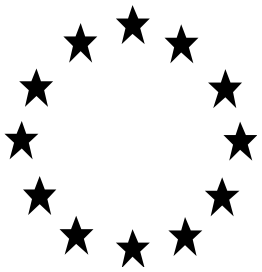
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT (FAMILY) FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

Amended PAR



Vaprox® Biocidal Product Family (Hydrogen Peroxide Sterilant and Vaprox®59 Hydrogen Peroxide Sterilant)

Product type(s): PT 2

Hydrogen Peroxide

Asset Number in R4BP: FI-0021179-0000

Evaluating Competent Authority: FI

Date: 12/4/2023

Note to the reader:

Please note that Finland has replaced the former refMS (UK). Below is provided a table specifying the history of the asset.

In 15/04/2019, UK as refMS, authorised the product family *Vaprox biocidal product family* (UK-0017015-0000) and then mutual recognitions in sequence were approved in several concerned Member States (Lithuania LT-0020911-0000, Sweden SE-0020885-0000, Spain ES-0020821-0000, Portugal PT-0022102-0000, Poland PL-0021197-0000, Netherlands NL-0020016-0000, Malta MT-0017934-0000, Luxembourg LU-0017907-0000, Italy IT-0016971-0000, Hungary HU-0025203-0000, Ireland IE-0020894-0000, Germany DE-0017070-0000, France FR-0016750-0000, Finland FI-0021179-0000, Denmark DK-0020827-0000, Czech Republic CZ-0021512-0000, Croatia HR-0021774-0000, Belgium BE-0017052-0000, Austria AT-0021244-0000, Iceland IS-0021037-0000 and Switzerland CH-0021205-0000).

Since 31 January 2020, the UK cannot act as the reference Member State as it is no longer an EU Member State. As proposed in the procedure agreed in CG42 (CG-42-2020-08 AP 6.2) and first noted during the 89th CA meeting (CA-Sept20-Doc.7.8) and preliminary agreed in the closed session of the 90th CA-meeting (CA-Dec20.Doc.7.2[1]), Finland agreed to take over the role of Reference Member State for this product.

11 February 2020 the applicant applied for a major change (NA-MAC) to fulfill a post authorization data requirement to provide information on the ED assessment of co-formulants for the product family *Vaprox biocidal product family*. Following the evaluation of this additional information, Finland, as new refMS substituting the UK, informed the concerned Member States that the post authorization data requirement has been fulfilled and accepted. There were no changes to the SPC of the product.

Please note that Finland as new refMS provided this amended PAR related to the major change assessment. The update of other parts of the assessment or SPC would only be performed at the renewal stage of the product.

13 December 2022 the applicant applied for an administrative change. The change included an addition of a product manufacturer and a change in the name and model of the VHP equipment. The SPC has been updated accordingly.

Please find all amendments made by the new refMS Finland highlighted in yellow in the PAR.

The history of the dossier:

Application type	refMS /eCA	Case number in the refMS/cMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)
NA-APP	UK	BC-EU028889-02	15/04/2019	Initial assessment by UK

[1] https://circabc.europa.eu/w/browse/c63a1f06-4ae7-43c7-b436-d20829fec75b

NA-MRP	FI	BC-XQ028895-98	17/07/2019	Mutual recognition in parallel in FI
NA-MAC	FI	BC-QJ057333-34	24/09/2020	PAC: ED assessment of the co-formulants
NA-ADC	FI	BC-XQ028895-98	x/4/2023	Addition of product manufacturer. Change in the name and model of the VHP equipment.

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1 CONCLUSION

1.1 Summary of decisions and restrictions

It is concluded after evaluation, that sufficient data have been provided to verify the outcome and conclusions, and permit authorisation of the biocidal product subject to the following conditions.

1.2 Usage area

Product type 2 (Disinfectants and algaecides not intended for direct application to humans or animals.

Indoors – Used for the disinfection of dry surfaces, which are not used for direct contact with food or feeding stuffs. Disinfection within sealed pre-cleaned enclosures in industrial, commercial and institutional settings.

1.3 User

Trained professional

1.4 Application method

Vaporisation applied using the Vaporized Hydrogen Peroxide (VHP) Unit, to deliver hydrogen peroxide. Disinfection of dry surfaces within sealed pre-cleaned enclusures in industrial, commercial and institutional settings.

1.5 Pests and application rate

Target organisms are:

- Bacteria
- Fungi
- Bacterial spores
- Viruses
- Yeast

Application rate: application to sealed, dry precleaned enclosures. When the target concentration of a 300 ppm H_2O_2 airborne concentration is achieved (sensors will be placed throughout the area in order to monitor the concentration of H_2O_2), initiate the application phase and maintain this concentration for 3 hours (against bacteria, bacterial spores, viruses or for 6 hours (against yeast and fungi).

Number and timing of applications: Only one application is required, but the concentration must be maintained at 300 ppm for a certain period of time (for 3 hours against bacteria, bacterial spores, viruses or for 6 hours against yeast and fungi).

1.6 Comparative assessment and authorisation

The active substance contained in the biocidal product family is not a candidate for substitution in accordance with Article 10 of BPR, nor for exclusion in accordance with Article 5(1) of the BPR. Therefore, a comparative assessment is not required.

1.7 Endocrine disruption

Evaluating bodies have to decide whether there is a need to evaluate a specific non-active substance in detail and, if necessary, to ask additional information to the applicant for the appropriate assessment. This should only occur where there are indications that a non-active substance may have ED properties based on the existing knowledge and the available scientific information.

The United Kingdom competent authority has assessed the ED potential of the non-active substances of this biocidal product and have determined none of these non-active substances to have an ED potential. Further information can be found in section 3.6.2.

1.8 Necessary issues accounted for in the product label

The following must appear on the label:

1. Protect from frost.
2. Wear protective chemical resistant gloves, a protective coverall and eye protection during product handling phase (glove material to be specified by the authorisation holder within the product information). Suitable respiratory mask should be worn as to specified by the authorisation holder within the product information.
3. Securing the Enclosure: Ensure all personnel have vacated the treatment enclosure prior to Vaprox application. Remove all plants, animals, beverages and food. Applicators must not re-enter the treated enclosure until exposure levels of hydrogen peroxide are at/or below required health and safety limits.

1.9 Requirement for further information

None

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier[2]	Country (if relevant)
Vaprox® Biocidal Product Family	United Kingdom

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	Name	STERIS® Ireland Limited
	Address	STERIS Ireland Limited IDA Business and Technology Park Country Offialy, Tullamore R35 X865, Ireland
Authorisation number	~~UK-2019-1204~~ FI-2019-0008	
Date of the authorisation	15/04/2019 (UK)	
Expiry date of the authorisation	14/04/2029	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	STERIS Corporation
Address of manufacturer	6100 Heisley Road, Mentor, Ohio OH 44060, United States
Location of manufacturing sites	6100 Heisley Road, Mentor, Ohio OH 44060, United States

Name of manufacturer	Cantel Medical (Italy) S.r.l
Address of manufacturer	Via Laurentina, 16900071Pomezia (RM) Italy
Location of manufacturing sites	Via Laurentina, 16900071Pomezia (RM) Italy

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

Active substance	Hydrogen Peroxide
Name of manufacturer	PeroxyChem Spain, s.l.u
Address of manufacturer	c/ Afueras, s/n, 50784 La Zaida, Zarragoza, Spain
Location of manufacturing sites	c/ Afueras, s/n, 50784 La Zaida, Zarragoza, Spain

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

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	99.5 % by wt
Structural formula	

2.1.2.2 Candidate(s) for substitution

Hydrogen peroxide is not considered a candidate for substitution in accordance with Article 10(1) of EU Regulation 528/2012.

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

The full formulation composition details are contained within the confidential annex 3.6.1.

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Hydrogen Peroxide dihydrogen dioxide	Hydrogen peroxide	Active substance	7722-84-1	231-765-0	34.8	59.4
Confidential (see confidential annex to this PAR)	Confidential	Non-active substance[3]	Confidential	Confidential	40.6	65.2

2.1.2.4 Information on technical equivalence

The biocidal product family - VAPOX® Biocidal Product Family contains the active substance hydrogen peroxide. The manufacturer (PeroxyChem Spain, s.l.u) is a member of the Hydrogen Peroxide Biocidal Task Force that submitted a dossier to the rapporteur member state for active substance approval.

PeroxyChem Spain, s.l.u., has provided the applicant (Steris solutions Ltd) with a letter of access to these data and therefore no further consideration is required.

2.1.2.5 Information on the substance(s) of concern

The biocidal product family contains the formulated active substance and co-formulants which are not considered substances of concern. See confidential annex 3.6.1 Product composition for a full description of the formulation. No further consideration is necessary.

2.1.2.6 Type of formulation

Ready-to-use (RTU) aqueous solution (AL)

[3] Non-active substance(s), of which knowledge is essential for proper use of the product. In the SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of non-active substance.

2.1.3 Hazard and precautionary statements

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

Classification of Meta SPC 1 - Vaprox® Hydrogen Peroxide Sterilant within the VAPROX Biocidal Product Family	
Hazard category	Acute Tox. 4 (Oral) Ox. Liq. 2 Skin Irrit. 2 Eye Dam. 1 STOT SE 3 Aquatic Chronic 3
Hazard statement	H302 - Harmful if swallowed. H272 - May intensify fire; oxidiser. H315 - Causes skin irritation. H318 - Causes serious eye damage. H335 - May cause respiratory irritation. H412 - Harmful to aquatic life with long lasting effects.
Labelling	
Signal words	Danger
Hazard statements	H302 - Harmful if swallowed. H272 - May intensify fire; oxidiser. H315 - Causes skin irritation. H318 - Causes serious eye damage. H335 - May cause respiratory irritation. H412 - Harmful to aquatic life with long lasting effects.
Precautionary statements	P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P220 - Keep away from clothing and other combustible materials. P261 - Avoid breathing vapours. P273 - Avoid release to the environment. P280 - Wear eye protection, protective clothing, protective gloves. P302+P352 - IF ON SKIN: Wash with plenty of water. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+351+338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor/… P403+P233 - Store in a well-ventilated place. Keep container tightly closed. P501: Dispose of contents/container in accordance with local regulation.
Note	

Classification of Meta SPC 2 - Vaprox® 59 Hydrogen Peroxide Sterilant within the VAPROX Biocidal Product Family	
Hazard category	Ox. Liq. 2 Acute Tox. 4 (oral/inhalation) Skin Corr. 1B Eye Dam. 1 STOT SE 3 Aquatic Chronic 3
Hazard statement	H272 - May intensify fire; oxidiser H302 - Harmful if swallowed H314 - Causes severe skin burns and eye damage H318 - Causes serious eye damage. H332 - Harmful if inhaled H335 - May cause respiratory irritation H412 - Harmful to aquatic life with long lasting effects
Labelling	
Signal words	Danger
Hazard statements	H272 - May intensify fire; oxidiser H302 - Harmful if swallowed H314 - Causes severe skin burns and eye damage H332 - Harmful if inhaled H335 - May cause respiratory irritation H412 - Harmful to aquatic life with long lasting effects
Precautionary statements	P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P220 - Keep away from clothing and other combustible materials. P260: Do not breathe vapours. P273 - Avoid release to environment. P280: Wear eye protection, protective clothing, protective gloves. P301+P330+P331 – IF SWALLOWED: Rinse mouth. Do not induce vomiting. P310: Immediately call a POISON CENTER/doctor/… P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P363: Wash contaminated clothing before reuse. P321: Specific treatment (see … on this label). P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents/container in accordance with local regulation.
Note	

2.1.4 Authorised use(s)

2.1.4.1 Use description – Table 1. Use # 1 and 2 – Disinfection of surfaces in industrial, commercial and institutional settings by vaporisation

Product Type	PT 2 - Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeast, fungi, bacterial spores and viruses
Field of use	Indoors Used for the disinfection of non-porous surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs, within sealed pre-cleaned enclosures in industrial, commercial and institutional settings.
Application method(s)	Disinfection by a Vaporized Hydrogen Peroxide (VHP) Unit. Vaporisation, applied using the VHP unit, using a machine to deliver hydrogen peroxide within sealed enclosures.
Application rate(s) and frequency	Application to sealed, dry precleaned enclosures. When the target concentration of 300 ppm (v/v) airborne H_2O_2 is achieved (sensors will be placed throughout the area in order to monitor the concentration of H_2O_2), initiate the application phase and maintain this concentration for 3 hours (against bacteria, bacterial spores and viruses or for 6 hours (against yeast and fungi). Number and timing of applications: Only one application is required, but the concentration must be maintained at 300 ppm (v/v) for a certain period of time (for 3 hours against bacteria, bacterial spores and viruses or for 6 hours against yeast and fungi).
Category(ies) of users	Trained professional
Pack sizes and packaging material	Please see section 2.1.7.

2.1.4.2 Use-specific instructions for use

Prepare the treatment enclosure as described under 2.1.4.3 .

<u>Directions for Use</u>

For application to sealed, dry precleaned enclosures at 300 ppm H_2O_2 for 3 hours (against bacteria, bacterial spores and viruses and or for 6 hours (against yeast and fungi).

Use undiluted product.

Secure that the produced aerosol of hydrogen peroxide do not enter the ventilation system of the enclosure throughout the treatment.

Place the hydrogen peroxide monitor in a location within the treatment enclosure which is most difficult for the vapor target concentration to reach. This is typically in a corner of the enclosure farthest away from the VHP generation unit. All drawers, closets & cabinet doors, etc. must be opened to permit exposure to hydrogen peroxide. Place chemical indicators throughout the enclosure to verify effective distribution of hydrogen peroxide. Place oscillating fans throughout the enclosure to facilitate effective distribution of the hydrogen peroxide.

Program the VHP Generator to initiate a DEHUMIDIFICATION phase to achieve < 70% relative humidity. Ensure the ambient temperature is not less than 21° C or 70°F initially and throughout the process. Once the DEHUMIDIFICATION phase is complete initiate a CONDITIONING phase to achieve a 300 ppm (v/v) hydrogen peroxide concentration in the sealed enclosure. When a 300 ppm (v/v) hydrogen peroxide concentration is achieved initiate the application phase and maintain this concentration for 3 hours (against bacteria, bacterial spores and viruses or for 6 hours (against yeast and fungi).

For room enclosures greater than 150 m^3 it may be necessary to utilise multiple VHP units to achieve the target concentration

During the APPLICATION phase, monitor areas adjacent to the sealed enclosure with devices such as Drager tubes to ensure hydrogen peroxide levels do not exceed health and safety limits. If this level is exceeded outside the treatment enclosure, the applicator should immediately abort the treatment process and ensure the enclosure is properly sealed. Upon completion of the APPLICATION phase, begin the AERATION phase to reduce the levels of hydrogen peroxide at or below the appropriate health and safety limits for hydrogen peroxide (1.25 mg/m^3).

The disinfection process shall be biologically validated in a suitable "standard room" with the device to be used, after which a protocol for disinfection of similar rooms can be made and followed. The biological validation demonstrates which dosing and parameters for vaporisation (temperature, humidity, concentration in the air, and contact time during each phase: preparation, conditioning, disinfection, and terminal phase) should be used for optimal disinfection of the room in question, i.e. sufficient killing of organisms on all surfaces in the room. Biological validation is performed by monitoring efficacy against a challenging test organism (e.g. *Geobacillus stearothermophilus* spores) during the room disinfection process. Indicator strips are placed at places that are difficult to reach. After the disinfection the strips can be processed to verify the effectiveness of the process.

Detailed description of the equipment and its characteristics

Equipment name and model:
STERIS VHP Biodecontamination Systems.

The STERIS VHP System uses an open/closed loop process utilising conditioned air as a carrier to deliver Vaprox® hydrogen peroxide Sterilant vapor to the exposed surfaces inside a pre-cleaned, dry, sealed Enclosure. This process allows the application process to take place at, or near, atmospheric pressure. The H2O2 vapor concentration depends on the temperature and humidity of the sealed Enclosure. Because application relies only on the contact of hydrogen peroxide with exposed surfaces, the transfer of heat and moisture required by steam processes is not necessary. Existing labeling for Vaprox clearly outlines that only STERIS VHP application equipment can be used with the product.

- diffusion principles (e.g. fogging, vapour, fumigation) and particles size distribution of aerosols or powder; Diffusion principle is vapour (vaporization of liquid to vapor and distributed using air movement). Particle size distribution is less than 1 micron.

- description of the diffusion performance of the equipment (e.g. volume to disinfect, diffusion speed); Liquid is flash vaporised in a vaporisation vessel and mixed and transported with incoming clean/dry air. Diffusion is accomplished with air velocity changes and additional air moving equipment to aid in complete diffusion and maintains a constant concentration during the decontamination cycle phase

- description of the ambient conditions (e.g. humidity, temperature) in which the process can be used; 70% or less on Relative humidity. Ensure temperature is not less than 21°C or 70°F initially and throughout the process.

- diffusion time for a specific volume; Diffusion times will vary based on the size or volume of the enclosed area to be treated. The diffusion time to reach the defined hydrogen peroxide vapor concentration is tied to the conditioning phase of the process cycle. As a result, only the conditioning phase will be variable. The defined contact time for the application or decontamination phase for hydrogen peroxide as defined in labelling will not change.

- precautions for over and under-dosing. Dosing is controlled by two variables; time and injection rate of the liquid into the vaporiser. Instruments within the injection system provide feedback of the performance of the system and automatically control changes within the system to keep dosing at the predetermined concentration. If an error occurs in the system or the process and dosing goes out of range the unit will have an aborting alarm which will immediately go into the aeration phase and breakdown the present peroxide to safe levels for human occupancy. At this point the cycle must be restarted from the beginning. The cycle must successfully complete all 4 phases consecutively for the cycle to complete.

2.1.4.3 Use-specific risk mitigation measures

Preparation of Enclosures:

1. Cleaning:

All the surfaces in the treatment area must be clean and dry prior to Vaprox application.

2. VHP Application Equipment:

Position or connect the VHP application equipment for optimum vapour distribution into the treatment enclosure. See Equipment User's Manual for proper equipment preparation and set-up.

3. Sealing:

Seal the treatment enclosure adequately to ensure that hydrogen peroxide levels outside the enclosure are kept at acceptable health and safety levels

4. Securing the Enclosure:

Ensure all personnel have vacated the treatment enclosure prior to Vaprox application. Remove all plants, animals, beverages and food. Applicators must not re-enter the treated enclosure until exposure levels of hydrogen peroxide are at/or below required health and safety limits. In case of emergency when the hydrogen peroxide

concentration is still above 1.25 mg/m3 entering in the room is only allowed by wearing appropriate PPE including SCBA (Self Contained Breathing Apparatus).

5. Placarding of Treatment Enclosure

The applicator must placard or post all entrances to the treatment enclosure with signs bearing:

1. The signal word “DANGER” in red. “Area under treatment, “DO NOT ENTER/NO ENTRY.”

2. The statement “This sign may only be removed 1 hour after the treatment enclosure has been aerated to hydrogen peroxide levels less than or equal to 1.25 mg/m^3”.

3. Identification of hydrogen peroxide as a hazard associated with the treatment process.

4. Contact information for the applicator.

During the APPLICATION phase, monitor areas adjacent to the sealed enclosure with devices such as Drager tubes to ensure hydrogen peroxide levels do not exceed health and safety limits. If this level is exceeded outside the treatment enclosure, the applicator should immediately abort the treatment process and ensure the enclosure is properly sealed.

Wear protective chemical resistant gloves, a protective coverall and eye protection during product handling phase (glove material to be specified by the authorisation holder within the product information). Suitable respiratory mask should be worn as specified by the authorisation holder within the product information.

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

First-aid measures general:

Never give anything by mouth to an unconscious person. In all cases of doubt, or when symptoms persist, seek medical attention.

If medical advice is need, have product container or label at hand.

First-aid measures after inhalation:

Remove to fresh air and keep at rest in a position comfortable for breathing. If not breathing, give artificial respiration. Immediately get medical attention.

First-aid measures after skin contact:

Remove contaminated clothing immediately. Immediately flush skin with plenty of water for at least 15 minutes. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

First-aid measures after eye contact:

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Immediately get medical attention.. Remove contact lenses, if present and easy to do. Continue rinsing..

First-aid measures after ingestion:

Give water if the person is fully conscious. Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

UK medical professionals should contact the National Poisons Information Service (www.npis.org) for further advice. Environmental precautions and accidental release measures:

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

Methods for cleaning up:

Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Do not absorb in sawdust, paper, cloth or other combustible absorbents. Comply with applicable local, national and international regulation. Collect spillage. Store away from other materials.

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

Waste disposal recommendations:
Do not re-use empty containers. Containers remain hazardous when empty.
Consult the appropriate authorities about waste disposal. Dispose in a safe manner in accordance with local/national regulations.

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

Storage conditions:
Keep only in the original container in a cool, dry, well-ventilated place.
Keep container tightly closed.
Shelf-life – 24-months.

Prohibitions on mixed storage:
Do not store near reducing or oxidizing agents.
Keep away from clothing and other combustible materials.

2.1.5 General directions for use

2.1.5.1 Instructions for use[4]

See 2.1.4.2 and 2.1.5.2

2.1.5.2 Risk mitigation measures

General measures:
Ensure adequate ventilation. Do not breathe fumes, vapours. Avoid contact with skin, eyes and clothes. Stop leak if safe to do so.

Protective equipment:
Wear protective gloves and eye/face protection. Exposure-controls/personal protection.

Emergency procedures:
Stop leak if safe to do so. Evacuate unnecessary personnel.

Environmental precautions:
Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

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

See 2.1.4.4 and 2.1.5.4

2.1.5.4 Instructions for safe disposal of the product and its packaging

See 2.1.4.5 and 2.1.5.5

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

See 2.1.5.6 and 2.1.5.6

2.1.6 Other information

None

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

2.1.7 Packaging of the biocidal product

Type of packaging	Size/ volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Cartridge - for Vaprox® Hydrogen Peroxide Sterliant	6 x 950 mL	plastic: HDPE	Not specified	Professional	Acceptable. No adverse interactions observed following accelerated temperature and ambient temperature storage.
Pail - for Vaprox® Hydrogen Peroxide Sterliant	18.9 L	plastic: HDPE		Professional	
Drum - for Vaprox® Hydrogen Peroxide Sterliant	200.6 L	Polyethylene		Professional	
Cup - for Vaprox® Hydrogen Peroxide Sterliant	8 x 141 mL	Plastic: Polypropylene copolymer		Professional	
Cartridge – for Vaprox® 59 Hydrogen Peroxide Sterliant	6 x 950 mL	plastic: HDPE	Not specified	Professional	Acceptable. No adverse interactions observed following accelerated temperature and ambient temperature storage.
Pail - Vaprox® 59 HydrogenPeroxideSterliant	18.9 L	plastic: HDPE		Professional	
Cup - Vaprox® 59 HydrogenPeroxideSterliant	3 x 113 mL (15 cycles)	Plastic: Polypropylene copolymer		Professional	
Cup - Vaprox® 59 HydrogenPeroxideSterliant	4 x 29 mL (4 cycles)	Plastic: Polypropylene copolymer		Professional	
Cup - Vaprox® 59 HydrogenPeroxideSterliant	2 x 70 mL (1 cycle /cartridge)	Plastic: Polypropylene copolymer		Professional	

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

The studies submitted in support of the product authorisation application are listed in Annex 3.1 of this PAR.

2.1.8.2 Access to documentation

PeroxyChem Spain, s.l.u., are part of the Hydrogen Peroxide Biocide Task Force that owns the Hydrogen Peroxide active substance dossier and has provided the applicant (STERIS® Solutions Limited) with appropriate letter of access to these data and therefore no further consideration is required.

2.2 Assessment of the biocidal product(family)

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

Table 2.Intended use # 1 – Surface disinfection by Vaporised Hydrogen Peroxide process
Please note this use relates to both Meta SPC's within the family

Product Type(s)	2
Where relevant, an exact description of the authorised use	Surface disinfection by VHP process.
Target organism (including development stage)	Bactericidal, fungicidal, sporicidal, virucidal and tuberculocidal activity
Field of use	Used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs.
Application method(s)	Vaporisation, applied using the VHP process, using a machine to deliver hydrogen peroxide within sealed enclosures.
Application rate(s) and frequency	Application rate: application to sealed, dry precleaned enclosures. When a 300 ppm Vaprox concentration is achieved (sensors will be placed throughout the area in order to detect the concentration of H_2O_2), initiate the application phase and maintain this concentration for 3 hours (against bacteria, bacterial spores, viruses) or for 6 hours (against fungi). Number and timing of applications: Only one application is required, but must be maintained at a concentration of 300 ppm for a certain period of time (3 against bacteria, bacterial spores, viruses) or for 6 hours (against fungi). The frequency of applications is determined by the user.
Category(ies) of user(s)	Trained professional
Pack sizes and packaging material	Please see section 2.1.7.

2.2.2 Physical, chemical and technical properties

'Vaprox® Biocidal Product Family' is a ready to use aqueous solution for use as a liquid vaporizer. The physical and chemical and storage stability data submitted to support the formulation are summarised in the following table. The biocidal family consists of Vaprox® Hydrogen peroxide sterilant (35%)' and 'Vaprox® 59 hydrogen peroxide sterilant composition (59%)'. The applicant has confirmed that 'Vaprox Max' and 'Vaprox HC' are alternate development names for the 'Vaprox® 59 hydrogen peroxide sterilant' product. As Vaprox® Hydrogen peroxide sterilant (35%) is a simple dilution of Vaprox® 59 hydrogen peroxide sterilant (59%), the physical chemical properties determined for one product can be extrapolated to the other.

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6303	Vaprox 59%	Homogeneous liquid	Ritts, B. 2007, Study 07002.00	Acceptable
	Visual assessment	Vaprox 35%	Homogeneous liquid	Haller, L. A., 1994, Study D500504	Acceptable
Colour at 20 °C and 101.3 kPa	OPPTS 830.6302	Vaprox 59%	Colourless	Ritts, B. 2007, Study 07002.00	Acceptable
	Visual assessment	Vaprox 35%	Colourless	Haller, L. A., 1994, Study D500504	Acceptable
Odour at 20 °C and 101.3 kPa	OPPTS 830.6304	Vaprox 59%	Sharp odour	Ritts, B. 2007, Study 07002.00	Acceptable
	Olefactory assessment	Vaprox 35%	Odourless	Haller, L. A., 1994, Study D500504	Acceptable
Acidity / alkalinity	OPPTS 830.7000	Vaprox 59%	pH = 3.02	Ritts, B. 2007, Study 07002.00	Acceptable. As the pH is <4, the acidity should also be determined. However, the Vaprox 35% product carries a H318 classification (causes serious eye damage) and Vaprox 59% product carries H314 classification (causes severe burns and serious eye damage). As the products already carry these

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
					classifications, no further data on acidity and pH are required.
Relative density / bulk density	OPPTS 830.7300	Vaprox 59%	1.2311 at 25 ºC	Ritts, B. 2007, Study 07002.00	Acceptable
Storage stability test – accelerated storage	Visual inspection Visual inspection Gravimetric Permanganate titration	Vaprox 59%	<u>Storage for 3 months at 40 ºC</u> <u>Packaging</u>: 70 mL polypropylene cartridge No change in packaging after 1 and 3 months at 40 ºC <u>Appearance of product</u> Initial and 1 month at 40 ºC: colourless liquid 3 months at 40 ºC: Colourless liquid <u>Weight change:</u> 1 month at 40 ºC: 0.33% 3 months at 40 ºC: 0.9% <u>Active content:</u> Initial: 59.3% 1 month at 40 ºC: 59.7% 3 months at 40 ºC: 58.8%	Bernardo, M. R., 2013, Study SSP187D	The usual storage regime for 40 ºC is 8 weeks, however the conditions applied for up to 3 months is more worse case so is acceptable. Test has been conducted in commercial packaging, acceptable. Acceptable. No significant weight change, acceptable. No significant change (0.84 % decrease) to active content, acceptable. The pH should also be determined. However the pH data has been provided as part of ambient temperature testing below.
	Visual inspection Visual inspection	Vaprox 35%	<u>40 ºC for 1 month, 300 mL bottle cartridge</u> <u>Packaging</u>: No change in packaging after 1 month at 40 ºC	Kaiser, H., 2006, Study SSP194.00	The usual storage regime for 40 ºC is 8 weeks, however the study was only conducted for 4 weeks. As the study on Vaprox 59% above can be extrapolated to Vaprox 35%, this study will be considered supplementary.

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
	Permanganate titration		Appearance of product Initial and 1 month at 40 ºC: colourless liquid Active content: Initial: 35.1% 1 month at 40 ºC: 35.4%		The test has been conducted in commercial packaging, acceptable. There is no change to the packaging, appearance to packaging or active content (1.14% decrease) after storage, acceptable.
Storage stability test – long term storage at ambient temperature	Visual inspection Visual inspection Gravimetric Permanganate titration	Vaprox 59%	25 ºC for 12 months, 950 mL bottle with gasket cap. Packaging: no change in appearance of packaging after storage Appearance of product 12 months at 25ºC: clear colourless liquid Weight change: 12 months at 25ºC: -0.17% Active content Initial: 58.4% 12 months at 25 ºC: 57.9%	2012, Study SSP187C.01	Ambient storage stability study was conducted for 12 months in 950 mL commercial packaging. There is no significant change to the appearance of packaging, product, weight change or active content (0.86 % decrease) after storage. Acceptable. The pH should also be determined. However the pH has been provided as part of ambient temperature testing.
	Visual inspection Visual inspection	Vaprox 59%	25 ºC for 12 months, 5 gallon container. Packaging: no change in appearance of packaging after storage Appearance of product	2012, Study SSP187C.01	Ambient storage stability study was conducted for 12 months in 5 gallon commercial packaging. There is no significant change to the appearance of packaging, product, or active content after storage. Acceptable.

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
	Permanganate titration		12 months at 25ºC: clear colourless liquid Active content Initial: 59% 12 months at 25 ºC: 58.16%		The pH should also be determined. However the pH has been provided as part of ambient temperature testing.
	Visual inspection Visual inspection Gravimetric Permanganate titration Not reported	Vaprox 59%	25 ºC for 12 months, cartridge container. Packaging: no change in appearance of packaging after storage Appearance of product 12 months at 25ºC: clear colourless liquid Active content Initial: 59% 12 months at 25 ºC: 58.2% pH Initial: 2.4 12 months at 25 ºC: 2.7	Kaiser, H., 2008, Study SSP187A	Ambient storage stability study was conducted for 12 months in commercial packaging. There is no significant change to the appearance of packaging, or active content (0.14 % decrease) after storage. Acceptable. The pH has also been determined, which shows no significant change after storage. As the pH is <4, the acidity should also be determined. However, the Vaprox 35% product carries a H318 classification (causes serios eye damage) and Vaprox 59% product carries H314 classification (causes severe burns and serious eye damage). As the products already carry these classifications, no further data on acidity and pH are required.
	Visual inspection Visual inspection	Vaprox 59%	25 ºC for 24 months, 950 mL container. Packaging: no change in appearance of packaging after storage Appearance of product	Bernardo M. R., 2013, Study SSP187C	Ambient storage stability study was conducted for 24 months in 950 mL commercial packaging. There is no significant change to the appearance of packaging, product, weight change or active content

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
	Gravimetric Permanganate titration		24 months at 25ºC: clear colourless liquid <u>Weight change</u>: 24 months at 25ºC: -0.35% <u>Active content</u> Initial: 58.5% 24 months at 25 ºC: 57.2%		(2.22 % decrease) after storage. Acceptable. The pH should also be determined which has been determined after ambient temperature storage for 12 months above. As this shows that there is no significant change after storage no further data is required. In addition, as previously stated the product label carries the following classifications H318 for Vaprox 35% and H314 for Vaprox 59% so no further data is required.
	Visual inspection Visual inspection Permanganate titration	Vaprox 59%	<u>25 ºC for 24 months, 5 gallon container.</u> <u>Packaging</u>: no change in appearance of packaging after storage <u>Appearance of product</u> 24 months at 25ºC: clear colourless liquid <u>Active content</u> Initial: 59% 24 months at 25 ºC: 57.6%	Bernardo M. R., 2013, Study SSP187C	Ambient storage stability study was conducted for 24 months in 5 gallon commercial packaging. There is no significant change to the appearance of packaging, product, or active content (2.37 % decrease) after storage. Acceptable. The pH should also be determined which has been determined after ambient temperature storage for 12 months above. As this shows that there is no significant change after storage no further data is required. In addition, as previously stated the product label carries the following classifications H318 for Vaprox 35% and H314 for Vaprox 59% so no futher data is required.
		Vaprox 35%	<u>25 ºC for 24 months, 950 mL bottle with gasket cap.</u>	Kaiser, H., 2004, Study SSP158.00	Ambient storage stability study was conducted for 24 months in 950 mL commercial packaging for Vaprox 35%.

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
	Visual inspection Visual inspection Gravimetric Permanganate titration		Packaging: No change in appearance of packaging after storage Appearance of product 24 months at 25ºC: clear colourless liquid Weight change: 24 months at 25 ºC: -0.4% Active content Initial:35.5% 24 months at 25 ºC: 35%		There is no significant change to the appearance of packaging, product, weight change or active content (1.41 % decrease) after storage. Acceptable. The pH should also be determined which has been determined after ambient temperature storage for 12 months above. As this shows that there is no significant change after storage no further data is required. In addition, as previously stated the product label carries the following classifications H318 for Vaprox 35% and H314 for Vaprox 59% so no further data is required.
Storage stability test – low temperature stability test for liquids	Case		'Protect from frost' is stated on the label.	IUCLID 3.1.4.3	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - light	Case		Biocidal product is marketed in cartridge, pail, drum and cup which are all opaque. The product will not be directly exposed to light, therefore further studies are not needed.	IUCLID 3.4.2.1	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity	Case		Both biocidal products within family have been shown to be stable in a range of storage stability studies. Several of these studies were conducted at elevated temperatures, which was not shown to have an adverse effect on the products.	IUCLID 3.4.2.2	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material	Not stated	Vaprox 35%	The product was stored for 6 weeks at room temperature in 3 types of in-use reservoirs: 2L HDPE Reservoir polycarbonate tube assembly Reservoir T4 polycarbonate. An open container stability study was conducted on vaprox at ambient temperature for a period of 6 months. The room temperature data indicates that the colour, clarity and packaging appearance have not changed during the course of the study. Based on the stability data, this batch of Vaprox in the container/closure system complied with the required specification for 6 month stability at room temperature. The container did not change in appearance during the course of the study.	2009, Study SSP158B.00	Acceptable. In addition the accelerated and ambient storage stability studies do not show any adverse reactions with the container material for both 35% and 59% products.
Wettability	Case		In accordance with Annex IV of the BPR and the ECHA Guidance on the BPR, Volume I, Part A, wettability data is required for solid preparations which are dispersed in water. The products within the Vaprox product family are	IUCLID 3.5.1	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
			marketed as aqueous ready to use sterilants that are applied indoors and are developed specifically for Vaporized Hydrogen Peroxide (VHP) generators, therefore the determination of wettability is not applicable.		
Suspensibility, spontaneity and dispersion stability	Case		In accordance with Annex IV of the BPR and the ECHA Guidance on the BPR, Volume I, Part A, suspensibility, spontaneity and dispersion stability data is required for powders, granules and suspension concentrates. The products within the Vaprox product family are marketed as aqueous ready to use sterilants that are applied indoors and are developed specifically for Vaporized Hydrogen Peroxide (VHP) generators, therefore the determination of suspensibility, spontaneity and dispersion stability is not applicable.	IUCLID 3.5.2	Acceptable
Wet sieve analysis and dry sieve test	Case		In accordance with Annex IV of the BPR and the ECHA Guidance on the BPR, Volume I, Part A, wet sieve analysis and dry sieve test data is required for powders, granules and suspension concentrates. The products within the	IUCLID 3.5.3	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
			Vaprox product family are marketed as aqueous ready to use sterilants that are applied indoors and are developed specifically for Vaporized Hydrogen Peroxide (VHP) generators, therefore the determination of wet sieve analysis and dry sieve test is not applicable.		
Emulsifiability, re-emulsifiability and emulsion stability	Case		In accordance with Annex IV of the BPR and the ECHA Guidance on the BPR, Volume I, Part A, emulsifiability, re-emulsifiability and emulsion stability data is required for preparations that form emulsions. The products within the Vaprox product family are marketed as aqueous ready to use sterilants that are applied indoors and are developed specifically for Vaporized Hydrogen Peroxide (VHP) generators, therefore the determination of emulsifiability, re-emulsifiability and emulsion stability data is not applicable.	IUCLID 3.5.4	Acceptable.
Disintegration time	Case		In accordance with Annex IV of the BPR and the ECHA Guidance on the BPR, Volume I, Part A, disintegration time is applicable to all products that are tablets. The products	IUCLID 3.5.5	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
			within the Vaprox product family are marketed as aqueous ready to use sterilants that are applied indoors and are developed specifically for Vaporized Hydrogen Peroxide (VHP) generators therefore the determination of disintegration time is not applicable.		
Particle size distribution, content of dust/fines, attrition, friability	Case		In accordance with Annex IV of the BPR and the ECHA Guidance on the BPR, Volume I, Part A, particle size distribution, content of dust/ fines, attrition, friability is applicable to powder biocidal products and granules. The products within the Vaprox product family are marketed as aqueous ready to use sterilants that are applied indoors and are developed specifically for Vaporized Hydrogen Peroxide (VHP) generators, therefore the determination of particle size distribution, content of dust/ fines, attrition, friability is not applicable.	IUCLID 3.5.6	Acceptable
Persistent foaming	Case		In accordance with Annex IV of the BPR and the ECHA Guidance on the BPR, Volume I, Part A, persistent foaming is determined to measure the amount of foam likely to be	IUCLID 3.5.7	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
			present in a spray tank or other application equipment following dilution of the preparation. The products within the Vaprox product family are marketed as aqueous ready to use sterilant No co-fomulants with foaming properties are used in any of the products. Aqueous solutions of hydrogen peroxide do not form persistent foams. During operations such as product mixing, packaging filling, no significant foaming is observed. Therefore, the determination of persistent foaming is not applicable.		
Flowability/Pourability/ Dustability	Case		In accordance with Annex IV of the BPR and the ECHA Guidance on the BPR, Volume I, Part A, flowabilty/ pourability/ dustability is applicable to powders, granules, suspension concentrates, capsule suspensions and suspoemulsions. The products within the Vaprox product family are marketed as aqueous ready to use sterilants that are applied indoors and are developed specifically for Vaporized Hydrogen Peroxide (VHP) generators, therefore the	IUCLID 3.5.8	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
			determination of flowabilty/ pourability/ dustability is not applicable.		
Physical compatibility	Case		In accordance with the ECHA Guidance on the BPR, Volume I, Part A, data to address the physical and chemical compatibility must be provided when label recommendations are made to co-apply the biocidal product with other substances, mixtures or biocidal or non-biocidal products. The biocidal products are not intended or marketed to be used in conjunction with other substances, mixtures or biocidal or non-biocidal products. Therefore, determination of physical compatibility is not applicable.	IUCLID 3.6.1	Acceptable
Chemical compatibility	Case		The following incompatible materials have been listed upon the safety data sheet and include Cyanides, Strong acids, Strong alkalis, Strong oxidizers, Reducing agent, Organic materials, Readily oxidizible materials such as paper, wood, sulphur and aluminium. Alkali metals, Metals, Metal salts. Copper and its alloys, Hexavalent chromium compounds and Potassium permanganate. The	IUCLID 3.6.2	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
			products within the Vaprox biocidal product family are not intended or marketed to be used in conjunction with other substances, mixtures or biocidal or non-biocidal products and therefore these products should not come into contact with the incompatible materials previously listed.		
Surface tension	Method A5	Vaprox 59%	72.4 mN/m at 20 ºC of 1 g/L solution	Tremain S.P., 2016, Study CS67XV	Acceptable. Product is not considered to be surface active.
Viscosity	OECD Method 114 and CIPAC MT 22	Vaprox 59%	The kinematic viscosity of Vaprox 59% was found to be 0.95 mm^2/s at 20°C and 0.67 mm^2/s at 40°C. The dynamic viscosity of Vaprox 59% was found to be 1.16 mPa.s at 20°C and 0.82 mPa.s at 40°C.	Cage S., 2016, Study DY78PP	Acceptable. Product is not considered an aspiration hazard as it does not contain hydrocarbons.
	OECD Method 114 and CIPAC MT 22	Vaprox 35%	The kinematic viscosity of Vaprox 35% was found to be 0.97 mm^2/s at 20°C and 0.66 mm^2/s at 40°C. The dynamic viscosity of Vaprox 35% was found to be 1.09 mPa.s at 20°C and 0.75 mPa.s at 40°C.	Cage S., 2016, Study VY87PH	Acceptable. Product is not considered an aspiration hazard as it does not contain hydrocarbons.
Dilution stability	Case	-	The Vaprox biocidal family products are ready to use liquid, and the active hydrogen peroxide is in liquid form. No further tests are necessary.	-	Acceptable

Conclusion on the physical, chemical and technical properties of the product
The physical, chemical and technical properties of Vaprox 59% and Vaprox 35% are acceptable for an aqueous solution. The studies conducted on Vaprox 59% and 35% can be extrapolated between each other as Vaprox 35% is a simple dilution of Vaprox 59%, consequently the physical, chemical and technical properties of the BPF are acceptable. The accelerated storage data and ambient temperature data for 24 months have been provided for Vaprox 59% and 35% and are acceptable from a chemistry perspective. Therefore a shelf life of 2 years is supported.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
Explosives	Method A14	Vaprox 59%	The test item was not found to be explosive in accordance with BAM friction test.	Tremain S.P., 2016, Study CD67XV	Acceptable
Flammable liquids	Case		The active substance hydrogen peroxide is not flammable, but it can cause spontaneous combustion of flammable materials and continued support of the combustion because of liberation of oxygen as it decomposes. None of the components of the biocidal product evolves vapours in such amounts that a flammable air/vapour mixture is produced. Furthermore, there are no	IUCLID 4.6	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
			structural alerts for flammable liquids and it is an inorganic substance. The biocidal products are not considered to be flammable liquids under normal conditions of use or storage. Therefore, the flashpoint has not been determined and is not considered to be scientifically justified.		
Self-reactive substances and mixtures	Case		The active substance hydrogen peroxide does not contain any functional groups that are associated with explosive or chemical properties. Therefore further testing in relation to the endpoint 'self-reactive substances and mixtures' has not been determined and this endpoint is considered to be not applicable.	IUCLID 4.8	Acceptable
Pyrophoric liquids	Case		In accordance with Annex IV of the BPR and Regulation (EC) No 1272/2008, CLP, a pyrophoric liquid is a mixture which, even in small quantities, is liable to ignite within 5 minutes after coming into contact with air and the auto-ignition temperature is lower than	IUCLID 4.9	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
			room (ambient) temperature. Several studies have been conducted on the biocidal products, including a storage stability study conducted at ambient temperature, which demonstrate that the biocidal products do not spontaneously ignite in air. Therefore, the endpoint 'pyrophoric liquids' has not been determined and is not considered to be scientifically justified.		
Self-heating substances and mixtures	Case		In accordance with Annex IV of the BPR and Regulation (EC) No 1272/2008, CLP, a self-heating mixture is a mixture which, by reaction with air and without energy supply, is liable to self-heat. The test methods for determining self-heating substances and mixtures are not appropriate for liquids. The products within the Vaprox® Biocidal Product Family are marketed as aqueous ready to use sterilants that are applied indoors and are developed specifically for Vaporized Hydrogen Peroxide (VHP)	IUCLID 4.11	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
			generators, therefore the endpoint 'self-heating substances and mixtures' has not been determined as it is not applicable.		
Substances and mixtures which in contact with water emit flammable gases	Case		In accordance with Annex IV of the BPR and Regulation (EC) No 1272/2008, CLP, a mixture which in contact with water, emit flammable gases, is a mixture which, by interaction with water, is liable to become spontaneously flammable or to give off flammable gases in dangerous quantities. This classification need not be applied if the substance or mixture is known to be soluble in water to form a stable mixture. The biocidal products are marketed and used as stable aqueous solutions. Therefore the endpoint 'substances and mixtures which in contact with water emit flammable gases' has not been determined and is considered to be not applicable.	IUCLID 4.12	Acceptable
Oxidising liquids	EC Method A21 UN test O.2	Vaprox 35%	The mean pressure rise time for the 1:1 w/w mixture of 65% w/w aqueous nitric acid	Cage S., 2016, Study JP97VF	Vaprox 35% Product is not oxidising according to the study results. However,

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
			and cellulose was 6.3 seconds, whilst the mean pressure rise time for the test item mixtures (1:1 w/w mixture of the test item and cellulose) was 7.8 seconds. The product was found to be non-oxidising.		hydrogen peroxide is known to be an oxidiser which may accelerate fire. The Vaprox 59% products have been classified as an 'oxidiser H272- may intensify fire' due to the greater content of hydrogen peroxide in this product. According to UN Recommendations on the Transport of Dangerous Goods (Vol.1, 20th rev. ed. 2017) Hydrogen peroxide is classified in Class 5.1, UN packing group II with UN number 2014 as "HYDROGEN PEROXIDE, AQUEOUS SOLUTION with not less than 20% but not more than 60% hydrogen peroxide (stabilized as necessary)". Therefore the following classification should apply to the biocidal product family: Oxidising liquid, Category 2.
Organic peroxides	Case		An organic peroxide is a carbon-containing compound which contains the -O-O- peroxy group in their molecular structure. The active substance of the biocidal products is hydrogen peroxide, however	IUCLID 4.15	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
			this substance does not contain carbon atoms and so does not meet the definition of an organic peroxide. Therefore the endpoint 'organic peroxides' has not been determined as it is not applicable.		
Corrosive to metals	UN manual test 37.4	Vaprox 59%	Hydrogen peroxide (59%) is not corrosive to metal. For both aluminium and steel, mass losses were negligible and no localised corrosion was observed.	Tremain S. P., 2016, Study CD67XV	Acceptable
Auto-ignition temperatures of products (liquids and gases)	EC method A15	Vaprox 59%	Hydrogen peroxide (59%) does not have an auto-ignition temperature < 650 °C.	Tremain S. P., 2016, Study CD67XV	Acceptable

Conclusion on the physical hazards and respective characteristics of the product
Vaprox 35% in the BPF contain no products classified as explosive or flammable therefore a non-classification of the BPF is acceptable from a chemistry perspective. However Vaprox 59% have been classified as an ‘oxidiser H272- may intensify fire’ due to the greater content of hydrogen peroxide in this product. In addition, based on existing information on the active substance (UN Recommendations on the Transport of Dangerous Goods) the following classification should apply to the biocidal product family: Oxidising liquid, Category 2.

2.2.4 Methods for detection and identification

Analytical methods for the active and impurities in the technical material

The source of the active substances are the same as those considered for active substance approval, therefore methods of analysis for the active substance and impurities have already been considered. No further consideration is required from a chemistry perspective.

Analytical methods for the active substance in the biocidal product

Report: Determination of Hydrogen Peroxide in Vaprox hydrogen peroxide sterilant, Thanavaro A., 2014, Study 10038.00.
Determination of hydrogen peroxide in Vaprox 59 hydrogen peroxide sterilant, Thanavaro A., 2013, Study 10034.00

Approximately 0.3 - 0.4 g of the sample was titrated with approximately 40 mL of potassium permanganate to determine hydrogen peroxide content.

The following equation was used to calculate the weight% H2O2
% H2O2 = (EP1 x 1.701) / (sample weight in g) x NKMnO4

EP1= Equivalence point
1.701 = molecular weight conversion factor
NKMnO4 = the normality of permanganate solution

The method for determining hydrogen peroxide content by potassium permanganate titration is a standardised CIPAC method (RE 56). Therefore further validation data is not required.

Analytical methods for the monitoring of residues (soil, water, air, body fluids and tissues and food)

Methods of analysis for the determination of hydrogen peroxide residues in air, soil and water have previously been evaluated active substance approval. The applicant has adequate letters of access to this data. Methods for detection in body fluids and tissues are not required as the active substance is not considered toxic. Methods for detection in food/feed of plant and animal origin are not available due to lack of exposure via the intended uses. Therefore, concerning product authorisation no further consideration is required from a chemistry perspective.

Conclusion on the methods for detection and identification of the product
The analytical method for the detection of hydrogen peroxide in the biocidal products is based on a CIPAC method and is acceptable. The monitoring method for soil, air and water have previously been evaluated at active substance approval. The monitoring methods for body fluids, food/feed of plant and animal origin are not relevant for the Vaprox® Biocidal Product Family.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The Vaprox® Biocidal Product Family are PT 2 disinfectant products intended for professional indoor use. The active substance is hydrogen peroxide (vapour) is applied at a concentration of 300 ppm. The products are intended for the disinfection of non-porous

surfaces, materials, equipment and furniture in dry, sealed pre-cleaned enclosures in industrial, commercial and institutional settings.

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

The products are intended to control bacteria, fungi, bacterial spores, viruses and mycobacteria.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Hydrogen peroxide causes irreversible damage to cellular components such as enzymes, membrane constituents and DNA which leads to cell death.

There are 2 products in the Biocide Product family, one containing 35 % w/w active substance and the other containing 59 % w/w active substance. As the data have been generated using the product with less active substance, this can be considered worst case and therefore supportive of the efficacy of both products. Furthermore, as the application rate is based on the active substance rather than the product, there is unlikely to be a substantial difference between the two products.

Applications should be made to sealed, dry, pre-cleaned enclosures. When a 300 ppm hydrogen peroxide concentration is achieved, the application phase should be initiated and this concentration should be maintained for 3 hours (against bacteria, bacterial spores, viruses and mycobacteria) or for 6 hours (against fungi). Only 1 application is required to control the present populations of bacteria, fungi, bacterial spores, viruses and mycobacteria.

The Vaprox Hydrogen Peroxide (VHP) generator should be programmed to initiate a dehumidification phase to achieve <70% relative humidity prior to the treatment. The ambient temperature should not be less than 21ºC throughout the process. All drawers, closets and cabinet doors etc. should be opened prior to the treatment to permit exposure to the hydrogen peroxide.

Hydrogen peroxide monitors should be placed in a location most difficult for the target concentration to be reached in the treatment enclosure e.g. in a corner of the enclosure farthest away from the VHP generation unit. Chemical indicators should be placed throughout the enclosure to verify effective distribution of hydrogen peroxide and oscillating fans should be placed throughout the enclosure to facilitate effective distribution of the hydrogen peroxide.

Mode of action, including time delay:

The applicant has provided the following statement on the mode of action:

'The antimicrobial action of hydrogen peroxide stems from its ability to form powerful oxidants such as the hydroxyl radical and singlet oxygen. These reactive oxygen species cause irreversible damage to cellular components such as enzymes, membrane constituents and DNA.'

The UK CA accepts the applicant's statement on the mode of action.

2.2.5.4 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)					
Function and field of use envisaged	Test substance	Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference
Disinfection of surfaces, materials, equipment and furniture in dry, sealed pre-cleaned enclosures in industrial, commercial and institutional settings.	Vaprox 35 %	Bacteria (*Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae*)	The EN 1276 standard protocol was followed. Phase 2, Step 1 test. Contact time: 5 minutes. Test temperature: 20ºC ± 1ºC. Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. Concentrations tested: 0.01 %, 0.3 % and 80 %.	For all of the test organisms, a reduction greater than 5 log reduction (the pass criterion for the standard) was observed with the 80 % concentration. The test failed at 0.3 % and 0.01 % with lower than 5 log reductions observed for each target organism. This indicates that these concentrations, when tested in suspension, do not possess sufficient bactericidal activity within a 5 minute contact time.	Esteban (2014) Reference No.: D/14/109
		Bacteria (*Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae*)	The EN 1276 standard protocol was followed. Phase 2, Step 1 test. Contact time: 5 minutes. Test temperature: 20ºC ± 1ºC. Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. Concentrations tested: 50 %, 75 % and 100 %	For all of the test organisms, a reduction greater than 5 log reduction (the pass criterion for the standard) was observed with the 50 %, 75 % and 100 % concentrations.	Novella (2010a) Reference No.: M-10-166695
		Fungi (*Aspergillus brasiliensis*); Yeast (*Candida albicans*)	The EN 1650 standard protocol was followed. Phase 2, Step 1 test. Contact time: 15 minutes. Test temperature: 20ºC ± 1ºC.	For all of the test organisms, a reduction greater than 4 log reduction (the pass criterion for the standard) was observed with the 80 % concentration. The test failed at 0.3 % and 0.01 % with lower than 4 log reductions observed for each target organism. This indicates that these concentrations, when tested in	Esteban (2015a) Reference No.: D/14/110

			Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. Concentrations tested: 0.01 %, 0.3 % and 80 %.	suspension, do not possess sufficient fungicidal or yeasticidal activity within a 15 minute contact time.	
		Fungi (*Aspergillus niger*); Yeast (*Candida albicans*)	The EN 1650 standard protocol was followed. Phase 2, Step 1 test. Contact time: 15 minutes. Test temperature: 20ºC ± 1ºC. Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. Concentrations tested: 50 %, 75 % and 100 %	For all of the test organisms, a reduction greater than 4 log reduction (the pass criterion for the standard) was observed with the 50 %, 75 % and 100 % concentrations.	Novella (2010b) Reference No.: M-10-166696
		Viruses (*Poliovirus* type 1, *Adenovirus* type 5, *Murine Norovirus*)	The EN 14476 standard protocol was followed. Phase 2, Step 1 test. Contact time: 5 and 60 minutes. Test temperature: 20ºC ± 1ºC. Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. Concentrations tested: 0.01 %, 25 %, 50 % and 80 %.	For all of the targets, a reduction greater than 4 log reduction (the pass criterion for the standard) was observed with the 25 %, 50 % and 80 % concentration at both 5 and 60 minute contact times. The test failed at 0.01 % with lower than 4 log reductions observed for each target. This indicates that this concentration, when tested in suspension, does not possess sufficient virucidal activity within a 5 or 60 minute contact time.	Esteban (2015b) Reference No.: D/15/45
		Bacterial spores (*Bacillus subtilis*)	The EN 13704 standard protocol was followed. Phase 2, Step 1 test. Contact time: 60 minutes. Test temperature: 20ºC ± 1ºC. Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. Concentrations tested: 0.01 %, 0.3 % and 80 %.	A reduction greater than 3 log reduction (the pass criterion for the standard) was observed with the 80 % concentration. The test failed at 0.3 % and 0.01 % with lower than 3 log reductions observed for each target organism. This indicates that these concentrations, when tested in suspension, do not possess sufficient sporicidal activity within a 60 minute contact time.	Esteban (2015b) Reference No.: D/14/111

		Bacterial spores (*Bacillus subtilis*)	The EN 13704 standard protocol was followed. Phase 2, Step 1 test. Contact time: 60 minutes. Test temperature: 20ºC ± 1ºC. Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. Concentrations tested: 50 %, 75 % and 100 %	A reduction greater than 3 log reduction (the pass criterion for the standard) was observed with the 50 %, 75 % and 100 % concentrations.	Novella (2010c) Reference No.: M-10-166697
		Bacteria (*Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae*); Yeast (*Candida albicans*); Fungi (*Aspergillus brasiliensis*); Spores (*Bacillus subtilis*); Viruses (*Adenovirus type 5, Murine Norovirus*)	The NF T 72-281:2014 method for airborne surface disinfection was followed. Semi-field trial approaching real-world practice. Exposure time: 3 hours for bacteria, bacterial spores and viruses; 6 hours for fungi and yeast. Test temperature: 20ºC ± 2ºC. Humidity: between 40 and 80 %. Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) for the virus tests; skimmed milk powder diluted 1/20 for bacteria, fungi, mycobacteria and spore tests. These both represent clean conditions. Test concentration: 300 ppm hydrogen peroxide. Room size: 67 m^3 for bacteria, fungi, mycobacteria and spore tests. 51.7 m^3 for viruses. Distance between disinfection process and test object: 3.6m for bacteria, fungi, mycobacteria and spore tests. 3.3 m for viruses.	The log reduction efficacy thresholds required are as follows: >5 for bacteria >4 for fungi and yeast >3 for spores >4 for viruses The log reductions demonstrated in the test were as follows: *Pseudomonas aeruginosa*: 6.2 *Escherichia coli*: 6.2 *Staphylococcus aureus*: 6.4 *Enterococcus hirae*: 6.6 *Candida albicans*: 5.7 *Aspergillus brasiliensis*: 4.8 *Bacillus subtilis*: 4.1 *Adenovirus type 5*: 4.6 *Murine Norovirus*: 4.3 Therefore, a log reduction greater than the pass criterion required for the standard has been demonstrated for all of the tested strains.	AH-DIP (2016) Reference No.: 2556.STE.15.BGm1

		Mycobacteria (*Mycobacterium terrae*)	The NF T 72-281:2014 method for airborne surface disinfection was followed. Semi-field trial simulating real-world practice. Exposure time: 3 hours Test temperature: 20ºC ± 2ºC. Humidity: between 40 and 80 %. Interfering substance: skimmed milk powder diluted 1/20 to represent clean conditions. Test concentration: 300 ppm hydrogen peroxide. Room size: 67 m^3 Distance between disinfection process and test object: 3.6m	The log reduction demonstrated in the test was 5.7. Therefore, a reduction greater than 4 log reduction (the pass criterion for the standard) was observed.	Bancod (2016) Reference No.: 2556.STE.15.2m.GB

Conclusion on the efficacy of the product

The products claim the following:

- 'VAPROX hydrogen peroxide is an aqueous solution ready to use and may be applied to dry, sealed pre-cleaned enclosures in industrial, commercial and institutional settings.'
- 'Application to Sealed, Dry Precleaned Enclosures at 300 ppm H_2O_2 for 3 hours (against bacteria, bacterial spores, viruses and mycobacteria) or for 6 hours (against fungi)'
- The following table of claims appears on one of the product labels:

Efficacy test Standard	Organism	Conditions
Bactericidal test NF T 72-281:2014	*Enterococcus hirae* CIP 58.55, *Escherichia coli* CIP 58.55, *Pseudomonas aeuruginosa* CIP 103467 and *Staphylococcus aureus* CIP 4.83	The combination VHP Application Equipment/ Vaprox demonstrates a bactericidal activity for a quantity of 300 ppm of hydrogen peroxide and after the sequence of operations of the process of the apparatus VHP Application Equipment after 3 hours contact time.
Fungicidal test NF T 72-281:2014	*Candida albicans* CBS 6431 and *Aspergillus brasilienssis* CBS 788.33 spores	The combination VHP Application Equipment/ Vaprox demonstrates a fungicidal activity for a quantity of 300 ppm of hydrogen peroxide and after the sequence of operations of the process of the apparatus VHP Application Equipment after 6 hours contact time.
Sporicidal test NF T 72-281:2014	*Bacillus subtilis* CIP 52.62 spores	The combination VHP Application Equipment/ Vaprox demonstrates a sporicidal activity for a quantity of 300 ppm of hydrogen peroxide and after the sequence of operations of the process of the apparatus VHP Application Equipment after 3 hours contact time.
Virucidal NF T 72-281:2014	Adenovirus type5/ HELLA and Murine Norovirus S99/RAW264.7	The combination VHP Application Equipment/ Vaprox demonstrates a sporicidal activity for a quantity of 300 ppm of

		hydrogen peroxide and after the sequence of operations of the process of the apparatus VHP Application Equipment after 3 hours contact time.
Tuberculocidal NF T 72-281:2014	*Mycobacterium terrae* CIP 104321	The combination VHP Application Equipment/ Vaprox demonstrates a sporicidal activity for a quantity of 300 ppm of hydrogen peroxide and after the sequence of operations of the process of the apparatus VHP Application Equipment after 3 hours contact time.

According to the TNsG, for room disinfection with a vaporised biocide the following data are normally required:

- when applicable, a quantitative suspension test (phase 2, step 1);
- semi-field trial such as European standard based on NF T 72-281 (EN standard in preparation) for disinfection using airborne application (phase 2, step 2).

The TNsG also states the following:

'*The CEN phase 2, step 1 tests are suitable as suspension tests under clean or dirty conditions, although only applicable for products that can be tested in suspension (e.g. not for gasses). These tests are not sufficient on their own, and should be combined with a semi-field trial for disinfection using airborne application. Where it is not possible to test the product in a suspension test, the semi-field trial will be sufficient*.'

The applicant has submitted both of the required data stated above. However, both the applicant and the UK CA consider that the Phase 2 Step 1 (suspension) tests are not relevant for the Vaprox® Biocidal Product Family as the active substance, hydrogen peroxide, is used as a vapour when using the product. Therefore, in accordance with the TNsG as stated above, the semi-field trials based on NF T 72-281 will be sufficient to demonstrate the efficacy of the product.

The applicant has submitted Phase 2 Step 1 studies according to the appropriate EN standards; however, the test concentrations, the tested contact times and the fact that these are suspension tests make these studies not relevant to the application rate and use of Vaprox® Biocidal Product Family. These studies can therefore only be considered to be supporting information demonstrating whether the product has an effect on the targets. As a result, the UK CA will rely on the tests conducted in accordance with NF T 72-281:2014 when evaluating the efficacy of the product.

The strains tested are named differently to those stated in the TNsG; however, the applicant has since clarified that these are the same strains but from a different culture collection. The UK CA therefore considers the use of these strains to be acceptable.

<u>Efficacy against bacteria</u>

Two Phase 2 step 1 tests against bacteria were conducted according to EN 1276 using the test product. These tests demonstrated greater than 5 log reductions against all of the bacteria species tested. However, as mentioned above, the test concentrations, the tested contact times and the fact that these are suspension tests make these studies not relevant to the application rate and use of Vaprox® Biocidal Product Family. The UK CA considers that the only conclusion that can be drawn from these studies is that hydrogen peroxide can have a bactericidal effect.

A test against bacteria was conducted according to NF T 72-281:2014 using the test product. This test demonstrated greater than 5 log reductions against all of the bacteria species tested, with a concentration of 300 ppm hydrogen peroxide and an exposure time of 3 hours. Therefore, UK CA considers that the test results are sufficient to support the efficacy of the product against bacteria.

Efficacy against fungi and yeast

Two Phase 2 step 1 tests against fungi and yeast were conducted according to EN 1650 using the test product. These tests demonstrated greater than 4 log reductions against the fungi and yeast species tested. However, as mentioned above, the test concentrations, the tested contact times and the fact that these are suspension tests make these studies not relevant to the application rate and use of Vaprox® Biocidal Product Family. The UK CA considers that the only conclusion that can be drawn from these studies is that hydrogen peroxide can have a fungicidal and yeasticidal effect.

A test against fungi and yeast was conducted according to NF T 72-281:2014 using the test product. This test demonstrated greater than 4 log reductions against the fungi and yeast species tested, with a concentration of 300 ppm hydrogen peroxide and an exposure time of 6 hours. Therefore, UK CA considers that the test results are sufficient to support the efficacy of the product against fungi and yeast.

Efficacy against spores

Two Phase 2 step 1 tests against bacterial spores were conducted according to EN 13704 using the test product. These tests demonstrated greater than 3 log reductions against the bacterial spores tested. However, as mentioned above, the test concentrations, the tested contact times and the fact that these are suspension tests make these studies not relevant to the application rate and use of Vaprox® Biocidal Product Family. The UK CA considers that the only conclusion that can be drawn from these studies is that hydrogen peroxide can have a sporicidal effect.

A test against bacterial spores was conducted according to NF T 72-281:2014 using the test product. This test demonstrated greater than 3 log reduction against the bacterial spores tested, with a concentration of 300 ppm hydrogen peroxide and an exposure time of 3 hours. Therefore, UK CA considers that the test results are sufficient to support the efficacy of the product against bacterial spores.

Efficacy against viruses

One Phase 2 step 1 test against viruses was conducted according to EN 14476 using the test product. This test demonstrated greater than 4 log reductions against all of the

viruses tested. However, as mentioned above, the test concentrations, the tested contact times and the fact that these are suspension tests make these studies not relevant to the application rate and use of Vaprox® Biocidal Product Family. The UK CA considers that the only conclusion that can be drawn from this study is that hydrogen peroxide can have a virucidal effect.

A test against viruses was conducted according to NF T 72-281:2014 using the test product. This test demonstrated greater than 4 log reductions against both of the viruses tested, with a concentration of 300 ppm hydrogen peroxide and an exposure time of 3 hours. Therefore, UK CA considers that the test results are sufficient to support the efficacy of the product against viruses.

NF T 72-281:2014 does state under section 5.2.1. that *Bovine enterovirus* should also be tested to support virucidal claims. However, this method clarifies in Annex D that testing against this virus is only required for claims of use in the veterinary industry. As the Vaprox® Biocidal Product Family are not claimed for use in the veterinary industry, testing against this virus is not required.

The TNsG stipulates Polio virus type 1 as a required test virus. This virus has not been used in the NF T 72-281 testing carried out in this study. However, the applicant has provided a statement explaining this, as follows.

'*According to the Technical Notes for Guidance (TNsG) for PT 1-5, the recommended phase 2 step 2 method is the NFT72-281. The same method is carried out for bactericidal, fungicidal, tuberculocidal, sporicidal and virucidal claims. According to the methodology, in order to have virucidal claims, the test is carried out on Murine Norovirus and Adenovirus. Poliovirus is not included in the test because it does not survive desiccation, as stated in section 4 of the EN16777. Therefore, it is not possible to include this specific microorganism as part of a phase 2 step 2 study.*'

The UK CA accepts the applicant's statement and thus does not consider the absence of Polio virus type 1 to be an issue. The applicant has, in any case, provided phase 2, step 1 data on Polio virus type 1, which shows the innate efficacy of the Vaprox product containing 35 % w/w active substance against this virus.

Efficacy against mycobacteria

A test against mycobacteria was conducted according to NF T 72-281:2014 using the test product. This test demonstrated a greater than 4 log reduction against the mycobacteria species tested, with a concentration of 300 ppm hydrogen peroxide and an exposure time of 3 hours.

This semi-field test only tested *Mycobacterium terrae* and can therefore only be used to support a tuberculocidal claim and not a claim against all mycobacteria. However, during the commenting stage of this application, the applicant chose to remove all tuberculocidal/mycobactericidal claims, as they have not submitted a phase 2 step 1 suspension test against mycobacteria.

Decision

The UK CA concludes that sufficient data have been provided to verify the outcome and conclusion, and permit the authorisation of the Vaprox® Biocidal Product Family.

The applicant has provided sufficient data to demonstrate that the product is efficacious at the requested application rate of hydrogen peroxide at 300 ppm with an exposure

time of 3 hours for bacteria, bacterial spores and viruses and 6 hours for yeast and fungi.

2.2.5.5 Occurrence of resistance and resistance management

The applicant has provided the following statement in relation to the occurrence of resistance and resistance management:

'*The lethal effects of oxidative molecular species generated from hydrogen peroxide can be avoided with any damage being repaired in microorganisms such as Escherichia coli and Salmonella typhimurium. When E.coli and S. typhimurium are exposed to low concentrations of H_2O_2, 3 µM and 60 µM respectively, cells produce enzymes and other proteins which are important for cellular defence and mitigate the toxic effects of the oxidative species. This adaptive response is triggered by nontoxic levels of the oxidative species to protect against and produce resistance to oxidative stress caused when challenged with higher concentrations, 10 mM (Dukan and Touati (1996), Christman et al (1985)). The resistance to oxidative stress that E.coli develops when exposed to H_20_2, as reported in literature papers, demonstrates an adaptive response only.*

The following information has been taken from the case insert of the product. Vaprox may be used in validated custom application cycles. The custom cycle developed for the treatment enclosure must be capable of consistently achieving the desired log reduction in the number of Geobacillus stearothermophilus ATCC 7953 spores inoculated on biological indicator substrates. The Vaprox effectiveness for applications must be validated using Biological Indicators (BIs) containing Geobacillus stearothermophilus spores. This organism has been shown to be the most hydrogen peroxide resistant organism.

Hydrogen peroxide has been intensively used as a disinfectant and preservative for more than three decades and has not lead to the development of significant resistance levels among field populations. Genetically inherited resistance is not expected when the products are used as recommended.'

The UK CA accepts that there is no significant risk of the development of resistance for this active substance and products when they are used as recommended, however, if the applicant becomes aware of any reports of resistance to the active substance hydrogen peroxide and/or the product these should be reported to appropriate bodies (such as the efficacy working group and/or concerned member states) so that it can be determined if further action is required.

2.2.5.6 Known limitations

There are no known limitations and no undesirable or unintended side effects have been observed.

2.2.5.7 Evaluation of the label claims

The UK CA considers that the following requested label claims have been supported:

- 'VAPROX hydrogen peroxide is an aqueous solution ready to use and may be applied to dry, sealed pre-cleaned enclosures in industrial, commercial and institutional settings.'

- 'Application to Sealed, Dry Precleaned Enclosures at 300 ppm hydrogen peroxide for 3 hours (against bacteria, bacterial spores and viruses or for 6 hours (against yeast and fungi)'

The table below shows the efficacy claims which will be made on the label of the product.

Efficacy test Standard	Organism	Conditions
Bactericidal test NF T 72-281:2014	*Enterococcus hirae* CIP 58.55, *Escherichia coli* CIP 58.55, *Pseudomonas aeuruginosa* CIP 103467 and *Staphylococcus aureus* CIP 4.83	The combination VHP Application Equipment/ Vaprox demonstrates a bactericidal activity for a quantity of 300 ppm of hydrogen peroxide and after the sequence of operations of the process of the apparatus VHP Application Equipment after 3 hours contact time.
Yeasticidal test NF T 72-281:2014	*Candida albicans* CBS 6431	The combination VHP Application Equipment/ Vaprox demonstrates a yeasticidal activity for a quantity of 300 ppm of hydrogen peroxide and after the sequence of operations of the process of the apparatus VHP Application Equipment after 6 hours contact time.
Fungicidal test NF T 72-281:2014	*Aspergillus brasilienssis* CBS 788.33 spores	The combination VHP Application Equipment/ Vaprox demonstrates a fungicidal activity for a quantity of 300 ppm of hydrogen peroxide and after the sequence of operations of the process of the apparatus VHP Application Equipment after 6 hours contact time.
Sporicidal test NF T 72-281:2014	*Bacillus subtilis* CIP 52.62 spores	The combination VHP Application Equipment/ Vaprox demonstrates a sporicidal activity for a quantity of 300 ppm of hydrogen peroxide and after the sequence of operations of the process of the apparatus VHP Application Equipment after 3 hours contact time.
Virucidal NF T 72-281:2014	Adenovirus type5/ HELLA and Murine Norovirus S99/RAW264.7	The combination VHP Application Equipment/ Vaprox demonstrates a sporicidal activity for a

		quantity of 300 ppm of hydrogen peroxide and after the sequence of operations of the process of the apparatus VHP Application Equipment after 3 hours contact time.

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

The products within the Vaprox® Biocidal Product Family are not intended or marketed to be used in conjunction with other substances, mixtures or biocidal or non-biocidal products.

2.2.6 Risk Assessment for Human Health

2.2.6.1 Assessment of effects on Human Health

The potential human health effects of the hydrogen peroxide stabalisers are discussed in the confidential Annex.

Skin corrosion and irritation

The Vaprox® Biocidal Product Family has not been tested either *in vivo* or *in vitro*. Instead, 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	Vaprox® Hydrogen Peroxide Sterilant: Skin irritation category 2 Vaprox® 59 Hydrogen Peroxide Sterilant: Skin corrosive 1B
Justification for the value/conclusion	Hydrogen peroxide (the active substance) is classified as category 1A for skin corrosion. The following SCLs are applicable: • Skin irrit 2 for 35 % ≤ C < 50 % • Skin corr 1B for 50% ≤C<70% • Skin corr 1A C≥ 70% Some stabalisers are classified for skin irritation/corrosivity, however; however, they are not present at concentrations which would change the proposed classification Vaprox® Hydrogen Peroxide Sterilant contains 35% hydrogen peroxide. This is below the SCL indicating classification as skin corrosive 1B. During the review of hydrogen peroxide, 35 % hydrogen peroxide was found to cause slight to moderate reversible erythema and oedema with irreversible desquamation when tested in a skin irritation study. Under CLP this triggers a classification of skin irritation category 2 (H315: Causes skin irritation). Vaprox® 59 Hydrogen Peroxide Sterilant contains 59% of hydrogen peroxide. This falls within the concentration range for classification as skin corrosive 1B.
Classification of the product according to CLP	Vaprox® Hydrogen Peroxide Sterilant: skin irritation category 2 with H315: Causes skin irritation. Vaprox® 59 Hydrogen Peroxide Sterilant: Skin corrosive 1B with H314 Causes severe skin burns and eye damage.

Data waiving	
Information requirement	Skin irritation/corrosion

Justification	Classification can be determined from the available toxicological information on the active substance and co-formulants.

Eye irritation

The Vaprox Biocidal Product Family has not been tested either *in vivo* or *in vitro*. Instead, 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	Vaprox® Hydrogen Peroxide Sterilant: Eye damage 1 Vaprox® 59 Hydrogen Peroxide Sterilant Skin corrosive 1B
Justification for the value/conclusion	Hydrogen peroxide (the active substance) is classified as category 1A for skin corrosion. The following SCLs are applicable for eye effects: • Skin corr 1B for 50% ≤ C <70% • Eye damage 1 for 8% ≤ C <50% • Eye irritant 2 for 5% ≤ C <8% No other components in the products are classified for skin irritation/corrosion. Vaprox® Hydrogen Peroxide Sterilant contains 35% hydrogen peroxide. This falls within the concentration range for classification as Eye damage 1. Vaprox® 59 Hydrogen Peroxide Sterilant contains 59% of hydrogen peroxide. This falls within the concentration range for classification as Skin corrosive 1B. As the product is already classified as skin corrosive no further classification is required.
Classification of the product according to CLP	Vaprox® Hydrogen Peroxide Sterilant Eye damage 1 with H318. Vaprox® 59 Hydrogen Peroxide Sterilant: No further classification is requied for eye irritancy as this is already covered by the classification for skin corrosion.

Data waiving	
Information requirement	Eye irritation
Justification	Classification can be determined from the available toxicological information on the active substance and co-formulants.

Respiratory tract irritation

The Vaprox® Biocidal Product Family has not been tested. Furthermore there is no specific test for respiratory irritation. Instead, classification of the products is addressed using available data on the individual components of the respective formulations.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Hydrogen peroxide has an SCL of ≥35% for triggering classification as STOT-SE3. Both Vaprox® Hydrogen Peroxide Sterilant and Vaprox® 59 Hydrogen Peroxide Sterilant contain hydrogen peroxide at a concentration in excess of 35% and therefore will be classified as STOT SE3.
Classification of the product according to CLP	STOT SE 3; H335: May cause respiratory irritation.

Data waiving	
Information requirement	Respiratory tract irritation
Justification	Classification can be determined from the available toxicological information on the active substance and co-formulants.

Skin sensitization

The Vaprox® Biocidal Product Family has not been tested either *in vivo* or *in vitro*. Instead, 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 sensitising
Justification for the value/conclusion	Hydrogen peroxide (the active substance) is not classified as a skin sensitiser. No other components in the products are classified as skin sensitisers. Therefore the product does not meet the criteria for classification for skin sensitisation according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified.

Data waiving	
Information requirement	Skin sensitisation
Justification	Classification can be determined from the available toxicological information on the active substance and co-formulants.

Respiratory sensitization (ADS)

There is no study to address respiratory sensitisation. Instead, the classification of the Vaprox® Biocidal Product Family 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 a respiratory sensitiser.
Justification for the value/conclusion	None of the components are classified for this endpoint.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Respiratory sensitisation.
Justification	Classification can be determined from the available toxicological information on the active substance and co-formulants. Furthermore there is no specific test to address this endpoint.

Acute toxicity

Acute toxicity by oral route

There are no studies with the Vaprox® Biocidal Product Family addressing this endpoint. Instead, 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	Category 4 (both products)
Justification for the selected value	Based on the data evaluated during the review of hydrogen peroxide (the active substance) it was found to be acutely toxic via the oral route and is classified as category 4 for acute oral toxicity. The assessment report includes information relating to several acute oral toxicity studies reporting. LD_{50} values for concentrations from 35 % to 70 % in the range of 694-1270 mg/kg bw. When corrected for 100% purity this gave LD_{50} values of around 500 mg/kg bw (As 100% 486 and 420 mg/kg bw for females and males, respectively). Hydrogen peroxide is classified therefore as category 4 for acute oral toxicity. No other co-formulants are classified for acute oral toxicity. One stabaliser is classified for acute oral toxicity, however; however, it is not present at a concentration which would change the proposed classification. Based on the concentration of hydrogen peroxide in the formulation the ATE for the products is calculated to be in the range of 700-1400 mg/kg bw. On this basis the Vaprox products are classified as acute tox 4.
Classification of the product according to CLP	Classification according to Regulation (EC) No 1272/2008: Acute Tox. 4 H302 Harmful if swallowed.

Data waiving	
Information requirement	Acute oral toxicity
Justification	Classification can be determined from the available toxicological information on the active substance and co-formulants.

Acute toxicity by inhalation

There are no studies with the Vaprox® Biocidal Product Family addressing this endpoint. Instead, 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	Vaprox® Hydrogen Peroxide Sterilant: not acutely toxic *via* the inhalation route. Vaprox® 59 Hydrogen Peroxide Sterilant: acutely toxic (cat 4) *via* the inhalation route
Justification for the selected value	Hydrogen peroxide is classified as acutely toxic *via* the inhalation route. No other co-formulants are classified for acute inhalation toxicity. Using the converted acute toxicity point estimate for vapours according to the Guidance on the application of the CLP criteria and the calculation method: • Vaprox® Hydrogen Peroxide Sterilant does not meet the criteria for classification for actue inhalation toxicity according to Regulation (EC) No 1272/2008. • Vaprox® 59 Hydrogen Peroxide Sterilant meets the criteria for classification for actue inhalation toxicity (cat 4) according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Vaprox® Hydrogen Peroxide Sterilant: Not classified Vaprox® 59 Hydrogen Peroxide Sterilant: Acute tox 4 (H332)

Data waiving	
Information requirement	Acute inhalation toxicity
Justification	Classification can be determined from the available toxicological information on the active substance and co-formulants.

Acute toxicity by dermal route

There are no studies with the Vaprox® Biocidal Product Family addressing this endpoint. Instead, 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 via the dermal route
Justification for the selected value	Hydrogen peroxide is not classified for acute dermal toxicity. No other component in the product is classified for acute dermal toxicity. Therefore the product does not meet the criteria for classification for acute dermal toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified

Data waiving

Information requirement	Acute dermal toxicity
Justification	Classification can be determined from the available toxicological information on the active substance and co-formulants.

Information on dermal absorption

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

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

Data waiving	
Information requirement	Dermal absorption
Justification	Default value of 100% applied. No study needed.

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

The Vaprox® Biocidal Product Family contains no substances of concern (see confidential annex for further details).

Available toxicological data relating to a mixture

Available toxicological data relating to a mixture that a substance(s) of concern is a component of:

Not relevant since the Vaprox® Biocidal Product Family do not contain any substance(s) of concern.

Other

The products within the Vaprox® Biocidal Product Family belong to PT2 and are based on a formulation of 35% w/w or 59% w/w active substance, hydrogen peroxide. These biocidal products are marketed as aqueous ready to use sterilants that are applied indoors and are developed specifically for Vaporized Hydrogen Peroxide (VHP) generators. The process occurs within a sealed enclosure meaning that exposure is unlikely. For this reason the products within the Vaprox® Biocidal Product Family are not expected to come into contact with food and feeding stuffs, therefore no further data has been generated on

- food and feeding stuffs studies,
- effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product
- and other test(s) related to the exposure to humans.

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

Vaprox® Biocidal Product Family are intended to be used by professionals to decontaminate dry surfaces in sealed pre-cleaned enclosures in industrial, commercial and institutional settings (e.g. laboratory equipment, hospital rooms, emergency vehicles etc.). There are 2 liquid vaporizer formulations within the Vaprox® Biocidal Product Family; 'Vaprox Hydrogen Peroxide Sterilant' containing 35% w/w hydrogen peroxide and 'Vaprox 59 Hydrogen Peroxide Sterilant' containing 59% w/w hydrogen peroxide.

Vaprox products are applied using a vaporized hydrogen peroxide unit (hereafter referred to as a VHP unit). The VHP units proposed by the applicant to apply Vaprox products operate with an internal sterilant reservoir which can be loaded by cartridges of up to 950 mL aqueous solution of hydrogen peroxide or by external supply using bulk units. The product is supplied in 29-141 mL cups, 950 mL cartridges and 18.9 L or 200.6 L drums.

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

List of scenarios

Summary table: scenarios			
Scenario number	Scenario (e.g. mixing/ loading)	Primary or secondary exposure Description of scenario	Exposed group (e.g. professionals, non-professionals, bystanders)
1.	Surface disinfection through the vaporised hydrogen peroxide (VHP) process	Primary exposure during application of Vaprox products using a VHP machine	Professionals
2.	Draining/disposal of expired product	Primary exposure during the draining and disposal of expired product from the VHP unit	Professionals
3.	Cleaning of the delivery hose	Primary exposure when cleaning the delivery hoses	Professionals
4.	Re-entering the treated post application	Secondary exposure when re-entering the treated area after application	Bystanders (general public)

Industrial exposure

The Vaprox® Biocidal Product Family is not intended for use by industrial users.

Professional exposure

Scenario 1 – Application of the Vaprox® Biocidal Product Family using a VHP machine

Description of Scenario 1
The products are supplied as an aqueous ready-to-use solution that are intended to be applied to dry, sealed pre-cleaned enclosures in industrial, commercial and institutional settings. The target concentration is 300 ppm; for treatment against bacteria, bacterial spores, viruses and mycobacteria the treated area must remain at this concentration for 3 hours; for treatment against fungi the treated area must be kept at this concentration for 6 hours. The professional user is responsible for sealing the area to be treated, inserting the sealed product into the VHP equipment and starting the machine. There is minimal potential for exposure during loading and exchange of cartridges; in most VHP units the sealed cartridge is placed in the cartridge holder and will be connected to the reservoir automatically, but not until the cartridge compartment door is closed and the cartridge control switched on. For external supply the bulk units are directly connected via hose assemblies with proper fittings to a dedicated fitting at the front of the generator. Alternatively a remote operator interface can be connected to the bulk supply and then feed up to five different VHP units. The VHP units have four phases • Dehumidification - reduction of relative humidity to pre-determined level • Condition - rapid increase to desired VHP concentration • Bio decontamination - maintenance of desired VHP concentration and relative humidity (for retention of vapour phase) • Aeration - rapid reduction of hydrogen peroxide vapour Whilst the VHP unit is in use, areas adjacent to the sealed enclosure will be monitored to assure hydrogen peroxide levels do not exceed health and safety limits. The monitors set up in the room will inform the user when the hydrogen peroxide level falls below 1.25 mg/m^3. The hydrogen peroxide monitor will be placed in a location most difficult for vapour target concentration to be reached in the treatment enclosure. Persons (including professional users) are not permitted into the treated area until the air concentration of hydrogen peroxide falls below the AEC of 1.25 mg/m^3. As the process is fully automated and the treated area sealed, exposure to hydrogen peroxide is not expected until re-entry. Operators are not permitted to enter the room until sensors give signal that the hydrogen peroxide concentration is below 1.25 mg/m^3.

Calculations for Scenario 1

Summary table: estimated exposure from professional uses		
Exposure scenario	Tier / PPE	Estimated air concentration (mg a.s. / m^3)
Scenario 1	1 (no PPE)	< 1.25

Further information and considerations on scenario 1

The adverse effects of hydrogen peroxide are limited to local effects at the site of contact with the body. Hydrogen peroxide has an AEC of 1.25 mg/m^3; as no exposure is expected during the whole decontamination process and users cannot enter the treated area until the sensors give an air concentration of < 1.25 mg/m^3, exposure to air concentrations above the AEC are not expected.

Vaprox (35% hydrogen peroxide) has been classified for H315 (causes skin irritation), H318 (causes serious eye damage), H302 (harmful if swallowed), H332 (harmful if inhaled) and H335 (May cause respiratory irritation). Vaprox (59% hydrogen peroxide) is

classified for H314 (causes severe skin burns and eye damage), H332 (harmful if inhaled), H302 (harmful if swallowed) and H335 (may cause respiratory irritation). Dermal exposure to the concentrated formulation is unlikely however, based on the hazard classification of the concentrated formulations, gloves, coveralls and eye protection must be worn when handling the product.

Scenario 2 – Draining and disposal of expired product from the VHP unit

Description of Scenario 2
The reservoir contents within the VHP machine may require emptying if the product goes beyond the shelf life. For this task, the mobile unit is moved to a waste disposal point where a drain hose will be connected to the bulk connector inlet. The contents will then be diluted with water (1:20) prior to disposal down a sink. For this task, two inhalation exposure scenarios are considered. Firstly, the evaporation of the hydrogen peroxide from the concentrated product during transfer and secondly, evaporation of hydrogen peroxide during disposal of the product down the sink. It is unlikely that a professional user would fill the internal reservoir (5L) and then leave the unit unused for an extended period therefore the disposal of 2.5 L of expired product is considered. Based on a relative density of 1.2348, this equates to 3087 g of product. The applicant has suggested a task duration of 30 minutes. This is based on 5 minutes for draining the concentrated product assuming a pumping rate of 0.5 L/min, and 25 minutes for the dilution and disposal. To dilute 2.5 L of product with 47.5 L of water in 25 minutes, a tap flow rate of ≥ 1.9 L /minute is required. As most taps have a flow rate of > 4 L/min (internet information), a task duration of 25 minutes is considered reasonable.

	Parameters	Value	
		Transfer of concentrated product	*Disposal of diluted product*
Tier 1 (ConsExpo Web)	Exposure and emission duration (minutes)	5 minutes	25 minutes
	Product amount	3087 g	
	Concentration of hydrogen peroxide	59% w/w	
	Product dilution	0 times	20 times
	Room volume	1 m^3	15 m^3
	Release area of concentrated product	20 cm^2	0.15 m^2
	Ventilation rate	2.5/hour	
	Application temperature	20 °C	
	Molecular weight of hydrogen peroxide	34 g/mol	
	Vapour pressure [1]	214 Pa	
	Mass transfer co-efficient	24.3 m/hr (Thibodeaux method)	
	Molecular weight matrix	18 g/mol	
Tier 2	A tier 2 assessment using the above Consexpo web scenario refined further to include a tenfold protection factor by the use of a suitable respiratory mask.		

[1] *The vapour pressure of pure hydrogen peroxide at 20 °C based on information provided in the CAR*

Tier 1 assessment

The air concentration whilst transferring the expired product using a disposal pipe has been calculated using ConsExpo Web and the guidance in the cleaning products factsheet for mixing and loading dishwasher liquid (RIVM report 320104003, p. 23 & 48). The air

concentration from disposal of the diluted product has been calculated using ConsExpo Web and the guidance in the cleaning products factsheet for dishwashing (RIVM report 320104003, p.49). As the quantity of Vaprox product handled during the disposal of expired product is likely to be greater than the amount of product handled when washing dishes, the default parameters for 'product amount', 'exposure duration' and 'emission duration' have been amended accordingly.

Tier 2 assessment

The tier 1 assessment was refined further by considering the use of of a suitable respiratory mask, type and specification of mask required for this scenario should be specified by the authorisation holder within the product information and where required adequate training provided to the wearer.

Calculations for Scenario 2

Summary table: estimated exposure from professional uses			
Exposure scenario	Tier/PPE	Estimated air concentration during transfer of the concentrate (mg a.s./m^3)	Estimated air concentration during disposal of the solution (mg a.s./m^3)
Scenario 2	1 (ConsExpo web, no PPE)	2.4	1.7
Scenario 2	2 (ConsExpo web, PPE – respiratory mask – providing 10 fold protection factor)	0.24	0.17
Detailed calculations are provided in Annex 3.2, Figures 1.1 – 1.2			

Further information and considerations on scenario 2

The adverse effects of hydrogen peroxide are limited to local effects at the site of contact with the body. Vaprox (35% hydrogen peroxide) has been classified for H315 (causes skin irritation), H318 (causes serious eye damage), H302 (harmful if swallowed), H332 (harmful if inhaled) and H335 (May cause respiratory irritation). Vaprox (59% hydrogen peroxide) is classified for H314 (causes severe skin burns and eye damage), H332 (harmful if inhaled), H302 (harmful if swallowed) and H335 (may cause respiratory irritation). Considering the hazard classification of the Vaprox products, gloves, coveralls and eye protection should be worn when handling the product. Possible exposure in excess of the acceptable limit requires suitable respiratory mask should be worn as specified by the authorisation holder within the product information.

Based on the tier 2 calculations and the use of suitable PPE, the AEC of 1.25 mg/m^3 will not be exceeded.

Scenario 3 – Cleaning of the delivery hoses used to supply Vaprox products to the VHP units

Description of Scenario 3
Delivery hoses must be cleaned periodically to remove dust and other debris from the interior surfaces. Cleaning of hoses is recommended annually, or whenever the interior of the hoses becomes soiled or dusty. For cleaning hoses it is recommended to submerge hoses in a clean sink or tub filled with water containing a mild detergent. Hoses should be soaked for 30 minutes and the sink or tub drained afterwards. The hoses will then be rinsed with distilled water. As only a negligible amount of product is expected to be present in the delivery hoses (and considering that any concentrated product will be heavily diluted with water for cleaning) this scenario is considered to be within the risk envelope of a user disposing of expired Vaprox products and no further calculations have been carried out. Please refer to scenario 2 for further details.

Combined scenarios

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

Non-professional exposure

The Vaprox® Biocidal Product Family is not intended for use by non-professional users.

Exposure of the general public

The general public are not expected to be present during the application of Vaprox products. The general public are only allowed to enter treated areas once the air concentration of hydrogen peroxide falls below the AEC of 1.25 mg/m^3.

Scenario 4 – General public re-entering treated areas

The adverse effects of hydrogen peroxide in humans are limited to local effects at the site of contact with the body. Hydrogen peroxide has an AEC of 1.25 mg/m^3; as the general public cannot enter treated areas until the air concentration of hydrogen peroxide is below this level, local effects from inhalation do not present a concern. As exposure to the concentrated product is not relevant to the general public, the hazard classification of the products does not need to be considered.

Combined scenarios

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

Dietary exposure

The product is not intended to be used on surfaces that may come into contact with food or feeding stuffs. Exposure to hydrogen peroxide via the diet is not expected. The SPC states that all plants, animals, beverages and food should be removed before application.

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

The modelling of exposures and subsequent risk characterisation during production and formulation of the Vaprox® Biocidal Product Family is addressed under EU legislation (e.g. Directive 98/24/EC) and is not repeated under BPR, Regulation (EU) 528/2012 (agreed at Biocides Technical Meeting TMI06). The UK has not considered exposure from production of the biocidal product further.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	Exposed group (e.g. professionals, non-professionals, bystanders)	Tier / PPE	Estimated total uptake
1.	Professionals user applying Vaprox products using a VHP unit	1 (no PPE)	< 1.25 mg/m^3
2.	Professional user disposing of Vaprox products from the VHP unit reservoir	1 (no PPE)	2.4 mg/m^3
		2 (PPE)	0.24 mg/m^3
3.	Professional user cleaning the delivery hoses used to supply Vaprox products to the VHP units	Covered by scenario 2	
4.	Bystanders re-entering treated areas	1	< 1.25 mg/m^3

2.2.6.3 Risk characterisation for human health

Risk for industrial users

This product is not intended for use by industrial users.

Risk for professional users

Systemic effects
The adverse effects of hydrogen peroxide in humans are limited to local effects at the site of contact with the body. As such, systemic effects are not relevant.

Local effects

Task / Scenario	Tier (PPE)	AEC (mg a.s. / m^3)	Estimated air conc. (mg a.s. / m^3)	Estimated air conc. / AEC (%)	Acceptable (yes / no)
Scenario 1 – application of Vaprox products using a VHP unit	1 (no PPE)	1.25	≤ 1.25	<100 %	yes

Scenario 2 – disposal of expired Vaprox products from the VHP unit reservoir	1 (no PPE)	1.25	2.4	192 %	no
	2 (PPE – Respiratory Mask)		0.24	19.2 %	yes
Scenario 3 - cleaning the delivery hoses	Covered by scenario 2				

Vaprox (35% hydrogen peroxide) has been classified for H315 (causes skin irritation), H318 (causes serious eye damage), H302 (harmful if swallowed), H332 (harmful if inhaled) and H335 (May cause respiratory irritation). Vaprox (59% hydrogen peroxide) is classified for H314 (causes severe skin burns and eye damage), H332 (harmful if inhaled), H302 (harmful if swallowed) and H335 (may cause respiratory irritation). Based on the hazard classification of the product, gloves, coveralls and eye protection must be worn when handling the product or contaminated surfaces. Possible exposure in excess of the AEC requires suitable respiratory mask should be worn as specified by the authorisation holder within the product information.

Conclusion

The risk to professional users is demonstrated to be acceptable if appropriate PPE is worn. The following operator protection phrase is required:

- Wear protective chemical resistant gloves, a protective coverall and eye protection during product handling phase (glove material to be specified by the authorisation holder within the product information). Suitable respiratory mask should be worn as specified by the authorisation holder within the product information.

Risk for non-professional users

The product is not intended for use by non-professional users.

Risk for the general public

Systemic effects
The adverse effects of hydrogen peroxide are limited to local effects at the site of contact with the body. As such, systemic effects are not relevant.

Local effects
Hydrogen peroxide has an AEC of 1.25 mg/m^3. Bystanders are not permitted to enter treated areas until the hydrogen peroxide air concentration is below this concentration therefore exposure above these levels is not expected.

Conclusion
The risk to the general public is acceptable.

Risk for consumers via residues in food

Exposure to hydrogen peroxide via the diet is not expected. The SPC states that all plants, animals, beverages and food should be removed before application.

2.2.7 Risk assessment for animal health

Not applicable.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The product contains only one active substance and no substances of concern. Therefore all ecotoxicity data can be obtained from the Assessment Report

http://dissemination.echa.europa.eu/Biocides/ActiveSubstances/1315-02/1315-02_Assessment_Report.pdf

The PNECs are summarised below:

Aquatic = 12.6 µg a.s./L
Sewage = 4.66 mg/L
Soil = 0.0018 mg/kg ww soil

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

No additional data are required.

Further Ecotoxicological studies

Data waiving	
Information requirement	Further Ecotoxicological studies
Justification	No additional data are required.

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

Data waiving	
Information requirement	Effects on other non-target organisms.
Justification	No additional data are required.

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

Data waiving	
Information requirement	Supervised trials.
Justification	No additional data are required.

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

Data waiving	
Information requirement	Acceptance by ingestion.
Justification	No additional data are required.

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

No additional data are required.

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

The products within the Vaprox® Biocidal Product Family for use in PT 2 are based on a formulation containing either 35 % w/w or 59 % w/w of active substance, hydrogen peroxide. These biocidal products are marketed as aqueous ready-to-use sterilants that are applied indoors and are developed specifically for use in Vaporized Hydrogen Peroxide (VHP) generators. For VHP processes (PT 2), the Assessment Report for Hydrogen Peroxide (PT 1 – 6) concluded that "*Emissions were estimated for disinfection of rooms using the vaporised hydrogen peroxide (VHP) process. Air emissions are minor, since vaporised hydrogen peroxide is decomposed by the VHP machine after disinfection. Likewise, only very minor amounts of hydrogen peroxide might be discharged to sewage*". In the case of Vaprox biocidal products, the Vaprox injection into the VHP generator is stopped and the flow of dry air continues to reduce the hydrogen peroxide concentration within the enclosure to an acceptable level prior to re-entry into that area. In conclusion, the Vaprox biocidal products used in PT 2 are applied exclusively indoors, and therefore, no further information about foreseeable routes of entry into the environment on the basis of the use envisaged is deemed necessary to cover the requirements of Annex III, point 10.1 (BPR Guidance on Information Requirements, Vol IV, Part A).

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

Based upon the PT 2 use pattern of the Vaprox® Biocidal Product Family (outlined in "Foreseeable routes of entry into the environment….") and information contained in the PT 1- 6 review document for hydrogen peroxide (including rapid degradation in soil, air, water and at STP), no further testing is deemed necessary to cover the requirements of Annex III, point 10.2 ((BPR Guidance on Information Requirements, Vol IV, Part A).

Study data already available on the active substance provide sufficient assessment of the environmental fate and behaviour of the biocidal products, within the Vaprox product family.

Leaching behaviour (ADS)

No additional data submitted: data reported in the CAR for the active substance (hydrogen peroxide) is sufficient for use in the environmental risk assessment.

Testing for distribution and dissipation in soil (ADS)

No additional data submitted: data reported in the CAR for the active substance (hydrogen peroxide) is sufficient for use in the environmental risk assessment.

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

No additional data submitted: data reported in the CAR for the active substance (hydrogen peroxide) is sufficient for use in the environmental risk assessment.

Testing for distribution and dissipation in air (ADS)

No additional data submitted: data reported in the CAR for the active substance (hydrogen peroxide) is sufficient for use in the environmental risk assessment.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Acute aquatic toxicity

Data waiving	
Information requirement	Acute aquatic toxicity
Justification	No additional data are required.

Chronic aquatic toxicity

Data waiving	
Information requirement	Chronic aquatic toxicity
Justification	No additional data are required.

Measured aquatic bioconcentration:

No additional data are required.

Estimated aquatic bioconcentration

No additional data are required.

Data waiving	
Information requirement	Aquatic bioconcentration
Justification	No additional data are required.

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)

No additional data are required.

2.2.8.2 Exposure assessment

The Vaprox® Biocidal Product Family all contain hydrogen peroxide as sole biocidal active substance and are stated to contain either 35 % w/w (Meta SPC 1 information states that the actual range is 34.8 – 35.8 % w/w) or 59 % w/w (Meta SPC 2 states that the actual range is 58.4 – 59.4 % w/w) of this active substance.

Products within the family (Meta SPC 1 and Meta SPC 2) are aqueous ready-for-use sterilants in PT 2 (Disinfectants and algaecides not intended for direct application to humans or animals) for application by professional operators by means of VHP generators to dry, sealed pre-cleaned enclosures in industrial, commercial and institutional settings. The products are only to be used indoors for the disinfection of surfaces, materials, equipment and furniture.

It is stated that VHP generators will deliver an airborne concentration into enclosures of 300 ppm for 3 hours (control of bacteria, bacterial spores, viruses and mycobacteria) or 6 hours (control of fungi). During treatment, airborne concentrations will be controlled and maintained by placement of H_2O_2 monitors in a location most difficult for vapour target concentration to be reached in the treatment enclosure (typically in corners in the enclosure farthest away from the VHP generation unit). For effective control, all drawers, closets, cabinet doors, etc. must be opened to permit exposure to hydrogen peroxide.

Oscillating fans must be placed throughout the enclosure to facilitate effective distribution of a.s. and this should be verified by placement of chemical indicators in the treatment area.

For simplicity, assessment will initially be based upon the most “worst case” concentration of a.s. found within the family (namely 59.4 % w/w of hydrogen peroxide) such that if risks are found to be acceptable for this specific formulation, then all products within the BPF can be authorised.

General information

Assessed PT	PT 2
Assessed scenarios	Scenario 1: Application of hydrogen peroxide based product (Vaprox family) via VHP generator indoors in sealed enclosures (assuming control measures are not working), leading to airborne emissions Scenario 2 : Application of hydrogen peroxide based product (Vaprox family) via VHP generator indoors in sealed enclosures, leading to discharges to drains
ESD(s) used	Currently, there is no default scenario available/applicable for the proposed scenarios via VHP generator in sealed enclosures within PT 2, since no emission to air, water and soil is expected during the process. Emissions to air during use of VHP generators is considered negligible as control measures will be in operation but the model used in the PT 2 review will be applied. Emissions to water might occur only during cleaning of empty cartridges / canister before disposal and emptying of the hydrogen peroxide reservoir of the VHP machine. Calculations have been undertaken in line with models presented in ECHA Guidance on ERA, Volume IV, Part B.

Approach	Scenario 1: consumption based approach. Scenario 2: consumption based approach. Scenario 1 modelling assumes a worst case situation whereby three VHP machines are used 3 times daily in a building to deliver a treatment dose of 300 ppm of a.s. and, due to failure of control measures, discharges to air may occur. Scenario 2 modelling assumes a worst case situation whereby the reservoirs of three VHP machines each containing 5 L of Vaprox 59 Hydrogen Peroxide Sterilant are drained into the sink, with losses to local STP. This scenario is considered to represent "worst case" cleaning of cartridges (≤ 0.95 L) and bulk units (18.9 L and 200.6 L) before disposal as the amounts potentially released from cleaning are considered very small. No calculator sheets are available but equations from ECHA guidance on ERA, Volume IV, Parts B+C (version 2.0, October 2017) have been used.
Distribution in the environment	Calculations based on principles laid out in ECHA Guidance on ERA, Volume IV, Parts B+C (version 2.0, October 2017).
Groundwater simulation	Not considered relevant, based upon decisions reached in the PT 1- 6 review of hydrogen peroxide.
Confidential Annexes	No
Life cycle steps assessed	Scenario 1: Application of hydrogen peroxide based product (Vaprox family) via VHP generator indoors in sealed enclosures, leading to airborne emissions. Scenario 2 : Application of hydrogen peroxide via VHP generator indoors in sealed enclosures, leading to discharges to drains. Production : No Formulation : No Use : Yes Service life : Not required due to 3 – 6 hr treatment period (so covered by daily "use" life cycle step)
Remarks	None

Emission estimation for PT 2

Scenario 1 : Application of hydrogen peroxide based product (Vaprox family) via VHP generator indoors in sealed enclosures (assuming control measures are not working), leading to airborne emissions

Currently, there is no default scenario available/applicable for the proposed scenario via VHP generator in sealed enclosures within the PT 2 ESD, since no emission to air, water and soil is expected during the process. Emissions to air during use of VHP generators are considered negligible as control measures will be in operation to restrict airborne concentrations of hydrogen peroxide and minimize operator exposure. Furthermore,

vaporisation only takes place in closed systems and hydrogen peroxide remaining in process air is decomposed afterwards.

However, it is noted that whilst similar arguments were presented in the hydrogen peroxide PT 2 CAR for surface disinfection by VHP process, the emission to air from ventilation was still calculated as it was assumed that residual hydrogen peroxide in the room air after the decomposition step may reach the environment by ventilation. A worst-case emission factor to air (F_{air}) of 0.004 was estimated as the quotient of the maximum residual concentration in air after the decomposition step and the minimum target concentration in air, i.e. 1 ppm/400 ppm = 0.0025. In this specific instance for the Vaprox® Biocidal Product Family, the target treatment concentration in air has been stated as only 300 ppm so a different F_{air} might seem appropriate. However, for simplicity and as a conservative step, the same fraction as applied in the CAR will be used in relation to the Vaprox® Biocidal Product Family, namely an F value of 0.004.

The applicant has stated that the Vaprox® Biocidal Product Family will be applied by VHP generator to deliver a rate of 300 ppm of hydrogen peroxide : using the correction factor based upon gas-phase density applied in the hydrogen peroxide CAR, then 1 ppm would be equivalent to 1.4 mg/m^3 and so the application rate would be 300 ppm or 420 mg/m^3.

A single large room of 150 m^3 (taken to be 50 m^2 x 3 m in the hydrogen peroxide CAR) has been assumed to be treated at the maximum target concentration of hydrogen peroxide (420 mg/m^3) regardless of H_2O_2 level in the product, leading to an applied amount (M_{appl}) of 150 m^3/appl x 420 mg/m^3 x 1.0E-6 kg/mg = 0.063 kg/appl. Up to three rooms might be treated daily with one machine (N_{appl} = 3/day; Information obtained from CEFIC, 2006). Finally, it was assumed that a maximum of three machines are in operation on the same day and used at the same location ($N_{machines}$ = 3). For air emissions, it was conservatively assumed that emissions from all machines would then go to the same emission cloud.

The consumption of hydrogen peroxide at the local scale can be calculated as follows :

Input parameters for calculating the local emission : Scenario 1			
Input	Value	Unit	Remarks
Scenario 1: Application of hydrogen peroxide based product (Vaprox family) via VHP generator indoors in sealed enclosures, leading to airborne emissions			
Amount of a.s. used per day to disinfect large room*	0.063	kg/application	Determination of this value is given in previous text
Number of applications per day with one machine	3		
Number of machines used daily	3	-	
Fraction released to air (F_{air} ascribed in CAR)	0.004	-	Default
Emission to air (worst case)	2.27E-3	kg/d	Output

*The calculated value in kg/application actually represents the maximum quantity of a.s. available for discharge at any time based on room volume and fixed airborne concentration of H_2O_2 being maintained by VHP equipment (regardless of how much a.s. has been released during treatment and degraded within the room)

The resulting PEC_{air} has been calculated in line with ECHA guidance on ERA, Volume IV, Parts B+C (equations 38 + 43), i.e. by multiplying the air emission of 2.27 g/d with the standard concentration at 100 m from the emission point calculated for a standard source of 1 kg/day (where $Cstd_{air}$ = 2.78E-4 mg/m^3). The resulting PEC_{air} is 6.31E-4 µg/m^3, which is an extreme worst-case approach as it is based upon several conservative assumptions.

The estimated PEC_{air} is significantly below the typical background concentration of hydrogen peroxide in air of 0.14-1.4 µg/m^3 (Document II-A of the hydrogen peroxide PT 1 – 6 review). Therefore, the additional emissions constitute only a negligible contribution to the ambient air concentrations even from a worst case assumption. Furthermore, the PT 1 – 6 review indicated that the troposphere has a buffer capacity for hydrogen peroxide, which is part of the equilibrium system of photo-oxidants. Potential minor air emissions of hydrogen peroxide are therefore not expected to alter the existing tropospheric background concentrations to any relevant degree.

As a consequence, no further consideration will be made for the potential of hydrogen peroxide to deposit from the air onto soil surfaces, as losses to air following use of VHP generators causes no significant increase to airborne concentrations of H_2O_2.

Scenario 2 : Application of hydrogen peroxide based product (Vaprox family) via VHP generator indoors in sealed enclosures, leading to emissions to drains

Currently, there is no default scenario available/applicable for the proposed scenario via VHP generator in sealed enclosures within the PT 2 ESD, since no emission to air, water and soil is expected during the process. Emissions to drain might occur only during cleaning of empty cartridges / canister before disposal and emptying of the hydrogen peroxide reservoir of the VHP machine.

It has been proposed by the applicant that emissions modelling can be undertaken on the basis of an “extreme worst case” situation whereby the reservoirs of two VHP machines (each containing 5 L of (expired) Vaprox 59 Hydrogen Peroxide Sterilant) are drained into the sink at the end of each working day, with losses to local STP. This scenario is considered representative for cleaning of cartridges (≤ 0.95 L) and bulk units (18.9 L and 200.6 L) before disposal as the amounts potentially released from cleaning are considered to be very small. However, it is noted that assessments undertaken in the PT 2 CAR for use of hydrogen peroxide in VHP generators assume the operation of three VHP generators at the same local scale and so a similar scale of use has been applied to Vaprox® Biocidal Product Family.

Input parameters for calculating the local emission (based on potential volume of sterilant poured away to drain) : Scenario 2a			
Input	Value	Unit	Remarks
Scenario 2a : Disinfection indoors using VHP generators, with worst case discharge of 5 litres of product from 3 machines poured to sink			

Discharge rate of biocidal product	15	L/d	Daily loss of 5 L from 3 machines (worst case)
Concentration of active substance in the product	59.4	% w/w	Highest level found in Vaprox BPF and is equivalent to an Fai of 0.594
Relative density of product	1.2348	Kg/L	Value at room temperature
Total loss of hydrogen peroxide poured to drain*	11.00	kg/d	

**Total loss of a.s. to drain per day (kg) has been derived from Discharge rate (in L) x Fai x RHOproduct (expressed in kg/L)*

However, it is noted that the PT 2 CAR for hydrogen peroxide takes a different approach to emission assessment to local drain, in that losses are only based upon the amount of hydrogen peroxide used to disinfect a large room that deposits on surfaces and could be released to drains from wet cleaning. To cover such minor losses, a worst-case emission factor to sewage (F_{water}) of 5 % of applied hydrogen peroxide was assumed. Although modelling used a fraction of 0.05, it was noted that in a realistic worst-case situation, no relevant amounts of hydrogen peroxide would be expected to reach sewage from this application.

Input parameters for calculating the local emission (based on quantity of hydrogen peroxide used to disinfect a typical large room) : Scenario 2b			
Input	Value	Unit	Remarks
Scenario 2b : Disinfection indoors using VHP generators, assuming wet cleaning of surfaces where deposition of hydrogen peroxide may have occurred			
Amount of a.s. used per day to disinfect large room*	0.063	kg/application	Determination of this value is given in previous text
Number of applications per day with one machine	3	-	
Number of machines used daily	3	-	
Fraction released to drain (F_{drain} value ascribed in CAR)	0.05	-	Default
Total loss of hydrogen peroxide to drain**	2.84E-2	kg/d	

**The calculated value in kg/application actually represents the maximum quantity of a.s. available for discharge at any time based on room volume and fixed airborne concentration of H_2O_2 being maintained by VHP equipment (regardless of how much a.s. has been released during treatment and degraded within the room)*
***Total loss of a.s. to drain per day (kg) has been derived from amount applied per treatment (in kg) x number of treatments per day x number of machines at same location x Fdrain*

Furthermore, due to the highly reactive nature of hydrogen peroxide, degradation of the molecule within drains whilst in transit to STP was considered relevant in its PT 2 CAR. As a consequence, a fraction of 0.024 of the discharged hydrogen peroxide was predicted to reach the STP and this has been applied to emissions in both Scenario 2a and 2b :

Resulting local emission to relevant environmental compartments (based upon loss of fixed volume of sterilant per VHP generator)		
Compartment	Local emission ($Elocal_{compartment}$) arriving at STP [kg/d]	Remarks
Scenario 2a	11.00 x 0.024 = 0.264	15 L of sterilant poured to drain each day (applicant)
Scenario 2b	2.84E-2 x 0.024 = 6.82E-4	Deposition from 3 VHP generators and wet cleaning of surfaces (CAR)

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
Scenario 1	N	N	NR	NR	N	Y	N	N
Scenario 2a	Y	Y	NR	NR	Y	Y	Y	Y
Scenario 2b	Y	Y	NR	NR	Y	Y	Y	Y

Y – receiving compartment ; N – not a receiving compartment ; NR – not relevant to use pattern

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	34.01	g mol^{-1}	
Melting point	-0.43	°C	
Boiling point	150.2	°C	
Vapour pressure (at 20°C)	214	Pa	
Water solubility (at 20°C)	1.0E+6	mg/l	Maximum EUSES value available
Log Octanol/water partition coefficient	-1.57	Log 10	
Organic carbon/water partition coefficient (Koc)	1.598	l/kg	Based on calculated log Koc of 0.2036
Henry's Law Constant (at 20°C)	7.5E-4	Pa/m^3/mol	
Biodegradability	Not relevant		Compound is not organic
Rate constant for STP *[if*	21	h^{-1}	
DT_{50} for biodegradation in surface water	5	d	Estimated value
DT_{50} for hydrolysis in surface water	-	d or hr (at 12ºC /pH)	
DT_{50} for photolysis in surface water	-	d or hr	
DT_{50} for degradation in soil	12	hr	Estimated value
DT_{50} for degradation in air	24	hr	Estimated value

[All values and conclusions taken from Doc II-A of the hydrogen peroxide CAR covering PTs 1-6]

Calculated fate and distribution in the STP *[if STP is a relevant compartment]*		
Compartment	Percentage [%]	Remarks
	Scenario 1	
Air	1.66E-4	SimpleTreat v3.1
Water	0.687	SimpleTreat v3.1
Sludge	0.0145	SimpleTreat v3.1
Degraded in STP	99.3	SimpleTreat v3.1

In line with policy outlined in the TAB (v1.3) under ENV 9 at the time of evaluation (July 2017), SimpleTreat v3.1 has been applied at product authorisation as SimpleTreat v4 is not yet required [AHEE-1, 2016; WG-I-2016; WG-I-2017]

Calculated PEC values

Compartmental PECs will therefore only be determined from discharge of waste sterilant solution (containing a maximum of 59.4 % a.s.) to local STP and resultant partitioning to sewage sludge and water discharge to from STP to receiving watercourse.

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]
Scenario 1	-	-	-	-	-	6.31E-7
Scenario 2a	9.07E-4	9.07E-5	Not calculated	1.71E-6	1.96E-3	1.22E-10
Scenario 2b	2.34E-6	2.34E-7	Not calculated	4.43E-9	5.06E-6	3.14E-13

**Sediment PEC not calculated in Scenario 2 as risk assumed to be identical to that posed to aquatic organisms (both PECsed and PNECsed can only be derived by EPM)*

As hydrogen peroxide rapidly degrades to water and oxygen, no consideration of metabolites or degradation products is considered necessary.

It should be noted that the EU review of hydrogen peroxide under PT 1 – 6 concluded in Doc II-A that the compound is a naturally existing substance in the environment and it is ubiquitous in air and all types of natural waters. Therefore the natural background concentrations and the natural formation and degradation pathways for each environmental compartment are presented in the following Table (originally copied from the taken from ESR risk assessment report (2003) for hydrogen peroxide):

Measured hydrogen peroxide concentrations in the environment (EU Risk Assessment Report, 2003)

Compartment	*Typical mean values*	*Highest values*	*Comments*
Air	*0.14-1.4 µg/m³ (0.1-1 ppb)*	*10 µg/m³ (7 ppb)*	
Cloud water	*50-1000 µg/L*	*> 8000 µg/L*	
Rain water, summer	*100-500 µg/L*	*> 8000 µg/L*	

Rain water, winter	*< 100 µg/L*		
Sea water	*0.5-5 µg/L*	*14 µg/L*	
Lake water	*1-30 µg/L*	*> 100 µg/L*	*Highest values: reliability poor, but probably realistic*
Groundwater	*0.7 µg/L*	*2.25 µg/L*	*Only one study referred*

As a conclusion, natural hydrogen peroxide concentrations in environmental media depend on the dynamic equilibrium of the simultaneous formation and decomposition reactions. Environmental media can therefore be expected to possess some capacities to buffer any anthropogenic emissions of hydrogen peroxide. Furthermore, the decomposition of hydrogen peroxide in air, water or soil generally cannot be investigated by standard guideline tests designed for biotic or abiotic degradation of organic compounds.

It is noted that predicted levels of hydrogen peroxide from worst case use of the product family fall below natural background levels in air, surface waters and groundwater.

Primary and secondary poisoning

Primary poisoning

Not required as the product is not a solid formulation used outside.

Secondary poisoning

Not required because Log Pow of the active substance is -1.57, which is below 3.

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: It is possible that emissions of hydrogen peroxide could reach air during indoor operation of VHP generators (Scenario 1) and at local STP following discharge of surplus sterilant solution to drains (Scenario 2a) or wet cleaning of internal surfaces in treated areas (Scenario 2b). These models are considered to represent unrealistic events but, even so, concentrations of hydrogen peroxide in air from PT 2 uses are negligible when compared to background levels of the compound and are not considered to pose an increase in risk.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{STP}$*
Scenario 2a – product poured to drain	1.95E-4
Scenario 2b – wet cleaning of internal surfaces	5.02E-7

* based upon a PNEC of 4.66 mg/l

Conclusion: The resulting PEC/PNEC ratios at local STP indicate acceptable risks to STP micro-organisms, even for worst case events where sterilising solution is poured away to drains (Scenario 2a) or internal surfaces are wet cleaned (Scenario 2b).

Aquatic compartment

Summary table on calculated PEC/PNEC values		
	$PEC/PNEC_{water}$*	$PEC/PNEC_{sed}$**
Scenario 2a – product poured to drain	7.20E-3	Identical to water risk
Scenario 2b – wet cleaning of internal surfaces	1.86E-5	Identical to water risk

* based upon a PNEC of 1.26E-2 mg/l

** sediment risk is identical to risk in water as both PEC and PNEC will be derived by EPM

Conclusion: Predicted surface water concentrations (PECs) have been calculated only from the indirect exposure to water via STP discharge, as direct aquatic exposure is not expected from the proposed biocidal uses. The resulting PEC/PNEC ratios at receiving watercourse indicate acceptable risks to aquatic and sediment dwelling organisms, even for worst case events where sterilising solution is poured away to drains (Scenario 2a) or internal surfaces are wet cleaned (Scenario 2b).

Terrestrial compartment

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$*
Scenario 2a – product poured to drain	9.29E-4
Scenario 2b – wet cleaning of internal surfaces	2.41E-6

*based upon a PNEC of 1.84E-3 mg/kg wwt

Conclusion: Predicted soil concentrations (PECs) have been calculated only from the indirect exposure to soil via sewage sludge application, as direct soil exposure is not expected from the proposed biocidal uses. The resulting PEC/PNEC ratios in receiving compartment indicate acceptable risks to terrestrial organisms, even for worst case events where sterilising solution is poured away to drains (Scenario 2a) or internal surfaces are wet cleaned (Scenario 2b).

Groundwater

Possible movement of hydrogen peroxide from soil to groundwater has been assessed at Tier 1 level by use of equations 67 and 68 taken from ECHA Guidance on ERA, Volume IV, Part B. In this approach, concentration in porewater of agricultural soil is taken as an indication for potential groundwater levels but it is acknowledged that this represents a worst-case assumption, neglecting transformation and dilution in deeper soil layers.

Exposure of hydrogen peroxide to agricultual soil via sludge application is possible in a worst case scenario whereby quantities of sterilant solution are poured away to drains (Scenario 2a) or where internal surfaces are wet cleaned (Scenario 2b). This gives rise

to worst case values of 2.86E-7 mg/kg wwt (Scenario 2a) and 7.38E-10 mg/kg wwt (Scenario 2b) in arable soil, which will act as $Clocal_{soil}$ in the porewater model (equation 67) : this equates to worst case Tier 1 groundwater concentrations of 1.96E-3 and 5.06E-6 µg/l for hydrogen peroxide.

Whilst this approach can be considered as simplistic, these values determined in porewater of non-specific "agricultural soil" fall significantly below the current quality standard set at 0.1 µg/l for "pesticide actives" in the EU Drinking Water Directive (98/83/EC). As a consequence, no further consideration need be undertaken as risks posed to groundwater can be considered as acceptable.

NOTE : it is observed that the generic drinking water standard value of 0.1 µg/l was intended for organic pesticides but, in the absence of a specific limit for hydrogen peroxide, the same approach as the one taken in section 13.4 (Doc II-C) of the PT 1 - 6 active review has been followed.

Whilst no concerns are raised at Tier 1 porewater screening, this still appears to be a very conservative approach, especially as EU background levels of this compound already exceed this drinking water standard. As such, it seems more logical / relevant to consider this inorganic compound in a similar way to iodate and iodide : groundwater risk should be based upon comparison of notional PEC against reported values (0.7 – 2.25 µg/l).

Primary and secondary poisoning

Primary poisoning

Not required as the product is not a solid formulation used outside.

Secondary poisoning

Not required because Log Pow of the active substance is -1.57, which is below 3.

Mixture toxicity

The applicant has provided formulation details of products within both the Meta SPC 1 and Meta SPC 2 to demonstrate that products are all simple aqueous sterilant products based upon hydrogen peroxide as single active substance. No "Substances of Concern" are evident within any formulation and therefore mixture toxicity assessment does not appear to relevant - no further assessment has been undertaken.

However, it is noted that the active substance itself is highly reactive and requires the presence of several stabilisers and passivators as part of the manufacturing process (as outlined in the hydrogen peroxide CAR) to prevent rapid breakdown during storage. When considering both the classification of these additives under latest CLH regulations and maximum concentrations likely to be present within Vaprox® Biocidal Product Family, none of the compounds can be considered as environmental "Substances of Concern" within formulations containing up to 59.4% hydrogen peroxide. Again, no mixture toxicity has been considered relevant.

Aggregated exposure (combined for relevant emission sources)

It was concluded in the Assessment Report for hydrogen peroxide (biocidal uses falling under PT 1 – 6) that only a minor fraction of total hydrogen peroxide manufactured in the EU is used as biocidal product. As this value is certainly <10 % (outlined in the Decision Tree as trigger level for the need to estimate aggregated exposure), then further consideration is not necessary.

Furthermore, the AR for hydrogen peroxide also stated that "*According to Article 10(1) of BPD, a cumulative risk assessment shall be performed where relevant. For hydrogen peroxide, it was agreed at WG-V-2014 that aggregated risk assessment is not regarded relevant due to the high reactivity of the substance*."

Taking both factors into account, aggregated exposure has been disregarded.

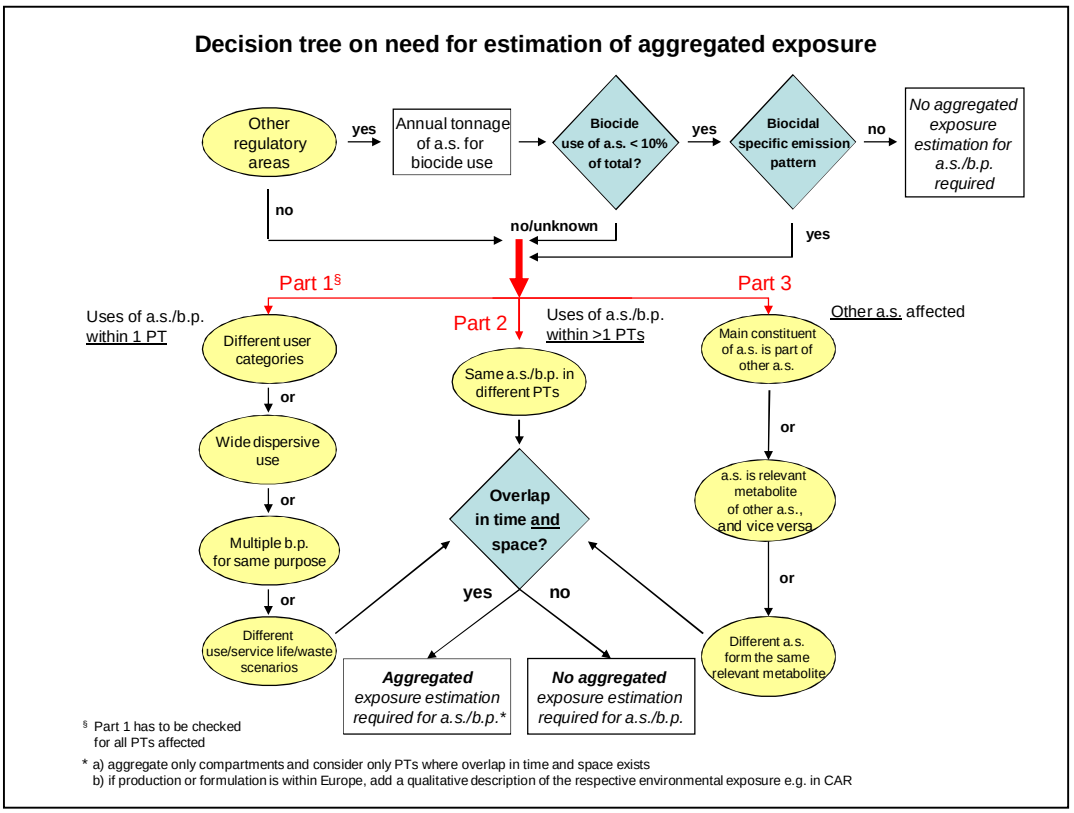

Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product
Based upon the proposed use patterns in PT 2 whereby products in the Vaprox® Biocidal Product Family will be applied indoors by trained professional operators using only VHP generators, then all risks to environmental compartments resulting from potential emissions during application and cleaning events have been shown to be acceptable. Furthermore, predicted worst case emissions in air and water have been shown to fall well below natural background levels of hydrogen peroxide and therefore use of this product family via specific generator devices as stated on product labelling does not give rise for concern.

Authorisation of this BPF at up to 59.4 % a.s. may therefore be granted in line with directions for use and instructions stated in the SPC and proposed product labelling. No further restrictions or mitigation measures are considered necessary from an environmental fate and behaviour perspective.

2.2.9 Measures to protect man, animals and the environment

Recommended methods and precautions concerning storage of the biocidal products and shelf life of the biocidal products:

The following information was provided by the applicant:
Conditions for safe storage, including any incompatibilities: Technical measures: Provide adequate ventilation. A washing facility/water for eye and skin cleaning purposes should be present. Floors should be impervious, resistant to liquids and easy to clean.

Storage conditions: Keep only in the original container in a cool, well ventilated place. Store only in vented containers. Keep container tightly closed. Keep/Store away from clothing. Ensure control measures are regularly inspected and maintained.

Incompatible materials: Strong alkalis. Strong oxidizing agents. Organic materials. Reducing agents. Metal salts. Alkali metals. Wood. Paper. Copper and its alloys. Metals. Cyanide. Hazardous reactions may occur on contact with certain chemicals. (Refer to the list of incompatible materials section 10: "Stability-Reactivity")

Prohibitions on mixed storage: Do not store near oxidizing agents. keep away from incompatible materials

Storage area: Store in dry, cool, well-ventilated area

Special rules on packaging: Correctly labelled

Recommended methods and precautions concerning handling and transport:
Precautions for safe handling : Read label before use. Avoid all eye and skin contact and do not breathe vapour and mist. keep away from incompatible materials. Do not wear leather soled shoes. 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. Avoid breathing dust, mist or spray. Use only in a well-ventilated area. Never return unused material to original container

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

Recommended methods and precautions concerning fire, in case of fire, nature of reaction products, combustion gases ect.
Suitable extinguishing media: Flood with plenty of water. Foam. Dry powder. Carbon dioxide. Water spray. Sand

Unsuitable extinguishing media: Organic compounds. As hydrogen peroxide may react with a variety of organic materials and can form explosive mixtures, shock sensitive compounds, and initiate fire. Foam is not effective as oxygen and heat continue to be generated under the foam blanket. Do not use a heavy water stream.

Special hazards arising from the substance or mixture
Hazardous decomposition products in case of fire: Hydrogen peroxide at these concentrations (59%) is a strong oxidant. On decomposition releases oxygen which may intensify fire. Containers may swell and Burst during a fire due to internal pressure caused by heat.

Particulars of likely direct or indirect adverse effects:
Most important symptoms and effects, both acute and delayed are listed below:

Symptoms/injuries: Hydrogen peroxide at these concentrations is a strong oxidant. Causes severe skin burns and eye damage.

Symptoms/injuries after inhalation: Harmful if inhaled. Possible inflammation of the respiratory tract. Medical observation is recommended for 24 to 48 hours after overexposure, as pulmonary edema may be delayed. May cause respiratory irritation.

Symptoms/injuries after eye contact: Eye contact with concentrated solutions may cause severe eye damage followed by loss of sight.

Symptoms/injuries after ingestion: Swallowing a small quantity of this material will result in serious health hazard. Severe irritation or burns to the mouth, throat, esophagus, and stomach.

First aid instructions, antidotes:
Description of first aid measures
First-aid measures general: Never give anything by mouth to an unconscious person. In all cases of doubt, or when symptoms persist, seek medical attention

First-aid measures after inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. If not breathing, give artificial respiration. Immediately get medical attention.

First-aid measures after skin contact: Remove contaminated clothing immediately. Immediately flush skin with plenty of water for at least 15 minutes. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

First-aid measures after eye contact: In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist. Immediately get medical attention. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.

First-aid measures after ingestion: If victim completely conscious/alert. Give water if the person is fully conscious. Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Call a POISON CENTER/doctor/physician if you feel unwell.

Emergency measures to protect environment in case of accident:
Environmental Exposure Controls:
Personal precautions, protective equipment and emergency procedures
General measures: Ensure adequate ventilation. Do not breathe fumes, vapors. Avoid contact with skin, eyes and clothes. Stop leak if safe to do so.

For non-emergency personnel

Protective equipment: Wear protective gloves and eye/face protection. For further information refer to section 8 : Exposure-controls/personal protection
Wear protective gloves and eye/face protection.
Emergency procedures: Stop leak if safe to do so. Evacuate unnecessary personnel

For emergency responders: Stop leak if safe to do so. Evacuate unnecessary personnel
For emergency responders: Protective equipment: Equip clean-up crew with proper protection

Emergency procedures:
Ventilate area
Early re-entry in the case of an emergency (when the concentration of hydrogen peroxide exceeds 1 ppm) requires wearing appropriate respirator.

Environmental precautions: Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

Methods and material for containment and cleaning up
Methods for cleaning up: Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Do not absorb in sawdust, paper, cloth or other combustible absorbents. Comply with applicable local, national and international regulation. Collect spillage. Store away from other materials.

Other information: Combustible materials exposed to hydrogen peroxide should be immediately submerged in or rinsed with large amounts of water to ensure that all hydrogen peroxide is removed. Residual hydrogen peroxide that is allowed to dry (upon evaporation hydrogen peroxide can concentrate) on organic materials such as paper, fabrics, cotton, leather, wood or other combustibles can cause the material to ignite and result in fire.

Control measures of repellents or poison included in the biocidal product, to prevent action against non-target organisms:

Not applicable. No non-target organisms will be present during the disinfection process.

2.2.10 Assessment of a combination of biocidal products

Not applicable as the biocidal products within the Vaprox® Biocidal Product Family are not intended to be authorised for use with other biocidal products.

2.2.11 Comparative assessment

A comparative assessment is not required since hydrogen peroxide is not considered a candidate for substitution in accordance with Article 10(1) of EU Regulation 528/2012, or for exclusion in accordance with Article 5(1). No further consideration is necessary.

3 ANNEXES[5]

3.1 List of studies for the biocidal product (family)

The following new data has been conducted on the Vaprox® Biocidal Product Family:

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
3.1.1/1 3.2/1 3.3/1 3.9/1	B. Ritts	2007	Vaprox HC Hydrogen Peroxide Solution (59%) Physical and Chemical Characteristics: Color, Physical State, Odor, pH, Viscosity, and Specific Gravity 07002.00 GLP Unpublished	Y	Steris Corporation
3.1.1/2 3.2/2 3.9/2	L.A. Haller	1994	Chemical Analysis and Product Chemistry Data For 35% Hydrogen Peroxide American Sterilizer Co., Erie, PA, USA D500504 GLP Unpublished	N	FMC
3.4.1.1/3	Illegible	2013	Stability Study Report SSP187D Non-GLP Unpublished	Y	Steris Limited
3.4.1.1/4	H. Kaiser	2006	Determination of Stability of PIDS Vaprox 35% Hydrogen Peroxide (1 Month @ 40 °C) SSP194A.00 GLP Unpublished	Y	Steris Limited
3.4.1.2/5	G. Walton	2002	Determination of the Long-term Stability of Vaprox at Accelerated Consitions (6 Months @ 40 °C) SSP158.00 GLP Unpublished	Y	Steris Limited
3.4.1.2/6	Illegible	2012	Stability Study Report SSP187C.01 Non-GLP Unpublished	Y	Steris Limited

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

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
3.4.1.2/7	Illegible	2013	Stability Study Report SSP187C Non-GLP Unpublished	Y	Steris Limited
3.4.1.2/8, 3.4.2.3/8	H. Kaiser	2008	Determination of Stability of Vaprox HC Hydrogen Peroxide Sterilant (59%) (12 Months @ 25 °C) SSP187A GLP Unpublished	Y	Steris Limited
3.4.1.2/9	H. Kaiser	2004	Determination of Long-Term Stability of Vaprox (24 Months @ 25 °C) SSP158.00 GLP Unpublished	Y	Steris Limited
3.4.1.2/10	Illegible	2004	24 Month Stability Study Report VAP001.25, VAP002.25, VAP003.25 Non-GLP Unpublished	Y	Steris Limited
3.4.1.2/11	G. Walton	2002	Determination of Chemical Stability of Vaprox in Contact with the In-use Reservoir (2 Weeks @ 40 °C) SSP158A.00 GLP Unpublished	Y	Steris Limited
3.4.2.3/12	Illegible	2009	Stability Study Report SSP158B.00 Non-GLP Unpublished	Y	Steris Limited
3.8/13 4.1/13 4.16/13 4.17.1/13	S.P. Tremain	2016	Vaprox 59%: Determination of Hazardous Physico-Chemical Properties Envigo Research Limited, UK CD67XV GLP Unpublished	Y	Steris Limited
3.9/14	S. Cage	2016	Vaprox 35%: Viscosity Envigo CRS Limited VY87PH GLP Unpublished	Y	Steris Limited
3.9/15	S. Cage	2016	Vaprox 59%: Viscosity Envigo CRS LimitedDY78PP GLP Unpublished	Y	Steris Limited

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
4.13/16	S. Cage	2016	Vaprox 35%: Oxidizing Properties Envigo CRS Limited JP97VF GLP Unpublished	Y	Steris Limited
5.1/17	A. Thanavaro	2013	Determination of Hydrogen Peroxide in Vaprox 59 Hydrogen Peroxide Sterilant 10034.00 GLP Unpublished	Y	Steris Corporation
5.1/18	A. Thanavaro	2014	Determination of Hydrogen Peroxide in Vaprox Hydrogen Peroxide Sterilant 10038.00 GLP Unpublished	Y	Steris Corporation
6.7/7	Biotech Germande	2016	Determination of the Tuberculocidal Activity of an Airborne surface disinfection process according to NF T 72-281:2014. Report: 2556.STE.15.2m.GB	Y	Steris Corporation
6.7/8	Biotech Germande	2016	Determination of the Bactericidal, Fungicidal, Sporicidal and Virucidal Activity of an Airborne surface disinfection process according to NF T 72-281:2014. Report: 2556.STE.15.GBm1	Y	Steris Corporation
Multiple/9	Finland CA	2015	Evaluation of active substances: Assessment report, Hydrogen Peroxide Product-types 1 - 6	N	-
5.1/10	Thanavaro A	2014	Determination of Hydrogen Peroxide in Vaprox Hydrogen Peroxide Sterilant GLP	Y	Steris Corporation
5.1/11	Thanavaro A	2013	Determination of Hydrogen Peroxide in Vaprox 59 Hydrogen Peroxide Sterilant GLP	Y	Steris Corporation
3.4.1.1/ 12	Steris Corporation	2002	Determination of chemical stability of Vaprox in contact with the in-use reservoir (2 weeks @ 40°C	Y	Steris Corporation
3.4.2.3/ 13	Steris Corporation	2010	Vaprox 35% H2O2, PB027 (open container study) vap005.6m.RT	Y	Steris Corporation
3.4.1.1/ 14	Steris Corporation	2002	Determination of the long term stability of vaprox at accelerated conditions (6 months at 40C) GLP	Y	Steris Corporation

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
3.4.1.2/ 15	Steris Corporation	2004	Determination of the Long-Term Stability of Vaprox (24 months @ 25°C) GLP	Y	Steris Corporation
3.4.1.2/ 16	Steris Corporation	2004	24 month stability study report GLP	Y	Steris Corporation
3.4.1.2/ 3.4.2.3/ 17	Steris Corporation	2008	Determination of Stability of Vaprox HC Hydrogen Peroxide Sterilent (59%) (12 months at 25 °C) GLP	Y	Steris Corporation
3.4.1.1/ 18	Steris Corporation	2013	Stability study report: Vaprox 59 (70 mL cartridge) Report SSP187D Not conducted to GLP	Y	Steris Corporation
6.7/19	Instituto Valenciano de Microbiologia, S.L.	2014	Bactericidal Activity Test with the product VAPROX HYDROGEN PEROXIDE STERILANT DESIN-1030-b	Y	STERIS Iberia, S.A.U.
6.7/20	Laboratorio de diagnostic general	2010	DETERMINATION OF SPOROCIDE ACTIVITY OF CHEMICAL DISINFECTANTS INF-CSG-10-144-Rev0	Y	STERIS LTD
6.7/21	Instituto Valenciano de Microbiologia,	2015	Sporicidal activity test (phase 2/ step 1) with VAPROX HYDROGEN PEROXIDE STERILANT DESIN-1044-b	Y	STERIS Iberia, S.A.U.
6.7/22	Laboratorio de diagnostic general	2010	DETERMINATION OF BASIC BACTERICIDAL ACTIVITY OF ANTISEPTICS AND CHEMICAL DISINFECTANTS INF-CSG-10-142-Rev0	Y	STERIS LTD
6.7/23	Laboratorio de diagnostic general	2010	DETERMINATION OF BASIC FUNGICIDAL ACTIVITY OF ANTISEPTICS AND CHEMICAL DISINFECTANTS INF-CSG-10-145-Rev0	Y	STERIS LTD
6.7/24	Instituto Valenciana de Microbiologia	2015	Virucidal test with the product Vaprox Hydrogen Peroxide Sterilant, 35%, against Poliovirus type 1, Adenovirus type 5 and Murine Norovirus (UNE EN 14476: 2014 Guideline) D/15/45	Y	STERIS Corporation

Section no. / Reference no.	Author(s)	Year	Title. Source (where different from company) Company, Report no. GLP (where relevant) / (un)published	Data Protection Claimed (Y/N)	Owner
6.7/25	Instituto Valenciano de Microbiologia.	2015	Fungicidal / Yeasticidal activity of VAPROX HYDROGEN PEROXIDE STERILANT European standard UNE-EN 1650: 2008 + A1: 2013 D/14/110	Y	STERIS Iberia

3.2 Output tables from exposure assessment tools

Figure 1.1. Tier 1 estimate for transferring the concentrate (ConsExpo Web)

	Value
Exposure model	Exposure to vapour - Evaporation
Exposure duration	5 minute
Product is substance in pure form	No
Molecular weight matrix	18 g/mol
The product is used in dilution	No
Amount of solution used	3087 g
Weight fraction substance	0.59
Room volume	1 m^3
Ventilation rate	2.5 per hour
Inhalation rate	1.25 m^3/hr
Application temperature	20 °C
Vapour pressure	214 Pa
Molecular weight	34 g/mol
Mass transfer coefficient	24.3 m/hr
Release area mode	Constant
Release area	20 cm^2
Emission duration	5 minute
Absorption model	Fixed fraction
Absorption fraction	1
Mean event concentration ***(average air concentration on exposure event. Note: depends strongly on chosen exposure duration)***	2.4 mg/m^3
Peak concentration (TWA 15 min) ***(peak concentration (TWA 15 min) is the 15 minute time weighted average of the air concentration. In case the exposure duration is less than 15 minutes, the mean event air concentration is given instead.)***	2.4 mg/m^3
Mean concentration on day of exposure	–

	Value
(average air concentration over the day (accounts for the number of events on one day))	
Year average concentration ***(mean daily air concentration averaged over a year)***	–
External event dose ***(the amount that can potentially be absorbed per kg body weight during one event)***	4.2×10^{-3} mg/kg bw
External dose on day of exposure ***(the amount that can potentially be absorbed per kg body weight during one day)***	–

Figure 1.2. Tier 1 estimate for disposal of the diluted product (ConsExpo Web)

Exposure model	Exposure to vapour - Evaporation
Exposure duration	25 minute
Product is substance in pure form	No
Molecular weight matrix	18 g/mol
The product is used in dilution	Yes
Dilution	20 times
Product amount	3090 g
Weight fraction substance	59 %
Room volume	15 m³
Ventilation rate	2.5 per hour
Inhalation rate	1.25 m³/hr
Application temperature	20 °C
Vapour pressure	214 Pa
Molecular weight	34 g/mol
Mass transfer coefficient	24.3 m/hr
Release area mode	Constant
Release area	0.15 m²
Emission duration	25 minute
Absorption model	Fixed fraction
Absorption fraction	1

Inhalation

Mean event concentration ***(average air concentration on exposure event. Note: depends strongly on chosen exposure duration)***	1.7 mg/m³
Peak concentration (TWA 15 min) ***(peak concentration (TWA 15 min) is the 15 minute time weighted average of the air concentration. In case the exposure***	2.3 mg/m³

duration is less than 15 minutes, the mean event air concentration is given instead.)	
Mean concentration on day of exposure ***(average air concentration over the day (accounts for the number of events on one day))***	2.9×10^{-2} mg/m³
Year average concentration ***(mean daily air concentration averaged over a year)***	2.9×10^{-2} mg/m³

Figure 1.3. Tier 2 estimate for transferring the concentrate (ART)

Details for Activity Disposal of expired product - pouring

Emission sources: Near field ✓ Far field

Duration (mins): 5

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	214 Pa
Liquid mole fraction	0.433
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	Handling that reduces contact between product and adjacent air. Note: This does not include processes that are fully contained by localised controls (see next questions).
Loading type	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?	No
General 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	Only good natural ventilation

Predicted exposure levels

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

Mechanistic model results

The predicted 75th percentile full-shift exposure is 1.1 mg/m³.

The 90% confidence interval is 0.21 mg/m³ to 6.2 mg/m³.

Figure 1.4. Tier 2 estimate for disposal of the diluted product (ART)

Emission sources: Near field ✓ Far field

Duration (mins): 25

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	214 Pa
Liquid mole fraction	0.0158
Activity coefficient	0.8
Activity emission potential	
Activity class	Activities with relatively undisturbed surfaces (no aerosol formation)
Situation	Open surface 0.1 – 0.3 m²
Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	No
General 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	Only good natural ventilation

Predicted exposure levels

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

Mechanistic model results

The predicted 75th percentile full-shift exposure is 0.36 mg/m³.

The 90% confidence interval is 0.069 mg/m³ to 2 mg/m³.

Figure 1.5. Estimate for pouring the concentrate and disposal of the diluted product

Emission sources: Near field ✓ Far field

Duration (mins): 5

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	214 Pa
Liquid mole fraction	0.433
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	Handling that reduces contact between product and adjacent air. Note: This does not include processes that are fully contained by localised controls (see next questions).
Loading type	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?	No
General 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	Only good natural ventilation

Emission sources: Near field ✓ Far field

Duration (mins): 25

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	214 Pa
Liquid mole fraction	0.0158
Activity coefficient	0.8
Activity emission potential	
Activity class	Activities with relatively undisturbed surfaces (no aerosol formation)
Situation	Open surface 0.1 – 0.3 m²
Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	No
General 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	Only good natural ventilation

Predicted exposure levels

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

Mechanistic model results

The predicted 75th percentile full-shift exposure is 0.48 mg/m³.

The 90% confidence interval is 0.094 mg/m³ to 2.7 mg/m³.

3.3 New information on the active substance

The BPC opinion for the active substance hydrogen peroxide for product type 2 requested that the following additional data should be generated on the active substance.

1) A new analytical method for the determination of hydrogen peroxide in air should be submitted.
2) A new analytical method for the determination of hydrogen peroxide in water should be submitted.

The above data has been generated and provided to the Finnish Competent Authority. Steris Limited have access to this additional data through their Letter of Access which has been supplied from their active substance supplier.

3.4 Residue behaviour

Not relevant.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[6]

An Iuclid dataset is available. Please see section 6.7 of our Iuclid file as this section contains robust study summaries of all the efficacy study data.

3.6 Confidential annex

3.6.1 Product (family) composition and formulation

Please see separate confidential PAR for further details on the product family composition.

3.6.2 Endocrine disruption

A targeted determination of whether any non-active substances (co-formulants) in the VAPROX biocidal product family are an endocrine disruptor (ED) or have “indications” of endocrine disrupting properties based on whether a decision has already been made within the EU programmes of work has been conducted, and identified the following:

Excluding from further assessment co-formulants which are simple food material (e.g. grain, flour, sugar, salt, water) do not require to be considered further as these are highly unlikely to possess endocrine disrupting properties.

The biocidal product family contain the active substance and a single co-formulant - water. Therefore no further consideration is applicable.

The active substance contains a number of stabilisers (Confidential to the active substance manufacturer) to prevent the active substance breaking down when it is stored. An ED assessment has been carried out on the stabilisers (Confidential PAR). Post authorisation requirement has been set – see Confidential PAR for further details. Update 09/2020 by

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

FI CA: Due to Brexit FI is a new refMS to evaluate the fulfilment of post authorisation requirement. Please see updated Confidential PAR for this.

3.7 Other

Environmental Risk Assessment models

Calculation of PEC_{air}

Calculations for direct emissions of hydrogen peroxide to air from operation of VHP generators are already included within the "Emissions estimation" section of this PAR.

In addition, hydrogen peroxide could become airborne at local STP, but this too does not give rise to significant concentrations at 100 m from this point source and its contribution to levels of a.s. in the terrestrial compartment can be discounted. Modelling presented in ECHA Guidance on ERA, Volume IV, Parts B+C, version 2.0, October 2017 (as equation 38) allows the indirect emission from the STP to air to be quantified as follows :

$Estp_{air} = Fstp_{air} * Elocal_{water}$

Where:
$Elocal_{water}$ = local emission to wastewater during episode (0.264 kg/d and 6.82E-4 kg/d)
$Fstp_{air}$ = fraction emission directed to air by STP (1.66E-6 based on SimpleTreat v3.1)
$Estp_{air}$ = local emission to air from STP during emission episode (4.38E-7 kg/d for Scenario 2a and 1.13E-9 kg/d for Scenario 2b)

The concentration in air ($PEClocal_{air}$) is then calculated as an average concentration at a distance of 100 metres for a point source – this distance is chosen to represent the typical distance between the emission source (local STP in this case) and the border of that "industrial site". With no other losses to air predicted during topical application of the insect repellent, then the PEC air (as $Clocal_{air}$) can be calculated by the following :

$Clocal_{air} = Estp_{air} * Cstd_{air}$

Where:
$Estp_{air}$ = local indirect emission to air from STP during episode (4.38E-7 kg/d and 1.13E-9 kg/d)
$Cstd_{air}$ = concentration in air at source strength of 1 kg d^{-1} (default of 2.78E-4 mg/m^3)
$Clocal_{air}$ = local concentration in air during emission episode (1.22E-10 mg/m^3 for Scenario 2a and 3.14E-13 mg/m^3 for Scenario 2b)

Calculation of PEC_{STP} and $PEC_{surface\_water}$ (and $PEC_{sediment}$)

Indoor scenarios

Taking the $Elocal_{water}$ values previously calculated, the aquatic PEC values can be calculated using the following equations and default values taken from the ECHA guidance on ERA.

$$Clocal_{\inf} = \frac{Elocal_{water} * 10^6}{EFFLUENT_{stp}} \quad (32)$$

$$Clocal_{eff} = Clocal_{inf} \cdot Fstp_{water} \quad (33)$$

$$Clocal_{water} = \frac{Clocal_{eff}}{(1 + Kp_{susp} * SUSP_{water} * 10^{-6}) * DILUTION} \quad (45)$$

As this product is intended for daily use, the $Clocal_{eff}$ will be used to assess the risk to micro-organisms at STP.

Calculation of PEC_{stp} following indoor application (worst case)

Parameters	Value	Value	Unit
PT 2 - Scenario 2	2a	2b	
$Elocal_{water}$	0.264	6.82E-4	kg /d
Effluent discharge rate of STP ($Effluent_{stp}$)	2.0E+6	2.0E+6	l
$Clocal_{inf}$	0.132	3.41E-4	mg /l
$Fstp_{water}$	6.87E-3	6.87E-3	
$Clocal_{eff}$ (PECstp)	9.07E-4	2.34E-6	mg /l

Calculation of $PEC_{surface\ water}$ following indoor application

Parameters	Nomenclature	Value	Unit
Weight fraction organic carbon in suspended solids	Foc_{susp}	0.1	
Partition coefficient organic carbon - water	Koc	1.598	l/ kg
Partition coefficient solid – water in suspended matter	Kp_{susp}	0.16	
Concentration of suspended matter	$SUSP_{water}$	15	mg/ l
	DILUTION	10	
$PEC_{surface\ water}$	$Clocal_{water}$	x	mg /l

Scenario 2a : PECwater is 9.07E-5 mg/l ; Scenario 2b : PECwater is 2.34E-7 mg/l

PEC sediment has not been determined as $PNEC_{sediment}$ can only be derived by EPM.

Calculation of PEC_{soil} and $PEC_{groundwater}$

Levels of hydrogen peroxide reaching the terrestrial compartment will only be as a result of the fraction sorbed to sewage sludge as the contribution from air (via deposition) can be discounted.

The concentration of any active substance in dry sewage sludge can be calculated using ECHA guidance on ERA, Volume IV, Part B (equations 36 and 37) plus default parameters presented in the same guidance document as follows :

$$C_{sludge} = \frac{Fstp_{sludge} \times Elocal_{water} \times 10^6}{SLUDGERATE}$$

where:

SLUDGERATE = 2 / 3 x $SUSPCONC_{inf}$ x $EFFLUENT_{stp}$ + $SURPLUS_{sludge}$ x $CAPACITY_{stp}$

and

$EFFLUENT_{stp}$ = $CAPACITY_{stp}$ x $WASTEW_{inhab}$

Calculation of PEC_{soil} following indoor application

Parameters	Nomenclature	Value : Scenario 2a	Value : Scenario 2b	Unit
Concentration of suspended matter in STP influent	$SUSPCONC_{inf}$	0.45	0.45	Kg/m^3
Effluent discharge rate of STP	$EFFLUENT_{stp}$	2.0E+6	2.0E+6	L/d
Surplus sludge per inhabitant	$SURPLUS_{sludge}$	0.019	0.019	Kg/d
Capacity of STP	$CAPACITY_{stp}$	10,000	10,000	
Sewage flow per inhabitant	$WASTEW_{inhab}$	200	200	L/d
Rate of sewage sludge production	SLUDGERATE	790	790	Kg/d
Local emission rate to water during treatment episode	$Elocal_{water}$	0.264	6.82E-4	Kg/d
Fraction of emission directed to sludge at STP	$Fstp_{sludge}$	1.45E-4	1.45E-4	
Concentration in dry sewage sludge	Csludge	4.85E-2	1.25E-4	mg/kg dwt

When rapid degradation in soil is taken into account (DT_{50} of 12 hr), the equivalent "k" rate would be 1.386 d^{-1} and this would crudely represent removal rate of the a.s. from top soil. At the end of each year, a fraction of the initial concentration (Facc) may potentially remain in the top soil layer and this can be determined by use of the equation stating:

$$Facc = e^{-365k}$$

where
Facc = fraction accumulation in 1 year (-)
k = first order rate constant for removal from top soil via degradation (d^{-1})

The fraction of initial concentration (Facc) remaining in the top soil layer after one year has therefore been determined as zero and clearly shows that the a.s. will not accumulate thus $Csludge_{soil\ 1\ (0)}$ = $Csludge_{soil\ 10\ (0)}$.

In line with guidance presented in the ECHA guidance on ERA (equation 60), the concentration of a.s. in soil (represented as $Csludge_{soil\ 1}$ (0)) after the first year of manure application can be given as;

$$Csludge_{soil\,1}\ (0) = \frac{C_{sludge} \cdot APPL_{sludge}}{DEPTH_{soil} \cdot RHO_{soil}}$$

Where:
C_{sludge} is the concentration in manure (4.85E-2 mg/kg dwt or 1.25E-4 mg/kg dwt)
$APPL_{sludge}$ is the sludge application rate (0.1 kg m^2 yr^{-1} for grass for cattle or 0.5 kg m^2 yr^{-1} for terrestrial ecosystems and crops for human consumption)
$DEPTH_{soil}$ is the mixing depth of soil (0.1 for grass for cattle or 0.2 m for terrestrial ecosystems and crops for human consumption)
RHO_{soil} is the bulk density (wet) of soil (1700 kg m^{-3}; default)
Csludge $_{soil\ 1}$ (0) is the concentration in soil due to manure in first year at t = 0 and is identical to Csludge $_{soil\ 10}$ (0)

C_{sludge} (mg/kg dwt)	$Csludge_{soil\ 1}$ (0) Arable (mg/kg wwt)	$Csludge_{soil\ 1}$ (0) Grass (mg/kg wwt)	$Csludge_{soil\ 1}$ (0) Local (mg/kg wwt)
(2a) : 4.85E-2	7.13E-5	2.85E-5	7.13E-5
(2b) : 1.25E-4	1.84E-7	7.36E-8	1.84E-7

The PEC for local soil (referred to as $Clocal_{soil}$) has been calculated using the following model taken from ECHA guidance on ERA, Volume IV (equation 55) :

$$Clocal_{soil} = \frac{D_{air}}{k} + \frac{1}{kT}\left[C_{soil}(0) - \frac{D_{air}}{k} \right] \cdot \left[1 - e^{-kT}\right]$$

Where :
D_{air} is the aerial deposition flux per kg of soil (taken to be zero)
T is the averaging time (180 d for arable land and grassland as a representative growing period for crops and 30 days for terrestrial ecosystems)
k is the first order rate constant for removal from top soil (1.386 d^{-1})
C_{soil} (0) is the initial concentration in soil after sludge application
$Clocal_{soil}$ is the average concentration in soil over T days

Csludge (mg/kg dwt)	$PEClocal_{soil}$ Grassland [mg/kg wwt]	$PEClocal_{soil}$ Arable land [mg/kg wwt]	$PEClocal_{soil}$ Ecosystem [mg/kg wwt]
(2a) : 4.85E-2	1.14E-7	2.86E-7	1.71E-6
(2b) : 1.25E-4	2.95E-10	7.38E-10	4.43E-9

Predicted concentrations of hydrogen peroxide in local agricultural soil can be used to crudely indicate groundwater levels in line with equation 67 from ECHA guidance on ERA, Volume IV, Part B but the approach is very simplistic and takes no account of soil characterisation (neglecting consideration of transformation plus dilution in deeper soil layers) :

$$PEClocal_{soil,\ porewater} = \frac{PEClocal_{soil} \times RHO_{soil}}{K_{soil\text{-}water} \times 1000}$$

where
$PECloca l_{soil,\ porewater}$ is the predicted environmental concentration in porewater (mg l^{-1})
$PECloca l_{soil}$ is the predicted environmental concentration in agricultural soil (2.86E-7 mg/kg wwt for Scenario 2a and 7.38E-10 mg/kg wwt for Scenario 2b)
RHO_{soil} is the bulk density of wet soil (default of 1700 kg m^{-3})
$K_{soil\text{-}water}$ is the soil-water partitioning co-efficient (calculated in $m^3\ m^{-3}$)

plus

$$K_{soil\text{-}water} = (Fair_{soil} * K_{air\text{-}water}) + Fwater_{soil} + (Fsolid_{soil} * (Kp_{soil} / 1000) * RHO_{solid})$$

where
$Fair_{soil}$ is the fraction of air in soil (default of 0.2 $m^3\ m^{-3}$)
$K_{air\text{-}water}$ is the air-water partitioning coefficient (= Henry's law constant/(R x Temp))
$Fwater_{soil}$ is the fraction of water in soil (default of 0.2 $m^3\ m^{-3}$)
$Fsolid_{soil}$ is the fraction of solids in soil (default of 0.6 $m^3\ m^{-3}$)
Kp_{soil} is the solids-water partitioning coefficient in soil (Foc_{soil} of 0.02 * Koc)
RHO_{solid} is the density of the solid phase (default of 2500 kg m^{-3})

Based upon properties outlined for hydrogen peroxide, the following values have been derived :

Property	Hydrogen peroxide
Henry's law constant	7.50E-4
$K_{air\text{-}water}$	3.17E-7
Kp_{soil}	0.032
$K_{soil\text{-}water}$	0.248

Using $PECloca l_{soil}$ for arable land (as representative of worst case application to agricultural land), $PECloca l_{soil,\ porewater}$ value can be predicted as follows :

$PECloca l_{ag.soil}$ (mg kg^{-1} wwt)	$PECloca l_{soil,\ porewater}$ (µg l^{-1})	$PEC_{surface\ water}$ (via soil run-off) in µg l^{-1}
(2a) : 2.86E-7	1.96E-3	1.96E-4
(2b) : 7.38E-10	5.06E-6	5.06E-7

Re-circulation of groundwater back into surface waters could result in a concentration of 1.96E-4 µg/l for Scenario 2a or 5.06E-7 µg/l for Scenario 2b but, when compared with a $PNEC_{aquatic}$ of 1.26E-2 mg/l (12.6 µg/l), this predicts only negligible risks (PEC/PNEC ratios <0.0001 in each case).