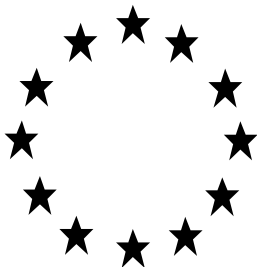
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR UNION AUTHORISATION APPLICATIONS



INTEROX Biocidal Product Family 1

Product types 2, 3 and 4

Hydrogen Peroxide

Case Number in R4BP: BC-WX029254-02

Evaluating Competent Authority: Finland

Date: [15/10/2021]

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1 CONCLUSION

The INTEROX Product Family 1 consists of products containing the active substance hydrogen peroxide (13 - 49.9 %) for disinfection in PT 2, PT 3 and PT 4. No substances of concern were identified in the biocidal product family.

The biocidal product family (BPF) consists of 9 meta SPCs for which the following uses have been assessed:

meta SPC 1:
- Surface disinfection of closed spaces by aerosolised hydrogen peroxide , PT2

meta SPC 2, *meta* SPC 3
- Surface disinfection of closed spaces by aerosolised hydrogen peroxide , PT2
- Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP), PT2

meta SPC 4:
- Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP), PT4

meta SPC 5:
- Disinfection of food packaging material (aseptic packaging) by immersion or aerosolised or vaporised hydrogen peroxide (VHP), PT4
- Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP), PT4

meta SPC 6, *meta* SPC 7:
- Disinfection of distribution and storage systems for drinking water, PT4
- Surface disinfection in food and feed processing by liquid application, PT4

meta SPC 8, *meta* SPC 9:
- Surface disinfection by liquid application in industrial and institutional areas, PT2
- Disinfection of surfaces associated with animal housing by spraying, PT3

Physico-chemical properties

The products in the INTEROX biocidal product family are clear, colourless liquids with acidic pH showing no surface active properties.

With regard to physical hazards, the products containing 25 to 49.9% (w/w) hydrogen peroxide are classified as oxidizing, category 2 (Ox. Liq. 2; H272: May intensify fire; oxidiser) (Meta SPC 2-9) and products containing 13% (w/w) hydrogen peroxide are classified as oxidizing, category 3 (Ox. Liq. 3; H272: May intensify fire; oxidiser) (Meta SPC 1).

The products are stable in HDPE packaging, which has been demonstrated by accelerated storage test low temperature stability test and long-term storage stability studies The shelf-life for the biocidal product family is set to 12 months at ambient temperature.

The validated analytical methods for determination of the active substance and impurities in the products as well as the relevant monitoring methods for the active substance are acceptable.

Efficacy

The meta SPCs 1-9 were shown to be efficacious against the following target organisms in the following uses:

.Meta SPC 1:
- Surface disinfection of closed spaces by aerosolised hydrogen peroxide, PT 2
  - bacteria - bacterial spores - fungi - yeasts - viruses

Meta SPC 2, meta SPC 3:
- Surface disinfection of closed spaces by aerosolised hydrogen peroxide, PT 2
  - bacteria - bacterial spores - fungi - yeasts - viruses
- Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP), PT 2
  - bacteria - bacterial spores – fungi – yeasts - viruses

Meta SPC 4:
- Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP), PT 4
  - bacterial spores

Meta SPC 5:
- Disinfection of food packaging material (aseptic packaging) by immersion or aerosolised or vaporised hydrogen peroxide (VHP), PT 4
  - bacterial spores
- Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP), PT 4
  - bacterial spores

Meta SPC 6, meta SPC 7:
- Surface disinfection in food and feed processing by liquid application, PT 4
  - bacteria - bacterial spores - yeasts - fungi - viruses
- Disinfection of distribution and storage systems for drinking water, PT 4
  - bacteria - bacterial spores - yeasts - fungi - viruses

Meta SPC 8, meta SPC 9:
- Surface disinfection by liquid application in industrial and institutional areas, PT 2
  - bacteria - bacterial spores - yeasts - fungi - viruses
- Disinfection of surfaces associated with animal housing by spraying, PT 3
  - bacteria - yeasts - fungi - viruses

Hydrogen peroxide concentrations shown to be efficacious ranged from 9.5% to 49% (w/w) depending on the use and the target organism.

Human health

Human health classification of the products according to CLP mixture rules is based on the content of hydrogen peroxide and pH values. Each Meta SPC in the biocidal product family is classified as follows:

Meta SPC 1
- Eye Dam. 1; H318: Causes serious eye damage.

Meta SPC 2, 5, 6, 8
- Acute Tox. 4; H302: Harmful if swallowed.
- Skin Irrit. 2; H315: Causes skin irritation.
- Eye Dam. 1; H318: Causes serious eye damage.
- STOT SE 3; H335: May cause respiratory irritation.

Meta SPC 3, 7, 9
- Acute Tox. 4; H302: Harmful if swallowed.
- Skin Corr. 1; H314: Causes severe skin burns and eye damage.

- Eye Dam. 1; H318: Causes serious eye damage.
- STOT SE 3; H335: May cause respiratory irritation.

Meta SPC 4
- Acute Tox. 4; H302: Harmful if swallowed.
- Eye Dam. 1; H318: Causes serious eye damage.

The products are intended for professional use only. Risk assessment for local effects was performed for dermal and inhalation exposure.

The risks are considered acceptable in the authorised uses with the use instructions and use-specific risk mitigation measures described in the SPC. Depending on the use the RMMs include technical measures such as automated loading, automated spraying or ventilation, and the use of PPE such as protective gloves, coverall or respiratory protective equipment. Eye protection is mandatory for all meta SPCs due to the classification.

Re-entry to disinfected premises is only allowed after safe level of hydrogen peroxide in the air has been reached. There is no risk for general public or consumers via residues in food.

Environment

The environmental risk assessment for the BPF has followed the agreements made within the active substance assessment and/or previously agreed at the WG for similar uses or for rapidly reacting substances.

The products in meta SPCs 2 – 9 are classified as Aquatic Chronic 3, H412: Harmful to aquatic life with long lasting effects.

Acceptable levels of risk to all environmental compartments have been demonstrated for the proposed uses of the BPF when applying specific risk mitigation measures as follows and indicated in the SPC:

Meta SPC 4, Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP), PT 4:

Use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Hydrogen peroxide emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.

Meta 5, Disinfection of food packaging material (aseptic packaging) by immersion or aerosolised or vaporised hydrogen peroxide (VHP), PT 4:

Aerosolised or vaporised application should be used only in closed aseptic packaging machines with no emission to water and negligible emission to air. Hydrogen peroxide emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.

Meta SPC 5, Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP), PT 4:

Use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Hydrogen peroxide emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.

Meta SPC 6 and meta SPC 7, Surface disinfection in food and feed processing by liquid application, PT 4:

The waste water from breweries should not be discharged direct to surface water after simple on-site treatment. The waste water from breweries should be discharged to the sewer connected to the sewage treatment plant (STP).

Meta SPC 6 and meta SPC 7, Disinfection of distribution and storage systems for drinking water, PT 4:

The use is limited to distribution and storage systems with volume ≤ 15 000 L.

Overall conclusion

Using the products belonging to this biocidal product family according to the conditions as stated in the SPC, the products will be efficacious and will not present an unacceptable risk to human and animal health nor the environment.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier[1]	**Country (if relevant)**
INTEROX Biocidal Product Family 1	Union authorisation

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Solvay Chemicals International S.A.
	Address	Rue De Ransbeek 310, B-1120 Bruxelles, Belgium
Pre-submission phase started on	09th June 2016	
Pre-submission phase concluded on	10th July 2016	
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Solvay Interox Limited
Address of manufacturer	Baronet Road, Solvay House, Warrington, Cheshire, WA4 6HA, UK
Location of manufacturing sites	As above

Name of manufacturer	Solvay Chemicals Finland Oy
Address of manufacturer	YRJONOJANTIE 2 VOIKKAA 45910 Finland
Location of manufacturing sites	As above

Name of manufacturer	Solvay Chemicals GmbH Germany
Address of manufacturer	KOETHENSCHE STRASSE 1-3 BERNBURG Deutschland 06406 DE
Location of manufacturing sites	As above

Name of manufacturer	Solvay Chemie BV Netherlands
Address of manufacturer	SCHEPERSWEG, 1 HERTEN 6049 CV NL

[1]Please fill in here the identifying product name from R4BP 3.

Location of manufacturing sites	As above

Name of manufacturer	Solvay Chimica Italia SpA Italy
Address of manufacturer	VIA PIAVE, 6 ROSIGNANO SOLVAY LI 57013 IT
Location of manufacturing sites	As above

Name of manufacturer	Solvay Chimie SA Belgium
Address of manufacturer	Rue de Ransbeek 310, 1120 Bruxelles, Belgium
Location of manufacturing sites	Solvay Chimie SA Belgium, RUE SOLVAY, 39, 5190 BE JEMEPPE-SUR-SAMBRE Belgium Solvay Chimie SA Belgium, SCHELDELAAN 600 – HAVEN 725, 2040 BE ANTWERP Belgium

Name of manufacturer	Solvay InteroxProdutosPeroxidados SA
Address of manufacturer	RUA ENG. CLEMENT DUMOULIN POVOA DE SANTA IRIA 2625-106 PT
Location of manufacturing sites	As above

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

Active substance	Hydrogen peroxide
Name of manufacturer	Solvay Interox Limited
Address of manufacturer	Baronet Road, Solvay House, Warrington, Cheshire, WA4 6HA, UK
Location of manufacturing sites	As above

Active substance	Hydrogen peroxide
Name of manufacturer	Solvay Chemicals Finland Oy
Address of manufacturer	YRJONOJANTIE 2 VOIKKAA 45910 Finland
	As above

Active substance	Hydrogen peroxide
Name of manufacturer	Solvay Chemicals GmbH Germany
Address of manufacturer	KOETHENSCHE STRASSE 1-3 BERNBURG Deutschland 06406 DE
Location of manufacturing sites	As above

Active substance	Hydrogen peroxide

Name of manufacturer	Solvay Chimica Italia SpA Italy
Address of manufacturer	VIA PIAVE, 6 ROSIGNANO SOLVAY LI 57013 IT
Location of manufacturing sites	As above

Active substance	Hydrogen peroxide
Name of manufacturer	Solvay Chimie SA Belgium
Address of manufacturer	Rue de Ransbeek 310, 1120 Bruxelles, Belgium
Location of manufacturing sites	Solvay Chimie SA Belgium, RUE SOLVAY, 39, 5190 BE JEMEPPE-SUR-SAMBRE Belgium Solvay Chimie SA Belgium, SCHELDELAAN 600 – HAVEN 725, 2040 BE ANTWERP Belgium

Active substance	Hydrogen peroxide
Name of manufacturer	Solvay InteroxProdutosPeroxidados SA
Address of manufacturer	RUA ENG. CLEMENT DUMOULIN POVOA DE SANTA IRIA 2625-106 PT
Location of manufacturing sites	As above

2.1.2 Product family composition and formulation

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

Do the products 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 ☒

The products evaluated in the active substance approval stage were not specific real-life products but considered as theoretical products containing hydrogen peroxide in concentrations of 35% (w/w) or 49.9% (w/w). Stabilisers were listed, and their maximum concentrations were defined when the composition of representative products were described in the CAR (2015) and its post-approval data. The concentrations of hydrogen peroxide for products in INTEROX Biocidal Product Family 1 are equal or lower as in the theoretical products and the concentrations of stabilisers are below their defined maximum concentrations.

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Hydrogen peroxide
IUPAC or EC name	Hydrogen peroxide
EC number	231-765-0
CAS number	7722-84-1
Index number in Annex VI of CLP	008-003-00-9
Minimum purity / content	< 70% (w/w), theoretical dry weight minimum content >99.5% (w/w)
Structural formula	

2.1.2.2 Candidate(s) for substitution

Not applicable.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family[2]

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Hydrogen peroxide	Hydrogen peroxide	Active substance	7722-84-1	231-765-0	13	49.9

Meta-SPC	Product name	Hydrogen peroxide (%)	
		Min	Max
1	INTEROX SG 12	13.0	13.5
2	INTEROX SG 35, INTEROX SG 35 PLUS	35.0	35.7
3	INTEROX SG 50, INTEROX SG 50 PLUS	49.0	49.9
4	INTEROX AG Spray 25S	25	25.7
5	INTEROX AG Spray 35, INTEROX AG Spray 35S, INTEROX AG Bath 35, INTEROX AG Bath 35S, INTEROX AG Dual 35	35.0	35.7
6	INTEROX FCC 35	35.0	35.7
7	INTEROX FCC 50	49.0	49.9
8	INTEROX BT 35	35.0	35.7
9	INTEROX BT 50	49.0	49.9

Please refer to the confidential annex for further information on the qualitative and quantitative information on the composition of the biocidal product family.

2.1.2.4 Information on technical equivalence

The source of substance is the same as was evaluated for inclusion in the Union list of approved active substances. Additional details of the active substance are described under section 3.6 (confidential annex).

2.1.2.5 Information on the substance(s) of concern

The products belonging to the INTEROX Biocidal Product Family 1 do not contain any substances of concern (See the Confidential Annex). Therefore, no information on the substance(s) of concern is required.

2.1.2.6 Type of formulation

Meta SPC´s 1-5: AL (any other liquid)
Meta SPC´s 6-9: SL (soluble concentrate)

2.1.3 Hazard and precautionary statements

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

In line with CA document CA-May15-Doc.4.4 all P-statements that are triggered by CLP need to be included. However, if P-statements are triggered, but considered as not applicable for the product, they can be omitted. This is indicated here in the Note column.

Meta SPC 1

- INTEROX SG 12

Classification	
Hazard category	Ox. Liq. 3 Eye Dam. 1
Hazard statement	H272: May intensify fire; oxidiser H318: Causes serious eye damage.
Labelling	
Hazard pictogram	 GHS03  GHS05
Signal words	Danger
Hazard statements	H272: May intensify fire; oxidiser H318: Causes serious eye damage.
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P220: Keep away from clothing and other combustible materials. P280: Wear eye protection. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P370 + P378: In case of fire: Use water to extinguish. P501: Dispose of contents/containers in accordance with local/regional/national/international regulation.
Note	-

Meta SPC 2

- INTEROX SG 35, INTEROX SG 35 PLUS

Classification	
Hazard category	Ox. Liq. 2 Acute Tox. 4 Skin Irrit. 2 Eye Dam. 1 STOT SE 3 Aquatic Chronic 3

Hazard statement	H272: May intensify fire; oxidiser H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects.
Labelling	
Hazard pictograms	 GHS03  GHS05  GHS07
Signal words	Danger
Hazard statements	H272: May intensify fire; oxidiser H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful 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. P220: Keep away from clothing and other combustible materials. P261: Avoid breathing vapours. 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. P280: Wear protective gloves, protective clothing, eye protection, face protection. P301 + P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P302 + P352: IF ON SKIN: Wash with plenty of water. P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P330: Rinse mouth. P332 + P313: If skin irritation occurs: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash it before reuse. P370 + P378: In case of fire: Use water to extinguish. P403 + P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents/containers in accordance with local/regional/national/international regulation.
Note	P321 (Specific treatment (see … on this label).) triggered by H315 has been omitted as there is no specific treatment available nor required.

Meta SPC 3
INTEROX SG 50, INTEROX SG 50 PLUS

Classification	
Hazard category	Ox. Liq. 2 Acute Tox. 4 Skin Corr. 1 Eye Dam. 1 STOT SE 3 Aquatic Chronic 3
Hazard statement	H272: May intensify fire, oxidiser. H302: Harmful if swallowed. H314: Causes severe skin burns and eye damage. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects.
Labelling	
Hazard pictograms	 GHS03  GHS05  GHS07
Signal words	Danger
Hazard statements	H272: May intensify fire, oxidiser. H302: Harmful if swallowed. H314: Causes severe skin burns and eye damage. H335: May cause respiratory irritation. H412: Harmful 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. P220: Keep away from clothing and other combustible materials. P260: Do not breathe vapours. 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. P280: Wear protective gloves, protective clothing, eye protection, face protection. P301 + P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P301 + P330 + P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303 + P361 + P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P363: Wash contaminated clothing before reuse. P370 + P378: In case of fire: Use water to extinguish. P403 + P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents/containers in accordance with local/regional/national/international regulation.
Note	P261 (Avoid breathing dust/fume/gas/mist/vapours/spray.) has been omitted as P260 is already selected. P321 (Specific treatment (see … on this label).) triggered by H314 has been omitted as there is no specific treatment available nor required.

Meta SPC 4

- INTEROX AG Spray 25S

Classification	
Hazard category	Ox. Liq. 2 Acute Tox. 4 Eye Dam. 1 Aquatic Chronic 3
Hazard statement	H272: May intensify fire; oxidiser H302: Harmful if swallowed. H318: Causes serious eye damage. H412: Harmful to aquatic life with long lasting effects.

Labelling	
Hazard pictograms	 GHS03  GHS05  GHS07
Signal words	Danger
Hazard statements	H272: May intensify fire; oxidiser H302: Harmful if swallowed. H318: Causes serious eye damage. H412: Harmful 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. P220: Keep away from clothing and other combustible materials. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P280: Wear eye protection. P301 + P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P330: Rinse mouth. P370 + P378: In case of fire: Use water to extinguish. P403 + P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents/containers in accordance with local/regional/national/international regulation.
Note	-

Meta SPC 5

- INTEROX AG Spray 35, INTEROX AG Spray 35S, INTEROX AG Bath 35, INTEROX AG Bath 35S, INTEROX AG Dual 35

Classification	
Hazard category	Ox. Liq. 2 Acute Tox. 4 Skin Irrit. 2 Eye Dam. 1 STOT SE 3 Aquatic Chronic 3
Hazard statement	H272: May intensify fire; oxidiser H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects.

Labelling	
Hazard pictograms	 GHS03  GHS05  GHS07
Signal words	Danger
Hazard statements	H272: May intensify fire; oxidiser H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful 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. P220: Keep away from clothing and other combustible materials. P261: Avoid breathing vapours. 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. P280: Wear protective gloves, protective clothing, eye protection, face protection. P301 + P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P302 + P352: IF ON SKIN: Wash with plenty of water. P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P330: Rinse mouth. P332 + P313: If skin irritation occurs: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash it before reuse. P370 + P378: In case of fire: Use water to extinguish. P403 + P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents/containers in accordance with local/regional/national/international regulation.
Note	P321 (Specific treatment (see … on this label).) triggered by H315 has been omitted as there is no specific treatment available nor required.

Meta SPC 6

- INTEROX FCC 35

Classification	
Hazard category	Ox. Liq. 2 Acute Tox. 4 Skin Irrit. 2 Eye Dam. 1 STOT SE 3 Aquatic Chronic 3
Hazard statement	H272: May intensify fire; oxidiser H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects.
Labelling	
Hazard pictograms	 GHS03  GHS05  GHS07
Signal words	Danger
Hazard statements	H272: May intensify fire; oxidiser H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful 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. P220: Keep away from clothing and other combustible materials. P261: Avoid breathing vapours. 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. P280: Wear protective gloves, protective clothing, eye protection, face protection. P301 + P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P302 + P352: IF ON SKIN: Wash with plenty of water. P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P330: Rinse mouth. P332 + P313: If skin irritation occurs: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash it before reuse. P370 + P378: In case of fire: Use water to extinguish. P403 + P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents/containers in accordance with local/regional/national/international regulation.
Note	P321 (Specific treatment (see … on this label).) triggered by H315 has been omitted as there is no specific treatment available nor required.

Meta SPC 7

- INTEROX FCC 50

Classification	
Hazard category	Ox. Liq. 2 Acute Tox. 4 Skin Corr. 1 Eye Dam. 1 STOT SE 3 Aquatic Chronic 3
Hazard statement	H272: May intensify fire, oxidiser. H302: Harmful if swallowed. H314: Causes severe skin burns and eye damage. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects.

Labelling	
Hazard pictograms	 GHS03  GHS05  GHS07
Signal words	Danger
Hazard statements	H272: May intensify fire, oxidiser. H302: Harmful if swallowed. H314: Causes severe skin burns and eye damage. H335: May cause respiratory irritation. H412: Harmful 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. P220: Keep away from clothing and other combustible materials. P260: Do not breathe vapours. 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. P280: Wear protective gloves, protective clothing, eye protection, face protection. P301 + P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P301 + P330 + P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303 + P361 + P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P363: Wash contaminated clothing before reuse. P370 + P378: In case of fire: Use water to extinguish. P403 + P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents/containers in accordance with local/regional/national/international regulation.
Note	P261 (Avoid breathing dust/fume/gas/mist/vapours/spray.) has been omitted as P260 already used. P321 (Specific treatment (see … on this label).) triggered by H314 has been omitted as there is no specific treatment available nor required.

Meta SPC 8

- INTEROX BT 35

Classification	
Hazard category	Ox. Liq. 2 Acute Tox. 4 Skin Irrit. 2 Eye Dam. 1 STOT SE 3 Aquatic Chronic 3
Hazard statement	H272: May intensify fire; oxidiser H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects.
Labelling	
Hazard pictograms	 GHS03  GHS05  GHS07
Signal words	Danger
Hazard statements	H272: May intensify fire; oxidiser H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful 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. P220: Keep away from clothing and other combustible materials. P261: Avoid breathing vapours and 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. P280: Wear protective gloves, protective clothing, eye protection, face protection. P301 + P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P302 + P352: IF ON SKIN: Wash with plenty of water. P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P330: Rinse mouth. P332 + P313: If skin irritation occurs: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash it before reuse. P370 + P378: In case of fire: Use water to extinguish. P403 + P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents/containers in accordance with local/regional/national/international regulation.
Note	P321 (Specific treatment (see … on this label).) triggered by H315 has been omitted as there is no specific treatment available nor required.

Meta SPC 9

- INTEROX BT 50

Classification	
Hazard category	Ox. Liq. 2 Acute Tox. 4 Skin Corr. 1 Eye Dam. 1 STOT SE 3 Aquatic Chronic 3
Hazard statement	H272: May intensify fire, oxidiser. H302: Harmful if swallowed. H314: Causes severe skin burns and eye damage. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects.

Labelling	
Hazard pictograms	 GHS03  GHS05  GHS07
Signal words	Danger
Hazard statements	H272: May intensify fire, oxidiser. H302: Harmful if swallowed. H314: Causes severe skin burns and eye damage. H335: May cause respiratory irritation. H412: Harmful 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. P220: Keep away from clothing and other combustible materials. P260: Do not breathe vapours and 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. P280: Wear protective gloves, protective clothing, eye protection, face protection. P301 + P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P301 + P330 + P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303 + P361 + P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P363: Wash contaminated clothing before reuse. P370 + P378: In case of fire: Use water to extinguish. P403 + P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents/containers in accordance with local/regional/national/international regulation.
Note	P261 (Avoid breathing dust/fume/gas/mist/vapours/spray.) has been omitted as P260 already used. P321 (Specific treatment (see … on this label).) triggered by H314 has been omitted as there is no specific treatment available nor required.

2.1.4 Authorised uses

Summary of uses and the allocated meta SPCs:

Use #1 – Surface disinfection of closed spaces by aerosolised hydrogen peroxide	Meta SPC 1, 2 and 3
Use #2 – Surface disinfection by liquid application in industrial and institutional areas	Meta SPC 8 and 9
Use #3 –Disinfection of surfaces associated with animal housing by spraying	Meta SPC 8 and 9
Use #4 – Disinfection of food packaging material (aseptic packaging) by immersion or aerosolised or vaporised hydrogen peroxide (VHP)	Meta SPC 5
Use #5 – Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP)	Meta SPC 5
Use #6 – Disinfection of distribution and storage systems for drinking water	Meta SPC 6 and 7
Use #7 – Surface disinfection in food and feed processing by liquid application	Meta SPC 6 and 7
Use #8 – Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP)	Meta SPC 4
Use #9 – Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP)	Meta SPC 2 and 3

2.1.4.1 Use 1. Surface disinfection of closed spaces by aerosolised hydrogen peroxide

2.1.4.1.1 Use description

Meta SPC 1, 2 and 3

Table 1. Use # 1 – Surface disinfection of closed spaces by aerosolised hydrogen peroxide

Product Type	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	bacteria - bacterial spores - fungi - yeasts - viruses
Field of use	Indoor, closed spaces Industrial – pharmaceutical industry or cosmetics industry, for example clean rooms Medical– healthcare facilities, hospitals, emergency vehicles Institutional Disinfection of non-porous surfaces
Application method(s)	Automated, non-directed aerosolization (e.g. fogging or spraying)

Application rate(s) and frequency	13%, 35% or 49% hydrogen peroxide (undiluted product) applied via aerosolization in closed rooms. Frequency - as required by user, for example up to 3 times per day. Treatment time depends on machine type, size of room or area of surfaces to be disinfected. Apply at room temperature.
Category(ies) of users	Professional
Pack sizes and packaging material	Pack sizes (L): 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L. Packaging material: Approved grades of HDPE.

2.1.4.1.2 Use-specific instructions for use[2]

Use an automated loading system.
13%, 35% or 49% (w/w) hydrogen peroxide (undiluted product) is applied via aerosolization by automated device in a sealed room. Rooms may be dehumidified to achieve higher hydrogen peroxide concentrations on surfaces.

Remove barriers that may hinder aerosolized product from reaching the surfaces to be disinfected.

The disinfected surfaces should be non-porous and cleaned before application of the product. The product is not intended to be used on surfaces that may come into contact with food or feeding stuffs.

The user should 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. The optimal operating conditions are validated on site (temperature, hygrometry, product to be used, diffusion time, extraction time, etc.). Besides biological validation chemical validation should be performed.

Efficacy of room disinfection was demonstrated according to norm NF T 72-281 by nebulization of 1 g of hydrogen peroxide per cubic meter of room volume in 22 min followed by 180 min contact time at room temperature.

Volume of disinfected space should be 30 - 150 m^3.

Median particle size should be <0.5 µm in aerosols used for disinfection.

Prevent entry during disinfection process.

2 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.

2.1.4.1.3 Use-specific risk mitigation measures

Surfaces in the treatment area must be clean and dry prior to application. Seal the treatment enclosure (e.g. with tape) to ensure that hydrogen peroxide levels outside the enclosure are kept at acceptable health and safety levels. Ensure all personnel have vacated the treatment enclosure prior to application. Remove all plants, animals, beverages and food. Re-entry is only permitted once the air concentration has dropped below the reference value (1.25 mg/m^3). 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. In case the room has to be entered when the hydrogen peroxide concentration is still above 1.25 mg/m^3 it is only allowed by wearing appropriate PPE including SCBA (Self Contained Breathing Apparatus). Place warning signs on all entrances to the treatment enclosure.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.1.4.2 Use 2. Surface disinfection by liquid application in industrial and institutional areas

2.1.4.2.1 Use description

Meta SPC 8 + 9

Table 2. Use # 2 – Surface disinfection by liquid application in industrial and institutional areas

Product Type	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	bacteria - bacterial spores - yeasts - fungi - viruses
Field of use	Indoor Industrial, institutional

	Disinfection of non-porous surfaces
Application method(s)	Automated spraying on surfaces Cleaning-in-Place (CIP) Immersion of equipment and utensils
Application rate(s) and frequency	Use concentration 13% w/w hydrogen peroxide • CIP (cleaning-in-place): volume of diluted product needed to fill the disinfected system • Automated spraying: 50 -100 mL diluted product/m^2 • Immersion: make solution and dip items Frequency - as required by the user. Apply at room temperature.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE packaging: 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 210, 220 and 1000 L (IBC). Approved grades of HDPE.

2.1.4.2.2 Use-specific instructions for use[3]

Use an automated loading system for CIP and automated spraying.
Dilute the product to reach the needed hydrogen peroxide concentration stated below.

Effective hydrogen peroxide concentration (w/w) and contact time:
Bactericidal - 13%, 10 min
Yeasticidal and fungicidal – 13%, 15 min
Sporicidal – 13%, 60 min
Virucidal – 13%, 30 min
All claimed microbes - 13%, 60 min

Each product label should give information on how the dilution should be made, e.g. to reach 13% (w/w) hydrogen peroxide concentration:

A product with 50% hydrogen peroxide concentration: The product should be diluted to 28% w/v (280 g or 230 mL of product, add water up to 1L).

A product with 35% hydrogen peroxide concentration: The product should be diluted to 39% w/v (390 g or 340 mL of product, add water up to 1L).

Precleaning of surfaces required before using disinfectants.

Automated spraying of diluted product 50 -100 mL /m^2 on non-porous surfaces. Surface needs to stay wet for the allocated contact time.

Immerse instruments in diluted product for the allocated contact time. Allow to drain and dry.

[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.

2.1.4.2.3 Use-specific risk mitigation measures

CIP: The processes must be fully automated and enclosed with no exposure in the case of tanks or piping systems. Automated spraying: In the case of automated spraying of surfaces such as conveyors or other fixed installations workers must leave the room before processing. Disinfection can only be processed after the end of a shift with all workers having left the room. The process must be started from outside the room. Warning notices indicating that entry is denied and temporary barriers must be placed on all entries. Air concentrations must be monitored to ensure that no leakage occurs during operations. For re-entry, the undercut of AECinhalation of 1.25 mg/m^3 shall be ensured with technical and organisational measures (e.g. sensor, defined ventilation period). Immersion: The use of eye protection during handling of the product is mandatory. 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 (at least type 6, EN 13034) shall be worn in loading. For stationary processes, a local exhaust ventilation (LEV) with a capture efficiency of at least 85% shall be specified. If no LEV, use respiratory protective equipment (RPE) providing a protection factor of 20 in loading and 5 for immersion. After use, immersion baths must be emptied or covered to prevent further evaporation.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.1.4.3 Use 3. Disinfection of surfaces associated with animal housing by spraying

2.1.4.3.1 Use description

Meta SPC 8 + 9

Table 3. Use # 3 –Disinfection of surfaces associated with animal housing by spraying

Product Type	3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	bacteria - yeasts - fungi - viruses
Field of use	Indoor Disinfection of non-porous materials and surfaces associated with the housing of animals
Application method(s)	Spraying with automated or manual equipment
Application rate(s) and frequency	Frequency depends on life-cycle of animals - as required by user. Use concentration 9.5-13% w/w hydrogen peroxide Spraying: 50 -100 mL diluted product/m^2
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE packaging: 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 210, 220 and 1000 L (IBC). Approved grades of HDPE.

2.1.4.3.2 Use-specific instructions for use[4]

Dilute the product to reach the needed hydrogen peroxide concentration stated below.

Effective hydrogen peroxide concentration (w/w) and contact time:
Bactericidal and yeasticidal - 9.5%, 30 min
Fungicidal – 13%, 60 min
Virucidal – 13%, 30 min
All claimed microbes - 13%, 60 min

Each product label should give information on how the dilution should be made, e.g. to reach 13% (w/w) hydrogen peroxide concentration:

A product with 35% hydrogen peroxide concentration: The product should be diluted to 39% w/v (390 g or 340 mL of product, add water up to 1L).

A product with 50% hydrogen peroxide concentration: The product should be diluted to 28% w/v (280 g or 230 mL of product, add water up to 1L).

Remove animals from spaces to be disinfected. Precleaning of surfaces required before using disinfectants.

[4] 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.

Spray diluted product 50 -100 mL /m^2 on non-porous surfaces. Surface needs to stay wet for the allocated contact time. Allow to drain and dry.

2.1.4.3.3 Use-specific risk mitigation measures

Automated spraying systems: During the operation worker must leave the area and access must be denied by appropriate barriers or locked doors. After operation efficient ventilation (10 ACH) must be used to reach a safe level. During this period access must also be denied. Air concentrations must be monitored to ensure that no leakage occurs during operations. For re-entry, the undercut of AECinhalation of 1.25 mg/m^3 shall be ensured with technical and organisational measures (e.g. sensor, defined ventilation period). For manual spraying: The use of eye protection during handling of the product is mandatory. 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 (at least type 6, EN 13034) shall be worn. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information). Only operators wearing the specified RPE should be present while spraying or fumigating. The operator must walk backward towards the exit while spraying the surfaces so always walking away from sprayed areas. Efficient ventilation (10 ACH) must be used during spraying and access must be denied by appropriate barriers and notices. Also after operation efficient ventilation (10 ACH) must be used to reach a safe level. During this period access must also be denied. Air concentrations must be monitored to ensure that no leakage occurs during operations. For re-entry, the undercut of AECinhalation of 1.25 mg/m^3 shall be ensured with technical and organisational measures (e.g. sensor, defined ventilation period). No secondary exposure is expected because of rapid decomposition of hydrogen peroxide.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.1.4.4 Use 4. Disinfection of food packaging material (aseptic packaging) by immersion or aerosolised or vaporised hydrogen peroxide (VHP)

2.1.4.4.1 Use description

Meta SPC 5

Table 4. Use # 4 – Disinfection of food packaging material (aseptic packaging) by immersion or aerosolised or vaporised hydrogen peroxide (VHP)

Product Type	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	bacterial spores
Field of use	Indoor Industrial use - food and feed area Disinfection of food package material
Application method(s)	Automated immersion of packaging material into bath of heated product in aseptic filling machine. Automated vaporisation or aerosolisation of product in sealed area in aseptic filling machine.
Application rate(s) and frequency	Undiluted product (35 % w/w hydrogen peroxide) is used. Product consumption in vapour and aerosol applications 0.1 – 1 mL per second per packaging line while the machine is operating. Number and timing of applications as required by user. Machines typically operate up to 120 hours per week.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE packaging: 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 210, 220 and 1000 L (IBC). Approved grades of HDPE.

2.1.4.4.2 Use-specific instructions for use[5]

Use an automated loading system. Immersion: immerse clean packaging material in undiluted product according to packaging machine operating instruction. Disinfection efficacy is determined by immersion time and temperature and packaging material.

[5] 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.

Efficacy was demonstrated by immersion of carton food packages in 80 °C bath for 2.5 s.

If concentration of hydrogen peroxide in the bath drops to less than 32% during operation, replace solution with fresh product.

Vaporization: vaporize and apply undiluted product to clean packaging material according to packaging machine operating instructions. Product vaporized at 100-250 °C. Efficacy was demonstreated with polyethylene terephthalate packages flushed with 100 °C air containing 1.1% (w/w) of product for 5.5 s.

After sterilisation, blow-dry the packaging with hot sterile air.

Suitable packaging materials included paperboard, polyethylene terephthalate, polystyrene and aluminium.

Disinfection performance of each packaging machine should be validated using biological and chemical indicators.

Follow machine operating instructions for disinfection period, extraction of hydrogen peroxide and re-entry. Prevent entry during disinfection process.

2.1.4.4.3 Use-specific risk mitigation measures

During operation, ensure adequate ventilation along the machines (LEV) and in the industrial halls (technical ventilation).
During manual maintenance tasks, ensure adequate ventilation inside the machine (LEV) before opening the doors of the aseptic area.

1. The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed.
2. Workplace release measurements with suitable measurement equipment shall be performed upon implementation of the aseptic packaging plant, at regular intervals (annual intervals recommended) and after any change in relevant boundary conditions. The national regulations for workplace measurements have to be followed.
3. In case of maintenance of the aseptic packaging plant (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment, chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required. The type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the product information. Glove material to be specified by the authorisation holder within the product information.

Aerosolised or vaporised application should be use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Hydrogen peroxide emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.1.4.5 Use 5. Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP)

2.1.4.5.1 Use description

Meta SPC 5

Table 5. Use # 5 – Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP)

Product Type	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	bacterial spores
Field of use	Indoor Industrial use - food and feed area Disinfection of non-porous surfaces
Application method(s)	Automated vaporisation or aerosolization in closed areas in aseptic filling machines.
Application rate(s) and frequency	Undiluted product (35 % w/w hydrogen peroxide) is used. 100 – 800 mL product consumed per machine in one disinfection cycle. Frequency – as required by user, typically once every 24 hours
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE packaging. 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 210, 220 and 1000 L (IBC). Approved grades of HDPE.

2.1.4.5.2 Use-specific instructions for use[6]

Use an automated loading system. Automated disinfection of closed areas in aseptic filling machines. Flash evaporation 130-250 °C or aerosolization (room temperature) of undiluted product using automated equipment integrated to the packaging machine. From 100 to 800 mL product required for one disinfection cycle. Minimum contact time 7 minutes starting from beginning of application. Disinfection performance of each packaging machine should be validated using biological and chemical indicators. Follow machine operating instructions for disinfection period, volume of disinfectant extraction of hydrogen peroxide and re-entry. Prevent entry during disinfection process.

2.1.4.5.3 Use-specific risk mitigation measures

During operation, ensure adequate ventilation along the machines (LEV) and in the industrial halls (technical ventilation). During manual maintenance tasks, ensure adequate ventilation inside the machine (LEV) before opening the doors of the aseptic area. 1. The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed. 2. Workplace release measurements with suitable measurement equipment shall be performed upon implementation of the aseptic packaging plant, at regular intervals (annual intervals recommended) and after any change in relevant boundary conditions. The national regulations for workplace measurements have to be followed. 3. In case of maintenance of the aseptic packaging plant (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment, chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required. The type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the product information. Glove material to be specified by the authorisation holder within the product information. Use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Hydrogen peroxide emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.

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

See general directions for use.

6 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.

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

See general directions for use.

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

See general directions for use.

2.1.4.6 Use 6. Disinfection of distribution and storage systems for drinking water

2.1.4.6.1 Use description

Meta SPC 6 + 7

Table 6. Use # 6 – Disinfection of distribution and storage systems for drinking water

Product Type	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	bacteria - bacterial spores - yeasts - fungi - viruses
Field of use	Indoor Industrial use - drinking water systems for human and animal drinking water Disinfection of non-porous surfaces
Application method(s)	Flooding of pipes Automated spraying (CIP)
Application rate(s) and frequency	Apply at room temperature. Use concentration 13% w/w hydrogen peroxide Frequency: once per week. Use following installation, maintenance or cleaning.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE packaging. 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 210, 220 and 1000 L (IBC). Approved grades of HDPE.

2.1.4.6.2 Use-specific instructions for use[7]

Use an automated loading system.

[7] 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;

Dilute the product to reach the needed hydrogen peroxide concentration stated below. Effective hydrogen peroxide (w/w) concentration and contact time: Bactericidal – 13%, 10 min Yeasticidal and fungicidal – 13%, 15 min Sporicidal – 13%, 60 min Virucidal – 13%, 30 min All claimed microbes - 13%, 60 min Each product label should give information on how the dilution should be made, e.g. to reach 13% (w/w) hydrogen peroxide concentration: A product with 50% hydrogen peroxide concentration: The product should be diluted to 28% w/v (280 g or 230 mL of product, add water up to 1L). A product with 35% hydrogen peroxide concentration: The product should be diluted to 39% w/v (390 g or 340 mL of product, add water up to 1L). Apply diluted product at room temperature on pre-cleaned surfaces. Add as aqueous solution to pipes as needed for flooding. Spray application to tanks until run-off. Surface need to be wet with disinfectant for the allocated contact time.

2.1.4.6.3 Use-specific risk mitigation measures

CIP and automated spraying: The processes must be fully automated and enclosed with no exposure in the case of tanks or piping systems. The use is limited to distribution and storage systems with volume ≤ 15 000 L. Rinse well with potable water.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.4.7 Use 7. Surface disinfection in food and feed processing by liquid application

2.1.4.7.1 Use description

Meta SPC 6 + 7

Table 7. Use # 7 – Surface disinfection in food and feed processing by liquid application

Product Type	4
Where relevant, an exact description of the authorised use	Disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed for humans and animals.
Target organism (including development stage)	bacteria - bacterial spores - yeasts - fungi - viruses
Field of use	Indoor Industrial use - food & feed area Disinfection of non-porous surfaces
Application method(s)	Automated spraying on surfaces Cleaning-in-Place (CIP) Immersion of equipment and utensils
Application rate(s) and frequency	Use concentration 13% w/w hydrogen peroxide • CIP (cleaning-in-place): volume of diluted product needed to fill the system to be disinfected • Automated spraying: 50 -100 mL diluted product/m^2 • Immersion: make solution and dip items As required by user - up to 1 or 2 times per day, often once per week. Apply at room temperature.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE packaging. 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 210, 220 and 1000 L (IBC). Approved grades of HDPE.

2.1.4.7.2 Use-specific instructions for use[8]

Disinfection of pre-cleaned, non-porous surfaces such as tables, floors, walls, machinery, equipment and untensils in food & feed areas in production, transport, storage or preparation and handling. CIP (cleaning in place) disinfection (terminal disinfection after cleaning) – pipes, tanks, mixer, other machine which comes into contact with food. Soaking of pre-cleaned items – dishes, cutlery, equipment, small machinery, machine items, crates, boxes. Use an automated loading system for CIP and automated spraying.

[8] 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.

Dilute the product to reach the needed hydrogen peroxide concentration stated below.

Effective hydrogen peroxide (w/w) concentration and contact time:
Bactericidal, yeasticidal, fungicidal – 13%, 15 min
Sporicidal – 13%, 60 min
Virucidal – 13%, 30 min
All claimed microbes - 13%, 60 min

Each product label should give information on how the dilution should be made, e.g. to reach 13% (w/w) hydrogen peroxide concentration:

A product with 50% hydrogen peroxide concentration: The product should be diluted to 28% w/v (280 g or 230 mL of product, add water up to 1L).

A product with 35% hydrogen peroxide concentration: The product should be diluted to 39% w/v (390 g or 340 mL of product, add water up to 1L).

Apply at room temperature.

Precleaning of surfaces required before using disinfectants.

Dosing
- Automated spraying 50 – 100 mL/m^2

Surface need to be wet with disinfectant for the allocated contact time.

Rinse well with potable water and allow to drain or dry with hot air.

2.1.4.7.3 Use-specific risk mitigation measures

CIP:
The processes must be fully automated and enclosed with no exposure in the case of tanks or piping systems.

Automated spraying:
In the case of automated spraying of surfaces such as conveyors or other fixed installations workers must leave the room before processing.
Disinfection can only be processed after the end of a shift with all workers having left the room. The process must be started from outside the room. Warning notices indicating that entry is denied and temporary barriers must be placed on all entries.
Air concentrations must be monitored to ensure that no leakage occurs during operations. For re-entry, the undercut of AECinhalation of 1.25 mg/m^3 shall be ensured with technical and organisational measures (e.g. sensor, defined ventilation period).

Immersion:
The use of eye protection during handling of the product is mandatory.
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 (at least type 6, EN 13034) shall be worn in loading.
For stationary processes, a local exhaust ventilation (LEV) with a capture efficiency of at least 85% shall be specified.

If no LEV, use respiratory protective equipment (RPE) providing a protection factor of 20 in loading and 5 for immersion. After use, immersion baths must be emptied or covered to prevent further evaporation. The waste water from breweries should not be discharged direct to surface water after simple on-site treatment. The waste water from breweries should be discharged to the sewer connected to the sewage treatment plant (STP).

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.1.4.8 Use 8. Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP)

2.1.4.8.1 Use description

Meta SPC 4

Table 8. Use # 8 – Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP)

Product Type	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	bacterial spores
Field of use	Indoor Industrial use - food & feed area Disinfection of food package material
Application method(s)	Automated vaporization in aseptic filling machines
Application rate(s) and frequency	Undiluted product (25 % w/w hydrogen peroxide) vaporized 400 g/h/packaging machine. Number and timing of applications as required by user. Machines typically operate up to 120 hours per week.
Category(ies) of users	Professional

Pack sizes and packaging material	HDPE packaging. 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 210, 220 and 1000 L (IBC). Approved grades of HDPE.

2.1.4.8.2 Use-specific instructions for use[9]

Use an automated loading system.

Use undiluted product (25 % w/w hydrogen peroxide) to disinfect polyethylene terephthalate food packages used in aseptic packaging in food industry.

Follow machine operating instructions for disinfection period, extraction of hydrogen peroxide and re-entry. Prevent entry during disinfection process.

Efficacy was demonstrated with a packaging machine running at 12480 bottles per hour with a production consumption rate of 400 g/h.

Disinfection performance of each packaging machine should be validated using biological and chemical indicators.

After sterilisation, blow-dry the packaging with hot sterile air.

2.1.4.8.3 Use-specific risk mitigation measures

During operation, ensure adequate ventilation along the machines (LEV) and in the industrial halls (technical ventilation).
During manual maintenance tasks, ensure adequate ventilation inside the machine (LEV) before opening the doors of the aseptic area.

1. The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed.
2. Workplace release measurements with suitable measurement equipment shall be performed upon implementation of the aseptic packaging plant, at regular intervals (annual intervals recommended) and after any change in relevant boundary conditions. The national regulations for workplace measurements have to be followed.
3. In case of maintenance of the aseptic packaging plant (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment, chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required. The type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the product information. Glove material to be specified by the authorisation holder within the product information.

Use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Hydrogen peroxide emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.

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

See general directions for use.

[9] 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.

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

See general directions for use.

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

See general directions for use.

2.1.4.9 Use 9. Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP)

2.1.4.9.1 Use description

Meta SPC 2 + 3

Table 9. Use # 9 – Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP)

Product Type	2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	bacteria - bacterial spores – fungi – yeasts - viruses
Field of use	Indoor Industrial – aseptic chambers in aseptic filling applied in pharmaceutical or cosmetics industry Disinfection of non-porous surfaces
Application method(s)	Automated, non-directed aerosolization (e.g. fogging or spraying, flash evaporation)
Application rate(s) and frequency	35% or 49% hydrogen peroxide (undiluted product) applied via flash evaporation or aerosolization in filling isolators. Frequency – as required by user, for example 1 or 2 times per day/week.
Category(ies) of users	Professional
Pack sizes and packaging material	Pack sizes (L): 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L. Packaging material: Approved grades of HDPE.

2.1.4.9.2 Use-specific instructions for use[10]

Use an automated loading system.

[10] 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;

35% or 49% (w/w) hydrogen peroxide (undiluted product) is applied via flash evaporation or aerosolization by automated device connected to an filling isolator. Filling isolators may be dehumidified to achieve higher hydrogen peroxide concentrations on surfaces.

The disinfected surfaces should be non-porous and cleaned before application of the product. The product is not intended to be used on surfaces that may come into contact with food or feeding stuffs.

The user should carry out a microbiological validation of the disinfection in the enclosures to be disinfected with the devices to be used, after which a protocol for disinfection of these enclosures can be made and used thereafter. Each device or specific installation is systematically validated when it is set up. The optimal operating conditions are validated on site (temperature, hygrometry, product to be used, diffusion time, extraction time, etc.). Besides biological validation chemical validation should be performed.

Efficacy of use against bacterial spores was demonstrated by flash evaporation of hydrogen peroxide at a rate of 0.35 g/m3/min for 51 min (18 g hydrogen peroxide / m3 / treatment).

Volume of disinfected enclosure should be 15 - 150 m^3.

Median particle size should be <0.5 µm in aerosols used for disinfection.

Prevent entry during disinfection process.

2.1.4.9.3 Use-specific risk mitigation measures

Surfaces in the treatment area must be clean and dry prior to application.
Seal the treatment enclosure (e.g. with tape) to ensure that hydrogen peroxide levels outside the enclosure are kept at acceptable health and safety levels.
Ensure all personnel have vacated the treatment enclosure prior to application. Remove all plants, animals, beverages and food. Re-entry is only permitted once the air concentration has dropped below the reference value (1.25 mg/m^3).
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. In case the room has to be entered when the hydrogen peroxide concentration is still above 1.25 mg/m^3 it is only allowed by wearing appropriate PPE including SCBA (Self Contained Breathing Apparatus).

Place warning signs on all entrances to the treatment enclosure.

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

See general directions for use.

particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

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

See general directions for use.

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

See general directions for use.

2.1.5 General directions for use

2.1.5.1 Instructions for use

2.1.5.2 Risk mitigation measures

The use of eye protection during handling of the product is mandatory. Wear face shield where splashing is possible. Meta SPC 6, 7, 8, 9: Ensure adequate ventilation during the application.

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

Particulars of likely direct or indirect adverse effects: • In case of inhalation: Breathing difficulties, cough, pulmonary oedema, nausea, vomiting. • In case of skin contact: Redness, swelling of tissue, skin irritation. • In case of eye contact: Redness, lachrymation, swelling of tissue, severe burns. • In case of ingestion: Nausea, abdominal pain, bloody vomiting, diarrhoea, suffocation, cough, severe shortness of breath, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach. Risk of respiratory disorder. **First aid instructions:** Meta SPC 2, 3, 5, 6, 7, 8, 9: IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. Meta SPC 1, 4: IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor. IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance. IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance. **Emergency measures to protect environment in case of accident:**

• Environmental precautions:
Should not be released into the environment. If the product contaminates rivers and lakes or drains inform respective authorities.

• Methods and materials for containment and cleaning up:
Dilute with plenty of water. Dam up. Do not mix waste streams during collection. Soak up with inert absorbent material. Keep in properly labelled containers. Keep in suitable, closed containers for disposal. Never return spills in original containers for re-use.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Do not allow undiluted product to enter the sewer. Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. Only pass on empty containers/packaging for recycling. Disposal of packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

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

Storage: Hydrogen peroxide should be stored in properly designed bulk storage tanks or in original vented container in upright position away from incompatible products. Use only approved materials of construction for equipment or approved packs. Store in a cool, ventilated area and protect from damage and direct sunlight. Do not store at temperatures above 40°C. Keep away from combustible materials and sources of ignition and heat.

Shelf-life: 12 months in HDPE packs at ambient temperature.

2.1.6 Other information

Please be aware of the European reference value of 1.25 mg/m³ for the active substance hydrogen peroxide (CAS No.: 7722-84-1) which was used for the risk assessment for this product.

2.1.7 Packaging of the biocidal product

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Bottle	0.25L Fill weight 0.25 – 0.27 kg	HDPE	Vented/degassing cap.	Professional	Yes*
Bottle	1L Fill weight 1.0 – 1.1 kg	HDPE	Vented/degassing cap.	Professional	Yes*
Bottle	2.5L	HDPE	Vented/degassing cap.	Professional	Yes*

	Fill weight 2.5 – 2.7 kg				
Bottle	5L Fill weight 5.0 – 5.2kg	HDPE	Vented/degassing cap.	Professional	Yes*
Jerrycan	10L Fill weight 10 – 12 kg	HDPE	Vented/degassing cap.	Professional	Yes*
Jerrycan	20L Fill weight 20 – 22 kg	HDPE	Vented/degassing cap.	Professional	Yes*
Jerrycan	22L Fill weight 22 – 25 kg	HDPE	Vented/degassing cap.	Professional	Yes*
Jerrycan	30L Fill weight 30 – 35 kg	HDPE	Vented/degassing cap.	Professional	Yes*
Jerrycan	60L Fill weight 60 – 70 kg	HDPE	Vented/degassing cap.	Professional	Yes*
Drum	200L Fill weight 200 – 220 kg	HDPE	Vented/degassing cap.	Professional	Yes*
Drum	220L Fill weight 220 – 240kg	HDPE	Vented/degassing cap.	Professional	Yes*
IBC	1000L Fill weight 1000 – 1150kg	HDPE	Vented/degassing cap.	Professional	Yes*

* Please see the results of ambient storage tests as these contained an assessment on the packaging after contact with the test material.
Before their use all packages have to pass the UN test to check for Material compatibility: the chemical compatibility by assimilation of filling substances in compliance with 4.1.1.19 of RID/ADR.
Any packaging which has been shown to be compatible with the standard liquid nitric acid can be used for transporting hydrogen peroxide up to 60% w/w.
All packaging used for hydrogen peroxide must comply with minimum construction requirements defined by the UN (including compatibility above).

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new (eco)tox data on the active substance contained in the products have been submitted. New data submitted for INTEROX Biocidal Product Family 1 are listed in the Annex 3.1.

2.1.8.2 Access to documentation

The applicant is the data holder of the product data. The applicant is a member of the Hydrogen Peroxide Subgroup of The Cefic Peroxygens Sector Group. A statement of The Cefic Peroxygens

Sector Group confirms that the applicant is entitling to use and refer to the complete evaluation dossier of Hydrogen Peroxide for any purposes under Regulation (EU) 528/2012 on biocidal products (BPR). The statement can be found in IUCLID section 13.

2.1.8.3 Similar conditions of use

Please see Annex 3.7

2.2 Assessment of the biocidal product (family)

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

Table 8.Intended use # 1 – name of the use[11]

Product Type(s)	
Where relevant, an exact description of the authorised use	Refer to section 2.1.4 Authorised uses(s)
Target organism (including development stage)	
Field of use	
Application method(s)	
Application rate(s) and frequency	
Category(ies) of user(s)	
Pack sizes and packaging material	

2.2.2 Physical, chemical and technical properties

eCA FI note on pH measurements (Meta SPC´s 1-9): the pH meter has been calibrated with certified buffers of pH 4, 7 and 10. Therefore, the measured pH values of the neat products are out of the calibration range of the pH meter and should be considered as approximate.

Please, refer to the confidential annex to PAR for discussion on read across coverage within the BPF.

Meta-SPC 1 - INTEROX® SG-12

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	12.99 % (w/w) INTEROX SG 12	Clear liquid.	Envigo Study Number: TM17VP
Colour at 20 °C and 101.3 kPa	Visual inspection	12.99 % (w/w) INTEROX SG 12	Colourless	Envigo Study Number: TM17VP
Odour at 20 °C and 101.3 kPa	-	-	The odour of the test item has not been assessed due to the acute toxicity classification H332: harmful if inhaled.	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Acidity / alkalinity	CIPAC 191 CIPAC MT 75.3	12.99 % (w/w) INTEROX SG 12	pH: 2.95 (GLP) Acidity 4.7 x 10^{-3} % w/w as equivalent sulphuric acid	Envigo Study Number: TM17VP Covance Study Number: KV38HN
Density	A.3 OECD 109	12.99 % (w/w) INTEROX SG 12	1.045 x 10^3 kg/m^3 at 20.5 ± 0.5 °C	Envigo Study Number: TM17VP
Storage stability test – **accelerated storage**	CIPAC MT 46.3	12-13.5 % (w/w) INTEROX SG 12	Test conditions: 40 ± 2 °C, 8 weeks in vented HDPE bottle (1L) **Appearance** T0: transparent colourless liquid. No damage or deviation in packaging. T8w: no change **Active substance, % (w/w)** T0: 13.1 T8w: 13.0 **Weight loss:** T8w: -0.58 %	Solvay study number: FHs/7120/2016/018
Storage stability test – **long term storage stability at ambient temperature**	Ambient temperature (25 ± 2 °C). Natural light/night variation.Vented black, opaque HDPE bottle (1L).	12.99 % (w/w) INTEROX SG 12 pH (QC-data): INTEROX AG Spray 25S	**Appearance** T0: colourless, homogenous, transparent liquid with no sedimentation or precipitation T12m: no change in appearance **Packaging** T0: No signs of corrosion, degradation or seepage T12m: no change **Weight loss** T12m: -0.200 % **Active ingredient content (% w/w)** T0: 13.0 T6m: 13.0 T9m: 12.9 T12m: 12.8 T15m: 12.8 (-1.5%) **pH (1 % aqueous dispersion)** T0: 5.52	Envigo study number: RQ58YQ Candy, T. (2019)

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			T6m: 6.06 T9m: 5.58 T12m: 4.56 pH of the (neat) product after storage: not determined. The decrease in the concentration of the active substance is minimal (-1.5%) during storage. The pH of 1% dispersion is presented. QC data of the applicant shows that pH of the neat aged product (12 months) has increased by 0.1 pH units (of a 25% w/w a.s. product) and acidity (0.3 mmol/l) has remained unchanged. Persistent foaming and dilution stability: waived. Please refer to the respective data endpoints.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	12.99 % (w/w) INTEROX SG 12	T0: clear colorless homogenous liquid , no signs of precipitate, sedimentation or separated phases. T7d: no change The test item has been determined to be physically stable to storage at 0 ± 2°C for 7 days	Envigo Study Number: TM17VP
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			The effect of light on stability of the product cannot be addressed by the long term storage stability study (RQ58YQ) as black, opaque HDPE packaging material has been used. Instead, read across from other studies is acceptable. Eg., the product tested for long term storage	

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			stability for MetaSPC 2 contains higher amount of active substance but lower amount of stabilizers and can thus be considered as worst case for MetaSPC 1. At T12m, 4.0% decrease in active substance content, at T18m, 7.1% decrease in active substance content, studied in translucent HDPE container (Study YQ78KR). No change in the appearance of the test item formulation or its commercial container after 18 months.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Temperature: 25 ± 2 °C. Relative humidity: maximum 72 %, minimum 11 %, average 30 %. And temperature 40 ± 2 °C	12.99 % (w/w) INTEROX SG 12 12-13.5 % (w/w) INTEROX SG 12	1.5% decrease in hydrogen peroxide content at 25 °C, 30% RH after 12 months and 0.8% decrease at 40 °C after 8 weeks. There was no change in the appearance of the test item formulation or its commercial container at 25 °C, 30% RH after 18 months nor at 40 °C after 8 weeks. The product is an aqueous solution and therefore effect of humidity on the stability of the product is considered negligible.	Envigo study number: RQ58YQ Solvay study number: FHs/7120/2016/018
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	The test item was stored at 40 ± 2 °C for 8 weeks in HDPE bottle (1L)	12-13.5 % (w/w) INTEROX SG 12	**Appearance** T0: transparent colourless liquid. No damage or deviation in packaging. T8w: no change	Solvay study number: FHs/7120-2016/018

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			Active substance, % (w/w) T0: 13.1 T8w: 13.0 **Weight loss:** T8w: -0.58 %	
Wettability	-	-	Not applicable. The products are aqueous solutions.	-
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable. The products are aqueous solutions.	-
Wet sieve analysis and dry sieve test	-	-	Not applicable. The products are aqueous solutions.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable. The products are aqueous solutions.	-
Disintegration time	-	-	Not applicable. The products are aqueous solutions.	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Determination of MMAD: waived. The product is not sold together with a spraying device and MMAD is not required as an imput parameter for human exposure assessment. The provided efficacy tests did not require determination of MMAD. In addition, when the product is used according to the instructions of use there is no exposure to the user.	-
Persistent foaming	-	-	Data waiving. The product(s) are used undiluted and therefore test for persistent foaming is not required.	-
Flowability/Pourability/ Dustability	-	-	Not applicable. The products are aqueous solutions.	-
Burning rate — smoke generators	-	-	Not applicable. The products are not smoke generators.	-
Burning completeness — smoke generators	-	-	Not applicable. The products are not smoke generators.	-
Composition of smoke — smoke generators	-	-	Not applicable. The products are not smoke generators.	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Spraying pattern — aerosols	-	-	Not applicable. The products are not sold as aerosols.	-
Physical compatibility	-	-	Not applicable. The products are not intended or marketed to be used in conjunction with other substances, mixtures or non-biocidal products.	-
Chemical compatibility	-	-	Not applicable. The products are not intended or marketed to be used in conjunction with other substances, mixtures or non-biocidal products.	-
Degree of dissolution and dilution stability	-	-	Data waiving. The product(s) are used undiluted and therefore test for dilution stability is not required.	-
Surface tension	A.5 OECD 115	12.99 % (w/w) INTEROX SG 12	72.5 mN/m at 20.0 ± 0.5 °C	Envigo Study Number: TM17VP
Viscosity	OECD 114	13.1 % (w/w) INTEROX SG 12	0.999 mm^2/s at 20.0 ± 0.5°C 0.673 mm^2/s at 40.0 ± 0.5°C	Envigo Study Number: QC98GP

Conclusion on the physical, chemical and technical properties of the product
The physical, chemical and technical properties have been reported sufficiently and the results are acceptable for the use of the product. The product is a clear, colourless liquid with acidic pH showing no surface active properties. The stability of the product in the commercial packaging (HDPE) has been demonstrated at 40°C and at ambient temperature with natural light/night variation. The product is physically stable at 0°C, too. A shelf life of 12 months can be granted for the product.

Meta-SPC 2 - INTEROX® SG-35, INTEROX® SG-35 Plus,

Majority of endpoints are covered by studies with INTEROX® SG-35 and INTEROX® SG-35-Plus.Read across from INTEROX® FCC-35 has been used to cover endpoints for acidity, density, surface tension and viscosity..

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	35.52 % (w/w) INTEROX SG 35	Clear liquid.	Envigo Study Number: MR77MM
Colour at 20 °C and 101.3 kPa	Visual inspection	35.52 % (w/w) INTEROX SG 35	Colourless	Envigo Study Number: MR77MM
Odour at 20 °C and 101.3 kPa	-	-	The odour of the test item has not been assessed due to the acute toxicity classification H332: harmful if inhaled.	-
Acidity / alkalinity	CIPAC 191 CIPAC MT 75.3	35.64 % (w/w) INTEROX FCC 35 35.4% (w/w) INTEROX FCC 35 35% (w/w) INTEROX FCC 35	pH: 2.53 (GLP) pH: 2.6 (QC) Acidity: 5.3 x 10^{-3} % w/w as equivalent sulphuric acid	Envigo Study Number: WX14JJ Covance Study Number: KV38HN Candy, T. (2019)
Density	A.3 OECD 109	35.64 % (w/w) INTEROX FCC 35	1.13 x 10^3 kg/m^3 at 20.0 ± 0.5 °C	Envigo Study Number: WX14JJ
Storage stability test – **accelerated storage**	CIPAC MT 46.3	35-35.7 % (w/w) INTEROX SG 35 Plus 35-35.7 % (w/w) INTEROX SG 35	INTEROX SG-35 Test conditions: 40 ± 2 °C, 8 weeks in vented HDPE bottles (2.5L) **Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 35.4 T8w: 35.2 **Weight loss** T8w: -0.07% INTEROX SG-35 Plus Test conditions: 40 ± 2 °C, 8 weeks in vented HDPE bottles (1L) **Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change	Solvay study number: FHs/7120/2016/019 and FHs/7120/2016/021

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			Active substance, % (w/w) T0: 35.4 T8w: 35.2 **Weight loss** T8w: -0.05%	
Storage stability test – **long term storage stability at ambient temperature**	Ambient temperature (25 ± 2 °C). Natural light/night variation Vented, black HDPE bottle (2.5L) and vented, translucent HDPE bottle (1L) with an HDPE coupon.	35.38 % (w/w) INTEROX SG 35 35% (w/w) INTEROX FCC 35	**Appearance** *Both container types:* T0: colourless, homogenous, transparent liquid with no sedimentation or precipitation T18: no change in appearance **Packagings (both types)** T0: no signs of corrosion or degradation T18m: no signs of corrosion, degradation or seepage. **Active ingredient content (% w/w)** *2.5 L black HDPE container* T0: 35.5 T6m: 35.1 T9m: 35.1 T12m: 35.3 T18m: 35.6 (+0.3%) *1 L translucent HDPE container with HDPE coupon* T0: 35.2 T6m: 34.5 T9m: 34.1 T12m: 33.8 T18m: 32.7 (-7.1%) **pH (1 % aqueous dispersion)** *2.5 L black HDPE container* T0: 4.96 T6m: 5.11 T9m: 5.64 T12m: 5.87 T18m: 5.53 *1 L translucent HDPE container with HDPE coupon* T0: 5.70 T6m: 5.73	Envigo study number: YQ78KR Candy, T. (2019)

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			T9m: 5.85 T12m: 5.89 T18m: 5.74 **Weight loss** 2.5 L black HDPE container T12m: -0.13 % 1 L translucent HDPE container (with HDPE coupon) T12m: -0.76 % pH of the (neat) product after storage: not determined. The decrease of the concentration of the active substance is acceptable (+0.3 - -7.1%) during storage. The pH of 1% dispersion is presented. QC data of the applicant shows that pH of the neat aged product (12 months) has decreased by 0.1 pH units and acidity (0.4 mmol/l) has remained unchanged. Persistent foaming and dilution stability: waived. Please refer to the respective data endpoints.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	35.52 % (w/w) INTEROX SG 35	T0: clear colourless homogenous liquid, no signs of precipitate, sedimentation or separated phases. T7d: no change The test item has been determined to be physically stable to storage at 0 ± 2°C for 7 days.	Envigo Study Number: MR77MM
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Ambient temperature (25 ± 2 °C). Natural light/night variation. Vented, translucent HDPE bottle (1L)	35.38 % (w/w) INTEROX SG 35	7.1 % decrease in hydrogen peroxide content after 18 months. There was no change in the appearance of the test item formulation or its commercial container after 18 months.	Envigo study number: YQ78KR

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Temperature 25 ± 2 °C. Relative humidity: max 72 %, min 10 %, average 34 %. And Temperature 40 ± 2 °C	35.38 % (w/w) INTEROX SG 35 35-35.7 % (w/w) INTEROX SG 35 Plus 35-35.7 % (w/w) INTEROX SG 35	7.1 % decrease in hydrogen peroxide content after 18 months at 25 °C, 34% RH and 0.6% decrease after 8 weeks at 40 °C. There was no change in the appearance of the test item formulation or its commercial container after 18 months at 25 °C, 34% RH nor after 8 weeks at 40 °C. The products are aqueous solutions and therefore effect of humidity on the stability of the products is considered negligible.	Envigo study number: YQ78KR Solvay study number: FHs/7120/2016/019 and FHs/7120/2016/021
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	The test item was stored at 40 ± 2 °C for 8 weeks in vented HDPE bottles (2.5L or 1L)	35-35.7 % (w/w) INTEROX SG 35 Plus 35-35.7 % (w/w) INTEROX SG 35	INTEROX SG-35 HDPE bottles (2.5L) **Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 35.4 T8w: 35.2 **Weight loss** T8w: -0.07% INTEROX SG-35 Plus HDPE bottles (1L) **Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 35.4 T8w: 35.2 **Weight loss** T8w: -0.05%	Solvay study number: FHs/7120/2016/019 and FHs/7120/2016/021
Wettability	-	-	Not applicable. The products are aqueous solutions.	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable. The products are aqueous solutions.	-
Wet sieve analysis and dry sieve test	-	-	Not applicable. The products are aqueous solutions.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable. The products are aqueous solutions.	-
Disintegration time	-	-	Not applicable. The products are aqueous solutions.	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Determination of MMAD: waived. The products are not sold together with a spraying device and MMAD is not required as an imput parameter for human exposure assessment. The provided efficacy tests did not require determination of MMAD. In addition, when the product is used according to the instructions of use there is no exposure to the user.	-
Persistent foaming	-	-	Data waiving. The product(s) are used undiluted and therefore test for persistent foaming is not required.	-
Flowability/Pourability/ Dustability	-	-	Not applicable. The products are aqueous solutions.	-
Burning rate — smoke generators	-	-	Not applicable. The products are not smoke generators .	-
Burning completeness — smoke generators	-	-	Not applicable. The products are not smoke generators.	-
Composition of smoke — smoke generators	-	-	Not applicable. The products are not smoke generators.	-
Spraying pattern — aerosols	-	-	Not applicable. The products are not sold as aerosols.	-
Physical compatibility	-	-	Not applicable. The products are not intended or marketed to be used in conjunction with other substances, mixtures or non-biocidal products.	-
Chemical compatibility	-	-	Not applicable. The products are not intended or marketed	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			to be used in conjunction with other substances, mixtures or non-biocidal products.	
Degree of dissolution and dilution stability	-	-	Data waiving. The product(s) are used undiluted and therefore test for dilution stability is not required.	-
Surface tension	A.5 OECD 115	35.64 % (w/w) INTEROX FCC 35	72.5 mN/m at 20.0 ± 0.5 °C	Envigo Study Number: WX14JJ
Viscosity	OECD 114	35.64% (w/w) INTEROX FCC 35	1.02 mm^2/s at 20.0 ± 0.5°C 0.708 mm^2/s at 40.0 ± 0.5°C	Envigo Study Number: WX14JJ

Conclusion on the physical, chemical and technical properties of the product
The physical, chemical and technical properties have been reported sufficiently and the results are acceptable for the use of the product. The products are clear, colourless liquids with acidic pH showing no surface active properties. The stability of the products in the commercial packaging (HDPE) has been demonstrated at 40°C and at ambient temperature with natural light/night variation. The products are physically stable at 0°C, too. A shelf life of 12 months can be granted for the products.

Meta-SPC 3 - INTEROX® SG-50, INTEROX® SG-50 Plus

Majority of endpoints are covered by studies with INTEROX® SG-50 and INTEROX® SG-50-Plus. Read across from INTEROX® BT-50 has been used to cover endpoints for physical state, colour, acidity, density, surface tension and viscosity..

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	49.57 % (w/w) INTEROX BT 50	Clear liquid.	Envigo Study Number: FJ79RX
Colour at 20 °C and 101.3 kPa	Visual inspection	49.57 % (w/w) INTEROX BT 50	Colourless	Envigo Study Number: FJ79RX
Odour at 20 °C and 101.3 kPa	-	-	The odour of the test item has not been assessed due to the acute toxicity classification H332: harmful if inhaled.	-
Acidity / alkalinity	CIPAC 191 CIPAC MT 75.3	49.57 % (w/w) INTEROX BT 50 49.4% (w/w) INTEROX BT 50 50% (W/W)	pH: 1.41 (GLP) pH: 1.3 (QC) Acidity 1.4 x 10^{-2} % w/w as equivalent sulphuric acid	Envigo Study Number: FJ79RX Covance Study Number: KV38HN Candy, T. (2019)

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		INTEROX BT 50		
Density	A.3 OECD 109	49.57 % (w/w) INTEROX BT 50	1.19 x 10^3 kg/m^3 at 20.0 ± 0.5 °C	Envigo Study Number: FJ79RX
Storage stability test – **accelerated storage**	CIPAC MT 46.3	49-49.9 % (w/w) INTEROX SG 50 Plus 49-49.9% (w/w) INTEROX SG 50	INTEROX SG-50 Test conditions: 40 ± 2 °C, 8 weeks in vented HDPE bottles (2.5L) **Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 49.2 T8w: 49.1 **Weight loss** T8w: -0.09% INTEROX SG-50 Plus Test conditions: 40 ± 2 °C, 8 weeks in vented HDPE bottles (1L) **Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 49.3 T8w: 49.3 **Weight loss** T8w: -0.10%	Solvay study number: FHs/7120/2016/020 and FHs/7120/2016/022
Storage stability test – **long term storage stability at ambient temperature**	Ambient temperature (25 ± 2 °C). Natural ligt/night variation. Vented, black HDPE bottle (1L) and vented, translucent	49.3 % (w/w) INTEROX SG 50 Plus 49-49.9 % (w/w) INTEROX BT 50	**Appearance** *Both container types* T0: colourless, homogenous, transparent liquid with no sedimentation or precipitation T18m: no change in appearance	Envigo study number: KQ44WC Candy, T. (2019)

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
	HDPE bottle (1L) with an HDPE coupon.		**Packaging (both types)** T0: No signs of corrosion or degradation T18m: No signs of corrosion, degradation or seepage. **Active ingredient content (% w/w)** *1 L black HDPE container* T0: 49.4 T6m: 49.2 T9m: 48.7 T12m: 48.9 (+1.0%) *1 L translucent HDPE container with HDPE coupon* T0: 49.4 T6m: 48.9 T9m: 48.9 T12m: 48.9 T18m: 48.4 (-2.0%) **pH (1 % aqueous dispersion)** *1 L black HDPE container* T0: 5.88 T6m: 5.12 T9m: 6.22 T12m: 5.76 T18m:7.16 *1 L translucent HDPE container with HDPE coupon* T0: 5.88 T6m: 5.11 T9m: 6.11 T12m: 5.89 T18m:6.84 **Weight loss** *1 L black HDPE container* T12m: -0.29 % *1 L translucent HDPE container* T12m: -0.28 % pH of the (neat) product after storage: not determined. The decrease of the concentration of the active substance is	

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			minimal (+1.0 - -2.0%) during storage. The pH of 1% dispersion is presented. QC data of the applicant shows that there is no change of pH of the neat aged product (12 months) and acidity has decreased by 0.4 mmol/l (from 2.2 to 1.8 mmol/l). Persistent foaming and dilution stability: waived. Please refer to the respective data endpoints. In addition, to cover all the products within Meta SPC 3, read across to long term storage stability study (YQ78KR) in MetaSPC 2 with same stabilizer composition is made. It is considered that MetaSPC 3 product with higher active substance content will be as stable as the product in MetaSPC 2 with lower active substance content as generally chemicals are more stable in more concentrated dilutions.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	49.3 % (w/w) INTEROX SG 50 Plus	T0: clear colourless homogenous liquid, no signs of precipitate, sedimentation or separated phases. T7d: no change The test item has been determined to be physically stable to storage at 0 ± 2°C for 7 days	Envigo Study Number: YG55GD
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Ambient temperature (25 ± 2 °C). Natural light/night variation. Vented, translucent HDPE bottle (1L)	49.3 % (w/w) INTEROX SG 50 Plus	2.0% decrease in hydrogen peroxide content after 18 months. There was no change in the appearance of the test item formulation or its commercial container after 18 months.	Envigo study number: KQ44WC

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Temperature 25 ± 2 °C. Relative humidity: max 72 %, min 10 %, average 34 %. And temperature 40 ± 2 °C	49.3 % (w/w) INTEROX SG 50 Plus 49-49.9 % (w/w) INTEROX SG 50 Plus 49-49.9% (w/w) INTEROX SG 50	2.0% decrease in hydrogen peroxide content after 18 months at 25 °C, 34% RH and 0.2% decrease after 8 weeks at 40 °C. There was no change in the appearance of the test item formulation or its commercial container at 25 ± 2 °C, 34% RH after 18 months nor at 40 °C after 8 weeks. The products are aqueous solutions and therefore effect of humidity on the stability of the products is considered negligible.	Envigo study number: KQ44WC Solvay study number: FHs/7120/2016/020 and FHs/7120/2016/022
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	The test item was stored at 40 ± 2 °C for 8 weeks in vented HDPE bottles (2.5L or 1L)	49-49.9 % (w/w) INTEROX SG 50 Plus 49-49.9% (w/w) INTEROX SG 50	INTEROX SG-50 Vented HDPE bottles (2.5L) **Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 49.2 T8w: 49.1 **Weight loss** T8w: -0.09% INTEROX SG-50 Plus Vented HDPE bottles (1L) **Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 49.3 T8w: 49.3 **Weight loss** T8w: -0.10%	Solvay study number: FHs/7120/2016/020 and FHs/7120/2016/022

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Wettability	-	-	Not applicable. The products are aqueous solutions.	-
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable. The products are aqueous solutions.	-
Wet sieve analysis and dry sieve test	-	-	Not applicable. The products are aqueous solutions.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable. The products are aqueous solutions.	-
Disintegration time	-	-	Not applicable. The products are aqueous solutions.	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Determination of MMAD: waived. The products are not sold together with a spraying device and MMAD is not required as an imput parameter for human exposure assessment. The provided efficacy tests did not require determination of MMAD. In addition, when the product is used according to the instructions of use there is no exposure to the user.	-
Persistent foaming	-	-	Data waiving. The product(s) are used undiluted and therefore test for persistent foaming is not required.	-
Flowability/Pourability/ Dustability	-	-	Not applicable. The products are aqueous solutions.	-
Burning rate — smoke generators	-	-	Not applicable. The products are not smoke generators.	-
Burning completeness — smoke generators	-	-	Not applicable. The products are not smoke generators.	-
Composition of smoke — smoke generators	-	-	Not applicable. The products are not smoke generators.	-
Spraying pattern — aerosols	-	-	Not applicable. The products are not sold as aerosols.	-
Physical compatibility	-	-	Not applicable. The products are not intended or marketed to be used in conjunction with other substances, mixtures or non-biocidal products.	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Chemical compatibility	-	-	Not applicable. The products are not intended or marketed to be used in conjunction with other substances, mixtures or non-biocidal products.	-
Degree of dissolution and dilution stability	-	-	Data waiving. The product(s) are used undiluted and therefore test for dilution stability is not required.	-
Surface tension	A.5 OECD 115	49.57 % (w/w) INTEROX BT 50	72.5 mN/m at 20.0 ± 0.5 °C	Envigo Study Number: FJ79RX
Viscosity	OECD 114	49.57 % (w/w) INTEROX BT 50	1.18 mm^2/s at 20.0 ± 0.5°C 0.844 mm^2/s at 40.0 ± 0.5°C	Envigo Study Number: FJ79RX

Conclusion on the physical, chemical and technical properties of the product
The physical, chemical and technical properties have been reported sufficiently and the results are acceptable for the use of the product. The products are clear, colourless liquids with acidic pH showing no surface active properties. The stability of the products in the commercial packaging (HDPE) has been demonstrated at 40°C and at ambient temperature with natural light/night variation. The products are physically stable at 0°C, too. A shelf life of 12 months can be granted for the products.

Meta-SPC 4 - INTEROX® AG-Spray-25S

The majority of endpoints are covered by studies with INTEROX® AG-Spray-25S . Only long term storage stability at ambient temperature has been covered by read across from INTEROX® AG-Spray-35S.

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	25.71 % (w/w) INTEROX AG Spray 25S	Clear liquid.	Envigo Study Number: WC17SG
Colour at 20 °C and 101.3 kPa	Visual inspection	25.71 % (w/w) INTEROX AG Spray 25S	Colourless	Envigo Study Number: WC17SG
Odour at 20 °C and 101.3 kPa	-	-	The odour of the test item has not been assessed due to the acute toxicity classification H332: harmful if inhaled.	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Acidity / alkalinity	CIPAC 191 CIPAC MT 75.3	25.71 % (w/w) INTEROX AG Spray 25S 25.7% (w/w) INTEROX AG Spray 25S 25% (w/w) INTEROX AG Spray 25S	pH: 2.80 (GLP) pH: 2.8 (QC) Acidity 5.0 x 10^{-3} % w/w as equivalent sulphuric acid	Envigo Study Number: WC17SG Covance Study Number: KV38HN Candy, T. (2019)
Density	A.3 OECD 109	25.71 % (w/w) INTEROX AG Spray 25S	1.09 x 10^3 kg/m^3 at 20.0 ± 0.5 °C	Envigo Study Number: WC17SG
Storage stability test – **accelerated storage**	CIPAC MT 46.3	25-25.7 % (w/w) INTEROX AG Spray 25S	INTEROX® AG-Spray-25S Test conditions: 40 ± 2 °C, 8 weeks in vented HDPE bottles (0.5L). **Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 25.5 T8w: 25.4 **Weight loss** T8w: -0.37%	Solvay study number: FHs/7120/2016/013
Storage stability test – **long term storage stability at ambient temperature**	Ambient temperature (25 ± 2 °C). Natural ligt/night variation. Vented, translucent HDPE bottle (1L) with an HDPE coupon.	35.67 % (w/w) INTEROX AG Spray 35S 25% (w/w) INTEROX AG Spray 25S	Read-across from INTEROX® AG-Spray-35S **Appearance** T0: colourless, homogenous, transparent liquid with no sedimentation or precipitation T12m: no change in appearance **Packaging** T0: No signs of corrosion or degradation T12m: No signs of corrosion, degradation or seepage. **Active ingredient content (% w/w)** T0: 35.5 T6m: 35.4	Envigo study number: JX07PK Candy, T. (2019)

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			T9m: 34.6 T12m: 33.4 T15m: 33.9 (-4.5%) **pH (1 % aqueous dispersion)** T0: 5.85 T6m: 6.04 T9m: 5.34 T12m: 6.70 **Weight loss** T12m: -0.733% pH of the (neat) product after storage: not determined. The decrease of the concentration of the active substance is minimal (-4.5%) during storage. The pH of 1% dispersion is presented. QC data of the applicant shows that pH of the neat aged product (12 months) has increased by 0.1 pH units and acidity (0.3 mmol/l) has remained unchanged. Persistent foaming and dilution stability: waived. Please refer to the respective data endpoints.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	25.71 % (w/w) INTEROX AG Spray 25S	T0: clear colourless homogenous liquid, no signs of precipitate, sedimentation or separated phases. T7d: no change The test item has been determined to be physically stable to storage at 0 ± 2°C for 7 days	Envigo Study Number: WC17SG
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Ambient temperature (25 ± 2 °C). Natural light/night variation, vented translucent HDPE bottle (1L)	35.67 % (w/w) INTEROX AG Spray 25S	Read-across from INTEROX® AG-Spray-35S. 4.5% decrease in hydrogen peroxide content after 15 months. There was no change in the appearance of the test item formulation or its commercial	Envigo study number: JX07PK

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			container after 15 months.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Temperature 25 ± 2 °C. Relative humidity: max 72 %, min 11 %, average 30 %. And temperature 40 ± 2 °C	35.67 % (w/w) INTEROX AG Spray 25S 25-25.7 % (w/w) INTEROX AG Spray 25S	Read-across from INTEROX® AG-Spray-35S. 4.5% decrease in hydrogen peroxide content after 15 months at 25 °C, 30% RH and 0.4% decrease after 8 weeks at 40 °C.. There was no change in the appearance of the test item formulation or its commercial container after 15 months at 25 °C, 30% RH nor after 8 weeks at 40 °C. The product is an aqueous solution and therefore effect of humidity on the stability of the product is considered negligible.	Envigo study number: JX07PK Solvay study number: FHs/7120/2016/013
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	The test item was stored at 40 ± 2 °C for 8 weeks in vented HDPE bottles (0.5L)	25-25.7 % (w/w) INTEROX AG Spray 25S	INTEROX® AG-Spray-25S **Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 25.5 T8w: 25.4 **Weight loss** T8w: -0.37%	Solvay study number: FHs/7120/2016/013
Wettability	-	-	Not applicable. The products are aqueous solutions.	-
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable. The products are aqueous solutions.	-
Wet sieve analysis and dry sieve test	-	-	Not applicable. The products are aqueous solutions.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable. The products are aqueous solutions.	-
Disintegration time	-	-	Not applicable. The products are aqueous solutions.	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Particle size distribution, content of dust/fines, attrition, friability	-	-	Determination of MMAD: waived. The product is not sold together with a spraying device and MMAD is not required as an imput parameter for human exposure assessment. The provided efficacy tests did not require determination of MMAD. In addition, when the product is used according to the instructions of use there is no exposure to the user.	-
Persistent foaming	-	-	Data waiving. The product(s) are used undiluted and therefore test for persistent foaming is not required.	-
Flowability/Pourability/ Dustability	-	-	Not applicable. The products are aqueous solutions.	-
Burning rate — smoke generators	-	-	Not applicable. The product is not a smoke generator.	-
Burning completeness — smoke generators	-	-	Not applicable. The product is not a smoke generator.	-
Composition of smoke — smoke generators	-	-	Not applicable. The product is not a smoke generator.	-
Spraying pattern — aerosols	-	-	Not applicable. The product is not sold as an aerosol.	-
Physical compatibility	-	-	Not applicable. The products are not intended or marketed to be used in conjunction with other substances, mixtures or non-biocidal products.	-
Chemical compatibility	-	-	Not applicable. The products are not intended or marketed to be used in conjunction with other substances, mixtures or non-biocidal products.	-
Degree of dissolution and dilution stability	-	-	Data waiving. The product(s) are used undiluted and therefore test for dilution stability is not required.	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Surface tension	A.5 OECD 115	25.71 % (w/w) INTEROX AG Spray 25S	72.3 mN/m at 20.0 ± 0.5 °C	Envigo Study Number: WC17SG
Viscosity	OECD 114	25.71 % (w/w) INTEROX AG Spray 25S	0.984 mm^2/s at 20.0 ± 0.5°C 0.684 mm^2/s at 40.0 ± 0.5°C	Envigo Study Number: WC17SG

Conclusion on the physical, chemical and technical properties of the product
The physical, chemical and technical properties have been reported sufficiently and the results are acceptable for the use of the product. The product is a clear, colourless liquid with acidic pH showing no surface active properties. The stability of the product in the commercial packaging (HDPE) has been demonstrated at 40°C and at ambient temperature with natural light/night variation. The product is physically stable at 0°C, too. A shelf life of 12 months can be granted for the product.

Meta-SPC 5 – INTEROX® AG-Spray-35, INTEROX® AG-Spray-35S, INTEROX® AG-Bath-35, INTEROX® AG-Bath-35S, INTEROX® AG-Dual-35

Read across from INTEROX® FCC-35 has been used for endpoints of physical state and colour, acidity, density, surface tension and viscosity. Studies related to the stability of the products are covered mainly with studies with INTEROX® AG Spray 35S, but accelerated storage stability studies and (QC) pH/acidity measurements have been performed with all the products within the MetaSPC.

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	35.64 % (w/w) INTEROX FCC 35	Clear liquid.	Envigo Study Number: CC17PP
Colour at 20 °C and 101.3 kPa	Visual inspection	35.64 % (w/w) INTEROX FCC 35	Colourless	Envigo Study Number: CC17PP
Odour at 20 °C and 101.3 kPa	-	-	The odour of the test item has not been assessed due to the acute toxicity classification H332: harmful if inhaled.	-
Acidity / alkalinity	CIPAC 191 CIPAC MT 75.3	35.64 % (w/w) INTEROX FCC 35 35.4% (w/w) INTEROX FCC 35 35% (w/w) INTEROX AG Spray 35S INTEROX AG Bath 35	pH: 2.53 (GLP) pH: 2.3-2.5, depending on the product (QC) Acidity: 5.3 x 10^{-3} % w/w as equivalent sulphuric acid	Envigo Study Number: WX14JJ Covance Study Number: KV38HN Candy, T. (2019)

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		INTEROX AG Bath 35S INTEROX AG Dual 35		
Density	A.3 OECD 109	25.71 % (w/w) INTEROX FCC 35	1.13 x 10^3 kg/m^3 at 20.0 ± 0.5 °C	Envigo Study Number: WX14JJ
Storage stability test – **accelerated storage**	CIPAC MT 46.3	35-35.7 % (w/w) INTEROX AG Dual 35 INTEROX AG Bath 35 INTEROX AG Bath 35S INTEROX AG Spray 35S INTEROX AG Spray 35	All products: Test conditions: 40 ± 2 °C, 8 weeks in vented HDPE bottles (0.5L) **Appearance (all products)** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change INTEROX AG-Dual-35 **Active substance, % (w/w)** T0: 35.5 T8w: 35.5 **Weight loss** T8w: -0.156% INTEROX AG-Bath-35 **Active substance, % (w/w)** T0: 35.6 T8w: 35.6 **Weight loss** T8w: -0.14% INTEROX AG-Bath-35S **Active substance, % (w/w)** T0: 35.7 T8w: 35.6 **Weight loss** T8w: -0.11% INTEROX AG-Spray-35S **Active substance, % (w/w)** T0: 35.5 T8w: 35.5 **Weight loss** T8w: -0.13% INTEROX AG-Spray-35	Solvay study numbers: FHs/7120-2016/005, FHs/7120-2016/009, FHs/7120-2016/010, FHs/7120-2016/011, FHs/7120/2016/012

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			Active substance, % (w/w) T0: 35.6 T8w: 35.5 **Weight loss** T8w: -0.12%	
Storage stability test – **long term storage stability at ambient temperature**	Ambient temperature (25 ± 2 °C). Natural ligt/night variation. Vented, translucent HDPE bottle (1L) with an HDPE coupon.	35.67 % (w/w) INTEROX AG Spray 35S 35% (w/w) INTEROX AG Spray 35S INTEROX AG Bath 35 INTEROX AG Bath 35S INTEROX AG Dual 35	Read-across from INTEROX® AG-Spray-35S. **Appearance** T0: colourless, homogenous, transparent liquid with no sedimentation or precipitation T12m: no change in appearance **Packaging** T0: No signs of corrosion or degradation. T12m: No signs of corrosion, degradation or seepage. **Active ingredient content (% w/w)** T0: 35.5 T6m: 35.4 T9m: 34.6 T12m: 33.4 T15m: 33.9 (-4.5%) **pH (1 % aqueous dispersion)** T0: 5.85 T6m: 6.04 T9m: 5.34 T12m: 6.70 pH of the (neat) product after storage: not determined. The decrease of the concentration of the active substance is minimal (-4.5%) during storage. The pH of 1% dispersion is presented. QC data of the applicant shows that pH of the neat aged products (12 months) within Meta SPC 5 have not changed and acidity has remained unchanged (Interox AG Bath 35S	Envigo study numbers: JX07PK Candy, T. (2019)

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			(0.6 mmol/l); Interox AG Dual 35 (0.4 mmol/l)) or increased by 0.1 mmol/l (Interox AG Spray 35S 0.4 to 0.5 mmol/l; Interox AG Bath 35 0.4 to 0.5 mmol/l). Persistent foaming and dilution stability: waived. Please refer to the respective data endpoints. In addition, to cover all the products within Meta SPC 5, read across to long term storage stability study (YQ78KR) in MetaSPC 2 with same stabilizer composition is made.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	35.67 % (w/w) INTEROX AG Spray 35S	Read-across from INTEROX® AG-Spray-35S T0: clear colourless homogenous liquid, no signs of precipitate, sedimentation or separated phases. T7d: no change The test item has been determined to be physically stable to storage at 0 ± 2°C for 7 days	Envigo Study Number: GN08TX
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Ambient temperature (25 ± 2 °C). Natural light/night variation. Vented, translucent HDPE bottle (1L) with an HDPE coupon.	35.67 % (w/w) INTEROX AG Spray 35S	Read-across from INTEROX® AG-Spray-35S. 4.5% decrease in hydrogen peroxide content after 15 months. There was no change in the appearance of the test item formulation or its commercial container after 12 months.	Envigo study number: JX07PK
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Temperature 25 ± 2 °C. Relative humidity: max 72 %, min 11 %, average 30 %. And temperature 40 ± 2 °C	35.67 % (w/w) INTEROX AG Spray 35S 35-35.7 % (w/w) INTEROX AG Dual 35 INTEROX AG Bath 35	Read-across from INTEROX® AG-Spray-35S. 4.5% decrease in hydrogen peroxide content after 15 months at 25 °C, 30% RH and 0% change after 8 weeks at 40 °C.	Envigo study number: JX07PK Solvay study numbers: FHs/7120-2016/005, FHs/7120-2016/009, FHs/7120-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		INTEROX AG Bath 35S INTEROX AG Spray 35S INTEROX AG Spray 35	There was no change in the appearance of the test item formulation or its commercial container after 12 months at 25 °C, 30% RH nor after 8 weeks at 40 °C. The products are aqueous solutions and therefore effect of humidity on the stability of the products is considered negligible.	2016/010, FHs/7120-2016/011, FHs/7120/2016/012
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	The test item was stored at 40 ± 2 °C for 8 weeks in vented HDPE bottles (0.5L)	35-35.7 % (w/w) INTEROX AG Dual 35 INTEROX AG Bath 35 INTEROX AG Bath 35S INTEROX AG Spray 35S INTEROX AG Spray 35	**Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 35.5-35.7 (depending on the product) T8w: 35.5-35.6 (depending on the product) **Weight loss** T8w: -0.11- -0.15% depending of the product	Solvay study numbers: FHs/7120-2016/005, FHs/7120-2016/009, FHs/7120-2016/010, FHs/7120-2016/011, FHs/7120-2016/012
Wettability	-	-	Not applicable. The products are aqueous solutions.	-
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable. The products are aqueous solutions.	-
Wet sieve analysis and dry sieve test	-	-	Not applicable. The products are aqueous solutions.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable. The products are aqueous solutions.	-
Disintegration time	-	-	Not applicable. The products are aqueous solutions.	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Determination of MMAD: waived. The products are not sold together with a spraying device and MMAD is not required as an imput parameter for human exposure assessment. The provided efficacy tests did not require	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			determination of MMAD. In addition, when the product is used according to the instructions of use there is no exposure to the user.	
Persistent foaming	-	-	Data waiving. The product(s) are used undiluted and therefore test for persistent foaming is not required.	-
Flowability/Pourability/ Dustability	-	-	Not applicable. The products are aqueous solutions.	-
Burning rate — smoke generators	-	-	Not applicable. The products are not smoke generators.	-
Burning completeness — smoke generators	-	-	Not applicable. The products are not smoke generators.	-
Composition of smoke — smoke generators	-	-	Not applicable. The products are not smoke generators.	-
Spraying pattern — aerosols	-	-	Not applicable. The products are not sold as aerosols.	-
Physical compatibility	-	-	Not applicable. The products are not intended or marketed to be used in conjunction with other substances, mixtures or non-biocidal products.	-
Chemical compatibility	-	-	Not applicable. The products are not intended or marketed to be used in conjunction with other substances, mixtures or non-biocidal products.	-
Degree of dissolution and dilution stability	-	-	Data waiving. The product(s) are used undiluted and therefore test for dilution stability is not required.	-
Surface tension	A.5 OECD 115	35.64 % (w/w) INTEROX FCC 35	72.5 mN/m at 20.0 ± 0.5 °C	Envigo Study Number: WX14JJ
Viscosity	OECD 114	35.64 % (w/w) INTEROX FCC 35	1.02 mm^2/s at 20.0 ± 0.5°C 0.708 mm^2/s at 40.0 ± 0.5°C	Envigo Study Number: WX14JJ

Conclusion on the physical, chemical and technical properties of the product

The physical, chemical and technical properties have been reported sufficiently and the results are acceptable for the use of the product. The products are clear, colourless liquids with acidic pH showing no surface active properties. The stability of the products in the commercial packaging (HDPE) has been demonstrated at 40°C and at ambient temperature with natural light/night variation. The products are physically stable at 0°C, too. A shelf life of 12 months can be granted for the products.

Meta-SPC 6 – INTEROX® FCC-35

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	35.64 % (w/w) INTEROX FCC 35	Clear liquid.	Envigo Study Number: WX14JJ
Colour at 20 °C and 101.3 kPa	Visual inspection	35.64 % (w/w) INTEROX FCC 35	Colourless	Envigo Study Number: WX14JJ
Odour at 20 °C and 101.3 kPa	-	-	The odour of the test item has not been assessed due to the acute toxicity classification H332: harmful if inhaled.	-
Acidity / alkalinity	CIPAC 191 CIPAC MT 75.3	35.64 % (w/w) INTEROX FCC 35 35.4% (w/w) INTEROX FCC 35 35% (w/w) INTEROX FCC 35	pH: 2.53 (GLP) pH: 2.6 (QC) Acidity 5.3 x 10^{-3} % w/w as equivalent sulphuric acid	Envigo Study Number: WX14JJ Covance Study Number: KV38HN Candy, T. (2019)
Density	A.3 OECD 109	25.71 % (w/w) INTEROX FCC 35	1.13 x 10^3 kg/m^3 at 20.0 ± 0.5 °C	Envigo Study Number: WX14JJ
Storage stability test – **accelerated storage**	CIPAC MT 46.3	35-35.7 % (w/w) INTEROX FCC 35	Test conditions: 40 ± 2 °C, 8 weeks in vented HDPE bottles (0.5L) **Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 35.6 T8w: 35.5 **Weight loss** T8w: -0.19%	Solvay study numbers: FHs/7120-2016/008
Storage stability test – **long term storage stability at ambient temperature**	Ambient temperature (25 ± 2 °C). Natural light/night variation.	35-35.7 % (w/w) INTEROX FCC 35 35% (w/w) INTEROX FCC 35	**Appearance** T0: colourless, homogenous, transparent liquid with no sedimentation or precipitation	Envigo study number: CC17PP. Candy, T. (2019)

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
	Vented, translucent HDPE bottle (1L) with an HDPE coupon.		T12m: no change in appearance **Packaging** T0: No signs of corrosion or degradation T12m: No signs of corrosion, degradation or seepage. **Active ingredient content (% w/w)** T0: 35.3 T6m: 35.3 T9m: 34.8 T12m: 34.4 15 months: 34.3 (-2.8%) **pH (1 % aqueous dispersion)** T0: 5.97 T6m: 5.57 T9m: 5.67 T12m: 5.77 pH of the (neat) product after storage: not determined. The decrease of the concentration of the active substance is minimal (-2.8%) during storage. The pH of 1% dispersion is presented. QC data of the applicant shows that pH of the neat aged product (12 months) has decreased by 0.1 pH units and acidity (0.4 mmol/l) has remained unchanged. Persistent foaming and dilution stability: please refer to the respective data endpoints.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	35.67 % (w/w) INTEROX FCC 35	T0:clear colourless homogenous liquid, no signs of precipitate, sedimentation or separated phases T7d: no change The test item has been determined to be physically stable to storage at 0 ± 2°C for 7 days	Envigo Study Number: WX14JJ

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Ambient temperature (25 ± 2 °C). Natural light/night variation. Vented, translucent HDPE bottle (1L) with a HDPE coupon.	35.67 % (w/w) INTEROX FCC 35	2.8% decrease in hydrogen peroxide content after 15 months. There was no change in the appearance of the test item formulation or its commercial container after 12 months.	Envigo study number: CC17PP
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Temperature 25 ± 2 °C. Natural light/night variation. Relative humidity: max 72 %, min 11 %, average 30 %. And temperature 40 ± 2 °C	35.67 % (w/w) INTEROX FCC 35 35-35.7 % (w/w) INTEROX FCC 35	2.8% decrease in hydrogen peroxide content after 15 months at 25 °C, 30% RH and 0.3% decrease after 8 weeks at 40 °C. There was no change in the appearance of the test item formulation or its commercial container after 12 months at 25 °C, 30% RH nor after 8 weeks at 40 °C. The product is an aqueous solution and therefore effect of humidity on the stability of the product is considered negligible.	Envigo study number: CC17PP Solvay study numbers: FHs/7120-2016/008
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	The test item was stored at 40 ± 2 °C for 8 weeks in vented HDPE bottles (0.5 L)	35-35.7 % (w/w) INTEROX FCC 35	**Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 35.6 T8w: 35.5 **Weight loss** T8w: -0.19%	Solvay study numbers: FHs/7120-2016/008
Wettability	-	-	Not applicable. The products are aqueous solutions.	-
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable. The products are aqueous solutions.	-
Wet sieve analysis and dry sieve test	-	-	Not applicable. The products are aqueous solutions.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable. The products are aqueous solutions.	-
Disintegration time	-	-	Not applicable. The products are aqueous solutions.	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not applicable. The product is not intended for any use forming spray.	-
Persistent foaming	CIPAC MT 47.2- Volume of foam detected at time points 0 sec, 10 sec, 1 min, 3 min, 12 min	INTEROX FCC 35 Fresh sample Batch C006221131 35.35% w/w Aged sample (12m) Batch A006820129 34.47% w/w	Lowest in-use concentration (4.8%) Fresh: no foam Aged: no foam Highest in-use concentration (13%) Fresh: no foam Aged: no foam	Candy (2021), INTEROX FCC 35: Determination of Persistent Foaming
Flowability/Pourability/ Dustability	-	-	Not applicable. The products are aqueous solutions.	-
Burning rate — smoke generators	-	-	Not applicable. The product is not a smoke generator.	-
Burning completeness — smoke generators	-	-	Not applicable. The product is not a smoke generator.	-
Composition of smoke — smoke generators	-	-	Not applicable. The product is not a smoke generator.	-
Spraying pattern — aerosols	-	-	Not applicable. The product is not sold as an aerosol.	-
Physical compatibility	-	-	Not applicable. The products are not intended or marketed to be used in conjunction with other substances, mixtures or non-biocidal products.	-
Chemical compatibility	-	-	Not applicable. The products are not intended or marketed to be used in conjunction with other substances, mixtures or non-biocidal products.	-
Degree of dissolution and dilution stability	CIPAC MT 41.1 Observation of solutions after 30 minutes and 24 hours.	INTEROX FCC 35 Fresh sample Batch C006221131 35.35% w/w Aged sample (12m) Batch A006820129 34.47% w/w	Highest in-use concentration (13%) Fresh: No sediment or visible solid particles Aged: No sediment or visible solid particles	Candy (2021), INTEROX FCC 35: Determination of Dilution stability

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Surface tension	A.5 OECD 115	35.64 % (w/w) INTEROX FCC 35	72.5 mN/m at 20.0 ± 0.5 °C	Envigo Study Number: WX14JJ
Viscosity	OECD 114	35.64 % (w/w) INTEROX FCC 35	1.02 mm^2/s at 20.0 ± 0.5°C 0.708 mm^2/s at 40.0 ± 0.5°C	Envigo Study Number: WX14JJ

Conclusion on the physical, chemical and technical properties of the product
The physical, chemical and technical properties have been reported sufficiently and the results are acceptable for the use of the product. The product is a clear, colourless liquid with acidic pH showing no surface active properties. The stability of the product in the commercial packaging (HDPE) has been demonstrated at 40°C and at ambient temperature with natural light/night variation. The product is physically stable at 0°C, too. A shelf life of 12 months can be granted for the product. The product does not produce foam upon dilution. Diluting the product does not give rise to any particles.

Meta-SPC 7 –INTEROX® FCC-50

Read-across from INTEROX® BT-50 for the majority of endpoints. INTEROX® FCC-50 is the test material in the following endpoints:, accelerated storage stability, effect of temperature and humidity and reactivity towards container material. .

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	49.57 % (w/w) INTEROX BT 50	Clear liquid.	Envigo Study Number: FJ79RX
Colour at 20 °C and 101.3 kPa	Visual inspection	49.57 % (w/w) INTEROX BT 50	Colourless	Envigo Study Number: FJ79RX
Odour at 20 °C and 101.3 kPa	-	-	The odour of the test item has not been assessed due to the acute toxicity classification H332: harmful if inhaled.	-
Acidity / alkalinity	CIPAC 191 CIPAC MT 75.3	49.57 % (w/w) INTEROX BT 50 49.4% (w/w) INTEROX BT 50 50% (W/W) INTEROX BT 50	pH: 1.41 (GLP) pH: 1.3 (QC) Acidity 1.4 x 10^{-2} % w/w as equivalent sulphuric acid	Envigo Study Number: FJ79RX Covance Study Number: KV38HN Candy, T. (2019)
Density	A.3 OECD 109	49.57 % (w/w) INTEROX BT 50	1.19 x 10^3 kg/m^3 at 20.0 ± 0.5 °C	Envigo Study Number: FJ79RX

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Storage stability test – **accelerated storage**	CIPAC MT 46.3	49-49.9 % (w/w) INTEROX FCC 50	Test conditions: 40 ± 2 °C, 8 weeks in vented HDPE bottles (1L) **Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 49.7 T8w: 49.6 **Weight loss** T8w: -0.16%	Solvay study numbers: FHs/7120/2016/017
Storage stability test – **long term storage stability at ambient temperature**	The test item was stored in 1 L HDPE bottle with a vented lid with the presence of an HDPE coupon at 25 ± 2 °C in natural light/night variation for 15 months.	49.57 % (w/w) INTEROX BT 50 49-49.9 % (w/w) INTEROX BT 50	Read across from INTEROX® BT-50. Night/light variation **Appearance** T0: colourless, transparent liquid with no sedimentation or precipitation. T12m: no change **Packaging** T0: No signs of corrosion or degradation T12m: no change **Active ingredient content (% w/w)** T0: 49.2 T6m: 49.4 T9m: 48.5 T12m: 47.5 T15m: 47.2 (-4.1%) **pH (1 % aqueous dispersion)** T0: 5.49 T6m: 5.13 T9m: 5.10 T12m: 5.50 **Weight loss** T12m: -0.70% **HDPE coupon weight change** T12m: +0.43% pH of the (neat) product after storage:	Envigo study number: GP25QL Candy, T. (2019)

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			not determined. The decrease of the concentration of the active substance is minimal (-1.8% - -4.1%) during storage. The pH of 1% dispersion is presented. QC data of the applicant shows that there is no change in pH of the neat aged product (12 months) and acidity has decreased by 0.4 mmol/l (2.2 to 1.8 mmol/l). Persistent foaming and dilution stability: please refer to the respective data endpoints.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	49.57 % (w/w) INTEROX BT 50	Read-across from INTEROX® BT-50. T0: clear colourless homogenous liquid, no signs of precipitate, sedimentation or separated phases T7d: no change The test item has been determined to be physically stable to storage at 0 ± 2°C for 7 days	Envigo Study Number: FJ79RX
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Ambient temperature (25 ± 2 °C). Natural light/night variation . Vented, translucent HDPE bottle (1L).	49-49.9 % (w/w) INTEROX BT 50	Read-across from INTEROX® BT-50. 4.1% decrease in hydrogen peroxide content after 15 months. There was no change in the appearance of the test item formulation or its commercial container after 15 months.	Envigo study number: GP25QL
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Temperature 25 ± 2 °C. Natural light/night variation Relative humidity: max 72%, min 11%, average 30% or 60 ± 5 % relative humidity.	49.2% (w/w) INTEROX BT 50 49-49.9 % (w/w) INTEROX BT 50 49-49.9% (w/w) INTEROX FCC 50	Read-across from INTEROX® BT-50. 1.8% decrease in hydrogen peroxide content after 10 months at 25 °C, 60% RH. There was no change in the appearance of the test item formulation or its commercial container after 10	Harlan study number: 1276/0046(a) Envigo study number: GP25QL Solvay study numbers: FHs/7120/2016/017

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
	And temperature 40 ± 2 °C		months at 25 °C, 60% RH. Read-across from INTEROX® BT-50. 4.1% decrease in hydrogen peroxide content after 15 months 25 °C, 30% RH. There was no change in the appearance of the test item formulation or its commercial container after 15 months at 25 °C, 30% RH. 0.2% decrease in hydrogen peroxide content after 8 weeks at 40 °C. There was no change in the appearance of the test item formulation or its commercial container after 8 weeks at 40 °C. The product is an aqueous solution and therefore effect of humidity on the stability of the product is considered negligible.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	The test item was stored at 40 ± 2 °C for 8 weeks in vented HDPE bottles (1L)	49-49.9 % (w/w) INTEROX FCC 50	**Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 49.7 T8w: 49.6 **Weight loss** T8w: -0.16%	Solvay study numbers: FHs/7120-2016/017
Wettability	-	-	Not applicable. The products are aqueous solutions.	-
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable. The products are aqueous solutions.	-
Wet sieve analysis and dry sieve test	-	-	Not applicable. The products are aqueous solutions.	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable. The products are aqueous solutions.	-
Disintegration time	-	-	Not applicable. The products are aqueous solutions.	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not applicable. The product is not intended for any use forming spray.	-
Persistent foaming	CIPAC MT 47.2 Volume of foam detected at time points 0 sec, 10 sec, 1 min, 3 min, 12 min	INTEROX FCC 50 Fresh sample Batch LH 000121133 49.65% w/w	Lowest in-use concentration (4.8%) Fresh: no foam Highest in-use concentration (13%) Fresh: no foam	Candy (2021), INTEROX FCC 50: Determination of Persistent Foaming
Flowability/Pourability/ Dustability	-	-	Not applicable. The products are aqueous solutions.	-
Burning rate — smoke generators	-	-	Not applicable. The product is not a smoke generator.	-
Burning completeness — smoke generators	-	-	Not applicable. The product is not a smoke generator.	-
Composition of smoke — smoke generators	-	-	Not applicable. The product is not a smoke generator.	-
Spraying pattern — aerosols	-	-	Not applicable. The product is not sold as an aerosol.	-
Physical compatibility	-	-	Not applicable. The products are not intended or marketed to be used in conjunction with other substances, mixtures or non-biocidal products.	-
Chemical compatibility	-	-	Not applicable. The products are not intended or marketed to be used in conjunction with other substances, mixtures or non-biocidal products.	-
Degree of dissolution and dilution stability	CIPAC MT 41.1 Observation of solutions after 30 minutes and 24 hours.	INTEROX FCC 50 Fresh sample Batch LH 000121133 49.65% w/w	Highest in-use concentration (13%) Fresh: No sediment or visible solid particles	Candy (2021), INTEROX FCC 50: Determination of Dilution stability

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Surface tension	A.5 OECD 115	49.57 % (w/w) INTEROX BT 50	72.5 mN/m at 20.0 ± 0.5 °C	Envigo Study Number: FJ79RX
Viscosity	OECD 114	49.57 % (w/w) INTEROX BT 50	1.18 mm^2/s at 20.0 ± 0.5°C 0.844 mm^2/s at 40.0 ± 0.5°C	Envigo Study Number: FJ79RX

Conclusion on the physical, chemical and technical properties of the product
The physical, chemical and technical properties have been reported sufficiently and the results are acceptable for the use of the product. The product is a clear, colourless liquid with acidic pH showing no surface active properties. The stability of the product in the commercial packaging (HDPE) has been demonstrated at 40°C and at ambient temperature with natural light/night variation. The product is physically stable at 0°C, too. A shelf life of 12 months can be granted for the product. The product does not produce foam upon dilution. Diluting the product does not give rise to any particles.

Meta-SPC 8 – INTEROX® BT-35

Read-across from INTEROX® FCC-35 for the majority of endpoints. INTEROX® BT-35 is the test material in the following endpoints: accelerated storage stability, effect of temperature and humidity and reactivity towards container material

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	35.64 % (w/w) INTEROX FCC 35	Clear liquid.	Envigo Study Number: WX14JJ
Colour at 20 °C and 101.3 kPa	Visual inspection	35.64 % (w/w) INTEROX FCC 35	Colourless	Envigo Study Number: WX14JJ
Odour at 20 °C and 101.3 kPa	-	-	The odour of the test item has not been assessed due to the acute toxicity classification H332: harmful if inhaled.	-
Acidity / alkalinity	CIPAC 191 CIPAC MT 75.3	35.64 % (w/w) INTEROX FCC 35 35.4% (w/w) INTEROX FCC 35 35% (w/w) INTEROX FCC 35	pH: 2.53 (GLP) pH: 2.2 (QC) Acidity 5.3 x 10^{-3} % w/w as equivalent sulphuric acid	Envigo Study Number: WX14JJ Covance Study Number: KV38HN Candy, T. (2019)
Density	A.3 OECD 109	25.71 % (w/w) INTEROX FCC 35	1.13 x 10^3 kg/m^3 at 20.0 ± 0.5 °C	Envigo Study Number: WX14JJ

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Storage stability test – **accelerated storage**	CIPAC MT 46.3	35-35.7 % (w/w) INTEROX BT 35	Test conditions: 40 ± 2 °C, 8 weeks in vented HDPE bottles (1L) **Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 35.7 T8w: 35.6 **Weight loss** T8w: -0.10%	Solvay study number: FHs/7120/2016/016
Storage stability test – **long term storage stability at ambient temperature**	The test item was stored in 1 L HDPE bottle with a vented lid with the presence of an HDPE coupon at 25 ± 2 °C in natural light/night variation for 15 months.	35-35.7 % (w/w) INTEROX FCC 35 35% (w/w) INTEROX FCC 35	Read-across from INTEROX® FCC-35. **Appearance** T0: colourless, homogenous, transparent liquid with no sedimentation or precipitation T12m: no change in appearance **Packaging** T0: No signs of corrosion or degradation T12m: No signs of corrosion, degradation or seepage. **Active ingredient content (% w/w)** T0: 35.3 T6m: 35.3 T9m: 34.8 T12m: 34.4 15 months: 34.3 (-2.8%) **pH (1 % aqueous dispersion)** T0: 5.97 T6m: 5.57 T9m: 5.67 T12m: 5.77 pH of the (neat) product after storage: not determined. The decrease of the concentration of the	Envigo study number: CC17PP. Candy, T. (2019)

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			active substance is minimal (-2.8%) during storage. The pH of 1% dispersion is presented. QC data of the applicant shows that there is no change in pH of the neat aged product (12 months) and acidity (1.2 mmol/l) has remained unchanged. Persistent foaming and dilution stability: please refer to the respective data endpoints.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	35.64 % (w/w) INTEROX FCC 35	T0:clear colourless homogenous liquid, no signs of precipitate, sedimentation or separated phases T7d: no change The test item has been determined to be physically stable to storage at 0 ± 2°C for 7 days	Envigo Study Number: WX14JJ
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Ambient temperature (25 ± 2 °C). Natural ligt/night variation. Vented, translucent HDPE bottle (1L) with a HDPE coupon	35.67 % (w/w) INTEROX FCC 35	2.8% decrease in hydrogen peroxide content after 15 months. There was no change in the appearance of the test item formulation or its commercial container after 12 months.	Envigo study number: CC17PP
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Temperature 25 ± 2 °C. Relative humidity: max 72 %, min 11 %, average 30 %. And temperature 40 ± 2 °C	35.67 % (w/w) INTEROX FCC 35 35.0-35.7% (w/w) INTEROX BT 35	2.8% decrease in hydrogen peroxide content after 15 months at 25 °C, 30% RH and 0.3% decrease after 8 weeks at 40 °C There was no change in the appearance of the test item formulation or its commercial container after 12 months at 25 °C, 30% RH nor after 8 weeks at 40 °C. The product is an aqueous solution and therefore effect of humidity on the stability of the product is considered negligible.	Envigo study number: CC17PP Solvay study number: FHs/7120/2016/016
Effects on content of the active substance	The test item was stored at	35-35.7 % (w/w)	**Appearance**	Solvay study numbers:

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
and technical characteristics of the biocidal product - **reactivity towards container material**	40 ± 2 °C for 8 weeks in vented HDPE bottles (0.5L or 1L))	INTEROX FCC 35 35-35.7 % (w/w) INTEROX BT 35	T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 35.6 T8w: 35.5 **Weight loss** T8w: -0.19% **Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 35.7 T8w: 35.6 **Weight loss** T8w: -0.10%	FHs/7120-2016/008 Solvay study number: FHs/7120/2016/016
Wettability	-	-	Not applicable. The products are aqueous solutions.	-
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable. The products are aqueous solutions.	-
Wet sieve analysis and dry sieve test	-	-	Not applicable. The products are aqueous solutions.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable. The products are aqueous solutions.	-
Disintegration time	-	-	Not applicable. The products are aqueous solutions.	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Determination of MMAD: waived. The product is not sold together with a spraying device and MMAD is not required as an imput parameter for human exposure assessment. The provided efficacy tests did not require determination of MMAD. In addition, when the product is used according to the instructions of use there	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			is no exposure to the user.	
Persistent foaming	CIPAC MT 47.2 Volume of foam detected at time points 0 sec, 10 sec, 1 min, 3 min, 12 min	INTEROX BT 35 Fresh sample Batch S006521127 35.0% w/w Aged sample (12m) Batch S005120133 33.35% w/w	Lowest in-use concentration (4.8%) Fresh: no foam Aged: no foam Highest in-use concentration (13%) Fresh: no foam Aged: no foam	Candy (2021), INTEROX BT 35: Determination of Persistent Foaming
Flowability/Pourability/ Dustability	-	-	Not applicable. The products are aqueous solutions.	-
Burning rate — smoke generators	-	-	Not applicable. The product is not a smoke generator.	-
Burning completeness — smoke generators	-	-	Not applicable. The product is not a smoke generator.	-
Composition of smoke — smoke generators	-	-	Not applicable. The product is not a smoke generator.	-
Spraying pattern — aerosols	-	-	Not applicable. The product is not sold as an aerosol.	-
Physical compatibility	-	-	Not applicable. The products are not intended or marketed to be used in conjunction with other substances, mixtures or non-biocidal products.	-
Chemical compatibility	-	-	Not applicable. The products are not intended or marketed to be used in conjunction with other substances, mixtures or non-biocidal products.	-
Degree of dissolution and dilution stability	CIPAC MT 41.1 Observation of solutions after 30 minutes and 24 hours.	INTEROX BT 35 Fresh sample Batch S006521127 35.0% w/w Aged sample (12m) Batch S005120133 33.35% w/w	Highest in-use concentration (13%) Fresh: No sediment or visible solid particles Aged: No sediment or visible solid particles	Candy (2021), INTEROX BT 35: Determination of Dilution stability
Surface tension	A.5 OECD 115	35.64 % (w/w) INTEROX FCC 35	72.5 mN/m at 20.0 ± 0.5 °C	Envigo Study Number: WX14JJ

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Viscosity	OECD 114	35.64 % (w/w) INTEROX FCC 35	1.02 mm^2/s at 20.0 ± 0.5°C 0.708 mm^2/s at 40.0 ± 0.5°C	Envigo Study Number: WX14JJ

Conclusion on the physical, chemical and technical properties of the product
The physical, chemical and technical properties have been reported sufficiently and the results are acceptable for the use of the product. The product is a clear, colourless liquid with acidic pH showing no surface active properties. The stability of the product in the commercial packaging (HDPE) has been demonstrated at 40°C and at ambient temperature with natural light/night variation. The product is physically stable at 0°C, too. A shelf life of 12 months can be granted for the product. The product does not produce foam upon dilution. Diluting the product does not give rise to any particles.

Meta-SPC 9 –INTEROX® BT-50

The composition of INTEROX ST 50 is identical to INTEROX BT 50, only the name of the product has changed.

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	49.57 % (w/w) INTEROX BT 50	Clear liquid.	Envigo Study Number: FJ79RX
Colour at 20 °C and 101.3 kPa	Visual inspection	49.57 % (w/w) INTEROX BT 50	Colourless	Envigo Study Number: FJ79RX
Odour at 20 °C and 101.3 kPa	-	-	The odour of the test item has not been assessed due to the acute toxicity classification H332: harmful if inhaled.	-
Acidity / alkalinity	CIPAC 191 CIPAC MT 75.3	49.57 % (w/w) INTEROX BT 50 49.4% (w/w) INTEROX BT 50 50% (W/W) INTEROX BT 50	pH: 1.41 (GLP) pH: 1.3 (QC) Acidity 1.4 x 10^{-2} % w/w as equivalent sulphuric acid	Envigo Study Number: FJ79RX Covance Study Number: KV38HN Candy, T. (2019)
Density	A.3 OECD 109	49.57 % (w/w) INTEROX BT 50	1.19 x 10^3 kg/m^3 at 20.0 ± 0.5 °C	Envigo Study Number: FJ79RX
Storage stability test – **accelerated storage**	CIPAC MT 46.3	49.0-49.9 % (w/w)	Test conditions: 40 ± 2 °C, 8 weeks in vented HDPE bottles (0.5L) **Appearance** T0: transparent colourless liquid, no damage or deviations in packaging.	Final report number: FHs/7120/2016/015

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			T8w: no change **Active substance, % (w/w)** T0: 49.3 T8w: 48.8 **Weight loss** T8w: -0.39%	
Storage stability test – **long term storage stability at ambient temperature**	Ambient temperature (25 ± 2 °C). Natural ligt/night variation. Vented, black HDPE bottle (1L) and vented, translucent HDPE bottle (1L) with an HDPE coupon.	49.57 % (w/w) INTEROX BT 50 49-49.9 % (w/w) INTEROX BT 50	**Appearance** T0: colourless, homogenous, transparent liquid with no sedimentation or precipitation T12m: no change in appearance **Packaging:** T0: No signs of corrosion or degradation T12m: No change **Active ingredient content (% w/w)** T0: 49.2 T6m: 49.4 T9m: 48.5 T12m: 47.5 T15m: 47.2 (-4.1%) **pH (1 % aqueous dispersion)** T0: 5.49 T6m: 5.28 T9m: 5.21 T12m: 5.36 **Weight loss** T12m: -0.70 % **Weight change of the HDPE coupon** T12m: +0.429 % pH of the (neat) product after storage: not determined. The decrease of the concentration of the active substance is minimal (-4.1%) during storage. The pH of 1% dispersion is presented. QC data of the applicant shows that there is no change in pH of the neat aged product (12 months) and acidity has	Envigo study number: GP25QL. Candy, T. (2019)

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			decreased by 0.4 mmol/l (2.2 to 1.8 mmol/l). Persistent foaming and dilution stability:please refer to the respective data endpoints.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	49.57 % (w/w) INTEROX BT 50	T0: clear colourless homogenous liquid, no signs of precipitate, sedimentation or separated phases. T7d: no change The test item has been determined to be physically stable to storage at 0 ± 2°C for 7 days	Envigo Study Number: FJ79RX
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Ambient temperature 25 ± 2 °C. Natural light/night variation for 15 month. Vented, translucent HDPE bottle (1L)	49-49.9 % (w/w) INTEROX BT 50	4.1% decrease in hydrogen peroxide content after 15 months. There was no change in the appearance of the test item formulation or its commercial container after 12 months	Envigo study number: GP25QL
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Temperature 25 ± 2 °C. Relative humidity max 72%, min 11%, average 30% or 60 ± 5 %. Temperature 40 ± 2 °C	49.2% (w/w) INTEROX BT 50 49-49.9 % (w/w) INTEROX BT 50 49.0-49.9% (w/w) INTEROX ST 50	1.8% decrease in hydrogen peroxide content after 10 months at 25 °C, 60% RH. There was no change in the appearance of the test item formulation or its commercial container after 10 months at 25 °C, 60% RH. 4.1% decrease in hydrogen peroxide content after 15 months. There was no change in the appearance of the test item formulation or its commercial container after 15 months at 25 °C, 30% RH. 1.0% decrease in hydrogen peroxide content after 8 weeks at 40 °C. There was no change in the appearance of the	Harlan study number: 1276/0046(a) Envigo study number: GP25QL Final report number: FHs/7120/2016/015

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			test item formulation or its commercial container after 8 weeks at 40 °C. The product is an aqueous solution and therefore effect of humidity on the stability of the product is considered negligible.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	The test item was stored at 40 ± 2 °C for 8 weeks in vented HDPE bottles (0.5L)	49-49.9 % (w/w) INTEROX ST 50	**Appearance** T0: transparent colourless liquid, no damage or deviations in packaging. T8w: no change **Active substance, % (w/w)** T0: 49.3 T8w: 48.8 **Weight loss** T8w: -0.39%	Solvay study number: FHs/7120-2016/015
Wettability	-	-	Not applicable. The products are aqueous solutions.	-
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable. The products are aqueous solutions.	-
Wet sieve analysis and dry sieve test	-	-	Not applicable. The products are aqueous solutions.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable. The products are aqueous solutions.	-
Disintegration time	-	-	Not applicable. The products are aqueous solutions.	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Determination of MMAD: waived. The product is not sold together with a spraying device and MMAD is not required as an imput parameter for human exposure assessment. The provided efficacy tests did not require determination of MMAD. In addition, when the product is used according to the instructions of use there is no exposure to the user.	-
Persistent foaming	CIPAC MT 47.2-	INTEROX BT 50 Fresh sample	Lowest in-use concentration (4.8%) Fresh: no foam	Candy (2021), INTEROX BT 50: Determination of

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
	Volume of foam detected at time points 0 sec, 10 sec, 1 min, 3 min, 12 min	Batch S006621130 49.50% w/w Aged sample (12m) Batch S005020132 48.66% w/w	Aged: no foam Highest in-use concentration (13%) Fresh: no foam Aged: no foam	Persistent Foaming
Flowability/Pourability/ Dustability	-	-	Not applicable. The products are aqueous solutions.	-
Burning rate — smoke generators	-	-	Not applicable. The product is not a smoke generator.	-
Burning completeness — smoke generators	-	-	Not applicable. The product is not a smoke generator.	-
Composition of smoke — smoke generators	-	-	Not applicable. The product is not a smoke generator.	-
Spraying pattern — aerosols	-	-	Not applicable. The product is not sold as an aerosol.	-
Physical compatibility	-	-	Not applicable. The products are not intended or marketed to be used in conjunction with other substances, mixtures or non-biocidal products.	-
Chemical compatibility	-	-	Not applicable. The products are not intended or marketed to be used in conjunction with other substances, mixtures or non-biocidal products.	-
Degree of dissolution and dilution stability	CIPAC MT 41.1 Observation of solutions after 30 minutes and 24 hours.	INTEROX BT 50 Fresh sample Batch S006621130 49.50% w/w Aged sample (12m) Batch S005020132 48.66% w/w	Highest in-use concentration (13%) Fresh: No sediment or visible solid particles Aged: No sediment or visible solid particles	Candy (2021), INTEROX BT 50: Determination of Dilution stability
Surface tension	A.5 OECD 115	49.57 % (w/w) INTEROX BT 50	72.5 mN/m at 20.0 ± 0.5 °C	Envigo Study Number: FJ79RX

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Viscosity	OECD 114	49.57 % (w/w) INTEROX BT 50	1.18 mm^2/s at 20.0 ± 0.5°C 0.844 mm^2/s at 40.0 ± 0.5°C	Envigo Study Number: FJ79RX

Conclusion on the physical, chemical and technical properties of the product
The physical, chemical and technical properties have been reported sufficiently and the results are acceptable for the use of the product. The product is a clear, colourless liquid with acidic pH showing no surface active properties. The stability of the product in the commercial packaging (HDPE) has been demonstrated at 40°C and at ambient temperature with natural light/night variation. The product is physically stable at 0°C, too. A shelf life of 12 months can be granted for the product. The product does not produce foam upon dilution. Diluting the product does not give rise to any particles.

2.2.3 Physical hazards and respective characteristics

Meta-SPC 1, 2, 3, 4, 5, 6, 7, 8 and 9

Read-across from INTEROX® FCC-35 (Meta-SPC 6) for the following products:
- Meta-SPC 1: INTEROX® SG-12
- Meta-SPC 2: INTEROX® SG-35, INTEROX® SG-35-Plus
- Meta-SPC 4: INTEROX® AG Spray-25S
- Meta-SPC 5: INTEROX® AG-Spray-35, INTEROX® AG-Spray-35S, INTEROX® AG-Bath-35, INTEROX® AG-Bath-35S, INTEROX® AG-Dual-35
- Meta-SPC 8: INTEROX® BT-35

Read-across from INTEROX® BT-50 (Meta-SPC 9) for the following products:
- Meta-SPC 3: INTEROX® SG-50, INTEROX® SG-50-Plus
- Meta-SPC 7: INTEROX® FCC-50

Property	Guideline and Method	Purity of the test substance % (w/w)	Results/Remarks	Reference
Explosives	-	-	Aqueous solution of hydrogen peroxide 87% (w/w) is not classified as explosive. The products are aqueous solutions with 13-49.9% (w/w) hydrogen peroxide and small amounts of stabilizers. The stabilizers do not contain functional groups indicating explosive properties according to Table A6.1 in Appendix 6 of the UN Manual of Tests and Criteria or they are present in the products as dissociated ions and in very small quantities. Therefore, the products	CAR (2017)

Property	Guideline and Method	Purity of the test substance % (w/w)	Results/Remarks	Reference
			are not classified as explosive.	
Flammable gases	-	-	Not applicable. The products are liquids.	-
Flammable aerosols	-	-	Not applicable. The products are liquids.	-
Oxidising gases	-	-	Not applicable. The products are liquids.	-
Gases under pressure	-	-	Not applicable. The products are liquids.	-
Flammable liquids	EC A.9 Closed cup equilibrium method	49.7% (w/w) Batch: Bulk Tank (Tank 28)	Interox BT 50: The product does not have a flash point below its boiling temperature. Not classified as a flammable liquid. Read across for all Meta SPC´s acceptable.	Covance Study number: 8457569
Flammable solids	-	-	Not applicable. No solids are present.	-
Self-reactive substances and mixtures	-	-	As the products containing >8% w/w hydrogen peroxide are classified as oxidising liquids they are not classified as self-reactive mixtures.	-
Pyrophoric liquids	-	-	Several studies have been conducted on the biocidal products, including a storage stability study conducted at ambient temperature, which demonstrate that the biocidal products do not spontaneously ignite in air.	Envigo study number: CC16PP Solvay report number: FHs/7120/2016/008 Solvay report number: FHs/7120/2016/017
Pyrophoric solids	-	-	Not applicable. No solids are present.	-
Self-heating substances and mixtures	-	-	The products are aqueous liquids. Liquids are not classified as self-heating. In addition, several studies have been conducted on the biocidal products, including a storage stability study conducted at ambient temperature for a minimum of 12 months, which demonstrate that the biocidal products do not self-heat by reacting with air.	Envigo study number: CC17PP Solvay report number: FHs/7120/2016/008 Solvay report number: FHs/7120/2016/017
Substances and mixtures which in	-	-	The products are stable aqueous solutions and do	-

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance % (w/w)</th><th>Results/Remarks</th><th>Reference</th></tr>
<tr><td>contact with water emit flammable gases</td><td></td><td></td><td>not emit flammable gases with water.</td><td></td></tr>
<tr><td>Oxidising liquids</td><td>UN RTDG Model Regulations, Class 5, Division 5.1</td><td>Meta SPC 1, 13.0-13.5% w/w H_2O_2</td><td>Oxidizing liquid, category 3</td><td></td></tr>
<tr><td></td><td></td><td>Meta SPC 2-9, 25.0-49.9% w/w H_2O_2</td><td>Oxidising liquid, category 2</td><td></td></tr>
<tr><td>Oxidising solids</td><td>-</td><td>-</td><td>Not applicable. No solids are present.</td><td>-</td></tr>
<tr><td>Organic peroxides</td><td>-</td><td>-</td><td>Not applicable. The products do not contain organic peroxides.</td><td>-</td></tr>
<tr><td>Corrosive to metals</td><td>UN Manual of tests and criteria, Test C.1.

Steel: S235JR
Aluminium: 7075-T6

55±1°C
7 days

Test item renewal at day 3 and day 6

Hydrogen peroxide content determination on day 3, day 6 and day 7 by titration</td><td>Interox SG 12: 12.9% w/w H_2O_2

Interox AG Spray 25S: 25.6% H_2O_2

Interox AG Spray 35S: H_2O_2 content not indicated</td><td>Uniform corrosion:
<table><tr><th>Exposure position</th><th>Metal</th><th>Mass loss (%)</th></tr><tr><td>Headspace</td><td>Al</td><td>0</td></tr><tr><td>Partially immersed</td><td>Al</td><td>0</td></tr><tr><td>Fully immersed</td><td>Al</td><td>0</td></tr><tr><td>Headspace</td><td>Steel</td><td>$1.321 \cdot 10^{-3}$</td></tr><tr><td>Partially immersed</td><td>Steel</td><td>$2.431 \cdot 10^{-3}$</td></tr><tr><td>Fully immersed</td><td>Steel</td><td>$2.627 \cdot 10^{-3}$</td></tr></table>Localized corrosion: no signs of pitting observed

Uniform corrosion:
<table><tr><th>Exposure position</th><th>Metal</th><th>Mass loss (%)</th></tr><tr><td>Headspace</td><td>Al</td><td>0</td></tr><tr><td>Partially immersed</td><td>Al</td><td>0</td></tr><tr><td>Fully immersed</td><td>Al</td><td>0</td></tr><tr><td>Headspace</td><td>Steel</td><td>$6.66 \cdot 10^{-4}$</td></tr><tr><td>Partially immersed</td><td>Steel</td><td>$2.00 \cdot 10^{-3}$</td></tr><tr><td>Fully immersed</td><td>Steel</td><td>0</td></tr></table>Localized corrosion: no signs of pitting observed

Uniform corrosion:</td><td>Covance Study Number: 8449202

Covance Study Number: 8449200

Draft, unaudited report, Covance</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance % (w/w)</th><th>Results/Remarks</th><th>Reference</th></tr>
<tr><td></td><td></td><td>Interox BT 50: H_2O_2 content not indicated</td><td>
<table>
<tr><th>Exposure position</th><th>Metal</th><th>Mass loss (%)</th></tr>
<tr><td>Headspace</td><td>Al</td><td>$7.33 \cdot 10^{-3}$</td></tr>
<tr><td>Partially immersed</td><td>Al</td><td>$1.09 \cdot 10^{-2}$</td></tr>
<tr><td>Fully immersed</td><td>Al</td><td>$1.20 \cdot 10^{-2}$</td></tr>
<tr><td>Headspace</td><td>Steel</td><td>$6.40 \cdot 10^{-4}$</td></tr>
<tr><td>Partially immersed</td><td>Steel</td><td>$2.61 \cdot 10^{-3}$</td></tr>
<tr><td>Fully immersed</td><td>Steel</td><td>$5.14 \cdot 10^{-3}$</td></tr>
</table>
Localized corrosion: no signs of pitting observed

Uniform corrosion:
<table>
<tr><th>Exposure position</th><th>Metal</th><th>Mass loss (%)</th></tr>
<tr><td>Headspace</td><td>Al</td><td>0</td></tr>
<tr><td>Partially immersed</td><td>Al</td><td>$6.56 \cdot 10^{-2}$</td></tr>
<tr><td>Fully immersed</td><td>Al</td><td>0.129</td></tr>
<tr><td>Headspace</td><td>Steel</td><td>$4.67 \cdot 10^{-3}$</td></tr>
<tr><td>Partially immersed</td><td>Steel</td><td>$1.05 \cdot 10^{-2}$</td></tr>
<tr><td>Fully immersed</td><td>Steel</td><td>$1.88 \cdot 10^{-2}$</td></tr>
</table>
Localized corrosion: no signs of pitting observed</td><td>Study Number: 8457570. The final report is expected to be available by end of April 2021

Covance Study Number: 8457571</td></tr>
<tr><td>Auto-ignition temperatures of products (liquids and gases)</td><td>ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7a: Endpoint specific guidance</td><td>-</td><td>Interox BT50 has no flash point below its boiling temperature. Auto-ignition temperature does not have to be determined for liquids having no flashpoint up to 200°.</td><td>Covance Study number: 8457569</td></tr>
<tr><td>Relative self-ignition temperature for solids</td><td>-</td><td>-</td><td>Not applicable. No solids are present.</td><td>-</td></tr>
<tr><td>Dust explosion hazard</td><td>-</td><td>-</td><td>Not applicable. The products are liquids.</td><td>-</td></tr>
<tr><td>Desensitised explosives</td><td>-</td><td>-</td><td>The products do not contain explosive components which would have been phlegmatized to suppress their explosive properties.</td><td></td></tr>
</table>

Conclusion on the physical hazards and respective characteristics of the product

The physical hazards have been evaluated sufficiently.
The products are not explosive, flammable nor corrosive to metal. The products are classified as oxidising liquids according to UN RTDG as follows: Meta SPC 1: Ox. Liq. 3 and Meta SPC´s 2-9: Ox. Liq. 2.

For detailed discussion on the testing of corrosivity to metals, please refer to confidential annex.

2.2.4 Methods for detection and identification

Hydrogen peroxide by titrimetric method:
Hydrogen peroxide is titrated with standardized potassium permanganate solution in acidic conditions (sulphuric acid).
$2\ KMnO_4 + 5\ H_2O_2 + 4\ H_2SO_4 \rightarrow 2\ KHSO_4 + 2\ MnSO_4 + 8\ H_2O + 5\ O_2$

Cd, As, Pb and Hg by ICP-MS:
Reference standard solutions of the metals were prepared in 2% cysteine in 4% HNO3 in water. Hydrogen peroxide solution (31.2%, w/w) for ultratrace analysis was used as matrix. Samples were analysed by Agilent 7500CE ICP-MS instrument using He as reaction gas and 25% oxygen as optional gas. Monitored isotopes for As, Cd, Hg and Pb for quantitation were 75 m/z, 111 m/z, 201 m/z and 208 m/z, respectively.

Analytical methods for the analysis of the product as such including the active substance and impurities									
Analyte	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Precision (content %)**			**Limit of quantification (LOQ)**	**Reference**
					Range	**Mean**	**RSD**		
Hydrogen peroxide (a.s.)	Titrimetric method	35% (w/w) n=5 70% (w/w) n=5	N/A as a titration method	Specific according to blank sample (water) showing pink colour after addition of potassium permanganate	35.4-35.4 69.9-70.1	35.4 70.0	0.021 0.061	N/A	WIL Research Project 510669
Cd, As, Pb, Hg	ICP-MS	0.05 mg/kg n=5 1.0 mg/kg n=5	Linearity range 0.5-100 µl/l, 5 levels in duplicate	Specific according to blank QC sample analyzed					
			As slope=28.5		85-95 86-93	90 90	4.4 3.2	0.05 mg/kg	WIL Research

			Intercept: 3.12 r=0.997	(intensity of background responses <30% of LOQ levels in hydrogen peroxide solution)					Project 510668
			Cd slope=89.1 Intercept =7.29 r=0.997		82-101 94-95	92 95	8.9 0.69	0.05 mg/kg	
			Hg slope=1.43·10^2 Intercept =11.7 r=0.9991		90-102 92-95	93 93	5.5 1.4	0.05 mg/kg	
			Pb slope=2.62·10^3 Intercept =6.31·10^2 r=0.9997		89-94 90-91	92 91	1.9 0.41	0.05 mg/kg	

Validated analytical methods for monitoring the active substance have been submitted for the relevant matrices, water and air. No methods for any other matrices are required for the reasons presented below.

Analytical methods for monitoring in soil
Hydrogen peroxide is very rapidly degraded in soil forming water and oxygen. The half-life is from few minutes to a maximum of 15 hours. In addition, due to the chemical properties, hydrogen peroxide is not adsorbed to soil, but remains in the soil water. Soil water may be analysed for hydrogen peroxide using the methods submitted for water. Consequently, no analytical method for soil matrix is required.

Hydrogen peroxide determination in air

Hydrogen peroxide reacts with titanium oxysulphate ($TiOSO_4$) to form a yellow coloured peroxo-complex absorbing UV radiation at 410 nm. Air is passed through bubblers at a flow rate of 0.8L/min at 35°C temperature and 80% relative air humidity. The collecting solution containing $TiOSO_4$ is analyzed spectrophotometrically.

Analytical methods for monitoring in air									
Analyte	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%) (accuracy)**			**Limit of quantification (LOQ)**	**Reference**
					Range	**Mean**	**RSD**		

Hydrogen peroxide (a.s.)	UV-Vis spectrophotometric	139 µg/m^3 n=5	1.60-7.50 mg/L (in end solution) slope $1.8 \cdot 10^{-2}$ Intercept $9.5 \cdot 10^{-4}$ r = 0.997	Specific according to UV spectrum of blank sample showing no absoption at the wavelenght of the peroxo-complex.	87-111	101	10	139µg/m^3	Study No. 510667
		1400 µg/m^3 n=5			95-115	108	7.9		

Hydrogen peroxide in water

Hydrogen peroxide acts as a cofactor with high selectivity for oxidation-reduction reaction where 4-hydroxyphenylacetic acid is dimerized to form 6,6'-dihydroxy-3,3'-biphenyldiacetic acid by enzymatic reaction with horseradish peroxidase. The dimer is readily detectable using a fluorescence detector. Chromatographic separation was performed by Acquity UPLC system with HSS T3 column (50x2.1mm; 1.8µm) with 10µl injection volume and acetonitrile – 0.1% formic acid gradient. Exitation wavelength 285 nm, emission 400 nm.

Analytical methods for monitoring in water									
Analyte	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%) (accuracy)**			**Limit of quantification (LOQ)**	**Reference**
					Range	**Mean**	**RSD**		
Hydrogen peroxide (a.s.)	UPLC-FLD	0.0100 mg/L n=5	0.008-0.120 mg/L (in end solution) Slope=$1.07 \cdot 10^8$ Intercept=$3.65 \cdot 10^5$ r = 0.998	Specific according to chromatograms of blank sample. A response at the retention time of the analyte was detected in the blank chromatogram with 31%	84-98	90	6.2	0.01 mg/L	Study No. 510666
		0.100 mg/L n=5			96-98	97	0.62		

				intensity of LOQ level.					

Analytical methods for monitoring in animal and human body fluids and tissues
Analytical methods for hydrogen peroxide in body fluids and tissues of humans or animals are not required, since the substance is not classified as toxic or highly toxic.

Analytical methods for monitoring of active substances and residues in food and feeding stuff
No residues of hydrogen peroxide are expected to be found in food and feeding stuff due to the rapid degradation of hydrogen peroxide in these matrices. Hence, no monitoring methods for these matrices are required.

Conclusion on the methods for detection and identification of the product
Validated analytical methods for detection and identification of the active substance and the impurity metals in the products are sufficiently established as well as methods for monitoring the active substance in the relevant matrices, water and air. The methods show linear response to concentration, are accurate, precise and specific. The limits of detection are below the concentration limits for the metal impurities, for hydrogen peroxide in water (PNEC in surface water 12.6 µg/L) and for hydrogen peroxide in air (European reference value 1.25 mg/m^3). Hydrogen peroxide is always directly produced as an aqueous solution and these solutions are used as biocidal products. Consequently, no analytical method for technical-grade active substance is presented. The formulations of hydrogen peroxide within the INTEROX Biocidal Product Family 1 are aqueous solutions containing a concentration of 13%, 25%, 35% or 49.9% (w/w) hydrogen peroxide. The hydrogen peroxide content in those aqueous solutions can be determined by titration with potassium permanganate under acidic conditions. The BPC Opinions for the active substance hydrogen peroxide for product type(s) 1 to 6 states that the following additional data should be generated on the active substance: • A new analytical method for the determination of hydrogen peroxide in air should be submitted. • A new analytical method for the determination of hydrogen peroxide in water should be submitted. The above methods (Study No. 510667 and Study No. 510666) have been generated and provided to the Finnish Competent Authority. Solvay Chemicals International SA has access to this data as they are part of the Hydrogen Peroxide Subgroup of CEFIC Peroxygen Sector Group. The study reports have been evaluated by eCA FI as part of the post-approval data package and approved by the BPC-22 Meeting. In the Assessment Report of the active substance hydrogen peroxide it is concluded that analytical methods are not required for monitoring the active substance in soil, since hydrogen peroxide is decomposed very rapidly, and therefore development and validation of an analytical method for this matrix is not technically feasible.

The Assessment Report concluded also that an analytical method for hydrogen peroxide in body fluids and tissues of humans or animals is not required, since the substance is not classified as toxic or highly toxic.

No residues of hydrogen peroxide are expected to be found in food and feeding stuff due to the rapid degradation of hydrogen peroxide in these matrices. Hence, no monitoring methods for these matrices are required.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Hydrogen peroxide is employed as a broad-spectrum biocide disinfectant for professional use against target organisms such as bacteria, fungi and viruses. The authorized products are applied to disinfect food packaging materials (PT 4), non-porous surfaces in industrial and institutional setting (PT 2 and PT 4) and surfaces associated with the housing of animals (PT 3).

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

Target organisms are bacteria, bacterial spores, fungi and viruses. Species to be protected are humans and animals.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Hydrogen peroxide is cytotoxic due to its capacity to generate more reactive and cytotoxic oxygen species such as the hydroxyl radical, which is a powerful oxidant, and which can initiate oxidation of biomolecules. Thus, a reduction of viability of cells is the effect on target microorganisms.

2.2.5.4 Mode of action, including time delay

The antimicrobial action of hydrogen peroxide stems from its ability to form powerful oxidants such as the hydroxyl radical and singlet oxygen. These reactive oxygen species can initate oxidation of biomolecules and cause irreversible damage to a host of cell components such as enzymes, membrane constituents, and DNA.

2.2.5.5 Efficacy data

Please see below a summary table of all the efficacy data generated for Interox product family 1.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference (IUCLID)**
Bactericidal	Surface disinfection of	INTEROX SG 12	*E. hirae,*	EN13727:2012 (0.3	Exposure time:	≥ 5 log reduction in	Interox SG 12_EN 13727

	closed spaces by aerosolised hydrogen peroxide (PT 2, use #1)	(meta SPC 1)	*S. aureus, P. aeruginosa*	g/L BSA, 20 °C)	5 min Concentration: *E. hirae* & *S. aureus*: 100, 80, 60% P. aeruginosa: 60, 40, 20%	viability of all test bacteria at "100%" (97%?); 12.5 % w/w HP in undiluted product	
Bactericidal	Surface disinfection of closed spaces by aerosolised hydrogen peroxide (PT 2, use #1)	INTEROX SG 12 (meta SPC 1)	*E. coli* *E. hirae* *S. aureus* *P. aeruginosa*	AFNOR NF T 72-281, 2014 (40-80% relative humidity, 20 °C, 50 m^3 room, steel carriers, interfering substance 0.5 % milk)	Undiluted product, nebulization time 22.35 min (S. aureus) or 15.45 min (other test bacteria), contact time after nebulization 180 min Product consumed 7.9 ml/m^3 (S. aureus), 6.6 ml/m^3 (other bacteria)	>5 log reduction of all test bacteria	INTEROX SG 12 - AFNOR – Bactericidal effectiveness
Mycobactericidal	Surface disinfection of closed spaces by aerosolised hydrogen peroxide (PT 2, use #1)	INTEROX SG 12 (meta SPC 1)	*Mycobacterium terrae* ATCC 15755, *Mycobacterium avium* ATCC 15769	AFNOR NF T 72-281, 2014 (40-80% relative humidity, 20 °C, 50 m^3 room, steel carriers, interfering substance 0.5 % milk)	Undiluted product, nebulization time 15.45 min, contact time after nebulization 180 min. Product consumed 6.6 ml/m^3 (0.82 g HP)	>5 log reduction of both test bacteria	INTEROX SG 12 - AFNOR – Mycobactericidal effectiveness

Yeasticidal / fungicidal	Surface disinfection of closed spaces by aerosolised hydrogen peroxide (PT 2, use #1)	INTEROX SG 12 (meta SPC 1)	*C. albicans, A. brasiliensis*	EN13624:2013 (0.3 g/L BSA, 20 °C)	Exposure time 15 min (*C. albicans*); 30, 60 min (*A. brasiliensis*); product concentration (w/v): 80, 70, 60, 40%	≥4 log reduction in viability at 40% (4.7 % w/w HP) 15 min *C. albicans*; 60% (7.0 w/w HP) 30 min *A. brasiliensis*	Interox SG 12_EN13624_2b-copy
Yeasticidal / fungicidal	Surface disinfection of closed spaces by aerosolised hydrogen peroxide (PT 2, use #1)	INTEROX SG 12 (meta SPC 1)	*C. albicans, A. brasiliensis*	AFNOR NF T 72-281, 2014 (40-80% relative humidity, 20 °C, 50 m^3 room, steel carriers, interfering substance 0.5 % milk)	Undiluted product, nebulization time 15.45 min, contact time after nebulization 180 min. Product consumed 5.4 ml/m^3 (0.68 g HP)	>4 log reduction of both test fungi	INTEROX SG 12 - AFNOR – Fungicidal effectiveness
Sporicidal	Surface disinfection of closed spaces by aerosolised hydrogen peroxide (PT 2, use #1)	INTEROX SG 12 (meta SPC 1)	*Bacillus subtilis*	EN13704:2002 (0.3 g/L BSA, 20 °C)	Exposure time 60 min; product concentration (w/v): 60, 40, 20 %	≥ 3 log reduction in viability at 40 % (4.7 % w/w HP)	6.7_INTEROX SG 12 - EN 13704-copy
Sporicidal	Surface disinfection of closed spaces by aerosolised hydrogen peroxide xide (PT 2, use #1)	INTEROX SG 12 (meta SPC 1)	*Bacillus subtilis* ATCC 6633	AFNOR NF T 72-281, 2014 (40-80% relative humidity, 20 °C, 50 m^3 room, steel carriers, interfering substance 0.5 % milk)	Undiluted product, nebulization time 15,45 min, contact time after nebulization 180 min. Product consumed 6.3 ml/m^3 (0.79 g HP)	>3 log reduction of spores	INTEROX SG 12 - AFNOR – Sporicidal effectiveness
Virucidal	Surface disinfection of closed spaces by aerosolised hydrogen peroxide (PT 2, use #1)	INTEROX SG 12 (meta SPC 1)	Poliovirus	EN14476:2013+A1:2015 (0.3 g/L BSA, 20 °C)	Exposure time 15 and 30 min; product concentration (v/v): 97,	≥ 4 log reduction in viability at 60% (7.3% w/w HP) in 15 min	6.7_INTEROX SG 12 – EN 14476 – poliovirus-copy

					80, 60, 40, 6%		
Virucidal	Surface disinfection of closed spaces by aerosolised hydrogen peroxide (PT 2, use #1)	INTEROX SG 12 (meta SPC 1)	Murine norovirus	EN14476:2013+A1:2015 (0.3 g/L BSA, 20 °C)	Exposure time 15 and 30 min; product concentration (v/v) 60, 40, 8%	≥ 4 log reduction in viability at 40% (4.9% w/w HP) in 30 min	6.7_INTEROX SG 12 – EN 14476 – murine norovirus copy
Virucidal	Surface disinfection of closed spaces by aerosolised hydrogen peroxide (PT 2, use #1)	INTEROX SG 12 (meta SPC 1)	Adenovirus	EN14476:2013+A1:2015 (0.3 g/L BSA, 20 °C)	Exposure time 15 and 30 min, product concentration (v/v): 97, 80, 60, 40%	≥ 4 log reduction in viability, at 97% (11.7% w/w HP) in 15 min	6.7_INTEROX SG 12 – EN 14476 – adenovirus type 5-copy
Virucidal	Surface disinfection of closed spaces by aerosolised hydrogen peroxide (PT 2, use #1)	INTEROX SG 12 (meta SPC 1)	Adenovirus type 5 and Murine norovirus (MNV, strain S99)	AFNOR NF T 72-281, 2014 (40-80% relative humidity, 20 °C, 50 m^3 room, steel carriers, interfering substance 0.03 % BSA)	Undiluted product, nebulization time 15,45 min, contact time after nebulization 180 min. Product consumed 6.5 ml/m^3 (0.81 g HP)	≥ 4 log reduction in viability of both test viruses	INTEROX SG 12 - AFNOR – virucidal effectiveness
Bactericidal	Surface disinfection of closed spaces by aerosolised hydrogen peroxide (PT 2, use #1)	INTEROX SG 35 Plus (meta SPC 2)	*E. hirae, S. aureus, P. aeruginosa*	EN 13727:2012 (0.3 g/L BSA, 20 °C)	Exposure time: 5 minutes Concentration 20%, 14%, 7% w/v (*P. aeruginosa*); 40%, 35%, 28% w/v (*S. aureus* and *E. hirae*)	≥ 5 log reduction in viability of *S. aureus* and *E. hirae* at 40 % (13 % w/w HP); *P. aeruginosa* at 14% (4.8 % w/w HP)	Interox SG 35 Plus_EN 13727
Fungicidal / yeasticidal	Surface disinfection of closed spaces by aerosolised hydrogen peroxide (PT 2, use #1)	INTEROX SG 35 Plus (meta SPC 2)	*C. albicans*; *A. brasiliensis*	EN 13624:2013 (0.3 g/L BSA, 20 °C)	Exposure time 15 min; product concentration (w/v) 50%, 42% and 28% for *A. brasiliensis*; 28%, 20% and 14% for *C. albicans*	≥ 4 log reduction in viability at 28% (9.5 w/w HP) for *A. brasilensis*; at 14 % (4.8 w/w HP) for *C. albicans*.	Interox SG 35 Plus_EN13624

Sporicidal	Surface disinfection of closed spaces by aerosolised hydrogen peroxide (PT 2, use #1)	INTEROX SG 35 Plus (meta SPC 2)	*Bacillus subtilis*	EN 13704:2002 (0.3 g/L BSA, 20 °C)	Exposure time 60 min; product concentration (w/v): 20%, 14%, 7%	≥ 3 log reduction in viability at 14% (4.8 % w/w HP)	INTEROX SG 35 Plus - EN 13704
Virucidal	Surface disinfection of closed spaces by aerosolised hydrogen peroxide (PT 2, use #1)	INTEROX SG 35 Plus (meta SPC 2)	Poliovirus type 1	EN14476:2013+A1:2015 (0.3 g/L BSA, 20 °C)	Exposure time:15 and 30 min; product concentration (v/v): 33, 21, 14, 2.1 %	≥ 4 log reduction in viability at 21 % (8.1 % w/w HP) in 15 min	Interox SG 35 Plus – EN 14476c_poliovirus
Virucidal	Surface disinfection of closed spaces by aerosolised hydrogen peroxide (PT 2, use #1)	INTEROX SG 35 Plus (meta SPC 2)	Murine norovirus	EN14476:2013+A1:2015 (0.3 g/L BSA, 20 °C)	Exposure time 15 and 30 min; product concentration (v/v): 21, 14, 3 %	≥ 4 log reduction in viability at 14% (5.4 % w/w HP) in 30 min	Interox SG 35 Plus – EN 14476c_murine norovirus
Virucidal	Surface disinfection of closed spaces by aerosolised hydrogen peroxide (PT 2, use #1)	INTEROX SG 35 Plus (meta SPC 2)	Adenovirus type 5	EN14476:2013+A1:2015 (0.3 g/L BSA, 20 °C)	Exposure time 15 and 30 min; product concentration (v/v): 33, 21, 14%	≥ 4 log reduction in viability at 33% (12.5 % w/w HP) in 15 min	Interox SG 35 Plus – EN 14476b_adenovirus type 5
Sporicidal	Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP) (PT 2, use #9)	INTEROX SG 35 Plus (meta SPC 2)	*Geobacillus stearothermophilus* ATCC 12980 in commercial biological indicators (BIs), 6.0 log CFU/BI	Simulated use test in filling isolator at 120 °C, relative humidy 100%, air speed 0.25 m/s.	HP dosed initially 280 g in seven minutes after which microbiological sampling started (t=0) and continued at one 1 min intervals for 30 min. HP dosing during sampling 9.6 g/ min. HP concentration in the chamber 800-900 ppm during sampling.	No growth in 10/10 sampled BI's when treatment time longer than 5 min	INTEROX SG 35 Plus – OEMa-cxv
Sporicidal	Surface disinfection of	INTEROX SG 35	*Geobacillus stearotherm*	Simulated use test in	Undiluted product	After treatment,	INTEROX SG 35–OEMd–kwg

	enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP) (PT 2, use #9)	(meta SPC 2)	*ophilus* ATCC 12980 in commercial biological indicators (BIs), min 6.3 log CFU / BI	SVP vial filling isolator with an integrated HP aerosolization system; operating temperature 21 °C, chamber volume 15 m^3	injected 1 g/ m^3/min (0.35 g HP) for 51 min	no growth in any of the BIs distributed in 44 locations as triplicates	
Sporicidal	Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP) (PT 2, use #9)	INTEROX SG 35 (meta SPC 2)	*Geobacillus stearotherm ophilus* ATCC 12980 in commercial biological indicators (BIs), 6.3 log CFU/BI	Simulated use test in filling isolator, operating T 120 °C, relative humidy 100%, air speed 0.25 m/s.	HP dosed initially 280 g in seven min. After this, microbiological sampling started (t=0) and continued at one 1 min intervals for 30 min. HP dosing during sampling 10 g/ min. HP concentration in the chamber was 600-800 ppm during sampling.	No growth in 10/10 sampled BI's when operating time longer than 5 min	INTEROX SG 35-OEMb-cxv
Bactericidal	Surface disinfection by liquid application in industrial and institutional areas (PT 2, use #2)	INTEROX BT 50 (meta SPC 9)	*E. coli* *E. hirae* *S. aureus* *P. aeruginosa*	BS EN1276:1997 (0.3 g/L BSA, 20 °C)	Exposure time 5 min; product concentration (v/v): 10%, 15%, 20%, 25%, 35% and 50%	≥ 5 log reduction in viability at 15.0% (8.5 % w/w HP) for all test organisms	INTEROX BT 50 – EN 1276
Bactericidal	Surface disinfection by liquid application in industrial and institutional areas (PT 2, use #2)	INTEROX BT 50 (meta SPC 9)	*E. hirae*	EN1276:2019 (0.3 g/L BSA, 20 °C)	Exposure time 5, 10, 15, 30 and 60 min; product concentration: 28.5% (w/v)	≥ 5 log reduction in viability at 28.5% (13% w/w HP) after all tested exposure times	INTEROX BT 50 - EN 1276_S32880 NEW STUDY ENR-2020-102-01

Bactericidal	Surface disinfection by liquid application in industrial and institutional areas (PT 2, use #2)	INTEROX BT 50 (same as ST 50; meta SPC 9)	*E. coli, E. hirae, S. aureus, P. aeruginosa*	BS EN13697:2001 (0.3 g/L BSA, 20 °C)	Exposure time 5 min; product concentration (v/v): 10%, 15%, and 25%	≥ 4 log reduction in viability at 15% (8.5 % w/w HP) for all test organisms	INTEROX ST50 – EN 13697a
Bactericidal	Surface disinfection by liquid application in industrial and institutional areas (PT 2, use #2)	INTEROX BT 50 (same as ST 50; meta SPC 9)	*E. coli, P. aeruginosa*	EN13697:2015 (0.3 g/L BSA, 20 °C)	Exposure time 5 min; product concentration (v/v): 25%, 20% and 15% *E. coli*, 10%, 5% and 2% *P. aeruginosa*	≥ 4 log reduction in viability. 15% *E. coli*; 10% *P. aeruginosa*; verification criteria not met for *E. coli*	INTEROX BT50 – EN 13697c
Fungicidal / yeasticidal	Surface disinfection by liquid application in industrial and institutional areas (PT 2, use #2)	INTEROX BT 50 (meta SPC 9)	*C. albicans, A. niger*	BS EN1650:1998 (0.3 g/L BSA, 20 °C)	Exposure time 15 min; product concentration (v/v): 10%, 15%, 20% and 25% *C. albicans*; 35%, 70% and 100% *A. niger*	≥4 log reduction in viability at 20% (12% w/w HP) for *C. albicans*; verification criteria not met for *A. niger*	6.7_Fungicidal activity, EN 1650: Crane E (2007e)/ key study/B5_10_02-05
Fungicidal	Surface disinfection by liquid application in industrial and institutional areas (PT 2, use #2)	INTEROX BT 50 (meta SPC 9)	*A. brasiliensis*	EN1650:2008+A1:2013 (0.3 g/L BSA, 20 °C)	Exposure time 15 min; product concentration (w/v): 50%, 30% and 20%	≥4 log reduction in viability; 20% (9.5 % w/w HP)	Interox BT 50 – EN 1650_A. brasiliensis
Fungicidal, yeasticidal	Surface disinfection by liquid application in industrial and institutional areas (PT 2, use #2)	INTEROX BT 50 (same as ST 50; meta SPC 9)	*C. albicans, A. brasiliensis*	BS EN13697:2001 (0.3 g/L BSA, 20 °C)	Exposure time 15 min; product concentration (v/v): 35%, 25% and 15% *C. albicans*; 50%, 35%, 25% *A. niger*	≥3 log reduction in viability at 15 % (8.5 % w/w HP) *C. albicans*; 25% (13,9 % w/w HP) *A. niger*	INTEROX ST50 – EN 13697a
Fungicidal, yeasticidal	Surface disinfection by liquid application in industrial and institutional areas (PT 2, use #2)	INTEROX BT 50 (same as ST 50; meta SPC 9)	*C. albicans, A. brasiliensis*	EN13697:2015 (0.3 g/L BSA, 20 °C)	Exposure time 15 min; product concentration (w/v): 15%, 10% and 5% *C. albicans*; 25%, 20%	≥ 3 log reduction in viability at 10 % (4.8 % w/w HP) *C. albicans*; 15.0 % (7.2 % w/w HP)	INTEROX ST50 – EN 13697c

					and 15% *A. brasiliensis*	*A. brasiliensis*	
Sporicidal	Surface disinfection by liquid application in industrial and institutional areas (PT 2, use #2)	INTEROX BT 50 (meta SPC 9)	*Bacillus subtilis*	EN13704:2002 (0.3 g/L BSA, 20 °C)	Exposure time: 60 min; product concentration (v/v): 20%, 15% and 10%	≥ 3 log reduction in viability at 15% (8.5 % w/w HP)	Interox BT 50 – EN 13704
Virucidal	Surface disinfection by liquid application in industrial and institutional areas (PT 2, use #2)	INTEROX BT 50 (meta SPC 9)	Poliovirus type 1	EN 14476:2013+A1 2015 (0.3 g/L BSA, 20 °C)	Exposure time 15 and 30 min; product concentration (v/v): 24, 15, 10, 1.5 %	≥ 4 log reduction in viability at 15.0% (8.5 % w/w HP) in 15 min; at 10.0% (5.7 % w/w HP) in 30 min	Interox BT 50 – EN 14476_poliovirus
Virucidal	Surface disinfection by liquid application in industrial and institutional areas (PT 2, use #2)	INTEROX BT 50 (meta SPC 9)	Murine norovirous	EN 14476:2013+A1 2015 (0.3 g/L BSA, 20 °C)	Exposure time 15 and 30 min; product concentration (v/v): 15, 10, 2 %	≥ 4 log reduction in viability at 10% (5.7 % w/w HP) in 30 min	Interox BT 50 – EN 14476_murine norovirus
Virucidal	Surface disinfection by liquid application in industrial and institutional areas (PT 2, use #2)	INTEROX BT 50 (meta SPC 9)	Adenovirus type 5	EN 14476:2013+A1 2015 (0.3 g/L BSA, 20 °C)	Exposure time 15 and 30 min; product concentration (v/v): 24, 15, 10 %	≥ 4 log reduction in viability at 24.0% (13.3 % w/w HP) in 15 min	Interox BT 50 – EN 14476_adenovirus type 5
Virucidal	Surface disinfection by liquid application in industrial and institutional areas (PT 2, use #2)	INTEROX BT 50 (meta SPC 9)	Poliovirus type 1, Adenovirus type 5	EN 14476:2013+A1 2015 (0.3 g/L BSA, 20 °C)	Exposure time 15 and 60 min; product concentration (v/v): 80, 70, 35%	≥ 4 log reduction in viability at 35.0% (19.1 % w/w HP) in 15 min	6.7_Virucidal activity, 14476: Woodall C (2007)/ key study/B5_10_02-07
Bactericidal	Disinfection of surfaces associated with animal housing by spraying (PT 3, use #3)	INTEROX BT 35 (meta SPC 8)	*Proteus vulgaris E. hirae, S. aureus, P. aeruginosa*	EN 1656:2009 (3 g/l BSA, 10 °C)	Exposure time 30 min; product concentration (w/v):14%, 7.0% and 3.0 % for *P. vulgaris*; 35%, 28% and 20% for *S. aureus* and *P.*	≥ 5 log reduction in viability at ≤ 28% (9.5 w/w HP) for all test organisms	INTEROX BT 35 – EN 1656 - P.vulgaris, E.hirae, S. aureus, P. aeruginosa

					aeruginosa; 40%, 35% and 28% for *E. hirae*		
Bacteri cidal	Disinfection of surfaces associated with animal housing by spraying (PT 3, use #3)	INTEROX BT 35 (meta SPC 8)	*P. aeruginosa, S. aureus, E. hirae, Proteus vulgaris*	EN 14349:2012 (3 g/l BSA, 10 °C)	Exposure time 30 min; product concentration (w/v): 28%, 21% and 14% for *P. vulgaris*; 35%, 28% and 21% for the other test organisms;	≥ 4 log reduction in viability at 28% (9.5 w/w HP) for all strains. Validation controls NT and NC not acceptable for *P. aeruginosa*	Interox BT 35 – EN 14349
Bacteri cidal	Disinfection of surfaces associated with animal housing by spraying (PT 3, use #3)	INTEROX BT 35 (meta SPC 8)	*P. aeruginosa*	EN 14349:2012 (3 g/l BSA, 10 °C)	Exposure time 30 min; product concentration (w/v): 35%, 28% and 21%	≥ 4 log reduction in viability at 21% (7.2 w/w HP)	INTEROX BT 35 - EN 14349 NEW study.
Fungici dal / yeastici dal	Disinfection of surfaces associated with animal housing by spraying (PT 3, use #3)	INTEROX BT 35 (meta SPC 8)	*A.brasiliensis , C. albicans*	EN 1657:2005 (3 g/l BSA, 10 °C)	Exposure time 30 and 60 min; product concentration (w/v):28%, 20% and 14% w/v	≥ 4 log reduction in viability at 20 % (6.8 % w/w HP) in 30 min for *C. albicans*; at 28% (9.5% w/w HP) in 60 min for *A. brasiliensis*	Interox BT 35 – EN 1657
Fungici dal / yeastici dal	Disinfection of surfaces associated with animal housing by spraying (PT 3, use #3)	INTEROX BT 35 (meta SPC 8)	*A. brasiliensis, C. albicans*	EN 16438:2014 (3 g/l BSA, 10 °C)	Exposure time: 30 min; product concentration (w/v): 60%, 50% and 40% for *A. brasiliensis*;42, 35 and 28% for *C. albicans*	≥ 3 log reduction in viability at 28 % (9.5 % w/w HP) for *C. albicans*: at 40 % (13.4 % w/w HP) for *A. brasiliensis*	Interox BT 35 – EN 16438
Virucid al activity	Disinfection of surfaces associated with animal housing by spraying (PT 3, use #3)	INTEROX BT 35 (meta SPC 8)	Bovine enterovirus type 1	EN 14675:2015 (3.0 g/l BSA, test at 10 °C °C)	Exposure time: 15 and 30 min; product concentration	≥ 4 log reduction in viability at 35% (13.2 % w/w HP) in 15 min	Interox BT 35 – EN 14675 – bovine enterovirus

					(v/v): 35, 15, 7.5 %		
Bactericidal	Disinfection of surfaces associated with animal housing by spraying (PT 3, use #3)	INTEROX BT 50 (meta SPC 9)	*P. aeruginosa, S. aureus, E. hirae, Proteus vulgaris*	BS EN 1656:2000 (3.0 g/l BSA, test at 10 °C)	Exposure time 30 min	≥ 5 log reduction in viability of all test organisms at 20 % (v/v) (11.2 % w/w HP), *E. hirae* dilution neutralisation control not acceptable when tested at product concentration of 70% (v/v)	6.7_Bactericidal activity, EN 1656: Crane E (2007h)/ key study/B5_10_02-09
Bactericidal	Disinfection of surfaces associated with animal housing by spraying (PT 3, use #3)	INTEROX BT 50 (meta SPC 9)	*P. aeruginosa, S. aureus, E. hirae, Proteus vulgaris*	EN 14349:2004 (3.0 g/l BSA, test at 10 °C)	Exposure time 30 min	≥ 4 log reduction in viability of all test organisms at 15 % (v/v) (8.5 % w/w HP)	6.7_Bactericidal activity, EN 14349: Crane E (2007j)/ key study/B5_10_02-11
Bactericidal	Disinfection of surfaces associated with animal housing by spraying (PT 3, use #3)	INTEROX BT 50 (meta SPC 9)	*P. aeruginosa, S. aureus, E. hirae, Proteus vulgaris*	EN 14349:2004 (10 g/l yeast extract + 10 g/l BSA, test at 10 °C)	Exposure time 30 min	≥ 4 log reduction in viability of all test organisms at 25 % (v/v) (13.9 % w/w HP)	6.7_Bactericidal activity, EN 14349: Crane E (2007k)/ key study/B5_10_02-12
Fungicidal / yeasticidal	Disinfection of surfaces associated with animal housing by spraying (PT 3, use #3)	INTEROX BT 50 (meta SPC 9)	*A. brasiliensis, C. albicans*	EN 1657:2005 (3.0 g/l BSA, test at 10 °C)	Exposure time 30 min; product concentration (v/v): 70, 50, 40, 35, 30, 25, 20%	≥ 3 log reduction in viability at 20 % (11.2 % w/w HP) for *C. albicans*: at 35 % (19.1 % w/w HP) for *A. brasiliensis*	6.7_Fungicidal activity, EN 1657: Crane E (2007i)/ key study/B5_10_02-10
sporicidal	Disinfection of food packaging material and equipment by vaporized HP (PT	INTEROX AG Spray 35S (meta SPC 5)	*Bacillus subtilis*	EN13704:2002 (0.3 g/L BSA, 20 °C)	Exposure time: 60 min, Product concentration: 20%, 14%	≥3 log reduction in viability at 14% (4.8 % w/w HP)	INTEROX AG Spray 35S_EN13704

	4, uses #4 and #5)				and 7% (w/v)		
sporicidal	Disinfection of food packaging material by vaporized HP (PT 4, use #4)	INTEROX AG Spray 35S (meta SPC 5)	*Bacillus atrophaeus* ATCC 9372	In-use test, inoculated preforms of PET bottles sterilized with vaporized product in packaging machine	Undiluted product vaporized and mixed with air resulting in product concentration 1.1% (w/w) in gas phase, gas heated to 100 °C, contact time 5,5 s	>5 log reduction in viability	Interox AG Spray 35S_OEM_a- tbv 130226_Solvay-Report_Update_07-2018
sporicidal	Disinfection of food packaging material by vaporized HP (PT 4, use #4)	33% HP solution	*Bacillus atrophaeus* (strain not specified)	In-use test, inoculated preforms of paperboard sleeves sterilized with vaporized product in packaging machine	33% HP solution vaporized and heated to 250 °C, 2.4 s contact time with preforms pre-heated to 225 °C	> 5 log reduction in viability (1.3 log reduction with water only)	INTEROX AG Spray 35S, INTEROX AG Spray 35 and INTEROX AG Dual OEM_b Information_ Peroxid_Solvay_7182018
sporicidal	Disinfection of food packaging material by immersion (PT 4, use #4)	30% (w/w) HP solution	*Bacillus subtilis* NCA 72-52	In-use test, inoculated carton preforms sterilized by immersion in packaging machine run at 15000 packages per hour	Immersion for 2.5 s in 30% HP bath heated at 80-81°C	> 5 log reduction in viability	Interox AG Bath 35, Interox AG Bath 35 S and Interox AG Dual 35_OEM_c 2018.08.30 HP efficacy report Solvay
sporicidal	Disinfection of food packaging material by immersion (PT 4, use #4)	32% HP solution	*Bacillus atrophaeus* NFL #SC-13-6 DC#1	In-use test, inoculated polystyrene cups and aluminium lids sterilized by	Immersion in 32% HP bath heated at 50 °C	> 5 log reduction in viability	INTEROX AG Bath 35S - cxv - OEM data

				immersion in packaging machine			
sporicidal	Disinfection of food packaging material by immersion (PT 4, use #4)	INTEROX AG Bath 35S (meta SPC 5)	*Bacillus subtilis* ATCC 19659, *Clostridium sporogenes* ATCC 3584	Modification of the AOAC Sporicidal method to determine efficacy of products used in aseptic filling stations	Immersion of spore-covered steel carriers to 80 °C solution; contact time 20 s; product concentration (v/v) 86% (30 % w/w HP); no soiling	All spores inactivated on 60/60 carriers (≥5.0 log CFU/carrier)	INTEROX AG Bath 35S_AOAC
Sporicidal	Disinfection of food packaging material by immersion (PT 4, use #4)	INTEROX AG Spray 25S (meta SPC 4)	*Bacillus subtilis* ATCC 19659, *Clostridium sporogenes* ATCC 3584	Modification of the AOAC Sporicidal method to determine efficacy of products used in aseptic filling stations	immersion of spore-covered carriers to 80 °C solution; contact time 20 s; product concentration (v/v) 100% (25 % w/w HP); no soiling	All spores inactivated on 60/60 carriers, acceptance criteria for carrier quantification control: ≥ 5.0 log CFU/carrier	INTEROX AG Spray 25S – AOAC-copy
sporicidal	Disinfection of food packaging equipment by vaporized HP (PT4, use #5)	33% HP solution	*Bacillus atrophaeus* (strain not specified)	In-use test, inoculated aluminium strips inserted in packaging machine which was sterilized by vaporized HP	33% HP solution vaporized, vapour mixed with air heated to 250 °C, machine treatment time 390 s	> 5 log reduction in viability (<3 log reduction with water only)	INTEROX AG Spray 35S, INTEROX AG Spray 35 and INTEROX AG Dual OEM_b Information_ Peroxid_Solvay_7 182018
sporicidal	Disinfection of food packaging equipment by vaporized HP (PT4, use #5)	32% HP solution	*Bacillus atrophaeus* NFL #SC-13-6 DC#1	In-use test, inoculated aluminium strips inserted in packaging machine which was sterilized	32% HP solution vaporized and mixed with 130 °C air, machine treatment time 400 s	> 5 log reduction in viability	INTEROX AG Bath 35S - cxv - OEM data

				by vaporized HP			
Bactericidal	Disinfection of pre-cleaned hard surfaces (PT 4, uses #6 and #7)	INTEROX FCC 35 (meta SPC 6)	*E.coli* *E. hirae,* *P. aeruginosa* *S.aureus*	EN 1276:2009 (0.3 g/L BSA, 20 °C)	Exposure time 5 min; product concentration (w/v) 28%, 20 and 14% (*E. hirae*); 20%, 14% and 7% (other organisms)	Efficacy not shown for *E. hirae*; ≥ 5 log reduction in viability at 20% for test organisms other than *E. hirae*	6.7_Bactericidal activity_Interox FCC 35_EN1276_a TRA-2016-146-01
Bactericidal	Disinfection of pre-cleaned hard surfaces (PT 4, uses #6 and #7)	INTEROX FCC 35 (meta SPC 6)	*E. hirae*	EN 1276:2009 (0.3 g/L BSA, 20 °C)	Exposure time 5 min; product concentration (w/v) 40%, 35% and 28%	Did not meet pass criteria (4.0 log reduction in viability at 40%(13.4 % w/w HP)	INTEROX FCC 35_EN1276_b
Bactericidal	Disinfection of pre-cleaned hard surfaces (PT 4, uses #6 and #7)	INTEROX FCC 35 (meta SPC 6)	*E. hirae*	EN 1276:2019 (0.3 g/L BSA, 20 °C)	Exposure time 10 min; product concentration (w/v) 40%,	Passed	ENR-2020-094-01 INTEROX FCC 35_EN1276_S33065_NEW STUDY
Bactericidal	Disinfection of pre-cleaned hard surfaces (PT 4, uses #6 and #7)	INTEROX FCC 35 (meta SPC 6)	*E. coli,* *E. hirae,* *P. aeruginosa,* *S. aureus*	EN 13697:2015 (soiling 8.5 g /l skimmed milk for *P. aeruginosa* and 0.3 g/L BSA for others; 20-23 °C;)	Exposure time 5 min; product concentartion (w/v): 35%, 25% and 20% against *E. coli*: 14%, 7% and 3% against *P. aeruginosa*; 28%, 20% and 14% against *S. aureus* and 35%, 28% and 20% against *E. hirae*	≥ 4 log reduction in viability at ≤ 28% (9.5 % w/w HP) for all test organisms	INTEROX FCC 35 – EN 13697
Fungicidal	Disinfection of pre-cleaned hard surfaces (PT 4, uses #6 and #7)	INTEROX FCC 35 (meta SPC 6)	*A. brasiliensis,* *C. albicans*	EN 1650:2008 + A1:2013 (0.3 g/L BSA, 20 °C)	Exposure time 15 min; product concentration (w/v): 28; 20 and 14 % for *C.*	≥ 4 log reduction in viability at 14 % (4.8 % w/w HP) for *C. albicans*; at	6.7_Fungicidal activity_INTEROX fcc 35/INTEROX DW 35 – EN 1650

					albicans 50%, 42% and 28% for *A. brasiliensis*	28 % (9.8 % w/w HP) for *A. brasiliensis*	
Fungicidal; yeasticidal	Disinfection of pre-cleaned hard surfaces (PT 4, uses #6 and #7)	INTEROX FCC 35 (meta SPC 6)	*C. albicans, A. brasiliensis*	EN 13697:2015 (0.3 g/L BSA; 21-22 °C)	Exposure time15 min; product concentration (w/v): 35%, 28% and 20% against *A. brasiliensis*; 20%, 14% and 7% against *C. albicans*	≥ 3 log reduction in viability at 14 % (4.8 % w/w HP) for *C. albicans*; 20 % (6.8 % w/w HP) for *A. brasilisensis*	INTEROX FCC 35 - EN 13697-New study
Sporicidal	Disinfection of pre-cleaned hard surfaces (PT 4, uses #6 and #7)	INTEROX FCC 35 (meta SPC 6)	*Bacillus subtilis*	EN 13704:2002 (0.3 g/L BSA, 20 °C)	Exposure time 60 min; product concentration (w/v): 20%, 14% and 7%	≥ 3 log reduction in viability at 14% (4.8% w/w HP)	INTEROX FCC 35/INTEROX DW 35 - EN 13704
Virucidal	Disinfection of pre-cleaned hard surfaces (PT 4, uses #6 and #7)	INTEROX FCC 35 (meta SPC 6)	Poliovirus type 1	EN 14476:2013 + A1:2015 (0.3 g/L BSA, 20 °C)	Exposure time 15 and 30 min; product concentration (v/v): 2.1, 14, 21, 33%	≥ 4 log reduction at 21% (8.1% w/w HP) in 15 min	INTEROX FCC 35-EN 14476_poliovirus
Virucidal	Disinfection of pre-cleaned hard surfaces (PT 4, uses #6 and #7)	INTEROX FCC 35 (meta SPC 6)	Murine norovirus	EN 14476:2013 + A1:2015 (0.3 g/L BSA, 20 °C)	Exposure time: 15 and 30 min; product concentration (v/v): 21, 14, 3 %	≥ 4 log reduction at 21% (8.1% w/w HP) in 30 min	6.7_INTEROX FCC 35-EN 14476_murine norovirus
Virucidal	Disinfection of pre-cleaned hard surfaces (PT 4, uses #6 and #7)	INTEROX FCC 35 (meta SPC 6)	Adenovirus type 5	EN 14476:2013 + A1:2015 (0.3 g/L BSA, 20 °C)	Exposure time 15 and 30 min: product concentration (v/v): 14, 21, 33%	≥ 4 log reduction at 33% (12.5% w/w HP) in 15 min	INTEROX FCC 35-EN 14476 adenovirus type 5
Bactericidal	Disinfection of pre-cleaned hard surfaces (PT 4, uses #6 and #7)	INTEROX AG Spray 25S (meta SPC 4)	*E. coli* *E. hirae* *S. aureus* *P. aeruginosa*	EN1276:2009 (0.3 g/L BSA, 20 °C)	Exposure time 5 min; product concentration (w/v): *E. coli, P. aeruginosa*: 30, 20, 10%;	≥ 5 log reduction in viability at 50% (12% w/w HP)	Interox-AG_Spray_25S_EN_1276_b-copy

					E. hirae: 60, 50, 40%; *S. aureus*: 40, 30, 20%		
Fungicidal	Disinfection of pre-cleaned hard surfaces (PT 4, uses #6 and #7)	INTEROX AG Spray 25S (meta SPC 4)	*A. brasiliensis, C. albicans*	EN 1650:2008 + A1:2013 (0.3 g/L BSA, 20 °C)	Exposure time 15 min; product concentration (w/v): 70%, 60% and 40% for *A. brasiliensis*; 40%, 30% and 20% for *C. albicans*	≥ 4 log reduction in viability at 20 % (4.9 % w/w HP) for *C. albicans*; at 40 % (9.7 % w/w HP) for *A. brasiliensis*	6.7_Fungicidal activity_INTEROX AG Spray 25S – EN 1650
Sporicidal	Disinfection of food packaging material by vaporized HP (PT 4, use #4)	INTEROX AG Spray 25S (meta SPC 4)	*Bacillus subtilis*	EN 13704:2002 (0.3 g/L BSA, 20 °C)	Exposure time 60 min; product concentration (w/v): 30, 20, 10%	≥ 3 log reduction in viability at 20% (4.9 % w/w HP)	6.7_ Sporicidal activity_Interox AG Spray 25S_EN13704
Sporicidal	Disinfection of food packaging material by vaporized HP (PT 4, use #4)	INTEROX AG Spray 25S (meta SPC 4)	*Bacillus atrophaeus* ATCC 9372 spores	In-use test, inoculated preforms of PET bottles sterilized with vaporized product in a packaging machine with on output of 12480 bottles per hour.	Undiluted product vaporized 400 g /h at 130 °C and mixed with air flowing at 40 L/min using a preform sterilization system.	> 5 log reduction in viability	INTEROX AG Spray 25S-OEM – zbe-copy

Conclusion on the efficacy of the product

Efficacy evaluation of majority of products is based on read-across. General justification for read-across is provided by the applicant in the document "Testing Justification phys-chem and stability BPF 1 240117" and the embedded document "efficacy-summary_BPF1_22.02.2017.docx". A separate document "Read_across_Justification_for_Interox_AG_grades_-_240918_b.docx d" was provided to justify read across of results for products belonging to meta 5. The documents are under the section 13 of the IUCLID dossier.

The opinion of the eCA is that the co-formulants listed in the composition of the BPF (see the table in the beginning of the confidential Annex) do not contribute to efficacy in maximum concentrations allowed for the BPF. Therefore, the concentration of hydrogen peroxide was

the only specification in the composition that was considered for the read-across of the efficacy tests.

A short summary of the documents is provided in the confidential annex of the PAR section 3.6.8.
Based on these documents and the composition of the products, the eCA considers that read across can be justified based on HP concentration only.

The following efficacy data is available to support
PT 2, use #1. Surface disinfection of closed spaces by aerosolised hydrogen peroxide; meta SPCs 1, 2 and 3
PT 2, use #9 Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP); meta SPCs 2 and 3

INTEROX SG 12:
Meta SPC 1

Bactericidal – undiluted product
- EN 13727:2012; the test report claims that undiluted product was tested which is not possible according to the standard. However, because the "100%" test solution was in fact diluted and passed the test, the undiluted product should pass too.
- AFNOR NF T 72-281, 2014
  - The test was passed when 7.9 ml of product (1.0 g HP) was aerosolized per m^3 of room volume followed by 180 min contact time
- eCA: the claim was supported for the authorized use #1

Mycobactericidal – undiluted product
- No phase 2 step 1 suspension test was provided to support the claim
- AFNOR NF T 72-281, 2014
  - The test was passed when 6.6 ml of product (0.82 g HP) was aerosolized per m^3 of room volume followed by 180 min contact time
- eCA: the claim was not supported because no phase 2 step 1 suspension test was provided

Yeasticidal, fungicidal - undiluted product
- EN 13624:2013
- AFNOR NF T 72-281, 2014
  - The test was passed when 5.4 ml of product (0.68 g HP) was aerosolized per m^3 of room volume followed by 180 min contact time
- eCA: the claim was supported for the authorized use #1

Sporicidal – undiluted product
- EN 13704:2002
- AFNOR NF T 72-281, 2014
  - The test was passed when 6.3 ml of product (0.79 g HP) was aerosolized per m^3 of room volume followed by 180 min contact time
- eCA: the claim was supported for the authorized use #1

Virucidal – undiluted product
- EN 14476:2013+A1:2015 (poliovirus, murine norovirus, adenovirus)
- AFNOR NF T 72-281, 2014 (murine norovirus, adenovirus type 5)
  - The test viruses are those specified in the test to support virucidal claim for PT 2 use

- The test was passed when 6.5 ml of product (0.81 g HP) was aerosolized per m^3 of room volume followed by 180 min contact time
- eCA: the claim was supported for the authorized use #1

INTEROX SG 35
Meta SPC 2

Sporicidal – undiluted product
- EN 13704: read across of INTEROX SG 35 PLUS test
- eCA: the claim was supported for the authorized use #1

Bactericidal, yeasticidal, fungicidal, virucidal – undiluted product
- no tests provided, read across of INTEROX SG 35 PLUS and INTEROX SG 12 tests with lower or the same HP concentration.

INTEROX SG 35 PLUS:
Meta SPC 2
Read across of INTEROX SG 12 AFNOR tests with AS concentration lower than that of INTEROX SG 35 PLUS
In addition:
Bactericidal – undiluted product
- EN 13727:2012
- eCA: the claim was supported for the authorized use #1

Yeasticidal – undiluted product
- EN 13624:2013
- eCA: the claim was supported for the authorized use #1

Fungicidal – undiluted product
- EN 13624:2013
- eCA: the claim was supported for the authorized use #1

Sporicidal - undiluted product
- EN 13704:2002
- eCA: the claim was supported for the authorized use #1

Virucidal – undiluted product
- EN 14476:2013+A1:2015 (poliovirus, murine norovirus, adenovirus)
- eCA: the claim was supported for the authorized use #1

INTEROX SG 50, INTEROX SG 50 plus
Meta SPC 3
No tests of these products were provided to support use #1. The eCA considers bactericidal, yeasticidal, fungicidal, sporicidal and virucidal claims for the undiluted product to be supported by read across of INTEROX SG 12, INTEROX SG 35 and INTEROX SG 35 PLUS tests with lower HP concentration.

In addition to the tests listed above, the following efficacy data is available to support **PT 2, use #9 Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP)**
meta SPCs 2 and 3

INTEROX SG 35
Meta SPC 2

Sporicidal – undiluted product
- Simulated use tests in filling isolators

- INTEROX SG 35-OEMb-Cxv
  - Vaporisation of HP
  - The test report does not specify chamber volume meaning that dose per m^3 cannot be calculated. 330 g of HP was consumed after 5 min sampling time corresponding to 12 minutes after initation of HP dosing
    - The eCA assumed that the dosing rate in the test was as it is written in the test report and the quantities refer to "amount H2O2" and not to amount of product
  - The test report does not specify whether the reported 600-800 ppm refers to volume or weight concentration. Typically, ppm refers to volume in gas phase.
- INTEROX SG 35–OEMd–kwg
  - HP aerosolized 0.35 g/m^3/min for 51 min (18 g HP/m^3/treatment)
  - chamber volume 15 m^3 (supports 15 m^3 lower end for the allowed volume range for room size)
- eCA: the claim was supported for the authorized use # 9

INTEROX SG 35 PLUS:
Meta SPC 2
Sporicidal - undiluted product

- Simulated use test in filling isolator - INTEROX SG 35 Plus – OEMa-cxv
  - Vaporisation of HP
  - The test report does not specify chamber volume meaning that dose per m^3 cannot be calculated. 330 g HP consumed after 5 min sampling time (12 minutes after initation of HP dosing)
  - The eCA assumed that the dosing rate in the test was as it is written in the test report and the quantities refer to "amount H2O2" and not to amount of product
  - The test report does not specify whether 800-900 ppm refers to volume or weight concentration. Typically, ppm refers to volume in gas phase.
- eCA: the claim was supported for the authorized use # 9

The following efficacy data is available to support
PT 2, use #2. Surface disinfection by liquid application in industrial and institutional areas
meta SPCs 8 and 9

INTEROX BT 35:
Meta SPC 8
No product specific tests were provided to support use # 2. Read across of INTEROX BT 50 results. Only the effective product concentrations (w/v) are given below for Interox BT 35. The other parameters are identical to those of Interox BT 50.

Bactericidal – 39% (w/v) product concentration (13% w/w HP)
Yeasticidal – 14% (w/v) product concentration (4.8% w/w HP)
Fungicidal - 28% (w/v) product concentration (9.5% w/w HP)
Sporicidal – 25% (w/v) product concentration (8.5% w/w HP)
Virucidal – 39% (w/v) product concentration (13% w/w HP)

INTEROX BT 50
Meta SPC 9
Same product as INTEROX ST 50 specified as the tested substance in some of the reports
Bactericidal – effective product concentration (w/v) 28.5% (13% w/w HP), 10 min contact time at 20 °C, clean conditions

- EN 1276:1997, EN 1276:2019, EN 13697:2001

- The EN 1276:1997 test provided was conducted according to a standard that was replaced by a newer version for more than two years before the application was filed
  - EN 1276:2019 test with E. hirae (shown to be the test strain most resistant against HP in all EN 1276 tests provided),
  - read across of Interox-AG_Spray_25S_EN_1276_b-copy, effective concentration 12% w/w HP
- EN 13697:2001 (INTEROX ST50 – EN 13697a) was considered acceptable by the eCA despite the currently outdated method
  - The subsequent version of the method, EN13697:2015, was published by CEN less than two years before filing of the application on 25th January 2017.
- eCA: the claim was supported for the authorized use #2

Yeasticidal – effective product concentration (w/v) 14% (4.8% w/w HP), 15 min contact time at 20 °C, clean conditions

- EN 1650:1998 (12% w/w HP was required for pass), EN 13697:2001 (8.5% w/w HP was required to pass), EN 13697:2015 (4.8% HP was required to pass)
- The EN 1650:1998 was replaced by newer version for more than two years before the filing of the application
  - Read across of "6.7_Fungicidal activity_INTEROX AG Spray 25S – EN 1650" EN 1650:2008 + A1:2013 (4.8% w/w HP was required to pass in 15 min)
- eCA: the claim was supported for the authorized use #2

Fungicidal - effective product concentration (v/v) 17% (9.5% w/w HP), 15 min contact time at 20 °C, clean conditions

- EN 1650:1998, EN 1650:2008 + A1:2013, EN 13697:2001, EN13697:2015
- Activity against *A. brasiliensis* was shown at 9.5% w/w HP.
- eCA: the claim was supported for the authorized use #2

Sporicidal – effective product concentration (v/v) 15% (8.5% w/w HP), 60 min contact time at 20 °C, clean conditions

- EN 13704:2002
- eCA: the claim was supported for the authorized use #2

Virucidal – effective product concentration (v/v) 24% (13% w/w HP), 30 min contact time at 20 °C, clean conditions

- EN 14476:2013 + A1:2015 (poliovirus, murine norovirus, adenovirus)
- eCA: the claim was supported for the authorized use #2

The following efficacy data is available to support

PT 3, use #3. Disinfection of surfaces associated with animal housing by spraying meta SPCs 8 and 9

INTEROX BT 35:

Meta SPC 8

Bactericidal - effective product concentration (w/v) 28% (9.5% w/w HP), 30 min contact time at 10 °C, low soiling

- EN 1656:2009; EN 14349:2012
- eCA: the claim was supported for the authorized use #3

Yeasticidal – effective product concentration (w/v) 28% (9.5% w/w HP), 30 min contact time at 10 °C, low soiling

- EN 1657:2005, EN 16438:2014
- eCA: the claim was supported for the authorized use #3

Fungicidal – effective product concentration (w/v) 40% (13% w/w HP), 60 min contact time at 10 °C, low soiling

- EN 1657:2005, EN 16438:2014
- eCA: 60 min is acceptable contact time because it has been defined as additional test condition in EN 1657:2005 and obligatory in EN 16438:2014
- eCA: the claim was supported for the authorized use #3

Virucidal - effective product concentration (v/v) 35% (13% w/w HP), 15 min contact time, 10 °C, low soiling
- EN 14675:2015
- eCA: the claim was supported for the authorized use #3

INTEROX BT 50:
Same product as INTEROX ST 50 specified as the test substance in some of the reports.
Meta SPC 9
Bactericidal - effective product concentration (v/v) 20 % (11% w/w HP), 30 min contact time, 10 °C, low soiling
- EN 1656:2000
  - The standard was replaced by a newer version for more than two years before the application was filed
  - Dilution-neutralisation control not acceptable for *E. hirae* (C = 0.22 x B, requirement at least 0.5 x B), when tested at product concentration 70% (v/v). This was considered acceptable deviation considering that only 20% (v/v) product was required to pass.
- EN 14349:2004
  - The standard was replaced by a newer version for more than two years before the application was filed
- The claim was supported by read across of INTEROX BT 35 results supporting use #3
- eCA: the claim was supported for the authorized use #3

Yeasticidal, fungicidal, virucidal – no tests of INTEROX BT 50 were provided to support use #3. According to eCA, the following claims were supported for the authorized use #3 by read across of INTEROX BT 35 results
Yeasticidal – effective product concentration (v/v) 17% (9.5 % w/w HP)
Fungicidal – effective product concentration (v/v) 24% (13 % w/w HP)
Virucidal - effective product concentration (v/v) 24% (13 % w/w HP)

The following efficacy data is available to support
PT 4, use #4. Disinfection of food packaging material (aseptic packaging) by immersion or aerosolised or vaporised hydrogen peroxide (VHP)
meta SPC 5
A document "Read_across_Justification_for_Interox_AG_grades_-_240918_b.docx d" was provided by the applicant to justify read across of results for products belonging to meta SPC 5.

INTEROX AG SPRAY 35S
Meta SPC 5
Sporicidal - undiluted product

- EN 13704:2002
- disinfection by vaporized HP
  - in use test "130226_Solvay-Report_Update_07-2018" with INTEROX AG SPRAY 35S at 1.1% (w/w) in gas phase, vapor heated to 100 °C, contact time 5.5 s, material polyethylene terephthalate
  - in use test "Information_Peroxid_Solvay_7182018" vapor heated to 250 °C, contact time 2.4 s, material paperboard, 33% HP solution tested (not Solvay product)
  - read across of in use test of INTEROX AG SPRAY 25S (use #8)
- disinfection by immersion
  - immersion for 2.5 s in 30% HP solution heated to 80 °C, packaging material carton; Solvay product was not tested (2018.08.30 HP efficacy report Solvay)

- immersion for unspecified time in 32% HP solution heated to 50 °C, packaging material polystyrene; Solvay product was not tested (2015-04-09 Report Cxv TFA validation NFL)
- read across of modified AOAC tests of INTEROX AG Bath 35S and INTEROX AG SPRAY 25S

- INTEROX AG SPRAY 35S was used only in one of the four in-use tests provided to support the use #4. From 30% to 33% HP solutions were used in the other tests. Other specifications for these solutions were not provided. The in-use tests were conducted by packaging machine manufacturers. The test reports were supplemented with documents stating the applicability of the meta SPC 5 products (including Interox AG Spray 35S) for use with the machine. The applicant provided also a document Read_across_Justification_for_Interox_AG_grades_-_240918_b for justification of read across within meta SPCs 4 and 5 and document "Solvay BPF1-Meta SPC 4 and 5 statement.docx" to justify the testing approach. Both of these documents can be found in section 13 of the IUCLID dossier. The eCA considered that efficacy in use #4 was shown. This view was based on 1) the test with with INTEROX AG SPRAY 35S; 2) read across of in use test of INTEROX AG SPRAY 25S 3) similar or lower HP concentrations in the unknown test solutions in comparison to INTEROX AG SPRAY 35S and 4) the presumed experience gained from different HP products by the machine manufactures.
- Except for one test, the in-use tests did not include a control tests showing inactivation of spores caused by temperature treatment without biocide, despite the high temperatures used in the tests. The results of the one test (sections 2.2.2.1 and 2.3.3.2 in the test report "Information_Peroxid_Solvay_718201",) were considered sufficient to show that heat treatment with 250 °C water vapor for 2.4 s or 390 s had a minor effect on reduction levels of *B. athrophaeus* (strain not specified) spores in comparison to effect of HP.
- eCA: the claim was supported for the authorized use #4

INTEROX AG Spray 35, INTEROX AG Bath 35, INTEROX AG Bath 35S, INTEROX AG Dual 35
Meta SPC 5
Sporicidal – undiluted product

- modified AOAC test with inoculated steel cylinders immersed in 80 °C HP solution (86% INTEROX AG Bath 35S, 30% w/w HP) for 20 s
  - the test was considered as supportive evidence of efficacy of products with ≥30% HP in immersion use.
- read across of INTEROX AG Spray 35S results
- eCA: the claim was supported for the authorized use #4

The following efficacy data is available to support
PT 4, use #5, Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP)
meta SPC 5
A document "Read_across_Justification_for_Interox_AG_grades_-_240918_b.docx d" was provided to justify read across of results for products belonging to meta SPC 5.

INTEROX AG SPRAY 35S
Meta SPC 5
Sporicidal – undiluted product

- EN 13704:2002 effective product concentration (w/v) 14% (4.8% w/w HP) 60 min contact time at 20 °C, clean conditions
- two in-use tests demonstrating disinfection of packaging machine by vaporized 32%-33% HP solution that was not defined in the test report.
  1. 33% HP solution vaporized, vapour mixed with air heated to 250 °C, machine treatment time 390 s

2. 32% HP solution vaporized and mixed with 130 °C air, machine treatment time 400 s

- reports describing in-use testing of INTEROX AG SPRAY 35S or other Solvay products were not provided specifically for use #5.
- The eCA considers that the in use tests of INTEROX AG SPRAY 25S (use #8) and INTEROX AG SPRAY 35S (use #4) demonstrating efficacy of packaging material disinfection by vapor support also use #5.
- The eCA considers that the simulated use #1 tests of INTEROX SG 12, INTEROX SG 35 and INTEROX SG 35 PLUS demonstrate efficacy also for use #5
  - aerosolization as on application for use #5 relies on read-across of use #1 tests (the other tests used vaporization)
- The results of the one test (test report "Information_Peroxid_Solvay_718201", sections 2.2.2.1 and 2.3.3.2) were considered sufficient to show that heat treatment with 250 °C water vapor for 2.4 s or 390 s had a minor effect on reduction levels of *B. athrophaeus* (strain not specified) spores in comparison to effect of HP.
- eCA: the claim was supported for the authorized use #5

INTEROX AG Spray 35, INTEROX AG Bath 35, INTEROX AG Bath 35S, INTEROX AG Dual 35
Meta SPC 5
Sporicidal – undiluted product

- read across of INTEROX AG Spray 35S (uses #4 and #5) and INTEROX AG SPRAY 25S (use #8) tests
- eCA: the claim was supported for the authorized use #5

The following efficacy data is available to support
PT 4, use #6, Disinfection of distribution and storage systems for drinking water
PT 4, use #7, Surface disinfection in food and feed processing by liquid application
meta SPCs 6 and 7

INTEROX FCC 35:
Meta SPC 6
Bactericidal – effective product concentration 40% w/v, (13% w/w HP) 10 min contact time at 20 °C, clean conditions

- EN 1276:2009 for test organisms other than *E. hirae*; EN 1276:2019 for *E. hirae*
- INTEROX FCC 35 passed EN 13697 at 9.5% w/w HP (test required for use #7 only)
- eCA: the claim was supported for the authorized uses #6 and #7

Yeasticidal – effective product concentration (w/v) 14% (4.8% w/w HP) 15 min contact time at 20 °C, clean conditions

- EN 1650:2008 + A1:2013
- EN 13697:2015 (required for use #7 only)
- eCA: the claim was supported for the authorized uses #6 and #7

Fungicidal – effective product concentration (w/v) 28% (9.5% w/w HP) 15 min contact time at 20 °C, clean conditions

- EN 1650:2008 + A1:2013
- EN 13697:2015 (required for use #7 only)
- eCA: the claim was supported for the authorized uses #6 and #7

Sporicidal - effective product concentration (w/v) 25% (8.5% w/w HP) 60 min contact time at 20 °C, clean conditions

- EN 13704:2002
- eCA: the claim was supported for the authorized uses #6 and #7

Virucidal – effective product concentration (v/v) 33% (13% w/w HP) 30 min contact time at 20 °C, clean conditions

- EN 14476:2013 + A1:2015 (poliovirus, murine norovirus, adenovirus)
- eCA: the claim was supported for the authorized uses #6 and #7

INTEROX FCC 50:
Meta SPC 7
No valid tests provided. According to eCA, the following claims were supported for the authorized uses #6 and #7 by read across of INTEROX FCC 35 results
Bactericidal – effective product concentration (v/v) 23%, (13% w/w HP)
Yeasticidal – effective product concentration (v/v) 8.3% (4.8% w/w HP)
Fungicidal – effective product concentration (v/v) 17% (9.5% w/w HP)
Sporicidal - effective product concentration (v/v) 15% (8.5% w/w HP)
Virucidal – effective product concentration (v/v) 23% (13% w/w HP)

The following efficacy data is available to support
PT 4, use #8 – Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP)
meta SPC 4

INTEROX AG SPRAY 25S
Meta SPC 4
Sporicidal - undiluted product

- EN 13704:2002
- One simulated use test: disinfection of packaging material (PET) with undiluted product vaporized at 130 °C
  - INTEROX AG Spray 25S-OEM – zbe-copy
- eCA: the claim was supported for the authorized use #8

2.2.5.6 Occurrence of resistance and resistance management

Hydrogen peroxide (H2O2) is capable of damaging nearly every biological macromolecule as it generates reactive oxidative species (hydroxyl radicals and oxygen singlet) which can attack DNA as well as causing damage to enzymes and membrane constituents. However, the lethal effects of these oxidative species can be avoided with any damage being repaired in microorganisms such as Escherichia coli and Salmonella typhimurium.
When E.coli and S.typhimurium are exposed to low concentrations of H2O2, 3 µM and 60 µM respectively, cells produce enzymes and other proteins which are important for cellular defence and mitigate the toxic effects of the oxidative species. This adaptive response is triggered by nontoxic levels of the oxidative species to protect against and produce resistance to oxidative stress caused when challenged with higher concentrations, 10 mM (Dukan and Touati (1996), Christman et al (1985)).

The resistance to oxidative stress that E.coli develops when exposed to H202, as reported in literature papers, demonstrates an adaptive response only. There are two major temporal classes of hydrogen peroxide-inducible proteins, "early" and "late" proteins. The "early" proteins are those for which synthesis is maximal during the first 10 minutes of exposure and the "late" proteins which are synthesized at a maximal rate starting 10- 30 minutes after H202 addition. Synthesis of the "early" and "late proteins return to normal with 30 minutes 60 minutes, respectively (Christman et al (1985)). This suggests that the adaptive responses are transient rather than permanent. Therefore, resistance, as described in TNsG on Annex I inclusion (April 2002), as a genetically inherited characteristic has not been demonstrated.

Nakamura et al (2012) reported that a novel disinfection method whereby hydroxyl radicals were artificially generated by photolysis of H2O2 had recently been developed. Hydroxyl radicals that had been generated by laser irradiation of hydrogen peroxide were found to kill pathogens of oral infectious diseases. Laser irradiation of bacterial suspensions in 1M H2O2 resulted in a >99.99 % reduction in the

number of bacteria within 3 minutes. However, the sensitivity of the bacteria to this disinfection system varied somewhat according to the species.

Staphulococcus. aureus and Candida albicans are frequently detected in the oral cavity and sometimes cause serious infectious diseases. 250mM H2O2 was found to hardly kill any microorganisms. However, this was believed to be too low a concentration to exert a fungicidal and bactericidal effect because 3 % H2O2, corresponding to approximately 890 mM, is the standard concentration used in disinfection. Furthermore, besides having strong bactericidal and fungicidal effects, disinfection by reactive oxygen species (ROS), such as hydroxyl radicals, probably would not lead to development of bacterial and fungal resistance to these agents because they interact directly with several cell structures and different metabolic pathways. In particular, hydroxyl radicals and singlet oxygen are thought to be free from induction of resistance because no defence mechanisms against these ROS have been reported in living cells (Nakamura et al (2012)).

In addition to the findings of Nakamura et al (2012), the target organisms of biocidal products registered under product type 1, 2, 3 and 6 are Escherichia coli, Staphulococcus. Aureus and Candida albicans. Hydrogen Peroxide has been intensively used as a disinfectant and preservative for more than 3 decades and has not lead to the development of significant resistance levels among field populations. Therefore, genetically inherited resistance is not expected when the product is used as recommended.

2.2.5.7 Known limitations

The products should be used in accordance with the instructions for use, as shown on the product label.
The products within the INTEROX Product Family 1 are not intended or marketed to be used in conjunction with other substances, mixtures or biocidal or non-biocidal products.

For the products in Meta SPC's 1, 2 and 3, the device instructions must be followed in order to achieve efficacy. The device instructions will include time of application, dose, relative humidity and temperature.

For use 2 (surface disinfection by liquid application in industrial and institutional areas) and use 6 (disinfection of distribution and storage systems for drinking water), to achieve efficacy ensure surfaces remain wet for specified contact time

For the asceptic packaging uses (uses 4, 5 and 8), the use of cold hydrogen peroxide is not efficacious, therefore temperatures above 80°C should be used. The individual machine instructions should be followed regarding disinfection period.

2.2.5.8 Evaluation of the label claims

The label claims that are in accordance with the authorized uses and instructions for use in the SPC are acceptable and supported by efficacy data.

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

The products within the Interox product family are not intended or marketed to be used in conjunction with other substances, mixtures or biocidal or non-biocidal products.

2.2.6 Risk assessment for human health

The INTEROX Biocidal Product Family 1 consists of 15 products, divided into 9 meta-SPCs based on the hazard classification of the products. No new toxicological information is provided for the evaluation on human health hazards of these products. Effects on human health are derived from the data in the CAR (PTs 1-6, 2015) for the active substance and representative products, and from information on the individual components, see chapter 2.2.6.1. Since no substance of concern has been identified, the human health risk assessment for these products are based on the active substance, hydrogen peroxide.

For human health exposure and risk assessment the intended uses of products are basically same as assessed in the CAR with modifications in e.g. type of applications, in-use concentrations and exposure modelling, see chapter 2.2.6.2.

Based on the CAR, the adverse effects of the active substance hydrogen peroxide in humans are mainly local effects at the site of first contact. In the absence of clear systemic adverse effects, the risk characterisation in chapter 2.2.6.3 will focus on local effects, and systemic exposure is not assessed. Only the inhalation route of exposure will be addressed in a quantitative risk assessment. The hydrogen peroxide airborne exposure concentration will be compared with the value 1.25 mg/m^3 derived in the CAR for inhalation (acceptable exposure concentration, AEC). Dermal and oral exposure will be addressed in a qualitative local risk assessment. Oral exposure of professionals in these uses is not considered relevant.

2.2.6.1 Assessment of effects on Human Health

For the human health effects assessment, no new information has been provided on the products of this hydrogen peroxide based biocidal product family. The applicant Solvay (member of CEFIC's Hydrogen peroxide sub-group of the Peroxygens Sector Group) has referred to the toxicological studies in the CAR as the representative products in the CAR are similar to products in this BPF. Applicant's texts in IUCLID format regarding these toxicological studies from the CAR have not been checked by the eCA.

All toxicological endpoints are assessed on the basis of the properties of the individual component of the concerned biocidal product. The classification is made based on the respective properties of the active substance and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).

A summary table on the products with hydrogen peroxide content in different meta-SPCs is given below. In addition to the active substance and water, the products contain only stabilisers (see the confidential annex for the exact composition and the classification of stabilisers). Although these stabilisers are classified for irritating properties, they are present in the products in such minor amounts that they do not trigger classification and are not substance of concern. **Therefore, the classification of the products according to CLP mixture rules is solely based on the concentration of hydrogen peroxide and its classification.**

Meta-SPC	Product name	Hydrogen peroxide (%)	
		Min	Max
1	INTEROX SG 12	13.0	13.5
2	INTEROX SG 35, INTEROX SG 35 PLUS	35.0	35.7
3	INTEROX SG 50, INTEROX SG 50 PLUS	49.0	49.9

Meta-SPC	Product name	Hydrogen peroxide (%)	
		Min	Max
4	INTEROX AG Spray 25S	25	25.7
5	INTEROX AG Spray 35, INTEROX AG Spray 35S, INTEROX AG Bath 35, INTEROX AG Bath 35S, INTEROX AG Dual 35	35.0	35.7
6	INTEROX FCC 35	35.0	35.7
7	INTEROX FCC 50	49.0	49.9
8	INTEROX BT 35	35.0	35.7
9	INTEROX BT 50	49.0	49.9

Skin corrosion and irritation

No specific studies on skin irritation are available for the products. Conclusion is based on pH values of the products and hydrogen peroxide data as other components are present in minor amounts not affecting the classification.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	No classification for products in meta-SPCs 1 and 4. Products in meta-SPCs 2, 5, 6, 8 are skin irritating. Products in meta-SPCs 3, 7, 9 are corrosive.
Justification for the value/conclusion	Hydrogen peroxide causes burns. The irritating property of hydrogen peroxide to the skin varies with its concentration. Specific concentration limits for hydrogen peroxide: Skin Corr. 1A; H314: C ≥ 70 % Skin Corr. 1B; H314: 50 % ≤ C < 70 % Skin Irrit. 2; H315: 35 % ≤ C < 50 % pH values for meta-SPCs 1, 2, 4, 5, 6, 8 > 2 pH values for meta-SPCs 3, 7, 9 ≤ 2 As the products in meta-SPCs 1 and 4 have pH values > 2 and the hydrogen peroxide concentrations are < 35 % no classification is triggered for skin irritation. As the products in meta-SPCs 2, 5, 6 and 8 have pH values > 2 and the hydrogen peroxide concentrations are ≥ 35 % but < 50 %, it triggers classification for skin irritation. As the products in meta-SPCs 3, 7 and 9 have pH values ≤ 2, it triggers classification for skin corrosive although the hydrogen peroxide concentrations are just below the SCL of 50 %. The skin irritation studies referred in the CAR (and for the harmonised classification) are also included in IUCLID of this INTEROX BPF1. In those studies a product containing 49.2 % hydrogen peroxide was tested with one animal causing ulceration and necrosis.

Classification of the products according to CLP	Products in meta-SPCs 1, 4: No classification Products in meta-SPCs 2, 5, 6, 8: Skin Irrit. 2; H315: Causes skin irritation. Products in meta-SPCs 3, 7, 9: Skin Corr. 1; H314: Causes severe skin burns and eye damage.

Eye irritation

No specific studies on eye irritation are available for the products. Conclusion is based on hydrogen peroxide data as other components are present in minor amounts not affecting the classification.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Corrosive to eyes.
Justification for the value/conclusion	At higher hydrogen peroxide concentrations, severe and irreversible damage to the rabbit eye has been demonstrated. Dilute formulations exert mild and reversible irritating effects. Specific Concentration limits for Hydrogen peroxide: Eye Dam. 1; H318: 8 % ≤ C < 50 % Eye Irrit. 2; H319: 5 % ≤ C < 8 %
Classification of the products according to CLP	Classification of the products for eye damage/irritation is based on CLP mixture rules. All products in this BPF contain hydrogen peroxide over 8 %, which triggers classification for serious eye damage. All products in this BPF: Eye Dam. 1; H318: Causes serious eye damage.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Irritating to the respiratory tract when ≥ 35 % hydrogen peroxide.
Justification for the conclusion	No studies on respiratory tract irritation is available for the biocidal products. Both animal data and human experience referred in the CAR indicate that hydrogen peroxide causes respiratory irritation. Specific Concentration limits for Hydrogen peroxide: STOT SE 3; H335: C ≥ 35 %
Classification of the products according to CLP	Classification of the products for respiratory tract irritation is based on CLP mixture rules: the products in meta-SPCs 2, 3, 5, 6, 7, 8, 9 contain ≥ 35 % hydrogen peroxide, which triggers classification for respiratory tract irritation. Products in meta-SPCs 1, 4: No classification Products in meta-SPCs 2, 3, 5, 6, 7, 8, 9: STOT SE 3; H335: May cause respiratory irritation.

Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to skin.
Justification for the value/conclusion	No studies on skin sensitisation is available for the biocidal products. Hydrogen peroxide and other components in the products have no classification for skin sensitisation and are not considered to be a potential skin sensitisers.
Classification of the products according to CLP	All products in this BPF: No classification for skin sensitisation.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to respiratory tract.
Justification for the value/conclusion	No studies on respiratory sensitisation is available for the biocidal products. Hydrogen peroxide and other components in the products have no classification for respiratory sensitisation.
Classification of the products according to CLP	All products in this BPF: No classification for respiratory sensitisation.

Acute toxicity

Acute toxicity by oral route

No specific studies on acute toxicity by oral route are available for the products. Conclusion is based on hydrogen peroxide data as other components are present in minor amounts not affecting the classification.

Value used in the Risk Assessment – Acute oral toxicity	
Value	Hydrogen peroxide data (from the CAR): LD50 = 805 mg/kg bw (70 % HP, combined), (486 mg/kg bw; as 100 % HP, females). LD50 = 1231 mg/kg bw (35 % HP, combined) (420 mg/kg bw; as 100 % HP, males)
Justification for the selected value	The results of acute oral toxicity studies performed in rats with formulations containing hydrogen peroxide at concentrations from 35 % to 70 % demonstrated acute oral LD50 values in the range of 694-1270 mg/kg bw, indicating that hydrogen peroxide, at the tested concentrations, is harmful by the oral route. When corrected to 100 % hydrogen peroxide, the LD50 values were around 500 mg/kg bw. The lowest LD50 derived for 100 % hydrogen peroxide, that is 420 mg/kg bw for male rats from the study with 35 % hydrogen peroxide product, is used as the Acute Toxicity Estimate to calculate the acute oral ATEmix values for the products in this BPF. ATEmix values for the meta-SPCs in this BPF are: • meta-SPC 1 (13.5 % HP): o ATEmix = 3111 mg/kg bw (100/ATEmix = 13.5/420) • meta-SPC 4 (25.7 % HP): o ATEmix = 1634 mg/kg bw (100/ATEmix = 25.7/420) • meta-SPCs 2, 5, 6, 8 (35.7 % HP): o ATEmix = 1176 mg/kg bw (100/ATEmix = 35.7/420) • meta-SPCs 3, 7, 9 (49.9 % HP): o ATEmix = 842 mg/kg bw (100/ATEmix = 49.9/420) o ATEmix = 1002 mg/kg bw (100/ATEmix = 49.9/500) [calculated with ATE 500 from the Table 3.1.2 in CLP] Since for meta-SPC 1 the ATEmix is greater than 2000 mg/kg bw, no classification is needed. Since for meta-SPCs 2, 3, 4, 5, 6, 7, 8, 9 the ATEmix values are greater than 300 mg/kg bw but less than 2000 mg/kg bw, these products need to be classified with Acute Tox. 4; H302.
Classification of the products according to CLP	Products in meta-SPC 1: no classification Products in meta-SPCs 2, 3, 4, 5, 6, 7, 8, 9: Acute Tox. 4; H302: Harmful if swallowed.

Acute toxicity by inhalation

No specific studies on acute toxicity by inhalation route are available for the products. Conclusion is based on hydrogen peroxide data as other components are present in minor amounts not affecting the classification.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Hydrogen peroxide data (from the CAR): LC50 >170 mg/m^3 (vapour, highest attainable vapour concentration)
Justification for the selected value	Hydrogen peroxide has a minimum classification in category 4 for acute inhalation toxicity on Annex VI of the CLP Regulation. In the opinions of Hydrogen peroxide (PTs 1-6) it is mentioned that "*For the acute inhalation toxicity category 4 some uncertainty remains, and therefore the minimum classification as category 4 cannot be confirmed.*" In similar product classification case it was concluded by WG to use the converted acute toxicity point estimate that corresponds to the state of the active substance originally tested for the harmonised classification. The available study with a test substance containing 49.3% hydrogen peroxide is performed with vapour where no mortalities occurred in the highest attainable vapour concentration, 0.17 mg/L. The study referred in the CAR is also included in IUCLID of this INTEROX BPF1 dossier as the composition of product is considered similar with meta-SPCs 3, 7, 9. With the highest hydrogen peroxide concentration of 49.9% in this BPF and converted acute toxicity point estimate for vapour the calculated ATEmix value is 22 mg/L (100/ATE_{mix} = 49.9/11). As the criterion for the Acute Tox. 4 is 10 < ATE ≤ 20, no classification is justified. Taking all this into account, no classification for acute inhalation toxicity is proposed for any meta SPCs. Additional labelling with EUH071 (Corrosive to the respiratory tract) is also not triggered for those meta SPCs classified as skin corrosive due to this inhalation study available.
Classification of the products according to CLP	All products in this BPF: No classification for acute inhalation toxicity.

Acute toxicity by dermal route

No specific studies on acute toxicity by dermal route are available for the products. Conclusion is based on hydrogen peroxide data as other components are present in minor amounts not affecting the classification.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Hydrogen peroxide data (from the CAR): LD50 >2000 mg/kg bw, not harmful
Justification for the selected value	The study with 35 % hydrogen peroxide provided LD50 result of >2000 mg/kg bw. Hydrogen peroxide has no classification for acute dermal toxicity.

Classification of the products according to CLP	Classification is based on CLP mixture rules. All products in this BPF: No classification for acute dermal toxicity.

Information on dermal absorption

No data is available in relation to dermal absorption of the biocidal products.

Value used in the Risk Assessment – Dermal absorption	
Substance	Hydrogen peroxide
Value(s)	100 % default
Justification for the selected value(s)	Hydrogen peroxide is reactive, and it degrades rapidly in contact with organic material. In the CAR it is explained that no standard dermal penetration studies with hydrogen peroxide have been successfully conducted. Based on the physico-chemical properties of hydrogen peroxide, 100 % dermal penetration should be used in the absence of more accurate information. However, in the absence of clear systemic effects, no dermal penetration parameter was needed in order to conclude on human health risks from the presented uses of hydrogen peroxide.

Data waiving	
Information requirement	Dermal absorption
Justification	No dermal penetration studies with hydrogen peroxide products have been conducted. In the absence of clear systemic effects of hydrogen peroxide and only local effects at the site of first contact, no dermal penetration value was needed in order to conclude on human health risks from the presented uses of the biocidal products. Only a qualitative exposure and risk assessment for the dermal route of exposure will be performed by taking into account appropriate risk mitigation measures. In conclusion, it was acceptable to waive the dermal penetration study.

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

In accordance with Annex III of the BPR, available toxicological data relating to non-active substance(s) (i.e. substance(s) of concern), or a mixture that a substance(s) of concern is a component of, should be provided. The products in this BPF are aqueous solutions containing one active substance, hydrogen peroxide, and low concentrations (<0.1 %) of stabilisers (see the confidential annex for the exact composition and the classification of stabilisers). These stabilisers are classified only for irritating properties, and they are present in the products in such minor amounts that they do not trigger classification and are not substance of concern. Two stabilisers have a Community workplace exposure limit value but based on the minor amounts, low hazard profile, potency and exposure potential of the substances they are not considered as SoCs and no risk assessment is needed.
As a conclusion, the biocidal products in this family do not contain any substances of concern. Therefore, no further toxicological data or assessment is required in relation to the co-formulants within this INTEROX Biocidal Product Family 1.

Available toxicological data relating to a mixture

Available toxicological data relating to a mixture that a substance(s) of concern is a component of is not relevant since the products within the INTEROX Biocidal Product Family 1, do not contain any substance(s) of concern.

Other

Toxic effects on livestock and pets: Specific studies on pets and livestock are not available. However, the toxic effects on livestock and pets can be predicted based on the available toxicity data on animals and humans. Animals will be removed prior to application so that no animal exposure during the application process in PT3 will occur.

Feeding and metabolism studies in livestock: There are no relevant residues of hydrogen peroxide expected in food and feeding stuff due to the rapid degradation of hydrogen peroxide to water and oxygen in the environment.

Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product: No further studies are available.

Other tests related to the exposure of humans: No further tests are considered required which might be related to the exposure of the active substance to humans.

2.2.6.2 Exposure assessment

The biocidal products of the hydrogen peroxide biocidal product family are intended to be used in product types 2, 3 and 4 by professional and industrial users only.

The following table gives an overview of the use patterns and in-use concentrations of hydrogen peroxide in the intended uses.

PT	No	Meta SPC, a.s.%	Field of use	Application method	In use concentration of a.s.
2	Use 1	1, 2, 3 13 %, 35 %, 49.9 %	Surface disinfection of closed spaces by aerosolised hydrogen peroxide	Automated, non-directed aerosolization (e.g. fogging or spraying) of closed rooms in industrial or institutional facilities. Applied using a machine to deliver hydrogen peroxide. • automated loading • application	1 g of HP per m^3 (based on the efficacy data)
2	Use 2	8, 9 35 % 49.9 %	Surface disinfection by liquid application in industrial and institutional areas	Automated spraying on surfaces Cleaning in place (CIP) • automated loading • automated spraying Immersion of equipment and utensils • loading of immersion bath • immersion	13 % w/w
3	Use 3	8, 9 35 %, 49.9 %	Disinfection of surfaces associated with animal housing by spraying	Automated and manual spraying of aqueous solutions onto clean surfaces by professionals. • automated and manual mixing and loading • automated and manual spraying	9.5-13 % w/w

4	Use 4	5 35 %	Disinfection of food packaging material (aseptic packaging) by immersion, aerosolised or vaporised hydrogen peroxide (VHP)	Immersion, VHP, Spraying (closed systems) • automated loading • application (around the machines, spraying is closed) • maintenance work	35 % w/w
4	Use 5	5 35 %	Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP)	Automated vaporisation or aerosolization in closed areas in aseptic filling machines. • automated loading • application	35 % w/w
4	Use 6	6, 7 35 %, 49.9 %	Disinfection of distribution and storage systems for drinking water	Flooding of pipes Automated spraying of tanks using CIP technologies • automated loading • automated spraying	13 % w/w
4	Use 7	6, 7 35 %, 49.9 %	Surface disinfection in food and feed processing by liquid application	Automated spraying on surfaces • automated loading • automated spraying Immersion of equipment and utensils • loading of immersion bath • immersion	13 % w/w
4	Use 8	4 25 %	Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP)	Automated vaporization in aseptic filling machines • automated loading • application (around the machines) • maintenance work	25 % w/w
2	Use 9	2, 3 35 %, 49.9 %	Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP)	Automated, non-directed aerosolization (e.g. fogging or spraying, flash evaporation) of filling isolators in industrial facilities. Applied using a machine to deliver hydrogen peroxide. • automated loading • application	18 g of HP per m^3 (based on the efficacy data)

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	n.a.	yes	yes	no	n.a.
Dermal	yes	yes	n.a.	n.a.	no	no	n.a
Oral	no	no	n.a.	n.a.	no	no	no

List of scenarios

The exposure scenarios in the intended uses in PT 2, 3 and 4 are based on the scenarios described and assessed in the Assessment Report of hydrogen peroxide (CAR for PTs1-6, 2015). Some additional use scenarios have been included and described in detail in this PAR.

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
Use 1: Surface disinfection of closed spaces by aerosolised hydrogen peroxide PT 2			
1	Automated loading	Primary exposure Loading scenario for automated applications: VHP process, spraying and fogging machines and aseptic packaging	Industrial Professionals
2	Application	Primary exposure No exposure during application as no persons present in the room during application.	Industrial Professionals
3	Re-entry	Primary exposure	Industrial Professionals
Use 2: Surface disinfection by liquid application in industrial and institutional areas PT 2			
4 (=1)	Automated loading	Primary exposure Loading scenario for automated applications: VHP process, spraying and fogging machines and aseptic packaging	Industrial Professionals
5	Automated spraying	Primary exposure No exposure during automated spraying with CIP technologies or automated spraying of surfaces such as conveyors or other fixed installations Re-entry	Industrial Professionals
6	Loading of immersion bath	Primary exposure Loading of immersion bath	Industrial Professionals
7	Immersion/ Dipping	Primary exposure Dipping of small food processing equipment in an immersion bath	Industrial Professionals
Use 3: Disinfection of surfaces associated with animal housing by spraying PT 3			
8 (=1)	Automated mixing and loading	Primary exposure Loading scenario for automated applications: VHP process, spraying and fogging machines and aseptic packaging	Professionals
9	Automated spraying	Primary exposure No exposure during application as no persons present in the closed areas during application. Re-entry	Professionals
10	Manual mixing and loading	Primary exposure Pouring of product into a portable vessel (e.g. sprayer, canister) and dilution to in-use concentration	Professionals
11	Manual spraying	Primary exposure Surface disinfection of animal housing via spraying Re-entry	Professionals
Use 4: Disinfection of food packaging material (aseptic packaging) by immersion, aerosolised or vaporised hydrogen peroxide (VHP) PT 4			
12 (=1)	Automated loading	Primary exposure Loading scenario for automated applications: VHP process, spraying and fogging machines and aseptic packaging	Industrial Professionals

13	Application in aseptic packaging	Primary exposure Disinfection of food packaging by immersion, vaporised hydrogen peroxide or spray application Application (around the machines)	Industrial Professionals
14	Maintenance	Maintenance work	Industrial Professionals
Use 5: Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP) PT 4			
15 (=1)	Automated loading	Primary exposure Loading scenario for automated applications: VHP process, spraying and fogging machines and aseptic packaging	Industrial Professionals
16	Application by VHP process	Primary exposure No exposure during application as no persons present in the closed areas during application.	Industrial Professionals
Use 6: Disinfection of distribution and storage systems for drinking water PT 4			
17 (=1)	Automated loading	Primary exposure Loading scenario for automated applications: VHP process, spraying and fogging machines and aseptic packaging	Industrial Professionals
18 (=5)	Automated spraying	Primary exposure No exposure during automated spraying with CIP technologies	Industrial Professionals
Use 7: Surface disinfection in food and feed processing by liquid application PT 4			
19 (=1)	Automated loading	Primary exposure Loading scenario for automated applications: VHP process, spraying and fogging machines and aseptic packaging	Industrial Professionals
20 (=5)	Automated spraying	Primary exposure No exposure during automated spraying with CIP technologies	Industrial Professionals
21 (=6)	Loading of immersion bath	Primary exposure Loading of immersion bath	Industrial Professionals
22 (=7)	Immersion/ Dipping	Primary exposure Dipping of small food processing equipment in an immersion bath	Industrial Professionals
Use 8: Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP) PT 4			
23 (=1)	Automated loading	Primary exposure Loading scenario for automated applications: VHP process, spraying and fogging machines and aseptic packaging	Industrial Professionals
24 (=13)	Application in aseptic packaging	Primary exposure Disinfection of food packaging by vaporised hydrogen peroxide Application (around the machines)	Industrial Professionals
25 (=14)	Maintenance	Maintenance work	Industrial Professionals
Use 9: Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP) PT 2			

26 (=1)	Automated loading	Primary exposure Loading scenario for automated applications: VHP process, spraying and fogging machines and aseptic packaging	Industrial Professionals
27 (=2)	Application	Primary exposure No exposure during application as no persons present in the room during application.	Industrial Professionals
28 (=3)	Re-entry	Primary exposure	Industrial Professionals

Principles for the human health exposure assessment

The adverse effects of hydrogen peroxide in humans are limited to local effects at the site of first contact, and systemic effects are considered to be caused by the corrosive properties of hydrogen peroxide and thus secondary to the local effects. Therefore, systemic exposure is not relevant and only local exposures have been considered in this assessment. The corrosive/irritating effects to the skin and mucous membranes are concentration dependent with no or only minor dependence from exposure duration.

Quantitative exposure and risk assessment via the inhalation route of exposure is performed considering the AEC for inhalation 1.25 mg/m^3, as derived for hydrogen peroxide in the CAR (PTs 1-6, 2015). Qualitative risk characterization for potential local effects via the dermal route of exposure is performed considering both the SCLs set for hydrogen peroxide in the CLP regulations as well as appropriate risk mitigation measures (i.e. gloves, coveralls, etc.) and label instructions (i.e. P-statements associated with the H-statements). Oral exposure of professionals in these uses are considered not relevant, and therefore it is not presented in the summary tables either.

Calculations with Advanced Reach Tool (ART)
The Advanced Reach Tool (ART) is used for the inhalation exposure assessment as it takes into account both vapour and aerosols. The 90th percentile exposure values calculated with the Advanced Reach Tool will be used to take into account the variability in exposure levels. It is noted that the calculated exposure may be an overestimation as the non-exposure period value was set to 0 in the ART-scenarios. However, as inhalation exposure is compared to the Acceptable Exposure Concentration (AEC) based on irritating effects, this short-term value from ART is in this case more adequate than the 8-hour shift value (with e.g. 460 min non-exposure period).
In the ART calculations, liquid mole fraction is used instead of weight fraction (see Annex 3.2 for details).
For activity coefficient the default of 1 is used as no real representative functional groups for hydrogen peroxide was found in the XL UNIFAC or AIOMFAC which are the software tools used specifically for activity coefficient calculation. The estimations with two OH groups would give values of little less than 1 with UNIFAC and values over 1 with AIOMFAC (the lower the activity coefficient the lower the exposure value from ART). Therefore, as a compromise, a default of 1 is selected for ART calculations.

Industrial exposure
The hydrogen peroxide products in this biocidal product family are intended only for industrial and professional use. Risk for professionals corresponds to industrial users.

Professional exposure

Use 1: Surface disinfection of closed spaces by aerosolised hydrogen peroxide PT 2

Based on the efficacy comments during peer review the original use 1 with all meta SPCs 1, 2, 3 was divided to use 1: (meta SPC 1, 2, 3): room disinfection by aerosolized hydrogen peroxide and use 9 (meta SPC 2, 3): disinfection of filling isolators by aerosolized and vaporized hydrogen peroxide. The same scenarios apply for both uses 1 and 9.

Scenario 1: Automated loading scenario for automated applications

This is a **general loading scenario for automated applications** such as VHP, spraying and fogging machines and aseptic packaging for surface disinfection in private and public hygiene (use 1, 9 and 2), in food and feed processing facilities (use 5 and 7) and for aseptic packaging machines (use 4 and 8) and disinfection of distribution and storage systems for drinking water (use 6).

Description of Scenario 1: Automated loading scenario for automated applications

Mobile VHP, fogging and spraying machines consist of a dedicated cartridge interface and/or a separate bulk sterilant inlet. There is minimal potential for exposure during loading and exchange of cartridges and external bulk supply anticipated. For the majority of the units the sealed cartridge is placed in a cartridge holder and will be connected to the reservoir automatically. For external supply the external bulk units are directly connected via hose/pipe assemblies with proper fittings to a dedicated fitting. Alternatively, remote operator interfaces can be connected to the bulk supply and then feed up several different units. Although exposure during loading and exchange of sterilant is considered minimal, a representative scenario was established.

Depending on the client the use frequency of VHP, spraying and fogging machines for disinfection varies between once a year to several times per day. The loading of 10 VHP machines for disinfection of large enclosures (up to 5000 m^3) was selected as representative worst-case scenario. In this scenario the ten VHP machines are distributed over the space and the activity can be described as connecting each of the VHP machines with a bulk unit of hydrogen peroxide product (49.9 % as a worst case). Assuming a 30 min conditioning phase in order to achieve a 2000 ppm hydrogen peroxide concentration and a subsequent 6 hours application phase with a worst-case maximum use rate of 40 g product/min (e.g. VHP machine) results in consumption of 15.6 L hydrogen peroxide product per unit. The duration of the activity of connecting the VHP machine with a bulk supply via hose is one minute and another minute for disconnecting when the decontamination process has finished. Exposure during carrying hoses in and out of the enclosure is considered negligible. Exposure duration from connecting and disconnecting 10 VHP machines therefore results in 20 minutes. An additional 10 minutes was added as worst-case consideration. Inhalation exposure was calculated with ART v1.5 where the activity was described as handling of contaminated objects and the emission source is located in the breathing zone of the worker (< 1m). For coupling and decoupling of hoses ART suggests surfaces of 1 to 3m^2, which is considered a too extreme worst-case, as all units are sealed and connected with pipes/hoses via dedicated connector with minimal potential for exposure. All INTEROX bottles, jerrycans and drums from 5 to 220L have a sealed cap/lid with a diameter of 5 cm, which corresponds to a surface of 0.002 m^2. Therefore, a surface of 0.1 – 0.3 m^2 with contamination level < 10 % is considered representative. There is no exposure from loading from IBC's and tank trucks as they are fitted with valves, which are opened only after connection to the pipe.

Dermal exposure: The operator must wear full protective clothing (rubber shoes, goggles, apron, gloves) due to theconcentrated solutions.

Oral exposure is considered very unlikely and therefore not estimated.

Description of loading of fixed installed applications such as CIP and aseptic packaging machines:
Aseptic packaging machines have a reservoir for hydrogen peroxide, which is connected to bulk units, containing the product of up 100 L volume, via pipes. In practice, a bulk unit of 100 L is exchanged per day by connecting the bulk unit with the pipe. The duration of the activity of connecting the aseptic packaging with a bulk via pipe is assumed to be one minute and another minute for disconnecting when the decontamination process has finished. Exposure duration from connecting and disconnecting 10 aseptic packaging machines as worst-case results in 20 minutes. As the activity and the connectors are identical to those for the loading of the mobile units, the ART scenario is considered representative for this use. CIP techniques such as cleaning and disinfection of e.g. conveyors without major disassembly and assembly work, the interior surfaces of pipelines and tanks and processing equipment in food and feed processing and in industrial areas of private hygiene (e.g. cosmetics industry) are permanently connected to the disinfectant supply via pipes. Supply tanks will be loaded by large units such as IBCs or tank trucks. Since no exposure during loading is expected, the ART scenario described above is considered as worst-case for these uses.
Please refer to Annex 3.2 for further details on the ART calculations.

	Parameters	**Value**
Tier 1	Concentration (worst case)	49.9 %[1)]
	Duration	30 min/day (non-exposure period 0 min)
	Activity class	Handling of contaminated objects
	Situation	Activities with treated/contaminated objects (surface 0.1 - 0.3 m²) (handling of contaminated tools)
	Contamination level	Contamination < 10 % surface
	Room size	Large workrooms only
	Ventilation	only good natural
	LEV	no

1) calculated liquid mole fraction value is 0.3452 which is used in ART

Summary table: estimated exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration**	**Estimated dermal concentration**
Automated loading of VHP, spraying and fogging machines ART (90th)	1/no PPE	0.52 mg/m^3	49.9 %

Based on the comment during peer review, calculations with the activity class of "falling liquids" and situation "transfer of liquid product" have been added. The same kind of modelling had already been used in CA reports of active substances in similar cases. The parameters differing from the calculations above are presented below:

Parameters	**Value**
Duration	15 min/day (non-exposure period 0 min)
Activity class	Falling liquids

Situation	Transfer of liquid product with flow of 1-10 L/min and 10-100 l/minute
Containment level	Open process*
Loading type	Submerged loading, where the liquid dispenser remains below the fluid level reducing the amount of aerosol formation
Room size	Any size workroom
Localised controls - primary	Medium level containment (99.00% reduction)**

* According to the note in ART, "Handling that reduces contact between product and adjacent air" does not include processes that are fully contained by localised controls. This means that "open process" needs to be selected if the localised control "containment – no extraction" is selected as parameter.

** According to the description in ART, physical containment or enclosure of the source of emission. The air within the enclosure is not actively ventilated or extracted. The enclosure is not opened during the activity. The material transfer is enclosed with the receiving vessel being docked or sealed to the source vessel. Examples include sealing heads, transfer containers and multiple o-rings. Inflatable packing head with continuous liner ensures a seal is maintained during the powder transfer and the continuous plastic liner prevents direct contact with the product. The correct type of tie off must be used.

Please refer to Annex 3.2 for further details on the ART calculations.
The inhalation exposure values with these parameters are 0.05 mg/m^3 calculated with flow rate 1-10 L/min and 0.17 mg/m^3 with flow rate 10-100 L/min. Values are lower than the concentration 0.52 mg/m^3 calculated first, and therefore that one is kept for risk chacacterisation.

Scenario 2: Surface disinfection by aerosolised hydrogen peroxide or VHP process (Fogging) in closed system

Machine based application via fogging/spraying is similar to the VHP machine used in the exposure assessment for the active substance. The same scenarios apply for both uses 1 and 9. It is written in the Opinion that the authorisation of biocidal products containing hydrogen peroxide used for surface disinfection applying the VHP (vaporised hydrogen peroxide) process should be restricted to professionals.
According to the Applicant this use is identical to the representative product used for the authorisation of the active substance for PT 2.01, surface disinfection by VHP process. Target levels are however higher than was claimed for the representative biocidal product but this has no effect on exposure as access to the vapour-treated area is denied during the disinfection process.

The area to disinfect is prepared for decontamination by removing standing liquids and visible soils by wiping down and installing biological and chemical indicators to validate the disinfection cycle. Professionals insert the sealed cartridge with e.g. 35 % (w/w) aqueous hydrogen peroxide solution as delivered by the manufacturer into a VHP machine, seal the enclosed space or room and initiate the decontamination cycle. At first in a dehumidification phase the VHP machine removes water from the atmosphere. Then the VHP machine injects vaporised hydrogen peroxide into the sealed area for decontamination to get the hydrogen peroxide concentration up to the effective levels. The succeeding sterilisation phase lasts 1 to 2 hours during which the hydrogen peroxide vapour disinfects the surfaces inside the sealed space.
As the access to the vapour-treated area is denied during the disinfection process no exposure occurs.

Scenario 3: Re-entry

After finishing the decontamination phase the aeration cycle starts in which the VHP machine breaks down the hydrogen peroxide in the sealed space to water and oxygen. When the aeration

cycle is complete sensors inform when the hydrogen peroxide level is below the AEC of 1.25 mg/m^3. **There is neither operator nor general public exposure to hydrogen peroxide as the safe level is reached before the re-entry. Sensors of the machine confirm when the safe level is reached.** Respiratory protective equipment (RPE) is needed if re-entry is necessary before the safe concentration has been reached.

No secondary exposure is expected because of rapid decomposition of hydrogen peroxide.

Summary table: estimated exposure from professional uses				
Exposure scenario		**Tier/PPE**	**Estimated inhalation concentration**	**Estimated dermal concentration**
Surface disinfection of closed spaces by aerosolised hydrogen peroxide	Automated loading	1/no PPE	0.52 mg/m^3	49.9 %
	Application (no entry)	1/no PPE	No exposure	No exposure
	Re-entry	1/no PPE	< 1.25 mg/m^3	No exposure

Use 2: Surface disinfection by liquid application in industrial and institutional areas PT 2

<u>Scenario 4: Automated loading</u>; same as Scenario 1

The loading of built-in and mobile systems for spraying is fully automated. Minor exposure may occur during connecting of pipes with the delivered product, which is considered to be covered by the loading scenario for VHP machines (see scenario 1).

<u>Scenario 5: Surface disinfection by automated spraying</u>

Qualitative assessment. All spraying applications are fully automated, and no manual spraying should take place.
The food processing industries and industrial areas in private hygiene such as cosmetics manufacturing use Cleaning-In-Place (CIP) process that ensures automatic cleaning and disinfection of e.g. conveyors without major disassembly and assembly work, the interior surfaces of pipelines and tanks and processing equipment. CIP techniques are usually applied in large industrial premises with room volumes and ventilation capacities of > 3 ACH. This type of disinfection is generally done with large tanks, kettles or piping systems where there are smooth surfaces. CIP involves circulation of detergent through equipment by use of a spray ball or spray to create turbulence. Conveyors are disinfected by spray nozzels while in motion. The in-use concentration is 13 % hydrogen peroxide. The application rate is 0.1 L/m^2. Principally the lowest possible volume to achieve wetting of all surfaces would be used. A conveyor with a typical length of 50 meter and 1 meter width has an overall area of 100 m^2 and thus requires 10 L product with 13 % hydrogen peroxide.

In general, a CIP operation involves the following steps:

- Removal of any small equipment parts that must be manually cleaned, making sure that CIP and processing components are clearly segregated.
- Cool temperature water (<80F = <27°C) is used to pre-rinse the equipment lines and piping to remove gross soil and to minimize coagulation of proteins.
- After the pre-rinse water is flushed from the lines, the appropriate cleaner solution or treatment is circulated for a requisite period of time to remove any soil, chemical or other residues. This step is followed by another water rinse.
- The final step is application of a sanitizing agent or method just prior to operation of the equipment. In aseptic operations, this step will be programmed into the system. Sanitizing can be with a chemical rinse or by the circulation of hot water.

The processes are fully automated and enclosed with no exposure in the case of tanks or piping systems. In the case of **automated spraying of surfaces such as conveyors or other fixed installations workers should leave the room before processing**. This is assured by the fact that disinfection can only be processed after the end of a shift with all workers having left the room. The last worker will press a button from outside the room to trigger the end of day cleaning process. Warning notices and temporary barriers on all entries indicate that entry is denied during and after processing for at least six hours.

There is neither operator nor general public exposure to hydrogen peroxide as the safe level is reached before re-entry the shift next day.
Air concentrations should be monitored to ensure that no leakage occurs during operations and levels are safe before entering the area, as no exact re-entry times can be given.

As an extreme worst case for this scenario, air concentration during spraying can be modelled with ART by calculating the exposure as in manual spraying of animal housing (spraying in all directions over 400 minutes (400 min x 0.3 (to 3) L/min = 120 (to 1200) L) and with ventilation rate option "No restriction on general ventilation characteristics", see the tables in scenario 11). This would result in an air concentration of 45 mg/m³. The Applicant also proposed another more realistic calculation with an application rate of 0.03 - (max) 0.3 L/min, ACH 3 and spraying only downwards resulting in an air concentration of 0.58 mg/m³.

The loading of built-in and mobile systems for spraying is fully automated. Minor exposure may

occur during connecting of pipes with the delivered product, which is considered to be covered by the loading scenario for VHP machines (see scenario 1).

Summary table: estimated exposure from professional uses				
Exposure scenario		**Tier/PPE**	**Estimated inhalation concentration**	**Estimated dermal concentration**
Surface disinfection by automated spraying	Automated loading	1/no PPE	0.52 mg/m^3	49.9 %
	Automated spraying	1/no PPE	no exposure	no exposure
	Re-entry is safe when the concentration is < 1.25 mg/m^3.			

Scenario 6: Loading of immersion bath

Description of Scenario 6: Loading of immersion bath		
For disinfection by immersion (dipping) a loading scenario is performed. In **loading of an immersion bath**, the ART activity was selected as falling liquids (open process with splash loading) with a flow rate of 1-10 L/min, again in a workroom of any size and only good natural ventilation and no localised controls in Tier 1. The size of the immersion bath is 5 L. Please refer to Annex 3.2 for further details on the ART calculations.		
	Parameters	**Value / Description**
Tier 1	Concentration	49.9 %[1)]
	Duration for loading	10 min/day (non-exposure period 0 min)[2)]
	Activity class	Falling liquids 1 - 10 L/min
	Containment level	Open process
	Loading type	Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely
	Room size	Any size workroom
	Ventilation	only good natural
	LEV	no
Tier 2	Penetration through respiratory protection equipment (RPE 20)	5 %
Tier 2a	Ventilation	Mechanical ventilation giving at least 1 ACH
	LEV: Fixed capturing hood	90 % reduction (Fixed capturing hoods located in close proximity of and directed at the source of emission. The design is such that the work is performed in the capture zone of the ventilation system and the capture is indicated at the workplace.)
Tier 2b	Ventilation	3 ACH

1) calculated liquid mole fraction value is 0.3452 which is used in ART
2) duration has no effect on the inhalation exposure value as the non-exposure period is 0 min

Summary table: estimated exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration**	**Estimated dermal concentration**
Loading of immersion bath ART (90th)	1/no PPE	15 mg/m^3	49.9 %
	2/RPE 20	0.75 mg/m^3	49.9 %
	2a/Mechanical ventilation giving at least 1 ACH + LEV: Fixed capturing hood	1.1 mg/m^3	49.9 %
	2b/Ventilation 3 ACH + LEV: Fixed capturing hood	0.72 mg/m^3	49.9 %

According to the Applicant the use of RPE is general practice in loading and mixing activities where high concentrated solutions are used.

Scenario 7: Immersion (dipping)

This scenario covers immersion bath in uses 2 and 7 in product types 2 and 4.

The Applicant has calculated only exposure by inhalation using the Advanced Reach Tool (ART) which takes into account both the vapour and aerosol phase. Calculations with the evaporation model in ConsExpo has been added as this is the model proposed in the HEAdhoc Recommendation 6.

The duration for immersion/dipping application is 30 minutes as agreed in the recommendation.

For dermal exposure Dipping model 1 (Indicative value for hands 25.7 mg/min and body 178 mg/min) is recommended. As there are no systemic effects for hydrogen peroxide, the dermal exposure is not quantitatively assessed. Use of gloves and clothing protection is however recommended in addition to eye protection as the use concentration is classified irritating to eyes.

Description of Scenario 7: Immersion (dipping)		
The scenario is described as **dipping of small food processing equipment in an immersion bath** with a hydrogen peroxide concentration of up to 13 % w/w. For immersion bath the ART activity class with open liquid surfaces or reservoirs was selected. The surface was assumed to be undisturbed as the worker is carefully dipping the object into the bath with no formation of aerosols. The breathing zone of the worker is within one meter of an immersion bath of 5L disinfectant solution (13 % hydrogen peroxide) with a surface of 0.15 m^2. The activity was carried over a duration of 30 minutes in a workroom of any size with only good natural ventilation and no localised controls in Tier 1. Please refer to Annex 3.2 for further details on the ART and ConsExpo calculations.		
	Parameters	**Value / Description**
Tier 1	Concentration	13 % [1)]
	Duration for immersion [2)]	30 min/day
	ART	
	Activity emission potential	Activities with relatively undisturbed surfaces (no aerosol formation)

		Open surface 0.1 – 0.3 m²
	Room size	Any size workroom
	Ventilation	only good natural
	LEV	no
Tier 2	Penetration through respiratory protection equipment (RPE 5)	20 %
Tier 2a	Ventilation	Mechanical ventilation giving at least 1 ACH
	LEV: Fixed capturing hood	90 % reduction (Fixed capturing hoods located in close proximity of and directed at the source of emission. The design is such that the work is performed in the capture zone of the ventilation system and the capture is indicated at the workplace.)
	ConsExpo	
Tier 1	room volume	55m^3
	ventilation rate	0.6
	applied amount	5 kg
	release area	0.15 m^2
	mass transfer coefficient	default 10 m/hr
Tier 2	Penetration through respiratory protection equipment (RPE 5)	20 %

1) calculated liquid mole fraction value is 0.0737 which is used in ART
2) Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure: Methods and models to assess exposure to biocidal products in different product types, Version 3.

Summary table: estimated exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration**	**Estimated dermal concentration**
Immersion/ dipping ConsExpo ART (90th)	1/no PPE no LEV	ART: 3.5 mg/m^3 ConsExpo: 1.4 mg/m^3	13 %
	2/RPE 5	ART: 0.7 mg/m^3 ConsExpo: 0.28 mg/m^3	13 %
	2a/Mechanical ventilation giving at least 1 ACH + LEV: Fixed capturing hood	ART: 0.26 mg/m^3	13 %

According to the Applicant the use of RPE is general practice in loading and mixing activities where high concentrated solutions are used.

Use 3: Disinfection of surfaces associated with animal housing by spraying PT 3

This use is surface disinfection of animal housing by spraying with an in-use concentration of up to 13 % w/w hydrogen peroxide. The product is diluted (mixing and loading) and sprayed in animal housing by **professionals** using **automated equipment** (scenarios 8 and 9) **or manual equipment** (scenarios 10 and 11). Animals are removed before treatment.

Scenario 8: Automated loading; same as Scenario 1

In the case of automated spraying the mixing and loading process corresponds to the loading of mobile systems for spraying in scenario 1, which is fully automated. Minor exposure may occur during connecting of pipes with the delivered product, which is considered to be covered by the loading scenario for VHP machines (see scenario 1).

Scenario 9: Surface disinfection of animal housing by automated spraying
Qualitative assessment.

According to the Applicant, for automated spraying systems the equipment used is more bespoke, the general processes involve a rotating spray head powered by a low-pressure system and this then moves around the room on a pre-determined path to ensure coverage (similar to an automated lawn moving systems).

In the case of automated spraying of animal housing workers should leave the room before processing. During surface disinfection in animal housing by automated spraying access to the spray-treated area is denied by blocked doors and warning notices.
After application all windows, vents and doors etc are opened from the outside to ensure a minimum of 10 ACH.
There is neither operator nor general public exposure to hydrogen peroxide as the safe level is reached before re-entry. Air concentrations should be monitored to ensure that no leakage occurs during operations and levels are safe before entering the area, as no exact re-entry times can be given.

Air concentration in this scenario can be modelled by ART calculation for manual spraying with the same assumptions and input parameter but "No restriction on general ventilation" which results in 45 mg/m³ (90th percentile) (see the tables in scenario 11). This can be seen as an extreme worst-case concentration after automated spraying since automatisation leads to less consumption of product.

Summary table: estimated exposure from professional uses				
Exposure scenario		**Tier/PPE**	**Estimated inhalation concentration**	**Estimated dermal concentration**
Surface disinfection of animal housing by automated spraying	Automated loading	1/no PPE	0.52 mg/m^3	49.9 %
	Automated spraying	1/no PPE	no exposure	no exposure
	Re-entry is safe when the concentration is < 1.25 mg/m^3.			

Scenario 10: Manual mixing and loading for spraying of animal housings PT 3

Description of Scenario 10: Manual mixing and loading for spraying of animal housings PT 3		
Inhalation exposure during manual mixing and loading is modelled. This scenario is described as pouring of product into a portable vessel (e.g. sprayer, canister) and dilution to in-use concentration. In the exposure assessment, only the exposure to 49.9 % (w/w) hydrogen peroxide is addressed since it is regarded as worst case. In this scenario where the diluted product is applied via spraying, the size of the receiving vessel is considered as in knapsack sprayer. Duration of the mixing and loading phase is estimated as 20 minutes on each day per week. The inhalation exposure during professional manual mixing and loading is calculated with the ART exposure assessment tool. Please refer to Annex 3.2 for further details on the ART calculations.		
	Parameters	**Value / Description**
Tier 1	Concentration (worst case)	49.9 %[1)]
	Duration	20 min (non-exposure period 0 min) [2)]
	Activity class	- Transfer of liquid products - Falling liquids (worst case) - 1 - 10 L/min *(Example: Filling of bottles, filling of paint gun)*
	Containment level	Handling that reduces contact between product and adjacent air *(Example situation: Transfer of liquid through a small filling opening (e.g. refuelling of vehicles))*
	Loading type	Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely (worst case)
	LEV	no
	Ventilation rate	Only good natural ventilation
Tier 2	Penetration through respiratory protection equipment (RPE 5)	20 %
Tier 2a	LEV	Other LEV systems (50.00 % reduction)
	Ventilation rate	3 air changes per hour (ACH)
Tier 2b	Loading type	Submerged loading where the liquid dispenser remains below the fluid level reducing the amount or aerosol formation
	Ventilation rate	Mechanical ventilation giving at least 1 ACH

1) calculated liquid mole fraction value is 0.3452 which is used in ART
2) duration has no effect on the inhalation exposure value as the non-exposure period is 0 min

Summary table: estimated exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration**	**Estimated dermal concentration**
Manual mixing and loading (ART 90th)	1/no PPE (splash loading, natural ventilation)	4.5 mg/m^3	49.9 %
	2/RPE 5	0.9 mg/m^3	49.9 %
	2a/no PPE (splash loading, LEV with 50% reduction, ACH 3)	1.1 mg/m^3	49.9 %
	2b/no PPE (submerged loading, mechanical ventilation)	1.1 mg/m^3	49.9 %

According to the Applicant the use of RPE is general practice in loading and mixing activities where high concentrated solutions are used.

Scenario 11: Surface disinfection of animal housing via manual spraying PT 3

Description of Scenario 11: Surface disinfection of animal housing via manual spraying PT 3

Professional exposure during spray application
Floors and walls of animal housings are disinfected by low pressure spraying (application rate 100 ml/m^2) with a backpack sprayer and hand-held spray wand. The spraying is performed at low pressure avoiding the formation of aerosols. The operator (wearing full PPE include face mask) walks backward towards the exit while spraying the surfaces so always walking away from sprayed areas.

The in-use concentration is 13 % w/w. For assessing the exposure while spraying the stable, Spraying Model 2 ('spraying with hand-held medium pressure sprayer in overhead and downward direction') is recommended for inhalation exposure (aerosols) in HEAdhoc Recommendation 6 (No. 11) with the indicative value of 76 mg/m^3. Duration of application is not harmonised, but it should be at least 120 min. In the Biocides Human Health Exposure Methodology document, for PT 3 disinfection of stables the worst case considered is poultry housings with typical size of 4000 m^2 and duration of application 400 min. As hydrogen peroxide is volatile, inhalation exposure should be also assessed with ConsExpo to take into account the vapour phase. Uncertainties regarding ConsExpo modelling for water-based disinfectants with lower vapour pressure than water have been presented in WG III 2019. Taken this into account, the inhalation exposure is here assessed with ART which includes both aerosol and vapour.
Dermal exposure is not quantitatively assessed. As the dermal load in spraying applications is high (indicative values in Spraying Model 2: hands (actual) 7.8 mg/min; hands (potential) 273 mg/min; body 222 mg/min) protective clothing is needed although the concentration limit for irritation is not reached (use concentration < 35 %).
Please refer to Annex 3.2 for further details on the ART calculations.

	Parameters	**Value**
Tier 1	In-use concentration	13 % [1)]
	Duration (exposure and application)	400 min [2)]

	Aerosol and vapour (ART)	
	Emission source	Far field
	Activity class	Spray application of liquids Surface spraying of liquids Moderate application rate (0.3 - 3 L/minute)
	Spray direction	Spraying in any direction (including upwards)
	Spray technique	Spraying with no or low compressed air use *(Examples: Paint spraying using HVLP or airless techniques and Pest control operations using backpack)*
	Room size of the work area	3000 m³ (max. in ART)
	Ventilation rate	10 ACH / No restriction on general ventilation characteristics
Tier 2	Penetration through respiratory protection equipment (RPE 10)	10 %

1) Calculated liquid mole fraction value is 0.0737 which is used in ART.
2) In ART, duration value has no effect on the inhalation exposure values as the non-exposure period is 0 min.

Summary table: estimated exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration**	**Estimated dermal concentration**
Spraying of animal housing ART (90th)	1/no PPE	aerosols and vapour: 4 mg/m^3 (10 ACH) 45 mg/m^3 (No restriction on general ventilation characteristics)	13 %
	2/RPE 10	aerosols and vapour: 0.4 mg/m^3 (10 ACH) 4.5 mg/m^3 (No restriction on general ventilation characteristics)	13 %
	Re-entry is safe when the concentration is < 1.25 mg/m^3.		

Cleaning of equipment: This task is undertaken by the operator, who typically wears a coverall and suitable protective gloves. Only hands will be exposed. As no systemic exposure will be considered for hydrogen peroxide and inhalation exposure during cleaning is negligible, no further assessment is needed for this scenario.

Use 4: Disinfection of food packaging material (aseptic packaging) by immersion, aerosolised or vaporised hydrogen peroxide (VHP) PT 4

Scenario 12: Automated loading; same as Scenario 1

Aseptic packaging – disinfection of food packaging by immersion, aerosolised or vaporised hydrogen peroxide (VHP)

Scenario 13: Application (around the machines)
Scenario 14: Maintenance work

Immersion of packaging material into bath of hot hydrogen peroxide in aseptic filling machine or contact of surface with hot spray or vapour phase hydrogen peroxide in sealed area in aseptic filling machine.

According to the Applicant the use is identical with the use in the CAR and this is presented here for transparency. The risk assessment for the representative product has been performed using measurements from disinfection via immersion-bath and the results are representative for VHP and spray application. Both techniques operate in closed systems where emissions to air are negligible.

The aseptic filling machines are based on the principle of aseptically forming a tube from a sterilized sheet of package material, which is continuously filled with commercially sterile liquid food product and subsequently transversally sealed to form pouches, which in turn are folded into the final package shape. The packaging sheet material is delivered to the machine in the form of reels. The machine unwinds the reel and sterilizes it by passage through a deep bath filled with 35 % (w/w) hydrogen peroxide at temperatures ranging from 68°C to 85°C, depending on the individual machine model. After the bath and before the tube is formed, the packaging sheet material is dried from residual hydrogen peroxide by a combination of mechanical means (rubber rollers) and hot air. Therefore, no relevant residual hydrogen peroxide remains in the packages which could contaminate food.

VHP: The principle is to sterilise the food package with vaporized hydrogen peroxide at the exit of the oven. Then blow the food packageswith sterile air in a sterile environment and maintain this sterility throughout the filling and capping process.
Spray: A certain amount of hydrogen peroxide is sprayed into each preformed container through a spray nozzle. For proper function (sterilisation), the food contact surface of the container needs to be covered completely with the spray solution. Hot sterile air is blown into the container to attain the temperature necessary for the sterilisation process and to remove the hydrogen peroxide from the food contact surface.

For loading see scenario 1 where exposure is calculated with a product containing 49.9 % hydrogen peroxide (worst case). This use in aseptic packaging is for products in meta SPCs 5 containing 35-35.7 % hydrogen peroxide.

Description of Scenario 13: Application (around the machines) and Scenario 14: Maintenance work

All operations involving exposure of the packaging material to hydrogen peroxide and subsequent drying occur in a closed environment, kept under constant flow of sterile air. The sterile air itself circulates in a closed loop.
At the end of the production forced ventilation is performed inside the aseptic area of the machine before the operator gets the consensus to open the doors of the aseptic area. Such ventilation is mandatory and automatically performed. The hydrogen peroxide concentration inside the machine after ventilation should be lower than the detection limit of 0.14 mg/m^3 (0.1 ppm).
In case of trouble the operator can only access this area when the machine has stopped in order to restore the machine condition. Restoring takes only a very limited period of time (typically less than 1 minute) and happens only occasionally. Spraying water for approximately 10 seconds before opening the machine reduces the vapour concentration of the hydrogen peroxide. The concentration is reduced to 0.7- 1.4 mg/m^3 (0.5 – 1 ppm) (measured data) when the operator opens the machine. However, it can be assumed that the hydrogen peroxide concentration drops immediately as soon as the machine is opened and the potential exposure to the maximum of 1 ppm is regarded as worst-case assumption. Wearing of RPE is recommended in these cases. The equipment is designed such that it cannot be open during use. In case of routine maintenance, the machine will be turned off and vented until all vapour is exhausted and the equipment is cooled off.

The values of hydrogen peroxide concentration measured around the aseptic filling machines during final internal validation are between 0.14 and 0.7 mg/m^3 (0.1 and 0.5 ppm). **According to the Applicant all aseptic packaging machines are enclosed and therefore measurements from immersion in the CAR are considered representative for all disinfection types (immersion, vaporised hydrogen peroxide and spray application).** Similar values were reported from measurements around the machine carried out for monitoring during several hours of operation using Dräger accuro 2000 instrument (detection range between 0.1 and 3 ppm).

Aseptic packaging	**Inhalation exposure Air concentration (measured data)**
Inside the machine after ventilation	< 0.14 mg/m^3 (detection limit)
While opening the machine	0.7−1.4 mg/m^3
Around the machines	0.14−0.7 mg/m^3

It is important that occupational hygienic measures in aseptic packaging limit the air levels of hydrogen peroxide to less than the AEC e.g. during maintenance work where peak exposures may occur.
Dermal exposure to the concentrated product (> 35 %) is possible during maintenance work, and therefore PPE (chemical gloves, protective coverall and eye protection) maybe needed.

Further information and considerations on use in aseptic packaging

Since the packaging sheet material is dried to remove residual hydrogen peroxide by a combination of mechanical means (rubber rollers) and hot air, no relevant residual hydrogen peroxide which could contaminate food remain in the packages. In some efficacy studies for aseptic packaging included in this dossier, hydrogen peroxide residuals have been analysed in distilled water directly after the filling process. These results show acceptable values against the requirements of common practice (< 0.5 ppm). Secondary exposure via food is therefore negligible.

Summary table: estimated exposure from professional uses				
Exposure scenario		**Tier/PPE**	**Estimated inhalation concentration**	**Estimated dermal concentration**
Aseptic packaging – disinfection of food packaging by immersion, vaporised hydrogen peroxide or spray application	Automated loading	1/no PPE	0.52 mg/m^3	49.9 % (worst case)
	Application (around machines)	1/no PPE	0.14-0.7 mg/m^3 (measured)	35.7 %
	Maintenance work	1/no PPE	0.7-1.4 mg/m^3 (measured)	35.7 %
		2/RPE 10	0.07-0.14 mg/m^3	

Use 5: Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP) PT 4

This use 5 in food processing facilities PT 4 is similar to use 1 in PT 2 and use 4 in PT 4 regarding the process (aerosolised or vaporised hydrogen peroxide, VHP). The difference is that in use 1 surfaces of closed spaces are disinfected, in use 4 food packaging material and in this use 5 closed areas in aseptic packaging machines.

Scenario 15: Automated loading; same as Scenario 1

Scenario 16: Surface disinfection by VHP process in closed system; same as Scenario 2

Please see the respective exposure scenarios 1 and 2 above. Only the summary table is copied here.

Summary table: estimated exposure from professional uses				
Exposure scenario		**Tier/PPE**	**Estimated inhalation concentration**	**Estimated dermal concentration**
Surface disinfection by VHP process	Automated loading	1/no PPE	0.52 mg/m^3	49.9 %
	VHP process (no entry)	1/no PPE	No exposure	No exposure

Use 6: Disinfection of distribution and storage systems for drinking water PT 4

Scenario 17: Automated loading; same as Scenario 1

Scenario 18: Disinfection of distribution and storage systems for drinking water

According to the Applicant, disinfection in this use is limited to flooding of pipes and automated spraying of tanks using CIP technologies, there is no manual surface disinfection.

Description of Scenario 18: Disinfection of distribution and storage systems for drinking water
For cleaning deposits and distribution systems the content (drinking water) has to be removed. Deposits are cleaned mechanically before disinfection starts. The distribution and storing systems get disinfected by either spraying or flooding 13 % w/w hydrogen peroxide in containers or pipes. After the contact time needed, the surface is rinsed. According to the Applicant, flooding of pipes is regarded as low risk application and spraying of tanks is automated using CIP technologies. Based on the statement of the Applicant, the processes are fully automated and enclosed with no exposure in the case of tanks or piping systems, **see the qualitative assessment in scenario 3.**

Summary table: estimated exposure from professional uses				
Exposure scenario		**Tier/PPE**	**Estimated inhalation concentration**	**Estimated dermal concentration**
Disinfection of distribution and storage systems for drinking water	Automated loading	1/no PPE	0.52 mg/m^3	49.9 %
	Automated spraying	1/no PPE	No exposure	No exposure

Use 7: Surface disinfection in food and feed processing by liquid application PT 4

According to the Applicant this use 7 in PT 4 is considered same as use 2 Surface disinfection by liquid application in PT 2. The application types are automated spraying and immersion as in PT 2. Please see the respective exposure scenarios 4, 5, 6 and 7 above. Only the summary tables are copied here. In both uses 2 and 7 the use concentration is 13 % hydrogen peroxide.

Scenario 19: Automated loading; same as Scenario 4

Scenario 20: Surface disinfection by automated spraying; same as Scenario 5

Summary table: estimated exposure from professional uses				
Exposure scenario		**Tier/PPE**	**Estimated inhalation concentration**	**Estimated dermal concentration**
Surface disinfection by automated spraying	Automated loading	1/no PPE	0.52 mg/m^3	49.9 %
	Automated spraying	1/no PPE	No exposure	No exposure

Scenario 21: Loading of immersion bath; same as Scenario 6

Scenario 22: Immersion (dipping); same as Scenario 7

Summary table: estimated exposure from professional uses				
Exposure scenario		**Tier/PPE**	**Estimated inhalation concentration**	**Estimated dermal concentration**
Immersion bath ConsExpo ART (90th)	Loading of immersion bath	1/no PPE	15 mg/m^3	49.9 %
		2/RPE 20	0.75 mg/m^3	49.9 %
		2a/Mechanical ventilation giving at least 1 ACH + LEV: Fixed capturing hood	1.1 mg/m^3	49.9 %
		2b/Ventilation 3 ACH + LEV: Fixed capturing hood	0.72 mg/m^3	49.9 %
	Immersion/ dipping	1/no PPE no LEV	ART: 3.5 mg/m^3 ConsExpo: 1.4 mg/m^3	13 %
		2/RPE 5	ART: 0.7 mg/m^3 ConsExpo: 0.28 mg/m^3	13 %
		2a/Mechanical ventilation giving at least 1 ACH + LEV: Fixed capturing hood	ART: 0.26 mg/m^3	13 %

According to the Applicant the use of RPE is general practice in loading and mixing activities where high concentrated solutions are used.

Use 8: Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP) PT 4

This use is described as disinfection of PET food packages by vaporized hydrogen peroxide using a commercial food package sterilization system. The application method is automated vaporization in aseptic filling machines.
This use 8 is similar to use 4 with the difference that the process involved is only vaporised hydrogen peroxide and the product contains 25 % hydrogen peroxide.

Scenario 23: Automated loading; same as Scenario 1
Scenario 24: Application (around the machines), same as Scenario 13
Scenario 25: Maintenance work, same as Scenario 14

Please see the respective exposure scenarios 1, 13 and 14 in use 4 above. Only the summary table is copied here.

Summary table: estimated exposure from professional uses				
Exposure scenario		**Tier/PPE**	**Estimated inhalation concentration**	**Estimated dermal concentration**
Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP)	Automated loading	1/no PPE	0.52 mg/m^3	49.9 % (worst case)
	Application (around machines)	1/no PPE	0.14-0.7 mg/m^3 (measured)	25 %
	Maintenance work	1/no PPE	0.7-1.4 mg/m^3 (measured)	25 %

Use 9: Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP) PT2

Based on the efficacy comments during peer review the original use 1 with all meta SPCs 1, 2, 3 was divided to use 1: (meta SPC 1, 2, 3): room disinfection by aerosolized hydrogen peroxide and use 9 (meta SPC 2, 3): disinfection of filling isolators by aerosolized and vaporized hydrogen peroxide. The same scenarios apply.

Scenario 26: Automated loading; same as Scenario 1
Scenario 27: Application; same as Scenario 2
Scenario 28: Re-entry; same as Scenario 3

Summary table: estimated exposure from professional uses				
Exposure scenario		**Tier/PPE**	**Estimated inhalation concentration**	**Estimated dermal concentration**
Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP)	Automated loading	1/no PPE	0.52 mg/m^3	49.9 %
	Application (no entry)	1/no PPE	No exposure	No exposure
	Re-entry	1/no PPE	< 1.25 mg/m^3	No exposure

Non-professional exposure

All products in this family are only for industrial and professional use, and therefore no non-professional exposure exist.

Exposure of the general public

Exposure of general public or secondary exposure in general is not considered as there is no residual hydrogen peroxide on treated surfaces or equipment. Volatile residues do not occur due to a rinsing step and high reactivity of the active substance. Inhalation exposure of general public is eliminated as re-entry is not possible before reaching the safe levels.

Monitoring data
No monitoring data has been submitted.

Dietary exposure

Hydrogen peroxide used in aseptic packaging (PT 4) evaporates while the wrapping material is heated before filled with food and no residues in food are expected. In some efficacy studies for aseptic packaging included in this dossier, hydrogen peroxide residuals have been analysed in distilled water directly after the filling process. These results show acceptable values against the requirements of common practice (< 0.5 ppm).

Pipes and containers disinfected with hydrogen peroxide are rinsed (flushed) before refilled with drinking water and relevant residual hydrogen peroxide is regarded as negligible under disinfection of distribution systems for drinking water (PT 4).

During disinfection of animal housing (PT 3) no animals are present, and therefore no livestock exposure is expected.

In conclusion, food, drinking water or livestock exposure to hydrogen peroxide is not expected.

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Plant protection products[1]	Basic substance	No MRL required Included in Annex IV of Regulation (EC) No 396/2005 based on Regulation (EU) 2017/1777
2.	Veterinary products	Veterinary active substance	No MRL required for all food producing species according to Regulation (EU) No 37/2010

[1] Hydrogen peroxide is an approved active substance under Regulation (EC) No 1107/2008, Commission Decision 2007/442/EC, Regulation (EU) 2017/409

Hydrogen peroxide is also used in cosmetics (in hair and skin products, nail hardening products, oral hygiene and tooth whitening products and products intended for eyelashes) and in various uses in Reach.

Exposure associated with production, formulation and disposal of the biocidal product

Hydrogen peroxide is always directly produced as an aqueous solution and the aqueous solutions of hydrogen peroxide are used as biocidal products. For this reason, the pure active substance hydrogen peroxide is never isolated. Biocidal products are manufactured in the same processes as the active substance not intended for biocidal use. Only a minor fraction of total hydrogen peroxide manufactured in the EU is used within biocidal products. The production of hydrogen peroxide aqueous solutions is evaluated in the EU Risk Assessment Report (2003) and is described as an automated, closed and continuous process. Some exposure may incidentally occur during distillation, stabilization, dilution and sampling/laboratory works. No further risk assessment is required under the BPR Regulation.

Residues in cartridges and bulk units are expected. Before disposal, cartridges and bulk units containing only small amounts of residual product will be diluted with water and emptied into a

sink with running water. Rinse water need to be disposed of in accordance with local and national regulations. Where possible recycling is preferred to disposal or incineration.

Aggregated exposure

There is no agreed guidance to asses aggregated exposure. For hydrogen peroxide products it is not considered relevant due to the high reactivity of the active substance and as hydrogen peroxide only exerts local effects at the site of first contact. Therefore, combination of different exposure sources is not necessary.

Summary of exposure assessment

Only inhalation exposure is quantitatively assessed. For dermal exposure the qualitative risk characterization for potential local effects is presented in next Chapter.

Scenarios and values to be used in risk assessment					
Scenario number	**Task/ Scenario**	**Hydrogen peroxide concent-ration %**	**Method for exposure assess-ment**	**Tier/PPE**	**Estimated exposure concentration in air [mg/m³]**
Use 1: Surface disinfection of closed spaces by aerosolised hydrogen peroxide PT 2					
1	Automated loading	49.9	ART	1/no PPE	0.52
2	Application	1 g of HP per m³	Qualitative	Closed process (no entry)	No exposure
3	Re-entry	No exposure	Qualitative	1/no PPE	< 1.25
Use 2: Surface disinfection by liquid application in industrial and institutional areas PT 2					
4	Automated loading	49.9	ART	1/no PPE	0.52
5	Automated spraying	13	Qualitative	Closed process	No exposure
	Re-entry	Re-entry is safe when the concentration is < 1.25 mg/m³.			
6	Loading of immersion bath	49.9	ART	1/no PPE	15
				2/RPE 20	0.75
				2a/Mechanical ventilation giving at least 1 ACH + LEV: Fixed capturing hood	1.1
				2b/Ventilation 3 ACH + LEV: Fixed capturing hood	0.72
7	Immersion/ Dipping	13	ART	1/no PPE no LEV	3.5
				2/RPE 5	0.7
			ConsExpo	1/no PPE no LEV	1.4
				2/RPE 5	0.28
			ART	2a/ Mechanical ventilation giving at least 1 ACH + LEV: Fixed capturing hood	0.26
Use 3: Disinfection of surfaces associated with animal housing by spraying PT 3					
8	Automated mixing and loading	49.9	ART	1/no PPE	0.52

9	Automated spraying	13	Qualitative	Closed process	No exposure
	Re-entry	Re-entry is safe when the concentration is < 1.25 mg/m^3.			
10	Manual mixing and loading	49.9	ART	1/no PPE (splash loading, natural ventilation)	4.5
				2/RPE 5	0.9
				2a/no PPE (splash loading, LEV with 50 % reduction, ACH 3)	1.1
				2b/no PPE (submerged loading, mechanical ventilation)	1.1
11	Manual spraying	13	ART	1/no PPE	4 (10 ACH) 45 (No restriction on general ventilation characteristics)
				2/RPE 10	0.4 (10 ACH) 4.5 (No restriction on general ventilation characteristics)
	Re-entry	Re-entry is safe when the concentration is < 1.25 mg/m^3.			
Use 4: Disinfection of food packaging material (aseptic packaging) by immersion, aerosolised or vaporised hydrogen peroxide (VHP)PT 4					
12	Automated loading	49.9 (worst-case)	ART	1/no PPE	0.52
13	Application in aseptic packaging	35.7	Measured	1/no PPE	0.14-0.7
14	Maintenance	35.7	Measured	1/no PPE	0.7-1.4
				2/RPE 10	0.07-0.14
Use 5: Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP) PT 4 (same as use 1)					
15	Automated loading	49.9 (worst-case)	ART	1/no PPE	0.52
16	Application by VHP process	0.2 (2000 ppm)	Qualitative	Closed process (no entry)	No exposure

Use 6: Disinfection of distribution and storage systems for drinking water PT 4					
17	Automated loading	49.9	ART	1/no PPE	0.52
18	Automated spraying	13	Qualitative	Closed process	No exposure
Use 7: Surface disinfection in food and feed processing by liquid application PT 4 (same as use 2)					
19	Automated loading	49.9	ART	1/no PPE	0.52
20	Automated spraying	13	Qualitative	Closed process	No exposure
21	Loading of immersion bath	49.9	ART	1/no PPE	15
				2/RPE 20	0.75
				2a/Mechanical ventilation giving at least 1 ACH + LEV: Fixed capturing hood	1.1
				2b/Ventilation 3 ACH + LEV: Fixed capturing hood	0.72
22	Immersion/ Dipping	13	ART	1/no PPE no LEV	3.5
				2/RPE 5	0.7
			ConsExpo	1/no PPE no LEV	1.4
				2/RPE 5	0.28
			ART	2a/Mechanical ventilation giving at least 1 ACH + LEV: Fixed capturing hood	0.26
Use 8: Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP) PT 4					
23	Automated loading	49.9 (worst-case)	ART	1/no PPE	0.52
24	Application in aseptic packaging	25	Measured	1/no PPE	0.14-0.7
25	Maintenance	25	Measured	1/no PPE	0.7-1.4
Use 9: Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP) PT 2					
26	Automated loading	49.9	ART	1/no PPE	0.52

27	Application	18 g of HP per m^3	Qualitative	Closed process (no entry)	No exposure
28	Re-entry	No exposure	Qualitative	1/no PPE	< 1.25

2.2.6.3 Risk characterisation for human health

Reference values to be used in risk characterisation

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

In view of the absence of systemic effects after exposure to hydrogen peroxide, only external reference values are relevant for potential local effects from dermal and inhalation exposure.

For inhalation exposure, an Acceptable Exposure Concentration (**AEC**) **of 1.25 mg/m³** has been derived for hydrogen peroxide for acute, medium-term and long-term exposure. This AEC is based on a NOAEC of 10 mg/m³ (highest concentration) derived from a 90-day inhalation study in rats and applying an overall assessment factor of 8 to account for interspecies (2.5) and intraspecies (3.2) variabilities. (CAR for PTs 1-6, 2015)

There are no relevant dermal toxicity studies available for derivation of dermal reference values. Based on the specific concentration limits for skin and eye effects of CLP hydrogen peroxide is corrosive at concentrations ≥ 50 %, irritant to skin at concentrations ≥ 35 to < 50 %, causes serious eye damage at concentrations ≥ 8 to < 50 % and eye irritation at concentrations ≥ 5 to < 8 %. The relevant concentration limit values are 35 % for local dermal effects and 8 % for eye effects in this INTEROX products family where the most concentrated product is 49.9 % and the concentration of in-use solutions are in the range of 9.5 to 13 %.

Reference	Study	NOAEC	AF	Correction for oral absorption	Value
$AEC_{short\text{-}term}$ for inhalation	NOAEC in 90-day inhalation study (rat)	7 ppm (10 mg/m³)	8	Not applicable	1.25 mg/m³
$AEC_{medium\text{-}term}$ for inhalation	NOAEC in 90-day inhalation study (rat)	7 ppm (10 mg/m³)	8	Not applicable	1.25 mg/m³
$AEC_{long\text{-}term}$ for inhalation	NOAEC in 90-day inhalation study (rat)	7 ppm (10 mg/m³)	8	Not applicable	1.25 mg/m³
Local dermal effects	specific concentration limit for skin irritation in CLP				35 %
Local eye effects	specific concentration limit for serious eye damage in CLP				8 %
ARfD	Not established				
ADI	ADI not established. The substance is not systemically available.				

Risk for industrial users

The hydrogen peroxide products in this biocidal product family are intended only for industrial and professional use. Risk for professionals corresponds to industrial users.

Risk for professional users

Systemic effects
In the absence of clear systemic adverse effects of hydrogen peroxide, no exposure assessment for systemic doses nor risk characterisation is required.

Local effects
The risk characterisation is focused on local effects. For inhalation route, the airborne exposure concentration is compared with the AEC inhalation of 1.25 mg/m^3. For the assessment of potential local effects to skin and eyes, the concentration of the product or the in-use solution is compared to the specific concentration limits for skin irritation and serious eye damage, 35 % and 8 %, respectively. The products in meta-SPCs 3, 7, 9 are considered corrosive to skin as the pH values are ≤ 2.

Inhalation exposure: quantitative risk assessment for local effects

Task / Scenario	AEC [mg/m³]	Tier / PPE	Estimated exposure concentration in air [mg/m³]	Exposure / AEC [%]	Acceptable (Yes / No)
Use 1: Surface disinfection of closed spaces by aerosolised hydrogen peroxide PT 2					
Automated loading	1.25	1/no PPE	0.52	42	Yes
Application	1.25	Closed process (no entry)	No exposure	-	Yes
Re-entry	1.25	1/no PPE	< 1.25	<100	Yes
Use 2: Surface disinfection by liquid application in industrial and institutional areas PT 2					
Automated loading	1.25	1/no PPE	0.52	42	Yes
Automated spraying	1.25	Closed process (no entry)	No exposure	-	Yes
• Re-entry	1.25	Re-entry is safe when the concentration is < 1.25 mg/m³.			
Loading of immersion bath	1.25	1/no PPE	15	1200	No
		2/RPE 20	0.75	60	Yes
		2a/ Mechanical ventilation giving at least 1 ACH + LEV: Fixed capturing hood	1.1	88	Yes
		2b/ Ventilation 3 ACH + LEV: Fixed capturing hood	0.72	58	Yes
Immersion/ Dipping	1.25	1/no PPE no LEV (ART)	3.5	280	No
		2/RPE 5	0.7	56	Yes
		1/no PPE no LEV (ConsExpo)	1.4	112	No
		2/RPE 5	0.28	22	Yes
		2a/ Mechanical ventilation giving at least 1 ACH + LEV: Fixed capturing hood (ART)	0.26	21	Yes
Use 3: Disinfection of surfaces associated with animal housing by spraying PT 3					
Automated loading	1.25	1/no PPE	0.52	42	Yes
Automated spraying	1.25	Closed process (no entry)	No exposure	-	Yes
• Re-entry	1.25	Re-entry is safe when the concentration is < 1.25 mg/m³.			

Manual mixing and loading	1.25	1/no PPE (splash loading, natural ventilation)	4.5	360	No
		2/RPE 5	0.9	72	Yes
		2a/no PPE (splash loading, LEV with 50 % reduction, ACH 3)	1.1	88	Yes
		2b/no PPE (submerged loading, mechanical ventilation)	1.1	88	Yes
Manual spraying	1.25	1/no PPE (ART)	4 (10 ACH) 45 (No restriction on general ventilation characteristics)	320 3600	No No
		2/RPE 10 (ART)	0.4 (10 ACH) 4.5 (No restriction on general ventilation characteristics)	32 360	Yes No
• Re-entry	1.25	Re-entry is safe when the concentration is < 1.25 mg/m^3.			
Use 4: Disinfection of food packaging material (aseptic packaging) by immersion, aerosolised or vaporised hydrogen peroxide (VHP) PT 4					
Automated loading	1.25	1/no PPE	0.52	42	Yes
Application in aseptic packaging	1.25	1/no PPE	0.14-0.7	11-56	Yes
Maintenance	1.25	1/no PPE	0.7-1.4	56-110	No
		2/RPE 10	0.07-0.14	5.6-11	Yes
Use 5: Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP) PT 4					
Automated loading	1.25	1/no PPE	0.52	42	Yes
Application by VHP process	1.25	Closed process (no entry)	No exposure	-	Yes
Use 6: Disinfection of distribution and storage systems for drinking water PT 4					
Automated loading	1.25	1/no PPE	0.52	42	Yes
Automated spraying	1.25	Closed process	No exposure	-	Yes
Use 7: Surface disinfection in food and feed processing by liquid application PT 4					

Automated loading	1.25	1/no PPE	0.52	42	Yes
Automated spraying	1.25	Closed process	No exposure	-	Yes
Loading of immersion bath	1.25	1/no PPE	15	1200	No
		2/RPE 20	0.75	60	Yes
		2a/ Mechanical ventilation giving at least 1 ACH + LEV: Fixed capturing hood	1.1	88	Yes
		2b/ Ventilation 3 ACH + LEV: Fixed capturing hood	0.72	58	Yes
Immersion/ Dipping	1.25	1/no PPE no LEV (ART)	3.5	280	No
		2/RPE 5	0.7	56	Yes
		1/no PPE no LEV (ConsExpo)	1.4	112	No
		2/RPE 5	0.28	22	Yes
		2a/ Mechanical ventilation giving at least 1 ACH + LEV: Fixed capturing hood (ART)	0.26	21	Yes
Use 8: Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP) PT 4					
Automated loading	1.25	1/no PPE	0.52	42	Yes
Application in aseptic packaging	1.25	1/no PPE	0.14-0.7	11-56	Yes
Maintenance	1.25	1/no PPE	0.7-1.4	56-110	No
		2/RPE 10	0.07-0.14	5.6-11	Yes
Use 9: Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP) PT 2					
Automated loading	1.25	1/no PPE	0.52	42	Yes
Application	1.25	Closed process (no entry)	No exposure	-	Yes
Re-entry	1.25	1/no PPE	< 1.25	<100	Yes

Combined scenarios
The adverse effects of hydrogen peroxide in humans is limited to local effects therefore combined exposure is not relevant.

Conclusion on quantitative risk assessment for inhalation exposure

The results are presented in the table above showing that the uses are acceptable provided the products are used according to the use instructions and with RMMs agreed.

Dermal, eye and inhalation exposure: qualitative risk assessment for local effects
Primary exposure: industrial/professional use.
Potential exposure route: skin, eye (splashes) and inhalation.

Task/ Scenario	HP concentration %	Hazard		Exposure information			Risk
		Hazard category	Effects (C&L)	Frequency and duration of potential exposure	Degree of potential exposure under best practice conditions	Relevant RMM and PPE	Conclusion on risk
Use 1: Surface disinfection of closed spaces by aerosolised hydrogen peroxide PT 2 **Use 9: Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP) PT 2**							
Automated loading	49.9	High for eyes High for skin Low for respiratory tract	Eye Dam. 1 (H318) Skin Corr. 1 (H314) STOT SE 3 (H335)	few minutes per day	Low potential for eye exposure Low potential for dermal exposure Negligible to low potential for respiratory tract exposure due to automated loading systems.	**RMM** • Labelling according to CLP • Containment as appropriate • Good standard of general ventilation • Regular cleaning of equipment and work area • Avoidance of contact with contaminated tools and objects **PPE** <u>Eye protection:</u> Safety goggles. Eye protection must be chosen based on level of activity and exposure. <u>Skin protection:</u> Gloves and coverall	**Acceptable** + Engineering controls; + Low frequency; + Short duration; + Professionals, using PPE ; + Professionals, following instructions for use; Good standard of personal hygiene.
Application	Not relevant, closed process, no exposure.						
Re-entry	Not relevant, concentrations for dermal exposure not irritating, inhalation exposure assessed qualitatively						
Use 2: Surface disinfection by liquid application in industrial and institutional areas PT 2							
Automated loading	see Automated loading scenario above						
Automated spraying	13	High for eyes	Eye Dam. 1 (H318)	Not relevant, closed process, no exposure.			

Loading for immersion	49.9	High for eyes High for skin Low for respiratory tract	Eye Dam. 1 (H318) Skin Corr. 1 (H314) STOT SE 3 (H335)	10 minutes per day	Medium potential for eye exposure Medium potential for dermal exposure Low/medium potential for respiratory tract exposure	**RMM** • Labelling according to CLP • Containment as appropriate • Good standard of general ventilation • Regular cleaning of equipment and work area • Avoidance of contact with contaminated tools and objects **PPE** <u>Eye protection:</u> Safety goggles. Eye protection must be chosen based on level of activity and exposure. <u>Skin protection:</u> Gloves and coverall <u>Respiratory protection:</u> Substance/task appropriate respirator	**Acceptable** + Engineering controls; + Low frequency; + Short duration; + Professionals, using PPE ; + Professionals, following instructions for use; Good standard of personal hygiene.
Immersion/ Dipping	13	High for eyes	Eye Dam. 1 (H318)	30 minutes per day	Medium potential for eye exposure Medium potential for dermal exposure	**RMM** • Labelling according to CLP • Containment as appropriate • Good standard of general ventilation • Regular cleaning of equipment and work area • Avoidance of contact with contaminated tools and objects **PPE** <u>Eye protection:</u> Safety goggles. Eye protection must be chosen based on level of activity and exposure.	**Acceptable** + Engineering controls; + Low frequency; + Short duration; + Professionals, using PPE ; + Professionals, following instructions for use; Good standard of personal hygiene.
Use 3: Disinfection of surfaces associated with animal housing by spraying PT 3							
Automated loading	see Automated loading scenario above						

Automated spraying	13	High for eyes	Eye Dam. 1 (H318)	Not relevant, no exposure.			
Manual mixing and loading	49.9	High for eyes High for skin Low for respiratory tract	Eye Dam. 1 (H318) Skin Corr. 1 (H314) STOT SE 3 (H335)	20 minutes per day	Medium potential for eye exposure Medium potential for dermal exposure Low/medium potential for respiratory tract exposure	**RMM** • Labelling according to CLP • Containment as appropriate • Good standard of general ventilation • Regular cleaning of equipment and work area • Avoidance of contact with contaminated tools and objects **PPE** <u>Eye protection:</u> Safety goggles. Eye protection must be chosen based on level of activity and exposure. <u>Skin protection:</u> Gloves and coverall <u>Respiratory protection:</u> Substance/task appropriate respirator	**Acceptable** + Engineering controls; + Low frequency; + Short duration; + Professionals, using PPE ; + Professionals, following instructions for use; Good standard of personal hygiene.
Manual spraying	13	High for eyes	Eye Dam. 1 (H318)	400 minutes per day	High potential for eye exposure High potential for dermal exposure	**RMM** • Labelling according to CLP • Containment as appropriate • Good standard of general ventilation • Regular cleaning of equipment and work area • Avoidance of contact with contaminated tools and objects **PPE** <u>Eye protection:</u> Safety goggles. Eye protection must be chosen based on level of activity and exposure. <u>Skin protection:</u> Gloves and coverall	**Acceptable** + Professionals, using PPE ; + Professionals, following instructions for use; Good standard of personal hygiene.
Use 4: Disinfection of food packaging material (aseptic packaging) by immersion, aerosolised or vaporised hydrogen peroxide (VHP) PT 4							

Automated loading	see Automated loading scenario above						
Application in aseptic packaging	35.7	High for eyes Low for skin Low for respiratory tract	Eye Dam. 1 (H318) Skin Irrit. 2 (H315) STOT SE 3 (H335)	a few hours per day	Negligible potential for eye exposure Negligible potential for dermal exposure Negligible to low potential for respiratory tract exposure due to mainly closed systems.	**RMM** • Labelling according to CLP • Containment as appropriate • Good standard of general ventilation • Regular cleaning of equipment and work area • Avoidance of contact with contaminated tools and objects	**Acceptable** + Engineering controls; + Low frequency; + Professionals, following instructions for use; Good standard of personal hygiene.
Maintenance	35.7	High for eyes Low for skin Low for respiratory tract	Eye Dam. 1 (H318) Skin Irrit. 2 (H315) STOT SE 3 (H335)	a few minutes per day	Low potential for eye exposure Low potential for dermal exposure Low potential for respiratory tract exposure	**RMM** • Labelling according to CLP • Containment as appropriate • Good standard of general ventilation • Regular cleaning of equipment and work area • Avoidance of contact with contaminated tools and objects **PPE** <u>Eye protection:</u> Safety goggles. Eye protection must be chosen based on level of activity and exposure. <u>Skin protection:</u> Gloves and coverall <u>Respiratory protection:</u> Substance/task appropriate respirator	**Acceptable** + Engineering controls; + Low frequency; + Short duration; + Professionals, using PPE ; + Professionals, following instructions for use; Good standard of personal hygiene.
Use 5: Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP) PT 4							
Automated loading	see Automated loading scenario above						

Application by VHP process	see Application by VHP process scenario above						
Use 6: Disinfection of distribution and storage systems for drinking water PT 4							
Automated loading	see Automated loading scenario above						
Automated spraying	see Automated spraying scenario above						
Use 7: Surface disinfection in food and feed processing by liquid application PT 4							
Automated loading	see Automated loading scenario above						
Automated spraying	see Automated spraying scenario above						
Loading for immersion	see Loading for immersion scenario above						
Immersion/ Dipping	see Immersion/ Dipping scenario above						
Use 8: Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP) PT 4							
Automated loading	see Automated loading scenario above						
Application in aseptic packaging	25	High for eyes	Eye Dam. 1 (H318)	a few hours per day	Negligible potential for eye exposure	**RMM** • Labelling according to CLP • Containment as appropriate • Good standard of general ventilation • Regular cleaning of equipment and work area • Avoidance of contact with contaminated tools and objects	**Acceptable** + Engineering controls; + Low frequency; + Professionals, following instructions for use; Good standard of personal hygiene.

Maintenance	25	High for eyes	Eye Dam. 1 (H318)	a few minutes per day	Low potential for eye exposure	**RMM** • Labelling according to CLP • Containment as appropriate • Good standard of general ventilation • Regular cleaning of equipment and work area • Avoidance of contact with contaminated tools and objects **PPE** <u>Eye protection:</u> Safety goggles. Eye protection must be chosen based on level of activity and exposure.	**Acceptable** + Engineering controls; + Low frequency; + Short duration; + Professionals, using PPE (goggles); + Professionals, following instructions for use; Good standard of personal hygiene.

Conclusion on the qualitative risk characterization for local effects
See the table above where the conclusion is presented in the last column.

Overall summary for professional uses

Use 1: Surface disinfection of closed spaces by aerosolised hydrogen peroxide PT 2 (Meta SPC 1, 2, 3)
Automated loading of product is acceptable without RPE. During application there is no exposure and re-entry is only allowed when the safe level has been reached.

Use 2: Surface disinfection by liquid application in industrial and institutional areas PT 2 (Meta SPC 8, 9)
Automated loading of product is acceptable without RPE. There is no exposure during automated spraying of closed systems (CIP). For automated surface spraying like conveyors or other fixed installations use-specific RMM has to be used (see Ch. 2.1.4.2.3). During manual loading of immersion bath and immersion phase efficient general and local exhaust ventilation should be used or RPE.

Use 3: Disinfection of surfaces associated with animal housing by spraying PT 3 (Meta SPC 8, 9)
Automated loading of product is acceptable without RPE. For manual mixing and loading efficient general and local exhaust ventilation should be used or RPE. For automated spraying use-specific RMM has to be used (see Ch. 2.1.4.3.3).
During manual spraying efficient ventilation and RPE should be used. In addition to mandatory eye protection, protective clothing and gloves are recommended due to significant dermal exposure to in-use solution.

Use 4: Disinfection of food packaging material (aseptic packaging) by immersion, aerosolised or vaporised hydrogen peroxide (VHP) PT 4 (Meta SPC 5)
Automated loading of product is acceptable without RPE. During application efficient ventilation outside the packaging machines is needed. During maintenance RPE may be needed.

Use 5: Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP) PT 4 (Meta SPC 5)
Automated loading of product is acceptable without RPE. During application efficient ventilation outside the packaging machines is needed. During maintenance RPE may be needed.

Use 6: Disinfection of distribution and storage systems for drinking water PT 4 (Meta SPC 6, 7)
Automated loading of product is acceptable without RPE. There is no exposure during automated spraying of closed systems (CIP).

Use 7: Surface disinfection in food and feed processing by liquid application PT 4 (Meta SPC 6, 7)
Automated loading of product is acceptable without RPE. There is no exposure during automated spraying of closed systems (CIP). For automated surface spraying like conveyors or other fixed installations specific RMM has to be used (see Ch. 2.1.4.7.3).
During loading of immersion bath efficient general and local exhaust ventilation should be used or RPE.

Use 8: Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP) PT 4 (Meta SPC 4)
Automated loading of product is acceptable without RPE. During application efficient ventilation outside the packaging machines is needed. During maintenance RPE may be

needed.

Use 9: Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP) PT 2 (Meta SPC 2, 3)
Automated loading of product is acceptable without RPE. During application there is no exposure and re-entry is only allowed when the safe level has been reached.

Furthermore, since the products in meta-SPCs 2, 3, 5, 6, 7, 8 and 9 are classified with Skin Corr. 1; H314/Skin Irrit. 2; H315 and Eye Dam. 1, H318, **protective clothing, gloves and eye protection are to be used when handling the concentrated products, e.g. during loading.** As those products are also classified with STOT SE 3; H335, respiratory protection equipment has to be used when potential for respiratory tract exposure exists, i.e. in manual mixing and loading and maintenance scenarios, in case of insufficient ventilation.

Risk for non-professional users

Non-professional use is not intended.

Risk for the general public

There is no risk for the general public as no exposure exists due to the absence of residual hydrogen peroxide on treated surfaces or equipment. Waiting periods before re-entry of by-standers to disinfected premises prevent the exposure to unacceptable air concentration of hydrogen peroxide.

Risk for consumers via residues in food

No residues in food are expected. In theory, secondary oral and dermal exposure of the general public to residual hydrogen peroxide in food and drinking water is possible under PT 4 (aseptic packaging, disinfection of distribution systems for drinking water). Pipes and containers disinfected with hydrogen peroxide are rinsed (flushed) before refilled with drinking water and relevant residual hydrogen peroxide is regarded as negligible under disinfection of distribution systems for drinking water (PT 4). Hydrogen peroxide used for aseptic packaging evaporates while the wrapping material is heated before filling with food and no residues in food are expected (CAR for PTs 1-6, 2015). In some efficacy studies for aseptic packaging included in this dossier, hydrogen peroxide residuals have been analysed in distilled water directly after the filling process. These results show acceptable values against the requirements of common practice (< 0.5 ppm). During disinfection of animal housing (PT 3) no animals are present, and therefore no livestock exposure exists.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

There is no combined exposure to several active substances as hydrogen peroxide is the only active substance in the products considered here.

2.2.7 Risk assessment for animal health

PT 3: Animals are removed before the disinfection processes of animal housing and therefore no exposure of animals is possible. Hydrogen peroxide is quickly broken down to oxygen and water in the environment and therefore no secondary exposure of animals is expected. The in-use concentrations are not irritating so no risk for local effects is expected in case of accidental dermal contact.

2.2.8 Risk assessment for the environment

The INTEROX Biocidal Product Family 1 consists of 15 hydrogen peroxide products divided into 9 meta-SPCs. No new ecotoxicological information is provided for active substance or products. Effect assessment on environment is based on the data provided in the CAR (2015). Since no relevant substance of concern has been identified, the environmental risk assessment for these products are based on the active substance.

For environmental exposure and risk assessment the intended uses of products are mainly same as assessed in the CAR with some modifications in e.g. type of applications and in-use concentrations, see chapter 2.2.8.2.

Hydrogen peroxide decomposes rapidly into water and oxygen in different environmental compartments, i.e. in surface water, soil, active sludge and air. In addition, hydrogen peroxide decomposes already in sewage before reaching the STP. In regards of the physico-chemical properties of hydrogen peroxide and its rapid degradation in surface waters, hydrogen peroxide is not considered to partition into the sediment in relevant amounts. Thus, in the absence of any ecotoxicological data for sediment-dwelling organisms the assessment conducted for the aquatic compartment covers also to the sediment compartment (CAR 2015).

2.2.8.1 Effects assessment on the environment

No new data regarding the active substance has been submitted, so the relevant PNEC values for the hydrogen peroxide from the Assessment report (AR) for PT 1 – 5 (2015) are presented in the following table.

Summary of PNECs for hydrogen peroxide (AR, 2015)		
Surface water	STP	Soil
12.6 µg/L	4.66 mg/L	0.0018 mg/kg ww

The estimated log K_{ow} for hydrogen peroxide is –1.57 indicating no potential for bioaccumulation and the calculated BCFs for fish and earthworm are 0.84, respectively (AR, 2015). The risk of secondary poisoning is considered negligible.

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

The active substance hydrogen peroxide is the only substance of environmental concern among the components of products in INTEROX Biocidal Product Family 1. There are no active substances from other PTs present in the products. The concentrations of non-active

substances are low in the products. In addition, the non-active substances are not classified regarding environment hazards based on valid information available on their material safety data sheets. Therefore, additional ecotoxicological studies are not required for product authorisation and the classification of the products can be based on active substance only.

The classification of the products was discussed at the WG-II-2021. The WG agreed to keep the approach as presented by the eCA in the CAR which is in line with the conclusion of a similar case drawn at ENV WG-II-2019, i.e. products having ≥ 25 % hydrogen peroxide will be classified as Aquatic Chronic 3.

Further Ecotoxicological studies

No further ecotoxicological studies have been conducted (see above).

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

Data waiving	
Information requirement	Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS).
Justification	Further assessment of other non-target organisms (flora and fauna), is not required since this is not part of the informationrequirements for product types 2-4. In addition, the products are used indoors, the active substance degrades rapidly and there is no direct release to the environment.

Supervised trials to assess risks to non-target organisms under field conditions

Data waiving	
Information requirement	Supervised trials to assess risks to non-target organisms under field conditions.
Justification	Further assessment of supervised trials to assess risks to non-targetorganisms under field conditions, is not required since this is not part of the information requirements for product types 2-4. In addition, the products are used indoors, the active substance degrades rapidly and there is no direct release to the environment.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

Data waiving	
Information requirement	Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk
Justification	Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk, is not required since this is not part of the information requirements for product types 2 -4. In

	addition, the products are used indoors, the active substance degrades rapidly and there is no direct release to the environment.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Further assessment of secondary ecological effects, is not required since this is not part of the information requirements for product types 2-4. In addition, the products are used indoors, the active substance degrades rapidly and there is no direct release to the environment.

Foreseeable routes of entry into the environment on the basis of the use envisaged

In accordance with Annex III of the BPR and the ECHA Guidance on the Biocidal Product Regulation, Volume IV: Environment, Part A: Information Requirements, this endpoint is only applicable to relevant components of the biocidal product. Hydrogen peroxide is always directly produced as an aqueous solution and the aqueous solutions of hydrogen peroxide are used as biocidal products. Information on how the biocidal product can be released to into the environment due to its use, sources of environmental exposure, details of aquatic recipients and information which can be used as predicted environmental concentrations in environmental compartments has already been assessed during the active substance approval and reported in Doc IIB, Appendix 2. As such, data on the foreseeable routes of entry into the environment on the basis of the use envisaged has not been presented in the biocidal product dossier as the data presented in the active substance dossier has been determined as acceptable.

Further studies on fate and behaviour in the environment (ADS)

Data waiving	
Information requirement	**Further studies on fate and behaviour in the environment**
Justification	A data waiver is proposed, in accordance with Point 10 of Annex III to the BPR, which states that the test requirements are applicable only to the relevant components of the biocidal products. Furthermore, point 10.2 of Annex III states that "Further studies chosen from among the endpoints referred to in Section 10 of Annex II for relevant components of the biocidal product or the biocidal product itself may be required. For products that are used outside, with direct emission to soil, water or surfaces, the components in the product may influence the fate and behaviour (and ecotoxicity) of the active substance. Data are required unless it is scientifically justified that the fate of the components in the product is covered by the data provided for the active substance and other identified substances of concern." The biocidal products within the biocidal product family are aqueous solutions containing one active substance, hydrogen peroxide, similar to the "dummy products" assessed as part of the active substance approval application. The Assessment Report states that hydrogen peroxide decomposes rapidly in different environmental compartments. The active substance is miscible with water in all

	proportions and has a low potential for adsorption to soil and for partitioning to suspended matter of sediment. Furthermore, hydrogen peroxide has a negligible potential of bioconcentration in biota and no accumulation is expected in the food chain. Based on the information identified in the Assessment Report and the similarity between the biocidal products within the biocidal product family and the "dummy products", no further testing is deemed necessary to cover the requirements of Annex III, point 10.2 (Further studies on fate and behaviour in the environment), as the study data already available on the active substance provides sufficient assessment of the environmental fate and behaviour of the biocidal product.

Leaching behaviour (ADS)

A data waiver is proposed, in accordance with Point 10 of Annex III to the BPR, which states that the test requirements are applicable only to the relevant components of the biocidal products. The biocidal products within the biocidal product family are aqueous solutions containing one active substance, hydrogen peroxide, with no other relevant impurities and/ or substances of concern. As such, the endpoint 10.3 Leaching behaviour is not considered to be applicable.

Testing for distribution and dissipation in soil, air and water and sediment (ADS)

No data available.

Distribution and Dissipation

Data waiving	
Information requirement	Distribution and Dissipation in soil Distribution and Dissipation in air Distribution and Dissipation in water and sediment.
Justification	A data waiver is proposed, in accordance with Point 10 of Annex III to the BPR, which states that the test requirements are applicable only to the relevant components of the biocidal products. Furthermore, the ECHA Guidance on the Biocidal Products Regulation, Volume IV: Environment, Part A: Information Requirements indicates that no further distribution and dissipation studies with the product in soil are required and information on distribution and degradation for the active substance, transformation products and substances of concern present in the biocidal product is sufficient. The biocidal products within the biocidal product family are aqueous solutions containing one active substance, hydrogen peroxide, similar to the "dummy products" assessed as part of the active substance approval application. The Assessment Report states that hydrogen peroxide decomposes rapidly in different environmental compartments. Hydrogen peroxide shows a very rapid biodegradation in sewage sludge and rapid degradation has also been observed in surface water and soil compartments. This degradation has been proposed to be mainly microbially derived based on the difference in degradation rates between the natural and

	filtered/sterilized samples. The low measured value of Henry's law constant indicates very low volatilsation of hydrogen peroxide from water. The active substance is miscible with water in all proportions and has a low potential for adsorption to soil and for partitioning to suspended matter of sediment. Furthermore, hydrogen peroxide has a negligible potential of bioconcentration in biota and no accumulation is expected in the food chain. Furthermore, hydrogen peroxide does not meet the PBT or POP criteria. Therefore, based on the information assessed at active substance approval, no further testing is deemed necessary to cover the requirements of Annex III, point 10.4 (Testing for distribution and dissipation), as the study data already available on the active substance provides sufficient assessment of the environmental fate and behaviour of the biocidal product.

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)

Acute aquatic toxicity
No data available

Chronic aquatic toxicity
No Data available

Data waiving	
Information requirement	**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**
Justification	A data waiver is proposed, in accordance with Point 10 of Annex III to the BPR, which states that the test requirements are applicable only to the relevant components of the biocidal products. Furthermore, point 10.5 of Annex III states that "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." The biocidal products within the biocidal product family are aqueous solutions containing one active substance, hydrogen peroxide, and are not intended to be sprayed near surface waters. As such, no further testing is deemed necessary to cover the requirements of Annex III, point 10.5 as it is not considered to be applicable.

Measured aquatic bioconcentration
No measured data for aquatic bioconcentration is available.

Estimated aquatic bioconcentration

Summary table – Estimated aquatic bioconcentration					
Basis for estimation	**Log K_{ow} (measured)**	**Estimated BCF for fish (freshwater)**	**Estimated BCF for fish eating**	**Remarks**	**Reference**

			bird/predator		
TGD	-1.57	1.4	Not stated in AR		AR 2015

Conclusion used in Risk Assessment –Aquatic bioconcentration	
Value/conclusion	BCF: Fish = 1.4
Justification for the value/conclusion	The estimated log K_{ow} of –1.57 indicates negligible potential of bioconcentration of hydrogen peroxide in biota. The BCFs calculated in the AR (2015) for fish and earthworm are 1.4 and 0.84, respectively. Therefore, no accumulation of hydrogen peroxide in the food chain is expected either.

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)

A data waiver is proposed, in accordance with Point 10 of Annex III to the BPR, which states that the test requirements are applicable only to the relevant components of the biocidal products. Furthermore, point 10.6 of Annex III states that "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."

The biocidal products within the biocidal product family are aqueous solutions containing one active substance, hydrogen peroxide. As such, there is no possibility for large scale formation of dust. Therefore, no further testing is deemed necessary to cover the requirements of Annex III, point 10.6 as it is not considered to be applicable.

2.2.8.2 Exposure assessment

Meta SPC 1, 2, 3 - Use #1 Surface disinfection of closed spaces by aerosolised hydrogen peroxide (PT 2)

The products in meta SPC 1-3 containing hydrogen peroxide up to 49.9% and intended for PT 2 - Surface disinfection of closed spaces by aerosolised hydrogen peroxide in industrial, institutional or medical area, are similar to the representative product used for the authorisation of the active substance for surface disinfection by VHP process. Target levels are however higher than claimed for the representative product in the CAR (2015). The products are intended for professional use of hydrogen peroxide as surface disinfectant in enclosed (sealed) spaces via machine based fogging/spray (aerosol). Machine based application via fogging/spray is identical to the VHP machine used in the exposure assessment for the active substance. Emission to air is controlled by the machines and catalytic decomposition of hydrogen peroxide may take place in some machines.

Meta SPC 2, 3 - Use #9 Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP) (PT 2)

The products in meta SPC 2-3 containing hydrogen peroxide up to 49.9% and intended for PT 2 - Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP) in industrial area, are similar to the representative product used for the authorisation of the active substance for surface disinfection by VHP process. Target levels are however higher than claimed for the representative product in the CAR (2015). The products are intended for professional use of hydrogen peroxide as surface disinfectant in enclosed (sealed) spaces via machine based VHP (vaporise hydrogen peroxide) or fogging/spray (aerosol). Machine based application via fogging/spray is identical to the VHP machine used in the exposure assessment for the active substance. Emission to air is controlled by the machines and catalytic decomposition of hydrogen peroxide may take place in some machines.

Meta SPC 4 - Use #8 Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP)

The products in meta SPC 4 are intended for specific use in aseptic packaging, i.e. to disinfect polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP). Based on the efficacy studies only this limited use is applicaple for products in the meta SPC 4. The exposure assessment of use #4 is considered to cover this use also.

Meta SPC 5 -Use #4 Disinfection of food packaging material (aseptic packaging) by immersion or aerosolised or vaporised hydrogen peroxide (VHP) (PT4) and use #5 Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP) (PT4)

The products in meta SPC 5 containing up to 35% hydrogen peroxide are intended for use in aseptic packaging, disinfection of food packaging by immersion or vaporised hydrogen peroxide or spray application (PT4) and are similar to the representative product used for authorisation of the active substance for aseptic packaging. The risk assessment for the representative product in the CAR has been performed for disinfection via immersion-bath. VHP and spray application operate in closed systems where emissions to air are negligible and there is no emission to water Therefore a qualitative approach was applied in the product authorisation.

VHP: The principle is to sterilise the food package with vaporized hydrogen peroxide at the exit of the oven. Then blow the food packages with sterile air in a sterile environment and maintain this sterility throughout the filling and capping process.
Spray: A certain amount of H2O2 is sprayed into each foos package container through a spray nozzle. For proper function (sterilisation), the food contact surface of the container needs to be covered completely with the spray solution. Hot sterile air is blown into the container to attain the temperature necessary for the sterilisation process and to remove the H2O2 from the food contact surface.
The products in meta SPC 5 are also intended for professional and industrial disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP). Both techniques operate in closed systems where emissions to air are negligible and there is no emission to water. Therefore, a qualitative approach was applied in the product authorisation.

META SPC 6 and SPC 7 – Use #6 Disinfection of distribution and storage systems for drinking water (PT4) and use #7 Surface disinfection in food & feed processing by liquid application (PT4)

The products in meta SPC 6 and 7 containing up to 49.9% hydrogen peroxide are intended for professional and industrial use in disinfection of distribution and storage systems for drinking water (PT 4) are similar to the representative product used for authorisation of the active substance for disinfection of distribution and storage systems for drinking water. Target in-use concentration of up to 13% hydrogen peroxide is however higher than claimed for the representative product (2%).

Surface disinfection in food & feed processing including equipment and utensils (PT4) by immersion or spraying was not covered by the dossier for the active substance.

META SPC 8 and SPC 9 – Use #2 Surface disinfection by liquid application in industrial and institutional areas (PT2) and use #3 Surface disinfection of animal housing via spraying (PT3)

Surface disinfection in industrial and institutional areas by spraying and immersion (PT 2) was not covered by the CAR (2015) for the active substance.

Surface disinfection of animal housing via spraying (PT3) was assessed in the CAR (2015). Even with an in-use concentration of 13% which is almost twice the concentration used for the representative product in the CAR the fraction remaining in the manure after degradation ($F_{deg} = 9{,}7 \times 10^{-29}$) is still considered to be low and therefore only negligible amounts of hydrogen peroxide may be present in manure when it is spread to soil. In addition to an above mentioned semi-qualitative assessment, in the product authorisation a worst case quantitative assessment for emission to STP was performed.

General information

Assessed PT	PT 2
Assessed scenarios	Scenario 1: Surface disinfection of closed spaces by aerosolised or vaporised hydrogen peroxide (VHP) (use #1, use #9) Scenario 2: Surface disinfection by liquid application in industrial and institutional areas (PT 2) 2a) Emission scenario for calculating the release of disinfectants used for sanitary purposes based on an average consumption (ESD for PT2, RIVM 2001, Table 2.2, p.10) 2b) Emission scenario for calculating the release of disinfectants used for sanitary purposes in hospitals based on the amount of solution of disinfectant used on a day (ESD for PT2, RIVM 2001, Table 3.6, p.20) 2c) Emission scenario for calculating the releases of disinfectants used in hospitals for disinfection of scopes and other articles in washers/disinfectors (ESD for PT2, RIVM 2001, Table 3.7, p.25 & TAB ENV 37, August 2017, scenario for Dipping disinfection system) 2d) Emission scenario for calculating the releases of disinfectants used in hospitals for disinfection of other contaminated instruments (ESD for PT2, RIVM 2001, Table 3.8, p.26) 2e) Emission scenario for calculating the releases of disinfectants used in industrial areas (ESD for PT2, JRC 2011, Table 2, p.12 & TAB ENV 24, Sept 2015)

	2f) Emission scenario for calculating the release of disinfectants used for sanitary purposes in institutional areas based on an average consumption (ESD for PT2, JRC 2011, Table 4, p.16) 2g) Emission scenario for clean-in-place (CIP). This scenario is covered by 7a) and 7b) in PT4.
ESD(s) used	Scenario 1: The agreed scenario used for approval of a.s. was applied. Scenarios 2a-d: ESD for PT 2: Emission scenarios for private and public health area disinfectants and other biocidal products (RIVM, 2001) Scenarios 2e-f: ESD for PT 2: Emission scenarios for private and public health area disinfectants and other biocidal products (JRC, 2011) Scenario 2g: See ESDs for scenarios 7a) and 7b)
Approach	Scenario 1: Maximum target concentration Scenarios 2a-g: Average consumption
Distribution in the environment	Calculated based on BPR Guidance Vol. IV Part B and EUSES 2.1.2
Groundwater simulation	No additional FOCUS groundwater simulation for any of the scenarios
Confidential Annexes	Tonnage scenarios for 2a, 2b and 2f available in the confidential annex.
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	Additional guidance according to the Technical Agreement for Biocides (TAB) were applied. The degradation in the sewer before STP was considered according to the CAR (2015). For PEC calculation is was assumed that once reaching sewage, hydrogen peroxide will rapidly react with microbes and organic matter and be decomposed by microbial catalase and dissolved transition metal ions such as iron. These effects were accounted for using the half-life in similar media regarding microbial density compared to raw sewage of 6 minutes (11.2 min transferred to 12 °C) from Document II A (2015), Section 4.1.1.1 (Spain et al. 1989). Assuming single first-order kinetics and a residence time in sewage of 1 hour (default according to the ESD for PT5), a fraction of 0.024 of the discharged hydrogen peroxide then reaches the STP: Fsewage = exp(- ln(2)/DT50 * 60 min) = 0.024. See confidential Annex for local emission estimation based on tonnage approach. Maximum local emission from the

	scenarios 2a-g was applied environmental exposure and risk assessment.

Assessed PT	PT 3
Assessed scenarios	Scenario 3: Disinfection of animal housing
ESD(s) used	3a) Emission to soil via manure: The agreed approach used for approval of a.s. was applied (CAR 2015) 3b) Emission to STP (turkey as a worst case): ESD for PT3: Veterinary hygiene biocidal products (JRC, 2011).
Approach	3a) Semi-quantitative approach 3b) Average consumption
Distribution in the environment	Calculated based on BPR Guidance Vol. IV Part B and EUSES 2.1.2
Groundwater simulation	No additional FOCUS groundwater simulation for any of the scenarios
Confidential Annexes	NO
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	Additional guidance according to the Technical Agreement for Biocides (TAB) were applied. The degradation in the manure before spreading to soil was considered according to the CAR (2015) applying the harmonised degradation rate constant of 3.65 h^{-1} (DT50 = 11.4 min) for liquid manure agreed at the WGIV2019 and WGIII2020 to be used for PT3. Assuming that the last application of the product containing hydrogen peroxide take place 12 hours before the manure is applied to agricultural land and using single first-order kinetics, fraction remaining in the manure after degradation can be calculated as follows: Fdeg = exp(- ln(2)/0.19 hours · 12 hours) = $9,7 \times 10^{-20}$ The fraction of hydrogen peroxide remaining after 12 hours (Fdeg) is so low that in practice hydrogen peroxide is completely degraded. The degradation in the sewer before STP was considered according to the CAR (2015). For PEC calculation is was assumed that once reaching sewage, hydrogen peroxide will rapidly react with microbes and organic matter and be decomposed by microbial catalase and dissolved transition metal ions such as iron. These effects were accounted for using the half-life in similar media regarding microbial density compared to raw sewage of 6 minutes (11.2 min transferred to 12 °C) from Document II A, Section 4.1.1.1 (Spain et al 1989). Assuming single first-order kinetics and a residence time in sewage of 1 hour (default according to the ESD for

	PT5), a fraction of 0.024 of the discharged hydrogen peroxide then reaches the STP: Fsewage = exp(- ln(2)/DT50 * 60 min) = 0.024.

Assessed PT	PT 4
Assessed scenarios	Scenario 4: Disinfection of food packaging material (aseptic packaging) by immersion or aerosolised or vaporised hydrogen peroxide (VHP) (use #4) 4a) Disinfection of food packaging material (aseptic packaging) by immersion 4b) Disinfection of food packaging material (aseptic packaging) by aerosolised or vaporised hydrogen peroxide (VHP) 4c) Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP) Scenario 5: Disinfection of closed areas in aseptic packaging machines by vaporised hydrogen peroxide (VHP) Scenario 6: Disinfection of distribution systems for drinking water (PT 4) Scenario 7: Surface disinfection in food & feed processing by liquid application (PT 4) 7a) Assessment of entire plants (e.g.breweries, dairies, beverage processing plants) (IHO 2006) (ESD for PT4, Table 5, p.15) 7b) General scenario for drink and beverage industry, dairy industry, breweries (ESD for PT4, Table 4, p.13) 7c) Emission scenario for calculating the releases of disinfectants used in large scale catering kitchens, canteens, slaughterhouses and butcheries (ESD for PT4, Table 10, p. 24) 7d) Emission scenario for calculating the release of disinfectants used in milking parlour systems (ESD for PT4, Table 11, p.26)
ESD(s) used	Scenario 4a: The agreed scenario used for approval of a.s. was applied. Scenario 4b) and 5) A qualitative approach was applied, since there is no emission to water or air from closed aseptic packaging machines. Scenario 6: The agreed scenario used for approval of a.s. was applied. Scenarios 7a-d: ESD for PT 4. Disinfectants used in food and feed areas (JRC, 2011).
Approach	Scenario 4: Maximum concentration Scenario 5: Maximum target concentration Scenario 6: Maximum concentration. Scenario 7: Average concentration
Distribution in the environment	Calculated based on BR Guidance Vol. IV Part B and EUSES 2.1.2

Groundwater simulation	No additional FOCUS groundwater simulation for any of the scenarios
Confidential Annexes	NO
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	Additional guidance according to the Technical Agreement for Biocides (TAB) were applied. A release pathway via slurry is possible regarding the disinfection of distribution and storage systems for animal drinking water and disinfectants used in milking parlour systems. The degradation in the manure before spreading to soil was considered according to the CAR (2015) applying the harmonised degradation rate constant of 3.65 h^{-1} (DT50 = 11.4 min) for liquid manure agreed at the WGIV2019 and WGIII2020 to be used for PT3. Assuming that the last application of the product containing hydrogen peroxide take place 12 hours before the manure is applied to agricultural land and using single first-order kinetics, fraction remaining in the manure after degradation can be calculated as follows: Fdeg = exp(- ln(2)/0.19 hours x 12 hours) =9,7 x 10^{-20} The fraction of hydrogen peroxide remaining after 12 hours (Fdeg) is so low that in practice hydrogen peroxide is completely degraded. The degradation in the sewer before STP was considered according to the CAR (2015). For PEC calculation is was assumed that once reaching sewage, hydrogen peroxide will rapidly react with microbes and organic matter and be decomposed by microbial catalase and dissolved transition metal ions such as iron. These effects were accounted for using the half-life in similar media regarding microbial density compared to raw sewage of 6 minutes (11.2 min transferred to 12 °C) from Document II A (2015), Section 4.1.1.1 (Spain et al. 1989). Assuming single first-order kinetics and a residence time in sewage of 1 hour (default according to the ESD for PT5), a fraction of 0.024 of the discharged hydrogen peroxide then reaches the STP: Fsewage = exp(- ln(2)/DT50 * 60 min) = 0.024. Maximum local emission from the scenarios 7a-d was taken for PEC calculation.

Emission estimation

Scenario 1 (Meta SPC1-3)

Input parameters for calculating the local emission

Input	Value	Unit	Remarks
Scenario: *Surface disinfection of closed spaces by aerosolised or vaporised hydrogen peroxide (VHP) (use #1, use #9)*			
Amount of hydrogen peroxide to disinfect a large room (150 m^3), worst case (covers all intended uses)	4.5	kg	As a worst case single room (150 m^3) is treated at the maximum target concentration of 30 g/m^3 for filling isolators, leading to an applied amount 4.5 kg.
Number of applications with one machine during one day, maximum	3	-	based on approach detailed in CAR (2015)
Number of machines operating daily at the same local scale, realistic worst case	3	-	based on approach detailed in CAR (2015)
Fraction of hydrogen peroxide that is emitted to air	0.004		based on approach detailed in CAR (2015)
Fraction of hydrogen peroxide that is emitted to sewage	0.05		based on approach detailed in CAR (2015)
Fraction of hydrogen peroxide remaining after degradation in sewage	0.024	-	based on approach detailed in CAR (2015)

Scenario 2 (Meta SPC 8 and 9)

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: *Surface disinfection by liquid application in industrial and institutional areas (use #2)*			
Subscenario 2a) Emission scenario for calculating the release of disinfectants used for sanitary purposes based on an average consumption			
Active substance in product	0.13	kg/L	
Consumption per capita	0.007	L cap^{-1} d^{-1}	Pick list (ESD PT 2, Excel sheet): general purposes (tiles, floors, sinks) + lavatory
Subscenario 2b) Emission scenario for calculating the release of disinfectants used for sanitary purposes in hospitals based on the amount of solution of disinfectant used on a day			
Concentration at which active substance is used: sanitary purposes	0.13	kg/L	
Concentration at which active substance is used: brushes	0.13	kg/L	

Subscenario 2c) Emission scenario for calculating the releases of disinfectants used in hospitals for disinfection of scopes and other articles in washers/disinfectors			
Disinfection systems	dipping		Pick list (ESD PT 2, Excel sheet) based on TAB ENV 37, August 2014
Working solution of active ingredient	13	%	
Volume of solution in machine/dipping bath	0.01	m^3	Pick list (ESD PT 2, Excel sheet) based on TAB ENV 37, August 2017
Maximum number of dipping bath per day	30	d^{-1}	TAB ENV 37, August 2017
Subscenario 2d) Emission scenario for calculating the releases of disinfectants used in hospitals for disinfection of other contaminated instruments			
Amount of active substance	250	kg	Default in ESD PT 2, 2001, Table 3.8
Subscenario 2e) Emission scenario for calculating the releases of disinfectants used in industrial areas			
Application rate of biocidal product	0.1	L/m^2	
Concentration of active substance in the product	130	g/L	
Surface area to be disinfected	1000	m^2	Pick list (Excel sheet): Large scale application
Subscenario 2f) Emission scenario for calculating the release of disinfectants used for sanitary purposes in institutional areas based on an average consumption			
Concentration of active substance in biocidal product	0.13	kg/L	
Subscenario 2g) Emission scenario for clean-in-place (CIP)			
This scenario is covered by available CIP scenarios 7a) and 7b) in PT4.			

Scenario 3 (Meta SPC 8 and 9)

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: *Disinfection of animal housing (use #3)*			
Subscenario 3a) Emission to soil via manure. The degradation in the manure before spreading to soil was taken into account according to the CAR (2015) applying the harmonised degradation rate constant of 3.65 h^{-1} (DT50 = 11.4 min) for liquid manure agreed at the WGIV2019 and WGIII2020 to be used for PT3. Assuming that the last application of the product containing hydrogen peroxide take place 12 hours before the manure is applied to agricultural land and using single first-order kinetics, fraction remaining in the manure after degradation can be calculated as follows: F_{deg} = exp(- ln(2)/0.19 hours · 12 hours) =9,7 x 10^{-20}			

The fraction of hydrogen peroxide remaining after 12 hours (F_{deg}) is so low that in practice hydrogen peroxide is completely degraded.			
Subscenario 3b) Emission to STP (turkey as a worst case)			
Input	**Value**	**Unit**	**Remarks**
Area of housing application	8040	[m^2]	Default in Table 8, ESD PT3
Amount of (undiluted) product prescribed to be used per m^2	0.1	[L]	
Content of active ingredient in product	0.13	[kg/L]	
Fraction of active ingredient released	0.2		Default in Table 10, ESD PT3

Scenario 4 (Meta 5)

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: *Disinfection of food packaging material (aseptic packaging) by immersion or aerosolised or vaporised hydrogen peroxide (VHP) (Use #4)*			
Subscenario 4a) Aseptic packaging with immersion baths (PT4a, Use #4)			
Amount of milk processed at a large-scale creamery, realistic worst case	10^8	kg/year	CAR 2015
Working days per year	231	day/year	
Consumption rate of disinfectant solution, worst case	0.000571	L/kg milk	
Concentration of hydrogen peroxide in disinfectant solution	0.35	kg/kg	
Bulk density of 35 % (w/w) hydrogen peroxide disinfectant solution	1.13	kg/L	
Fraction of a.s. remaining at discharge into sewage, realistic worst case	0.9	-	
Fraction of a.s remaining after degradation in sewage, realistic worst case	0.024		
Fraction remaining after on-site waste treatment (aerobic/biological), conservatively ignored here	1		
Subscenario 4b) Aseptic packaging with VHP or spray application (Use #4)			
There is no specific emission scenario available for aseptic packaging with VHP or spray application. The aseptic packaging machines are enclosed to prevent any contamination and therefore there is no emission to water and only negligible emission to air. According to the applicant significant amounts of hydrogen peroxide will decompose within the machine and the remaining hydrogen peroxide is either treated catalytically or through a gas scrubber. It is proposed to add a risk mitigation measure (RMM) to the use instructions "Aerosolised or vaporised application should use only in closed aseptic packaging machines with no emission to water and negligible emission to			

air." Hydrogen peroxide emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.", since the emission were not quantitatively assessed.

Scenario 5 (Meta SPC 5)

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: *Disinfection of closed areas in aseptic packaging machines by aerosolised or vaporised hydrogen peroxide (VHP) (use #5)*			
This use is covered by subscenario 4b. It is proposed to add an RMM to the use instructions "Use only in closed aseptic packaging machines with no emission to water and negligible emission to air." Hydrogen peroxide emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.			

Scenario 6 (Meta SPC 6 and 7)

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: *Disinfection of distribution and storage systems for drinking water (#6)*			
Concentration of hydrogen peroxide in the disinfection solution, maximum value	0.13	kg/L	13 %
Volume of disinfection solution used, realistic worst case	15 000	L	based on approach detailed in the CAR (2015), but volume limited to 15000 L
Fraction of hydrogen peroxide that is emitted to sewage	0.75	-	based on approach detailed in the CAR (2015)
Fraction of hydrogen peroxide peroxide remaining after degradation in sewage	0.024	-	based on approach detailed in the CAR (2015)
Fraction of hydrogen peroxide peroxide remaining after degradation in slurry	$9{,}7 \times 10^{-20}$		based on approach detailed in the CAR (2015) and agreed (WGIV2019, WGIII2020) degradation rate constant of 3.65 h^{-1} (DT50 = 11.4 min) was defined for liquid manure

Scenario 7 (Meta SPC 6 and 7)

Input parameters for calculating the local emission

Input	Value	Unit	Remarks
Scenario: *Surface disinfection in food & feed processing by liquid application (use #7)*			
Subscenario 7a) *Assessment of entire plants (e.g.breweries, dairies, beverage processing plants)*			
Amount of biocidal active substance used per year in the local plant	191	kg/yr	Pick list (Table 6 in ESD for PT4)
Fraction of substance eliminated due to on-site pre-treatment of plant waste water	0.9	-	According to the AHEE-2 a default value of 0.9 for F_{elim} can applied for rapidly reacting substances like e.g. oxidizing substances for all scenarios in PT4 besides breweries.
Subscenario 7b) *General scenario for drink and beverage industry, dairy industry, breweries*			
Concentration of active ingredient	130	g/L	
Volume of disinfectant used for cleaning of the installation, process lines	100[1)]	L	Information provided by the applicant
Volume of disinfectant used for cleaning of the mixing tanks	4[1)]	L	Information provided by the applicant
Volume of disinfectant used for cleaning of the storage tanks	294[1)]	L	Information provided by the applicant
Number of application per day	2	d^{-1}	Provided by the applicant
Subscenario 7c) *Emission scenario for calculating the releases of disinfectants used in large scale catering kitchens, canteens, slaughterhouses and butcheries*			
Application rate of the active substance	13	g/m^2	
Number of applications per day	2		Provided by the applicant.
Subscenario 7d*) Emission scenario for calculating the release of disinfectants used in milking parlour systems*			
Concentration of active ingredient	130	g/L	
Fraction of hydrogen peroxide peroxide remaining after degradation in slurry	$9{,}7 \times 10^{-20}$		based on approach detailed in the CAR (2015) and agreed (WGIV2019, WGIII2020) degradation rate constant of 3.65 h^{-1} (DT50 = 11.4 min) was defined for liquid manure

[1)] The used values are only applicable for this specific case and do not create a precedent.

Scenario 8 (Meta SPC 4)

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: *Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP) (use #8)*			
This use is covered by subscenario 4b. It is proposed to add an RMM "Use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Hydrogen peroxide emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.", since the emission were not quantitatively assessed.			

Calculations for Scenario 1

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($E_{local_{compartment}}$) [kg/d]**	**Remarks**
STP	0.0486	Degradation in sewer assumed as in the CAR (2015)
Air	0.162	Negligible emission to air

Calculations for Scenario 2

2a-f) Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($E_{local_{compartment}}$) [kg/d]**	**Remarks**
STP	1.3 - 39	Local emission for subscenarios 2a-f, subscenario 2g) is covered by scenarios 7.
	0.936	Using the worst case $E_{local_{compartment}}$ of 39 kg/d and applying an Fsewage of 0.024, i.e. degradation in sewer assumed as in the CAR (2015)

Calculations for Scenario 3

3a) Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($E_{local_{compartment}}$) [kg/d]**	**Remarks**
Soil	-	Degradation in manure assumed as in the CAR (2015)

3a) Resulting local emission to relevant environmental compartments		
Compartment	**Local emission (Elocal$_{compartment}$) [kg/d]**	**Remarks**
3b) Resulting local emission to relevant environmental compartments		
STP	0.50	Degradation in sewer assumed as in the CAR (2015)

Calculations for Scenario 4

4a) Resulting local emission to relevant environmental compartments		
Compartment	**Local emission (Elocal$_{compartment}$) [kg/d]**	**Remarks**
STP	2.11	Degradation in sewer assumed as in the CAR (2015)
4b) Resulting local emission to relevant environmental compartments		
STP	-	No emission to sewer
Air	-	Negligible emission to air

Calculations for Scenario 5

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission (Elocal$_{compartment}$) [kg/d]**	**Remarks**
STP	-	No emission to sewer
Air	-	Negligible emission to air

Calculations for Scenario 6

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission (Elocal$_{compartment}$) [kg/d]**	**Remarks**
STP	35.1	Degradation in sewer assumed as in the CAR (2015)

Calculations for Scenario 7

7a) Resulting local emission to relevant environmental compartments		
Compartment	**Local emission [mg/L]**	**Remarks**
Freshwater	0.0459 [mg/L]	Effluent concentration of active substance in the effluent of the on-site STP (Ceffluent =PECsw); Tier 1
	0.00459 [mg/L]	A F_{elim} of 0.9 is applied as a refinement to reduce risk for surface water in the case of other plants than breweries; Tier 2
STP	0.413 [mg/L]	Influent concentration of active substance in the off-site STP
7b-d) Resulting local emission to relevant environmental compartments [kg/d]		
STP	22.8 - 260	Scenarios 7b - d, this covers also scenario 7a) regarding off-site STP
	6.24	Using the worst case $Elocal_{compartment}$ of 260 kg/d and applying an Fsewage of 0.024, i.e. degradation in sewer assumed as in the CAR (2015)

Calculations for Scenario 8

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	-	No emission to sewer
Air	-	Negligible emission to air

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway				
Representative scenario	**STP**	**Freshwaterincl. sediment**	**Soil incl. groundwater**	**Air**
Scenario 1	**++**	**+**	**+**	**+**
Scenario 2a-f	**++**	**+**	**+**	**+**
Scenario 3a	**-**	**-**	**Q**	**-**
Scenario 3b	**++**	**+**	**+**	**+**
Scenario 4a	**++**	**+**	**+**	**+**
Scenario 4b	**-**	**-**	**-**	**Q**
Scenario 5	**-**	**-**	**-**	**Q**
Scenario 6	**++**	**+**	**+** (via STP) **Q** (slurry)	**+**
Scenario 7a	**-**	**+**	**-**	**-**
Scenario 7a (off-site STP), **7b-d**	**++**	**+**	**+** (via STP) **7d Q** (slurry)	**+**
Scenario 8	**-**	**-**	**-**	**Q**

++ compartment directly exposed; + compartment indirectly exposed; - compartment not exposed; Q will be assessed qualitatively

Input parameters (only set values) for calculating the fate and distribution in the environment (Scenario 1, 2, 3, 4)			
Input	Value	Unit	Remarks
Molecular weight	34.01	g/mol	
Melting point	-0.43	°C	
Boiling point	150.2	°C	
Vapour pressure (at 20 °C)	214	Pa	
Water solubility (at 20°C)	1.E5	mg/L	100% miscible, max value used
Log Octanol/water partition coefficient	-1.57	Log 10	
Organic carbon/water partition coefficient (Koc)	1.59	L/kg	
Henry's Law Constant (at 25° C)	7.5E-4	Pa/m3/mol	
Biodegradability	Not applicable to inorganic substances		However, due to rapid decomposition in the presence of organic matter, degradation in the STP was considered
Total rate constant for degradation in STP	0.033	hr DT50 (at 20ºC)	
Total rate constant for degradation in bulk soil	12	hr DT50 (at 20ºC)	

Rate constant for degradation in air	24	hr DT50 (at 20ºC)	

Calculated fate and distribution in the STP *[if STP is a relevant compartment]*		
Compartment	Percentage [%]	Remarks
Air	7.9E-05	
Water	0.685	
Sludge	0.0144	
Degraded in STP	99.3	

Please note, that the STP distribution presented in the table above is not compliant to the STP distribution with the harmonised HP values agreed at the WGIV2019 and the ENVIII2020 (Harmonisation of UA cases PAA). The STP distribution was not updated with the agreed values, since the proposed harmonisation has no impact on the outcome of this environmental risk assessment.

Calculated PEC values

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/L]	[mg/L]	[mg/m^3]	[mg/L]	[mg/m^3]
Scenario 1	1.66E-04	1.66E-05	5.87E-07	6.71E-07	4.5E-05[1)] 1.41E-11[2)]
Scenario 2a-f	3.21E-03	3.21E-04	1.13E-05	1.29E-05	2.72E-10
Scenario 3a	n.r.	n.r.	Q	Q	n.r.
Scenario 3b	1.71E-03	1.71E-04	6.04E-06	6.9E-06	1.10E-10
Scenario 4a	7.23E-03	7.23E-04	2.55E-05	2.91E-05	4.65E-10
Scenario 4b	n.r.	n.r.	n.r.	n.r.	Q
Scenario 5	n.r.	n.r.	n.r.	n.r.	Q
Scenario 6	0.121	0.012	2.22E-04	3.7E-05	1.18E-06
Scenario 7a (Tier 1)	n.r.	0.0458	n.r.	n.r.	n.r.
Scenario 7a (Tier 2)	n.r.	0.00458	n.r.	n.r.	n.r.
Scenario 7a (off-site STP), **7b-d**	0.0214	2.14E-03	7.53E-05	8.61E-05	1.38E-09
Scenario 8	n.r.	n.r.	n.r.	n.r.	Q

n.r. not relevant compartments
Q qualitative assessment
[1)] Direct emission to air. PECair was calculated by equation 43 of BPR Guidance, Vol. IV Part B.
[2)] Indirect emission to air via STP.

Primary and secondary poisoning

Primary poisoning
Residues in food and feed are not expected. The products are not intended or expected to come into contact with food and feeding stuff since hydrogen peroxide would rapidly decompose in contact with any type of food.

Secondary poisoning
Hydrogen peroxide is unlike to bioaccumulate in aquatic or terrestrial environment (AR 2015). It has a low log Kow (-1.57), it is not highly adsorptive, it does not belong to a class of substances known to have a potential to accumulate in living organisms, its structural features do not indicate accumulation and it is readily biodegradable and has a short degradation half-life of 5 days in water. The low accumulation potential is supported by low BCF and BMF for fish and earthworms of 1.4 and 0.84, respectively (AR 2015). No further assessment of secondary exposure via the food chain is therefore considered necessary.

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: Emissions to air from the products and uses considered here are negligible and do not alter existing background concentrations of hydrogen peroxide in air of 0.14-1.4 µg/m^3 (CAR 2015). Therefore, the additional emissions constitute only a negligible contribution to the ambient air concentrations.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{STP}$
Scenario 1	3.6E-05
Scenario 2a-f	6.7E-04
Scenario 3a	n.r.
Scenario 3b	3.7E-04
Scenario 4a	1.6E-03
Scenario 4b	n.r.
Scenario 5	n.r.
Scenario 6	0.03
Scenario 7a (Tier 1)	n.r.
Scenario 7a (Tier 2)	n.r.
Scenario 7a (off-site STP), **7b-d**	4.6E-03

Scenario 8	n.r.

Conclusion: All PEC/PNEC ratios for STP micro-organisms are below 1 indicating that the products covered by Meta SPCs 1 to 9 do not cause unacceptable risk to biological processes at the sewage treatment plant concerning the evaluated use.

Aquatic compartment

Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{water}$
Scenario 1	1.3E-03
Scenario 2a-f	0.025
Scenario 3a	n.r.
Scenario 3b	0.0141
Scenario 4a	0.06
Scenario 4b	n.r.
Scenario 5	n.r.
Scenario 6	0.95
Scenario 7a (Tier 1)	3.63
Scenario 7a (Tier 2)	0.37
Scenario 7a (off-site STP)**, 7b-d**	0.18
Scenario 8	n.r.

Conclusion: All PEC/PNEC ratios for water are below 1 indicating that the products covered by Meta SPCs 1 to 9 do not cause unacceptable risk to aquatic organisms and sediment-dwelling organisms concerning the evaluated use, when feasible risk mitigation methods are applied. A proposed RMM for scenario 7a in Meta SPC 6 and 7 (Surface disinfection in food & feed processing by liquid application in entire plants) is "The waste water from breweries should not be discharged direct to surface water after simple on-site treatment. The waste water from breweries should be discharged to the sewer connected to the sewage treatment plant (STP).".

Terrestrial compartment

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
Scenario 1	3.3E-04
Scenario 2a-f	6.3E-03
Scenario 3a	Q

Scenario 3b	3.4E-03
Scenario 4a	0.014
Scenario 4b	n.r.
Scenario 5	n.r.
Scenario 6	0.13 (via STP) Q (via slurry)
Scenario 7a (Tier 1)	n.r.
Scenario 7a (Tier 2)	n.r.
Scenario 7a (off-site STP)**, 7b-d**	0.041 Q (via slurry)
Scenario 8	n.r.

Conclusion: Direct exposure of soil in all uses is assessed to be negligible. The fraction remaining in the slurry after degradation is considered to be low and therefore only negligible amounts of hydrogen peroxide may be present in slurry when it is spread to soil. It is possible that soil may become exposed following the spreading of sewage sludge from a sewage treatment plant that has been exposed to hydrogen peroxide from use of the products covered by Meta SPCs 1 to 9. The estimated PEC/PNEC ratios are below 1 indicating no unacceptable risk to soil organisms. Other terrestrial organisms are not regarded to be exposed with the proposed use pattern.

Groundwater

The WG-II-2019 agreed that for rapidly reacting substances no groundwater assessment is needed since it is very unlikely that any substance will reach the groundwater. For this reason also no groundwater assessment for hydrogen perioxide is considered necessary.

Primary and secondary poisoning

Primary poisoning

Not relevant

Secondary poisoning

The estimated log Kow of hydrogen peroxide is –1.57 indicating a negligible potential for bioconcentration in biota. Therefore, accumulation of hydrogen peroxide in the food chain is not expected, and the risk secondary poisoning in aquatic and terrestrial predators is considered negligible.

Conclusion: The risk secondary poisoning in aquatic and terrestrial predators is considered negligible

Mixture toxicity

Not relevant

Aggregated exposure (combined for relevant emmission sources)

According to Article 19 of BPR a cumulative risk assessment shall be performed where relevant. For hydrogen peroxide it was agreed at the WG V 2014 that aggregated risk assessment is not regarded relevant due to the high reactivity of the substance.

Overall conclusion on the risk assessment for the environment of the product
There is no risk to any of the environmental compartments and therefore the use of the products covered by meta SPC's 1 to 9 is considered safe when feasible risk mitigation methods as described in the SPC are applied..

2.2.9 Measures to protect man, animals and the environment

Recommended methods and precautions concerning storage of the biocidalproducts and shelf life of the biocidal products:
Conditions for storage, including incompatibilities
- Storage:
Keep only in the original container.
Store in a receptacle equipped with a vent.
Store in a well-ventilated place. Keep cool.
Keep in properly labelled containers.
Keep container closed.
Keep in a bunded area.
Keep away from Incompatible products.
Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Regularly check the condition and temperature of the containers.

Incompatible materials:
Acids, bases, metals, heavy metal salts, powdered metal salts, reducing agents, organic materials, flammable materials

- Packaging material:
Suitable material: approved grades of HDPE.

Recommended methods and precautions concerning handling and transport:
Precautions for safe handling:
Use only in well-ventilated areas.
Before all operations, passivate the piping circuits and vessels according to the procedure recommended by the
producer.
Use only clean and dry utensils.
Never return unused material to storage receptacle.
Keep away from heat.
Avoid inhalation, ingestion and contact with skin and eyes.
Keep away from Incompatible products.

Transport hazard class(es):
Class (UN) : 5.1
Classification code (UN) : OC1

Recommended methods and precautions concerning fire, in case of fire, nature

of reaction products, combustion gases ect.
- Extinguishing media:
Suitable extinguishing media: Water, Water spray.
Unsuitable extinguishing media: None.

- Special hazards arising from the substance or mixture:
Decomposition will cause oxygen release which may intensify fire
Contact with combustible material may cause fire.
Contact with flammables may cause fire or explosions.
Risk of explosion if heated under confinement.

- Advice for firefighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
Wear chemical resistant oversuit.
Keep product and empty container away from heat and sources of ignition.
Keep containers and surroundings cool with water spray.
Approach from upwind.
Prevent fire extinguishing water from contaminating surface water or the ground water system.

Particulars of likely direct or indirect adverse effects:
• In case of inhalation: Breathing difficulties, cough, pulmonary oedema, nausea, vomiting.
• In case of skin contact: Redness, swelling of tissue, skin irritation.
• In case of eye contact: Redness, lachrymation, swelling of tissue, severe burns.
• In case of ingestion: Nausea, abdominal pain, bloody vomiting, diarrhoea, suffocation, cough, severe shortness of breath, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach. Risk of respiratory disorder.

First aid instructions:
• If inhaled: Move to fresh air. Oxygen or artificial respiration if needed. Victim to lie down in the recovery position, cover and keep him warm. Call a physician immediately.
• In case of eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention.
• In case of skin contact: Wash off immediately with plenty of water for at least 15 minutes. Use a mild soap if available. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention immediately.
• If swallowed: Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Take to hospital.

Emergency measures to protect environment in case of accident:
Environmental Exposure Controls:
Personal precautions, protective equipment and emergency procedures
- Advice for non-emergency personnel:
Evacuate personnel to safe areas.
Keep people away from and upwind of spill/leak.

- Advice for emergency responders:
Use personal protective equipment.
Drying of this product on clothing or combustible materials may cause fire.
Keep wetted with water.

Prevent further leakage or spillage.
Keep away from incompatible products

- Environmental precautions:
Should not be released into the environment.
If the product contaminates rivers and lakes or drains inform respective authorities.

- Methods and materials for containment and cleaning up:
Dilute with plenty of water.
Dam up.
Do not mix waste streams during collection.
Soak up with inert absorbent material.
Keep in properly labelled containers.
Keep in suitable, closed containers for disposal.
Never return spills in original containers for re-use.

Control measures of repellents or poison included in the biocidal product, to prevent action against non-target organisms:
Not applicable.

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.
Not relevant as the biocidal products within the Interox biocidal product family are not intended to be authorised for use with other biocidal products.

2.2.11 Comparative assessment

Not relevant as the active substance is not a candidate for substitution.

2.2.12 Endocrine disruption (ED) assessment

Based on available information the biocidal products in the INTEROX Biocidal Product Family 1 are not considered to have ED properties. The conclusion from the CAR of hydrogen peroxide (PTs 1-6, 2015) was that there is no evidence of any endocrine disruption potential in the human health or ecotoxicological studies presented in the dossier. In addition, there is no concern regarding ED properties of the co-formulants. Please see the confidential annex to the PAR for further details of ED assessment for co-formulants.

3 Annexes[12]

3.1 List of studies for the biocidal product family

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
	Envigo	2016	INTEROX SG 12: Determination of Viscosity Study Report QC98GP GLP	Y	Solvay Interox Ltd
	Envigo	2016	INTEROX SG 12: Determination of Physico-Chemical Properties Study Report TM17VP GLP	Y	Solvay Interox Ltd
	Envigo	2016	INTEROX AG Spray 25S: Determination of Physico-Chemical Properties Study Report WC17SG GLP	Y	Solvay Interox Ltd
	Envigo	2016	INTEROX SG 35: Determination of Low Temperature Stability Study Report MR77MM GLP	Y	Solvay Interox Ltd
	Envigo	2017	INTEROX AG Spray 35S: Determination of Low Temperature Stability Study Report GN08TX GLP	Y	Solvay Interox Ltd
	Envigo	2016	INTEROX FCC 35: Determination of Physico-Chemical Properties Study Report WX14JJ GLP	Y	Solvay Interox Ltd
	Envigo	2016	INTEROX SG 50 Plus: Determination of Low Temperature Stability Study Report YG55GD GLP	Y	Solvay Interox Ltd
	Envigo	2016	INTEROX BT 50: Determination of Physico-Chemical Properties Study Report FJ79RX GLP	Y	Solvay Interox Ltd
	Envigo	2016	INTEROX FCC 35: Oxidising Properties Study Report PH25XC GLP	Y	Solvay Interox Ltd

12 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
	Envigo	2015	INTEROX SG 12: Determination of Long-Term Storage Stability Study Report RQ58YQ GLP	Y	Solvay Interox Ltd
	Envigo	2016	INTEROX SG 35: Determination of Long-Term Storage Stability Study Report YQ78QR GLP	Y	Solvay Interox Ltd
	Envigo	2015	INTEROX AG Spray 35S: Determination of Long-Term Storage Stability Study Report JX07PK GLP	Y	Solvay Interox Ltd
	Envigo	2015	INTEROX FCC 35 / INTEROX DW35: Determination of Long-Term Storage Stability Study Report CC17PP GLP	Y	Solvay Interox Ltd
	Envigo	2015	INTEROX BT 50: Determination of Long-Term Storage Stability Study Report GP25QL GLP	Y	Solvay Interox Ltd
	Envigo	2016	INTEROX SG 50 Plus: Determination of Long-Term Storage Stability Study Report KQ44WC GLP	Y	Solvay Interox Ltd
	Solvay Interox Ltd	2017	Accelerated Shelf-Life study for 8 weeks at 40°C on INTEROX AG-Dual-35 Study Report FHs/7120/2016/005 Non-GLP	Y	Solvay Interox Ltd
	Solvay Interox Ltd	2017	Accelerated Shelf-Life study for 8 weeks at 40°C on INTEROX AG-Bath-35 Study Report FHs/7120/2016/009 Non-GLP	Y	Solvay Interox Ltd
	Solvay Interox Ltd	2017	Accelerated Shelf-Life study for 8 weeks at 40°C on INTEROX AG-Bath-35S Study Report FHs/7120/2016/010 Non-GLP	Y	Solvay Interox Ltd
	Solvay Interox Ltd	2017	Accelerated Shelf-Life study for 8 weeks at 40°C on INTEROX AG-Spray-25S Study Report FHs/7120/2016/013 Non-GLP	Y	Solvay Interox Ltd
	Solvay Interox Ltd	2017	Accelerated Shelf-Life study for 8 weeks at 40°C on INTEROX AG-Spray-35 Study Report FHs/7120/2016/012 Non-GLP	Y	Solvay Interox Ltd

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
	Solvay Interox Ltd	2017	Accelerated Shelf-Life study for 8 weeks at 40°C on INTEROX AG-Spray-35S Study Report FHs/7120/2016/011 Non-GLP	Y	Solvay Interox Ltd
	Solvay Interox Ltd	2017	Accelerated Shelf-Life study for 8 weeks at 40°C on INTEROX FCC-35 Study Report FHs/7120/2016/008 Non-GLP	Y	Solvay Interox Ltd
	Solvay Interox Ltd	2017	Accelerated Shelf-Life study for 8 weeks at 40°C on INTEROX ST-50 Study Report FHs/7120/2016/015 Non-GLP	Y	Solvay Interox Ltd
	Solvay Interox Ltd	2017	Accelerated Shelf-Life study for 8 weeks at 40°C on INTEROX BT-35 Study Report FHs/7120/2016/016 Non-GLP	Y	Solvay Interox Ltd
	Solvay Interox Ltd	2017	Accelerated Shelf-Life study for 8 weeks at 40°C on INTEROX FCC-35 Study Report FHs/7120/2016/017 Non-GLP	Y	Solvay Interox Ltd
	Solvay Interox Ltd	2017	Accelerated Shelf-Life study for 8 weeks at 40°C on INTEROX SG-12 Study Report FHs/7120/2016/018 Non-GLP	Y	Solvay Interox Ltd
	Solvay Interox Ltd	2017	Accelerated Shelf-Life study for 8 weeks at 40°C on INTEROX SG-35 Plus Study Report FHs/7120/2016/019 Non-GLP	Y	Solvay Interox Ltd
	Solvay Interox Ltd	2017	Accelerated Shelf-Life study for 8 weeks at 40°C on INTEROX SG-35 Plus Study Report FHs/7120/2016/020 Non-GLP	Y	Solvay Interox Ltd
	Solvay Interox Ltd	2017	Accelerated Shelf-Life study for 8 weeks at 40°C on INTEROX SG-35 Study Report FHs/7120/2016/021 Non-GLP	Y	Solvay Interox Ltd
	Solvay Interox Ltd	2017	Accelerated Shelf-Life study for 8 weeks at 40°C on INTEROX SG-50 Study Report FHs/7120/2016/022 Non-GLP	Y	Solvay Interox Ltd
	Candy	2019	Determination of pH and acidity of Solvay Biodical products (Internal laboratory results) Non-GLP	Y	Solvay Interox Ltd

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
	Woolley	2020	INTEROX SG 12, INTEROX AG SPRAY 25S, INTEROX FCC 35, INTEROX BT 50: Determination of pH Covance Study Number: KV38HN GLP	Y	Solvay Interox Ltd
	Tremain	2021	INTEROX BT 50: Determination of Flash Point Covance Study Number: 8457569 GLP	Y	Solvay Interox Ltd
	Tremain	2020	INTEROX SG 12 : Classification of Corrosion to Metals Covance Study Number : 8449202 GLP	Y	Solvay Interox Ltd
	Tremain	2020	INTEROX AG SPRAY 25S : Classification of Corrosion to Metals Covance Study Number : 8449200 GLP	Y	Solvay Interox Ltd
	Tremain	2021	INTEROX AG SPRAY 35S : Classification of Corrosion to Metals Covance Study Number : 8457570 (GLP) – nonaudited, draft report. The final report is expected to be available by end of April 2021.	Y	Solvay Interox Ltd
	Tremain	2021	INTEROX BT 50: Classification of Corrosion to Metals Covance Study Number 8457571 GLP	Y	Solvay Interox Ltd
	Candy	2021	INTEROX FCC 35: Determination of Persistent Foaming. Solvay report 25/05/2021.	Y	Solvay Interox Ltd
	Candy	2021	INTEROX FCC 50: Determination of Persistent Foaming. Solvay report 25/05/2021.	Y	Solvay Interox Ltd
	Candy	2021	INTEROX BT 35: Determination of Persistent Foaming. Solvay report 25/05/2021.	Y	Solvay Interox Ltd
	Candy	2021	INTEROX BT 50: Determination of Persistent Foaming. Solvay report 25/05/2021.	Y	Solvay Interox Ltd
	Candy	2021	INTEROX FCC 35: Determination of Dilution Stability. Solvay report 25/05/2021.	Y	Solvay Interox Ltd
	Candy	2021	INTEROX FCC 50: Determination of Dilution Stability. Solvay report 25/05/2021.	Y	Solvay Interox Ltd

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
	Candy	2021	INTEROX BT 35: Determination of Dilution Stability. Solvay report 25/05/2021.	Y	Solvay Interox Ltd
	Candy	2021	INTEROX BT 50: Determination of Dilution Stability. Solvay report 25/05/2021.	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2017	INTEROX SG 12: Microbiological Analysis based on EN 13727 (2012) Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants used in the medical area (Phase 2/Step 1) Study Report TRA-201-001-02	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2016	INTEROX SG 12: Microbiological Analysis based on EN 13624 (2013) Quantitative suspension test for the evaluation of yeasticidal/fungicidal activity of chemical disinfectants used in the medical area (Phase 2/Step 1) Study Report TRA-2016-147-02	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2016	INTEROX SG 12: EN 13704 (2002) Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (Phase 2/Step 1) Study Report TRA-2016-125-01	Y	Solvay Interox Ltd
	Dr. Brill + Partner GmbH	2016	INTEROX SG 12: Evaluation of the effectiveness of INTEROX SG12, Test virus: murine norovirus (as surrogate of human norovirus) Study Report L16/0701dM.1	Y	Solvay Interox Ltd
	Dr. Brill + Partner GmbH	2016	INTEROX SG 12: Evaluation of the effectiveness of INTEROX SG12, Test virus: adenovirus type 5 Study Report L16/0701dA.1	Y	Solvay Interox Ltd
	Dr. Brill + Partner GmbH	2016	INTEROX SG 12: Evaluation of the effectiveness of INTEROX SG12, Test virus: poliovirus type 1 strain LSc-2ab Study Report L16/0701dPo.1	Y	Solvay Interox Ltd
	Eurofins	2019	INTEROX® SG12: Mycobacterial effectiveness by airborne disinfection of surfaces on INTEROX® SG12 Study report: STULV18AA3147-1		Solvay Interox Ltd

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
	Eurofins	2019	INTEROX® SG12: Bactericidal effectiveness by airborne disinfection of surfaces on INTEROX® SG12 Study report: STULV18AA3139-1		Solvay Interox Ltd
	Eurofins	2019	INTEROX® SG12: Fungicidal effectiveness by Airborne disinfection of surfaces on Interox SG 12 Study report: STULV18AA3143-1		Solvay Interox Ltd
	Eurofins	2019	INTEROX® SG12: Viricidal effectiveness by Airborne disinfection of surfaces on Interox SG 12 Study report: STUL V18AA3148-1		Solvay Interox Ltd
	Eurofins	2019	INTEROX® SG12: Sporicidal effectiveness by Airborne disinfection of surfaces on Interox SG 12 Study report: STULV18AA3145-1		Solvay Interox Ltd
	MGS Laboratories Ltd	2017	INTEROX SG 35 Plus: Microbiological Analysis Based on EN 13727 (2012) Chemical Disinfectant and Antiseptics - Quantitative Suspension Test for the evaluation of Bactericidal activity in the medical area - Test Method and Requirements (Phase 2/Step 1) Study Report TRA-2016-124-02	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2016	INTEROX SG 35 Plus: Microbiological Analysis Based on EN 13624 (2013) Quantitative suspension test for the evaluation of yeasticidal/fungicidal activity of chemical disinfectants used in the medical area (Phase 2/Step 1) Study Report TRA-2016-148-01	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2016	INTEROX SG 35 Plus: Microbiological Analysis Based on EN 13704 (2002) Quantitative suspension test for the evaluation of sporicidal activity of of chemical disinfectants and antispetics used in the food, industrial, domestic and institutional areas - Test methods and requirements (Phase 2/Step 1) Study Report TRA-2016-126-01	Y	Solvay Interox Ltd
	Dr. Brill + Partner GmbH	2016	INTEROX SG 35 Plus: Evaluation of the effectiveness of INTEROX SG35 Plus, Test virus: murine norovirus (as surrogate of human norovirus) Study Report L16/0701cM.1	Y	Solvay Interox Ltd

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
	Dr. Brill + Partner GmbH	2016	INTEROX SG 35 Plus: Evaluation of the effectiveness of INTEROX SG35 Plus, Test virus: adenovirus type 5 Study Report L16/0701cA.1	Y	Solvay Interox Ltd
	Dr. Brill + Partner GmbH	2016	INTEROX SG 35 Plus: Evaluation of the effectiveness of INTEROX SG35 Plus, Test virus: poliovirus type 1 strain LSc-2ab Study Report L16/0701cPo.1	Y	Solvay Interox Ltd
	Confidential (code cxv)	2014	INTEROX SG 35 Plus: Check of the D-Value of Biological Indicators	Y	Solvay Interox Ltd
	Confidential (code cxv)	2013	INTEROX SG 35 Plus: Check of the D-Value of Biological Indicators	Y	Solvay Interox Ltd
	Confidential (code kwg)	2014	INTEROX SG 35: Isolator H2O2 Decontamination Requalification Report Study Report OAB_SVP_ISO_RQR	Y	Solvay Interox Ltd
	Confidential (code kwg)	2014	INTEROX SG 35: Isolator Lethality Check with Biological and Chemical Indicators Study Report OAB_SVP_ISO_RQ_LC	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2016	INTEROX AG Spray 25S: Microbiological Analysis Based on EN 1276 (2009) Quantitative suspension test for the evaluation of bactericidal activity of of chemical disinfectants and antiseptics used in the food, industrial, domestic and institutional areas - Test methods and requirements (Phase 2/Step 1) Study Report TRA-2016-144-02	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2016	INTEROX AG Spray 25S: Microbiological Analysis Based on EN 1650 (2008) + A1:2013 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the food, industrial, domestic and institutional areas - Test methods and requirements (Phase 2/Step 1) Study Report TRA-2016-159-01	Y	Solvay Interox Ltd

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
	MGS Laboratories Ltd	2016	INTEROX AG Spray 25S: Microbiological Analysis Based on EN 13704 (2002) Quantitative suspension test for the evaluation of sporicidal activity of of chemical disinfectants and antiseptics used in the food, industrial, domestic and institutional areas - Test methods and requirements (Phase 2/Step 1) Study Report TRA-2016-127-01	Y	Solvay Interox Ltd
	Dr. Brill + Partner GmbH	2016	INTEROX SAG Spray 25S: Evaluation of the effectiveness of INTEROX AG Spray 25S, Test virus: murine norovirus (as surrogate of human norovirus) Study Report L16/0701fM.1	Y	Solvay Interox Ltd
	Dr. Brill + Partner GmbH	2016	INTEROX AG Spray 25S: Evaluation of the effectiveness of INTEROX AG Spray 25S, Test virus: adenovirus type 5 Study Report L16/0701fA.1	Y	Solvay Interox Ltd
	Dr. Brill + Partner GmbH	2016	INTEROX AG Spray 25S: Evaluation of the effectiveness of INTEROX AG Spray 25S, Test virus: poliovirus type 1 strain LSc-2ab Study Report L16/0701fPo.1	Y	Solvay Interox Ltd
	ATS LABS	2016	INTEROX AG Spray 25S: Modification of the AOAC Sporicidal Method to Determine Efficacy of Products Used in Aseptic Filling Applications Study Report SVY01020508.CUST.2	Y	Solvay Interox Ltd
	Confidential (code zbe)	2013	INTEROX AG Spray 25S: Validation report synthesis. Dry H2O2 preform decontamination	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2017	INTEROX AG Spray 35S: Microbiological Analysis Based on EN 1276 (2009) Quantitatitive suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the food, industrial, domestic and institutional areas - Test methods and requirements (Phase 2/Step 1) Study Report TRA-2016-145-03	Y	Solvay Interox Ltd

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
	MGS Laboratories Ltd	2007	INTEROX AG Spray 35S: Microbiological Analysis Based on EN 1276 (2009) Quantitatitive suspension test for the evaluation of bactericidal activity of of chemical disinfectants and antiseptics used in the food, industrial, domestic and institutional areas - Test methods and requirements (Phase 2/Step 1) Study Report 11462 / SO no.880	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2016	INTEROX AG Spray 35S: Microbiological Analysis Based on EN 1650 (2008) + A1:2013 Chemical disinfectants and antiseptics - Quantitatitive suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics Study Report TRA-2016-160-01	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2016	INTEROX AG Spray 35S: Microbiological Analysis Based on EN 13704(2002) Quantitatitive suspension test for the evaluation of sporicidal activity of chemical disinfectants and antiseptics used in the food, industrial, domestic and institutional areas - Test methods and requirements (Phase 2/Step 1) Study Report TRA-2016-128-02	Y	Solvay Interox Ltd
	Dr. Brill + Partner GmbH	2016	INTEROX AG Spray 35S: Evaluation of the effectiveness of INTEROX AG Spray 35S, Test virus: murine norovirus (as surrogate of human norovirus) Study Report L16/0701eM.1	Y	Solvay Interox Ltd
	Dr. Brill + Partner GmbH	2016	INTEROX AG Spray 35S: Evaluation of the effectiveness of INTEROX AG Spray 25S, Test virus: adenovirus type 5 Study Report L16/0701eA.1	Y	Solvay Interox Ltd
	Dr. Brill + Partner GmbH	2016	INTEROX AG Spray 35S: Evaluation of the effectiveness of INTEROX AG Spray 35S, Test virus: poliovirus type 1 strain LSc-2ab Study Report L16/0701ePo.1	Y	Solvay Interox Ltd

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
	ATS LABS	2007	INTEROX AG Bath 35S: Modification of the AOAC Sporicidal Method to Determine Efficacy of Products Used in Aseptic Filling Applications Study Report SVY01100107.CUST.3	Y	Solvay Interox Ltd
	Confidential (code cxv)	2015	INTEROX AG Bath 35S: Microbiological challenge testing of an aseptic filler Study report: #MY7160	Y	Solvay Interox Ltd
	Confidential (code tbv)	2007	INTEROX AG Spray 35S: Approval of Interox AG Spray 35S for an aseptic Machine	Y	Solvay Interox Ltd
	Confidential (code oyd)	2013	INTEROX AG Spray 35S, INTEROX AG Spray 35 & INTEROX AG Dual: Hydrogen Peroxide Sterilization Code of Practice - Filling Machines of VDMA Hygiene Claa V: Testing the Effectiveness of Packaging Sterilization Devices	Y	Solvay Interox Ltd
	Confidential (code oyd)	2016	INTEROX AG Spray 35: Release of the hydrogen peroxide type AG Spray 35.	Y	Solvay Interox Ltd
	Confidential (code oyd)	2016	INTEROX AG Spray 35S: Release of the hydrogen peroxide type AG Spray 35S.	Y	Solvay Interox Ltd
	Confidential (code oyd)	2016	INTEROX AG Spray Dual: Release of the hydrogen peroxide type AG Dual 35.	Y	Solvay Interox Ltd
	Confidential (code fhq)	2016	INTEROX Hydrogen Peroxide: Use and efficacy of Hydrogen Peroxide in aseptic filling and packaging machines	Y	Solvay Interox Ltd
	Confidential (code fhq)	2016	INTEROX AG Bath 35: Approval of Interox AG Bath 35 for Aseptic Machines	Y	Solvay Interox Ltd
	Confidential (code fhq)	2016	INTEROX AG Bath 35S: Approval of Interox AG Bath 35S for Aseptic Machines	Y	Solvay Interox Ltd
	Confidential (code fhq)	2016	INTEROX AG Dual 35: Approval of Interox AG Dual 35 for Aseptic Machines	Y	Solvay Interox Ltd

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
	MGS Laboratories Ltd	2016	INTEROX FCC 35/DW 35: Microbiological Analysis Based on EN 1276 (2009) Quantitative suspension test for the evaluation of bactericidal activity of of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (Phase 2/Step 1) Study Report TRA-2016-146-01	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2016	INTEROX FCC 35/DW 35: Microbiological Analysis Based on EN 1276 (2009) Quantitative suspension test for the evaluation of bactericidal activity of of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (Phase 2/Step 1) Study Report TRA-2016-204-01	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2016	INTEROX FCC 35/DW 35: Microbiological Analysis Based on EN 1650 (2008) + A1:2013 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (Phase 2/Step 1) Study Report TRA-2016-161-01	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2016	INTEROX FCC 35/DW 35: Microbiological Analysis Based on EN 13704 (2002) Quantitative suspension test for the evaluation of sporicidal activity of of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (Phase 2/Step 1) Study Report TRA-2016-129-01	Y	Solvay Interox Ltd
	Dr. Brill + Partner GmbH	2016	INTEROX FCC 35: Evaluation of the effectiveness of INTEROX FCC 35, Test virus: murine norovirus (as surrogate of human norovirus) Study Report L16/0701gM.1	Y	Solvay Interox Ltd

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
	Dr. Brill + Partner GmbH	2016	INTEROX FCC 35: Evaluation of the effectiveness of INTEROX FCC 35, Test virus:adenovirus type 5 Study Report L16/0701gA.1	Y	Solvay Interox Ltd
	Dr. Brill + Partner GmbH	2016	INTEROX FCC 35: Evaluation of the effectiveness of INTEROX FCC 35, Test virus: poliovirus type 1 strain LSc-2ab Study Report L16/0701gPo.1	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2017	INTEROX FCC 35: EN 13697 (2001) Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas (Phase 2/Step 2) Study Report TRB-2017-003-03	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2019	INTEROX FCC 35: EN 13697 (2015) Quantitative non-pourous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas (phase 2 step 2) Study report: S30884	Y	Solvay Interox Ltd
	Ox CTA	2016	INTEROX DW 50: CERTIFICATION BPD TEST Animal drinking water in poultry production (Phase 3) Study Report OX-CTA	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2016	INTEROX BT 35: Microbiological Analysis Based on EN 1656 (2009) Quantitative suspension test for the evaluation of bactericidal activity of of chemical disinfectants used in the veterinary field (Phase 2/Step 1) Study Report TRA-2016-113-02	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2016	INTEROX BT 35: Microbiological Analysis Based on EN 1657 (2016) Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of of chemical disinfectants and antiseptics used in the veterinary field (Phase 2/Step 1) Study Report TRA-2016-114-01	Y	Solvay Interox Ltd

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
	MGS Laboratories Ltd	2019	EN 14349 (2012) Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on non-porous surfaces without mechanical action (phase 2 step 2). Study report: S30883	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2007	INTEROX ST 50: EN 13704(2002) Quantitative suspension test for the evaluation of sporicidal activity of of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (Phase 2/Step 1) Study Report MGS: 123198 / SO No:1037	Y	Solvay Interox Ltd
	Dr. Brill + Partner GmbH	2016	INTEROX BT 35: Evaluation of the effectiveness of INTEROX BT 35, Test virus: bovine enterovirus type 1 (Entero Cytopathogenic Bovine Orphan _ ECBO) Study Report L16/0701bE.2	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2017	INTEROX BT 35: EN 14349 (2014) Quantitative surface test for the evaluation of bactericidal activity of of chemical disinfectants and antiseptics used in the veterinary area on non-porous of chemical disinfectants and antiseptics used in the veterinary area on non-porous Study Report TRB-2017-004-02	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2016	INTEROX BT 35: EN 16348 (2014) Quantitative surface test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action (Phase 2/Step 2) Study Report TRA-2016-177-02	Y	Solvay Interox Ltd

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
	MGS Laboratories Ltd	2007	INTEROX ST 50: EN 1276(1997) Quantitative suspension test for the evaluation of bactericidal activity of of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (Phase 2/Step 1) Study Report MGS: 12319 / SO No:1037	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2007	INTEROX ST 50: EN 1650 (1998) Quantitative suspension test for the evaluation of fungicidal activity of of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (Phase 2/Step 1) Study Report MGS: 12319/ SO No:1037	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2016	INTEROX BT 50: Microbiological Analysis Based on EN 1650 (2008) + A1:2013 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (Phase 2/Step 1) Study Report TRA-2016-162-01	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2007	INTEROX ST 50: EN 13704 (2002) Quantitative suspension test for the evaluation of sporicidal activity of of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (Phase 2/Step 1) Study Report MGS: 12319 / SO No: 1037	Y	Solvay Interox Ltd
	Dr. Brill + Partner GmbH	2016	INTEROX BT 50: Evaluation of the effectiveness of INTEROX BT 50, Test virus: murine norovirus (as surrogate of human norovirus) Study Report L16/0701aM.1	Y	Solvay Interox Ltd

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
	Dr. Brill + Partner GmbH	2016	INTEROX BT 50: Evaluation of the effectiveness of INTEROX BT 50, Test virus: adenovirus type 5 Study Report L16/0701aA.1	Y	Solvay Interox Ltd
	Dr. Brill + Partner GmbH	2016	INTEROX BT 50: Evaluation of the effectiveness of INTEROX BT 50, Test virus: poliovirus type 1 strain LSc-2sb Study Report L16/0701aPo.1	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2017	INTEROX BT 50: EN 13697 (2015) Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas (Phase 2/Step 2) Study Report TRB-2017-002-03	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2007	INTEROX ST 50: EN 13697 (2001) Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal (sporicidal) activity of chemical disinfectants (Phase 2/Step 2) Study Report MGS: 12319 / SO No:1037	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2007	INTEROX ST 50: EN 13697 (2001) Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants (Phase 2/Step 2) Study Report MGS: 12319 / SO No:1037	Y	Solvay Interox Ltd
	MGS Laboratories Ltd	2007	Chemical disinfectants and antiseptics – Basic bactericidal activity (Phase 1).	Y	Cefic
	MGS Laboratories Ltd	2007	Chemical disinfectants and antiseptics – Basic fungicidal activity (Phase 1).	Y	Cefic
	MGS Laboratories Ltd	2007	Chemical disinfectants and antiseptics – Basic sporicidal activity (Phase 1).	Y	Cefic
	MGS Laboratories Ltd	2007	Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics (Phase 2/ Step 1).	Y	Cefic

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
	MGS Laboratories Ltd	2007	Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics (Phase 2/Step 1)	Y	Cefic Peroxygen Sector Group
	MGS Laboratories Ltd	2007	Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants and antiseptics (Phase 2/Step 1).	Y	Cefic Peroxygen Sector Group
	BluScientific Test Data	2007	Chemical disinfectants and antiseptics – Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine- test method and requirements (phase 2/step 1).	Y	Cefic Peroxygen Sector Group
	MGS Laboratories Ltd	2007	Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants (Phase 2 / Step 2)	Y	Cefic Peroxygen Sector Group. Hydrogen peroxide subgroup
	MGS Laboratories Ltd	2007	Chemical disinfectants and antiseptics–Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary field (Phase 2/ Step 1).	Y	Cefic Peroxygen Sector Group
	MGS Laboratories Ltd	2007	Chemical disinfectants and antiseptics–Quantitative suspension test for the evaluation of fungicidal and yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary field (Phase 2/ Step 1).	Y	Cefic Peroxygen Sector Group
	MGS Laboratories Ltd	2007	Chemical disinfectants and antiseptics-Quantitative surface test for the evaluation of bacterial activity of chemical disinfectants and antiseptics used in the veterinary field on non-porous surfaces without mechanical action (Phase 2/Step 2)	Y	Cefic Peroxygen Sector Group

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
	MGS Laboratories Ltd	2007	Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bacterial activity of chemical disinfectants and antiseptics used in the veterinary field on non-porous surfaces without mechanical action. (Phase 2, Step 2)	Y	Cefic Peroxygen Sector Group
	MGS Laboratories Ltd	2007	Efficacy of antimicrobials as preservatives for aqueous-based products used in the paper industry (Phase 2/ Step 2).	Y	Cefic Peroxygen Sector Group
	MGS Laboratories Ltd	2007	Efficacy of antifungals as preservatives for aqueous-based products used in the paper industry (Phase 2/ Step 2).	Y	Cefic Peroxygen Sector Group
	Solvay Interox Ltd	2019	Evaluation of preform decontamination level without hydrogen peroxide	Y	Solvay Interox Ltd

3.2 Output tables from exposure assessment tools

HUMAN EXPOSURE

Calculations of liquid mole fraction values to be used in ART:

Product containing 49.9 % hydrogen peroxide

Ingredient	Content % (w/w)	CAS	Molecular Formula	Molecular Weight [g/mol]
Hydrogen peroxide (HP)	49,9	7722-84-1	H2O2	34,01
Water	50,1		H2O	18
Total	**100**			

Ingredient	Content g in 1 kg	Ingredient	Corresponding mole amount	Mole fraction
Hydrogen peroxide (HP)	499	HP	14,672	0,3452
Water**	501	water	27,833	0,6548
Total	**1000**	**Sum**	**42,505**	**1**

Use solution containing 13 % hydrogen peroxide

Ingredient	Content % (w/w)	CAS	Molecular Formula	Molecular Weight [g/mol]
Hydrogen peroxide	13,000	7722-84-1	H2O2	34,01
Water	87,000		H2O	18
Total	**100**			

Ingredient	Content g in 1 kg	Ingredient	Corresponding mole amount	Mole fraction
Hydrogen peroxide (HP)	130,00	HP	3,8224052	0,07365764
Water**	870,00	water	48,3333333	0,93138193
Total	**1000**	**Sum**	**52,156**	**1,005039567**

Scenario 1: Loading scenario for automated applications: VHP process, spraying and fogging machines and aseptic packaging (in uses 1, 2, 4, 5, 6, 7, 8 and 9)

v2

Chemical details	
Chemical	Hydrogen peroxide
CAS No.	7722-84-1

Scenario details	
Number of activities	1
Total duration (mins)	30
Nonexposure period (mins)	0

Details for Activity (untitled)

Emission sources: Near field ✓ Duration (mins): 30

Far field

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	293 K
Vapour pressure	214 Pa
Liquid mole fraction	0.3452 (for 49.9% HP product)
Activity coefficient	1

Activity emission potential	
Activity class	Handling of contaminated objects
Situation	Activities with treated/contaminated objects (surface 0.1-0.3 m²) (Examples: Handling of contaminated tools)
Contamination level	Contamination < 10 % surface

Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes

Dispersion	
Work area	Indoors
Room size	Large workrooms only

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)

Dispersion	
Ventilation rate	Only good natural ventilation

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). Th use of RPE must be considered separately.

Mechanistic model results

The predicted 90th percentile full-shift exposure is 0.52 mg/m³.

The inter-quartile confidence interval is 0.25 mg/m³ to 1.1 mg/m³.

Alternative calculations for automated loading scenario with the activity class of "falling liquids" and situation "transfer of liquid product" *(added after peer review as the same kind of modelling had already been used in CA reports of active substances in similar cases)*

Chemical details	
Chemical	Hydrogen peroxide
CAS No.	7722-84-1

Scenario details	
Number of activities	1
Total duration (mins)	15
Nonexposure period (mins)	0

Details for Activity (untitled)

Duration (mins): 15

Emission sources: Near field ✓

Far field

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	293 K
Vapour pressure	214 Pa
Liquid mole fraction	0.3452 (for 49.9% HP product)
Activity coefficient	1

Activity emission potential	
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 1 - 10 l/minute
	Transfer of liquid product with flow of 10 - 100 l/minute
Containment level	Open process
Loading type	Submerged loading, where the liquid dispenser remains below the fluid level reducing the amount of aerosol formation

Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes

Dispersion	
Work area	Indoors
Room size	Any size workroom

Risk Management Measures

Localised controls	
Primary	Medium level containment (99.00 % reduction)
Secondary	No localized controls (0.00 % reduction)

Dispersion	
Ventilation rate	Only good natural ventilation

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). Th use of RPE must be considered separately.

Mechanistic model results

The predicted 90th percentile full-shift exposure is 0.05 mg/m³.

The inter-quartile confidence interval is 0.024 mg/m³ to 0.1 mg/m³.

The predicted 90th percentile full-shift exposure is 0.17 mg/m³.

The inter-quartile confidence interval is 0.081 mg/m³ to 0.34 mg/m³.

Scenario 6: Loading of immersion bath (in uses 2 and 7)

Chemical details	
Chemical	Hydrogen peroxide
CAS No.	7722-84-1

Scenario details	
Number of activities	1
Total duration (mins)	10
Nonexposure period (mins)	0

Details for Activity (untitled)

Duration (mins): 10

Emission sources: Near field ✓

Far field

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	293 K
Vapour pressure	214 Pa
Liquid mole fraction	0.3452 (for 49.9% HP product)
Activity coefficient	1
Activity emission potential	
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 1 - 10 l/minute
Containment level	Open process
Loading type	Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely

Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes

Dispersion	
Work area	Indoors
Room size	Any size workroom

Risk Management Measures

Localised controls	
Primary	Tier 1: No localized controls (0.00 % reduction) Tier 2a: Fixed capturing hood (90.00 % reduction)

	Tier 2b: Fixed capturing hood (90.00 % reduction)
Secondary	No localized controls (0.00 % reduction)
Dispersion	
Ventilation rate	Tier 1: Only good natural ventilation Tier 2a: Mechanical ventilation giving at least 1 ACH Tier 2b: ACH 3 air changes per hour (ACH)

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). Th use of RPE must be considered separately.

Mechanistic model results

Tier 1 (natural ventilation + no LEV):

The predicted 90th percentile full-shift exposure is 15 mg/m³.

The inter-quartile confidence interval is 7.4 mg/m³ to 31 mg/m³.

Tier 2a (Mechanical ventilation giving at least 1 ACH + LEV: Fixed capturing hood (90.00 % reduction):

The predicted 90th percentile full-shift exposure is 1.1 mg/m³.

The inter-quartile confidence interval is 0.54 mg/m³ to 2.3 mg/m³.

Tier 2b (3 ACH + LEV: Fixed capturing hood (90.00 % reduction):

The predicted 90th percentile full-shift exposure is 0.72 mg/m³.

The inter-quartile confidence interval is 0.35 mg/m³ to 1.5 mg/m³.

Scenario 7: Immersion/Dipping (in uses 2 and 7)

Dipping of small medical or food processing equipment in an immersion bath with a hydrogen peroxide concentration of 13 %.

ART

Chemical details	
Chemical	Hydrogen peroxide
CAS No.	7722-84-1

Scenario details	
Number of activities	1
Total duration (mins)	30
Nonexposure period (mins)	0

Details for Activity (untitled)

Duration (mins): 30

Emission sources: Near field ✓

Far field

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	293 K
Vapour pressure	214 Pa
Liquid mole fraction	0.0737
Activity coefficient	1

Activity emission potential	
Activity class	Activities with relatively undisturbed surfaces (no aerosol formation)
Situation	Open surface 0.1 – 0.3 m²

Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes

Dispersion	
Work area	Indoors
Room size	Any size workroom

Risk Management Measures

Localised controls	
Primary	Tier 1: No localized controls (0.00 % reduction) Tier 2a: Fixed capturing hood (90.00 % reduction)

Secondary	No localized controls (0.00 % reduction)
Dispersion	
Ventilation rate	Tier 1: Only good natural ventilation Tier 2a: Mechanical ventilation giving at least 1 ACH

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). Th use of RPE must be considered separately.

Mechanistic model results

Tier 1 (no LEV):
The predicted 90th percentile full-shift exposure is 3.5 mg/m³.

The inter-quartile confidence interval is 1.7 mg/m³ to 7.4 mg/m³.

Tier 2 (Mechanical ventilation giving at least 1 ACH + LEV: Fixed capturing hood (90.00 % reduction):

The predicted 90th percentile full-shift exposure is 0.268 mg/m³.

The inter-quartile confidence interval is 0.13 mg/m³ to 0.54 mg/m³.

ConsExpo
Report for assessment Immersion/Dipping

Assessment settings

Label	Value
Substance	
Name	Hydrogen peroxide
CAS number	7722-84-1
Molecular weight	34 g/mol
K_{ow}	–
Product	
Name	
Weight fraction substance	14 %
Population	
Name	EU framework Biocides adult
Body weight	60 kg

Scenario Immersion/dipping

Frequency 1 per day

Description

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	30 minute
Product is substance in pure form	No
Molecular weight matrix	18.7 g/mol
The product is used in dilution	No

Amount of solution used	5000 g
Weight fraction substance	13 %
Room volume	55 m^3
Ventilation rate	0.6 per hour
Inhalation rate	1.25 m^3/hr
Application temperature	20 °C
Vapour pressure	214 Pa
Molecular weight	34 g/mol
Mass transfer coefficient	10 m/hr
Release area mode	Constant
Release area	0.15 m^2
Emission duration	30 minute
Absorption model	n.a.

Results for scenario Immersion/dipping
Inhalation

Mean event concentration *(average air concentration on exposure event. Note: depends strongly on chosen exposure duration)*	**1.4 mg/m^3**
Peak concentration (TWA 15 min) *(peak concentration (TWA 15 min) is the 15 minute time weighted average of the air concentration. In case the exposure duration is less than 15 minutes, the mean event air concentration is given instead.)*	2.1 mg/m^3
Mean concentration on day of exposure *(average air concentration over the day (accounts for the number of events on one day))*	2.9×10^{-2} mg/m^3
Year average concentration *(mean daily air concentration averaged over a year)*	2.9×10^{-2} mg/m^3
External event dose *(the amount that can potentially be absorbed per kg body weight during one event)*	1.5×10^{-2} mg/kg bw
External dose on day of exposure *(the amount that can potentially be absorbed per kg body weight during one day)*	1.5×10^{-2} mg/kg bw

Scenario 10: Manual mixing and loading for spraying of animal houses (use 3)

Pouring of product (max 49.9% hydrogen peroxide) into a portable vessel (e.g. sprayer, canister) and dilution to in-use concentration

ART

Chemical details	
Chemical	Hydrogen peroxide
CAS No.	7722-84-1

Scenario details	
Number of activities	1
Total duration (mins)	20
Nonexposure period (mins)	0

Details for Activity (untitled)

	✓	Duration (mins):	20
Emission sources:	Near field		
	Far field		

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	293 K
Vapour pressure	214 Pa
Liquid mole fraction	0.3452 (for 49.9% HP product)
Activity coefficient	1
Activity emission potential	
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 1 - 10 l/minute
Containment level	Handling that reduces contact between product and adjacent air. Note: This does not include processes that are fully contained by localised controls (see next questions).
Loading type	Tier 1 and 2a: Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely Tier 2b: Submerged loading, where the liquid dispenser remains below the fluid level reducing the amount of aerosol formation

Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes

Dispersion

Work area	Indoors
Room size	Any size workroom

Risk Management Measures

Localised controls	
Primary	Tier 1 and 2b: No localized controls (0.00 % reduction) Tier 2a: Other LEV systems (50.00 % reduction)
Secondary	No localized controls (0.00 % reduction)
Dispersion	
Ventilation rate	Tier 1: Only good natural ventilation Tier 2a: 3 air changes per hour (ACH) Tier 2b: Mechanical ventilation giving at least 1 ACH

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). Th
use of RPE must be considered separately.

Mechanistic model results

Tier 1:
The predicted 90th percentile full-shift exposure is 4.5 mg/m³.

The inter-quartile confidence interval is 2.2 mg/m³ to 9.4 mg/m³.

Tier 2a:
The predicted 90th percentile full-shift exposure is 1.1 mg/m³.

The inter-quartile confidence interval is 0.53 mg/m³ to 2.3 mg/m³.

Tier 2b:
The predicted 90th percentile full-shift exposure is 1.1 mg/m³.

The inter-quartile confidence interval is 0.53 mg/m³ to 2.3 mg/m³.

Scenario 11: Disinfection of animal housing (use 3)

Manual spraying of diluted product (13 % hydrogen peroxide) for disinfection of animal housing

ART

Chemical details	
Chemical	Hydrogen peroxide
CAS No.	7722-84-1
Scenario details	
Number of activities	1
Total duration (mins)	400
Nonexposure period (mins)	0
Details for Activity Spraying	

Emission sources: Near field — Duration (mins): 400

Far field ✓

Far-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	293 K
Vapour pressure	214 Pa
Liquid mole fraction	0.0737
Activity coefficient	1

Activity emission potential	
Activity class	Surface spraying of liquids
Situation	Moderate application rate (0.3 - 3 l/minute)
Spray direction	In any direction (including upwards)
Spray technique	Spraying with no or low compressed air use

Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes

Dispersion	
Work area	Indoors
Room size	3000 m³

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)

Secondary	No localized controls (0.00 % reduction)
Segregation	No segregation (0.00 % reduction)
Personal enclosure	No personal enclosure (0.00 % reduction)
Dispersion	
Ventilation rate	No restriction on general ventilation characteristics, 10 air changes per hour (ACH)

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). Th use of RPE must be considered separately.

Mechanistic model results

ACH 1:
The predicted 90th percentile full-shift exposure is 45 mg/m³.

The inter-quartile confidence interval is 22 mg/m³ to 94 mg/m³.

ACH 10:
The predicted 90th percentile full-shift exposure is 4 mg/m³.

The inter-quartile confidence interval is 1.9 mg/m³ to 8.4 mg/m³.

ENVIRONMENTAL EXPOSURE

Environmental Emission Scenarios for Product Type 2: Private and public health area disinfectants

Scenario 2a) Emission scenario for calculating the release of disinfectants used for sanitary purposes based on an average consumption (ESD for PT2, RIVM 2001, Table 2.2, p.10)

Calculation of the break-even point tonnage (regional tonnage) (ESD RIVM 2001, p.9-10 & Appendix 3)

Instructions for using the table:
1. Enter the active substance in product ($C_{product}$).
2. Select the "Consumption per capita" ("General purpose" or "Lavatory"). $Q_{product}$ will be automatically filled in.
3. The break-even point tonnage will be automatically calculated.

Input

Variable/parameter		*Symbol*	*Value*	*Unit*	*S/D/O/P* [1]	*References / Calculation formulas / Explanations*
Number of inhabitants feeding one STP		Nlocal	10000	[-]	D	
Active substance in product		$C_{product}$	0,13	$kg.l^{-1}$	S	
Consumption per capita	General purpose (tiles, floors, sinks) + Lavatory	$Q_{product}$	0,007	$l.cap^{-1}.d^{-1}$	S	Pick list: ESD Table 2.2
Penetration factor of disinfectant		F_{penetr}	0,5	[-]	D	
Fraction of the main source (STP)		$Fmainsource_{water}$	0,002	[-]	D	
Number of emission days for life cycle stage 4 (private use) [2]		$Temission_4$	365	$d.yr^{-1}$	D	

Output

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P* [1]	*References / Calculation formulas / Explanations*
Break-even point tonnage	TONNAGEREG	8,30E+02	$tonnes.yr^{-1}$	O	**TONNAGEREG** = Nlocal * $Q_{product}$ * $C_{product}$ * F_{penetr} * $Temission_4$ / (10^3 * $Fmainsource_{water}$)

Above this regional tonnage the scenario based on the tonnage should be applied preferably.

1) S: data set; D: default; O: output; P: pick list
2) The subscript "4" refers to the stage of private use in conformity with EUSES 1.0 and USES 2.0.

Emission scenario for calculating the release of disinfectants used for sanitary purposes based on an average consumption (ESD RIVM 2001, Table 2.2, p.10)

Instructions for using the table:
1. Enter the active substance in product ($C_{product}$).
2. Select the "Consumption per capita" ("General purpose" or "Lavatory"). $Q_{product}$ will be automatically filled in.
3. $Elocal_{4,water}$ will be automatically calculated.

Input

Variable/parameter		*Symbol*	*Value*	*Unit*	*S/D/O/P* [1]	*References / Calculation formulas / Explanations*
Number of inhabitants feeding one STP		Nlocal	10000	[-]	D	
Fraction released to wastewater		$F_{4,water}$	1	[-]	D	
Active substance in product		$C_{product}$	0,13	$kg.l^{-1}$	S	
Consumption per capita	General purpose (tiles, floors, sinks) + Lavatory	$Q_{product}$	0,007	$l.cap^{-1}.d^{-1}$	S	Pick list: ESD Table 2.2
Penetration factor of disinfectant		F_{penetr}	0,5	[-]	D	

Output

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P* [1]	*References / Calculation formulas / Explanations*
Emission rate to wastewater (standard STP) [2]	$Elocal_{4,water}$	4,55E+00	$kg.d^{-1}$	O	**$Elocal_{4,water}$** = Nlocal * $Q_{product}$ * $C_{product}$ * F_{penetr} * $F_{4,water}$

1) S: data set; D: default; O: output; P: pick list
2) The subscript "4" refers to the stage of private use in conformity with EUSES 1.0 and USES 2.0.

Scenario 2b) Emission scenario for calculating the release of disinfectants used for sanitary purposes in hospitals based on the amount of solution of disinfectant used on a day (ESD for PT2, RIVM 2001, Table 3.6, p.20)

Calculation of the break-even point tonnage (regional tonnage) (ESD RIVM 2001, p.19-20 & Appendix 3)

Instructions for using the table:
1. Enter the concentration at which the active substance is used for sanitary purposes and/or brushes (C_{san} or C_{obj}).
2. The break-even point tonnage will be automatically calculated for sanitary purposes and/or brushes.

Input

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*References / Calculation formulas / Explanations*
Fractions released to wastewater [2]					
Sanitary purposes	$Fsan_{3,water}$	0,55	[-]	D	
Brushes	$Fobj_{3,water}$	0,95	[-]	D	
Concentration at which active substance is used					
Sanitary purposes	C_{san}	0,13	$kg.l^{-1}$	S	
Brushes	C_{obj}	0,13	$kg.l^{-1}$	S	
Amount of water with active substance					
Sanitary purposes	Q_{water_san}	25	$l.d^{-1}$	D	
Brushes	Q_{water_obj}	25	$l.d^{-1}$	D	
Fraction for the hospital	$F_{hospital}$	0,007	[-]	D	
Fraction released to wastewater	$F_{3,water}$	0,75	[-]	D	
Number of emission days for life cycle stage 3 (processing) [2]	$Temission_3$	260	$d.yr^{-1}$	D	

Output

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*References / Calculation formulas / Explanations*
Break-even point tonnage for sanitary purposes	TONNAGEREG	**8,85E+01**	$tonnes.yr^{-1}$	O	**TONNAGEreg** = $Q_{water\_san} * C_{san} * Temission_3 * Fsan_{3,water} / (10^3 * F_{hospital} * F_{3,water})$
Break-even point tonnage for objects	TONNAGEREG	**1,53E+02**	$tonnes.yr^{-1}$	O	**TONNAGEreg** = $Q_{water\_obj} * C_{obj} * Temission_3 * Fobj_{3,water} / (10^3 * F_{hospital} * F_{3,water})$
Break-even point tonnage for sanitary purposes + objects	TONNAGEREG	**2,41E+02**	$tonnes.yr^{-1}$	O	**TONNAGEreg** = $(Q_{water\_san} * C_{san} * Temission_3 * Fsan_{3,water} + Q_{water\_obj} * C_{obj} * Temission_3 * Fobj_{3,water}) / (10^3 * F_{hospital} * F_{3,water})$

Above this regional tonnage the scenario based on the tonnage should be applied preferably.

1) S: data set; D: default; O: output; P: pick list
2) The subscript "3" refers to the stage of processing in conformity with EUSES 1.0 and USES 2.0.

Emission scenario for calculating the release of disinfectants used for sanitary purposes in hospitals based on the amount of solution of disinfectant used on a day (ESD RIVM 2001, Table 3.6, p.20)

Instructions for using the table:
1. Enter the concentration at which the active substance is used for sanitary purposes and/or brushes (C_{san} or C_{obj}).
2. $Elocal_{3,water}$ will be automatically calculated for sanitary purposes and/or brushes.

Input

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*References / Calculation formulas / Explanations*
Fractions released to wastewater [2]					
Sanitary purposes	$Fsan_{3,water}$	0,55	[-]	D	
Brushes	$Fobj_{3,water}$	0,95	[-]	D	
Concentration at which active substance is used					
Sanitary purposes	C_{san}	0,13	$kg.l^{-1}$	S	
Brushes	C_{obj}	0,13	$kg.l^{-1}$	S	
Amount of water with active substance					
Sanitary purposes	Q_{water_san}	25	$l.d^{-1}$	D	
Brushes	Q_{water_obj}	25	$l.d^{-1}$	D	

Output

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*References / Calculation formulas / Explanations*
Emission rate to wastewater (standard STP) [2]					
for sanitary purposes	$Elocal_{3,water}$	**1,79E+00**	$kg.d^{-1}$	O	**Elocal$_{3,water}$** = $Q_{water\_san} * C_{san} * Fsan_{3,water}$
for brushes	$Elocal_{3,water}$	**3,09E+00**	$kg.d^{-1}$	O	**Elocal$_{3,water}$** = $Q_{water\_obj} * C_{obj} * Fobj_{3,water}$
for sanitary purposes + brushes	$Elocal_{3,water}$	**4,88E+00**	$kg.d^{-1}$	O	**Elocal$_{3,water}$** = $Q_{water\_san} * C_{san} * Fsan_{3,water} + Q_{water\_obj} * C_{obj} * Fobj_{3,water}$

1) S: data set; D: default; O: output; P: pick list
2) The subscript "3" refers to the stage of processing in conformity with EUSES 1.0 and USES 2.0.

Scenario 2c) Emission scenario for calculating the releases of disinfectants used in hospitals for disinfection of scopes and other articles in washers/disinfectors (ESD for PT2, RIVM 2001, Table 3.7, p.25 & TAB ENV 37, August 2017, scenario for Dipping disinfection system)

Emission scenario for calculating the releases of disinfectants used in hospitals for disinfection of scopes and other articles in washers/disinfectors (ESD RIVM 2001, Table 3.7, p.25 & TAB ENV 23, Sept 2015, scenario for Dipping disinfection system)

Instructions for using the table:
1. Select the "Disinfection system" ("Replacement", "Once-through" or "Dipping").
2. Enter the working concentration of active ingredient (C_{disinf}) in % (please note 1% = 0.01kg/L)
3. $Elocal_{3,water}$ will be automatically calculated.

Input

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*References / Calculation formulas / Explanations*
Disinfection system		Dipping		P	Pick list: ESD Table 3.7 and TAB [4]
Working concentration of active ingredient	C_{disinf}	13	%	S	
Volume of solution in machine/dipping bath	$Q_{machine\_bath}$	0,01	m^3	P/D	
Additional input parameters relevant for "Replacement" and "Once-through" systems:					
Maximum number of washers/disinfectors [2]	$N_{rep-max}$	3	[-]	D	
Additional input parameters relevant for "Replacement" systems:					
Replacement interval	T_{repl}	14	d	D	
Fraction carry-over	$F_{carry-over}$	0,015	[-]	D	
Rate constant for chemical conversion	$kdeg_{disinf}$	0	d^{-1}	D	
Additional input parameters relevant for "Dipping" systems:					
Maximum number of dipping bath per day	Nbath	30	d^{-1}	D	
Fraction released to wastewater	Fwater	1	[-]	D	

Output

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*References / Calculation formulas / Explanations*
Maximum emission rate to water [3]					
A) Replacement	$Elocal_{3,water}$	??	$kg.d^{-1}$	O	**$Elocal_{3,water}$** = $N_{rep-max}$ * $Q_{machine\_bath}$ * 10^{-6} * C_{disinf} * $e^{-kdegdisinf * Trepl}$ / $(1+F_{carry-over})^{Trepl}$
B) Once-through	$Elocal_{3,water}$	??	$kg.d^{-1}$	O	**$Elocal_{3,water}$** = $N_{rep-max}$ * $Q_{machine\_bath}$ * 10^{-2} * C_{disinf} [5]
C) Dipping	$Elocal_{3,water}$	3,90E+01	$kg.d^{-1}$	O	**$Elocal_{3,water}$** = Cdisinf * $Q_{machine\_bath}$ * Fwater * Nbath * 10

1) S: data set; D: default; O: output; P: pick list
2) For "replacement" assumption that replacement occurs on the same day.
3) The subscript "3" refers to the stage of processing in conformity with EUSES 1.0 and USES 2.0.
4) Dipping disinfection system was added to the spreadsheet, following the TAB / approach taken for a substance discussed at WG I 2015.
5) The equation in the ESD is not correct; instead of 10^{-6} a factor of 10^{-2} should be used. The corrected equation was implemented in this spreadhseet .

Subscenario 2d) Emission scenario for calculating the releases of disinfectants used in hospitals for disinfection of other contaminated instruments

Emission scenario for calculating the releases of disinfectants used in hospitals for disinfection of other contaminated instruments (ESD RIVM 2001, Table 3.8, p.26)

Input

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*References / Calculation formulas / Explanations*
Amount of active substance	$Qyear_{disinf}$	250	$kg.yr^{-1}$	D	
Emission days = number of replacements per year [2]	$Temission_3$	100	yr^{-1}	D	
Rate constant for chemical conversion	$kdeg_{disinf}$	0	d^{-1}	D	

Output

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*References / Calculation formulas / Explanations*
Average time a disinfectant solution is in use	T_{repl}	4	d	O	Intermediate calculation: T_{repl} = INT (365 / $Temission_3$ + 0.5)
Maximum emission rate at the day of a replacement [2]	$Elocal_{3,water}$ (= Q_{repl})	2,5	$kg.d^{-1}$	O	**$Elocal_{3,water}$ (= Q_{repl})** = $Qyear_{disinf}$ / $Temission_3$ * $e^{-kdegdisinf * Trepl}$

1) S: data set; D: default; O: output; P: pick list
2) The subscript "3" refers to the stage of processing in conformity with EUSES 1.0 and USES 2.0.

Subscenario 2e) Emission scenario for calculating the releases of disinfectants used in industrial areas

Emission scenario for calculating the releases of disinfectants used in industrial areas (ESD JRC 2011, Table 2, p.12 & TAB ENV 24, Sept 2015)

Instructions for using the table:
1. Enter the application rate of biocidal product (V_{form}) and the concentration of active substance in the product (C_{form}).
2. Select "Large scale application" or "Small scale application" (RTU).
3. $Elocal_{water}$ will be automatically calculated.

Input

Variable/parameter		*Symbol*	*Value*	*Unit*	*S/D/O/P* [1]	*References / Calculation formulas / Explanations*
Application rate of biocidal product [2]		Vform	0,1	$l.m^{-2}$	S	
Concentration of active substance in the product		Cform	130	$g.l^{-1}$	S	
Surface area to be disinfected	Large scale application	$AREA_{surface}$	1000	m^2	D/P	$AREA_{surface}$ for small scale applications according to TAB ENV 24, Sept 2015
Number of applications per day		Nappl	1	d^{-1}	D	
Fraction of substance disintegrated during or after application (before release to the sewage system)		F_{dis}	0	[-]	D	
Fraction released to wastewater		F_{water}	1	[-]	D	

Output

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P* [1]	*References / Calculation formulas / Explanations*
Local release to wastewater (without pre-treatment)	$Elocal_{water}$	1,30E+01	$kg.d^{-1}$	O	**$Elocal_{water}$** = V_{form} * C_{form} * $AREA_{surface}$ * N_{appl} * (1-F_{dis}) * F_{water} / 1000

1) S: data set; D: default; O: output; P: pick list

Scenario 2f) Emission scenario for calculating the release of disinfectants used for sanitary purposes in institutional areas based on an average consumption

Emission scenarios for calculating the releases of disinfectants used in institutional areas

Two types of emission scenarios may be distinguished: one based on the **annual tonnage** and the other on the **consumption**. Above a certain regional tonnage (at the **break-even tonnage**), the scenario based on the tonnage is more appropriate, since the scenario based on consumption would underestimate the actual amount of disinfectant reaching one STP. The break-even point tonnage can be calculated below before selecting the appropriate scenario.

Calculation of the break-even point tonnage (regional tonnage) (ESD JRC 2011, p.16 & Appendix 1)

Instructions for using the table:
1. Enter the concentration of active substance in biocidal product (Cform).
2. The break-even point tonnage will be automatically calculated, for "General purpose (tiles, floors, sinks)" and for "Lavatory".

Input

Variable/parameter		*Symbol*	*Value*	*Unit*	*S/D/O/P* [1]	*References / Calculation formulas / Explanations*
Number of inhabitants feeding one STP		Nlocal	10000	[-]	D	
Concentration of active substance in biocidal product		Cform	0,13	$kg.l^{-1}$	S	
Consumption per capita						
	General purpose (tiles, floors, sinks)	Vform	0,005	$l.cap^{-1}.d^{-1}$	D	
	Lavatory	Vform	0,002	$l.cap^{-1}.d^{-1}$	D	
Penetration factor of disinfectant		Fpenetr	0,5	[-]	S	
Fraction of the main source (STP)		Fmainsource	0,002	[-]	D	
Number of emission days for life cycle stage 4 (private use) [2]		$Temission_4$	260	$d.yr^{-1}$	S	

Output

Variable/parameter		*Symbol*	*Value*	*Unit*	*S/D/O/P* [1]	*References / Calculation formulas / Explanations*
Break-even point tonnage						**TONNAGEreg** = Nlocal * Vform *Cform * Fpenetr * Temission / (1000 * Fmainsource)
	General purpose (tiles, floors, sinks)	TONNAGEreg	4,23E+02	$tonnes.yr^{-1}$	O	
	Lavatory	TONNAGEreg	1,69E+02	$tonnes.yr^{-1}$	O	

Above this regional tonnage the scenario based on the tonnage should be applied preferably.

1) S: data set; D: default; O: output; P: pick list
2) The subscript "4" refers to the stage of private use in conformity with EUSES 1.0 and USES 2.0.

Emission scenario for calculating the release of disinfectants used for sanitary purposes based on an average consumption (ESD JRC 2011, Table 4, p.16)

Instructions for using the table:
1. Enter the concentration of active substance in biocidal product (C_{form}).
3. $Elocal_{4,water}$ will be automatically calculated, for "General purpose (tiles, floors, sinks)" and for "Lavatory".

Input

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P* [1]	*References / Calculation formulas / Explanations*
Number of inhabitants feeding one STP	Nlocal	10000	[-]	D	
Fraction released to wastewater	$F_{4,water}$	1	[-]	D	
Concentration of active substance in biocidal product	Cform	0,13	$kg.l^{-1}$	S	
Consumption per capita					
General purpose (tiles, floors, sinks)	Vform	0,005	$l.cap^{-1}.d^{-1}$	D	
Lavatory	Vform	0,002	$l.cap^{-1}.d^{-1}$	D	
Fraction of substance disintegrated during or after application (before release to the sewage system)	F_{dis}	0	[-]	D	
Penetration factor of disinfectant	Fpenetr	0,5	[-]	D	

Output

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P* [1]	*References / Calculation formulas / Explanations*
Emission rate to wastewater (standard STP) [2]					**$Elocal_{4,water}$** = Nlocal * Vform * Cform * Fpenetr * (1-F_{dis}) * $F_{4,water}$
General purpose (tiles, floors, sinks)	$Elocal_{4,water}$	**3,25E+00**	$kg.d^{-1}$	O	
Lavatory	$Elocal_{4,water}$	**1,30E+00**	$kg.d^{-1}$	O	

1) S: data set; D: default; O: output; P: pick list
2) The subscript "4" refers to the stage of private use in conformity with EUSES 1.0 and USES 2.0.

Environmental Emission Scenarios for Product Type 4: Disinfectants used in food and feed areas

Subscenario 7a) Assessment of entire plants (e.g.breweries, dairies, beverage processing plants), Tier 1 (Felim=0)

Assessment of entire plants (e.g.breweries, dairies, beverage processing plants) (IHO 2006) (ESD Table 5, p.14-15)

Instructions for using the table:
1. In the "Input" table select the active substance used for disinfection in the local plant.
2. The field Qai (amount of biocidal active substance used per year in the local plant) will be automatically populated.
3. $C_{effluent}$ and $C_{influent}$ will be automatically calculated in the "Output" table.

Input

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*Pick list / Calculation formula*
Active ingredient applied in breweries		Hydrogen peroxide	[-]	P	Pick list: ESD Table 6
Amount of biocidal active substance used per year in the local plant	Qai	191	$kg.yr^{-1}$	D	ESD Table 6
					Input needed **only** if "Introduce value below" is displayed above.
Number of emission days per year	Temission	231	$d.yr^{-1}$	D	
Fraction released to waste water	F_{water}	1	[-]	D	
Fraction of substance eliminated due to on-site pre-treatment of the plant waste water	F_{elim}	0	[-]	D	
Fraction of substance disintegrated during or after application (before release to the sewage system)	F_{dis}	0	[-]	D	
Capacity of the STP					
On-site STP	$CAP_{STP\_on\text{-}site}$	112,7	$m^3.d^{-1}$	D	
Off-site STP (standard STP according to the TGD)	$CAP_{STP\_off\text{-}site}$	2000	$m^3.d^{-1}$	D	
Dilution factor in surface water (standard default according to the TGD) [2]	DIL	160	[-]	D	

Output

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*Pick list / Calculation formula*
Effluent concentration of active substance in the effluent of the on-site STP [3]	$C_{effluent}$ = $Clocal_{water}$	4,59E-02	$mg.l^{-1}$	O	**$C_{effluent}$ = $Clocal_{water}$** = (Qai/Temission) * 1000 * (1-F_{dis}) * (1-F_{elim}) * F_{water} / ($CAP_{STP\_on\text{-}site}$ * DIL)
Influent concentration of active substance in the off-site STP	$C_{influent}$	4,13E-01	$mg.l^{-1}$	O	**$C_{influent}$** = (Qai/Temission) * 1000 * (1-F_{dis}) * (1-F_{elim}) * F_{water} / $CAP_{STP\_off\text{-}site}$

1) S: data set; D: default; O: output; P: pick list

2) The dilution factor was calculated as follows. The effluent of a standard STP according to the TGD is 2000 m^3/d which is diluted 1:10 in a river in which complete mixing is assumed. The corresponding river flow rate according to equation 46 of the TGD is 18000 m3/d. This river flow rate of a small river was assumed as river flow rate of the surface water receiving the effluent of an on-site STP of a brewery. The corresponding dilution factor calculated according to equation 46 of the TGD is 160.7 (= (112.7 m3/d + 18000 m3/d) / 112.7 m3/d = 160.7). The resulting dilution factor was conservatively rounded down to 160.

Subscenario 7a) Assessment of entire plants (e.g.breweries, dairies, beverage processing plants), Tier 2 (Felim=0.9)

Assessment of entire plants (e.g.breweries, dairies, beverage processing plants) (IHO 2006) (ESD Table 5, p.14-15)

Instructions for using the table:
1. In the "Input" table select the active substance used for disinfection in the local plant.
2. The field Qai (amount of biocidal active substance used per year in the local plant) will be automatically populated.
3. $C_{effluent}$ and $C_{influent}$ will be automatically calculated in the "Output" table.

Input

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*Pick list / Calculation formula*
Active ingredient applied in breweries		Hydrogen peroxide	[-]	P	Pick list: ESD Table 6
Amount of biocidal active substance used per year in the local plant	Qai	191	$kg.yr^{-1}$	D	ESD Table 6 Input needed **only** if "Introduce value below" is displayed above.
Number of emission days per year	Temission	231	$d.yr^{-1}$	D	
Fraction released to waste water	F_{water}	1	[-]	D	
Fraction of substance eliminated due to on-site pre-treatment of the plant waste water	F_{elim}	0,9	[-]	D	
Fraction of substance disintegrated during or after application (before release to the sewage system)	F_{dis}	0	[-]	D	
Capacity of the STP					
On-site STP	$CAP_{STP\_on\text{-}site}$	112,7	$m^3.d^{-1}$	D	
Off-site STP (standard STP according to the TGD)	$CAP_{STP\_off\text{-}site}$	2000	$m^3.d^{-1}$	D	
Dilution factor in surface water (standard default according to the TGD) [2]	DIL	160	[-]	D	

Output

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*Pick list / Calculation formula*
Effluent concentration of active substance in the effluent of the on-site STP [3]	$C_{effluent}$ = $Clocal_{water}$	4,59E-03	$mg.l^{-1}$	O	$\mathbf{C_{effluent} = Clocal_{water}}$ = (Qai/Temission) * 1000 * (1-F_{dis}) * (1-F_{elim}) * F_{water} / ($CAP_{STP\_on\text{-}site}$ * DIL)
Influent concentration of active substance in the off-site STP	$C_{influent}$	4,13E-02	$mg.l^{-1}$	O	$\mathbf{C_{influent}}$ = (Qai/Temission) * 1000 * (1-F_{dis}) * (1-F_{elim}) * F_{water} / $CAP_{STP\_off\text{-}site}$

1) S: data set; D: default; O: output; P: pick list

2) The dilution factor was calculated as follows. The effluent of a standard STP according to the TGD is 2000 m^3/d which is diluted 1:10 in a river in which complete mixing is assumed. The corresponding river flow rate according to equation 46 of the TGD is 18000 m3/d. This river flow rate of a small river was assumed as river flow rate of the surface water receiving the effluent of an on-site STP of a brewery. The corresponding dilution factor calculated according to equation 46 of the TGD is 160.7 (= (112.7 m3/d + 18000 m3/d) / 112.7 m3/d = 160.7). The resulting dilution factor was conservatively rounded down to 160.

3) An additional dilution factor of 10 according to Guidance Vol IV Part B should be added in addition.

Subscenario 7b) General scenario for drinking and beverage industry, dairy industry and breweries

General scenario for drink and beverage industry, dairy industry, breweries (Bakker 2006) (ESD Table 4, p.12-13)

Instructions for using the table:
1. In the "Input" table insert the values for Cform, $Vform_{inst}$, $Vform_{mix}$, $Vform_{tank}$ and Nappl.
2. Qa.i. and $Elocal_{water}$ will be automatically calculated in the "Output" table.

Input

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*References / Calculation formulas / Explanations*
Concentration of active ingredient	Cform	130	$g.l^{-1}$	S	
Volume of disinfectant used for cleaning of the installation, process lines	$Vform_{inst}$	100	l	S	Spraying of 1000 m2 with 0,1 L/m2
Volume of disinfectant used for cleaning of the mixing tanks	$Vform_{mix}$	4	l	S	Spraying of 41 m2 with 0,1 L/m2; see applicant's explanation below
Volume of disinfectant used for cleaning of the storage tanks	$Vform_{tank}$	294	l	S	Spraying of 2944 with 0,1 l/m2; see applicant's explanation below
Fraction of the emission to waste water	F_{water}	1	[-]	D	
Fraction of substance disintegrated during or after application (before release to the sewer system)	F_{dis}	0	[-]	D	
Number of application per day	Nappl	2	d^{-1}	S	
Number of days for the emission	Temission	365	d	D	

Output

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*References / Calculation formulas / Explanations*
Quantity of active ingredient used	Qa.i.	5,17E+04	g	O	**Qa.i.** = Cform * ($Vform_{inst}$ + $Vform_{mix}$ + $Vform_{tank}$)
Emission to waste water	$Elocal_{water}$	1,03E+02	$kg.d^{-1}$	O	**$Elocal_{water}$** = Qa.i. * F_{water} * (1-F_{dis}) * Nappl / (1000 * (365/Temission))

1) S: data set; D: default; O: output; P: pick list

Information from applicant (Additional and refined scenario on request of TUKES, 26.6.2018): With regard to brewery tank sizes we found the following information within a German newspaper: Reference: http://www.sueddeutsche.de/muenchen/augustiner-brauerei-grosseinsatz-fuer-bruno-den-starken-1.2211705.
The brewery can be considered a medium size brewery and has replaced all its storage (fermentation) tanks. Overall they have a capacity of 4.3 million litre beer, i.e. 4300 m^3. The mixing tanks were estimated according to the attached document.

Sizing-systems-for-the-brewer.pdf

Assuming that the brewery is brewing five times per week, we divide 4.3 million litre by 5 and additionally by 50 (weeks operation per year), which results in 17200 litre (17.2 m^3) for the brewing/mixing tank.
The surface, S, of cylinder is calculated as $S = 2 \cdot \pi \cdot r \cdot (r + h)$. For simplification purposes we assuming there is only one fermentation/storage tank with r=20 m and V=4300 m^3. This gives h=3.422 m and S=2943.274 m^2 for the fermentation tank. For the brewing/mixing tank size of 17.2 m^3 a radius of 1m is assumed. This results in h=5.475 and S=40.683 m^2.

Subscenario 7c) Emission scenario for calculating the releases of disinfectants used in large scale catering kitchens, canteens, slaughterhouses and butcheries

Emission scenario for calculating the releases of disinfectants used in large scale catering kitchens, canteens, slaughterhouses and butcheries (ESD § 2.2, p.17)

Note:

The default values can be overwritten. Once overwritten, in order to revert to the default values, these need to be manually introduced. Alternatively replace this worksheet by copying the one from the excel file in ECHA website.

Instructions for using the table:

1. Select the type of application ("Spraying/Wiping" or "Fogging/Smoke generation") and the size of the area treated (small or large scale application); the $Area_{surface}$ or Volume will be automatically filled in.
2. Insert Qai_{appl} value (application rate of the active substance).
3. The local releases to water, from slaughterhouses and from large scale catering kitchens will be automatically calculated.

Input

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*References / Calculation formulas / Explanations*
Type of application	[-]	Spraying/Wiping	[-]	P	Fogging/Smoke generation: TAB, item ENV 28
Size of the area treated	[-]	Large scale application	[-]	P	"Small scale application" can only be chosen if **"Spraying/Wiping"** is chosen above
Application rate of the active substance	Qai_{appl}	13	g/m2	S	
Surface area or Volume to be disinfected [2]					
Slaughterhouses and butcheries	$AREA_{surface}$ or Volume	10000		D	Fogging/Smoke generation: TAB, item ENV 28 / Small scale applications: TAB, item ENV 29
Large scale catering kitchens and canteens	$AREA_{surface}$ or Volume	2000		D	Fogging/Smoke generation: TAB, item ENV 28 / Small scale applications: TAB, item ENV 29
Number of applications per day	Nappl	2	d^{-1}	D	
Fraction of substance disintegrated during or after application (before release to the sewage system)	F_{dis}	0	[-]	D	
Fraction of substance eliminated due to on-site pre-treatment of the plant waste water	F_{elim}	0	[-]	D	
Fraction released to waste water	F_{water}	1	[-]	D	

Output

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*References / Calculation formulas / Explanations*
Local release to waste water	$Elocal_{water}$				**$Elocal_{water}$** = Qai_{appl} * $AREA_{surface}$ * Nappl * (1-F_{dis}) * (1-F_{elim}) * F_{water} /1000 or **$Elocal_{water}$** = Qai_{appl} * Volume * Nappl * (1-F_{dis}) * (1-F_{elim}) * F_{water} /1000
from slaughterhouses		2,60E+02	$kg.d^{-1}$	O	
from large scale catering kitchens		5,20E+01	$kg.d^{-1}$	O	

1) S: data set; D: default; O: output; P: pick list
2) In case of "Spraying" application, "Surface area" is considered. In case of "Fogging/Smoke generation" application, "Volume" is considered.

Subscenario 7d) Emission scenario for calculating the release of disinfectants used in milking parlour systems

Emission scenario for calculating the release of disinfectants used in milking parlour systems (ESD § 2.3, p.24)

Note:
The default values can be overwritten. Once overwritten, in order to revert to the default values, these need to be manually introduced. Alternatively replace this worksheet by copying the one from the excel file in ECHA website.

Instructions for using the table:
1. Insert Cform value (concentration of active ingredient).
2. The quantity of active ingredient used and the local emission to waste water are automatically calculated.

Input

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*References / Calculation formulas / Explanations*
Concentration of active ingredient	Cform	130	$g.l^{-1}$		
Amount of disinfectant used for cleaning of the milking installation	$Vform_{inst}$	130	$l.d^{-1}$	D	130 = 2 *65 (the milk installation is cleaned twice a day)
Amount of disinfectant used for cleaning of the milk storage tank	$Vform_{tank}$	45	$l.d^{-1}$	D	
Fraction of substance disintegrated during or after application (before release to the sewage system)	F_{dis}	0	[-]	D	
Fraction of the emission to waste water	F_{water}	1	[-]	D	

Output

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*	*References / Calculation formulas / Explanations*
Quantity of active ingredient used	Qai	2,28E+04	$g.d^{-1}$	O	**Qai** = Cform * ($Vform_{inst}$ + $Vform_{tank}$)
Local emission to waste water	$Elocal_{water}$	2,28E+01	$kg.d^{-1}$	O	**$Elocal_{water}$** = Qai * (1-F_{dis}) * F_{water} /1000

1) S: data set; D: default; O: output; P: pick list

3.3 New information on the active substance

The BPC opinion for the active substance hydrogen peroxide for product type(s) 1 to 6 requested that the following additional data should be generated on the active substance.

1) A new analytical method for the determination of hydrogen peroxide in air should be submitted.
2) A new analytical method for the determination of hydrogen peroxide in water should be submitted.

The above data has been generated and provided to the Finnish Competent Authority. Solvay Chemicals International SA has access to this data as they are a part of the Hydrogen peroxide subgroup of CEFIC Peroxygen sector group. The study reports have been evaluated by eCA FI as part of the post-approval data package and approved by the BPC-22 Meeting. See Section 2.2.4, above.

Furthermore, the post-approval data include also information on the compliant manufacturing sites.

3.4 Residue behaviour

Not relevant.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[13]

An IUCLIDdataset is available. Please see section 6.7 of our IUCLID file as this section contains robust study summaries of all the efficacy study data. Alternatively please see section 2.2.5 of this document.

[13]If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

3.6 Confidential annex

Solvay Chemicals International SA wish to keep the chemical composition of the active substance as well as the identity and the percentage information relating to the stabilisers which appears in very small concentrations in their products as confidential.

The full composition of the individual members of the family is reported in the separate confidential annex.

3.7 Other

ECHA outcome of the pre-submission consultation for union authorisation application under regulation (EU) No 528/2012.

UA-APP_Outcome_SolvayChemicalsIntern