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

(submitted by the applicant)

STERI-PEROX®

Product type 2

Hydrogen Peroxide

Case Number in R4BP: BC-GQ029577-18

Evaluating Competent Authority: Netherlands

Date: 14 September 2023

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1 CONCLUSION

The STERI-PEROX product family consists of two meta SPCs both containing 6.4% w/w hydrogen peroxide. The products are sold as soaked wipes, bottles with or without a separate sprayer and drums. These packagings are supported by storage stability studies. The following storage conditions are assigned:

- Protect from frost.
- Do not store at temperatures >40°C.

None of the meta SPCs of this product family should be classified under any physical hazard according to Regulation (EC) No 1272/2008.
The validation of the methods to determine the active substance content in the products are provided and are acceptable.

The STERI-PEROX product family comprises of PT 2 disinfectants containing the active substance hydrogen peroxide and are intended for indoor use only. Product use in disinfection of industrial areas was assessed based on the liquid product as a representative worst-case. Following product use, it is assumed that exposure of the STP via wastewater will occur due to wet cleaning of treated areas, followed by indirect exposure of the environment. No marine or air exposure is anticipated based on intended product use.

Acceptable risk was demonstrated for human health following product use under worst-case assumptions. It is therefore concluded that use of the STERI-PEROX product family as a PT 2 disinfectant is acceptable although the use of respiratory protective equipment (RPE) is required dependent on the ventilation rate predominantly influencing the in-air hydrogen peroxide concentrations.

The following risk mitigation measures are therefore proposed:

- During application only the user of the product can be present in the room.
- During application and for re-entry, the airborne hydrogen peroxide levels may not exceed the AEC inhalation limit of 1.25 mg/m3 (or a lower relevant national reference value). A calibrated sensor shall be used to establish that the airborne hydrogen peroxide levels are not exceeded.

Acceptable risk was demonstrated for all relevant environmental compartments following product use under worst-case assumptions. It is therefore concluded that use of the STERI-PEROX product family as a PT 2 disinfectant is acceptable.

The product is used to disinfect surfaces and the target organisms are bacteria, yeasts, fungi and bacterial spores. Efficacy is substantiated by the required tests as described in the BPR guidance for the claimed uses for all test organisms. It is therefore concluded that use of the STERI-PEROX product family as a PT 2 disinfectant is acceptable.

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)**
STERI PEROX®	EU

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Veltek Associates, Inc. Europe
	Address	Branch Office Europe Rozengaard 1940 8212DT Lelystad Netherlands
Pre-submission phase started on		
Pre-submission phase concluded on		
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	Veltek Associates, Inc.
Address of manufacturer	15 Lee Blvd. Malvern PA19355 USA
Location of manufacturing sites	As above

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

Active substance	Hydrogen Peroxide
Name of manufacturer	Evonik Operations GmbH (Acting for Evonik Active Oxygens, LLC (US))
Address of manufacturer	

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

	One Commerce Square 2005 Market Street Suite 3200 PA 19103 Philadelphia United States
Location of manufacturing sites	PeroxyChem Bayport Plant, 12000 Bay Area Blvd Pasadena, TX 77507 USA

2.1.1.5 Product family structure

Veltek Associates Inc. wishes to authorise a 'product family' based on two individual disinfectant formulations each containing the active substance hydrogen peroxide:

- Meta SPC 1: Wipes: STERI-PEROX 6% WIPES – Wipe product for PT2.
- Meta SPC 2: STERI-PEROX 6% - A Ready-To-Use (RTU) liquid formulation for PT2

The products all comprise a formulation containing the active substance hydrogen peroxide. The active substance is present at 6.4 % w/w in each product and therefore in terms of the active substance content, all products are within a similar efficacious and human health risk range and as such may be included within a family.

The purpose of all products is for the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs, and are not for use in medical areas. All the products in the family are specified for indoor use by industrial users. The target species are bacteria, yeast, fungi and bacterial spores for Meta SPC 2 and bacteria and yeast for Meta SPC 1.

All products are classified as Eye Irritant 2 (H319). The products all have the same precautionary statements. The hazard classification and precautionary statements are required based on the concentration of the disinfectant hydrogen peroxide present in the products.

In PT2, products are intended for use as disinfectants not intended for direct application to humans or animals. Products are marketed for industrial activities manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries. The users of all products are industrial users.

Efficacy testing methods are available for the type of claims being supported by the products in the 'product family'. The required tests have been performed and the necessary criteria met in line with the latest ECHA efficacy guidance. The microorganisms were appropriate target organisms and the contact times and soiling was commensurate with the type of applications envisaged for the products. The efficacy test results support label claims of bactericidal, yeasticidal, fungicidal and bacterial sporicidal for Meta SPC 2 bactericidal and yeasticidal for Meta SPC 1. As the formulations are all based on a 6.4% hydrogen peroxide, the efficacy data is proposed to be used for read across to all products in the family.

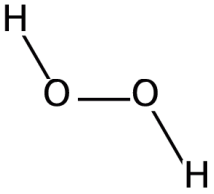
2.1.2 Product (family) composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	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	35% w/w (technical concentrate) 99.5% w/w (calculated dry weight)
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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Hydrogen Peroxide (35%)	Hydrogen peroxide	Active substance	7722-84-1	231-765-0	18.3 (TK) 6.4 (TC and pure)	18.3 (TK) 6.4 (TC and pure)
		Non-active substance[3]		See Confidential Annex 3.6		

2.1.2.4 Information on technical equivalence

The Peroxychem source was evaluated in the CAR (post approval) and is a reference source.

2.1.2.5 Information on the substance(s) of concern

There are no substances of concern in the product.

2.1.2.6 Type of formulation

AL (any other liquid) – RTU wipe AL (any other liquid)

2.1.3 Hazard and precautionary statements

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

[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]

Classification	
Hazard category	Eye Irrit 2.
Hazard statement	H319 - Causes serious eye irritation
Labelling	
Signal words	Warning
Hazard statements	H319 - Causes serious eye irritation
Precautionary statements	P264 - Wash face, hands thoroughly after handling P280 - Wear eye protection/face 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. P337+P313 - If eye irritation persists: Get medical advice/attention
Note	

2.1.4 Authorised use(s)

2.1.4.1 Use description- Meta SPC 1: Wipes

Table 1. Use # 1.1 – Industrial use – Wipe - Indoors - Meta SPC 1

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, Yeasts
Field of use	Indoor use. Disinfectant of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs. Not for use in medical areas. Disinfectant for use in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic product manufacturing facilities.
Application method(s)	Wiping
Application rate(s) and frequency	The product is ready to use. 30.5 cm x 30.5 cm wipe – 32.5 ml per wipe. 7.5 ml is freely available per wipe. 1 wipe = 7.5 ml per m^2 Frequency: 3 applications per day Contact time: 10 minutes Use temperature: room temperature
Category(ies) of users	Industrial
Pack sizes and packaging material	Wipe is composed of 100% continuous filament polyester fibre. Pack sizes are detailed below: Sterile (gamma irradiated) or non-sterile Wipes: 12x 12 inches (30.5 cmx30.5 cm). 20 wipes per pack. 10 packs per case. Re closable (peel and seal) low density polyethylene (opaque) bags.

2.1.4.2 Use-specific instructions for use

See General directions for use

2.1.4.3 Use-specific risk mitigation measures

See General Directions for use

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

See General Directions for use

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

See General directions for use

2.1.4.6 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 of Meta SPC 1

2.1.5.1 Instructions for use

Apply away from eyes and face. Pre-clean surface before application. Only use wet wipes. Remove one or two wipes at a time. Completely wet the surface and make sure the contact time is respected. Allow surface to remain wet for 10 minutes (bactericidal and yeasticidal uses). Discard wipe after use. Close the package after opening.

2.1.5.2 Risk mitigation measures

• During application only the user of the product can be present in the room. • During application and for re-entry, the airborne hydrogen peroxide levels may not exceed the AEC inhalation limit of 1.25 mg/m3 (or a lower relevant national reference value). A calibrated sensor shall be used to establish that the airborne hydrogen peroxide levels are not exceeded.

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

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor. IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor. IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations. Ecology – waste materials: Avoid release to the environment

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

Keep container tightly closed. Keep in a cool, well-ventilated place. Reseal package between uses to retain moisture.
Store in original container. Protect from frost. Do not store at temperatures >40°C.
Shelf-life = 2 years

2.1.6 Other information

Trade name:
STERI-PEROX® 6% WIPE

2.1.6.1 Use description- Meta SPC 2: Liquid

Table 2. Use # 2.1 – Industrial use – Liquid spraying - Indoors - Meta SPC 2

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts, fungi
Field of use	Indoor use. Disinfectant of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs. Not for use in medical areas. Disinfectant for use in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries.
Application method(s)	Spraying
Application rate(s) and frequency	The product is ready to use. 60 ml product per m^2 Frequency: 3 applications per day Contact time: 10 minutes for bacteria and yeasts, 20 minutes for fungi Use temperature: room temperature
Category of users	Industrial
Pack sizes and packaging material	473 mL bottle (sterile only). Trigger spray attachment is supplied separately. Packaging materials: **Bottles** Bottles are made of high density polyethylene (opaque). A separate hand sprayer has a polypropylene dip tube. The bottle cap is polypropylene, the induction seal is polypropylene. Bottles are provided with a polyethylene sprayer separately within the bags, the sprayers are not connected to the bottles and are supplied separately. The sterile versions are individually double-bagged and bags are heat-sealed shut. Optional quadruple bagging is available. Distributors distribute sealed cases, not individual containers

2.1.6.2 Use-specific instructions for use

Pre-clean surface before application. Unwrap and apply trigger to bottle. Direct the spray onto the surface from a distance of 15-20 cm away. Thoroughly wet surface with product and allow to take effect for 10 minutes (bactericidal, yeasticidal uses) or 20

minutes (for fungicidal use). Allow surface to air dry, or after the required contact time has been achieved, wipe dry with sterilised cloth or wipe, if necessary.

2.1.6.3 Use-specific risk mitigation measures

See General directions for use.

2.1.6.4 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

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

See general directions for use

2.1.6.6 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

Table 2. Use # 2.2 – Industrial use – Liquid Soaking – Indoors – Meta SPC 2

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria, yeast, fungi, bacterial spores
Field(s) of use	Indoor use. Disinfectant of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs. Not for use in medical areas. Disinfectant for use in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries.
Application method(s)	Soaking
Application rate(s) and frequency	The product is ready to use. Frequency: 3 applications per day

	Contact time: 10 minutes (bactericidal, yeasticidal), 20 minutes (fungicidal), 60 minutes (sporicidal) Use temperature: room temperature
Category(ies) of users	Industrial
Pack sizes and packaging material	***Bottles:*** 473 mL bottle (sterile only) Bottles are made of high density polyethylene (opaque). The bottle cap is polypropylene, the induction seal is polypropylene. The sterile versions are individually double-bagged and bags are heat-sealed shut. Optional quadruple bagging is available. 3.79 L (sterile and non-sterile) Containers made of high density polyethylene (opaque) with a moulded carrying handle and small screw-capped pouring spout moulded towards the top edge. Polypropylene screw cap with liner covers the pouring opening, the induction seal is polypropylene. All bottle caps are screw caps and able to be re-applied onto the bottle. Distributors distribute sealed cases, not individual containers. The sterile versions are individually double-bagged and bags are heat-sealed shut. Optional quadruple bagging is available. **Drum:** 200L (sterile only) High Density polyethylene (opaque). Blow moulded, closed head. Molded integral top ring. Double bagged and shrink wrapped to secure it. For secure dispensing after opening, the 200L drum has a 5 centimeter top-mounted polypropylene screw cap having a one-way directional dip tube attached to a length of 0.95 cm Santoprene® 73A FDA rubber tubing to connect to a peristaltic non-product contact dispensing pump of the customer's choice – not supplied. The pump and tubing remain attached and ready for dispensing during the entire use period. There are no fittings for adding material back into the drum.

2.1.6.7 Use-specific instructions for use

Pre-clean surface before application. Immerse item in a basin with product and allow to remain in the basin for a minimum of 10 minutes (bactericidal and yeasticidal uses), 20 minutes (fungicidal use) or 60 minutes (sporicidal use). After the required contact time has been achieved, allow surface to air dry, or wipe dry with sterilised cloth or wipe, if necessary. Only use dipping bath once.

2.1.6.8 Use-specific risk mitigation measures

See General directions for use.

2.1.6.9 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

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

See general directions for use

2.1.6.11 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

2.1.7 General directions for use of Meta SPC 2

2.1.7.1 Instructions for use

Use with adequate ventilation and apply away from eyes and face.

2.1.7.2 Risk mitigation measures

• During application only the user of the product can be present in the room. • During application and for re-entry, the airborne hydrogen peroxide levels may not exceed the AEC inhalation limit of 1.25 mg/m3 (or a lower relevant national reference value). A calibrated sensor shall be used to establish that the airborne hydrogen peroxide levels are not exceeded.

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

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.
IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.
IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

2.1.7.4 Instructions for safe disposal of the product and its packaging

Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations. Ecology – waste materials: Avoid release to the environment

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

Keep container tightly closed. Keep in a cool, well-ventilated place. Reseal package between uses to retain moisture. For the liquid discard 60 days after opening
Store in original container. Protect from frost. Do not store at temperatures >40°C.
Shelf-life = 2 years

2.1.8 Other information

Trade name:
STERI-PEROX® 6%

2.1.9 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)
STERI-PEROX 6% WIPE					
Plastic bag containing pre-saturated wipes.	Size of wipe: 12x 12 inches (30.5 cmx30.5 cm). 20 wipes per pack, 32.5	Primary packaging Low density polyethylene (opaque)	Reclosable (peel and seal)	Professional /Industrial	Yes

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)
Wipe is composed of 100% continuous filament polyester fibre.	mls per wipe . Sterile (gamma irradiated) or non-sterile				
STERI-PEROX 6%					
Bottle	473 mL bottle (sterile only)	<u>Primary packaging</u> Bottles are made of high density polyethylene (opaque). A separate hand sprayer has a polypropylene dip tube. <u>Secondary packaging</u> The sterile versions are individually double-bagged and bags are heat-sealed shut. Optional quadruple bagging is available. Distributors distribute sealed cases, not individual containers	The bottle screw cap is polypropylene, the induction seal is polypropylene. Bottles are provided with a polyethylene sprayer separately within the first outer bag, the sprayers are not connected to the bottles and are supplied separately.	Professional /Industrial	Yes
Bottle	3.79L (sterile and non sterile)	<u>Primary packaging</u> Containers made of	Polypropylene screw cap with liner covers the	Professional /Industrial	Yes

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)
		high density polyethylene (opaque) with a moulded carrying handle and small screw-capped pouring spout moulded towards the top edge. <u>Secondary packaging</u> Distributors distribute sealed cases, not individual containers. The sterile versions are individually double-bagged and bags are heat-sealed shut. Optional quadruple bagging is available.	pouring opening, the induction seal is polypropylene. All bottle caps are screw caps and able to be re-applied onto the bottle.		
Drum	200L (sterile only)	<u>Primary packaging</u> High Density polyethylene (opaque). Blow moulded, closed head. Molded integral top ring. <u>Secondary</u>	For secure dispensing after opening, the 200L drum has a 5 centimeter top-mounted polypropylene screw cap (NPS threads)	Professional /Industrial	Yes

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)
		packaging Double bagged and shrink wrapped to secure it.	having a one-way directional dip tube attached to a length of 3/8 inch (0.95 cm) Santoprene® 73A FDA rubber tubing to connect to a peristaltic non-product contact dispensing pump of the customer's choice – not supplied. The pump and tubing remain attached and ready for dispensing during the entire use period. There are no fittings for adding material back into the drum.		

2.1.10 Documentation

2.1.10.1 Data submitted in relation to product application

A reference list is presented in Annex 3.1.

2.1.10.2 Access to documentation

The applicant has submitted a letter of access to the data available on the active substance, hydrogen peroxide (Section 13, IUCLID).

2.1.10.3 Similar conditions of use

The products have similar conditions of use throughout the European Union.

2.2 Assessment of the biocidal product (family)

2.2.1 Intended use Meta SPC 1: Wipes

Table 3. Intended Use # 1.1 – Professional/industrial use – Wipe - Indoors - Meta SPC 1

Product Type	Product type 2; disinfectant
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria and yeast
Field of use	Indoor use. Disinfectant of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs. Not for use in medical areas. Disinfectant for use in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic product manufacturing facilities.
Application method(s)	Wiping
Application rate(s) and frequency	30.5 cm x 30.5 cm wipe – 32.5 mls per wipe. 7.5 mls is freely available per wipe. 1 wipe = 7.5 mls per m^2 Wet surface completely and leave for ten minutes Frequency: 3 applications per day
Category(ies) of users	Professional, industrial
Pack sizes and packaging material	Wipe is composed of 100% continuous filament polyester fibre. Pack sizes are detailed below: Sterile (gamma irradiated) or non-sterile 12x 12 inches (30.5 cmx30.5 cm). 20 wipes per pack. 10 packs per case. Reclosable (peel and seal) low density polyethylene bags.

Table 2. Intended Use # 2.1 – Professional/industrial use – Liquid spraying - Indoors - Meta SPC 2

Product Type	Product type 2; disinfectant
Where relevant, an exact description of the authorised use	-

Target organism (including development stage)	Bacteria, yeast, fungi
Field of use	Indoor use. Disinfectant of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs. Not for use in medical areas. Disinfectant for use in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic
Application method(s)	Spraying
Application rate(s) and frequency	The product is ready to use 60 ml per m^2 Frequency: 3 applications per day
Category(ies) of users	Professional, industrial
Pack sizes and packaging material	473 mL bottle (sterile only). Trigger spray is supplied separately. Packaging materials: **Bottles** Bottles are made of high density polyethylene. A separate hand sprayer has a polypropylene dip tube. The bottle cap is polypropylene, the induction seal is polypropylene. Bottles are provided with a polyethylene sprayer separately within the bags, the sprayers are not connected to the bottles and are supplied separately. The sterile versions are individually double-bagged and bags are heat-sealed shut. Optional quadruple bagging is available. Distributors distribute sealed cases, not individual containers

Table 3. Intended Use # 2.2 – Professional/industrial use – Liquid Soaking – Indoors – Meta SPC 2

Product Type	Product type 2; disinfectant
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria, yeast, fungi, bacterial spores
Field(s) of use	Indoor use. Disinfectant of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs. Not for use in medical areas. Disinfectant for use in manufacturing facilities

	including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries.
Application method(s)	Pouring
Application rate(s) and frequency	The product is ready to use. 60 ml per m^2 Frequency: 3 applications per day
Category(ies) of users	Professional, industrial
Pack sizes and packaging material	***Bottles:*** 473 mL bottle (sterile only) Bottles are made of high density polyethylene. The bottle cap is polypropylene, the induction seal is polypropylene. The sterile versions are individually double-bagged and bags are heat-sealed shut. Optional quadruple bagging is available. Distributors distribute sealed cases, not individual containers. 3.79 L (sterile and non-sterile) Containers made of high density polyethylene with a moulded carrying handle and small screw-capped pouring spout moulded towards the top edge. Polypropylene screw cap with liner covers the pouring opening, the induction seal is polypropylene. All bottle caps are screw caps and able to be re-applied onto the bottle. Distributors distribute sealed cases, not individual containers. The sterile versions are individually double-bagged and bags are heat-sealed shut. Optional quadruple bagging is available. **Drum:** 200L (sterile only) High Density polyethylene. Blow moulded, closed head. Molded integral top ring. Double bagged and shrink wrapped to secure it. For secure dispensing after opening, the 200L drum has a 5 centimeter top-mounted polypropylene screw cap (NPS threads) having a one-way directional dip tube attached to a length of 3/8 inch (0.95 cm) Santoprene® 73A FDA rubber tubing to connect to a peristaltic non-product contact dispensing pump of the customer's choice – not supplied. The pump and tubing remain attached and ready for dispensing during the entire use period. There are no fittings for adding material back into the drum.

2.2.2 Physical, chemical and technical properties

Meta SPC	Product
1	STERI-PEROX 6% WIPE
2	STERI-PEROX 6% (RTU formulation)

eCA remark: The methods used are not always those prescribed by the BPR guidance (e.g., EU Test Method Regulation CIPAC, OECD). It was explained that the used methods were comparable to the methods prescribed by the BPR guidance. Often, the EU test methods/CIPAC/OECD methods were referred to in the study reports. Therefore, we consider it acceptable.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6303	6.4% w/w hydrogen peroxide	'Steri-Perox 6%' liquid was determined to be a liquid substance with no signs of clumping or phase separation.	Sanow 2015a
	N/A	6.39% w/w hydrogen peroxide	Laundered polyester wipes impregnated with liquid product	Zehr 2019
Colour at 20 °C and 101.3 kPa	EPA OPPTS 830.6302	6.4% w/w hydrogen peroxide	'Steri-Perox 6%' liquid is clear and <1 on the Lovibond colour scale.	Sanow 2015a
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304	6.4% w/w hydrogen peroxide	'Steri-Perox 6%' liquid was determined to be odour free.	Sanow 2015a
Acidity / alkalinity	EPA OPPTS 830.7000, considered equivalent to CIPAC MT 75.3 as both methods use the same test procedure (i.e. pH meter calibrated with two buffers)	6.4% w/w hydrogen peroxide	The pH of 'Steri-Perox 6%' was measured to be 4.02 at ambient temperature (21°C).	Sanow 2015a
	EPA OPPTS 830.700; CIPAC MT 191	6 % w/w hydrogen peroxide Batch No. 20-SPER-011994	0.01723% m/m H_2SO_4	Zeller, C., 2020b Report No. A30709
	eCA remark: The study from Zeller (A30709, 2020b) was not included in IUCLID and could therefore not be evaluated. Therefore, data from this study cannot be relied on.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	Acidity was measured as part of the long term storage stability studies (see below). Therefore, the end point is considered sufficiently addressed.			
	CIPAC MT 75.3; CIPAC MT 191	6.39 % w/w hydrogen peroxide	The pH and acidity of the neat liquid squeezed from 'Steri-Perox 6% WIPES' was measured to be 3.61 and 0.017% m/m H_2SO_4, respectively, at room temperature (25 °C).	Zehr 2019
Relative density / bulk density	EPA OPPTS 830.7300, considered equivalent to OECD 109, using the same test procedure. Pycnometer method.	6.4% w/w hydrogen peroxide	1.0209 g/mL at 21.2°C.	Sanow 2015a
	eCA remark: Density was provided instead of relative density. Since the density gives a good indication of the relative density, this is considered acceptable.			
Storage stability test – **accelerated storage**	The liquid product: An accelerated study is not necessary as a completed long-term storage stability study is available and accelerated storage stability studies are provided for the wipes.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	In-house method (SOP Clab 410) equivalent to CIPAC MT 46.3 The analytical method SOP CLab519 is validated in Sanow 2015b (see section 2.2.4)	6.5 % w/w hydrogen peroxide	<u>Pre-saturated wipes 8 weeks at 40 °C in polyethylene bag results:</u> Weight change after storage: 12.3 g loss (-1.3%). No evidence of container corrosion. Active substance content before storage: 6.5 %. Active content after storage 6.4 % (0.1 % absolute loss on T0). Acidity before storage: 0.012% m/m as H_2SO_4 Acidity after storage: 0.0039% m/m as H_2SO_4	Sampura 2018
	eCA remark: Since the effects on content of the active substance and technical characteristics of the biocidal product were only assessed up to 40°C, the sentence 'Do not store at temperatures >40°C' is included on the label.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **long term storage at ambient temperature**	EPA OPPTS 830.6317; EPA OPPTS 830.6320. Methods considered equivalent to the analogous EU method as they use the same test procedure.	6.4% w/w hydrogen peroxide	<u>Liquid formulation 24 months in HDPE (16 oz/~455 mL) results:</u> Weight change after storage: 1.13 g loss. No change in physical appearance. No evidence of container corrosion. Active substance content before storage 6.38% w/w Active substance content after storage 6.50% w/w (0.12% absolute gain). pH (neat) 4.02[2] following storage = 4.01. Appearance after storage: non-viscous liquid	Sanow 2015a Pitt 2018b, A19642
	EPA OPPTS 830.6317; EPA OPPTS 830.6320. Methods considered equivalent to the analogous EU method as they use the same test procedure.	6.5 % w/w hydrogen peroxide	Laundered polyester wipes impregnated with liquid formulation, stored 24 months at room temperature in white plastic pouches with HDPE fill ports inside polyethylene bags (double bagged) Results: No change in appearance of expelled liquid from the wipes, the	Zehr, 2019

[2] pH measurements were not undertaken at the initial time point in the Zeller 2020b study, however the Sanow 2015a study provides a pH value of unstored Steri-Perox for a sample with lot number that shares the same primary elements (including year, 2015) as the lot number for the sample tested in the Zeller 2020b study. As such we consider this value can be relied upon as the initial pH value for the storage stability assessment. This avoids the disproportionate initiation of a new storage stability study to retrieve a single pH value, considering all other parameters in the Zeller 2020b study indicate the product to be stable after two years.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			packaging or the wipes. Weight change after storage: -3.03%. Active substance content before storage 6.39% Active substance content after storage 6.15% (-0.93% relative change). pH (neat) Time 0 = 3.61; following storage = 3.43. Acidity Time 0 = 0.017 m/m H_2SO_4; following storage = 0.016 m/m H_2SO_4.	
	eCA remark: Active substance content was experimentally determined using a titration with potassium permanganate and is validated (see section 2.2.4)			
Storage stability test – **Satisfactory operation of trigger sprays**	In-house method	6.4% w/w hydrogen peroxide	Steri-Perox 6%, tested weekly during 60 days (8 data points). Four samples were tested, 2 from an aged batch and 2 from fresh batch. Tested parameters: - Amount of liquid per spray - circumference and area per spray - spray pattern - nozzle blockage Results: Amount of liquid per spray: 0.6 ± 0.2 g Circumference per spray: 31.4-59.9 cm Area per spray: 78.5-265.9 cm^2	Singh 2017

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Spray pattern: Some variability was measured probably due to atmospheric pressure, laboratory temperature and usage technique. Nozzle blockage: none The average weight of liquid delivered was 0.6 g. The spray pattern was variable and was considered to be due to changes in environmental factors (temperature, pressure etc.) and the usage technique. Although, any variability recorded did not affect the ability to coat the surface of the tray sufficiently and no dry areas were observed within the dispensing area on any testing points. No blockages were observed. The successful operation of the trigger sprayer following storage was not assessed as the formulation is not supplied with the trigger sprayer attached - it is assembled before use.	
	eCA remark: Spray distance is not provided. Spray diameter and spray area depend on the spray distance, hence the information provided is incomplete. Since these parameters are not required following storage (as the trigger sprayer is not attached during storage) this is acceptable.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	In house method	6% w/w hydrogen peroxide 20-SPER-012464	Total spray rate T=0: 0.95 gram per act After 2 weeks at 54°C: 0.91 g per act Min-max diameter T=0: 31mm-94mm After 2 weeks at 54°C: T=0: 61mm-145mm Ovality ratio: T=0: 0.58 After 2 weeks at 54°C: 0.64 No blockage or changes in spray ability were observed.	J Balarashti et al., 2020a, Report No. 10875.90.B
Storage stability test – **low temperature stability test for liquids**	All wipe products: this endpoint is not applicable to the product as presented as it is a liquid on a solid support. Liquid product: based on the composition, the product will be stable at low temperatures and there will be no change in the appearance upon storage for 1 week at 0 °C.			
	eCA remark: The eCA does not consider the waiver to be acceptable. Since no low temperature stability test is provided, 'Protect from frost' is added under 'Conditions of storage and shelf-life of the product under normal conditions of storage'			
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	All product containers are opaque. This conclusion is not affected by the presence of an inert polyester matrix in the wipes.			
Effects on content of the active substance and technical characteristics of the biocidal product –	An accelerated storage stability study assessed the effects of temperature on the wipe product (8 weeks at 40 °C). No significant changes were noted. Humidity should not affect the stability of the products as they all have a high water content.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
temperature and humidity				
Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material	EPA OPPTS 830.6320	6.4% w/w hydrogen peroxide	Liquid product 24 month results following ambient storage: No evidence of container corrosion.	Pitt 2018b
	In-house method (SOP Clab 410) equivalent to CIPAC MT 46.3	6.5 % w/w hydrogen peroxide	Wipes product 8 weeks at 40°C: No evidence of container corrosion	Sampura 2018
Wettability	For all liquid products: not applicable to this product type (AL – other liquids applied undiluted). For all wipe products: not applicable to the product as presented.			
Suspensibility, spontaneity and dispersion stability	For all liquid products: not applicable to this product type (AL – other liquids applied undiluted). For all wipe products: not applicable to the product as presented.			
Wet sieve analysis and dry sieve test	For all liquid products: not applicable to this product type (AL – other liquids applied undiluted). For all wipe products: not applicable to the product as presented.			
Emulsifiability, re-emulsifiability and emulsion stability	For all liquid products: not applicable to this product type (AL – other liquids applied undiluted). For all wipe products: not applicable to the product as presented.			
Disintegration time	For all liquid products: not applicable to this product type (AL – other liquids applied undiluted). For all wipe products: not applicable to the product as presented.			
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187 (Mass median aerodynamic diameter (MMAD))	6% w/w hydrogen peroxide Lot: 20-SPER-012464	At t=0 D[10] = 61.55 µm D[50] = 131.93 µm D[90] = 304.32 µm At t=15months D[10] = 65.55 µm D[50] = 138.13 µm	J Balarashti et al., 2020b, Report No. 10875.9

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			D[90] = 297.67 µm Percentage of particles <50 µm: <10%	
	eCA remark: Currently, only MMAD data after 15 months instead of 24 months of storage months was provided. However, given the composition of the biocidal products, available data on the MMAD after accelerated storage (see below), the fact that the MMAD is not an input parameter for the assessment and the stability of the technical characteristics of the product after 24 months of storage, the eCA is of the opinion that the determination of the MMAD after storage is sufficiently addressed.			
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187 (Mass median aerodynamic diameter (MMAD))	6% w/w hydrogen peroxide Lot: 20-SPER-012464	At t=0 D[10] = 61.55 µm D[50] = 131.93 µm D[90] = 304.32 µm After 2 weeks at 54°C D[10] = 62.42 µm D[50] = 163.23 µm D[90] = 422.82 µm	J Balarashti et al., 2020a, Report No. 10875.90.B
Persistent foaming	For all liquid products: not applicable to this product type (AL – other liquids applied undiluted). For all wipe products: not applicable to the product as presented.			
Flowability/Pourability/Dustability	For all liquid products: not applicable to this product type (AL – other liquids applied undiluted). For all wipe products: not applicable to the product as presented.			
Burning rate — smoke generators	Not applicable as the products are not smoke generators.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Burning completeness — smoke generators	Not applicable as the products are not smoke generators.			
Composition of smoke — smoke generators	Not applicable as the products are not smoke generators.			
Spraying pattern — aerosols	Not applicable as the products are not aerosols.			
Spraying pattern — trigger sprayer	CIPAC MT 187	6% w/w hydrogen peroxide Lot: 20-SPER-012464	Normal sprayability and no blockages	J Balarashti et al., 2020, Report No. 10875.9
Other technical characteristics	In-house method – Evaporation effects of opening and closing Steri-Perox 6% wipes (20 pack) over 30 days	6% H_2O_2	The difference between the package weight before removal of each wipe and the weight after removal the previous day was ≤0.5 g – the wipes remained constantly wet throughout continuous opening and closing. The seal remained consistently good throughout the test and showed no sign of leaks. The average weight of each wipe was 44.4 g.	Singh 2019 Report No. VP-8047
	In-house method – Volume of liquid dispensed from Steri-Perox 6% wipe	6.5% w/w hydrogen peroxide	An average of 7.48 mL (7.64 g) of Steri-Perox 6% liquid solution was dispensed onto a 1 m^2 steel surface. Therefore ca. 7.5 mL of liquid will be dispensed by one wipe onto 1 m^2 surface during full coverage.	Singh 2018 Report No. VP-8046

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical compatibility	Not applicable. The products within this product family are not intended to be used in combination with other products.			
Chemical compatibility	Not applicable. The products within this product family are not intended to be used in combination with other products.			
Degree of dissolution and dilution stability	For all liquid products: not applicable to this product type (AL – other liquids applied undiluted). For all wipe products: not applicable to the product as presented.			
Surface tension	OECD 115 (plate method)	6.4% w/w hydrogen peroxide	71.66 mN/m at 22.7 °C of the neat liquid product (not surface active).	Baldwin 2017 Report No. 118550v2_Surface tension
Viscosity	OECD 114 (rotational viscometer)	6.4% w/w hydrogen peroxide	0.98 mPa s at 20 °C. Not measureable at 40 °C as sample was observed to form bubbles in the liquid. The viscosity of the sample was found to be independent of shear rate, so the sample is a Newtonian fluid.	Voth 2017 Report No. 118550v2_Viscosity

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

The 'Steri-Perox 6%' liquid product (nominal active substance content 6.4% w/w) was determined to be a liquid substance with no signs of clumping nor phase separation, the colour was clear and < 1 on the Lovibond colour scale and the test substance was odour free. These observations were performed at ambient temperature (21.0 °C). The pH of Steri-Perox 6% was measured to be 4.02 and the density of Steri-Perox 6% was measured to be 1.0209 g/mL at 21.2 °C.

A GLP ambient temperature storage stability study on the liquid product in commercial packaging (HDPE) is presented. Over the 24 month storage period, the following properties were measured before, during and after storage: weight of the test item & container, appearance of the test item and container, and active substance content. Neat pH was measured following storage for 12, 18 and 24 months. Colour, odour and aggregate state were measured after storage for 24 months. The formulation was observed to be stable following storage at ambient temperature for 24 months.

An accelerated storage stability on the wipes product in commercial packaging (LDPE) is presented. Over the 8 weeks at 40°C, the following properties were measured before, during and after storage: weight of the test item and container, appearance of the container, active substance content and acidity. The formulation was observed to be stable following storage at 40°C for 8 weeks.

Shelf life is 2 years.

The sprayability of the trigger spray has been tested with four sample bottles containing the test item over a period of 60 days. The following parameters were assessed at each testing point: weight of the dispensed material, spray pattern, size and circumference and any occurrence of blockages. The average weight of liquid delivered was 0.6 g. The spray pattern was variable and was considered to be due to changes in environmental factors (temperature, pressure etc.) and the usage technique. Although, any variability recorded did not affect the ability to coat the surface of the tray sufficiently and no dry areas were observed within the dispensing area on any testing points. No blockages were observed. The successful operation of the trigger sprayer following storage was not assessed as the formulation is not supplied with the trigger sprayer attached - it is assembled before use.

The wipe product is described as laundered polyester wipes. The viscosity of the liquid product was measured to be 0.98 mPa s at 20 °C and was not measurable at 40 °C. The surface tension of the neat liquid product was measured to be 71.66 mN/m at 22.7 °C.

For the wipe product only, the evaporation effects of opening and closing a full wipe package and removing a wipe daily was determined. The difference between the package weight before removal of each wipe and the weight after removal the previous day was ≤0.5 g – the wipes remained constantly wet throughout continuous opening and closing. The average volume of Steri-Perox 6% liquid solution dispensed by one wipe onto 1 m^2 surface during full coverage is ca. 7.5 mL.

No other technical characteristics are applicable to the product types within this product family which are AL (any other liquid) and AL (any other liquid) – ready to use wipe.

eCA remark: Since the accelerated storage stability studies are performed at 40°C, the sentence 'Do not store at temperatures >40°C' is included on the label.

2.2.3 Physical hazards and respective characteristics

eCA remark: Testing the liquid for addressing the physical hazards and respective characteristics is acceptable for meta 1 (wipes; a type A biocidal product with carrier component) as described in CA-Nov16-Doc4.3 'Handling "carriers" in the authorisation of biocidal products'.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	STERI-PEROX 6% should be 'Not classified' under this endpoint given the composition of the product. Although the active substance, hydrogen peroxide, does contain a chemical group associated with explosive properties (i.e. contiguous oxygen atom – peroxide; as outlined in the United Nations Recommendations on the transport of dangerous goods, manual of tests and criteria), hydrogen peroxide is included in Annex VI of the CLP Regulation (Index number 008-003-00-9) and has the following harmonised classification:[3]			

[3] https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/53297

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td colspan="4">
<table>
<tr><th colspan="2">Classification</th><th colspan="3">Labelling</th><th rowspan="2">Specific concentration limits, M-factors, Acute Toxicity Estimates (ATE)</th></tr>
<tr><th>Hazard class and Category Code(s)</th><th>Hazard statement Code(s)</th><th>Hazard statement Code(s)</th><th>Supp. Statement Code(s)</th><th>Pictograms, Signal Word Code(s)</th></tr>
<tr><td>Ox. Liq. 1</td><td>H271</td><td>H271</td><td rowspan="4">None</td><td rowspan="4">GHS03
GHS05
GHS07
Dgr</td><td rowspan="4">-: STOT SE 3; H335; C ≥ 35 %
Eye Dam. 1; H318: 8 % ≤ C < 50 %
Eye Irrit. 2; H319: 5 % ≤ C < 8 %
Ox. Liq. 1; H271: C ≥ 70 %****
Ox. Liq. 2; H272: 50 % ≤ C < 70 % ****
Skin Corr. 1A; H314: C ≥ 70 %
Skin Corr. 1B; H314: 50 % ≤ C < 70 %
Skin Irrit. 2; H315: 35 % ≤ C < 50 %</td></tr>
<tr><td>Acute Tox.4*</td><td>H302</td><td>H302</td></tr>
<tr><td>Skin Corr. 1A</td><td>H314</td><td>H314</td></tr>
<tr><td>Acute Tox.4*</td><td>H332</td><td>H332</td></tr>
</table>
*Must apply at least this minimum classification but must classify in a more severe hazard category in the event that further information is available which shows that the hazard(s) meet the criteria for classification in the more severe category.
A ca. 6% hydrogen peroxide solution (i.e. STERI-PEROX 6%) would be classified as: Acute Tox.4 (H302, H332) and Eye Irrit. 2 (H319) only. In no situation is pure H_2O_2, or aqueous mixtures thereof, classified under CLP for explosivity.

In addition, the product contains a high proportion of water – where water is a known suppressant of explosive properties – and the 2015 BPR active substance assessment report for H_2O_2 (PT1-6) states "Hydrogen peroxide itself is not flammable but it can cause spontaneous combustion of flammable materials. Explosive vapour phases can only be formed of aqueous hydrogen peroxide solutions with concentrations higher than 70% (w/w) at temperatures above 110°C."

Overall, STERI-PEROX 6% is not classified for explosive properties. This conclusion is not affected by the presence of an inert polyester matrix in the wipe product (i.e. for STERI-PEROX 6% wipes).
</td></tr>
<tr><td></td><td colspan="4">eCA remark: The eCA does not consider the waiver of the applicant (see above) to be acceptable. The active substance is a category 1 inorganic oxidiser and the concentration is <15% w/w. Hence, explosive properties can be waived based on inorganic oxidiser content. No further testing required.</td></tr>
<tr><td>Flammable gases</td><td colspan="4">Not applicable as the products are not gases.</td></tr>
<tr><td>Flammable aerosols</td><td colspan="4">Not applicable as the products are not aerosols.</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Oxidising gases	Not applicable as the products are not gases.			
Gases under pressure	Not applicable as the products are not gases.			
Flammable liquids	STERI-PEROX 6% should be 'Not classified' under this endpoint given the composition of the product. The product contains 6% hydrogen peroxide. Hydrogen peroxide has a harmonised CLP classification that includes Oxidising Liquids (Ox. Liq. 1 at C ≥ 70%, Ox. Liq. 2 at 50% ≤ C < 70%) but no other physicochemical hazard CLP endpoint (i.e. flammability). Indeed, ECHA Guidance on the Application of the CLP Criteria (Version 5.0 – July 2017) states "*Inorganic oxidising liquids are not flammable and therefore do not have to be subjected to the classification procedures for the hazard classes flammable liquids or pyrophoric liquids."* Based on the specified concentration limits, STERI-PEROX 6% – that is a ca. 6% solution of hydrogen peroxide – would not even be classified as an oxidising liquid. In addition, the product contains a high proportion of water – where water is a known suppressant of flammable properties – and the 2015 BPR active substance assessment report for H_2O_2 (PT1-6) states "*Hydrogen peroxide itself is not flammable but it can cause spontaneous combustion of flammable materials. Explosive vapour phases can only be formed of aqueous hydrogen peroxide solutions with concentrations higher than 70% (w/w) at temperatures above 110°C*." As hydrogen peroxide itself is not considered flammable, and water is not flammable, the predominantly aqueous formulation of STERI-PEROX 6% would not be flammable. It is clear that all other non-active substance component(s) of the mixture (See Confidential Annex 3.6) are non-flammable nor would they contribute in any way to flammability, particularly considering the very high-water content. Overall, STERI-PEROX 6% is not classified as a flammable liquid. Determination of flash point, to ascertain the specific classification category of the mixture under the flammable liquid endpoint, is therefore not necessary in this case. This conclusion is not affected by the presence of an inert polyester matrix in the wipe product (i.e. for STERI-PEROX 6% wipes). As a Type A biocidal product featuring a carrier, physicochemical hazard tests would be performed on the mixture before it is applied to the carrier component, i.e. on STERI-PEROX 6%.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	To support this conclusion a study was conducted to measure the flashpoint; see below			
	eCA remark: The eCA does not consider the waiver of the applicant (see above) to be acceptable. The data on the flash point (see below) are used to address this end point.			
Flashpoint	ASTM D93 *Standard Test Methods for Flash Point by Pensky-Martens Closed Cup Tester* Regulation (EC) No 440/2008 A9	6 % w/w hydrogen peroxide	No flash point, sample foamed out of apparatus before a flash could be observed	Frawley, T.J, (2020)
Flammable solids	For all liquid products: Not applicable as the product is a liquid. For all wipe products: This endpoint is not applicable to the product as presented.			
Self-reactive substances and mixtures	ASTM E 537-20	6.4% w/w hydrogen peroxide	No self-reactive properties. A DSC scan up to 350°C showed one exothermic event with an extrapolated onset temperature of 45.7°C and an exothermic decompositio n energy of 149.7 J/g. This is below the threshold of 300 J/g.	Ziemba 2023
Pyrophoric liquids	According to the additional classification considerations in CLP Annex I, 2.9.4, the classification procedure for pyrophoric liquids need not be applied to the Steri-Perox 6 % liquid product as experience in its manufacture and handling shows that the liquid does not ignite spontaneously on coming into contact with air at normal temperatures. The liquid is known to be stable at room			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	temperature for prolonged periods of time (days) as demonstrated by the various storage stability studies included as part of this submission.			
Pyrophoric solids	For all liquid products: Not applicable as the product is not a solid. For all wipe products: This endpoint is not applicable to the product as presented.			
Self-heating substances and mixtures	Theoretical assessment	6.4% w/w hydrogen peroxide	Self-heating generally only applies to solid material (e.g. piles of powders, crystals, splinters, other rough surfaces etc.) or liquids absorbed onto a large surface (e.g. on powder particles). No self-heating properties	Albaya 2016
Substances and mixtures which in contact with water emit flammable gases	This endpoint is not applicable as all products have a high water content. This conclusion is not affected by the presence of an inert polyester matrix in the wipe product.			
Oxidising liquids	Theoretical assessment	6.4 w/w hydrogen peroxide	Based on the concentration limits within the EU CLP harmonised classification of hydrogen peroxide, substances or mixtures containing hydrogen peroxide should only be classified under this endpoint if they contain >50% H_2O_2,	Albaya 2016

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			provided no other constituent/additive contributes to this classification. As all products within this product family contain 6% hydrogen peroxide and no other oxidising constituents, all products in the family do not need classification under this endpoint. This conclusion is not affected by the presence of an inert polyester matrix for the wipe product.	
	eCA remark: The eCA does not consider the waiver of the applicant (see above) to be acceptable. The classification limit according to the transport of dangerous goods regulations is 8%. This product contains <8% hydrogen peroxide and as a result should not be classified as oxidising liquid.			
Oxidising solids	For all liquid products: Not applicable as the product is not a solid. For all wipe products: This endpoint is not applicable to the product as presented.			
Organic peroxides	Based on CLP legislation annex point 2.15, hydrogen peroxide is not an organic peroxide			
Corrosive to metals	UN Manual of Tests and Criteria part III Section 37.4.1.1 Test C.1	6.9% w/w hydrogen peroxide	Tested for 1 week at 55±1 ºC. Aluminium Max. mass loss: <0.2%. No intrusion observed. Steel	Singh 2019

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Max. mass loss: <0.1%. No intrusion observed. The test item does not meet the criteria for classification as corrosive to metal.	
Corrosive to metals	UN Manual of Tests and Criteria part III Section 37.4.1.1 Test C.1	6-7 % w/w hydrogen peroxide Batch number 22-SPER-216767L	Tested for 9 days (see below for explanation) at 55±1 ºC. Results are recalculated to reflect annual corrosion rates Aluminium Max. mass loss: 0.1 mm/year. Max intrusion: 2.7 mm. Steel Max. mass loss: 0.2 mm/year. Max intrusion: 4.4 mm. The test liquid was replaced every day. During the weekend, the test item was not replaced. The test ran for an	Erning 2022

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			additional two days to compensate for the weekend and the results were compared to the corrosion rate limits for 7 days (as worst case). The test item does not meet the criteria for classification as corrosive to metal.	
Auto-ignition temperatures of products (liquids and gases)	The auto-ignition temperature is the lowest temperature at which the test substance will ignite when mixed with air under the conditions defined in the test method. The test is applicable to gases, liquids and vapours which, in the presence of air, can be ignited by a hot surface. STERI-PEROX 6% contains a high proportion of water, so would not be expected to be ignited by a hot surface. Further, STERI-PEROX 6% is neither flammable, explosive nor self-reactive (refer to other endpoints). The 2015 BPR active substance assessment report for H_2O_2 (PT1-6) also stated: "*Hydrogen peroxide itself is not flammable but it can cause spontaneous combustion of flammable materials. Explosive vapour phases can only be formed of aqueous hydrogen peroxide solutions with concentrations higher than 70% (w/w) at temperatures above 110°C*." Overall, the auto-flammability test is not necessary for STERI-PEROX 6%. This conclusion is not affected by the presence of an inert polyester matrix in the wipe product (i.e. for STERI-PEROX 6% wipes). As a Type A biocidal product featuring a carrier, physicochemical hazard tests would be performed on the mixture before it is applied to the carrier component, i.e. on STERI-PEROX 6%. To support this conclusion a study was conducted to measure the auto-ignition temperature; see below			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	eCA remark: The eCA does not consider the waiver to be acceptable. The data on the auto-ignition temperature (see below) are used to address this end point.			
Auto-ignition temperature for liquids	ASTM E659, *Standard Test Method for Autoignition Temperature of Liquid Chemicals.* Regulation (EC) No 440/2008 A15	6 % w/w hydrogen peroxide	>599 °C	Frawley, T.J, (2020)
Relative self-ignition temperature for solids	For all liquid products: Not applicable as the product is not a solid. For all wipe products: This endpoint is not applicable to a liquid on a solid support.			
Dust explosion hazard	For all liquid products: Not applicable as the product is not a solid. For all wipe products: This endpoint is not applicable to the product as presented.			

Conclusion on the physical hazards and respective characteristics of the product
No products supported by this product family should be classified under any physical hazard EU CLP endpoint.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues

Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Hydrogen peroxide *Active substance*	Titration using potassium permanganate	7.8% (n=3) (120%) 6.5% (n=3) (100%)	3.242-9.727%(H_2O_2), i.e. 50-150% of nominal r^2=1.00	No interferences expected – placebo solution (analysed in	120 % 100 % 80 %	100 (120 %) 100 (100 %)	Precision %RSD = 0.30 (n=6) %RSDr = 2.02 (mean	Not determined (not applicable)	Sanow 2015b

		5.2% (n=3) (80%)	n = 5 (duplicate)	duplicate) did not require titrant.		99 (80 %)	content: 6.445%)		
Hydrogen peroxide *Active substance*	Titration using potassium permanganate	70% (n=1) 138% (n=1)	0.61-2.48 % H_2O_2, (48-193% of nominal) r^2=1.00 y= 18.218 x – 0.0542	No interference expected	70% 138 %	98.7 % 98.4 %	Precision (n=5) RSD:0.18 %	Not determined (not applicable)	Zehr 2019

eCA remark: the equation for the linearity is not available in the report of Sanow.

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Methods for the determination of hydrogen peroxide in soil, water and air are presented in the active substance dossier and are considered adequate since the co-formulant(s) [see Confidential annex for complete composition] will not influence the behaviour of hydrogen peroxide should it be released into the environment. Methods for determining hydrogen peroxide in body fluids and tissues are not necessary since hydrogen peroxide is not classified as toxic or highly toxic under EU CLP. This is supported by the hydrogen peroxide biocide assessment report. Methods for the determination of hydrogen peroxide in/on food of plant and animal origin is considered not necessary as formulated products supported by this product family (PT 2) will not come into contact with food producing animals, food of plant or animal origin, or feeding stuffs.									

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
See 'Analytical methods for monitoring'									

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
See 'Analytical methods for monitoring'									

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
See 'Analytical methods for monitoring'									

Analytical methods for animal and human body fluids and tissues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
See 'Analytical methods for monitoring'									

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
See 'Analytical methods for monitoring'									

Conclusion on the methods for detection and identification of the product
The analytical methods used to determine the active substance (hydrogen peroxide) content of 'Steri-Perox 6%' shows acceptable specificity, linearity, precision and accuracy. The method is validated for 'Steri-Perox 6%' but is applicable to all products within this product family containing the same active substance content including 'wipe products'.

Methods for the determination of hydrogen peroxide in soil, water and air are presented in the active substance dossier and are considered adequate. Methods for determining hydrogen peroxide in body fluids and tissues are not necessary since hydrogen peroxide is not classified as toxic or highly toxic under EU CLP. Methods for the determination of hydrogen peroxide in/on food of plant and animal origin is considered not necessary as formulated products supported by this product family (PT 2) will not come into contact with food producing animals, food of plant or animal origin, or feeding stuffs.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The STERI-PEROX® Product Family contains disinfectant products for use in Product Type 2. The products are for use in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries.

The products are intended for the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs. The products are for professional/industrial use only. The STERI-PEROX 6% WIPES are bactericidal and yeasticidal; STERI-PEROX 6% liquid products are bactericidal, yeasticidal, fungicidal and sporicidal (bacteria).

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

The STERI-PEROX® Product Family contains disinfectant products which are intended to control bacteria, bacterial spores, yeast and fungi on surfaces, materials and equipment in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The STERI-PEROX® Product Family contains disinfectant products based on the active substance hydrogen peroxide. The active substance is bactericidal, yeasticidal, fungicidal and sporicidal.

2.2.5.4 Mode of action, including time delay

Hydrogen peroxide, exhibits an unspecific mode of action. It destroys the cell membrane causing alteration of membrane fluidity and leakageThis process, referred to as oxidative stress, leads to a loss of cellular activity resulting in the cell’s death.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use**	**Test substance**	**Test organism(s)**	**Test**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant	*PT 2*	*STERI-PEROX 6% (measured content 6.6% hydrogen peroxide)*	*Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442, Escherichia coli ATCC 10536, Enterococcus hirae ATCC 10541*	EN 1276 (2009) P2S1	Four different bacterial species were exposed to an 80%, 50% and 33% dilution of a 6.4% aqueous hydrogen peroxide solution (5.3%, 3.3% and 2.2% as tested) for 10 mins, with the interfering substance bovine albumin (0.03%). The test was performed at 20°C.	>99.999% (>5 log) reduction observed at 5.3% H_2O_2, 10 minute contact time for all organisms.	*Brambilla (2013) IUCLID 6.7-01*
Disinfectant	*PT 2*	*STERI-PEROX 6%(measured content 6.6% hydrogen peroxide)*	*Candida albicans ATCC 10231, Aspergillus niger ATCC 16404*	EN 1650 (2008) P2S1	One fungal specie and one yeast were exposed to an 80%, 50% and 33% dilution of a 6.6% aqueous hydrogen peroxide solution (5.3%, 3.3% and 2.2% as tested) for 10 mins, with the interfering substance bovine albumin (0.03%). The test was performed at 20°C.	>99.99% (>4 log) reduction observed at 5.3% H_2O_2, 10 minute contact time for all organisms. **eCA remark**: During the WGII 2023 EFF meeting it was concluded that the provided EN1650 was performed with an outdated protocol and that the test cannot be used to substantiate the claim against fungi in meta-SPC 2. A new test was provided in the ad hoc follow up stage that	*Brambilla (2013) IUCLID 6.7-03*

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use**	**Test substance**	**Test organism(s)**	**Test**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
						supports the fungicidal claim in meta SPC 2 (see test L23/00273.2).	
Disinfectant Fungicidal	PT2	*STERI-PEROX 6%*	*A. brasiliensis*	EN 1650 (2019) P2S1	25%, 50% and 80% product Contact time: 15, 20 and 30 minutes 0.3 g/l of bovine albumin (clean conditions), 20°C	Reduction ≥log 4 80% product 20 min Clean conditions 20°C	*L23/00273.2*
Disinfectant	*PT 2*	STERI-PEROX 6% WIPES	*Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442, Enterococcus hirae ATCC 10541*	EN 16615 (2015) P2S2	A test-surface is marked with 4 squares of 5 x 5 cm, the "test fields", in a row. Test field 1 on the test-surface is inoculated with a test suspension of bacteria in a solution of interfering substances (bovine albumin (0.03%). The inoculum is dried. The test-surface is wiped with the wipe across the four marked test fields, starting in front of test field 1, turning immediately after test field 4 and wiped back to the starting point. In parallel a water control is performed: a wipe is soaked with water instead of the product. The test was performed at 22-25°C.	>99.999% (>5 log) reduction observed at the 5 minute contact time for all organisms.	Woodall (2017) IUCLID 6.7-07
Disinfectant	*PT 2*	STERI-PEROX 6% WIPES	*Candida albicans ATCC 10231*	EN 16615 (2015) P2S2	A test-surface is marked with 4 squares of 5 x 5 cm, the "test fields", in a row. Test field 1 on the test-surface is inoculated with a test suspension of yeasts in a solution of interfering substances (bovine albumin (0.03%). The inoculum is dried. The test-surface is wiped with the wipe across the four marked test	>99.999% (>5 log) reduction observed at the 8 and 10 minute contact time for all organisms.	Woodall (2018) IUCLID 6.7-09

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use**	**Test substance**	**Test organism(s)**	**Test**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					fields, starting in front of test field 1, turning immediately after test field 4 and wiped back to the starting point. In parallel a water control is performed: a wipe is soaked with water instead of the product. The test was performed at 20°C.		
Disinfectant	*PT 2*	*STERI-PEROX 6%(measured content 6.2% hydrogen peroxide)*	*Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442, Escherichia coli ATCC 10536, Enterococcus hirae ATCC 10541*	EN 13697 (2001) P2S2	The test organisms were dried as pure cultures onto target surface coupons together with bovine albumin (0.03%). The test item – neat (100%), 50% and 33% dilutions of a 6.2% aqueous hydrogen peroxide solution (6.2%, 3.1% and 2.0% as tested) and allowed 5 min and 10 min contact time. The test was performed at 20°C.	>99.99% (>4 log) reduction observed at 6.2% H_2O_2, 5 and 10 minute contact time for all organisms.	*Brambilla (2013) IUCLID 6.7-02*
Disinfectant	*PT 2*	*STERI-PEROX 6% (measured content 6.2% hydrogen peroxide)*	*Candida albicans ATCC 10231, Aspergillus niger ATCC 16404*	EN 13697 (2001) P2S2	The test organisms were dried as pure cultures onto target surface coupons together with bovine albumin (0.03%). The test item – neat (100%), 33% and 25% dilutions of a 6.2% aqueous hydrogen peroxide solution (6.2%, 2.0% and 1.6% as tested) and allowed 10 min and 15 min contact time. The test was performed at 20°C.	>99.9% (>3 log) reduction observed at 6.2% H_2O_2, 10 and 15 minute contact time for all organisms	*Brambila (2014) IUCLID 6.7-06*
Disinfectant	*PT 2*	*STERI-PEROX 6% (measured content 6.6% hydrogen peroxide)*	*Bacillus subtilis ATCC 6633*	EN 13704 (2002) P2S1	One bacterial species was exposed to an 80%, 50% and 9% dilution of a 6.6% aqueous hydrogen peroxide solution (5.3%, 3.3% and 0.6% as tested) for 60 mins and 120 mins, with the interfering substance bovine albumin (0.03%).	>99.9% (>3 log) reduction observed at 5.3% H_2O_2, 60 minute contact time.	*Brambilla (2013) IUCLID 6.7-04*

Conclusion on the efficacy of the product

The STERI-PEROX® Product family consists of both a liquid product and a wipe product.

The product is used to disinfect surfaces and the target organisms are bacteria yeast, fungi and bacterial spores.

Efficacy data was developed to support the activity against the above organisms. Efficacy was developed on the liquid product (STERI-PEROX® 6%) with the intent to read across to support the claims for the wipes product. The wipes product will, additionally, be supported by data from a test to EN 16615.

STERI-PEROX 6% has a nominal concentration of 6.4%(w/w) hydrogen peroxide. The tested products that were analysed had a hydrogen peroxide content of 6.2-6.6%. STERI-PEROX 6% WIPES contain 32.5ml of product per wipe. It was experimentally determined that 7.5 ml is freely available per wipe.

The product STERI-PEROX® 6% was tested to and met the criteria required to pass the EN Norm EN 1276 under clean conditions (0.03% soil) with a 10 minute contact time. EN 1276 is a suspension test (Phase 2 Step 1 test) for the determination of disinfectant efficacy, it forms a key part of the evidence of a product to perform as a disinfectant and is referenced in the ECHA Draft Disinfectant Guidance Document (December 2015).

The product STERI-PEROX® 6%, was tested to, and met the criteria required to pass the Norm EN 13697; under clean conditions against all test bacteria within 5 minutes. The product meets the 'PASS' criteria of the test. EN 13697 is a surface test without mechanical action (Phase 2 Step 2 test) for the determination of disinfectant efficacy, it forms a key part of the evidence of a product to perform as a disinfectant and is referenced in the ECHA Draft Disinfectant Guidance Document (December 2015).

The product STERI-PEROX® 6% WIPES, was tested to, and met the criteria required to pass the Norm EN 16615; under clean conditions against all test bacteria within 5 minutes and against yeasts within 8 minutes. The product meets the 'PASS' criteria of the test. EN 16615 is a surface test with mechanical action (Phase 2 Step 2 test) for the determination of disinfectant efficacy, it forms a key part of the evidence of a product to perform as a disinfectant and is referenced in the ECHA Draft Disinfectant Guidance Document (December 2015).

The product STERI-PEROX® 6% met the criteria required to 'pass' and be defined as yeasticidal and fungicidal as determined by the EN Norm EN 1650 (2008) under clean conditions (0.03% soil) with a 10 minute contact time in a suspension test defined for that purpose. EN 1650 is a suspension test (Phase 2 Step 1 test) for the determination of disinfectant efficacy, it forms a key part of the evidence of a product to perform as a disinfectant and is referenced in the ECHA Draft Disinfectant Guidance Document (December 2015).

The product STERI-PEROX® 6%, was tested to, and met the criteria required to pass the Norm EN 13697; under clean conditions against yeast and fungi within 10 minutes. The product meets the 'PASS' criteria of the test. EN 13697 is a surface test without mechanical (Phase 2 Step 2 test) for the determination of disinfectant efficacy, it forms

a key part of the evidence of a product to perform as a disinfectant and is referenced in the ECHA Draft Disinfectant Guidance Document (December 2015).

The product STERI-PEROX® 6% was tested to and met the criteria required to pass the EN Norm EN 13704 under clean conditions (0.03% soil) with a 60 minute contact time. EN 13704 is a suspension test (Phase 2 Step 1 test) for the determination of disinfectant efficacy, and provides evidence of a product to perform as a disinfectant sporicide.

The above efficacy data is typical of all members of the STERI-PEROX® 6% Product Family and therefore these data can be considered valid for read-across use where appropriate.

2.2.5.6 Occurrence of resistance and resistance management

Due to the unspecific mode of action of hydrogen peroxide, the development of resistance is not expected and not reported.

2.2.5.7 Known limitations

There are no known limitations for the products included in the STERI-PEROX® Product Family.

2.2.5.8 Evaluation of the label claims

In general, hydrogen peroxide is known as an effective disinfectant and within the frame of authorising the STERI-PEROX® Product Family the disinfection effect proven by the efficacy data supports the claim for bactericidal, yeasticidal, fungicidal and sporicidal action.

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

STERI-PEROX® Product Family disinfectant products are not intended to be used with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

A waiver is presented for skin corrosion and irritation (IUCLID Section 8.1), on the basis that conducting studies would be scientifically unjustified (see table below). Classification of the products is addressed using available data on the individual components of the respective formulations. No human data are available.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not corrosive or irritating
Justification for the value/conclusion	Information obtained from the Competent authority report (CAR) states that no dermal irritation was noted after application of 10% hydrogen peroxide. Hydrogen peroxide (the active substance) is classified as being corrosive to the skin due to its oxidising properties, with specific concentration limits (SCLs) in place. According to Regulation (EC) No 1272/2008, hydrogen peroxide is classified as a Category 2 Skin Irritant at concentrations greater than or equal to 35% and less than 50%, as Skin Corrosive Category 1B at concentrations greater than or equal to 50% and less than 70%, and as Skin Corrosive Category 1A at concentrations greater than or equal to 70%. Products in the STERI-PEROX product family contain a maximum of 6.4% hydrogen peroxide; this is well below the SCLs triggering classification for skin corrosion/irritation and therefore classification of the products for skin corrosion/irritation is not required. Furthermore, co-formulant(s) are not classified for this endpoint.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	IUCLID Section 8.1
Justification	Data waiving: study scientifically unjustified. The classification of the biocidal products can be addressed based on their constituents, as detailed in Regulation (EC) No 1272/2008 and without the need for additional testing.

Eye irritation

A waiver is presented for eye irritation (IUCLID Section 8.2), on the basis that conducting studies would be scientifically unjustified (see table below). Classification of the products is addressed using available data on the individual components of the respective formulations. No human data are available.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Eye irritation Category 2; H319
Justification for the value/conclusion	The CAR for hydrogen peroxide (the active substance) states that 5% hydrogen peroxide caused only mild eye irritation with effects that do not meet the criteria classification. According to Regulation (EC) No 1272/2008, hydrogen peroxide is classified as a Category 2 Eye Irritant at concentrations greater than /equal to 5% and less than 8% and as Eye Damage Category 1 at concentrations greater than or equal to 8% and less than 50%. Products in the STERI-PEROX product family contain 6.4% hydrogen peroxide and therefore meet the criteria to be classified in Category 2 for Eye Irritation (H319). Furthermore, co-formulant(s) are not classified for this endpoint.
Classification of the product according to CLP and DSD	Eye irritation Category 2; H319

Data waiving	
Information requirement	IUCLID Section 8.2
Justification	Data waiving: study scientifically unjustified. The classification of the biocidal products can be addressed based on their constituents, as detailed in Regulation (EC) No 1272/2008 and without the need for additional testing.

Respiratory tract irritation

A waiver is presented for respiratory tract irritation (IUCLID Section 8.4), on the basis that conducting studies is scientifically unjustified (see table below). Classification of the products is addressed using available data on the individual components of the respective formulations. No human data are available.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating
Justification for the conclusion	According to the CAR for hydrogen peroxide (the active substance), both animal and human exposure studies indicate that hydrogen peroxide (the active substance) causes respiratory tract irritation. According to Regulation (EC) No 1272/2008, hydrogen peroxide is classified as Category 3 specific target organ toxicity (single exposure) at concentrations greater than or equal to 35%. Products in the STERI-PEROX product family contain a maximum of 6.4% hydrogen peroxide which is below the specific concentration limit that triggers classification for STOT SE category 3 therefore; classification of the products for respiratory tract irritation is not required. Furthermore, co-formulant(s) are not classified for this endpoint.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	IUCLID Section 8.4
Justification	Data waiving: study scientifically unjustified. The classification of the biocidal products can be addressed based on their constituents, as detailed in Regulation (EC) No 1272/2008 and without the need for additional testing. Specific testing for respiratory irritation is not required and is not possible in the absence of any recognised and validated test method.

Skin sensitization

A waiver is presented for skin sensitization (IUCLID Section 8.3), on the basis that conducting studies would be scientifically unjustified (see table below). Classification of the products is addressed using available data on the individual components of the respective formulations. No human data are available.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitizing
Justification for the value/conclusion	Hydrogen peroxide (the active substance) is not classified as a skin sensitiser according to Regulation (EC) No 1272/2008. No other components in the products are classified as skin sensitisers. The products in the STERI-PEROX product family do not therefore meet the criteria for classification for skin sensitisation according to Regulation (EC) No 1272/2008. Furthermore, co-formulant(s) are not classified for this endpoint.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	IUCLID Section 8.3
Justification	Data waiving: Studies scientifically unjustified. The classification of the biocidal products can be addressed based on their constituents, as detailed in Regulation (EC) No 1272/2008 and without the need for additional testing.

Respiratory sensitization (ADS)

A waiver is presented for skin sensitization (IUCLID Section 8.3), on the basis that conducting studies would be scientifically unjustified (see table below). Classification of the products is addressed using available data on the individual components of the respective formulations. No human data are available.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising
Justification for the value/conclusion	None of the components of the products are classified for respiratory sensitisation according to Regulation (EC) No 1272/2008. The products in the STERI-PEROX product family do not therefore meet the criteria for classification as respiratory sensitizers according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	IUCLID Section 8.4
Justification	Data waiving: studies scientifically unjustified. The classification of the biocidal products can be addressed based on their constituents, as detailed in Regulation (EC) No 1272/2008 and without the need for additional testing. Specific testing for respiratory sensitisation is not required and is not possible in the absence of any recognised and validated test method.

Acute toxicity

Acute toxicity by oral route

A waiver is presented for acute toxicity by the oral route (IUCLID Section 8.5.1), on the basis that conducting studies would be scientifically unjustified (see table below). Classification of the products is addressed using available data on the individual components of the respective formulations. No human data are available.

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via the oral route
Justification for the selected value	Hydrogen peroxide (the active substance) is classified in Category 4 for Acute Oral Toxicity according to Regulation (EC) No 1272/2008, and data provided for hydrogen peroxide and considered in the CAR indicates that the acute toxicity of hydrogen peroxide is concentration dependent. No other components in the products are classified for acute oral toxicity. The acute toxicity estimate (ATE) calculation method (specified in Regulation (EC) No 1272/2008) was used to determine the acute oral toxicity classification of the products. Based on the LD_{50} value of 420 mg/kg bw/day for hydrogen peroxide (from the CAR) and 6.4% hydrogen peroxide in the STERI-PEROX products the ATEmix was 6563 mg/kg bw/day. Therefore, the products in the STERI-PEROX product family do not require classification for acute oral toxicity according to Regulation (EC) No 1272/2008. Furthermore, co-formulant(s) are not classified for this endpoint.
Classification of the product	Not classified

according to CLP and DSD	

Data waiving	
Information requirement	IUCLID Section 8.5.1
Justification	Data waiving: Studies scientifically unjustified. The classification of the biocidal products can be addressed based on their constituents, as detailed in Regulation (EC) No 1272/2008 and without the need for additional testing.

Acute toxicity by inhalation

A waiver is presented for acute toxicity by inhalation (IUCLID Section 8.5.2), on the basis that conducting studies would be scientifically unjustified (see table below). Classification of the products is addressed using available data on the individual components of the respective formulations. No human data are available.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route
Justification for the selected value	Hydrogen peroxide (the active substance) is classified in Category 4 for Acute Inhalation Toxicity according to Regulation (EC) No 1272/2008. No other components in the products are classified for acute inhalation toxicity. The acute toxicity estimate (ATE) calculation method (specified in Regulation (EC) No 1272/2008) for vapours was used to determine the acute inhalation toxicity classification of the products. Based on the LC_{50} value of 11 mg/L for hydrogen peroxide vapour and 6.4% hydrogen peroxide in the STERI-PEROX products the ATEmix was 171.88 mg/L. Therefore, the products in the STERI-PEROX product family do not require classification for acute inhalation toxicity according to Regulation (EC) No 1272/2008. Furthermore, co-formulant(s) are not classified for this endpoint. This conclusion was confirmed in the CAR of hydrogen peroxide (Finland, 2017), where is stated that mixtures with a concentration below 50% hydrogen peroxide do not have to be classified as the vapour in-air concentration is below the threshold of 11 mg/m3, in STERI-PEROX BPF the maximum concentration of hydrogen peroxide is 6.4%. **eCA note:** During WGII 2023, the potential need to revise the acute inhalation toxicity classification of the BPF was discussed. This point was also discussed during the authorisation of a similar product. The conclusion was the following: "*Currently (June 2022), a new CLH proposal for hydrogen peroxide is under preparation by FI, where the acute tox inhalation endpoint will be re-evaluated. While the members agreed on the difference in classification outcome for the BPF if the LC50 of 0.3 mg/L is applied instead of the default ATE of 11 mg/L for H2O2, the members supported the eCA's approach in line with the agreements in WG-II-2019 until the new RAC CLH opinion is released. This was decided considering that H2O2 has an harmonised*

	classification, uncertainties associated with the LC50 of 0.3 mg/L derived from a very old, non-GLP study in mice, with unclear reliability, and not yet peer reviewed as well as an equal treatment for H2O2 dossiers under evaluation. In the absence of any further reliable information on LC50 values for H2O2, the WG supported the use the default ATE value of 11 mg/L until a decision from the RAC is available Moreover, it was proposed by one member state to use of the ideal gas equation for deriving acute toxicity, however, the Working group agreed to follow the previous agreements and the harmonised value based on the last RAC opinion.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	IUCLID Section 8.5.2
Justification	Data waiving: Studies scientifically unjustified. The classification of the biocidal products can be addressed based on their constituents, as detailed in Regulation (EC) No 1272/2008 and without the need for additional testing.

Acute toxicity by dermal route

A waiver is presented for acute toxicity by the dermal route (IUCLID Section 8.5.3), on the basis that conducting studies would be scientifically unjustified (see table below). Classification of the products is addressed using available data on the individual components of the respective formulations. No human data are available.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic by the dermal route.
Justification for the selected value	Hydrogen peroxide (the active substance) is not classified for acute dermal toxicity according to Regulation (EC) No 1272/2008. No other components in the products are classified for acute dermal toxicity. Therefore the products in the STERI-PEROX product family do not meet the criteria for classification for acute dermal toxicity according to Regulation (EC) No 1272/2008. Furthermore, co-formulant(s) are not classified for this endpoint.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	IUCLID Section 8.5.3
Justification	Data waiving: Studies scientifically unjustified.

	The classification of the biocidal products can be addressed based on their constituents, as detailed in Regulation (EC) No 1272/2008 and without the need for additional testing.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Hydrogen peroxide
Value(s)*	100%
Justification for the selected value(s)	No acceptable studies of dermal absorption are available; according to the CAR, hydrogen peroxide (the active substance) will degrade rapidly upon contact with the skin and systemic exposure will only occur in exceptional cases or when in contact with damaged skin. Based on the physico-chemical properties of hydrogen peroxide, the CAR concluded that 100% dermal penetration should be used in the absence of more accurate information. On this basis, a default dermal absorption value of 100% is used in the risk assessment for the STERI-PEROX product family. Furthermore, the following information was included in the AR of hydrogen peroxide: *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	IUCLID Section 8.6
Justification	Data waiving: Other justification; no data are available and therefore a default value is proposed.

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

Not applicable as there are no substances of concern in accordance to the CA document "CA-Nov14-Doc.5.11 - SoC guidance_final.doc".

Available toxicological data relating to a mixture

The classification of the biocidal products can be addressed based on their constituents, as detailed in Regulation (EC) No 1272/2008 and without the need for additional testing.

Other

Food and feeding stuffs

Biocidal products in the STERI-PEROX family are not used in areas relevant to the processing or manufacturing of food and are not labelled for use on food or food contact surfaces. These do not have any applications relevant to farm animals or livestock. Testing in this respect is not therefore necessary.

Effects of industrial processing and / or domestic preparation

Industrial processing and domestic preparation are not relevant to biocidal products in the STERI-PEROX family. Testing in this respect is therefore not necessary.

Other tests related to exposure to humans

The toxicity of the active substance hydrogen peroxide has been characterised in a comprehensive set of studies (evaluated in the CAR for hydrogen peroxide) and the substance has been approved for use in biocidal products. Based on the classification of the active substance (hydrogen peroxide), products in the STERI-PEROX product family are classified in Category 2 for eye irritation (CLP Cat. 2 H319). The toxicity and hazard of products in the STERI-PEROX product family is predicted to be low. There are no concerns relating to the proposed use of the products and no additional studies are required.

Endocrine disruption

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides.

No toxicological studies are available for the product STERI-PEROX. The product was not tested for potential endocrine disruption properties.

According to the CAR there is no indication that hydrogen peroxide affects the endocrine system. To examine if any of the co-formulants contained in the product may possess ED properties, a screening was performed by examining whether the co-formulants are

- Classified as CMR or PBT;
- Identified as ED in the DG Santé's Impact Assessment study on Screening of available evidence on chemical substances for the identification of endocrine disruptors;
    - Identified as ED in the EU list of potential endocrine disruptors; or
    - Listed in CoRAP linked to ED concerns.
    - included in ToxCast and EDSP21.

The ED screening was performed by NL CA for all co-formulant(s) and did not result in a potential alert.

The following text is included in the BPC opinion of hydrogen peroxide: *Hydrogen peroxide is not considered to have endocrine disrupting properties*. NL CA therefore concludes that STERI-PEROX does not possess co-formulant(s) with ED alerts for human health.

2.2.6.2 Exposure assessment

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

Intended uses:

Products in the STERI-PEROX product family are ready-for-use, disinfectant products which are intended to be used as under the general biocidal product category "private and public health area disinfectants": Product Type 2 (PT 2). Their use is restricted to disinfection of hard, non-porous surfaces; materials and equipment in industrial/manufacturing settings only (e.g. clean rooms). Treated surfaces are allowed to dry after the treatment time interval has elapsed. These products will not be used in private areas (home, day care, food or beverage preparation establishments). The products in this family all contain the active substance: hydrogen peroxide (CAS 7722-84-1; EC 231-765-0) at a nominal concentration of 6.4% w/w.

These products are effective against bacteria, yeast and fungi. They are designed for use indoors, for the disinfection of manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries. These products are used in strictly controlled, occupational settings (there is no consumer use of these products and they are not intended to be used in public areas; members of the public will be excluded from areas where these products will be used). The products are applied to surfaces as such (i.e. undiluted) and no post-application rinsing of surfaces is required, since the ingredients in these products are in the pure form and will leave no dry residue.

The products are produced in different packaging types: wipes, trigger sprays and ready to use liquids (e.g. 3.79 L container and 200 L drum). The products can therefore be applied by wiping, pouring or spraying, and will be used according to different disinfection regimes.

The products in this family are intended for professional/industrial use only and are provided ready-to-use. Nevertheless, decanting of products from larger containers to smaller containers is required, for example when transferring the product into trigger spray bottles from 1 gallon containers and also when pouring the product into a basin for soaking purposes. Primary exposure will occur during application of the product (dermal and inhalation exposure). Secondary exposure may occur in bystanders who inhale residues of active substance in the room where the product has been used (e.g. other workers: non-users working in the same room where the product has been used).

The STERI- PEROX product family consists of the following biocidal products:

Summary table of biocidal products in the STERI- PEROX product family

Product	Trade Names
META SPC 1: Wipes	STERI-PEROX 6% WIPE
META SPC 2: Liquid Trigger Spray, Drum and Bottle	STERI-PEROX 6%

Human exposure:

Biocidal products in the STERI-PEROX product family are used specifically in "clean rooms". A clean room is an environment, typically used in industrial manufacturing or laboratory settings (e.g. to produce pharmaceutical products or scientific research), in which low levels

of environmental pollutants such as dust, airborne microbes, aerosol particles and chemical vapours must be critically maintained. A clean room is a specially designed and constructed room in which the air supply, materials of construction, and operating procedures, are regulated to control airborne particle concentrations to meet appropriate cleanliness levels and standards. Processes for controlling particles include the use of filtration systems such as wall mounted high efficiency particulate air (HEPA) filters, ceiling mounted filters and return air filter grilles. Clean rooms will therefore have specialised ventilation systems to comply with national or international regulatory standards for the classification of air cleanliness. Air ventilation rates associated with clean rooms will vary, ranging from 20-720+ air changes per hour (ACH) and differ from more typical workplace settings where ventilation rates will be in the region of 3-10 ACH. Products in the STERI-PEROX product family will therefore be used under strictly controlled conditions, with enhanced ventilation systems in place.

The STERI-PEROX products are used in both aseptic and non-aseptic disinfection of the non-product contact surfaces on filling and packaging machinery, made of stainless steel, Lexan, polycarbonate, glass, and any critical surface of a processing area except the actual product-contact processing parts.

In the first instance it is assumed that clean rooms will be exhausted at comparable rates to laboratories (8 ACH: based on data from Klima Partner 2007 and The Engineering Tool Box 2005). Where appropriate, exposure estimates have been refined considering higher ventilation rates comparable with those found in ISO Class 8 (20 ACH), Class 6 (60 ACH) and Class 5 (200 ACH) clean room facilities. For all scenarios, the room volume of the industrial/manufacturing setting (clean room) of use, is assumed to be 55 m^3 (default for laboratory, clean rooms, cosmetics manufacturing facilities and pharmaceutical manufacturing facilities).

Workers who operate in clean room settings (e.g. in pharmaceutical manufacturing processes) will wear uniforms/gowns and hygienic gloves which are specifically designed to protect the sterile products from the contaminants and particles that humans carry and could be inadvertently introduced into products (e.g. an effective "barrier uniform" will be worn). While these uniforms are not intended to protect workers against chemical or other hazards, to some extent, they will protect the workers from splashes and direct contact with the disinfectants that are in use. Hence direct dermal contact with the disinfectant products will be limited in practise.

Tier 1 assessments have been carried out assuming no personal protective equipment (PPE) or respiratory protective equipment (RPE) is used, although hygienic hand gloves may be worn.

The toxicological profile of the active substance, hydrogen peroxide, has been summarised in the Competent Authority (Finland) Assessment Report for Hydrogen peroxide Product type 1-6 Evaluation of active substances: Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (March 2015; referred to as the "CAR" for Hydrogen peroxide). Due to the oxidising properties of hydrogen peroxide, the primary concern for human health is limited to irritation (and corrosion) of the skin, eyes and respiratory tract (i.e. sites of first contact) and embolism in some cases at high concentrations. Local effects may arise both after short-term and repeated /long term exposure. According to the CAR these effects are concentration dependent with no or minor dependence on exposure duration.

Hydrogen peroxide will degrade rapidly upon contact with the skin and systemic exposure will only occur in exceptional cases or when in contact with damaged skin. The CAR for hydrogen peroxide indicates that the substance lacks the potential to cause systemic effects following dermal contact and no reference values have been derived in respect of systemic effects following dermal exposures. According to the CAR, regarding local effects, no dermal irritation is associated with solutions of hydrogen peroxide at concentrations at or below 10 %. Products in the STERI-PEROX product family contain hydrogen peroxide at 6.4 % w/w which is below the skin irritating threshold (the concentration limit for classification as skin irritating is 35 %). No assessment is therefore required in respect of local dermal effects.

On this basis, only the inhalation route of exposure has been identified to be relevant in the quantitative exposure and risk assessment. An $AEC_{acute/medium/long-term}$ value for inhalation exposure of 1.25 mg/ m^3 was proposed in the CAR based on the NOAEC of 7 ppm (10 mg/ m^3) determined in rats following nose-only exposures and the application of an assessment factor of 8. For comparison with the AEC value, inhalation exposures have been determined as air concentrations in mg/m^3.

Summary table of the relevant paths of human exposure to hydrogen peroxide from the use of biocidal products in the STERI-PEROX product family

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	Yes	Yes	No	Yes	Yes	No	No
Dermal	Yes	Yes	No	Yes	Yes	No	No
Oral	No	No	No	No	No	No	No

The assessment of the STERI-PEROX product family has been undertaken using a tiered approach in accordance with ECHA guidance[4] (2015) on the assessment of human exposure to biocides. In the first instance exposure scenarios have been assessed using worst-case assumptions (e.g. task duration, assuming no protective equipment is worn). Where the risks to human health were acceptable, the exposure scenario was not refined further. If an unacceptable risk was identified for an exposure scenario, then the assessment was refined further (e.g. by the addition of PPE).

eCA note: For the current exposure assessment with hydrogen peroxide HEAdhoc recommendation 16 was not applied, as the dossier was submitted before the publication of this recommendation in May 2019. The harmonized approach at the time of submission was applied for the exposure scenarios. For renewal of this biocidal product family HEAdhoc recommendation 16 should be taken into account.

List of scenarios

4 ECHA (2015) The Biocides Human Health Exposure Methodology Document, Version 1.

The following scenarios have been considered in the assessment of human health risks from the use of biocidal products in the STERI-PEROX product family:

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
PT2-1	Mixing and loading	**Primary:** Professional/Industrial worker (e.g. in an industrial/manufacturing setting; clean room) decanting product from a container (e.g. 3.79 L (1 gallon container)): e.g. filling trigger spray bottles or a basin	Professional (PT2)
PT2-2	Application	**Primary:** Professional/Industrial worker (e.g. in an industrial/manufacturing setting; clean room) disinfecting hard surfaces using wiping tissues	Professional (PT2)
PT2-3	Application	**Primary:** Professional/industrial worker (e.g. in an industrial/manufacturing setting; clean room) disinfecting hard surfaces using a trigger spray bottle, including leaving on to soak and wiping	Professional (PT2)
PT2-4	Application	**Primary:** Professional/Industrial worker (e.g. in an industrial/manufacturing setting; clean room) disinfecting articles by immersing them in a basin	Professional (PT2)
PT2-5	Adult	**Secondary (indirect exposure):** Bystanders (workers) – inhalation of hydrogen peroxide in air after application by other workers in an industrial/manufacturing setting; clean room)	Bystanders (PT2)

eCA note: For re-entry it was not necessary to add a specific scenario, as this was covered with the risk mitigation measures: The professional/industrial user may only enter the room in emergency situations when the hydrogen peroxide level has dropped below 18 ppm (25 mg/ m3), when wearing respiratory protection equipment (RPE) with an assigned protection factor (APF) 20 according to EN 14387 or similar. At least a half/full mask with combination filter gas/P2 is required (filter type B1, grey) must we worn.

Please see section 2.1.5.2 and 2.1.7.2.

Industrial

This section considers exposures to hydrogen peroxide which may occur in industrial workers during the use of ready-for-use disinfectant biocidal products in the STERI-PEROX product family for the routine disinfection of hard surfaces in industrial/manufacturing settings such as clean rooms.

Scenario PT2-1 - Primary exposure: A industrial user decants/pours the product 'STERI-PEROX 6%' prior to its application.

Industrial users will be required to conduct loading/pouring tasks prior to applying the RTU product 'STERI-PEROX 6%' as a surface disinfectant. Pouring the biocidal product into a receiving vessel may result in exposure to hydrogen peroxide via the dermal and inhalation routes.

The primary mode of action of hydrogen peroxide is characterised by local irritation/corrosion at the site of first contact; health effects are concentration rather than time-dependent. The peak estimated in-air hydrogen peroxide concentration has been compared with the relevant external inhalation exposure limit value.

In accordance with Recommendation 6 of the BPC Ad hoc Working Group on Human Exposure[5], inhalation exposure during mixing/loading tasks has been estimated using TNsG Mixing and Loading Model 7[6]. Mixing and Loading Model 7 contains exposure data pertaining to the pouring of liquids during the application of industrial antimicrobial pesticides. The model expresses inhalation exposure as mg of product per m^3 of respired air.

Inhalation exposure to an individual during mixing and loading activities is considered comparable across all proposed application methods. In each instance the product is manually poured into a receiving vessel prior (e.g. a trigger spray bottle) to use. Since the manual re-filling of trigger spray bottles from a 3.79 L container presents the greatest potential for exposure, this is considered to be a representative worst-case scenario for all decanting tasks and is considered to cover all other tasks including filling a basin and transferring the product from a 200 L bulk container using an automated/closed transfer process.

5 ECHA (2017) Recommendation 6 of the BPC Ad hoc Working Group on Human Exposure: Methods and models to assess exposure to biocidal products in different product types, Version3.

6 TNsG Human Exposure to Biocidal Products, 2002, p140: Mixing and Loading Model 7 – Professionals pouring and pumping liquid, and dumping solids into systems. Data source: Popendorf et al. Am. Ind Hyg. Ass. J. 56:993-1001, 1995.

Table 2.2.6.2-1: Primary exposure in a professional/industrial user during the pouring/decanting of the RTU product 'STERI-PEROX 6%'.

An adult pouring the RTU product 'STERI-PEROX 6%' *into a receiving vessel prior to application. Potential exposures are via the dermal and inhalation routes. Based on the high volatility of hydrogen peroxide, Advanced Reach Tool (ART) Version 1.5 was selected as the most suitable model to predict the air concentration of hydrogen peroxide during pouring/decanting.*

Models/assessment approach:
Inhalation exposure: Advanced Reach Tool (ART) Version 1.5

Tier	Parameters	Value
1	Concentration of hydrogen peroxide in 'STERI-PEROX 6%'	6.4% (w/w)
	Total duration	10 min
	Primary emission source	In the breathing zone
	Substance product type	Liquids
	Process temperature	Room temperature
	Activity class	Transfer of liquid products - Falling liquids
	Transfer flow	0.1 - 1 l/minute
	Loading type	Splash loading
	Level of containment	Open process
	Primary localised controls	No localised controls Low level containment
	Surface Contamination/Fugitive Emission Sources	No enclosure Housekeeping in place
	Dispersion	indoors
	Room size	Any size workroom
	Ventilation	No restriction on general ventilation characteristics

Tier 1 assessment

It is assumed that no protective equipment is worn. The results of the assessment are detailed in the following table.

Table 2.2.6.2-2: Primary exposure to hydrogen peroxide in a professional/industrial user decanting/pouring the product 'STERI-PEROX 6%' prior to its application.

Tier/PPE	Hydrogen peroxide content in product (w/w)	Hydrogen peroxide in-air concentration (mg/m^3)
Tier 1 (No PPE)	6.4%	0.64
Full calculations are contained in Annex 3.2 of this report.		

NL CA note: the calculations made could be considered an overestimation since a non-exposure period of 0 minutes was used. However, considering the exposure is compared to the AEC which is based on irritating effects, this setting is considered more relevant than considering a complete working day with a 470 min non-exposure period. Calculations are currently made with the 75th percentile. According to Guidance on BPR Vol III PARTs B+C Appendix 3-2, a high percentile such as 90th could be considered when a dataset is small. Considering ART is not a dataset but a simulation, it could be argued whether a high percentile 90th percentile is more appropriate as tier 1. However, considering the scenario as a whole assumes the worst case and therefore it is unlikely that combination of this worst case and deviation from the majority of the data point would occur. It should be noted that even when using the 90th percentile, the exposure to hydrogen peroxide still does not exceed the AEC (i.e. 1.1 mg/m3).

Scenario PT2-2 - Primary exposure: A industrial user disinfects hard surfaces using the product 'STERI-PEROX 6% WIPE'.

The product 'STERI-PEROX 6% WIPE' is used in cleanroom environments for the intensive small-scale disinfection of 'clean critical' surfaces (e.g. the non-product contact surfaces on filling and packaging machinery). A typical user would clean an area of ≈2m^2 at the start of a production shift, or potentially when processes/equipment are halted for maintenance activities. It is not envisaged that a professional/industrial user would perform more than three separate cleaning events over an 8-hr production shift; a greater frequency of cleaning would significantly disrupt the cleanroom production process.

For the dermal exposure route, the concentration of hydrogen peroxide in the product (6.4% w/w) has been compared to the concentration limit for classification as skin irritating (35 % w/w). No further assessment is required in respect of local dermal effects.

In accordance with Recommendation 6 of the BPC Ad hoc Working Group on Human Exposure[7], inhalation exposure has been assessed using Consexpo Web[8] and the RIVM Cleaning Product Factsheet 5.4 (report 320104003; 2006), scenario: "wet tissues", p. 63.

The primary mode of action of hydrogen peroxide is characterised by local irritation/corrosion at the site of first contact; health effects are concentration rather than time-dependent. The peak estimated in-air hydrogen peroxide concentration has been compared with the relevant external inhalation exposure limit value.

A study (2018)[9] undertaken by Veltek Associates Inc determined the amount of liquid dispensed onto a 1-meter square surface following the use of the product ''STERI-PEROX 6% WIPE'. Six individual wipes were weighed before and after use on a 200 cm x 50 cm stainless steel surface. The study demonstrated that an average of 7.6 grams of liquid was dispensed onto the 1m^2 surface from a single wipe during a standardized wiping procedure. Therefore, the following Consexpo Web assessment considers a total dispensed product amount of 15.3 g (equating to the use of 2 wipes to clean an area of 2 m^2).

Table 2.2.6.2-3: Primary exposure in a professional/industrial user disinfecting hard surfaces using the product 'STERI-PEROX 6% WIPE'.

A professional/industrial worker uses wiping tissues to wipe a surface or article. The surface is wiped thoroughly until visibly wet and is left to dry. The wiping tissues are discarded after use. A professional user disinfects an area of 2 m^2 (using 2 wipes) for a duration of five minutes. The parameters listed below were used to calculate the peak in-air hydrogen peroxide concentration during a single disinfection event (2 m^2 cleaned using 2 pre-impregnated 'STERI-PEROX 6 WIPE%' products).

Models/assessment approach:

- **Inhalation exposure**: ConsExpo Web model: ***"Exposure to vapour";*** release mode: ***"evaporation from increasing surface"*** (RIVM Cleaning Products Factsheet 5.4, default scenario: ***"wet tissues"*** p. 63, adapted for use in a controlled manufacturing/industrial setting).

Tier	Parameters	Value
1	Molecular weight hydrogen peroxide (g/mol)	34.01
	Molecular weight matrix (g/mol)	18
	Application temperature (◦C)	20
	Vapour pressure hydrogen peroxide (Pa)	214

7 ECHA (2017) Recommendation 6 of the BPC Ad hoc Working Group on Human Exposure: Methods and models to assess exposure to biocidal products in different product types, Version3.

8 RIVM (2018) Consumer Exposure Tool (ConsExpo Web).

9 Veltek Associates Inc (2018): Determination of Liquid Content Dispensed onto a Surface by a Pre-saturated Wipe Product. Study Number VP-8046.

	Exposure event duration (mins)	30
	Product amount (g)	15.3
	Weight fraction compound (hydrogen peroxide)	0.064
	Room volume (m^3)*	55
	Ventilation rate (air changes/hr)	8
	Release area (m2)	2
	Application duration (mins)	5
	Mass transfer coefficient (m/hr)	10
2	Ventilation rate (air changes/hr)#	20
3	Ventilation rate (air changes/hr) #	60
4	Ventilation rate (air changes/hr) #	8
	Respiratory protective equipment (APF)	20

* As there is no default available for manufacturing, 55m3 was used as a worst case. This is small for an industrial process; manufacturing rooms are expected to be larger than clean rooms.

Different refinement options have been presented. For cleanrooms with a ventilation rate > 60, no RPE is required. For cleanrooms with a ventilation rate < 60, RPE is required.

Tier 1 assessment

It is assumed that no protective equipment is worn. It is also assumed that clean rooms will be exhausted at comparable rates to laboratories (8 ACH: based on data from Klima Partner 2007 and The Engineering Tool Box 2005).

Tier 2 assessment

Exposure estimates have been refined considering a ventilation rates of 20 ACH as proposed in Recommendation 15 of the BPC Ad hoc Working Group on Human Exposure[10].

Tier 3 assessment

Exposure estimates have been refined considering a ventilation rates of 60 ACH which is representative of the ventilation rate required in an ISO Class 6 certified clean room facility.

Tier 4 assessment

10 ECHA (2019) Recommendation 15 of the BPC Ad hoc Working Group on Human Exposure: Harmonisation of PT2 small surface disinfection exposure scenarios.

The assessment considers the use of RPE (APF 20) in a clean room facility with a ventilation rate of 8 ACH.

Table 2.2.6.2-4: Primary exposure to hydrogen peroxide in a professional/industrial user disinfecting surfaces using the product 'STERI-PEROX 6% WIPE'.

Tier/PPE	Hydrogen peroxide content in product (w/w)	Hydrogen peroxide in-air concentration mg/m^3 (peak event concentration)
Tier 1 (No PPE)	6.4%	2.7
Tier 2 (No PPE)	6.4%	1.3
Tier 3 (No PPE)	6.4%	0.46
Tier 4 (RPE)	6.4%	0.14
Full calculations are contained in Annex 3.2 of this report.		

Scenario PT2-3 - Primary exposure: A industrial user applies 'STERI-PEROX 6%' to hard surfaces using a hand-held trigger sprayer and subsequently wipes the product off.

The RTU product 'STERI-PEROX 6%' may be applied using a hand-held trigger sprayer as a surface disinfectant. Exposure to an individual decanting the product into the trigger sprayer reservoir/bottle has been considered in Scenario PT2-1 above. The product 'STERI-PEROX 6%' is used in cleanroom environments for the intensive disinfection of 'clean critical' surfaces (e.g. the non-product contact surfaces on filling and packaging machinery). As stated in Scenario PT2-2, a typical user would be expected to clean an area of ≈2m^2 at the start of a production shift, or potentially when processes/equipment are halted for maintenance activities. The time taken to perform such a cleaning task (wiping phase) is considered comparable to that for an individual cleaning the same sized area using wet wipes (5 mins).

It is not envisaged that a professional/industrial user would exceed three (2m^2 cleaned per event) cleaning events over an 8-hr production shift; a greater frequency of cleaning would significantly disrupt the site production process.

For the dermal exposure route, the concentration of hydrogen peroxide in the product (6.4% w/w) has been compared to the concentration limit for classification as skin irritating (35 % w/w). No further assessment is required in respect of local dermal effects.

Inhalation exposure during the spray application phase has been assessed in accordance with HEADhoc recommendation 6[11] using Consumer Spraying & Dusting Model 2[12]. The model expresses inhalation exposure as mg of product per m^3 of respired air. Inhalation exposure during the wiping phase has been assessed using Consexpo Web[13] *"Exposure to vapour";* release mode: *"evaporation from increasing surface"* model.

The calculated in-air hydrogen peroxide concentration value (75th percentile) during the spray application phase and the peak estimated in-air concentration value during the wiping phase have been summed and compared with the relevant external inhalation exposure limit value. The primary mode of action of hydrogen peroxide is characterised by local irritation/corrosion at the site of first contact; health effects are concentration rather than time-dependent.

11 ECHA (2017) Recommendation 6 of the BPC Ad hoc working Group on Human Exposure: Methods and models to assess exposure of biocidal products in different product types (Version 3).

12 TNsG Human Exposure to Biocidal Products, 2002, p197: Consumer product spraying and dusting Model 2– Non-professional surface spraying with pre-pressurised aerosol cans, trigger sprays and dust applicator pack. Data source: HSL 20001.

13 RIVM (2018) Consumer Exposure Tool (ConsExpo Web).

Table 2.2.6.2-5: Primary exposure in a industrial worker disinfecting hard surfaces using a trigger spray

Primary application scenario: A professional/industrial worker (e.g. in an industrial/manufacturing setting; clean room) uses a trigger spray bottle to spray a hard surface or article until thoroughly wet, leaves the surface or article for the desired time and wipes dry with a sterilised cloth or wipe, as necessary.

The parameters listed below were used to calculate the peak in-air hydrogen peroxide concentration during a single disinfection event where a $2m^2$ area is cleaned using 123 g of 'STERI-PEROX 6%.

Models/assessment approach:

- **Inhalation exposure during the spray application phase:** TnSG Consumer Spraying and Dusting Model 2
- **Inhalation exposure during wiping phase:** ConsExpo Web model: ***"Exposure to vapour";*** release mode: ***"evaporation from increasing surface"*** (RIVM Cleaning Products Factsheet 5.4)

Tier	Parameters	Value
1	**Inhalation exposure spray application phase**	
	Concentration of hydrogen peroxide in 'STERI-PEROX 6%'	6.4% (w/w)
	Inhalation exposure value (75th percentile indicative value)	10.5 mg product/m^3
	Inhalation exposure wiping phase	
	Molecular weight hydrogen peroxide (g/mol)	34.01
	Molecular weight matrix (g/mol)	18
	Application temperature (◦C)	20
	Vapour pressure hydrogen peroxide (Pa)	214
	Exposure event duration (mins)	30
	Product amount (g)	123
	Weight fraction compound (hydrogen peroxide)	0.064
	Room volume (m3)	55
	Ventilation rate (air changes/hr)	8
	Release area (m2)	2

	Application duration (mins)	5
	Mass transfer coefficient (m/hr)	10
2	Ventilation rate (air changes/hr)#	20
3	Ventilation rate (air changes/hr) #	60
4	Ventilation rate (air changes/hr) #	200
5	Ventilation rate (air changes/hr) #	8
	Respiratory protective equipment (APF)	20

Different refinement options have been presented.

Tier 1 assessment

It is assumed that no protective equipment is worn. It is also assumed that clean rooms will be exhausted at comparable rates to laboratories (8 ACH: based on data from Klima Partner 2007 and The Engineering Tool Box 2005).

Tier 2 assessment

Exposure estimates have been refined considering a ventilation rates of 20 ACH as proposed in Recommendation 15 of the BPC Ad hoc Working Group on Human Exposure[14].

Tier 3 assessment

Exposure estimates have been refined considering a ventilation rates of 60 ACH which is representative of the ventilation rate required in an ISO Class 6 certified clean room facility.

Tier 4 assessment

Exposure estimates have been refined considering a ventilation rates of 200 ACH which is representative of the ventilation rate required in an ISO Class 5 certified clean room facility.

Tier 5 assessment

The assessment considers the use of RPE (APF 20) in a clean room facility with a ventilation rate of 8 ACH.

14 ECHA (2019) Recommendation 15 of the BPC Ad hoc Working Group on Human Exposure: Harmonisation of PT2 small surface disinfection exposure scenarios.

Table 2.2.6.2-6: Primary exposure to hydrogen peroxide in a professional/industrial user disinfecting surfaces using a trigger sprayer containing the product 'STERI-PEROX 6%'.		
Tier/PPE	Hydrogen peroxide content in product (w/w)	Hydrogen peroxide in-air concentration mg/m^3 (wiping and spraying phase)
Tier 1 (No PPE)	6.4%	(0.672 (10.5x6.4%) + 3.9)= 4.572
Tier 2 (No PPE)	6.4%	(0.672 + 1.7) = 2.375
Tier 3 (No PPE)	6.4%	(0.672 + 0.59) = 1.262
Tier 4 (No PPE)	6.4%	(0.675 + 0.18) = 0.855
Tier 5 (RPE)	6.4%	(0.0336 (APF20) + 0.195) = 0.2286
Full calculations are contained in Annex 3.2 of this report.		

Scenario PT 2-4 - Primary exposure: A industrial user disinfects equipment using an immersion bath containing the product 'STERI-PEROX 6%'.

The product 'STERI-PEROX 6%' may be used to disinfect equipment or components via the use of a small-scale immersion bath. Exposure to an individual decanting the product into the immersion bath has been considered in Scenario PT2-1 above.

For the dermal exposure route, the concentration of hydrogen peroxide in the product (6.4% w/w) has been compared to the concentration limit for classification as skin irritating (35 % w/w). In accordance with ECHA guidance (2017, pg.11)[15] TNsG Dipping Model 4[16] has been used to assess inhalation exposure to a professional/industrial worker using an immersion bath to perform the small-scale disinfection of equipment/objects. In addition, ConsExpo Web Evaporation Model (constant rate) has been used to assess inhalation exposure to vapour.

15 ECHA (2017) Recommendation 6 of the BPC Ad hoc working Group on Human Exposure: Methods and models to assess exposure of biocidal products in different product types (Version 3).

16 TNsG Human Exposure to Biocidal Products, 2002, p170: Dipping Model 4– Aquaculture – net dipping, dispensing to pit from IBC, stirring and crane-assisted dipping, solvent-based and water-based products. Data source: HSE survey 1999.

Table 2.2.6.2-7: Primary exposure in a industrial user disinfecting equipment using an immersion bath containing the RTU product 'STERI-PEROX 6%'.

An adult disinfects equipment using the product 'STERI_PEROX 6%' contained in an immersion bath. ECHA guidance[17] (2015, p.107) informs that disinfection will occur for a duration of 30 minutes per day. Potential exposures are via the dermal and inhalation routes.

Tier	Parameters	Value
1	TNsG Dipping Model 4	
	Concentration of hydrogen peroxide in the product 'STERI-PEROX 6%'	6.4% (w/w)
	Inhalation exposure value (maximum recorded value)	0.2 mg product/m^3
	Exposure to vapour (ConsExpo Web Evaporation Model)	
	Product amount	10000 g
	Application Concentration	6.4% (w/w)
	Mol. Weight matrix	18 g/mol
	Mass transfer rate	10 m/hr
	Exposure duration	30 min
	Application duration	30 min
	Vapour pressure	214 Pa
	Application temperature	20 °C
	Room size	55 m^3
	Release area	1 m^2
	Ventilation rate	8 times/hr
	Evaporation	yes - release area is constant
2	Ventilation rate	20 times/hr
3	RPE	APF 20

*ECHA (2015) The Biocides Human Health Exposure Methodology Document. Source: European Chemicals Agency

17 ECHA (2015) The Biocides Human Health Exposure Methodology Document. Source: European Chemicals Agency.

Tier 1 assessment

It is assumed that no protective equipment is worn. It is also assumed that clean rooms will be exhausted at comparable rates to laboratories (8 ACH: based on data from Klima Partner 2007 and The Engineering Toolbox 2005).

Tier 2 assessment

Exposure estimates have been refined considering a ventilation rates of 20 ACH as proposed in Recommendation 15 of the BPC Ad hoc Working Group on Human Exposure[10].

Tier 3 assessment

The assessment considers the use of RPE (APF 20) in a clean room facility with a ventilation rate of 8 ACH.

The results of the assessment are shown in the table below.

Table 2.2.6.2-8: Primary exposure to hydrogen peroxide in a industrial user using an immersion bath containing the RTU product 'STERI-PEROX 6%'.

Tier/PPE	Hydrogen peroxide content in product (w/w)	Hydrogen peroxide in-air concentration (mg/m^3)
Tier 1 (No PPE)	6.4%	2.2
Tier 2 (No PPE)	6.4%	0.94
Tier 3 (RPE)	6.4%	0.11
Full calculations are contained in Annex 3.2 of this report.		

Scenario PT 2-5 - Secondary exposure: A bystander (workers) is present during the trigger spray application of the RTU product 'STERI-PEROX 6%' and/or contacts wet treated surfaces.

A secondary exposure scenario describes the exposure of individuals to a substance through being present during an application task or being present in places where a substance had been used. Secondary exposure to the product 'STERI-PEROX 6%' may occur where an individual is present in a room either during or following the application of the product.

Individuals would typically be excluded from treated areas during the disinfection process, with access permitted only when surfaces have dried, and the cleaning regime is complete.

Clean rooms do not allow bystanders to enter as this would increase the risk of accidental contamination. In the unlikely event that bystanders are present during disinfection

activities, they would not be exposed to in-air concentrations greater than those experienced by the worker performing the cleaning task. The calculation of professional exposure (Scenario 2-3) is considered 'worst case' and forms the risk envelope for the assessment of professional bystanders (workers) during disinfection activities. As clean rooms are strictly controlled environments, professional bystanders (workers) required to enter the area during disinfection would wear the same PPE as an operator completing these activities.

Summary table: Estimated exposure from professional/industrial uses (PT2)

Table 2.2.6.2-9: Estimated exposure to hydrogen peroxide resulting from the industrial PT2 use of the STERI-PEROX' BPF.				
Exposure scenario	**Tier/PPE**	**Hydrogen peroxide content in product**	**Inhalation AEC (long term)**	**Hydrogen peroxide in-air concentration**
Primary exposure scenario [PT2-1] **Professional/Industrial worker decanting biocidal product from large containers to a bottle or basin**	Tier 1 No PPE	6.4% (w/w)	1.25 mg/m^3	0.64 mg/m^3
Primary exposure scenario [PT2-2] **Professional/Industrial worker disinfecting hard surfaces using pre-impregnated wiping tissues**	Tier 1 No PPE	6.4% (w/w)	1.25 mg/m^3	2.7 mg/m^3
	Tier 2 No PPE	6.4% (w/w)	1.25 mg/m^3	1.3 mg/m^3
	Tier 3 No PPE	6.4% (w/w)	1.25 mg/m^3	0.46 mg/m^3
	Tier 4 RPE	6.4% (w/w)	1.25 mg/m^3	0.14 mg/m^3
Primary exposure scenario [PT2-3] **Professional/Industrial worker disinfecting hard surfaces using a trigger spray bottle, including leaving on to soak and wiping**	Tier 1 No PPE	6.4% (w/w)	1.25 mg/m^3	4.5726 mg/m^3
	Tier 2 No PPE	6.4% (w/w)	1.25mg/m^3	2.375 mg/m^3
	Tier 3 No PPE	6.4% (w/w)	1.25mg/m^3	1.262 mg/m^3
	Tier 4 No PPE	6.4% (w/w)	1.25mg/m^3	0.855 mg/m^3
	Tier 5 RPE	6.4% (w/w)	1.25mg/m^3	0.22864 mg/m^3
Primary exposure scenario [PT2-4] **Professional/Industrial worker disinfecting articles by immersing in a basin**	Tier 1 No PPE	6.4% (w/w)	1.25 mg/m^3	2.2 mg/m^3
	Tier 2 No PPE	6.4% (w/w)	1.25 mg/m^3	0.94 mg/m^3
	Tier 3 RPE	6.4% (w/w)	1.25 mg/m^3	0.11 mg/m^3

Combined scenarios

The human health risk assessment for hydrogen peroxide considers local effects only. Combined exposure is not considered relevant based on the absence of systemic effects following exposure to hydrogen peroxide. The primary mode of action is characterised by local irritation/corrosion at the site of first contact; health effects are concentration rather than time-dependent.

The highest individual exposure level (concentration as % hydrogen peroxide or mg hydrogen peroxide/m^3) per exposure event has been used for risk characterisation; the addition of exposure levels and the calculation of a combined exposure during the different tasks is consider not relevant.

Non-professional exposure

Biocidal products in the STERI- PEROX product family are intended to be used by professional/industrial workers only in industrial/manufacturing settings (e.g. clean rooms) only. There are no non-professional (consumer) uses of these products.

Exposure of the general public

Biocidal products in the STERI- PEROX product family are intended to be used by professional/industrial workers only in industrial/manufacturing settings (e.g. clean rooms) only. These are strictly controlled environments and members of the general public will be excluded from entering these premises. Consideration of exposures in members of the general public is not therefore relevant to the use of these products.

Monitoring data

No surveys or study data using biocidal products in the STERI- PEROX product family are available.

Dietary exposure

Biocidal products in the STERI- PEROX product family are not used in areas relevant to the processing or manufacturing of food and do not have any applications relevant to farm animals or livestock. The consideration of dietary residues and dietary exposure is not therefore relevant to this product family.

Information of non-biocidal use of the active substance

- Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s) [2]**
1.	Plant protection product	Hydrogen peroxide (basic substance – approved on 29/03/2017)	No MRLs required (Reg 396/2005)
2.	Veterinary use	Hydrogen peroxide: all food producing species	No MRL required (Reg 37/2010)
3.	Processing aid – National regulation in France	Hydrogen peroxide – directly used on food or in rinsing water for food[3]	Maximum concentration of H_2O_2 in washing solution for salads: 2mM (68 ppm), Remaining level: Technically unavoidable content

[1] e.g. plant protection products. veterinary use. food or feed additives

[2] e.g. MRLs. Use footnotes for references.

[3] Arrêté du 19 octobre 2006 relatif à l'emploi d'auxiliaires technologiques dans la fabrication de certaines denrées alimentaires

[4] EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2014. Scientific Opinion on the evaluation of the safety and efficacy of peroxyacetic acid solutions for reduction of pathogens on poultry carcasses and meat. EFSA Journal 2014;12(3):3599, 60 pp. doi:10.2903/j.efsa.2014.3599

[5] Council Directive 2011/84/EU of 20 September 2011 amending Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress – Official Journal of The European Union - L 283/36

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

Potential exposures during the manufacture of the active substance, hydrogen peroxide, and its formulation into the biocidal products in the STERI- PEROX product family are considered under The Chemical Agents at Work Directive (98/24/EC, within 89/391/EEC) and are minimised by the use of automated processes and engineering controls integral to the processes and further reduced by the requirements to wear suitable protective equipment (including gloves, protective clothing and eye protection[18]) whenever exposure to the active substance or other ingredients is likely. These regulations competently control for operator exposure to the biocidal products in the STERI- PEROX product family during production, formulation and disposal.

Risk characterisation for human health

This section addresses the risk characterisation for human health associated with the uses of the products containing hydrogen peroxide as the active substance. The products contain hydrogen peroxide at 6.4% w/w.

Reference values to be used in Risk Characterisation

[18] The Personal Protective Equipment as Work Regulations 1992 (EU Directive 89/656/EEC)

Reference	Study	NOAEC (LOAEC)	AF[1]	Correction for oral absorption	Value
AEC inhalation acute/medium-term/long-term	90-day inhalation rat study	7 ppm (10 mg/ m^3)	8	-	1.25. mg/m^3

An Acceptable Exposure Concentration (AEC) for hydrogen peroxide has been derived in the CAR (2015) and has been used in the risk assessment.

An AEC (acute/medium/long-term) value for inhalation exposure of 1.25 mg/ m^3 was proposed in the CAR based on the NOAEC of 7 ppm (10 mg/ m^3) derived in rats following nose-only exposures and the application of an assessment factor of 8.

The concentration of hydrogen peroxide in the product (6.4% w/w) has been compared to the concentration limit for classification as skin irritating (35 % w/w).

Maximum residue limits or equivalent

Biocidal products in the STERI- PEROX family are not used in areas relevant to the processing or manufacturing of food and do not have any applications relevant to farm animals or livestock. The uses of the products therefore will not result in any residues arising in food consumed by the general population and there is no potential for dietary exposure. Information on residues is therefore not relevant.

Risk for industrial users

Estimated exposure to hydrogen peroxide resulting from the professional/industrial PT2 use of the STERI-PEROX' BPF.					
Exposure scenario	**Tier/PPE**	**Inhalation AEC (long term)**	**Hydrogen peroxide in-air concentration**	**% AEC**	**Acceptable**
Primary exposure scenario [PT2-1] **Professional/Industrial worker decanting biocidal product from large containers to a bottle or basin**	Tier 1 No PPE	1.25 mg/m^3	0.64 mg/m^3	51%	Yes
Primary exposure scenario [PT2-2] **Professional/Industrial worker disinfecting hard surfaces using wiping tissues**	Tier 1 No PPE	1.25 mg/m^3	2.7 mg/m^3	216%	No
	Tier 2 No PPE	1.25 mg/m^3	1.3 mg/m^3	104%	No
	Tier 3 No PPE	1.25 mg/m^3	0.46 mg/m^3	37%	Yes
	Tier 4 RPE	1.25 mg/m^3	0.14 mg/m^3	11%	Yes
Primary exposure scenario [PT2-3] **Professional/Industrial worker disinfecting hard surfaces using a trigger spray bottle, including leaving on to soak and wiping**	Tier 1 No PPE	1.25 mg/m^3	4.572 mg/m^3	366%	No
	Tier 2 No PPE	1.25mg/m^3	2.375 mg/m^3	190%	No
	Tier 3 No PPE	1.25mg/m^3	1.262 mg/m^3	101%	No
	Tier 4 No PPE	1.25mg/m^3	0.855 mg/m^3	68.4%	Yes
	Tier 4 RPE	1.25mg/m^3	0.2286 mg/m^3	18.2%	Yes
Primary exposure scenario [PT2-4] **Professional/Industrial worker disinfecting articles by immersing in a basin**	Tier 1 No PPE	1.25 mg/m^3	2.2 mg/m^3	177%	No
	Tier 2 No PPE	1.25 mg/m^3	0.94 mg/m^3	75%	Yes
	Tier 3 RPE	1.25 mg/m^3	0.11 mg/m^3	9%	Yes

Conclusion

The results of the quantitative risk assessments for local effects predict acceptable levels of inhalation to hydrogen peroxide for a professional/industrial user decanting the product into a receiving vessel (Scenario PT 2-1). No risk mitigation measures or use of respiratory protective equipment (RPE) is required when using the product 'STERI-PEROX 6%' as described in Scenarios PT 2-1.

In considering Scenario PT2-2 (surface disinfection using 'STERI-PEROX 6% WIPE') inhalation exposure to hydrogen peroxide exceeds the AEC when disinfection activities are undertaken in facilities with a ventilation rate <60 ACH . The use of respiratory protective equipment (RPE) is required when using the product 'STERI-PEROX 6% WIPE' in areas with a ventilation rate <60 ACH. Where ventilation rates are ≥60 ACH RPE is not required.

In considering Scenario PT2-3 (surface disinfection using a trigger sprayer containing 'STERI-PEROX 6%') inhalation exposure to hydrogen peroxide exceeds the AEC when disinfection activities are undertaken in facilities with a ventilation rate <200 ACH. The use of respiratory protective equipment (RPE) is required when using the product 'STERI-PEROX 6% WIPE' in areas with a ventilation rate <200 ACH. Where ventilation rates are ≥200 ACH RPE is not required.

In considering PT2-4 (professional/industrial worker disinfecting articles by immersing in basin containing 'STERI-PEROX 6%') inhalation exposure to hydrogen peroxide exceeds the AEC when disinfection activities are undertaken in facilities with a ventilation rate < 20 ACH. The use of respiratory protective equipment (RPE) is required when using the product 'STERI-PEROX 6%' in areas with a ventilation rate <20 ACH. Where ventilation rates are ≥20 ACH RPE is not required.

It is noted that several parameters (e.g. room size, treated area, ventilation rate etc) considered in the Consexpo Web exposure model may influence the predicted peak in-air hydrogen peroxide concentration values. The following risk mitigation measures are therefore proposed:

General risk mitigation measures:

- During application only the user of the product can be present in the room.
- During application and for re-entry, the airborne hydrogen peroxide levels may not exceed the AEC inhalation limit of 1.25 mg/m3 (or a lower relevant national reference value). A calibrated sensor shall be used to establish that the airborne hydrogen peroxide levels are not exceeded.

The concentration of hydrogen peroxide in the product family (6.4% w/w) is below the concentration limit for classification as skin irritating (35 % w/w). No risk mitigation measures or PPE are required having regard to exposure via the dermal route.

Combined exposure

Combined exposure is not considered relevant based on the absence of systemic effects following exposure to hydrogen peroxide. The primary mode of action is characterised by

local irritation/corrosion at the site of first contact; health effects are concentration rather than time-dependent.

The highest individual exposure level (concentration as % hydrogen peroxide or mg hydrogen peroxide/m^3) has been used for risk characterisation; the addition of exposure levels and/or the calculation of a combined exposure from multiple events is consider not relevant.

Local effects

A further qualitative assessment has also been conducted considering the classification of the RTU products within the biocide product family. Products in the STERI-PEROX product family are classified in Category 2 for eye irritation (CLP Cat. 2 H319). According to ECHA "Guidance on information requirements and chemical safety assessment, Part E: risk Characterisation" and ECHA "Guidance on the Biocidal Products Regulation, Part B: Risk Assessment" (2015), Table 24; p. 245, the products may be regarded as "low" hazard in respect to the potential effects to the eyes.

Qualitative risk assessment matrix for local effects									
Hazard		Exposure							Risk
Hazard Category	Effects in terms of C&L	PT	Who is exposed?	Uses	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk
Low	Eye Irritation Category 2, H319	- 2	Professional/Industrial worker, operator/user	Hard surface disinfection by application of the RTU product (encompassing spraying, wiping, pouring and/or use of immersion bath)	Eye	<1 hour per day.	Controlled exposure – cleaning work with high ventilation and PPE (goggles).	Technical and organisational RMM adequate for the hazard category are achievable* PPE: The wearing of chemical goggles.	**Acceptable**: No eye exposure expected as technical and organisational RMM adequate for the high hazard category are achievable

* RMM detailed below

The product family is applied by trained professional/industrial users (only) in controlled cleanroom settings; the following RMM and PPE requirements would be followed when handling/using the 'STERI-PEROX' products:

RMMs (Technics and Organisational)

- Trained workers (good practice/minimisation of exposure to biocidal product)
- Intensive supervision of workers to ensure proper use of RMMs and organisational controls.
- Proper instructions provided for use of biocidal product.
- Good standards of personal hygiene.
- Avoidance of contact with contaminated objects

PPE

- The wearing of chemical goggles.

Suitable operational conditions and risk management measures should be applied to protect workers. Direct contact with the eyes is not expected during normal use and users would be expected to follow the manufacturer's instructions for safe handling to avoid eye contact. In cases of accidental eye contact, appropriate safety instructions should be followed. Good occupational hygiene practise should be followed to ensure exposure to the eyes during normal use is prevented. For tasks were large quantities are handled or where splashing is likely, appropriate eye protection should be worn.

It is not envisaged the use of the pre-impregnated product 'STERI-PEROX 6% WIPES' would result in exposure to the eyes of the user due to splashes or the generation of aerosols. The use of eye protection PPE is not required whilst using this wet-wipe product. As a pre-cautionary measure "Avoid contact with eyes" will be included as a RMM.

Conclusion

Based on the predicted exposure and risk characterisation for health effects, the use of Biocidal products in the STERI-PEROX family product family by professional/industrial workers in industrial settings (e.g. clean-rooms) are not considered to pose an unacceptable risk to human health. Similarly, exposures to adult bystanders are not considered to pose an unacceptable risk to human health.

Considering the quantitative exposure assessments and the classification of the RTU 'STERI-PEROX' product family the following risk mitigation measures are proposed:

General risk mitigation measures:

- During application only the user of the product can be present in the room.
- During application and for re-entry, the airborne hydrogen peroxide levels may not exceed the AEC inhalation limit of 1.25 mg/m3 (or a lower relevant national reference value). A calibrated sensor shall be used to establish that the airborne hydrogen peroxide levels are not exceeded.

Risk for non-professional users

Biocidal products in the STERI-PEROX product family are intended to be used by professional/industrial workers only in industrial/manufacturing settings (e.g. clean rooms) only. There are no non-professional (consumer) uses of these substances.

Risk for the general public

Biocidal products in the STERI-PEROX product family are intended to be used by professional/industrial workers only in industrial/manufacturing settings (e.g. clean rooms). These are strictly controlled environments and members of the general public will be excluded from entering these premises. Consideration of exposures in members of the general public is not therefore relevant to the use of these products.

Risk for consumers via residues in food

Biocidal products in the STERI-PEROX family are not used in areas relevant to the processing or manufacturing of food and do not have any applications relevant to farm animals or livestock. The consideration of dietary residues or a consumer dietary risk assessment is not therefore relevant to this product family.

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

Biocidal products in the STERI-PEROX family contain only one active substance: hydrogen peroxide. The consideration of combined exposures to several active substances or substances of concern is not relevant to products in this product family.

2.2.6.3 Risk assessment for animal health

Biocidal products in the STERI-PEROX family are not used in areas relevant to the processing or manufacturing of food and do not have any applications relevant to farm animals or livestock. The consideration of a risk assessment for animal health is not therefore relevant to this product family.

2.2.7 Risk assessment for the environment

The STERI-PEROX product family consists of different formulation types: wipes, trigger sprays and liquids (delivered via a bottle or dispenser) containing nominal 6.4% w/w hydrogen peroxide. All products have identical areas of use in PT 2 (general disinfection of hard surfaces, industrial and institutional areas). Liquid product may also be applied by immersing an item in a basin of STERI-PEROX (i.e. soaking), allowing to remain wet for a

minimum of 5, 10 or 60 minutes (depending on the desired use), followed by allowing the surface of the item to be air dried or (after the desired contact time) wiped dry with sterilised cloth or wipe. In all cases (soaking, spray application and wiping or use of already impregnated wipes) the disinfectant is a leave on product and should not be rinsed immediately afterwards.

Hydrogen peroxide has been reviewed under the EU Review programme and details of the evaluation are included in the Assessment Report for PTs 1-6[19]. No new data are submitted over and above those evaluated under the EU review of this active substance.

Hydrogen peroxide was evaluated as PT 2 in the Assessment Report, although certain aspects of the use pattern may differ; therefore a new environmental risk assessment has been performed for the proposed uses.

2.2.7.1 Effects assessment on the environment

The PNECs agreed for Hydrogen peroxide under the EU review and detailed in the AR (2015) are presented in the table below. No further ecotoxicology data are submitted.

Agreed PNECs for Hydrogen peroxide

PNEC	PNEC (from AR 2015)	Justification
$PNEC_{STP}$	4.66 mg/L	Assessment factor of 100 applied to EC_{50} of 466 mg/L
$PNEC_{aquatic, freshwater}$	0.0126 mg/L	Assessment factor of 50 (as 2 long term studies available covering 2 trophic levels) applied to NOEC of 0.63 mg/L from the chronic Daphnia study.
$PNEC_{sediment, freshwater}$	0.0103 mg/kg wwt (0.0474 mg/kg dw)	Equilibrium partitioning method
$PNEC_{terrestrial}$	0.0018 mg/kg wwt (0.00208 mg/kg dw)	Equilibrium partitioning method
$PNEC_{secondary\ poisoning}$*	-	
Air	Not applicable	No hazard identified

[19] Assessment Report, Hydrogen peroxide, Product-Type 2 (Private area and public health area disinfectants and other biocidal products), March 2015

*Not determined in Assessment Report (2015). Given the extremely low estimated log k_{ow} and short half-life, there should be no risk of secondary poisoning.

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 product family does not contain any co-formulants which are classified as hazardous to the aquatic environment. Therefore, classification of the product with regard to environmental hazard is based on the data for the active substance only. No further data on the formulation are submitted.

Under the harmonised classification (Annex VI) of the 'Classification, labelling and packaging of substances and mixtures (CLP) Regulation (1272/2008)', hydrogen peroxide is 'Not Classified' as hazardous to the aquatic environment. However, in the assessment report of hydrogen peroxide (2015), it was stated that Aquatic Chronic 3 (H412) classification should be applied according to the 2 ATP to CLP Regulation (Regulation (EC) No 286/2011). For the products within this family containing 6.4% hydrogen peroxide, no environmental classification applies.

Further Ecotoxicological studies

No further ecotoxicology data are submitted, given that sufficient information is available on the active substance and the products contain no co-formulants which are likely to alter the ecotoxicological profile of the active substance, it is not considered necessary to generate further product-specific data.

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

No further effects data on specific non-target flora and fauna are submitted, given that sufficient information is available on the active substance and the products contain no co-formulants which are likely to alter the ecotoxicological profile of the active substance, it is not considered necessary to generate further product-specific data.

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

Supervised field trials to assess risk to non-target organisms are not relevant, given that sufficient information is available on the active substance and the products contain no co-formulants which are likely to alter the ecotoxicological profile of the active substance, therefore it is not considered necessary to generate further product-specific data. Moreover, environmental risk assessment based on data available within the hydrogen peroxide assessment report demonstrated no unacceptable risk to potentially exposed environmental compartments, hence higher tier studies under field conditions are unnecessary.

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

Studies on acceptance by ingestion by non-target organisms are not considered relevant. Given how products within this family are used (i.e. indoors as wipes, trigger sprays and/or liquids), there is no risk of ingestion by non-target organisms. Moreover, sufficient information is available on the active substance and the products contain no co-formulants which are likely to alter the ecotoxicological profile of the active substance, it is not considered necessary to generate further product-specific data.

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

Secondary ecological effects are not relevant. Sufficient information is available on the active substance and the products contain no co-formulants which are likely to alter the ecotoxicological profile of the active substance, therefore it is not considered necessary to generate further product-specific data. Additionally, the product family is intended for indoor application and is not intended for use in directly treating large portions of habitats. As such, this data point is not relevant for this product family.

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

All products within this product family are intended for use indoors, hence there will be no direct exposure of the environment. However, according to the ESD for PT 2 there could be exposure of the STP via waste water after wet cleaning of the treated area and subsequent indirect exposure of freshwater sediment and surface water and agricultural land due to spreading of sewage sludge. Indirect environmental exposure is expected to be low however, since almost complete degradation of hydrogen peroxide is expected in the STP. No marine or air exposure is anticipated based on the intended use these products.

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

No further data on fate and behaviour in the environment are submitted. The fate and behaviour of the active substance will not be influenced by the product co-formulants. As there is sufficient data available for the active substance it is not considered necessary to generate any further information on the fate and behaviour of the product family.

Leaching behaviour (ADS)

The biocidal product family considered here are formulated products and are not treated articles. Additionally, the products are not intended for addition to a matrix or impregnation into another material. The intended uses are for indoor disinfection of hard surfaces in industrial facilities.

As such, testing on leaching behaviour is neither relevant nor required for this product type according to the Guidance on the Biocidal Product Regulation, Volume IV, Part A.

Testing for distribution and dissipation in soil (ADS)

No further testing on distribution and dissipation has been conducted for the biocidal product family. Sufficient information is already available for distribution and dissipation of the active substance and the products contain no co-formulants which are likely to alter the fate and behaviour of the active substance, therefore it is not considered necessary to generate further information for the biocidal product family.

Testing for distribution and dissipation in water and sediment (ADS)

No further testing on distribution and dissipation has been conducted for the biocidal product family. Sufficient information available for distribution and dissipation of the active substance and the products contain no co-formulants which are likely to alter the fate and behaviour of the active substance, therefore it is not considered necessary to generate further information for the biocidal product family.

Hydrogen peroxide has a low Henry's law constant (0.00075 Pa/m^3/mol), indicating very poor volatilisation from water to air. Hydrogen peroxide is not persistent in surface water, showing an estimated surface water DT_{50} value of 5 days. Hydrogen peroxide also has a low estimated Koc value (1.598 L/kg) and therefore has low potential for partitioning to suspended matter or sediment.

Testing for distribution and dissipation in air (ADS)

No further testing on distribution and dissipation has been conducted for the biocidal product family. Sufficient information available for distribution and dissipation of the active substance and the products contain no co-formulants which are likely to alter the fate and behaviour of the active substance, therefore it is not considered necessary to generate further information for the biocidal product family.

Hydrogen peroxide has a low Henry's law constant (0.00075 Pa/m^3/mol), indicating very poor volatilisation from water to air. Hydrogen peroxide is also not persistent in air, showing an estimated air DT_{50} value of 24 hours.

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)

Overspray studies are not relevant given that these products are intended for indoor use (either as wipes, trigger sprays and/or liquids). As such, there will be no spray near surface waters under normal intended use of these products.

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)

Overspray studies to assess risks to bees and non-target arthropods are not relevant, given that these products are intended for indoor use (either as wipes, trigger sprays and/or liquids). As such, there will be no outdoor spray under normal intended use.

2.2.7.2 Exposure assessment

The STERI-PEROX product family consists of different formulation types: wipes, trigger sprays and liquids (delivered via a bottle or dispenser) containing a nominal concentration of 6.4% w/w of the active substance, hydrogen peroxide. In all cases (soaking, spray application and wiping or use of already impregnated wipes) the disinfectant is a leave on product and should not be rinsed immediately afterwards.

All products within this product family are intended for use indoors, hence there will be no direct exposure of the environment. However, there could be exposure of the STP via waste water after wet cleaning of treated areas and subsequent indirect exposure of freshwater sediment and surface water and agricultural land due to spreading of sewage sludge. No marine or air exposure is anticipated based on the intended use these products.

General information

Assessed PT	PT 2
Assessed scenarios	Use of disinfectants in industrial areas (based on consumption)
ESD(s) used	Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products, JRC 2011
Approach	Average consumption
Distribution in the environment	Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C: Assessment and Evaluation. European Chemicals Agency, Report no. ECHA-17-G-23-EN, Helsinki, Finland, 2017. SimpleTreat version 4.0 (in accordance with TAB ENV-9)
Groundwater simulation	Groundwater values based on concentrations in pore water
Confidential Annexes	NO
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	None

Emission estimation

PT 2 – disinfection of industrial areas (consumption based approach)

The STERI-PEROX product family consists of different formulation types: wipes, trigger sprays and liquids (delivered via a bottle or dispenser) containing nominal 6.4% w/w hydrogen peroxide, with identical areas of use in PT 2. The products are intended for use in disinfection of industrial areas and may be applied up to three times per day. Liquid

product may also be applied by soaking items, followed by air drying or wiping the soaked item dry with sterilised cloth or wipe.

The local release rate for wastewater was based on the liquid product type acting as a representative worst case, given that these products show the highest application rate of the different formulation types. Although repeated applications may be made using the wipe products, the total amount of active substance applied by the wipes will not exceed that applied by the liquid. Note that the scenario applied to assess emission from soaking is not realistic for the uses intended by the applicant and could be considered as worst-case, the scenario was still applied as no agreed alternatives are currently available.

According to the CAR, hydrogen peroxide has a DT50 of 2.98 minutes in activated sludge at 15 °C (2 minutes at 20 °C). Hydrogen peroxide will also abiotically degrade in raw sewage and manure with a half-life of 11.4 minutes in the sewer at 12 °C. This half-life will result in a degradation of 97.3% of the hydrogen peroxide in the sewer system, when assuming a 1 hour residence in the sewer before entering the STP. Therefore, next to the local emission based on the ESD, also the actual amount of hydrogen peroxide reaching the STP (after degradation) will be given. These values are used for the further exposure and risk assessment. Please note that the half-life in the sewer is not mentioned in the publicly available AR, but only in the final CAR.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks S/D/O/R***
Scenario: disinfection of industrial areas by spraying or wiping			
Application rate of biocidal product	0.06	[L/m^2]	S (worst case recommended application rate based on liquids)
Concentration of active substance in the product	64	[g/L]	S (based on 6% active substance on a w/w basis)
Surface area to be disinfected	1000	[m^2]	D (worst-case application area)
Number of applications per day	3	[d]	S
Fraction released to wastewater	1	[-]	D
*Set, Default, Output, Refined			

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
sewer	11.52	Resulting fraction that reaches the primary sedimentation tank of the STP is 0.30 kg/d.-
Air	0	-

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks S/D/O/R***
Scenario: disinfection of industrial areas by soaking			
Volume of dipping bath	10	[L]	D (according to ENV 45 of the TAB)
Concentration of active substance in the product	64	[g/L]	S (based on 6% active substance on a w/w basis)
Maximum number of dipping bath per day	30	[d]	D (according to ENV 45 of the TAB)
Fraction released to wastewater	1	[-]	D
*Set, Default, Output, Refined			

Calculations

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
sewer	19.2	Resulting fraction that reaches the primary sedimentation tank of the STP is 0.50 kg/d.-
Air	0	-

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Disinfection of industrial areas by spraying or wiping	[Yes]	[Yes]	No	No	Yes	No	[Yes]	[Yes]	-
Disinfection of industrial areas by soaking	[Yes]	[Yes]	No	No	Yes	No	[Yes]	[Yes]	-

[] indicates indirect exposure

Input parameters (only set values) for calculating the fate and distribution in the environment			
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 25°C)	100,000	mg/L	Hydrogen peroxide is miscible in water, hence highest recommended value used in the risk assessment as worst case
Log Octanol/water partition coefficient	-1.57	Log 10	Estimated value
Organic carbon/water partition coefficient (Koc)	1.598	L/kg	Estimated value
Henry's Law Constant (at 20°C)	0.00075	$Pa/m^3/mol$	
Biodegradability	Yes		'Ready biodegradability' is not applicable for inorganic compounds, however hydrogen peroxide has shown a DT_{50} of 2 min in sewage sludge (at 20°C), so will not

			persist in the environment
DT_{50} for STP (at 15ºC)	2.98	min	Value from Assessment Report
DT_{50} for degradation in sewer	7.92E-03	d	Measured half-life in sewer system: 11.4 minutes at 12°C. Value from CAR II-A (PT 1-6, July 2013, Table 4.1.1-2) (PT 11 & 12, Oct 2017, Table 4.1.1-2)
DT_{50} for biodegradation in surface water (at 12ºC)	5	d	Value from Assessment Report
DT_{50} for hydrolysis in surface water (at 12ºC)	Stable	d	Value from Assessment Report
DT_{50} for photolysis in surface water	Stable	d	Value from Assessment Report
DT_{50} for degradation in soil (at 12ºC)	12	hr	Value from Assessment Report
DT_{50} for degradation in air	24	hr	Value from Assessment Report
Bioaccumulation	BCF fish: 1.4 BCF earthworm: 0.84	L/kg ww	Estimated values

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
	All scenarios	
Air	0.0002	Calculated with SimpleTtreat version 4.0 using 3.1 settings for Css according to ENV 9 of the TAB
Water	0.6637	
Sludge	0.0145	
Degraded in STP	99.32	

Calculated PEC values

The Predicted Environmental Concentrations (PECs) were calculated according to SimpleTreat 4.0 and the guidance by using the default values and the active substance properties as presented previously. The PECs are summarised below.

Summary table on calculated PEC values

	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]	[mg/m^3]
Disinfection of industrial areas by spraying or wiping	9.95E-04	9.95E-05	7.81E-05	7.87E-05	2.63E-03	6.41E-09
Disinfection of industrial areas by soaking	1.66E-03	1.66E-04	1.30E-04	1.31E-04	4.39E-03	1.07E-08

Marine PEC/PNEC values were not calculated since exposure is not anticipated.

Primary and secondary poisoning

Primary poisoning

The proposed indoor use of the product preclude any exposure via primary poisoning.

Secondary poisoning

Based on the physicochemical properties of hydrogen peroxide, an estimation of the bioconcentration factors (BCFs) can be calculated according to the guidance (2017). The estimated log K_{ow} value of hydrogen peroxide is -1.57, which resulted in a calculated BCF_{Fish} of 1.4 L/kg ww and a $BCF_{Earthworm}$ of 0.84 L/kg ww. Based on these low log K_{ow} and BCF values, aquatic and terrestrial bioaccumulation potential in the food chain is not expected, and the risk of secondary poisoning in aquatic and terrestrial predators is considered negligible.

2.2.7.3 Risk characterisation

Atmosphere

Conclusion: No hazard for air has been identified and as such no risk to air is predicted and PEC/PNEC ratios have not been derived.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Disinfection of industrial areas by spraying or wiping	< 0.001
Disinfection of industrial areas by soaking	< 0.001

Conclusion: From the assessment presented above, the use of hydrogen peroxide in PT 2 does not pose an unacceptable risk to the local STP.

Aquatic compartment

Summary table on calculated PEC/PNEC values		
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
Disinfection of industrial areas by spraying or wiping	0.008	0.008
Disinfection of industrial areas by soaking	0.013	0.013

Conclusion: From the assessment presented above, the use of hydrogen peroxide in PT 2 does not pose an unacceptable risk to surface water and sediment. Marine PEC/PNEC values were not calculated since exposure is not anticipated.

Terrestrial compartment

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
Disinfection of industrial areas by spraying or wiping	0.044
Disinfection of industrial areas by soaking	0.073

Conclusion: From the assessment presented above, the use of hydrogen peroxide in PT 2 does not pose an unacceptable risk to the terrestrial environment.

Groundwater

Calculated PECs in groundwater are below the cut off value of 0.1 µg/L (according to the Drinking Water Directive and the Groundwater Directive). No unacceptable risk of hydrogen peroxide to groundwater is therefore expected.

Primary and secondary poisoning

Primary poisoning

The proposed uses of the product preclude any exposure via primary poisoning. The products are only intended for indoor use and are not applied in granule form.

Secondary poisoning

Based on the low estimated BCF values in aquatic and terrestrial indicator species, hydrogen peroxide is not expected to accumulate in the environment. The risk of

secondary poisoning via ingestion of contaminated food by birds or mammals is therefore negligible.

Conclusion: No unacceptable risk of primary or secondary poisoning is expected of hydrogen peroxide in aquatic or terrestrial environments.

Mixture toxicity

The products are a formulation of only the active substance in water. A mixture assessment is therefore not necessary.

Aggregated exposure (combined for relevant emission sources)

An aggregated exposure is performed for hydrogen peroxide by summing the releases for the described scenarios in PT2.

Summary table on calculated ΣPEC/PNEC values				
ΣPEC/PNEC$_{STP}$	**ΣPEC/PNEC$_{water}$**	**ΣPEC/PNEC$_{sed}$**	**ΣPEC/PNEC$_{soil}$**	**ΣPEC/PNEC$_{groundwater}$**
0.002	0.021	0.021	0.117	0.007

Conclusion: The combined use of the products in this BPF does not result in a risk to the environment.

Overall conclusion on the risk assessment for the environment of the product
The STERI-PEROX product family comprises of PT 2 disinfectants containing the active substance hydrogen peroxide and are intended for indoor use only. Product use in disinfection of industrial areas was assessed based on the liquid product as a representative worst-case. Following product use, it is assumed that exposure of the STP via wastewater will occur due to wet cleaning of treated areas or emptying of soaking baths, followed by indirect exposure of the environment. No marine or air exposure is anticipated based on intended product use. Acceptable risk was demonstrated for all relevant environmental compartments following product use under worst-case assumptions. It is therefore concluded that use of the STERI-PEROX product family as a PT 2 disinfectant is acceptable.

2.2.8 Measures to protect man, animals and the environment

Precautions for safe handling

Avoid contact with skin, eyes and clothing. Wear protective gloves/protective clothing/eye protection/face protection. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

Risk mitigation measures

General risk mitigation measures:

- During application only the user of the product can be present in the room.
- During application and for re-entry, the airborne hydrogen peroxide levels may not exceed the AEC inhalation limit of 1.25 mg/m3 (or a lower relevant national reference value). A calibrated sensor shall be used to establish that the airborne hydrogen peroxide levels are not exceeded.

First aid instructions

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.
IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.
IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

Emergency measures to protect environment in case of accident

Prevent entry to sewers and public water. Notify authorities if product enters sewers or public waters. Avoid release to the environment.

Instructions for safe disposal of the biocidal product and its packaging

Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations. Avoid release to the environment.
Dispose of contents/container to an authorised waste collection point.

2.2.9 Assessment of a combination of biocidal products

Not relevant. The products are not intended to be used in combination with other products.

2.2.10 Comparative assessment

Not relevant. Hydrogen peroxide is not a candidate for substitution. As a result, a comparative assessment is not required.

3 ANNEXES

3.1 List of studies for the biocidal product family

BPR reference No	IUCLID Section No. / Reference No.	Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Section 3						
IIIB 3.1.1 IIIB 3.1.2 IIIB 3.1.3 IIIB 3.2 IIIB 3.3	3.1/01 3.2/01 3.3/01	Sanow, W.	2015a	Product Chemistry Testing Report No.: A19641 GLP, unpublished	Yes	Veltek Associates Inc.
IIIB 3.2	3.3/02	Pitt, A.	2018a	Determination of Acidity or Alkalinity of a Chemical Report No.: A25249 GLP, unpublished	Yes	Veltek Associates Inc
IIIB 3.2	3.3/03	Zehr, P.	2019	STERI-PEROX 6 % WIPES: Storage Stability and Corrosion Characteristics – Time 0 Interim Report Report No.: 49854 GLP, unpublished	Yes	Veltek Associates Inc.
IIIB 3.4.1.2 IIIB 3.4.2	3.4.1.2/01 3.4.2.3/01	Pitt, A.	2018b	Long Term Storage Stability of Test Substances Report No.: A19642 GLP, unpublished	Yes	Veltek Associates Inc.
IIIB 3.4.1.2	3.4.1.2/03	Singh, G.	2017	Sprayer Performance with Steri-Perox 6% Report No.: 07122016GS Non-GLP, unpublished	No	Veltek Associates Inc.
IIIB 3.4.1.1	3.4.1.1	Sampura, S.	2018	Evaluation of STERI-PEROX 6 % Wipe Stability in Accelerated Condition Report No.: SS30042018 Non-GLP, unpublished	Yes	Veltek Associates Inc.

BPR reference No	IUCLID Section No. / Reference No.	Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIB 3.4.1.1	3.4.1.1	Jamie Balarashti et al.	2020a	Accelerated Aging Two Week at 54°C: Following CIPAC MT 187 and ISO 13320:2009 guidelines for - Particle size analysis by laser diffraction- STERI-PEROX 6% 16oz Aerosol Research and Engineering Laboratories, Inc. 10875.90.B GLP Unpublished	Yes	Veltek Associates Inc.
IIIB 3.4.2.2	3.4.2.2/01	Singh, G.	2018	Determination of Liquid Content Dispensed onto a Surface by a Pre-Saturated Wiper Product Report No.: VP-8046 Non-GLP, unpublished	No	Veltek Associates Inc.
IIIB 3.4.2.2	3.4.2.2/02	Singh, G.	2019	Steri-Perox 6% Wipe Evaporation and Seal Test Report No.: VP-8047 Non-GLP, unpublished	No	Veltek Associates Inc.
IIIB 3.8	3.8/01	Baldwin, J.	2017	Surface Tension Analysis of STERI-PEROX 6% Report No.: 118550v1_Surface tension Non-GLP, unpublished	Yes	Veltek Associates Inc.
III 3.5.6	3.5	Jamie Balarashti et al.	2020b	Spray Characterization: Following CIPAC MT 187 and ISO 13320:2009 guidelines for - Particle size analysis by laser diffraction – 16 oz STERI-PEROX 6 % Aerosol Research and Engineering Laboratories, Inc. 10875.9 GLP Unpublished	Yes	Veltek Associates, Inc.
IIIB 3.9	3.9/01	Voth, S.	2017	Viscosity Determination of STERI-PEROX 6% Report No.: 118550v1_Viscosity Non-GLP, unpublished	Yes	Veltek Associates Inc.
Section 4						

BPR reference No	IUCLID Section No. / Reference No.	Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIB 4.6 IIIB 4.17.1	4.6 4.17.1	Frawley, T.J.	2020	Flash Point and Autoignition Temperature of Steri-Perox 6% Flammability Testing and Consulting Services Report No.: FLM-1096 Non-GLP, unpublished	Yes	Veltek Associates Inc.
IIIB 4.8 IIIB 4.11 IIIB 4.16	4.8/01 4.11/01 4.16/01	Albaya, J.	2016	Expert Statement on the EU Classification, Labelling and Packaging (CLP) Characteristics of STERI-PEROX 6 % (Hydrogen Peroxide 6 % in Water Solution): Self-Reacting, Self-Heating and Corrosive to Metals Report No.:TSGE_22-003-06_CLP Non-GLP, unpublished	Yes	Veltek Associates Inc.
IIIB 4.8	tba	Ziembla, E	2023	Differential Scanning Calorimetry for Steri-Perox 6% Report No.: FAI-2023-0434 Non-GLP, unpublished		Veltek Associates Inc.
	4.16/02	Erning, W.	2022	Evaluation of the Corrosive Effect of a Hydrogen- Peroxide-Based Product,Regarding its Classification as Dangerous Good of Class 8 “Corrosive Substances” According to Regulations for Transportation on Road (ADR, GGVS), by Ship (IMDG-Code) and in Air (IATA-Reg.) as well as its “corrosive”-Classification According GHS/CLP, BAM reference: 22042493	No	Veltek Associates Inc.
Section 5						

BPR reference No	IUCLID Section No. / Reference No.	Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIB 5.1	5.1/01	Sanow, W.	2015b	Enforcement Analytical Titration Validation for Chemical Characterization Report No.: A19635 GLP, unpublished	Yes	Veltek Associates Inc.
IIIB 5.1	5.1/02	Zehr, P.	2019	STERI-PEROX 6 % WIPES: Storage Stability and Corrosion Characteristics – Time 0 Interim Report Report No.: 49854 GLP, unpublished	Yes	Veltek Associates Inc.
Section 6						
IIIB 6.7	6.7-01	Brambilla, L.	2013	Suspension Bactericidal Effectiveness on STERI-PEROX 6% Report no.: S-2013-00669 Ami GLP, unpublished	Yes	Veltek Associates Inc.
IIIB 6.7	6.7-02	Brambilla, L.	2014	Surface Bactericidal Effectiveness on STERI-PEROX 6% Report no.: S-2014-01377 AMi GLP, unpublished	Yes	Veltek Associates Inc.
IIIB 6.7	6.7-03	Brambilla, L.	2013	Suspension Fungicidal Effectiveness Simulating Clean Conditions on STERI-PEROX 6% Report no.: S-2013-01462 AMi GLP, unpublished	Yes	Veltek Associates Inc.

BPR reference No	IUCLID Section No. / Reference No.	Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIB 6.7	6.7-04	Brambilla, L.	2013	Suspension Sporicidal Effectiveness on STERI-PEROX 6% Report no.: S-2013-01997 AM GLP, unpublished	Yes	Veltek Associates Inc.
IIIB 6.7	6.7-06	Brambilla, L.	2014	Surface Bactericidal Effectiveness on STERI-PEROX 6%- fungi. Report no.: S-2014-1360 GLP, unpublished	Yes	Veltek Associates Inc.
IIIB 6.7	6.7-07	Woodall, C	2017	Test Report: EN 16615 2015 Chemical disinfectants and antiseptics. Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4- field test).	Yes	Veltek Associates Inc.
IIIB 6.7	6.7-08	Place holder				
IIIB 6.7	6.7-09	Place holder				

BPR reference No	IUCLID Section No. / Reference No.	Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIB 6.7	6.7-10	Place holder				

3.2 Output tables from exposure assessment tools

Human health risk assessment

Predicted exposures for scenario: Primary application – Disinfecting articles/items by trigger spray application (spraying phase) : PT2-3

Inhalation Exposure (Consumer Spraying and Dusting Model 2)	
75th percentile recorded indicative value [mg of product/m^3]	10.5
Concentration of the active substance in the in-use product [% w/w]	6.4
Inhalation air concentration of active substance during task (mg/m^3]	**0.672**
RPE Protection factor	**20**
Inhalation air concentration of active substance during task (mg/m^3] with RPE	**0.0336**

Predicted exposures for scenario: Primary application – Disinfecting articles/items by immersing them in a basin : PT2-4

Inhalation Exposure (TNsG Mixing and Loading Model 7)	
Max recorded indicative value [mg of product/m^3]	0.2
Concentration of the active substance in the in-use product [% w/w]	6.4
Inhalation air concentration of active substance during task (mg/m^3]	**0.0128**

Scenario PT2-1 – TIER 1: Primary exposure: A professional/industrial user decants/pours the product 'STERI-PEROX 6%' prior to its application

Emission sources:	Near field	✓	Duration (mins): 10
	Far field		

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	214 Pa
Liquid mole fraction	0.064
Activity coefficient	1
Activity emission potential	
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 0.1 - 1 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	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)
Dispersion	
Ventilation rate	No restriction on general ventilation characteristics

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results

The predicted 75th percentile full-shift exposure is 0.64 mg/m³.

The inter-quartile confidence interval is 0.32 mg/m³ to 1.3 mg/m³.

Scenario PT2-2 – TIER 1: Primary exposure: A professional/industrial user disinfects hard surfaces using the product 'STERI-PEROX 6% WIPE'.

Substance	
Name	Hydrogen peroxide
Molecular weight	34.01 g/mol
Weight fraction substance	6.4 %

Inhalation

Exposure model	Exposure to vapour – Evaporation
Release Area Mode	Increasing
Release Area	2 m2
Application duration	5 minutes
Weight fraction substance	6.4 %
Room volume	55 m³
Ventilation rate	8 per hour
Amount of solution used	15.3g
Application temperature	20 ◦C
Vapour pressure	214 Pa
Mass transfer coefficient	10 m/hr

Dermal

Exposure model n.a.

Oral

Exposure model n.a

Inhalation

Peak event concentration 2.7 mg/m³

Scenario PT2-2 – TIER 2: Primary exposure: A professional/industrial user disinfects hard surfaces using the product 'STERI-PEROX 6% WIPE'.

Substance	
Name	Hydrogen peroxide
Molecular weight	34.01 g/mol
Weight fraction substance	6.4 %

Inhalation

Exposure model	Exposure to vapour – Evaporation
Release Area Mode	Increasing
Release Area	2 m2
Application duration	5 minutes
Weight fraction substance	6.4 %
Room volume	55 m³
Ventilation rate	20 per hour
Amount of solution used	15.3g
Application temperature	20 ◦C
Vapour pressure	214 Pa
Mass transfer coefficient	10 m/hr

Dermal

Exposure model n.a.

Oral

Exposure model n.a

Inhalation

Peak event concentration 1.3 mg/m³

Scenario PT2-2 – TIER 3: Primary exposure: A professional/industrial user disinfects hard surfaces using the product 'STERI-PEROX 6% WIPE'.

Substance	
Name	Hydrogen peroxide
Molecular weight	34.01 g/mol
Weight fraction substance	6.4 %

Inhalation

Exposure model	Exposure to vapour – Evaporation
Release Area Mode	Increasing

Release Area	2 m2
Application duration	5 minutes
Weight fraction substance	6.4 %
Room volume	55 m³
Ventilation rate	60 per hour
Amount of solution used	15.3g
Application temperature	20 ◦C
Vapour pressure	214 Pa
Mass transfer coefficient	10 m/hr

Dermal

Exposure model n.a.

Oral

Exposure model n.a

Inhalation

Peak event concentration 0.46 mg/m³

Scenario PT2-2 – TIER 4: Primary exposure: A professional/industrial user disinfects hard surfaces using the product 'STERI-PEROX 6% WIPE'.

Substance	
Name	Hydrogen peroxide
Molecular weight	34.01 g/mol
Weight fraction substance	6.4 %

Inhalation

Exposure model	Exposure to vapour – Evaporation
Release Area Mode	Increasing
Release Area	2 m2
Application duration	5 minutes
Weight fraction substance	6.4 %
Room volume	55 m³

Ventilation rate	8 per hour
Amount of solution used	15.3g
Application temperature	20 ◦C
Vapour pressure	214 Pa
Mass transfer coefficient	10 m/hr

Dermal

Exposure model n.a.

Oral

Exposure model n.a

Inhalation

Peak event concentration	2.7 mg/m³
RPE protection factor	20
Peak concentration with RPE	0.14 mg/m3

Scenario PT2-3 (Wiping phase) -TIER 1: Primary exposure: A professional/industrial user applies 'STERI-PEROX 6%' to hard surfaces using a hand-held trigger sprayer and subsequently wipes the product off.

Substance	
Name	Hydrogen peroxide
Molecular weight	34.01 g/mol
Weight fraction substance	6.4 %

Inhalation

Exposure model	Exposure to vapour – Evaporation
Release Area Mode	Increasing
Release Area	2 m2
Application duration	5 minutes
Weight fraction substance	6.4 %
Room volume	55 m³
Ventilation rate	8 per hour

Amount of solution used	123g
Application temperature	20 ◦C
Vapour pressure	214 Pa
Mass transfer coefficient	10 m/hr

Dermal

Exposure model n.a.

Oral

Exposure model n.a

Inhalation

Peak event concentration 3.9 mg/m³

Scenario PT2-3 (Wiping phase) -TIER 2: Primary exposure: A professional/industrial user applies 'STERI-PEROX 6%' to hard surfaces using a hand-held trigger sprayer and subsequently wipes the product off.

Substance	
Name	Hydrogen peroxide
Molecular weight	34.01 g/mol
Weight fraction substance	6.4 %

Inhalation

Exposure model	Exposure to vapour – Evaporation
Release Area Mode	Increasing
Release Area	2 m2
Application duration	5 minutes
Weight fraction substance	6.4 %
Room volume	55 m³
Ventilation rate	20 per hour
Amount of solution used	123g
Application temperature	20 ◦C
Vapour pressure	214 Pa
Mass transfer coefficient	10 m/hr

Dermal

Exposure model n.a.

Oral

Exposure model n.a

Inhalation

Peak event concentration 1.7 mg/m³

Scenario PT2-3 (Wiping phase) -TIER 3: Primary exposure: A professional/industrial user applies 'STERI-PEROX 6%' to hard surfaces using a hand-held trigger sprayer and subsequently wipes the product off.

Substance	
Name	Hydrogen peroxide
Molecular weight	34.01 g/mol
Weight fraction substance	6.4 %

Inhalation

Exposure model	Exposure to vapour – Evaporation
Release Area Mode	Increasing
Release Area	2 m2
Application duration	5 minutes
Weight fraction substance	6.4 %
Room volume	55 m³
Ventilation rate	60 per hour
Amount of solution used	123g
Application temperature	20 ◦C
Vapour pressure	214 Pa
Mass transfer coefficient	10 m/hr

Dermal

Exposure model n.a.

Oral

Exposure model n.a

Inhalation

Peak event concentration 0.59 mg/m³

Scenario PT2-3 (Wiping phase) -TIER 4: Primary exposure: A professional/industrial user applies 'STERI-PEROX 6%' to hard surfaces using a hand-held trigger sprayer and subsequently wipes the product off.

Substance	
Name	Hydrogen peroxide
Molecular weight	34.01 g/mol
Weight fraction substance	6.4 %

Inhalation

Exposure model	Exposure to vapour – Evaporation
Release Area Mode	Increasing
Release Area	2 m2
Application duration	5 minutes
Weight fraction substance	6.4 %
Room volume	55 m³
Ventilation rate	200 per hour
Amount of solution used	123g
Application temperature	20 ◦C
Vapour pressure	214 Pa
Mass transfer coefficient	10 m/hr

Dermal

Exposure model n.a.

Oral

Exposure model n.a

Inhalation

Peak event concentration 0.18 mg/m³

Scenario PT2-3 (Wiping phase) - TIER 5: Primary exposure: A professional/industrial user applies 'STERI-PEROX 6%' to hard surfaces using a hand-held trigger sprayer and subsequently wipes the product off.

Substance	
Name	Hydrogen peroxide
Molecular weight	34.01 g/mol
Weight fraction substance	6.4 %

Inhalation

Exposure model	Exposure to vapour – Evaporation
Release Area Mode	Increasing
Release Area	2 m2
Application duration	5 minutes
Weight fraction substance	6.4 %
Room volume	55 m³
Ventilation rate	8 per hour
Amount of solution used	123g
Application temperature	20 ◦C
Vapour pressure	214 Pa
Mass transfer coefficient	10 m/hr

Dermal

Exposure model n.a.

Oral

Exposure model n.a

Inhalation

Peak event concentration	3.9 mg/m³
RPE protection factor	20
Peak concentration RPE	0.195

Scenario PT2-4 (Immersion bath) -TIER 1: Primary exposure: A professional/industrial user disinfects equipment using an immersion bath containing the product 'STERI-PEROX 6%'.

Substance	
Name	Hydrogen peroxide
Molecular weight	34.01 g/mol
Weight fraction substance	6.4 %

Inhalation

Exposure model	Exposure to vapour – Evaporation
Release Area Mode	Constant
Release Area	1 m2
Emission duration	30 minutes
Weight fraction substance	6.4 %
Room volume	55 m³
Ventilation rate	8 per hour
Amount of solution used	10000 g
Application temperature	20 ◦C
Vapour pressure	214 Pa
Mass transfer coefficient	10 m/hr

Dermal

Exposure model n.a.

Oral

Exposure model n.a

Inhalation

Peak event concentration 2.2 mg/m³

Scenario PT2-4 (Immersion bath) -TIER 2: Primary exposure: A professional/industrial user disinfects equipment using an immersion bath containing the product 'STERI-PEROX 6%'.

Substance	
Name	Hydrogen peroxide
Molecular weight	34.01 g/mol
Weight fraction substance	6.4 %

Inhalation

Exposure model	Exposure to vapour – Evaporation
Release Area Mode	Constant
Release Area	1 m2
Emission duration	30 minutes
Weight fraction substance	6.4 %
Room volume	55 m³
Ventilation rate	20 per hour
Amount of solution used	10000 g
Application temperature	20 ◦C
Vapour pressure	214 Pa
Mass transfer coefficient	10 m/hr

Dermal

Exposure model n.a.

Oral

Exposure model n.a

Inhalation

Peak event concentration 0.94 mg/m³

Scenario PT2-4 (Immersion bath) -TIER 3: Primary exposure: A professional/industrial user disinfects equipment using an immersion bath containing the product 'STERI-PEROX 6%'.

Substance	
Name	Hydrogen peroxide
Molecular weight	34.01 g/mol
Weight fraction substance	6.4 %

Inhalation

Exposure model	Exposure to vapour – Evaporation
Release Area Mode	Constant
Release Area	1 m2

Emission duration	30 minutes
Weight fraction substance	6.4 %
Room volume	55 m³
Ventilation rate	8 per hour
Amount of solution used	10000 g
Application temperature	20 ◦C
Vapour pressure	214 Pa
Mass transfer coefficient	10 m/hr

Dermal

Exposure model n.a.

Oral

Exposure model n.a

Inhalation

Peak event concentration	2.2 mg/m³
RPE protection factor	20
Peak concentration RPE	0.11 mg/m³

3.3 New information on the active substance

There is no new data submitted for the active substance hydrogen peroxide.

3.4 Residue behaviour

Biocidal products in the STERI- PEROX family are not used in areas relevant to the processing or manufacturing of food and do not have any applications relevant to farm animals or livestock. The uses of the products therefore will not result in any residues arising in food consumed by the general population and there is no potential for dietary exposure. Information on residues is therefore not relevant.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[20]

Efficacy study summaries are located in the IUCLID file under point 6.7

20 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

3.6 Confidential annex

Please see separate document for information.

3.7 Other