}$ = 16.03 % w/w $[H_2O_2]_{t3m}$ = 14.97 % w/w $Variation_{t3m}$: 6.6% $[H_2O_2]_{t6m}$ = 14.15 % w/w Variation $_{t6m}$: 11.72% Appearance remains conform Packaging appearance remains conform, weight loss 4.7% pH after storage: 0.5 Dilution stability after storage: no separated material after 18hours	Test report REGU013-162-NORM: Stability study in normal conditions SOPUROXID 5C, 23/07/2019 SOPUROXID BIOCIDE PRODUCT FAMILY, Stability study in normal conditions (20°C). Additionaltest parameters, 30/10/20
		Sopuroxid 3.2	$[PAA]_{t0}$ = 3.48 % w/w	Test report REGU013-1692-NORM:

		Packaging: 1L HDPE with venting caps	$[PAA]_{t6m}$ = 3.27 % w/w Variation: 6% $[H_2O_2]_{t0}$ = 23.13 % w/w $[H_2O_2]_{t6m}$ = 22.25 % w/w Variation: 3.8% Appearance remains conform Packaging appearance remains conforme, weight loss 1.9% pH after storage: 0.7 No data on dilution stability has been provided. However, this data requirement are covered by the worst case formulations: Sopuroxid 5C and Sopuroxid 15. These two formulations have been considered as representing the extreme compositions: means highest sulfuric acid content and highest peracetic acid content.	Stability study in normal conditions SOPUROXID 3.2, 19/07/2019 SOPUROXID BIOCIDE PRODUCT FAMILY, Stability study in normal conditions (20°C). Additionaltest parameters, 30/10/20
		Acidofoam CF Packaging: 1L HDPE with venting caps	$[PAA]_{t0}$ = 3.17 % w/w $[PAA]_{t26w}$ = 3.0 % w/w Variation: 5.4% $[H_2O_2]_{t0}$ = 23.8 % w/w $[H_2O_2]_{t26w}$ = 22.37 % w/w Variation: 6.0% Appearance remains conform	Test report REGU002-G: Stability study in normal storage conditions ACIDOFOAM CF, 03/08/2016 Erratum from 04/06/2019

			Packaging appearance remains conform No data on pH stability, dilution stability and weight change of the packaging has been provided. However a read across can be made to the data on the Sopuroxid 3.2 formulation. Indeed, the composition is very similar between these two products, except 2.5 % w/w foaming agent.	
		Sopuroxid 15 Packaging: 1L HDPE with venting caps	$[PAA]_{t0}$ = 15.09 % w/w $[PAA]_{t6m}$ = 14.09 % w/w Variation: 6.6% $[H_2O_2]_{t0}$ = 22.84 % w/w $[H_2O_2]_{t6m}$ = 21.14 % w/w Variation: 7.4% Appearance remains conform Packaging appearance remains conforme, weight loss 3.8% pH after storage: 0.6 Dilution stability after storage: no separated material after 18hours	Test report REGU013-152-NORM: Stability study in normal conditions SOPUROXID 15, 19/07/2019 SOPUROXID BIOCIDE PRODUCT FAMILY, Stability study in normal conditions (20°C). Additionaltest parameters, 30/10/20 Test report REGU013-751-NORM: Stability study in normal conditions OXYPUR CS, 16/07/2019

		OXYPUR CS Packaging: 1L HDPE with venting caps	$[PAA]_{t0}$ = 15.02 % w/w $[PAA]_{t6m}$ = 13.92 % w/w Variation: 7.3% $[H_2O_2]_{t0}$ = 22.43 % w/w $[H_2O_2]_{t6m}$ = 20.16 % w/w Variation: 10.1% Appearance remains conform Packaging appearance remains conform, weight loss 5.7% pH after storage: 0.8 No data on dilution stability has been provided. However, this data requirement are covered by the worst case formulations: Sopuroxid 5C and Sopuroxid 15. These two formulations have been considered as representing the extreme compositions: means highest sulfuric acid content and highest peracetic acid content.	SOPUROXID BIOCIDE PRODUCT FAMILY, Stability study in normal conditions (20°C). Additionaltest parameters, 30/10/20

Storage stability test – **low temperature stability test for liquids**	MT 39.3 0°C	All products	No separated material (neither solid nor oily matter) after 2 trials	Test reports REGU010-C: Stability at 0°C of SOPUROXID 5, 03/08/2016 Test report REGU002-C: Stability at 0°C of ACIDOFOAM CF, 03/08/2016 Test report REGU011-C: Stability at 0°C of SOPUROXID 15, 03/08/2016 Test report REGU015-C: Stability at 0°C of SOPUROXID 3.2, 06/06/2019
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Waiver	Ingredients are not known to be UV-sensitive and products are packaged in HDPE packaging.		
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waiver	Water is one of the major compounds of the products, thus humidity issue is not relevant. Temperature effect is addressed during storage tests.		
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Waiver	No reactivity towards the container material was observed during the storage tests.		

Wettability	Waiver	The products are water-based liquids		
Suspensibility, spontaneity and dispersion stability	Waiver	The products are water-based liquids		
Wet sieve analysis and dry sieve test	Waiver	The products are water-based liquids		
Emulsifiability, re-emulsifiability and emulsion stability	Waiver	The products are not emulsifiable concentrates		
Disintegration time	Waiver	The products are water-based liquids		
Particle size distribution, content of dust/fines, attrition, friability	Statement/ Waiver	Sopuroxid 5 Sopuroxid 15 Acidofoam CF	The products of meta SPC1 and meta SPC 4 can be used by spraying. The applicant is of the meaning that the non-submission of a MMAD particle distribution report is justified for following reasons: 1. The products from SOPUROXIDare sold separately from the spraying cans, hence the spraying cans are not part of the authorisation. 2. The MMAD is not an input parameter in the human exposure assessment because the type of spraying which is used doesn't lead to particles < 50 µm. 3. The MMAD is not at all relevant for efficacy assessments for the products used in CIP and surface disinfection. For the efficacy evaluation of	Technical information nozzles and spraying statement by Sopura.

			SOPUROXID 3.2 (fogging), specific testing protocole applies for the test but the MMAD was not a requirement. For meta SPC 3, ACIDOFOAM CF may be foamed/sprayed with several types of equipment, providing the technical compatibility (corrosion, …) is checked.	
Persistent foaming	MT 47.1 20°C MT 47.2 20°C	Sopuroxid 5 Sopuroxid 5C Sopuroxid 3.2	0.25% v/v dilution: volume of foam does not exceed 60 ml after 1 min 1% v/v dilution: 0 ml 3% v/v dilution : volume of foam does not exceed 60 ml after 1 min 0.25% v/v dilution: volume of foam does not exceed 60 ml after 1 min 1% v/v dilution: 0 ml 3% v/v dilution : volume of foam does not exceed 60 ml after 1 min 0.25% v/v dilution: volume of foam does not exceed 60 ml after 1 min 1% v/v dilution: 0 ml 40% v/v dilution : **volume of foam does exceed 60 ml after 1 min** The applicant has submitted the following statement of safe use of	Test report REGU010-F: Physico-chemical characteristics of SOPUROXID 5, 03/08/2016 Test report REGU010-H, Measure of persistent foaming SOPUROXID 5, 26/04/2019 Test report REGU012-I, Measure of persistent foaming SOPUROXID 5C, 26/04/2019 Test report REGU015-F: Physico-chemical characteristics of SOPUROXID 3.2, 03/08/2016

			Sopuroxid 3.2: No safety issue is expected. Indeed, Sopuroxid 3.2 is only intended to be used by industrial/ professional users by means of a fogging device. The use dilution is prepared by filling slowly & manually a 1 litre-bottle (use of PPE is mandatory during the pouring) with the neat product, then water is added (also manually) to reach the required product concentration -. The bottle is then directly inserted (screwed) in the fogging device to proceed to the nebulization phase. Taking the small volume of diluted product prepared, furthermore in a closed container, the amount of the foam that could possibly be generated is of no concern for the user.	Test report REGU015-H, Measure of persistent foaming SOPUROXID 3.2, 26/04/2019 Statement of safe use of Sopuroxid 3.2, 29/07/2019 Test report REGU011-F: Physico-chemical characteristics of SOPUROXID 15, 03/08/2016 Test report REGU015-H, Measure of persistent foaming SOPUROXID 15, 26/04/2019
		Sopuroxid 15	0.25% v/v dilution: volume of foam does not exceed 60 ml after 1 min 1% v/v dilution: 0 ml 3% v/v dilution : volume of foam does not exceed 60 ml after 1 min	Test report REGU013-G, Measure of persistent foaming OXYPUR CS, 26/04/2019

		OXYPUR CS	0.25% v/v dilution: volume of foam does not exceed 60 ml after 1 min 1% v/v dilution: 0 ml 3% v/v dilution : volume of foam does not exceed 60 ml after 1 min	
		Acidofoam CF	The product is intended to be applied as a foam	
Flowability/ Pourability/ Dustability	MT 148	All products	Residue for all products <1%: Sopuroxid 5: 0.85% Sopuroxid 5C: 0.57% Sopuroxid 3.2: 0.06% Acidofoam CF:0.06% Sopuroxid 15: 0.73% Oxypur CS: 0.07 % Rinsed residue for all products > 0.25%: Sopuroxid 5: 1.75% Sopuroxid 5C: 0.79% Sopuroxid 3.2: 1.33% Acidofoam CF:1.33% Sopuroxid 15: 0.31% Oxypur CS: 0.40% The rinsed residue is above 0.25%: The peracetic acid solutions have a surface tension lower than water: - 54.0 mN/m at 20°C for the	Test report REGU010-E: Pourability (rinsability) of SOPUROXID 5, 03/08/2016 Test report REGU012-E: Pourability (rinsability) of SOPUROXID 5C, 06/10/2016 Test report REGU015-E: Pourability (rinsability) of SOPUROXID 3.2, 03/08/2016 Test report REGU002-E: Pourability (rinsability) of ACIDOFOAM CF, 03/08/2016 Test report REGU011-E: Pourability (rinsability) of SOPUROXID 15, 03/08/2016 Test report REGU013-E: Pourability (rinsability) of OXYPUR CS, 03/08/2016

			neat solution (5%) - 47.7 mN/m at 20°C (ring method) for the neat solution (15 %) - 72 mN/m at 20°C for water. The equilibrium PAA has a slightly lower surface tension compared to pure water and therefore slightly enhanced liquid spreading and wetting of solid surfaces caused by PAA solutions compared to pure water is expected. One can understand that there (in theory) will stay slightly more residue on the walls of the container that in the case of pure water, and thus the weight of the container will be higher than expected, leading to higher percentage. Nevertheless since higher residues may cause hazardous situations during waste disposal, the applicant is willing to provide specific instructions for waste disposal in the SPC and via SDS.	
Burning rate — smoke generators	Waiver	All products	The products are not intended to be used as smoke generator (During the fogging application, the product Sopuroxid 3.2 is intended to be used as nebulizer and not as smoke generator).	
Burning completeness — smoke generators	Waiver	All products	The products are not intended to be used as smoke generator (During the fogging application, the product Sopuroxid 3.2 is intended to be used as nebulizer and not as smoke generator).	
Composition of	Waiver	All products	The products are not intended to be used as smoke generator	

smoke — smoke generators			(During the fogging application, the product Sopuroxid 3.2 is intended to be used as nebulizer and not as smoke generator).	
Spraying pattern — aerosols	Waiver	The products are not intended to be used by aerosol application		
Physical compatibility	Waiver	The products are not intended to be used in combination with other substances/ mixtures / biocidal / non-biocidal products.		
Chemical compatibility	Waiver	The product is not intended to be used in combination with other substances/ mixtures / biocidal / non-biocidal products		
Degree of dissolution and dilution stability	MT 41 Measurement performed at highest in use concentration	Sopuroxid 5	Product diluted at 3% v/v: no separated material is observed	Test report REGU010-D-V2: Dilution stability of SOPUROXID 5 aqueous solution, 22/07/2019
		Sopuroxid 5C	Product diluted at 3% v/v: no separated material is observed	Test report REGU012-D-V2: Dilution stability of SOPUROXID 5C aqueous solution, 22/07/2019
		Sopuroxid 3.2	Product diluted at 40% v/v: no separated material is observed	Test report REGU015-D-V2: Dilution stability of SOPUROXID 3.2 aqueous solution, 22/07/2019
		Acidofoam CF	Product diluted at 3% v/v: no separated material is observed	Test report REGU002-D: Dilution stability of ACIDOFOAM CF aqueous solution, 03/08/2016
		Sopuroxid 15	Product diluted at 3% v/v: no separated material is observed	Test report REGU011-D-V2: Dilution stability of SOPUROXID 15, 22/07/2019
		Oxypur CS	Product diluted at 3% v/v: no separated material is observed	Test report REGU013-D-V2: Dilution stability of OXYPUR CS, 22/07/2019

Surface tension	OECD 115 20°C	All products except Acidofoam CF	Sopuroxid 5: At 0.05 % v/v dilution = 68.6 mN/m At 1 % v/v dilution = 66.5 mN/m Sopuroxid 5C: At 0.05 % v/v dilution = 69.1 mN/m At 0.1 % v/v dilution = 69.1 mN/m Sopuroxid 3.2: At 0.1 % v/v dilution = 70.4 mN/m At 3 % v/v dilution = 64.8 mN/m Sopuroxd 15: At 0.1 % v/v dilution = 69.4 mN/m At 0.5 % v/v dilution = 65.8 mN/m Oxypur CS: At 0.1 % v/v dilution = 69.7 mN/m At 0.5 % v/v dilution = 68.9 mN/m	Test report REGU010-F: Physico-chemical characteristics of SOPUROXID 5, 03/08/2016 Test report REGU012-F: Physico-chemical characteristics of SOPUROXID 5C, 06/10/2016 Test report REGU015-F: Physico-chemical characteristics of SOPUROXID 3.2, 03/08/2016 Test report REGU011-F: Physico-chemical characteristics of SOPUROXID 15, 03/08/2016 Test report REGU013-F: Physico-chemical characteristics of OXYPUR CS, 03/08/2016
		Acidofoam CF	2% v/v solution : 24.9 mN/m 3% v/v solution : 24.1 mN/m	Test report REGU002-F: Physico-chemical characteristics of ACIDOFOAM CF, 03/08/2016

Viscosity	OECD 114, Rotational viscosimeter Shear rate: 13.2 s^{-1}	All products	Sopuroxid 5: At 20°C = 4.5 mPa.s At 40°C = 4 mPa.s Sopuroxid 5C: At 20°C = 6.7 mPa.s At 40°C = 5.1 mPa.s Sopuroxid 3.2: At 20°C = 4.7 mPa.s At 40°C = 4.8 mPa.s Acidofoam CF: At 20°C = 3.7 mPa.s At 40°C = 3.4 mPa.s Sopuroxid 5C: At 20°C = 3.8 mPa.s At 40°C = 3.7 mPa.s Oxypur CS: At 20°C = 4.8 mPa.s At 40°C = 3.7 mPa.s	Test report REGU010-F: Physico-chemical characteristics of SOPUROXID 5, 03/08/2016 Test report REGU015-F: Physico-chemical characteristics of SOPUROXID 3.2, 03/08/2016 Test report REGU002-F: Physico-chemical characteristics of ACIDOFOAM CF, 03/08/2016 Test report REGU011-F: Physico-chemical characteristics of SOPUROXID 15, 03/08/2016 Test report REGU013-F: Physico-chemical characteristics of OXYPUR CS, 03/08/2016 Test report REGU012-F: Physico-chemical characteristics of SOPUROXID 5C, 06/10/2016

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<tr>
<td>Conductivity</td>
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<td>Sopuroxid 5C</td>
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<tr><th colspan="6">Conductivity</th></tr>
<tr><td>Temperature (°C)</td><td>22,1</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Concentration (%v/v)</td><td>0,05</td><td>0,25</td><td>0,5</td><td>0,75</td><td>1</td></tr>
<tr><td>Conductivity</td><td>Conductivity (mS/cm)</td><td>Conductivity (mS/cm)</td><td>Conductivity (mS/cm)</td><td>Conductivity (mS/cm)</td><td>Conductivity (mS/cm)</td></tr>
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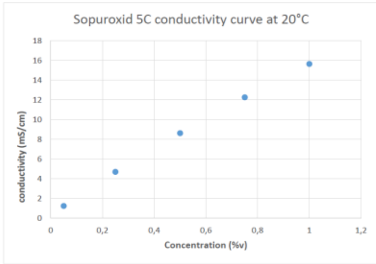

The temperature coefficient is 0.1%/°C between 20°C and 60°C.
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<td>Test report REGU012-G: Conductivity of SOPUROXID 5C, 06/10/2016</td>
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Regarding the storage data the table below summarizes the results for the entire SOPUROXID Family.

For storage tests, the content in H_2O_2 and PAA has been monitored, in combination with appearance and packaging appearance. Acetic acid being intrinsically stable, its concentration was not systematically followed during the stability tests. According to the applicant, as supplementary supporting information, QC sampling was done on a random basis, this on different peracetic acid-based products, aged from 22 to 52 weeks. Samples were analyzed to determine the possible acetic acid degradation. The average variation in the acetic acid concentration at the end of the 3 stability periods is lower than 6.5%.

- The product Sopuroxid 5 demonstrates a shelf life of 6 months.

  Sopuroxid 5C is stable in regard with PAA content at 3 and 6 months. Since it is the only active ingredient, that means that the efficacy can be ensured at 6 months. Tests on Sopuroxid 5C demonstrates however a high variability of H_2O_2 during the accelerated and ambient-temperature tests at 6 months, but is acceptable at 3 months. The applicant has submitted efficacy tests on the aged products, but they were not accepted by the efficacy expert. However, considering that the PAA content (the active substance itself) is stable and the content of only one member of equilibrium is higher than the admitted variation and in accordance with Sopuroxid 5 stability tests, BE eCA proposes a **shelf-life of 6 months for meta-SPC 1**.

  In order to take into account a decrease in H_2O_2 content higher than 10% at 30°C for Sopuroxid 5C, the following RMM should be taken into account: do not store at temperatures higher than +30°C.

- The product Sopuroxid 3.2 shows good stability during the accelerated storage test and ambient temperature test. Therefore, a **shelf-life of 6 months is demonstrated for meta-SPC 2**.

- **Meta-SPC 3 product: Acidofoam CF demonstrates a shelf-life of 26 weeks**. The applicant requests **6 months**, that is granted according to the results of both storage tests.

- Sopuroxid 15 shows enough stability for 18 weeks when stored at 30°C and 6 months at ambient temperature. Oxypur CS shows enough stability for 6 months at ambient temperature and for 12 weeks at 30°C. **The shelf life of 6 months can thus be granted for meta-SPC 4.**

It is important to note that, according to the Applicant experience, the content of the iron in sulfuric acid is to be less than 5ppm. The value of 3 ppm has been provided by the Applicant and corresponds in fact to their exact internal quality standard. The value of 5 ppm is a maximal quantity accepted to not affect the stability of the products. Indeed, higher content may lead to severe issues with stability of peracetic acid.

Meta-SPC	Product	Accelerated	Ambient	Test eff on aged product	Conclusion	Conclusion by meta-SPC
1	Sopuroxid 5	**40°C – 12 w** PAA **OK** H_2O_2 **OK**	**20°C – 6 m** PAA **OK** H_2O_2 **OK**	-	Shelf life of 6 m	Shelf-life of 6 months + RMM: do not store at temperatures higher than 30°C
	Sopuroxid 5C	**30°C – 18 w** PAA **OK** H_2O_2 **NOK** **30°C – 12 w** PAA **OK** H_2O_2 **OK**	**20°C – 6m** PAA **OK** H_2O_2 **NOK** **20°C – 3m** PAA **OK** H_2O_2 **OK**	Available at the end of Test report REGU012-A	Shelf life of 6 m based on the storage studies Since the hydrogen peroxide content is sensitive to the temperature for the reference product, the following RMM is to be indicated: do not store at temperatures higher than 30°C.	
2	Sopuroxid 3.2	**30°C – 18 w** PAA **OK** H_2O_2 **OK**	**20°C – 6m** PAA **OK** H_2O_2 **OK**	-	Shelf life of 6m Since the accelerated storage test has been performed at 30°C only, the following RMM is to be indicated: do not store at temperatures higher than 30°C.	Meta SPC: shelf-life of 6 months + RMM: do not store at temperatures higher than 30°C
3	Acidofoam CF	**30°C – 18 w** PAA **OK** H_2O_2 **OK**	**20°C – 26w** PAA **OK** H_2O_2 **OK**	-	Shelf life of 26w = 6m Since the accelerated storage test has been performed at 30°C only, the following RMM is to be indicated: do not store at temperatures higher than 30°C.	Meta SPC: shelf-life of 6 months + RMM: do not store at temperatures higher than 30°C
4	Sopuroxid 15	**30°C – 18 w** PAA **OK** H_2O_2 **OK**	**20°C – 6m** PAA **OK** H_2O_2 **OK**	Available at the end of Test report REGU011-A	Shelf life of 6 m	Meta SPC: shelf-life of 6 months + RMM: store at ambient

	OXYPUR CS	**30°C – 18 w** PAA **NOK** H_2O_2 **NOK** **30°C – 12 w** PAA **OK** H_2O_2 **OK**	**20°C – 6m** PAA **OK** H_2O_2 **OK**	Available at the end of Test report REGU013-A	Shelf life of 6 m Since the hydrogen peroxide content is sensitive to the temperature for the reference product and Oxypur CS does not show acceptable variation of PAA for the accelerated test the following RMM is to be indicated: store at ambient temperature.	temperature

1.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Waiver	According to the Guidance on the Application of the CLP Criteria, chapter 2.15.3 (based on CLP Annex I, Chapter 2.1), explosive properties are incorporated in the decision logic for organic peroxides.		
Flammable gases	Waiver	Not relevant regarding the formulation of the products		
Flammable aerosols	Waiver	Not relevant regarding the formulation of the products		
Oxidising gases	Waiver	Not relevant regarding the formulation of the products		
Gases under pressure	Waiver	Not relevant regarding the formulation of the products		
Flammable liquids	ISO 3679, method I	Sopuroxid 5 [PAA]: 5% [H_2O_2]: 21%	Flash point > SADT (60°C) → no flammability hazard	PML 1995-C18 Physico-chemical properties of three peroxy acetic acid formulations, W. Mak, April 1995.
		Sopuroxid 15 [PAA]: 15% [H_2O_2]: 22%	Flash point > SADT (55°C)→ flammability hazard cat 3.	
		For the rest of products, please see the explanation a) below		
Flammable solids	Waiver	Not relevant regarding the formulation of the products		
Self-reactive substances and mixtures	Waiver	According to the CLP Annex I, 2.8.1.1 : "*Self-reactive substances or mixtures are thermally unstable liquid or solid substances or mixtures liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). This definition excludes substances and mixtures classified according to this Part as explosives, organic peroxides or as oxidising.*"		
Pyrophoric liquids	Waiver	The liquid is known to be stable at room temperature for prolonged periods of time.		
Pyrophoric solids	Waiver	Not relevant regarding the formulation of the products		
Self-heating substances and mixtures	Waiver	According to the CLP Guidance: "In general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore liquids are not classified as self-heating."		

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
Substances and mixtures which in contact with water emit flammable gases	Waiver	Experience in handling and use of the products shows that the products are not known to emit flammable gases.		
Oxidising liquids	Waiver	According to the Guidance on the Application of the CLP Criteria: "*In general, organic peroxides do not have or have only weak oxidising properties*" and "*Under CLP organic peroxides are comprised in a separate hazard class and they must not be considered according to the procedures described for oxidising liquids*". For more information, please see also organic peroxide, below the table.		
Oxidising solids	Waiver	Not relevant regarding the formulation of the products		
Organic peroxides	1) Detonation test in accordance with UN MTC, test A.6 2) Deflagration test in accordance with UN MTC, test C.1 and test C.2 3) Heating under confinement in accordance	Sopuroxid 15 [PAA]: 15% [H_2O_2]: 22%	1) The average fragmentation lenght is 160 mm (reference value: 227 mm) → No detonation. 2) Deflagration tests were performed under confinement (as result: deflagrating slowly) and under atmospheric pressure (as result: not deflagrating) → The overall conclusion is thus the sample does not deflagrate. 3) No rupture of the test tubes in both tests E.1 and E.2 → no sensitivity to	TNO 20176 R10466 Classification of Sopuroxid 15, March 2017.

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
	with UN MTC, test E.1 and E.2 4) Explosive power in accordance with UN MTC, test F.4		heating under confinement 4) the average net expansion is around 12 ml, classifying the explosive power as low	
		All the rest of products	No tests (please see the explanation b) below: exception case)	
Corrosive to metals	For safety reasons, before conducting the test according to the UN Test C.1 requirements, a pre-test has been made by immersion of mild steel in a limited quantity of peracetic acid product. Based on the outcome of the pre-test, decision is made to pursue the testing according to UN Test C.1 The C.1 test has been realised at	Tested on each product of the SOPUROXID Family + placebo formulations (exactly the same compo than the products of the Sopuroxid family, whithout hydrogen peroxide and PAA)	**Result of pre-test :** clear observation of attack (oxygen production and hydrogen peroxide degradation) on the suface of metal strips (visual appreciation) ➔ the UN C.1 test has been conducted on placebo formulations without hydrogen peroxide and consequently whihout PAA. **Result of UN C.1 test on steel plate :** the loss of weight in 7 days for all of	REGU030: Determination of the metal corrosion properties of the "SOPUROXID BPF" products according to UN C.1 test, 8/6/20

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	ambient temperature instead of 55°C Duration of the test: 1 week, except for Sopuroxid 5C – like formulation: 1 hour was enough to demonstrate metal corrosion		products of SOPUROXIDis higher than 13.5% threshold (ranging from 19.2 to 30.2 %). The weight loss corresponds to the corrosion rates from 1.198 mmy to 1.886 mmy. Even if the value is lower than the threshold defined by the CLP (could be explained by the temperature of testing), there is a clear corrosion on the steel plate, whithout PAA / H2O2. The presence of the hydrogen peroxide and peracetic acid would still increase the level of corrosion. Since the effect on steel is evident, no aluminium plates have been tested. The long term experience of the applicant also confirm the	

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
			experimental data: the products of SOPUROXIDare metal corrosive	
Auto-ignition temperatures of products (liquids and gases)	Waiver	The determination of the auto ignition temperature is not relevant for organic peroxides. Available test methods are for non-decomposing vapour phases but the vapours of organic peroxides decompose during execution of the test and auto ignition of these organic peroxide can never be excluded.		
Relative self-ignition temperature for solids	Waiver	Not relevant regarding the formulation of the products		
Dust explosion hazard	Waiver	Not relevant regarding the formulation of the products		

a) The determination of flash point was performed on two formulation Sopuroxid 5 and Sopuroxid 15. Additionnaly the CAR of the active substance states that most of the PAA equilibrium solutions ranging from 5% to 15% PAA show flash point of 68°C and higher. By taking into account the experimentally measured SADT, the CAR statement and long-term experience in handling such products from the applicant, BE eCA is of opinion that:
- the product Sopuroxid 5 should be classified as non flammable liquid. All products containing ≤ 5% PAA should also be considered as non flammable liquids.
- the product Sopuroxid 15 should be classified as flammable liquid cat. 3.

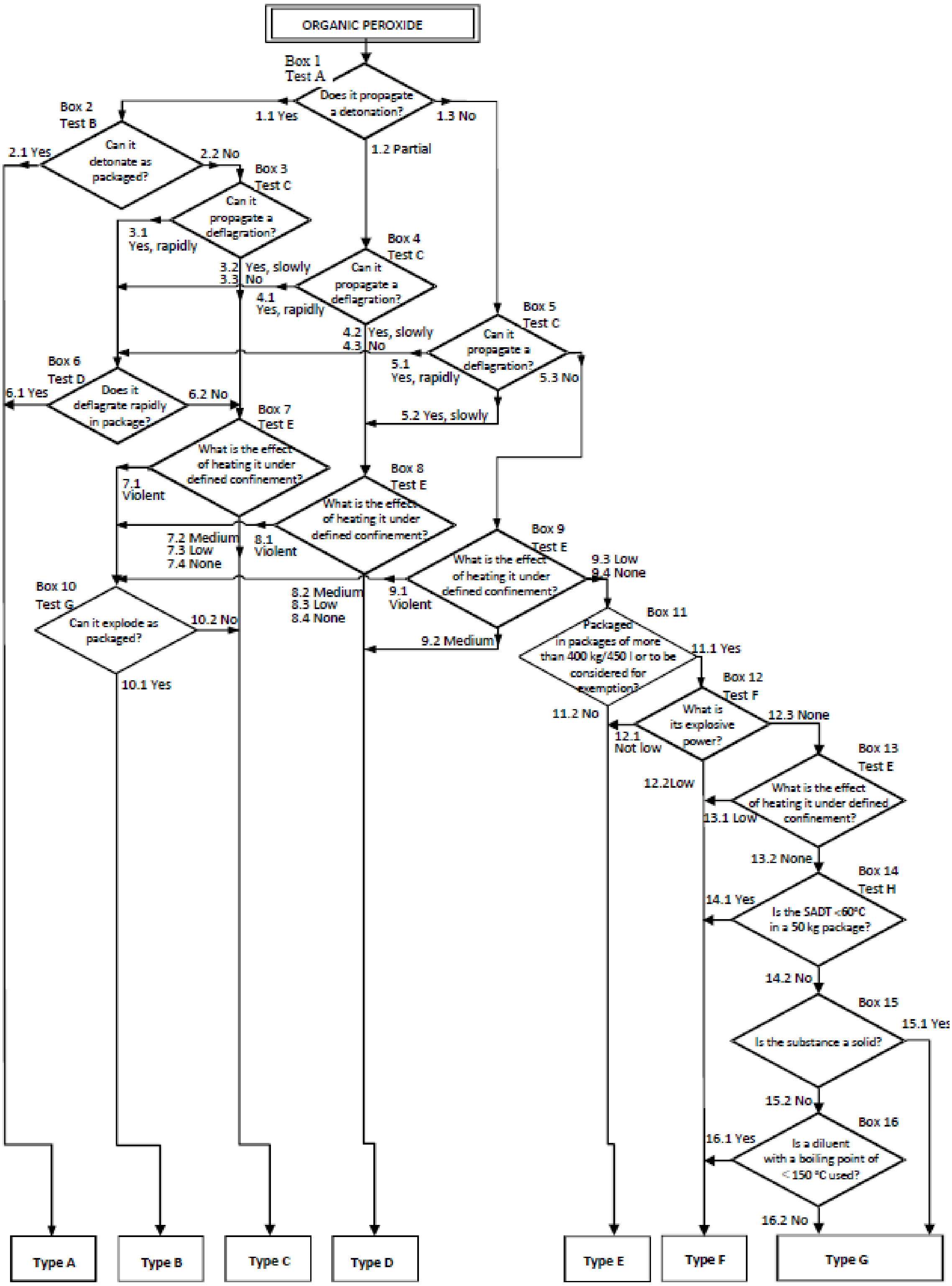
b) Because of the presence of peracetic acid, the products of this SOPUROXID Family are classed as organic peroxide, on basis of the chemical structure of these substances.

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 Sopuroxid 15, covering meta-SPC 4.

The applicant has submitted a set of tests for Sopuroxid 15 (covering meta-SPC 4):
- 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

All tests were 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.

By following the decision tree described in the CLP Guidance (see above), the category experimentally determined for Sopuroxid 15 **is F**.



Does it propagate a detonation? →NO → Can it propagate a deflagration? → NO → What is the effect of heating it under defined confinement? → NONE → Packaged in packages of more than 400 kg/ 450 l or to be considered for exemption? → YES → What is its explosive power? → LOW → **Type F** .

Since the products of **meta-SPC 4** are classified in **organic peroxide hazard F** and in accordance with the Guidance on the Application of the CLP Criteria: "*In general, organic peroxides do not have or have only weak oxidising properties*" and "*Under CLP organic peroxides are comprised in a separate hazard class and they must not be considered according to the procedures described for oxidising liquids*".

Based on the tests results of the worst case, the rest of the meta-SPCs, containing less PAA than meta-SPC 4, should be classified in the same (type F) or less strict organic peroxide (type G) hazard class. Since the main solvent of all of these products is water, the very last bullet in the decision tree: "is a diluent with boiling point <150°C used" will automatically classify all products of this family in organic peroxide class F.

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 & 3**, containing respectively, 5, 3.2, 3.2 and 5 % w/w PAA. Based on this exemption, the Meta-SPCs 1, 2 & 3, 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 according ot the decision tree and because of water as a diluent) to avoid duplicate labelling as oxidising liquid and organic peroxide.

The resulting classification is summarized in the table below:

	Classification	H-phrase	Labelling
Meta-SPC 1 (5% PAA)	Ox Liq 2 Org Perox G Met Corr 1	H272: May intensify fire; oxidiser - H290: May be corrosive to metals	GHS03, Danger - GHS05, Warning
Meta-SPC 2 (3.2% PAA)	Ox Liq 2 Org Perox G Met Corr 1	H272: May intensify fire; oxidiser - H290: May be corrosive to metals	GHS03, Danger - GHS05, Warning
Meta-SPC 3 (3.2% PAA)	Ox Liq 2 Org Perox G Met Corr 1	H272: May intensify fire; oxidiser - H290: May be corrosive to metals	GHS03, Danger - GHS05, Warning
Meta-SPC 4 (15% PAA)	Flam Liq 3 Org Perox F Met Corr 1	H226: Flammable liquid and vapour H242: Heating may cause a fire H290: May be corrosive to metals	GHS02, Warning GHS02, Warning GHS05, Warning

1.2.4 Methods for detection and identification

The applicant has submitted validation of the method for peracetic acid, hydrogen peroxid, acetic acid and HEDP.

The blank solutions for the PAA, H2O2 and acetic acid, are not technically feasible. Indeed, the preparation of a co-formulant mix (blank sample containing all components except peracetic acid) is not possible because the simultaneous presence of the components hydrogen peroxide and acetic acid in the blank would inevitably lead to the formation of peracetic acid and thus alter the reference value.
The preparation of a blank containing all components except hydrogen peroxide (but including peracetic acid) is not possible since the presence of peracetic acid is always linked to the simultaneous presence of hydrogen peroxide. Thus, blank solutions are technically not feasible.

Owing to the fact that the method is titration and thus is, by definition, a direct method, interference of other components would only be possible if such components could react themselves with the titration solutions. This would only be the case if they were also oxidizing substances, which is, however, not the case for the standard co-formulants of peracetic acid products.

- Permanganate and iodometric titration are reductive titrators and by definition can only react with oxidative components.
- The other components are fully inert towards reductors, as could be seen in the robustness check where various concentrations in acetic acid and sulphuric acid doesn’t impact the titration.
- Sopuroxid 15 and oxypur CS have the same behaviour in the robustness check, meaning that HEDP doesn’t impact the measurement.
- Acidofoam CF and Sopuroxid 3.2 do have the same behaviour, so no impact of the amineoxide.

Analytical methods for the analysis of the product 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 and hydrogen peroxide	Oxido-reduction titration by $KMnO_4$, KI and $Na_2S_2O_3$ The validation was realized on the SOPUROXID 5 product. The robustnes	5 fortifications - Triplicates	Linearity[4] for H_2O_2: R^2 = 0.9978 between 878 mg/L (15% w/w) and 2297 mg/L (25% w/w) (5 points) (y=1.0707x - 62.241) Linearity for PAA: R^2	Under controlled reaction conditions, the method is specifc for both PAA and HP	H_2O_2: 99 - 104 PAA: 98 - 110	102 103	0.03 0.16	PAA: 2.5 g/kg (From CAR of PAA) HP: 3.4 g/kg (From CAR of PAA)	Hydrogen peroxide and peracetic acid determination – report IT.LCT.08, 07/06/2006 Validation report: Peroxide and peracetic acids assays by titration in the concentration product – report VAL028

[4] The methods described under this section point are titration methods. The volumes of the titration solutions consumed in the titration (i.e. the consumption of sodium thiosulphate solution in case of peracetic acid determination or the consumption of ceric acid in case of hydrogen peroxide determination) are directly related to the amount of the respective analyte in the test solution. In other words, the consumption of the titration solution is a stoichiometric reaction and the relation between the amount of the analyte in the test solution and the consumption of the titration solution cannot be but linear.
Non-linearity as observable in indirect detection systems such as HPLC or GC methods can therefore be excluded. Consequently, it is scientifically not justified to request data on linearity.

	s of the method was tested on Sopuroxid 15, Sopuroxid 5C, Sopuroxid 3.2 and Oxypur CS. The method is considered as robust.		= 0.9931 between 219 mg/L (3,0 % w/w) and 518 mg/L (16,0 % w/w) (5 points) (y = 1.0259x + 1.4655)						– Febrary 03, VAL157:Validation report of the analytical method to determine the peracetic acid & hydrogen peroxide content of a product by titration, 07/05/2019
Acetic acid[5]	HPLC – DAD	5 replicates for 2 fortification levels (1x and 2x LOQ)	0.2 to 2 g of Acetic acid /L (6 points) r = 0.99996 y = -2.5 + 4.3x	Retention time : 10.8 min No analytical interferences were detected.	100 - 103%	101.4%	1%	0.283 g Acetic acid / L	Peracetic acid 15%, Method Validation for Acetic Acid, 26/04/2017
HEDP[6]	Ion exchange	6 replicates for 3 fortification	Conductivity detection:	No ingredient contribute	99.01 - 102.48 (fortificati	101.3% (fortification level 80%)	0.8%	Signal to noise ratio of the lowest	Validation report, Method validation of

[5] The method for acetic acid has already been assessed during the evaluation of the active substance dossier.
[6] The method for HEDP has already been assessed during the evaluation of the active substance dossier.

	chromatography with conductivity/ UV detection	levels (80, 100, 120%)	r^2 = 0.9999 (6 points, from 0.1 to 1.7 %) y = -0.0093+16.53x UV detection : r^2 = 0.9957 (6 points,	s to an extent of more than +- 3% to the total quantity of the analyte	on level 80%) 100.11 – 102.79 (fortification level 100%) 98.93 – 101.11 (fortification level 120%) 95.87 - 104.78 (fortification level 80%) 103.32 – 104.88 (fortification level 100%)	101.7%(fortification level 100%) 100.6% (fortification level 120%) 101.2% (fortification level 80%) 104.2%(fortification level 100%)	0.83 %	calibration sample (1.2 mg/L) is better than 10:1	the Determination of the Stabilizer Hydroxyethane-1.1-Diphosphonic Acid (HEDP) in Peracetic Acid Solutions, April 2014

			from 0.1 to 1.7 %) y = 5.0373 + 2.7481x The first detection method shows a slightly better linearity		94.56 – 96.28 (fortification level 120%)	95.6% (fortification level 120%)			
Sulphuric acid	According to the CAR of active substance (doc IIA) an analytical method has been provided in CAR and consequently no new method is requested.								

No analytical method has been submitted for the detection of persulfuric acid. The formation of persulfuric acid is not likely to occur since a very high concentration of hydrogen peroxide (60-90%) and sulfuric acid is needed for persulfuric acid to form. In the BPF, the high water content makes such formation unlikely. In addition, persulfuric acid is highly unstable. If persulfuric acid is present, it is not expected to be found in any significant concentration.

Analytical methods for monitoring
No general monitoring method is available for peracetic acid. Therefore, reference is made to the different relevant analytical methods for the different matrixes, as presented in the sections here below.

Analytical methods for soil
Because absorption to sediment/soil is not likely to occur due to the physico-chemical properties of peracetic acid and because of rapid degradation in contact with organic material, no analytical method for soil needs to be provided.

Analytical methods for air
Analytical method for detection in air was submitted in the CAR dossier.

Analytical methods for water
Analytical method for detection in water was submitted in the CAR dossier.

Analytical methods for animal and human body fluids and tisues
Analytical method for detection in blood was submitted in the CAR dossier.

Analytical methods for monitoring of active substances and residues in food and feeding stuff
The applicant has provided a justification for a non-submission of data for analytical method for residues in/on food or feedstuffs based on to the properties of peracetic acid (highly unstable and rapid degradation upon contact with organic matter).

1.2.5 Efficacy against target organisms

1.2.5.1 Function (organisms to be controlled) and field of use (products/objects to be protected) for the products of the ***SOPUROXID FAMILY***

Main group 01: DISINFECTANTS
Product types :

- PT2 (*Disinfectants and algaecides not intended for direct applications to humans or animals*)
- PT3 (*Veterinary Hygiene*)
- PT4 (*Food & feed Area*)

The biocidal products within SOPUROXIDcontain Peracetic acid (CAS N° 79-21-0) as active substance.

SOPUROXIDis divided into 4 Meta SPCs.

According to the product and the intended uses, the following main use procedures are considered :
1) CIP (Cleaning In Place) with circulation
2) Water Disinfection (only in food industries – for rinsing of recycled items)
3) Disinfection of surfaces/equipment by
   a. Manual treatment
   b. Spraying
   c. Soaking
   d. Foaming
   e. Room disinfection by fogging

The biocidal products within SOPUROXIDare liquid concentrates that need to be diluted with tap water. They are intended to be used by professional and industrial users only.

Target organisms may include (besides bacteria and yeasts as mandatory target organisms), fungi, viruses, bacteriophages, bacterial spores relevant to the products' areas of use and in-use conditions.

All the product of SOPUROXIDare intended to be used to control microorganisms responsible for infectious diseases and to avoid contamination of food/feed (PT4 applications).

For PT2 applications, the "organisms to be protected" is human beings. For PT4 applications, the "organisms to be protected" are human beings and animals. For PT3 applications, the "organisms to be protected" are first animals and second human beings as animal consumers.

Please find below a table summarizing all the intended uses with target organisms as originally claimed by the Applicant for SOPUROXID:

	Meta SPC-1 (5% PAA) & Meta SPC-4 (15% PAA)	***Target Organisms claimed***
PT2	Use #1.1/4.1: Disinfection of surfaces in industrial, public and health care areas - manual treatment (mopping)	**Bacteria** **Yeasts**
	Use #1.2/4.2: Disinfection of surfaces in industrial, public and health care areas - manual treatment (spraying)	
	Use #1.3/4.3 : CIP in the pharmaceutical and cosmetic industry	
	Use #1.4/4.4 : Surface disinfection in greenhouses by spraying with personal enclosure (in absence of plants - for general hygiene purpose only)	
	Use #1.5/4.5 : Surface disinfection in greenhouses by spraying without personal enclosure (in absence of plants - for general hygiene purpose only)	
	Use #1.6/4.6: Disinfection of agriculture/horticulture equipment by soaking (in absence of plants - for general hygiene purpose only)	
	Use #1.7/4.7 : Disinfection of surfaces and agriculture/horticulture equipment by spraying (in absence of plants - for general hygiene purpose only)	
	Use #1.8/4.8 : Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (in absence of plants - for general hygiene purpose only)	
	Use #1.9/4.9 : Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (closed room) (in absence of plants - for general hygiene purpose only)	
PT3	Use #1.10/4.10 : Disinfection of animal housing by low-pressure manual spraying – spraying with personal enclosure	**Bacteria** **Yeasts** **Viruses**
	Use #1.11/4.11 : Disinfection of animal housing by low-pressure manual spraying – spraying without personal enclosure	
	Use #1.12/4.12 : Disinfection of boots in footbaths in animal housing/husbandries	
	Use #1.13/4.13 : Disinfection of equipment by dipping	
PT4	Use #1.14/4.14 : Disinfection in Aseptic Filling Lines (crown corks, cheese moulds and food crates) - Automated spraying closed systems	**Bacteria** **Yeasts** **Viruses (+ bacteriophages)** **bacterial spores**
	Use #1.15/4.15 : Disinfection of equipment in the food and beverage industry by immersion	
	Use #1.16/4.16 : Disinfection of heat and ion exchangers, membrane filters and glass and PET bottles – CIP procedures	
	Use #1.17/4.17 : Disinfection of surfaces and equipment by low pressure spraying – spraying with personal enclosure	
	Use #1.18/4.18 : Disinfection of surfaces and equipment by low pressure spraying – spraying without personal enclosure	
	Use #1.19/4.19 : Disinfection of surfaces and equipment by low pressure spraying, manually	
	Use #1.20/4.20 : Disinfection of surfaces and equipment by low pressure spraying, automatically	
	Use #1.21/4.21 : Disinfection of surfaces and equipment by low pressure spraying – automatic spraying (closed room)	
	Use #1.22/4.22 : General Disinfection of inner surfaces (pipelines, tanks, vessels, …) by CIP procedures in food industries under clean conditions	
	Use #1.23/4.23 : Disinfection of water used for rinsing of recycled items during the washing process	**Bacteria** **Yeasts**
	Meta SPC-2 with product ***SOPUROXID 3.2* (3.2% PAA)** – by fogging	
PT2	Use #2.1 : Room Disinfection by fogging - In industrial, public and health care areas (pharmaceutical and cosmetic industry)	**Bacteria** **Yeasts** **Viruses** **bacterial spores**
	Use #2.2 : Room Disinfection by fogging - In agriculture/horticulture areas (in absence of plants - for general hygiene purpose only)	**Bacteria** **Yeasts**
PT3	Use #2.3 : Room Disinfection by fogging – In animal housing	**Bacteria** **Yeasts** **Viruses**
PT4	Use #2.4 : Room Disinfection by fogging – In storage rooms with special device in storage cellar or room	**Bacteria** **Yeasts**

		Viruses (+ bacteriophages) bacterial spores
	Meta SPC-3 (3.2% PAA) – by foaming	
PT2	Use #3.1 : Disinfection of surfaces in industrial, public and health care areas – foam application on surfaces	**Bacteria Yeasts**
	Use #3.2 : Disinfection of surfaces and agriculture/horticulture equipment by foaming, manually (in absence of plants - for general hygiene purpose only)	
	Use #3.3 : Disinfection of surfaces and agriculture/horticulture equipment by automatic foaming (in absence of plants - for general hygiene purpose only)	
	Use #3.4 : Disinfection of surfaces and agriculture/horticulture equipment by automatic foaming (closed rooms) (in absence of plants - for general hygiene purpose only)	
PT3	Use #3.5 : Disinfection of animal housing by foaming – foaming with personal enclosure	**Bacteria Yeasts Viruses bacterial spores**
	Use #3.6 : Disinfection of animal housing by foaming – foaming without personal enclosure	
PT4	Use #3.7 : Disinfection of surfaces by foaming with personal enclosure	**Bacteria Yeasts Viruses (+ bacteriophages) bacterial spores**
	Use #3.8 : Disinfection of surfaces by foaming without personal enclosure	

NOTE #1: Disinfection in greenhouses, in horticulture areas

The products are intended to be used ***for general hygiene purpose ONLY*** to disinfect surfaces (such as windows, tables, floors, …) in greenhouses and horticulture rooms in absence of plants (between two productions, …) & gardening/horticulture equipment to prevent spread of harmful organisms via soil and possible surface contaminations, but also to prevent infections of the users caused by injury with the gardening equipment. Furthermore, there is no specific claim against strains (or diseases) that are harmful to plants. According to the CA document from July 2019 (Doc. 8.1), the uses are considered to be biocidal products.

NOTE #2: Micro-preservation of water (use #1.23 & #4.23)

Micro-preservation of rinsing water (PT 4 - Meta SPC1 and Meta SPC 4)

1) Clarification on the intended uses (from the Applicant)

Rinsing water to be used in the food-industry to rinse vessels, surfaces, etc… after they have been cleaned and/or disinfected should be rinsed off before contact with food/feed. This water is per definition "potable" water as it is considered to be conform to the water quality standards for human consumption.
Nevertheless, during the storage of this water in a food plant or during the transfer, this water could be slightly re(contaminated). In order to avoid this new contamination to the food/feed, it is in some circumstances recommended to treat this water with a very limited quantity of PAA. (= micro preservation).
Example: bottle washer for recycled bottles. The bottles are cleaned/washed and have to be rinsed off after the cleaning. It is important to have this water 100% sterile. The use of chlorine is not recommended for this application because of the off-flavors it creates, even at ppb level.

2) BE eCA opinion : no comment. Use very well described and acceptable.
3) Final decision after peer review & WG discussion :

   The name of this use has been amended into: "Disinfection of water used for rinsing of recycled items during the washing process".

   Water from drinking water quality shortly stored in tanks until use to rinse items such as bottles. The water should be disinfected to avoid recontamination and in

extention also to avoid cross-contamination of inner bottle surfaces. After rinsing, the items will be turned upside down in order to remove the residual water. The water is not intended to be drunk.
Considering the minutes of the CA meeting from May 2016 (agenda item 8.1), this use should fall under PT4.

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

Mode of action
As also explained in the CAR of PAA, Cords and Dychdala, 1996, conclude from literature data (status 1993) that the destruction of the microbial cell by PAA can be grouped into three mechanisms:

- Denaturation of cell proteins and interruption of cell transport
- Inactivation of enzymes essential to cell metabolism, and
- Disruption of cell membranes and their permeability.

More recent publications add further aspects:

- It is claimed that the hydroxyl radical is the lethal species and that iron species are also involved in the mechanism of action.
- It is speculated that organic (oxygen) radicals formed from PAA such as $CH_3C(=O)O.$ or $CH_3C(=O).$, because of their greater longevity than the hydroxyl radical, are involved in the sporicidal action of PAA.
- Organic radicals formed from PAA are claimed to be sporicidal and to act as reducing agents for spores that are normally in a highly oxidised state.

In literature it is often claimed that PAA is not deactivated by catalase or peroxidase and that this should be the reason for its higher efficacy in comparison to hydrogen peroxide. This is not correct: It is well known that certain micro-organisms such as *Pseudomonas* species (gram-negative) and *Micrococcus* species (gram-positive) can contain high levels of anti-oxidant enzymes. These enzymes consume PAA so that the PAA concentration can decrease during the course of the disinfection (1 mmol to undetectable level in less than 10 minutes) resulting in non-linear disinfection.

When comparing the biocidal activity of peracetic equilibrium solutions (containing the active substances hydrogen peroxide and peracetic acid) with the activity of hydrogen peroxide alone, it becomes evident that peracetic has intrinsic biocidal properties, which exceeds the activity of hydrogen peroxide.

Time delay
Peracetic acid is known to be fast acting. The contact time depends on a combination of (i) the organism to be controlled, (ii) the PAA concentration applied, (iii) pH, (iv) temperature and (v) media. In the efficacy tests set-up, this difference in time delay has been taken into account.

1.2.5.3 Efficacy data

The product *Acidofoam CF* (3.2 % PAA) has been chosen as the representative product for the majority of efficacy testing of SOPUROXIDproducts, since it has the lowest concentration active substance compared to the other products of the SOPUROXID Family
Since the product *Sopuroxid 3.2* is only applied in fogging installations, additional tests with *Sopuroxid 3.2* were performed specifically to cover the use of the fogging installations.

Efficacy tests performed according to suspension and surface standards have been submitted : Phase 2/Step 1 efficacy tests are mandatory for products intended to be used for CIP with circulation procedures and water stream disinfection. Phase 2/Step 1 and Step 2 efficacy tests are mandatory for products intended to be used for soaking, spraying, fogging, foaming and manual cleaning procedures.

Since the applicant recommends sufficient rinsing or cleaning upfront disinfection on the label, clean conditions were assumed to perform all efficacy tests.

Impact of co-formulants on the efficacy of the BP
The biocidal product Sopuroxid 5C also contains 24.04 % sulfuric acid for conductivity reasons. This product is used in CIP installations where the product is recovered via conductivity.
To demonstrate that sulfuric acid does not have any intrinsic biocidal effect independent of the active substance peracetic acid, the efficacy of the biocidal formulation Sopuroxid 5C was compared with a placebo formulation Sopuroxid 5C without sulfuric acid. The bactericidal, fungicidal and yeasticidal effect was assessed according to EN 13697. Results of the different tests conducted are summarized in the table below.

Summary efficacy tests Sopuroxid 5C with and without sulfuric acid					
Test method	**Claim**	**Test substance**	**T°C**	**Contact time**	**Minimum effect concentration-**
EN 13697	Bactericidal	Sopuroxid 5C	22.1 °C	5	0.5 %
		Placebo	21.5 °C	5	0.5 %
	Yeasticidal	Sopuroxid 5C	22.4 °C	15	0.5 %
		Placebo	21.5 °C	15	0.5 %
	Fungicidal	Sopuroxid 5C	22.4 °C	15	1 %
		Placebo	21.5 °C	15	1 %

The efficacy was not increased or decreased in the treatments using Sopuroxid 5C as compared to the placebo. Therefore, we can conclude that sulfuric acid does not contribute to the bactericidal, fungicidal or yeasticidal activity of the whole formulation For details on the studies, please refer to the IUCLID Robust Study Summaries and the table on section #2.2.5.3.

Please see Confidential Annex for information about the other co-formulants.

Experimental data on the efficacy of the biocidal products against target organisms				
Test product **Please see Confidential Annex for PAA / H_2O_2 concentrations related to the Batch N° used**	**Function & Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results : effects**	**Reference & R.I.**
ACIDOFOAM CF (doc. 1) Batch N° F2996 ***SOPUROXID 3.2*** (doc. 8) Batch N° F2997	**Bactericidal activity** <u>Obligatory test organisms</u>: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus* <u>Additional test organisms:</u> *Salmonella typhimurium* *Listeria monocytogenes* *Campylobacter jejuni* *Enterobacter cloacae* *Lactobacillus brevis* *Pediococcus damnosus*	**EN 1276 (2010)** Quantitative suspension test <u>Temperature</u> : +4°C or 20°C ± 1°C <u>Contact time</u> : 5 min <u>Concentrations tested</u> : 0.25 – 1 – 1.5 % <u>I.S.</u> : 0.3g/L BSA (clean conditions)	***ACIDOFOAM CF*** Bactericidal activity (including *Salmonella typhimurium*, *Listeria monocytogenes*, *Campylobacter jejuni, Enterobacter cloacae, Lactobacillus brevis & Pediococcus damnosus*) in clean conditions : - at 0.25% ***ACIDOFOAM CF*** in 5 min at +20°C - at 1% ***ACIDOFOAM CF*** in 5 min at +4°C ***SOPUROXID 3.2 (wo foaming agent)*** Bactericidal activity in clean conditions : - at 0.25% ***SOPUROXID 3.2 (wo foaming agent)*** in 5 min at +20°C => The foaming agent in the product ***ACIDOFOAM CF*** does not impact the efficacy of the product.	Doc 1 – "EN 1276 Acidofoam CF - 2017-06-09 BT-SPU-02-01 (2) EN1276 Report 14 Mar 17 LM CW LM CW LM CW" Doc 8 – "EN 1276 Sopuroxid 3.2 - BT-SPU-02-02 (2) EN1276 SA EC EH PA Results 23 Feb 17 LM CW LM CW LM CW" **R.I. 1**
ACIDOFOAM CF Batch N° F2996	**Fungicidal/yeasticidal activity** <u>Obligatory test</u>	**EN 1650 + A1 (2013)** Quantitative suspension test <u>Temperature</u> : +4°C or 20°C ± 1°C	**Yeasticidal activity in clean conditions** - 0.12% ***ACIDOFOAM CF*** in 15 min at +20°C (including *Saccharomyces diastaticus* & *Saccharomyces cerevisiae*)	Doc 2 – "EN 1650 Acidofoam CF - BT-SPU-02-01 (1) EN1650 Report 14

	organisms: *Candida albicans* *Aspergillus brasiliensis* Additional test organisms: *Saccharomyces diastaticus* *Saccharomyces cerevisiae*	Contact time : 15 min Concentrations tested : 0.12 – 0.5 – 0.75 % I.S. : 0.3g/L BSA (clean conditions)	- At +4°C : contradictory results. ***NO** Fungicidal/Yeasticidal activity in clean conditions in 15 min at +20°C or +4°C at 0.75% (highest concentration tested).*	Mar 17 LM CW LM CW" **R.I. 1**
ACIDOFOAM CF Batch N° F3757	**Yeasticidal activity** Obligatory test organisms: *Candida albicans*	**EN 1650 + A1 (2013)** Quantitative suspension test Temperature : +4°C or 20°C ± 1°C Contact time : 5 or 15 min Concentrations tested : 0.06 - 0.12 – 0.25% I.S. : 0.3g/L BSA (clean conditions)	**Yeasticidal activity in clean conditions** - 0.12% ***ACIDOFOAM CF*** in 15 min at +4°C - 0.25% ***ACIDOFOAM CF*** in 5 min at +20°C	Doc. "Sopura Acidofoam CF EN 1650-2013 L19-0834-1 engl_V01" "Sopura Acidofoam CF EN 1650-2013 L19-0834-3 engl_V01" **R.I. 1**
ACIDOFOAM CF Batch N° F3864	**Fungicidal activity** Obligatory test organisms: *Aspergillus brasiliensis*	**EN 1650 + A1 (2013)** Quantitative suspension test Temperature : 20°C ± 1°C Contact time : 15 min Concentrations tested : 2 – 3 – 4 - 5% I.S. : 0.3g/L BSA (clean conditions)	**Fungicidal activity in clean conditions** 2% ***ACIDOFOAM CF*** in 15 min at +20°C	Doc. "SOPURA ACIDOFOAM CF EN 1650-2019 L20-0580-1_engl_V01" **R.I. 1**
ACIDOFOAM CF Batch N° F2996	**Sporicidal activity** Obligatory test organisms: *Bacillus subtilis* Additional test organisms: *Bacillus*	**EN 13704 (2002)** Quantitative suspension test Temperature : +4°C or 20°C ± 1°C Contact time : 60 min Concentrations tested : 0.5 – 2 - 3 % I.S. : 0.3g/L BSA (clean conditions)	**Sporicidal activity in clean conditions :** - at 2% ***ACIDOFOAM CF*** in 60 min at +20°C (including *Bacillus cereus & Clostridium sporogenes*) - at 2% ***ACIDOFOAM CF*** in 60 min at +4°C (including *Bacillus cereus &*	Doc 3 – "EN 13704 Acidofoam CF - 2017-06-09 BT-SPU-02-01 (2) EN13704 BC BS CS Report 14 Mar 17 LM CW LM CW LM

	cereus *Clostridium sporogenes*		*Clostridium sporogenes*)	CW" **R.I. 1**
ACIDOFOAM CF Batch N° F2996	**Activity against bacteriophages** Phages P001 (lytic for *Lactococcus lactis subspecies lactis)* Phages P008 (lytic for *Lactococcus lactis subspecies lactis*)	**EN 13610 (2003)** Quantitative suspension test Temperature : +20 ± 1°C Contact time : 15 min Concentrations tested : 0.5 – 2 - 3 % I.S. : 1% Acid Whey	**Active against bacteriophages** at 0.5% ***ACIDOFOAM CF*** in 15 min at +20°C in presence of 1% Acid whey.	Doc 4 – "EN 13610 Acifodoam CF - BT-SPU-02-01 EN13610 P001 Report 10 Jul 17 LM CW" + Doc. "BT-SPU-02-01 EN13610 P008 Report 06 Sep 17 LM CW LM" **R.I. 1**
ACIDOFOAM CF Batch N° F3696	**Virucidal activity** Poliovirus Adenovirus Murine Norovirus	**EN 14476 + A1 (2015)** Quantitative suspension test Temperature : +20 ± 1°C Contact time : 5 – 30 - 60 min Concentrations tested : 0.04 – 0.4 – 0.8 – 2 – 4 – 6 – 8 % I.S. : 0.3g/L BSA (clean conditions)	**FULL Virucidal activity** at +20°C in clean conditions : - At 8 % ***ACIDOFOAM CF*** in 5 min - At 2% ***ACIDOFOAM CF*** in 60 min	3 Docs : « SOPURA ACIDOFOAM CF L19-0604A-1 Adeno test report EN 14476 clean 16.09.2019 » ; « SOPURA ACIDOFOAM CF L19-0604M-1 MNV test report EN 14476 clean 09.09.2019 » ; « SOPURA ACIDOFOAM CF L19-0604Po-2 Polio test report EN

				14476 clean 26.08.2019 » **R.I. 1**
ACIDOFOAM CF Batch N°203770	**Bactericidal + Fungicidal/yeasticidal activity** <u>Obligatory test organisms</u>: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus* *Candida albicans* *Aspergillus brasiliensis*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces <u>Temperature</u> : +20 ± 1°C <u>Contact time</u> : 5 min - 15 min for F/Y <u>Concentrations tested</u> : 0.75 – 1 – 1.5 % 0.25 – 0.5 – 0.75% (F/Y) <u>I.S.</u> : 0.3g/L BSA (clean conditions)	**Bactericidal activity** At 1.5% ***ACIDOFOAM CF*** in 5 min at +20°C on hard/non-porous surfaces with prior cleaning **Yeasticidal activity** At 0.25% ***ACIDOFOAM CF*** in 15 min at +20°C on hard/non-porous surfaces with prior cleaning **Fungicidal/yeasticidal activity** at 0.75% ***ACIDOFOAM CF*** in 15 min at +20°C on hard/non-porous surfaces with prior cleaning	Doc 5 – " EN 13697 Acidofoam CF - 1448-ACIDOFOAM CF-EN13697-OBLIGATORY " (revision with Doc. a) **R.I. 1**
ACIDOFOAM CF Batch N° F3757	**Yeasticidal activity** <u>Obligatory test organisms</u>: *Candida albicans* <u>Additional test organisms:</u> *Saccharomyces diastaticus* *Saccharomyces cerevisiae*	**EN 13697 (2019)** Quantitative carrier test – hard & non-porous surfaces <u>Temperature</u> : +4°C or 20°C ± 1°C <u>Contact time</u> : 5 - 15 min <u>Concentrations tested</u> : 0.12 – 0.25 – 0.5 % <u>I.S.</u> : 0.3g/L BSA (clean conditions)	**Yeasticidal activity in clean conditions** - 0.5% ***ACIDOFOAM CF*** in 15 min at +4°C (including *Saccharomyces diastaticus* & *Saccharomyces cerevisiae*) - 0.25% ***ACIDOFOAM CF*** in 5 min at +20°C (including *Saccharomyces diastaticus* & *Saccharomyces cerevisiae*)	Doc. "Sopura Acidofoam CF EN 13697-2019 L19-0834-2 engl_V02" "Sopura Acidofoam CF EN 13697-2019 L19-0834-4 engl_V01" **R.I. 1**
ACIDOFOAM CF Batch N°203770	**Bactericidal activity** <u>Obligatory test organisms</u>: *Enterococcus hirae*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces <u>Temperature</u> : +4 ± 1°C	**Bactericidal activity** (including *Salmonella typhimurium*, *Listeria monocytogenes*, *Campylobacter jejuni, Enterobacter cloacae, Lactobacillus brevis & Pediococcus damnosus*)	Doc 6 – "EN 13697 Acidofoam CF - 1448-ACIDOFOAM CF-EN13697-PRACTICAL"

	E.coli *Pseudomonas aeruginosa* *Staphylococcus aureus* Additional test organisms: *Salmonella typhimurium* *Listeria* monocytogenes *Campylobacter jejuni* *Enterobacter cloacae* *Lactobacillus brevis* *Pediococcus damnosus*	Contact time : 15 min Concentrations tested : 0.75 – 1 – 1.5 % I.S. : 0.3g/L BSA (clean conditions)	At 1.5% ***ACIDOFOAM CF*** in 15 min at +4°C on hard/non-porous surfaces with prior cleaning	(revision with Doc. b) **R.I. 1**
ACIDOFOAM CF Batch N°203770	**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 : 60 min Concentrations tested : 0.5 – 2 – 3 % I.S. : 0.3g/L BSA (clean conditions)	**Sporicidal activity** (including *Bacillus cereus & Clostridium sporogenes*) At 2% ***ACIDOFOAM CF*** in 60 min at +20°C on hard/non-porous surfaces with prior cleaning.	Doc 7 – "EN 13697 Acidofoam CF - 2017-06-09 BT-SPU-02-01 (3) EN13697 BC BS CS Report 23 Feb 17 LM CW LM CW LM CW LM ..." **R.I. 1**
ACIDOFOAM CF Batch N° F2996	**Bactericidal activity** Obligatory test organisms: *Enterococcus hirae* *Proteus vulgaris* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1656 (2009)** Quantitative suspension test Temperature : +10°C ± 1°C Contact time : 30 min Concentrations tested : 0.25 – 1 – 1.5 % I.S. : 3g/L BSA (clean conditions)	**Bactericidal activity** at 0.25% ***ACIDOFOAM CF*** in 30 min at +10°C in clean conditions.	Doc 14 – "v1. EN 1656 Acidofoam CF - 2017-06-09 BT-SPU-02-01 (3) EN1656 SA EH PA PV Report 23 Feb 17 LM CW LM CW LM CW" **R.I. 1**

ACIDOFOAM CF Batch N° F2996	**Fungicidal/yeasticidal activity** Obligatory test organisms: *Candida albicans* *Aspergillus brasiliensis*	**EN 1657 (2016)** Quantitative suspension test Temperature : +10°C ± 1°C Contact time : 30 min Concentrations tested : 0.12 – 0.5 – 0.75% I.S. : 3g/L BSA (clean conditions)	**Yeasticidal activity** at 0.5% ***ACIDOFOAM CF*** in 30 min at +10°C in clean conditions. ***NO*** *Fungicidal/Yeasticidal activity in clean conditions in 30 min at +10°C at 0.75% (highest concentration tested).*	Doc 15 – "v2. EN 1657 Acidofoam CF - BT-SPU-02-01 (1) EN1657 AB CA Report 14 Mar 17 LM CW LM CW" **R.I. 1**
ACIDOFOAM CF Batch N° F2996	**Virucidal activity** Bovine enterovirus (ECBO)	**EN 14675 (2015)** Quantitative suspension test Temperature : +20 ± 1°C Contact time : 5 – 30 - 60 min Concentrations tested : 1 – 3 - 4% I.S. : 3g/L BSA (clean conditions)	**Virucidal activity** at 1% ***ACIDOFOAM CF*** in 30 min at +10°C in clean conditions	Doc 16 – "v3. EN 14675 Acidofoam CF - BT-SPU-02-01 ECBO EN14675 Report 06-Dec-16 LM CW" **R.I. 1**
ACIDOFOAM CF Batch N°203770	**Bactericidal activity** Obligatory test organisms: *Enterococcus hirae* *Proteus vulgaris* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 14349 (2012)** Quantitative carrier test – hard & non-porous surfaces Temperature : +4°C or +10°C ± 1°C Contact time : 30 min Concentrations tested : 0.25 – 1 – 1.5 % I.S. : 3g/L BSA (clean conditions)	**Bactericidal activity** - At 1.5% ***ACIDOFOAM CF*** in 30 min at +10°C - At 2% ***ACIDOFOAM CF*** in 30 min at +4°C on hard/non-porous surfaces with prior cleaning	Doc 18 – "v5. EN 14349 Acidofoam CF - 1448-ACIDOFOAM CF-EN14349-BACTERIAL OBLIGATORY" (revision with Doc. c) Doc 19 – "v6. EN 14349 Acidofoam CF - 1448-ACIDOFOAM CF-EN14349-BACTERIAL PRACTICAL"

				(revision with Doc. d) **R.I. 1**
ACIDOFOAM CF Batch N°203770	**Fungicidal/yeasticidal activity** <u>Obligatory test organisms</u>: *Candida albicans* *Aspergillus brasiliensis*	**EN 16438 (2014)** Quantitative carrier test – hard & non-porous surfaces <u>Temperature</u> : +10°C ± 1°C <u>Contact time</u> : 60 min <u>Concentrations tested</u> : 1 – 2 - 3 % 0.25 – 0.5 – 0.75% <u>I.S.</u> : 3g/L BSA (clean conditions)	**Yeasticidal activity** at 0.25% ***ACIDOFOAM CF*** in 60 min at +10°C on hard/non-porous surfaces with prior cleaning **Fungicidal/yeasticidal activity** at 3% ***ACIDOFOAM CF*** in 60 min at +10°C on hard/non-porous surfaces with prior cleaning	Doc 20 – "v7. EN 16438 Acidofoam CF - 1448-ACIDOFOAM CF-EN16438-FUNGICIDAL OBLIGATORY" (revision with Doc. e) + Doc 21 – "v8. EN 16438 Acidofoam CF - 1448-ACIDOFOAM CF-EN16438-YEASTICIDAL OBLIGATORY" (revision with Doc. f) **R.I. 1**
SOPUROXID 3.2 Batch N° 245144	**Bactericidal + Fungicidal/yeasticidal activity** *Staphylococcus aureus* *Enterococcus hirae* *E. coli* *Proteus vulgaris* *Pseudomonas aeruginosa*	**NF T 72-281 (2014)** **Quantitative Surface Test (room disinfection by fogging)** - Temperature : +21-22 °C - Contact time : 120 min	***Bactericidal, yeasticidal & sporicidal activity*** <u>via nebulization</u> with 5.6 mL ***SOPUROXID 3.2*** (diluted at 40%) /m^3 in 120 min contact time at +20°C on hard/non-porous surfaces with prior cleaning.	Doc. "SOPURA SOPUROXID 3_2 NF T 72-281-2014 L18-0259-3 engl_V03" **R.I. 1**

	Candida albicans *Bacillus subtilis* *Clostridium difficile*	- Dosage: 5.6 mL/m³ - Concentrations tested : 40% - I.S. : 3g/L BSA (dirty conditions for PT2 & PT4 - clean conditions for PT3) - Device used : HySpray 230V (one device) 5µm particles size - Room volume : 62.48 m³ With germ carriers were placed vertically in 3.6 m distance to the device		
SOPUROXID 5C	**Bactericidal activity** <u>Obligatory test organisms</u>: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1276 (2010)** Quantitative suspension test <u>Temperature</u> : 20°C ± 1°C <u>Contact time</u> : 5 min <u>Concentrations tested</u> : 0.05 – 0.1 – 0.2 – 0.3 % <u>I.S.</u> : 0.3g/L BSA (clean conditions)	**Bactericidal activity** at 0.2% ***SOPUROXID 5C*** in 5 min at +20°C in clean conditions	27/09/2019 => Doc. "Sopura SOPUROXID 5C EN 1276 2009 L19-0647-1 engl"
SOPUROXID 5C (after 6 weeks of storage at +40°C in a HEPD container with screw cap) <u>After 6 weeks of</u>	**Bactericidal activity** <u>Obligatory test organisms</u>: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa*	**EN 1276 (2010)** Quantitative suspension test <u>Temperature</u> : 20°C ± 1°C <u>Contact time</u> : 5 min <u>Concentrations tested</u> : 0.1 – 0.2 – 0.3 % <u>I.S.</u> : 0.3g/L BSA (clean conditions)	**Bactericidal activity** at 0.2% ***SOPUROXID 5C*** (after 6 weeks of storage at +40°C in a HEPD container with screw cap) in 5 min at +20°C in clean conditions	Doc.23 "TEST REPORT REGU012-A Stability study – accelerated conditions - SOPUROXID 5C"

storage at +40°C : Loss of active matter > 10%.	*Staphylococcus aureus*			
Sulfuric Acid 78%	**Bactericidal activity** Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1276 (2010)** Quantitative suspension test Temperature : 20°C ± 1°C Contact time : 5 min Concentrations tested : 0.0154 – 0.0308 – 0.0616 – 0.0924% I.S. : 0.3g/L BSA (clean conditions)	**NO bactericidal activity** at 0.0924% ***Sulfuric Acid*** 78% in 5 min at +20°C in clean conditions	27/09/2019 => Doc. "Sopura SOPUROXID 5C EN 1276 2009 L19-0647-2 engl" **R.I. 1**
SOPUROXID 5C (sans sulfuric acid) Batch N°F2743 ***SOPUROXID 5C*** Batch N°F2743	**Bactericidal activity** Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces Temperature : +20 ± 1°C Contact time : 5 min Concentrations tested : 0.25 - 0.5 – 1 % I.S. : 0.3g/L BSA (clean conditions)	***SOPUROXID 5C* w/wo sulfuric acid** Bactericidal activity : At 0.5% ***SOPUROXID 5C* w/wo sulfuric acid** in 5 min at +20°C on hard/non-porous surfaces with prior cleaning ***SOPUROXID 5C*** Bactericidal activity : At 0.5% ***SOPUROXID 5C*** in 5 min at +20°C on hard/non-porous surfaces with prior cleaning ⇨ **NO impact of Sulfuric Acid on the efficacy of the product.**	Doc 9 – "old doc EN 13697 Sopuroxid 5C - 162-SOPUROXID 5C WITHOUT SULFURIC ACID B" (similar to Doc 10 – "Sopuroxid 5C test 1 - EN 13697 Sopuroxid 5C - 162-SOPUROXID 5C WITHOUT SULFURIC ACID B") Doc 11 – "Sopuroxid 5C test 2 - EN 13697 Sopuroxid 5C - 162-Sopuroxid 5C-EN13697-BACT-

				CLEAN-CTL Microb.-09.07.14” **R.I. 1**
SOPUROXID 5C (sans sulfuric acid) Batch N°F2743	**Fungicidal/yeasticidal activity** Obligatory test organisms: *Aspergillus brasiliensis* *Candida albicans*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces Temperature : +20 ± 1°C Contact time : 15 min Concentrations tested : 0.5 – 1 - 2 % I.S. : 0.3g/L BSA (clean conditions)	**Yeasticidal activity** at 0.5% ***SOPUROXID 5C (sans sulfuric acid)*** in 15 min at +20°C on hard/non-porous surfaces with prior cleaning **Fungicidal/yeasticidal activity** at 1% ***SOPUROXID 5C (sans sulfuric acid)*** in 15 min at +20°C on hard/non-porous surfaces with prior cleaning	Doc 12 – “Sopuroxid 5C test 3 - EN 13697 Sopuroxid 5C - 162-SOPUROXID 5C WITHOUT SULFURIC ACID F” (similar to Doc 13 – “Sopuroxid 5C test 4 - EN 13697 Sopuroxid 5C - 162-Sopuroxid 5C-EN13697-FUNG-CLEAN-CTL MICROB.-09.07.14”) **R.I. 1**

Conclusion on the efficacy of the representative product *ACIDOFOAM CF* (which contains 3.2% PAA)
- *Summary of the use conditions validated after evaluation of the studies* :

Activity	Test Method P2S1	Validated conditions (in clean conditions)	Test Method P2S2	Validated conditions (in clean conditions)
PT2 – PT4 – PT5				
Bactericidal (including *Campylobacter jejuni, Salmonella typhimurium, Enterobacter cloacae, Lactobacillus brevis, Pediococcus damnosus* & *Listeria monocyogenes*)	EN 1276	0.25% (⇔ 0.008% PAA) - 5 min at +20°C	EN 13697 Bacteria	1.5% (⇔ 0.048% PAA) - 5 min at +20°C
		1% (⇔ 0.032% PAA) - 5 min at +4°C		1.5% (⇔ 0.048% PAA) - 15 min at +4°C
Yeasticidal (including *Saccharomyces diastaticus* & *Saccharomyces cerevisiae*)	EN 1650	0.25% (⇔ 0.008% PAA) - 5 min at +20°C	EN 13697 Yeasts	0.25% (⇔ 0.008% PAA) - 5 min at +20°C
		0.12% (⇔ 0.004% PAA) - 15 min at +20°C		0.25% (⇔ 0.008% PAA) - 15 min at +20°C
		0.12% (⇔ 0.004% PAA) - 15 min at +4°C		0.5% (⇔ 0.016% PAA) - 15 min at +4°C
Fungicidal	EN 1650	2% (⇔.064% PAA) - 15 min at +20°C	EN 13697 Fungi/Yeasts	0.75% (⇔ 0.024% PAA) for F/Y - 15 min at +20°C
Sporicidal (including *Bacillus cereus* & *Clostridium sporogenes*)	EN 13704	2% (⇔ 0.064% PAA) - 60 min at +20°C	EN 13697 Spore-forming bacteria	2% (⇔0.064% PAA) - 60 min at +20°C
		2% (⇔ 0.064% PAA) - 60 min at +4°C		
Virucidal (Full)	EN 14476	8% (⇔ 0.256% PAA) - 5 min at +20°C		
		2% (⇔ 0.064% PAA) - 60 min at +20°C		
Active against bacteriophages	EN 13610	0.5% (⇔ 0.016% PAA) - 15 min at +20°C		
PT3				
Bactericidal	EN 1656	0.25% (⇔ 0.008% PAA) – 30 min at +10°C	EN 14349	1.5% (⇔ 0.048% PAA) – 30 min at +10°C
				2% (⇔ 0.064% PAA) – 30 min at +4°C
Yeasticidal	EN 1657	0.5% (⇔ 0.016% PAA) – 30 min at +10°C	EN 16438	Y : 0.25% (⇔ 0.008% PAA) – 60 min at +10°C F/Y : 3% (⇔ 0.096% PAA) – 60 min at +10°C
Virucidal	EN 14675	1% (⇔ 0.032% PAA) – 30 min at +10°C		

<table>
<tr><td colspan="3">Conclusion on the efficacy of the products of the SOPUROXID Family
and validated label claims</td></tr>
<tr><td colspan="3">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 also note that one single use instructions (with Use concentration/Contact Time/T°C) will be validated for basic efficacy requirements.

Please note that herebelow the use concentrations are expressed only in percentage of pure peracetic acid (% PAA) :</td></tr>
<tr><td colspan="2">Meta SPC-1 (5% PAA)
Meta SPC-4 (15% PAA)</td><td>Validated label claims</td></tr>
<tr><td>PT2</td><td>Use #1.1/4.1: Disinfection of surfaces in industrial, public and healthcare/non-medical areas - manual treatment (mopping)</td><td>On hard/non-porous surfaces with prior cleaning

• ~~HEALTHCARE / non-medical areas~~
• non-medical healthcare areas
Active against bacteria and yeasts
0.048% PAA - 5 min - at Room Temperature

• Use other than in HEALTHCARE
Active against bacteria and yeasts
0.048% PAA - 15 min - Efficient use temperature from +4°C up to Room Temperature.

<u>REMARK from the EFF expert :</u>
Since the application has been submitted in Nov. 2017, discussion during the WG III 2019 and decision made about additional efficacy tests required for mopping procedures (i.e. efficacy tests performed according to EN 16615 standard required or not ?) are not applicable. A precautionnary sentence will be added on the label such as : “be sure to wet surfaces completely”</td></tr>
</table>

<table>
<tr><td rowspan="7"></td><td>Use #1.2/4.2: Disinfection of surfaces in industrial, public and healthcare/non-medical areas - manual treatment (spraying)</td><td>On hard/non-porous surfaces with prior cleaning

• ~~**HEALTHCARE / non-medical areas**~~
• **non-medical healthcare areas**
Active against bacteria and yeasts
0.048% PAA - 5 min - at Room Temperature

• **Use other than in HEALTHCARE**
Active against bacteria and yeasts
0.048% PAA - 15 min - Efficient use temperature from +4°C up to Room Temperature.</td></tr>
<tr><td>Use #1.3/4.3 : CIP in the pharmaceutical and cosmetic industry</td><td>On hard/non-porous surfaces with prior cleaning
ctive against bacteria and yeasts
0.032% PAA - 15 min - Efficient use temperature from +4°C up to Room Temperature.</td></tr>
<tr><td>Use #1.4/4.4 : Surface disinfection in greenhouses by spraying with personal enclosure (in absence of plants - for general hygiene purpose only)</td><td rowspan="5">On hard/non-porous surfaces with prior cleaning
Active against bacteria and yeasts
0.048% PAA - 60 min - +10°C</td></tr>
<tr><td>Use #1.5/4.5 : Surface disinfection in greenhouses by spraying without personal enclosure (in absence of plants - for general hygiene purpose only)</td></tr>
<tr><td>Use #1.6/4.6: Disinfection of agriculture & horticulture equipment by soaking (in absence of plants - for general hygiene purpose only)</td></tr>
<tr><td>Use #1.7/4.7 : Disinfection of surfaces and agriculture/horticulture equipment by spraying (in absence of plants - for general hygiene purpose only)</td></tr>
<tr><td>Use #1.8/4.8 : Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (in absence of plants - for general hygiene purpose only)</td></tr>
</table>

	Use #1.9/4.9 : Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (closed room) (in absence of plants - for general hygiene purpose only)	
PT3	Use #1.10/4.10 : Disinfection of animal housing by low-pressure spraying – spraying with personal enclosure	On hard/non-porous surfaces with prior cleaning Active against bacteria, yeasts and viruses 0.064% PAA - 60 min - +10°C
	Use #1.11/4.11 : Disinfection of animal housing by low-pressure manual spraying – spraying without personal enclosure	
	Use #1.12/4.12 : Disinfection of boots in footbaths in animal housing /husbandries	On boots with prior cleaning Active against bacteria, yeasts and viruses 0.064% PAA - 60 min - +10°C
	Use #1.13/4.13 : Disinfection of equipment by dipping	On hard/non-porous surfaces with prior cleaning Active against bacteria, yeasts and viruses 0.064% PAA - 60 min - +10°C
PT4	Use #1.14/4.14 : Disinfection in Aseptic Filling Lines (crown corks, cheese moulds and food crates) - Automated spraying closed systems	On hard/non-porous surfaces with prior cleaning • Active against bacteria and yeasts 0.048% PAA - 15 min - Efficient use temperature from +4°C up to Room Temperature. • Active against bacteria (including bacterial spores) and yeasts: 0.064% PAA - 60 min - Efficient use temperature from +4°C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.
	Use #1.15/4.15 : Disinfection of equipment in the food and beverage industry by immersion	
	Use #1.16/4.16 : Disinfection of heat and ion exchangers, membrane filters and glass and PET bottles – CIP procedures	
	Use #1.17/4.17 : Disinfection of surfaces and equipment by low pressure spraying – spraying with personal enclosure	
	Use #1.18/4.18 : Disinfection of surfaces and equipment by low pressure spraying – spraying without personal enclosure	
	Use #1.19/4.19 : Disinfection of surfaces and equipment by low pressure spraying, manually	
	Use #1.20/4.20 : Disinfection of surfaces and equipment by low pressure spraying, automatically	
	Use #1.21/4.21 : Disinfection of surfaces and equipment by low pressure spraying – automatic spraying (closed room)	
	Use #1.22/4.22 : Disinfection of inner surfaces (pipelines, tanks, vessels, …) by CIP	
	Use #1.23/4.23 : Disinfection of water used for rinsing of recycled items during the washing process	In clean conditions Active against bacteria and yeasts

	Water from drinking water quality shortly stored in tanks until use to rinse items such as bottles. The water should be disinfected to avoid recomtamination and in a extent to avoid cross-contamination of inner bottle surfaces	0.008% PAA - 15 min - +20°C
Meta SPC-2 *with product **SOPUROXID 3.2 (3.2% PAA)** – by fogging*		**Validated label claims**
PT2	Use #2.1 : Room Disinfection by fogging - In industrial, public and healthcare/non-medical areas (pharmaceutical and cosmetic industry)	On hard/non-porous surfaces without prior cleaning Active against bacteria (including bacterial spores) and yeasts 5.6 mL/m^3 (product diluted at 40% => 1.28% PAA) – 2h contact time (after fogging) - at Room Temperature
	Use #2.2 : Room Disinfection by fogging - In agriculture & horticulture areas (in absence of plants - for general hygiene purpose only)	On hard/non-porous surfaces with prior cleaning Active against bacteria and yeasts 5.6 mL/m^3 (product diluted at 40% => 1.28% PAA) – 2h contact time (after fogging) - at Room Temperature
PT3	Use #2.3 : Room Disinfection by fogging – In animal housing	On hard/non-porous surfaces with prior cleaning Active against bacteria and yeasts 5.6 mL/m^3 (product diluted at 40% => 1.28% PAA) – 2h contact time (after fogging) - at Room Temperature
PT4	Use #2.4 : Room Disinfection by fogging – In storage rooms with special device in storage cellar or room	On hard/non-porous surfaces without prior cleaning Active against bacteria (including bacterial spores) and yeasts 5.6 mL/m^3 (product diluted at 40% => 1.28% PAA) – 2h contact time (after fogging) - at Room Temperature
Meta SPC-3 (3.2% PAA) – by foaming		**Validated label claims**
PT2	Use #3.1 : Disinfection of surfaces in industrial, public and healthcare/non-medical areas – foam application on surfaces	On hard/non-porous surfaces with prior cleaning • ~~**HEALTHCARE / non-medical areas**~~ • **non-medical healthcare areas** Active against bacteria and yeasts 0.048% PAA - 5 min - at Room Temperature • **Use other than in HEALTHCARE** Active against bacteria and yeasts 0.048% PAA - 15 min - Efficient use temperature from +4°C up to Room Temperature.
	Use #3.2 : Disinfection of surfaces and agriculture/horticulture	On hard/non-porous surfaces with prior cleaning

	equipment by foaming, manually (in absence of plants - for general hygiene purpose only)	Active against bacteria and yeasts 0.048% PAA - 60 min
	Use #3.3 : Disinfection of surfaces and agriculture/horticulture equipment by automatic foaming (in absence of plants - for general hygiene purpose only)	
	Use #3.4 : Disinfection of surfaces and agriculture/horticulture equipment by automatic foaming (closed rooms) (in absence of plants - for general hygiene purpose only)	
PT3	Use #3.5 : Disinfection of animal housing by foaming – foaming with personal enclosure	On hard/non-porous surfaces with prior cleaning Active against bacteria, yeasts and viruses 0.064% PAA - 60 min
	Use #3.6 : Disinfection of animal housing by foaming – foaming without personal enclosure	
PT4	Use #3.7 : Disinfection of surfaces by foaming with personal enclosure	On hard/non-porous surfaces with prior cleaning • Active against bacteria and yeasts 0.048% PAA - 15 min - Efficient use temperature from +4°C up to Room Temperature. • Active against bacteria (including bacterial spores), yeasts and viruses (including bacteriophages) : 0.064% PAA - 60 min - at Room Temperature
	Use #3.8 : Disinfection of surfaces by foaming without personal enclosure	

The use concentrations are expressed along the SPC in percentage of pure peracetic acid (% PAA in gram).
The conversion table below details the volume of concentrated product needed (in mL) to reach the required peracetic acid content level for 100L of use solution. Once concentrated product is poured in the tank, tap water is to be added to reach 100L of use solution :

Required PAA %	Dilution rate of the concentrated biocidal products (%v/v) Litres of concentrated products needed to prepare 100L of use solution			
	META SPC 1 (5% PAA)	**META SPC 2 (3.2% PAA)**	**META SPC 3 (3.2% PAA)**	**META SPC 4 (15% PAA)**
	SOPUROXID 5 SOPUROXID 5C	SOPUROXID 3.2	ACIDFOAM CF	SOPUROXID 15 OXYPUR CS
0.008	160 mL	-	-	53.33 mL
0.032	640 mL	-	-	213.33 mL
0.048	960 mL	-	1500 mL	320 mL
0.064	1280 mL	-	2000 mL	426.66 mL

1.28	-	40 L	-	-

Application rate for spraying of diluted product should be between minimum 20 mL/m² and maximum 30 mL/m² (Maximum Application Rate used in ENV Risk Assessment).
Application rate for fogging of diluted product should be 5.6 mL/m³

1.2.5.4 Occurrence of resistance and resistance management

As outlined in the CAR, the mode of action of peracetic acid is very unspecific. Consequently, it is very unlikely that resistance to peracetic acid can develop. The authors of one publication claim to have isolated a peracetic acid resistant *Rhodococcus* strain (*Rhodococcus erythropolis* Vi16) from a dairy after frequent applications of disinfectants. However, it remains uncertain whether the low level of sensitivity of Vi16 is an intrinsic property of this strain or whether it is based on acquired resistance.

The development of specific resistance management strategies for the use of PAA does not seem to be an urgent task. Nevertheless, the general principle of alternating use of disinfectants with different modes of action is recommended.
In professional hygiene programs, the use of disinfectants with different chemical structure and different modes of action seems to be the general practice aiming at reducing the chance of any development of resistance. In these programs peracetic acid is one of the active substances used.

1.2.5.5 Known limitations

Nothing to mention.

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

Nothing to mention. The biocidal products within the SOPUOXID Family are not intended to be used in combination with other biocidal products.

2.2.6 Risk assessment for human health

The example products presented in the CAR, have an equal (or higher) PAA and HP concentration than the products of this product family. Hence, no new data using the biocidal products was generated for the assessment of effects on human health.
The human health risk assessment can be summarized as follows:

Toxicokinetics: No standard dermal penetration studies have been successfully conducted with aqueous PAA. Instead, based on the physical properties of PAA, 100 % dermal penetration is assumed in the absence of more accurate information.

Acute toxicity:

- *Oral:* Formulations containing 5 to 15% PAA, have an LD_{50} value ranging between 1020.5 and 1922 mg/kg BW. The corresponding formulations are considered **harmful if swallowed**.
- *Dermal:* The acute dermal LD_{50} for formulations containing 5-15% PAA was between 1147 and 1957 mg/kg BW. The products are hence considered as **harmful in contact with skin** (for META SPC 1, 2 & 3) and as **toxic in contact with skin** (for META SPC 4).
- *Inhalation*: The LC_{50} value for acute inhalation toxicity for products containing 5% PAA is 4.08 mg/L. Formulations at similar concentration should therefore be considered **harmful if inhaled**.

The same conclusion and hence classification applies for formulations containing 3.2 % PAA, as Sopuroxid 3.2 and Acidofoam CF.

Irritation and corrosion:

Due to the low pH (pH < 2) of the biocidal products of the SOPUROXID family, the biocidal products are considered to be **corrosive 1A** (H314). For completeness reasons, results on PAA are reported.

- *Skin:* PAA at actual topical concentrations of < 1 % is not irritating to skin. In short-term, acute or accidental exposure situations, exposure to PAA concentrations > 1 % should be avoided to exclude the possibility of irreversible damage to human skin (skin corrosion). 0.2 % PAA is proposed to be used as a dermal NOAEC for short-term and medium term exposure. With an additional uncertainty factor of 2 this results in a **$NOAEC_{dermal}$ = 0.1 % for skin irritation.**
- *Eye:* Concentration dependent eye lesions: from mildly irritating effects to severe and irreversible eye damage. As a corrosive substance, PAA is considered to cause also serious eye damage. Therefore the **dermal NOAEC value should be used**.
- *Respiratory tract:* Respiratory tract irritation due to the corrosive/irritating properties of the PAA formulations. RD_{50} values ranged from 12 to 24.1 mg/m^3 PAA. In short-term, acute (or accidental) exposure situations peracetic acid concentrations less than 0.5% (AEC) should not cause irreversible damage to the mucuous membranes of exposed persons via direct chemical reactivity. **For respiratory irritation, an AEC value of 0.16 ppm or 0.5 mg/m^3 should be used.**

Sensitisation:

- *Skin*: Formulations containing PAA are not considered skin sensitising.

The key values to be used in risk assessment are:

PAA	HP
$NOEC_{dermal}$ = 0.10 %	$NOEC_{dermal}$ = not relevant as all applied concentrations < 35% threshold for classification as skin irritant
AEC_{inhal} = 0.5 mg/m^3	AEC_{inhal} = 1.25 mg/m^3

Based on available information the products should be classified according to CLP for the following human health endpoints:

CLP classification for Biocidal Product Family – human health For META SPC 1, 2 & 3 :	
Hazard category	Skin corrosion cat. 1A Eye Damage cat. 1 Acute tox 4 (oral, dermal and inhalation) STOT SE 3
Hazard statement	H314: Causes severe skin burns and eye damage H318: Causes serious eye damage H302: Harmful if swallowed. H312: Harmful in contact with skin. H332: Harmful if inhaled. H335: May cause respiratory irritation.

CLP classification for Biocidal Product Family – human health For META SPC 4 :	
Hazard category	Skin corrosion cat. 1A Eye Damage cat. 1 Acute tox 4 (oral, dermal and inhalation) STOT SE 3
Hazard statement	H314: Causes severe skin burns and eye damage H318: Causes serious eye damage H302: Harmful if swallowed. H311: Toxic in contact with skin. H332: Harmful if inhaled. H335: May cause respiratory irritation.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

No studies on skin corrosion or irritation are available for any of the members of the Sopuroxid biocidal product family. However, the composition of the products indicates that all products have a pH < 2 and cause severe burns. This results in a classification of the different products as Corrosive 1A, H314.

For the sake of completeness, test results on the active substance have been added to this application. Reference to the CAR II A and B document is made for additional details.

Summary table of in vitro studies on skin corrosion/irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
No in vitro studies have been conducted					

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
Method is comparable to OECD Guideline 404 GLP Reliability 2 (no proof of concentrations)	Rabbit 1 male	PAA~ 5% H2O2 ~22% AA ~10% Duration of exposure: 4h	-Erythema: mean average score from 24 to 72 hours was 0. -Oedema: mean average score from 24 to 72 hours was 1.0. Skin demonstrated brown crust formation. **Result:** The test material is considered to be corrosive to the rabbit skin.	Reversibility: No	Doc. No.: 565-004; A6.1.4/01
Method is comparable to OECD Guideline 404 Reliability 2 (no proof of concentrations)	Rabbit 1 male	PAA ~15% H2O2 ~14% AA ~28% Duration of exposure: 4h	-Erythema: Mean average score from 24 to 72 hours: no irritation index determined due to corrosive effects (hard, dry yellow/brown crust formation)	Reversibility: No	Doc. No.: 565-004; A6.1.4/01

			-Oedema: Mean average score from 24 to 72 hours: no irritation index determined due to corrosive effects (hard, dry yellow/brown crust formation) **Result:** The test material is considered to be corrosive to the rabbit skin.		
Method is comparable to OECD Guideline 404 GLP Reliability 1	Rabbit 3 males and females	PAA 4.7% H_2O_2 22.3% AA 7.8%	-Erythema: 3 minutes exposure: mean average score from 24 to 72 hours was 2.0 45 minutes exposure: no irritation index determined due to corrosive effects (discolouration of skin) -Oedema: 3 minutes exposure: mean average score from 24 to 72 hours was 1.25. 45 minutes exposure: mean average score from 24 to 72 hours was 2-4. **Result:** The test material is considered to be corrosive to the rabbit skin. Moderate to severe erythema, slight	Reversibility: -3 minutes exposure: Yes -45 minutes exposure: No	Doc. No.: 565-008; A6.1.4/02

			eschar formation and very slight to slight oedema in the 3 minutes group LOAEC 5%PAA (Draize score 4 for Erythema and Eschar formation in one animal at 72 h)		
Method is comparable to OECD Guideline 404 GLP Reliability 2 (assessed based on the study summary)	Rabbit 3 females	PAA 14-16% H2O2 21.4-22.3% AA 15.8-17.4% Duration of exposure: 4h	-Eryhema: Mean average score from 24 to 72 hours was 4.0. -Oedema: Mean average score from 24 to 72 hours was 0.22 **Result:** The test material is considered to be corrosive to the rabbit skin.	Reversibility: No	Doc. No.: 565-011; A6.1.4/03

Summary table of human data on skin corrosion irritation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
No human data on skin corrosion/irritation studies carried out				

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The results demonstrate that peracetic acid at actual topical concentrations of less than 1 % is neither corrosive nor irritating to skin while 5 % peracetic acid caused burns and warrants classification in Skin Corr. 1B with hazard statement H314: "Causes severe skin burns and eye damage" in accordance with the classification criteria of the CLP Regulation. Higher concentrations resulted in even more sever skin damage and warrant classification in the highest subcategory, i.e. Skin Corr. 1A.
Justification for the value/conclusion	No studies on skin and eye irritation are available for any member of the Sopuroxid Biocidal Product Family. However the composition of the products indicate that all products of the Sopuroxid Biocidal Product Family have a pH < 2 and cause severe burns. This results in classification of the different products as Corrosive Cat 1A or 1B, H314
Classification of the	For consistency reasons Skin Corrosion Cat. 1A H314, was applied

product according to CLP and DSD	for all BP within the SOPUROXID family.

Eye irritation

In the CAR (document IIA and IIB) studies which have been conducted on a variety of PAA formulations containing 5% or more PAA are reported. No additional studies were conducted, as these allow to draw conclusions on the classification and risk assessment of the biocidal products.

Moreover, given that the biocidal products of SOPUROXIDhave a pH < 2 and that they are all classified for Skin Corrosion Cat. 1A or 1B, no additional studies to assess the eye irritation potential are required.

Summary table of in vitro studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Test substanc e, Doses**	**Relevant information about the study**	**Results**	**Remarks**	**Reference**
No in vitro studies have been conducted					

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance , Dose levels, Duration of exposure**	**Results**	**Remarks**	**Reference**
US EPA guidelines PB82-232984	Rabbit 4 males and 2 females	PAA 5%	Cornea: Slight signs of corneal opacity after 24 h, which had resolved in all animals after4 days. Opacity/area: 0.8/1.2, 0.3/0.5, 0.2/0.2 Conjunctiva: -Redness: Medium to pronounced redness of the conjunctiva, which had completely resolved in all animals after 4 days. 1.5, 1.3, 0.3 -Chemosis: Medium to pronounced chemosis of the conjunctiva,	Reversibility: Yes No findings on Iris	Doc. No.: 566-002; A6.1.4/04

			which had completely resolved in all animals after 4 days. 1.3, 0.5, 0 **Result:** Test material was 5 % peracetic acid and applied as a 0.15% aqueous dilution. Under the conditions of the study the test material is considered to be mildly irritating. The classification criteria based on individual means are not met either.		
US EPA guidelines PB82-232984	Rabbit 3 males and females	PAA 17% (usually contains) H2O2 23.2% AA 16%	<u>Cornea:</u> Grade 4 opacity of total cornea <u>Conjunctiva:</u> -Redness: Mean score: 1.0 (unwashed eye) 0.3 (washed eye) -Chemosis: Mean score: 3.6 (unwashed eye) 3.5 (washed eye); No reversibility until termination, risk of series damage to the eye **Result:** Test material was 17 % peracetic acid Under the conditions of this study, the test material is judged to be extremely irritating to both unwashed and washed eyes. In the light of the necrosis noted, the test material is considered to be corrosive to the eye.	Reversibility: No Iris: not visible: Mean score: 2.0 (unwashed/ washed eye)	Doc. No.: 566-001; A6.1.4/05

Summary table of human data on serious eye damage and eye irritation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
No human data on eye irritation carried out				

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Peracetic acid causes concentration dependent eye lesions. For all concentrated biocidal products, serious eye damage is expected due to the low pH (pH < 2).
Justification for the value/conclusion	Peracetic acid formulations containing peracetic acid at concentrations of 5 % or higher have been tested for their eye irritating potential in rabbits. 2 studies have been reported according to US EPA guidelines PB82-232984.
Classification of the product according to CLP	As stipulated above, for consistency reasons all products within SOPUROXIDare classified by Sopura as Skin Corrosion 1A, H314. Additionally, studies demonstrate that Peracetic acid products warrant classification as Eye Dam. 1 with hazard statement H318: "Causes serious eye damage" in accordance with the classification criteria of the CLP Regulation.

Respiratory tract irritation

Considering the strong skin and eye irritation properties of the members of the Sopuroxid Biocidal Product Family, also respiratory tract hazard has to be assumed. No studies have been conducted on the different biocidal products, as the studies available from the active allows valid human exposure and risk assessments and there are no indications of risk due to specific properties of the product.

Reference is made to the CAR documents IIA and IIB for details on the studies listed below.

Summary table of animal studies on respiratory tract irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels, Duration of exposure**	**Results**	**Remarks**	**Reference**
Sensory irritation test by measuring the effect of the test material on respiration rate (No standard guideline available) Reliability 1	Mouse OF 1 Male 8/group	Route: inhalation Head only Test substance: 39 % PAA, 45 % AA, 6 % H2O2 and 36 % PAA, 53 % AA, 11 % H2O2 Dose levels: 1.8, 4, 6 and 25 ppm (5.7, 12.6, 18.9 and 78.7 mg/m^3). and 1.6, 3, 5.6 and 11.6 ppm (5.1, 9.5, 17.7 and 36.6 mg/m^3). Duration of exposure: 60 minutes	Value RD50: RD_{50} 5.4 ppm PAA (17 mg/m^3) approx. 0.00054% (which corresponds approx. 0.0014% test substance atmosphere) and 3.8 ppm PAA (12 mg/m^3) approx. 0.00038% (which corresponds approx. 0.0011% test substance atmosphere)	Pathology not performed Comparison of test items: AA (227 ppm) < HP (113 ppm)< PAA mixture (10.6 ppm or 3.8 ppm) < "pure" PAA (5.4 ppm)	A6.1.3/03

Sensory irritation test by measuring the effect of the test material on respiration rate (No standard guideline available) Reliability 1	Rat Wistar CPB-WU males 3/group	Route: Inhalation Nose-only Test substance: 15 % PAA, 28 % AA, 14 % H2O2 Dose levels: a) 9.5-40.3 mg/m^3 b) 221.0-487.5 mg/m^3 Duration of exposure: 25 minutes	Value RD50: a) 21.5 – 24.1 mg/m^3 b) respiratory rates decreased from 76.3 – 78.4 % (group means)	a) back-ground level inflammatory changes in all groups b) necrosis of nose epithelium in all dose groups	A6.1.3/06

Summary table of human data on respiratory tract irritation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
The cases of two subjects (subject 1: 48-years-old male, subject 2: 47-years-old female) who developed cough and shortness of breath after being exposed to peracetic acid-hydrogen peroxide (PAA-HP) vapours are reported. Chest radiography, skin prick tests to common allergens, baseline spirometric measurements and methacholine challenge tests (PC20) were conducted. The main symptoms observed were rhinorrhea, 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.				

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Both animal data and human experience indicate that peracetic acid may cause respiratory tract irritation.
Justification for the conclusion	The current classification stems from the known corrosivity of the substance.
Classification of the product according to CLP	Specific Target Organ Toxicity Single Exposure Cat. 3 (STOT SE 3), H335: May cause respiratory irritation

Skin sensitization

None of the ingredients of the members of the Sopuroxid Biocidal Product Family is classified as skin sensitizer, which would trigger a classification for the formulation.

One skin sensitisation test has been performed on the active substance. No additional tests have been performed on the biocidal products covered by this application.

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure**	**Results**	**Remarks**	**Reference**
Method comparable to OECD 406, GPMT GLP Reliability 1	Guinea pig	PAA 10.4% (w/v), 8.9% (w/w) *Full composition of the test substance could not be specified due to confidentiality reasons.*	Not sensitising Number of animals sensitised/total number of animals: 0/10		Doc. No. 567-006 A6.1.5/01 Key study

Summary table of human data on skin sensitisation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
No human data on skin sensitisation carried out				

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Non sensitising
Justification for the value/conclusion	The skin sensitising potential of peracetic acid was investigated in a skin sensitisation test according to Magnusson-Kligman. 1 study

	based on OECD 406. The active substance proved to be non-sensitising. Moreover, none of the ingredients of the members of the Sopuroxid Biocidal Product Family is classified as skin sensitizer, which would trigger a classification for the biocidal products.
Classification of the product according to CLP	Not classified.

Respiratory sensitization (ADS)

No data are available to estimate the hazard for respiratory sensitization. Human data on two persons who developed cough and shortness of breath after being exposed to peracetic acid-hydrogen peroxide vapours are reported. However, an irritant induced asthma thesis was suggested.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising
Justification for the value/conclusion	It is assumed that the main toxicological mechanism of action is irritation by direct membrane destruction and consequent inflammatory reactions and there are no metabolites of concern.
Classification of the product according to CLP	Not classified

Acute toxicity

No additional studies have been performed on the biocidal products of SOPUROXIDbecause data available from the active substance dossier for PAA are deemed to be sufficient. Additionally, due to the corrosive properties of the concentrated products, additional testing is considered scientifically unjustified.

For data on acute toxicity, reference is made to CAR documents IIA and IIB.

- *Acute toxicity by oral route*

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levelsType of administration**	**Signs of toxicity**	**Value LD50**	**Remarks**	**Reference**
OECD 401 GLP Reliability 1	Rat CD 5 males and 5 females	Oral Gavage PAA 5% H2O2 22% AA 10%	Dose levels: 1000, 2000 and 4000 mg/kg bw	1922 mg/kg bw test substance *96.1 mg/kg bw 100%PAA	Classification according to EC-Directive 93/21: Xn R22	A 6.1.1/01
EPA Guideline No. 81-1 Reliability 1	Rat Sprague-Dawley, HC/CFY Remote 5 males and 5 females	Oral PAA 5% H2O2 26.7% AA 6.7%	Dose levels: 1260, 2000, 3200, 5000 mg/kg bw	1700 mg/kg bw test substance *85 mg/kg bw 100%PAA		A 6.1.1/02

Test method not specified. The procedures followed are in-line with current Guideline requirements Reliability 2	Rat Wistar Bor:WISW 5 males and 5 females	Oral PAA 15% H_2O_2 % and AA % not available	Dose levels: 532, 781, 1146, 1682 mg/kg bw	1020.5 mg/kg bw test substance *153 mg/kg bw 100%PAA		A 6.1.1/03
Test method not specified. The procedures followed are in-line with current Guideline requirements GLP Reliability 1	Rat Sprague-Dawley 5 males and 5 females	Oral PAA 15.2% H_2O_2 11.2% AA 36.3%	Dose levels: 1250, 1880, 2500 mg/kg bw	1780 mg/kg bw test substance *271 mg/kg bw 100%PAA		A 6.1.1/04

Summary table of human data on acute oral toxicity				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
No human data on acute oral toxicity studies carried out				

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50} values in the range of 1020.5-1922 mg/kg bw indicating that equilibrium peracetic acid, at the tested concentrations, is moderately toxic by the oral route.
Justification for the selected value	Based on the results obtained in rabbits, classification of the aforementioned formulations (PAA conc. 5-15 %) as Acute Tox. 4 with the hazard statement H302: "Harmful if swallowed" in accordance with the criteria of the CLP Regulation (reference value 300 < ATE 2000 ≤ mg/kg bw) is warranted.
Classification of the product according to CLP	As stipulated above, for consistency reasons within the PAA Consortium, all products within SOPUROXIDare classified by Sopura as Acute tox 4, H302.

- *Acute toxicity by inhalation*

Summary table of animal studies on acute inhalation toxicity						
Method, Guideline, GLP status , Reliability	**Species, Strain, Sex, No/group**	**Test substance, form and particle size (MMAD) Actual and nominal concentration, Type of administration**	**Signs of toxicity**	**LC50**	**Remarks**	**Reference**
OECD Guideline 403 from May 12, 1981 GLP Reliability 2	Rat Wistar 5 males and 5 females	Inhalation Nose-only PAA 5% H2O2 19% AA 10%	Dose levels: 87, 163, 185, 267 mg/m^3 PAA (actual) Duration of exposure: 4h	204 mg/m^3 PAA* 100% PAA corresp. 4080 mg/m^3 =4.08 mg/l of the test substance (5% solution)	Deaths in the two highest groups. Clinical symptoms most likely due to irritating/corrosive action of the test material in the respiratory tract, in all treatment groups. LOAEC 87mg/m^3 (28 ppm)	A 6.1.3/01 Key study

Summary table of human data on acute inhalation toxicity				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
No human data on acute inhalation toxicity studies carried out				

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	LC_{50} value for the test substance containing 5 % peracetic acid was 4.08 mg/l/4 h.

Justification for the selected value	Based on the most reliable study in rats, the acute inhalation LC_{50} value for the test substance containing 5 % peracetic acid was 4.08 mg/l/4 h. Classification of the formulation as Acute Tox. 4 with the hazard statement H332: "Harmful if inhaled" in accordance with the criteria of the CLP Regulation (reference value 1.0 < ATE ≤ 5.0 mg/l) is warranted.
Classification of the product according to CLP	As stipulated above, for consistency reasons within the PAA Consortium, all products within SOPUROXIDare classified by Sopura as Acute tox 4, H332.

- *Acute toxicity by dermal route*

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity**	**LD50**	**Remarks**	**Reference**
EPA Guideline No. 81-1 Reliability 1	Rabbit New Zealand White 5 males and 5 females	Dermal PAA 4.89% H2O2 19.7% AA 10%	Dose levels: 500, 1000, 2020 mg/kg bw Duration of exposure: single application with 14 day post exposure period	1147 mg/kg bw test substance *56.1 mg/kg bw 100% PAA	Well-defined to severe erythema, slight to severe oedema, atonia, blanching, bleeding, coriaceousness, desquamation, eschar, fissuring, sloughing and necrosis at all doses LOAEC 4.89% PAA	A 6.1.2/01
EPA Guideline No. 81-1 Reliability 1	Rabbit New Zealand White 5 males and 5 females	Dermal PAA 11.7% H2O2 18% AA 20%	Dose levels: 500, 2020, 2293 mg/kg bw Duration of exposure: single application with 14 day post exposure	1957 mg/kg bw test substance *228.8 mg/kg bw		A 6.1.2/02

			period	100% PAA		

Summary table of human data on acute dermal toxicity				
Type of data/ report, reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
No human data on acute dermal toxicity carried out				

Value used in the Risk Assessment – Acute dermal toxicity	
Value	The acute dermal LD_{50} of formulations containing 5 – 15 % peracetic acid was between 1147 and 1957 mg/kg bw in the rabbit indicating that equilibrium peracetic acid, at the tested concentrations, is moderately toxic by the dermal route. Rat dermal LD50 values greater than 200 mg/kg bw have been reported (ECETOC 2001).
Justification for the selected value	Based on the results obtained in rabbits, classification of the aforementioned formulations (PAA conc. 5-15 %) as Acute Tox 3 or Acute Tox. 4 with the hazard statement H311 or H312: "Harmful in contact with skin" in accordance with the criteria of the CLP Regulation (reference value 1000 < ATE 2000 ≤ mg/kg bw) is warranted.
Classification of the product according to CLP	As stipulated above, for consistency reasons within the PAA Consortium, all products within SOPUROXIDare classified by Sopura as Acute tox 4, H332. Products having 15 % PAA are classified as Acute tox 3, H311.

Information on dermal absorption

No studies on the dermal absorption of the biocidal products of SOPUROXIDare available. For the sake of completeness, the results reported in the active substance dossier (CAR IIA and IIB).

Based on the physico-chemical properties of PAA, 100 % dermal penetration is assumed as default value for the risk assessments.

Summary table of animal studies on dermal absorption						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Concentra tion of test substance /Label, Duration of**	**Absorption data for each compartment and final absorption value**	**Signs of toxici ty**	**Remark s**	**Reference**

		exposure				
Absorption, distribution and excretion of ^{14}C-radiolabelled Proxitane 0510 in rats OECD GL 417 (incorporating 427) a single dermal administration GLP	Sprague Dawley rat (4 males per group)	5% PAA Vehicle: Solutions used as prepared	**Results:** - approx. 31 – 46 % of the administered dose was recovered as CO_2 after an initial lag phase of approx. 1 hour - no volatilisation from treated skin - about 3 % of given radioactivity excreted *via* the faeces and 11 % *via* urine - 12 % of radio-activity tissue-bound with highest levels found in liver, gastro-intestinal tract and exposed skin		Toxicokinetic data Reliability 1 -only male rats -only one concentration	Doc. No.: 511-001 A6.2/01 Key study

Value(s) used in the Risk Assessment – Dermal absorption	
Value(s)	Default value of 100 % is established for oral, inhalation and dermal absorption.

Information on metabolism in blood and tissues

Summary table of in vitro studies on metabolism in blood and tissues					
Method, Guideline, GLP status, Reliability	**Species, Number of skin samples tested per dose, Other relevant information about the study**	**Test substance, Doses**	**Absorption data for each compartment and final absorption value**	**Remarks**	**Reference**
In vitro metabolism in blood GLP	Wistar rat (one)	1.0 and 5.0 mg/L PAA vehicle: physiological salt solution	- rapid degradation of peracetic acid in blood diluted 1000 times - half-life of less than 5 minutes.	Toxicokinetic data Reliability 2	Doc. No.: 593-001 A6.2/02
In vitro metabolism in blood GLP	Wistar rat (one)	0, 5.4, 10.8, 21.6 mg/L PAA vehicle: physiological salt solution	- rapid degradation of peracetic acid in blood diluted 1000 times - half-life of less than 5 minutes with conc. of <10 mg/l.	Toxicokinetic data Reliability 2	Doc. No.: 514-001 A6.2/03
In vitro metabolism in different tissues	n.a.	n.a.	Fast degradation of Peracetic acid by catalases found in blood, stomach fluid, saliva as well as in various organs	Metabolism/ kinetic data	Doc. No.: 092-003 A6.2/05

Value(s) used in the Risk Assessment – Metabolism in blood	
Value(s)	PAA degrades rapidly in diluted rat blood.

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

Hydrogen peroxide and sulfuric acid are other substances contained in the biocidal product formulations.
Majority of the non-active substances are also classified as irritants/corrosive. Therefore, the classification of these non-active substances carry through the classification of the concentrated biocidal products which all have pH < 2.

Additional justification for (not) taking into account these substances in the risk assessment is provided in Section 2.1.2.6.

The information listed below is summarised from the information available on the applicable SDS of the raw materials.

Substance	Function	Relevant toxicological data
Hydrogen peroxide	2nd active substance*	Acute Tox 4 (H302 and H332) Skin irritation cat. 2 (H315) Eye damage cat. 1 (H318) STOT SE 3 (H335) AEC_{inhal}= 1.25 mg/m^3 $NOEC_{dermal}$ = 35%
Sulphuric acid	Catalyzer	Skin corrosion cat. 1A (H314) $OEL_{long-term}$ = 0.05 mg/m^3 OEL_{acute} = 0.1 mg/m^3
Other co-formulants		Please see Confidential Annex

**Hydrogen peroxide has an active substance function, but is not to be regarded as an "official" active.*

Available toxicological data relating to a mixture
Not relevant.

2.2.6.2 Exposure assessment

Introductory remarks

- *Theoretical products*

In this section human exposure related to the different uses of the products will be assessed. Based on the products to be authorised, two theoretical products have been defined. The 2 theoretical products can be regarded as representative for all the biocidal products being authorised. Theoretical product 1 contains 5 % peracetic acid (PAA) and 25 % hydrogen peroxide (HP) as active substances and theoretical product 2 contains 15 % PAA and 25 % HP (see detailed composition below). The compositions of the theoretical products were defined at the active substance approval stage, and are still considered applicable for this biocidal product authorisation dossier of the SOPUROXID Biocidal Product Family. Note that the exact composition of the co-formulants differs for SOPUROXIDproducts compared to the theoretical products but that this is not assumed to have any impact on the exposure/risk assessment.

Theoretical product 1

Ingredient of preparation	Function	Content % (w/w)
Peracetic acid (PAA)	Active substance	5
Hydrogen peroxide (HP)	Equilibrium partner of PAA and second active substance	25
Acetic acid	Equilibrium partner of PAA	7
1-hydroxyethane-1,1-diphosphonic acid (HEDP)	Stabiliser	0.8
Dipicolinic acid	Stabiliser	-
Sulphuric acid	Catalyst	1

Water	Solvent/reaction product	61.2

Theoretical product 2

Ingredient of preparation	Function	Content % (w/w)
Peracetic acid (PAA)	Active substance	15
Hydrogen peroxide (HP)	Equilibrium partner of PAA and second active substance	25
Acetic acid	Equilibrium partner of PAA	15
1-hydroxyethane-1,1-diphosphonic acid (HEDP)	Stabiliser	0.8
Dipicolinic acid	Stabiliser	0.02
Sulphuric acid	Catalyst	-
Water	Solvent/reaction product	44.18

- *Selecting the appropriate theoretical product for exposure assessment*

An overview of the different scenarios considered for the exposure assessment is given below. In scenarios where different products and dilutions are being used, the concentrations considered in the exposure assessment are based on the highest in-use concentration observed per scenario.

For each scenario it is assessed which theoretical product can be used to model the exposure. For example, mixing and loading of undiluted Acidofoam CF (3.2% PAA and 17.6% HP) can best be approached by theoretical product 1 (5% PAA and 25% HP). By selecting theoretical product 1 for modelling the mixing and loading in such a scenario a conservative approach is taken.

In applications where the diluted product is used (e.g. during application and post-application tasks), we similarly aimed at finding the best combination between theoretical product and dilution factor, to approach the in use concentrations. In following example it is demonstrated how this is done:

For application in scenario 1 (manual treatment), following products are being used as xx % solutions in application. We then calculated to which final concentration of PAA and HP this corresponds. The maximum concentration of PAA and HP is derived and we then try to find the best combination between theoretical product and dilution factor to cover the maximum concentration.

As a theoretical example, please see table below:

Product	% used during application	Final conc PAA (%)	Final conc HP (%)
Acidofoam CF	3.0	0.096	0.705
Sopuroxid 5	1.5	0.075	0.330
Sopuroxid 15	0.5	0.075	0.110
Oxypur CS	0.5	0.075	0.110
Max in use concentration		0.096	0.705
33.33 x dilution of theoretical product 1		0.15	0.75

Model calculations are then made assuming that this task is performed with theoretical product 1, diluted with a factor 33.33.

Note that with this approach it is possible that for mixing and loading a different theoretical product is used than in the application. Nevertheless, for both tasks the most conservative approach is used.

- *Primary and secondary exposure – relevant properties of the active substances for human exposure*

The uses of peracetic acid and hydrogen peroxide are industrial and/or professional. Non-professional uses are not relevant in the intended applications of peracetic acid and hydrogen peroxide. Industrial and professional applications of the products in the different uses may result in **primary exposure** via dermal and inhalation route. Ingestion is not considered to be relevant. The following basic assumptions and considerations apply:

Both peracetic acid and hydrogen peroxide are highly reactive and degrade rapidly at the site of first contact with organic material.

Based on the evaluated information, peracetic acid and hydrogen peroxide are the most critical ingredients in the products with regard to possible human health risks.

- Dermal exposure: The mode of action of peracetic acid is characterised by local irritation/corrosion. Moreover, due to oxidation, a fast degradation of peracetic acid can be assumed. Hydrogen peroxide is very comparable to peracetic acid in terms of mode of action: oxidising ability, local irritation/corrosion. The underlying mechanism of toxicity via dermal route is considered to be direct chemical reactivity without prior metabolism. It seems that peracetic acid and hydrogen peroxide do not become systemically available upon dermal contact. For this reason, the observed toxic effects are mainly limited to the site of first contact. Systemic risk assessment following dermal exposure is not needed in the absence of systemic availability and systemic distribution. Due to the underlying mechanism and chemical nature of the substance, the observed dermal irritation/corrosion is mainly concentration dependent and less affected by duration of exposure.

PAA	**HP**
$NOEC_{dermal}$ = 0.10 %	$NOEC_{dermal}$ = not relevant as all applied concentrations < 35% threshold for classification as skin irritant

Reference: CAR of PAA and HP

- Inhalation exposure: Besides the local irritation/corrosion related effects in the mucous membranes of the respiratory tract, peracetic acid was shown to cause sensory irritation of the respiratory tract. This effect may be caused by lower concentrations than those caused by the direct chemical reactivity observed also on the skin upon exposure. Both types of respiratory tract irritation are mainly concentration dependent and much less affected by duration of exposure. Similarly to dermal exposure, systemic risk assessment following inhalation exposure is not needed in the absence of systemic availability and systemic distribution.

PAA	HP
AEC_{inhal} = 0.5 mg/m^3	AEC_{inhal} = 1.25 mg/m^3

Reference: CAR of PAA and HP

Remark: Hydrogen peroxide at a concentration of 25% is classified with 'risk of serious damage to eyes'. Consequently, wearing of gloves and goggles during handling of concentrated products is mandatory.

In addition to the primary exposure, a potential **for secondary exposure** has to be considered. Secondary exposure that could occur is: via dermal contact with disinfected equipment; dermal contact with treated surfaces or equipment or inhalation exposure of non-users or bystanders.

The dermal secondary exposure following application, however, is considered to be not relevant. Both peracetic acid and hydrogen peroxide are highly unstable and will rapidly degrade at the site of first contact which effectively further reduces the possibility of any residual concentrations. Damaged skin could potentially be more prone to the adverse effects of residual peracetic acid but even this scenario is speculative due to the high reactivity and rapid degradation. Therefore, only exposure via the inhalation route after application of peracetic acid solutions is considered to be relevant for the assessment of secondary exposure.

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

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	No	Yes	Yes	Yes	No
Dermal	Yes	Yes	No	No	No	No	No
Oral	No	No	No	No	No	No	No

Selection of models

The models considered for assessing the scenarios are exposure scenarios from the TNsG, part II, and ART (Advanced Reach Tool, v. 1.5). The latter was however selected as the preferred model because the TNsG models do not take into account the volatility of the substances. ART does take the volatility into account and thus allows the inhalation exposure estimation to vapours of peracetic acid (and hydrogen peroxide). This is in line with the request from the eCA based on the CAR document provided for PAA: "*the applied TNsG models do not take into account the volatility of the substance. Other more advanced models or available measurement data should be used additionally at product authoritisation to estimate the inhalation exposure to vapour of peracetic acid".*

Results of the TNsG modelling are not represented in this document as they are no longer considered relevant.

With regard to the use of ART, there is however one parameter which is to be flagged prior to evaluation of the scenarios that are listed below. Due to the fact that the effects of concern of PAA and HP are local effects, the duration of the activity is less important than the highest concentration that can be reached during the related activity. The consequence of this is the fact that 8hr TWA values are of little importance here. Within ART, the non-exposure duration was therefore always set to 0. This results in an exposure estimate for which the time factor has no impact.
For additional information on the Activity coefficients for H_2O_2, please refer to Annex 3.3.

Discussion on Ventilation

There is no Tier 2 calculation performed in order to take into account higher and more effective ventilation rate. There are multiple reasons for this. There is no 'ready to use' information available regarding the ventilation rates of the areas where disinfection takes place, especially given the fact that some of the uses described cover widely different areas (industrial, health and public areas). It is highly improbable that all such areas could be covered with the same kind of (enhanced) ventilation. Furthermore, the diversity of areas covered by the same scenarios make it difficult to put in place coherent ventilation rate obligation.
The need for the implementation of a good ventilation rate where possible has however been stressed in the general RMM section.

Remark on the use of scenario for the assessment:

It is to be noted that, due to the shortcomings of all currently available tools (Consexpo, ART,…) in assessing correctly the evaporation rate of products like peracetic acid and hydrogen peroxide, there remains an important level of uncertainty for human health risk assessment for all application made by spraying. Discussions are currently ongoing to solve this issue, and the agreed upon and updated scenario will have to be taken into account for the renewal of this family.

List of the intended uses (claimed by the Applicant) & overview of the scenario used to cover them

Meta SPC-1 (5% PAA) Meta SPC-4 (15% PAA)		Link to SCENARIO	Scenario (e.g. mixing/ loading)	Primary or secondary exposure - Description of scenario	Exposed group
PT2	Use #1.1/4.1: Disinfection of surfaces in industrial, public and health care areas - manual treatment (mopping)	**N°1**	Manual treatment	Primary Professional surface disinfection by mopping Models: ART	**Professionals**
	Use #1.2/4.2: Disinfection of surfaces in industrial, public and health care areas - manual treatment (spraying)	**N°4f**	Spraying – Manual application without personal enclosure –downward application – low application rate	Primary Professional equipment and surfaces disinfection by spraying liquid. Spraying requires human intervention. The professional does not have a personal enclosure. Models: ART	
	Use #1.3/4.3 : CIP in the pharmaceutical and cosmetic industry	**N°2**	CIP	Primary Cleaning in place, closed system Models: ART	
	Use #1.4/4.4 : Surface disinfection in greenhouses by spraying with personal enclosure (in absence of plants - for general hygiene purpose only)	**N°4a**	Spraying - Automated application with personal enclosure – application in all directions	Primary Professional surface disinfection by spraying liquid Spraying takes place using an automated system, human intervention with actual application of liquid but the professional is in a cabin (personal enclosure) without ventilation. Models: ART	
	Use #1.5/4.5 : Surface disinfection in greenhouses by spraying without personal enclosure (in absence of plants - for general hygiene purpose only)	**N°4b**	Spraying- Automated or manual application without personal enclosure – application in all directions	Primary Professional surface disinfection by spraying liquid Spraying is done automatically in the presence of an operator. The professional does not have a personal enclosure. Models: ART	
	Use #1.6/4.6: Disinfection of agriculture & horticulture equipment by soaking (in absence of plants - for general hygiene purpose only)	**N°5**	Soaking	Primary Professional disinfection by use of an immersion bath for dipping of equipment Models: ART	
	Use #1.7/4.7 : Disinfection of surfaces and agriculture/horticulture equipment by spraying (in absence of plants - for general hygiene purpose only)	**N°4c**	Spraying – Automated or manual application without personal enclosure –horizontal and downward application	Primary Professional equipment disinfection by spraying liquid Spraying requires human intervention with actual application of	

				the solution. The professional does not have a personal enclosure. Models: ART
	Use #1.8/4.8 : Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (in absence of plants - for general hygiene purpose only)	**N°4d**	Spraying - Automated application with personal enclosure –horizontal and downward application	Primary Professional equipment disinfection by spraying liquid Spraying does not require human intervention with actual application of the solution. The professional is in a personal enclosure without ventilation. Models: ART
	Use #1.9/4.9 : Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (closed room) (in absence of plants - for general hygiene purpose only)	**N°4e**	Spraying - Fully automated application not requiring the presence of operator	Primary Professional equipment disinfection by spraying liquid Spraying does not require human intervention with actual application of the liquid. Spraying is done in a closed room. Models: ART
PT3	Use #1.10/4.10 : Disinfection of animal housing by low-pressure manual spraying – spraying with personal enclosure	**N°4a**	Spraying - Automated application with personal enclosure – application in all directions	Primary Professional surface disinfection by spraying liquid Spraying takes place using an automated system, human intervention with actual application of liquid but the professional is in a cabin (personal enclosure) without ventilation. Models: ART
	Use #1.11/4.11 : Disinfection of animal housing by low-pressure manual spraying – spraying without personal enclosure	**N°4b**	Spraying- Automated or manual application without personal enclosure – application in all directions	Primary Professional surface disinfection by spraying liquid Spraying is done automatically in the presence of an operator. The professional does not have a personal enclosure. Models: ART
	Use #1.12/4.12 : Disinfection of boots in footbaths in animal housing /husbandries	**N°5**	Soaking	Primary Professional disinfection by use of an immersion bath for dipping of equipment Models: ART
	Use #1.13/4.13 : Disinfection of equipment by dipping	**N°5**	Soaking	Primary Professional disinfection by use of an immersion bath for dipping of equipment Models: ART

PT4	Use #1.14/4.14 : Disinfection in Aseptic Filling Lines (crown corks, cheese moulds and food crates) - Automated spraying closed systems	**N°4e**	Spraying - Fully automated application not requiring the presence of operator	Primary Professional equipment disinfection by spraying liquid Spraying does not require human intervention with actual application of the liquid. Spraying is done in a closed room. Models: ART	
	Use #1.15/4.15 : Disinfection of equipment in the food and beverage industry by immersion	**N°5**	Soaking	Primary Professional disinfection by use of an immersion bath for dipping of equipment Models: ART	
	Use #1.16/4.16 : Disinfection of heat and ion exchangers, membrane filters and glass and PET bottles – CIP procedures	**N°2**	CIP	Primary Cleaning in place, closed system Models: ART	
	Use #1.17/4.17 : Disinfection of surfaces and equipment by low pressure spraying – spraying with personal enclosure	**N°4a**	Spraying - Automated application with personal enclosure – application in all directions	Primary Professional surface disinfection by spraying liquid Spraying takes place using an automated system, human intervention with actual application of liquid but the professional is in a cabin (personal enclosure) without ventilation. Models: ART	
	Use #1.18/4.18 : Disinfection of surfaces and equipment by low pressure spraying – spraying without personal enclosure	**N°4b**	Spraying- Automated or manual application without personal enclosure – application in all directions	Primary Professional surface disinfection by spraying liquid Spraying is done automatically in the presence of an operator. The professional does not have a personal enclosure. Models: ART	
	Use #1.19/4.19 : Disinfection of surfaces and equipment by low pressure spraying, manually	**N°4c**	Spraying -Automated or manual application without personal enclosure –horizontal and downward application	Primary Professional equipment disinfection by spraying liquid Spraying requires human intervention with actual application of the solution. The professional does not have a personal enclosure. Models: ART	
	Use #1.20/4.20 : Disinfection of surfaces and equipment by low pressure spraying, automatically	**N°4d**	Spraying - Automated application with personal enclosure –horizontal and downward application	Primary Professional equipment disinfection by spraying liquid Spraying does not require human intervention with actual application of the solution. The professional is in a personal	

				enclosure without ventilation. Models: ART	
	Use #1.21/4.21 : Disinfection of surfaces and equipment by low pressure spraying – automatic spraying (closed room)	**N°4e**	Spraying - Fully automated application not requiring the presence of operator	Primary Professional equipment disinfection by spraying liquid Spraying does not require human intervention with actual application of the liquid. Spraying is done in a closed room. Models: ART	
	Use #1.22/4.22 : Disinfection of inner surfaces (pipelines, tanks, vessels, …) by CIP	**N°2**	CIP	Primary Cleaning in place, closed system Models: ART	
	Use #1.23/4.23 : Disinfection of water used for rinsing of recycled items during the washing process	**N°3**	Water stream	Primary Closed system Models: ART	
Meta SPC-2 with product ***SOPUROXID 3.2* (3.2% PAA)** – by fogging		**Link to SCENARIO**	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure - Description of scenario**	**Exposed group**
PT2	Use #2.1 : Disinfection of surfaces and/or equipment in industrial, public and health care areas (pharmaceutical and cosmetic industry) – fogging	**N°7**	Fogging	Primary Professional surface disinfection by fogging Fogging takes place using an automated system, no operator present, no exposure assessment. After application, concentrations are assessed before entering into the room is allowed. Models: ART	**Professionals**
	Use #2.2 : Disinfection of hard surfaces equipment by fogging (e.g. agriculture & horticulture equipment, in absence of plants – for general hygiene purpose only)	**N°7**			
PT3	Use #2.3 : Disinfection of animal housing by fogging	**N°7**			
PT4	Use #2.4 : Disinfection of storage rooms with special device in storage cellar or room	**N°7**			
Meta SPC-3 (3.2% PAA) – by foaming		**Link to SCENARIO**	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure - Description of scenario**	**Exposed group**
PT2	Use #3.1 : Disinfection of surfaces in industrial, public and health care areas – foam application on surfaces	**N°6f**	Foaming – Manual application without personal enclosure – horizontal and downward application – low application rate	Primary Professional equipment and surfaces disinfection by foaming liquid. Foaming requires human intervention. The professional does not have a personal enclosure. Models: ART	**Professionals**
	Use #3.2 : Disinfection of equipment and surfaces by foaming (e.g. agriculture & horticulture equipment – for general hygiene	**N°6c**	Foaming - Automated or manual application without personal enclosure –horizontal and	Primary Professional equipment disinfection by foaming liquid	

	purpose only), manually		downward application	Foaming requires human intervention with actual application of foam. The professional does not have a personal enclosure. Models: ART	
	Use #3.3 : Disinfection of surfaces and equipment by foaming (e.g. agriculture & horticulture equipment – for general hygiene purpose only) automatically	**N°6d**	Foaming - Automated application with personal enclosure –horizontal and downward application	Primary Professional equipment disinfection by foaming liquid Foaming does not require human intervention with actual application of foam. The professional is in a personal enclosure without ventilation. Models: ART	
	Use #3.4 : Disinfection of surface and equipment by foaming (e.g. agriculture & horticulture equipment – for general hygiene purpose only) – automatic foaming (closed room)	**N°6e**	Foaming - Fully automated application not requiring the presence of operator	Primary Professional equipment disinfection by foaming liquid Foaming does not require human intervention with actual application of foam. Foaming is done in a closed room. Models: ART	
PT3	Use #3.5 : Disinfection of animal housing by foaming – foaming with personal enclosure	**N°6a**	Foaming - Automated application with personal enclosure – application in all directions	Primary Professional surface disinfection by foaming liquid Foaming takes place using an automated system, human intervention with actual application of foam but the professional is in a cabin (personal enclosure) without ventilation Models: ART	
	Use #3.6 : Disinfection of animal housing by foaming – foaming without personal enclosure	**N°6b**	Foaming - Automated or manual application without personal enclosure – application in all directions	Primary Professional surface disinfection by foaming liquid Foaming requires human intervention with actual application of foam. The professional does not have a personal enclosure. Models: ART	
PT4	Use #3.7 : Disinfection of surfaces by foaming with personal enclosure	**N°6a**	Foaming - Automated application with personal enclosure – application in all directions	Primary Professional surface disinfection by foaming liquid Foaming takes place using an automated system, human intervention with actual application of foam but the professional is in a cabin (personal enclosure) without ventilation Models: ART	
	Use #3.8 : Disinfection of surfaces by foaming without personal enclosure	**N°6b**	Foaming - Automated or manual application without personal enclosure – application in all directions	Primary Professional surface disinfection by foaming liquid Foaming requires human intervention with actual application of	

				foam. The professional does not have a personal enclosure. Models: ART	
Meta SPC-5 (5% PAA) Meta SPC-6 (15% PAA)		**Link to SCENARIO**	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure - Description of scenario**	**Exposed group**
PT5	Use #5.1/6.1 : Disinfection of animal drinking water – closed system	**N°3**	Water stream	Primary Closed system Models: ART	**Professionals**

PLEASE NOTE that, during the peer review, due to insufficient data to confirm their efficacy, the uses in META-SPC 5 and 6 have been removed from the draft PAR and SPC and, consequently, have not been discussed further by the BPC WGs.

For local effects, the combined exposure (i.e. the sum of different tasks such as mixing and loading, application and post-application) is not relevant. Nevertheless, scenarios were defined as a sequence of the 3 tasks (Mixing and loading, application and post-application). The peak concentrations estimated for a task are more important than the concentration averaged over a shift therefore within one scenario, the evaluation of the highest exposure level determined drives the “total daily exposure”.

Industrial exposure

Manufacturing of the active substances PAA and HP, as well as the formulation of products is not relevant at the product approval stage within the BPR.

Professional exposure

Only industrial users or professionals perform the scenarios described here.

***Scenario 1**: Manual treatment*

Scenario 1 covers the following uses :
PT2 - Use #1.1/4.1 "Disinfection of surfaces in industrial, public and health care areas - manual treatment (mopping)"

The biocidal products used for this scenario are:
- Sopuroxid 5
- Sopuroxid 15
- Oxypur CS

Description of Scenario 1, Manual treatment

The product is applied by wiping of hard surfaces with flat mops or cleaning cloths.

During these tasks, the worker/operator will dilute the concentrated product in a bucket (mixing/loading) and use the diluted solutions for cleaning of hard surfaces (application). After completion of the cleaning procedure, the content of the bucket will be drained (post-application). Exposure of the worker/operator will therefore occur during mixing/loading, application and draining, respectively.

Mixing and loading (M&L): Preparation of disinfecting solution

- Concentrated product corresponds to theoretical product 2:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	15	0.0536	0.48
HP	25	0.1996	0.93

- Models used: ART model as described in detail below.
- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 - 10 L/min
- Containment level: Handling that reduces contact between product and adjacent air
- Loading type: splash loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

Application: Cleaning of surfaces, manual application of the disinfection solution

- Diluted product, corresponds to a 1:33 dilution of theoretical product 1:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	0.15	0.00036	2.39
HP	0.75	0.00399	1.19

- Model used: ART model as described in detail below.
- Duration: 30 minutes
- Activity class: spreading of liquid products, > 3 m^2/h
- Room size: 100 m^3
- Ventilation rate: 1 ACH
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

Post-application: Draining of cleaning solutions and handling of empty containers

- Diluted product, corresponds to a 1:33 dilution of theoretical product 1:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	0.15	0.00036	2.39
HP	0.75	0.00399	1.19

- Models used: ART model as described in detail below. The same assumptions were taken as for mixing and loading of concentrated products.
- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 - 10 L/min
- Containment level: Handling that reduces contact between product and adjacent air
- Loading type: splash loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

	Parameters[1]	Value
Tier 1	Content of active substance (maximum theoretical concentrations): Mixing & loading undiluted product: Application diluted product: Post-application diluted product:	 15 % PAA, 25 % HP 0.15 % PAA, 0.75 % HP 0.15 % PAA, 0.75 % HP
	Undiluted product	Theoretical product 2 Activity coefficient PAA: 0.48 Activity coefficient HP: 0.93
	Dilution of the applied product (theoretical product):	33 (theoretical product 1) Activity coefficient PAA: 2.39 Activity coefficient HP: 1.19
	Inhalation exposure: Dermal exposure:	Temperature: 20°C Vapour pressure PAA: 1410 Pa Vapour pressure HP: 214 Pa /
	Exposure duration: Mixing & loading: Application: Post-application:	 15 min 330 min 15 min

The activity coefficients were calculated using the AIOMFAC tool published by ETH, Zurich on http://www.aiomfac.caltech.edu/cgi_bin/model.pl. The attached excel (2017-02-13 Activity coefficients calculations, see Annex) shows how the activity coefficients have been calculated based on the mole fraction of the different constituents for each theoretical product and the in-use applications. The print files of the modeled results are provided also.

Justification for the choice of parameters:

- *A flow rate of 1-10 L/min does correspond to the filling of bottles and paint guns, and is thus seen as an appropriate approximation for this mixing and loading activity.*
- *Room size for application: 100 m^3. As a smaller room volume represent a worst case situation for inhalation exposure, a total room volume of 100 m^3 seems an acceptable worst case.*
- *Spreading rate for application: >3m^2/h: a spreading rate of >3 m^2/h corresponds to painting on walls or ships, and is thus considered as a worst case approach. This is moreover the highest ART parameter that can be selected for wiping.*

Calculations for Scenario 1, Manual treatment
Details on the calculations are provided in Annex 3.2

DERMAL
Direct dermal contact to the product is possible in function of normal work practice. The maximum dermal exposure potential for this scenario use results from the use of the concentrated product, containing up to 15 % PAA and 25 % HP. When compared to the $NOEC_{dermal}$ values for PAA and HP, the $NOEC_{dermal}$ is exceeded for PAA, but at the threshold for HP. Note that also when working with a diluted solution at 0.15 % PAA, the $NOEC_{dermal}$ (i.e. 0.10 %) is exceeded. When this concentration would be used and since there is potential dermal contact, PPE (chemical resistant gloves, acid-proof protective coverall, safety glasses and/or face shield) are to be worn to prevent direct dermal contact. This is applicable due to the immediate and direct effect of these BP's as being corrosive in undiluted form. This represents a worst-case assessment as on the basis of the efficacy data, a 0.048 % PAA would be the desired in-use concentration. Since this is below the $NOEC_{dermal}$ no PPE are required at this prescribed in-use concentrations.

INHALATION
Inhalation exposure cannot be excluded due to the volatile nature of the active ingredients PAA and HP. The inhalation exposures of the different tasks (mixing and loading, application and post-application) are calculated using ART.

The highest concentration was found to be 8.8 mg/m^3 for PAA and 7.4 mg/m^3 for HP during application. Based on these exposure estimates, additional RPE is required to ensure that the exposure is reduced below the inhalation AEC's set for PAA and HP.
The use of RPE having an APF of 10 should be enough during the handling of the concentrated products. During the application of the disinfection solution, the use of RPE with an APF of 20 is needed.

Taking into account that according to the efficacy data, a use concentration of 0.064 % PAA, rounded to 0.075 % PAA, is sufficient, the above calculations are very conservative. Use concentrations of 0.075 % PAA (instead of 0.15 % PAA) and 0.375% HP (instead of 0.75% HP) would reduce the exposure to 4.4 mg/m^3 for PAA and 3.7 mg/m^3 for HP. Making use of RPE having an APF of 20 would hence offer sufficient protection in this scenario.

The details for calculation of the dermal and inhalation exposure using ART are available in Annex 3.2. The summary of the results is presented here.

<u>Peracetic acid</u>:
Modelled – worst-case:

Task	Maximum PAA concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	15	2.2	No RPE
		0.22	RPE APF = 10
Application	0.15	8.8	No RPE
		0.44	RPE APF = 20
Post-application	0.15	0.025	No RPE

Hydrogen peroxide:

Task	Local dermal exposure Maximum concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	25	2.4	No RPE
		0.6	RPE APF = 10
Application	0.75	7.4	No RPE
		0.37	RPE APF = 20
Post-application	0.75	0.02	No RPE

***Scenario 2**: CIP*

Scenario 2 covers the following uses :

PT2 - Use #1.3/4.3 "CIP in the pharmaceutical and cosmetic industry"

PT4 - Use #1.16/4.16 "Disinfection of heat and ion exchangers, membrane filters and glass and PET bottles – CIP procedures" and Use #1.22/4.22 "Disinfection of inner surfaces of pipelines, tanks, vessels, … in milking parlours (only by CIP procedures)"

The biocidal products used for this scenario are:

- Sopuroxid 5
- Sopuroxid 5C
- Sopuroxid 15
- Oxypur CS

Description of Scenario 2, CIP

For CIP-procedures, the product is automatically circulated from the CIP holding tanks through pipework and installations during application of the product. Thus, installations do not need to be dismantled for cleaning/disinfection procedures. Since the application is automated and a closed process, no worker/operator will be present during the cleaning/disinfection step. After cleaning/disinfection are completed, pipework and tanks are rinsed with water, which is done under closed system conditions as well.

Exposure of the worker/operator during CIP processes, only occurs during mixing and loading, i.e. when the concentrated product is pumped or poured into the CIP holding tanks. Connecting and disconnecting containers in the pumping scenario is of only short duration, pumping operations do not require the presence of a worker/operator and occur under closed system conditions. The mixing and loading process can therefore be considered as automated mixing and loading.

Mixing and loading (M&L): Automated loading into the CIP holding tanks

- Concentrated product corresponds to theoretical product 2:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	15	0.0536	0.48
HP	25	0.1996	0.93

- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 – 10 L/min
- Containment level: Open process
- Loading type: Submerged loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: Medium level containment (99% reduction), no secondary risk management measures
- Emissions Sources: Near field

Application: CIP

- Content of active substance in the cleaning/disinfection solutions to be applied: 0.1% (1000 ppm) peracetic acid and 0.5% (5000 ppm) hydrogen peroxide (1:50 dilution of theoretical product 1).
- CIP does not require the presence of a worker/operator during the cleaning/disinfection procedure of the pipework/installations and the product is circulated/dosed through the system under closed system conditions. Thus, worker/operator exposure during the CIP process (application) is not relevant.

Post-application: Draining of cleaning solutions and handling of empty containers

- After cleaning of installations, equipment or machines, the pipework and installations are rinsed with water under closed system conditions and the water is transferred automatically. Thus, worker/operator exposure during the rinsing process with water is not relevant.
- Following dosing (i.e. pouring/pumping) of the content of the containers into the CIP holding tank, empty containers are screwed down, stored and finally disposed of. During these tasks, no exposure is assumed.

	Parameters[1]	Value
Tier 1	Content of active substance: Mixing & loading undiluted product: Application diluted product: Post-application diluted product:	 15 % PAA, 25 % HP 0.1 % PAA, 0.5 % HP 0.1 % PAA, 0.5 % HP

	Undiluted product	Theoretical product 2 Activity coefficient PAA: 0.48 Activity coefficient HP: 0.93
	Dilution of the applied product (theoretical product):	50 (theoretical product 1) Activity coefficient PAA: 2.42 Activity coefficient HP: 1.20
	Inhalation exposure: Dermal exposure:	Temperature: 20°C Vapour pressure PAA: 1410 Pa Vapour pressure HP: 214 Pa /
	Exposure duration: Mixing & loading: Application: Post-application:	 15 min Not relevant Not relevant

The activity coefficients were calculated using the AIOMFAC tool published by ETH, Zurich on http://www.aiomfac.caltech.edu/cgi_bin/model.pl. The attached excel (2017-02-13 Activity coefficients calculations, see Annex) shows how the activity coefficients have been calculated based on the mole fraction of the different constituents for each theoretical product and the in-use applications. The print files of the modeled results are provided also.

Justification for the choice of parameters:

M&L:

- *A flow rate of 1-10 L/min does correspond to the filling of bottles and paint guns, and is thus seen as an appropriate approximation.*
- *Room size: Any size workroom. Mixing and Loading could be done out of a "central" storage room with automatic pumping to the CIP vessels or "decentralized", but nearly in most cases the mixing and loading is done in an automated way. The selection of 'any size room' is seen as a relevant (and rather conservative) selection of room size.*

Calculations for Scenario 2, CIP

Details on the calculations are provided in Annex 3.2

DERMAL

Dermal exposure towards peracetic acid during automated transfer of the product into the CIP holding tanks for subsequent cleaning/disinfection of pipework, installations and tanks is limited but nevertheless possible. The concentrated product peracetic acid is known to be corrosive and the hydrogen peroxide solution (concentration of 25 %) is classified with 'risk of serious damage to eyes`. Consequently, wearing of gloves and goggles during handling of the concentrated products is mandatory. The dermal exposure for this scenario results from the concentrated product, containing up to 15 % PAA and 25 % HP. As the operator is not present during the application and post-application, no PPE is to be prescribed.

INHALATION

The risk for inhalation exposure is only expected when pipes are being connected and disconnected from the CIP installation. When modelling the exposure using ART, automated mixing and loading of the concentrated product is assumed. The inhalation exposure during the mixing and loading is estimated to be 0.024 mg/m^3 for peracetic acid and 0.027 mg/m^3 for hydrogen peroxide. As both values are below the respective AEC_{inhal}, no RPE is necessary during mixing and loading. Since there is no worker exposure during application and post-application, also for these activities no use of RPE is prescribed.

The details for calculation of inhalation exposure using ART are available in Annex 3.2. The summary of the results is presented here:

Peracetic acid:

Task	Local dermal exposure Maximum concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	15	0.024	No RPE
		0.006	RPE APF = 4
Application	0.1	Not relevant	Not relevant
Post-application	0.1	Not relevant	Not relevant

Hydrogen peroxide:

Task	Local dermal exposure Maximum concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	25	0.027	No RPE
		0.007	RPE APF = 4
Application	0.5	Not relevant	Not relevant
Post-application	0.5	Not relevant	Not relevant

Sulphuric acid:

Sopuroxid 5C (META SPC1) is only used for CIP applications. This BP product contains 24.04 % sulphuric acid (other BP products of the product family contain maximally 0.8 % H_2SO_4). As sulphuric acid is a substance of concern, inhalation exposure to sulphuric acid during the mixing and loading of Sopuroxid 5C has also been assessed using ART modelling. For modelling the same parameters as for PAA and HP have been used:

- Mole fraction: 0.0688 and actitvity coefficient (modelled using AIOMFAC): 2.61
- Vapour pressure: 214 Pa (measured for 65% H_2SO_4 solution at 20°C, source: REACH registration dossier).
- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 – 10 L/min
- Containment level: Open process
- Loading type: Submerged loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: Medium level containment (99% reduction), no secondary risk management measures

The inhalation exposure is estimated to be 0.026 mg/m^3 during mixing and loading of Sopuroxid 5C. This is below the AEC for sulphuric acid of 0.05 mg/m^3. No protective measures are hence required due to the presence of sulphuric acid in the biocidal product.

***Scenario 3**: Water stream*

Scenario 3 covers the following uses :

PT4 - Use #1.23/4.23 "Disinfection of water used for rinsing of recycled items during the washing process" Micro-preservation of water used for final rinse"

The biocidal products used for this scenario are:
- Sopuroxid 5
- Sopuroxid 15
- Oxypur CS

Description of Scenario 3, Water stream

During these tasks, the operator will pump the concentrated product into the reservoir from which it is continuously dosed into the water stream. Dilution of the product to the intended in-use concentration occurs in the water stream. Exposure of the worker/operator will therefore occur during mixing/loading (i.e. pumping of the product into reservoir) only. Connecting and disconnecting containers in the pumping scenario is of only short duration, pumping operations do not require the presence of a worker/operator and occur under closed system conditions. The mixing and loading process can therefore be considered as automated mixing and loading.

Since the application is automated and a closed process, no worker/operator will be present during the process. At regular times, pipework and tanks are rinsed with water, which is done under closed system conditions as well.

Mixing and loading (M&L): Dosing into the water stream reservoir
- Concentrated product corresponds to theoretical product 2:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	15	0.0536	0.48
HP	25	0.1996	0.93

- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 – 10 L/min
- Containment level: Open process
- Loading type: Submerged loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: Medium level containment (99% reduction), no secondary risk management measures
- Emissions Sources: Near field

Application: • Content of active substance in the cleaning/disinfection solutions to be applied: 0.025% (250 ppm) peracetic acid and 0.075% (750 ppm) hydrogen peroxide (1:200 dilution of theoretical product 1). • This process does not require the presence of a worker/operator during the cleaning/disinfection procedure of the pipework/installations and the product is circulated/dosed through the system under closed system conditions. Thus, worker/operator exposure during the application is not relevant. Post-application: Draining of cleaning solutions and handling of empty containers • Following dosing (i.e. pouring/pumping) of the content of the containers into holding tanks, empty containers are screwed down, stored and finally disposed of. During these tasks, no exposure is assumed.		
	Parameters[1]	Value
Tier 1	Content of active substance: Mixing & loading undiluted product: Application diluted product: Post-application diluted product:	 15 % PAA, 25 % HP 0.025 % PAA, 0.125 % HP 0.025 % PAA, 0.125 % HP
	Undiluted product	Theoretical product 2 Activity coefficient PAA: 0.48 Activity coefficient HP: 0.93
	Dilution of the applied product (theoretical product):	200 (theoretical product 1) Activity coefficient PAA: 2.46 Activity coefficient HP: 1.20
	Inhalation exposure: Dermal exposure:	Temperature: 20°C Vapour pressure PAA: 1410 Pa Vapour pressure HP: 214 Pa /
	Exposure duration: Mixing & loading: Application: Post-application:	 15 min Not relevant Not relevant

The activity coefficients were calculated using the AIOMFAC tool published by ETH, Zurich on http://www.aiomfac.caltech.edu/cgi_bin/model.pl. The attached excel (2017-02-13 Activity coefficients calculations, see annex) shows how the activity coefficients have been calculated based on the mole fraction of the different constituents for each theoretical product and the in-use applications. The print files of the modeled results are provided also.

Justification for the choice of parameters:

M&L:

- *A flow rate of 1-10 L/min during mixing and loading does correspond to the filling of bottles and paint guns, and is thus seen as an appropriate approximation*
- *Room size: Any size workroom. Mixing and Loading could be done out of a "central" storage room with automatic pumping to the water stream vessels or "decentralized", but nearly in most cases the mixing and loading is done in an*

automated way. The selection of 'any size room' is seen as a relevant (and rather conservative) selection of room size.

Calculations for Scenario 3, Water stream
Details on the calculations are provided in Annex 3.2

DERMAL
Dermal exposure towards peracetic acid during automated transfer of the product into the reservoir is limited but nevertheless possible. The concentrated product peracetic acid is known to be corrosive and the hydrogen peroxide solution (concentration of 25 %) is classified with 'risk of serious damage to eyes`. Consequently, wearing of gloves and goggles during handling of the concentrated products is mandatory. The dermal exposure for this scenario results from the use of the concentrated product, containing up to 15 % PAA and 25 % HP. As the operator is not present during the application and post-application, no PPE is to be prescribed.

INHALATION
The risk for inhalation exposure is only expected when pipes are being connected and disconnected from the installation. When modelling the exposure using ART, the maximal exposure is expected during the automated mixing and loading of the concentrated product. The inhalation exposure during the mixing and loading is estimated to be 0.024 mg/m^3 for peracetic acid and 0.027 mg/m^3 for hydrogen peroxide. As both values are below the respective AEC_{inhal}, no RPE is necessary during mixing and loading. Since there is no worker exposure during application and post-application, also for these activities no use of RPE is prescribed.

The details for calculation of inhalation exposure using ART are available in Annex 3.2. The summary of the results is presented here:

<u>*Peracetic acid:*</u>

Task	Maximum PAA concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	15	0.024	No RPE
Application	0.025	Not relevant	Not relevant
Post-application	0.025	Not relevant	Not relevant

<u>*Hydrogen peroxide:*</u>

Task	Maximum HP concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	25	0.027	No RPE
Application	0.125	Not relevant	Not relevant
Post-application	0.125	Not relevant	Not relevant

***Scenario 4a**: Spraying - Automated application with personal enclosure – application in all directions*

Scenario 4a covers the following uses :

PT2 - Use #1.4/4.4 "Disinfection by spraying in greenhouses (in absence of plants - for general hygiene purpose only) – spraying with personal enclosure"
PT3 - Use #1.10/4.10 "Disinfection of animal housing by low-pressure manual spraying – spraying with personal enclosure"
PT4 - Use #1.17/4.17 "Disinfection of surfaces and equipment by low pressure spraying – spraying with personal enclosure"

The biocidal products used for this scenario are:

- Sopuroxid 5
- Sopuroxid 15
- Oxypur CS

Description of Scenario 4a, Spraying - Automated application with personal enclosure – application in all directions

During these tasks, the concentrated peracetic acid solution will be diluted to the recommended in-use concentrations prior to application of the product in animal housing or greenhouses. The dilutions, i.e. "mixing/loading" of the concentrated solution will be manually done by pouring or automatically by pumping into the reservoir of the spraying equipment. The application of the disinfectant is done automatically using of spraying equipment. The worker or operator is present but in a personal enclosure. Spraying is done in all directions. An example for this scenario is a tractor with spraying equipment and the operator seated in a closed cabin. After the disinfection procedure is completed, surfaces and equipment are rinsed with water and the water rinse drained into the sewer system.

In order to estimate worker/operator exposure during filling of the concentrate into the reservoir of the sprayer, the worst-case exposure is assumed, i.e. that of manual mixing and loading.

During application, the diluted solution is sprayed in the presence of the worker. The spraying of the diluted product is done in all directions, i.e. spraying of floor, walls and ceiling.

Dermal and inhalation exposure during rinsing of equipment and surfaces is considered to be far below the exposure during spray application and is thus, negligible.

Mixing and loading (M&L): Preparation of the spraying solution

- Concentrated product corresponds to theoretical product 2:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	15	0.0536	0.48
HP	25	0.1996	0.93

- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 - 10 L/min
- Containment level: Handling that reduces contact between product and adjacent air
- Loading type: splash loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

Application: Automated spraying with personal enclosure

- Dilution 1:33 of theoretical product 1:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	0.15	0.00036	2.39
HP	0.75	0.00399	1.19

- Duration: 30 minutes
- Activity class: Surface spraying of liquids, moderate application rate (0.3-3 L/min)
- Spray direction: spraying in any directions, including upwards
- Spray technique: no or low compressed air use
- Room size: 3000 m^3
- Ventilation rate: 1 ACH
- Primary risk management: Partial personal enclosure without ventilation (30.00 % reduction), no secondary localized controls
- Emissions Sources: Far field

Post-application: Rinsing of equipment/surfaces and disposal of empty containers

- After disinfection of animal housing and greenhouses is completed, equipment is rinsed with water and treated surfaces are normally rinsed with water after the required contact time. During rinsing of equipment and treated surfaces with water, possible residues on equipment and on 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).
- Emptied containers are disposed after filling of spraying equipment. No exposure during disposal is assumed.

	Parameters[1]	Value
Tier 1	Content of active substance: Mixing & loading undiluted product: Application diluted product: Post-application diluted product:	 15 % PAA, 25 % HP 0.15 % PAA, 0.75 % HP 0.15 % PAA, 0.75 % HP
	Undiluted product	Theoretical product 2 Activity coefficient PAA: 0.48 Activity coefficient HP: 0.93
	Dilution of the applied product (theoretical product):	33 (theoretical product 1) Activity coefficient PAA: 2.39 Activity coefficient HP: 1.19
	Inhalation exposure: Dermal exposure:	Temperature: 20°C Vapour pressure PAA: 1410 Pa Vapour pressure HP: 214 Pa /
	Exposure duration: Mixing & loading: Application: Post-application:	 15 min 30 min Not relevant

The activity coefficients were calculated using the AIOMFAC tool published by ETH, Zurich on http://www.aiomfac.caltech.edu/cgi_bin/model.pl. The attached excel (2017-02-13 Activity coefficients calculations) shows how the activity coefficients have been calculated based on the mole fraction of the different constituents for each theoretical *product and the in-use applications. The print files of the modeled results are provided also.*

Justification for the choice of parameters:

M&L:

- *A flow rate of 1-10 L/min during mixing and loading does correspond to the filling of bottles and paint guns, and is thus seen as an appropriate approximation*
- *Room size for Mixing & loading: Any size workroom. Mixing and Loading could be done out of a "central" storage room manually, but in nearly all cases the mixing and loading is done in an automated way. The selection of 'any size room' is seen as a relevant (and rather conservative) selection of room size.*

Application:

- *Room Size for Application phase: 3000 m^3. Automated spraying is typically performed in production halls, greenhouses or animal housing. 3000 m^3 is thus seen as a realistic selection for this use.*
- *Application rate: 0.3-3 L/min: This is selected in accordance with Ad Hoc WG Recommendation 3 when using ART.*

Calculations for Scenario 4a, Spraying- Automated application with personal enclosure – application in all directions

Details on the calculations are provided in Annex 3.2

DERMAL

In the application of peracetic acid solutions for the disinfection of animal housing and greenhouses by spraying, dermal exposure is possible to 15% PAA and 25% HP during mixing/loading of the spraying equipment, especially when manual instead of automated mixing and loading is done. Moreover, during spraying exposure to 0.15% PAA and 0.75% HP solutions is possible. The concentrated product peracetic acid is known to be corrosive and the hydrogen peroxide solution (concentration of 25 %) is classified with ‘risk of serious damage to eyes`. Consequently, wearing of gloves and goggles during handling of the concentrated products is mandatory. Once the product is diluted, the dermal exposure is considerably lower. The operator is however not required to wear PPE during spraying as automated spraying takes place, (3) the operator is in a personal enclosure and as a result there is no direct contact with the diluted product.

INHALATION

Inhalation exposure cannot be excluded due to the volatile nature of the active ingredients PAA and HP. The inhalation exposures of the different tasks (mixing and loading and application) are calculated using ART. The inhalation exposure during post-application (rinsing of equipment) is considered negligible.

The highest concentration was found to be 2.2 mg/m^3 for PAA and 2.4 mg/m^3 for HP during mixing and loading of the concentrated product. Based on these exposure estimates, additional RPE is required to ensure that the exposure is reduced below the inhalation AEC’s set for PAA and HP. The use of RPE having an APF of 10 during mixing and loading of the concentrated product provides sufficient protection.

The details for calculation of inhalation exposure using ART are available in Annex 3.2. The summary of the results is presented here:

Peracetic acid:

Modelled – worst-case:

Task	Maximum PAA concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	15	2.2	No RPE
		0.22	RPE APF = 10
Application	0.15	2.1	No RPE
		0.21	RPE APF = 10
Post-application	0.0015	Not relevant	Not relevant

Hydrogen peroxide:

Task	Local dermal exposure Maximum concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	25	2.4	No RPE
		0.6	RPE APF = 4
Application	0.75	2.9	No RPE
		0.29	RPE APF = 10
Post-application	0.0075	Not relevant	Not relevant

***Scenario 4b**: Spraying - Automated or manual application without personal enclosure – application in all directions*

Scenario 4b covers the following uses :

PT2 - Use #1.5/4.5 "Disinfection by spraying in greenhouses (in absence of plants - for general hygiene purpose only) – spraying without personal enclosure"
PT3 - Use #1.11/4.11 "Disinfection of animal housing by low-pressure manual spraying – spraying without personal enclosure"
PT4 - Use #1.18/4.18 "Disinfection of surfaces and equipment by low pressure spraying – spraying without personal enclosure"

The biocidal products used for this scenario are:
- Sopuroxid 5
- Sopuroxid 15
- Oxypur CS

Description of Scenario 4b, Spraying - Automated or manual application without personal enclosure – application in all directions
The concentrated peracetic acid solution will be diluted to the recommended in-use concentrations prior to application of the product. The dilutions, i.e. "mixing/loading" of the concentrated solution will be done manually by pouring or automatically by pumping into the reservoir of the spraying equipment. The application of the disinfectant is done manually using the spraying equipment or automatically with the operator/worker not having a personal enclosure (not in a cabin). The spray is applied in all directions. After the disinfection procedure is completed, surfaces and equipment are rinsed with water and the water rinse drained into the sewer system.

In order to estimate worker/operator exposure during filling of the concentrate into the reservoir of the spraying equipment, the worst-case exposure is assumed, i.e. that of manual mixing and loading.

As the spraying activities occur in the presence of an operator/worker, exposure cannot be excluded.

During rinsing of the equipment and surfaces (post-application), the dermal exposure can be considered negligible due to the dilution with water.

Mixing and loading (M&L): Preparation of the disinfectant solution and filling of the spraying equipment

- Concentrated product corresponds to theoretical product 1:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	15	0.0536	0.48
HP	25	0.1996	0.93

- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 - 10 L/min
- Containment level: Handling that reduces contact between product and adjacent air
- Loading type: splash loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

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<u>Application</u>: Manual or automated spraying of surfaces

- Dilution 1:33 of theoretical product 1:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	0.15	0.00036	2.39
HP	0.75	0.00399	1.19

- Duration: 30 minutes
- Activity class: Surface spraying of liquids, moderate application rate (0.3-3 L/min)
- Spray direction: spraying in any directions, including upwards
- Spray technique: no or low compressed air use
- Room size: 3000 m3
- Ventilation rate: 1 ACH
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

<u>Post-application</u>: Rinsing of surfaces and disposal of empty containers

- After the disinfection procedure is completed, surfaces and equipment are rinsed with water after the desired contact time and the water rinse drained into the sewer system. During rinsing of treated surfaces with water, possible residues on treated surfaces are highly diluted with water; possible dermal exposure is therefore considered to be negligible and far below the exposure determined during application of the disinfection solution by foaming (assumed dilution by a factor of 100).
- Emptied containers are disposed after filling of spraying equipment. No exposure during disposal is assumed.

</td></tr>
<tr><td></td><td>Parameters[1]</td><td>Value</td></tr>
<tr><td rowspan="5">Tier 1</td><td>Content of active substance:
Mixing & loading undiluted product:
Application diluted product:
Post-application diluted product:</td><td>
15 % PAA, 25 % HP
0.15 % PAA, 0.75 % HP
0.0015 % PAA, 0.0075 % HP</td></tr>
<tr><td>Undiluted product</td><td>Theoretical product 2
Activity coefficient PAA: 0.48
Activity coefficient HP: 0.93</td></tr>
<tr><td>Dilution of the applied product (theoretical product):</td><td>33 (theoretical product 1)
Activity coefficient PAA: 2.39
Activity coefficient HP: 1.19</td></tr>
<tr><td>Inhalation exposure:

Dermal exposure:</td><td>Temperature: 20°C
Vapour pressure PAA: 1410 Pa
Vapour pressure HP: 214 Pa
/</td></tr>
<tr><td>Exposure duration:
Mixing & loading:
Application:
Post-application:</td><td>
15 min
30 min
not relevant</td></tr>
</table>

The activity coefficients were calculated using the AIOMFAC tool published by ETH, Zurich on http://www.aiomfac.caltech.edu/cgi_bin/model.pl. The attached excel (2017-02-13 Activity coefficients calculations) shows how the activity coefficients have been calculated based on the mole fraction of the different constituents for each theoretical product and the in-use applications. The print files of the modeled results are provided also.

Justification for the choice of parameters:

M&L:

- *A flow rate of 1-10 L/min during mixing and loading corresponds to the filling of bottles and paint guns, and is thus seen as an appropriate approximation.*
- *Room size for Mixing & loading: Any size workroom. Mixing and Loading could be done out of a "central" storage room with automatic pumping to the vessels or "decentralized" and manually. The selection of 'any size room' is seen as a relevant (and rather conservative) selection of room size.*

Application:

- *Room Size for Application phase: 3000 m^3. Automated spraying is typically performed in production halls, greenhouses and animal housing. 3000 m^3 is thus seen as an acceptable worst case for this approach.*
- *Application rate: 0.3-3 L/min: This is selected in accordance with Ad Hoc WG Recommendation 3 when using ART.*

Calculations for Scenario 4b – Automated or manual application without personal enclosure – application in all directions

Details on the calculations are provided in Annex 3.2

DERMAL

In the application of peracetic acid solutions for the disinfection of surfaces and equipment by spraying, dermal exposure is possible to 15% PAA and 25% HP during manual mixing/loading of the spraying equipment and 0.15 % PAA and 0.75 % HP during application. The concentrated product peracetic acid is known to be corrosive and the hydrogen peroxide solution (concentration of 25 %) is classified with 'risk of serious damage to eyes`. Consequently, wearing of gloves and goggles during handling of the concentrated products is mandatory. Once the product is diluted, the dermal exposure is considerably lower, but still above NOECdermal. Since dermal contact cannot be completely excluded, the operator is recommended to use PPE.

INHALATION

Inhalation exposure cannot be excluded due to the volatile nature of the active ingredients PAA and HP. The inhalation exposures of the different tasks (mixing and loading and application) are calculated using ART.

During the spraying activities, it is assumed that spraying is done in all directions with the spraying equipment. Moreover, it is supposed that the operator is present during the application without personal enclosure.

The highest concentration was found to be 16 mg/m^3 for PAA and 14 mg/m^3 for HP during application of the disinfectant. Based on these exposure estimates, additional RPE is required to ensure that the exposure is reduced below the inhalation AEC's set for PAA and HP. The use of RPE having an APF of 40 during the application of the disinfection foam provides sufficient protection.
During mixing and loading RPE with APF 10 offers sufficient protection.

The details for calculation of inhalation exposure using ART are available in Annex 3.2. The summary of the results is presented here:

<ins>*Peracetic acid:*</ins>

Modelled – worst-case:

Task	Maximum PAA concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	15	2.2	No RPE
		0.22	RPE APF = 10
Application	0.15	16	No RPE
		0.4	RPE APF = 40
Post-application	0.0015	Not relevant	Not relevant

Hydrogen peroxide:

Task	Local dermal exposure Maximum concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	25	2.4	No RPE
		0.6	RPE APF = 4
Application	0.75	14	No RPE
		0.35	RPE APF = 40
Post-application	0.0075	Not relevant	Not relevant

***Scenario 4c**: Spraying – Automated and manual application without personal enclosure – horizontal and downward application*

Scenario 4c covers the following uses :

PT2 - Use #1.7/4.7 "Disinfection of equipment and surfaces by spraying (e.g. agriculture & horticulture equipment - for general hygiene purpose only)"
PT4 - Use #1.19/4.19 " Disinfection of surfaces and equipment by low pressure spraying, manually"

The biocidal products used for this scenario are:
- Sopuroxid 5
- Sopuroxid 15
- Oxypur CS

Description of Scenario 4c, Spraying – Automated and manual application without personal enclosure –horizontal and downward application

The concentrated peracetic acid solution will be diluted to the recommended in-use concentrations prior to application of the product. The dilutions, i.e. "mixing/loading" of the concentrated solution will be done manually by pouring or automatically by pumping into the reservoir of the spraying equipment. The application of the disinfectant is done manually using the spraying equipment, but can also be automated. The disinfectants is only applied downwards and in horizontal direction. After the disinfection procedure is completed, equipment is rinsed with water and the water rinse drained into the sewer system.

In order to estimate worker/operator exposure during filling of the concentrate into the reservoir of the spraying equipment, the worst-case exposure is assumed, i.e. that of manual mixing and loading.

As the spraying activities occur in the presence of an operator/worker, exposure cannot be excluded.

During rinsing of the equipment and surfaces (post-application), the dermal exposure can be considered negligible due to the dilution with water.

Mixing and loading (M&L): Preparation of the solution and filling of the spraying equipment

- Concentrated product corresponds to theoretical product 2:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	15	0.0536	0.48
HP	25	0.1996	0.93

- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 - 10 L/min
- Containment level: Handling that reduces contact between product and adjacent air
- Loading type: splash loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

Application: Manual spraying of equipment

- Dilution 1:50 of theoretical product 2:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	0.1	0.00024	2.42
HP	0.5	0.00266	1.20

- Duration: 30 minutes
- Activity class: Surface spraying of liquids, moderate application rate (0.3-3 L/min)
- Spray direction: Only horizontal and downward spraying
- Spray technique: no or low compressed air use
- Room size: 300 m^3
- Ventilation rate: 1 ACH
- Primary risk management measures: no localized controls, no secondary localized controls
- Emissions Sources: Near field

Post-application: Rinsing of surfaces and disposal of empty containers

- After the disinfection procedure is completed, surfaces and equipment are rinsed with water after the required contact time and the water rinse drained into the sewer system. During rinsing of treated surfaces with water, possible residues on treated surfaces are highly diluted with water; possible dermal exposure is therefore considered to be negligible and far below the exposure determined during application of the disinfection solution by spraying (assumed dilution by a factor of 100).
- Emptied containers are disposed after filling of spraying equipment. No exposure during disposal is assumed.

	Parameters[1]	Value
Tier 1	Content of active substance: Mixing & loading undiluted product: Application diluted product: Post-application diluted product:	 15 % PAA, 25 % HP 0.1 % PAA, 0.5 % HP 0.001 % PAA, 0.005 % HP
	Undiluted product	Theoretical product 2 Activity coefficient PAA: 0.48 Activity coefficient HP: 0.93
	Dilution of the applied product (theoretical product):	50 (theoretical product 2) Activity coefficient PAA: 2.42 Activity coefficient HP: 1.20
	Inhalation exposure: Dermal exposure:	Temperature: 20°C Vapour pressure PAA: 1410 Pa Vapour pressure HP: 214 Pa /
	Exposure duration: Mixing & loading: Application: Post-application:	 15 min 30 min not relevant

The activity coefficients were calculated using the AIOMFAC tool published by ETH, Zurich on http://www.aiomfac.caltech.edu/cgi_bin/model.pl. The attached excel (2017-02-13 Activity coefficients calculations) shows how the activity coefficients have been calculated based on the mole fraction of the different constituents for each theoretical product and the in-use applications. The print files of the modeled results are provided also.

Justification for the choice of parameters:

- *A flow rate of 1-10 L/min during mixing and loading does correspond to the filling of bottles and paint guns, and is thus seen as an appropriate approximation*
- *Room size for Mixing & loading: Any size workroom. Mixing and Loading could be done out of a "central" storage room with automatic pumping to the vessels or "decentralized". But nearly in most cases the mixing and loading is done in an automated way. The selection of 'any size room' is seen as a relevant (and rather conservative) selection of room size.*
- *Room Size for Application phase: 300 m^3. No automated spraying, which typically implies smaller surfaces (and thus smaller volumes). As no agreed values exist for this kind of installation, a decrease in volume of a factor 10 was deemed sufficiently worst case. 300 m^3 is thus seen as an acceptable worst case for this approach.*
- *Application rate: 0.3-3 L/min: This is selected in accordance with Ad Hoc WG Recommendation 3 when using ART.*

Calculations for Scenario 4c, Spraying – Automated or manual application without personal enclosure –horizontal and downward application
Details on the calculations are provided in Annex 3.2

DERMAL
In the application of peracetic acid solutions for the disinfection of surfaces and equipment by spraying, dermal exposure is possible to 15% PAA and 25% HP during manual mixing/loading of the spraying equipment and 0.1 % PAA and 0.5 % HP during application. The concentrated product peracetic acid is known to be corrosive and the hydrogen peroxide solution (concentration of 25 %) is classified with 'risk of serious damage to eyes`. Consequently, wearing of gloves and goggles during handling of the concentrated products is mandatory. Once the product is diluted, the dermal exposure is considerably lower(≤ $NOEC_{dermal}$ for PAA). Therefore, the operator is not required to use PPE.

INHALATION
Inhalation exposure cannot be excluded due to the volatile nature of the active ingredients PAA and HP. The inhalation exposures of the different tasks (mixing and loading and application) are calculated using ART.

During the spraying activities, it is assumed that spraying is only applied in downwards or horizontal direction. Moreover, it is supposed that the operator is present during the application without personal enclosure.

The highest concentration was found to be 8.5 mg/m^3 for PAA and 7.2 mg/m^3 for HP during application of the disinfectants. Based on these exposure estimates, additional RPE is required to ensure that the exposure is reduced below the inhalation AEC's set for PAA and HP. The use of RPE having an APF of 40 during the application of the diluted product provides sufficient protection. During mixing and loading RPE with APF 10 offers sufficient protection.

The details for calculation of inhalation exposure using ART are available in Annex 3.2. The summary of the results is presented here:

Peracetic acid:

Task	Maximum PAA concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	15	2.2	No RPE
		0.22	RPE APF = 10
Application	0.10	8.5	No RPE
		0.425	RPE APF = 20
Post-application	0.0010	Not relevant	Not relevant

Hydrogen peroxide:

Task	Maximum HP concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	25	2.4	No RPE
		0.6	RPE APF = 4
Application	0.5	7.2	No RPE
		0.36	RPE APF = 20
Post-application	0.005	Not relevant	Not relevant

***Scenario 4d**: Spraying - Automated application with personal enclosure – horizontal and downward application*

Scenario 4d covers the following uses :

PT2 - Use #1.8/4.8 "Disinfection of equipment and surfaces by spraying (e.g. agriculture & horticulture – for general hygiene purpose only) – automatically"
PT4 - Use #1.20/4.20 "Disinfection of surfaces and equipment by low pressure spraying, automatically"

The biocidal products used for this scenario are:

- Sopuroxid 5
- Sopuroxid 15
- Oxypur CS

Description of Scenario 4d, Spraying - Automated application with personal enclosure – horizontal and downward application

The concentrated peracetic acid solution will be diluted to the recommended in-use concentrations prior to application of the product. The dilutions, i.e. "mixing/loading" of the concentrated solution will be done manually by pouring or automatically by pumping into the reservoir of the spraying equipment. The application of the disinfectant is done automatically using a fixed spraying installation (e.g. spraying on conveyor belt). The disinfectants is only applied downwards and in horizontal direction. After the disinfection procedure is completed, equipment is rinsed with water and the water rinse drained into the sewer system.

In order to estimate worker/operator exposure during filling of the concentrate into the reservoir of the spraying equipment, the worst-case exposure is assumed, i.e. that of manual mixing and loading.

During the spraying activities the operator/worker oversees the activities from a control room. It is as worst-case assumed that this personal enclosure is not actively ventilated.
With regard to the description of the scenario. It is to be noted that there is no actual containment of the source. We decided to select the conservative approach and evaluate exposure as near field. Within near field there is not the option to indicate that the operator is often in a control room separated from the area, hence the option for medium containment.
The spraying activity in general takes place in a fully automated way. Only horizontal or downwards spraying is applicable here. The operator will typically initiate the process from his control area. However, this control area is not necessarily a fully separated room with independent ventilation.

During rinsing of the equipment and surfaces (post-application), the dermal exposure can be considered negligible due to the dilution with water.

Mixing and loading (M&L): Preparation of the solution and filling of the spraying equipment

- Concentrated product corresponds to theoretical product 1:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	15	0.0536	0.48
HP	25	0.1996	0.93

- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 - 10 L/min
- Containment level: Handling that reduces contact between product and adjacent air
- Loading type: splash loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

Application: Automated spraying of equipment

- Dilution 1:50 of theoretical product 2:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	0.1	0.00024	2.42
HP	0.5	0.00266	1.20

- Duration: 30 minutes
- Activity class: Surface spraying of liquids, moderate application rate (0.3-3 L/min)
- Spray direction: Only horizontal and downward spraying
- Spray technique: no or low compressed air use
- Room size: 300 m^3
- Ventilation rate: 1 ACH
- Primary and secondary risk management measures: No primary or secondary localized controls
- Emissions Sources: Near field

Description of Scenario 4d, Spraying - Automated application with personal enclosure – horizontal and downward application
The concentrated peracetic acid solution will be diluted to the recommended in-use concentrations prior to application of the product. The dilutions, i.e. "mixing/loading" of the concentrated solution will be done manually by pouring or automatically by pumping into the reservoir of the spraying equipment. The application of the disinfectant is done automatically using a fixed spraying installation (e.g. spraying on conveyor belt). The disinfectants is only applied downwards and in horizontal direction. After the disinfection procedure is completed, equipment is rinsed with water and the water rinse drained into the sewer system. In order to estimate worker/operator exposure during filling of the concentrate into the reservoir of the spraying equipment, the worst-case exposure is assumed, i.e. that of manual mixing and loading. During the spraying activities the operator/worker oversees the activities from a control room. It is as worst-case assumed that this personal enclosure is not actively ventilated. With regard to the description of the scenario. It is to be noted that there is no actual containment of the source. We decided to select the conservative approach and evaluate exposure as near field. Within near field there is not the option to indicate that the operator is often in a control room separated from the area, hence the option for medium containment. The spraying activity in general takes place in a fully automated way. Only horizontal or downwards spraying is applicable here. The operator will typically initiate the process from his control area. However, this control area is not necessarily a fully separated room with independent ventilation. During rinsing of the equipment and surfaces (post-application), the dermal exposure can be considered negligible due to the dilution with water. <u>Mixing and loading (M&L)</u>: Preparation of the solution and filling of the spraying equipment • Concentrated product corresponds to theoretical product 1: Ingredient / Concentration (%) / Mole fraction / Activity coefficient PAA / 15 / 0.0536 / 0.48 HP / 25 / 0.1996 / 0.93 • Duration: 15 minutes • Activity class: falling liquids • Flow rate: 1 - 10 L/min • Containment level: Handling that reduces contact between product and adjacent air • Loading type: splash loading • Room size: Any size workroom • Ventilation rate: only good natural ventilation • Primary and secondary risk management measures: No localized controls • Emissions Sources: Near field
<u>Post-application</u>: Rinsing of surfaces and disposal of empty containers • After the disinfection procedure is completed, surfaces and equipment are rinsed with water after the required contact time and the water rinse drained into the sewer system. During rinsing of treated surfaces with water, possible residues on treated surfaces are highly diluted with water; possible dermal exposure is therefore considered to be negligible and far below the exposure determined during application of the disinfection solution by spraying (assumed dilution by a factor of 100). • Emptied containers are disposed after filling of spraying equipment. No exposure during disposal is assumed.

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	15	0.0536	0.48
HP	25	0.1996	0.93

	Parameters[1]	Value

Tier 1	Content of active substance: Mixing & loading undiluted product: Application diluted product: Post-application diluted product:	 15 % PAA, 25 % HP 0.1 % PAA, 0.5 % HP 0.001 % PAA, 0.005 % HP
	Undiluted product	Theoretical product 2 Activity coefficient PAA: 0.48 Activity coefficient HP: 0.93
	Dilution of the applied product (theoretical product):	50 (theoretical product 1) Activity coefficient PAA: 2.42 Activity coefficient HP: 1.20
	Inhalation exposure: Dermal exposure:	Temperature: 20°C Vapour pressure PAA: 1410 Pa Vapour pressure HP: 214 Pa /
	Exposure duration: Mixing & loading: Application: Post-application:	 15 min 30 min not relevant

The activity coefficients were calculated using the AIOMFAC tool published by ETH, Zurich on http://www.aiomfac.caltech.edu/cgi_bin/model.pl. The attached excel (2017-02-13 Activity coefficients calculations, see Annex) shows how the activity coefficients have been calculated based on the mole fraction of the different constituents for each theoretical product and the in-use applications. The print files of the modeled results are provided also.

Justification for the choice of parameters:

M&L:

- *A flow rate of 1-10 L/min during mixing and loading does correspond to the filling of bottles and paint guns, and is thus seen as an appropriate approximation*
- *Room size for Mixing & loading: Any size workroom. Mixing and Loading could be done out of a "central" storage room with automatic pumping to the CIP vessels or "decentralized", but nearly in most cases the mixing and loading is done in an automated way. The selection of 'any size room' is seen as a relevant (and rather conservative) selection of room size.*

Application:

- *Room Size for Application phase: 300 m^3. Despite automated spraying, which typically implies higher surfaces (and thus smaller volumes), the volume from scenario 4C was kept, as it implies a worst case situation.*
- *Application rate: 0.3-3 L/min: This is selected in accordance with Ad Hoc WG Recommendation 3 when using ART.*

Calculations for Scenario 4d, Spraying - Automated application with personal enclosure –horizontal and downward application

Details on the calculations are provided in Annex 3.2

DERMAL

In the application of peracetic acid solutions for the disinfection of surfaces and equipment by spraying dermal exposure is possible to 15% PAA and 25% HP during manual mixing/loading of the spraying equipment and 0.5 % PAA and 0.5 % HP during application. The concentrated product peracetic acid is known to be corrosive and the hydrogen peroxide solution (concentration of 25 %) is classified with 'risk of serious damage to eyes`. Consequently, wearing of gloves and goggles during handling of the concentrated products is mandatory. Once the product is diluted, the dermal exposure is considerably lower (≤ $NOEC_{dermal}$ of PAA). The operator is not recommended to use PPE since (1) the recommended in-use concentration of PAA is below the threshold and (2) the operator oversees the spraying activity from a control room (personal enclosure) and there is no dermal exposure to the substance.

INHALATION
Inhalation exposure cannot be excluded due to the volatile nature of the active ingredients PAA and HP. The inhalation exposures of the different tasks (mixing and loading and application) are calculated using ART.

During the spraying activities, it is assumed that spraying is only applied in downwards or horizontal direction. There is an operator overseeing the spraying activities from a control room without active ventilation.

The highest concentration was found to be 2.2 mg/m^3 for PAA and 2.4 mg/m^3 for HP during mixing and loading of the concentrated product. Based on these exposure estimates, additional RPE is required to ensure that the exposure is reduced below the inhalation AEC's set for PAA and HP. The use of RPE having an APF of 10 during the handling of the concentrated product provides sufficient protection. During the spraying activities, the operator does not need wear RPE on the condition that he stays in the control room and does not open windows or doors as long as the activity is on-going.

The details for calculation of inhalation exposure using ART are available in Annex 3.2. The summary of the results is presented here:

<u>*Peracetic acid:*</u>

Task	Maximum PAA concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	15	2.2	No RPE
		0.22	RPE APF = 10
Application	0.15	0.086	Not relevant
		not relevant	Not relevant
Post-application	0.0015	Not relevant	Not relevant

<u>*Hydrogen peroxide:*</u>

Task	Maximum HP concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	25	2.4	No RPE
		0.6	RPE APF = 4
Application	0.5	0.071	No RPE
Post-application	0.005	Not relevant	Not relevant

***Scenario 4e**: Spraying - Fully automated application not requiring the presence of operator*

Scenario 4e covers the following uses :

PT2 - Use #1.9/4.9 "Disinfection of equipment and surfaces by spraying (e.g. agriculture & horticulture – for general hygiene purpose only) – automatic spraying (closed room)"
PT4 - Use #1.14/4.14 "Automated spraying closed systems (aseptic filling and sterilization of crown corks, cheese moulds and food crates in the food and beverage industry) – automatic spraying (closed room)" and Use #1.21/4.21 "Disinfection of surfaces and equipment by low pressure spraying – automatic spraying (closed room)"

The biocidal products used for this scenario are:

- Sopuroxid 5
- Sopuroxid 15
- Oxypur CS

Description of Scenario 4e, Spraying - Fully automated application not requiring the presence of operator

The concentrated peracetic acid solution will be diluted to the recommended in-use concentrations prior to application of the product. The dilutions, i.e. "mixing/loading" of the concentrated solution will be done manually by pouring or automatically by pumping into the reservoir of the spraying equipment. The application of the disinfectant is done automatically using a fixed spraying installation in a closed room. The application of the disinfectants does not require the presence of an operator/worker. After the disinfection procedure is completed, equipment is rinsed with water and the water rinse drained into the sewer system.

In order to estimate worker/operator exposure during filling of the concentrate into the reservoir of the spraying equipment, the worst-case exposure is assumed, i.e. that of manual mixing and loading.

During the spraying activities the operator/worker is not present, hence, the exposure is considered not relevant.

During rinsing of the equipment and surfaces (post-application), the dermal exposure can be considered negligible due to the dilution with water.

Mixing and loading (M&L): Preparation of the spraying solution and filling of the spraying equipment

- Concentrated product corresponds to theoretical product 2:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	15	0.0536	0.48
HP	25	0.1996	0.93

- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 - 10 L/min
- Containment level: Handling that reduces contact between product and adjacent air
- Loading type: splash loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

Application: Automated spraying of equipment

- The application is done in a closed room, for example storage room and the presence of an operator is not required. No exposure during application is assumed.

Post-application: Rinsing of surfaces and disposal of empty containers

- After the disinfection procedure is completed, surfaces and equipment are rinsed with water after the required contact time and the water rinse drained into the sewer system. During rinsing of treated surfaces with water, possible residues on treated surfaces are highly diluted with water; possible dermal exposure is therefore considered to be negligible and far below the exposure determined during application of the disinfection solution by spraying (assumed dilution by a factor of 100).
- Emptied containers are disposed after filling of spraying equipment. No exposure during disposal is assumed.

	Parameters[1]	Value
Tier 1	Content of active substance: Mixing & loading undiluted product: Application diluted product: Post-application diluted product:	 15 % PAA, 25 % HP 0.15 % PAA, 0.75 % HP 0.0015 % PAA, 0.0075 % HP

	Undiluted product	Theoretical product 2 Activity coefficient PAA: 0.48 Activity coefficient HP: 0.93
	Dilution of the applied product (theoretical product):	50 (theoretical product 1) Activity coefficient PAA: 2.42 Activity coefficient HP: 1.20
	Inhalation exposure: Dermal exposure:	Temperature: 20°C Vapour pressure PAA: 1410 Pa Vapour pressure HP: 214 Pa /
	Exposure duration: Mixing & loading: Application: Post-application:	 15 min not relevant not relevant

The activity coefficients were calculated using the AIOMFAC tool published by ETH, Zurich on http://www.aiomfac.caltech.edu/cgi_bin/model.pl. The attached excel (2017-02-13 Activity coefficients calculations, see Annex) shows how the activity coefficients have been calculated based on the mole fraction of the different constituents for each theoretical product and the in-use applications. The print files of the modeled results are provided also.

Justification for the choice of parameters:

M&L:

- *A flow rate of 1-10 L/min for mixing and loading does correspond to the filling of bottles and paint guns, and is thus seen as an appropriate approximation*
- *Room size for Mixing & loading: Any size workroom. Mixing and Loading could be done out of a "central" storage room with automatic pumping to the vessels or "decentralized", but nearly in nearly all cases the mixing and loading is done in an automated way. The selection of 'any size room' is seen as a relevant (and rather conservative) selection of room size.*

Calculations for Scenario 4e, Spraying - Fully automated application not requiring the presence of operator

Details on the calculations are provided in Annex 3.2

DERMAL

In the application of peracetic acid solutions for the disinfection of surfaces and equipment by spraying, dermal exposure is possible to 15% PAA and 25% HP during manual mixing/loading of the spraying equipment and 0.15 % PAA and 0.75 % HP during application. The concentrated product peracetic acid is known to be corrosive and the hydrogen peroxide solution (concentration of 25 %) is classified with 'risk of serious damage to eyes`. Consequently, wearing of gloves and goggles during handling of the concentrated products is mandatory. Once the product is diluted, the dermal exposure is considerably lower, but above the $NOEC_{dermal}$ threshold for PAA. Since the presence of the operator is not required during the application, no PPE have to be prescribed.

INHALATION

Inhalation exposure cannot be excluded due to the volatile nature of the active ingredients PAA and HP. The inhalation exposures of mixing and loading of the concentrated product are calculated using ART.

The highest concentration was found to be 2.2 mg/m^3 for PAA and 2.4 mg/m^3 for HP during mixing and loading of the concentrated product. Based on these exposure estimates, additional RPE is required to ensure that the exposure is reduced below the inhalation AEC's set for PAA and HP. The use of RPE having an APF of 10 during the mixing and loading provides sufficient protection.

The details for calculation of inhalation exposure using ART are available in Annex 3.2. The summary of the results is presented here:

Peracetic acid:

Task	Maximum PAA concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	15	2.2	No RPE
		0.22	RPE APF = 10
Application	0.15	Not relevant	Not relevant
		Not relevant	Not relevant
Post-application	0.0015	Not relevant	Not relevant

Hydrogen peroxide:

Task	Maximum HP concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	25	2.4	No RPE
		0.6	RPE APF = 4
Application	0.75	Not relevant	Not relevant
Post-application	0.0075	Not relevant	Not relevant

***Scenario 4f:** Spraying - Manual application without personal enclosure – downward application – low application rate*

Scenario 4f covers the following uses :

PT2 - Use #1.2/4.2 "Disinfection of surfaces in industrial, public and health care areas - manual treatment (spraying)"

The biocidal products used for this scenario are:

- Sopuroxid 5
- Sopuroxid 15
- Oxypur CS

Description of Scenario 4f, Spraying - Manual application without personal enclosure – downward application – low application rate

The concentrated peracetic acid solution will be diluted to the recommended in-use concentrations prior to application of the product. The dilutions, i.e. "mixing/loading" of the concentrated solution will be done manually by pouring into the reservoir of the spraying equipment (typically small volume containers e.g. spraying cans). The application of the disinfectant is done manually using the spraying equipment. The disinfectant is only applied downwards. After the disinfection procedure is completed, equipment is rinsed with water and the water rinse drained into the sewer system.

As the spraying activities occur in the presence of a professional, exposure during application cannot be excluded.

During rinsing of the equipment and surfaces (post-application), the dermal exposure can be considered negligible due to the dilution with water.

Mixing and loading (M&L): Preparation of the spraying solution and filling of the spraying equipment

- Concentrated product corresponds to theoretical product 2:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	15	0.0536	0.48
HP	25	0.1996	0.93

- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 - 10 L/min
- Containment level: Handling that reduces contact between product and adjacent air
- Loading type: splash loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

Application: Manual spraying of equipment

- Dilution 1:50 of theoretical product 2:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	0.1	0.00024	2.42
HP	0.5	0.00266	1.20

- Duration: 30 minutes
- Activity class: Surface spraying of liquids, low application rate (0.03-0.3 L/min)
- Spray direction: Only downward spraying
- Spray technique: no or low compressed air use
- Room size: 100 m^3
- Ventilation rate: 1 ACH
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

Post-application: Rinsing of surfaces and disposal of empty containers

- After the disinfection procedure is completed, surfaces and equipment are rinsed with water after the desired contact time and the water rinse drained into the sewer system. During rinsing of treated surfaces with water, possible residues on treated surfaces are highly diluted with water; possible dermal exposure is therefore considered to be negligible and far below the exposure determined during application of the disinfection solution by foaming (assumed dilution by a factor of 100).
- Emptied containers are disposed after filling of spraying equipment. No exposure during disposal is assumed.

	Parameters[1]	Value

Tier 1	Content of active substance: Mixing & loading undiluted product: Application diluted product: Post-application diluted product:	15 % PAA, 25 % HP 0.1 % PAA, 0.5 % HP 0.001 % PAA, 0.005 % HP
	Undiluted product	Theoretical product 2 Activity coefficient PAA: 0.48 Activity coefficient HP: 0.93
	Dilution of the applied product (theoretical product):	50 (theoretical product 2) Activity coefficient PAA: 2.42 Activity coefficient HP: 1.20
	Inhalation exposure: Dermal exposure:	Temperature: 20°C Vapour pressure PAA: 1410 Pa Vapour pressure HP: 214 Pa /
	Exposure duration: Mixing & loading: Application: Post-application:	 15 min 30 min not relevant

The activity coefficients were calculated using the AIOMFAC tool published by ETH, Zurich on http://www.aiomfac.caltech.edu/cgi_bin/model.pl. The attached excel (2017-02-13 Activity coefficients calculations, see Annex) shows how the activity coefficients have been calculated based on the mole fraction of the different constituents for each theoretical product and the in-use applications. The print files of the modeled results are provided also.

Justification for the choice of parameters:

M&L:

- *A flow rate of 1-10 L/min for mixing and loading does correspond to the filling of bottles and paint guns, and is thus seen as an appropriate approximation*
- *Room size for Mixing & loading: Any size workroom. Mixing and Loading could be done out of a "central" storage room with automatic pumping to the vessels or "decentralized", but nearly in most cases the mixing and loading is done in an automated way. The selection of 'any size room' is seen as a relevant (and rather conservative) selection of room size.*

Application:

- *Room Size for Application phase: 100 m^3. As the application step is manual, this concerns mainly smaller surfaces. As a smaller volume does present here in this case a worst case situation, a total room volume of 100 m^3 is seen as being acceptable.*
- *Application rate: 0.03-0.3 L/min: This application rate is below the advised application rate as per Ad Hoc WG Recommendation 3 when using ART, however this is seen as a realistic assumption as it relates to a manual application with a low application rate (use of spraying can).*

Calculations for Scenario 4f, Manual application without personal enclosure – downward application – low application rate

Details on the calculations are provided in Annex 3.2

DERMAL

In the application of peracetic acid solutions for the disinfection of surfaces and equipment by spraying, dermal exposure is possible to 15% PAA and 25% HP during manual mixing/loading of the spraying equipment and 0.1 % PAA and 0.5 % HP during application. The concentrated product peracetic acid is known to be corrosive and the hydrogen peroxide solution (concentration of 25 %) is classified with 'risk of serious damage to eyes`. Consequently, wearing of gloves and goggles during handling of the concentrated products is mandatory. Once the product is diluted to the recommended in-use concentration, the dermal exposure is considerably lower, (i.e. ≤ $NOEC_{dermal}$ of PAA). Consequently there is no recommendation to wear PPE during application.

INHALATION

Inhalation exposure cannot be excluded due to the volatile nature of the active ingredients PAA and HP. The inhalation exposures of the different tasks (mixing and loading and application) are calculated using ART.

During the spraying activities, it is assumed that spraying is only applied in downwards direction. Moreover, it is supposed that the operator is present during the application without personal enclosure.

The highest concentration was found to be 1.8 mg/m^3 for PAA and 1.5 mg/m^3 for HP during application of the disinfectants. Based on these exposure estimates, additional RPE is required to ensure that the exposure is reduced below the inhalation AEC's set for PAA and HP.

The use of RPE having an APF of 10 during the mixing and loading of the spraying equipment and 40 during the application of the disinfection spray provides sufficient protection.

The details for calculation of inhalation exposure using ART are available in Annex 3.2. The summary of the results is presented here:

Peracetic acid:

Task	Maximum PAA concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	15	2.2	No RPE
		0.22	RPE APF = 10
Application	0.15	1.8	No RPE
		0.45	RPE APF =4
Post-application	0.0015	Not relevant	Not relevant

Hydrogen peroxide:

Task	Maximum HP concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	25	2.4	No RPE
		0.6	RPE APF = 4
Application	0.5	1.5	No RPE
		0.375	RPE APF = 4
Post-application	0.005	Not relevant	Not relevant

***Scenario 5**: Soaking*

Scenario 5 covers the following uses :

PT2 - Use #1.6/4.6 "Disinfection of equipment by soaking (for agriculture & horticulture equipment – for general hygiene purpose only)"
PT3 - Use #1.12/4.12 "Disinfection of boots in footbaths in animal housing /husbandries" and Use #1.13/4.13 "Disinfection of equipment by dipping"
PT4 - Use #1.15/4.15 "Disinfection of equipment in the food and beverage industry by immersion"

The biocidal products used for this scenario are:

- Sopuroxid 5
- Sopuroxid 15
- Oxypur CS

Description of Scenario 5, Soaking

During these tasks, the operating person will prepare a disinfection solution by diluting the concentrated peracetic acid solution to the in-use concentrations prior to application of the product. The dilutions, i.e. "mixing/loading" of the concentrated solution will be done manually by pouring or pumping the concentrated product into vessels. The equipment will be dipped in the disinfection solution. After completion of the disinfection procedure, the equipment will be removed, rinsed with water and the bath drained off. Exposure of the worker/operator will occur during the mixing and loading, placing and removal of equipment into/from the vessels and draining of the disinfection solutions.

In order to estimate worker/operator exposure during filling of the concentrate into the reservoir of the sprayer, the worst-case exposure is assumed, i.e. that of manual mixing and loading.

During application and post-application, the worker can be exposed to the disinfection solution when placing equipment in the bath and when removing the equipment after disinfection and when draining the disinfection solutions needs to be considered.

Mixing and loading (M&L): Preparation of the disinfection solution

- Concentrated product corresponds to theoretical product 2:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	15	0.0536	0.48
HP	25	0.1996	0.93

- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 - 10 L/min
- Containment level: Handling that reduces contact between product and adjacent air
- Loading type: splash loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

<table>
<tr><td colspan="3">
<u>Application:</u> Placing of equipment into disinfection solution

Dilution 1:200 of theoretical product 1:
<table>
<tr><th>Ingredient</th><th>Concentration (%)</th><th>Mole fraction</th><th>Activity coefficient</th></tr>
<tr><td>PAA</td><td>0.025</td><td>0.00006</td><td>2.46</td></tr>
<tr><td>HP</td><td>0.125</td><td>0.00067</td><td>1.20</td></tr>
</table>
Duration: 5 minutes
Activity class: Activities with open, relatively undisturbed surfaces, > 3 m^2
Work area: Indoors
Room size: 100 m^3
Ventilation rate: 1 ACH
Primary and secondary risk management measures. No localized controls
Emissions Sources: Near field

<u>Post-application:</u> Removal/rinsing of equipment and draining of disinfection solution

After disinfection is completed, equipment is taken out of the bath, rinsed with water and the bath disposed of. During these removal and pouring procedures, a potential exposure does exist. The exposure during post-application is considered to be identical to the exposure during application.
During rinsing of equipment with water, possible residues on equipment are highly diluted with water; exposure is therefore considered to be negligible and far below the exposure determined during placing and removal of equipment into or from disinfection solutions
Emptied containers are disposed after pouring them into baths/vessels. No exposure during disposal is assumed.

</td></tr>
<tr><td></td><td>Parameters[1]</td><td>Value</td></tr>
<tr><td rowspan="5">Tier 1</td><td>Content of active substance:
Mixing & loading undiluted product:
Application diluted product:
Post-application diluted product:</td><td>15 % PAA, 25 % HP
0.064 % PAA, 0.32 % HP
0.064 % PAA, 0.32 % HP</td></tr>
<tr><td>Undiluted product</td><td>Theoretical product 2
Activity coefficient PAA: 0.48
Activity coefficient HP: 0.93</td></tr>
<tr><td>Dilution of the applied product (theoretical product):</td><td>200 (theoretical product 1)
Activity coefficient PAA: 2.46
Activity coefficient HP: 1.20</td></tr>
<tr><td>Inhalation exposure:

Dermal exposure:</td><td>Temperature: 20°C
Vapour pressure PAA: 1410 Pa
Vapour pressure HP: 214 Pa
/</td></tr>
<tr><td>Exposure duration:
Mixing & loading:
Application:
Post-application:</td><td>
15 min
5 min
5 min</td></tr>
</table>

The activity coefficients were calculated using the AIOMFAC tool published by ETH, Zurich on http://www.aiomfac.caltech.edu/cgi_bin/model.pl. The attached excel (2017-02-13 Activity coefficients calculations, see Annex) shows how the activity coefficients have been calculated based on the mole fraction of the different constituents for each theoretical product and the in-use applications. The print files of the modeled results are provided also.

Justification for the choice of parameters:

M&L:

- *A flow rate of 1-10 L/min for mixing and loading corresponds to the filling of bottles and paint guns, and is thus seen as an appropriate approximation.*
- *Room size for Mixing & loading: Any size workroom. Mixing and Loading could be done out of a "central" storage room with automatic pumping to the CIP vessels or "decentralized", but nearly in most cases the mixing and loading is done in an automated way. The selection of 'any size room' is seen as a relevant (and rather conservative) selection of room size.*

Application:

- *Room Size for Application phase: 100 m^3. The room size was determined on base of an expert judgment call due to the lack of available agreed upon tables with data on surface and room volume. Given the amount of surfaces usually involved, 100m^3 is a reasonable worst case. As a smaller volume does present here in this case a worst case situation, a total room volume of 100 m^3 is seen as being acceptable.*

Calculations for Scenario 5, Soaking

Details on the calculations are provided in Annex 3.2

DERMAL

In the application of peracetic acid solutions for the disinfection of surfaces and equipment by soaking, dermal exposure is possible to 15% PAA and 25% HP during manual mixing/loading into the soaking bath and 0.025 % PAA and 0.125 % HP during application and post-application. The concentrated product peracetic acid is known to be corrosive and the hydrogen peroxide solution (concentration of 25 %) is classified with 'risk of serious damage to eyes`. Consequently, wearing of gloves and goggles during handling of the concentrated products is mandatory. Once the product is diluted, the dermal exposure is considerably lower (< $NOEC_{dermal}$ for PAA) . As the operator could still be exposed to the diluted solution, we recommend the use of PPE.

INHALATION

Inhalation exposure cannot be excluded due to the volatile nature of the active ingredients PAA and HP. The inhalation exposures of the different tasks (mixing and loading, application and post-application) are calculated using ART.

It is assumed that the exposure during application and post-application is similar.

The highest concentration was found to be 1.5 mg/m^3 for PAA and 1.2 mg/m^3 for HP during application and post-application. Based on these exposure estimates, additional RPE is required to ensure that the exposure is reduced below the inhalation AEC's set for PAA and HP. The use of RPE having an APF of 10 during the mixing and loading and 4 during the application and post-application of the disinfection solution provide sufficient protection.

The details for calculation of inhalation exposure using ART are available in Annex 3.2. The summary of the results is presented here:

<u>*Peracetic acid:*</u>

Task	Local dermal exposure	Local inhalation exposure (mg/m^3)
		ART

Mixing/loading	15	2.2	No RPE
		0.22	RPE APF = 10
Application	0.15	3.9	No RPE
		0.39	RPE APF = 10
Post-application	0.0015	3.9	No RPE
		0.39	RPE APF = 10

Hydrogen peroxide:

Task	Local dermal exposure Maximum concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	25	2.4	No RPE
		0.6	RPE APF = 4
Application	0.125	3.2	No RPE
		0.32	RPE APF = 10
Post-application	0.125	3.2	No RPE
		0.32	RPE APF = 10

***Scenario 6a**: Foaming - Automated application with personal enclosure – application in all directions*

Scenario 6a covers the following uses :

PT3 - Use #3.5 "Disinfection of animal housing by foaming – foaming with personal enclosure"
PT4 - Use #3.7 "Disinfection of surfaces by foaming with personal enclosure"

The biocidal products used for this scenario are:

- Acidofoam CF

Description of Scenario 6a, Foaming - Automated application with personal enclosure – application in all directions

The concentrated peracetic acid solution will be diluted to the recommended in-use concentrations prior to application of the product. The dilutions, i.e. "mixing/loading" of the concentrated solution will be done manually by pouring or automatically by pumping into the reservoir of the foaming equipment. The application of the disinfectant is done automatically with the foaming equipment. The worker or operator is present but in a cabin. Foam is applied in all directions. For example: a tractor with foaming equipment and operator seated in a closed cabin. After the disinfection procedure is completed, surfaces and equipment are rinsed with water and the water rinse drained into the sewer system.

In order to estimate worker/operator exposure during filling of the concentrate into the reservoir of the foaming equipment, the worst-case exposure is assumed, i.e. that of manual mixing and loading.

As the foaming activities occur in the presence of an operator/worker, exposure cannot be excluded. However, the operator is present in a cabin, which is not actively ventilated. It is assumed that this personal enclosure is not opened during the activity.

During rinsing of the equipment and surfaces (post-application), the dermal exposure can be considered negligible due to the dilution with water.

Mixing and loading (M&L): Preparation of the foaming solution and filling of the foaming equipment

- Concentrated product corresponds to theoretical product 1:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	5	0.0149	0.70
HP	25	0.1664	1.07

- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 - 10 L/min
- Containment level: Handling that reduces contact between product and adjacent air
- Loading type: splash loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

<u>Application:</u> Automated foaming of surfaces

- Dilution 1:33 of theoretical product 1:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	0.15	0.00036	2.39
HP	0.755	0.00399	1.19

- Duration: 30 minutes
- Activity class: Surface spraying of liquids, moderate application rate (0.3-3 L/min)
- Spray direction: spraying in any directions, including upwards
- Spray technique: no or low compressed air use
- Room size: 3000 m^3
- Ventilation rate: 1 ACH
- Primary risk management measures: No localized controls
- Emissions Sources: Far field
- Enclosure taken into account: Partial personal enclosure without ventilation (30.00 % reduction)

<u>Post-application:</u> Rinsing of surfaces and disposal of empty containers

- After the disinfection procedure is completed, surfaces and equipment are rinsed with water after the desired contact time and the water rinse drained into the sewer system. During rinsing of treated surfaces with water, possible residues on treated surfaces are highly diluted with water; possible dermal exposure is therefore considered to be negligible and far below the exposure determined during application of the disinfection solution by foaming (assumed dilution by a factor of 100).
- Emptied containers are disposed after filling of spraying equipment. No exposure during disposal is assumed.

	Parameters[1]	Value
Tier 1	Content of active substance: Mixing & loading undiluted product: Application diluted product: Post-application diluted product:	 5 % PAA, 25 % HP 0.15 % PAA, 0.75 % HP 0.0015 % PAA, 0.0075 % HP
	Undiluted product	Theoretical product 1 Activity coefficient PAA: 0.70 Activity coefficient HP: 1.07
	Dilution of the applied product (theoretical product):	33 (theoretical product 1) Activity coefficient PAA: 2.39 Activity coefficient HP: 1.19
	Inhalation exposure: Dermal exposure:	Temperature: 20°C Vapour pressure PAA: 1410 Pa Vapour pressure HP: 214 Pa /
	Exposure duration: Mixing & loading: Application: Post-application:	 15 min 30 min not relevant

The activity coefficients were calculated using the AIOMFAC tool published by ETH, Zurich on http://www.aiomfac.caltech.edu/cgi_bin/model.pl. The attached excel (2017-02-13 Activity coefficients calculations) shows how the activity coefficients have been calculated based on the mole fraction of the different constituents for each theoretical product and the in-use applications. The print files of the modeled results are provided also.

Justification for the choice of parameters:

M&L:

- *A flow rate of 1-10 L/min for mixing and loading does correspond to the filling of bottles and paint guns, and is thus seen as an appropriate approximation*
- *Room size for Mixing & loading: Any size workroom. Mixing and Loading could be done out of a "central" storage room with automatic pumping to the CIP vessels or "decentralized", but nearly in most cases the mixing and loading is done in an automated way. The selection of 'any size room' is seen as a relevant (and rather conservative) selection of room size.*

Application:

- *Room Size for Application phase: 3000 m^3. Automated spraying is typically performed in production halls or animal housing. 3000 m^3 is thus seen as an acceptable worst case for this approach.*
- *Application rate: 0.3-3 L/min: This is selected in accordance with Ad Hoc WG Recommendation 3 when using ART.*

Calculations for Scenario 6a, Foaming - Automated application with personal enclosure – application in all directions

Details on the calculations are provided in Annex 3.2

DERMAL

In the application of peracetic acid solutions for the disinfection of surfaces and equipment by foaming, dermal exposure is possible to 5% PAA and 25% HP during manual mixing/loading of the spraying equipment and 0.15 % PAA and 0.75 % HP during application. The concentrated product peracetic acid is known to be corrosive and the hydrogen peroxide solution (concentration of 25 %) is classified with 'risk of serious damage to eyes`. Consequently, wearing of gloves and goggles during handling of the concentrated products is mandatory. Once the product is diluted, the dermal exposure is considerably lower, but above the $NOEC_{dermal}$ for PAA. Nevertheless, the operator is not recommended to use PPE since the operator has a personal enclosure.

INHALATION

Inhalation exposure cannot be excluded due to the volatile nature of the active ingredients PAA and HP. The inhalation exposures of the different tasks (mixing and loading and application) are calculated using ART.

During the foaming activities, it is assumed that foaming is done in all directions with the foaming equipment, but that the operator is in a personal enclosure (i.e. cabin).

The highest concentration was found to be 2.2 mg/m^3 for PAA and 2.4 mg/m^3 for HP during mixing and loading. Based on these exposure estimates, additional RPE is required to ensure that the exposure is reduced below the inhalation AEC's set for PAA and HP. The use of RPE having an APF of 4 during the mixing and loading of the disinfection solution provides sufficient protection.

During application RPE with an APF of 10 are required on the condition that the operator/worker stays in the cabin and that the cabin is not opened during application. The details for calculation of inhalation exposure using ART are available in Annex 3.2. The summary of the results is presented here :

<u>*Peracetic acid*</u>*:*

Task	Local dermal exposure	Local inhalation exposure (mg/m³)	
		ART	
Mixing/loading	15	2.2	No RPE
		0.22	RPE APF = 10
Application	0.15	2.1	No RPE
		0. 0.21	RPE APF = 10
Post-application	0.0015	Not relevant	Not relevant

Hydrogen peroxide:

Task	Local dermal exposure Maximum concentration (%)	Local inhalation exposure (mg/m³)	
		ART	
Mixing/loading	25	2.4	No RPE
		0.6	RPE APF = 4
Application	0.75	2.9	No RPE
		0.29	RPE APF = 10
Post-application	0.0075	Not relevant	Not relevant

***Scenario 6b**: Foaming - Automated or manual application without personal enclosure – application in all directions*

Scenario 6b covers the following uses :

PT3 - Use #3.6 "Disinfection of animal housing by foaming – foaming without personal enclosure"
PT4 - Use #3.8 "Disinfection of surfaces by foaming without personal enclosure"

The biocidal products used for this scenario are:
- Acidofoam CF

Description of Scenario 6b, Foaming - Automated or manual application without personal enclosure – application in all directions

The concentrated peracetic acid solution will be diluted to the recommended in-use concentrations prior to application of the product. The dilutions, i.e. "mixing/loading" of the concentrated solution will also be done manually by pouring or automatically by pumping into the reservoir of the foaming equipment. The application of the disinfectant is done manually using the foaming equipment or automatically with the operator/worker not having a personal enclosure (not in a cabin). The foam is applied in all directions. After the disinfection procedure is completed, surfaces and equipment are rinsed with water and the water rinse drained into the sewer system.

In order to estimate worker/operator exposure during filling of the concentrate into the reservoir of the foaming equipment, the worst-case exposure is assumed, i.e. that of manual mixing and loading.

As the foaming activities occur in the presence of an operator/worker, exposure cannot be excluded.

During rinsing of the equipment and surfaces (post-application), the dermal exposure can be considered negligible due to the dilution with water.

Mixing and loading (M&L): Preparation of the foaming solution and filling of the foaming equipment

- Concentrated product corresponds to theoretical product 1:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	5	0.0149	0.70
HP	25	0.1664	1.07

- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 - 10 L/min
- Containment level: Handling that reduces contact between product and adjacent air
- Loading type: splash loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

Application: Manual foaming of surfaces

- Dilution 1:33 of theoretical product 1:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	0.15	0.00036	2.39
HP	0.755	0.00399	1.19

- Duration: 30 minutes
- Activity class: Surface spraying of liquids, moderate application rate (0.3-3 L/min)
- Spray direction: spraying in any directions, including upwards
- Spray technique: no or low compressed air use
- Room size: 3000 m^3
- Ventilation rate: 1 ACH
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

Post-application: Rinsing of surfaces and disposal of empty containers

- After the disinfection procedure is completed, surfaces and equipment are rinsed with water after the required contact time and the water rinse drained into the sewer system. During rinsing of treated surfaces with water, possible residues on treated surfaces are highly diluted with water; possible dermal exposure is therefore considered to be negligible and far below the exposure determined during application of the disinfection solution by foaming (assumed dilution by a factor of 100).
- Emptied containers are disposed after filling of spraying equipment. No exposure during disposal is assumed.

	Parameters[1]	Value
Tier 1	Content of active substance: Mixing & loading undiluted product: Application diluted product: Post-application diluted product:	 5 % PAA, 25 % HP 0.15 % PAA, 0.75 % HP 0.0015 % PAA, 0.0075 % HP
	Undiluted product	Theoretical product 1 Activity coefficient PAA: 0.70 Activity coefficient HP: 1.07
	Dilution of the applied product (theoretical product):	33 (theoretical product 1) Activity coefficient PAA: 2.39 Activity coefficient HP: 1.19
	Inhalation exposure: Dermal exposure:	Temperature: 20°C Vapour pressure PAA: 1410 Pa Vapour pressure HP: 214 Pa /
	Exposure duration: Mixing & loading: Application: Post-application:	 15 min 30 min not relevant

The activity coefficients were calculated using the AIOMFAC tool published by ETH, Zurich on http://www.aiomfac.caltech.edu/cgi_bin/model.pl. The attached excel (2017-02-13 Activity coefficients calculations, see Annex) shows how the activity coefficients have been calculated based on the mole fraction of the different constituents for each theoretical product and the in-use applications. The print files of the modeled results are provided also.

Justification for the choice of parameters:

M&L:

- *A flow rate of 1-10 L/min for mixing and loading does correspond to the filling of bottles and paint guns, and is thus seen as an appropriate approximation*
- *Room size for Mixing & loading: Any size workroom. Mixing and Loading could be done out of a "central" storage room with automatic pumping to the CIP vessels or "decentralized", but nearly in most cases the mixing and loading is done in an automated way. The selection of 'any size room' is seen as a relevant (and rather conservative) selection of room size.*

Application:

- *Room Size for Application phase: 3000 m^3. Automated spraying is typically performed in production halls. 3000 m^3 is thus seen as an acceptable worst case for this approach.*
- *Application rate: 0.3-3 L/min: This is selected in accordance with Ad Hoc WG Recommendation 3 when using ART.*

Calculations for Scenario 6b, Foaming – Automated or manual application without personal enclosure – application in all directions

Details on the calculations are provided in Annex 3.2

DERMAL

In the application of peracetic acid solutions for the disinfection of surfaces and equipment by foaming, dermal exposure is possible to 5% PAA and 25% HP during manual mixing/loading of the spraying equipment and 0.15 % PAA and 0.75 % HP during application. The concentrated product peracetic acid is known to be corrosive and the hydrogen peroxide solution (concentration of 25 %) is classified with 'risk of serious damage to eyes`. Consequently, wearing of gloves and goggles during handling of the concentrated products is mandatory. Once the product is diluted, the dermal exposure is considerably lower, but still above $NOEC_{dermal}$ for PAA. Therefore, it is recommended to use PPE during application..

INHALATION

Inhalation exposure cannot be excluded due to the volatile nature of the active ingredients PAA and HP. The inhalation exposures of the different tasks (mixing and loading and application) are calculated using ART.

During the foaming activities, it is assumed that foaming is done in all directions with the foaming equipment. Moreover, it is supposed that the operator is present during the application without personal enclosure.

The highest concentration was found to be 16 mg/m^3 for PAA and 14 mg/m^3 for HP during application of the foam. Based on these exposure estimates, additional RPE is required to ensure that the exposure is reduced below the inhalation AEC's set for PAA and HP. The use of RPE having an APF of 40 during the application of the disinfection foam provides sufficient protection. During mixing and loading RPE with APF 4 offers satisfactory protection.

Note that in above calculations we assume a use concentration of 0.15 % PAA and 0.75% HP. Based on the efficacy data that demonstrate that 0.064 % PAA is sufficient to support the efficacy claims, above exposure concentrations are very conservative. Assuming a realistic use concentration of 0.075 % PAA and 0.375 % HP results in exposure concentrations of 8 mg/m^3 and 7 mg/m^3 for PAA and HP respectively. It can hence be concluded that wearing RPE with APF of 20 provides sufficient protection.

The details for calculation of inhalation exposure using ART are available in Annex 3.2. The summary of the results is presented here:

Peracetic acid:

Task	Local dermal exposure Maximum concentration (%)	Local inhalation exposure (mg/m^3) ART	
Mixing/loading	5	0.89	No RPE
		0.22	RPE APF = 4
Application	0.15	16	No RPE
		0.4	RPE APF = 40
Post-application	0.0015	Not relevant	Not relevant

Hydrogen peroxide:

Task	Local dermal exposure Maximum concentration (%)	Local inhalation exposure (mg/m^3) ART	
Mixing/loading	25	2.3	No RPE
		0.575	RPE APF = 4
Application	0.75	14	No RPE
		0.35	RPE APF = 40
Post-application	0.0075	Not relevant	Not relevant

***Scenario 6c**: Foaming - Automated or manual application without personal enclosure – horizontal and downward application*

Scenario 6c covers the following uses :

PT2 - Use #3.2 "Disinfection of equipment and surfaces by foaming (e.g. agriculture & horticulture equipment – for general hygiene purpose only), manually"

The biocidal products used for this scenario are:

- Acidofoam CF

Description of Scenario 6c, Foaming – Automated or manual application without personal enclosure –horizontal and downward application

The concentrated peracetic acid solution will be diluted to the recommended in-use concentrations prior to application of the product. The dilutions, i.e. "mixing/loading" of the concentrated solution will also be done manually by pouring or automatically by pumping into the reservoir of the foaming equipment. The application of the disinfectant is done manually using the foaming equipment, or can be automated. The foam is only applied downwards and in horizontal direction. After the disinfection procedure is completed, equipment is rinsed with water and the water rinse drained into the sewer system.

In order to estimate worker/operator exposure during filling of the concentrate into the reservoir of the foaming equipment, the worst-case exposure is assumed, i.e. that of manual mixing and loading.

As the foaming activities occur in the presence of an operator/worker, exposure cannot be excluded.

During rinsing of the equipment and surfaces (post-application), the dermal exposure can be considered negligible due to the dilution with water.

Mixing and loading (M&L): Preparation of the foaming solution and filling of the foaming equipment

- Concentrated product corresponds to theoretical product 1:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	5	0.0149	0.70
HP	25	0.1664	1.07

- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 - 10 L/min
- Containment level: Handling that reduces contact between product and adjacent air
- Loading type: splash loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

<table>
<tr><td colspan="3">

<u>Application:</u> Manual foaming of equipment

- Dilution 1:33 of theoretical product 1:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	0.15	0.00036	2.39
HP	0.75	0.00399	1.19

- Duration: 30 minutes
- Activity class: Surface spraying of liquids, moderate application rate (0.3-3 L/min)
- Spray direction: Only horizontal and downward spraying
- Spray technique: no or low compressed air use
- Room size: 300 m^3
- Ventilation rate: 1 ACH
- Primary risk management measures: no localized controls, no secondary localized controls
- Emissions Sources: Near field

<u>Post-application:</u> Rinsing of surfaces and disposal of empty containers

- After the disinfection procedure is completed, surfaces and equipment are rinsed with water after a contact time of 15 – 30 minutes and the water rinse drained into the sewer system. During rinsing of treated surfaces with water, possible residues on treated surfaces are highly diluted with water; possible dermal exposure is therefore considered to be negligible and far below the exposure determined during application of the disinfection solution by foaming (assumed dilution by a factor of 100).
- Emptied containers are disposed after filling of spraying equipment. No exposure during disposal is assumed.

</td></tr>
<tr><td></td><td>Parameters[1]</td><td>Value</td></tr>
<tr><td rowspan="5">Tier 1</td><td>Content of active substance:
Mixing & loading undiluted product:
Application diluted product:
Post-application diluted product:</td><td>
5 % PAA, 25 % HP
0.15 % PAA, 0.75 % HP
0.0015 % PAA, 0.0075 % HP</td></tr>
<tr><td>Undiluted product</td><td>Theoretical product 1
Activity coefficient PAA: 0.70
Activity coefficient HP: 1.07</td></tr>
<tr><td>Dilution of the applied product (theoretical product):</td><td>33 (theoretical product 1)
Activity coefficient PAA: 2.39
Activity coefficient HP: 1.19</td></tr>
<tr><td>Inhalation exposure:

Dermal exposure:</td><td>Temperature: 20°C
Vapour pressure PAA: 1410 Pa
Vapour pressure HP: 214 Pa
/</td></tr>
<tr><td>Exposure duration:
Mixing & loading:
Application:
Post-application:</td><td>
15 min
30 min
not relevant</td></tr>
</table>

The activity coefficients were calculated using the AIOMFAC tool published by ETH, Zurich on http://www.aiomfac.caltech.edu/cgi_bin/model.pl. The attached excel (2017-02-13 Activity coefficients calculations, see Annex) shows how the activity coefficients have been calculated based on the mole fraction of the different constituents for each theoretical product and the in-use applications. The print files of the modeled results are provided also.

Justification for the choice of parameters:

- *A flow rate of 1-10 L/min does correspond to the filling of bottles and paint guns, and is thus seen as an appropriate approximation*
- *Room size for Mixing & loading: Any size workroom. Mixing and Loading could be done out of a "central" storage room with automatic pumping to the CIP vessels or "decentralized", but nearly in most cases the mixing and loading is done in an automated way. The selection of 'any size room' is seen as a relevant (and rather conservative) selection of room size.*
- *Room Size for Application phase: 300 m^3. No Automated spraying, which typically implies smaller surfaces (and thus smaller volumes). As no agreed values exist for this kind of installation, a decrease in volume of a factor 10 was deemed sufficiently worst case. 300 m^3 is thus seen as an acceptable worst case for this approach.*
- *Application rate: 0.3-3 L/min: This follow Recommendation 3 in the use of ART.*

Calculations for Scenario 6c, Foaming – Automated or manual application without personal enclosure – application in all directions
Details on the calculations are provided in Annex 3.2

DERMAL
In the application of peracetic acid solutions for the disinfection of surfaces and equipment by foaming, dermal exposure is possible to 5% PAA and 25% HP during manual mixing/loading of the spraying equipment and 0.15 % PAA and 0.75 % HP during application. The concentrated product peracetic acid is known to be corrosive and the hydrogen peroxide solution (concentration of 25 %) is classified with 'risk of serious damage to eyes`. Consequently, wearing of gloves and goggles during handling of the concentrated products is mandatory. Once the product is diluted, the dermal exposure is considerably lower, but still above $NOEC_{dermal}$ for PAA. Therefore, it is recommended to use PPE during application.

INHALATION
Inhalation exposure cannot be excluded due to the volatile nature of the active ingredients PAA and HP. The inhalation exposures of the different tasks (mixing and loading and application) are calculated using ART.

During the foaming activities, it is assumed that foaming is only applied in downwards or horizontal direction. Moreover, it is supposed that the operator is present during the application without personal enclosure.

The highest concentration was found to be 13 mg/m^3 for PAA and 11 mg/m^3 for HP during application of the foam. Based on these exposure estimates, additional RPE is required to ensure that the exposure is reduced below the inhalation AEC's set for PAA and HP. The use of RPE having an APF of 40 during the application of the disinfection foam provides sufficient protection.

During mixing and loading RPE with APF 4 offers sufficient protection.
Based on the efficacy data, an in use PAA concentration of 0.048 % PAA (rounded to 0.075 % PAA) is sufficient to support the efficacy claims made. Therefore, it is realistic to assume that the actual exposure is a factor 2 lower: 7.5 mg/m^3 for PAA and 5.5

mg/m^3 for HP. As a result, using RPE with APF of 40 during the application of the disinfectant offers enough protection.

The details for calculation of inhalation exposure using ART are available in Annex 3.2. The summary of the results is presented here:

Peracetic acid:

Task	Local dermal exposure Maximum concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	5	0.89	No RPE
		0.22	RPE APF = 4
Application	0.15	13	No RPE
		0.32	RPE APF = 40
Post-application	0.0015	Not relevant	Not relevant

Hydrogen peroxide:

Task	Local dermal exposure Maximum concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	25	2.3	No RPE
		0.575	RPE APF = 4
Application	0.75	11	No RPE
		0.275	RPE APF = 40
Post-application	0.0075	Not relevant	Not relevant

***Scenario 6d**: Foaming - Automated application with personal enclosure –horizontal and downward application*

Scenario 6d covers the following uses :

PT2 - Use #3.3 "Disinfection of surfaces and equipment by foaming (e.g. agriculture & horticulture equipment – for general hygiene purpose only) automatically"

The biocidal products used for this scenario are:
- Acidofoam CF

Description of Scenario 6d, Foaming - Automated application with personal enclosure – horizontal and downward application

The concentrated peracetic acid solution will be diluted to the recommended in-use concentrations prior to application of the product. The dilutions, i.e. "mixing/loading" of the concentrated solution will be done manually by pouring or automatically by pumping into the reservoir of the foaming equipment. The application of the disinfectant is done automatically using a fixed foaming installation (e.g. foaming on conveyor belt). The foam is only applied downwards and in horizontal direction. After the disinfection procedure is completed, equipment is rinsed with water and the water rinse drained into the sewer system.

In order to estimate worker/operator exposure during filling of the concentrate into the reservoir of the foaming equipment, the worst-case exposure is assumed, i.e. that of manual mixing and loading.

During the foaming activities the operator/worker oversees the activities from a control room. It is as worst-case assumed that this personal enclosure is not actively ventilated.

With regard to the description of the scenario. It is to be noted that there is no actual containment of the source. We decided to select the conservative approach and evaluate exposure as near field. Within near field there is not the option to indicate that the operator is often in a control room separated from the area, hence the option for medium containment.
The spraying activity in general takes place in a fully automated way. Only horizontal or downwards spraying is applicable here. The operator will typically initiate the process from his control area. However, this control area is not necessarily a fully separated room with independent ventilation.

During rinsing of the equipment and surfaces (post-application), the dermal exposure can be considered negligible due to the dilution with water.

Mixing and loading (M&L): Preparation of the foaming solution and filling of the foaming equipment
- Concentrated product corresponds to theoretical product 1:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	5	0.0149	0.70
HP	25	0.1664	1.07

- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 - 10 L/min
- Containment level: Handling that reduces contact between product and adjacent air
- Loading type: splash loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: No localized controls

• Emissions Sources: Near field		
Application: Automated foaming of equipment • Dilution 1:33 of theoretical product 1: Ingredient / Concentration (%) / Mole fraction / Activity coefficient PAA / 0.15 / 0.00036 / 2.39 HP / 0.75 / 0.00399 / 1.19 • Duration: 30 minutes • Activity class: Surface spraying of liquids, moderate application rate (0.3-3 L/min) • Spray direction: Only horizontal and downward spraying • Spray technique: no or low compressed air use • Room size: 300 m^3 • Ventilation rate: 1 ACH • Primary and secondary risk management measures: No localized controls • Emissions Sources: Near field Post-application: Rinsing of surfaces and disposal of empty containers • After the disinfection procedure is completed, surfaces and equipment are rinsed with water after the required contact time and the water rinse drained into the sewer system. During rinsing of treated surfaces with water, possible residues on treated surfaces are highly diluted with water; possible dermal exposure is therefore considered to be negligible and far below the exposure determined during application of the disinfection solution by foaming (assumed dilution by a factor of 100). • Emptied containers are disposed after filling of spraying equipment. No exposure during disposal is assumed.		
	Parameters[1]	Value
Tier 1	Content of active substance: Mixing & loading undiluted product: Application diluted product: Post-application diluted product:	 5 % PAA, 25 % HP 0.15 % PAA, 0.75 % HP 0.0015 % PAA, 0.0075 % HP
	Undiluted product	Theoretical product 1 Activity coefficient PAA: 0.70 Activity coefficient HP: 1.07
	Dilution of the applied product (theoretical product):	33 (theoretical product 1) Activity coefficient PAA: 2.39 Activity coefficient HP: 1.19
	Inhalation exposure: Dermal exposure:	Temperature: 20°C Vapour pressure PAA: 1410 Pa Vapour pressure HP: 214 Pa /
	Exposure duration: Mixing & loading: Application: Post-application:	 15 min 30 min not relevant

The activity coefficients were calculated using the AIOMFAC tool published by ETH, Zurich on http://www.aiomfac.caltech.edu/cgi_bin/model.pl. The attached excel (2017-02-13 Activity coefficients calculations) shows how the activity coefficients have been calculated based on the mole fraction of the different constituents for each theoretical product and the in-use applications. The print files of the modeled results are provided also.

Justification for the choice of parameters:

M&L:

- *A flow rate of 1-10 L/min during mixing and loading does correspond to the filling of bottles and paint guns, and is thus seen as an appropriate approximation*
- *Room size for Mixing & loading: Any size workroom. Mixing and Loading could be done out of a "central" storage room with automatic pumping to the CIP vessels or "decentralized", but nearly in most cases the mixing and loading is done in an automated way. The selection of 'any size room' is seen as a relevant (and rather conservative) selection of room size.*

Applicationl

- *Room Size for Application phase: 300 m^3. Despite Automated spraying, which typically implies higher surfaces (and thus smaller volumes), the volume from scenario 4C was kept, as it implies a worst case situation.*
- *Application rate: 0.3-3 L/min: This is selected in accordance with Ad Hoc WG Recommendation 3 when using ART.*

Calculations for Scenario 6d, Foaming - Automated application with personal enclosure –horizontal and downward application

Details on the calculations are provided in Annex 3.2

DERMAL

In the application of peracetic acid solutions for the disinfection of surfaces and equipment by foaming, dermal exposure is possible to 5% PAA and 25% HP during manual mixing/loading of the spraying equipment and 0.15 % PAA and 0.75 % HP during application. The concentrated product peracetic acid is known to be corrosive and the hydrogen peroxide solution (concentration of 25 %) is classified with 'risk of serious damage to eyes`. Consequently, wearing of gloves and goggles during handling of the concentrated products is mandatory. Once the product is diluted, the dermal exposure is considerably lower. Nevertheless, the operator is not required to wear PPE during spraying as (1) the recommended in-use concentration is 0.048 % PAA, which is below $NOEC_{dermal}$ and (2) automated spraying takes place the operator is in a personal enclosure and as a result there is no direct contact with the diluted product.

INHALATION

Inhalation exposure cannot be excluded due to the volatile nature of the active ingredients PAA and HP. The inhalation exposures of the different tasks (mixing and loading and application) are calculated using ART.

During the foaming activities, it is assumed that foaming is only applied in downwards or horizontal direction. There is an operator overseeing the foaming activities from a control room without active ventilation.

The highest concentration was found to be 0.89 mg/m^3 for PAA and 2.3 mg/m^3 for HP during mixing and loading of the concentrated product. Based on these exposure estimates, additional RPE is required to ensure that the exposure is reduced below the inhalation AEC's set for PAA and HP. The use of RPE having an APF of 4 during the handling of the concentrated product provides sufficient protection. During the foaming activities, the operator does not need wear RPE on the condition that he stays in the control room and does not open windows or doors as long as the foaming is on-going.

The details for calculation of inhalation exposure using ART are available in Annex 3.2. The summary of the results is presented here:

Peracetic acid:

Task	**Local dermal exposure Maximum concentration (%)**	**Local inhalation exposure (mg/m³)**	
		ART	
Mixing/loading	5	0.89	No RPE
		0.22	RPE APF = 4
Application	0.15	0.13	No RPE
Post-application	0.0015	Not relevant	Not relevant

Hydrogen peroxide:

Task	**Local dermal exposure Maximum concentration (%)**	**Local inhalation exposure (mg/m³)**	
		ART	
Mixing/loading	25	2.3	No RPE
		0.575	RPE APF = 4
Application	0.75	0.11	No RPE
Post-application	0.0075	Not relevant	Not relevant

***Scenario 6e**: Foaming - Fully automated application not requiring the presence of operator*

Scenario 6e covers the following uses :

PT2 - Use #3.4 "Disinfection of surface and equipment by foaming (e.g. agriculture & horticulture equipment – for general hygiene purpose only) – automatic foaming (closed room)"

The biocidal products used for this scenario are:

- Acidofoam CF

Description of Scenario 6e, Foaming - Fully automated application not requiring the presence of operator

The concentrated peracetic acid solution will be diluted to the recommended in-use concentrations prior to application of the product. The dilutions, i.e. "mixing/loading" of the concentrated solution will be done manually by pouring or automatically by pumping into the reservoir of the foaming equipment. The application of the disinfectant is done automatically using a fixed foaming installation in a closed room. The application of the foam does not require the presence of an operator/worker. After the disinfection procedure is completed, equipment is rinsed with water and the water rinse drained into the sewer system.

In order to estimate worker/operator exposure during filling of the concentrate into the reservoir of the foaming equipment, the worst-case exposure is assumed, i.e. that of manual mixing and loading.

During the foaming activities the operator/workeris not present, hence, the exposure is considered not relevant.

During rinsing of the equipment and surfaces (post-application), the dermal exposure can be considered negligible due to the dilution with water.

Mixing and loading (M&L): Preparation of the foaming solution and filling of the foaming equipment

- Concentrated product corresponds to theoretical product 1:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	5	0.0149	0.70
HP	25	0.1664	1.07

- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 - 10 L/min
- Containment level: Handling that reduces contact between product and adjacent air
- Loading type: splash loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

Application: Automated foaming of equipment

- The application of foam is done in a closed room, for example storage room and the presence of an operator is not required. No exposure during application is assumed.

Post-application: Rinsing of surfaces and disposal of empty containers

- After the disinfection procedure is completed, surfaces and equipment are rinsed with water after the required contact time and the water rinse drained into the sewer system. During rinsing of treated surfaces with water, possible residues on treated surfaces are highly diluted with water; possible dermal exposure is therefore considered to be negligible and far below the exposure determined during application of the disinfection solution by foaming (assumed dilution by a factor of 100).
- Emptied containers are disposed after filling of spraying equipment. No exposure during disposal is assumed.

	Parameters[1]	Value
Tier 1	Content of active substance: Mixing & loading undiluted product: Application diluted product: Post-application diluted product:	 5 % PAA, 25 % HP 0.15 % PAA, 0.75 % HP 0.0015 % PAA, 0.0075 % HP
	Undiluted product	Theoretical product 1 Activity coefficient PAA: 0.70 Activity coefficient HP: 1.07
	Dilution of the applied product (theoretical product):	33 (theoretical product 1) Activity coefficient PAA: 2.39 Activity coefficient HP: 1.19
	Inhalation exposure: Dermal exposure:	Temperature: 20°C Vapour pressure PAA: 1410 Pa Vapour pressure HP: 214 Pa /
	Exposure duration: Mixing & loading: Application: Post-application:	 15 min not relevant not relevant

The activity coefficients were calculated using the AIOMFAC tool published by ETH, Zurich on http://www.aiomfac.caltech.edu/cgi_bin/model.pl. The attached excel (2017-02-13 Activity coefficients calculations) shows how the activity coefficients have been calculated based on the mole fraction of the different constituents for each theoretical product and the in-use applications. The print files of the modeled results are provided also.

Justification for the choice of parameters:

M&L:

- *A flow rate of 1-10 L/min for mixing and loading does correspond to the filling of bottles and paint guns, and is thus seen as an appropriate approximation*
- *Room size for Mixing & loading: Any size workroom. Mixing and Loading could be done out of a "central" storage room with automatic pumping to the CIP vessels or "decentralized", but nearly in most cases the mixing and loading is done in an automated way. The selection of 'any size room' is seen as a relevant (and rather conservative) selection of room size.*

Calculations for Scenario 6e, Foaming - Fully automated application not requiring the presence of operator

Details on the calculations are provided in Annex 3.2

DERMAL
In the application of peracetic acid solutions for the disinfection of surfaces and equipment by foaming, dermal exposure is possible to 5% PAA and 25% HP during manual mixing/loading of the spraying equipment and 0.15 % PAA and 0.75 % HP during application. The concentrated product peracetic acid is known to be corrosive and the hydrogen peroxide solution (concentration of 25 %) is classified with 'risk of serious damage to eyes`. Consequently, wearing of gloves and goggles during handling of the concentrated products is mandatory. Once the product is diluted, the dermal exposure is considerably lower, but still above $NOEC_{dermal}$ for PAA. Nevertheless, since the application does not require the presence of an operator, no PPE need to be recommended.

INHALATION
Inhalation exposure cannot be excluded due to the volatile nature of the active ingredients PAA and HP. The inhalation exposures of mixing and loading of the concentrated product are calculated using ART.

The highest concentration was found to be 0.89 mg/m^3 for PAA and 2.3 mg/m^3 for HP during mixing and loading of the concentrated product. Based on these exposure estimates, additional RPE is required to ensure that the exposure is reduced below the inhalation AEC's set for PAA and HP. The use of RPE having an APF of 4 during the handling of the concentrated product provides sufficient protection.

The details for calculation of inhalation exposure using ART are available in Annex 3.2. The summary of the results is presented here:

Peracetic acid:

Task	Maximum HP concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	5	0.89	No RPE
		0.22	RPE APF = 4
Application	0.15	Not relevant	Not relevant
Post-application	0.0015	Not relevant	Not relevant

Hydrogen peroxide:

Task	Maximum PAA concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	25	2.3	No RPE
		0.575	RPE APF = 4
Application	0.75	Not relevant	Not relevant
Post-application	0.0075	Not relevant	Not relevant

***Scenario 6f**: Foaming - Manual application without personal enclosure – downward application – low application rate*

Scenario 6f covers the following uses :

PT2 - Use #3.1 "Disinfection of surfaces in industrial, public and health care areas – foam application on surfaces"

The biocidal products used for this scenario are:
- Acidofoam CF

Description of Scenario 6f, Foaming - Manual application without personal enclosure – downward application – low application rate

The concentrated peracetic acid solution will be diluted to the recommended in-use concentrations prior to application of the product. The dilutions, i.e. "mixing/loading" of the concentrated solution will be done manually by pouring into the reservoir of the spraying equipment (typically small volume containers e.g. spraying cans). The application of the disinfectant is done manually using the spraying equipment. The disinfectant is only applied downwards. After the disinfection procedure is completed, equipment is rinsed with water and the water rinse drained into the sewer system.

As the foaming activities occur in the presence of a professional, exposure during application cannot be excluded.

During rinsing of the equipment and surfaces (post-application), the dermal exposure can be considered negligible due to the dilution with water.

Mixing and loading (M&L): Preparation of the spraying solution and filling of the spraying equipment

- Concentrated product corresponds to theoretical product 2:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	5	0.0149	0.70
HP	25	0.1664	1.07

- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 - 10 L/min
- Containment level: Handling that reduces contact between product and adjacent air
- Loading type: splash loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

Application: Manual spraying of equipment

- Dilution 1:33 of theoretical product 1:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	0.15	0.00036	2.39
HP	0.75	0.00399	1.19

- Duration: 30 minutes
- Activity class: Surface spraying of liquids, low application rate (0.03-0.3 L/min)
- Spray direction: Only downward spraying
- Spray technique: no or low compressed air use
- Room size: 100 m^3
- Ventilation rate: 1 ACH
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

Post-application: Rinsing of surfaces and disposal of empty containers

- After the disinfection procedure is completed, surfaces and equipment are rinsed with water after the required contact time and the water rinse drained into the sewer system. During rinsing of treated surfaces with water, possible residues on treated surfaces are highly diluted with water; possible dermal exposure is therefore considered to be negligible and far below the exposure determined during application of the disinfection solution by foaming (assumed dilution by a factor of 100).
- Emptied containers are disposed after filling of spraying equipment. No exposure during disposal is assumed.

	Parameters[1]	Value

Tier 1	Content of active substance: Mixing & loading undiluted product: Application diluted product: Post-application diluted product:	 5 % PAA, 25 % HP 0.15 % PAA, 0.75 % HP 0.0015 % PAA, 0.0075 % HP
	Undiluted product	Theoretical product 1 Activity coefficient PAA: 0.70 Activity coefficient HP: 1.07
	Dilution of the applied product (theoretical product):	33 (theoretical product 1) Activity coefficient PAA: 2.39 Activity coefficient HP: 1.19
	Inhalation exposure: Dermal exposure:	Temperature: 20°C Vapour pressure PAA: 1410 Pa Vapour pressure HP: 214 Pa /
	Exposure duration: Mixing & loading: Application: Post-application:	 15 min 30 min not relevant

The activity coefficients were calculated using the AIOMFAC tool published by ETH, Zurich on http://www.aiomfac.caltech.edu/cgi_bin/model.pl. The attached excel (2017-02-13 Activity coefficients calculations, see Annex) shows how the activity coefficients have been calculated based on the mole fraction of the different constituents for each theoretical product and the in-use applications. The print files of the modeled results are provided also.

Justification for the choice of parameters:

M&L

- *A flow rate of 1-10 L/min for mixing and loading does correspond to the filling of bottles and paint guns, and is thus seen as an appropriate approximation*
- *Room size for Mixing & loading: Any size workroom. Mixing and Loading could be done out of a "central" storage room with automatic pumping to the CIP vessels or "decentralized", but nearly in most cases the mixing and loading is done in an automated way. The selection of 'any size room' is seen as a relevant (and rather conservative) selection of room size.*

Application:

- *Room Size for Application phase: 100 m^3. As the application step is manual, this concerns mainly smaller surfaces. As a smaller volume does present here in this case a worst case situation, a total room volume of 100 m^3 is seen as being acceptable.*
- *Application rate: 0.3-3 L/min: This is selected in accordance with Ad Hoc WG Recommendation 3 when using ART.*

Calculations for Scenario 6f, Foaming – Manual application without personal enclosure –downward application – low application rate

Details on the calculations are provided in Annex 3.2

DERMAL

In the application of peracetic acid solutions for the disinfection of surfaces and equipment by foaming, dermal exposure is possible to 15% PAA and 25% HP during manual mixing/loading of the spraying equipment and 0.1 % PAA and 0.5 % HP during application. The concentrated product peracetic acid is known to be corrosive and the hydrogen peroxide solution (concentration of 25 %) is classified with 'risk of serious damage to eyes`. Consequently, wearing of gloves and goggles during handling of the concentrated products is mandatory. Once the product is diluted, the dermal exposure is considerably lower, but still above $NOEC_{dermal}$ for PAA. Therefore, the operator is recommended to use PPE also during the application phase.

INHALATION

Inhalation exposure cannot be excluded due to the volatile nature of the active ingredients PAA and HP. The inhalation exposures of the different tasks (mixing and loading and application) are calculated using ART.

During the foaming activities, it is assumed that foaming is only applied in downwards direction. Moreover, it is supposed that the operator is present during the application without personal enclosure.

The highest concentration was found to be 2.6 mg/m^3 for PAA and 2.2 mg/m^3 for HP during application of the disinfectants. Based on these exposure estimates, additional RPE is required to ensure that the exposure is reduced below the inhalation AEC's set for PAA and HP.

The use of RPE having an APF of 4 during the mixing and loading of the foaming equipment and an APF of 10 during the application of the disinfection foam provides sufficient protection.

Based on the efficacy data, an in use PAA concentration of 0.064 % PAA (rounded to 0.075 % PAA) is sufficient to support the efficacy claims made. Therefore, it is realistic to assume that the actual exposure is a factor 2 lower: 7.5 mg/m^3 for PAA and 5.5 mg/m^3 for HP. As a result, using RPE with APF of 4 during the application of the disinfectant offers enough protection.

The details for calculation of inhalation exposure using ART are available in Annex 3.2. The summary of the results is presented here:

Peracetic acid:

Task	Local dermal exposure Maximum concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	5	0.89	No RPE
		0.22	RPE APF = 4
Application	0.15	2.6	No RPE
		0.13	RPE APF = 10
Post-application	0.0015	Not relevant	Not relevant

Hydrogen peroxide:

Task	Maximum HP concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	25	2.3	No RPE
		0.575	RPE APF = 4

Application	0.75	2.2	No RPE
		0.11	RPE APF = 10
Post-application	0.0075	Not relevant	Not relevant

*Please note that **additional refinement of the use concentration** as stipulated above leads to a further reduction of the potential exposure with 50% as of the application phase. Therfore the APF can also be less stringent and an **APF of 4 is sufficient**.*

***Scenario 7**: Fogging*

Details on the calculations are provided in Annex 3.2

Scenario 7 covers the following uses :

PT2 - Use #2.1 “Disinfection of surfaces and/or equipment in industrial, public and health care areas (pharmaceutical and cosmetic industry) – fogging” and Use #2.2 “ Disinfection of hard surfaces equipment by fogging (e.g. agriculture & horticulture equipment, in absence of plants – for general hygiene purpose only)”
PT2 - Use #2.2 : Disinfection of hard surfaces equipment by fogging (e.g. agriculture & horticulture equipment, in absence of plants – for general hygiene purpose only)
PT3 - Use #2.3 “ Disinfection of animal housing by fogging”
PT4 - Use #2.4 “ Disinfection of storage rooms with special device in storage cellar or room”

The biocidal products used for this scenario are:

- Sopuroxid 3.2

Description of Scenario 7, Fogging

For fogging, the procedures applied for mixing/loading of the concentrated peracetic acid solutions and for application of the diluted solutions are in principle identical to the spraying and foaming. The concentrated peracetic acid solution will be diluted to the recommended in-use concentrations prior to application of the product. The dilutions, i.e. "mixing/loading" of the concentrated solution will also be done manually by pouring or automatically by pumping into the reservoir of the fogging equipment. The fogger is placed as a fixed-position machine within the animal house or storage room or installed outside the building with the nozzles of the fogger directed from the outside of the animal house into its interior. The animal house will be tightly sealed thereafter and during fogging, no worker/operator will be present. After completion of fogging, the building is left closed for about 60 min, thoroughly ventilated for another 60 min thereafter and re-entry occurs after 90 min. following ventilation.

In order to estimate worker/operator exposure during filling of the concentrate into the reservoir of the sprayer, the worst-case exposure is assumed, i.e. that of manual mixing and loading.

The fogging activity itself takes places in the absence of an operator in a closed building. Exposure during application is hence considered negligible.

After disinfection, premises are thoroughly ventilated before a worker/operator can enter. The air concentrations are checked before a worker/operator is allowed to enter the disinfected area. The air concentration of PAA should have dropped to 0.5 mg/m^3. The air concentration of HP should have dropped to 1.25 mg/m^3.

Mixing and loading (M&L): Preparation of the fogging solution

- Concentrated product corresponds to theoretical product 1:

Ingredient	Concentration (%)	Mole fraction	Activity coefficient
PAA	5	0.0149	0.70
HP	25	0.1664	1.07

- Duration: 15 minutes
- Activity class: falling liquids
- Flow rate: 1 – 10 L/min
- Containment level: Handling that reduces contact between product and adjacent air
- Loading type: splash loading
- Room size: Any size workroom
- Ventilation rate: only good natural ventilation
- Primary and secondary risk management measures: No localized controls
- Emissions Sources: Near field

Application: Fogging of animal housing or storage rooms

- Fogging of the animal housing or storage rooms (with or without equipment) is done in the absence of an operator/worker. The exposure during this activity is hence considered not relevant.

Post-application: Ventilation and disposal of empty containers

- After disinfection by fogging is completed, premises are left closed for about 60 min, and is thoroughly ventilated. Nobody is allowed to re-enter the disinfected rooms until the PAA concentrations have dropped below 0.5 mg/m^3. This should be assessed by measurement.
- Emptied containers are disposed after filling of spraying equipment. No exposure during disposal is assumed.

	Parameters[1]	Value

Tier 1	Content of active substance: Mixing & loading undiluted product: Application diluted product: Post-application diluted product:	 5 % PAA, 25 % HP 0.25 % PAA, 1.25 % HP 0.25 % PAA, 1.25 % HP
	Undiluted product	Theoretical product 1 Activity coefficient PAA: 0.70 Activity coefficient HP: 1.07
	Dilution of the applied product (theoretical product):	5 (theoretical product 1) Activity coefficient PAA: 1.97 Activity coefficient HP: 1.17
	Inhalation exposure: Dermal exposure:	See details on parameters in Annex 3.2 Temperature: 20°C Vapour pressure PAA: 1410 Pa Vapour pressure HP: 214 Pa /
	Exposure duration: Mixing & loading: Application: Post-application:	 15 min not relevant 30 min

The activity coefficients were calculated using the AIOMFAC tool published by ETH, Zurich on http://www.aiomfac.caltech.edu/cgi_bin/model.pl. The attached excel (2017-02-13 Activity coefficients calculations) shows how the activity coefficients have been calculated based on the mole fraction of the different constituents for each theoretical product and the in-use applications. The print files of the modeled results are provided also.

Justification for the choice of parameters:

M&L:

- *A flow rate of 1-10 L/min for mixing and loading does correspond to the filling of bottles and paint guns, and is thus seen as an appropriate approximation*
- *Room size for Mixing & loading: Any size workroom. Mixing and Loading could be done out of a "central" storage room with automatic pumping to the CIP vessels or "decentralized", but nearly in most cases the mixing and loading is done in an automated way. The selection of 'any size room' is seen as a relevant (and rather conservative) selection of room size.*

Calculations for Scenario 7, Fogging

DERMAL

In the application of peracetic acid solutions for the disinfection of surfaces and equipment by fogging, dermal exposure is possible to 5% PAA and 25% HP during manual mixing/loading of the fogging equipment. The concentrated product peracetic acid is known to be corrosive and the hydrogen peroxide solution (concentration of 25 %) is classified with ‘risk of serious damage to eyes`. Consequently, wearing of gloves and goggles during handling of the concentrated products is mandatory. Once the product is diluted, the dermal exposure is considerably lower, but still above $NOEC_{dermal}$ of PAA. Since fogging takes place without the presence of an operator, there is no risk for dermal contact during application. Therefore, no PPE are to be recommended.

INHALATION
Inhalation exposure cannot be excluded due to the volatile nature of the active ingredients PAA and HP. Inhalation exposure of the worker/operator during application and post-application is not relevant as no worker/operator is present during the fogging procedure. However, a potential inhalation exposure could occur when the concentrated product is handled. The inhalation exposures of the mixing and loading is calculated using ART.

The highest concentration was found to be 0.88 mg/m^3 for PAA and 2.8 mg/m^3 for HP during mixing and loading of the concentrated product. Based on these exposure estimates, additional RPE is required to ensure that the exposure is reduced below the inhalation AEC's set for PAA and HP. The use of RPE having an APF of 4 provides sufficient protection.

The details for calculation of inhalation exposure using ART are available in Annex 3.2. The summary of the results is presented here:

<u>*Peracetic acid:*</u>

Task	Maximum PAA concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	5	0.88	No RPE
		0.22	RPE APF = 4
Application	0.25	Not relevant	Not relevant
Post-application	0.25	Not relevant	Not relevant

<u>*Hydrogen peroxide:*</u>

Task	Maximum HP concentration (%)	Local inhalation exposure (mg/m^3)	
		ART	
Mixing/loading	25	2.8	No RPE
		0.7	RPE APF = 4
Application	1.25	Not relevant	Not relevant
Post-application	1.25	Not relevant	Not relevant

Non-professional exposure

No applications related to non-professional users were identified. Therefore exposure to non-professionals is not further considered.

Exposure of the general public

Dermal exposure
The dermal secondary exposure following application is considered to be not relevant. Both peracetic acid and hydrogen peroxide are highly unstable and will rapidly degrade at the site of first contact which effectively further reduces the possibility of any residual concentrations. Damaged skin could potentially be more prone to the adverse effects of residual peracetic acid but even this scenario is speculative due to the high reactivity and rapid degradation.

Inhalation exposure
Systemic effects can be considered non-relevant due to rapid degradation/metabolism of the ingredients. Therefore, only local exposure via the inhalation route after application of peracetic acid solutions is considered to be relevant for the assessment of secondary exposure.

During the cleaning and disinfection of surfaces in public and health care areas, exposure to non-users or bystanders passing by is possible. To prevent the exposure of non-users or bystanders, warning signs informing the non-professional that disinfection is ongoing and that they should not pass the disinfected area. Only when the air concentrations are reduced below the AEC_{inhal} levels, passage is allowed. As a consequence, passage despite the warning signs is considered as accidental and not within the scope of this risk assessment.

Following disinfection of areas such as animal housing, greenhouses or storage rooms by spraying, foaming or fogging, premises are opened again for ventilation. Warning signs should be put at the entrance so that the non-professional does not enter the premises without appropriate protective measures. Only when the concentrations of PAA and HP have dropped below the AEC_{inhal} levels, warning signs can be removed. Entering the premises without due consideration of the warning signs is considered as accidental exposure, and is therefore not assessed.

Monitoring data
There are no monitoring data available.

Dietary exposure

Accidental oral exposure is unlikely to cause a negative effect because PAA and HP will be rapidly degraded by the efficient detoxification mechanism of the organisms. at the application step, the product has been highly diluted (1% of product in water), which means that, for a classification such as H302, the dilution leads to a solution that is too diluted to still be classified.
Regarding dietary exposure though food that would be accidentally exposed to the product (diluted or undiluted), given the fact that the active substance as a high vapore pressure, is highly reactive and tend to degrade, especially in contact with organic material, it is not expected that any trace of the active substance would remain on food when it consumed.
Regarding accidental exposure through water, we believe that the high dilution would remove the conditions for classification.
The combination of a high level of dilution and a high reactivity and instability of the active substance makes any exposure through food highly unlikely.

Human exposure
Peracetic acid and hydrogen peroxide degrade very rapidly after application on surfaces and equipment. Moreover, both PAA and HP are not expected to be prone to residue formation following application. Therefore secondary exposure via food or drinking water is not expected. Due to the known high reactivity of the substances and also taking into account that equipment and surfaces are rinsed after completion of the disinfection procedures, no residues are thus expected in foodstuffs.

Animal exposure
Please note that all PT5 applications have been removed from the list of accepted uses.

SOPUROXIDcontains biocidal products intended to be used for the disinfection of surfaces that may come into contact with foodstuffs (meta SPC 1, 2, 3 and 4).
These products contain only substances that have local toxicological effects due to their physicochemical properties, therefore no systemic effects are expected. Local effects (oral exposure) only have to be assessed for the active substances peracetic acid (CAS: 79-21-0) and for hydrogen peroxide (CAS: 7722-84-1) as well as for any substance of concern (in this case, only sulphuric acid (CAS: 7664-93-9)).

Disinfection of surfaces and equipment which may enter into contact with food:
Since the products "Sopuroxid 5", "Sopuroxid 5C", "Sopuroxid 3.2", "Acidofoam CF", "Sopuroxid 15" and "Oxypur CS" (meta SPC 1, 2, 3 and 4) are intended to be used as surface disinfectants, cross-contamination of food is thus possible.
Use of peracetic acid (CAS: 79-21-0) does not lead to the presence of hazardous residues as it degrades into acetic acid and hydrogen peroxide. Peracetic acid forms an equilibrium in water solution with acetic acid and hydrogen peroxide (CAS: 7722-84-1). This well-known quick degradation of peracetic acid allows us to postulate that the concentration of peracetic acid on surfaces will be negligible after disinfection (contact time 15-60 min), especially in presence of organic matter.
Hydrogen peroxide (CAS: 7722-84-1) presents the same characteristics (a substance that tends to react quickly and non-specifically with the surrounding molecules by oxidoreduction reactions). It is therefore relevant to assume that the residue of hydrogen peroxide on surfaces will also be negligible after disinfection (contact time 15-60 min).

The human exposure to sulphuric acid (CAS: 7664-93-9) after dilution is limited. This substance has a maximum concentration of 0.31 % (meta SPC 1). In the absence of an oral exposure limit value, the derived SCL for dermal exposure was used (H314: C ≥ 15 % or H315: 5 % ≤ C < 15 %). The concentration of sulphuric acid is lower than the SCLs, meaning that no concern is expected for the human health.

Exposure associated with production, formulation and disposal of the biocidal product

Exposure during the production and formulation of the biocidal production is not considered within the scope of this assessment.
Exposure during the disposal of the biocidal product has been taken into consideration for the exposure assessment under "post-application" in earlier sections.

Aggregated exposure

Not relevant. The biocidal products of the Sopuroxid Biocidal Product Family should not be applied in combination with other biocidal products. Hence, no aggregated exposure was assessed.

Summary of exposure assessment

A summary of the exposure assessement for professional users is presented in the table below. Results reported in this table take into account the PPE or RPE measures needed for safe exposure.

Peracetic acid – dermal

Scenarios and values to be used in risk assessment (%)			
Scenario number	**Mixing & Loading**	**Application***	**Post-application**
1	15	0.15*	0.15
2	15	0.1	0.1
3	15	0.025	0.025
4a	15	0.15	0.0015
4b	15	0.15*	0.0015
4c	15	0.15	0.0015
4d	15	0.15	0.0015
4e	15	0.1	0.001
4f	15	0.1	0.001
5.	15	0.025	0.025
6a	5	0.15	0.0015
6b	5	0.15*	0.0015
6c	5	0.15*	0.0015
6d	5	0.15	0.0015
6e	5	0.15	0.0015
6f	5	0.15	0.0015
7	5	1	1

Peracetic acid – inhalation

Scenarios and values to be used in risk assessment (mg/m^3)			
Scenario number	**Mixing & Loading**	**Application**	**Post-application**
1	0.22	0.44*	0.025
2	0.006	Not relevant	Not relevant
3.	0.024	Not relevant	Not relevant
4a	0.22	0.16	Not relevant
4b	0.22	0.4*	Not relevant
4c	0.22	0.422	Not relevant
4d	0.22	0.086	Not relevant
4e	0.22	Not relevant	Not relevant
4f	0.22	0.45	Not relevant
5	0.22	0.375	0.375
6a	0.22	0.16	Not relevant
6b	0.22	0.4*	Not relevant

6c	0.22	0.32*	Not relevant
6d	0.22	0.13	Not relevant
6e	0.22	Not relevant	Not relevant
6f	0.22	0.26	Not relevant
7	0.22	Not relevant	Not relevant

Hydrogen peroxide - dermal

Scenarios and values to be used in risk assessment (%)			
Scenario number	**Mixing & Loading**	**Application**	**Post-application**
1	25	0.75*	0.75
2	25	0.5	0.5
3	25	0.125	0.125
4a	25	0.75	0.0075
4b	25	0.75*	0.0075
4c	25	0.5	0.005
4d	25	0.5	0.005
4e	25	0.75	0.0075
4f	25	0.5	0.005
5	25	0.125	0.125
6a	25	0.75	0.0075
6b	25	0.75*	0.0075
6c	25	0.75*	0.0075
6d	25	0.75	0.0075
6e	25	0.75	0.0075
6f	25	0.75	0.0075
7	25	5	5

Hydrogen peroxide - inhalation

Scenarios and values to be used in risk assessment (mg/m^3)			
Scenario number	**Mixing & Loading**	**Application**	**Post-application**
1	0.6	0.37*	0.02
2	0.007	Not relevant	Not relevant
3	0.027	Not relevant	Not relevant
4a	0.6	0.13	Not relevant

4b	0.6	0.35	Not relevant
4c	0.6	0.36	Not relevant
4d	0.6	0.071	Not relevant
4e	0.6	Not relevant	Not relevant
4f	0.6	0.375	Not relevant
5	0.6	0.31	0.3
6a	0.575	0.13	Not relevant
6b	0.575	0.35*	Not relevant
6c	0.575	0.275*	Not relevant
6d	0.575	0.11	Not relevant
6e	0.575	Not relevant	Not relevant
6f	0.575	0.22	Not relevant
7	0.7	Not relevant	Not relevant

2.2.6.3 Risk characterisation for human health

Risk for industrial and professional users

In the absence of systemic adverse effects, the risk characterisation is focused on local effects only. Hence, concentration rather than duration of exposure determines whether there is a risk.

- **Local effects - inhalation**

Besides the local irritation/corrosion related effect in the mucous membranes of the respiratory tract, peracetic acid was shown to cause sensory irritation of the respiratory tract. This effect may be caused by lower concentrations than that caused by the direct chemical reactivity observed also on the skin upon exposure. Both types of respiratory tract irritation are mainly concentration dependent and much less affected by duration of exposure. Similarly to dermal exposure, systemic risk assessment following inhalation exposure is not needed in the absence of systemic availability and systemic distribution.

The AEC values have been derived in the CAR for PAA and HP:

PAA	HP
AEC_{inhal} = 0.5 mg/m^3	AEC_{inhal} = 1.25 mg/m^3

***Scenario 1:** Manual treatment*

Peracetic acid:

Task	Local inhalation exposure (mg/m^3)		% AEC
	ART		
Mixing/loading	2.2	No RPE	440

	0.22	RPE APF = 10	44
Application	8.8	No RPE	1760
	0.44	RPE APF = 20	88
Post-application	0.025	No RPE	5

Hydrogen peroxide:

Task	Local inhalation exposure (mg/m³) ART		% AEC
Mixing/loading	2.4	No RPE	192
	0.6	RPE APF = 10	48
Application	7.4	No RPE	592
	0.37	RPE APF = 20	29.6
Post-application	0.02	No RPE	1.6

When assessing the worst-case exposure estimations generated with the ART model, it is clear that the AEC_{inhal} is exceeded during the mixing and loading and the application of the disinfectant, indicating the need for protective measures. To reduce the inhalation exposure below AEC_{inhal}, RPE with an AF of 20 is needed.

***Scenario 2:** CIP*

Peracetic acid:

Task	Local inhalation exposure (mg/m³) ART		% AEC
Mixing/loading	0.024	No RPE	4.8
	0.006	RPE APF = 4	1.2
Application	Not relevant	Not relevant	/
Post-application	Not relevant	Not relevant	/

Hydrogen peroxide:

Task	Local inhalation exposure (mg/m³) ART		% AEC
Mixing/loading	0.027	No RPE	2.16
	0.007	RPE APF = 4	0.56
Application	Not relevant	Not relevant	/
Post-application	Not relevant	Not relevant	/

For automated mixing and loading, the inhalation exposure is estimated to be very low.

***Scenario 3:** Water stream*

Peracetic acid:

Task	Local inhalation exposure (mg/m³) ART		% AEC
Mixing/loading	0.024	No RPE	4.8
Application	Not relevant	Not relevant	/
Post-application	Not relevant	Not relevant	/

Hydrogen peroxide:

Task	Local inhalation exposure (mg/m^3)		% AEC
	ART		
Mixing/loading	0.027	No RPE	2.16
Application	Not relevant	Not relevant	/
Post-application	Not relevant	Not relevant	/

For automated mixing and loading, the inhalation exposure is estimated to be very low.

Scenario 4a: *Spraying - Automated application with personal enclosure – application in all directions*

Peracetic acid:

Task	Local inhalation exposure (mg/m^3)		% AEC
	ART		
Mixing/loading	2.2	No RPE	440
	0.22	RPE APF = 10	44
Application	2.1	No RPE	420
	0. 0.21	RPE APF = 10	42
Post-application	Not relevant	Not relevant	/

Hydrogen peroxide:

Task	Local inhalation exposure (mg/m^3)		% AEC	
	ART			
Mixing/loading	2.4	No RPE	192	
	0.6	RPE APF = 10	19.2	
Application	2.9	No RPE	232	
	0.29	RPE APF = 10	23.2	
Post-application	Not relevant	Not relevant	/	

During mixing and loading, inhalation exposure to the concentrated is possible and exceeds the AEC_{inhal} set for both PAA and HP. However, if automated mixing and loading can be performed, this risk is reduced considerably. The operator is recommended to use RPE with APF = 10 during mixing and loading. During application, i.e. spraying in all directions, the operator performing the spraying activities is exposed to concentration below the AECinhal for both substances. Hence, no RPE is recommended during spraying activity (seen the use of a personal enclosure).

Scenario 4b: *Spraying - Automated or manual application without personal enclosure – application in all directions*

Peracetic acid:

Task	Local inhalation exposure (mg/m^3) ART		% AEC
Mixing/loading	2.2	No RPE	440
	0.22	RPE APF = 10	44
Application	16	No RPE	3200
	0.4	RPE APF = 40	80
Post-application	Not relevant	Not relevant	/

Hydrogen peroxide:

Task	Local inhalation exposure (mg/m^3) ART		% AEC
Mixing/loading	2.4	No RPE	192
	0.6	RPE APF = 4	120
Application	14	No RPE	720
	0.35	RPE APF = 40	28
Post-application	Not relevant	Not relevant	/

During mixing and loading, inhalation exposure to the concentrated is possible and exceeds the AEC_{inhal} set for bot PAA and HP. However, if automated mixing and loading can be performed, this risk is reduced considerably. Also during application, i.e. spraying in all directions, the operator performing the spraying activities is exposed to concentration far above the AEC_{inhal}. Therefore, protective measures should be taken, RPE with a APF of 40 is needed to ensure sufficient protection.

***Scenario 4c:** Spraying - Automated or manual application without personal enclosure – horizontal and downward application*

Peracetic acid:

Task	Local inhalation exposure (mg/m^3) ART		% AEC
Mixing/loading	2.2	No RPE	440
	0.22	RPE APF = 10	44
Application	8.5	No RPE	1700
	0.422	RPE APF = 20	84.4
Post-application	Not relevant	Not relevant	/

Hydrogen peroxide:

Task	Local inhalation exposure (mg/m^3) ART		% AEC
Mixing/loading	2.4	No RPE	192
	0.6	RPE APF = 4	4.8
Application	7.2	No RPE	576
	0.36	RPE APF = 20	28.8
Post-application	Not relevant	Not relevant	/

During mixing and loading, inhalation exposure to the concentrated is possible and exceeds the AEC_{inhal} set for bot PAA and HP. However, if automated mixing and loading can be performed, this risk is reduced considerably although not sufficient for peracetic acid. Also during application, i.e. spraying in horizontal and downward directions, the operator performing the spraying activities is exposed to concentration far above the AEC_{inhal}. Therefore, protective measures should be taken, RPE with a APF of 20 is needed to ensure sufficient protection.

Scenario 4d: *Spraying - Automated application with personal enclosure – horizontal and downward application*

Peracetic acid:

Task	Local inhalation exposure (mg/m^3) ART		% AEC
Mixing/loading	2.2	No RPE	440
	0.22	RPE APF = 10	44
Application	0.086	No RPE	17.2
Post-application	Not relevant	Not relevant	/

Hydrogen peroxide:

Task	Local inhalation exposure (mg/m^3) ART		% AEC
Mixing/loading	2.4	No RPE	192
	0.6	RPE APF = 4	48
Application	0.071	No RPE	5.68
Post-application	Not relevant	Not relevant	/

During mixing and loading, inhalation exposure to the concentrated is possible and exceeds the AEC_{inhal} set for both PAA and HP. Therefore RPE with APF 10 is required. However, if automated mixing and loading can be performed, this risk is reduced considerably although not sufficient for peracetic acid. Also during application, i.e. spraying in horizontal and downward directions, the operator performing the spraying activities is exposed to concentration below the AEC_{inhal} for both substances. Hence, no RPE is recommended during spraying activities. (seen the use of a personal enclosure).

Scenario 4e: *Spraying - Fully automated application not requiring the presence of operator*

Peracetic acid:

Task	Local inhalation exposure (mg/m^3) ART		% AEC
Mixing/loading	2.2	No RPE	440
	0.22	RPE APF = 10	44
Application	Not relevant	Not relevant	/
Post-application	Not relevant	Not relevant	/

Hydrogen peroxide:

Task	Local inhalation exposure (mg/m³) ART		% AEC
Mixing/loading	2.4	No RPE	192
	0.6	RPE APF = 4	48
Application	Not relevant	Not relevant	/
Post-application	Not relevant	Not relevant	/

During mixing and loading, inhalation exposure to the concentrated is possible and exceeds the AECinhal set for both PAA and HP. However, if automated mixing and loading can be performed, this risk is reduced considerably although not sufficient for peracetic acid. Therefore the use of RPE with APF 10 is recommended during mixing and loading.

***Scenario 4f:** Spraying - Manual application without personal enclosure – downward application – low application rate*

Peracetic acid:

Task	Local inhalation exposure (mg/m³) ART		% AEC
Mixing/loading	2.2	No RPE	440
	0.22	RPE APF = 10	44
Application	1.8	No RPE	360
	0.45	RPE APF = 4	90
Post-application	Not relevant	Not relevant	/

Hydrogen peroxide:

Task	Local inhalation exposure (mg/m³) ART		% AEC
Mixing/loading	2.4	No RPE	192
	0.6	RPE APF = 4	4.8
Application	1.5	No RPE	120
	0.375	RPE APF = 4	30
Post-application	Not relevant	Not relevant	/

During mixing and loading, inhalation exposure to the concentrated is possible and exceeds the AEC_{inhal} set for both PAA and HP. Also during application, i.e. spraying in downward direction, the professional performing the spraying activities is exposed to concentration above the AECinhal. Therefore, protective measures should be taken: RPE with a APF of 10 is needed to ensure sufficient protection during mixing and loading, while for application an APF of 4 is sufficient.

***Scenario 5:** Soaking*

Peracetic acid:

Task	Local inhalation exposure (mg/m³) ART		% AEC
Mixing/loading	2.2	No RPE	440

	0.22	RPE APF = 10	44
Application	3.9	No RPE	780
	0.39	RPE APF = 10	78
Post-application	3.9	No RPE	780
	0.39	RPE APF =10	78

Hydrogen peroxide:

Task	Local inhalation exposure (mg/m^3)		% AEC
	ART		
Mixing/loading	2.4	No RPE	192
	0.6	RPE APF = 4	48
Application	3.2	No RPE	256
	0.32	RPE APF = 10	25.6
Post-application	3.2	No RPE	256
	0.32	RPE APF = 10	25.6

During mixing and loading, inhalation exposure to the concentrated is possible and exceeds the AECinhal set for both PAA and HP. Therefore RPE with APF = 10 is required during mixing and loading. However, if automated mixing and loading can be performed, this risk is reduced considerably. Also during application and post-application, i.e. dipping or soaking equipment and removing the disinfected equipment from the solution again, the operator is exposed to concentration far above the AECinhal for PAA. Therefore, protective measures should be taken, RPE with a APF of 4 is needed to ensure sufficient protection.

Scenario 6a: *Foaming - Automated application with personal enclosure – application in all directions*

Peracetic acid:

Task	Local inhalation exposure (mg/m^3)		% AEC
	ART		
Mixing/loading	2.2	No RPE	440
	0.22	RPE APF = 10	44
Application	2.1	No RPE	420
	0. 0.21	RPE APF = 10	42
Post-application	Not relevant	Not relevant	/

Hydrogen peroxide:

Task	Local inhalation exposure (mg/m^3)		% AEC
	ART		
Mixing/loading	2.4	No RPE	192
	0.6	RPE APF = 10	19.2
Application	2.9	No RPE	232
	0.29	RPE APF = 10	23.2
Post-application	Not relevant	Not relevant	/

During the mixing and loading of the biocidal product into the foaming installation, inhalation exposure occurs and exceeds the AEC_{inhal} for PAA and HP. Therefore, RPE with APF 4 is recommended. If automated loading and pumping into the installation would be used, the exposure can be reduced considerably. During the foaming activity, i.e. foaming in all directions, the operator is not exposed to concentrations above the AEC_{inhal} thresholds, hence no RPE is recommended (due to the use of a personal enclosure).

Scenario 6b: *Foaming - Automated or manual application without personal enclosure – application in all directions*

Peracetic acid:

Task	Local inhalation exposure (mg/m³)		% AEC
	ART		
Mixing/loading	0.89	No RPE	178
	0.22	RPE APF = 4	44
Application	16	No RPE	3200
	0.4	RPE APF = 40	80
Post-application	Not relevant	Not relevant	/

Hydrogen peroxide:

Task	Local inhalation exposure (mg/m³)		% AEC
	ART		
Mixing/loading	2.3	No RPE	184
	0.575	RPE APF = 4	46
Application	14	No RPE	1120
	0.35	RPE APF = 40	70
Post-application	Not relevant	Not relevant	/

During the mixing and loading of the biocidal product into the foaming installation, inhalation exposure occurs and exceeds the AEC_{inhal} for PAA and HP. If automated loading and pumping into the installation would be used, the exposure can be reduced considerably. During the foaming activity, i.e. foaming in all directions, the operator can be exposed to concentrations above the AEC_{inhal} thresholds. To reduce the inhalation exposure protective equipment should be worn with an APF of 40.

Scenario 6c: *Foaming - Automated or manual application without personal enclosure – horizontal and downward application*

Peracetic acid:

Task	Local inhalation exposure (mg/m³)		% AEC
	ART		
Mixing/loading	0.89	No RPE	178
	0.22	RPE APF = 4	44
Application	13	No RPE	2600
	0.32	RPE APF = 40	64
Post-application	Not relevant	Not relevant	/

Hydrogen peroxide:

Task	Local inhalation exposure (mg/m³) ART		% AEC
Mixing/loading	2.3	No RPE	184
	0.575	RPE APF = 4	46
Application	11	No RPE	880
	0.275	RPE APF = 40	22
Post-application	Not relevant	Not relevant	/

During the mixing and loading of the biocidal product into the foaming installation, inhalation exposure occurs and exceeds the AEC_{inhal} for PAA and HP. If automated loading and pumping into the installation would be used, the exposure can be reduced considerably. During the foaming activity, i.e. foaming in horizontal and downward directions, the operator can be exposed to concentrations above the AEC_{inhal} thresholds. To reduce the inhalation exposure protective equipment should be worn with an APF of 40.

***Scenario 6d:** Foaming - Automated application with personal enclosure –horizontal and downward application*

Peracetic acid:

Task	Local inhalation exposure (mg/m³) ART		% AEC
Mixing/loading	0.89	No RPE	178
	0.22	RPE APF = 4	44
Application	0.13	No RPE	26
Post-application	Not relevant	Not relevant	/

Hydrogen peroxide:

Task	Local inhalation exposure (mg/m³) ART		% AEC
Mixing/loading	2.3	No RPE	184
	0.575	RPE APF = 4	46
Application	0.11	No RPE	8.8
Post-application	Not relevant	Not relevant	/

During the mixing and loading of the biocidal product into the foaming installation, inhalation exposure occurs and exceeds the AEC_{inhal} for PAA and HP. Therefore RPE with an APF of 4 should be worn during mixing and loading. If automated loading and pumping into the installation would be used, the exposure can be reduced considerably. During the foaming activity, i.e. foaming in horizontal and downward directions, the operator is not exposed to concentrations above the AECinhal thresholds, hence there is no recommendation to wear RPE (seen the use of a personal enclosure).

***Scenario 6e:** Foaming - Fully automated application not requiring the presence ofoperator*

Peracetic acid:

Task	Local inhalation exposure (mg/m³) ART		% AEC
Mixing/loading	0.89	No RPE	178
	0.22	RPE APF = 4	44
Application	Not relevant	Not relevant	/
Post-application	Not relevant	Not relevant	/

Hydrogen peroxide:

Task	Local inhalation exposure (mg/m³) ART		% AEC
Mixing/loading	2.3	No RPE	184
	0.575	RPE APF = 4	46
Application	Not relevant	Not relevant	/
Post-application	Not relevant	Not relevant	/

During the mixing and loading of the biocidal product into the foaming installation, inhalation exposure occurs and exceeds the AECinhal for PAA and HP. Therefore, the use of RPE with APF = 4 is recommended during mixing and loading. If automated loading and pumping into the installation would be used, the exposure can be reduced considerably.

***Scenario 6f:** Foaming - Manual application without personal enclosure – downward application – low application rate*

Peracetic acid:

Task	Local inhalation exposure (mg/m³) ART		% AEC
Mixing/loading	0.89	No RPE	178
	0.22	RPE APF = 4	44
Application	2.6	No RPE	520
	0.26	RPE APF = 10	52
Post-application	Not relevant	Not relevant	/

Hydrogen peroxide:

Task	Local inhalation exposure (mg/m³) ART		% AEC
Mixing/loading	2.4	No RPE	192
	0.6	RPE APF = 4	4.8
Application	2.2	No RPE	176
	0.22	RPE APF = 10	17.6
Post-application	Not relevant	Not relevant	/

During mixing and loading, inhalation exposure to the concentrated is possible and exceeds the AEC_{inhal} set for bot PAA and HP. Also during application, i.e. foam application in downward direction, the professional performing the spraying activities is exposed to concentration above the AEC_{inhal}. Therefore, protective measures should be taken: RPE with an APF of 10 is needed to ensure sufficient protection.

Scenario 7: *Fogging*

Peracetic acid:

Task	Local inhalation exposure (mg/m^3)		% AEC
	ART		
Mixing/loading	0.88	No RPE	176
	0.22	RPE APF = 4	44
Application	Not relevant	Not relevant	/
Post-application	Not relevant	Not relevant	/

Hydrogen peroxide:

Task	Local inhalation exposure (mg/m^3)		% AEC
	ART		
Mixing/loading	2.8	No RPE	224
	0.7	RPE APF = 4	56
Application	Not relevant	Not relevant	/
Post-application	Not relevant	Not relevant	/

During the mixing and loading of the concentrated product into the fogging installation, inhalation exposure exceeds the pre-set AECinhal thresholds. Therefore, the use of an RPE with APF = 4 is recommended. If instead of manual loading, automated loading and pumping is used, the exposure is reduced considerably. During the application the operator is not present hence no RPE are to be recommended.

List of the intended uses & acceptability of the scenario used to cover them

Meta SPC-1 (5% PAA) Meta SPC-4 (15% PAA)		Link to SCENARIO	Scenario (e.g. mixing/ loading)	Primary or secondary exposure - Description of scenario	Acceptability (Y/N)
PT2	Use #1.1/4.1: Disinfection of surfaces in industrial, public and health care areas - manual treatment (mopping)	N°1	Manual treatment	Primary Professional surface disinfection by wiping Models: ART	Y
	Use #1.2/4.2: Disinfection of surfaces in industrial, public and health care areas - manual treatment (spraying)	N°4f	Spraying – Manual application without personal enclosure – downward application – low application rate	Primary Professional equipment and surfaces disinfection by spraying liquid. Spraying requires human intervention. The professional does not have a personal enclosure. Models: ART	Y
	Use #1.3/4.3 : CIP in the pharmaceutical and cosmetic industry	N°2	CIP	Primary Cleaning in place, closed system Models: ART	Y
	Use #1.4/4.4 : Surface disinfection by spraying in greenhouses (in absence of plants - for general hygiene purpose only) – spraying with personal enclosure	N°4a	Spraying - Automated application with personal enclosure – application in all directions	Primary Professional surface disinfection by spraying liquid Spraying takes place using an automated system, human intervention with actual application of liquid but the professional is in a cabin (personal enclosure) without ventilation. Models: ART	Y
	Use #1.5/4.5 : Surface disinfection by spraying in greenhouses (in absence of plants - for general hygiene purpose only) – spraying without personal enclosure	N°4b	Spraying- Automated or manual application without personal enclosure – application in all directions	Primary Professional surface disinfection by spraying liquid Spraying is done automatically or manual in the presence of an operator. The professional does not have a personal enclosure. Models: ART	Y
	Use #1.6/4.6: Surface s disinfection of equipment by	N°5	Soaking	Primary Professional disinfection by use of an immersion	Y

	soaking (for agriculture & horticulture equipment – for general hygiene purpose only)			bath for dipping of equipment Models: ART	
	Use #1.7/4.7 : Disinfection of equipment and surfaces by spraying (e.g. agriculture & horticulture equipment - for general hygiene purpose only)	**N°4c**	Spraying – Automated or manual application without personal enclosure –horizontal and downward application	Primary Professional equipment disinfection by spraying liquid Spraying requires human intervention with actual application of the solution. The professional does not have a personal enclosure. Models: ART	**Y**
	Use #1.8/4.8 : Disinfection of equipment and surfaces by spraying (e.g. agriculture & horticulture – for general hygiene purpose only) - automatically	**N°4d**	Spraying - Automated application with personal enclosure –horizontal and downward application	Primary Professional equipment disinfection by spraying liquid Spraying does not require human intervention with actual application of the solution. The professional is in a personal enclosure without ventilation. Models: ART	**Y**
	Use #1.9/4.9 : Disinfection of equipment and surfaces by spraying (e.g. agriculture & horticulture – for general hygiene purpose only) – automatic spraying (closed room)	**N°4e**	Spraying - Fully automated application not requiring the presence of operator	Primary Professional equipment disinfection by spraying liquid Spraying does not require human intervention with actual application of the liquid. Spraying is done in a closed room. Models: ART	**Y**
PT3	Use #1.10/4.10 : Disinfection of animal housing by low-pressure manual spraying – spraying with personal enclosure	**N°4a**	Spraying - Automated application with personal enclosure – application in all directions	Primary Professional surface disinfection by spraying liquid Spraying takes place using an automated system, human intervention with actual application of liquid but the professional is in a cabin (personal enclosure) without ventilation. Models: ART	**Y**
	Use #1.11/4.11 : Disinfection of animal housing by low-pressure	**N°4b**	Spraying- Automated or manual	Primary	**Y**

	manual spraying – spraying without personal enclosure		application without personal enclosure – application in all directions	Professional surface disinfection by spraying liquid Spraying is done automatically or manually in the presence of an operator. The professional does not have a personal enclosure. Models: ART	
	Use #1.12/4.12 : Disinfection of boots in footbaths in animal housing /husbandries	**N°5**	Soaking	Primary Professional disinfection by use of an immersion bath for dipping of equipment Models: ART	**Y**
	Use #1.13/4.13 : Disinfection of equipment by dipping	**N°5**	Soaking	Primary Professional disinfection by use of an immersion bath for dipping of equipment Models: ART	**Y**
PT4	Use #1.14/4.14 : Automated spraying closed systems (aseptic filling and sterilization of crown corks, cheese moulds and food crates in the food and beverage industry) – automatic spraying (closed room)	**N°4e**	Spraying - Fully automated application not requiring the presence of operator	Primary Professional equipment disinfection by spraying liquid Spraying does not require human intervention with actual application of the liquid. Spraying is done in a closed room. Models: ART	**Y**
	Use #1.15/4.15 : Disinfection of equipment in the food and beverage industry by immersion	**N°5**	Soaking	Primary Professional disinfection by use of an immersion bath for dipping of equipment Models: ART	**Y**
	Use #1.16/4.16 : Disinfection of heat and ion exchangers, membrane filters and glass and PET bottles – CIP procedures	**N°2**	CIP	Primary Cleaning in place, closed system Models: ART	**Y**
	Use #1.17/4.17 : Disinfection of surfaces and equipment by low pressure spraying – spraying with personal enclosure	**N°4a**	Spraying - Automated application with personal enclosure – application in all directions	Primary Professional surface disinfection by spraying liquid Spraying takes place using an automated system, human intervention with actual application of liquid but the professional is in a	**Y**

				cabin (personal enclosure) without ventilation. Models: ART	
	Use #1.18/4.18 : Disinfection of surfaces and equipment by low pressure spraying – spraying without personal enclosure	**N°4b**	Spraying- Automated or manual application without personal enclosure – application in all directions	Primary Professional surface disinfection by spraying liquid Spraying is done automatically or manually in the presence of an operator. The professional does not have a personal enclosure. Models: ART	**Y**
	Use #1.19/4.19 : Disinfection of surfaces and equipment by low pressure spraying, manually	**N°4c**	Spraying – Automated or manual application without personal enclosure –horizontal and downward application	Primary Professional equipment disinfection by spraying liquid Spraying requires human intervention with actual application of the solution. The professional does not have a personal enclosure. Models: ART	**Y**
	Use #1.20/4.20 : Disinfection of surfaces and equipment by low pressure spraying, automatically	**N°4d**	Spraying - Automated application with personal enclosure –horizontal and downward application	Primary Professional equipment disinfection by spraying liquid Spraying does not require human intervention with actual application of the solution. The professional is in a personal enclosure without ventilation. Models: ART	**Y**
	Use #1.21/4.21 : Disinfection of surfaces and equipment by low pressure spraying – automatic spraying (closed room)	**N°4e**	Spraying - Fully automated application not requiring the presence of operator	Primary Professional equipment disinfection by spraying liquid Spraying does not require human intervention with actual application of the liquid. Spraying is done in a closed room. Models: ART	**Y**
	Use #1.22/4.22 : Disinfection of inner surfaces (pipelines, tanks, vessels, …) by CIP	**N°2**	CIP	Primary Cleaning in place, closed system Models: ART	**Y**

	Use #1.23/4.23 : Disinfection of water used for rinsing of recycled items during the washing process	**N°3**	Water stream	Primary Closed system Models: ART	**Y**
Meta SPC-2 with product ***SOPUROXID* 3.2 (3.2% PAA)** – by fogging		**Link to SCENARIO**	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure - Description of scenario**	**Acceptability (Y/N)**
PT2	Use #2.1 : Disinfection of surfaces and/or equipment in industrial, public and health care areas (pharmaceutical and cosmetic industry) – fogging	**N°7**	Fogging	Primary Professional surface disinfection by fogging Fogging takes place using an automated system, no operator present, no exposure assessment. After application, concentrations are assessed before entering into the room is allowed. Models: ART	**Y**
PT2	Use #2.2 : Disinfection of hard surfaces equipment by fogging (e.g. agriculture & horticulture equipment, in absence of plants – for general hygiene purpose only)	**N°7**			**Y**
PT3	Use #2.3 : Disinfection of animal h housing by fogging	**N°7**			**Y**
PT4	Use #2.4 : Disinfection of storage rooms with special device in storage cellar or room	**N°7**			**Y**
Meta SPC-3 (3.2% PAA) – by foaming		**Link to SCENARIO**	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure - Description of scenario**	**Acceptability (Y/N)**
PT2	Use #3.1 : Disinfection of surfaces in industrial, public and health care areas – foam application on surfaces	**N°6f**	Foaming – Manual application without personal enclosure – horizontal and downward application – low application rate	Primary Professional equipment and surfaces disinfection by foaming liquid. Foaming requires human intervention. The professional does not have a personal enclosure. Models: ART	**Y**
PT2	Use #3.2 : Disinfection of equipment and surfaces by foaming (e.g. agriculture & horticulture equipment – for general hygiene purpose only), manually	**N°6c**	Foaming - Automated or manual application without personal enclosure –horizontal and downward application	Primary Professional equipment disinfection by foaming liquid Foaming requires human intervention with actual application of foam. The professional does not have a personal enclosure. Models: ART	**Y**
PT2	Use #3.3 : Disinfection of surfaces and equipment by foaming (e.g. agriculture & horticulture	**N°6d**	Foaming - Automated application with personal enclosure –	Primary Professional equipment disinfection by foaming	**Y**

	equipment – for general hygiene purpose only) automatically		horizontal and downward application	liquid Foaming does not require human intervention with actual application of foam. The professional is in a personal enclosure without ventilation. Models: ART	
	Use #3.4 : Disinfection of surface and equipment by foaming (e.g. agriculture & horticulture equipment – for general hygiene purpose only) – automatic foaming (closed room)	**N°6e**	Foaming - Fully automated application not requiring the presence of operator	Primary Professional equipment disinfection by foaming liquid Foaming does not require human intervention with actual application of foam. Foaming is done in a closed room. Models: ART	**Y**
PT3	Use #3.5 : Disinfection of animal housing by foaming – foaming with personal enclosure	**N°6a**	Foaming - Automated application with personal enclosure – application in all directions	Primary Professional surface disinfection by foaming liquid Foaming takes place using an automated system, human intervention with actual application of foam but the professional is in a cabin (personal enclosure) without ventilation Models: ART	**Y**
	Use #3.6 : Disinfection of animal housing by foaming – foaming without personal enclosure	**N°6b**	Foaming - Automated or manual application without personal enclosure – application in all directions	Primary Professional surface disinfection by foaming liquid Foaming requires human intervention with actual application of foam. The professional does not have a personal enclosure. Models: ART	**Y**
PT4	Use #3.7 : Disinfection of surfaces by foaming with personal enclosure	**N°6a**	Foaming - Automated application with personal enclosure – application in all directions	Primary Professional surface disinfection by foaming liquid Foaming takes place using an automated system, human intervention with actual application of foam but the professional is in a cabin (personal enclosure) without ventilation	**Y**

				Models: ART	
	Use #3.8 : Disinfection of surfaces by foaming without personal enclosure	**N°6b**	Foaming - Automated or manual application without personal enclosure – application in all directions	Primary Professional surface disinfection by foaming liquid Foaming requires human intervention with actual application of foam. The professional does not have a personal enclosure. Models: ART	**Y**

➢ **Local effects - dermal**

The mode of action of peracetic acid is characterised by local irritation/corrosion and oxidation resulting in fast degradation of both peracetic acid and hydrogen peroxide. The underlying mechanism of toxicity via dermal route is considered to be direct chemical reactivity without prior metabolism. It seems that peracetic acid and hydrogen peroxide do not become systemically available upon dermal contact. For this reason, the observed toxic effects are mainly limited to the site of first contact. Systemic risk assessment following dermal exposure is not needed in the absence of systemic availability and systemic distribution. Due to the underlying mechanism and chemical nature of the substance, the observed dermal irritation/corrosion is mainly concentration dependent and less affected by duration of exposure.

The $NOEC_{dermal}$ values have been derived in the CAR of PAA and HP:

PAA	HP
$NOEC_{dermal}$ = 0.10 %	$NOEC_{dermal}$ = not relevant as all applied concentrations < 35% threshold for classification as skin irritant

Due to the classification of the meta-SPC of the family as Sin corr. 1A, all products of the family Sopuroxid fit the conditions to be considered as **very high risk** for local effects.

***Scenario 1:** Manual treatment*

Peracetic acid:

Task	Local dermal exposure	% $NOEC_{dermal}$
	Maximum concentration (%)	
Mixing/loading	15	15000
Application	0.15	150
Post-application	0.15	150

Hydrogen peroxide:

Task	Local dermal exposure	% $NOEC_{dermal}$
	Maximum concentration (%)	
Mixing/loading	25	71
Application	0.75	2
Post-application	0.75	2

During the mixing and loading of the concentrated product (15 % PAA and 25 % HP), the $NOEC_{dermal}$ is exceeded for PAA, but not for HP. As there is potential dermal contact, PPE (chemical resistant gloves, acid-proof protective coverall, safety glasses and/or face shield) are to be worn to prevent direct dermal contact. This is applicable due to the immediate and direct effect of these BP’s as being corrosive in undiluted form. Accidental spillages to the bare skin should be immediately washed off and the contaminated skin rinsed with water, if this happens. Therefore, residues of spillages remaining on bare skin are not expected and the use of PPE is assumed for direct handling of the biocidal product.

Assessment of the acceptability of the risk for professional users:

Very High Hazard				
Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE
Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is a such concentration that the product can't be considered as being classified as H314).	Manual Mixing & Loading is the principal step with risk of exposure to the concentrated product.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

Given the duration of the use with the concentrated product, the existence of training provided to all users and the extensive use of PPE, the risk is deemed acceptable.

Scenario 2: *CIP*

Peracetic acid:

Task	Local dermal exposure	% $NOEC_{dermal}$
	Maximum concentration (%)	
Mixing/loading	15	15000
Application	0.1	100
Post-application	0.1	100

Hydrogen peroxide:

Task	Local dermal exposure	% $NOEC_{dermal}$
	Maximum concentration (%)	
Mixing/loading	25	71
Application	0.5	1.4
Post-application	0.5	1.4

During the mixing and loading of the concentrated product (15 % PAA and 25 % HP), during application (i.e. the CIP operation) and post-application (i.e. draining of cleaning solutions ans handling of empty containers), the $NOEC_{dermal}$ is exceeded for PAA, but not for HP. As there is potential dermal contact, PPE (chemical resistant gloves, acid-proof protective coverall, safety glasses and/or face shield) are to be worn to prevent direct dermal contact. This is applicable due to the immediate and direct effect of these BP's as being corrosive in undiluted form. Moreover, wearing of safety goggles is advised due to the classification of HP as 'risk of serious damage to the eyes' at a concentration of 25%.

Assessment of the acceptability of the risk for professional users:

Very High Hazard				
Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE

Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is at such concentration that the product can't be considered as being classified as H314).	Automatic Mixing & Loading is the principal step with risk of exposure to the concentrated product. As the process is automatic and takes place in a CIP installation, it is considered that there is a very high level of containment.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

Given the duration of the use with the concentrated product, the very high level of containment, the existence of training provided to all users and the extensive use of PPE, the risk is deemed acceptable.

***Scenario 3:** Water stream*

Peracetic acid:

Task	Local dermal exposure Maximum concentration (%)	% NOEC$_{dermal}$
Mixing/loading	15	15000
Application	0.025	25
Post-application	0.025	25

Hydrogen peroxide:

Task	Local dermal exposure Maximum concentration (%)	% NOEC$_{dermal}$
Mixing/loading	25	71
Application	0.125	0.36
Post-application	0.125	0.36

During the mixing and loading of the concentrated product (15 % PAA and 25 % HP), during application and post-application (i.e. draining of cleaning solutions ans handling of empty containers), the NOEC$_{dermal}$ is exceeded for PAA, but not for HP. As there is potential dermal contact, PPE (chemical resistant gloves, acid-proof protective coverall, safety glasses and/or face shield) are to be worn to prevent direct dermal contact. This is applicable due to the immediate and direct effect of these BP's as being corrosive in undiluted form. Moreover, wearing of safety goggles is advised due to the classification of HP as 'risk of serious damage to the eyes' at a concentration of 25%.

Assessment of the acceptability of the risk for professional users:

Very High Hazard

Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE
Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is a such concentration that the product can't be considered as being classified as H314).	Automated Mixing & Loading is the principal step with risk of exposure to the concentrated product. As the process is automatic and takes place in an installation, it is considered that there is a very high level of containment.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

Given the duration of the use with the concentrated product, the very high level of containment, the existence of training provided to all users and the extensive use of PPE, the risk is deemed acceptable.

Scenario 4a: *Spraying - Automated application with personal enclosure – application in all directions*

Peracetic acid:

Task	Local dermal exposure Maximum concentration (%)	% NOEC$_{dermal}$
Mixing/loading	15	15000
Application	0.15	150
Post-application	0.0015	1.5

Hydrogen peroxide:

Task	Local dermal exposure Maximum concentration (%)	% NOEC$_{dermal}$
Mixing/loading	25	71
Application	0.75	2.1
Post-application	0.0075	0.021

Dermal exposure during mixing and loading of the concentrated products and the application of the diluted product by spraying in all directions can result in dermal exposure exceeding the NOEC$_{dermal}$ value for PAA. As there is potential dermal contact, PPE (chemical resistant gloves, acid-proof protective coverall, safety glasses and/or face shield) are to be worn to prevent direct dermal contact. This is applicable due to the immediate and direct effect of these BP's as being corrosive in undiluted form. Moreover, wearing of safety goggles is advised due to the classification of HP as 'risk of serious damage to the eyes' at a concentration of 25%.

Assessment of the acceptability of the risk for professional users:

Very High Hazard				
Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE
Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is a such concentration that the product can't be considered as being classified as H314).	Manual Mixing & Loading is the principal step with risk of exposure to the concentrated product. As the process is automatic and takes place in an installation, it is considered that there is a very high level of containment.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

Given the duration of the use with the concentrated product, the very high level of containment, the existence of training provided to all users and the extensive use of PPE, the risk is deemed acceptable.

Scenario 4b: *Spraying - Automated or manual application without personal enclosure – application in all directions*

Peracetic acid:

Task	**Local dermal exposure**	**% NOEC$_{dermal}$**
	Maximum concentration (%)	
Mixing/loading	15	15000
Application	0.15	150
Post-application	0.0015	1.5

Hydrogen peroxide:

Task	**Local dermal exposure**	**% NOEC$_{dermal}$**
	Maximum concentration (%)	
Mixing/loading	25	71
Application	0.75	2.1
Post-application	0.0075	0.021

Dermal exposure during mixing and loading of the concentrated products and the application of the diluted product by spraying in all directions can result in dermal exposure exceeding the NOEC$_{dermal}$ value for PAA. As there is potential dermal contact, PPE (chemical resistant gloves, acid-proof protective coverall, safety glasses and/or face shield) are to be worn to prevent direct dermal contact. This is applicable due to the immediate and direct effect of these BP's as being corrosive in undiluted form. Moreover, wearing of safety goggles is advised due to the classification of HP as 'risk of serious damage to the eyes' at a concentration of 25%.

Assessment of the acceptability of the risk for professional users:

Very High Hazard				
Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE
Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is a such concentration that the product can't be considered as being classified as H314).	Manual Mixing & Loading is the principal step with risk of exposure to the concentrated product. As the process is automatic and takes place in an installation, it is considered that there is a very high level of containment.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

Given the duration of the use with the concentrated product, the very high level of containment, the existence of training provided to all users and the extensive use of PPE, the risk is deemed acceptable.

***Scenario 4c:** Spraying - Automated or manual application without personal enclosure – horizontal and downward application*

Peracetic acid:

Task	**Local dermal exposure** **Maximum concentration (%)**	**% NOEC$_{dermal}$**
Mixing/loading	5	5000
Application	0.1	100
Post-application	0.001	1

Hydrogen peroxide:

Task	**Local dermal exposure** **Maximum concentration (%)**	**% NOEC$_{dermal}$**
Mixing/loading	25	71
Application	0.5	1.4
Post-application	0.005	0.014

Dermal exposure during mixing and loading of the concentrated products and the application of the diluted product by spraying in horizontal and downward directions can result in dermal exposure exceeding the NOEC$_{dermal}$ value for PAA. As there is potential dermal contact, PPE (chemical resistant gloves, acid-proof protective coverall, safety glasses and/or face shield) are to be worn to prevent direct dermal contact. This is applicable due to the immediate and direct effect of these BP's as being corrosive in undiluted form. Moreover, wearing of safety goggles is advised due to the classification of HP as 'risk of serious damage to the eyes' at a concentration of 25%.

Assessment of the acceptability of the risk for professional users:

Very High Hazard				
Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE
Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is a such concentration that the product can't be considered as being classified as H314).	Manual Mixing & Loading is the principal step with risk of exposure to the concentrated product. As the process is automatic and takes place in an installation, it is considered that there is a very high level of containment.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

Given the duration of the use with the concentrated product, the very high level of containment, the existence of training provided to all users and the extensive use of PPE, the risk is deemed acceptable.

Scenario 4d: *Spraying - Automated application with personal enclosure – horizontal and downward application*

Peracetic acid:

Task	**Local dermal exposure**	**% NOEC$_{dermal}$**
	Maximum concentration (%)	
Mixing/loading	5	5000
Application	0.1	100
Post-application	0.001	1

Hydrogen peroxide:

Task	**Local dermal exposure**	**% NOEC$_{dermal}$**
	Maximum concentration (%)	
Mixing/loading	25	71
Application	0.5	1.4
Post-application	0.005	0.014

Dermal exposure during mixing and loading of the concentrated products and the application of the diluted product by spraying in horizontal and downward directions can result in dermal exposure exceeding the NOEC$_{dermal}$ value for PAA. As there is potential dermal contact, PPE (chemical resistant gloves, acid-proof protective coverall, safety glasses and/or face shield) are to be worn to prevent direct dermal contact. This is applicable due to the immediate and direct effect of these BP's as being corrosive in undiluted form. Moreover, wearing of safety goggles is advised due to the classification of HP as 'risk of serious damage to the eyes' at a concentration of 25%.

Assessment of the acceptability of the risk for professional users:

Very High Hazard				
Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE
Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is a such concentration that the product can't be considered as being classified as H314).	Manual Mixing & Loading is the principal step with risk of exposure to the concentrated product. As the process is automatic and takes place in an installation, it is considered that there is a very high level of containment.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

Given the duration of the use with the concentrated product, the very high level of containment, the existence of training provided to all users and the extensive use of PPE, the risk is deemed acceptable.

Scenario 4e: *Spraying - Fully automated application not requiring the presence of operator*

Peracetic acid:

Task	Local dermal exposure	% $NOEC_{dermal}$
	Maximum concentration (%)	
Mixing/loading	5	5000
Application	0.15	150
Post-application	0.0015	1.5

Hydrogen peroxide:

Task	Local dermal exposure	% $NOEC_{dermal}$
	Maximum concentration (%)	
Mixing/loading	25	71
Application	0.75	2.1
Post-application	0.0075	0.021

Dermal exposure during mixing and loading of the concentrated products and the application of the diluted product by spraying can result in dermal exposure exceeding the $NOEC_{dermal}$ value for PAA. As there is potential dermal contact, PPE (chemical resistant gloves, acid-proof protective coverall, safety glasses and/or face shield) are to be worn to prevent direct dermal contact. This is applicable due to the immediate and direct effect of these BP's as being corrosive in undiluted form. Moreover, wearing of safety goggles is advised due to the classification of HP as 'risk of serious damage to the eyes' at a concentration of 25%.

Assessment of the acceptability of the risk for professional users:

Very High Hazard				
Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE
Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is a such concentration that the product can't be considered as being classified as H314).	Manual Mixing & Loading is the principal step with risk of exposure to the concentrated product. As the process is automatic and takes place in an installation, it is considered that there is a very high level of containment.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

Given the duration of the use with the concentrated product, the very high level of containment, the existence of training provided to all users and the extensive use of PPE, the risk is deemed acceptable.

Scenario 4f: *Spraying - Manual application without personal enclosure – downward application – low application rate*

Peracetic acid:

Task	Local dermal exposure Maximum concentration (%)	% $NOEC_{dermal}$
Mixing/loading	5	5000
Application	0.1	100
Post-application	0.001	1

Hydrogen peroxide:

Task	Local dermal exposure Maximum concentration (%)	% $NOEC_{dermal}$
Mixing/loading	25	71
Application	0.5	1.4
Post-application	0.005	0.014

Dermal exposure during mixing and loading of the concentrated products and the application of the diluted product by spraying in horizontal and downward directions can result in dermal exposure exceeding the $NOEC_{dermal}$ value for PAA. As there is potential dermal contact, PPE (chemical resistant gloves, acid-proof protective coverall, safety glasses and/or face shield) are to be worn to prevent direct dermal contact. This is applicable due to the immediate and direct effect of these BP's as being corrosive in undiluted form. Moreover, wearing of safety goggles is advised due to the classification of HP as 'risk of serious damage to the eyes' at a concentration of 25%.

Assessment of the acceptability of the risk for professional users:

Very High Hazard				
Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE
Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is a such concentration that the product can't be considered as being classified as H314).	Manual Mixing & Loading is the principal step with risk of exposure to the concentrated product. As the process is automatic and takes place in an installation, it is considered that there is a very high level of containment.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

Given the duration of the use with the concentrated product, the very high level of containment, the existence of training provided to all users and the extensive use of PPE, the risk is deemed acceptable.

Scenario 5: *Soaking*

Peracetic acid:

Task	**Local dermal exposure** **Maximum concentration (%)**	**% $NOEC_{dermal}$**
Mixing/loading	15	15000
Application	0.025	25
Post-application	0.025	25

Hydrogen peroxide:

Task	**Local dermal exposure** **Maximum concentration (%)**	**% $NOEC_{dermal}$**
Mixing/loading	25	71
Application	0.125	0.36
Post-application	0.125	0.36

Only during mixing and loading, the dermal exposure exceeds the $NOEC_{dermal}$ value for PAA. Hence, protective measures should be taken when handling the concentrated products. This is applicable due to the immediate and direct effect of these BP's as being corrosive in undiluted form. Moreover, wearing of safety goggles is advised due to the classification of HP as 'risk of serious damage to the eyes' at a concentration of 25%.

Assessment of the acceptability of the risk for professional users:

Very High Hazard				
Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE
Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is a such concentration that the product can't be considered as being classified as H314).	Manual Mixing & Loading is the principal step with risk of exposure to the concentrated product. As the process is automatic and takes place in an installation, it is considered that there is a very high level of containment.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

Given the duration of the use with the concentrated product, the very high level of containment, the existence of training provided to all users and the extensive use of PPE, the risk is deemed acceptable.

***Scenario 6a:** Foaming - Automated application with personal enclosure – application in all directions*

Peracetic acid:

Task	Local dermal exposure Maximum concentration (%)	% $NOEC_{dermal}$
Mixing/loading	5	50000
Application	0.15	150
Post-application	0.0015	1.5

Hydrogen peroxide:

Task	Local dermal exposure	% $NOEC_{dermal}$
	Maximum concentration (%)	
Mixing/loading	25	71
Application	0.75	2.1
Post-application	0.0075	0.021

During mixing and loading as well as during the foaming activity, which is conducted in all directions, the dermal exposure exceeds the $NOEC_{dermal}$ value for PAA. Hence, protective measures should be taken when handling the concentrated products and when performing the disinfection by foaming. Moreover, wearing of safety goggles is advised due to the classification of HP as 'risk of serious damage to the eyes' at a concentration of 25%.

Assessment of the acceptability of the risk for professional users:

Very High Hazard				
Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE
Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is a such concentration that the product can't be considered as being classified as H314).	Manual Mixing & Loading is the principal step with risk of exposure to the concentrated product. As the process is automatic and takes place in an installation, it is considered that there is a very high level of containment.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

Given the duration of the use with the concentrated product, the very high level of containment, the existence of training provided to all users and the extensive use of PPE, the risk is deemed acceptable.

Scenario 6b: *Foaming - Automated or manual application without personal enclosure – application in all directions*

Peracetic acid:

Task	Local dermal exposure	% $NOEC_{dermal}$
	Maximum concentration (%)	
Mixing/loading	5	50000
Application	0.15	150
Post-application	0.0015	1.5

Hydrogen peroxide:

Task	Local dermal exposure	% NOEC$_{dermal}$
	Maximum concentration (%)	
Mixing/loading	25	71
Application	0.75	2.1
Post-application	0.0075	0.021

During mixing and loading as well as during the foaming activity, which is conducted in all directions, the dermal exposure exceeds the NOEC$_{dermal}$ value for PAA. Hence, protective measures should be taken when handling the concentrated products and when performing the disinfection by foaming. Moreover, wearing of safety goggles is advised due to the classification of HP as 'risk of serious damage to the eyes' at a concentration of 25%.

Assessment of the acceptability of the risk for professional users:

Very High Hazard				
Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE
Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is a such concentration that the product can't be considered as being classified as H314).	Manual Mixing & Loading is the principal step with risk of exposure to the concentrated product. As the process is automatic and takes place in an installation, it is considered that there is a very high level of containment.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

Given the duration of the use with the concentrated product, the very high level of containment, the existence of training provided to all users and the extensive use of PPE, the risk is deemed acceptable.

***Scenario 6c:** Foaming - Automated or manual application without personal enclosure – horizontal and downward application*

Peracetic acid:

Task	Local dermal exposure	% NOEC$_{dermal}$
	Maximum concentration (%)	
Mixing/loading	5	50000
Application	0.15	150
Post-application	0.0015	1.5

Hydrogen peroxide:

Task	Local dermal exposure	% NOEC$_{dermal}$
	Maximum concentration (%)	
Mixing/loading	25	71
Application	0.75	2.1
Post-application	0.0075	0.021

During mixing and loading as well as during the foaming activity, which is conducted in horizontal and downward direction, the dermal exposure exceeds the NOEC$_{dermal}$ value for PAA. Hence, protective measures should be taken when handling the concentrated products and when performing the disinfection by foaming. Moreover, wearing of safety goggles is advised due to the classification of HP as 'risk of serious damage to the eyes' at a concentration of 25%.
Assessment of the acceptability of the risk for professional users:

Very High Hazard				
Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE
Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is a such concentration that the product can't be considered as being classified as H314).	Manual Mixing & Loading is the principal step with risk of exposure to the concentrated product. As the process is automatic and takes place in an installation, it is considered that there is a very high level of containment.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

Given the duration of the use with the concentrated product, the very high level of containment, the existence of training provided to all users and the extensive use of PPE, the risk is deemed acceptable.

***Scenario 6d:** Foaming - Automated application with personal enclosure –horizontal and downward application*

Peracetic acid:

Task	Local dermal exposure	% NOEC$_{dermal}$
	Maximum concentration (%)	
Mixing/loading	5	50000
Application	0.15	150
Post-application	0.0015	1.5

Hydrogen peroxide:

Task	Local dermal exposure	% $NOEC_{dermal}$
	Maximum concentration (%)	
Mixing/loading	25	71
Application	0.75	2.1
Post-application	0.0075	0.021

During mixing and loading as well as during the foaming activity, which is conducted in horizontal and downward direction, the dermal exposure exceeds the $NOEC_{dermal}$ value for PAA. Hence, protective measures should be taken when handling the concentrated products and when performing the disinfection by foaming. Moreover, wearing of safety goggles is advised due to the classification of HP as 'risk of serious damage to the eyes' at a concentration of 25%.

Assessment of the acceptability of the risk for professional users:

Very High Hazard				
Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE
Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is a such concentration that the product can't be considered as being classified as H314).	Manual Mixing & Loading is the principal step with risk of exposure to the concentrated product. As the process is automatic and takes place in an installation, it is considered that there is a very high level of containment.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

Given the duration of the use with the concentrated product, the very high level of containment, the existence of training provided to all users and the extensive use of PPE, the risk is deemed acceptable.

***Scenario 6e:** Foaming - Fully automated application not requiring the presence of operator*

Peracetic acid:

Task	Local dermal exposure	% $NOEC_{dermal}$
	Maximum concentration (%)	
Mixing/loading	5	50000
Application	0.15	150
Post-application	0.0015	1.5

Hydrogen peroxide:

Task	Local dermal exposure	% NOEC$_{dermal}$
	Maximum concentration (%)	
Mixing/loading	25	71
Application	0.75	2.1
Post-application	0.0075	0.021

During mixing and loading as well as during the foaming activity, the dermal exposure exceeds the NOEC$_{dermal}$ value for PAA. Hence, protective measures should be taken when handling the concentrated products and when performing the disinfection by foaming. Moreover, wearing of safety goggles is advised due to the classification of HP as 'risk of serious damage to the eyes' at a concentration of 25%.

Assessment of the acceptability of the risk for professional users:

Very High Hazard				
Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE
Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is a such concentration that the product can't be considered as being classified as H314).	Manual Mixing & Loading is the principal step with risk of exposure to the concentrated product. As the process is automatic and takes place in an installation, it is considered that there is a very high level of containment.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

Given the duration of the use with the concentrated product, the very high level of containment, the existence of training provided to all users and the extensive use of PPE, the risk is deemed acceptable.

***Scenario 6f:** Foaming - Automated application with personal enclosure –horizontal and downward application*

Peracetic acid:

Task	Local dermal exposure	% NOEC$_{dermal}$
	Maximum concentration (%)	
Mixing/loading	5	5000
Application	0.15	150
Post-application	0.0015	1.5

Hydrogen peroxide:

Task	Local dermal exposure	% NOEC$_{dermal}$

	Maximum concentration (%)	
Mixing/loading	25	71
Application	0.75	2.1
Post-application	0.075	0.021

Dermal exposure during mixing and loading of the concentrated products and the application of the diluted product by spraying in horizontal and downward directions can result in dermal exposure exceeding the $NOEC_{dermal}$ value for PAA. As there is potential dermal contact, PPE (chemical resistant gloves, acid-proof protective coverall, safety glasses and/or face shield) are to be worn to prevent direct dermal contact. This is applicable due to the immediate and direct effect of these BP's as being corrosive in undiluted form. Moreover, wearing of safety goggles is advised due to the classification of HP as 'risk of serious damage to the eyes' at a concentration of 25%.

Assessment of the acceptability of the risk for professional users:

Very High Hazard				
Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE
Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is a such concentration that the product can't be considered as being classified as H314).	Manual Mixing & Loading is the principal step with risk of exposure to the concentrated product. As the process is automatic and takes place in an installation, it is considered that there is a very high level of containment.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

Given the duration of the use with the concentrated product, the very high level of containment, the existence of training provided to all users and the extensive use of PPE, the risk is deemed acceptable.

***Scenario 7:** Fogging*

Peracetic acid:

Task	Local dermal exposure Maximum concentration (%)	% $NOEC_{dermal}$
Mixing/loading	5	50000
Application	1	1000
Post-application	1	1000

Hydrogen peroxide:

Task	Local dermal exposure	% NOEC$_{dermal}$
	Maximum concentration (%)	
Mixing/loading	25	71
Application	5	14
Post-application	5	14

During mixing and loading, during fogging (application) and after the fogging (post-application), dermal exposure exceeds the NOEC$_{dermal}$ value for PAA. Hence, protective measures should be taken. Moreover, wearing of safety goggles is advised due to the classification of HP as 'risk of serious damage to the eyes' at a concentration of 25%.

Assessment of the acceptability of the risk for professional users:

Very High Hazard				
Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE
Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is a such concentration that the product can't be considered as being classified as H314).	Manual Mixing & Loading is the principal step with risk of exposure to the concentrated product. As the process is automatic and takes place in an installation, it is considered that there is a very high level of containment.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

Given the duration of the use with the concentrated product, the very high level of containment, the existence of training provided to all users and the extensive use of PPE, the risk is deemed acceptable.

Risk for non-professional users

No application related to non-professional use were identified, therefore the risk assessment for non-professional users is not further assessed.

Risk for the general public

- **Local effects - inhalation**

The AEC values have been derived in the CAR for PAA and HP:

PAA	HP
AEC$_{inhal}$ = 0.5 mg/m^3	AEC$_{inhal}$ = 1.25 mg/m^3

Unlike for professionals, no protective measures can be assumed for the general public (bystanders). Therefore other measures are taken to prevent exposure.

During the cleaning and disinfection of surfaces in public and health care areas, exposure to non-users or bystanders passing by is possible. To prevent the exposure of non-users or bystanders, warning signs informing the non-professional that disinfection is ongoing and that they should not pass the disinfected area. Only when the air concentrations are reduced below the AEC_{inhal} levels, passage is allowed. As a consequence, passage despite the warning signs is considered as accidental and not within the scope of this risk assessment.

Following disinfection of areas such as animal housing, greenhouses or storage rooms by spraying, foaming or fogging, premises are opened again for ventilation. Warning signs should be put at the entrance so that the non-professional does not enter the premis without appropriate protective measures. Only when the concentrations of PAA and HP have dropped below the AEC_{inhal} levels, warning signs can be removed. Entering the premises without due consideration of the warning signs is considered as accidental exposure, and is therefore not assessed.

- **Local effects – dermal**

Dermal exposure of the general public is considered to be not relevant due to the chemical properties of peracetic acid and hydrogen peroxide. Both peracetic acid and hydrogen peroxide are highly unstable and will rapidly degrade at the site of first contact which effectively further reduces the possibility of any residual concentrations. Damaged skin could potentially be more prone to the adverse effects of residual peracetic acid but even this scenario is speculative due to the high reactivity and rapid degradation.

Risk for consumers via residues in food

The risks for consumers via food residues is considered not relevant due to the rapid degradation of PAA and HP.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Based on the feedback of the Finnish RMS, *"there is no agreed way to present combined exposure for local effects from many substances and therefore the %-AEC values for PAA and HP are not to be summed up".* Consequently, also for this SOPUROXID Family application, the sum of the risks was not considered applicable.

2.2.7 Risk for animal health

Exposure and risk assessment for animals have not been performed.
However, the following RMM should be added "Only treatment of empty animal housings. Re-entry of animals only after adequate ventilation and when surfaces are dried".

2.2.8 Risk assessment for the environment

The following assessment covers SOPUROXIDgrouping a range of products used as disinfectants not intended for direct application to humans or animals (PT 2), disinfectant for veterinary hygiene (PT 3) and disinfectants in food and feed areas (PT4). SOPUROXIDis divided in four Meta SPC (please refer to 2.1.2 Product (family) composition and formulation and Table "Overview of the maximum concentration of the active substance and co-formulants in the meta SPC of the SOPUROXID Family" in the Confidential Annex). The products of SOPUROXID Family contain one active substance, the Peracetic acid (PAA), with a concentration ranging from 3.2% to 15%. They also contain Hydrogen peroxide at a concentration ranging from 16.0 to 23.5 %. Indeed Peracetic acid is formed by the reaction between acetic acid and Hydrogen peroxide in presence of a strong acid (sulfuric acid) as catalyst:
$H_2O_2 + CH_3CO_2H \rightleftharpoons CH_3CO_3H + H_2O$

Hydrogen peroxide has therefore an active substance function but is not to be regarded as an active substance according to the 20th meeting of the Biocidal Products Committee (BPC)[7]. However it is still considered for the exposure and risk assessment for the environment (please refer to the chapter "2.2.2. Environmental Risk Assessment" of the CAR of PAA).

Although Meta SPC1 and 4 and meta SPC2 and 3 have the same concentration in active substance, their product do not always have the same use (e.g. fogging and foaming for meta SCP2 and 3, respectively). Therefore the risk assessment have been performed according to the use of the products.

2.2.8.1 Effects assessment on the environment

All data used for the effect assessment of SOPUROXIDare based on the available information on the active substances Peracetic acid and Hydrogen peroxide, such as they are presented in their respective CAR.
In addition five new tests on the products SOPUROXID 5 (5% of PAA , meta SPC 1) and ACIDOFOAM CF (3.2% of PAA, meta SPC 3) have been submitted by the applicant as supporting information for the effect on aquatic organisms (please refer to the paragraph "Further Ecotoxicological studies" below).

An overview of the physico-chemical characteristics and ecotoxicity data of PAA and Hydrogen peroxide, taken from their respective CAR, is summarised below.

<u>Environmental fate and behaviour</u>

Environmental fate and behaviour of Peracetic acid and Hydrogen peroxide are summarised below. All data are available in their respective CAR.

- **Peracetic acid**

7 Minutes of the 20th meeting of the Biocidal Products Committee (BPC) held on 27 April 2017. BPC-M-20-2017, 16 June 2017

Peracetic acid (PAA) decomposes rapidly in all environmental compartments, i.e. in sewage treatment plant, surface water, soil and air. The following processes are involved in the decomposition of PAA in the environment:

- Biotic degradation is catalysed by microbial catalase and peroxidase enzymes
- Abiotic degradation :
    - Spontaneous decomposition in acetic acid and oxygen
    - Hydrolysis in acetic acid and Hydrogen peroxide
    - Metal (Fe, Mn, Cr) catalysed decomposition in acetic acid and oxygen
    - Oxidation of organic compounds

Resulting degradation products of PAA are oxygen, acetic acid and Hydrogen peroxide. Acetic acid and Hydrogen peroxide are further degraded to H_2O, CO_2 and O_2. Acetic acid is not regarded to be a substance of concern, because it does not trigger classification and labelling for the environment and it is listed in the Annex I of the BPR. The predominant degradation pathway in aquatic ecosystems is the reaction of PAA with organic matter and metal cations, leading to the formation of acetic acid and oxygen. Half-lives for the different environmental compartments are shown in **Table 2.2.8–30**.

Peracetic acid degrades rapidly where organic matter and microbial activity are present. Although it has not been unequivocally proved in ready biodegradability tests, PAA is considered as readily biodegradable substance as long as its concentrations are low enough as not to interfere with the biological degradation.
No reliable DT_{50} was determined for fresh waters. However PAA is not expected to be persistent because organic substances and metal ions promoting its decomposition are usually available in natural aquatic environments. In seawaters, the degradation of PAA is expected to be very rapid.
No half-life has been determined for aerobic degradation in soil. However PAA is not expected to be persistent in soil because it is known to degrade rapidly when in contact with organic material (please refer to the test with activated sludge). Therefore it was agreed to use the DT_{50} from Hydrogen peroxide in the absence of a DT_{50} for PAA (BPC WG ENV II-2016).

PAA does not absorb light in the visible wavelength range but it degrades in the atmosphere with a DT_{50} of 95.26 hours (AOPWIN). PAA is thus not expected to persist in the atmosphere. Moreover as the molecule does not contain olefin carbon-carbon double or acetylic triple bonds, PAA is not expected to react with ozone.

Between pH 5.5 and 8.2, hydrolysis is negligible and PAA consumption is mainly due to spontaneous decomposition. However hydrolysis rate increases with pH and with temperature.
As PAA does not absorb light in the visible wavelength range, phototransformation is not a significant pathway of degradation in water. Indeed, in the aquatic environment PAA decomposes rapidly to H_2O_2 and acetic acid and finally to CO_2 and H_2O in contact with organic substance and metals ions.

The measured Henry's Law constant of 0.217 Pa m³/mol indicates that volatilisation of PAA from surface water into atmosphere is low and adsorption to aerosol particles is negligible. Thus, PAA mainly distributes in the aqueous phase when released into the environment.

PAA is liquid at room temperature and is completely miscible in water at any ratio. With a measured log Kow of -0.60 (at pH 7), the QSAR derived adsorption coefficient (Koc) is determined to be 1.46 L/kg. As PAA is completely miscible with water and has a very low adsorption coefficient, it should thus be considered as mobile in soil and sediment.

➢ Hydrogen peroxide

Hydrogen peroxide (HP) decomposes rapidly in all environmental compartments, i.e. in sewage treatment plant, surface water, soil and air. The following processes are involved in the decomposition of Hydrogen peroxide in the environment:

- Biotic degradation is catalysed by microbial catalase and peroxidase enzymes
- Abiotic degradation :
    - Catalysed by transition metal (Fe, Mn, Cu) and heavy metal
    - Oxidoreduction processes with organic compounds
    - Formation of compounds with (in)organic substances

The most common degradation route leads to formation of water and oxygen:

$$2H_2O_2 \rightarrow 2H_2O + O_2$$

Under environmental conditions, natural HP concentrations in the different compartments depend on the dynamic equilibrium of the simultaneous formation and decomposition reactions and these reactions depend on the environmental conditions (e.g. presence of micro-organisms, concentration of catalysers, temperature, solar radiations,…). Half-lives for different environmental compartments are shown in **Table 2.2.8–30**.

HP is considered to fulfil the ready biodegradability criteria. Very rapid degradation of H_2O_2 has been observed in sewage treatment plant as well as surface water and soil compartment. Degradation is considered to be mainly microbially derived, although abiotic degradation processes can also affect the fate of HP.

HP is part of a complex equilibrium system of photo-oxidants in the troposphere : the phototransformation of H_2O_2 in air can proceed directly via photolysis or indirectly via photo-induced production of OH radicals that rapidly react with H_2O_2. Photolysis has a minor role compared to indirect photolysis and other processes decreasing the atmospheric H_2O_2 concentrations, such as oxidation of SO_2 and wet deposition. HP is not expected to persist in the atmosphere.

Based on its molecular structure, HP is not expected to be hydrolysed. Furthermore, no direct photolysis is expected in water. Though the decomposition of H_2O_2 into water and oxygen can be catalysed abiotically via transition metals (especially Fe, Mn and Cu and heavy metals) or by reacting with various functional groups of organic and inorganic compounds, biotic catalysis is likely to have a stronger influence on decomposition in surface water.

The Henry's law constant of 7.5×10^{-4} Pa × m^3/mol (at 20°C) indicates that volatilisation of HP from water is very low.

HP is liquid at room temperature and is completely miscible in water. No experimental data is available about the adsorption/desorption of H_2O_2 in soil. However its adsorption coefficient (Koc), calculated applying QSAR, is estimated to be 1.598 L/kg. Given that HP is completely miscible with water and has a very low adsorption coefficient, it should be considered as theoretically mobile in soil.

Ecotoxicity data

Table 2.2.8–1 summarises the PNEC for PAA and HP depending to the different compartments. All data are available in the respective CARs of Peracetic acid and of Hydrogen Peroxide for PT 1 to 6 (Document II-A.4.2 Effects on environmental organisms).

Table 2.2.8–1 Predicted Non Effect Concentrations of Peracetic acid and Hydrogen peroxide according to the environmental compartment

PNEC by compartment	Unit	Peracetic acid	Hydrogen peroxide
$PNEC_{STP\ micro\text{-}organisms}$	mg/L	5.1×10^{-2}	4.66
$PNEC_{water}$	mg/L	6.9×10^{-5}	1.26×10^{-2}
$PNEC_{sediment}$	mg/kg dwt	5.6×10^{-5}	-
$PNEC_{soil}$	mg/kg dwt	3.2×10^{-1}	2.08×10^{-3}

For PAA, the PNEC for sediment-dwelling organisms ($PNEC_{sediment}$) was calculated from $PNEC_{water}$ by using the equilibrium partitioning method.
Due to his low octanol-water partition coefficient (log Kow = –1.57), HP is not expected to adsorb to organic matter (log K_{OC} = 0.204). Moreover due to its rapid degradation in surface waters, HP is not expected to partition into the sediment. Because of the lack of exposure, the risk for benthic organisms is thus considered to be unlikely and adequately covered by the risk assessment for the water phase.

No study is available concerning the effects of HP on terrestrial organisms. Toxicity testing is deemed not necessary since there is no use resulting in direct release of the product to the terrestrial compartment. Indirect release via sewage, sludge or manure is expected to pose a low risk due to the very fast degradation of HP in sewage treatment plants. However a $PNEC_{soil}$ based on the aquatic data has been calculated by using the equilibrium partitioning method.

Log Pow values of PAA (-0.60 at 25°C, pH 7) and of HP (-1.57 at pH 7) are below the trigger value of 3, suggesting a low risk for bioaccumulation. Moreover both substances dissipate rapidly in the environment, which further decreases the risk of bioaccumulation. H_2O_2 especially is a reactive and polar substance with short half-lives in the environment. Moreover the enzymes catalase and GHS peroxidase, commonly found in biotic systems, enable the organisms to convert any excess H_2O_2 into water and oxygen. The active substances are thus not expected to accumulate, neither in the organisms, nor in the food chain. Therefore no BCF for fish and earthworms is available in their respective CAR.
No toxicity tests was performed on birds and mammals as the active substances degrade rapidly and have a low bioconcentration potential. Therefore the secondary exposure of wild fauna is unlikely and is no further considered in the risk assessment.

The physico-chemical properties of PAA and HP do not suggest that they may pose a risk to the atmospheric environment. Therefore no PNECs where calculated for air compartment.

No further information is available on the active substances or on the products.

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

According to the Classification & Labelling Inventory of ECHA[8] (C&L Inventory), Peracetic acid (CAS 79-21-0) has a harmonized classification for environment and is classified as "Aquatic Acute 1 – H400" (Very toxic to aquatic life).
The active substance in the formulated products is the same as evaluated in the CAR (2015), therefore no new data is required. Based on the maximum concentrations of PAA in the formulated products (3.2-15 % depending on the meta-SPC), its lowest acute and chronic endpoint (0.16 mg/L for algae and 6.90 x 10^{-4} mg/L for *Danio rerio*, respectively), as well as its very low persistence in aquatic systems (DT_{50} = 9.5 min at 12°C in sewer system) the active substance is considered as being "Aquatic Acute 1" with a M-factor of 1 and "Aquatic Chronic 1"with a M-factor of 10.

In addition, one co-formulant could be potentially of concern for the environment (Please refer to the Confidential annex).

All formulated products of SOPUROXIDshould be classified as Aquatic chronic 1 based on PAA toxicity and concentration.

Conclusion on the environmental classification and labelling of family
SOPUROXIDrequires an environmental classification as "Aquatic Chronic 1 – H410" (Very toxic to aquatic life with long-lasting effects) due to the toxicity and the concentration of the active substance Peracetic acid.

Further Ecotoxicological studies

In addition to the studies available in the CAR of Peracetic Acid (2015), five new studies have been submitted by the applicant. They have been conducted on SOPUROXID 15 (16.7% PAA, 22% H_2O_2), except the study of Van den Broek & Appels (2015), which has been conducted on Acidofoam CF (3.2% PAA, 23.5% H_2O_2). They are summarised in Table 2.2.8–2 below.

8 https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/24363

Table 2.2.8–2 Summary table - Further ecotoxicological studies

Summary table of further ecotoxicological studies											
Guideline	**GLP status**	**Reliability**	**Species**	**End point**	**Exposure**		**Results**			**Remarks**	**Reference[1]**
					Design	**Duration**	**EC_0**	**EC_{50}**	**EC_{100}**		
OECD 203	Yes	No	*Danio rerio*	Mortality	Semi-static	96 h	3.2	7.2	18	Concentration of a.s. not recorded	The acute toxicity of SOPUROXID 15 to *Branchydanio rerio*. TNO. Report no. R87/376. Company owner: Sopura
OECD 202	Yes	No	*Daphnia magna*	Mortality	Static	48 h	1.8	3.2	5.6	Concentration of a.s. not recorded	The acute toxicity of SOPUROXID 15 to *Daphnia magna*. TNO. Report no. R87/375. Company owner: Sopura.
OECD 201	Yes	No	*Selenastrum capricornutum*	Growth rate	Static	72 h	0.56	5.7	-	8 concentrations of a.s. tested but only 3 of them were measured. Only 1 measured concentration in all replicates was over the LOQ or the LOD and it was only 77% of nominal.	The determination of the effect of SOPUROXID 15 on the growth of the alga. TNO. Report no. IMW-98-0044-01. Company owner: Sopura
OECD 209	Yes	Yes	Activated sludge	Respiration inhibition	Static	3 h	100	231	1002		Screening of the effect of

											SOPUROXID 15 on the respiration rate of activated sludge. TNO. Report no. IMW-98-0044-02. Company owner: Sopura
No	No	No	Activated sludge	Carbon oxidation inhibition	Static	15h	> 80	> 80	> 80	Concentration of a.s. not recorded	Inhibition assessment of aerobic/ anaerobic waste water treatment process by Acidofoam CF. Company owner: Sopura
No	No	No	Activated sludge	Nitrification inhibition	Static	-	< 10	40-60	> 80	Concentration of a.s. not recorded	
No	No	No	Activated sludge	Carbon reduction	Static	37.1 days	> 80	> 80	> 80	Concentration of a.s. not recorded	

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	Supporting information
Justification for the value/conclusion	As these studies are not reliable (except the respiration inhibition test on activated sludge) and not strictly required for the registration of biocidal products, they are considered as supporting information. The results obtained with the biocidal products do not contradict the conclusions based on the active substance Peracetic acid.

(III) Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No further data is available.

(IV) Supervised trials to assess risks to non-target organisms under field conditions

No further data is available.

(V) Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

The product is not in the form of bait or granules, so no such data is required.

(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

According to the intended uses of the SOPUROXID Family, the main emission pathways to the environment are assumed to be the waste water and the soil, depending on the intended use.
It is assumed that after a cleaning event, waste water is emitted to the surface water after treatment in a local waste water treatment plant (PT 2, 3 and 4). Fresh water and fresh water sediments could thus be exposed to the residues of active substances. The soil could be exposed through the application of the sludge from the sewage treatment plant, leading to an emission to groundwater.
The soil could also be exposed after application of contaminated manure or slurry (PT3 and 5). Emission to air is considered to be negligible). More information is available below in Section 2.2.3 Fate and distribution in exposed environmental compartments.

Please note that it was agreed at ENV WG-II-2019 that no groundwater assessment is needed for rapidly reacting substances since it is very unlikely that these substances will reach the groundwater compartment. Moreover it was confirmed at WG-IV-2019 that no groundwater assessment is needed for PAA and HP, given their short half-lives in sludge and manure, as well as their quick degradation in soil.

(VIII) Further studies on fate and behaviour in the environment (ADS)

No further data is available.

(IX) Leaching behaviour (ADS)

Not relevant.

(X) Testing for distribution and dissipation in soil (ADS)

For details, please refer to the respective CAR of Peracetic acid and Hydrogen peroxide (Document II-A and III-A). No new data, neither on the products, nor on the active substances, have been submitted by the applicant.

Conclusion used in Risk Assessment –Distribution and dissipation in soil	
Value/conclusion	PAA and HP can be both considered to be readily biodegradable. DT_{50} in soil is estimated to be 12 hours for HP while no DT_{50} soil value has been determined for PAA. However it was agreed to use the same DT_{50} as for HP, as PAA is not expected to be persistent in soil due to its fast degradation when in contact with organic matter. The QSAR derived Koc are determined to be 1.46 L/kg for PAA and 1.598 L/kg for HP. Both substances are thus considered to be mobile in soil.

(XI) Testing for distribution and dissipation in water and sediment (ADS)

For details, please refer to the respective CAR of Peracetic acid and Hydrogen peroxide (Document II-A and III-A). No new data, neither on the products, nor on the active substances, have been submitted by the applicant.

Conclusion used in Risk Assessment –distribution and dissipation in water and sediment	
Value/conclusion	PAA degrades rapidly where organic matter and microbial activity are present. A DT_{50} < 5 minutes (20°C, corresponding to 9.5 min at 12°C) is to be used for the risk assessment of STP. This value is also transferable to the sewer system. A DT_{50} of 3 min. has been measured for STP aeration tank. Between pH 5.5 and 8.2, PAA is mainly degraded by spontaneous decomposition and hydrolysis is negligible, although it increases with temperature. Phototransformation is also negligible in water, where PAA decomposes rapidly to H_2O_2 and acetic acid and finally to CO_2 and water in contact with organic substances and metals ions. The DT_{50} in freshwater is 31.7h at pH 7 and 20°C (corresponding to 60.1h at 12°C). In seawaters, DT_{50} is expected to be 2 minutes. As PAA is completely miscible in water and has a very low adsorption coefficient (Koc= 1.46 L/kg), it is considered as mobile in sediment. However PAA mainly distributes in the aqueous phase when released into the environment. Regarding HP, no hydrolysis and no direct photolysis is expected due to its molecular structure. Though the decomposition into water and O_2 can be catalysed abiotically, via transition metals or by reacting with organic and inorganic compounds, biotic catalysis

	is likely to have a stronger influence on decomposition in surface water. The DT_{50} in water is estimated to be 5 days in unfavourable conditions and the DT_{50} in STP is estimated to be 89 min. (20°C, corresponding to 169 min. at 12°C). As HP is completely miscible in water and has a very low adsorption coefficient (Koc= 1.598 L/kg), it is considered as theoretically mobile in sediment, though it mainly remains in the water phase.

(XII) Testing for distribution and dissipation in air (ADS)

For details, please refer to the respective CAR of Peracetic acid and Hydrogen peroxide (Document II-A and III-A). No new data, neither on the products, nor on the active substances, have been submitted by the applicant.

Conclusion used in Risk Assessment –distribution and dissipation in air	
Value/conclusion	The DT_{50} air value has been estimated to be 95.26 h for PAA and 24h for HP. None of the compounds are expected to persist in the atmosphere. Henry's Law constant of 0.217 Pa m^3/mol for PAA and 7.5 × 10^{-4} Pa × m^3/mol for HP (at 20°C) indicate that volatilisation from surface water into atmosphere is low and adsorption to aerosol particles is negligible. Both compounds thus mainly distribute in the aqueous phase when released into the environment.

(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

The environmental exposure assessment has been performed in accordance with the Emission Scenario Documents for Product Type 2 (Disinfectants and algaecides not intended for direct application to humans or animals)[9], 3 (Disinfectants for veterinary hygiene)[10], 4 (Disinfectants used in food and feed areas)[11] and 5 (Disinfectant for drinking water)[12] as well as the Guidance on the Biocidal Product Regulation (ECHA, 2017)[13] and the EUSES Background report (EC 2004)[14]. Moreover it is based on information relating to the Intended Use (Chapter 3 of this document) and confidential information available in the respective CAR of PAA and Hydrogen peroxide (Doc. II-B confidential). The environmental exposure assessment has been conducted for the local scale only. The emission estimations have been calculated for a theoretical product having a Peracetic acid concentration of 15% and a Hydrogen peroxide concentration of 23.5% as a worst-case situation.

Pease note that all uses are only for industrial/ professional users.

Please find below a table summarizing of the Intended uses (claimed by the Applicant) together with an overview of the emissions scenarios used to perform the risk assessment. The explanations for linking these scenarios to the intended uses are available below (please refer to each relevant PT section).

9 JRC scientific and technical reports (2011). Emission Scenario Document for Product Type 2 : Private and public health area disinfectants and other biocidal products

10 JRC scientific and technical reports (2011). Emission Scenario Document for Product Type 3 : Veterinary hygiene biocidal products

11 JRC scientific and technical reports (2011). Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas.

12 Umweltbundesamt (2003). Emission Scenario Document on drinking water disinfectants

13 ECHA (2017). Guidance on Biocidal Products Regulation: Volume IV Environment - Assessment and Evaluation (Parts B + C), Version 2.0. European Chemicals Agency, Helsinki, Finland. Available via https://echa.europa.eu/

14 EC (2004) European Union System for the Evaluation of Substances 2.0 (EUSES 2.0). Prepared for the European Chemicals Bureau by the National Institute of Public Health and the Environment (RIVM), Bilthoven, The Netherlands (RIVM Report no. 601900005). Available via http://ecb.jrc.ec.europa.eu/euses/.

List of intended uses (claimed by the Applicant) & overview of the linked scenarios

Meta SPC-1 (5% PAA, 16.5-22% HP) Meta SPC-4 (15% PAA, 22% HP)		Dilution (max. PAA concentration)	Link to SCENARIO	Scenario (description)
PT2	Use #1.1/4.1: Disinfection of surfaces in industrial, public and health care areas - manual treatment (mopping)	0.048%	PT 2 Scenario 1	Scenario 1: Average consumption (Industrial area & sanitary purpose) Scenario 1: Daily consumption (Sanitary purpose)
	Use #1.2/4.2: Disinfection of surfaces in industrial, public and health care areas - manual treatment (spraying)	0.048%	PT 2 Scenario 1	Scenario 1: Average consumption (Industrial area & sanitary purpose) Scenario 1: Daily consumption (Sanitary purpose)
	Use #1.3/4.3 : CIP in the pharmaceutical and cosmetic industry	0.032%	PT4 Scenario 1	Scenario 1: Assessment of entire plants – Disinfection by automated spraying
	Use #1.4/4.4 : Disinfection of surfaces by spraying in greenhouses (in absence of plants - for general hygiene purpose only) – spraying with personal enclosure	0.048%	PT4 Scenario 4	Scenario 4: Disinfection in large scale catering kitchens and canteens
	Use #1.5/4.5 : Disinfection of surfaces by spraying in greenhouses (in absence of plants - for general hygiene purpose only) – spraying without personal enclosure	0.048%	PT4 Scenario 4	Scenario 4: Disinfection in large scale catering kitchens and canteens
	Use #1.6/4.6: Disinfection of equipment by soaking (for agriculture & horticulture equipment – for general hygiene purpose only)	0.064%	PT4 Scenario 4	Scenario 4: Disinfection in large scale catering kitchens and canteens
	Use #1.7/4.7 : Disinfection of surfaces & equipment by spraying (e.g. agriculture & horticulture equipment - for general hygiene purpose only) - manually	0.048%	PT4 Scenario 4	Scenario 4: Disinfection in large scale catering kitchens and canteens
	Use #1.8/4.8 : Disinfection of surfaces & equipment by spraying (e.g. agriculture & horticulture – for general hygiene purpose only) - automatically	0.048%	PT4 Scenario 1	Scenario 1: Assessment of entire plants – Disinfection by automated spraying
	Use #1.9/4.9 : Disinfection of surfaces & equipment by spraying (e.g. agriculture & horticulture – for general hygiene purpose only) – automatic spraying (closed room)	0.048%	PT4 Scenario 1	Scenario 1: Assessment of entire plants – Disinfection by automated spraying
PT3	Use #1.10/4.10 : Disinfection of animal housing by low-pressure manual spraying – spraying with personal enclosure	0.064%	PT 3 Scenario 1	Scenario 1 – Disinfection of animal housing by spray
	Use #1.11/4.11 : Disinfection of animal housing by low-pressure manual spraying – spraying without personal enclosure	0.064%	PT 3 Scenario 1	Scenario 1 – Disinfection of animal housing by spray
	Use #1.12/4.12 : Disinfection of boots in footbaths in animal housing /husbandries	0.064%	PT 3 Scenario 3	Scenario 3 – Disinfection of footwear
	Use #1.13/4.13 : Disinfection of equipment by dipping	0.064%	PT 3 Scenario 4	Scenario 4 – Disinfection by dipping
PT4	Use #1.14/4.14 : Disinfection in Aseptic Filling Lines (crown corks, cheese moulds and food crates) - Automated spraying closed systems	0.064%	PT4 Scenario 1	Scenario 1: Assessment of entire plants – Disinfection by automated spraying
	Use #1.15/4.15 : Disinfection of equipment in the food and beverage industry by immersion	0.064%	PT4 Scenario 1	Scenario 1: Assessment of entire plants – Disinfection by automated spraying
	Use #1.16/4.16 : Disinfection of heat and ion exchangers, membrane filters and glass and PET bottles – CIP procedures	0.064%	PT4 Scenario 1	Scenario 1: Assessment of entire plants – Disinfection by automated spraying
	Use #1.17/4.17 : Disinfection of surfaces and equipment by low pressure spraying – spraying with personal enclosure	0.064%	PT4 Scenario 4	Scenario 4 – Disinfection of large scale catering kitchens,

	Use #1.18/4.18 : Disinfection of surfaces and equipment by low pressure spraying – spraying without personal enclosure	0.064%		canteens, slaughterhouses and butcheries
	Use #1.19/4.19 : Disinfection of surfaces and equipment by low pressure spraying, manually	0.064%		
	Use #1.20/4.20 : Disinfection of surfaces and equipment by low pressure spraying, automatically	0.064%		
	Use #1.21/4.21 : Disinfection of surfaces and equipment by low pressure spraying – automatic spraying (closed room)	0.064%		
	Use #1.22/4.22 : Disinfection of inner surfaces (pipelines, tanks, vessels, …) by CIP	0.064%	PT 4 Scenario 9	Scenario 4 – Disinfection of milking parlours systems
	Use #1.23/4.23 : Disinfection of water used for rinsing of recycled items during the washing process	0.008%	PT4 Scenario 1	Scenario 1: Assessment of entire plants – Disinfection by automated spraying
Meta SPC-2 (3.2% PAA, 23.5% HP) – by fogging		**Dilution** (max. PAA concentration)	**Link to SCENARIO**	**Scenario** (description)
PT2	Use #2.1 : Disinfection of surfaces & equipment in industrial, public and health care areas (pharmaceutical and cosmetic industry) – fogging	1.28%	PT 2 Scenario 10	Scenario 10: Average consumption (Industrial area & sanitary purpose) Scenario 10: Daily consumption (Sanitary purpose)
	Use #2.2 : Disinfection of hard surfaces & equipment by fogging (e.g. agriculture & horticulture equipment, in absence of plants – for general hygiene purpose only)	1.28%		
PT3	Use #2.3 : Disinfection of animal housing by fogging	1.28%	PT 3 Scenario 1	Scenario 1 – Disinfection of animal housing by spray
PT4	Use #2.4 : Disinfection of storage rooms with special device in storage cellar or room	1.28%	PT 4 Scenario 11	Scenario 11 – Disinfection of large scale catering kitchens, canteens, slaughterhouses and butcheries (fogging)
Meta SPC-3 (3.2% PAA, 23.5% HP) – by foaming		**Dilution** (max. PAA concentration)	**Link to SCENARIO**	**Scenario** (description)
PT2	Use #3.1 : Disinfection of surfaces by foaming in industrial, public and health care areas, manually – mopping	0.048%	PT 2 Scenario 1	Scenario 1: Average consumption (Industrial area & sanitary purpose) Scenario 1: Daily consumption (Sanitary purpose)
	Use #3.2 : Disinfection of surfaces & equipment by foaming (e.g. agriculture & horticulture equipment – for general hygiene purpose only), manually – spraying	0.048%	PT4 Scenario 4	Scenario 4: Disinfection in large scale catering kitchens and canteens
	Use #3.3 : Disinfection of surfaces & equipment by foaming (e.g. agriculture & horticulture equipment – for general hygiene purpose only) automatically	0.048%	PT4 Scenario 1	Scenario 1: Assessment of entire plants – Disinfection by automated spraying
	Use #3.4 : Disinfection of surface & equipment by foaming (e.g. agriculture & horticulture equipment – for general hygiene purpose only) – automatic foaming (closed room)	0.048%		
PT3	Use #3.5 : Disinfection of animal housing by foaming – foaming with personal enclosure	0.064%	PT 3 Scenario 1	Scenario 1 – Disinfection of animal housing by spray
	Use #3.6 : Disinfection of animal housing by foaming – foaming without personal enclosure	0.064%		

PT4	Use #3.7 : Disinfection of surfaces by foaming with personal enclosure	0.064%	PT4 Scenario 4	Scenario 4 – Disinfection of large scale catering kitchens, canteens, slaughterhouses and butcheries
	Use #3.8 : Disinfection of surfaces by foaming without personal enclosure	0.064%		

(I) General information on PT 2 - Disinfectants and algaecides not intended for direct application to humans or animals (meta SPC 1, 2, 3 and 4)

Assessed PT	PT 2 – Disinfectants not intended for direct application to humans or animals
Use of the product	*1. INDUSTRIAL, PUBLIC AND HEALTH CARE AREAS - MANUAL DISINFECTION OF SURFACES - MOPPING* Apply manually the diluted solution with the appropriate tool e.g. flat mops or cleaning cloths on hard surfaces. After application, the recipient containing the solution is drained. Rinse surface after use. Peracetic acid concentration: 0.048%.
	2. INDUSTRIAL, PUBLIC AND HEALTH CARE AREAS - MANUAL DISINFECTION OF SURFACES - SPRAYING CAN Apply manually the diluted solution by spraying on surfaces using a small spraying can. Rinse surface after use. Peracetic acid concentration: 0.048%.
	3. CIP IN PHARMACEUTICAL AND COSMETIC INDUSTRY The product is automatically circulated from the CIP holding tanks through closed pipework and installations. After application, the CIP vessel is drained and rinsed. Peracetic acid concentration: 0.032%.
	4. DISINFECTION OF SURFACES BY SPRAYING (PERSONAL ENCLOSURE) Disinfection of surfaces, e.g. in greenhouses. The application of the diluted disinfectant is done automatically using of spraying equipment. The worker or operator is present but in a personal enclosure. Spraying is done in all directions. After disinfection, surfaces and equipment are rinsed with water and the water is drained into the sewer system. Peracetic acid concentration: 0.048%.
	5. DISINFECTION OF SURFACES BY SPRAYING (WITHOUT PERSONAL ENCLOSURE) Disinfection of surfaces, e.g. in greenhouses. The application of the diluted disinfectant is done automatically using of spraying equipment. The worker or operator is present. Spraying is done in all directions. After the disinfection, surfaces and equipment are rinsed with water and the water is drained into the sewer system. Peracetic acid concentration: 0.048%.

	6. DISINFECTION OF EQUIPMENT BY SOAKING Disinfection of small parts (equipment, spare parts, tools, valves, hoses, ...) The equipment is dipped in soaking baths containing the diluted product, then rinsed with water and the water is drained into the sewer system. Peracetic acid concentration: 0.064%.
	7. DISINFECTION OF SURFACES & EQUIPMENT BY MANUAL SPRAYING Disinfection of equipment and surfaces (e.g. agriculture & horticulture equipment - for general hygiene purpose only). The diluted solution is manually sprayed on the equipment and surfaces using spraying equipment. Spraying is only applied downwards and in a horizontal direction. After disinfection, surfaces and equipment are rinsed with water and the water is drained into the sewer system. Peracetic acid concentration: 0.048%.
	8. DISINFECTION OF SURFACES & EQUIPMENT BY AUTOMATIC SPRAYING Disinfection of equipment and surfaces by spraying (e.g. agriculture & horticulture equipment – for general hygiene purpose only) on conveyor belt, in an automated way while the operator is present within a personal enclosed area. Spraying is only applied downwards and in a horizontal direction. After disinfection, surfaces and equipment are rinsed with water and the water is drained into the sewer system. Peracetic acid concentration: 0.048%.
	9. DISINFECTION OF SURFACES & EQUIPMENT BY AUTOMATIC SPRAYING - CLOSED ROOM Disinfection of equipment and surfaces by spraying (e.g. agriculture & horticulture equipment – for general hygiene purpose only) in an automated way without any operator being present. After disinfection, surfaces and equipment are rinsed with water and the water is drained into the sewer system. Peracetic acid concentration: 0.048%.
	10. INDUSTRIAL, PUBLIC AND HEALTH CARE AREAS – DISINFECTION OF EQUIPMENT & SURFACES BY FOGGING Disinfection of surfaces & equipment within the pharmaceutical and cosmetic industry. The diluted solution is applied on the surfaces and equipment that is to be disinfected by fogging. The room where the fogging activity takes place is tightly sealed during fogging. Entrance in the room is allowed after verification of the concentrations of PAA (0.5 mg/m³). Peracetic acid concentration: 1.28%.

	11. DISINFECTION OF EQUIPMENT & SURFACES BY FOGGING Disinfection of surfaces & equipment by fogging (for agriculture & horticulture area – for general hygiene purpose only). The room where the fogging activity takes place is tightly sealed during fogging . Entrance in the room is allowed after verification of the concentrations (0.5 mg/m³). Peracetic acid concentration: 1.28%.
	12. INDUSTRIAL, PUBLIC AND HEALTH CARE AREAS – DISINFECTION OF SURFACES BY FOAMING Disinfection of hard surfaces by foam application using a small foaming can. After disinfection, surface is rinsed with water and the water is drained into the sewer system. Peracetic acid concentration: 0.048%.
	13. DISINFECTION OF EQUIPMENT & SURFACES BY MANUAL FOAMING Disinfection of equipment and surfaces (e.g. agriculture & horticulture equipment – for general hygiene purpose only) by foam application via a small foaming can. Foaming is only applied downwards and in a horizontal direction. Peracetic acid concentration: 0.048%.
	14. DISINFECTION OF EQUIPMENT & SURFACES BY AUTOMATIC FOAMING Disinfection of surface and equipment (e.g. agriculture & horticulture equipment – for general hygiene purpose only) by foaming in an automated way while the operator is present within a personal enclosed area. Foaming is only applied downwards and in a horizontal direction. After disinfection, equipment is rinsed with water and the water is drained into the sewer system. Peracetic acid concentration: 0.048%.
	15. DISINFECTION OF EQUIPMENT & SURFACES BY AUTOMATIC FOAMING - CLOSED ROOM Disinfection of surface and equipment (e.g. agriculture & horticulture equipment – for general hygiene purpose only) by foaming in an automated way without any operator being present, in a closed room. After disinfection, equipment is rinsed with water and the water is drained into the sewer system. Peracetic acid concentration: 0.048%.
Assessed scenarios	Scenario 1: Disinfection of surfaces in industrial, public and health care areas - Spraying
ESD(s) used	Emission Scenario Document for Product Type 2: Private and public

	health area disinfectants and other biocidal products (EUR 25115 EN - 2011)
Approach	Scenario 1: Average consumption (Industrial area & sanitary purpose) Scenario 1: Daily consumption (Sanitary purpose) SCENARIO 10 : Disinfection of surfaces in industrial, public and health care areas – Fogging
Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulation - Volume IV Environment - Assessment and Evaluation (Parts B + C) - Version 2.0, October 2017
Groundwater simulation	Not relevant
Confidential Annexes	NO
Life cycle steps assessed	Scenario: 1 & 4 Production: No Formulation: No Use: Yes Service life: No
Remarks	-

Emission estimation

SCENARIO 1: Disinfection of surfaces in industrial, public and health care areas – Manual treatment

Scenario 1 – Disinfection in industrial areas and for sanitary purpose

Peracetic acid and Hydrogen peroxide are emitted into the environment via waste water. Emissions to air are considered to be negligible. The emission estimation were based on the ESD for PT2 for industrial and institutional areas (2011, p. 12 and p. 16) and for medical sector (van der Poel, 2001, p. 20).

Intermediate calculation for Scenario 1 - Concentration of active substances in the applied product

A theoretical product 1 (PAA 15% w/w, H_2O_2 23.5% w/w) is used for the disinfection of surfaces. The applicant has considered that 100mL of formulated product was diluted in a 10L bucket (i.e. dilution of the theoretical product: 1%)..

The concentration of the active substances in the product applied for disinfection was calculated according to the following equation (results are available in Table 2.2.8–3 below):

$$C_{form} = C_{FP} \times \rho_{a.i} \times DIL$$

Table 2.2.8–3 Concentration of Peracetic acid and Hydrogen Peroxide in the theoretical product 1 used for the disinfection of surfaces.

Concentration of the active substances in the applied product					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA (15%)	**HP (23.5%)**		
Concentration of a.s. in formulated product	C_{FP}	150	235	g/kg	Provided by the applicant
Relative density of formulated product (SOPUROXID 5C)[1]	$\rho_{a.i.}$	1.235		kg/L	Provided by the applicant
Dilution of the pure product	DIL	1		%	Provided by the applicant
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Concentration of a.s. in used product	C_{form}	**1.85**	**2.90**	g/L	Output

[1]Relative density of SOPUROXID 5C was used as worst-case value as this formulated product showed the highest relative density, please refer to section 2.2.2 Physical, chemical and technical properties.

Please note that these theoretical emissions cover the uses #1.1/4.1, #1.2/4.2 and #3.1. Indeed the actual worst-case emissions are due to Sopuroxid 5C (density : 1.235 kg/L), diluted to reach a final PAA concentration of 0.048%. This would lead to the following concentrations : 0.59 g/L PAA and 2.61 g/L HP. Instead a worst-case calculation is made, assuming 1.85 g/L PAA and 2.90 g/L HP as concentration of PAA and HP in the in-use product Sopuroxid 5C.

Final calculations for scenario 1 – Industrial area

The local release to the wastewater after application of the product in industrial area ($E_{local\ water}$) is calculated according to the following equations:

$$E_{local\ water} = C_{form} \times V_{form} \times AREA_{surface} \times Nappl \times (1-F_{dis}) \times F_{water}$$

The applicant has considered that 30 mL of diluted product is used per m² of surface. The parameters used for calculations and the results are available in Table 2.2.8–4.

Table 2.2.8–4 Local release to wastewater of disinfectants used in industrial areas (JRC, 2011)

Scenario 1: Disinfection of surfaces in industrial, public and health care areas Manual treatment – Industrial areas				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**

		PAA	HP		
Concentration of a.s. in used product	C_{form}	1.85×10^{-3}	2.90×10^{-3}	kg/L	Provided by the applicant
Application rate of biocidal product	V_{form}	0.03		L/m²	Provided by the applicant
Surface area to be disinfected	$AREA_{surface}$	1000		m²	Default
Number of applications per day	Nappl	1		d^{-1}	Default
Fraction of substance disintegrated during or after application (before release to the sewer system)	F_{dis}	0		/	Default
Fraction released to wastewater	F_{water}	1		/	Default
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water (without pretreatment)	$E_{local\ water}$	5.55×10^{-2}	8.71×10^{-2}	kg/d	Output

Final calculations for scenario 1 – Sanitary purpose based on average consumption

The local release to the wastewater after application of the product used for sanitary purposes based on average consumption ($E_{local\ water}$) is calculated according to the following equations:

$$E_{local\ water} = C_{form} \times V_{form\ general} \times Nlocal \times F_{penetr} \times (1-F_{dis}) \times F_{water}$$

The applicant has considered that 20 mL of treatment solution are used per m². Please note that only the consumption per capita in general purpose (0.005 L per capita per day) was taken into account as this scenario is worst-case compared to the consumption per capita in lavatory (0.002 L per capita per day). The parameters used for calculations and the results are available in Table 2.2.8–5.

Table 2.2.8–5 Local release to wastewater of disinfectants used for sanitary purposes based on average consumption (Van der Poel, 2001)

Scenario 1: Disinfection of surfaces in industrial, public and health care areas Manual treatment – Sanitary purposes based on average consumption					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Concentration of a.s. in used product	C_{form}	1.85×10^{-3}	2.90×10^{-3}	kg/L	Provided by the applicant
Consumption per capita for general purpose (tiles, floors, sinks)	$V_{form\ general}$	0.005		L/cap. × d	Default
Number of inhabitants feeding one STP	Nlocal	10,000		cap.	Default

Penetration factor of disinfectant	F_{penetr}	0.5		/	Default
Fraction of substance disintegrated during or after application (before release to the sewer system)	F_{dis}	0		/	Default
Fraction released to wastewater	F_{water}	1		/	Default
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water (without pretreatment)	$E_{local\ water}$	4.63×10^{-2}	7.26×10^{-2}	kg/d	Output

Intermediate calculations for scenario 1 – Break-even point tonnage

The calculation of break-event point tonnage ($TONNAGE_{regional}$) is calculated according to the following equations:

$$TONNAGE_{regional} = N_{local} \times C_{form} \times V_{form} \times F_{penetr} \times T_{emission} / (1000 \times F_{main\ source})$$

The parameters used for calculations and the results are available in Table 2.2.8–6 below:

Table 2.2.8–6 Break-even point tonnage of disinfectants used for sanitary purpose (JRC, 2011)

Scenario 1: Break-even point tonnage of disinfectants used for sanitary purpose Manual treatment					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Number of inhabitants feeding one STP	N_{local}	10,000		-	Default
Concentration of a.s. in used product	C_{form}	1.85×10^{-3}	2.90×10^{-3}	kg/L	Provided by the applicant
Application rate of biocidal product – consumption per capita for general purpose	V_{form}	0.005		L/cap / day	Default
Penetration factor of disinfectant	F_{penetr}	0.5		/	Default
Fraction of the main source (STP)	$F_{main\ source}$	0.002		/	Default
Number of emission days	$T_{emission}$	365		d/y	Default
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Break-even point tonnage	$TONNAGE_{reg}$	8.44	13.2	Ton/y	Output

Final calculations for scenario 1 –Sanitary purpose based on annual tonnage

The calculation of releases of disinfectants used for sanitary purposes based on the annual tonnage is performed according to the following equations:

$$E_{local\ water} = TONNAGE_{reg} \times F_{main\ source} \times (1-F_{dis}) \times F_{water} \times 10^3 / T_{emission}$$

The parameters used for calculations and the results are available in Table 2.2.8–7:

Table 2.2.8–7 Local release to wastewater of disinfectants used for sanitary purposes based on annual tonnage (JRC, 2011)

Scenario 1: Disinfection of surfaces in industrial, public and health care areas Manual treatment – Sanitary purposes based on annual tonnage					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Break-even point tonnage	$TONNAGE_{reg}$	8.44	13.2	Ton/y	Table 2.2.8-6
Fraction of the main source (STP)	$F_{main\ source}$	0.002		/	Default
Fraction disintegrated during or after application (before release to the sewage system)	F_{dis}	0		-	
Fraction released to wastewater	F_{water}	1		-	
Number of emission days	$T_{emission}$	365		d/y	Default
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water (without disintegration)	$E_{local\ water}$	4.63×10^{-2}	7.25×10^{-2}	kg/d	Output

Please note that the emission based on annual tonnage being the same than those based on average consumption, only the emissions based on average consumption are further considered in the risk assessment as worst-case approach.

Final calculations for scenario 1 – Sanitary purpose in hospital based on daily consumption

The local release to the wastewater after application of the product used for sanitary purposes in hospitals based on the amount of solution of disinfectant used on a day ($E_{local\ water}$) is calculated according to the following equations (results are available in Table 2.2.8–8 below):

$$E_{local\ water} = (C_{san} \times Q_{water\_san} \times F_{sanwater}) + (C_{obj} \times Q_{water\_obj} \times F_{objwater})$$

Table 2.2.8–8 Local release to wastewater of disinfectants used for sanitary purposes in hospitals based on the amount of solution of disinfectant used on a day (RIVM, 2001)

Scenario 1: Disinfection of surfaces in industrial, public and health care areas Manual treatment – Sanitary purposes in hospitals based on daily consumption					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Concentration of a.s. in used product for sanitary purposes	C_{san}	1.85×10^{-3}	2.90×10^{-3}	kg/L	Provided by the applicant
Concentration of a.s. in used product for brushes	C_{obj}	1.85×10^{-3}	2.90×10^{-3}	kg/L	Provided by the applicant
Amount of water with active substance in sanitary purposes	Q_{water_san}	25		L/d	Default
Amount of water with active substance in brushes	Q_{water_obj}	25		L/d	Default
Fraction of substance released to waste by sanitary purposes	$F_{sanwater}$	0.55		/	Default
Fraction of substance released to waste by brushes	$F_{objwater}$	0.95		/	Default
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water (without pretreatment)	$E_{local\ water}$	6.94×10^{-2}	1.09×10^{-1}	kg/d	Output

Intermediate calculations for scenario 1 – Break-even point tonnage for sanitary purpose in hospital

The calculation of break-event point tonnage ($TONNAGE_{regional}$) for sanitary purpose in hospital is calculated according to the following equations:

$$TONNAGE_{regional} = Q_{water} \times C_{san/obj} \times T_{emission} \times F_{san/obj} / (1000 \times F_{hopsital} \times F_{water})$$

The parameters used for calculations and the results are available in Table below :

Table 2.2.8–9 Break-even point tonnage of disinfectants used for sanitary purpose in hospital (JRC, 2011)

Scenario 1: Break-even point tonnage of disinfectants used for sanitary purpose in hospital – Manual treatment					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Concentration of a.s. in used product	C_{form}	1.85×10^{-3}	2.90×10^{-3}	kg/L	Provided by the applicant
Fractions released to wastewater	F_{san}	0.55		-	Default

from sanitary purpose					
Fractions released to wastewater from brushes	F_{obj}	0.95		-	Default
Amount of water with active substance used daily	Q_{water}	25		L/day	Default
Fraction for the hospital	$F_{hospital}$	0.007		/	Default
Fraction released to waste water	F_{water}	0.75		/	Default
Number of emission days	$T_{emission}$	260		day/y	Default
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Break-even point tonnage for sanitary purpose	$TONNAGE_{reg}$	1.26	1.97	Ton/y	Output
Break-even point tonnage for objects	$TONNAGE_{reg}$	2.18	3.41	Ton/y	Output
Total break-even point tonnage	$TONNAGE_{reg}$	3.44	5.39	Ton/y	Output

Final calculations for scenario 1 –Sanitary purpose in hospital based on annual tonnage

The calculation of releases of disinfectants used for sanitary purposes based on the annual tonnage is performed according to the following equations:

$$E_{local\ water} = TONNAGE_{reg} \times F_{hospital} \times F_{water} \times 10^3 / T_{emission}$$

The parameters used for calculations and the results are available in Table 2.2.8–10 below:

Table 2.2.8–10 Local release to wastewater of disinfectants used for sanitary purposes in hospital based on annual tonnage (JRC, 2011)

Scenario 1: Disinfection of surfaces in industrial, public and health care areas Manual treatment – Sanitary purposes in hospital based on annual tonnage					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Break-even point tonnage	$TONNAGE_{reg}$	3.44	5.39	Ton/y	Table 2.2.8-9
Fraction of the main source (STP)	$F_{hospital}$	0.007		/	Default
Fraction released to wastewater	F_{water}	0.75		-	
Number of emission days	$T_{emission}$	260		d/y	Default
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water	$E_{local\ water}$	6.94	1.09	kg/d	Output

(without disintegration)		$\times 10^{-2}$	$\times 10^{-1}$		

Please note that the emission based on annual tonnage being lower than those based on average consumption, only the emissions based on average consumption are further considered in the risk assessment as worst-case approach.

Scenario 1 – Total release to waste water

As the biocidal products could be used simultaneously in industrial premises, institutional and health care areas for disinfection of surfaces, a worst case scenario summing all emissions is used for exposure assessment:

Table 2.2.8–11 Total local release to wastewater of disinfectants used in industrial areas and for sanitary purpose

Scenario 1: Disinfection of surfaces in industrial, public and health care areas Manual treatment – Total local release				
Local release to waste water	**Value**		**Unit**	**Remarks**
	PAA	**HP**		
Industrial areas	5.55×10^{-2}	8.71×10^{-2}	kg/d	Table 2.2.8–8
Sanitary purposes based on average consumption	4.63×10^{-2}	7.26×10^{-2}	kg/d	Table 2.2.8–9
Sanitary purposes in hospitals based on daily consumption	6.94×10^{-2}	1.09×10^{-1}	kg/d	Table 2.2.8–10
Output	**Value**		**Unit**	**Remarks**
	PAA	**HP**		
Total local release to waste water	1.71×10^{-1}	2.68×10^{-1}	kg/d	Output

SCENARIO 2: Disinfection of surfaces in industrial, public and health care areas – Spraying can

This scenario is considered to be covered by the scenario described for PT2 – Scenario 1. The area in which the application could take place is identical and the maximum use concentration applicable to Scenario 1 (0.048%) is also applicable here.

SCENARIO 3: CIP in pharmaceutical and cosmetic industry

This scenario is considered to be covered by the CIP application scenarios described for PT4 - Scenario 1.

Indeed the way of application is similar to CIP applications in the food processing industry. Moreover for both CIP applications, the same theoretical products are used for exposure estimation (PAA 15% w/w, H_2O_2 23.5% w/w). The product concentration to be used is 0.032% for CIP disinfection in pharmaceutical and cosmetic industry, while the product concentration to be used for CIP disinfection in the food processing industry is 0.064% (please refer to the intended uses). Therefore the emission estimation and exposure assessment of CIP applications in PT4 is considered to be representative for PT2 CIP applications and can be seen as worst case scenario.

SCENARIO 4: Disinfection of surfaces by spraying (with personal enclosure)

This scenario is considered to be covered by the spraying applications described for PT4 – Scenario 4 (Disinfection in large scale catering kitchens and canteens).

According to the applicant, the way of application of this scenario is similar to spraying/foaming applications in the food processing industry for which processes are highly automated. Although the environment within which the exposure takes place according to the intended use (i.e. in an agriculture/horticulture/greenhouse) is different compared to a PT4 environment, where spraying applications are always performed within areas with concrete or water tight floors and guaranteed connection to the sewer system for drainage of used solutions, it was assumed that for this PT2 application a similar water tight or concrete flooring and a connection to a sewer system is available. PT4 exposure scenario is thus applicable for the intended use.

However applications could also take place in e.g. non-paved greenhouses where direct emissions to soil cannot be excluded. Nevertheless in those situations the soil is assumed to be highly enriched with organic matter - as the activity takes place in an agricultural or horticultural environment - enhancing the already fast degradation of PAA and HP (please refer to the CAR and to the degradation values in the part on environmental fate). Therefore no significant exposure or risk is expected under these conditions.

The same theoretical products are used for exposure estimation of PT2 and PT4 applications and the maximum product concentration to be used for disinfection with PT2 (0.048%) is lower than the concentration applicable for PT4 (0.064%). The emission estimation and exposure assessment presented for PT4 (scenario 1) is therefore considered to be representative for this PT2 scenario and can be seen as worst case scenario.

SCENARIO 5: Disinfection of surfaces by spraying (without personal enclosure)

This scenario is considered to be covered by the spraying applications described for PT4 – Scenario 4 (Disinfection in large scale catering kitchens and canteens). The way of application of this scenario is similar to the manual spraying (at low and high pressure) and foaming applications in the food processing industry.

It was assumed that for this kind of application, a water tight or concrete flooring and a connection to a sewer system is available, as in PT4 scenario. Moreover when direct emissions to soil cannot be excluded due to, e.g. non-paved greenhouses, the active substances are assumed to quickly degrade due to the enrichment of the soil with organic matter (please refer to explanations for scenario 7).

The same theoretical products are used for exposure estimation of PT2 and PT4 applications and the maximum product concentration to be used for disinfection with PT2 (0.048%) is lower than the concentration applicable for PT4 (0.064%). The emission estimation and exposure assessment presented for PT4 (scenario 2) is therefore considered to be representative for this PT2 scenario and covers it.

SCENARIO 6: Disinfection of equipment by soaking

This scenario is considered covered by the soaking application scenarios described for PT4 – Scenario 4 (Disinfection in slaughterhouses and butcheries). The way of application of this scenario is similar to soaking applications in the food processing industry.

For both soaking applications, the same theoretical product are used for exposure estimation. The maximum product concentration to be used for disinfection with PT2 (0.048%) is lower than the concentration applicable for PT4 (0.064%). The emission estimation and exposure assessment presented for PT4 (scenario 2) is therefore considered to be representative for this PT2 scenario and can be seen as worst case scenario.

SCENARIO 7 : Disinfection of surfaces by manual spraying

This scenario is considered to be covered by the spraying applications described for PT4 – Scenario 4 (Disinfection in large scale catering kitchens and canteens). The way of application of this scenario is similar to the manual spraying /foaming applications in the food processing industry (please refer to explanations for scenario 5).

SCENARIO 8 : Disinfection of surfaces by automatic spraying

This scenario is considered to be covered by the spraying/foaming applications described for PT4 – Scenario 4 (Disinfection in large scale catering kitchens and canteen).
According to the applicant, the way of application of this scenario is similar to spraying/foaming applications in the food processing industry for which processes are highly automated (please refer to explanations for scenario 4).

SCENARIO 9 : Disinfection of surfaces by automatic spraying – Closed room

This scenario is considered to be covered by the spraying/foaming applications described for PT4 – Scenario 4 (Disinfection in large scale catering kitchens and canteen). The way of application of this scenario is similar to spraying/foaming applications in the food processing industry for which processes are highly automated (please refer to scenario 4).

SCENARIO 10 : Disinfection of surfaces in industrial, public and health care areas – Fogging

Scenario 10 – Disinfection in industrial areas and for sanitary purpose - Fogging

Peracetic acid and Hydrogen peroxide are emitted into the environment via waste water. Emissions to air are considered to be negligible. Indeed the room is tightly sealed during fogging and still left closed for about 60 min before be ventilated, it has been considered that most of the product has settled on the surfaces and only a negligible amount of

active substances will end to the air compartment, especially as PAA and HP have a low vapour pressure.
The emission estimation were based on the ESD for PT2 for industrial and institutional areas (2011, p. 12 and p. 16) and for medical sector (van der Poel, 2001, p. 20), with adaption to fogging application according to TAB ENV 52 (TAB, 2019).

Intermediate calculation for Scenario 10 - Concentration of active substances in the applied product

The emissions are based on the actual use use #2.1 : Sopuroxid 3.2, with 3.2% PAA and 23.5% HP is diluted to reach a final PAA concentration of 1.28% and applied at a rate of 5.6 mL/m³

The concentration of the active substances in the product applied for disinfection was calculated according to the following equation (results are available in Table 2.2.8–12 below):

$$C_{form} = C_{FP} \times \rho_{a.i} \times DIL$$

Table 2.2.8–12 Concentration of Peracetic acid and Hydrogen Peroxide used for the disinfection of surfaces by fogging.

Concentration of the active substances in the applied product					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Concentration of a.s. in formulated product	C_{FP}	32	235	g/kg	Provided by the applicant
Relative density of formulated product (SOPUROXID 3.2)	$\rho_{a.i.}$	1.108		kg/L	Provided by the applicant
Dilution of the pure product	DIL	1.28	9.4[1]	%	Provided by the applicant
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Concentration of a.s. in used product	C_{form}	**14.2**	**104**	g/L	Output

[1]With a PAA concentration of 1.28%, the HP concentration is calculated as (23.5/3.2)*1.28 =9.4%

Final calculations for scenario 10 – Industrial area

The local release to the wastewater after application of the product in industrial area ($E_{local\ water}$) is calculated according to the following equations:

$$E_{local\ water} = C_{form} \times V_{form} \times VOL \times Nappl \times (1-F_{dis}) \times F_{water}$$

The applicant has considered that 5.6 mL of diluted product is used per m³. The parameters used for calculations and the results are available in Table 2.2.8–13.

Table 2.2.8–13 Local release to wastewater of disinfectants used in industrial areas – fogging (JRC, 2011)

Scenario 10: Disinfection of surfaces in industrial, public and health care areas Fogging – Industrial areas					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Concentration of a.s. in used product	C_{form}	1.42×10^{-2}	1.04×10^{-1}	kg/L	Provided by the applicant
Application rate of biocidal product	V_{form}	0.0056		L/m³	Provided by the applicant
Volume area to be disinfected	VOL	4000		m³	TAB ENV 52
Number of applications per day	Nappl	1		d^{-1}	Default
Fraction of substance disintegrated during or after application (before release to the sewer system)	F_{dis}	0		/	Default
Fraction released to wastewater	F_{water}	1		/	Default
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water (without pretreatment)	$E_{local\ water}$	3.18×10^{-1}	2.33	kg/d	Output

Final calculations for scenario 10 – Sanitary purpose in hospitals based on average consumption

Please refer to scenario 1 here above for detailed explanation. The parameters used for calculations and the results are available in Table 2.2.8–14.

Table 2.2.8–14 Local release to wastewater of disinfectants used for sanitary purposes based on average consumption – fogging (Van der Poel, 2001)

Scenario 10: Disinfection of surfaces in industrial, public and health care areas Fogging – Sanitary purposes based on average consumption					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Concentration of a.s. in used product	C_{form}	1.42×10^{-2}	1.04×10^{-1}	kg/L	Provided by the applicant
Consumption per capita for general purpose (tiles, floors, sinks)	$V_{form\ general}$	0.005		L/cap. × d	Default
Number of inhabitants feeding	Nlocal	10000		cap.	Default

one STP					
Penetration factor of disinfectant	F_{penetr}	0.5		/	Default
Fraction of substance disintegrated during or after application (before release to the sewer system)	F_{dis}	0		/	Default
Fraction released to wastewater	F_{water}	1		/	Default
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water (without pretreatment)	$E_{local\ water}$	3.55×10^{-1}	2.60	kg/d	Output

Final calculations for scenario 10 – Sanitary purpose in hospitals based on daily consumption

Please refer to scenario 1 here above for detailed explanation. The parameters used for calculations and the results are available in Table 2.2.8–15 below.

Table 2.2.8–15 Local release to wastewater of disinfectants used for sanitary purposes in hospitals based on the amount of solution of disinfectant used on a day – fogging (RIVM, 2001)

Scenario 1: Disinfection of surfaces in industrial, public and health care areas Fogging – Sanitary purposes in hospitals based on daily consumption					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Concentration of a.s. in used product for sanitary purposes	C_{san}	1.42×10^{-2}	1.04×10^{-1}	kg/L	Provided by the applicant
Concentration of a.s. in used product for brushes	C_{obj}	1.42×10^{-2}	1.04×10^{-1}	kg/L	Provided by the applicant
Amount of water with active substance in sanitary purposes	Q_{water_san}	25		L/d	Default
Amount of water with active substance in brushes	Q_{water_obj}	25		L/d	Default
Fraction of substance released to waste by sanitary purposes	$F_{sanwater}$	0.55		/	Default
Fraction of substance released to waste by brushes	$F_{objwater}$	0.95		/	Default
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water (without pretreatment)	$E_{local\ water}$	5.32×10^{-1}	3.91	kg/d	Output

Scenario 10 – Total release to waste water

As the biocidal products could be used simultaneously in industrial premises, institutional and health care areas for disinfection of surfaces, a worst case scenario summing all emissions is used for exposure assessment:

Table 2.2.8–16 Total local release to wastewater of disinfectants used in industrial areas and for sanitary purpose - Fogging

Scenario 1: Disinfection of surfaces in industrial, public and health care areas Fogging – Total local release				
Local release to waste water	**Value**		**Unit**	**Remarks**
	PAA	**HP**		
Industrial areas	3.18×10^{-1}	2.33	kg/d	Table 2.2.8–13
Sanitary purposes based on average consumption	3.55×10^{-1}	2.60	kg/d	Table 2.2.8–14
Sanitary purposes in hospitals based on daily consumption	5.32×10^{-1}	3.91	kg/d	Table 2.2.8–15
Output	**Value**		**Unit**	**Remarks**
	PAA	**HP**		
Total local release to waste water	1.20	8.84	kg/d	Output

Degradation in the sewer system

A risk being identified for aquatic compartments with the standard scenario (please refer to Table 2.2.8-47) the applicant has suggested to take into account the degradation in the sewer system following the approach described previously (please refer to PT2 scenario 1). The parameters used for calculations and the results are available in Table 2.2.8–17.

Table 2.2.8–17 Local release to the plant of disinfectants used in industrial areas and for sanitary purpose - Fogging

Scenario 10 – Local release to the plant of disinfectants used in industrial areas and for sanitary purpose - Fogging					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water at T0 for industrial area & sanitary purpose (=$Elocal_{water\ indus\ \&\ sanit\ fog}$)	$M_{T0\ indus\ \&\ sanit\ fog}$	1.20	8.84	Kg/d	Table 2.2.8–16
Rate constant	k	4.38[1]	0.25[2]	h^{-1}	Calculated as Ln 2 / DT_{50}
Time	T	1		h	CAR
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water at	$M_{T\ indus\ \&\ sanit\ degr}$	1.51	6.89	Kg/d	Output

T1 for industrial area & sanitary purpose (=$Elocal_{water\ indus\ \&\ sanit\ degr\ fog}$)	fog	× 10^{-2}			

[1] For PAA, k was calculated from the DT_{50} of 9.5min at 12°C.
[2] For HP, k was calculated from the DT_{50} of 169 min at 12°C.

SCENARIO 11 : Disinfection of equipment & surfaces by fogging

This scenario is considered to be covered by the spraying/foaming applications described for PT2 – Scenario 10 (Disinfection in industrial areas and for sanitary purpose - Fogging). The way of application of this scenario is similar to spraying/foaming applications in the food processing industry for which processes are highly automated (please refer to scenario 4).

SCENARIO 12 : Disinfection of surfaces in industrial, public and health care areas – Foaming on small surfaces

This scenario is considered covered by the scenario described for PT2 – Scenario 1. The area in which the application could take place is identical and the maximum use concentration (0.048%) applicable to Scenario 1 are also applicable here.

SCENARIO 13 : Disinfection of surfaces by manual foaming

This scenario is considered to be covered by the spraying/foaming applications described for PT4 – Scenario 4 (Disinfection in large scale catering kitchens and canteens). The way of application of this scenario is similar to the manual spraying/foaming applications in the food processing industry (please refer to explanations for scenario 5) and the maximum use concentration (0.048%) applicable to Scenario 1 is also applicable here.

SCENARIO 14 : Disinfection of surfaces by automatic foaming

This scenario is considered to be covered by the spraying/foaming applications described for PT4 – Scenario 1 (Disinfection in food, drink and milk industries - Assessment of entire plants). The way of application of this scenario is similar to spraying/foaming applications in the food processing industry for which processes are highly automated (please refer to scenario 4) and the maximum use concentration (0.048%) applicable to Scenario 1 is also applicable here.

SCENARIO 15 : Disinfection of surfaces by automatic foaming - Closed room

This scenario is considered to be covered by the spraying/foaming applications described for PT4 – Scenario 1 (Disinfection in food, drink and milk industries - Assessment of entire plants). The way of application of this scenario is similar to spraying/foaming applications in the food processing industry for which processes are highly automated (please refer to scenario 4) and the maximum use concentration (0.048%) applicable to Scenario 1 is also applicable here.

(II) General information on PT 3 - Disinfectants for veterinary hygiene (meta SPC 1, 2, 3 and 4)

Assessed PT	**PT 3 – Veterinary hygiene**

Use of the product	*1. DISINFECTION OF ANIMAL HOUSING BY LOW-PRESSURE MANUAL SPRAYING (PERSONAL ENCLOSURE)* Disinfection of surfaces (animal housing) by spraying via a spraying device. The worker or operator is present but in a personal enclosure. Spraying is done in all directions. After the disinfection, surfaces and equipment are rinsed with water and the water is drained into the sewer system. Peracetic acid concentration : 0.064%.
	2*. DISINFECTION OF ANIMAL HOUSING BY LOW-PRESSURE MANUAL SPRAYING (WITHOUT PERSONAL ENCLOSURE)* Disinfection of animal house surfacesby spraying on the surface either manually or via a spraying device. Spraying is done in all directions. After the disinfection, surfaces and equipment are rinsed with water and the water is drained into the sewer system. Peracetic acid concentration : 0.064%.
	3. DISINFECTION OF BOOTS IN FOOTBATHS in animal housing /husbandries Disinfection of boots in footbaths (not for walk-through) in animal housing/husbandries sites. The boots are first rinsed off and then the worker walks through a soaking bath containing the biocidal solution during maximum 1 minute. No final rinse applies. Peracetic acid concentration : 0.064%.
	4. DISINFECTION OF EQUIPMENT BY DIPPING Disinfection of small parts (spare parts, tools, valves, hoses,...) by immersion in soaking baths containing the product diluted to the use concentration. After the disinfection, equipment or small parts are rinsed with water and the water is drained into the sewer system. Peracetic acid concentration : 0.064%.
	5. DISINFECTION ANIMAL HOUSING BY FOGGING The diluted solution is applied on the surfaces and/or equipment that is to be disinfected by fogging. The room where the fogging activity takes place is tightly sealed during fogging.. Entrance in the room is allowed after verification of the concentrations (0.5 mg/m³). Peracetic acid concentration : 1.28%.
	6. DISINFECTION OF ANIMAL HOUSING BY FOAMING (PERSONAL ENCLOSURE) The diluted solution is foamed on the surfaces/walls via a foaming device. The application of the disinfectant is done automatically using of foaming equipment. The worker or operator is present but in a personal enclosure. Foaming is done in all directions. After the disinfection, surfaces and equipment are rinsed with water and the water is drained into the sewer system.

	Peracetic acid concentration : 0.064%.
	7. DISINFECTION OF ANIMAL HOUSING BY FOAMING (WITHOUT PERSONAL ENCLOSURE) The diluted solution is foamed on the surfaces/walls either manually or via a spraying device. The worker or operator is not present within a personal enclosure (e.g. cabin). Spraying is done in all directions. After the disinfection, surfaces and equipment are rinsed with water and the water is drained into the sewer system. Peracetic acid concentration : 0.064%.
Assessed scenarios	Scenario 1: Disinfection of animal housing by spraying Scenario 3 : Disinfection of boots in footbaths Scenario 4 : Disinfection of equipment by dipping
ESD(s) used	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products (EUR 25116 EN - 2011)
Approach	Scenario 1: Emission after one application Scenario 3 : Emission after one application Scenario 4 : Emission after one application
Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulation - Volume IV Environment - Assessment and Evaluation (Parts B + C) - Version 2.0, October 2017
Groundwater simulation	Not relevant
Confidential Annexes	NO
Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: No
Remarks	-

Emission estimation

SCENARIO 1: Disinfection of animal house by low-pressure manual spraying (Personal enclosure)

Scenario 1 – Disinfection of animal housing by spray

Peracetic acid and Hydrogen peroxide are emitted into the environment by air and via the application of manure/slurry to agricultural land. Moreover emission to the sewage treatment plant via waste water can also take place for some type of poultry housing.
The emission estimations were based on the ESD for PT3 for animal housing (p. 10-19; default values available in appendix 1, Table 8-13).

The worst-case emission is due to the use of the formulated product Sopuroxid 5C (density : 1.235), diluted to reach 0.064% PAA. The final in-use concentrations are 0.79 g/L PAA & 3.48 g/L HP, respspectively. According to the applicant, the application rate to be used is 300 mL per m².

The local release to the air ($E_{direct\ air}$), to the sewage treatment plant ($E_{local\ water}$) and to manure ($Q_{a.i.\ manure/slurry}$) after one application of the product in animal housing is calculated according to the following equation:

Local release = $F_{bioc} \times V_{prod} \times AREA \times F_{air/STP/manure/slurry} \times 10^{-3}$

The concentration of the active substance (F_{bioc}) and the volume of product to be used (V_{prod}) are provided by the applicant while the surface to be disinfected (AREA) and the fraction released to the air (F_{air}) to the sewage treatment plant (F_{STP}) and to manure (F_{manure}) are default values taken from the ESD for PT3 (Tables 8 and 10 from appendix 1). The parameters used for calculations and the results are available in Table 2.2.8–19 and Table 2.2.8–20.

Please note that the default value of the the fraction released to the air (F_{air}) being zero for all animal categories, the local release to the air ($E_{direct\ air}$) is also equal to zero.

Please note that the emissions from the rinsing of surfaces and equipment after disinfection are considered to be covered by those calculated below, as the emsissions are based on the amount of active substances used for disinfection and not the amount of active substances washed after the treatement.

Degradation in the sewer system

A risk being identified for surface water and sediment with the standard scenarios (please refer to Table 2.2.8-47), the applicant has suggested to take into account the degradation in the sewer system. Following the approach described in the CAR of PAA, the degradation of PAA and HP in the sewer system was considered according to the equation:

$M_T = M_{T0} \times E^{(-k \times T)}$

The rate constant (k) were calculated from the DT_{50} values ($k=\ln2/DT_{50}$) of PAA (k = 4.38 h^{-1}, from a DT_{50} of 9.5 min. at 12°C) and HP (k = 3.65 h^{-1}, from a DT_{50} of 11.4 min. at 12°C) and are available in Table 2.2.8-38 (Input parameters for calculating the fate and distribution of Peracetic acid and Hydrogen peroxide in the environment).
It was assumed that the residence time in the sewer system before reaching the Sewage Treatment Plant is one hour (T=1h).
Please note that only the highest value of $E_{local\ water}$ (i.e. emission from turkeys : 3.81E-01 kg/d for PAA and 1.68 kg/d for HP) is used in further exposure calculation as worst-case scenario. The parameters used for calculations and the results are available in Table 2.2.8–18.

Table 2.2.8–18 Local release to wastewater of disinfectants used in animal housing following degradation in sewer system

Scenario 1: Disinfection of surfaces in animal housing – Spraying Local release following degradation in sewer system					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water from animal housing at T0	$M_{T0\ housing}$	3.81 × 10^{-1}	1.68	Kg/d	Table 2.2.8–19

(=$E_{local\ water}$)					
Rate constant	k	4.38[1]	0.25[2]	h^{-1}	Calculated as Ln 2 / DT_{50}
Time	T	1		h	CAR
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water from animal housing at T1 (=$E_{local\ water\ with\ degradation}$)	$M_{T\ housing}$	4.78×10^{-3}	1.31	Kg/d	Output

[1] For PAA, k was calculated from the DT_{50} of 9.5min at 12°C.
[2] For HP, k was calculated from the DT_{50} of 169 min at 12°C.

Degradation in manure

A risk being identified for terrestrial compartment with the standard scenario (Please refer to Table 2.2.8-49), the applicant has suggested to take into account the degradation in manure/slurry. Indeed PAA and HP react rapidly with organic substances and metal cations which are present abundantly in liquid manure. Therefore, their degradation was taken into account in the same way as the CAR of PAA, according to the equation:

$$M_T = M_{T0} \times E^{(-k \times T)}$$

The rate constant (k) were calculated from the DT_{50} values ($k=\ln2/DT_{50}$) of PAA (k = 4.38 h^{-1}, from a DT_{50} of 9.5 min. at 12°C) and HP (k = 3.65 h^{-1}, from a DT_{50} of 11.4 min. at 12°C) and are available in Table 2.2.8-38 (Input parameters for calculating the fate and distribution of Peracetic acid and Hydrogen peroxide in the environment).

It was assumed that the last application of the product containing PAA and HP take place two hours before the liquid manure is applied to agricultural land (T= 2h). This assumption is the worst case since the maximum time span between the disinfection process and the application of manure to agricultural land is up to 6 months. It was further assumed that residues of PAA and HP resulting from former applications during the manure storage period were negligible.

The total amount of active substances at T0 (M_{T0} = Qai) and the local release to manure or slurry after degradation (M_T = $Qa\_{\ degr}$) are available in Table 2.2.8–20.

Please note that according to the TAB (ENV 168), a combined assessment for emission to manure/slurry and waste water has to be perfomed in case that poultry stables are not connected to the municipal sewer system. In such situation, all wastewater would remain on site and be stored with the slurry for application to agricultural land, leading to direct exposure of soil. TAB ENV 168 was not applicable at the time of the dossier submission. However this scenario must be taken into account at the renewal of the authorization.

Table 2.2.8‑19 Local release to air and sewage treatment plant of Peracetic acid and Hydrogen peroxide used in animal housing

N°	CATEGORY		F_{bioc}*	V_{prod}*	AREA	F_{air}	F_{STP}	$E_{direct\ air}$ PAA & HP	$E_{local\ water}$ PAA	$E_{local\ water}$ HP
			g/L	L/m²	m²	-	-	kg	kg	kg
1	Cattle	Beef	0.79 (PAA), 3.48 (HP)	0.3	3230	0	0	0	0	0
2	Cattle	Dairy			1750	0	0	0	0	0
3	Cattle	Veal calves			650	0	0	0	0	0
4	Pig	Sows - individual			1930	0	0	0	0	0
5	Pig	Sows - groups			2200	0	0	0	0	0
6	Pig	Fattening pigs			2020	0	0	0	0	0
7	Poultry	Battery -No treatment			4410	0	0	0	0	0
8	Poultry	Battery -Belt trying			4410	0	0.2	0	2.09E-01	9.20E-01
9	Poultry	Battery -Deep pit			3810	0	0	0	0	0
10	Poultry	Battery -Compact			3510	0	0	0	0	0
11	Poultry	Free-range -Litter Laying hens			4610	0	0.2	0	2.19E-01	9.62E-01
12	Poultry	Free-range -Litter -Broilers			2730	0	0.2	0	1.29E-01	5.70E-01
13	Poultry	Free-range -Grating - Laying hens			4992	0	0	0	0	0
14	Poultry	Free-range -Grating - Parents broilers			1290	0	0	0	0	0
15	Poultry	Free-range -Grating - Parents broilers in rearing			1640	0	0	0	0	0
16	**Poultry**	**Free-range -Litter -Turkeys**			8040	0	0.2	0	**3.81E-01**	**1.68**
17	Poultry	Free-range -Litter -Ducks			4880	0	0.2	0	2.31E-01	1.02
18	Poultry	Free-range -Litter -Geese			6060	0	0.2	0	2.87E-01	1.26

* Provided by the applicant. In bold, maximum release values used further in the risk assessment

Table 2.2.8‑20 Local release to manure and slurry of Peracetic acid and Hydrogen peroxide used in animal housing disinfection, with (Qai_degr) or without degradation process (Qai)

N°	CATERGORY	F_{bioc}*	V_{prod}*	AREA	F_{manure}	F_{slurry}	Qai PAA	Qai_degr PAA	Qai HP	Qai_degr HP

			g/L	L/m²	m²	-	-	kg	kg	kg	kg
1	Cattle	Beef	0.79 (PAA), 3.48 (HP)	0.3	3230	0	0.5	3.83E-01	6.01E-05.	1.68E+00	1.14E-03.
2	Cattle	Dairy			1750	0	0.5	2.07E-01	3.26E-05.	9.13E-01	6.17E-04.
3	**Cattle**	**Veal calves**			650	0	0.5	**7.71E-02**	**1.21E-05.**	**3.39E-01**	**2.29E-04.**
4	Pig	Sows - individual			1930	0	0.5	2.29E-01	3.59E-05.	1.01E+00	6.80E-04.
5	Pig	Sows - groups			2200	0	0.5	2.61E-01	4.09E-05.	1.15E+00	7.75E-04.
6	Pig	Fattening pigs			2020	0	0.5	2.39E-01	3.76E-05.	1.05E+00	7.12E-04.
7	Poultry	Battery -No treatment			4410	0	0.5	5.23E-01	8.20E-05.	2.30E+00	1.55E-03.
8	Poultry	Battery -Belt trying			4410	0	0.5	5.23E-01	8.20E-05.	2.30E+00	1.55E-03.
9	Poultry	Battery -Deep pit			3810	0.5	0	4.52E-01	7.09E-05.	1.99E+00	1.34E-03.
10	Poultry	Battery -Compact			3510	0	0.5	4.16E-01	6.53E-05.	1.83E+00	1.24E-03.
11	Poultry	Free-range -Litter Laying hens			4610	0.3	0	3.28E-01	5.14E-05.	1.44E+00	9.75E-04.
12	Poultry	Free-range -Litter - Broilers			2730	0.3	0	1.94E-01	3.05E-05.	8.54E-01	5.77E-04.
13	Poultry	Free-range -Grating Laying hens			4992	0	0.5	5.92E-01	9.29E-05.	2.60E+00	1.76E-03.
14	Poultry	Free-range -Grating Parents broilers			1290	0	0.5	1.53E-01	2.40E-05.	6.73E-01	4.55E-04.
15	Poultry	Free-range -Grating Parents broilers in rearing			1640	0	0.5	1.94E-01	3.05E-05.	8.56E-01	5.78E-04.
16	Poultry	Free-range -Litter - Turkeys			8040	0.3	0	5.72E-01	8.97E-05.	2.52E+00	1.70E-03.
17	**Poultry**	**Free-range -Litter - Ducks**			4880	0.3	0	**3.47E-01**	**5.45E-05.**	**1.53E+00**	**1.03E-03.**
18	Poultry	Free-range -Litter - Geese			6060	0.3	0	4.31E-01	6.76E-05.	1.90E+00	1.28E-03.

* Provided by the applicant. In bold, maximum release values used further in the risk assessment

SCENARIO 2: Disinfection of animal housing by low-pressure manual spraying (Without personal enclosure)

This scenario is considered to be covered by the spraying applications described in scenario 1 (disinfection of animal housing by spray). For both spraying applications, the maximum product concentration to be used for disinfection is 0.064%. The emission estimation and exposure assessment presented for scenario 1 is therefore considered to be representative for this scenario.

SCENARIO 3: Disinfection of boots in footbaths in animal housing/husbandries

Scenario 3 – Disinfection of footwear

The solution of the footbath is either discharged to the waste water or to the manure while emission to air is considered negligible. PAA and HP are thus emitted into the environment via the application of manure/slurry to agricultural land or via waste water to the sewage treatment plant. The emission estimations were based on the ESD for PT3 for footwear (p. 28-32; default values available in appendix 1, Table 7-13).

The worst-case emission is due to the use of the formulated product Sopuroxid 5C (density : 1.235), diluted to reach 0.064% PAA. The final in-use concentrations are 0.79 g/L PAA & 3.48 g/L HP, respsectively.

The local emissions to manure/slurry storage tank ($E_{direct\ manure\ storage}$) or to waste water ($E_{local\ waste\ water}$) are calculated according to the following equation:

Local release = $F_{bioc} \times V_{reserv} \times F_{manure/slurry/STP} \times 10^{-3}$

Default values for the emission estimation were taken from the ESD for PT3, Table 4a (p. 28). The parameters used for calculations and the results are available in Table 2.2.8–21.

Table 2.2.8–21 Local release to the manure/slurry and sewage treatment plant of disinfectants used in footbaths (animal housing/husbandries)

Scenario 6: Disinfection of boots in footbaths (animal housing/husbandries)					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Concentration of a.s. in used product	F_{bioc}	0.79	3.48	g/L	Provided by the applicant
Volume of reservoir	V_{reserv}	10		L	Default
Fraction released to manure/slurry	$F_{manure/slurry}$	1		/	Default
Fraction released to STP	F_{STP}	1		/	Default
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		

Local release to manure/slurry	$E_{direct\ manure\ storage}$	7.90×10^{-3}	3.48×10^{-2}	Kg/d	Output
Local release to waste water	$E_{local\ water}$	7.90×10^{-3}	3.48×10^{-2}	Kg/d	Output

Degradation in manure

A risk being identified for terrestrial compartment with the standard scenario (Please refer to Table 2.2.8-49), the applicant has suggested to take into account the degradation in manure/slurry. As for scenario 1, the degradation of active substances was taken into account in the same way as the CAR of PAA, according to the equation:

$$M_T = M_{T0} \times E^{(-k \times T)}$$

The rate constant (k) were calculated from the DT_{50} values ($k=\ln 2/DT_{50}$) of PAA ($k = 4.38\ h^{-1}$, from a DT_{50} of 9.5 min. at 12°C) and HP ($k = 3.65\ h^{-1}$, from a DT_{50} of 11.4 min. at 12°C). Please also refer to Table 2.2.8-38.

It was assumed that the last application of the product containing PAA and HP take place two hours before the liquid manure is applied to agricultural land (T= 2h). It was further assumed that residues of PAA and HP resulting from former applications during the manure storage period were negligible.

The total amount of active substances at T0 ($M_{T0} = Qai_{grass/arabl}$) are available in Table 2.2.8–21. The local release to manure or slurry after degradation ($M_T = Qai_{grass/arabl\ degradation}$) is expressed in kilogram. The parameters used for calculations and the results are available in Table 2.2.8–22.

Table 2.2.8–22 Local release of disinfectants used in footbaths (animal housing/husbandries) following their degradation in manure

Scenario 6: Disinfection of boots in footbaths (animal housing/husbandries) Local release following degradation in manure					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to manure/slurry at T0 (=$E_{direct\ manure\ storage}$)	$M_{T0\ manure\ storage}$	7.90×10^{-3}	3.48×10^{-2}	Kg/d	Table 2.2.8–21
Rate constant for manure	k_{manure}	4.38[1]	3.65[2]		Calculated as $\ln 2 / DT_{50}$
Residence time in manure	T_{manure}	2		h	CAR
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to manure/slurry at T0 (=$E_{direct\ manure\ storage\ degrd}$)	MT manure storage	1.24× 10-6	2.35× 10-5	Kg/d	Output

[1] For PAA, k was calculated from the DT_{50} of 9.5 min. at 12°C.
[2] For HP, k was calculated from the DT_{50} of 11.4 min. at 12°.

<u>*SCENARIO 4: Disinfection of equipment by dipping*</u>

Scenario 4 – Disinfection by dipping

The solution of the soaking bath is either discharged to the waste water or to the manure while emission to air is considered negligible. PAA and HP are thus emitted into the environment via the application of manure/slurry to agricultural land or via waste water to the sewage treatment plant. The emission estimations were based on the ESD for PT3 for footwear (p. 28-32), revised according to TAB ENV 46 (Technical Agreements for Biocides, 2017)

The worst-case emission is due to the use of the formulated product Sopuroxid 5C (density : 1.235), diluted to reach 0.064% PAA. The final in-use concentrations are 0.79 g/L PAA & 3.48 g/L HP, respspectively.

The local emissions to manure/slurry storage tank ($E_{direct\ manure\ storage}$) or to waste water ($E_{local\ waste\ water}$) are calculated according to the following equation:

$$E_{local\ water} = F_{bioc} \times V_{reserv} \times F_{STP} \times 10^{-3}$$

Default values for the emission estimation were taken from the ESD for PT3, Table 4a (p. 28). The parameters used for calculations and the results are available in Table 2.2.8–23.

Table 2.2.8–23 Local release to the sewage treatment plant of disinfectants used for dipping (animal housing/husbandries)

Scenario 4: Disinfection by dipping (animal housing /husbandries)					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Concentration of a.s. in used product	F_{bioc}	0.79	3.48	g/L	Provided by the applicant
Volume of reservoir	V_{reserv}	100		L	TAB – ENV 46
Fraction released to manure/slurry	$F_{manure/slurry}$	1		/	Default
Fraction released to STP	F_{STP}	1		/	Default
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to manure/slurry	$E_{direct\ manure\ storage}$	7.90×10^{-2}	3.48×10^{-1}	Kg/d	Output
Local release to waste water	$E_{local\ water}$	7.90×10^{-2}	3.48×10^{-1}	Kg/d	Output

Degradation in manure

A risk being identified for terrestrial compartment with the standard scenario (Please refer to Table 2.2.8-49), the applicant has suggested to take into account the degradation in manure/slurry. As for scenario 1, the degradation of active substances was taken into account in the same way as the CAR of PAA, according to the equation:

$$M_T = M_{T0} \times E^{(-k \times T)}$$

The rate constant (k) were calculated from the DT_{50} values ($k=ln2/DT_{50}$) of PAA (k = 4.38 h^{-1}, from a DT_{50} of 9.5 min. at 12°C) and HP (k = 3.65 h^{-1}, from a DT_{50} of 11.4 min. at 12°C). Please also refer to Table 2.2.8-38.

It was assumed that the last application of the product containing PAA and HP take place two hours before the liquid manure is applied to agricultural land (T= 2h). It was further assumed that residues of PAA and HP resulting from former applications during the manure storage period were negligible. The total amount of active substances at T0 (M_{T0} = $Qai_{grass/arabl}$) are available in Table 2.2.8–23. The local release to manure or slurry after degradation (M_T = $Qai_{grass/arabl\ degradation}$) is expressed in kilogram. The parameters used for calculations and the results are available in Table 2.2.8–24.

Table 2.2.8–24 Local release of disinfectants used in footbaths (animal housing /husbandries) following their degradation in manure

Scenario 4: Disinfection of boots in footbaths (animal housing /husbandries) Local release following degradation in manure and sewer system					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to manure/slurry at T0 (=$E_{direct\ manure\ storage}$)	$M_{T0\ manure\ storage}$	7.90× 10^{-2}	3.48× 10^{-1}	Kg/d	Table 2.2.8–23
Rate constant for manure	k_{manure}	4.38[1]	3.65[2]		Calculated as Ln 2 / DT_{50}
Residence time in manure	T_{manure}	2		h	CAR
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to manure/slurry at T0 (=$E_{direct\ manure\ storage\ degrd}$)	$M_{T\ manure\ storage}$	1.24× 10^{-5}	2.35× 10^{-4}	Kg/d	Output

[1] For PAA, k was calculated from the DT_{50} of 9.5 min. at 12°C.
[2] For HP, k was calculated from the DT_{50} of 11.4 min. at 12°C.

SCENARIO 5: Disinfection animal house by fogging

PAA and HP are emitted into the environment by air and via the application of manure/slurry to agricultural land. Moreover emission to the sewage treatment plant via waste water can also take place for some type of poultry housing.

Scenario 5 – Disinfection of animal housing by fogging

The emissions calculated for scenario 1 (disinfection of animal housing by spray) cover the uses #2.3. Indeed the actual worst-case emissions are due to Sopuroxid 3.2 (density : 1,108 kg/L), diluted to reach a final PAA concentration of 1.28% and applied at a rate of 5.6 mL/m³. This would lead to the following emissions :

A.S.	**$Q_{local\ water}$ Turkey**	**Q_{ai} veal calves**	**Q_{ai} ducks**
PT3 - Disinfection of animal housing by fogging			
PAA	1.79E-01	2.11E-02	1.61E-01
HP	1.32	1.55E-01	1.18

The emission estimations and exposure assessment presented for spraying application here above are therefore considered to cover scenario 5 according to use # 2.3.

Please note that, instead of fogging application, the spray application does not take the emission to air into account. However as the room is tightly sealed during fogging and still left closed for about 60 min before be ventilated, it has been considered that most of the product has settled on the surfaces and only a negligible amount of active substances will end to the air compartment, especially as PAA and HP have a low vapour pressure.

SCENARIO 6: Disinfection of animal house by foaming (Personal enclosure)

No specific scenario is available to calculate the emission from disinfection of animal house by foaming. However the type of application and the emission pathway to the environment are similar to the spray application and are thus considered to be covered by the spray scenarios (WG-III-2014).

Moreover the same dilution of the formulated product (0.064%) is to be used for both spraying and foaming application. The emission estimations and exposure assessment presented for spraying applications - scenario 1 (disinfection of animal housing by spray) are therefore considered to be representative for this scenario and covered by it.

SCENARIO 7: Disinfection of animal house by foaming (Without personal enclosure)

No specific scenario is available to calculate the emission from disinfection of animal house by foaming. However the type of application and the emission pathway to the environment are similar to the spray application and are thus considered to be covered by the spray scenario (WG-III-2014).

Moreover the same dilution of the formulated product (0.064%) is to be used for both spraying and foaming application. The emission estimations and exposure assessment presented for spraying applications - scenario 1 (disinfection of animal housing by spray by spray) are therefore considered to be representative for this scenario and covered by it.

(III) General information on PT 4 - Disinfectants used in food and feed areas (meta SPC 1, 2, 3 and 4)

Assessed PT	**PT 4 – Food and Feed Area**
Use of the product	*1. DISINFECTION BY AUTOMATED SPRAYING IN CLOSED SYSTEMS (CLOSED ROOMS)* For aseptic filling and sterilization of crown corks, cheese moulds & food crates in the food and beverage industry. Diluted solution is sprayed on the surfaces in an automated way without any operator being present. After the disinfection, equipment is rinsed with water and the water is drained into the sewer system. Peracetic acid concentration (maximum): 0.064%
	2. DISINFECTION OF EQUIPMENT IMMERSION Disinfection of small parts (equipment, spare parts, tools, valves, hoses,…) by dipping in soaking baths containing the diluted solution. After the disinfection, equipment or small parts are rinsed carefully with water and the water is drained into the sewer system. Peracetic acid concentration (maximum): 0.064%
	3. DISINFECTION IN ASEPTIC FILLING LINES (CROWN CORKS, CHEESE MOULDS AND FOOD CRATES) - AUTOMATED SPRAYING CLOSED SYSTEMS For CIP-procedures, the product is automatically circulated from the CIP holding tanks through closed pipework and installations during application of the product. After cleaning/disinfection are completed, pipework and tanks are rinsed with water, which is done under closed system conditions as well. After application, the CIP vessel is drained. Peracetic acid concentration (maximum): 0.064%
	4. DISINFECTION OF SURFACES & EQUIPMENT BY LOW-PRESSURE SPRAYING (PERSONAL ENCLOSURE) Diluted solution is sprayed on the surface via a spraying device. The application of the disinfectant is done automatically using of spraying equipment. The worker or operator is present but in a personal enclosure. Spraying is done in all directions.. After the disinfection, surfaces and equipment are rinsed with water and the water is drained into the sewer system. Peracetic acid concentration (maximum): 0.064%
	5. DISINFECTION OF SURFACES & EQUIPMENT BY LOW-PRESSURE SPRAYING (WITHOUT PERSONAL ENCLOSURE) Diluted solution is sprayed on the surface, either manually or via a spraying device. The worker or operator is not present within a

	personal enclosure. Spraying is done in all directions. After the disinfection, surfaces and equipment are rinsed with water and the water is drained into the sewer system. Peracetic acid concentration (maximum): 0.064%
	6. DISINFECTION OF SURFACES & EQUIPMENT BY LOW-PRESSURE SPRAYING (MANUAL) Disinfection of surfaces and equipment by low pressure spraying equipment, manually. Spraying is done only downwards and horizontal. After the disinfection, surfaces and equipment are rinsed with water and the water is drained into the sewer system. Peracetic acid concentration (maximum): 0.064%
	7. DISINFECTION OF SURFACES & EQUIPMENT BY LOW-PRESSURE SPRAYING (AUTOMATIC) Disinfection of surfaces and equipment by low pressure spraying equipment, on conveyor belt, automatically, while the operator is present within a personal enclosed area. Spraying is done only downwards and horizontal. After the disinfection, surfaces and equipment are rinsed with water and the water is drained into the sewer system. Peracetic acid concentration (maximum): 0.064%
	8. DISINFECTION OF SURFACES & EQUIPMENT BY AUTOMATIC LOW-PRESSURE SPRAYING (AUTOMATIC – CLOSED ROOM) Disinfection of a specific area (room). The diluted solution is sprayed on the surfaces in an automated way without any operator being present. After the disinfection, surfaces and equipment are rinsed with water and the water is drained into the sewer system. Peracetic acid concentration (maximum): 0.064%
	9. DISINFECTION OF INNER SURFACES BY CIP (PIPELINES, TANKS, VESSELS, …) For CIP-procedures, the biocidal product is automatically circulated from the CIP holding tanks through closed pipework and installations during application of the product. After cleaning/disinfection are completed, pipework and tanks are rinsed with water, which is done under closed system conditions as well. After application, the CIP vessel is drained. Peracetic acid concentration (maximum): 0.064%
	10. DISINFECTION OF WATER USED FOR RINSING OF RECYCLED ITEMS DURING THE WASHING PROCESS Concentrated product will be pumped into a reservoir from which it is continuously dosed into the water stream. Dilution of the product to the intended in-use concentration occurs in the water

	stream. This application is a closed, automated process. Final rinsing is not applicable. Peracetic acid concentration: 0.008%
	11. DISINFECTION OF STORAGE ROOMS BY FOGGING Disinfection of storage rooms: diluted solution is applied on the surfaces within the storage rooms which are to be disinfected by fogging. The room where the fogging activity takes place is tightly sealed during fogging. Entrance in the room is allowed after verification of the concentrations (0.5 mg/m^3). Peracetic acid concentration: 1.28%
	12. DISINFECTION OF SURFACES BY FOAMING (PERSONAL ENCLOSURE) Diluted solution is foamed on the surfaces / walls in an automated way via a foaming device. The worker or operator is present but in a personal enclosure. Foaming is done in all directions. After the disinfection, surfaces and equipment are rinsed with water and the water is drained into the sewer system. Peracetic acid concentration (maximum): 0.064%
	13. DISINFECTION OF SURFACES BY FOAMING (WITHOUT PERSONAL ENCLOSURE) Diluted solution is foamed on the surfaces, either manually or via a spraying device. Foaming is done in all directions. After the disinfection, surfaces and equipment are rinsed with water and the water is drained into the sewer system. Peracetic acid concentration (maximum): 0.064%
Assessed scenarios	Scenario 1: Assessment of entire plants – Disinfection by automated spraying Scenario 4: Large scale catering kitchens, canteens, slaughterhouses and butcheries – Low-pressure spraying Scenario 9: Disinfection of milking parlour systems Scenario 11: Large scale catering kitchens, canteens, slaughterhouses and butcheries – Fogging
ESD(s) used	Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas (EUR 25117 EN – 2011)
Approach	Scenario 1: Tonnage based Scenario 4: Average daily consumption Scenario 9: Average daily consumption Scenario 11: Average daily consumption
Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulation – Volume IV Environment - Part B Risk Assessment (active substances) – Version 1.0, April 2015

Groundwater simulation	Not relevant
Confidential Annexes	NO
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	-

Emission estimation

<u>*SCENARIO 1: Disinfection by automated spraying in closed systems (closed rooms)*</u>

Scenario 1 – Assessment of entire plants

PAA and HP are emitted into the environment via waste water. Emissions to air are considered to be negligible. The emission estimation were based on the ESD for PT4 (2011) using the scenario for disinfection in food, drink and milk industries (FDM) via assessment of entire plants.

Tonnage based scenario

The emission estimation is based on the annual tonnage of the active substances used and on the annual waste water amount discharged by a processing plant as local point source. This is based on the fact that the disinfection measures using different application techniques such as CIP, automated spraying, foaming, bottle rinsing, etc. take place on the same time and end up in the same waste water collecting tank before release to the sewer system.

Concerning the STP to which the waste water is released, two cases have been distinguished:

- The waste water is released to an **on-site STP**. It was further assumed that the on-site treated waste water is directly released to surface water where it can expose both fresh water and fresh water sediments. Exposure to other compartments, such as soil is not considered relevant.

- The waste water is released to an **off-site STP** (municipal STP without on-site treatment) with the standard default values according to the Guidance on the Biocidal Product Regulation (BPR, 2015). The soil can be exposed through sludge application.

The concentration of active substance in influent (on-site STP) and effluent (off-site STP) are calculated according to the following equations:

Concentration of the active substances in the effluent of an on-site STP:

$$C_{effluent} = (Qa.i. / T_{emission}) \times 1{,}000 \times (1 - F_{dis}) \times (1 - F_{elim}) \times F_{water} / (CAP_{STP\_on\text{-}site} \times DIL)$$

Concentration of the active substances in the influent of an off-site STP:

$C_{influent} = (Qa.i. / T_{emission}) \times 1{,}000 \times (1 - F_{dis}) \times (1 - F_{elim}) \times F_{water} / CAP_{STP\_off\text{-}site}$

The average annual amount of active substances (Qai) is a default value provided by the ESD of PT 4 for Peracetic acid but it was calculated for Hydrogen peroxide according to the following reasoning:

PAA (15%) = 407kg/year PAA (ESD default value)
→ Theoretical product 1 = 407 kg/year
→ Hydrogen peroxide (23.5%) = (407 / 0.15) × 0.235 = 638 kg/year

However this would not represent the worst-case PAA/HP ratio. In the actual formulated products, the worst-case ratio is provided by meta SPC 2 (Sopuroxid 3.2) and meta SPC 3 (Acidofoam CF), where PAA and HP represent respectively 5% and 23.5% of the formulated product. Therefore, the worst-case HP tonnage would be :

→ Hydrogen peroxide = (407 / 0.032) × 0.235 = 2,989 kg/year

The parameters used for calculations and result are available in Table 2.2.8–25 (default values were taken from the ESD for PT 4, Table 5, p. 15).

Table 2.2.8–25 Input parameter for calculating the local emission to the entire plants after disinfection in food, drink and milk industries (FDM) by automated spraying in closed systems (IHO, 2006)

Scenario 1: Disinfection in food, drink and milk industries (FDM) by automated spraying in closed systems - Assessment of entire plants					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA (15%)	**HP (23.5%)**		
Amount of biocidal active substance used per year in the local plant	$Q_{a.i}$	407	2,989	kg/year	Default & calculated
Number of emission days per year	$T_{emission}$	231		d/year	Default
Fraction released to wastewater	F_{water}	1		/	Default
Fraction of substance eliminated due to on-site pre-treatment of the plant waste water	F_{elim}	0		/	Default
Fraction of substance eliminated due to on-site pre-treatment of the plant waste water	$F_{elim\ Tier\ 2}$	0.9895[1]	0.9932[1]	/	Table 2.2.8–38
Fraction of substance disintegrated during or after application (before release to the sewer system)	F_{dis}	0		/	Default

Capacity of the on-site STP	$CAP_{STP\_on-site}$	112.7	m³/d	Default
Capacity of the off-site STP	$CAP_{STP\_off-site}$	2,000	m³/d	Default
Dilution factor in surface water for on-site STP	DIL	160	/	Default

[1] Please note that according to the TAB (ENV A12), a default value of 0.9 for F_{elim} is applicable for rapidly reacting substances for all scenarios in PT04. TAB ENV A12 was not applicable at the time of the dossier submission. However the default value must be taken into account at the renewal of the authorization.

Degradation in the sewer system and in on-site STP

A risk being identified for surface water and sediment with the standard scenario for on-site STP as well as for soil in scenario with off-site STP (please refer to Table 2.2.8-47 and Table 2.2.8-48), the applicant has suggested to take into account the degradation in the sewer system following the approach considered previously (please refer to PT3, scenario 1).

The local release to waste water at T0 (M_{T0}) is the amount of active substances released per day in the local plant (Qa.i. / $T_{emission}$). The parameters used for calculations and the results are available in Table 2.2.8–26.

Table 2.2.8–26 Local emission to the entire plants following degradation in sewer system of disinfectant used in food, drink and milk industries (FDM) in automated spraying closed systems (IHO, 2006)

Scenario 1: Disinfection in food, drink and milk industries (FDM) by automated spraying in closed systems - Assessment of entire plants Local release following degradation in sewer system					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water at T0 (=Qa.i. / $T_{emission}$)	M_{T0}	1.76	12.9	Kg/d	
Rate constant	k	4.38[1]	0.25[2]	h^{-1}	Calculated as Ln 2 / DT_{50}
Time	T	1		h	CAR
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water at T1 (=Qa.i. / $T_{emission\ after\ degradation}$)	M_T	2.21×10^{-2}	10,1	Kg/d	Output

[1] For PAA, k was calculated from the DT_{50} of 9.5min at 12°C.
[2] For HP, k was calculated from the DT_{50} of 169 min at 12°C.

The local release to waste water at T1 (M_T = Qa.i. / $T_{emission\ after\ degradation}$) was used to calculate the concentration of the active substances in the effluent of an on-site STP and in the influent of an off-site STP accordingly.
Moreover the fraction of substance eliminated due to the degradation by the micro-organisms of the on-site plant waste water (F_{elim}) was considered in Tier 2 assessment (Please refer to Table 2.2.8–39 'Fate and distribution of Peracetic acid and Hydrogen peroxide in the sewage treatment plant'). The results are available in Table 2.2.8–27.

Table 2.2.8–27 Local waste water emission to the entire plants (e.g. beverage processing plants) after disinfection in food, drink and milk industries (FDM) by automated spraying in closed systems

Resulting local emission to relevant environmental compartments				
Compartment	**Nomenclature**	**On site**	**Off site**	**Remarks**
Peracetic acid [mg/L]				
On-site waste water effluent	$C_{effluent}$	9.77×10^{-2}	-	Standard scenario
On-site waste water effluent	$C_{effluent}$	1.29×10^{-5}	-	Refinement with degradation process
Off-site waste water influent	$C_{influent}$	-	8.81×10^{-4}	Standard scenario
Off-site waste water influent	$C_{influent}$	-	1.10×10^{-5}	Refinement with degradation process
Hydrogen peroxide [mg/L]				
On-site waste water effluent	$C_{effluent}$	7.18×10^{-1}	-	Standard scenario
On-site waste water effluent	$C_{effluent}$	3.80×10^{-3}	-	Refinement with degradation process
Off-site waste water influent	$C_{influent}$	-	6.47×10^{-3}	Standard scenario
Off-site waste water influent	$C_{influent}$	-	5.04×10^{-3}	Refinement with degradation process

SCENARIO 2: Disinfection of equipment by dipping and immersion

The release from industrial uses of disinfectants in food and feed areas is calculated on the basis of the annual use of disinfectants and based on the fact that the disinfection measures using different application techniques such as CIP, automated spraying, foaming, bottle rinsing, etc. take place on the same day. The residues from these different disinfection measures end up in the same waste water collecting tank before release to the sewer system. As the area in which the application take place and the maximum concentrations to be used (0.064%) are identical, the scenario described for PT4 – Scenario 1 here above is considered to cover this use.

Please note that a dipping scenario was agreed for PT04 at WG ENV-I-2015 for the active substance PHMB. However this scenario has not been added to the TAB and it thus not available in the TAB v2.0 (2017).
According to this scenario, the default volume of disinfectant used for the dipping bath is 500L (please also refer to PHMB CAR for PT04, Doc II B). The emissions from a worst-

case theoretical product containing 15% PAA and 23.5% HP (density : 1.235 kg/L), diluted to reach a final PAA concentration of 0.064%, would be :

A.S.	Elocal water (kg/d)	Elocal water after sewer degradation (kg/d)
PHMB : Dipping bath for PT04		
PAA	3.95E-01	4.95E-03
HP	6.19E-01	4.82E-01

Therefore the emissions from scenario described for PT4 – Scenario 1 (please see above) covers those from use #1.15/4.15 according to the dipping bath scenario agree at WG ENV-I-2015.

SCENARIO 3: Disinfection in Aseptic Filling Lines (crown corks, cheese moulds and food crates) - Automated spraying closed systems

This scenario is considered to be covered by the scenario described for PT4 – Scenario 1 (please see above), especially as the maximum concentrations to be used (0.064%) are identical.

SCENARIO 4: Disinfection of surfaces & equipment by low-pressure spraying (personal enclosure)

Scenario 4 – Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries

Average consumption based scenario

PAA and HP are emitted into the environment via waste water. Emissions to air are considered to be negligible. The emission estimation was based on the ESD for PT4 (2011) using the scenario for large scale catering kitchens, canteens, slaughterhouses and butcheries. Within this scenario, all other spraying and foaming activities not covered by Scenario 1 of PT4 are considered.

The local emission is based on the number of applications, the application rate of disinfectant per m² and the area of the treated surface. A theoretical product 1 (PAA 15% w/w, H_2O_2 23.5% w/w) is used for the disinfection of surfaces by low pressure spraying or by foaming. According to the applicant, the maximum in-use concentrations of active substances are 1 g PAA/L and 5 g HP/L and the application rate of the diluted product is 200 mL/ m².

Intermediate calculation for Scenario 4 - Application rate of the active substance

To determine the application rates of active substances according to the characteristics and the intended uses of the product, the following equation was applied (parameters used for calculations and results are available in Table 2.2.8–28):

$$Q_{a.i\ appl} = Q_{prod\ appl} \times f_{ai}$$

Table 2.2.8–28 Application rate of the active substances for disinfection of large scale catering kitchens, canteens, slaughterhouses and butcheries by low-pressure spraying

Scenario 4 – Application rate of the active substances for disinfection of large scale catering kitchens, canteens, slaughterhouses and butcheries by low-pressure spraying					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Application rate of use concentration of product	$Q_{prod\ appl}$	200		mL/m^2	Applicant
Fraction of active substance in product	f_{ai}	0.001	0.005	g/cm^3	Applicant
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Application rate of the active substance	$Q_{a.i\ appl}$	0.20	1.00	g/m^2	Output

Final calculation for Scenario 4

The local release to wastewater was calculated according to the following equation:

$$Elocal_{water} = Q_{a.i.appl} \times AREA \times Nappl \times (1 - F_{dis}) \times (1 - F_{elim}) \times F_{water} / 1000$$

By default, one application per day is considered as a reasonable worst-case value. The parameters used for calculations and the results are available in Table 2.2.8–29 (default values were taken from the ESD for PT 4, Table 10, p. 24).

Table 2.2.8–29 Local emission to the plant after disinfection of large scale catering kitchens, canteens, slaughterhouses and butcheries by low-pressure spraying (IHO, 2006)

Scenario 4 – Releases from large scale catering kitchens, canteens, slaughterhouses and butcheries after disinfection by low-pressure spraying					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA (15%)	**HP (23.5%)**		
Application rate of active substance	$Q_{a.i.appl}$	0.20	1.00	g/m^2	Table 2.2.8–28
Surface area to be disinfected in slaughterhouses & butcheries	$AREA_{slaughterhouse}$	10,000		m^2	Default
Surface area to be disinfected in kitchens & canteens	$AREA_{kitchen}$	2,000		m^2	Default
Number of applications per day	Nappl	1		d^{-1}	Default

Fraction of substance disintegrated during or after application, before release to the sewer system	F_{dis}	0		-	Default
Fraction of the substance eliminated due to on-site pre-treatment of the plant waste water	F_{elim}	0		-	Default
Fraction released to wastewater	F_{water}	1		-	Default
Output	**Nomenclature**	**Local emission [kg/d]**		**Unit**	**Remarks**
		PAA	**HP**		
Waste water – Butcheries & slaughterhouses	$Elocal_{water\ butchery}$	2.00	10.0	Kg/d	Output
Waste water – Kitchens & canteens	$Elocal_{water\ kitchen}$	0.40	2.00	Kg/d	Output

Degradation in the sewer system

A risk being identified for all compartments with the standard scenario (please refer to Table 2.2.8-46, 47 and 48), the applicant has suggested to take into account the degradation in the sewer system following the approach described previously (please refer to PT2 and 3, scenario 1). The parameters used for calculations and the results are available in Table 2.2.8–30.

Table 2.2.8–30 Local release to the plant of disinfectants sprayed in large scale catering kitchens, canteens, slaughterhouses and butcheries following their degradation in sewer system

Scenario 4 – Local release to the plant of disinfectants used large scale catering kitchens, canteens, slaughterhouses and butcheries following their degradation in sewer system					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water at T0 for butcheries & slaughterhouses (=$E_{local\ water}$)	$M_{T0\ butchery}$	2.00	10.0	Kg/d	Table 2.2.8–29
Local release to waste water at T0 for kitchens & canteens (=$E_{local\ water}$)	$M_{T0\ kitchen}$	0.40	2.00	Kg/d	Table 2.2.8–29
Rate constant	k	4.38[1]	0.25[2]	h^{-1}	Calculated as Ln 2 / DT_{50}
Time	T	1		h	CAR
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water at T1 for butcheries & slaughterhouses	$M_{T\ butchery}$	2.51×10^{-2}	7.79	Kg/d	Output

(=$E_{local\ water\ butchery\ degradation}$)					
Local release to waste water at T1 for kitchens & canteens (=$E_{local\ water\ with\ degradation}$)	$M_{T\ kitchen}$	5.01 × 10^{-3}	1.56	Kg/d	Output

[1] For PAA, k was calculated from the DT_{50} of 9.5min at 12°C.
[2] For HP, k was calculated from the DT_{50} of 169 min at 12°C.

SCENARIO 5: Disinfection of surfaces & equipment by low-pressure spraying (without personal enclosure)

This scenario is considered to be covered by the scenario described for PT4 – Scenario 4 (please see above), especially as the maximum concentrations to be used (0.064%) are identical.

SCENARIO 6: Disinfection of surfaces & equipment by manual low-pressure spraying (manual)

This scenario is considered to be covered by the scenario described for PT4 – Scenario 4 (please see above), especially as the maximum concentrations to be used (0.064%) are identical.

SCENARIO 7: Disinfection of surfaces & equipment by automatic low-pressure spraying (automatic)

This scenario is considered to be covered by the scenario described for PT4 – Scenario 4 (please see above), especially as the maximum concentrations to be used (0.064%) are identical.

SCENARIO 8: Disinfection of surfaces & equipment by automatic low-pressure spraying (automatic – closed room)

This scenario is considered to be covered by the scenario described for PT4 – Scenario 4 (please see above), especially as the maximum concentrations to be used (0.064%) are identical.

SCENARIO 9: Disinfection of inner surfaces by cip (pipelines, tanks, vessels, …)

Scenario 9 – *Disinfection of inner surfaces by cip (pipelines, tanks, vessels, …)*

Average consumption based scenario

Disinfection of milking parlours is performed by CIP after each milking event. It is assumed that the waste water from the milking parlour system is mainly released to the sewer system. Therefore PAA and HP are emitted into the environment via the sewer system. Emission to air is considered to be negligible. The emission estimation was based on the ESD for PT4 (2011) using the scenario for disinfection of milking parlour systems.
The worst-case emission is due to the use of the formulated product Sopuroxid 5C (density : 1.235), diluted to reach 0.064% PAA. The final in-use concentrations are 0.79 g/L PAA & 3.48 g/L HP, respectively.

Intermediate calculation for Scenario 9: Quantity of active ingredient

The quantity of active ingredient was calculated according to the following equation:

$Q_{a.i.} = C_{form} \times (V_{form\ inst} + V_{form\ tank})$

The parameters used for calculations and the results are available in Table 2.2.8–31 (default values were taken from the ESD for PT 4, Table 11, p. 26).

Table 2.2.8–31 Application rate of the active substances for disinfection of milking parlour systems (Baumann, 2000)

Scenario 9: Application rate of the active substances for disinfection of milking parlour systems					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Concentration of active substance	C_{form}	0.79	3.48	g/L	Applicant
Amount of disinfectant used for cleaning of the milking installation	$V_{form\ inst}$	130		L/d	Default
Amount of disinfectant used for cleaning of the milking storage tank	$V_{form\ tank}$	45		L/d	Default
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Quantity of active ingredient used	$Q_{a.i}$	$1.38 \times 10^{+2}$	$6.09 \times 10^{+2}$	g/d	Output

Final calculation for Scenario 9

The local release to wastewater was calculated according to the following equation:

$Elocalwater = Q_{a.i.} \times (1 - Fdis) \times Fwater / 1000$

Input parameters and the results of calculations are available in Table 2.2.8–32 (default values were taken from the ESD for PT 4, Table 11, p. 26).

Table 2.2.8–32 Local emission to the plant for milking parlour systems after disinfection by CIP (Baumann, 2000)

Scenario 9: Local emission to the plant for milking parlour systems after disinfection by CIP					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		

Quantity of active ingredient used	$Q_{a.i}$	$1.38x10^{+2}$	$6.09x10^{+2}$	g/d	Table 2.2.8–31
Fraction of substance disintegrated during or after application, before release to the sewer system	F_{dis}	0		-	Default
Fraction released to wastewater	F_{water}	1		-	Default
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to wastewater after one application	$E_{localwater}$	$1.38x10^{-1}$	$6.09x10^{-1}$	Kg/d	Output

Please note that according to the TAB (ENV A-13), the emission via manure need to be assessed for the milking parlour scenario. TAB ENV A-13 was not applicable at the time of the dossier submission. However this emission pathway must be taken into account at the renewal of the authorization.

SCENARIO 10: Disinfection of water used for rinsing of recycled items during the washing process

According to this use, water used for a final rinsing step in industrial processes is disinfected with a diluted solution of the formulated product. This final rinsing step could for example take place during the cleaning of glass bottles. The diluted solution is applied within a closed water circuit system, within which the water is recycled for re-use. In a final stage, the soiled solution is disposed to the sewer system.

No specific scenario is available to calculate the emission micropreservation of water used for final rinse. However this process and the related emission pathway to the environment are considered similar to the use described in scenario 1 (please refer to ESD for PT4). This scenario is therefore considered to be covered by the scenario described for PT4 – Scenario 1, especially as the concentrations to be used for micropreservation of water (0.008%) is well below the maximum concentration to be used for disinfection by automated spraying in closed systems (0.064%).

SCENARIO 11: Disinfection of storage rooms by fogging

Scenario 11 – Disinfection of large scale catering kitchens, canteens, slaughterhouses and butcheries by fogging

Average consumption based scenario

PAA and H_2O_2 are emitted into the environment via waste water, after wet cleaning of the room where fogging took place. Emissions to air are considered to be negligible as the room is tightly sealed during fogging and re-entry is only allowed after verification of the concentrations, once the product was deposited on the surfaces. The emission estimation was based on the ESD for PT4 (2011) using the scenario for large scale catering kitchens, canteens, slaughterhouses and butcheries, with adaptation of the default values to application by fogging (WG-V-2014, TAB ENV 66).

The local emission is based on the number of applications, the application rate of disinfectant and the volume to be treated. A theoretical product 1 (PAA 15% w/w, H_2O_2 23.5% w/w) is used for the disinfection of surfaces by fogging. According to the applicant, the maximum in-use concentrations of active substances are 1 g PAA/L and 5 g HP/L and the application rate of the diluted product is 200 mL/ m³.

Intermediate calculation for Scenario 11 - Application rate of the active substance

To determine the application rates of active substances according to the characteristics and the intended uses of the product, the following equation was applied (parameters used for calculations and results are available in Table 2.2.8–33):

$$Q_{a.i\ appl} = Q_{prod\ appl} \times f_{ai}$$

Table 2.2.8–33 Application rate of the active substances for disinfection of large scale catering kitchens, canteens, slaughterhouses and butcheries by fogging

Scenario 11 – Application rate of the active substances for disinfection of large scale catering kitchens, canteens, slaughterhouses and butcheries by fogging					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA (15%)	**HP (23.5%)**		
Application rate of use concentration of product	$Q_{prod\ appl}$	200		mL/m³	Applicant
Fraction of active substance in product	f_{ai}	0.001	0.005	g/cm³	Applicant
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Application rate of the active substance	$Q_{a.i\ appl}$	0.20	1.00	g/m³	Output

Final calculation for Scenario 11

The local release to wastewater was calculated according to the following equation:

$$Elocal_{water} = Q_{a.i.appl\ fog} \times VOL \times Nappl \times (1 - F_{dis}) \times (1 - F_{elim}) \times F_{water} / 1000$$

By default, one application per day is considered as a reasonable worst-case value. The parameters used for calculations and results are available in Table 2.2.8–34 (default values were taken from the ESD for PT 4, Table 10, p. 24).

Table 2.2.8–34 Local emission to the plant after disinfection of large scale catering kitchens, canteens, slaughterhouses and butcheries by fogging (IHO, 2006)

Scenario 11 – Releases from large scale catering kitchens, canteens,

slaughterhouses and butcheries after disinfection by fogging					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA (15%)	**HP (23.5%)**		
Application rate of the active substance	$Q_{a.i\ appl\ fog}$	0.20	1.00	g/m^3	Table 2.2.8–33
Surface area to be disinfected in slaughterhouses & butcheries	$VOL_{slaughterhouse}$	50,000		m^3	TAB – ENV 66
Surface area to be disinfected in kitchens & canteens	$VOL_{kitchen}$	6,000		m^3	TAB – ENV 66
Number of applications per day	Nappl	1		d^{-1}	Default
Fraction of substance disintegrated during or after application, before release to the sewer system	F_{dis}	0		-	Default
Fraction of the substance eliminated due to on-site pre-treatment of the plant waste water	F_{elim}	0		-	Default
Fraction released to wastewater	F_{water}	1		-	Default
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Waste water – Butcheries & slaughterhouses	$Elocal_{water\ butchery\ fog}$	10.0	50.0	Kg/d	Output
Waste water – Kitchens & canteens	$Elocal_{water\ kitchen\ fog}$	1.20	6.00	Kg/d	Output

Please note that these theoretical emissions cover the use #2.4. Indeed the actual worst-case emissions are due to Sopuroxid 3.2 (density : 1,108 kg/L), diluted to reach a final PAA concentration of 1.28% and applied at a rate of 5.6 mL/m³. This would lead to the following emissions : 3.97 kg/d PAA and 29.2 kg/d HP for butcheries and 0.47 kg/d PAA and 3.50 kg/d HP for kitchens.

Degradation in the sewer system

A risk being identified for all compartments with the standard scenario (please refer to Table 2.2.8-46, 47 and 48) the applicant has suggested to take into account the degradation in the sewer system following the approach described previously (please refer to PT2 and 3, scenario 1). The parameters used for calculations and the results are available in Table 2.2.8–35.

Table 2.2.8–35 Local release to the plant after disinfection of large scale catering kitchens, canteens, slaughterhouses and butcheries by fogging following the degradation of disinfectants in sewer system

Scenario 11 – Local release after disinfection of large scale catering kitchens, canteens, slaughterhouses and butcheries by fogging following the degradation of disinfectants in sewer system					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water at T0 for butcheries & slaughterhouses (=$Elocal_{water\ butchery\ fog}$)	$M_{T0\ butchery\ fog}$	10.0	50.0	Kg/d	Table 2.2.8–34
Local release to waste water at T0 for kitchens & canteens (=$Elocal_{water\ kitchen\ fog}$)	$M_{T0\ kitchen\ fog}$	1.20	6.00	Kg/d	Table 2.2.8–34
Rate constant	k	4.38[1]	0.25[2]	h^{-1}	Calculated as Ln 2 / DT_{50}
Time	T	1		h	CAR
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		PAA	**HP**		
Local release to waste water at T1 for butcheries & slaughterhouses (=$E_{local\ water\ butchery\ degradation}$)	$M_{T\ butchery}$	1.25×10^{-1}	$3.89 \times 10^{+1}$	Kg/d	Output
Local release to waste water at T1 for kitchens & canteens (=$E_{local\ water\ with\ degradation}$)	$M_{T\ kitchen}$	1.50×10^{-2}	4.67	Kg/d	Output

[1] For PAA, k was calculated from the DT_{50} of 9.5min at 12°C.
[2] For HP, k was calculated from the DT_{50} of 169 min at 12°C.

<u>*SCENARIO 12: Disinfection of surfaces by foaming (personal enclosure)*</u>

This scenario is considered to be covered by the scenario described for PT4 – Scenario 4 (please see above), especially as the maximum concentrations to be used (0.064%) are identical.

<u>*SCENARIO 13: Disinfection of surfaces by foaming (without personal enclosure)*</u>

This scenario is considered to be covered by the scenario described for PT4 – Scenario 4 (please see above), especially as the maximum concentrations to be used (0.064%) are identical.

(V) Summary of emission estimations

Please find in Table 2.2.8–36 below the summary of the emissions estimations. For each scenario, only the highest local releases are presented here. Indeed only these releases

are further considered in the risk assessment as they are considered to be worst-case and thus to cover all other intended uses.
Please note that the animal categories selected to present the local releases to manure/slurry in the table below (i.e. veal calves and ducks) are those that show the highest subsequent PIECs. However local release to manure/slurry were calculated for all animal categories and are available in the Annex (Please refer to 'Output tables from exposure assessment tools').

Table 2.2.8–36 Summary table on the emission estimations calculated from intended uses for PT 2, PT 3 and PT 4.

Scenario	PAA	HP
PT2		
Scenario 1 – Disinfection of surfaces after spraying (Total) Local release to waste water (kg/d)	1.71×10^{-1}	2.68×10^{-1}
Scenario 10 – Disinfection of surfaces after fogging (Total) Local release to waste water (kg/d)	1.20	8.84
Scenario 10 – Disinfection of surfaces after fogging (Total) Local release to waste water after degradation (kg/d)	1.51×10^{-2}	6.89
PT3		
Scenario 1 – Animal housing (Turkeys) Local release to waste water (kg/d)	3.81×10^{-1}	1.68
Scenario 1 – Animal housing (Turkeys) Local release to waste water after degradation (kg/d)	4.78×10^{-3}	1.31
Scenario 1 – Animal housing (Veal calves) Local release to manure/slurry (kg)	7.71×10^{-2}	3.39×10^{-1}
Scenario 1 – Animal housing (Veal calves) Local release to manure/slurry after degradation (kg)	1.21×10^{-5}	2.29×10^{-4}
Scenario 1 – Animal housing (Duck) Local release to manure/slurry (kg)	3.47×10^{-1}	1.53
Scenario 1 – Animal housing (Duck) Local release to manure/slurry after degradation (kg)	5.45×10^{-5}	1.03×10^{-3}
Scenario 3 – Footwear Local release to waste water (kg/d)	7.90×10^{-3}	3.48×10^{-2}
Scenario 3 – Footwear (Veal calves) Local release to manure/slurry (kg)	7.90×10^{-3}	3.48×10^{-2}
Scenario 3 – Footwear (Veal calves) Local release to manure/slurry after degradation (kg)	1.24×10^{-6}	2.35×10^{-5}

Scenario 4 – Disinfection by dipping Local release to waste water (kg/d)	7.90×10^{-2}	3.48×10^{-1}
Scenario 4 – Dipping (Veal calves) Local release to manure/slurry (kg)	7.90×10^{-2}	3.48×10^{-1}
Scenario 4 – Dipping (Veal calves) Local release to manure/slurry after degradation (kg)	1.24×10^{-5}	2.35×10^{-4}
PT4		
Scenario 1 –FDM industry (on-site) Local release to waste water (mg/L)	$9.77\text{x}10^{-2}$	$7.18\text{x}10^{-1}$
Scenario 1 –FDM industry (on-site) Local release to waste water after degradation (mg/L)	$1.29\text{x}10^{-5}$	$3.80\text{x}10^{-3}$
Scenario 1 –FDM industry (off-site) Local release to waste water (mg/L)	$8.81\text{x}10^{-4}$	$6.47\text{x}10^{-3}$
Scenario 1 –FDM industry (off-site) Local release to waste water after degradation (mg/L)	$1.10\text{x}10^{-5}$	$5.04\text{x}10^{-3}$
Scenario 4 – Kitchens & canteens Local release to waste water (kg/d)	0.40	2.00
Scenario 4 – Kitchens & canteens Local release to waste water after degradation (kg/d)	5.01×10^{-3}	1.56
Scenario 4 – Butcheries & slaughterhouses Local release to waste water (kg/d)	2.00	10.0
Scenario 4 – Butcheries & slaughterhouses Local release to waste water after degradation (kg/d)	2.51×10^{-2}	7.79
Scenario 9 – Milking parlour Local release to waste water (kg/d)	$1.38\text{x}10^{-1}$	$6.09\text{x}10^{-1}$
Scenario 11 – Kitchens & canteens (Fogging) Local release to waste water (kg/d)	1.20	6.00
Scenario 11 – Kitchens & canteens (Fogging) Local release to waste water after degradation (kg/d)	1.50×10^{-2}	4.67
Scenario 11 – Butcheries & slaughterhouses (Fogging) Local release to waste water (kg/d)	10.0	50.0
Scenario 11 – Butcheries & slaughterhouses (Fogging) Local release to waste water after degradation (kg/d)	1.25×10^{-1}	$3.89 \times 10^{+1}$

(VI) Fate and distribution in exposed environmental compartments

The release of PAA and HP in the environment and the resulting predicted environmental concentrations (PEC) for relevant environmental compartments were calculated per product type on the basis of the local emissions rates as calculated above.

After release to the first receiving environmental compartment (i.e. waste water or soil), PAA and HP are further distributed to the other compartments. Table 2.2.8–37 gives an overview of all relevant environmental compartments to which the active substances may be distributed and which are therefore considered in the exposure assessment.

The environmental exposure assessment was conducted based on fate and distribution properties of the active substances, available in their respective CAR (please refer to Document I, Appendix I, List of Endpoints). SimpleTreat v4 was used to calculate the distribution in the environment and the PECs were calculated from the relevant equations of the "Guidance on the Biocidal Products Regulation, Volume IV Environment - Assessment and Evaluation (Parts B + C)", Version 2.0 of October 2017 (GBPR – VI, 2017).

Table 2.2.8–37 Identification of relevant receiving environmental compartments based on the exposure pathways

Identification of relevant receiving compartments based on exposure pathway								
Scenario	**Air**	**STP**	**Freshwater**	**Freshwater sediment**	**Seawater**	**Seawater sediment**	**Soil**	**Groundwater[1]**
PT 2								
Scenario 1	(No)	Yes	Yes	Yes	No	No	Yes	No
Scenario 10	(No)	Yes	Yes	Yes	No	No	Yes	No
PT 3								
Scenario 1 – Animal housing Release to waste water	(No)	Yes	Yes	Yes	No	No	Yes	No
Scenario 1 – Animal housing Release to manure/slurry	No	No	No	No	No	No	Yes	No
Scenario 3 – Footwear Release to waste water	(No)	Yes	Yes	Yes	No	No	Yes	No
Scenario 3 – Footwear Release to manure/slurry	No	No	No	No	No	No	Yes	No
Scenario 4 – Dipping Release to waste water	(No)	Yes	Yes	Yes	No	No	Yes	No
Scenario 4 – Dipping Release to manure/slurry	No	No	No	No	No	No	Yes	No
PT 4								
Scenario 1 – FDM (STP on site)	(No)	No	Yes	Yes	No	No	No	No
Scenario 1 – FDM (STP off site)	(No)	Yes	Yes	Yes	No	No	Yes	No
Scenario 4 – Kitchens & butcheries	(No)	Yes	Yes	Yes	No	No	Yes	No

Scenario 9 – Milking parlour	(No)	Yes	Yes	Yes	No	No	Yes	No
Scenario 11 - Kitchens & butcheries (fogging)	(No)	Yes	Yes	Yes	No	No	Yes	No

[1] No groundwater assessment is needed for rapidly reacting substances as PAA & HP (WG-II-2019, WG-IV-2019)

(VII) Calculated PEC values

The input parameters for calculating the distribution of PAA and HP in the environment are available in Table 2.2.8–38 and the results, calculated with Simple Treat v4.0 (method 1) are available in Table 2.2.8–39. All values were agreed at WG-IV-2019.

Table 2.2.8–38 Input parameters for calculating the fate and distribution of Peracetic acid and Hydrogen peroxide in the environment

Input parameters for calculating the fate and distribution in the environment				
Parameter	**PAA**	**HP**	**Unit**	**Remarks**
Molecular weight	76.05	34.01	g/mol	
Melting point	-73[1]	-0.43	°C	
Boiling point	105[2]	150.2[3]	°C	
Vapour pressure	1,410	214	Pa	At 20°C
Water solubility	Completely miscible	Completely miscible	mg/L	Default value of 10^6 mg/L is used
Log octanol-water partition coefficient (Kow)	-0.6	-1.57	Log 10	At pH 7
Organic carbon-water partition coefficient (Koc)	1.46	1.598 [4]	L/kg	QSAR
Henry's Law Constant	2.17×10^{-1}	7.5×10^{-4}	Pa•m³/mol	
Biodegradability	Readily biodegradable	Readily biodegradable		10 days windows passed
DT_{50} for biodegradation in sewer system	< 9.5	11.4	min	At 12°C, pH 7
Rate constant in sewer system	4.38	3.65	hours^{-1}	At 12°C, pH 7
DT_{50} for biodegradation in STP - Aeration tank	< 3	2	min	At 20°C, pH 7
Rate constant in STP - Aeration tank	< 3	2	min	At 20°C, pH 7
DT_{50} for biodegradation in STP-effluent stream	< 9.5	169	min	At 12°C, pH 7
Rate constant in STP- effluent	4.38	0.25	hours^{-1}	At 12°C, pH 7
DT_{50} for degradation in liquid manure	9.5 [5]	11.4	min	At 12°C
Rate constant in liquid manure	4.38 [5]	3.65	hours^{-1}	At 12°C
DT_{50} for biodegradation in surface water	-	5	d	
DT_{50} for hydrolysis in surface water	31.7	Not applicable	hr	At 25°C, pH 7
DT_{50} for photolysis in surface water	Not applicable	Not applicable	hr	
DT_{50} for degradation in soil	12 [6]	12 [6,7]	h	
DT_{50} for degradation in air	95.26	24 [7]	hr	AOPWIN
Accumulation BCF_{fish}	1.41	1.41	L/kg_{ww}	EUSES
Accumulation $BCF_{earthworm}$	0.843	0.84	L/kg_{ww}	EUSES

[1] Melting point of the representative "Peracetic acid 15%".

[2] Boiling point of the representative "Peracetic acid 15%".
[3] Boiling point at 101.3 kPa
[4] Log K_{OC} = 0.2036
[5] DT50 measured in effluent stream is transferable to and used for the liquid manure (CAR, Table 8.3-1).
[6] Default value to be used according to WG-II-2016
[7] Worst-case DT_{50} based on literature (CAR)

Table 2.2.8–39 Fate and distribution of Peracetic acid and Hydrogen peroxide in the sewage treatment plant

Calculated fate and distribution in the STP				
Compartment	**Nomenclature**	**PAA [%]**	**HP [%]**	**Remarks**
Air	F_{air}	4.35×10^{-2}	2.00×10^{-4}	
Sludge	F_{sludge}	1.33×10^{-2}	1.45×10^{-2}	
Water	F_{water}	9.90×10^{-1}	6.64×10^{-1}	
Degraded in STP	$F_{degradation}$	98.95	99.32	

PEC in air

Peracetic acid and Hydrogen peroxide might reach the air compartment indirectly by volatilisation from the sewage treatment plant (PT2, PT3 and PT4). The indirect emission from the STP to air is given by the fraction of the emission to wastewater and calculated from equation 38 of the Volume IV of the Guidance on the Biocidal Products Regulation[15] (2017).

Calculated PEC_{air} are summarised in Table 2.2.8–40.

Table 2.2.8–40 Summary table on the predicted environmental concentrations for the air compartment

Summary table on PEC values for air compartment		
Scenario	**PAA**	**HP**
	[mg/m³]	**[mg/m³]**
PT2		
Scenario 1	2.07E-08	1.49E-10
Scenario 10 - Fogging	1.46E-07	4.29E-09
PT3		
Scenario 1 – Animal housing	4.16E-08	9.33E-10
Scenario 3 - Footwear	9.56E-10	1.93E-11
Scenario 4 - Dipping	9.56E-09	1.93E-10
PT4		
Scenario 1 – FDM (STP on site)	2.13E-04	7.19E-06

[15] Guidance on the Biocidal Products Regulation - Volume IV Environment - Assessment and Evaluation (Parts B + C) – Version 2.0, October 2017

Scenario 1 – FDM (STP off site)	2.13E-07	7.19E-09
Scenario 4 – Kitchens	4.84E-08	1.11E-09
Scenario 4 – Butcheries	2.42E-07	5.56E-09
Scenario 9 – Milking parlour	1.67E-05	3.38E-07
Scenario 11 - Kitchens (fogging)	1.45E-07	3.34E-09
Scenario 11 - Butcheries (fogging)	1.21E-06	2.78E-08

PEC in STP

Predicted environmental concentrations in the STP (PEC_{STP}) are determined after the elimination processes took place, i.e. degradation, volatilization and sedimentation of the active substances. PEC_{STP} were calculated from equation 41 of GBPR – VI (2017). Please note that the fractions of substances remaining in the sludge (F_{sludge}) and in the water phase (F_{water}) after elimination processes in STP were taken from Table 2.2.8–39. The results of the calculation are available in Table 2.2.8–41 below.

Table 2.2.8–41 Summary table on the predicted environmental concentrations for the Sewage Treatment Plant compartment

Summary table on PEC values for STP		
Scenario	**PAA**	**HP**
	[mg/L]	**[mg/L]**
PT2		
Scenario 1	8.47E-04	8.91E-04
Scenario 10 - Fogging	5.96E-03	2.93E-02
PT3		
Scenario 1 – Animal housing (Turkeys)	1.89E-03	5.57E-03
Scenario 3 - Footwear	3.91E-05	1.15E-04
Scenario 4 - Dipping	3.91E-04	1.15E-03
PT4		
Scenario 1 – FDM (STP on site)	1.56E+01	1.15E+02
Scenario 1 – FDM (STP on site) After degradation process	2.06E-03	6.08E-01
Scenario 1 – FDM (STP off site)	8.72E-06	4.29E-05
Scenario 4 – Kitchens	1.98E-03	6.64E-03
Scenario 4 – Butcheries	9.90E-03	3.32E-02
Scenario 9 – Milking parlour	6.85E-04	2.02E-03
Scenario 11 - Kitchens (fogging)	5.94E-03	1.99E-02
Scenario 11 - Butcheries (fogging)	4.95E-02	1.66E-01

Scenario 11 - Butcheries (fogging) After degradation process	6.20E-04	1.29E-01

PEC in surface water

According to the Intended Use, no direct exposure to surface water is expected. Only indirect exposure via STP is possible. PEC_{water} were calculated from equation 51 of GBPR – IV (2017).
Please note that the fractions of substances remaining in water phase (F_{water}) after elimination processes in STP were taken from Table 2.2.8–39. Koc values used to calculate the solid-water partitioning coefficient in suspended matter ($K_{p,\ susp}$) are 1.46 L/kg for PAA and 1.598 L/kg for HP (please refer to Table 2.2.8–38)
Please note that for PT4, scenario 1 (on-site), the treatment of the waste water is performed through an on-site STP. Degradation in the sewer system is not taken into account in this scenario as the distance between the point of release to the waste water system and the on-site STP is considered negligible. Moreover according to ESD of PT4, it is assumed that the on-site treated waste water is directly released to surface water. Therefore PEC_{water} (on-site) is considered to be equal to the concentration of the active substances in effluent of the on-site STP ($C_{effluent}$, please refer to Table 2.2.8–27).
The results of the calculation are available in Table 2.2.8–42 below.

Table 2.2.8–42 Summary table on the predicted environmental concentrations for the surface water

Summary table on PEC values for surface water		
Scenario	**PAA**	**HP**
	[mg/L]	**[mg/L]**
PT2		
Scenario 1	8.47E-05	8.91E-05
Scenario 10 - Fogging	5.96E-04	2.93E-03
Scenario 10 – Fogging After degradation process	7.47E-06	2.29E-03
PT3		
Scenario 1 – Animal housing (Turkeys)	1.89E-04	5.57E-04
Scenario 1 – Animal housing (Turkeys) After degradation process	2.36E-06	4.34E-04
Scenario 3 - Footwear	3.91E-06	1.15E-06
Scenario 4 - Dipping	3.91E-05	1.15E-04
PT4		
Scenario 1 – FDM (STP on site)	9.77E-02	7.18E-01
Scenario 1 – FDM (STP on site) After degradation process	1.29E-05	3.80E-03
Scenario 1 – FDM (STP off site)	8.72E-07	4.29E-06-04
Scenario 1 – FDM (STP off site) After degradation process	1.09E-05	7.59E-04

Scenario 4 – Kitchens	1.98E-04	6.64E-04
Scenario 4 – Kitchens After degradation process	2.48E-06	5.17E-04
Scenario 4 – Butcheries	9.90E-04	3.32E-03
Scenario 4 – Butcheries After degradation process	1.24E-05	2.58E-03
Scenario 9 – Milking parlour	6.85E-05	2.02E-04
Scenario 11 - Kitchens (fogging)	5.94E-04	1.99E-03
Scenario 11 - Kitchens (fogging) After degradation process	7.44E-06	1.55E-03
Scenario 11 - Butcheries (fogging)	4.95E-03	1.66E-02
Scenario 11 - Butcheries (fogging) After degradation process	6.20E-05	1.29E-02

PEC in sediment

The concentration in the solid phase of the sediment is derived from the concentrations in surface water according to equilibrium partition method. $PEC_{sediment}$ were calculated from equation 53 of GBPR – IV (2017). The results of the calculation are available in Table 2.2.8–43 below.

Table 2.2.8–43 Summary table on the predicted environmental concentrations for the sediment compartment

Summary table on PEC values for sediment		
Scenario	**PAA** **[mg/kg dwt]**	**HP** **[mg/kg dwt]**
PT2		
Scenario 1	3.17E-04	3.35E-04
Scenario 10 - Fogging	2.23E-03	1.10E-02
Scenario 10 – Fogging After degradation process	2.80E-05	8.59E-03
PT3		
Scenario 1 – Animal housing (Turkeys)	7.07E-04	2.09E-03
Scenario 1 – Animal housing (Turkeys) After degradation process	8.86E-06	1.63E-03
Scenario 3 - Footwear	1.47E-05	4.34E-05
Scenario 4 - Dipping	1.47E-04	4.34E-04
PT4		
Scenario 1 – FDM (STP on site)	3.66E-01	2.70
Scenario 1 – FDM (STP on site) After degradation process	4.81E-05	1.43E-02

Scenario 1 – FDM (STP off site)	3.27E-06	1.61E-05
Scenario 1 – FDM (STP off site) After degradation process	4.09E-05	2.68E-03
Scenario 4 – Kitchens	7.42E-04	2.50E-03
Scenario 4 – Kitchens After degradation process	9.29E-06	1.94E-03
Scenario 4 – Butcheries	3.71E-03	1.25E-02
Scenario 4 – Butcheries After degradation process	4.65E-05	9.72E-03
Scenario 9 – Milking parlour	2.57E-04	7.59E-04
Scenario 11 - Kitchens (fogging)	2.23E-03	7.49E-03
Scenario 11 - Kitchens (fogging) After degradation process	2.79E-05	5.83E-03
Scenario 11 - Butcheries (fogging)	1.85E-02	6.24E-02
Scenario 11 - Butcheries (fogging) After degradation process	2.32E-04	4.86E-02

PEC in soil

According to the Indented Use, direct emissions to the soil compartment is not relevant. The indirect exposure is due to sludge or manure applications. PEC_{soil} after sludge applications (PT 2, 3 & 4) were calculated from equation 69 of GBPR – IV (2017). As biodegradation of the active substances during storage of sludge as well as transformation and dilution in deeper soil layers are not taken into account, it can be considered as a worst-case scenario. Please note that only PEC_{soil} for grassland (averaged on 30 days) is presented below, as worst-case scenario. However all results are available in the Confidential annex ('Output tables from exposure assessment tools'). Results available in Table 2.2.8–44 below.

For PT4, it should be noted that the PEC_{soil} are the same, whether degradation process in the sewer system is taken into account or not. Please note that no PEC_{soil} has been calculated for PT4 - scenario 1 (on-site), as the sludge of on-site STP is not supposed to be released in the environment.

Table 2.2.8–44 Summary table on the predicted environmental concentrations for the soil compartment after sludge application (PT2, 3 & 4)

Summary table on PEC values for soil after sludge applications (grassland - averaged 30 days)		
Scenario	**PAA**	**HP**
	[mg/kg dwt]	**[mg/kg dwt]**
PT2		
Scenario 1	4.39E-06	7.63E-06
Scenario 10 – Fogging	8.02E-06	1.96E-06
PT3		

Scenario 1 – Animal housing (Turkeys)	9.79E-06	4.77E-05
Scenario 3 - Footwear	2.03E-07	9.88E-07
Scenario 4 - Dipping	5.27E-07	2.54E-06
PT4		
Scenario 1 – FDM (STP off site) Before & after degradation process	4.52E-05	3.68E-04
Scenario 4 – Kitchens Before & after degradation process	1.03E-05	5.68E-05
Scenario 4 – Butcheries Before & after degradation process	5.13E-05	2.84E-04
Scenario 9 – Milking parlour	3.73E-06	1.73E-05
Scenario 11 - Kitchens (fogging) Before & after degradation process	3.08E-05	1.70E-04
Scenario 11 - Butcheries (fogging) Before & after degradation process	2.57E-04	1.42E-03

PIECs after manure/slurry applications (PT 3, scenario 1, 6 and 7) were calculated from the ESD of PT 3 and the Technical Agreements for Biocides – Environment (2017). They are based on emission standards for nitrogen and phosphate. Indeed depending on the amount of nitrogen and phosphate in the manure and the type of soil to which it is applied (grassland or arable land), these emission standards define the maximum amount of manure/slurry that can be applied per hectare and per year. Please note that only the animal categories showing the highest PIECs (i.e. veal calves and ducks) are presented in Table 2.2.8–45 but PIECs were calculated for all animal categories and are available in the Annex (Please refer to 'Output tables from exposure assessment tools').

Table 2.2.8–45 Summary table on the predicted environmental concentrations for the soil compartment after manure and slurry applications (PT3)

Summary table on PEC values for soil								
Scenario	**PAA**				**HP**			
	PIEC grass P2O5	PIEC arable P2O5	PIEC grass N	PIEC arable N	PIEC grass P2O5	PIEC arable P2O5	PIEC grass N	PIEC arable N
	mg/kg wwt	mg/kg wwt	mg/kg wwt	mg/kg wwt	mg/kg wwt	mg/kg wwt	mg/kg wwt	mg/kg wwt
Scenario 1 – Animal housing (Veal calves)	3.32E-01	3.73E-02	3.05E-01	4.46E-02	1.46E00	1.64E-01	1.34E00	1.96E-01
Scenario 1 – Animal housing (Veal calves) After degradation process	5.19E-05	5.85E-06	4.77E-05	6.99E-06	9.82E-04	1.11E-04	9.07E-04	1.32E-04
Scenario 1 – Animal housing (Duck)	1.21E-01	6.83E-03	8.95E-02	6.51E-03	5.34E-01	3.00E-02	3.95E-01	2.87E-02
Scenario 1 – Animal housing (Duck) After degradation process	1.91E-05	1.07E-06	1.40E-05	1.02E-06	3.62E-04	2.03E-05	2.66E-04	1.94E-05
Scenario 3 – Footwear (Veal calves)	3.38E-02	3.83E-03	3.13E-02	4.55E-03	1.49E-01	1.68E-02	1.38E-01	2.01E-02
Scenario 3 – Footwear (Veal calves) After degradation process	5.31E-06	5.98E-07	4.90E-06	7.15E-07	1.01E-04	1.14E-05	9.29E-05	1.35E-05
Scenario 4 – Dipping (Veal calves)	1.70E-01	1.91E-02	1.57E-01	2.28E-02	7.46E-01	8.40E-01	6.89E-01	1.00E-01
Scenario 4 – Dipping (Veal calves) After degradation process	2.66E-05	2.99E-06	2.46E-05	3.58E-06	5.04E-04	5.67E-05	4.65E-04	6.77E-05

PEC in groundwater

As stated above, it was agreed at ENV WG-II-2019 that no groundwater assessment is needed for rapidly reacting substances since it is very unlikely that these substances will reach the groundwater compartment. It was confirmed at WG-IV-2019 that no groundwater assessment is needed for PAA and HP. Therefore, no $PEC_{groundwater}$ was calculated.

(VIII) Primary and secondary poisoning

Primary poisoning

Not relevant.

Secondary poisoning

Chemicals showing bioaccumulation or biomagnification potential may pose a threat due to exposure of organisms higher in the food chain, e.g. top predators, because of secondary poisoning. The oral intake via fish and worms is therefore assessed for mammals and birds for each substance showing a log Pow value over the trigger value of 3.

The calculated octanol-water partition coefficient of Peracetic acid (-0.60 at 25°C, pH 7) and Hydrogen peroxide (-1.57 at pH 7) being both below the trigger value of 3, these substances show a low risk of bioaccumulation. Moreover they dissipate rapidly in the environment, which further decreases the risk of accumulation. PAA and HP are thus not expected to accumulate in the organisms. Therefore the secondary exposure of wild fauna is unlikely and no PEC_{oral} was calculated.

2.2.8.3 Risk Characterisation

Please note that all PNEC values are available in Table 2.2.8–1. PEC values are available in Table 2.2.8–40 to 45 above.

(I) Atmosphere

Based on the physico-chemical properties of the active substances and on the Intended Use, the emission to air during and after the application of the product can be considered as negligible, even after direct release to the air (please see above, "PEC in air" Table 2.2.8–40).
Moreover on the basis of the physico-chemical properties of the active substances (absence of absorption bands in the atmospheric window, short atmospheric lifetimes, absence of Cl, F, N or S substituents in the molecules), neither Peracetic acid, nor Hydrogen peroxide is expected to display adverse abiotic effects on the atmospheric environment (please refer to the respective CAR of the active substances).

Conclusion:

Only negligible exposure to the atmosphere is expected and no threat to the atmosphere is expected.

(II) Sewage treatment plant (STP)

The risk assessment for STP is determined by dividing the PEC_{STP} by the $PNEC_{STP\ micro-organisms}$ (please, refer to Table 2.2.8–46). If the result of this ratio is below 1, an acceptable risk to micro-organisms of STP can be concluded.

Table 2.2.8–46 Summary table of the PEC/PNEC values for Peracetic acid and Hydrogen peroxide for the sewage treatment plant. Values in bold are over the trigger of 1.

Summary table on PEC/PNEC values for STP		
Scenario	**PAA**	**HP**
PT2		
Scenario 1	1.66E-02	1.91E-04
Scenario 10 - Fogging	1.17E-01	6.30E-03
PT3		
Scenario 1 – Animal housing (Turkeys)	3.70E-02	1.19E-03
Scenario 3 - Footwear	7.67E-04	2.48E-05
Scenario 4 - Dipping	7.67E-03	2.48E-04
PT4		

Scenario 1 – FDM (STP on site)	**3.07E+02**	**2.46E+01**
Scenario 1 – FDM (STP on site) After degradation process	4.03E-02	1.30E-01
Scenario 1 – FDM (STP off site)	1.71E-04	9.21E-06
Scenario 4 – Kitchens	3.88E-02	1.42E-03
Scenario 4 – Butcheries	1.94E-01	7.12E-03
Scenario 9 – Milking parlour	1.34E-02	4.33E-04
Scenario 11 - Kitchens (fogging)	1.17E-01	4.27E-03
Scenario 11 - Butcheries (fogging)	9.71E-01	3.56E-02
Scenario 11 - Butcheries (fogging) After degradation process	1.22E-02	2.77E-02

After taking into account degradation process in the sewer system (PT4, scenario 1 and 13), HP and PAA did not show any risks for the Sewage Treatment Plant organisms.

Conclusion:

No unacceptable effect to the aquatic micro-organisms of the STP is expected.

(III) Aquatic compartment

The risk assessment is performed for fresh water and sediment-dwelling organisms and is determined by dividing the PEC_{water} (or PEC_{sed}) by the $PNEC_{water}$ (or the $PNEC_{sed}$). Where the result of this ratio is below the trigger of 1, an acceptable risk to aquatic organisms can be concluded.

Please note that PEC_{sed} and $PNEC_{sed}$ being calculated from the PEC_{water} and $PNEC_{water}$, respectively, by using equilibrium partitioning method, the results for sediment-dwelling organisms are equal to those for pelagic organisms. Therefore, only results for freshwater organisms are presented below in Table 2.2.8–47 below.

Table 2.2.8–47 Summary table of the PEC/PNEC values for Peracetic acid and Hydrogen peroxide for the aquatic compartment. Values in bold are over the trigger of 1.

Summary table on PEC/PNEC values for aquatic compartment		
Scenario	**PAA**	**HP**
PT2		
Scenario 1	9.01E-01	7.07E-03
Scenario 10 - Fogging	**6.34**	2.33E-01
Scenario 10 – Fogging After degradation process	7.94E-02	1.81E-01
PT3		

Scenario 1 – Animal housing (Turkeys)	**2.01**	4.42E-02
Scenario 1 – Animal housing (Turkeys) After degradation process	2.52E-02	3.44E-02
Scenario 3 - Footwear	4.16E-02	9.16E-04
Scenario 4 - Dipping	4.16E-01	9.16E-03
PT4		
Scenario 1 – FDM (STP on site)	**1.04E+03**	**5.70E+01**
Scenario 1 – FDM (STP on site) After degradation process	1.37E-01	3.02E-01
Scenario 1 – FDM (STP off site)	9.28E-039.28	3.41E-04
Scenario 4 – Kitchens	**2.11**	5.27E-02
Scenario 4 – Kitchens After degradation process	2.64E-02	4.10E-02
Scenario 4 – Butcheries	**1.05E+01**	2.63E-01
Scenario 4 – Butcheries After degradation process	1.32E-01	2.05E-01
Scenario 9 – Milking parlour	7.29E-01	1.60E-02
Scenario 11 - Kitchens (fogging)	**6.32**	1.58E-01
Scenario 11 - Kitchens (fogging) After degradation process	7.92E-02	1.23E-01
Scenario 11 - Butcheries (fogging)	**5.27E+01**	**1.32**
Scenario 11 - Butcheries (fogging) After degradation process	6.60E-01	**1.03**

After taking into account degradation process in the sewer system, no adverse effect on pelagic or sediment-dwelling organisms is expected from the active substances, except after fogging treatment of butcheries and slaughterhouses (PT4, scenario 11). Indeed the RCR for HP (1.03) is slightly over the trigger of 1.

However it should be remembered that HP decomposes rapidly in environment due to biotic degradation catalysed by microbial enzymes (catalase and peroxidase) but also via abiotic degradation catalysed by transition metal, through formation of compounds with (in)organic substances or by oxidoreduction processes with organic compounds. These degradation processes were not taken into account during the calculation of the PECs in the aquatic compartment. Indeed only biotic degradation is taken into account in sewer system and in STP. Moreover the residence time considered in the sewer system (T= 1h) is worst-case, limiting the degradation of HP taken into account before it reaches the STP.

Furthermore degradation will already occur before the entry in the sewer system. Indeed it is stated in the Use-specific instructions for use for fogging treatment : "Entry in the treated room only after verification of the exposure concentration." (please note that the scenario used for human health exposure account that "after completion of fogging, the building is left closed for about 60 min, thoroughly ventilated for another 60 min and thereafter and re-entry can only occurs after 90 min. following ventilation"). Hence a part of HP will have already degraded before entering in the sewer system, although this was not taken into account in the scenario for fogging application. The calculated PECs are therefore clearly worst-case.

Additionally the degradation in the STP effluent was not considered for calculating PEC_{water} and $PEC_{sediment}$. Finally, the degradation products of HP (H_2O and O_2) are not harmful to aquatic and sediment-dwelling organisms. Given the fast degradation of HP in the environment and the resulting degradation products, unacceptable effect to the aquatic compartment is thus considered unlikely.

Conclusion:

Unacceptable effect to the aquatic compartment is not expected, neither for sediment-dwelling organisms, nor for pelagic organisms.

(IV) Terrestrial compartment

The risk to terrestrial compartment is assessed by dividing the PEC_{soil} by the $PNEC_{soil}$ calculated via the equilibrium partitioning method. If the result of this ratio is below 1, an acceptable risk to aquatic organisms can be concluded. Please note that as soil contamination takes place through application of sludge in agricultural area and no sludge application is expected for PT4, scenario 1 (on-site), no risk has been calculated for this scenario. Results are available in the Table 2.2.8–48 below.

Table 2.2.8–48 Summary table of the PEC/PNEC values for Peracetic acid and Hydrogen peroxide for the soil compartment after sludge application (PT2, 3 & 4). Values in bold are over the trigger of 1.

Summary table on PEC/PNEC values for soil after sludge application (grassland - averaged 30 days)		
Scenario	**PAA**	**HP**
PT2		
Scenario 1	6.00E-04	1.58E-01
Scenario 10 - Fogging	1.06E-03	3.94E-02
PT3		
Scenario 1 – Animal housing (Turkeys)	3.06E-05	2.29E-02
Scenario 3 - Footwear	6.34E-07	4.74E-04
Scenario 4 - Dipping	6.93E-05	1.22E-03
PT4		
Scenario 1 – FDM (STP off site) Before & after degradation process	6.18E-03	1.76E-01
Scenario 4 – Kitchens Before & after degradation process	1.40E-03	2.73E-02
Scenario 4 – Butcheries Before & after degradation process	7.01E-03	1.36E-01
Scenario 9 – Milking parlour	4.86E-04	3.58E-01
Scenario 11 - Kitchens (fogging) Before & after degradation process	4.21E-03	8.18E-02

Scenario 11 - Butcheries (fogging) Before & after degradation process	3.51E-02	6.82E-01

No adverse effect on soil organisms is expected from HP and PAA for PT2, PT3 and PT4 uses.

Regarding manure and slurry applications (PT3), no adverse effect on soil organisms is expected, neither from HP, nor from PAA once the degradation process in manure/slurry is taken into account (please refer to Table 2.2.8–49 below).

Table 2.2.8–49 Summary table of the PIEC/PNEC values for Peracetic acid and Hydrogen peroxide for the soil compartment after manure and slurry applications (PT3). Values in bold are over the trigger of 1.

Summary table on PIEC/PNEC values for soil after manure and slurry applications								
Scenario	**PAA**				**HP**			
	PIEC grass P2O5	PIEC arable P2O5	PIEC grass N	PIEC arable N	PIEC grass P2O5	PIEC arable P2O5	PIEC grass N	PIEC arable N
Scenario 1 – Animal housing (Veal calves)	1.04E+00	1.17E-01	9.53E-01	1.39E-01	**7.00E+02**	**7.88E+01**	**6.46E+02**	**9.40E+01**
Scenario 1 – Animal housing (Veal calves) After degradation process	1.62E-04	1.83E-05	1.49E-04	2.18E-05	4.72E-01	5.32E-02	4.36E-01	6.35E-02
Scenario 1 – Animal housing (Duck)	3.79E-01	2.13E-02	2.80E-01	2.04E-02	**2.57E+02**	**1.44E+01**	**1.90E+02**	**1.38E+01**
Scenario 1 – Animal housing (Duck) After degradation process	5.96E-05	3.35E-06	4.39E-05	3.20E-06	1.74E-01	9.76E-03	1.28E-01	9.32E-03
Scenario 3 – Footwear (Veal calves)	1.06E-01	1.20E-02	9.78E-02	1.42E-02	**7.18E+01**	**8.08**	**6.62E+01**	**9.64**
Scenario 3 – Footwear (Veal calves) After degradation process	1.66E-05	1.87E-06	1.53E-05	2.23E-06	4.84E-02	5.46E-03	4.47E-02	6.51E-03
Scenario 4 – Dipping (Veal calves)	5.30E-01	5.96E-02	4.89E-01	7.12E-02	**3.59E+02**	**4.04E+01**	**3.31E+02**	**4.82E+01**
Scenario 4 – Dipping (Veal calves) After degradation process	8.32E-05	9.36E-06	7.67E-05	1.12E-05	2.42E-01	2.73E-02	2.24E-01	3.26E-02

Conclusion:

No unacceptable effect to the soil compartment is expected.

(V) Groundwater

As stated above, it was agreed at ENV WG-II-2019 that no groundwater assessment is needed for rapidly reacting substances since it is very unlikely that these substances will reach the groundwater compartment. It was confirmed at WG-IV-2019 that no groundwater assessment is needed for PAA and HP.

(VI) Primary and secondary poisoning

Primary poisoning

Not relevant.

Secondary poisoning

The calculated Pow of Peracetic acid and Hydrogen peroxide being both below the trigger value of 3, these substances show a low risk of bioaccumulation. Moreover they dissipates rapidly in the environment, which further decreases the risk of accumulation. PAA and HP are thus not expected to accumulate in organisms. Therefore the secondary exposure of wild fauna is unlikely and is no further considered in the risk assessment.

Conclusion: No risk of primary of secondary poisoning is expected from the active substances

(VII) Mixture toxicity

Given that SOPUROXIDcontains a mixture of two active substances. i.e. Peracetic acid and Hydrogen peroxide, a risk assessment regarding the mixture toxicity has been performed according to the GBPR – IV (2017).

Screening step

Screening Step 1: Identification of the concerned environmental compartments

To determine which environmental compartments are likely to be at risk, please refer to Table 2.2.8–37.

Screening Step 2: Identification of relevant substances

Beside on the actives substances, the products of SOPUROXID Family contain 2 co-formulants potentially of concern for environment according to the definition of Guidance on the Biocidal Products Regulation - Volume IV Environment (Version 2.0, 2017). For more information, please refer to the Confidential annex. However to conclude, the mixture toxicity is only assessed on the basis of the cumulative toxicity of Peracetic acid and Hydrogen peroxide.

Screening Step 3: Screen on synergistic interactions

No literature data have been submitted about synergistic interactions between the components of the formulated products. However none of these substances is part of the Appendix 11 of the Guidance on the Biocidal Products Regulation - Volume IV Environment (2017). Given the composition of the formulated products (please refer to the Confidential Annex), no synergistic interactions are expected between their components.

Screening step	
Y	Significant exposure of environmental compartments?
Y	Number of relevant substances >1?
N	Indication for synergistic effects for the product or its constituents in the literature?
	No synergistic interactions is expected between the assessed components

Tiered approach

The assessment scheme is based on a series of four tiers that begins with simple and conservative screening steps and moves to higher tiers as necessary:

- Tier 1: PEC/PNEC-Summation.
- Tier 2: Modified Toxic Unit Summation (TUS)separated for trophic levels.
- Tier 3: Standard Toxic Unit Summation (TUS) separated for trophic levels.
- Tier 4: Experimental testing.

Each of the higher tiers involves a less conservative and more accurate assessment than the previous tiers but requires also more resources, including additional exposure and toxicity data.

Tier 1. PEC/PNEC summation

Where the PEC/PNEC ratios are available for all relevant ingredients. the risk quotient of the product can be simply estimated by their sum:

$$RQ = \sum \frac{PEC}{PNEC}$$

At this step. the PNECs from the relevant compounds might be based on data from completely different endpoints and species. Consequently. it is considered as a conservative approximation. Where RQ is below 1, an acceptable risk is assumed.

The PEC/PNEC values of PAA and HP are available in Table 2.2.8–46 (STP), Table 2.2.8–47 (aquatic compartment), Table 2.2.8–48 and Table 2.2.8–49 (terrestrial compartment). Results of the calculations are available in 2.2.8–50 (STP), Table 2.2.8–51 (aquatic compartment) and Table 2.2.8–52 and 53 (terrestrial compartment).

Table 2.2.8–50 Risk quotient of the Biocidal Product Family SOPUROXID for the Sewage Treatment Plant. Values in bold are over the trigger of 1.

Mixture toxicity Sewage Treatment Plant			
Scenario	**RQ product**	**Acceptable risk for environment? (Y/N)**	**Remarks**

PT 2			
Scenario 1	1.68E-02	Y	
Scenario 10 - Fogging	1.23E-01	Y	
PT 3			
Scenario 1 – Animal housing (Turkeys)	3.82E-02	Y	
Scenario 3 - Footwear	7.92E-04	Y	
Scenario 4 - Dipping	7.92E-03	Y	
PT 4			
Scenario 1 – FDM (STP on site)	**3.31E+02**	N	
Scenario 1 – FDM (STP on site) After degradation process	1.71E-01	Y	
Scenario 1 – FDM (STP off site)	1.80E-04	Y	
Scenario 4 – Kitchens	4.03E-02	Y	
Scenario 4 – Butcheries	2.01E-01	Y	
Scenario 9 – Milking parlour	1.39E-02	Y	
Scenario 11 - Kitchens (fogging)	1.21E-01	Y	
Scenario 11 - Butcheries (fogging)	**1.01**	N	
Scenario 11 - Butcheries (fogging) After degradation process	3.99E-02	Y	

After refinement with degradation process regarding (PT4, scenario 1 and 13), the values were below the trigger of 1 for all scenarios. Therefore unacceptable effect to the sewage treatment plant is not expected from the products of SOPUROXID Family.

Table 2.2.8–51 Risk quotient of the Biocidal Product Family SOPUROXID for the aquatic compartment (surface water & sediment-dwelling organisms). Values in bold are over the trigger of 1.

Mixture toxicity Aquatic compartment			
Scenario	**RQ product**	**Acceptable risk for environment? (Y/N)**	**Remarks**
PT 2			
Scenario 1	9.08E-01	Y	
Scenario 10 - Fogging	**6.58**	N	
Scenario 10 – Fogging After degradation process	2.61E-01	Y	
PT 3			
Scenario 1 – Animal housing (Turkeys)	**2.05**	N	
Scenario 1 – Animal housing (Turkeys) After degradation process	5.96E-02	Y	
Scenario 3 - Footwear	4.26E-02	Y	
Scenario 4 - Dipping	4.26E-01	Y	
PT 4			
Scenario 1 – FDM (STP on site)	**1.10E+03**	N	
Scenario 1 – FDM (STP on site) After degradation process	4.38E-01	Y	

Scenario 1 – FDM (STP off site)	9.62E-039.35	N	
Scenario 4 – Kitchens	**2.16**	N	
Scenario 4 – Kitchens After degradation process	6.74E-02	Y	
Scenario 4 – Butcheries	**1.08E+01**	N	
Scenario 4 – Butcheries After degradation process	3.37E-01	Y	
Scenario 9 – Milking parlour	4.75E-01	Y	
Scenario 11 - Kitchens (fogging)	**6.48**	N	
Scenario 11 - Kitchens (fogging) After degradation process	2.02E-01	Y	
Scenario 11 - Butcheries (fogging)	**5.40**	N	
Scenario 11 - Butcheries (fogging) After degradation process	**1.69**	N	

After taking into account degradation process in the sewer system, no adverse effect on aquatic organisms is expected from the SOPUROXID Family, except after fogging treatment of butcheries and slaughterhouses (PT4, scenario 11). Indeed the RCR is slightly over the trigger of 1 (1.69) due to HP.

However as mentioned above, HP decomposes rapidly in environment due to biotic degradation catalysed by microorganisms and via abiotic degradation (oxidoreduction processes with organic compounds, formation of compounds with (in)organic substances or via transition metal). Though abiotic degradation was not taken into account during the calculation of the concentrations in the aquatic compartment, leading to increased PEC_{water} and $PEC_{sediment}$. Moreover the residence time in the sewer system (T= 1h) is considered as worst-case, limiting the degradation of HP taken into account before it reaches the STP. Furthermore degradation occurring before re-entry in the treated room – and thus taking place before the entry in the sewer system – is not taken into account in the scenario for fogging application. The calculated PECs are therefore clearly worst-case. Please also note that the degradation in the STP effluent was not considered when calculating PEC_{water} and $PEC_{sediment}$. Finally, the degradation products of HP (H_2O and O_2) are not harmful to aquatic organisms. Therefore unacceptable effect to the aquatic compartment is thus considered unlikely.

Table 2.2.8–52 Risk quotient of the Biocidal Product Family SOPUROXID for the terrestrial compartment after sludge application (PT2, 3 & 4).

Mixture toxicity Terrestrial compartment after sludge application			
Scenario	**RQ product**	**Acceptable risk for the environment? (Y/N)**	**Remarks**
PT 2			
Scenario 1	1.58E-01	Y	
Scenario 10 - Fogging	4.05	Y	
PT 3			
Scenario 1 – Animal housing (Turkeys)	2.29E-02	Y	
Scenario 3 - Footwear	4.74E-04	Y	
Scenario 4 - Dipping	1.29E-03	Y	

PT 4			
Scenario 1 – FDM (STP off site) Before & after degradation process	1.83E-01	Y	
Scenario 4 – Kitchens Before & after degradation process	2.87E-02	Y	
Scenario 4 – Butcheries Before & after degradation process	1.43E-01	Y	
Scenario 9 – Milking parlour	3.58E-01	Y	
Scenario 11 - Kitchens (fogging) Before & after degradation process	8.60E-02	Y	
Scenario 11 - Butcheries (fogging) Before & after degradation process	7.17E-01	Y	

Table 2.2.8–53 Risk quotient of the Biocidal Product Family SOPUROXID for the terrestrial compartment after manure/slurry applications (PT3). Values in bold are over the trigger of 1.

Mixture toxicity Terrestrial compartment after manure/slurry applications						
Scenario	**PIEC grass P2O5**	**PIEC arable P2O5**	**PIEC grass N**	**PIEC arable N**	**Acceptable risk for the environment? (Y/N)**	**Remarks**
Scenario 1 – Animal housing (Veal calves)	**7,01E+02**	**7,89E+01**	**6,47E+02**	**9,42E+01**	**N**	
Scenario 1 – Animal housing (Veal calves) After degradation process	4,72E-01	5,33E-02	4,36E-01	6,36E-02	Y	
Scenario 1 – Animal housing (Duck)	**2,57E+02**	**1,45E+01**	**1,90E+02**	**1,38E+01**	**N**	
Scenario 1 – Animal housing (Duck) After degradation process	1,74E-01	9,77E-03	1,28E-01	9,33E-03	Y	
Scenario 3 – Footwear (Veal calves)	**7.19E+01**	**8.09E+00**	**6.63E+01**	**9.66E+00**	**N**	
Scenario 3 – Footwear (Veal calves) After degradation process	4.84E-02	5.46E-03	4.47E-02	6.52E-03	Y	
Scenario 4 – Dipping (Veal calves)	**3.59E+02**	**4.04E+01**	**3.32E+02**	**4.83E+01**	**N**	
Scenario 4 – Dipping (Veal calves) After degradation process	2.43E-01	2.73E-02	2.24E-01	3.26E-02	Y	

After refinement with with degradation process, the values were below the trigger of 1 for all scenarios. Therefore unacceptable effect to the terrestrial compartment is not expected from the products of the SOPUROXID Family.

Tier 2: Modified Toxic Unit Summation (TUS)

Not relevant

Tier 3: Standard Toxic Unit Summation (TUS)

Not relevant

Tier 4: Experimental testing

Not relevant

Conclusion:
Mixture toxicity assessment showed that no unacceptable risk is expected from the product of the SOPUROXID Family.

(VIII) Aggregated exposure (combined for relevant emission sources)

According to the BPR (Article 19(2))[16], the evaluation shall take into account the cumulative effects as well as the synergistic effects of the biocidal product or of its components. This refers to the environmental risk assessment of the substances which are contained in different products of the same Product Type (PT) or of different PTs. A decision tree on the need for estimation of aggregated exposure (Figure 1 below) was available in the BPR to determine when such exposure is needed.

According to the registered substance database of ECHA, PAA[17] is registered under REACH with an annual tonnage band of 1.000−10.000 tonnes while HP [18] is registered with an annual tonnage band of 1.000 000−10.000 000 tonnes. This is far over their use as biocide that represent less than 10% of the annual tonnage of these substance (please refer to their Brief Profile[19,20]).
Therefore it has been checked if the emission pattern of the active substances was specific to biocides. Both active substances are notified for inclusion in the EU list of approved active substances for use in biocidal products (PT 1, 2, 3, 4, 5, 6, 11 and 12).

According to their respective CAR (2015), all uses can reach the environmental compartments. However according to the registered substance database of ECHA, several other registered uses have a similar emission pattern (washing & cleaning products, agriculture, fishing, perfumes and fragrances, manufacture of food products, textiles or paper products, etc.), which is not specific to biocides. Therefore, no

16 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L167, 27.6.2012, p. 166.

17 https://echa.europa.eu/substance-information/-/substanceinfo/100.001.079
18 https://echa.europa.eu/substance-information/-/substanceinfo/100.028.878
19 https://echa.europa.eu/brief-profile/-/briefprofile/100.028.878
20 https://echa.europa.eu/brief-profile/-/briefprofile/100.001.079

aggregated exposure estimation is required for the biocidal products as the main emissions to the environment are considered to be already covered by REACH.

<u>Conclusion</u>:
As less than 10% of the total tonnage of the active substances is used for biocide products and as the emission pattern is not specific to biocides, the aggregated exposure is not considered to be relevant.

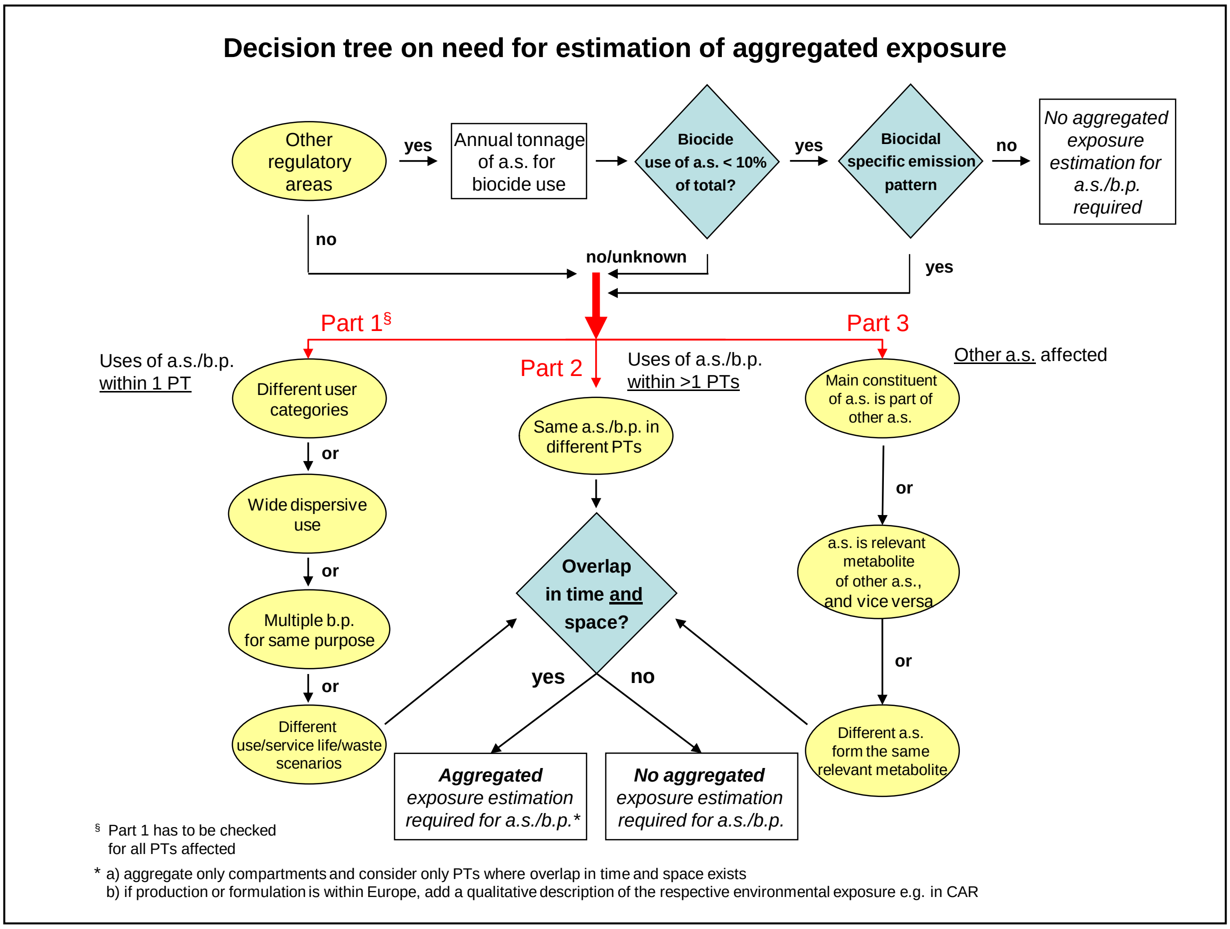

Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the SOPUROXID Family
No unacceptable effect to the environment is expected from the SOPUROXID Family, neither for the Sewage Treatment Plant, nor for aquatic compartment or for the terrestrial compartment. Moreover no unacceptable risk of secondary poisoning trough the aquatic or the terrestrial food chain is to be expected from the products of the SOPUROXID Family. No unacceptable risk to the groundwater is expected from SOPUROXIDand the requirements of Directive 98/83/EC and 2006/118/EC are complied with.

2.2.9 Assessment of endocrine disrupting properties

Since 7 June 2018, Regulation (EU) 2017/2100 is applicable. Therefore the assessment of endocrine disruptive (ED) properties of the products is mandatory according to Article 19 of the BPR. A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the ED properties of the substances in SOPUROXID Family:

1. Assessment of the ED properties of the active substances in SOPUROXID Family:
   - According to section 2.1.1 of CA-March18.Doc.7.b-final, 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 and Hydrogen Peroxide are not part of the list[21] 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 and Hydrogen Peroxide.

2. Assessment of the ED properties of non-active substances (co-formulants) in SOPUROXID Family:
   - After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex), 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 endocrine disruptive properties of the SOPUROXID Family
Based on the existing knowledge and on data provided by the applicant, there is no indication of concern regarding the ED properties of the substances used in the SOPUROXID Family. 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 CA-March18.Doc.7.b-final, section 2.3 (47).

2.2.10 Measures to protect man, animals and the environment

Not relevant

2.2.11 Comparative assessment

The active substance Peracetic Acid contained in SOPUROXIDdo not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and are not considered candidates for substitution. Therefore, a comparative assessment of SOPUROXIDin accordance with Article 23 of the BPR is not required.

[21] Please refer to CA-September18.Doc.7.5.a-final .

3 Annexes[22]

3.1 List of studies for the *SOPUROXID FAMILY*

Reference is made to the IUCLID file where all studies are included as study summaries and original reports are attached.

22 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
[redacted]	2016	Physico-chemical characteristics of SOPUROXID 5	Sopura Laboratory	REGU010-F	No	No	Yes	SOPURA	3.1, 3.2, 3.3, 3.5, 3.8, 3.9
[redacted]	2016	Stability study in accelerated conditions (40°C) Sopuroxid 5.	Sopura Laboratory	REGU010-B	No	No	Yes	SOPURA	3.4
[redacted]	2016	Stability study in normal conditions (20°C) Sopuroxid 5.	Sopura Laboratory	REGU010-A	No	No	Yes	SOPURA	3.4
[redacted]	2016	Stability at 0°C of Sopuroxid 5.	Sopura Laboratory	REGU010-C	No	No	Yes	SOPURA	3.4
[redacted]	2016	Pourability (rinsability) of Sopuroxid 5	Sopura Laboratory	REGU010-E	No	No	Yes	SOPURA	3.5
[redacted]	2019	Dilution stability of Sopuroxid 5 aqueous solution.	Sopura Laboratory	REGU010-D-V2	No	No	Yes	SOPURA	3.4
[redacted]	2016	Physico-chemical characteristics of SOPUROXID 5C	Sopura Laboratory	REGU012-F	No	No	Yes	SOPURA	3.1, 3.2, 3.3, 3.5, 3.8, 3.9
[redacted]	2019	Stability study in accelerated conditions (40°C) Sopuroxid 5C.	Sopura Laboratory	REGU013-162-ACCEL	No	No	Yes	SOPURA	3.4
[redacted]	2019	Stability study in normal conditions (20°C) Sopuroxid 5C.	Sopura Laboratory	REGU013-162-NORM	No	No	Yes	SOPURA	3.4
[redacted]	2016	Stability at 0°C of Sopuroxid	Sopura	REGU012-C	No	No	Yes	SOPURA	3.4

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
		5C.	Laboratory						
[redacted]	2016	Pourability (rinsability) of Sopuroxid 5C	Sopura Laboratory	REGU012-E	No	No	Yes	SOPURA	3.5
[redacted]	2019	Dilution stability of Sopuroxid 5C aqueous solution.	Sopura Laboratory	REGU012-D-V2	No	No	Yes	SOPURA	3.4
[redacted]	2016	Physico-chemical characteristics of SOPUROXID 15	Sopura Laboratory	REGU011-F	No	No	Yes	SOPURA	3.1, 3.2, 3.3, 3.5, 3.8, 3.9
[redacted]	2019	Stability study in accelerated conditions (40°C) Sopuroxid 15.	Sopura Laboratory	REGU013	No	No	Yes	SOPURA	3.4
[redacted]	2019	Stability study in normal conditions (20°C) Sopuroxid 15.	Sopura Laboratory	REGU013-152-NORM	No	No	Yes	SOPURA	3.4
[redacted]	2016	Stability at 0°C of Sopuroxid 15.	Sopura Laboratory	REGU011-C	No	No	Yes	SOPURA	3.4
[redacted]	2016	Pourability (rinsability) of Sopuroxid 15	Sopura Laboratory	REGU011-E	No	No	Yes	SOPURA	3.5
[redacted]	2019	Dilution stability of Sopuroxid 15 aqueous solution.	Sopura Laboratory	REGU011-D-V2	No	No	Yes	SOPURA	3.4
[redacted]	2016	Physico-chemical characteristics of OXYPUR CS	Sopura Laboratory	REGU013-F	No	No	Yes	SOPURA	3.1, 3.2, 3.3, 3.5, 3.8, 3.9
[redacted]	2019	Stability study in accelerated conditions (40°C) OXYPUR CS.	Sopura Laboratory	REGU013-751-ACCEL	No	No	Yes	SOPURA	3.4

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
[redacted]	2019	Stability study in normal conditions (20°C) OXYPUR CS.	Sopura Laboratory	REGU013-751-NORM	No	No	Yes	SOPURA	3.4
[redacted]	2016	Stability at 0°C of OXYPUR CS	Sopura Laboratory	REGU013-C	No	No	Yes	SOPURA	3.4
[redacted]	2016	Pourability (rinsability) of OXYPUR CS	Sopura Laboratory	REGU013-E	No	No	Yes	SOPURA	3.5
[redacted]	2019	Dilution stability of OXYPUR CS aqueous solution.	Sopura Laboratory	REGU013-D-V2	No	No	Yes	SOPURA	3.4
[redacted]	2016	Physico-chemical characteristics of SOPUROXID 3.2	Sopura Laboratory	REGU015-F	No	No	Yes	SOPURA	3.1, 3.2, 3.3, 3.5, 3.8, 3.9
[redacted]	2019	Stability study in accelerated conditions (40°C) SOPUROXID 3.2.	Sopura Laboratory	REGU013-1692-ACCEL	No	No	Yes	SOPURA	3.4
[redacted]	2019	Stability study in normal conditions (20°C) SOPUROXID 3.2	Sopura Laboratory	REGU013-162-NORM	No	No	Yes	SOPURA	3.4
[redacted]	2016	Stability at 0°C of SOPUROXID 3.2	Sopura Laboratory	REGU015-C	No	No	Yes	SOPURA	3.4
[redacted]	2016	Pourability (rinsability) of SOPUROXID 3.2	Sopura Laboratory	REGU015-E	No	No	Yes	SOPURA	3.5
[redacted]	2019	Dilution stability of SOPUROXID 3.2 aqueous solution.	Sopura Laboratory	REGU015-D-V2	No	No	Yes	SOPURA	3.4

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
[redacted]	2016	Physico-chemical characteristics of ACIDOFOAM CF	Sopura Laboratory	REGU002-F	No	No	Yes	SOPURA	3.1, 3.2, 3.3, 3.5, 3.8, 3.9
[redacted]	2019	Stability study in accelerated conditions (40°C) ACIDOFOAM CF.	Sopura Laboratory	REGU13-1448-ACCEL	No	No	Yes	SOPURA	3.4
[redacted]	2016	Stability study in normal conditions (20°C) ACIDOFOAM CF	Sopura Laboratory	REGU002-A	No	No	Yes	SOPURA	3.4
[redacted]	2016	Stability at 0°C of ACIDOFOAM CF	Sopura Laboratory	REGU002-C	No	No	Yes	SOPURA	3.4
[redacted]	2016	Pourability (rinsability) of ACIDOFOAM CF	Sopura Laboratory	REGU002-E	No	No	Yes	SOPURA	3.5
[redacted]	2016	Dilution stability of ACIDOFOAM CF aqueous solution.	Sopura Laboratory	REGU002-D	No	No	Yes	SOPURA	3.4
[redacted]	1995	Physico-chemical properties of three peroxy. Acetic acid formulations	TNO, Defence Research	PML 1995-C18	No	No	Yes	SOPURA	4.2
[redacted]	2017	Classification of Sopuroxid 15	TNO, Industrial innovation	TNO 2017 R10466	No	No	Yes	SOPURA	4.2
[redacted]	2005	Statistical Evaluation of the Test Results for Peracetic Acid and Hydrogen Peroxide in a Disinfectant	SCC Scientific Consulting Company,	411-018	No	No	Yes	Peracetic Acid Registration Group.	5.1

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
			GmbH						
[redacted]	2017	Peracetic acid 15% - Method validation for acetic acid.	Noack Laboratorien GmbH	161104AC/CM V17511.	No	No	Yes	Peracetic Acid Registration Group.	5.1
[redacted]	2007	Ion-Chromatographic Determination of Sulfate in Oxonia Active 150.	Henkel KGaA	412-002	No	No	Yes	Peracetic Acid Registration Group.	5.1
[redacted]	2017	Method validation of the determination of the stabilizer hydroxyethane-1,1-diphosphonic acid (HEDP) in peracetic acid.	Henkel Ag & Co KGaA	23MV17001.E 2	No	No	Yes	Peracetic Acid Registration Group.	5.1
[redacted]	2004	Simultaneous Sampling of Peroxyacetic Acid and Hydrogen Peroxide in Workplace Atmospheres	Ann. Occup. Hyg.	2004, 48, 715-721	No	Yes	Yes	Peracetic Acid Registration Group	5.2
[redacted]	2006	Evaluation of the Degradation of Peracetic Acid and Hydrogen Peroxide in Effluent from a Waste Water Treatment Plant.	Solvay Pharmaceuticals	E.SOL.S.025	No	No	Yes	Peracetic Acid Registration Group	5.2
[redacted]	2005	Degradation of Peracetic Acid in Diluted Rat Blood (HPLC Method).	Solvay Pharmaceuticals	E.SOL.S.013, Doc.	No	No	Yes	Peracetic Acid Registration Group	5.2
[redacted]	2017	Disinfectants and antiseptics – Quantitative suspension test for the evaluation of	BLUTEST Laboratories	BT-SPU-02-01	No	No	Yes	SOPURA	6.7

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
		bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas — Test method and requirements							
[redacted]	2017	Chemical disinfectants— Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas — Test method and requirements	BLUTEST Laboratories	BT-SPU-02-01(2)	No	No	Yes	SOPURA	6.7
[redacted]	2017	Chemical disinfectants– Quantitative suspension test for the evaluation of virucidal activity against bacteriophages of chemical disinfectants used in food and industrial areas.	BLUTEST Laboratories	BT-SPU-02-01	No	No	Yes	SOPURA	6.7
[redacted]	2017	Chemical disinfectants– Quantitative suspension test for the evaluation of virucidal activity against bacteriophages of chemical disinfectants used in food and industrial areas.	BLUTEST Laboratories	BT-SPU-02-01	No	No	Yes	SOPURA	6.7

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
[redacted]	2016	Evaluation of the bacterial and fungicidal activity according to the European standard test method EN 13697 (2015-06) Quantitative non-porous surface test for food, industrial, domestic and institutional areas (Obligatory conditions)	Institut Meurice	1448	No	No	Yes	SOPURA	6.7
[redacted]	2016	Evaluation of the bacterial and fungicidal activity according to the European standard test method EN 13697 (2015-06) Quantitative non-porous surface test for food, industrial, domestic and institutional areas (Obligatory conditions)	Institut Meurice	1448	No	No	Yes	SOPURA	6.7
[redacted]	2017	Chemical disinfectants & antiseptics-Quantitative non-porous surface test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas-Test method and requirements without mechanical action. (ACIDOFOAM CF)	Blutest Laboratories	BT-SPU-02-01	No	No	Yes	SOPURA	6.7

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
[redacted]	2017	Chemical disinfectants and antiseptics–Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas—Test method and requirements (SOPUROXID 3.2)	Blutest Laboratories	BT-SPU-02-01	No	No	Yes	SOPURA	6.7
[redacted]	2017	Chemical disinfectants and antiseptics — Quantitative suspension tests for evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary field — Test method and requirements.	Blutest Laboratories	BT-SPU-02-01	No	No	Yes	SOPURA	6.7
[redacted]	2017	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area.	Blutest Laboratories	BT-SPU-02-01	No	No	Yes	SOPURA	6.7
[redacted]	2017	Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation	Blutest Laboratories	BT-SPU-02-01(1)	No	No	Yes	SOPURA	6.7

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
		of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on porous surfaces without mechanical action.							
[redacted]	2016	Evaluation of the bactericidal activity according to the European standard test method EN 14349 (2012) Veterinary tests on non-porous surfaces (Obligatory conditions).	Institut Meurice	1448	No	No	Yes	SOPURA	6.7
[redacted]	2016	Evaluation of the bactericidal activity according to the European standard test method EN 14349 (2012) Veterinary tests on non-porous surfaces (Practical conditions).	Institut Meurice	1448	No	No	Yes	SOPURA	6.7
[redacted]	2016	Evaluation of the yeasticidal activity according to the European standard test method EN 16438 (2014) Veterinary tests on non-porous surfaces (Obligatory conditions).	Institut Meurice	1448	No	No	Yes	SOPURA	6.7
[redacted]	2016	Evaluation of the fungicidal	Institut	1448	No	No	Yes	SOPURA	6.7

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
		activity according to the European standard test method EN 16438 (2014) Veterinary tests on non-porous surfaces (Obligatory conditions).	Meurice						
[redacted]	2006	Hydrogen peroxide and peracetic acid determination	Sopura Laboratory	IT-LCT-08	No	No	Yes	SOPURA	5.1
[redacted]	2015	Test mousse, Evaluation d'un produit.	Sopura Laboratory	IT-LMA175V5	No	No	Yes	SOPURA	3.5
[redacted]	2016	Stability study in normal storage conditions, SOPUROXID 3.2	Sopura Laboratory	REGU015-G	No	No	Yes	SOPURA	3.4
[redacted]	2009-2010	Determination of the MBAA residual concentration at the release point of a brewery STP to a municipal STP under real operational conditions	-	7512V2	MBA Task Force / ALBEMARLE - SOPURA	No	Yes	SOPURA	10.1
[redacted]	2012	Determination of fatty acids (octanoic & decanoic acids) residual concentration in the effluent of a brewery under real operational conditions following the OECD 314 guidelines.	-	10607	SOPURA	No	Yes	SOPURA	10.1
[redacted]	2007	Foreseeable routes of entry	-	Document III-	No	No		Peracetic Acid	10.1

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
		into the environment on the basis of the use envisaged		B, Section B7				Registration Group	
[redacted]	2019	Measure of persistent foaming – Oxypur CS	Sopura Laboratory	-	No	No	Yes	SOPURA	3.5
[redacted]	2019	Statement on the safe use of SOPUROXID 3.2	-	-	-	No	Yes	SOPURA	3.5
[redacted]	2019	VAL157: Validation report of the analytical method to determine the peracetic acid & hydrogen peroxide content of a product by titration	Sopura Laboratory	VAL157	No	No	Yes	SOPURA	5.1
[redacted]	2019	Quantitative suspension test for the evaluation of bactericidal activity of Sulfuric acid 78 % in Food, Industrial, Domestic and Institutional Areas (DIN EN 1276 Ber 1:2010; Phase 2, Step 1*)	Dr. Brill + Partner GmbH - Institute for Hygiene and Microbiology ,	L19/0647.2	No	No	Yes	SOPURA	6.7
[redacted]	2019	Expert opinion Bactericidal Activity of SOPUROXID 5C in the quantitative suspension test according to DIN EN 1276 Ber 1:2010 (Phase 2, Step 1)	Dr. Brill + Partner GmbH - Institute for Hygiene and Microbiology ,	L19/0647.1	No	No	Yes	SOPURA	6.7

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
[redacted]	2019	Summary: Virus-inactivating properties (limited spectrum virucidal activity) of ACIDOFOAM CF of SOPURA S.A. according to EN 14476:2013 +A1:2015/prA2:2016 under clean conditions	Dr. Brill + Partner GmbH - Institute for Hygiene and Microbiology ,	L19/0604	No	No	Yes	SOPURA	6.7
[redacted]	2019	Summary: Virus-inactivating properties (virucidal) of ACIDOFOAM CF of SOPURA S.A. in a quantitative suspension test according to EN 14476:2013+A1:2015 under clean conditions	Dr. Brill + Partner GmbH - Institute for Hygiene and Microbiology ,	L19/0604	No	No	Yes	SOPURA	6.7
[redacted]	2019	Evaluation of the effectiveness of ACIDOFOAM CF Test virus: adenovirus type 5 Method: EN 14476:2013 +A1:2015 (clean conditions) quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in human medicine (phase 2/step 1)	Dr. Brill + Partner GmbH - Institute for Hygiene and Microbiology ,	L19/0604A.1	No	No	Yes	SOPURA	6.7
[redacted]	2019	Expert opinion Activity of ACIDOFOAM CF	Dr. Brill + Partner	L19/0604A.1	No	No	Yes	SOPURA	6.7

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
		against adenovirus type 5 in a quantitative suspension test according to EN 14476:2013+A1:2015 under clean conditions	GmbH - Institute for Hygiene and Microbiology ,						
[redacted]	2019	Expert opinion Activity of ACIDOFOAM CF against murine norovirus (MNV) in a quantitative suspension test according to EN 14476:2013 +A1:2015 under clean conditions	Dr. Brill + Partner GmbH - Institute for Hygiene and Microbiology ,	L19/0604M.1	No	No	Yes	SOPURA	6.7
[redacted]	2019	Evaluation of the effectiveness of ACIDOFOAM CF Test virus: murine norovirus (as surrogate of human norovirus) Method: EN 14476:2013+A1:2015 (clean conditions) quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in human medicine (phase 2/step 1)	Dr. Brill + Partner GmbH - Institute for Hygiene and Microbiology ,	L19/0604M.1	No	No	Yes	SOPURA	6.7
[redacted]	2019	Expert opinion Activity of ACIDOFOAM CF against poliovirus type 1 in a	Dr. Brill + Partner GmbH -	L19/0604Po.2	No	No	Yes	SOPURA	6.7

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
		quantitative suspension test according to EN 14476:2013+A1:2015 under clean conditions	Institute for Hygiene and Microbiology ,						
[redacted]	2019	Evaluation of the effectiveness of ACIDOFOAM CF Test virus: poliovirus type 1 strain LSc-2ab Method: EN 14476:2013 +A1:2015 (clean conditions) quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in human medicine (phase 2/step 1)	Dr. Brill + Partner GmbH - Institute for Hygiene and Microbiology	L19/0604Po.2	No	No	Yes	SOPURA	6.7
[redacted]	2019	Quantitative Non-Porous Surface Test for Evaluation of Bactericidal and/or Fungicidal Activity of Chemical Disinfectants and Antiseptics Used in Food, Industrial, Domestic, and Institutional Areas (NF T 72-281: 2014; Phase 2/Step 2)	Dr. Brill + Partner GmbH - Institute for Hygiene and Microbiology ,	L18/0259.1	No	No	Yes	SOPURA	6.7
[redacted]	2019	Quantitative Non-Porous Surface Test for Evaluation of Bactericidal and/or Fungicidal	Dr. Brill + Partner GmbH -	L18/0259.	No	No	Yes	SOPURA	6.7

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
		Activity of Chemical Disinfectants and Antiseptics Used in Food, Industrial, Domestic, and Institutional Areas (NF T 72-281: 2014; Phase 2/Step 2)	Institute for Hygiene and Microbiology						
[redacted]	2019	Quantitative Non-Porous Surface Test for Evaluation of Bactericidal and/or Fungicidal Activity of Chemical Disinfectants and Antiseptics Used in Food, Industrial, Domestic, and Institutional Areas (NF T 72-281: 2014; Phase 2/Step 2)	Dr. Brill + Partner GmbH - Institute for Hygiene and Microbiology ,	L18/0259.3	No	No	Yes	SOPURA	6.7
[redacted]	2016	EN 13610:2002 Chemical disinfectants– Quantitative suspension test for the evaluation of virucidal activity against bacteriophages of chemical disinfectants used in food and industrial areas- Test method and requirements (Phase 2/Step 1) – P008	Blutest Laboratories	BT-SPU-02-01	No	No	Yes	SOPURA	6.7
Rösler	2018	Listing certificate - List of disinfectants for animal husbandry of the German Veterinary Medicine Society	-	DVG Institute	-	Yes	No	SOPURA	6.7

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
		{DVG)							
[redacted]	2018	Bestimmung der viruziden Wirksamkeit des Mittels Acidofoam CF gegen Newcastle Disease-Virus (NDV) und Bovines Enterovirus {ECBO) - Eckwertbestimmung / Benchmark testing -	-	Institut für Tierhygiene und Ôffentliches Veterinarwesen		No	Yes	SOPURA	6.7
[redacted]	2017	Expert opinion: Virucidal activity of ACIDOFOAM CF according DVG Guidelines	D117-2017	Laboklin	-	No	Yes	SOPURA	6.7
[redacted]	2017	ITLMA 82: Guideline for the validation of analytical methods	Sopura Laboratory	IT-LMA82	No	No	Yes	SOPURA	5.1
[redacted]	2018	Validation report of the analytical method for the determination of sulfuric acid content in a peracetic acid based product (concentration range: 22 to 25%w sulfuric acid)	Sopura Laboratory	REG-012	No	No	Yes	SOPURA	5.1
[redacted]	2018	Validation report of the analytical method for the determination of sulfuric acid content in a peracetic acid based product (concentration range: 0.6 to 0.95%w sulfuric acid)	Sopura Laboratory	REG-025	No	No	Yes	SOPURA	5.1

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
[redacted]	2017	ASTM E1052: The Evaluation of antiviral properties of a product using a Virucidal Suspension Assay	BluTest Laboratories Ltd	BT-SPU-02	No	No	Yes	SOPURA	6.7
[redacted]	2015	Inhibition assessment of aerobic/anaerobic wastewater treatment process by Acidofoam CF	KULeuven.	Report no. 20151020	No	No	Yes	SOPURA	10.1
[redacted]	1999	Screening of the effect of Sopuroxid 15 on the respiration rate of activated sludge	TNO	IMW-98-0044-02.	Yes	No	Yes	SOPURA	10.1
[redacted]	2019	Drinking water (animals): Waiver for the non-submission of a field test	-	-	No	No	Yes	SOPURA	6.7
M. Profaizer, A. Massone, C. Nurizzo and F. Bandera	1997	The behaviour of peracetic acid as a water disinfectant.	Universiteit Gent	-	No	Yes	No	-	6.7
[redacted]	2012	Decontamination of a drinking water pipeline system contaminated with adenovirus and Escherichia coli utilizing peracetic acid and chlorine.	IWA Publishing 2012 Journal of Water and Health	-	No	Yes	No	-	6.7

3.2 Output tables from exposure assessment tools (HH)

Please see Confidential Annex (p. 17-18).

3.3 Determination of the activity coefficient

Please see Confidential Annex (p. 18).

3.4 tables from exposure assessment tools (ENV)

Please see Confidential Annex (p. 22).

3.5 New information on the active substance

No new information on the actives substances has been provided in support of this biocidal product family.

3.6 Residue behaviour

There is no specific additional information necessary or relevant.

3.7 Summaries of the efficacy studies

Please see section 3.1 above and the efficacy section 2.2.5 of this PAR which summarises these data.

3.8 Confidential annex

Please see the Confidential PAR in annex.

3.9 Other

Confirmation membership to the Peracetic Acid Registration Group.

PAR – Peracetic Acid Registration Group

cefic sector group

January 2017

Statement of membership of the Peracetic Acid Registration Group

The Cefic Peracetic Acid Registration Group (PAR) hereby confirms that the PAR members and their affiliates listed in Appendix 1 are entitled to use and refer to the complete evaluation dossiers on peracetic acid and peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate for any purposes under Regulation (EU) 528/2012 on biocidal products (BPR), including inclusion in the Article 95 list and product authorisation.

The data remain commercially sensitive and may not be transferred wither in writing or by any electronic means to any third party, without the express written permission of the respective data owners.

In accordance with the BPR, peracetic acid has been notified and evaluated as an active substance for the product-types 1 to 6 and 11, 12 and peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate as an active substance for product-types 2 to 4.

Regulation (EU) 2016/672 approved peracetic acid as a biocidal active substance for PT 1 to 6 in April 2016 and Regulation (EU) 2016/2290 approved peracetic acid as a biocidal active substance for PT 11 and 12 in December 2016. The opinions of the Biocidal Products Committee for the approval of in-situ PAA for PT 2 to 4 were adopted in December 2016.

Flore Cognat
Manager

For more information please contact:
Flore Cognat
+32 2.676.72.03 or fco@cefic.be

About PAR
The Peracetic Acid Registration Group (PAR) is a registration group of Cefic, composed of 14 members supporting the approval of peracetic acid and in-situ peracetic acid generated from sodium percabonate and tetra-acetylethylenediamine (TAED) as active substances under the Biocidal Products Regulation (EU) 528/2012.

PAR – Peracetic Acid Registration Group

cefic sector group

January 2017

Appendix 1 - Members of PAR in January 2017

1. ANTI-GERM International GmbH
2. Bioxal SA
3. Christeyns N.V.
4. Evonik Resource Efficiency GmbH
5. Ecolab Deutschland GmbH (acting for Ecolab Inc. (US)
6. Hypred SAS
7. Kemira Oyj
8. ITW Novadan ApS
9. Peroxychem Spain s.l.u.
10. Promox SpA
11. Quaron SA
12. Solvay SA
13. Sopura SA
14. Stockmeier Holding GmbH

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Avenue E. van Nieuwenhuyse 4 B-1160 Brussels Belgium
Tel. +32 2.676.72.11 mail@cefic.be www.cefic.org

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