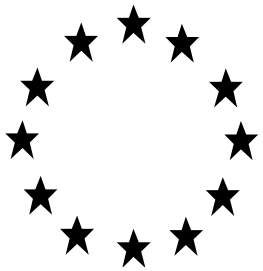
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL FAMILY FOR UNION AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



PeridoxRTU Product Family

Product type 2

Peracetic Acid as included in the Union list of approved active substances

Case Number in R4BP: BC-HT057172-25

Evaluating Competent Authority: Belgium

Date [19/03/20]

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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. Surface disinfection to clean, hard non-porous surfaces in cleanrooms in industrial settings.

1.3 User

Professional

1.4 Application method and application rate

Trigger spray onto a suitable cleanroom wipe and use the wipe to distribute the liquid on the surface – 50 ml/m^2

Pour into a container and use a suitable cleanroom mop / wipe to distribute the liquid onto the surface - 50 ml/m^2

Uniform distribution of the product on the surface should be ensured and the entire surface should remain visibly wet for the required contact time to kill the target organisms.

- Contact time against bacteria for 2 minutes.
- Contact time against fungi, yeasts and bacterial spores is 3 minutes.

1.5 Pests

- Bacteria
- Fungi
- Yeast
- Bacterial Spores

1.6 Comparative assessment and authorisation

Peracetic acid is not considered a candidate for substitution in accordance with Article 10(1) of EU Regulation 528/2012. A comparative assessment is therefore not required under Article 23 of Regulation (EU) 528/2012.

1.7 Necessary issues accounted for in the product label

The following PPE phrase must appear on the SPC and label:

- Wear protective chemical resistant gloves and eye protection during product handling phase (glove material to be specified by the authorisation holder within the product information)

- A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

1.8 Endocrine disruptor

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.

For the human health assessment, a targeted determination of whether any non-active substances (co-formulants) in the PeridoxRTU Biocidal Product Family are endocrine disruptors (ED) or have "indications" of endocrine disrupting properties was performed. For each component the following was considered:

- Has it been identified as an ED under BPR/PPPR, REACH substance evaluation, CoRAP or the EU priority list?
- Is it a food of feedstuff?
- Have any ED alerts been found in USEPA EDSP21, USEPA ToxCast, CLP classification or the open literature?.

No information was found in any of these data sources that identified any of the substances in the PeridoxRTU Product Family as an ED. It was therefore concluded that the products in the PeridoxRTU Product Family are not endocrine disruptors

For the ecotox assessment no information was found in any of these data sources that identified any of the substances in the PeridoxRTU Product Family as an ED, however the literature review required by the guidance was missing so the assessment could not be finalised.

Further information can be found in section 3.6 CONFIDENTIAL ANNEX.

1.9 BPC Conclusions of the evaluation

Summary of the evaluation of the risk assessment

The sections in 1.9 below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product family.

General

The biocidal product family PeridoxRTU Product Family consists of products containing the active substance peracetic acid. The formulated active substance contains 0.23 % peracetic acid. The product is for disinfection of hard surfaces in cleanrooms in products type 2. Two substances of concern were identified in the biocidal product family: Hydrogen peroxide (for Human health and Environment) and acetic acid (for Human health only).

The biocidal product family (BPF) consists of a single meta SPC for which the following uses have been assessed:

Meta SPC 1

Use 1

- Application method: Trigger spray onto a suitable cleanroom wipe followed by application to a surface
- Formulation type: RTU solution/trigger spray
- Users: Professionals
- Use: Disinfection hard surfaces in cleanrooms.

Use 2

- Application method: Pour into a container and then apply using a suitable cleanroom Mop / Wipe
- Formulation type: RTU solution
- Users: Professionals
- Use: Disinfection hard surfaces in cleanrooms

Physico-chemical properties

The physical, chemical and technical properties for PeridoxRTU Product Family are acceptable for the liquid formulation supplied to the user as trigger spray and RTU product. The data provided are sufficient to support the BPF requested.

Accelerated storage data for the liquid formulation alone were acceptable after 12 weeks at 40°C and showed no adverse interactions between the liquid formulation and the HDPE packaging. Acceptable storage data were also submitted relating to storage for 12 months at ambient temperature.

Therefore, a shelf life of 12-months is supported for the BPF.

A low temperature storage stability study was not required as the label carries the phrase "do not freeze".

Based on the results of UN Test C.1 The product is assigned the hazard "H290: May be corrosive to metals".

Based on expert consideration of the composition, PeridoxRTU Product Family is considered not to be flammable, explosive, oxidising, self-reactive or self-heating.

The detection and identification of peracetic acid, hydrogen peroxide and acetic acid in the biocidal product family has been performed by HPLC-UV analytical method validated in accordance with the relevant guidance.

Efficacy

The efficacy of the BPF is demonstrated for use at a concentration of 0.23 % w/w peracetic acid.

Meta SPC 1

Use #1: The application rate for application by a wipe is 50 ml/m^2. For this application method a contact time of 2 min is required for bacteria. A contact time of 3 min is required for bacterial spores, fungi and yeast.

Use #2: The application rate is 50 ml/m^2. For this application a contact time of 2 min is required for bacteria. A contact time of 3 min is required for bacterial spores, fungi and yeast.

Sufficient data were provided to demonstrate that the BPF is efficacious against bacteria, fungi, yeast, bacterial spores in clean conditions at room temperature.

Human health

Based on a pH of 1.72, the products should be classified:

- Skin Corr. 1A - H314: Causes severe skin burns and eye damage.

The active substance assessments for peracetic acid and hydrogen peroxide informs that the AEC for professional users of 0.5 mg/m^3 and 1,25 mg/m^3. Exposure at above these levels was modelled for users of the product. The risk to professional users was demonstrated to be acceptable when gloves and eye protection were modelled to be worn and increased ventilation rates are considered.

Professional user risk assessment

Primary exposure has been considered for a professional user using a trigger spray, pouring the product into a container and also through disinfection of surfaces using a dry wipe or mop.

Secondary exposure has been modelled for professionals re-entering an area treated by mopping/wiping or spraying onto a wipe.

When taking into account primary exposure from the use of products from the PeridoxRTU Product Family the following conclusions can be drawn:

- Spraying of the product onto a wipe: gloves, coveralls and eye protection must be worn when handling the product.
- Pouring of the product into a container from a 5 L bottle and the use of a mop or wipe to spread the product: gloves, coveralls and eye protection must be worn when handling the product.

When taking into account secondary exposure from the use of products from the PeridoxRTU Product Family the following conclusions can be drawn:

- Exposure when a professional bystander re-enters a treated area after disinfection through spraying onto a wipe: acceptable exposure without PPE;
- Exposure when a professional bystander re-enters a treated area after disinfection through mopping/wiping: acceptable exposure without PPE.

When taking into account exposure scenarios for products from the PeridoxRTU Product Family, the following conclusions can be drawn:

The risk to professional users is demonstrated to be acceptable when protective gloves and coveralls and eye protection are worn and with an increased ventilation rate for Use #1 and Use #2.

The following risk mitigation measures are required for Use #1:

- Wear protective chemical resistant gloves and eye protection during product handling phase (glove material to be specified by the authorisation holder within the product information);
- A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information);
- A ventilation rate of at least 20/hr is mandatory when handling the product;
- The product must only be applied for disinfection of small surfaces.

The following risk mitigation measures are required for Use #2:

- Wear protective chemical resistant gloves and eye protection during product handling phase (glove material to be specified by the authorisation holder within the product information);
- A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information);
- Application of technical or engineering controls to remove airborne residues is mandatory (e.g. room ventilation or LEV) during product application. A minimum ventilation rate of 100 air change per hour is mandatory;
- Technical or engineering controls to remove airborne residues is mandatory (e.g. ventilation or LEV) before operatives are permitted to enter into treated areas after surface disinfection. Where necessary, a waiting restriction of sufficient duration must be set to allow time for the removal of airborne residues.

In addition, given it can be expected that the product still evaporates from the used wipe after the product is distributed on the surface by wiping, the following use instructions should be added to the product label : "Used wipes must be disposed in a closed container".

General public risk assessment

The BPF is not intended for use by the general public therefore no primary exposure scenarios have been identified.

The BPF is intended for use in controlled professional cleanroom environments. As such no general public bystander exposure scenarios are foreseen.

Consumer risk assessment

Exposure to peracetic acid via the diet is not expected for the proposed use of PeridoxRTU Product Family in cleanrooms.

Environment

The PeridoxRTU Product Family contains peracetic acid as the active substance at 0.23 % w/w plus hydrogen peroxide as "substance of concern" at 4.4 % w/w (in line with agreement reached at BPC-M-20-2017 under agenda item 8.2). No other co-formulants are reported to give rise to concerns for the environment so has been discounted from the assessment process.

With a product density of 1.022 g/ml at 20 °C (section 2.2.2 of this PAR), the product application rates of 50 ml/m^2 and 80 ml/m^2 used in the environmental risk assessment are equivalent to 51.10 g/m^2 and 81.76 g/m^2 respectively. In line with respective PT 1 - 6 CARs for both peracetic acid and hydrogen peroxide, rapid degradation of both compounds during transit in sewer systems / drains and in a STP will be taken into account within the emissions assessment.

With regard to the PT 1 – 6 review of hydrogen peroxide, Doc II-A and Doc II-B of the Final CAR concluded that emissions to air from indoor application would be negligible in the absence of heating or pressurised spraying operations. Additionally, hydrogen peroxide would not evaporate from aqueous solutions, based on its low Henry's law constant of 7.5E-4 Pa/ m^3/mol (at 20 °C).

As a consequence, no further consideration will be made for the potential of peracetic acid and hydrogen peroxide to be discharged from industrial premises into the air compartment. However, some consideration of airborne concentrations will be investigated at STP (using

respective $Fstp_{air}$ fractions derived using SimpleTreat modelling), to consider likely levels at 100 m from this point source.

A worst-case concentration of 0.23% peracetic acid and 4.4.% w/w hydrogen peroxide has been modelled at two different application rates : 50 ml/m^2 for trigger spray application and 80 ml/m^2 for mop / wipe / cloth application.

Acceptable levels of risk to all environmental compartments (air, STP, surface water, sediment, soil, groundwater and non-target biota) have been demonstrated for the proposed uses of the BPF.

Overall conclusion

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended uses of the biocidal product family have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product family are met.

The physico-chemical properties of the biocidal product family are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised uses, according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product family is sufficiently effective;
2. the biocidal product family has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance;
3. the biocidal product family has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product family has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
    - the fate and distribution of the biocidal product family in the environment,
    - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
    - the impact of the biocidal product on non-target organisms,
    - the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the uses described in the SPC, may be authorised.

1.10 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 / product family

Identifier	**Country (if relevant)**
PeridoxRTU Product Family	Belgium

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Contec Europe
	Address	Du Prat, Avenue Paul Duplaix, 56000, Vannes, France
Pre-submission phase started on	14th March 2017	
Pre-submission phase concluded on	13th April 2017 Decision number: UPP-D-1247737-86-00/F	
Authorisation number	To be inserted when authorised	
Date of the authorisation	To be inserted when authorised	
Expiry date of the authorisation	10-years from the date of authorisation.	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Enviro Tech Chemical Services, Inc.
Address of manufacturer	500 Winmoore Way Modesto, CA 95358, USA
Location of manufacturing site 1	724 Phillips Rd 411 Helena, AR 72342, USA
Location of manufacturing site 2	500 Winmoore Way Modesto, CA 95358, USA

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

Active substance	Peracetic Acid
Name of manufacturer	Evonik Peroxid GmbH
Address of manufacturer	Industriestraße 1, 9721 Weißenstein, Austria
Location of manufacturing sites	Industriestraße 1, 9721 Weißenstein, Austria

2.1.2 Product (family) composition and formulation

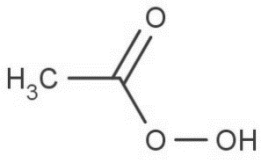
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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	Peracetic acid
IUPAC or EC name	Peroxyethanoic acid
EC number	201-186-8
CAS number	79-21-0
Index number in Annex VI of CLP	607-094-00-8
Minimum purity / content	The active substance is peracetic acid in an aqueous solution containing acetic acid, hydrogen peroxide and water. Pure peracetic acid does neither exist commercially nor is it an intermediate in the production of peracetic acid products. Furthermore, any attempt to produce pure peracetic acid would be prevented by the explosion risks of such a compound. Peracetic acid is produced by reacting hydrogen peroxide (H_2O_2) with acetic acid in aqueous solution. In this process, peracetic acid is not obtained as a pure substance but in the form of aqueous solutions containing peracetic acid, acetic acid, hydrogen peroxide and water. The peracetic acid content in existing aqueous equilibrium solutions (products) can be as low as < 0.1% or as high as > 15% (w/w). The equilibrium solution is typically the biocidal product which is placed on the market. The specifications are based on the starting materials acetic acid and hydrogen peroxide. The specification of (starting material) acetic acid is as in accordance to Regulation 231/2012. The minimum purity of acetic acid is >99.8% For (starting material) hydrogen peroxide the specification is as in the hydrogen peroxide CAR in PTs 1-6, and the purity/contents in aqueous solution is 35 - 69.9%, as in Regulation (EU) 2015/1730.

Structural formula	

2.1.2.2 Candidate(s) for substitution

Peracetic acid is not considered a candidate for substitution in accordance with Article 10(1) of EU Regulation 528/2012. A comparative assessment is therefore not required under Article 23 of Regulation (EU) 528/2012.

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

Two substances of concern, acetic acid and hydrogen peroxide, were identified.

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Peracetic acid	Peroxyethanoic acid	Active substance	79-21-0	201-186-8	0.23	0.23
Acetic acid	Acetic acid	Non-active substance	64-19-7	200-580-7	5.00	5.00
Hydrogen Peroxide	Hydrogen Peroxide	Non-active substance	7721-84-1	231-765-0	4.40	4.40
Other non-active ingredients of formulation					90.37	90.37

The full product family formulation composition details are contained within the Confidential Annex of this PAR (section 3.6.1).

2.1.2.4 Information on technical equivalence

The sources of the active substance are the same as those considered for BPR approval.

2.1.2.5 Information on the substance(s) of concern

Please see the confidential annex for further details.

2.1.2.6 Type of formulation

AL – Any other liquid (RTU)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Skin Corr. 1 Eye Dam 1 Aquatic Chronic 3
Hazard statement	H314 Causes severe skin burns and eye damage. H318 Causes serious eye damage H290 May be corrosive to metals. H412 'Harmful to aquatic life with long lasting effects'
Labelling	
Signal words	Danger
Hazard statements	H314 Causes severe skin burns and eye damage. H290 May be corrosive to metals. H412 'Harmful to aquatic life with long lasting effects'
Precautionary statements	P260 Do not breathe vapour/ spray. P234 Keep only in original packaging. P264 Wash… thoroughly after handling.* P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. P301+330+331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P304+340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER or doctor/physican.* P321 Specific treatment (see… on this label).* P363 Wash contaminated clothing before reuse.* P390 Absorb spillage to prevent material damage. P405 Store locked up.* P501 Dispose of contents/container in accordance with local/regional/ national/international regulations (to be specified).*
Note	H318 may be omitted if H314 is given on the label *The following P statements are triggered by the classification but have not been applied by the applicant: P264, P363, P310, P321, P405 and P501. P406 may be omitted if P234 is given on the label.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Application by trigger spray onto a suitable cleanroom wipe and using the wipe to distribute the liquid on the surface

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	Surface disinfection of clean, hard surfaces in cleanrooms not associated with food or feed areas, by spraying onto a suitable cleanroom wipe and using the wipe to distribute the liquid on the surface.
Target organism (including development stage)	Bacteria Fungi Yeast Bacterial Spores
Field of use	Indoor
Application method(s)	Spray onto a suitable cleanroom wipe and use the wipe to distribute the liquid on the surface. Uniform distribution of the biocidal product should be ensured.
Application rate(s) and frequency	Ready-to-use product. 50 ml/m2 Ensure the surface is uniformly covered with the product and leave for the required contact time. Contact time for bacteria – 2-minutes. Contact time for fungi, yeasts and bacterial spores – 3-minutes.
Category(ies) of users	Professional
Pack sizes and packaging material	900 ml HDPE bottle, delivered with a Poly Propylene screw cap which is replaced with the Poly Propylene trigger

2.1.4.2 Use-specific instructions for use

For use only on visibly clean surfaces. Cleaning prior to disinfection is required. Physically remove contaminants from the surface before disinfection using a suitable cleanroom wipe and a recommended wiping technique for optimum contamination control.
Spray directly onto a suitable cleanroom wipe. Use a wipe to distribute the liquid on the surface. Ensure the surface is uniformly covered with the product and leave for the required contact time indicated to kill bacteria, fungi, yeast and bacterial spores.
Do not apply more than 50 ml/m².
Leave for required contact time and wipe to dry afterwards.
For use at room temperature (20±2°C).
Suitable wipe materials should be used in order to minimise interaction with the product.
Used wipes must be disposed in a closed container.

2.1.4.3 Use-specific risk mitigation measures

Wear protective chemical resistant gloves and eye protection during product handling phase (glove material to be specified by the authorisation holder within the product information)

A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

A ventilation rate of at least 20/hr is mandatory when handling the product.

The product must only be applied for disinfection of small surfaces.

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

Inhalation: Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Maintain an open airway. Loosen tight clothing such as collar, tie or belt. When breathing is difficult, properly trained personnel may assist affected person by administering oxygen. Get medical attention. Place unconscious person on their side in the recovery position and ensure breathing can take place.

Skin contact: It is important to remove the substance from the skin immediately. Rinse immediately with plenty of water. Continue to rinse for at least 15 minutes and get medical attention. Chemical burns must be treated by a physician.

Eye contact: Rinse immediately with plenty of water. Do not rub eye. Remove any contact lenses and open eyelids wide apart. Continue to rinse for at least 15 minutes and get medical attention.

Ingestion: Rinse mouth thoroughly with water. Give a few small glasses of water or milk to drink. Stop if the affected person feels sick as vomiting may be dangerous. Never give anything by mouth to an unconscious person. Place unconscious person on their side in the recovery position and ensure breathing can take place. Keep affected person under observation. Get medical attention if symptoms are severe or persist.

Indication of any immediate medical attention and special treatment needed: Treat symptomatically.

Environmental precautions: Prevent from entering into soil, ditches, sewers, waterways and/or groundwater. Spills or discharge to natural waterways is likely to kill aquatic organisms.

Personal precautions, protective equipment and emergency procedures in case of accidental release measures: Evacuate area.

Keep upwind of spill. Ventilate area of leak or spill. Only trained and properly protected personnel must be involved in clean-up operations. Use appropriate safety equipment.

Methods and materials for containment and cleaning up: Avoid making contact with spilled material. When cleaning up a spill always wear the appropriate protective equipment, including respiratory protection, gloves and protective clothing. A self-contained breathing apparatus or respirator and absorbents may be necessary, depending on the size of the spill and the adequacy of ventilation.

Small spills: Wear the correct protective equipment and cover the liquid with absorbent

material. Collect and seal the material and the dirt that has absorbed the spilled material in polyethylene bags and place in a drum for transit to an approved disposal site. Rinse away the remaining spilled material with water to reduce odour and discharge the rinsate into a municipal or industrial sewer, not into a natural waterway.

Large spills: In case of nasal and respiratory irritation, vacate the room immediately. Personnel cleaning up should be trained and equipped with a self-contained breathing apparatus, or an officially approved or certified full-face respirator equipped with an organic vapour cartridge, gloves, and clothing impervious, including rubber boots or shoe protection.

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

This biocidal product, when being disposed of in its unused and uncontaminated state should be treated as a hazardous waste according to EC Directive 2008/98/EC. Any disposal practices must be in compliance with all national and provincial laws and any municipal or local by-laws governing hazardous waste.

Do not dump into any sewers, on the ground, or into any body of water. Avoid release to the environment.

High-temperature incineration is an acceptable practice.

Containers are non-refillable. Do not reuse or refill the containers. Containers should be triple or pressure rinsed with water promptly after they are emptied. They can then be offered for recycling or reconditioning for biocidal products, or they can be punctured and disposed of in a sanitary landfill or by other procedures approved by national and local authorities. Send waste liquid from rinsing of used containers to an approved waste handling facility.

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

Store in a cool, well ventilated area.

Keep this product in the original container tightly closed.

Container must be stored and transported in an upright position to prevent spilling the contents.

Keep away from direct sunlight.

Do not freeze.

Store below 30°C.

The shelf-life is 12 months (unopened).

2.1.4.7 Use description

Table 2. Use # 2 – Application by pouring into a container and then using a suitable cleanroom mop / wipe to apply the liquid on the surface

Product Type	PT 2
Where relevant, an exact description of the authorised use	Surface disinfection of clean, hard surfaces in cleanrooms not associated with food or feed areas, by pouring into a container and then applying the liquid on the surface with a suitable cleanroom mop or a wipe.

Target organism (including development stage)	Bacteria Fungi Yeast Bacterial spores
Field of use	Indoor
Application method(s)	Pour into a container and then apply with a suitable cleanroom mop / wipe
Application rate(s) and frequency	Ready-to-use product. 50 ml/m2 Ensure the surface is uniformly covered with the product and leave for the required contact time. Contact time for bacteria – 2-minutes. Contact time for fungi, yeasts and bacterial spores – 3-minutes.
Category(ies) of users	Professional
Pack sizes and packaging material	3750 ml HDPE bottle with a poly propylene screw cap 900 ml HDPE bottle, delivered with a Poly Propylene screw cap which is replaced with the Poly Propylene push/pull cap

2.1.4.8 Use-specific instructions for use

For use only on visibly clean surfaces. Cleaning prior to disinfection is required. Physically remove contaminants from the surface before disinfection using a suitable cleanroom wipe/mop and a recommended wiping technique for optimum contamination control.

Pour the product into a container and then mop onto the surface.
Ensure the surface is uniformly covered with the product and leave for the required contact time indicated to kill bacteria, fungi, yeast and bacterial spores.

Do not apply more than 50 ml/m².

Leave for required contact time and wipe to dry afterwards.

For use at room temperature (20±2°C).

Suitable wipe and mop materials should be used in order to minimise interaction with the product.

Used wipes must be disposed in a closed container.

2.1.4.9 Use-specific risk mitigation measures

Wear protective chemical resistant gloves and eye protection during product handling phase (glove material to be specified by the authorisation holder within the product information)

A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

Application of technical or engineering controls to remove airborne residues is mandatory (e.g. room ventilation or LEV) during product application. A minimum ventilation rate of 100 air change per hour is mandatory.

Technical or engineering controls to remove airborne residues is mandatory (e.g. ventilation or LEV) before operatives are permitted to enter into treated areas after surface disinfection. Where necessary, a waiting restriction of sufficient duration must be set to allow time for the removal of airborne residues.

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

Inhalation: Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Maintain an open airway. Loosen tight clothing such as collar, tie or belt. When breathing is difficult, properly trained personnel may assist affected person by administering oxygen. Get medical attention. Place unconscious person on their side in the recovery position and ensure breathing can take place.

Skin contact: It is important to remove the substance from the skin immediately. Rinse immediately with plenty of water. Continue to rinse for at least 15 minutes and get medical attention. Chemical burns must be treated by a physician.

Eye contact: Rinse immediately with plenty of water. Do not rub eye. Remove any contact lenses and open eyelids wide apart. Continue to rinse for at least 15 minutes and get medical attention.

Ingestion: Rinse mouth thoroughly with water. Give a few small glasses of water or milk to drink. Stop if the affected person feels sick as vomiting may be dangerous. Never give anything by mouth to an unconscious person. Place unconscious person on their side in the recovery position and ensure breathing can take place. Keep affected person under observation. Get medical attention if symptoms are severe or persist.

Indication of any immediate medical attention and special treatment needed: Treat symptomatically.

Environmental precautions: Prevent from entering into soil, ditches, sewers, waterways and/or groundwater. Spills or discharge to natural waterways is likely to kill aquatic organisms.

Personal precautions, protective equipment and emergency procedures in case of accidental release measures: Evacuate area.

Keep upwind of spill. Ventilate area of leak or spill. Only trained and properly protected personnel must be involved in clean-up operations. Use appropriate safety equipment.

Methods and materials for containment and cleaning up: Avoid making contact with spilled material. When cleaning up a spill always wear the appropriate protective equipment, including respiratory protection, gloves and protective clothing. A self-contained breathing apparatus or respirator and absorbents may be necessary, depending on the size of the spill and the adequacy of ventilation.

Small spills: Wear the correct protective equipment and cover the liquid with absorbent material. Collect and seal the material and the dirt that has absorbed the spilled material in polyethylene bags and place in a drum for transit to an approved disposal site. Rinse away the remaining spilled material with water to reduce odour and discharge the rinsate into a municipal or industrial sewer, not into a natural waterway.

Large spills: In case of nasal and respiratory irritation, vacate the room immediately.

Personnel cleaning up should be trained and equipped with a self-contained breathing apparatus, or an officially approved or certified full-face respirator equipped with an organic vapour cartridge, gloves, and clothing impervious, including rubber boots or shoe protection.

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

This biocidal product, when being disposed of in its unused and uncontaminated state should be treated as a hazardous waste according to EC Directive 2008/98/EC. Any disposal practices must be in compliance with all national and provincial laws and any municipal or local by-laws governing hazardous waste.

Do not dump into any sewers, on the ground, or into any body of water. Avoid release to the environment.

High-temperature incineration is an acceptable practice.

Containers are non-refillable. Do not reuse or refill the containers. Containers should be triple or pressure rinsed with water promptly after they are emptied. They can then be offered for recycling or reconditioning for biocidal products, or they can be punctured and disposed of in a sanitary landfill or by other procedures approved by national and local authorities. Send waste liquid from rinsing of used containers to an approved waste handling facility.

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

Store in a cool, well ventilated area.

Keep this product in the original container tightly closed.

Container must be stored and transported in an upright position to prevent spilling the contents.

Keep away from direct sunlight.

Do not freeze.

Store below 30°C.

The shelf-life is 12 months (unopened).

2.1.5 General directions for use

2.1.5.1 Instructions for use

See 2.1.4.2 & 2.1.4.8

2.1.5.2 Risk mitigation measures

See 2.1.4.3 & 2.1.4.9

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 & 2.1.4.10

2.1.5.4 Instructions for safe disposal of the product and its packaging

See 2.1.4.5 & 2.1.4.11

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

See 2.1.4.6 & 2.1.4.12

2.1.6 Other information

-

2.1.7 Packaging of the biocidal product

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Bottle	900 ml	HDPE	PP screw cap (PP trigger sprayer/push-pull cap fitted at point of use)	Professional use only	No compatibility issues noted in the stability testing
Bottle	3750 ml	HDPE	PP screw cap	Professional use only	No compatibility issues noted in the stability testing

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

Letter of access received from the active substance manufacturer, part of the Peracetic Acid Registration Group (PAR). This active substance dossier has been included onto the Union List of Approved Active Substances. See https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval

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 – Application by trigger spray

Product Type(s)	PT 2 - Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Surface Disinfection by spray, to hard surfaces not associated with food or feed areas
Target organism (including development stage)	*Bacteria Gram +ve – vegetative cells* *Bacteria Gram -ve – vegetative cells* *Fungi/yeasts – vegetative cells* Spores
Field of use	Indoor. The biocidal product is recommended for the control of bacteria, fungi, yeast and bacterial spores on hard surfaces.
Application method(s)	Spray onto a wipe and then apply to the surface or spray directly onto surface Ensure the entire surface is visibly wet for the contact time indicated to kill bacteria, fungi, yeast and bacterial spores. Uniform distribution of the biocidal product should be ensured.
Application rate(s) and frequency	Dose rate: 50.0 mL/m^2 Concentration of active in products: ca. 0.23 % (w/w) Concentration of products: ca. 100.0% (0% dilution, ready to use) Specific to the users site and requirements. No waiting periods are necessary. Ready to use (RTU) liquid spray: could be daily application to disinfect equipment or could be ongoing throughout the day in which case 480 mins would be worst case. Application rate 50 mL/m^2.

Category(ies) of user(s)	Professional use only.
Pack sizes and packaging material	0.9L (32oz) HDPE trigger spray bottles sold capped with the trigger sprayer fitted at point of use

Use # 2 – Application by pouring.

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	Surface Disinfection by pouring/wipe, to hard surfaces not associated with food or feed areas
Target organism (including development stage)	*Bacteria Gram +ve – vegetative cells* *Bacteria Gram -ve – vegetative cells* *Fungi/yeasts – vegetative cells* Spores
Field of use	Indoor. The biocidal product is recommended for the control of bacteria, fungi, yeast and spores on hard surfaces.
Application method(s)	Pour into a bucket and then apply with a cleanroom mop. Ensure the entire surface is visibly wet for the contact time indicated to kill bacteria, fungi, yeast, spores. Uniform distribution of the biocidal product should be ensured.
Application rate(s) and frequency	Dose rate: 50.0 mL/m2 Concentration of active in products: ca. 0.23 % (w/w) Concentration of products: ca. 100.0% (0% dilution, ready to use) Specific to the users site and requirements. No waiting periods are necessary. Pour on RTU liquid: could be daily application to walls and floors via a dry wipe or mop and bucket. It could take several hours to clean a really big facility during an annual shutdown, in which case 480 mins would be worst case. Application rate 50 mL/m2.
Category(ies) of users	Professional use only.
Pack sizes and packaging material	0.9L (32oz) HDPE trigger spray bottles sold capped with the trigger sprayer/push pull cap fitted at point of use 3.75L (1 US gallon): tamper evident cap HDPE bottle

2.2.2 Physical, chemical and technical properties

Contec PeridoxRTU is an RTU liquid (AL) and was not the representative formulation considered for BPR inclusion for the active substance peracetic acid. The physical, chemical and storage stability data submitted to support the biocidal product family are summarised in the following table.

Property	Guideline and Method	Purity of the test substance (%w/w)	Results	Reference	BE CA Comments
Physical state at 20 °C and 101.3 kPa Colour at 20 °C and 101.3 kPa Odour at 20 °C and 101.3 kPa	OPPTS 830.6303	Contec PeridoxRTU Batch number: GH32080731171B	Homogeneous, opaque liquid The odour has not been investigated: The product is corrosive and, even if there is no direct STOT or Acute Tox inhal. risk, it is reasonable to suspect that the product could also bring an hazard to the investigator by inhalation.	IUCLID 3.1 Belussi, 2017	Acceptable
Acidity / alkalinity	EPA OPPTS 830.7000 (pH meter)	Contec PeridoxRTU Lot#: CET R052208 SI71	pH = 2.11 at 24.6 °C.	IUCLID 3.2 C. Wo, 2008	Acceptable. Noted that the product has been classified as "Skin Corr. 1A" (see Section 2.1.3)
	CIPAC MT 75 CIPAC MT 31	Contec PeridoxRTU Batch number: GH32080731171B	pH = 1.72 (4.38 % hydrogen peroxide, 0.26% peracetic acid and 4.64% acetic acid present in the formulation) Acidity was measured as 3.95 %w/w of H_2SO_4	IUCLID 3.4.1 Belussi, 2019	
Relative density / bulk density	OECD 109, CIPAC MT-3 and ASTM D891-95	Contec PeridoxRTU Lot#: CET R052208 SI71	The density of Contec PeridoxRTU is 1.022 g/mL at 20 °C.	IUCLID 3.3 C. Wo, 2008	Acceptable
Storage stability test – **accelerated storage**	Waiver	-	Not required. The product label sates *"Store at temperatures not exceeding 30 °C."*	IUCLID 3.4.1	Acceptable. Long term ambient storage data demonstrates the stability of the biocidal product and the

Property	Guideline and Method	Purity of the test substance (%w/w)	Results	Reference	BE CA Comments
					label contains states "Store at temperatures not exceeding 30 ºC."
Storage stability test – **accelerated storage - trigger spray pattern**	In-house method	Contec PeridoxRTU	**Trigger Spray Pattern (meta-SPC1)** 6x Contec PeridoxRTU batches were sprayed onto a stainless steel table pre- and post-accelerated storage (40 °C for 12 weeks). Each trigger was sprayed 150x with results taken after each 30x spray interval with weight of the expelled spray of 10 actuations. Post-storage, 3 triggers were sprayed until emptied and the result of 10x actuations taken after every 200 actuations until empty. Spray pattern was measured by spraying 30 cm above the surface at a 45° angle. Pre-storage the mean reduction in mass delivered (150 sprays) was 0.35 %. Post-storage the mean reduction in mass delivered (1000 sprays) was 1.67 %. Negligible change in the diameter and formation of the spray pattern was observed both pre- and post-storage. No blocking of the nozzle or inconsistent spraying was noted on any samples tested.	IUCLID 3.4.1 N. Simpson, 2017	Acceptable. The submitted data indicate satisfactory operation of the trigger sprayer prior to and following accelerated storage. This is considered sufficient to support a 12-month product shelf-life, with satisfactory trigger spray performance confirmed following ambient storage.
Storage stability test – **long term**		Peracetic acid 0.22 %	Samples were stored for one year in 20 and 500 mL HDPE bottles at ambient	IUCLID 3.4.1	The active substance content remained constant over the

Property	Guideline and Method	Purity of the test substance (%w/w)	Results	Reference	BE CA Comments
storage at ambient temperature	Titration with ceric sulfate (AS analysis) Visual observation		temperature (20 - 27 °C) and were protected from light. Chemical analyses and observations were conducted at 0, 3, 6, 9 & 12 months. **Peracetic acid content** Peracetic acid content remained at 0.22 % at all tested intervals in both containers. **Appearance** The product remained a clear, light hazy liquid at all tested intervals in both containers. **Packaging** No signs of cracking or pitting were observed. The maximum mean weight change observed was -1.3 % (small container).	W. D. Gravelle, 2010	test period and therefore within the specified FAO tolerance limits. Note that only initial and 12-month data have been included in the table as insufficient validation data was available for the analytical method used for the determination of peracetic acid and two stabilizers and therefore these storage stability results cannot be used to support the shelf-life of the product. Please see confidential PAR for full results.
	Visual CIPAC MT 75.3 CIPAC MT 31	Contec PeridoxRTU Batch number: GH32080731171B	**T = 0 (Initial) Results** Appearance = Homogeneous opaque blank liquid Packaging = HDPE bottle with screw cap and trigger dispenser pH **=** 1.72 Acidity = 3.95 (%w/w of H_2SO_4)	IUCLID 3.4.1 Belussi, 2019	Acceptable. T6 and T12 month results indicate that Contec PeridoxRTU is stable when stored under ambient conditions for up to 12 months.

Property	Guideline and Method	Purity of the test substance (%w/w)	Results	Reference	BE CA Comments
	S-2017-03323AMMdP FAO Internal method FEA 644 Visual CIPAC MT 75.3 CIPAC MT 31 S-2017-03323AMMdP FAO		Peracetic Acid content = 0.26 % No valve clogging was observed Spray rate = 1.45 g (RSD = 5.2%) Spray pattern = "like a spray" **T = 6 Month Results** Appearance = No variation from initial Packaging = No variation from initial pH **=** 1.73 Acidity = 3.93 (%w/w of H_2SO_4) Peracetic Acid content = 0.25 % No valve clogging was observed Spray rate = 1.40 g (RSD = 3.1%) Spray pattern = "like a spray" **T = 12 Month Results**		See "Conclusions" green box below table for consideration of trigger spray data. Note: Peracetic acid forms in equilibrium upon treatment of intentionally added stabilizers, therefore these substances content were also analysed – See confidential PAR for results.

Property	Guideline and Method	Purity of the test substance (%w/w)	Results	Reference	BE CA Comments
	Internal method FEA 644 Visual CIPAC MT 75.3 CIPAC MT 31 S-2017-03323AMMdP FAO Internal method FEA 644		Appearance = No variation from initial Packaging = No variation from initial pH **=** 1.90 Acidity = 4.01 (%w/w of H_2SO_4) Peracetic Acid content = 0.25 % No valve clogging was observed Spray rate = 1.37 g (RSD = 3.2%) Spray pattern = "in progress"		
Storage stability test – **low temperature stability test for liquids**	Waiver	-	Applicant waiver: *"Not required. The product label states that the product cannot be frozen."*	IUCLID 3.4.1	Acceptable. Label states "Do not freeze".
Effects on content of the active substance	Waiver	-	Applicant waiver:	IUCLID 3.4.2	Acceptable

Property	Guideline and Method	Purity of the test substance (%w/w)	Results	Reference	BE CA Comments
and technical characteristics of the biocidal product - **light**			*The product is stored in opaque container, therefore exposure to light is not relevant."*		
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waiver	-	Applicant waiver: *"Label recommends storing at temperatures below 30 °C. The product is an aqueous solution stored in a sealed container; therefore humidity is of low relevance for storage stability."*	IUCLID 3.4.2	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	EPA OPPTS 830.6320	Hydrogen peroxide 4.44 % Peracetic acid 0.22 %	A storage stability test was carried out in small plastic or large Nalgene HDPE for 12 months. At the end of each storage phase, physical changes in the product and bottles were observed and recorded. No corrosion of the storage container was observed.	IUCLID 3.4.2 W. D. Gravelle, 2010	Acceptable
Wettability	Waiver	-	Applicant waiver: *"Not relevant as the product is a ready to use liquid."*	IUCLID 3.5.1	Acceptable
Suspensibility, spontaneity and dispersion stability	Waiver	-	Applicant waiver: *"Not relevant as the product is a ready to use liquid and not a suspension or dispersion."*	IUCLID 3.5.2	Acceptable
Wet sieve analysis and dry sieve test	Waiver	-	Applicant waiver: *"Not relevant as the product is a ready to use liquid."*	IUCLID 3.5.3	Acceptable
Emulsifiability, re-emulsifiability and emulsion stability	Waiver	-	Applicant waiver: *"Not relevant as the product is a ready to use liquid and not an emulsion."*	IUCLID 3.5.4	Acceptable

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (%w/w)</th><th>Results</th><th>Reference</th><th>BE CA Comments</th></tr>
<tr><td>Disintegration time</td><td>Waiver</td><td>-</td><td>Applicant waiver:
"Not relevant as the product is a ready to use liquid."</td><td>IUCLID 3.5.5</td><td>Acceptable</td></tr>
<tr><td>Particle size distribution, content of dust/fines, attrition, friability</td><td>CIPAC MT 187</td><td>Hydrogen peroxide 4.40 %
Peracetic acid 0.23 %</td><td>The particle size distribution of the test item was determined using 3 samples:

<table><tr><th>Test item</th><th>Dv(10%) [µm]</th><th>Dv(50%) [µm]</th><th>Dv(90%) [µm]</th></tr><tr><td>1</td><td>377.18</td><td>576.06</td><td>807.50</td></tr><tr><td>2</td><td>426.10</td><td>591.02</td><td>784.52</td></tr><tr><td>3</td><td>405.66</td><td>583.74</td><td>791.78</td></tr><tr><td>mean</td><td>402</td><td>584</td><td>795</td></tr></table>
Assuming that the particle shape is spherical and the density of the airborne particles is 1 g/cm^3 the MMAD is equal to the Dv(50) of 584 µm.</td><td>IUCLID 3.5.6
N. Rodriguez, 2018</td><td>Acceptable
The applicant assessment of the particle size distribution and MMAD is considered sufficient to demonstrate that there will be a negligible percentage of particles in mass with aerodynamic diameter <50 µm (Dv_{10} = 402 µm).</td></tr>
<tr><td>Persistent foaming</td><td>Waiver</td><td>-</td><td>Applicant waiver:
"Not relevant as the product is a ready to use liquid."</td><td>IUCLID 3.5.7</td><td>Acceptable</td></tr>
<tr><td>Flowability/Pourability/Dustability</td><td>Waiver</td><td>-</td><td>Applicant waiver:
"Not relevant as the product is a ready to use liquid."</td><td>IUCLID 3.5.8</td><td>Acceptable</td></tr>
<tr><td>Burning rate — smoke generators</td><td>Waiver</td><td>-</td><td>Applicant waiver:
"Not relevant as the product is a ready to use liquid."</td><td>IUCLID 3.5.9</td><td>Acceptable</td></tr>
<tr><td>Burning completeness — smoke generators</td><td>Waiver</td><td>-</td><td>Applicant waiver:
"Not relevant as the product is a ready to use liquid."</td><td>IUCLID 3.5.10</td><td>Acceptable</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (%w/w)	Results	Reference	BE CA Comments
Composition of smoke — smoke generators	Waiver	-	Applicant waiver: *"Not relevant as the product is a ready to use liquid."*	IUCLID 3.5.11	Acceptable
Spraying pattern — aerosols	Internal method	Contec PeridoxRTU Batch number: GH32080731171B	**T=0 (Initial) Results** No valve clogging was observed Spray rate = 1.45 g (RSD = 5.2%)	IUCLID 3.5.12 Belussi, 2017	T6 and T12 month ambient storage results are presented above and include spray pattern data. IUCLID 3.4.1 (N. Simpson, 2017, see above) includes data indicating satisfactory operation of the trigger sprayer prior to and following accelerated storage.
Physical compatibility	Waiver	-	Applicant waiver: *"The label does not recommend the biocidal product is applied with other products. Therefore compatibility details are not required."*	IUCLID 3.6	Acceptable
Chemical compatibility	Waiver	-	Applicant waiver: *"The label does not recommend the biocidal product is applied with other products. Therefore compatibility details are not required."*	IUCLID 3.6	Acceptable
Degree of dissolution and dilution stability	Waiver	-	Applicant waiver: *"Not relevant as the product is a ready to use liquid."*	-	Acceptable
Surface tension	EU Method A.5	Contec PeridoxRTU	57.7 mN/m at 20 °C	IUCLID 3.8 A. Mazzei, 2017	Acceptable
Viscosity	EPA OPPTS 830.7300	Contec PeridoxRTU	1.126 mPa s at 20 °C 0.740 mPa s at 40 °C	IUCLID 3.9 C. Wo, 2008	Acceptable.

Property	Guideline and Method	Purity of the test substance (%w/w)	Results	Reference	BE CA Comments
	(Capillary viscometer)	Lot#: CET R052208 SI71			The product does not contain ≥10% hydrocarbons; therefore consideration of aspiration hazard classification is not required.

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

Contec PeridoxRTU is a ready-to-use homogeneous, opaque, liquid (AL). The biocidal product family consists of 2 meta-SPCs (spray/push-pull cap dispense or capped bottle to pour into a bucket), each with identical formulations. The pH was initially reported as 2.11 (pH meter), and subsequently as 1.72 (CIPAC MT 75, with 4.38 % hydrogen peroxide, 0.26 % peracetic acid and 4.64 % acetic acid present in the system at 20 °C). Acidity was measured as 0.28 %w/w of H_2SO_4. It is noted that the product has been classified as "Skin Corr. 1A" (see Section 2.1.3).

The density of Contec PeridoxRTU is 1.022 g/mL at 20 °C, the surface tension is 57.7 mN/m at 20 °C, and the viscosity is 1.126 mPa s at 20 °C and 0.740 mPa s at 40 °C.

Ambient storage data (W. D. Gravelle, 2010) confirmed that the product is stable for 12 months when stored under ambient conditions with no adverse packaging effects observed; however, insufficient validation data was available for the analytical method used for the determination of two stabilizers and therefore these storage stability results cannot be used to support the shelf-life of the product.

Further ambient storage data (Belussi, 2019) have been provided and indicate that the product is stable for at least 12 months when stored under ambient conditions with no adverse packaging effects observed. These data also confirm the acceptable operation of the trigger sprayer following ambient storage for 12 months and that no clogging of the packaging valve was observed during this time. Although only 6-month data was provided for the "spray pattern", the lack of valve clogging, the negligible decrease in spray mass delivered, and the acceptable spray pattern results observed in the accelerated study (N. Simpson, 2017) are considered sufficient to demonstrate satisfactory operation of the trigger sprayer.

Accelerated storage data (N. Simpson, 2017) indicate satisfactory operation of the trigger sprayer prior to and following accelerated storage. No other accelerated storage data was provided; however the label contains instructions to avoid storage at temperatures above 30 °C, therefore the ambient storage stability data (Belussi, 2019) is considered sufficient to support the biocidal product family.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	BE CA Comments
Explosives	Waiver	-	In the peracetic acid CAR it is stated: *5% and 15% equilibrium products ("PEROXYACETIC ACID 5% and 15%"): not explosive (no mechanical and thermal sensitivity). Pure or highly concentrated stabilized PAA may form explosive vapour/air mixtures above 40.5 °C. Detailed explosive limits are unknown in the literature. Under CLP, explosive property determination as described for the hazard class 'explosives' needs not to be conducted for organic peroxides.* Based on this statement and it is not expected that a 0.23% equilibrium product will be explosive.	IUCLID 4.1	Acceptable. Based on the CAR assessment it is not expected that a 0.23% equilibrium product will be explosive. The BPF is not classified as an organic peroxide (see below) and as explosiveness is part of this test the product therefore is not considered to be explosive.
Flammable gases	Waiver	-	Not relevant for aqueous RTU liquid.	-	Acceptable
Flammable aerosols	Waiver	-	Not relevant for aqueous RTU liquid.	-	Acceptable
Oxidising gases	Waiver	-	Not relevant for aqueous RTU liquid.	-	Acceptable
Gases under pressure	Waiver	-	Not relevant for aqueous RTU liquid.	-	Acceptable
Flammable liquids	Waiver	-	Contec PeridoxRTU is largely aqueous and contains only low levels of water-soluble organic materials. For this reason, the product is not flammable.	IUCLID 4.6	Acceptable. The product contains >90 % water and the flashpoint of premix PERACLEAN 15 is 79 °C, therefore the product is not expected to be flammable.
Flammable solids	Waiver	-	Not relevant for aqueous RTU liquid.	-	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	BE CA Comments
Self-reactive substances and mixtures	Waiver	-	Classification procedures for self-reactive substances and mixture are not required if there are no chemical groups associated with explosive or self-reacting properties. It can be seen that a 0.23% equilibrium product is not explosive. Additionally the structure of the active ingredients and other components of the test item were assessed for chemical groups that imply self-reactive properties. Based on the chemical structures of the active ingredients and the other components of the of the test item that are either known to be non-self-reacting or are present in insignificant amounts, the result for the self-reacting substances and mixtures has been predicted negative.	IUCLID 4.8	Acceptable. The product is an aqueous liquid and is not expected to be explosive and does not contain chemical groups associated with self-reacting properties. In addition, the product contains >90 % water and is not expected to be self-reactive.
Pyrophoric liquids	Waiver	-	Based on experience in handling and use of the test item during testing, the result of the pyrophoric properties test has been predicted negative, using a procedure designed to be compatible with Method A13	IUCLID 4.9	Acceptable
Pyrophoric solids	Waiver	-	Not relevant for aqueous RTU liquid.	-	Acceptable
Self-heating substances and mixtures	Waiver	-	Based on the chemical structures of active ingredients and the other components of the test item and that the test item is an aqueous solution none of the components are predicted to be self-heating, additionally the product does not have a flash point. The result for the test is therefore predicted negative.	IUCLID 4.11	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	BE CA Comments
Substances and mixtures which in contact with water emit flammable gases	Waiver	-	Based on the chemical structures of active ingredients and the other components of the test item and that the test item is an aqueous solution none of the components are predicted to emit a flammable gas on contact with water, the result for the test is therefore predicted negative.	IUCLID 4.12	Acceptable
Oxidising liquids	Test 0.2 UN Test for Oxidizing Liquids	Contec PeridoxRTU Lot# GE05102016411 29	Not classified as oxidising liquid: at a 1: 1 ratio of sample/cellulose tested, the sample had a pressure rise of less than 2070 kPa (300 psi)	IUCLID 4.13 T.E. Basham, 2017	Acceptable. The maximum observed pressure rise was 281.3 psi.
Oxidising solids	Waiver	-	Not relevant for aqueous RTU liquid.	-	Acceptable
Organic peroxides	Waiver	-	Based on the concentration of peracetic acid in the aqueous solution, the product is not considered to be thermally unstable.	IUCLID 4.15	CLP Annex I states: ***2.15.2.1.*** *Any organic peroxide shall be considered for classification in this class, unless it contains: a) not more than 1.0% available oxygen from the organic peroxides when containing not more than 1.0% hydrogen peroxide; or b) not more than 0.5% available oxygen from the organic peroxides when containing more than 1.0% but not more than 7.0% hydrogen peroxide.* Contec PeridoxRTU meets point (b) above (see confidential section for

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	BE CA Comments
					formulation details); therefore consideration for classification is not required.
Corrosive to metals	UN Test C.1	Contec PeridoxRTU™	<table><tr><td>Coupons made of</td><td>Aluminium</td><td>Steel</td></tr><tr><td>Material code</td><td>AL 7075</td><td>S355J2+N</td></tr><tr><td>Total exposure hours</td><td>168</td><td>168</td></tr><tr><td>Temperature during exposure (°C)</td><td>55±1</td><td>55±1</td></tr><tr><td>Corrected mass loss of most corroded coupon (%)</td><td>No mass loss observed</td><td>71.73%</td></tr><tr><td>Test result for uniform corrosion</td><td>Negative</td><td>Positive</td></tr><tr><td>Classification of test item for uniform corrosion</td><td>Non corrosive</td><td>Corrosive</td></tr><tr><td>Localised corrosion observed?</td><td>No</td><td>Yes</td></tr><tr><td>Depth of the deepest intrusion / µm</td><td><10</td><td>260</td></tr><tr><td>Test result for localised corrosion</td><td>Negative</td><td>Positive</td></tr><tr><td>Classification of test item for localised corrosion</td><td>Non corrosive</td><td>Corrosive</td></tr></table> Contec PeridoxRTU is non-corrosive for aluminium and corrosive for steel.	IUCLID 4.16 J. Benitez, 2018	The data indicate that Contec PeridoxRTU is corrosive to metals; therefore the Category 1 classification applies (*H290: May be corrosive to metals*).
Auto-ignition temperatures of products (liquids and gases)	EU Method A.15 ASTM E659	Contec PeridoxRTU™	Contec PeridoxRTU did not ignite up to 600 °C at 1014 mBar with the smallest aliquot of test material used (50 µL).	IUCLID 4.17.1 A. Mazzei, 2017	Acceptable
Relative self-ignition temperature for solids	Waiver	-	Not relevant for aqueous RTU liquid.	-	Acceptable
Dust explosion hazard	Waiver	-	Not relevant for aqueous RTU liquid.	-	Acceptable

Conclusion on the physical hazards and respective characteristics of the product
Non-classification is acceptable for the physical hazards of Contec PeridoxRTU with the following exception: The product is assigned the hazard "H290: May be corrosive to metals" and should be labelled accordingly.

2.2.4 Methods for detection and identification

Analytical methods for the active and impurities in the technical material

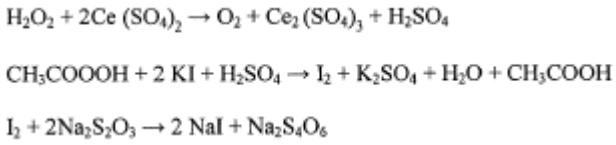
The sources of the active substance are the same as those considered for BPR approval, therefore methods of analysis for the active substance and impurities have already been considered. No further consideration is required from a chemistry perspective.

Analytical methods for the active substance in the biocidal product

Determination of peracetic acid by titration with ceric sulfate

Study title: Storage stability and Corrosion Characteristics (W. D. Gravelle; Study No. 25689; 2010)

Peracetic acid, acetic acid, and hydrogen peroxide content in the biocidal product were determined by an oxidation reduction titration with ceric sulfate. At the titration endpoint an excess of potassium iodine was added to the solution, the hydroiodic acid formed reacting with peracetic acid to liberate iodine. A standard solution of sodium thiosulfate was then used to titrate the liberated iodine. The endpoint of this titration was used to calculate the peracetic acid content:



$$H_2O_2 + 2Ce(SO_4)_2 \rightarrow O_2 + Ce_2(SO_4)_3 + H_2SO_4$$

$$CH_3COOOH + 2\,KI + H_2SO_4 \rightarrow I_2 + K_2SO_4 + H_2O + CH_3COOH$$

$$I_2 + 2Na_2S_2O_3 \rightarrow 2\,NaI + Na_2S_4O_6$$

Approximately 0.75 g of test sample was weighed into a 250 mL flask and 50 mL of 1N H2SO4 added to give a resulting sample concentration of 15 mg/mL; and therefore a nominal peracetic acid concentration of 0.035 mg/mL, a nominal acetic acid content of 0.75 mg/mL, and a nominal hydrogen peroxide concentration of 0.66 mg/mL.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues						
Matrix	**Analyte**	**Recovery fortification level (mg/mL)**	**Recovery % (mean)**	**Repeatability % RSD (n)**	**Linearity***	**Specificity**
	Peracetic acid	"small" "large"	(100.78) (101.68)	0.98 1.03	No data	No data

Contec Peridox RTU			n=3	(n=5)		
	Hydrogen peroxide	"small" "large"	(105.73) (105.77) n=3	0.43 0.12 (n=5)	No data	

* It is widely accepted that titration is a linear technique; therefore linearity data is not considered essential.

Insufficient method validation data are available, therefore the method is not considered acceptably validated.

Determination of peracetic acid by HPLC-UV

Study title: Validation of an HPLC-UV method for the quantification of the hydrogen peroxide, acetic acid and peracetic acid in the test item "Contec PeridoxRTU" (A. Meluso; Report No. S-2017-03323AM; 2017)
Hydrogen peroxide, acetic acid and peracetic acid content in the biocidal product were determined simultaneously using an HPLC-UV method. The following conditions were noted:

INSTRUMENT	HPLC-UV
COLUMNS	Luna Phenyl-Hexyl; 150 x 4.6mm x 3µm
COLUMN TEMPERATURE	25 °C
WAVELENGTH	260 nm for H_2O_2 (scan 210 nm - 400 nm) 230 nm for PAA and AA (scan 210 nm - 400 nm)
BW and REFERENCE	4 nm and 360 nm
INJECTION VOLUME	7.0 µl
FLOW	0.6 ml/min
AUTOSAMPLER TEMPERATURE	4 °C
RUN TIME	15 min
MOBILE PHASE	A%: (25 mM KH_2PO_4 at pH 2.1, with H_3PO_4) B%: methanol
RETENTION TIME	t_{H2O2} (260 nm) ~ 2.9 min t_{AA} (230 nm) ~ 4.8 min t_{PAA} (230 nm) ~ 5.1 min

time (min)	0	7	7.1	10	10.1	15
A (%)	100	100	30	30	100	100
B (%)	0	0	70	70	0	0

TEST METHOD

High-performance liquid chromatography with a diode array detector (HPLC-DAD).

EQUIPMENT AND MATERIALS

- Standard laboratory equipment
- pH meter Crison, model GLP21, s/n 1713 (internal code B0752)
- Column Phenomenex, Luna Phenyl-hexyl - 150mm x 4.6mm, 3-µm particle size – s/n 762015-5 (internal code C569HP).
- Agilent Series 1200 High Performance Liquid Chromatograph (HPLC) equipped with an Agilent Series 1200 variable wavelength UV-DAD detector, a binary pump, an autosampler and a data station with Chemstation (Internal Code B1562).

Samples were prepared for analysis as follows. Approximately 1300 mg of test sample was weighed into a 20 mL volumetric flask and brought to volume with phosphate buffer (pH 2.1). This gives a resulting sample concentration of 65 mg/mL and therefore a nominal peracetic acid concentration of 0.15 mg/mL, a nominal acetic acid concentration of 3.25 mg/mL, and a nominal hydrogen peroxide concentration of 2.86 mg/ml.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues						
Matrix	**Analyte**	**Recovery fortification level (mg/mL)**	**Recovery % (mean)**	**Repeatability % RSD (n)**	**Linearity**	**Specificity**
Contec Peridox RTU	Peracetic acid	0.075 (0.0075%) 0.150 (0.015%) 0.225 (0.0225%)	100.12 99.44 98.68 (99.41)	0.34 (n=6) Acceptable Horowitz = 3.34	0.075 - 0.225 mg/mL (50 - 150 % nominal content) R^2 = 0.9999 (n=5)	Spectra of the blank, standard solutions and test solutions were provided showing no interferences. The UV spectrum confirmed the presence of each analyte in the sample.
	Acetic acid	1.63 (0.163%) 3.25 (0.325%) 4.88 (0.488%)	101.29 101.08 100.29 (100.89)	0.30 (n=6) Acceptable Horowitz = 2.11	1.63 - 4.88 mg/mL (50 - 150 % nominal content) R^2 = 0.9999 (n=5)	
	Hydrogen peroxide	1.43 (0.143%) 2.86 (0.286%) 4.29 (0.429%)	101.12 101.00 100.47 (100.86)	0.34 (n=6) Acceptable Horowitz = 2.14	1.43 - 4.29 mg/mL (50 - 150 % nominal content) R^2 = 1.0000 (n=5)	

The method is satisfactorily validated in accordance with the ECHA BPR Guidance (Nov. 2014) and the EU guidance document SANCO/3030/99 rev. 4 with LOQs of 0.075 mg/mL (peracetic acid), 1.63 mg/mL (acetic acid) and 1.43 mg/mL (hydrogen peroxide).

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

Methods of analysis for the determination of peracetic acid for monitoring method purposes have previously been evaluated in the EU CAR and accepted for BPR inclusion.

Analytical methods for body fluids and tissues are not required as the product is not classified as toxic.

Analytical methods for monitoring of active substances and residues in food and feeding stuff are not required as the active substance does not come into contact with food producing animals, food of plant or animal origin, or feeding stuffs.

Conclusion on the methods for detection and identification of the product
Insufficient method validation data are available for the titration method used to determine peracetic acid and hydrogen peroxide (W. D. Gravelle, 2010); therefore the method is not considered acceptably validated. However, the HPLC-UV analytical method for the determination of peracetic acid, hydrogen peroxide and acetic acid in the biocidal product family is acceptable. The analytical methods for the monitoring of residues have been either evaluated at EU level and accepted for BPR inclusion or are not relevant for the PeridoxRTU Product Family.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

PeridoxRTU Product Family consists of PT 2 disinfectant products intended for professional indoor use. The active substance is peracetic acid at a concentration of 0.23 %. The products are intended for use on clean hard non-porous surfaces in cleanrooms in industrial 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, yeasts and spores (bacterial spores).

2.2.5.3 Effects on target organisms, including unacceptable suffering

The products are sold in bottles in the form of a ready to use solution, applied via spraying or pouring and then wiping or mopping onto the surface.

The spray products are applied by spraying onto a suitable cleanroom wipe and then wiping the surface at up to 50 ml m^{-2}.

The pour products are applied by pouring into a container and mopping onto the surface with a cleanroom mop at up to 50 ml m^{-2}.

Uniform distribution of the products on the surface should be ensured and the surface should be left for the required contact time to kill the target organisms.

2.2.5.4 Mode of action, including time delay

The applicant referred to the mode of action details covered in the CAR. According to the CAR:

'Peracetic acid exerts toxic (bactericidal, fungicidal, etc.) rather than bacteriostatic, fungistatic effects on target organisms.'

'The mode of action of peracetic acid is very unspecific.'

The BE CA accepts the above statements on the mode of action of peracetic acid.

2.2.5.5 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**

Disinfectant for use on PT 2 clean hard non porous surfaces not associated with food and feed areas	Contec Peridox RTU	Bacteria (*Pseudomonas aeruginosa, Salmonella enterica, Staphylococcus aureus*)	The AOAC Germicidal spray test - Healthcare (to meet the EPA Guidelines 810.2100 (c), (d), (e)) was followed. Simulated use surface test. 180 replicates per species in total. Contact time: 2 minutes. Test temperature: 21°C. Interfering substance: 5 % horse serum. Concentrations tested: Ready to use (RTU).	No growth was observed for all test organisms. The controls were sufficient to validate the test. The product therefore passed the test criteria required to demonstrate bactericidal activity.	Peters (2008) Project 535-115 IUCLID reference: 6.7-1a
	Contec Peridox RTU	Bacteria (*Acinetobacter baumannii, Campylobacter jejuni, Escherichia coli,* Extended spectrum ß-lactamase *Escherichia coli Enterococcus hirae,* methicillin resistant *Staphylococcus aureus,* community acquired methicillin resistant *Staphylococcus aureus,* vancomycin resistant *Enterococcus faecalis, Klebsiella pneumoniae, Legionella pneumophila,*	The AOAC Germicidal spray test - Healthcare (to meet the EPA Guidelines 810.2100 (c), (d), (e)) was followed. Simulated use surface test. 30 replicates per species in total. Contact time: 2 minutes. Test temperature: 20°C. Interfering substance: 5 % horse serum. Concentrations tested: Ready to use (RTU).	No growth was observed for all test organisms. The controls were sufficient to validate the test. The product therefore passed the test criteria required to demonstrate bactericidal and yeasticidal activity.	Dormstetter (2008) Project 535-118 IUCLID reference: 6.7-1b

		Proteus vulgaris, Serratia marcescens, Shigella sonnei, Penicillin resistant *Streptococcus pneumoniae, Streptococcus pyogenes, Haemophilus influenzae*); Yeast (*Candida albicans*);			
	Contec Peridox RTU	Bacterial spores (*Bacillus subtilis, Clostridium sporogenes*)	The test guideline OCSPP 810.2100 (EPA guideline) was followed using a modification of the AOAC Sporicidal Activity Method. Laboratory study. Inoculated steel cylinders are submerged into tubes of the test product during the exposure period. Contact time: 3 minutes. Test temperature: 20°C. Interfering substance: None required according to the test. Concentrations tested: Ready to use (RTU).	No growth was observed for both test organisms. The controls were sufficient to validate the test. The product therefore passed the test criteria required to demonstrate sporicidal activity.	Sathe (2014) Project A16499 IUCLID reference: 6.7-2
	Contec Peridox RTU	Bacteria (*Pseudomonas aeruginosa, Escherichia coli,*	The EN 13697 (phase 2, step 2) standard protocol was followed.	The following log reductions were observed: *P. aeruginosa*: >4.5 for 3 min,	Lambert (2014) Report: ECLIPSE/14/024

		Staphylococcus aureus, Enterococcus hirae); Fungi (*Aspergillus brasiliensis*); Yeast (*Candida albicans*); Bacterial spores (*Bacillus subtilis*)	Contact time: 3 minutes and 5 minutes. Test temperature range: 18-25ºC Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. Concentration: Ready to use (RTU).	>4.5 for 5 min *E. coli*: >4.6 for 3 min, >4.6 for 5 min *S. aureus*: >4.4 for 3 min, >4.6 for 5 min *E. hirae*: >4.5 for 3 min, >4.5 for 5 min *A. brasiliensis*: >4.8 for 3 min, >4.8 for 5 min *C. albicans*: >5.0 for 3 min, >4.9 for 5 min *B. subtilis*: >2.6 for 3 min, >2.6 for 5 min >4 log reduction was observed for all species of bacteria after 3 minutes. The product has therefore demonstrated bactericidal activity. >3 log reduction was observed for yeast and fungi after 3 minutes. The product has therefore demonstrated yeasticidal and fungicidal activity. >2.6 log reduction was observed for	IUCLID reference: 6.7-3

				bacterial spores after 3 minutes. [Note: Bacterial spores are not normally tested in EN 13697 so there is pass criterion. EN 13704 (phase 2, step 1) requires a 3 log reduction. However, for other organisms, EN 13697 requires a lower log reduction than the corresponding phase 2, step 1 test.]	
	Contec Peridox RTU	Bacteria (*Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae*)	The EN 1276 (phase 2, step 1) standard protocol was followed. Contact time: 2 minutes. Test temperature: 20°C. Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. Concentrations tested: Ready to use (RTU).	The following log reductions were observed: *P. aeruginosa*: >5.28 *E. coli*: >5.28 *S. aureus*: >5.39 *E. hirae*: >5.25 >5 log reduction was observed for all test organisms. The product has therefore demonstrated bactericidal activity.	James (2016a) Doc No. TRA-2016-135-01 IUCLID reference: 6.7-4
	Contec Peridox RTU	Fungi (*Aspergillus brasiliensis*);	The EN 1650 (phase 2, step 1) standard protocol was followed.	The following log reductions were observed: *A. brasiliensis*:	James (2016b) Doc No. TRA-2016-134-01

		Yeast (*Candida albicans*)	Contact time: 2 minutes for yeast; 3 minutes for fungi. Test temperature: 20ºC. Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. Concentration: Ready to use (RTU).	>4.46 *C. albicans*: >4.47 >4 log reduction was observed for all test organisms. The product has therefore demonstrated fungicidal and yeasticidal activity.	IUCLID reference: 6.7-5
	Contec Peridox RTU	Bacterial spores (*Bacillus subtilis*)	The EN 13704 (phase 2, step 1) standard protocol was followed. Contact time: 3 minutes Test temperature: 21.4ºC. Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. Concentration: Ready to use (RTU).	>3.39 log reduction was observed. The product has therefore demonstrated sporicidal activity.	James (2016c) Doc No. TRA-2016-141-01 IUCLID reference: 6.7-6
	Contec Peridox RTU	Bacterial spores (*Bacillus cereus*)	The EN 13697 (phase 2, step 2) standard protocol was followed. Contact time: 3 minutes Test temperature: 21.9ºC. Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. Concentration: Ready to use (RTU).	3.69 log reduction was observed. [Note: Bacterial spores are not normally tested in EN 13697 so there is pass criterion. EN 13704 (phase 2, step 1) requires a 3 log reduction. However, for other organisms, EN 13697 requires a lower log	James (2016d) Doc No. TRA-2016-136-01 IUCLID reference: 6.7-7

				reduction than the corresponding phase 2, step 1 test.]	
	Contec Peridox RTU	Bacteria (*Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae*); Fungi (*Aspergillus brasiliensis*); Yeast (*Candida albicans*); Bacterial spores (*Bacillus subtilis*)	The EN 13697 (phase 2, step 2) standard protocol was followed. Contact time: 2 minutes (bacteria) 3 minutes (fungi, yeast and spores). Test temperature range: 18-25ºC. Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. 8.5 g/l skimmed milk was used for *P. aeruginosa*. Concentration: Ready to use (RTU), 75 % RTU and 25 % RTU.	The following log reductions were observed at the RTU concentration: *P. aeruginosa*: >5.57 *E. coli*: >5.27 *S. aureus*: >5.74 *E. hirae*: >5.73 *A. brasiliensis*: >4.74 *C. albicans*: >4.43 *B. subtilis*: 3.69 >4 log reduction was observed for all species of bacteria with all tested concentrations. The product has therefore demonstrated bactericidal activity. >3 log reduction was observed for yeast at all test concentrations. The product has therefore demonstrated	James (2017) Doc No. TRA-2017-223-01 IUCLID reference: 6.7-8

				yeasticidal activity. >3 log reduction was observed for fungi at 75 % and RTU. The product has therefore demonstrated fungicidal activity. 3.65 log reduction was observed for bacterial spores at RTU. [Note: Bacterial spores are not normally tested in EN 13697 so there is no pass criterion. EN 13704 (phase 2, step 1) requires a 3 log reduction. However, for other organisms, EN 13697 requires a lower log reduction than the corresponding phase 2, step 1 test.]	

Conclusion on the efficacy of the product
The applicant proposed the following claims: - 2 minutes contact time for bacteria in EN1276 and EN 13697 - 3 minutes contact time for fungi in EN1650 and EN 13697 - 3 minutes contact time for spores in EN13704 - 3 minutes contact time for spores in EN13697 PeridoxRTU Product Family are intended for use as disinfectants on clean hard non-porous surfaces in cleanrooms in industrial settings (PT 2). The products are intended to kill bacteria, yeast, fungi and bacterial spores.

Efficacy against bacteria

For claims of bactericidal activity for PT 2 hard non-porous surface disinfectants, it is recommended to test the product in accordance with EN 1276 (phase 2, step 1) and EN 13697 (phase 2, step 2).

A phase 2 step 1 test according to EN 1276 (James (2016a)) was provided, which demonstrated the required log reduction against bacteria after a contact time of 2 minutes in clean conditions.

Two phase 2 step 2 tests according to EN 13697 (Lambert (2014) and James (2017)) were provided, which demonstrated the required log reduction against bacteria after contact times of 3 minutes and 2 minutes respectively in clean conditions.

Two simulated use surface tests according to the AOAC Germicidal spray test – Healthcare were provided, which both demonstrated no bacterial growth after a contact time of 2 minutes. A high concentration of horse serum (5%) was used for soiling, but as this is a non-standard interfering substance, the BE CA considers that the conditions tested were 'clean'.

Therefore, the BE CA considers that these data sufficiently support the use of the products against bacteria on PT 2 clean hard non-porous surfaces with a contact time of 2 minutes in clean conditions.

Efficacy against yeasts

For claims of yeasticidal activity for PT 2 hard non-porous surface disinfectants, it is recommended to test the product in accordance with EN 1650 (phase 2, step 1) and EN 13697 (phase 2, step 2).

A phase 2 step 1 test according to EN 1650 (James (2016b)) was provided, which demonstrated the required log reduction against yeast after a contact time of 2 minutes in clean conditions.

Two phase 2 step 2 tests according to EN 13697 (Lambert (2014) and James (2017)) were provided, which both demonstrated the required log reduction against yeast after a contact time of 3 minutes in clean conditions.

A simulated use surface test according to the AOAC Germicidal spray test – Healthcare was provided, which demonstrated no yeast growth after a contact time of 2 minutes. A high concentration of horse serum (5%) was used for soiling, but as this is a non-standard interfering substance, the BE CA considers that the conditions tested were 'clean'.

Therefore, the BE CA considers that these data sufficiently support the use of the products against yeast on PT 2 clean hard non-porous surfaces with a contact time of 3 minutes in clean conditions.

Efficacy against fungi

For claims of fungicidal activity for PT 2 hard non-porous surface disinfectants, it is recommended to test the product in accordance with EN 1650 (phase 2, step 1) and EN 13697 (phase 2, step 2).

A phase 2 step 1 test according to EN 1650 (James (2016b)) was provided, which demonstrated the required log reduction against fungi after a contact time of 3 minutes in clean conditions.

Two phase 2 step 2 tests according to EN 13697 (Lambert (2014) and James (2017)) were provided, which both demonstrated the required log reduction against fungi after a contact time of 3 minutes in clean conditions.

Therefore, the BE CA considers that these data sufficiently support the use of the products against fungi on PT 2 clean hard non-porous surfaces with a contact time of 3 minutes in clean conditions.

Efficacy against bacterial spores

There are currently no recommended tests to support claims of sporicidal activity for PT 2 hard non-porous surface disinfectants. However, for PT 4 hard surface disinfectants, it is recommended to test the product in accordance with EN 13704 (phase 2, step 1). The BE CA considers it to be reasonable to extrapolate the PT 4 requirement to PT 2 uses.

A phase 2 step 1 test according to EN 13704 (James (2016c)) was provided, which demonstrated the required log reduction against bacterial spores after a contact time of 3 minutes in clean conditions.

Three phase 2 step 2 tests according to EN 13697 (Lambert (2014), James (2017) and James (2016d)) were provided, which demonstrated log reductions against bacterial spores of >2.6, 3.65 and 3.69 respectively after a contact time of 3 minutes in clean conditions. There is no required log reduction for bacterial spores in EN 13697 as spores are not normally tested in EN 13697.

Therefore, the BE CA considers that these data sufficiently support the use of the products against spores on PT 2 clean hard non-porous surfaces with a contact time of 3 minutes in clean conditions.

However, the BE CA does not consider claims relating to spores in EN 13697 are acceptable, as at this stage EN 13697 is not an agreed standard for testing spores and there is no established log reduction which can be used to confirm this test has been passed. A claim against spores in EN 13704 would be acceptable.

Decision

The BE CA concludes that sufficient data have been provided to verify the outcome and conclusion and permit the authorisation of the PeridoxRTU Product Family.

The BE CA considers that sufficient data have been provided to demonstrate that the products are efficacious as disinfectants against bacteria, yeast, fungi and bacterial spores at the claimed contact times on clean hard non-porous surfaces.

2.2.5.6 Occurrence of resistance and resistance management

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

'As the mode of action of peracetic acid is very unspecific, it is very unlikely that resistance to peracetic acid can develop. The development of specific resistance management strategies for the use of peracetic acid does not seem to be an urgent task.

The BE CA accepts that there is no significant risk of the development of resistance for this active substance and product, however, if the applicant becomes aware of any reports of resistance to the active substance peracetic acid 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.

2.2.5.7 Known limitations

The product label states 'For use on clean hard surfaces' and the product is for use only in cleanrooms. Therefore, the use in dirty conditions is not relevant. However, the label needs to state 'For use on clean non-porous hard surfaces.'

Suitable wipe and mop materials should be used in order to minimise interaction with the product(s).

2.2.5.8 Evaluation of the label claims

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

- 2 minutes contact time for bacteria in EN1276/EN13697
- 3 minutes contact time for fungi in EN1650/EN13697
- 3 minutes contact time for bacterial spores in EN13704
- 3 minutes contact time for yeast in EN1650/EN13697

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

PeridoxRTU Product Family is not to be used in-conjunction with other biocidal products; therefore this section is not relevant for this product.

2.2.6 Risk assessment for human health

There are no studies with the Peridox RTU Product Family addressing the effects on human health. Instead, classification of the products is addressed using available data on the individual components of the respective formulations. No human data are available.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Skin corrosive 1
Justification for the value/conclusion	Based on a pH of 1.72. See confidential annex for further details.
Classification of the product according to CLP and DSD	H314 Causes severe skin burns and eye damage.

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

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Eye damage 1
Justification for the value/conclusion	No further consideration is required given that classification as skin corrosive 1A is already applied. Based on this classified classification as Eye Damage 1 is implicit.
Classification of the product according to CLP and DSD	H318 Causes serious eye damage

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

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Hydrogen peroxide has an SCL of ≥35% triggering classification as STOT-SE3. It is present in the formulation below this concentration and therefore the classification of STOT SE3 for the PeridoxRTU Product Family is not triggered based on the presence of hydrogen peroxide in the products. Other components classified for respiratory tract irritation are present at a concentration of less than 1%. Classification for respiratory tract irritation is not triggered by these components.
Classification of the product according to CLP and DSD	Not classified.

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

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not a skin sensitizer
Justification for the value/conclusion	None of the components in the PeridoxRTU Product Family are classified for skin sensitisation. Therefore the products do not meet the criteria for classification for skin sensitisation according to Regulation (EC) 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)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not a respiratory sensitizer.

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

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via the oral route
Justification for the selected value	Based on the data evaluated during the EU review of hydrogen peroxide 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 (486 and 420 mg/kg bw for 35% and 70% concentrations respectively). Hydrogen peroxide is therefore classified therefore as category 4 for acute oral toxicity. No other components are classified for acute oral toxicity. The acute oral toxicity of the products has been determined using the converted acute toxicity point estimate according to the Guidance on the application of the CLP criteria and the calculation method. Based on this none of the products in the PeridoxRTU Product Family meets the criteria for classification as acutely toxic via the oral route. See confidential annex for further details.
Classification of the product according to CLP	Not classified.

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

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route

Justification for the selected value	Hydrogen peroxide is classified as acutely toxic category 4 *via* the inhalation route. None of the other components in the PeridoxRTU Product Family are classified for this endpoint. The acute inhalation toxicity of the products has been determined using the converted acute toxicity point estimate according to the Guidance on the application of the CLP criteria and the calculation method: Based on this none of the products in the PeridoxRTU Product Family meets the criteria for classification as acutely toxic via the oral route.
Classification of the product according to CLP	Not classified

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

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via the dermal route
Justification for the selected value	None of the components in the PeridoxRTU Product Family is classified for acute dermal toxicity. Therefore the products do 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

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Peracetic acid

Value(s)*	100% (default)
Justification for the selected value(s)	Based on the physico-chemical properties of PAA, it was agreed at active substance approval that 100% dermal penetration should be used in the absence of more accurate information. However, in this particular case, 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 peracetic acid. In conclusion, it was acceptable to "waive" the dermal penetration study.

Data waiving	
Information requirement	Dermal absorption
Justification	Default values can be applied. No study needed.

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

Peracetic acid is not a pure active substance but is in the form of an aqueous solution containing peracetic acid, acetic acid and hydrogen peroxide. Both acetic acid and hydrogen peroxide are approved components of active substance and were considered during the evaluation of peracetic acid.

Hydrogen peroxide is in itself a biocidal a biocidal active substance. For further information on its toxicity please refer to the CAR for hydrogen peroxide.

The toxicity of acetic acid was reviewed during the evaluation of peracetic acid. For further information please see Doc IIB of the CAR for peracetic acid.

Both acetic acid and hydrogen peroxide have harmonised classifications under Annex VI of the CLP Regulation, including specific concentration limits for some endpoints. The current harmonised classifications are:

Name	**Hazard Class and Category Code(s)**	**Hazard statement Code(s)**	**Specific Conc. Limits, M-factors**
acetic acid	Skin Corr. 1A	H314	Skin Corr. 1B; H314: 25% ≤ C < 90% Skin Corr. 1A; H314: C ≥ 90% Skin Irrit. 2; H315: 10% ≤ C < 25% Eye Irrit. 2; H319: 10% ≤ C < 25%
hydrogen peroxide	Acute Tox. 4 Acute Tox. 4 Skin Corr. 1A	H332 H302 H314	Skin Corr. 1A; H314: C ≥ 70% Skin Corr. 1B; H314: 50% ≤ C <70% Skin Irrit. 2; H315: 35% ≤ C <50% Eye Dam. 1; H318: 8 % ≤ C <50 % Eye Irrit. 2; H319: 5% ≤ C <8 % STOT SE 3; H335; C ≥ 35%

Available toxicological data relating to a mixture

Not applicable.

Other

No other relevant information.

2.2.6.2 Exposure assessment

The PeridoxRTU Product Family contains ready-to-use liquid products containing 0.23 % w/w peracetic acid and 4.4% w/w hydrogen peroxide intended to be used by professionals to decontaminate hard surfaces in cleanrooms. The product is supplied in a 0.9 L trigger spray bottle (Use 1) and 0.9 L and 3.75 L bottles (Use 2). The application rate for trigger spray application is 50 mL/m^2; the application rate for pouring is 80 mL/m^2.

INFOBOX : Application rate modelled for Use#2 (wipe and mop) [Feb 2020]

It should be noted that since the product was first evaluated by the eCA, its application rate for Use#2 has subsequently been reduced from 80 ml/m^2 to 50 ml/m^2. However, as all predicted risks at the higher concentration (worst case) were considered to be acceptable, the risk with 50 ml/m² is also acceptable. Therefore, no change has been made to the Human Health assessment.

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

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	N/A	Yes	N/A	N/A	Yes	No	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.	Application (spraying)	Primary exposure: disinfection of surfaces via a trigger spray onto a wipe and using the wipe to distribute the liquid on the surface (Use 1)	Professionals
2.	Pouring	Primary exposure: pouring of the product from a 0.9 L or 3.75 L container (Use 2)	Professionals
3.	Application (mopping/ wiping)	Primary exposure: disinfection of surfaces via a dry wipe or mop (Use 2)	Professionals
4.	Inhalation of volatilised residues (mopping/ wiping)	Secondary exposure: inhalation of volatilised residues (mop / dry wipe application; Use 2)	Professionals
5.	Inhalation of volatilised residues (spraying)	Secondary exposure: inhalation of volatilised residues (trigger spray application; Use 1)	Professionals

Industrial exposure

The PeridoxRTU Product Family is not intended for industrial use.

Professional exposure

Scenario 1- Primary exposure during disinfection of surfaces via a trigger sprayer onto a wipe and using the wipe to distribute the liquid on the surface (Use 1)

Description of Scenario 1		
A professional user disinfects surfaces in a cleanroom using a trigger sprayer at an application rate of 50 ml/m^2. The product is sprayed onto a wipe and the wipe is used to distribute the liquid on the surface. Due to the high vapour pressure of peracetic acid and hydrogen peroxide, the evaporation phase of the product is the worst-case scenario. The air concentration of peracetic acid and hydrogen peroxide has been calculated using ConsExpo Web exposure to vapour: evaporation model (increasing area) for the Tier 1 assessment.		
	Parameters[1]	Value
Tier 1	Adult body weight	60 kg
	Concentration of peracetic acid	0.23% w/w
	Concentration of hydrogen peroxide	4.4% w/w
	Product density	1.022 g/ml
	Product amount	25.55 g (50 ml x 0.5m^2 x 1.022 g/ml)
	Inhalation rate	1.25 m^3/hr
	Molecular weight of peracetic acid	76 g/mol
	Molecular weight of hydrogen peroxide	34 g/mol
	Vapour pressure for peracetic acid at 20°C	1410 Pa
	Vapour pressure for hydrogen peroxide at 20°C	214 Pa
	Exposure duration	45 mins
	Room volume	55 m^3
	Release area	0.5 m^2
	Application duration	1 min
	Ventilation rate	20/hr
	Molecular weight matrix of peracetic acid[1]	19.1 g/mol
	Molecular weight matrix of hydrogen peroxide[1]	19.6 g/mol
	Mass transfer rate[2]	10 m/hr
[1] Calculated as the average molecular weight of the rest of the total product (the product minus hydrogen peroxide)(RIVM Report 2016-0171, p. 31) [2] Default value (RIVM Report 2017-0197, update for ConsExpo Web 1.0.2, p.35)		

Tier 1 assessment

It is assumed that no personal protective equipment is worn.

The tier 1 assessment has been calculated using ConsExpo Web evaporation model (increasing area mode) and the parameters described in the table above.

HEAdhoc Recommendation 15 informs that trigger sprayers are intended for small surface disinfection and no product specific information has been provided by the Applicant to the contrary. Therefore, in accordance with HEAdhoc Recommendation 15, a first-tier consideration of 0.5 m^2 per event and an exposure duration (per event) of 45 mins similar to a laboratory setting can be applied. The contact time for this product is 3 minutes, the assessed exposure duration therefore covers this.

For peracetic acid, the estimated peak concentration (TWA 15 mins) is 0.079 mg/m^3. The residual air concentration after 45 mins is 0.054 mg/m^3. The sum of the peak concentration per application and residual air concentration after each application is 0.133 mg/m^3

For hydrogen peroxide, the estimated peak concentration (TWA 15 mins) is 0.32 mg/m^3. The residual air concentration after 45 mins is 0.29 mg/m^3. The sum of the peak concentration per application and residual air concentration after each application is 0.61 mg/m^3.

Calculations for Scenario 1

Summary table: estimated exposure to peracetic acid from professional uses		
Exposure scenario	**Tier/PPE**	**Mean event concentration (mg a.s./m^3)**
Scenario 1	1 (no RPE)	0.133
Detailed calculations can be found in Annex 3.2		

Summary table: estimated exposure to hydrogen peroxide from professional uses		
Exposure scenario	**Tier/PPE**	**Mean event concentration (mg a.s./m^3)**
Scenario 1	1 (no RPE)	0.61
Detailed calculations can be found in Annex 3.2		

Further information and considerations on scenario 1

The adverse effects of peracetic acid and hydrogen peroxide in humans are limited to local effects at the site of contact with the body. Peracetic acid has an AEC of 0.5 mg/m^3 [the peak air concentration (TWA 15 mins) is predicted to be 0.079 mg/m^3 and residual air concentration after application is 0.054 mg/m^3] and hydrogen peroxide has an AEC of 1.25 mg/m^3 [the peak air concentration (TWA 15 mins) is predicted to be 0.32 mg/m^3 and residual air concentration after application is 0.29 mg/m^3]. PeridoxRTU Product Family is classified as H314 (causes serious skin burns and eye damage). Based on classification, a user must wear gloves, coveralls and eye protection to avoid direct contact with the product.

Scenario 2 – Primary exposure during pouring of the product from a 0.9 or 3.75 L container (Use 2)

Description of Scenario 2		
The product is poured into a suitable vessel and then applied by a mop / dry wipe on the surface to be treated. The air concentration of peracetic acid and hydrogen peroxide during pouring has been calculated using ART tool (version 1.5). Assuming that professional users may pour the product into suitable containers outside of the working area (cleanroom), only good ventilation has been accounted for as a worst-case scenario instead of higher ventilation present in specific cleanroom classes.		
	Parameters	Value
Tier 1	Exposure duration per day	10 mins
	Liquid mole fraction of hydrogen peroxide	0.025
	Liquid mole fraction of peracetic acid	0.0006
	Activity coefficient (default)	1
	Activity class	Falling liquids
	Situation	Transfer of liquid product with flow of 0.1 – 1 L/min
	Contamination level	Open process
	Loading type	Splash loading
	Room volume	Any size workroom
	Ventilation rate	Only good ventilation
	General control measures	No localised controls

Tier 1 assessment

It is assumed that no personal protective equipment is worn.

Calculations for Scenario 2

Summary table: estimated exposure to peracetic acid from professional uses		
Exposure scenario	**Tier/PPE**	**Mean event concentration (mg a.s./m³)**
Scenario 2	1 (no RPE)	0.057
Detailed calculations can be found in Annex 3.2.		

Summary table: estimated exposure to hydrogen peroxide from professional uses		
Exposure scenario	**Tier/PPE**	**Mean event concentration (mg a.s./m³)**
Scenario 2	1 (no RPE)	0.36
Detailed calculations can be found in Annex 3.2.		

Further information and considerations on scenario 2

The adverse effects of peracetic acid and hydrogen peroxide are limited to local effects at the site of contact with the body. Peracetic acid has an AEC of 0.5 mg/m^3 ; the 90th percentile full-shift exposure for this scenario is 0.057 mg/m^3 and hydrogen peroxide has an AEC of 1.25 mg/m^3; the 90th percentile full-shift exposure for this scenario is 0.36 mg/m^3. The product family is classified as H314 (causes serious skin burns and eye damage). Based on the classification, a user must wear gloves, coveralls and eye protection to avoid direct contact with the product.

Scenario 3 - Primary exposure during disinfection of surfaces via mop / dry wipe application (Use 2)

Description of Scenario 3		
A user pours the ready-to-use liquid directly onto a vessel; the product is then applied using a dry wipe or mop at an application rate of 80 mL/m^2. Pouring of the product is considered under scenario 2 above. Mopping can be used to disinfect large areas such as floors and walls where as dry wipes are likely to be used to disinfect smaller surface areas. Biocides Human Health Exposure Methodology Document (2015, p.105) recommends using Surface Disinfection Model 1 for the estimation of inhalation exposure however, given the high volatility of peracetic acid and hydrogen peroxide, this model is not appropriate to assess exposure to vapour. As such, the air concentration of peracetic acid and hydrogen peroxide has been calculated using ConsExpo Web exposure to vapour: evaporation model (increasing area) for the Tier 1 assessment.		
	Parameters[1]	Value
Tier 1	Adult body weight	60 kg
	Maximum concentration of peracetic acid	0.23 % w/w
	Maximum concentration of hydrogen peroxide	4.4 % w/w
	Molecular weight of peracetic acid	76 g/mol
	Molecular weight of hydrogen peroxide	34 g/mol
	Inhalation rate	1.25 m^3/hr
	Vapour pressure of peracetic acid[1]	1410 Pa (20°C)
	Vapour pressure of hydrogen peroxide	214 Pa (20°C)
	Product density	1.022 g/ml
	Product amount (80 ml product/m^2 x 22 m^2 x 1.022 g/ml)	1799 g
	Exposure duration	15 mins
	Room volume	~~4~~ 55 m^3
	Ventilation rate	20/hr
	Application duration	5 mins
	Release area	22 m^2
	Molecular weight matrix for peracetic acid[1]	19.1 g/mol
	Molecular weight matrix for hydrogen peroxide[1]	19.6 g/mol
	Mass transfer rate[2]	10 m/hr
Tier 2	Mass transfer rate (refinement using US-EPA Consumer |Exposure Model (CEM)	4.7 m/h [hydrogen peroxide]
Tier 3 (reverse reference)	Ventilation rate	100/hr [hydrogen peroxide] 30/hr [peracetic acid]

[1] Calculated as the average molecular weight all substances in the mixture except the substance in question (RIVM Report 2016-0171, p. 31)
[2] Default value (RIVM Report 2017-0197, update for ConsExpo Web 1.0.2, p.35)
[3] Detailed calculations can be found in Annex 3.2.

Tier 1 assessment

It is assumed that no personal protective equipment is worn.

A professional user is exposed during evaporation of the cleaned surface via inhalation. The tier 1 assessment has been calculated using ConsExpo Web evaporation model (increasing area release mode) and the parameters described in the table above. The BE CA considers that mopping can be considered as a worst case based on the larger surface area treated and the higher amount of product required. In accordance with HEAdhoc Recommendation 15, the default value for a cleanroom manufacturing setting is 55 m^3. Assuming a room height of 2.5 m, a floor area of 22 m^2 can be calculated. As a reasonable worst case, the calculations are based on a user mopping the entire floor area (i.e. 22 m^2) at the proposed application rate of 80 ml product/m^2. In line with HEAdhoc recommendation 2, it is assumed a user remains in the room for a total of 15 minutes and spends 5 minutes of this time mopping.

Tier 1b is a refinement of Tier 1 by adding RPE (APF 10).

Tier 2 assessment

Hydrogen peroxide
The tier 1 assessment has been refined using the US-EPA Consumer Exposure Model (CEM) as proposed in ConsExpo Web to refine the default mass transfer value.

The US-EPA Consumer Exposure Model (CEM) user's guide (US-EPA, 2016) proposes a method to estimate the mass transfer coefficient as:

$$h_m = 46.8 \times \frac{3.3}{(2.5 + MW^{1/3})^2}$$

Where hm is the mass transfer coefficient in m/h and MW is the molecular weight in g/mol.

Hm = 46.8 x 3.3 / $(2.5 + 34^{1/3})^2$
= 4.7 m/h

Peracetic acid
Hm = 48.8 x 3.3 / $(2.5 + 76.1^{1/3})^2$
= 3.4 m/h

Tier 3 assessment

Hydrogen Peroxide
The tier 2 assessment is refined by taking into account the hierarchy of control measures in accordance with COSHH. In considering the scale of use during mopping, where large surfaces are disinfected, it is appropriate to consider technical/engineering control measures before PPE. In order to maintain the removal of airborne residues of hydrogen peroxide and peracetic acid during use, the maximum ventilation should be in operation during large surfaces disinfection. [Note that tier 1 assessment has considered the

minimum ventilation in the highest cleanroom standard for the worst-case scenario however higher ventilation rates exist for lower cleanroom standards[1]]

A reverse reference exposure prediction from ConsExpo, based on the above assumptions for the scenario, demonstrates that a ventilation rate of at least 100 per hour is required for professional inhalation exposure to be within acceptable limits during large surface disinfection for hydrogen peroxide and 30 per hour for peracetic acid. Therefore, the following use specific description and risk mitigation measure is required for Use #2 (pouring into a container and then mopping/wiping):

- Application of technical or engineering controls to remove airborne residues is mandatory (e.g. room ventilation or LEV) during product application. A minimum ventilation rate of 100 air change per hour is mandatory.
- Technical or engineering controls to remove airborne residues is mandatory (e.g. ventilation or LEV) before operatives are permitted to enter into treated areas after surface disinfection. Where necessary, a waiting restriction of sufficient duration must be set to allow time for the removal of airborne residues.

Calculations for Scenario 3

Summary table: estimated exposure to peracetic acid from professional uses		
Exposure scenario	**Tier/PPE**	**Mean event concentration (mg a.s./m³)**
Scenario 3	1 (no RPE)	1.4
Scenario 3	1b (with RPE APF10)	0.14
Scenario 3	2 (no RPE)	0.53
Scenario 3	3 (no RPE)	0.36
Detailed calculations can be found in Annex 3.2.		

Summary table: estimated exposure to hydrogen peroxide from professional uses		
Exposure scenario	**Tier/PPE**	**Mean event concentration (mg a.s./m³)**
Scenario 3	1 (no RPE)	8.5
Scenario 3	1b (with RPE APF10)	0.85
Scenario 3	2 (no RPE)	4.3
Scenario 3	3 (no RPE)	1.1
Detailed calculations can be found in Annex 3.2.		

Further information and considerations on scenario 3

The adverse effects of peracetic acid and hydrogen peroxide are limited to local effects at the site of contact with the body. Peracetic acid has an AEC of 0.5 mg/m^3; the peak air concentration (TWA 15 mins) is predicted to be 0.36 mg/m^2 when minimum ventilation of 30 per hour is in place during disinfection in the cleanroom and hydrogen peroxide has an AEC of 1.25 mg/m^3; the peak air concentration (TWA 15 mins) is predicted to be 1.1 mg/m2 when minimum ventilation of 100 per hour is in place during disinfection in the cleanroom. The product family is classified as H314 (causes serious skin burns and eye damage). Based on the classification, a user must wear gloves, coveralls and eye protection to avoid direct contact with the product.

1 https://www.cleanairproducts.com/resources/industry-standards

Scenario 4 - Secondary exposure when a professional bystander (e.g. technician) re-enters a treated area after disinfection through mopping/wiping (Meta use 2)

Description of Scenario 4
Exposure may occur to professional bystanders (e.g. technicians) in cleanrooms where surface disinfection is performed by mopping/wiping. It is reasonable to assume that bystanders in a treated clean room will be exposed to an air concentration ≤ to that of professional users applying the product. However, professional bystander re-entry into treated areas after large surface disinfection requires consideration since re-entry could occur whilst high levels of hydrogen peroxide and peracetic acid residues are present in the air. As such a waiting period is necessary for professional bystanders who re-enter the room after disinfection for air concentrations to be below the relevant AECs. For illustrative purposes, when the exposure duration in Scenario 3 is extrapolated the air concentration is 1.2 mg/m^3 for hydrogen peroxide 84 mins after application and therefore below the AEC of 1.25 mg/m^3 ; the air concentration is 0.45 mg/m^3 for peracetic acid 1 min after application and therefore below the AEC of 0.5 mg/m3. Detailed calculations are provided in Annex 3.2.

Further information and considerations on scenario 4

The adverse effects of peracetic acid and hydrogen peroxide are limited to local effects at the site of contact with the body. Peracetic acid has an AEC of 0.5 mg/m^3 ; the air concentration is predicted to be 0.45 mg/m^3 for professional bystanders 1 min after application. Hydrogen peroxide has an AEC of 1.25 mg/m^3; the air concentration is predicted to be 1.2 mg/m^3 for professional bystanders 84 mins after application. Dermal contact with the product is not expected.

On this basis, the following risk mitigation measure is required for pouring into a container and then mopping/wiping:

- Technical or engineering controls to remove airborne residues is mandatory (e.g. ventilation or LEV) before operatives are permitted to enter into treated areas after surface disinfection. Where necessary, a waiting restriction of sufficient duration must be set to allow time for the removal of airborne residues.

Scenario 5 – Secondary exposure when a professional bystander (e.g. technician) re-enters a treated area after disinfection through trigger spraying onto a wipe and using the wipe to distribute the liquid on the surface (meta Use 1)

Description of Scenario 5
Exposure may occur to professional bystanders (e.g. technicians) in cleanrooms where surface disinfection is performed by trigger spray onto a wipe application. It is reasonable to assume that bystanders in a treated clean room will be exposed to an air concentration ≤ to that of professional users applying the product. For disinfection through spraying and wiping, PPE is not required for the primary use as peak air concentration is below the AEC of 1.25 mg/m^3 for hydrogen peroxide and 0.5 mg/m^3 for peracetic acid (see scenario 1). In a worst-case scenario, assuming that the bystander stays in the room where disinfection is performed (i.e. necessary to cover the contact time and to wipe the surface dry) the primary scenario considered 45 mins exposure duration which covers the contact time of 3 minutes when disinfecting small surfaces. Therefore, the level of inhalation exposure of a bystander is estimated to be equivalent or lower compared to the professional user applying the product and no further risk assessment is required.

Further information and considerations on scenario 5

The adverse effects of peracetic acid and hydrogen peroxide are limited to local effects at the site of contact with the body. Peracetic acid has an AEC of 0.5 mg/m^3 ; the air concentration is predicted to be 0.133 mg/m^3 for professional bystanders and hydrogen peroxide has an AEC of 1.25 mg/m^3; the air concentration is predicted to be 0.61 mg/m^3 for professional bystanders (please refer to scenario 1). Dermal contact with the product is not expected.

Combined scenarios

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

Non-professional exposure

The PeridoxRTU Product Family is not intended for non-professional use.

Exposure of the general public

The general public are not expected to have entry into industrial cleanrooms.

Dietary exposure

Exposure to hydrogen peroxide via the diet is not expected for the proposed use of the PeridoxRTU Product Family in cleanrooms.

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 PeridoxRTU 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 BE CA has not considered exposure from production of the biocidal product further.

Summary of exposure assessment

Scenarios and values to be used in risk assessment for peracetic acid			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1.	Professionals: primary exposure during disinfection of surfaces via a trigger sprayer onto a wipe (Use 1)	1 (no RPE)	0.133
2.	Professionals: primary exposure during pouring of the product from a 0.9 or 3.75 L container (meta SPC 2)	1 (no RPE)	0.057
3.	Professionals: primary exposure during disinfection of surfaces via a mop / dry wipe (meta SPC 2)	1 (no RPE)	1.4
		1b (with RPE)	0.14
		2 (no RPE)	0.53
		3 (no RPE)	0.36
4.	Professional bystanders: secondary exposure via inhalation of volatilised residues (mop/dry wipe application; meta SPC 2)	1 (no RPE)	Please refer to Scenario 3 for full details of the assessment conducted
5.	Professional bystanders: secondary exposure via inhalation of volatilised residues (trigger sprayer onto a wipe application; meta SPC 1)	1 (no RPE)	≤0.133

Scenarios and values to be used in risk assessment for hydrogen peroxide			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated air concentration of hydrogen peroxide (mg/m^3)**
1.	Professionals: primary exposure during disinfection of surfaces via a trigger sprayer onto a wipe (Use 1)	1 (no RPE)	2.0
2.	Professionals: primary exposure during pouring of the product from a 0.9 or 3.75 L container (meta SPC 2)	1 (no RPE)	0.36
3.	Professionals: primary exposure during disinfection of surfaces via a mop / dry wipe (meta SPC 2)	1 (no RPE)	8.5
		1b (with RPE)	0.85
		2 (no RPE)	4.3
		3 (no RPE)	1.1
4.	Professional bystanders: secondary exposure via inhalation of volatilised residues (mop/dry wipe application; meta SPC 2)	1 (no RPE)	Please refer to Scenario 3 for full details of the assessment conducted
5.	Professional bystanders: secondary exposure via inhalation of volatilised residues (trigger sprayer onto a wipe application; meta SPC 1)	1 (no RPE)	≤0.61

2.2.6.3 Risk characterisation for human health

Risk for industrial users

This product is not intended for industrial use.

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

Local effects for peracetic acid

Task/ Scenario	Tier (PPE)	AEC (mg a.s. /m³)	Air conc. (mg a.s./m³)	Air conc. / AEC (%)	Acceptable (yes/no)
Scenario 1 - primary exposure during disinfection of surfaces via a trigger sprayer onto a wipe (Use 1)	1 (no RPE)	0.5	0.133	26.6%	yes
Scenario 2 – primary exposure during pouring of the product (meta SPC 2)	1 (no RPE)	0.5	0.057	11.4%	yes
Scenario 3 – primary exposure during disinfection of surfaces via a mop / dry wipe (meta SPC 2)	1 (no RPE)	0.5	1.4	280%	no
	1b (with RPE)		0.14	28%	yes
	2 (no RPE)		0.53	106%	no
	3 (no RPE)		0.36	72%	yes
Scenario 4 – secondary exposure via inhalation of volatilised residues (mop/dry wipe application; meta SPC 2)	1 (no RPE)	0.5	Please refer to Scenario 3 for full details of the assessment conducted		yes
Scenario 5 - secondary exposure via inhalation of volatilised residues (trigger sprayer onto a wipe application; meta SPC 1)	1 (no RPE)	0.5	≤0.133	≤26.6%	yes

During the evaluation of peracetic acid (AR 2017 FI) dermal NOAEC values of ≤0.2% short/medium term and ≤0.1% long term was derived. Therefore, a semi-quantitative local risk characterisation for dermal exposure to peracetic acid can be performed.

Concentration of peracetic acid in this product family is 0.23% w/w which exceeds these NOAECs. Therefore, this can be mitigated by relevant PPE. PeridoxRTU Product Family is classified as H314 (Skin Corr. 1A) and H318 (Eye Dam.1.). Based on this, a user must wear gloves, coveralls and eye protection to avoid direct contact with the product.

Local effects for hydrogen peroxide

Task/ Scenario	Tier (PPE)	AEC (mg a.s. /m³)	Air conc. (mg a.s./m³)	Air conc. / AEC (%)	Acceptable (yes/no)
Scenario 1 - primary exposure during disinfection of surfaces via a trigger sprayer onto a wipe(Use 1)	1 (no RPE)	1.25	0.61	48.8%	yes
Scenario 2 – primary exposure during pouring of the product (meta SPC 2)	1 (no RPE)	1.25	0.36	28.8	yes
Scenario 3 – primary exposure during disinfection of surfaces via a mop / dry wipe (meta SPC 2)	1 (no RPE)	1.25	8.5	680%	no
	1b (with RPE)		0.85	68%	yes
	2 (no RPE)		4.3	344%	no
	3 (no RPE)		1.1	88%	yes
Scenario 4 – secondary exposure via inhalation of volatilised residues (mop/dry wipe application; meta SPC 2)	1 (no RPE)	1.25	Please refer to Scenario 3 for full details of the assessment conducted		yes
Scenario 5 - secondary exposure via inhalation of volatilised residues (trigger sprayer onto a wipe application; meta SPC 1)	1 (no RPE)	1.25	≤0.61	≤48.8%	yes

PeridoxRTU Product Family is classified as H314 (causes serious skin burns and eye damage). Based on this, a user must wear gloves, coveralls and eye protection to avoid direct contact with the product.

Local effects for acetic acid

According to the peracetic acid CAR, toxicity tests have been performed with the aqueous solution containing an equilibrium of peracetic acid, hydrogen peroxide and acetic acid. Hence, the results also inherently contain the effects of each ingredients. Moreover, peracetic acid is the most critical ingredient for human health toxicity. Therefore, the local effects assessment for peracetic acid already covers potential effects from acetic acid.

Conclusion

Based on a pH of 1.72, the products should be classified:

- Skin Corr. 1A - H314: Causes severe skin burns and eye damage.

The active substance assessments for peracetic acid and hydrogen peroxide informs that the AEC for professional users is 0.5 mg/m^3 and 1.25 mg/m^3, respectively. Exposure above these levels was modelled for users of the product. The risk to professional users was demonstrated to be acceptable when gloves and eye protection were modelled to be worn.

Professional user risk assessment

Primary exposure has been considered for a professional user using a trigger spray, pouring the product into a container and also through disinfection of surfaces using a dry wipe or mop.

Secondary exposure has been modelled for professionals re-entering an area treated by mopping/wiping or spraying onto a wipe.

When taking into account primary exposure from the use of products from the PeridoxRTU Product Family the following conclusions can be drawn:

- Spraying of the product onto a wipe: gloves, coveralls and eye protection must be worn when handling the product.
- Pouring of the product into a container from a 5 L bottle and the use of a mop or wipe to spread the product: gloves, coveralls and eye protection must be worn when handling the product.

When taking into account secondary exposure from the use of products from the PeridoxRTU Product Family the following conclusions can be drawn:

- Exposure when a professional bystander re-enters a treated area after disinfection through spraying onto a wipe: Acceptable exposure without PPE.
- Exposure when a professional bystander re-enters a treated area after disinfection through mopping/wiping: Acceptable exposure without PPE.

When taking into account exposure scenarios for products from the PeridoxRTU Product Family, the following conclusions can be drawn:

The risk to professional users is demonstrated to be acceptable when protective gloves, coveralls and eye protection and increased ventilation rate for Use 1 and Use 2.

The following risk mitigation measures are required for Use #1 (spraying onto a wipe) :

- Wear protective chemical resistant gloves and eye protection during product handling phase (glove material to be specified by the authorisation holder within the product information).
- A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).
- A ventilation rate of at least 20/hr is mandatory when handling the product.
- The product must only be applied for disinfection of small surfaces.

The following risk mitigation measures are required for Use #2 (pouring into a container and then mopping/wiping):

- Wear protective chemical resistant gloves and eye protection during product handling phase (glove material to be specified by the authorisation holder within the product information).
- A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).
- Application of technical or engineering controls to remove airborne residues is mandatory (e.g. room ventilation or LEV) during product application. A minimum ventilation rate of 100 air change per hour is mandatory.
- Technical or engineering controls to remove airborne residues is mandatory (e.g. ventilation or LEV) before operatives are permitted to enter into treated areas after surface disinfection. Where necessary, a waiting restriction of sufficient duration must be set to allow time for the removal of airborne residues.

In addition, given it can be expected that the product still evaporates from the used wipe after the product is distributed on the surface by wiping, the following use instructions should be added to the product label : "Used wipes must be disposed in a closed container".

Risk for non-professional users

The product is not intended for non-professional use.

Risk for the general public

The general public are not expected to have access to industrial cleanrooms.

Risk for consumers via residues in food

Exposure to hydrogen peroxide via the diet is not expected from the proposed use on PeridoxRTU Product Family in cleanrooms.

2.2.7 Risk assessment for animal health

Not applicable because animals will not be present in industrial cleanrooms.

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 one substances of concern for the environment. Therefore all toxicity data for the active substance can be obtained from the Assessment Report and the data for the Substance of Concern, however the substance identified as a Substance of Concern is also a biocide active substance, so the PNECs can come from the Assessment Report, supplemented by the REACH registration report where necessary. The PNECs are summarised below:

Source of PNEC: Assessment Report for peracetic acid (November 2015) and Document IIA for peracetic acid.

Peracetic acid (active substance)	
$PNEC_{aquatic}$	0.069 µg/L
$PNEC_{marine}$	0.0069 µg/L
$PNEC_{sediment}$	0.056 µg/kg
$PNEC_{stp}$	0.051 mg/L
$PNEC_{soil}$ / $PNEC_{terrestrial}$	0.282 mg/kg_{wwt} soil or 0.320 mg/kg_{dwt} soil

Source of PNEC: Assessment Report for hydrogen peroxide (March 2015).

Hydrogen peroxide	
$PNEC_{aqua}$	12.6 µg/L
$PNEC_{stp}$	4.66 mg/L
$PNEC_{soil}$ (equilibrium partitioning method)	0.0018mg/kg soil dw

Source of PNEC: REACH registration dossier for hydrogen peroxide

Hydrogen peroxide (SoC)	
$PNEC_{marine}$	12.6 µg/L
$PNEC_{sediment}$	0.047 mg/kg sediment dw
$PNEC_{soil}$	0.0018 mg/kg

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

See confidential annex (Section 3.6.6). According to an agreement made at ENV WG-V-2019.

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

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 PeridoxRTU Product Family all contain peracetic acid (PAA) as sole biocidal active substance at 0.23 % w/w plus hydrogen peroxide as "substance of concern" at 4.4 % w/w (in line with agreement reached at BPC-M-20-2017 under agenda item 8.2). No other co-formulants are reported to give rise to concerns for the environment (see confidential annex) so has been discounted from the assessment process.

Products within the family are supplied as aqueous ready-for-use formulations in PT 2 ("disinfectants and algaecides not intended for direct application to humans or animals") with application to internal hard surfaces such as walls, floor and equipment by trained professional operators using:

- trigger spray from 0.9 litre bottles at 50 ml of product per m^2 (Use 1) and;
- pour product from 0.9 litre and 3.75 litre bottles into a suitable container and apply by mop / wipe **or** spray / pour onto a dry wipe / cloth to ensure even spread when applying 80 ml of product per m^2 (Use 2).

INFOBOX 1 : Application rate modelled for Use#2 (wipe and mop) [Dec 2019]

It should be noted that since the product was first evaluated by the eCA, its application rate for Use#2 has subsequently been reduced from 80 ml/m^2 to 50 ml/m^2. However, as all predicted risks at the higher concentration were considered to be acceptable, no change has been made to the ERA (environmental risk assessment).

Assessment carried out in relation to effects on environmental compartments therefore represents a worst case approach.

With a product density of 1.022 g/ml at 20 °C (section 2.2.2 of this PAR), the product application rates of 50 ml/m^2 and 80 ml/m^2 are equivalent to 51.10 g/m^2 and 81.76 g/m^2 respectively.

As indicated previously, the PeridoxRTU Product Family will be supplied in 0.9 litre and 3.75 litre containers so, even where the product may be delivered to limited treatment areas, the criteria outlined under ENV 38 of Technical Agreements for Biocides (TAB v1.3) are not met so default areas of only 25 m^2 cannot be applied in emissions assessment. Therefore, a default large area application of 1000 m^2 per day must be used in the environmental risk assessment.

It should be noted that use of a 1000 m^2 area in emissions assessment does represent an extreme worst case in terms of scale of use for this product (especially with regard to trigger spray application from a 0.9 litre bottle). Therefore, it is proposed that the daily application area will be set at 1000 m^2 for an Nappl of 1 (one treatment per day within the building) as this would be sufficiently protective of situations where multiple applications could be made to small areas (such as several repeat treatments of equipment).

In line with respective PT 1 - 6 CARs for both PAA and hydrogen peroxide, rapid degradation of both compounds during transit in sewer systems / drains and at STP will be taken into account within the emissions assessment.

As identified within the 2011 PT 2 ESD, "*Surface disinfection in industrial, institutional and primary health care areas is usually done on a regular basis (daily) by using a ready-for-use product (e.g. wipe, trigger spray) or using a diluted concentrate which can be applied by scrubbing, mopping or wiping. The post-application includes either wiping the surfaces or letting them dry*." This treatment regime outlined in the ESD summarises the proposed use pattern of PeridoxRTU Product Family at industrial premises.

In terms of modelling emissions, the ESD assumes that even where biocidal a.s. could be released to air within the industrial premises, it is most likely to settle onto a surface and be subject to wet cleaning (hence the use of a worst case default F_{water} of 1). Furthermore, Doc II-A of the PAA CAR concludes that the compound has a DT_{50} of 22 min indoors when in the vapour phase so is not expected to persist in the atmosphere and thus "*Air is not an environmental compartment of concern*".

With regard to the PT 1 – 6 review of hydrogen peroxide, Doc II-A and Doc II-B of the Final CAR concluded that emissions to air from indoor application would be negligible in the absence of heating or pressurised spraying operations. Additionally, hydrogen peroxide would not evaporate from aqueous solutions, based on its low Henry's law constant of 7.5E-4 Pa/ m^3/mol (at 20 °C).

As a consequence, no further consideration will be made for the potential of PAA and hydrogen peroxide to be discharged from industrial premises into the air compartment. However, some consideration of airborne concentrations will be investigated at STP (using respective $Fstp_{air}$ fractions derived using SimpleTreat modelling), to consider likely levels at 100 m from this point source.

General information

Assessed PT	PT 2

Assessed scenarios	Scenario 1 : Tonnage based assessment of discharges to STP considering application of PeridoxRTU Product Family as a surface disinfectant within industrial premises (as detailed in section 2.1.4.2 and Table 3 of PT 2 ESD) ; Scenario 2a : Consumption based assessment of PAA + hydrogen peroxide based product (PeridoxRTU Product Family) for trigger spray application indoors in industrial premises (as detailed in section 2.1.4.1 and Table 2 of PT 2 ESD) ; Scenario 2b : Consumption based assessment of PAA + hydrogen peroxide based product (PeridoxRTU Product Family) for mop / dry wipe / cloth application indoors in industrial premises (as detailed in section 2.1.4.1 and Table 2 of PT 2 ESD). All applications will be undertaken by professional operators
ESD(s) used	Emission Scenario Document for Product Type 2 (private and public health disinfectants plus other biocidal products), 2011. Further calculations have also been undertaken in line with models presented in ECHA Guidance on ERA, Volume IV, Part B + C (2017)
Approach	Scenario 1: tonnage based approach. Scenario 2a + 2b: consumption based approach. Calculator sheets are available on ECHA website with PT 2 ESD predicting discharges from industrial premises to drains. However, calculations for resultant emissions to ENV compartments are also supplied in Annex 3.7 of this PAR (consumption based PECs) and confidential Annex (tonnage based values)
Distribution in the environment	Calculations based on principles laid out in ECHA Guidance on ERA, Volume IV, Part B + C (2017).
Groundwater simulation	Not considered relevant to perform higher tier FOCUS PEARL 4.4.4 models, as acceptable concentrations have been demonstrated by porewater screening calculations. Both compounds are accepted as being rapidly degradable in sewer system / drains, STP, manure and soil so are not expected to reach local aquifers.
Confidential Annexes	Yes – tonnage based information and calculations (Scenario 1) are confidential to applicant and have been presented in section 3.6 (Confidential Annex) to this PAR.
Life cycle steps assessed	Production : No Formulation : No Use : Yes Service life : No, as both PAA and hydrogen peroxide are highly reactive in the presence of organic material and metals and are therefore transient compounds
Remarks	None

Emission estimation for PT 2

Scenario 1: Tonnage based assessment considering application of Contec PeridoxRTU for industrial premises (based upon section 2.1.4.2 and Table 3 of PT 2 ESD)

Tonnage based assessment has been undertaken in line with the simplistic model presented in Table 3 of section 2.1.4.2 of the 2011 ESD for PT 2. It represents a modification of the 2001 (Van der Poel) model designed for calculating the releases of disinfectants used for institutional and private health care area disinfection in the sanitary sector – it follows the approach for IC 5 at the stage of private use but has been adapted to align the scenarios with this specific application. However, all releases from the treatment area take place to an STP during the working week.

Annual tonnage values have been provided by the Applicant but remain confidential, so all relevant calculations to derive $Elocal_{wastewater}$ in kg/d are supplied within the Confidential Annex to this PAR.

Output value for local emission : Scenario 1 (a.s. based)			
	Value	**Unit**	**Remarks**
Scenario 1: Tonnage* based assessment considering emissions to drain from application of PeridoxRTU Product Family indoors within industrial premises			
Emission to wastewater ($Elocal_{water}$) discharged to sewer system	*confidential*	kg/d	Output derived from ***confidential*** values – full details can be found in annex 3.6

*For reasons of confidentiality, the actual value for annual tonnage given by the applicant plus all relevant input values to derive $Elocal_{wastewater}$ and final daily discharge value can be found in the confidential annex to this PAR (annex 3.6.5)

It should be noted that only one value for a.s. can be determined from this scenario, so it is not clear how the approach can be used to predict emissions of both peracetic acid and hydrogen peroxide.

Scenario 2a: Consumer based assessment of PAA + hydrogen peroxide based product (PeridoxRTU Product Family) for trigger spray application indoors in industrial premises (detailed within section 2.1.4.1 and Table 2 of PT 2 ESD)

As indicated within section 2.1.4.1 of the PT 2 ESD (2011), "*Industrial premises such as biotechnology plants, production plants for pharmaceuticals, cosmetics or toiletries or production plants for computers are considered as local point sources which release their waste water to a local STP (Sewage Treatment Plant). Surfaces to be disinfected in such industrial premises can greatly vary. They can be surfaces of the rooms themselves (2 m² up to > 200 m²) such as floors, walls and ceilings, or smaller surfaces (< 2 m²) such as furniture, equipment, working places, isolator benches etc. The largest surface area to be disinfected in industrial premises was identified to be 1,000 m².*

Nappl: Since disinfection can take place from "after each use" to "monthly", one disinfection per day is considered a reasonable default value.

AREAsurface: The variation in the size of the surface area to be disinfected is quite high and depends on the nature and size of the industrial plant. Based on the above summarised information on sizes of treated surfaces (< 2 m² to 1,000 m²), it is assumed that a default surface area of 1,000 m² to be disinfected on a daily base in an industrial plant (including room floors and walls, furniture and working places) is a reasonable default value representing a worst case."

The PeridoxRTU Product Family will be applied from a 0.9 litre trigger spray bottle and whilst this pack size is too large to permit use of the "25 m^2 small scale area" refinement in its emissions assessment, treatment of 1000 m^2 per day within an industrial building can be considered as extremely conservative.

No consideration of losses to air have been considered during application as it is assumed that use of the trigger spray device will deliver product onto a suitable cleanroom wipe. Application by this method is not expected to give rise to significant airborne concentrations of either PAA or hydrogen peroxide, especially as both compounds are highly reactive. Even if airborne concentrations could be achieved, the product is being applied within industrial premises where control measures would prevent can be applied, so models assume 100 % loss to waste water as worst case.

Input parameters for calculating the local emission (based on potential volume of disinfectant lost to drain from wet cleaning of surfaces treated with trigger spray) : Scenario 2a			
Input	**Value**	**Unit**	**Remarks**
Scenario 2a : Disinfection indoors in industrial premises using trigger spray			
Application rate of biocidal product (Vform)	0.05	l/m^2	
Amount of active substance (PAA) in the product	0.23	%	
Amount of SOC (hydrogen peroxide) in the product	4.4	%	
Relative density of product	1.022	g/ml	Value given in PAR
Concentration of active substance (PAA) in the product [Cform]	2.35	g/l	
Concentration of SOC (hydrogen peroxide) in the product [Cform]	44.97	g/l	
Area to be disinfected ($AREA_{surface}$)	1000	m^2	
Number of daily applications (Nappl)	1	d^{-1}	
Fraction disintegrated before release to sewer (F_{dis})	0		
Fraction released to wastewater (F_{water})	1		

Total loss of PAA discharged to drain / sewer ($Elocal_{water}$)	0.1175	kg/d	
Total loss of hydrogen peroxide discharged to drain / sewer ($Elocal_{water}$)	2.2485	kg/d	

These $Elocal_{water}$ values assume no breakdown of PAA or hydrogen peroxide during the disinfection process on surfaces, which is another extreme worst case assumption due to the high reactivity of both compounds with metals, micro-organisms and organic material.

Scenario 2b : Consumer based assessment of PAA + hydrogen peroxide based product (PeridoxRTU Product Family) for dry wipe / mop / cloth application indoors in industrial premises (as per section 2.1.4.1 and Table 2 of PT 2 ESD)

As discussed earlier within Scenario 2a (trigger spray application), a default $AREA_{surface}$ of 1000 m^2 and Nappl of once per day are considered to represent reasonable (realistic worst case) assumptions for emissions assessment from application in industrial premises. The product will be supplied in either a 0.9 litre or 3.75 litre bottle as a ready-for-use formulation for application onto surfaces using either a mop, dry wipe or cloth so the largest container would treat <50 m^2. The need to store and use multiple containers on a daily basis to treat large surface areas would strongly suggest that total application to 1000 m^2 per day represents a conservative approach in risk assessment.

Again, no consideration of losses to air have been considered during application as it is assumed that use of the poured product will only deliver product onto suitable containers followed by application to the surface using a suitable cleanroom wipe or mop. Even if airborne concentrations could be achieved, the product is being applied within industrial premises where control measures would prevent can be applied, so models assume 100 % loss to waste water as worst case.

Input parameters for calculating the local emission (based on potential volume of disinfectant lost to drain from wet cleaning of surfaces treated with mop / cloth / dry wipe) : Scenario 2b			
Input	**Value**	**Unit**	**Remarks**
Scenario 2b : Disinfection indoors in industrial premises using mop / cloth / wipe delivery methods			
Application rate of biocidal product (Vform)	0.08	l/m^2	
Amount of active substance (PAA) in the product	0.23	%	
Amount of SOC (hydrogen peroxide) in the product	4.4	%	
Relative density of product	1.022	g/ml	Value given in PAR
Concentration of active substance (PAA) in the product [Cform]	2.35	g/l	
Concentration of SOC (hydrogen peroxide) in the product [Cform]	44.97	g/l	

Area to be disinfected ($AREA_{surface}$)	1000	m^2	
Number of daily applications (Nappl)	1	d^{-1}	
Fraction disintegrated before release to sewer (F_{dis})	0		
Fractio relased to wastewater (F_{water})	1		
Total loss of PAA discharged to drain / sewer ($Elocal_{water}$)	0.188	kg/d	
Total loss of hydrogen peroxide discharged to drain / sewer ($Elocal_{water}$)	3.5976	kg/d	

These $Elocal_{water}$ values assume no breakdown of PAA or hydrogen peroxide during the disinfection process on surfaces, which is another extreme worst case assumption due to the high reactivity of both compounds with metals, micro-organisms and organic material.

Tonnage v Consumption approach

Emissions of disinfectants in private and public health areas (PT 2) can be predicted using either a tonnage-based approach (Table 3 in section 2.1.4.1 of the ESD) or an estimated consumption approach based upon daily application within industrial premises (Table 2 in section 2.1.4.1). The tonnage approach predicts emissions based solely on EU market production values and is therefore independent from the size of the treated area – as this is based upon confidential sales information, all calculations and outcomes have been provided in the confidential Annex. On the other hand, the local consumption approach is based on the size of the treated area and the frequency of application at individual industrial premises. Both approaches are used in the emissions estimation for completeness. Furthermore, the consumption-based local emissions estimated within this document have been used to calculate the PECs as these would be representative of the worst case scenario and will therefore be suitably protective of the wider environment.

(Further detail on the comparison of predicted $Elocal_{water}$ values from tonnage based and consumption based approaches can be found in the confidential annex (section 3.6.5)).

Degradation in the sewer system for discharges to drain in Scenario 2a and 2b:

Peracetic acid and hydrogen peroxide are released into the wastewater from industrial premises, where further degradation occurs. Several studies provided in their respective CARs demonstrate that both compounds decompose rapidly in contact with organic material or metal cations. The load of organic substances and trace elements in raw sewage in the facility drain or in waste water collecting tanks is considered to be very high and therefore degradation of peracetic acid and hydrogen peroxide in the raw sewage is likely to occur and was therefore considered as a suitable refinement in relevant emission estimations.

Table 8.3-1 in Doc II-B of the PT 1 - 6 review for peracetic acid reports a DT_{50} in effluent stream (transferable to sewer system) of 9.5 min when normalised to 12 °C – this equates to a *k* rate of 4.38 h^{-1}. Additionally, Table 8.3.1-1 in Doc II-B of the PT 1 – 6 review for hydrogen peroxide reports a DT_{50} in effluent stream of 6 min at 20 °C (11.2 min when normalised to 12 °C) – this equates to a *k* rate of 3.71 h^{-1}.

It was further reported that normalised *k* rates were used in sewer system modelling as this was considered to best represent the likely temperature in drains during transit to STP. Furthermore, a sewer residence time of 1 h was proposed as default value, based upon the assumptions that :

- the average distance between the point of release into the drain and local STP is approximately 4.5 km ;
- the estimated flow rate in the municipal canal sewer system is assumed to be approximately 1.5 km in 20 min (i.e. 4.5 km/h).

The amounts of peracetic acid (PAA) and hydrogen peroxide that arrive at local STP after one-hour residence time in the sewer system (Mt1) can be calculated assuming first order kinetics using the following equation:

Mt1 = Mt0* EXP(-k * t1)

Where :
Mt1 = total amount of substance present at t 1 [kg]
Mt0 = total amount of substance at t 0 [kg] (= Elocalwater in kg/d)
k = rate constant at 12 °C ($ln2/DT_{50}$)
t1 = time [h] (taken to be 1 h)

Resulting local emission to relevant environmental compartments (based upon loss of PAA and hydrogen peroxide to drain and resultant degradation in sewer system)		
Compartment	**Local emission ($Elocal_{compartment}$) arriving at STP [kg/d]**	**Remarks**
Scenario 2a	PAA : 1.47E-3 Hydrogen peroxide : 5.50E-2	Revised values arriving at STP which takes account of degradation within the sewer system
Scenario 2b	PAA : 2.35E-3 Hydrogen peroxide : 8.81E-2	

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	-	-	-	-	-	-	-	-	
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 or behaviour of compounds.

Note: no further consideration has been made in relation to Scenario 1, which represents a tonnage based approach to emissions assessment. $Elocal_{water}$ values predicted by this

model are significantly lower than those predicted in line with Scenario 2a and 2b (consumption approach to trigger spray and pour application) and so a worst case (protective) approach has been taken in the environmental risk assessment.

INFOBOX 2 : INPUT PARAMETERS USED FOR EMISSIONS MODELLING OF PERACETIC ACID AND HYDROGEN PEROXIDE (OCTOBER 2019)

At the time that evaluation was completed [May 2018], input parameters were taken from the respective PT 1 – 6 CARs for peracetic acid and hydrogen peroxide (and more specifically from what was considered to be relevant data found in each Doc II-A and Doc II-B).

However, it must be noted that discussion at WG-IV-2019 has led to the production of harmonised endpoints for both peracetic acid and hydrogen peroxide to ensure consistency of approach for all future products assessed under BPR.

Whilst the values used in this UA document are considered to be "fit for purpose" at the time of evaluation and submission for MS peer review in 2019, any future product assessment for a peracetic acid and hydrogen peroxide product should rely upon 2019 ENV WG guidance on harmonised input parameters for emissions modelling.

Input parameters (only set values) for calculating the fate and distribution in of peracetic acid the environment			
Input	Value	Unit	Remarks
Molecular weight	76.05	g mol^{-1}	
Melting point	0	°C	
Boiling point	110	°C	
Vapour pressure (at 20°C)	1410	Pa	
Water solubility (at 20°C)	1.0E+6	mg/l	Miscible in water at all proportions
Log Octanol/water partition coefficient	-0.60	Log 10	Kow of 0.251
Organic carbon/water partition coefficient (Koc)	1.02	l/kg	
Henry's Law Constant (at 25°C) *[if measured data available]*	0.217	$Pa/m^3/mol$	
(pKa)	8.24		
Biodegradability	Readily biodegradable		
Rate constant for STP *[if measured data available]*	7.30	h^{-1} (at 12 °C)	Based on DT_{50} of 5.7 min at 12 °C
Rate constant for sewer drain *[if measured data available]*	4.38	h^{-1} (at 12 °C)	Based on DT_{50} of 9.5 min at 12 °C
DT_{50} for biodegradation in surface water	60.1	hr (at 12 °C)	Estimated value based upon hydrolysis
DT_{50} for hydrolysis in surface water	60.1	hr (at 12ºC)	
DT_{50} for photolysis in surface water	-	d or hr	Not expected
DT_{50} for degradation in soil	<1	hr (at 12 °C)	Estimated value (non-guideline)

DT_{50} for degradation in air	-	hr	No reliable value but not expected to persist

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

Calculated fate and distribution* of peracetic acid in the STP *[if STP is a relevant compartment]*		
Compartment	Percentage [%]	Remarks
	All scenarios	
Air	4.63E-2	SimpleTreat v4.0.9
Water	0.929	SimpleTreat v4.0.9
Sludge	9.26E-3	SimpleTreat v4.0.9
Degraded in STP	99.02	SimpleTreat v4.0.9

* Note : as well as using tabulated input parameter values for molecular weight, vapour pressure, Kow, Koc, water solubility and Henry Coefficient, peracetic acid falls into the chemical class of "acid" and so pKa is also required. Biodegradation is based upon a k rate of 7.30 h^{-1} at 12 °C using Method 3 (activated sludge simulation) and, in accordance with ENV 9 of Tab v2.0, a revised value of 0.03 kg/m^3 (30 mg/l) is used for concentration in suspended solids effluent.

Current policy outlined in the TAB (v1.3) under ENV 9 indicates that modelling of STP behaviour using SimpleTreat v4 need not be performed until 25-01-2019 for product authorisation. Although the biocidal product application for Union Authorisation is being evaluated by the eCA during 2018, its reported due date on ECHA systems (i.e. R4BP3) is listed as 06-02-2019 and therefore SimpleTreat v4 will be used in modelling instead of SimpleTreat v3.1.

Input parameters (only set values) for calculating the fate and distribution of hydrogen peroxide 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	Miscible in water at all proportions
Log Octanol/water partition coefficient	-1.57	Log 10	
Organic carbon/water partition coefficient (Koc)	1.598	l/kg	Based on QSAR log Koc of 0.2036
Henry's Law Constant (at 20°C) *[if measured data available]*	7.50E-4	Pa/m^3/mol	
Biodegradability	Not relevant		Compound is not organic
Rate constant for STP *[if measured data available]*	10.96	h^{-1} (at 12 °C)	Based on DT_{50} of 2 min at 20 °C
Rate constant for sewer drain *[if measured data available]*	3.71	h^{-1} (at 12 °C)	Based on DT_{50} of 11.2 min at 12 °C
DT_{50} for biodegradation in surface water	5	d (at 12 °C)	Worst case value
DT_{50} for hydrolysis in surface water	-	d or hr	Not expected
DT_{50} for photolysis in surface water	-	d or hr	Not expected

DT_{50} for degradation in soil	12	hr (at 12 °C)	Worst case value
DT_{50} for degradation in air	24	hr	Worst case value

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

Calculated fate and distribution* of hydrogen peroxide in the STP *[if STP is a relevant compartment]*		
Compartment	Percentage [%]	Remarks
	All scenarios	
Air	1.56E-4	SimpleTreat v4.0.9
Water	0.621	SimpleTreat v4.0.9
Sludge	1.45E-2	SimpleTreat v4.0.9
Degraded in STP	99.36	SimpleTreat v4.0.9

* Note : behaviours have been determined using tabulated input parameter values for molecular weight, vapour pressure, Kow, Koc, water solubility and Henry Coefficient. Biodegradation is based upon a k rate of 10.96 h^{-1} at 12 °C using Method 3 (activated sludge simulation) and, in accordance with ENV 9 of Tab v2.0, a revised value of 0.03 kg/m^3 (30 mg/l) is used for concentration in suspended solids effluent.

Current policy outlined in the TAB (v1.3) under ENV 9 indicates that modelling of STP behaviour using SimpleTreat v4 need not be performed until 25-01-2019 for product authorisation. Although the biocidal product application for Union Authorisation is being evaluated by the eCA during 2018, its reported due date on R4BP3 is listed as 06-02-2019 and therefore SimpleTreat v4 will be used in modelling instead of SimpleTreat v3.1.

Calculated PEC values

Compartmental PECs have only been determined for discharge of waste disinfectant solution (containing 0.23% of PAA and 4.40% of hydrogen peroxide) to local STP following wet cleaning of treated surfaces and resultant partitioning to sewage sludge, local air and water discharge to from STP to receiving watercourse.

Summary table on calculated PEC values for peracetic acid						
	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 2a	6.52E-6	6.52E-7	Not calculated	1.22E-9	1.50E-6	1.88E-10
Scenario 2b	1.04E-5	1.04E-6	Not calculated	1.95E-9	2.39E-6	3.00E-10

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

Summary table on calculated PEC values for hydrogen peroxide						
	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 2a	1.63E-4	1.63E-5	Not calculated	3.57E-7	4.08E-4	2.39E-11
Scenario 2b	2.61E-4	2.61E-5	Not calculated	5.72E-7	6.53E-4	3.81E-11

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

As peracetic acid and hydrogen peroxide rapidly degrade, no consideration of metabolites or degradation products is considered necessary.

It should be noted that in relation to the "substance of concern", 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 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 both active substances are -0.60 (peracetic acid) and -1.57 (hydrogen peroxide), which are both below 3.

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: It is possible that emissions of peracetic acid (PAA) and hydrogen peroxide could reach the air compartment at local STP following discharge of disinfectant solution to drains following wet cleaning of internal surfaces in treated areas (Scenario 2a and 2b). However, models presented in Annex 3.7 of this PAR predict insignificant levels of both compounds at 100 m from the point source (STP) and thus risks are acceptable.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values for peracetic acid	
	$PEC/PNEC_{STP}$*
Scenario 2a – trigger spray application	1.28E-4
Scenario 2b – mop, cloth, wipe application	2.04E-4

* based upon a PNEC of 0.051 mg/l

Summary table on calculated PEC/PNEC values for hydrogen peroxide	
	$PEC/PNEC_{STP}$*
Scenario 2a – trigger spray application	3.50E-5
Scenario 2b – mop, cloth, wipe application	5.61E-5

* 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, for situations where disinfectant solution is discharged to drains following wet cleaning of internal surfaces in treated areas (Scenario 2a and 2b).

Aquatic compartment

Summary table on calculated PEC/PNEC values for peracetic acid		
	PEC/PNEC$_{water}$*	**PEC/PNEC$_{sed}$****
Scenario 2a – trigger spray application	9.44E-3	Identical to water risk
Scenario 2b – mop, cloth, wipe application	1.51E-2	Identical to water risk

* based upon a PNEC of 6.90E-5 mg/l

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

Summary table on calculated PEC/PNEC values for hydrogen peroxide		
	PEC/PNEC$_{water}$*	**PEC/PNEC$_{sed}$****
Scenario 2a – trigger spray application	1.30E-3	Identical to water risk
Scenario 2b – mop, cloth, wipe application	2.07E-3	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, where disinfectant solution is discharged to drains following wet cleaning of internal surfaces (Scenario 2a and 2b).

Terrestrial compartment

Calculated PEC/PNEC values for peracetic acid	
	PEC/PNEC$_{soil}$*
Scenario 2a – trigger spray application	4.32E-9
Scenario 2b – mop, cloth, wipe application	6.91E-9

*based upon a PNEC of 0.282 mg/kg wwt

Calculated PEC/PNEC values for hydrogen peroxide	
	PEC/PNEC$_{soil}$*
Scenario 2a – trigger spray application	1.94E-4
Scenario 2b – mop, cloth, wipe application	3.11E-4

*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 soil (local ecosystem as worst case) indicate acceptable risks to terrestrial organisms, where disinfectant solution is discharged to drains following wet cleaning of internal surfaces (Scenario 2a and 2b).

Groundwater

Possible movement of PAA and hydrogen peroxide from soil to groundwater has been assessed at Tier 1 level by use of equation 70 taken from ECHA Guidance on ERA, Volume IV, Part B + C. 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 PAA to agricultural soil via sludge application can be predicted in a worst case assessment, whereby 100 % of daily applied product within an industrial premises is discharged to drains following trigger spray application (Scenario 2a) and pour application (Scenario 2b). This gives rise to values of 2.03E-10 – 3.25E-10 mg/kg wwt in arable soil, which will act as $Clocal_{soil}$ in the porewater model: this equates to worst case Tier 1 groundwater concentrations of 2.39E-6 µg/l for PAA.

In the same way, exposure of hydrogen peroxide to agricultural soil via sludge application can be determined in the same worst case scenarios. This would give rise to values of 5.95E-8 – 9.53E-8 mg/kg wwt in arable soil, which will act as $Clocal_{soil}$ in the porewater model: this equates to worst case Tier 1 groundwater concentrations of 6.53E-4 µg/l for hydrogen peroxide.

Whilst noted as being a simplistic approach, 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.

INFOBOX 3 : DISCUSSION ON THE NEED TO PERFORM GROUNDWATER ASSESSMENT FOR HYDROGEN PEROXIDE (OCTOBER 2019)

At the time that evaluation was completed [May 2018], it was considered that, for completeness, a standard groundwater assessment incorporating porewater screening (plus higher tier FOCUS PEARL 4.4.4 modelling if required) should be undertaken, wherever possible, in order to quantify possible risks to local aquifers from discharges to wastewater.

However, subsequent discussion at ENV WG-II-2019 has led to confirmation that hydrogen peroxide can be thought of as a rapidly reacting substance in the presence of metals, micro-organisms and organic material so would be extremely unlikely to ever reach porewater at concentrations that give rise to concern. As such, no groundwater assessment will now be required for hydrogen peroxide products and the presence of a porewater screening assessment in this PAR simply confirms / supports that assumption.

Re-circulation of groundwater back into surface waters could result in maximum concentrations of 2.39E-7 µg/l for PAA and 6.53E-5 µg/l for hydrogen peroxide. However, when compared with their $PNEC_{aquatic}$ values of 6.90E-5 mg/l (6.90E-2 µg/l) and 1.26E-2 mg/l (12.6 µg/l) respectively, only negligible risks can be predicted (PEC/PNEC ratios <0.00001 in all cases).

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 both active substances are -0.60 (peracetic acid) and -1.57 (hydrogen peroxide), which are both below 3.

Mixture toxicity

It should be noted that all formulations in the PeridoxRTU Product Family contain both peracetic acid and hydrogen peroxide – both are compounds that have been reviewed under PT 2 and approved as biocidal actives.

However, following discussion at BPC, it was agreed at BPC-M-20-2017 under agenda item 8.2) that, in the case of peracetic acid based products, an excess of both hydrogen peroxide and acetic acid would be required to ensure formation of peracetic acid. In terms of environmental effects, acetic acid can be ignored (more details in the confidential annex) but hydrogen peroxide must be considered as an SOC whilst peracetic acid acts as sole active substance.

At present, no other components are included in the environmental assessment as the product is not considered to contain any other compounds giving rise to concern.

Individual risks posed by peracetic acid (PAA) and hydrogen peroxide have been presented in section 2.2.8.3 ("***Risk Characterisation***") of the PAR and all compartmental values are considered to be acceptable.

Cumulative risks posed by the formulation due to the presence of both PAA (a.s.) and hydrogen peroxide (SOC) are presented in the "***Aggregated Exposure***" section but, again, it is noted that all ∑PEC/PNEC values are considered acceptable.

Aggregated exposure (combined for relevant emission sources)

At the time of product evaluation, there is no regulatory interpretation how an identified unacceptable cumulative risk should be taken into account when approving active substances, since for approval of one safe use is considered sufficient. Thus, approval of an active substance cannot be based on the outcome of the aggregated risk assessment. However, it is important to indicate whether a potential cumulative risk can be identified.

Peracetic acid (PAA)
Aggregated environmental exposure assessment was performed for PAA in its review under several PT (including PT 2). Cumulative assessment of emissions to local STP from wide dispersive use patterns were considered but risks were considered to fall significantly below 1 and thus be acceptable. However, it must be further noted that the CAR for PAA concluded that the compound degrades rapidly by both abiotic and biotic processes. Depending on environmental conditions, abiotic decomposition can follow three different reactions, namely spontaneous decomposition, metal catalysed decomposition and hydrolysis. In addition, PAA degrades rapidly under conditions where organic matter and microbial activity are present and it can be considered as readily biodegradable substance. DT_{50} values for biodegradation in sewage sludge of 3 minutes (at 20°C) and in effluent water from a sewage treatment plant of 5 minutes were accepted. With >99% removal of PAA during transit in sewer systems and >99% removal within the STP itself, significant emissions to receiving surface waters or terrestrial compartment are extremely unlikely.

Public literature reports that peracetic acid has numerous "biocidal" applications, including use as a chemical disinfectant in healthcare, as a sanitizer in the food industry, and as a disinfectant during water treatment. Peracetic acid has also previously been used during the manufacture of chemical intermediates for pharmaceuticals. The compound is also stated as being very widely used for non-biocidal uses (at much higher concentrations of 35 - 40% w/w) for chemical synthesis where oxidation reactions are required, namely:

- Epoxidation of olefins;
- Selective epoxidation of various unsaturated compounds;
- Oxidation of thioethers to sulfoxides or sulfones;
- Oxidation of tertiary amines to amine oxides;
- Oxidation of pyridines to pyridine oxides;
- Oxidation of ketones to esters or lactones;
- Baeyer-Villiger oxidation of acylbenzenes to o-acylphenols.

It is extremely difficult to quantify the relationship between biocidal and non-biocidal use patterns of PAA to determine whether or not the 10% threshold is reached (see first step in the decision tree for cumulative assessment). However, non-biocidal uses appear to use concentrations of PAA that are 10 times greater than those typically indicated for biocidal concentrates (and 100 times greater than those being used for this RTU product family). On that basis, it is likely that biocidal uses could represent only a minor fraction of the total use of PAA.

Hydrogen peroxide (same-PT active but treated as an SOC)
With regard to this compound, it was concluded in the Assessment Report for PT 1 – 6 uses) that only a minor fraction of total hydrogen peroxide manufactured in the EU is ever 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 all of these factors into account for both PAA) and hydrogen peroxide, aggregated exposure has not been taken further.

It is noted as the PeridoxRTU Product Family contains 0.23 % of peracetic acid (a.s.) plus 4.40 % of hydrogen peroxide ("substance of concern"), cumulative risk posed by both components needs to be considered as follows :

Scenario	$\Sigma PEC/PNEC_{STP}$	$\Sigma PEC/PNEC_{water}$	$\Sigma PEC/PNEC_{sed}$	$\Sigma PEC/PNEC_{soil}$
2a	1.63E-4	1.07E-2	Identical to water risk	1.94E-4
2b	2.60E-4	1.72E-2	Identical to water risk	3.11E-4

Note: cumulative values have not been generated for groundwater or the air compartment as they are not considered relevant.

Conclusion: Aggregated exposure has not been considered further, in line with conclusions made in respective CARs for peracetic acid and hydrogen peroxide in various PTs (including PT 2). Cumulative risks posed by both compounds have been considered in STP, surface water, sediment and soil compartments, where they have been found to be acceptable in all cases. No mitigation measures are required.

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 PeridoxRTU Product Family will be applied indoors at industrial premises for surface cleaning by trained professional operators using trigger spray (Use 1) plus wipe / cloth / mop delivery methods (Use 2), then all risks to relevant environmental compartments resulting from potential emissions of peracetic acid and hydrogen peroxide following wet 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 identified within the reviews of the compound under PT 1- 6.

Authorisation of PeridoxRTU Product Family at up to 0.23 % a.s. (and 4.4 % of named SOC) 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

Store in a cool, well ventilated area.

Keep this product in the original container tightly closed.

Container must be stored and transported in an upright position to prevent spilling the contents.

Wear protective chemical resistant gloves and eye protection during product handling phase (glove material to be specified by the authorisation holder within the product information)

A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

Environmental precautions: Prevent from entering into soil, ditches, sewers, waterways and/or groundwater. Spills or discharge to natural waterways is likely to kill aquatic organisms.

Personal precautions, protective equipment and emergency procedures in case of accidental release measures: Evacuate area.
Keep upwind of spill. Ventilate area of leak or spill. Only trained and properly protected personnel must be involved in clean-up operations. Use appropriate safety equipment.

Methods and materials for containment and cleaning up: Avoid making contact with spilled material. When cleaning up a spill always wear the appropriate protective equipment, including respiratory protection, gloves and protective clothing. A self-contained breathing apparatus or respirator and absorbents may be necessary, depending on the size of the spill and the adequacy of ventilation.

Small spills: Wear the correct protective equipment and cover the liquid with absorbent material. Collect and seal the material and the dirt that has absorbed the spilled material in polyethylene bags and place in a drum for transit to an approved disposal site. Rinse away the remaining spilled material with water to reduce odour and discharge the rinsate into a municipal or industrial sewer, not into a natural waterway.

Large spills: In case of nasal and respiratory irritation, vacate the room immediately. Personnel cleaning up should be trained and equipped with a self-contained breathing apparatus, or an officially approved or certified full-face respirator equipped with an organic vapour cartridge, gloves, and clothing impervious, including rubber boots or shoe protection.

2.2.10 Assessment of a combination of biocidal products

Not applicable, the biocidal product family of products are not intended to be used in conjunction with other biocidal products.

2.2.11 Comparative assessment

Peracetic acid is not considered a candidate for substitution in accordance with Article 10(1) of EU Regulation 528/2012. A comparative assessment is therefore not required under Article 23 of Regulation (EU) 528/2012.

3 Annexes[2]

3.1 List of studies for the biocidal product (family)

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
3.1-1	Wo, C.	2008	Peridox RTU – Physical and Chemical characteristics, Physical state, pH, Viscosity, and Density/Relative density Eurofins Biolab Srl Clean Earth Technologies, LLC Study Number - 25690 GLP, Unpublished	Y	CON
3.1-2 3.2-2 3.2-3 3.4.1.2-3	Belussi, C.	2017	Shelf-Life Stability Study At 25°C/60% RH For 12 Months on the test item "Contec PeridoxRTU" Eurofins Biolab Srl Contec Cleanroom (UK) Study Number - 2017/308 AM GLP, Unpublished	Y	CON
3.2-1	Wo, C.	2008	Peridox RTU – Physical and Chemical characteristics, Physical state, pH, Viscosity, and Density/Relative density Eurofins Biolab Srl Clean Earth Technologies, LLC Study Number - 25690 GLP, Unpublished	Y	CON
3.3	Wo, C.	2008	Peridox RTU – Physical and Chemical characteristics, Physical state, pH, Viscosity, and Density/Relative density Eurofins Biolab Srl Clean Earth Technologies, LLC Study Number - 25690 GLP, Unpublished	Y	CON
3.4.1.2-1	Gravelle, W. D.	2010	Storage Stability and Corrosion study Eurofins Product Safety Laboratories, 2394 US Highway 130 Dayton, NJ 08810 Eurofins – PSL Laboratory Study Number - 25689 GLP, Unpublished	Y	CON
3.4.1.2-1a	Brister, P. C.	2014	Storage Stability Addendum BioMed Protect LLC, 13475 Lakefront Drive, Earth City, MO 63045 BioMed Protect LLC, EPA reg. no: 8809-4 Not GLP, Unpublished	Y	CON
3.4.1.2-1b	Brister, P. C.	2014	Storage Stability Addendum BioMed Protect LLC, 13475 Lakefront Drive, Earth City, MO 63045 BioMed Protect LLC, EPA reg. no: 8809-2 Not GLP, Unpublished	Y	CON
3.4.2.3 a	Gravelle, W. D.	2010	Storage Stability and Corrosion study Eurofins Product Safety Laboratories, 2394 US Highway 130 Dayton, NJ 08810 Eurofins – PSL Laboratory Study Number - 25689 GLP, Unpublished	Y	CON
3.4.1.2-2	Simpson, N	2017	Contec PeridoxRTU – Spray Pattern Investigation Contec Cleanroom (UK) Ltd Non-GLP, Unpublished	Y	CON
3.8	Mazzei, A.	2017	Determination of Surface Tension and Auto-Ignition Temperature on the Sample Peridox RTU® Bulk Chemical	Y	CON

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
			Innovhub – Stazioni Sperimentali per l'Industria, Area Combustibili, Via G. Galilei, 20097 San Donato Milanese – Milano, ITALY Contec, Cleanroom (UK) Ltd., Unit 6A, Wansbeck Business Park, Ashington, NE63 8QW Report Number - 1703769 GLP, Unpublished		
3.9	Wo, C.	2008	Peridox RTU – Physical and Chemical characteristics, Physical state, pH, Viscosity, and Density/Relative density Eurofins Biolab Srl Clean Earth Technologies, LLC Study Number - 25690 GLP, Unpublished	Y	CON
4.13	Basham, T.	2008	Division 5.1 oxidizer and in vitro corrositex Dermal Corrosion Analyses on a liquid material STRESAU LABORATORY INC., N8265 Medley Road, Spooner, WI 54801-7819 Contec, inc. 525 Locust Grove, Spartanburg, USA, Report Number: 16054 Not GLP, Unpublished	Y	CON
4.16	Purdum, W. R. Martin, C.W.	2005	Peridox Product Properties Group B Clean Earth Technologies, LLC GLP, Unpublished	Y	CON
4.17	Mazzei, A.	2017	Determination of Surface Tension and Auto-Ignition Temperature on the Sample Peridox RTU® Bulk Chemical Innovhub – Stazioni Sperimentali per l'Industria, Area Combustibili, Via G. Galilei, 20097 San Donato Milanese – Milano, ITALY Contec, Cleanroom (UK) Ltd., Unit 6A, Wansbeck Business Park, Ashington, NE63 8QW Report Number - 1703769 GLP, Unpublished	Y	CON
5.1-1	Meluso, A.	2017	Validation of an HPLC-UV Method for the quantification of the hydrogen peroxide, acetic acid and peracetic acid in the test item "Contec PeridoxRTU" Eurofins Biolab srl, Via B. Buozzi, 20090 Vimodrone (MI) Italy Contec, Cleanroom (UK) Ltd., Unit 6A, Wansbeck Business Park, Ashington, NE63 8QW Report Number: S-2017-03323 AM Not-GLP, Unpublished	Y	CON
6.1- 02	Bolton, B.	2017	A review of the biocidal efficacy of peracetic acid, hydrogen peroxide and acetic acid JSC International Limited, The Exchange, Station Parade, Harrogate, North Yorkshire, HG1 1TS Contec Cleanroom (UK) Ltd, Not-GLP, Unpublished	Y	CON
6.7-1&2	Livsey, A	2017	History of PeridoxRTU ownership and alternative names Contec Cleanroom (UK) Ltd Non-GLP, Unpublished	Y	CON
6.7-1a	Peters, A. A.	2008	AOAC Germicidal Spray Test – Healthcare – Peridox RTU Microbiotest, 105 Carpentry Drive, Sterling, Virginia 20164 Clean Earth Technologies LLC, 13378 Lakefront Drive, Earth City, MO 63045, Report No. – 535-115 Non-GLP, Unpublished	Y	CON

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
6.7-1b	Dormstetter, K. D.	2008	AOAC Germicidal Spray Test – Supplemental – Peridox RTU Microbiotest, 105 Carpentry Drive, Sterling, Virginia 20164 Clean Earth Technologies LLC, 13378 Lakefront Drive, Earth City, MO 63045, Report No. – 535-118 Non-GLP, Unpublished	Y	CON
6.7-2	Sathe, M.	2014	Sporicidal Activity of Disinfectants on Hard Surfaces ATS Labs, 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121, BioMed Protect LLC, 13475 Lakefront Drive, Earth City, MO 63045, report number - A16499 GLP, Unpublished	Y	CON
6.7-3	Lambert, E.	2014	Pharm-MO15 Based upon BS EN 1397:2001E ALS, Food and Pharmaceutical, 2 Bartholomew's Walk, Angel Drove, Ely, Cambridgeshire, CB7 4ZE Contec Cleanroom (UK) Ltd. Report No.: ELY 294956 Not GLP, Unpublished	Y	CON
6.7-4	James, L.	2016	Microbiological Analysis Based on EN 1276 (2009), Quantitative suspension test for the evaluation of bacterial activity of chemical disinfectants and antiseptics. MGS Laboratories Ltd Unit 20 Hoeford Point Barwell Lane Gosport Hampshire P013 OAU Contec Cleanroom (UK) Ltd, Report No.: TRA-2016-135-01 Not-GLP, Unpublished	Y	CON
6.7-5	James, L.	2016	Microbiological Analysis Based on EN 1650 (2008) + A1:2013, Chemical disinfectants and antiseptics- Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, Industrial, domestic and Institutional areas- Test method and requirements, (phase 2, step 1) MGS Laboratories Ltd Unit 20 Hoeford Point Barwell Lane Gosport Hampshire P013 OAU Contec Cleanroom (UK) Ltd, Report No.: TRA-2016-134-01 Not-GLP, Unpublished	Y	CON
6.7-6	James, L.	2016	Microbiological Analysis Based on EN 13704 (2002) Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants (Phase 2, Step 1) MGS Laboratories Ltd Unit 20 Hoeford Point Barwell Lane Gosport Hampshire P013 OAU Contec Cleanroom (UK) Ltd, Report No.: TRA-2016-141-01 Not-GLP, Unpublished	Y	CON
6.7-7	James, L.	2016	Microbiological Analysis Based on EN 13697 (2015) Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used In food, industrial, domestic and institutional areas (Phase 2, Step 2) MGS Laboratories Ltd Unit 20 Hoeford Point Barwell Lane Gosport Hampshire P013 OAU Contec Cleanroom (UK) Ltd, Report No.: TRA-2016-136-01 Not-GLP, Unpublished	Y	CON
6.7-8	James, L.	2016	Microbiological Analysis Based on EN 13697 (2015) Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, Industrial, domestic and institutional areas (Phase 2 I Step 2)	Y	CON

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
8.1	Basham, T.	2008	Division 5.1 oxidizer and in vitro corrositex Dermal Corrosion Analyses on a liquid material STRESAU LABORATORY INC., N8265 Medley Road, Spooner, WI 54801-7819 Contec, inc. 525 Locust Grove, Spartanburg, USA, Report Number: 16054 Non-GLP, Unpublished	Y	CON
12.7.1 (a to d)	Rossington, K and Livsey, A	2017	Draft Label – Sterile/Non Sterile Contec Peridox RTU Hydrogen Peroxide / PAA Contec Not-GLP, Unpublished	Y	CON
12.7-2 to 12.7-9	Phalen, E		Various packaging specifications	N	-
13-1	Jones, K	2017	Agreement from HSE as eCA	N	-
13-2	Dr. Leininger, S., Liebmann, J.	2017	LoA – Data/Dossier on Hydrogen Peroxide for Peridox RTU Evonik Resource Efficiency GmBH Contec Cleanroom (UK) Ltd Not-GLP, Unpublished	Y	CON
13-3	Dr. Leininger, S., Liebmann, J.	2017	LoA – Data/Dossier on Peracetic Acid for Peridox RTU Evonik Resource Efficiency GmBH Contec Cleanroom (UK) Ltd Not-GLP, Unpublished	Y	CON
13-5a	Rossington, K and Livsey, A	2017	Safety Data Sheet – Peridox RTU Contec Not-GLP, Unpublished	Y	CON
13-5b	Rossington, K and Livsey, A	2017	Safety Data Sheet – Peridox RTU Sterile Contec Not-GLP, Unpublished	Y	CON
13-6 to 13-8	Phalen, E	-	Various Raw material SDS	N	-
13-9	Anonymous	2017	Structure of the BP family	Y	CON
13-10	ECHA	2017	OUTCOME OF THE PRE-SUBMISSION CONSULTATION FOR UNION AUTHORISATION APPLICATION UNDER REGULATION (EU) NO 528/2012	N	-
13-11	Anonymous	2017	Biocidal Product family Overview spreadsheet	Y	CON

3.2 Output tables from exposure assessment tools

Figure 1.1 Scenario 1, Tier 1. Estimated air concentration of peracetic acid for a professional user applying PeridoxRTU Product Family (meta SPC 1) via a trigger sprayer

Inhalation

Label	Value
Exposure model	Exposure to vapour - Evaporation
Exposure duration	45 minute
Product is substance in pure form	No
Molecular weight matrix	19.1 g/mol

Label	Value
The product is used in dilution	No
Amount of solution used	25.55 g
Weight fraction substance	0.23 %
Room volume	55 m³
Ventilation rate	20 per hour
Inhalation rate	1.25 m³/hr
Application temperature	20 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	10 m/hr
Release area mode	Increasing
Release area	0.5 m²
Application duration	1 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)***	0.054 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 duration is less than 15 minutes, the mean event air concentration is given instead.)***	0.079 mg/m³

Details for Activity Spraying PAA

Emission sources: Near field ✓ Far field

Duration (mins): 480

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	1410 Pa
Liquid mole fraction	0.0006
Activity coefficient	1
Activity emission potential	
Activity class	Surface spraying of liquids
Situation	Very low application rate (< 0.03 l/minute)
Spray direction	Only horizontal or downward
Spray technique	Spraying with no or low compressed air use
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	30 air changes per hour (ACH)

Figure 1.2-Scenario 1, Tier 1. Estimated air concentration of hydrogen peroxide for a professional user applying PeridoxRTU Product Family via a trigger sprayer

Inhalation

Label	Value
Exposure model	Exposure to vapour - Evaporation
Exposure duration	45 minute
Product is substance in pure form	No
Molecular weight matrix	19.6 g/mol

Label	Value
The product is used in dilution	No
Amount of solution used	25.55 g
Weight fraction substance	4.4 %
Room volume	5 m³
Ventilation rate	20 per hour
Inhalation rate	1.25 m³/hr
Application temperature	20 °C
Vapour pressure	214 Pa
Molecular weight	34 g/mol
Mass transfer coefficient	10 m/hr
Release area mode	Increasing
Release area	0.5 m²
Application duration	1minute
Absorption model	Fixed fraction
Absorption fraction	1

Inhalation

Mean event concentration ***(average air concentration on exposure event. Note: depends strongly on chosen exposure duration)***	0.29 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 duration is less than 15 minutes, the mean event air concentration is given instead.)***	0.32 mg/m³

Emission sources: Near field ✓ Duration (mins): 220
Far field

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	214 Pa
Liquid mole fraction	0.025
Activity coefficient	1
Activity emission potential	
Activity class	Surface spraying of liquids
Situation	Very low application rate (< 0.03 l/minute)
Spray direction	Only horizontal or downward
Spray technique	Spraying with no or low compressed air use
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	30 air changes per hour (ACH)

Figure 1.3 Scenario 2, Tier 1: Calculation of air concentration of hydrogen peroxide during pouring of the product into a container

Details for Activity (Mixing and Loading Hydrogen Peroxide component)

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

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	214 Pa
Liquid mole fraction	0.025
Activity coefficient	1
Activity emission potential	
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 0.1 - 1 l/minute
Containment level	Open process
Loading type	Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely
Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes
Dispersion	
Work area	Indoors
Room size	Any size workroom

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)
Dispersion	
Ventilation rate	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 90th percentile full-shift exposure is 0.36 mg/m³.

The inter-quartile confidence interval is 0.18 mg/m³ to 0.75 mg/m³.

The inter-quartile confidence interval is 0.028 mg/m³ to 0.12 mg/m³.

Figure 1.4 Scenario 2, Tier 1: Calculation of air concentration of peracetic acid during pouring of the product into a container

Details for Activity (Mixing and Loading Peracetic acid component)

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

Far field

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	1410 Pa
Liquid mole fraction	0.0006
Activity coefficient	1
Activity emission potential	
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 0.1 - 1 l/minute
Containment level	Open process
Loading type	Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely
Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes
Dispersion	
Work area	Indoors
Room size	Any size workroom

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)
Dispersion	
Ventilation rate	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 90th percentile full-shift exposure is 0.057 mg/m³.

The inter-quartile confidence interval is 0.028 mg/m³ to 0.12 mg/m³.

Figure 1.5 Scenario 3, Tier 1. Estimated air concentration of peracetic acid for a professional user applying PeridoxRTU Product Family (meta SPC 2) via wiping/mopping

Inhalation

Label	Value
Exposure model	Exposure to vapour - Evaporation
Exposure duration	15 minute
Product is substance in pure form	No
Molecular weight matrix	19.1 g/mol
The product is used in dilution	No
Amount of solution used	1799 g
Weight fraction substance	0.23 %
Room volume	55 m³
Ventilation rate	20 per hour
Inhalation rate	1.25 m³/hr
Application temperature	20 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	10 m/hr
Release area mode	Increasing
Release area	22 m²
Application duration	5 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)***	1.4 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 duration is less than 15 minutes, the mean event air concentration is given instead.)***	1.4 mg/m³

Figure 1.6 Scenario 3, Tier 2. Estimated air concentration of peracetic acid for a professional user applying PeridoxRTU Product Family (meta SPC 2) via wiping/mopping

Inhalation

Label	Value
Exposure model	Exposure to vapour - Evaporation
Exposure duration	15 minute
Product is substance in pure form	No
Molecular weight matrix	19.1 g/mol
The product is used in dilution	No
Amount of solution used	1799 g
Weight fraction substance	0.23 %
Room volume	55 m³
Ventilation rate	20 per hour
Inhalation rate	1.25 m³/hr
Application temperature	20 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	3.4 m/hr
Release area mode	Increasing
Release area	22 m²
Application duration	5 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)***	0.53 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 duration is less than 15 minutes, the mean event air concentration is given instead.)***	0.53 mg/m³

Figure 1.7 Scenario 3, Tier 3 reverse reference: Estimated air concentration of peracetic acid for a professional user applying PeridoxRTU Product Family (meta SPC 2) via wiping/mopping

Inhalation

Label	Value
Exposure model	Exposure to vapour - Evaporation
Exposure duration	15 minute
Product is substance in pure form	No
Molecular weight matrix	19.1 g/mol
The product is used in dilution	No
Amount of solution used	1799 g
Weight fraction substance	0.23 %
Room volume	55 m³
Ventilation rate	30 per hour
Inhalation rate	1.25 m³/hr
Application temperature	20 °C
Vapour pressure	1.41E+03 Pa
Molecular weight	76.1 g/mol
Mass transfer coefficient	3.4 m/hr
Release area mode	Increasing
Release area	22 m²
Application duration	5 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)***	0.36 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 duration is less than 15 minutes, the mean event air concentration is given instead.)***	0.36 mg/m³

Details for Activity Mopping/wiping PAA

Emission sources: Near field ✓
Far field

Duration (mins): 480

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	1410 Pa
Liquid mole fraction	0.0006
Activity coefficient	1
Activity emission potential	
Activity class	Spreading of liquid products
Situation	Spreading of liquids at surfaces or work pieces > 3 m² / hour
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	30 air changes per hour (ACH)

Figure 1.8 Scenario 3, Tier 1. Estimated air concentration of hydrogen peroxide for a professional user applying PeridoxRTU Product Family (meta SPC 2) via wiping/mopping

Inhalation

Label	Value
Exposure model	Exposure to vapour - Evaporation
Exposure duration	15 minute
Product is substance in pure form	No
Molecular weight matrix	19.6 g/mol
The product is used in dilution	No
Amount of solution used	1799 g
Weight fraction substance	4.4 %
Room volume	55 m³
Ventilation rate	20 per hour
Inhalation rate	1.25 m³/hr
Application temperature	20 °C
Vapour pressure	214 Pa
Molecular weight	34 g/mol
Mass transfer coefficient	10 m/hr
Release area mode	Increasing
Release area	22 m²
Application duration	5 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)***	8.5 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 duration is less than 15 minutes, the mean event air concentration is given instead.)***	8.5 mg/m³

Figure 1.9 Scenario 3, Tier 2. Estimated air concentration of hydrogen peroxide for a professional user applying PeridoxRTU Product Family (meta SPC 2) via wiping/mopping

Inhalation

Label	Value
Exposure model	Exposure to vapour - Evaporation
Exposure duration	15 minute
Product is substance in pure form	No
Molecular weight matrix	19.6 g/mol
The product is used in dilution	No
Amount of solution used	1799 g
Weight fraction substance	4.4 %
Room volume	55 m³
Ventilation rate	20 per hour
Inhalation rate	1.25 m³/hr
Application temperature	20 °C
Vapour pressure	214 Pa
Molecular weight	34 g/mol
Mass transfer coefficient	4.7 m/hr
Release area mode	Increasing
Release area	22 m²
Application duration	5 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)***	4.3 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 duration is less than 15 minutes, the mean event air concentration is given instead.)***	4.3 mg/m³

Figure 1.10 Scenario 3, Tier 3 reverse reference: Estimated air concentration of hydrogen peroxide for a professional user applying PeridoxRTU Product Family (meta SPC 2) via wiping/mopping

Inhalation

Label	Value
Exposure model	Exposure to vapour - Evaporation
Exposure duration	15 minute
Product is substance in pure form	No
Molecular weight matrix	19.6 g/mol
The product is used in dilution	No
Amount of solution used	1799 g
Weight fraction substance	4.4 %
Room volume	55 m³
Ventilation rate	100 per hour
Inhalation rate	1.25 m³/hr
Application temperature	20 °C
Vapour pressure	214 Pa
Molecular weight	34 g/mol
Mass transfer coefficient	4.7 m/hr
Release area mode	Increasing
Release area	22 m²
Application duration	5 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)***	1.1 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 duration is less than 15 minutes, the mean event air concentration is given instead.)***	1.1 mg/m³

Details for Activity Mopping

Emission sources: Near field ✓
Far field

Duration (mins): 480

Near-field exposure

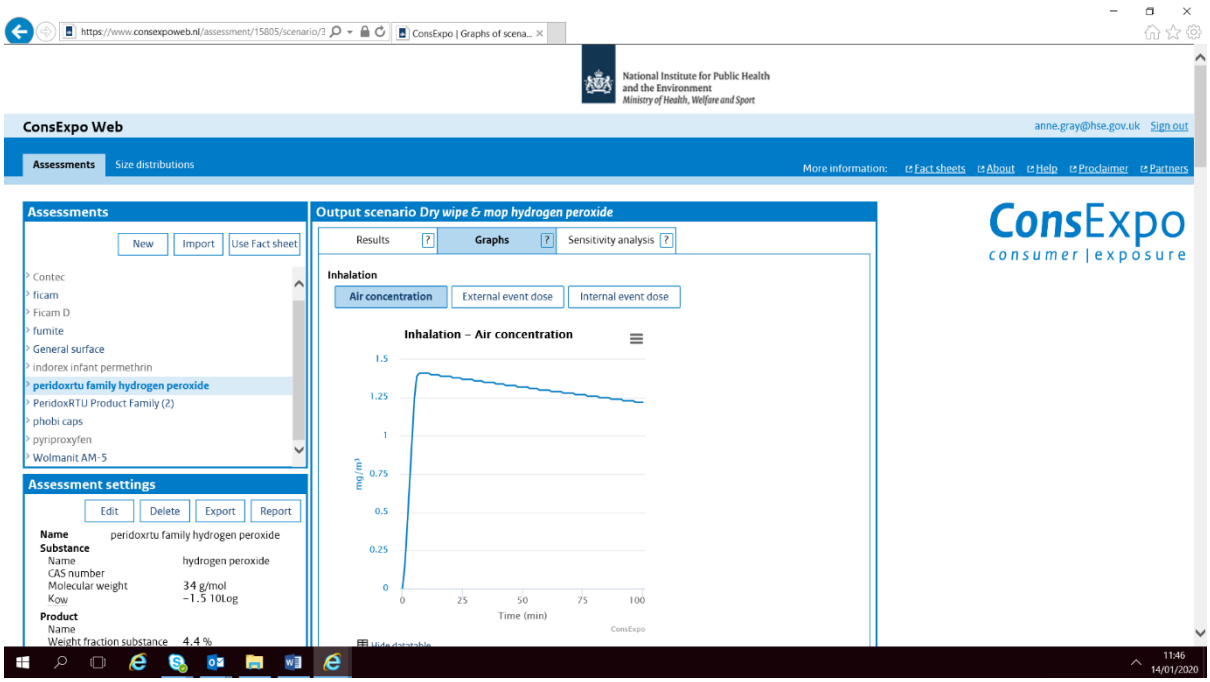
Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	214 Pa
Liquid mole fraction	0.025
Activity coefficient	1
Activity emission potential	
Activity class	Spreading of liquid products
Situation	Spreading of liquids at surfaces or work pieces > 3 m² / hour
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

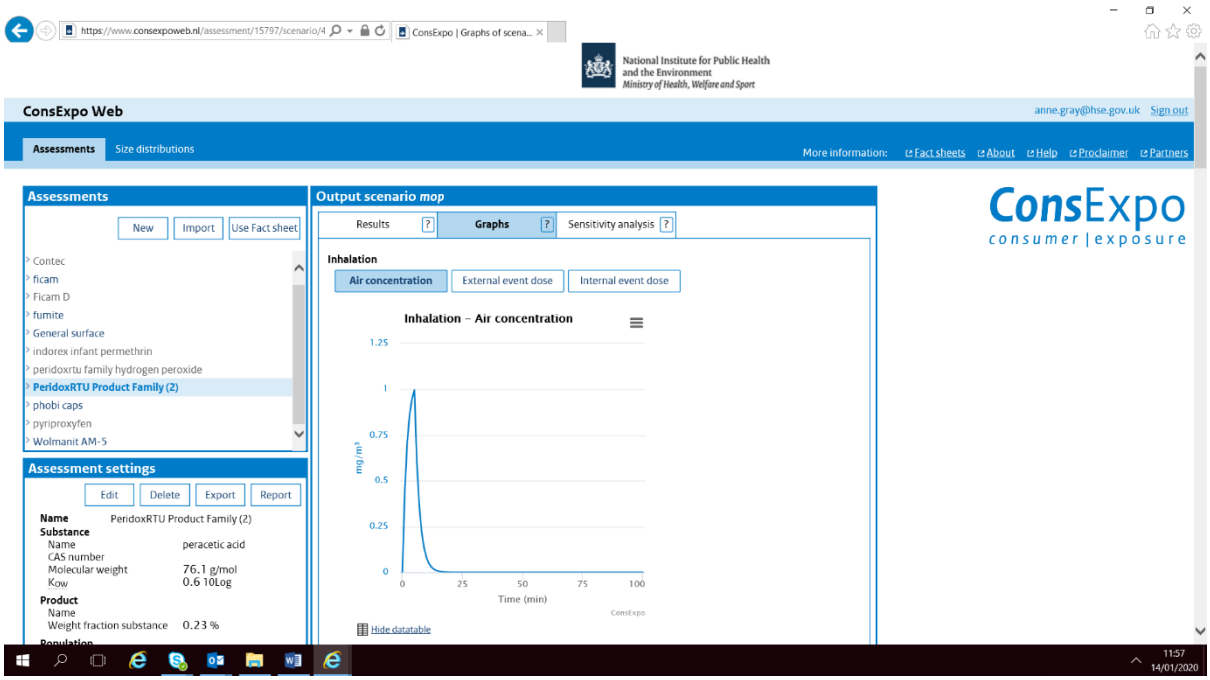
Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)
Dispersion	
Ventilation rate	30 air changes per hour (ACH)

Figure 1.11 Scenario 4 Illustrative calculation of air concentration of hydrogen peroxide when a professional bystander re-enters a treated area after disinfection through mopping/wiping Hydrogen peroxide



82	1.3 mg/m³	3.6×10^{-2} mg/kg bw	3.6×10^{-2} mg/kg bw
83	1.3 mg/m³	3.7×10^{-2} mg/kg bw	3.7×10^{-2} mg/kg bw
84	1.2 mg/m³	3.7×10^{-2} mg/kg bw	3.7×10^{-2} mg/kg bw
85	1.2 mg/m³	3.8×10^{-2} mg/kg bw	3.8×10^{-2} mg/kg bw
86	1.2 mg/m³	3.8×10^{-2} mg/kg bw	3.8×10^{-2}

Peracetic acid



Inhalation Exposure & absorption

Time (min)	Air concentration (mg/m³)	External event dose (mg/kg bw)	Internal event dose (mg/kg bw)
0	0 mg/m³	0 mg/kg bw	0 mg/kg bw
1	4.5×10^{-1} mg/m³	7.8×10^{-5} mg/kg bw	7.8×10^{-5} mg/kg bw
2	7.1×10^{-1} mg/m³	2.7×10^{-4} mg/kg bw	2.7×10^{-4}

Details for Activity Mopping/wiping PAA

Emission sources: Near field
Far field ✓

Duration (mins): 480

Far-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	1410 Pa
Liquid mole fraction	0.0006
Activity coefficient	1
Activity emission potential	
Activity class	Spreading of liquid products
Situation	Spreading of liquids at surfaces or work pieces > 3 m² / hour
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)
Segregation	No segregation (0.00 % reduction)
Personal enclosure	No personal enclosure (0.00 % reduction)
Dispersion	
Ventilation rate	30 air changes per hour (ACH)

Details for Activity Mopping

Emission sources: Near field
Far field ✓

Duration (mins): 480

Far-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	214 Pa
Liquid mole fraction	0.025
Activity coefficient	1
Activity emission potential	
Activity class	Spreading of liquid products
Situation	Spreading of liquids at surfaces or work pieces > 3 m² / hour
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)
Segregation	No segregation (0.00 % reduction)
Personal enclosure	No personal enclosure (0.00 % reduction)
Dispersion	
Ventilation rate	30 air changes per hour (ACH)

Details for Activity Spraying PAA

Emission sources: Near field
Far field ✓

Duration (mins): 480

Far-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	1410 Pa
Liquid mole fraction	0.0006
Activity coefficient	1
Activity emission potential	
Activity class	Surface spraying of liquids
Situation	Very low application rate (< 0.03 l/minute)
Spray direction	Only horizontal or downward
Spray technique	Spraying with no or low compressed air use
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)
Segregation	No segregation (0.00 % reduction)
Personal enclosure	No personal enclosure (0.00 % reduction)
Dispersion	
Ventilation rate	30 air changes per hour (ACH)

Emission sources:	Near field Far field ✓	Duration (mins):	480

Far-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	214 Pa
Liquid mole fraction	0.025
Activity coefficient	1
Activity emission potential	
Activity class	Surface spraying of liquids
Situation	Very low application rate (< 0.03 l/minute)
Spray direction	Only horizontal or downward
Spray technique	Spraying with no or low compressed air use
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)
Segregation	No segregation (0.00 % reduction)
Personal enclosure	No personal enclosure (0.00 % reduction)
Dispersion	
Ventilation rate	30 air changes per hour (ACH)

3.3 New information on the active substance

No new information on the active substance has been submitted by the applicant.

3.4 Residue behaviour

The product is not intended to be used on surfaces associated with food preparation for humans or animals and so a residues evaluation is not relevant.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[3]

See section 2.2.5.5

3.6 Confidential annex

See separate confidential annex of the PAR.

3.7 Other

3.7.1 Environmental Risk Assessment models - compartments

Calculation of PEC_{air}

No consideration has been made for direct emissions of peracetic acid (PAA) and hydrogen peroxide to air during application as this has been considered as extremely unlikely to occur - this has already been discussed within the "Emissions estimation" section of this PAR.

However, both PAA and 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, Part B + C (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 arriving at STP following degradation in sewer system (in kg/d)
$Fstp_{air}$ = fraction emission directed to air by STP (value derived by SimpleTreat v4.0.9)
$Estp_{air}$ = local emission to air from STP during emission episode (in kg/d)

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 (in 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 (in mg/m^3)

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

Parameters for PAA	Value	Value	Unit
PT 2 - Scenario 2	2a	2b	
$Elocal_{water}$ after degradation in sewer system	1.47E-3	2.35E-3	kg/d
Fraction emitted to air at STP ($Fstp_{air}$)	4.63E-4	4.63E-4	
$Estp_{air}$	6.78E-7	1.08E-6	kg/d
$Cstp_{air}$	2.78E-4	2.78E-4	mg/m^3
$Clocal_{air}$	1.88E-10	3.00E-10	mg/m^3

Parameters for hydrogen peroxide	Value	Value	Unit
PT 2 - Scenario 2	2a	2b	
$Elocal_{water}$ after degradation in sewer system	5.50E-2	8.81E-2	kg/d
Fraction emitted to air at STP ($Fstp_{air}$)	1.56E-6	1.56E-6	
$Estp_{air}$	8.58E-8	1.37E-7	kg/d
$Cstp_{air}$	2.78E-4	2.78E-4	mg/m^3
$Clocal_{air}$	2.39E-11	3.81E-11	mg/m^3

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.

$$Clocal_{\inf} = \frac{Elocal_{water} * 10^6}{EFFLUENT_{stp}} \quad (35)$$

$$Clocal_{eff} = Clocal_{inf} \cdot Fstp_{water} \quad (36)$$

$$Clocal_{water} = \frac{Clocal_{eff}}{(1 + Kp_{susp} * SUSP_{water} * 10^{-6}) * DILUTION} \quad (48)$$

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 at industrial premises

Parameters for PAA	Value	Value	Unit
PT 2 - Scenario 2	2a	2b	
$Elocal_{water}$ after degradation in sewer system	1.47E-3	2.35E-3	kg /d
Effluent discharge rate of STP ($Effluent_{stp}$)	2.0E+6	2.0E+6	l
$Clocal_{inf}$	7.35E-4	1.18E-3	mg /l
$Fstp_{water}$	9.29E-3	9.29E-3	
$Clocal_{eff}$ **(PECstp)**	6.52E-6	1.04E-5	mg /l

Parameters for hydrogen peroxide	Value	Value	Unit
PT 2 - Scenario 2	2a	2b	
$Elocal_{water}$ after degradation in sewer system	5.50E-2	8.81E-2	kg /d
Effluent discharge rate of STP ($Effluent_{stp}$)	2.0E+6	2.0E+6	l
$Clocal_{inf}$	2.75E-2	4.41E-2	mg /l
$Fstp_{water}$	6.21E-3	6.21E-3	
$Clocal_{eff}$ **(PECstp)**	1.63E-4	2.61E-4	mg /l

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

Parameters for PAA	Value	Value	Unit
PT 2 - Scenario 2	2a	2b	
Weight fraction organic carbon in suspended solids: Foc_{susp}	0.1	0.1	
Partition coefficient organic carbon – water: Koc	1.02	1.02	l/kg
Partition coefficient solid – water in suspension: Kp_{susp}	0.1	0.1	
Concentration of suspended matter: SUSPwater	15	15	mg/l
Dilution	10	10	
$PEC_{surface\ water}$	6.52E-7	1.04E-6	mg/l

Parameters for hydrogen peroxide	Value	Value	Unit
PT 2 - Scenario 2	2a	2b	
Weight fraction organic carbon in suspended solids: Foc_{susp}	0.1	0.1	
Partition coefficient organic carbon – water: Koc	1.598	1.598	l/kg
Partition coefficient solid – water in suspension: Kp_{susp}	0.16	0.16	
Concentration of suspended matter : SUSPwater	15	15	mg/l
Dilution	10	10	
$PEC_{surface\ water}$	1.63E-5	2.61E-5	mg/l

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

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

Levels of PAA and 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 + C (equations 39 and 40) plus default parameters presented in the same guidance document as follows :

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

where:

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

and

$EFFLUENT_{stp} = CAPACITY_{stp} \times WASTEW_{inhab}$

Calculation of PEC_{soil} following indoor application at industrial premises

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 in wastewater reaching STP – PAA	$Elocal_{water\ (PAA)}$	1.47E-3	2.35E-3	kg/d
Local emission rate in wastewater reaching STP – hydrogen peroxide	$Elocal_{water\ (H2O2)}$	5.50E-2	8.81E-2	kg/d
Fraction of emission directed to sludge at STP - PAA	$Fstp_{sludge\ (PAA)}$	9.26E-5	9.26E-5	
Fraction of emission directed to sludge at STP – hydrogen peroxide	$Fstp_{sludge\ (H2O2)}$	1.45E-4	1.45E-4	
Concentration in dry sewage sludge - PAA	Csludge (PAA)	1.72E-4	2.75E-4	mg/kg dwt
Concentration in dry sewage sludge – hydrogen peroxide	Csludge (H2O2)	1.01E-2	1.62E-2	mg/kg dwt

When rapid degradation in soil is taken into account at normalised EU temperature (DT_{50} values of <1 hr for PAA and 12 hr for hydrogen peroxide), the equivalent "k" rates would be 16.5 d^{-1} and 1.39 d^{-1} respectively - these would crudely represent removal rates of each compound 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 PAA and hydrogen peroxide will not accumulate, thus $Csludge_{soil\ 1\ (0)} = Csludge_{soil\ 10\ (0)}$. In line with guidance presented in the ECHA guidance on ERA (equation 61), the concentration of a.s. and SOC 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 (in 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)

Scenario	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)
PAA concentrations				
2a	1.72E-4	2.53E-7	1.01E-7	2.53E-7
2b	2.75E-4	4.05E-7	1.62E-7	4.05E-7
Hydrogen peroxide concentrations				
2a	1.01E-2	1.48E-5	5.94E-6	1.48E-5
2b	1.62E-2	2.38E-5	9.51E-6	2.38E-5

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, Part B + C (equation 66) :

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

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 (in 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

Scenario	Csludge (mg/kg dwt)	PEClocal$_{soil}$ Grassland [mg/kg wwt]	PEClocal$_{soil}$ Arable land [mg/kg wwt]	PEClocal$_{soil}$ Ecosystem [mg/kg wwt]
PAA concentrations				
2a	1.72E-4	8.12E-11	2.03E-10	**1.22E-9**
2b	2.75E-4	1.30E-10	3.25E-10	**1.95E-9**
Hydrogen peroxide concentrations				
2a	1.01E-2	2.38E-8	5.95E-8	**3.57E-7**
2b	1.62E-2	3.81E-8	9.53E-8	**5.72E-7**

Predicted concentrations of PAA and hydrogen peroxide in local agricultural soil can be used to crudely indicate groundwater levels in line with equation 70 from ECHA guidance on ERA, Volume IV, Part B + C 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
$PEClocal_{soil,\ porewater}$ is the predicted environmental concentration in porewater (in mg l^{-1})
$PEClocal_{soil}$ is the predicted environmental concentration in agricultural soil (mg/kg wwt)
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 PAA and hydrogen peroxide, the following parameters have been derived:

Property	Peracetic acid	Hydrogen peroxide	Units
Henry's law constant	0.217	7.50E-4	Pa/m^3/mol
$K_{air\text{-}water}$	9.16E-5	3.17E-7	
Kp_{soil}	0.020	0.032	l/kg
$K_{soil\text{-}water}$	0.230	0.248	

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

Compound	Scenario	PEClocal$_{ag.soil}$ (mg/kg wwt)	PEClocal$_{soil,\ porewater}$ (µg/l)	PEC$_{surface\ water}$ via soil run-off (µg/l)
PAA	2a	2.03E-10	1.50E-6	1.50E-7
PAA	2b	3.25E-10	2.39E-6	2.39E-7
Hydrogen peroxide	2a	5.95E-8	4.08E-4	4.08E-5
Hydrogen peroxide	2b	9.53E-8	6.53E-4	6.53E-5

Groundwater levels of both compounds in both scenarios fall significantly below the current drinking water standard for "pesticide" actives, namely 0.1 µg/l.

Re-circulation of groundwater back into surface waters could result in concentrations of 1.50E-7 – 2.39E-7 µg/l for PAA and 4.08E-5 – 6.53E-5 µg/l for hydrogen peroxide. However, when compared with their PNEC$_{aquatic}$ values of 6.90E-5 mg/l (6.90E-2 µg/l) and 1.26E-2 mg/l (12.6 µg/l) respectively, only negligible risks can be predicted (PEC/PNEC ratios <0.00001 in all cases).