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

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

Contec Hydrogen Peroxide Biocidal Product Family

Product type 2

Hydrogen Peroxide

Case Number in R4BP: BC-PP063133-29

Evaluating Competent Authority: Slovenia

Date: December 2021

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NOTE OF THE eCA SI

The application for the biocidal product family Contec Hydrogen Peroxide of product-type 2 was originally submitted to United Kingdom under R4BP case number: BC-VJ029379-17. Due to the withdrawal of the United Kingdom of the European Union, the competent authority of Slovenia accepted to take over the role of the evaluating Competent Authority (eCA), as of 1 February 2020. The application was recorded under case number BC-GN057178-26 in the R4BP. According to the opinion of the Agency, the applicant did not demonstrate that Contec Hydrogen Peroxide is sufficiently effective, due to inconsistencies within the originally and ad hoc submitted efficacy studies. Relevant criteria were not met in the efficacy studies. The biocidal product family Contec Hydrogen Peroxide did not meet the condition laid down in Article 19(1)(b)(i) of that Regulation therefore a Union authorisation was not granted.

The Applicant resubmitted an updated application under R4BP case number BC-PP063133-29. The evaluation of the biocidal product family Contec Hydrogen Peroxide Biocidal Product Family has been carried out and aligned with the conclusions of the Working Groups (WG) V 2019 of the Biocidal Products Committee for the Contec Hydrogen Peroxide. Related to the biocidal product family Contec Hydrogen Peroxide Biocidal Product Family the following amendments to the previous evaluation have been made:

- All required efficacy studies are new and efficacy chapter was completely rewritten.
- The exposure and risk for the professional user when using biocidal products in isolators and RABS (Restricted Access Barrier Systems) was additionally assessed.
- The environmental exposure has been recalculated based on hydrogen peroxide content of 6.67%.

1 CONCLUSION

The outcome of the assessment for the biocidal product family 'Contec Hydrogen Peroxide Biocidal Product Family' is specified in the BPC opinion following discussions at the BPC-41 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2 ASSESSMENT REPORT

2.1 Summary of the product family assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	Country (if relevant)
Contec Hydrogen Peroxide Biocidal Product Family	Union Authorisation (Members States of the EEA and Switzerland)

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Contec Europe
	Address	ZI Du Prat, Avenue Paul Duplaix, Vannes, 56000, France
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer of the product

Name of manufacturer	Contec Inc
Address of manufacturer	525 Locust Grove, Spartanburg, South Carolina, 29303, USA
Location of manufacturing sites	Unit 6A, Wansbeck Business Park, Rotary Parkway, Ashington, Northumberland, NE63 8QW, UK

2.1.1.4 Manufacturers of the active substance

Active substance	Hydrogen Peroxide
Name of manufacturer	Solvay Chemicals International
Address of manufacturer	Rue Ransbeek 310, 1120 Brussels, BE
Location of manufacturing site	Rue Solvay 39, Jemeppe-sur-Sambre, B-5190, BE
Location of manufacturing site	Via Piave 6, Rosignano Solvay LI, I-57013, IT
Location of manufacturing site	Köthensche Strasse 1-3, Bernburg, D06406, DE
Location of manufacturing site	Baronet Road, Warrington, Cheshire, WA4 6HA, UK
Location of manufacturing site	Yrjönojantie 2, Voikkaa, 45910, FI
Location of manufacturing site	Rua Eng. Clement Dumoulin, Povoa de Santa, Iria, P-2625-106, PT

2.1.2 Product family composition and formulation

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 Similarity of the group of products for which the authorisation as a biocidal product family is sought

The application for authorisation as a BPF explicitly identified the maximum risks to human health, animal health and the environment, and the minimum level of efficacy.

The products applied for include the same active substance and have the same composition. Information on the composition and the identified tested product representative for the whole product family are provided in the confidential annex.

Overview regarding the similarity of the intended uses

Use number	Product type	Reference[1]	Use pattern[2]
Use #1: Application by trigger spray onto a suitable cleanroom wipe to distribute onto the inner surface of isolators and Restricted Access Barrier Systems (RABS)	PT02	#4	(1)b: Hard surfaces/ instrument/ equipment disinfection.
Use #2: Application by pouring into a container and using a suitable cleanroom wipe or mop to distribute onto the inner surface of isolators and Restricted Access Barrier Systems (RABS)			
Use #3: Application by trigger spray onto a suitable cleanroom wipe to distribute onto the surface of cleanrooms			
Use #4: Application by pouring into a container and using a suitable cleanroom wipe or mop to distribute onto the surface of cleanrooms			

[1,2] As indicated in the Note for Guidance "Implementing the concept of biocidal product family" (CA-July19-Doc4.2-Final).

The agreed general criteria for deciding on whether the intended uses can be considered as similar were applied, according to the document CA-July19-Doc.4.2-Final entitled "Implementing the concept of biocidal product family".

In accordance with the agreed general criteria, all the intended uses are considered similar uses, in line with the document CG-34-2019-12 AP 15.1 Assessment of similarity in biocidal product families ("Section 2 - Similarity of uses"). The corresponding justification provided by the applicant is considered acceptable.

The intended uses as applied for by the applicant have been assessed. By considering only those uses appropriate for authorisation which bears a consistent set of instructions for use, RMMs etc., it was ensured that all products of the BPF have a similar level of risk and efficacy.

2.1.2.2 Identity of the active substance

Main constituent	
ISO name	Hydrogen Peroxide
IUPAC or EC name	Hydrogen Peroxide
EC number	231-765-0
CAS number	7722-84-1
Index number in Annex VI of CLP	008-003-00-9
Minimum purity / content	Purity: 99.5% w/w (calculated dry weight) Content: 35% w/w (Please see Member State Confidential Annex for full details)
Structural formula	HO — OH

2.1.2.3 Candidate for substitution

In accordance with Article 10 of the BPR, hydrogen peroxide is not considered a candidate for substitution.

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

For further details please see the confidential annex of this PAR.

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen Peroxide	Hydrogen Peroxide	Active substance	7722-84-1	231-765-0	6.67
Confidential	Confidential	Non-active ingredient	Confidential	Confidential	93.33

The full formulation composition details are contained within the Member State Confidential Annex.

2.1.2.5 Information on technical equivalence

The notified source of hydrogen peroxide, Solvay SA, is supplied to the applicant. Solvay SA is a Member of the Hydrogen Peroxide Biocide Task Force and is therefore a data owner for the Hydrogen Peroxide PT2 active substance dossier assessed in the Review Programme under Regulation No. 528/2012.

2.1.2.6 Information on the substance of concern

There are no environmental or human health substances of concern identified in this product family.

2.1.2.7 Type of formulation

Ready to use liquid

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Eye Irrit. Cat 2
Hazard statement	H319: Causes serious eye irritation
Labelling	
Hazard pictograms	 GSH07
Signal words	Warning
Hazard statements	H319: Causes serious eye irritation
Precautionary statements	P264: Wash hands thoroughly after handling. P280: Wear eye protection/face protection. P305+ P351+ P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313: If eye irritation persists: Get medical advice/attention.
Note	-

2.1.4 Authorised uses

2.1.4.1 Use description # 1 – Application by trigger spray onto a suitable cleanroom wipe to distribute onto the inner surface of isolators and Restricted Access Barrier Systems (RABS)

Table 1. Use # 1

Product Type	PT 2 – Disinfectants and algaecides not intended for direct application to humans or animals.
Where relevant, an exact description of the authorised use	/
Target organism (including development stage)	Bacteria, yeasts and fungi
Field of use	Indoor – in isolators and Restricted Access Barrier Systems (RABS) positioned in cleanrooms: disinfection of hard/non-porous surfaces. Not for use in healthcare.
Application method	Spraying the product onto a suitable cleanroom wipe used to distribute the product on the surface.

Application rate and frequency	Ready-to-use product active against bacteria in 15 min and against yeasts and fungi in 30 min contact time at room temperature (~ 20 °C). Application frequency is specific to the user's site and requirements.
Category of users	Professional user
Pack sizes and packaging material	1L adjustable trigger spray HDPE bottle sealed with a polyethylene outer bag.

2.1.4.1.1 Use-specific instructions for use

Spray the product onto a cleanroom wipe inside the isolator or RABS and use to apply the product to the surface to be disinfected. Ensure the entire surface is visibly wet for the contact time: 15 minutes for bacteria and 30 minutes for yeasts and fungi. Do not use more than 50 mL product/m². Uniform distribution of the biocidal product should be ensured. For visibly soiled surfaces, cleaning prior to the disinfection is required.

2.1.4.1.2 Use-specific risk mitigation measures

Avoid hand to eye transfer.

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

See general directions for use (Section 2.1.5).

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

See general directions for use (Section 2.1.5).

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

See general directions for use (Section 2.1.5).

2.1.4.2 Use description # 2 – Application by pouring into a container and using a suitable cleanroom wipe or mop to distribute onto the inner surface of isolators and Restricted Access Barrier Systems (RABS)

Table 2. Use # 2

Product Type	PT 2 – Disinfectants and algaecides not intended for direct application to humans or animals.
Where relevant, an exact description of the authorised use	/

Target organism (including development stage)	Bacteria, yeasts and fungi
Field of use	Indoor – in isolators and Restricted Access Barrier Systems (RABS) positioned in cleanrooms: disinfection of hard/non-porous surfaces. Not for use in healthcare.
Application method	Pouring the product into a suitable container and then distributing it on the surface with a suitable cleanroom wipe or mop.
Application rate and frequency	Ready-to-use product active against bacteria in 15 min and against yeasts and fungi in 30 min contact time at room temperature (~ 20 °C). Application frequency is specific to the user's site and requirements.
Category of users	Professional user
Pack sizes and packaging material	0.5 L, 1 L and 5 L tamper evident cap HDPE bottle sealed with a polyethylene outer bag.

2.1.4.2.1 Use-specific instructions for use

Pour the product into a suitable container inside the isolator or RABS and use a cleanroom wipe or mop to apply the product to the surface to be disinfected. Ensure the entire surface is visibly wet for the contact time: 15 minutes for bacteria and 30 minutes for yeasts and fungi. Do not use more than 50 mL product/m². Uniform distribution of the biocidal product should be ensured. For visibly soiled surfaces, cleaning prior to the disinfection is required.

2.1.4.2.2 Use-specific risk mitigation measures

Avoid hand to eye transfer.

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

See general directions for use (Section 2.1.5).

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

See general directions for use (Section 2.1.5).

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

See general directions for use (Section 2.1.5).

2.1.4.3 Use description # 3 – Application by trigger spray onto a suitable cleanroom wipe to distribute onto the surface of cleanrooms

Table 3. Use # 3

Product Type	PT 2 – Disinfectants and algaecides not intended for direct application to humans or animals.
Where relevant, an exact description of the authorised use	/
Target organism (including development stage)	Bacteria, yeasts and fungi
Field of use	Indoor - Disinfection of hard, non-porous surfaces in cleanrooms Not for use in healthcare.
Application method(s)	Spray the product onto a suitable cleanroom wipe used to distribute the product on the surface.
Application rate(s) and frequency	Ready-to-use product active against bacteria in 15 min and against yeasts and fungi in 30 min contact time at room temperature (~ 20 °C). Application frequency is specific to the user's site and requirements.
Category(ies) of users	Professional user
Pack sizes and packaging material	1 L adjustable trigger spray HDPE bottle sealed with a polyethylene outer bag.

2.1.4.3.1 Use-specific instructions for use

Spray the product onto a cleanroom wipe and use to apply the product to the surface to be disinfected in the cleanroom. Ensure the entire surface is visibly wet for the contact time: 15 minutes for bacteria and 30 minutes for yeasts and fungi. Do not use more than 50 mL product/m². Uniform distribution of the biocidal product should be ensured. For visibly soiled surfaces, cleaning prior to the disinfection is required.

2.1.4.3.2 Use-specific risk mitigation measures

The product must only be applied for disinfection of small surfaces.
The use of eye protection during handling of the product is mandatory.
For use in cleanrooms, adequate technical/engineering controls to remove airborne residues is mandatory e.g. room ventilation or LEV. A minimum ventilation rate of 360/hr is mandatory for cleanrooms where the product is applied.

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

See general directions for use (Section 2.1.5).

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

See general directions for use (Section 2.1.5).

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

See general directions for use (Section 2.1.5).

2.1.4.4 Use description # 4 – Application by pouring into a container and using a suitable cleanroom wipe or mop to distribute onto the surface of cleanrooms

Table 4. Use # 4

Product Type	PT 2 – Disinfectants and algaecides not intended for direct application to humans or animals.
Where relevant, an exact description of the authorised use	/
Target organism (including development stage)	Bacteria, yeasts and fungi
Field of use	Indoor - Disinfection of hard, non-porous surfaces in cleanrooms Not for use in healthcare.
Application method(s)	Pouring the product into a suitable container and then distributing it on the surface with a suitable cleanroom wipe or mop.
Application rate(s) and frequency	Ready-to-use product active against bacteria in 15 min and against yeasts and fungi in 30 min contact time at room temperature (~ 20 °C). Application frequency is specific to the user's site and requirements.
Category(ies) of users	Professional user
Pack sizes and packaging material	0.5 L, 1 L and 5 L tamper evident cap HDPE bottle sealed with a polyethylene outer bag.

2.1.4.4.1 Use-specific instructions for use

Pour the product into a suitable container and use a cleanroom wipe or mop to apply the product to the surface to be disinfected in the cleanroom. Ensure the entire surface is visibly wet for the contact time: 15 minutes for bacteria and 30 minutes for yeasts and fungi. Do not use more than 50 mL product/m². Uniform distribution of the biocidal product should be ensured. For visibly soiled surfaces, cleaning prior to the disinfection is required.

2.1.4.4.2 Use-specific risk mitigation measures

Pouring of product shall be done in ventilated rooms only (with min. 3 air change/h).
The use of eye protection during handling of the product is mandatory.
For use in cleanrooms, adequate technical/engineering controls to remove airborne residues is mandatory e.g. room ventilation or LEV. A minimum ventilation rate of 360/hr is mandatory for cleanrooms where the product is applied.
If the product is applied by wiping, the disinfection must be limited to small area.
When using the product with a mop to disinfect floors or other large surfaces in cleanrooms, additional risk mitigation measures must be in place:

- Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory for the professional user and all other personnel within the room. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).
- All personnel must leave the room after mopping.
- Technical or engineering controls to remove airborne residues is mandatory (e.g. ventilation or LEV) before personnel are permitted to enter into treated areas after large surface disinfection. Monitor the air concentration and ensure that the limit value (1.25 mg/m^3) is not exceeded when personnel re-enter the area.

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

See general directions for use (Section 2.1.5).

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

See general directions for use (Section 2.1.5).

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

See general directions for use (Section 2.1.5).

2.1.5 General directions for use

2.1.5.1 Instructions for use

See Use-specific instructions for use.

2.1.5.2 Risk mitigation measures

Used wipes must be disposed in a closed container.

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

DIRECT/INDIRECT EFFECTS
Causes serious eye irritation. No other health injuries are known or expected under normal use.

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

EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT
Avoid release to the environment.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Disposal of this packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.
Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.

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

Store in a dry well ventilated area and protect from damage and direct sunlight.
Store in properly designed bulk storage tanks or in original vented container.
Keep container tightly closed.
Do not freeze.
Do not store at temperature above 30 °C.
The shelf-life: 24 months.

2.1.6 Other information

Not relevant.

2.1.7 Packaging of the biocidal product family

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)
Trigger spray	1 L	HDPE bottle	PP trigger device and lock type cap	Professional	Acceptable. There were no adverse interactions between the product and the packaging (HDPE) during accelerated storage for 18 weeks at 30°C and 24 months ambient storage.
Capped bottle	0.5 and 1 L	HDPE container	PP tamper evident cap with venting foil* on the lid of the bottle	Professional	
Capped bottle	5 L	HDPE jerrycan	PP tamper evident cap with venting foil* on the lid of the bottle	Professional	

* Venting foil liners allow for gas exchange and prevent leaking while also acting as a tamper-evident seal.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product family application

No new data for the active substance has been submitted as part of this product family application. Concerning product data in support of this biocidal product family dossier, please refer to reference list provided in the Annex 3.1.

2.1.8.2 Access to documentation

The notified source of hydrogen peroxide, Solvay SA, is supplied to the applicant via the distributer. Solvay SA is a Member of the Hydrogen Peroxide Biocide Task Force and is therefore a data owner for the Hydrogen Peroxide PT2 active substance dossier assessed in the review programme under Regulation No. 528/2012. The letter of access to the active substance hydrogen peroxide dossier is attached in section 13 of the IUCLID file.

2.1.8.3 Similar conditions of use

Based on the information provided by the applicant it appears that the application could meet the basic requirement of Article 42(1) of the Biocidal Products Regulation and the Contec Hydrogen Peroxide Biocidal Product Family is deemed eligible for Union Authorisation. The pre-consultation was not launched but the applicant submitted the required information requested by ECHA. The information serves the grounds that products fall within the scope of Biocidal Products Regulation, products have similar conditions of use across the EU and that the appropriate PT has been identified.

2.2 Assessment of the biocidal product family

2.2.1 Intended uses as applied for by the applicant

Meta SPC 1

Intended use # 1 – Application by trigger spray onto a suitable cleanroom wipe to distribute onto the surface of isolators and Restricted Access Barrier Systems (RABS)

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	Disinfection of hard, non-porous surfaces in isolators and Restricted Access Barrier Systems (RABS). Not for use in healthcare.
Target organism (including development stage)	Bacteria Fungi Yeast
Field of use	Indoor.
Application method(s)	Spray the product onto a suitable cleanroom wipe and apply to the surface to be disinfected. Ensure the entire surface is visibly wet for the contact time (15 minutes for bacteria, 30 minutes for yeast and fungi). Uniform distribution of the biocidal product should be ensured.
Application rate(s) and frequency	50 mL/m^2. Application frequency is specific to the user's site and requirements. No waiting periods are necessary
Category(ies) of users	Professional
Pack sizes and packaging material	1 L adjustable trigger spray HDPE bottle sealed with a polyethylene outer bag.

Intended use # 2 – Application by pouring into a container and using a suitable cleanroom wipe or mop to distribute onto the surface of isolators and Restricted Access Barrier Systems (RABS)

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	Disinfection of hard, non-porous surfaces in isolators and Restricted Access Barrier Systems (RABS). Not for use in healthcare.
Target organism (including development stage)	Bacteria Fungi Yeast
Field of use	Indoor.
Application method(s)	Pour the product into a suitable container and then use a suitable cleanroom wipe or mop and apply to the surface to be disinfected. Ensure the entire surface is visibly wet for the contact time (15 minutes for bacteria, 30 minutes for yeast and fungi). Uniform distribution of the biocidal product should be ensured.

Application rate(s) and frequency	50 mL/m^2. Application frequency is specific to the user's site and requirements. No waiting periods are necessary
Category(ies) of users	Professional
Pack sizes and packaging material	0.5 L, 1 L and 5 L tamper evident cap HDPE bottle sealed with a polyethylene outer bag.

Intended use # 3 – Application by trigger spray onto a suitable cleanroom wipe to distribute onto the surface of cleanrooms

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	Disinfection of hard, non-porous surfaces in cleanrooms. Not for use in healthcare.
Target organism (including development stage)	Bacteria Fungi Yeast
Field of use	Indoor.
Application method(s)	Spray the product onto a suitable cleanroom wipe and apply to the surface to be disinfected. Ensure the entire surface is visibly wet for the contact time (15 minutes for bacteria, 30 minutes for yeast and fungi). Uniform distribution of the biocidal product should be ensured.
Application rate(s) and frequency	50 mL/m^2. Application frequency is specific to the user's site and requirements. No waiting periods are necessary
Category(ies) of users	Professional
Pack sizes and packaging material	1 L adjustable trigger spray HDPE bottle sealed with a polyethylene outer bag.

Intended use # 4 – Application by pouring into a container and using a suitable cleanroom wipe or mop to distribute onto the surface of cleanrooms

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	Disinfection of hard, non-porous surfaces in cleanrooms. Not for use in healthcare.
Target organism (including development stage)	Bacteria Fungi Yeast
Field of use	Indoor

Application method(s)	Pour the product into a suitable container and then use a suitable cleanroom wipe or mop and apply to the surface to be disinfected. Ensure the entire surface is visibly wet for the contact time (15 minutes for bacteria, 30 minutes for yeast and fungi). Uniform distribution of the biocidal product should be ensured.
Application rate(s) and frequency	50 mL/m^2 Application frequency is specific to the user's site and requirements. No waiting periods are necessary
Category(ies) of users	Professional
Pack sizes and packaging material	0.5 L, 1 L and 5 L tamper evident cap HDPE bottle sealed with a polyethylene outer bag.

Meta SPC 2*

Intended use # 5 – Application using a pre-saturated cleanroom wipe to distribute onto hard surfaces in isolators and Restricted Access Barrier Systems (RABS)

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	Disinfection of hard, non-porous surfaces in isolators and Restricted Access Barrier Systems (RABS). Not for use in healthcare.
Target organism (including development stage)	Bacteria Fungi Yeast
Field of use	Indoor.
Application method(s)	Use the pre-saturated wipe to distribute the product onto the surface to be disinfected. Ensure the entire surface is visibly wet for the contact time (15 minutes for bacteria and yeast). Uniform distribution of the biocidal product should be ensured.
Application rate(s) and frequency	2 wipes/m^2 (approx. 40 mL/m^2) Application frequency is specific to the user's site and requirements. No waiting periods are necessary
Category(ies) of users	Professional
Pack sizes and packaging material	PET/PE pack sealed with a polyethylene outer bag.

Intended use # 6 – Application using a pre-saturated cleanroom wipe to distribute onto hard surfaces in cleanrooms

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	Disinfection of hard, non-porous surfaces in cleanrooms. Not for use in healthcare.

Target organism (including development stage)	Bacteria Fungi Yeast
Field of use	Indoor.
Application method(s)	Use the pre-saturated wipe to distribute the product onto the surface to be disinfected. Ensure the entire surface is visibly wet for the contact time (15 minutes for bacteria and yeast). Uniform distribution of the biocidal product should be ensured.
Application rate(s) and frequency	2 wipes/m^2 (approx. 40 mL/m^2) Application frequency is specific to the user's site and requirements. No waiting periods are necessary
Category(ies) of users	Professional
Pack sizes and packaging material	PET/PE pack sealed with a polyethylene outer bag.

*The original submission from the applicant included two additional uses (Intended use #5 and #6 (meta SPC 2)) related to pre-saturated wipes. These uses were not assessed further at this point due to a data gap related to physical-chemical properties and physical hazard. The pre-saturated wipes are not currently being placed on the market.

2.2.2 Physical, chemical and technical properties

Contec Hydrogen Peroxide Biocidal Product Family is a ready for use product family that consist of 1 formulation and 2 products. The physical and chemical and storage stability data submitted with the products 'Contec HydroPure'/'Contec HydroKlean' to support the formulation are summarised in the following table.

Justification for the determination of the worst case scenario product for testing and assessment has been provided in the confidential PAR (Chapter 1.1.4).

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20°C and 101.3 kPa	Organo leptic analysis	'Contec HydroPure' SBT16HPW (6.7% w/w hydrogen peroxide) Batch 160700455	Transparent colourless liquid with a faint smell of peroxide	[redacted] 2016a
Colour at 20°C and 101.3 kPa				
Odour at 20°C and 101.3 kPa				
Acidity, alkalinity	OECD 122	'Contec HydroPure' SBT16HPW (6.7% w/w hydrogen peroxide) Batch 160700455	Neat formulation pH at 20 °C = 4.11. pH of 1% water solution of the product was not measured. As pH of the neat formulation is within the range 4 - 10 acidity or alkalinity data are not required.	[redacted] 2016a
	OECD 122	'Contec HydroKlean' Batch 1671100730	0.019% of H_2SO_4	[redacted] 2018b
		'Contec HydroPure' SBT16HPW Batch 170400602	0.012% of H_2SO_4	[redacted] 2018a
pH	CIPAC MT 75.3. OECD 122	'Contec HydroKlean' Batch 1671100730	3.90	[redacted] 2018b
		'Contec HydroPure' SBT16HPW Batch 170400602	3.99	[redacted] 2018a

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Relative density / bulk density	OECD 109	'Contec HydroPure' SBT16HPW (6.7% w/w hydrogen peroxide) Batch 160700455	1.02	[redacted] 2016a
Storage stability test – **accelerated storage**	CIPAC MT 46.3 Visual assessment CIPAC MT 3 Validated HPLC-UV method S-2016-03142AM-MdP	'Contec HydroPure' SBT16HPW (6.7% w/w hydrogen peroxide) Batch 160700455	1 L trigger spray bottle contained in three sealed transparent plastic bags (the type of plastic not specified) of the product were stored for 18 weeks at 30°C and 65% relative humidity. Appearance No variation, remained a colourless liquid Packaging No variation, no seepage Relative density No change Active content (% w/w) Initial: 6.34% w/w 18 weeks: 6.23% w/w (1.7% loss) The storage period and temperature are suitable. The product label contains the phrase "Do not store at temperature above 30°C." The product appearance and packaging remain stable after accelerated storage. No significant decrease (1.7% after 18 weeks) in the active substance content after accelerated storage. These cleanroom products are supplied to end users in triple or double bag systems as they will pass through different grades of cleanrooms, where each layer of packaging is removed as the product enters into critical pharmaceutical manufacturing environments. This does not affect the product, container or storage conditions of the product.	[redacted] 2017
Storage stability test – **long term storage at**	Visual assessment	'Contec HydroPure' SBT16HPW (6.7% w/w	1 L trigger spray bottle contained in three sealed transparent plastic bags of the product were stored for 24 months at	[redacted] 2018

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td>ambient temperature</td><td>CIPAC MT 3

CIPAC MT 75.3

Validated HPLC-UV method</td><td>hydrogen peroxide)
Batch 160700455</td><td>ambient temperature.
The testing was carried out using a HDPE trigger spray bottle.

<table>
<tr><td></td><td>T0</td><td>T6 mths</td><td>T12 mths</td><td>T18 mths</td><td>T24 mths</td></tr>
<tr><td>Appearance</td><td colspan="5">No variation, remained a colourless liquid</td></tr>
<tr><td>Packaging</td><td colspan="5">No variation, no seepage</td></tr>
<tr><td>Weight loss %</td><td>-</td><td>0.146% (loss)</td><td>0.285% (loss)</td><td>0.439% (loss)</td><td>0.553% (loss)</td></tr>
<tr><td>Relative density</td><td>1.022</td><td>1.023</td><td>1.022</td><td>1.021</td><td>1.021</td></tr>
<tr><td>pH neat</td><td>-</td><td>-</td><td>4.15</td><td>4.12</td><td>4.03</td></tr>
<tr><td>ai content % w/w</td><td>6.35</td><td>6.26 (-1.4%)</td><td>6.17 (-2.8%)</td><td>6.02 (-5.2%)</td><td>5.90 (-7.1%)</td></tr>
</table>

No change in product appearance or packaging after 24 months storage. The initial active substance content is within the tolerance limits of ±10%.</td><td></td></tr>
<tr><td>Storage stability test – low temperature stability test for liquids</td><td>Waiver</td><td>-</td><td>The product label will include the phrase "Do not freeze."</td><td>-</td></tr>
<tr><td>Effects on content of the active substance and technical</td><td>Waiver</td><td>-</td><td>The product label will include the phrase "Store away from light."</td><td>-</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
characteristics of the biocidal product – **light**				
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waiver	-	The product label will include the phrase "Store in dry conditions at temperatures not exceeding 30 °C."	-
Effects on content of the active substance and technical characteristics of the biocidal product – **reactivity towards container material**	-	-	When the container was stored at 30 °C from accelerated and ambient storage stability the packaging remained fit for purpose (see 'accelerated storage' and 'long term storage at ambient temperature').	-
Wettability	Waiver	-	Not relevant. The product is a ready to use liquid.	-
Suspensibility, spontaneity and dispersion stability				
Wet sieve analysis and dry sieve test				
Emulsifiability, re-emulsifiability and emulsion stability				
Disintegration time				
Particle size distribution, content of dust/fines, attrition, friability				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Persistent foaming				
Flowability/Pourability/ Dustability				
Burning rate – smoke generators				
Burning completeness – smoke generators				
Composition of smoke – smoke generators				
Spraying pattern – aerosols				
Degree of dissolution and dilution stability				
Particle size distribution (MMAD)	CIPAC MT 187	'Contec HydroPure' SBT16HPW (6.7% w/w hydrogen peroxide) Batch 160700455	1 L plastic bottle with trigger Result at T0 Dv (50) = 98.4 µm 50% of particle size is >50 µm. Result at T24m Dv (50) = 107.24 µm	[redacted] 2018
Trigger spray properties	In-house method	'Contec HydroPure' SBT16HPW (6.7% w/w hydrogen peroxide) Batch: 1503400228	New trigger spray heads were attached to 1 L bottle products pre-storage. Each trigger was sprayed 150 times. After every 20 spray actuations, the weight of the 10 actuations was taken. The % change of discharge amount is the overall weight change from the initial (zero number of sprays) to after 150 times spraying. Spray diameter was determined by spraying 30 cm above the surface at a 45° angle.	[redacted] 2016

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
Mean of 6 results from a 1 L trigger sprayer
<table>
<tr><td>% Change of discharge amount (max.)</td><td>-0.4
(-0.6)</td></tr>
<tr><td>Spray diameter (mm)</td><td>194</td></tr>
</table>
New trigger spray heads were attached to 1 L bottle products post-storage for 16 weeks at 40°C.

Each trigger sprayer was sprayed until emptied. After every 200 actuations, the weight of the 10 actuations was taken.

Spray diameter was determined by spraying 30 cm above the surface at a 45° angle.

Mean of 3 results from a 1 L trigger sprayer
<table>
<tr><td>% Change of discharge amount (max.)</td><td>-1.45
(-2.16)</td></tr>
<tr><td>Spray diameter (mm)</td><td>184</td></tr>
</table>
In addition, Contec HydroPure Bottle (Batch: 1503400228) at 30 months ambient was tested:

Mean of 3 results from a 1 L trigger sprayer
<table>
<tr><td>% Change of discharge amount (max.)</td><td>-0.36
(0.40)</td></tr>
<tr><td>Spray diameter (mm)</td><td>187</td></tr>
</table>
No significant change to trigger sprayer properties after 30 months storage, although no data on nozzle blockage was
</td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>submitted, but was addressed below in 24 month study of Belussi, C. 2018.</td><td></td></tr>
<tr><td></td><td>FEA 644
FEA 643
FOA</td><td>'Contec HydroPure' SBT16HPW (6.7% w/w hydrogen peroxide) Batch 160700455</td><td>1 L trigger spray bottle contained in three sealed transparent plastic bags of the product were stored for 24 months at ambient temperature.
(These cleanroom products are supplied to end users in triple or double bag systems as they will pass through different grades of cleanrooms, where each layer of packaging is removed as the product enters into critical pharmaceutical manufacturing environments).
<table><tr><td></td><td>T0</td><td>T18</td><td>T24</td></tr><tr><td>Spray and stream character</td><td>Spray</td><td>Spray</td><td>Spray</td></tr><tr><td>Discharge rate</td><td>1.01 g</td><td>0.97 g</td><td>0.95 g</td></tr><tr><td>Valve clogging</td><td>None</td><td>None</td><td>None</td></tr></table>
No significant change to trigger sprayer properties after 24 months storage.</td><td>[redacted] 2018</td></tr>
<tr><td>Physical compatibility
Chemical compatibility</td><td>Waiver</td><td>-</td><td>The label does not recommend that the biocidal product is co-applied with other products. Therefore, further compatibility details are not required.</td><td>-</td></tr>
<tr><td>Surface tension</td><td>OECD 115</td><td>'Contec HydroPure' SBT16HPW (6.7% w/w hydrogen peroxide)</td><td>Mean surface tension at 20°C = 55.4 mN/m
The tested product is surface active (surface tension <60 mN/m).</td><td>[redacted] 2016</td></tr>
<tr><td>Viscosity (dynamic)</td><td>OECD 114</td><td>'Contec HydroPure' SBT16HPW (6.7% w/w hydrogen peroxide) Batch 160700455</td><td>Mean of 10 results at 20°C = 1.4 mPa·s
Mean of 10 results at 40°C = 1.0 mPa·s</td><td>[redacted] 2016a</td></tr>
</table>

Conclusion on the physical, chemical and technical properties of the product
All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The product is stable for 24 months at ambient temperature. **Implications for labelling:** Do not freeze. Store away from light. Store in dry conditions at temperatures not exceeding 30°C.

2.2.3 Physical hazards and respective characteristics

Contec Hydrogen Peroxide Biocidal Product Family is a ready for use product family that consist of 1 formulation and 2 products. The physical hazards data submitted with the product 'Contec HydroPure' to support the formulation are summarised in the following table.

Justification for the determination of the worst-case scenario product for testing and assessment has been provided in the confidential PAR (Chapter 1.1.4).

Property	**Guideline and Method**	**Tested product (SD % (w/w)**	**Results**
Explosives	ST/SG/AC.10/11/Rev. 5 (2009), Appendix 6, Section 3	'Contec HydroPure' Batch number: 210501736	The total heat of decomposition of the test item is < 500 $J \cdot g^{-1}$ and no exothermic behaviour was observed below 500 °C, therefore the test item is not a candidate for classification as a UN Class 1. Reference: [redacted] 2021
Flammable gases Flammable aerosols Oxidising gases Gasses under pressure	-	-	Not relevant. The product is a ready to use liquid.
Flammable liquids	EC 440/2008 No. A.9	'Contec HydroPure' Batch number: 210501736	Flash point: 102°C (Not flammable liquid) Reference: [redacted] 2021
Flammable solid	-	-	Not relevant. The product is a ready to use liquid.
Self-reactive substances and mixtures	ST/SG/AC.10/11/Rev. 5 (2009), Appendix 6, Section 3	-	The total heat of decomposition of the test item is < 300 $J \cdot g^{-1}$ and no exothermic behaviour was observed below 300 °C, therefore the test item is not a candidate for classification as a UN Class 1.

Property	Guideline and Method	Tested product (SD % (w/w)	Results
			Reference: [redacted], 2021
Pyrophoric liquids	Waiver	-	H_2O_2 is not pyrophoric. Use of the product demonstrates that the 6.67% solution does not ignite when in contact with air. None of the components of the product confer pyrophoric substances. Therefore, the products would not be classified as pyrophoric.
Pyrophoric solids	-	-	Not relevant. The product is a ready to use liquid.
Self-heating substances and mixtures	Waiver	-	The product is a liquid. Liquids are not considered as self-heating unless adsorbed on a large surface.
Substances and mixtures which in contact with water emit flammable gases	Waiver	-	The formulated product is an aqueous solution. Therefore, the product is not expected to emit flammable gases.
Oxidising liquids	UN Test 0.2	'Contec HydroPure' SBT16HPW (6.7% w/w hydrogen peroxide)	According to 2.13. of CLP, oxidising liquid means a liquid substance or mixture which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material. As agreed at APCP working group (Sept 2019), only products containing hydrogen peroxide in the concentration > 8% need to be classified as oxidising. Reference: [redacted], 2014
Oxidising solids	-	-	Not relevant. The product is a ready to use liquid.
Organic peroxides	Waiver	-	The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of test and criteria. Even though the product contains the bivalent -O-O- structure it is not an organic derivative of peroxide. Therefore, the products would not be classified as organic peroxide.
Corrosive to metals	UN manual test 37.4 UN Test C.1	'Contec HydroPure' SBT16HPW (6.7% w/w hydrogen peroxide)	Because of a large disintegration of hydrogen peroxide at 55°C, the test was conducted with the daily change of the solution with the fresh one. For the entire duration of the test (1 month), coupons of both materials in all 3 test elevations did not exceed the maximum corrosion rate of 6.25 mm/yr. Furthermore, neither the minimum weight loss nor the

Property	Guideline and Method	Tested product (SD % (w/w)	Results
			minimum pit depth was exceeded for either material during these tests. The results showed that the product is not corrosive to metals. Reference: [redacted] 2020
Auto-ignition temperatures of products (liquids and gasses)	EC 440/2008 No. A.15	Contec HydroPure Batch number: 210501736	Test item does not ignite until 600°C (maximum test temperature). Reference: [redacted] 2021
Relative self-ignition temperature for solids		-	Not relevant. The product is a ready to use liquid.
Dust explosion hazard		-	Not relevant. The product is a ready to use liquid.

Conclusion on the physical hazards and respective characteristics of the product
Based on the assessment of the representative product Contec HydroPure meta SPC 1 is not classified for the physical hazards in the table above.

2.2.4 Methods for detection and identification

Analytical methods for the active substance in the product

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

447.8 mg of the test sample was weighed into a 50 mL volumetric flask and brought to a volume with Milli-Q water. This gives a resulting sample concentration of 8.956 mg/mL and therefore a nominal hydrogen peroxide concentration of 0.6 mg/mL.
Hydrogen peroxide was determined using HPLC-UV (isocratically, 20 mM potassium phosphate (pH 2.5)) on Allure organic acids column (300 x 4.6 mm, 5 µm) at 250 nm.

Analyte	Linearity	Specificity	Fortification range, level and number of measurements at each level	Recovery rate (%)	Precision (%)	Limit of Quantification LOQ	Reference
Hydrogen peroxide	0.3 - 0.9 mg/mL, equivalent to 50 - 150% of the nominal content (3.4 - 10.1% hydrogen peroxide) n = 5 y = 1706x + 13 r^2 = 0.9999	Spectra of the blank, standard solutions and test solutions were provided showing no interferences. Identity was confirmed using $KMnO_4$ colour-change test to confirm the presence of hydrogen peroxide.	0.3 mg/mL (equivalent to 3.3% w/w) n = 2 0.6 mg/mL (equivalent to 6.7% w/w) n = 2 0.9 mg/mL (equivalent to 9.9% w/w) n = 2	Range (%): 102.4 - 103.3; Mean (%): 103; RSD (%): 0.4 Range (%): 101.1 - 101.5; Mean (%): 101.3; RSD (%): 0.2 Range (%): 100.1 - 100.4; Mean (%): 100.2; RSD (%): 0.13 Overall: 101.5 (n = 6)	mean content of 6.32% w/w (n = 6) % RSD = 0.17% Acceptable Horwitz = 2.03%	-	[redacted] 2016b

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

Methods of analysis for the determination of hydrogen peroxide residues in air and water have previously been evaluated at active substance approval. Considering hydrogen peroxide is not adsorbed to soil but remains in the soil water, no analytical method was submitted for soil. The applicant has adequate letter of access to this data. An analytical method for hydrogen peroxide in body fluids and tissues is not required since the substance is not classified as toxic or highly toxic. The monitoring methods for food/feed of plant and animal origin are not relevant for the Contec Hydrogen Peroxide Biocidal Product Family. Therefore, concerning product authorisation no further consideration is required from a chemistry perspective.

Conclusion on the methods for detection and identification of the product
An analytical method (, 2016b) for the determination of the active substance hydrogen peroxide is available. Specificity, linearity, accuracy and precision were checked and found acceptable. Methods for the detection of the active substance hydrogen peroxide in soil, air, water, and animal and human body fluids and tissues were addressed and deemed acceptable at EU level. No other data is required.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The products in the biocidal product family are surface disinfectants (product type 2) used in cleanrooms and in isolators and RABS positioned in cleanrooms. They are applied either by spraying onto a wipe or by pouring into a container and by use of a wipe/mop distributed onto a surface. All products contain 6.67% hydrogen peroxide as the active substance and are the same in composition. They are intended to be used by professional users only and are not intended for use in healthcare.

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

The products are intended to be used for disinfection of hard surfaces against contamination with bacteria, yeasts and fungi in cleanrooms. A cleanroom by definition has a controlled level of contamination that is specified by the number of particles per cubic metre at a specified particle size and hence the products in biocidal product family protect the environment in cleanrooms as well as humans.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Products in the family possess bactericidal, yeasticidal and fungicidal activity. No unacceptable suffering is relevant for the target organisms in PT2.

2.2.5.4 Mode of action, including time delay

Hydrogen peroxide belongs to the group of oxidising disinfectants. Hydrogen peroxide reacts very fast. It will then disintegrate into hydrogen and water, without the formation of by-products and this increases the amount of oxygen in water. It is believed that hydrogen peroxide works by inflicting multiple cell damage to cells and removal of protein, ending in cell death. It produces destructive hydroxyl-free radicals that can attack membrane lipids, DNA and essential cell components resulting in cell death.

2.2.5.5 Efficacy data

The efficacy data are summarised in the following table. Contec HydroPure is identical in composition to all biocidal products in the biocidal product family.

Experimental data on the efficacy of the biocidal product against target organisms							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
bactericide	PT2 – hard surfaces other than in healthcare	Contec HydroPure (RTU), 6.67% H_2O_2; batch DEV004	Bacteria: *E. coli, E. hirae, S. aureus* and *P. aeruginosa*	EN1276 (2019) - Phase 2 Step 1 test	Quantitative suspension test Clean conditions (interfering substance: 0.3 g/L BSA) Test temp.: 20°C Contact time: 5 and 15 minutes Test conc.: RTU (actual conc. 80%) Reduction factor (pass): ≥5 lg	Based on test results Contec HydroPure possesses bactericidal activity after 15 min contact time under clean conditions. Test validation criteria were met and test was accepted as valid. Test pass criteria were met: log ≥5 reduction of referenced strains of *E. coli, E. hirae, S. aureus* and *P. aeruginosa* was demonstrated. Deviation from standard: only 1 concentration of test product instead of minimum 3 was used.	[redacted] 19-02-2020 [redacted]
bactericide	PT2 – hard surfaces other than in healthcare	Contec HydroPure (RTU), 6%; batch 200101302	Bacteria: *E. coli, E. hirae, S. aureus* and *P. aeruginosa*	EN1276 (2019) - Phase 2 Step 1 test	Quantitative suspension test Clean conditions (interfering substance: 0.3 g/L BSA) Test temp.: 20°C Contact time: 5 and 15 minutes Test conc.: 80.0% v/v (RTU); 50.0% v/v; 10.0% v/v Reduction factor (pass): ≥5 lg	Based on test results Contec HydroPure at concentration 80% (RTU) possesses bactericidal activity after 15 min contact time under clean conditions. Test validation criteria were met and test was accepted as valid. Test pass criteria were met: log ≥5 reduction of referenced strains of *E. coli, E. hirae, S. aureus* and *P. aeruginosa* was demonstrated.	[redacted] 29-05-2020 [redacted]

Experimental data on the efficacy of the biocidal product against target organisms							
fungicide	PT2 – hard surfaces other than in healthcare	Contec HydroPure (RTU), 6%; batch 200101302	Fungi: mould *A. brasiliensis*	EN1650 (2019) - Phase 2 Step 1 test	Quantitative suspension test Clean conditions (interfering substance: 0.3 g/L BSA) Test temp.: 20°C Contact time: 15 and 30 minutes Test conc.: 80.0% v/v (RTU); 50.0% v/v; 10.0% v/v Reduction factor (pass): ≥4 lg	Based on test results Contec HydroPure at concentration 80% (RTU) possesses fungicidal activity after 30 min contact time under clean conditions. Test validation criteria were met and test was accepted as valid. Test pass criteria were met: log ≥4 reduction of referenced mould *A. brasiliensis* was demonstrated with 80% (RTU) product. Deviation from standard: yeast *C. albicans* was not tested.	[redacted] 29-05-2020 [redacted]
fungicide	PT2 – hard surfaces other than in healthcare	Contec HydroPure (RTU), 6.67%; batch DEV004	Fungi: yeast *C. albicans*; mould *A. brasiliensis*	EN1650 (2019) - Phase 2 Step 1 test	Quantitative suspension test Clean conditions (interfering substance: 0.3 g/L BSA) Test temp.: 20°C Contact time: 15 and 30 minutes Test conc.: RTU (actual conc. 80%) Reduction factor (pass): ≥4 lg	Based on test results Contec HydroPure possesses fungicidal activity after 30 min contact time under clean conditions. Test validation criteria were met and test was accepted as valid. Test pass criteria were met: log ≥4 reduction of referenced yeast *C. albicans* and mould *A. brasiliensis* was demonstrated. Deviation from standard: only 1 concentration of test product instead of minimum 3 was used.	[redacted] 19-02-2020 [redacted]
fungicide	PT2 – hard surfaces other than in	Contec HydroPure (RTU), 6%;	Fungi: yeast *C. albicans*	EN1650 (2019) - Phase 2	Quantitative suspension test Clean conditions (interfering	Based on test results Contec HydroPure at concentration 80% (RTU) possesses fungicidal activity after 30 min contact	[redacted] [redacted]

Experimental data on the efficacy of the biocidal product against target organisms							
	healthcare	batch 201201619		Step 1 test	substance: 0.3 g/L BSA) Test temp.: 20°C Contact time: 30 minutes Test conc.: 80.0% v/v (RTU); 50.0% v/v; 10.0% v/v Reduction factor (pass): ≥4 lg	time under clean conditions. Test validation criteria were met and test was accepted as valid. Test pass criteria were met: log ≥4 reduction of referenced yeast *C. albicans* was demonstrated with 80% (RTU) product. Deviation from standard: mould *A. brasiliensis* was not tested.	[redacted]
Bactericide and fungicide	PT2 – hard surfaces other than in healthcare	Contec HydroPure (RTU), 6%; batch DEV004	Bacteria: *E. coli, E. hirae, S. aureus* and *P. aeruginosa* Fungi: yeast *C. albicans* and mould *A. brasiliensis*	EN13697 (2015)+A1: 2019 - Phase 2 Step 2 test	Quantitative non-porous surface test without mechanical action Clean conditions (interfering substance: 0.3 g/L BSA) Test temp.: 20°C Contact time: 15 minutes for bacteria and 30 minutes for fungi Test conc.: RTU (actual conc. 80%) Surface: stainless steel Grade 304 Reduction factor (pass): - Bacteria ≥4 lg - Fungi ≥3 lg	Based on test results Contec HydroPure possesses fungicidal activity after 30 min contact time under clean conditions. Bactericidal activity was not demonstrated with this study as the test pass criteria were not met for *P. aeruginosa*. Test validation criteria were met and test was accepted as valid. Test pass criteria were met for following target organisms: - log ≥3 reduction of referenced yeast *C. albicans* and mould *A. brasiliensis* was demonstrated; - log ≥4 reduction of referenced *E. coli, E. hirae* and *S. aureus* strains was demonstrated.	[redacted] 24-02-2020 [redacted]
Bactericide	PT2 – hard	Contec	Bacteria:	EN13697	Quantitative non-porous surface test	Based on test results Contec HydroPure	[redacted]

Experimental data on the efficacy of the biocidal product against target organisms							
and fungicide	surfaces other than in healthcare	HydroPure (RTU), 6%; batch 210201651	*E. coli, E. hirae, S. aureus* and *P. aeruginosa* Fungi: yeast *C. albicans* and mould *A. brasiliensis*	(2015)+A1: 2019 - Phase 2 Step 2 test	without mechanical action Clean conditions (interfering substance: 0.3 g/L BSA) Test temp.: 20°C Contact time: 15 minutes for bacteria and 30 minutes for fungi Test conc.: RTU (actual conc. 80%) Surface: stainless steel Grade 304 Reduction factor (pass): - Bacteria ≥4 lg - Fungi ≥3 lg	possesses bactericidal and fungicidal activity after 15 and 30 minutes contact time under clean conditions, respectively. Test validation criteria were met and test was accepted as valid. Test pass criteria were met for all target organisms: - log ≥3 reduction of referenced yeast *C. albicans* and mould *A. brasiliensis* was demonstrated; - log ≥4 reduction of referenced *E. coli, E. hirae, P. aeruginosa* and *S. aureus* strains was demonstrated.	[redacted]
Bactericide and yeasticide	PT2 – hard surfaces other than in healthcare	CONTEC SATWipes HydroPure (RTU), 6.67%; batch 200601442	Bacteria: *E. hirae, S. aureus* and *P. aeruginosa* Fungi: yeast *C. albicans*	EN16615 (2015) - Phase 2 Step 2 test	Quantitative test method on non-porous surfaces with mechanical action employing wipes Clean conditions (interfering substance: 0.3 g/L BSA) Test temp.: 20°C Contact time: 15 minutes for bacteria and yeasts A test-surface: 4 squares of 5 × 5	Based on test results, product CONTEC SATWipes HydroPure possess bactericidal and yeasticidal activity after 15 min contact time under clean conditions employing wipes as a means of mechanical action. Test validation criteria were met and test was accepted as valid. Water control demonstrated for bacteria and yeasts an average > 10 CFU on test fields 2 to 4. Test pass criteria were met for all target organisms in test field 1:	[redacted] 18/02/2021 [redacted]

Experimental data on the efficacy of the biocidal product against target organisms							
					cm, the "test fields", in a row. Test field 1 inoculated with suspension of bacteria and yeasts and dried. The test-surface is wiped across the four marked test fields. Test conc.: RTU wipe Reduction factor (pass) in test field 1: - Bacteria ≥5 lg - Yeasts ≥4 lg	- log ≥4 reduction of referenced yeast *C. albicans* was demonstrated; - log ≥5 reduction of referenced *E. hirae*. *P. aeruginosa* and *S. aureus* strains was demonstrated.	
Bactericide and yeasticide	PT2 – hard surfaces other than in healthcare	Contec HydroPure (RTU), 6%; batch 200601442	Bacteria: *E. hirae, S. aureus* and *P. aeruginosa* Fungi: yeast *C. albicans*	EN16615 (2015) - Phase 2 Step 2 test	Quantitative test method on non-porous surfaces with mechanical action employing wipes Clean conditions (interfering substance: 0.3 g/L BSA) Test temp.: 20°C Contact time: 15 minutes for bacteria and yeasts A test-surface: 4 squares of 5 × 5 cm, the "test fields", in a row. Test field 1 inoculated with suspension of bacteria and yeasts and dried. The test-surface is wiped across the four marked test fields. Test conc.: RTU wipe	Based on test results Contec HydroPure possesses bactericidal and yeasticidal activity after 15 min contact time under clean conditions employing wipes as a means of mechanical action. Test validation criteria were met and test was accepted as valid. Water control demonstrated for bacteria and yeasts an average > 10 CFU on test fields 2 to 4. Test pass criteria were met for all target organisms in test field 1: - log ≥4 reduction of referenced yeast *C. albicans* was demonstrated; - log ≥5 reduction of referenced *E. hirae*. *P. aeruginosa* and *S. aureus* strains was demonstrated.	[redacted] 03-03-2021 [redacted]

Experimental data on the efficacy of the biocidal product against target organisms							
					Reduction factor (pass) in test field 1: - Bacteria ≥5 lg - Yeasts ≥4 lg		

Conclusion on the efficacy of the product family

Efficacy data were provided for Contec HydroPure which contains 6.67% hydrogen peroxide and this is comparable with Contec Sterile HydroPure products included in the BPF. The products are identical in composition except that they are applied either from a trigger or capped bottle. In addition, when a test method on non-porous surfaces with mechanical action employing wipes was done, the liquid used to saturate the wipes is identical to the Contec HydroPure. It is considered that the efficacy data performed for the test product Contec HydroPure are sufficient to demonstrate the efficacy of the Contec Hydrogen Peroxide Biocidal Product Family.

Efficacy of the products in biocidal product family was demonstrated for 4 intended uses as follows:

1) Application by trigger spray onto a suitable cleanroom wipe to distribute onto the inner surface of isolators and Restricted Access Barrier Systems (RABS)
2) Application by pouring into a container and using a suitable cleanroom wipe or mop to distribute onto the inner surface of isolators and Restricted Access Barrier Systems (RABS)
3) Application by trigger spray onto a suitable cleanroom wipe to distribute onto the surface of cleanrooms
4) Application by pouring into a container and using a suitable cleanroom wipe or mop to distribute onto the surface of cleanrooms

Uses #1 and #3 and uses #2 and #4 were not merged because the risk assessment for these uses would be different. Namely, when the product is used in isolators and RABS there is a zero exposure to the user as these are closed, ventilated systems. Cleanroom use refers to use on work surfaces where the user is exposed to the product.

A tiered approach for demonstration of efficacy of the family was used. Since all products in the family have the same composition, Contec HydroPure, which has been used in the efficacy studies, is considered as a worst-case composition product. The nominal amount of active substance for product Contec HydroPure is set as 6.67%. According to the Table 5, p. 66, Guidance on the BPR: Volume I Parts A+B+C Version 2.0 May 2018, the tolerance limit of the active substance content at the point of manufacture is ± 10% of the declared nominal amount. Hence, for some study reports in Table: Experimental data on the efficacy of the biocidal product against target organism(s) the concentration of hydrogen peroxide is indicated as 6%.

All tests were done in 'clean' conditions (0.3 g/L bovine serum albumin (BSA)) as the products are intended to be used in cleanrooms where a controlled level of contamination, specified by the number of particles per cubic metre at a specified particle size, is significant. Hence, cleaning prior to the disinfection is required for visibly soiled surfaces.

Bactericidal, yeasticidal and fungicidal activity was shown with quantitative suspension tests (phase 2, step 1) performed according to the latest versions of EN1276 and EN1650, respectively.

All products are RTU products. Nevertheless, 3 different concentrations (80% (RTU), 50% and 10% solutions) were tested in suspension tests according to the norm and the Guidance on the BPR: Volume II Parts B+C, p 55. (2. and 4. paragraph), where it is stated that while it is not mandatory to perform the tests under obligatory test conditions of the standards if the claimed use conditions of the products are different from these obligatory tests conditions, suspension tests should be performed with

Conclusion on the efficacy of the product family
several dose rates, including at least one rate lower than the effective rate. Therefore, two EN1276 and three EN1650 tests were submitted to be aligned with the mentioned request of different dose rates. Different quantitative surface tests (phase 2, step 2) were employed to demonstrate bactericidal, yeasticidal and fungicidal activity of products. Surface tests according to the latest version of EN13697 showed that products will be efficacious for the intended use of surface disinfection in cleanrooms and in isolators and Restricted Access Barrier Systems (RABS) positioned in cleanrooms. Applicant indicated that products are either sprayed onto a wipe or poured into a container and further wiping or mopping is only a way of distributing a product without any real mechanical action involved. In such cases EN13697 is considered applicable according to the Technical Agreements for Biocides (TAB) – EFF v.2.1. Nevertheless, wipes saturated with Contec HydroPure were used in EN16615, a test method on non-porous surfaces with mechanical action employing wipes. Two studies, performed by two different laboratories as instructed in EN16615, were submitted and both demonstrated bactericidal and yeasticidal activity of used wipes for surface disinfection in cleanrooms. In conclusion, when the RTU products from the biocidal product family will be used as instructed, they will be efficacious against bacteria, yeasts and fungi for surface disinfection in cleanrooms and in isolators and Restricted Access Barrier Systems (RABS) positioned in cleanrooms for the determined contact time.

2.2.5.6 Occurrence of resistance and resistance management

The applicant has provided the following statement regarding the potential occurrence of resistance:

'The lethal effects of oxidative molecular species generated from hydrogen peroxide can be avoided with any damage being repaired in micro-organisms such as *E. coli* and *S. typhimurium*. When *E. coli* and *S. typhimurium* are exposed to low concentrations of H_2O_2, 3 µM and 60 µM respectively, cells produce enzymes and other proteins which are important for cellular defence and mitigate toxic effects of the oxidative species. This adaptive response is triggered by nontoxic levels of the oxidative species to protect against and produce resistance to oxidative stress caused when challenged with higher concentrations, 10 mM (Dukan and Touati (1996), Christman et al (1985)). The resistance to oxidative stress that *E. coli* develops when exposed to H_2O_2, as reported in literature papers, demonstrates an adaptive response only. Hydrogen peroxide had been intensively used as a disinfectant and preservative for more than 3 decades and has not led to the development of significant resistance levels among field populations. Genetically inherited resistance is not expected when the products are used as recommended.

The SI eCA accepts this statement and agrees that for the relevant target organisms and intended use, resistance is unlikely to be an issue.

2.2.5.7 Known limitations

Appropriate cleanroom 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 future labels for products pertaining to the BPF will be prepared in line with the final SPC and will give clear instructions for use, application procedure and relevant contact time as proven efficacious in the relevant efficacy tests. Thus, it can be concluded that sufficient efficacy is ensured by following the use instructions on the labels. See the SPC and section "Authorised uses" of this PAR (section 2.1.4) for the authorised label claims and use instructions.

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

Not applicable.

2.2.6 Risk assessment for human health

There is no new data on the product family Contec Hydrogen Peroxide Biocidal Product Family and the submission relies upon the data on the active substance and information on the co-formulants. A letter of access to the active substance dossier has been provided to support its use thus there is sufficient information available to fulfil the product data requirements under the Regulation (EU) 528/2012 and classification under Regulation (EU) 1272/2008.

Overall, the active substance, hydrogen peroxide, is classified as Acute Tox 4 H302 (Oral), Acute Tox 4 H332 (inhalation) and Skin Corr. 1A H314. Specific concentration limits have been applied for skin, eye and respiratory tract irritation:

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 %

These values will be applied to the assessment on human health alongside the information provided on the co-formulants. Please note that the conclusion made in the human health assessment applies to all products in the family.

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	Not a skin irritant
Justification for the value/conclusion	There is sufficient information on the active substance and the co-formulants to determine the hazard of the product family Contec Hydrogen Peroxide Biocidal Product Family without additional data. The concentration of active substance is below the specific concentration limit for skin corrosion and irritation in all products within each meta SPC. The co-formulants are not skin corrosive or irritants.
Classification of the product according to CLP	Contec Hydrogen Peroxide Biocidal Product Family is not classified for skin corrosion or irritation.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Eye Irrit. 2
Justification for the value/conclusion	There is sufficient information on the active substance and the co-formulants to determine the hazard of the product family Contec Hydrogen Peroxide Biocidal Product Family without additional data. The concentration of the active substance in all products falls

	within the range for eye irritation (SCL 5% ≤C <8%).
Classification of the product according to CLP	Contec Hydrogen Peroxide Biocidal Product Family is classified for eye irritation; Eye Irrit. 2 H319 - causes serious eye irritation.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	There is sufficient information on the active substance and its subsequent classification to determine the hazard of the product family Contec Hydrogen Peroxide Biocidal Product Family. The concentration of the active substance is below the specific concentration limit for respiratory tract irritation (<35%) and the co-formulants do not possess any known respiratory tract irritation effects.
Classification of the product according to CLP and DSD	Contec Hydrogen Peroxide Biocidal Product Family is not classified for respiratory tract irritation.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not a skin sensitiser
Justification for the value/conclusion	There is sufficient information on the active substance and co-formulants to determine the hazard of the product family Contec Hydrogen Peroxide Biocidal Product Family. Neither the active substance nor co-formulants are known to cause skin sensitisation.
Classification of the product according to CLP and DSD	Contec Hydrogen Peroxide Biocidal Product Family is not classified for skin sensitisation.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not a respiratory sensitiser
Justification for the value/conclusion	It can be reliably concluded from the available information on the active substance and the co-formulants that the product family Contec Hydrogen Peroxide Biocidal Product Family is not a respiratory sensitiser.
Classification of the product according to CLP and DSD	Contec Hydrogen Peroxide Biocidal Product Family is not classified for respiratory sensitisation.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	>2000 mg/kg bw/d, not acutely toxic by the oral route
Justification for the selected value	Acute oral toxicity was extensively studied during the active substance evaluation of hydrogen peroxide and there is sufficient information on the co-formulants to determine the hazard of the product family. Using this information, the calculation method under Regulation (EC) 1272/2008 was applied to the Contec Hydrogen Peroxide Biocidal Product Family. The active substance is classified for acute oral toxicity cat 4 (H302). In the assessment report, LD_{50} values for concentrations from 35 % to 70 % were 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). To address the classification for oral toxicity of the product, the calculation method can be applied using the corrected LD_{50} value from the CAR and the maximum concentration of hydrogen peroxide within the BPF as a worst case. ATE_{mix} in accordance with Regulation (EC) 1272/2008 $100/ATE_{mix} = C_i / ATE_i$ $100/ATE_{mix} = 6.67/500$ $100/ATE_{mix} = 0.013$ $ATE_{mix} = 100/0.013$ $ATE_{mix} = 7692$ mg/kg This exceeds the cut-off for classification for acute oral toxicity and therefore the products do not require classification under Regulation (EC) 1272/2008.
Classification of the product according to CLP and DSD	Contec Hydrogen Peroxide Biocidal Product Family is not classified for acute oral toxicity

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	>20 mg/L
Justification for the selected value	The active substance is classified for acute inhalation toxicity cat 4 (H332). The CAR states the highest attainable concentration is 170 mg/m^3 but this value does not directly relate to classification in Category 4 for vapours and therefore an acute toxicity point estimate has been used instead i.e. 11 mg/L. Furthermore, the maximum concentration of active substance has been included in the calculation as a worst case. ATE_{mix} in accordance with Regulation (EC) 1272/2008

Value used in the Risk Assessment – Acute inhalation toxicity	
	$100/ATE_{mix} = Ci/ATE_i$ $100/ATE_{mix} = 6.67/11$ $100/ATE_{mix} = 0.6$ $ATE_{mix} = 100/0.6$ $ATE_{mix} = 167$ mg/L This exceeds the cut-off for classification for acute inhalation toxicity and therefore the products do not require classification under Regulation (EC) 1272/2008. This is supported by the conclusion in the CAR that only products containing >50% active substance would require classification for acute inhalation toxicity and the products within the biocidal product family contain a nominal content of 6.67%.
Classification of the product according to CLP and DSD	Contec Hydrogen Peroxide Biocidal Product Family is not classified for acute inhalation toxicity.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	>2000 mg/kg bw/d
Justification for the selected value	There is sufficient information on the active substance and co-formulants to determine the hazard and classification of the product family. Contec Hydrogen Peroxide Biocidal Product Family biocidal product family is not acutely toxic by the dermal route as neither the active substance nor co-formulants are toxic by this route.
Classification of the product according to CLP and DSD	The Contec Hydrogen Peroxide Biocidal Product Family is not classified for acute dermal toxicity.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Hydrogen peroxide
Value(s)*	100%
Justification for the selected value(s)	In the CAR for the active substance, no dermal absorption value was required due to the product type and use. In the absence of data and if needed for this assessment, 100% has been proposed by the applicant which is a conservative approach given these products are not corrosive.

Data waiving	
Information requirement	Dermal absorption
Justification	No data is required as a default value can be applied in the absence of data.

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

There are no substances of concern within the Contec Hydrogen Peroxide Biocidal Product Family. This includes co-formulants (confidential annex) and stabilisers in the active substance (Member State Confidential Annex).

Available toxicological data relating to a mixture

See Member State Confidential Annex.

Available toxicological data relating to endocrine disruption

The BPF contains the active substance hydrogen peroxide, which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) No 2017/2100. The Assessment report for hydrogen peroxide concluded that "There is no evidence of any endocrine disruption potential in the human health or ecotoxicological studies presented in the dossier.". For the assessment of endocrine-disrupting properties of non-active substances, refer to the respective section of the confidential annexes.

Based on the considered data, neither the active substance, nor the co-formulants of these BPs have shown endocrine disrupting properties for human health. Therefore, in line with document CA-March18-Doc.7.3.b-final, it could be concluded that the BPF has no ED potential either.

Other

No other data is available as the products are not expected to come into contact with food or feeding stuffs or are not intended to be used in combination with other biocidal products and no other human exposure is predicted.

2.2.6.2 Exposure assessment

Biocidal products in the Contec Hydrogen Peroxide Biocidal Product Family are ready to use liquid products intended to be used by professionals to disinfect non-porous hard surfaces in cleanrooms, isolators and Restricted Access Barrier Systems (RABS). The biocidal products are supplied in a 1 L trigger spray bottle and 0.5, 1 and 5 L bottles. The products supplied in the trigger spray bottle are sprayed onto suitable cleanrooms wipes at an application rate of 50 mL/m^2; the products supplied in the 0.5, 1 or 5 L bottles are poured into a suitable container and applied using a suitable cleanroom wipe or mop at an application rate of 50 mL/m^2 (Figure 1 and Figure 2). The biocidal products may be used either on surfaces in cleanrooms or inside isolators and RABS (Figure 3 and Figure 4). Cleanrooms are highly controlled environments designed to reduce/eliminate contamination and are only accessed by professionals.

This exposure assessment is based on the use of products supplied as trigger spray and capped bottles as described above.

EasyReach Cleaning Tool

Figure 1: Head Frame 19 x 6 cm supplied with one-piece 40 cm handles or extending handles (40 – 75 cm).

VertiKlean MAX Mop Wipe System

Figure 2: Head Frame 19 x 11 cm supplied with one-piece 40 cm handles or extending handles (40 – 75 cm).

Figure 3: Example of Restricted Access Barrier System (RABS).

Figure 4: Example of isolators used in cleanrooms.

Identification of main paths of human exposure towards active substance 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	Primary or secondary exposure Description of scenario	Exposed group
1.	Pouring	Primary exposure: pouring of the product from a 0.5, 1 or 5 L container	Professionals
2a.	Application (wiping)	Primary exposure: disinfection of surfaces using a cleanroom wipe (0.5, 1 or 5 L bottle) – small area	Professionals
2b.	Application (mopping)	Primary exposure: disinfection of surfaces using a cleanroom mop (0.5, 1 or 5 L bottle) – large area	Professionals
3.	Application (spraying)	Primary exposure: disinfection of hard surfaces with wipes (product sprayed onto wipe then applied to surface) (1 L trigger spray bottle)	Professionals
4.	Re-entry into treated areas (wiping/mopping)	Secondary exposure: re-entering a treated area after disinfection through wiping/mopping	Professionals
5.	Re-entry into treated areas (spraying)	Secondary exposure: re-entering a treated area after disinfection through spraying (product sprayed onto wipe then applied to surface)	Professionals
6.	Application (inside isolators and RABS)	Primary exposure: application of the product inside isolators and Restricted Access Barrier Systems (RABS)	Professionals

Industrial exposure

The products in the Contec Hydrogen Peroxide Biocidal Product Family are not intended for industrial use.

Professional exposure

Scenario 1 – Primary exposure during pouring of the product from a 0.5, 1 or 5 L container

Description of Scenario 1		
When Contec HydroPure is supplied in a 0.5, 1 or 5 L container the product is poured into a suitable container where cleanroom wipes or a cleanroom mop are saturated with the product. The air concentration of hydrogen peroxide during pouring of the product from a 5 L container 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. In practice, pouring of the biocidal product into containers will only take place in cleanroom environments. Refinement of the ventilation rate has been done in Tier 2 assuming that pouring of the product is done in a ventilated room (minimum 3 air change/h).		
	Parameters	Value
Tier 1 (ART tool v1.5)	Exposure duration per day[1]	10 mins
	Liquid mole fraction of hydrogen peroxide[2]	0.04
	Activity coefficient[3]	0.8
	Activity class	Falling liquids
	Situation[4]	Transfer of liquid product with flow of 1 – 10 L/min
	Contamination level[5]	Open process
	Loading type[5]	Splash loading
	Room volume[5]	Any size workroom
	Ventilation rate[4]	Only good ventilation
	General control measures[5]	No localised controls
Tier 2 (ART tool v1.5)	Ventilation rate	3/h
[1] according to Cleaning Products Fact Sheet, default value for cleaning and wipes during loading and applicant's estimation (0.75 min/loading; around 10 loadings per day → worst case = 10 min) [2] moles of water present: 0.93 g / 18 g/mol = 0.051 mol. Moles of hydrogen peroxide: 0.07 g / 34 g/mol = 0.002 mol. Mole fraction of hydrogen peroxide: 0.002 mol / 0.053 total moles = 0.04 [3] calculated using XLUNIFAC (2 x OH sub-groups) [4] reflects the worst case situation of pouring the product in a suitable container [5] worst case situation in ART tool v1.5		

Calculations for Scenario 1

Summary table: estimated exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated air concentration (mg a.s./m³)**
Scenario 1	1 (no RPE)	1.4
	2 (no RPE)	0.66

Scenario 2a: Primary exposure during disinfection of surfaces by wiping – small area

Description of Scenario 2a – (small area)		
The product is poured into a suitable container where cleanroom wipes are saturated with the product. The product is then applied to the surface to be disinfected using a cleanroom wipe at an application rate of 50 mL/m². Pouring of the product into a suitable container is considered under Scenario 1 above. Cleanroom wipes are intended to be used to disinfect small surface areas. A professional user is exposed to the product during evaporation of the disinfected surface via inhalation. 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 hydrogen peroxide, this model does not take into account exposure to vapour. As such, the air concentration of hydrogen peroxide has been calculated using ConsExpo Web exposure to vapour: evaporation model (increasing area) for the Tier 1 assessment with the model option "product is used in a pure form" as recommended in the Recommendation no. 16 BPC Ad hoc Working Group on Human Exposure Applicability of ConsExpo for water-based disinfectants (Agreed at the Human Health Working Group III-2019 on 23 May 2019). Furthermore, specific settings that apply for small areas of cleanrooms were taken into account based on Recommendation no. 15 BPC Ad hoc Working Group on Human Exposure Harmonisation of PT2 small surface disinfection exposure scenarios for biocidal products containing highly volatile active substances by RTU wipes and trigger sprayer (Agreed at the Human Health Working Group VII-2018 on 4 December 2018).		
	Parameters	Value
Tier 1	Adult body weight	60 kg
	Maximum concentration of hydrogen peroxide (see 2.2.6.2 text box)	6.67 % w/w
	Product density	1 g/mL
	Inhalation rate[1]	1.25 m³/h
	Molecular weight	34 g/mol
	Vapour pressure of hydrogen peroxide at 20°C	214 Pa
	Product amount	25 g (50 mL product/m² x 0.5 m²)
	Exposure duration[3]	60 mins
	Room volume[2]	55 m³
	Ventilation rate[4]	360/h

Description of Scenario 2a – (small area)		
	Application duration[2]	1 min
	Release area[2]	0.5 m^2
	Mass transfer rate (default value)[2]	10 m/h

[1] default inhalation rate according to General Fact Sheet, General default parameters for estimating consumer exposure (RIVM report 090013003/2014)
[2] according to Recommendation no. 15 BPC Ad hoc Working Group on Human Exposure Harmonisation of PT2 small surface disinfection exposure scenarios for biocidal products containing highly volatile active substances by RTU wipes and trigger sprayer (Agreed at the Human Health Working Group VII-2018 on 4 December 2018)
[3] according to HH WGTOX IV2019 (the user may stay in the room after disinfection)
[4] provided by the applicant according to the standard ISO 14644-1:2015 Cleanrooms and associated controlled environments — Part 1, Class A/B.

Calculations for Scenario 2a

Summary table: estimated exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated air concentration (mg a.s./m^3)**
Scenario 2a	1 (no RPE)	0.32

Scenario 2b: Primary exposure during disinfection of surfaces by mopping – large area

Description of Scenario 2b – (large area)
The product is poured into a suitable container where cleanroom mops are saturated with the product. The product is then applied to the surface to be disinfected using a cleanroom mop at an application rate of 50 mL/m^2. Pouring of the product into a suitable container is considered under Scenario 1 above. Mopping can be used to disinfect large areas such as floors, walls and ceilings. A professional user is exposed to the product during evaporation of the disinfected surface via inhalation. Mopping in cleanrooms is usually performed once a week or month depending on cleanroom protocols. Workers are likely to be designated to mop cleanrooms and therefore not stay in the room after mopping (i.e. in contrast to a laboratory worker whom disinfects small surfaces routinely e.g. work bench prior to conducting tasks in the cleanroom). As such, it is assumed that the worker will disinfect the floor from the furthest side towards the exit, leaving the room when the task is finished. 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 hydrogen peroxide, this model does not take into account exposure to vapour. As such, the air concentration of hydrogen peroxide has been calculated using ConsExpo Web exposure to vapour: evaporation model (increasing area) for the Tier 1 assessment with the model option "product is used in a pure form" as recommended in the Recommendation no. 16 BPC Ad hoc Working Group on Human Exposure Applicability of ConsExpo for water based disinfectants (Agreed at the Human Health Working Group III-2019 on 23 May 2019). Referring to the Recommendation no. 16, as the scenario covers a short exposure duration, this approach can overestimate exposure, because the delayed evaporation that can occur in the beginning of the application is not considered. A refined modelling

Description of Scenario 2b – (large area)		
(2-componet model) and risk mitigation measures are considered in Tier 2.		
	Parameters	Value
Tier 1	Adult body weight	60 kg
	Maximum concentration of hydrogen peroxide (see 2.2.6.2 text box)	6.67 % w/w
	Product density	1 g/mL
	Inhalation rate[1]	1.25 m^3/h
	Molecular weight	34 g/mol
	Vapour pressure of hydrogen peroxide at 20°C	214 Pa
	Product amount	1100 g (50 mL product/m^2 x 22 m^2)
	Exposure duration[2]	5 mins
	Room volume[3]	55 m^3
	Ventilation rate[4]	360/h
	Application duration[2]	5 mins
	Release area	22 m^2
	Mass transfer rate (default value)	10 m/h
Tier 3	Penetration through respiratory protection equipment (RPE with gas/vapour filter: APF = 10)	10%
[1] default Inhalation rate according to General Fact Sheet, General default parameters for estimating consumer exposure (RIVM report 090013003/2014) [2] according to Recommendation no. 6 – PT2, mopping 5 min/room [3] according to Recommendation no. 15 – size of a cleanroom [4] provided by the applicant according to the standard ISO 14644-1:2015 Cleanrooms and associated controlled environments — Part 1, Class A/B.		

Calculations for Scenario 2b

Summary table: estimated exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated air concentration (mg a.s./m^3)**
Scenario 2b	1 (no RPE)	15
Scenario 2b	2 (no RPE)	1.22
Scenario 2b	3 (RPE)	0.12

Scenario 3 – Primary exposure during spray application using a trigger spray bottle

Description of Scenario 3		
A professional user disinfects surfaces in a cleanroom using a trigger spray bottle at an application rate of 50 mL/m². The product is sprayed onto a suitable cleanroom wipe and then applied to the surface to be disinfected. Due to the high vapour pressure of hydrogen peroxide, the evaporation phase of the product on the surface is the worst-case scenario. As such, the air concentration of hydrogen peroxide has been calculated using ConsExpo Web exposure to vapour: evaporation model (increasing area) for the Tier 1 assessment with the model option "product is used in a pure form" as recommended in the Recommendation no. 16 BPC Ad hoc Working Group on Human Exposure Applicability of ConsExpo for water based disinfectants (Agreed at the Human Health Working Group III-2019 on 23 May 2019). The ventilation rate in cleanrooms varies based on cleanroom standards where lower ventilation rates are observed in higher classed cleanrooms with higher levels of particulates. According to the guidelines produced by the FDA (Guidance for Industry: Sterile drug products produced by aseptic processing – Current Good Manufacturing Practice, 2004), the minimum air exchange rate for ISO 8 cleanrooms is 20 times/hour therefore a ventilation rate of 20 air changes/hour is used in ConsExpo Web as a worst-case scenario. Referring to the Recommendation no. 16, as the scenario covers a short exposure duration, this approach can overestimate exposure, because the delayed evaporation that can occur in the beginning of the application is not considered. A refined modelling (2-componet model) and risk mitigation measures are considered in Tier 2.		
	Parameters	Value
Tier 1	Adult body weight	60 kg
	Concentration of active (see 2.2.6.2. text box)	6.67% w/w
	Product density	1 g/mL
	Vapour pressure for hydrogen peroxide at 20°C	214 Pa
	Inhalation rate[1]	1.25 m³/h
	Molecular weight	34 g/mol
	Product amount[2]	25 g (50 mL product/m² x 0.5 m²)
	Exposure duration[2]	45 mins
	Room volume[2]	55 m³
	Release area[2]	0.5 m²
	Application duration[2]	1 min
	Ventilation rate[2]	20/h
	Mass transfer rate (default value)	10 m/h
Tier 3	Ventilation rate[3]	360/h
[1] Default Inhalation rate according to General Fact Sheet, General default parameters for		

Description of Scenario 3
estimating consumer exposure (RIVM report 090013003/2014) [2] according to Recommendation no. 15 BPC Ad hoc Working Group on Human Exposure Harmonisation of PT2 small surface disinfection exposure scenarios for biocidal products containing highly volatile active substances by RTU wipes and trigger sprayer (Agreed at the Human Health Working Group VII-2018 on 4 December 2018) [3] provided by the applicant according to the standard ISO 14644-1:2015 Cleanrooms and associated controlled environments — Part 1, Class A/B.

Calculations for Scenario 3

Summary table: estimated exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated air concentration (mg a.s./m³)**
Scenario 3	1 (no RPE)	5.8
Scenario 3	2 (no RPE)	5.5
Scenario 3	3 (no RPE)	0.34

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

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 cleanroom will be exposed to an air concentration that is less than 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 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 AEC.

Scenario 5 – Secondary exposure when a professional bystander (e.g. technician) re-enters a treated area after disinfection through spraying

Description of Scenario 5
Exposure may occur to professional bystanders (e.g. technicians) in cleanrooms where surface disinfection is performed using a trigger spray to apply the product to a cleanroom wipe and then onto the surface to be disinfected. It is reasonable to assume that bystanders in a treated cleanroom 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 user as peak air concentration is below the AEC of 1.25 mg/m³ (please refer to Scenario 3). 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 cleanroom wipe the surface dry) the primary scenario considered 30 mins exposure duration covers the contact time 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.

Scenario 6 – Application (inside isolators and Restricted Access Barrier Systems (RABS))

Description of Scenario 6
The professional user applies the product inside the isolator or RABS either by spraying onto a suitable cleanroom wipe and applying to the surface, or by pouring the product into a suitable container and applying it to the surface using a cleanroom wipe or mop (Figures 1 and 2). The isolator or RABS is a closed system whereby users place their hands inside built-in gloves to apply the product to the surface or equipment to be disinfected. Please see Figures 3 and 4 for examples. Users will also be wearing standard cleanroom PPE (garments, gloves, masks and glasses). The isolators and RABS have their own High Efficiency Particulate Air (HEPA) filters and/or Ultra Low Particulate Air (ULPA) air filtration units and are present within cleanrooms as isolated units which prevent transfer of air, particulates and other contaminants between the unit and the user. Such units provide the most effective protection from airborne impurities and act as a barrier which excludes inhalation exposure during use of the biocidal products.

Combined scenarios

The adverse effects of hydrogen peroxide in humans are limited to local effects and potential systemic effects are secondary, therefore combined exposure scenarios are not relevant for hydrogen peroxide.

Exposure of the general public

The general public do not have entry into cleanrooms, which are highly controlled environments.

Dietary exposure

Exposure to hydrogen peroxide via the diet is not expected for the proposed uses of the Contec Hydrogen Peroxide Biocidal Product Family.

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

The modelling of exposures and subsequent risk characterisation during production and formulation of products in Contec Hydrogen Peroxide Biocidal Product Family is addressed under EU legislation (e.g. Directive 98/24/EC) and is not repeated under BPR, Regulation (EU) 528/2012 (agreed at Biocides Technical Meeting TMI06).

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated air conc. of hydrogen peroxide (mg/m^3)**
1.	Professionals: primary exposure during pouring of the product from a 0.5, 1 or 5 L container	1 (no PPE)	1.4
		2 (no PPE)	0.66
2a.	Professionals: primary exposure during disinfection of surfaces via wiping – small area	1 (no PPE)	0.32
2b.	Professionals: primary exposure during disinfection of surfaces via mopping – large area	1 (no PPE)	15
		2 (no PPE)	1.22
		3 (RPE)	0.12
3.	Professionals: primary exposure during disinfection of hard surfaces via a trigger spray (sprayed onto wipe then applied by wiping)	1 (no PPE)	5.8
		2 (no PPE)	5.5
		3 (no PPE)	0.34
4.	Professionals: secondary exposure from re-entering a treated area disinfected via mopping/wiping	1 (no PPE)	Please refer to Scenario 4 in section 2.2.4.2 for full details of the scenario conducted.
5.	Professionals: secondary exposure from re-entering a treated area disinfected via spraying (sprayed onto wipe then applied by wiping)	1 (no PPE)	≤0.32
6.	Application (inside isolators and RABS)	1	-

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
$AEL_{short-term}$	N/A	-	-	-	-
$AEL_{medium-term}$	N/A	-	-	-	-
$AEL_{long-term}$	N/A	-	-	-	-
AEC short, medium and long	90 Day rat inhalation study	10 mg/m³	8	-	1.25 mg/m³
ARfD	N/A	-	-	-	-
ADI	ADI not established; the substance is not systemically available.	-	-	-	-

[1] Assessment factor is based on interspecies variability (2.5) and an intraspecies factor (3.2)

Risk for industrial users

This product family 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

Inhalation exposure: quantitative risk assessment for local respiratory effects

Task/ Scenario	Tier (PPE)	AEC (mg a.s./ m³)	Estimated air conc. (mg a.s./ m³)	Estimated air conc./ AEC (%)	Acceptable (yes/no)
Scenario 1 – primary exposure during pouring of the product from a 0.5 L, 1 L or 5 L container	1 (no PPE)	1.25	1.4	112%	no
	2 (no PPE)		0.66	53%	yes
Scenario 2a – primary exposure during disinfection of surfaces by wiping – small area	1 (no PPE)	1.25	0.32	26%	yes
Scenario 2b – primary exposure during disinfection of surfaces by mopping – large area	1 (no PPE)	1.25	15	1200%	no
	2 (no PPE)		1.22	98%	yes
	3 (RPE)		0.12	10%	yes

Task/ Scenario	Tier (PPE)	AEC (mg a.s./ m³)	Estimated air conc. (mg a.s./ m³)	Estimated air conc./ AEC (%)	Acceptable (yes/no)
Scenario 3 - primary exposure during disinfection of hard surfaces via a trigger spray (sprayed onto wipe then applied by wiping)	1 (no PPE)	1.25	5.8	464%	no
	2 (no PPE)	1.25	5.5	440%	no
	3 (no PPE)	1.25	0.34	27 %	yes
Scenario 4 – secondary exposure from re-entering areas treated via wiping/mopping	1 (no PPE)	1.25	Please refer to Scenario 4 in section 2.2.4.2 for full details of the scenario conducted.		yes
Scenario 5 - secondary exposure from re-entering areas treated via spraying (sprayed onto wipe then applied by wiping)	1 (no PPE)	1.25	≤0.32	≤26%	yes
Scenario 6 - Application (inside isolators and RABS)	1	1.25	0	0	yes

The risk to professional users is demonstrated to be acceptable during pouring of the product from a container taking into account a risk mitigation measure related to a ventilation rate 3 air changes/hour.

The risk to professional users is demonstrated to be acceptable for wiping in small areas and for spraying application taking into account a risk mitigation measures related to a ventilation rate of 360 air changes/hour. The risk to professional users is demonstrated to be acceptable for mopping application in large scale, after refinement taking into account respiratory protective equipment (RPE 10) and a risk mitigation measures related to a ventilation rate of 360 air changes/hour. Although the exposure is lower than the AEC even in the case of the use of sufficient ventilation (360 air changes/ hour), we are of the opinion that the simultaneous use of RPE is necessary for the following reasons:

- The exposure value is near the AEC (98 % AEC). As the exposure duration (5 min) may vary in the course of the practical work, the additional safety measure (RPE) is justified.
- Possible and feasible technical measures (such as the ventilation rate) should be preferred to organizational measures and to personal safety equipment.
- The lower ventilation rate would result in significant higher exposure. Based on the modelled data, the worker would still be protected by RPE. On the contrary, in case of insufficient use of RPE or accident, the worker would be much more exposed and endangered. Therefore, the use of technical protection measures (such as the ventilation rate of 360 air changes/ hour) is nevertheless recommended.

The risk to professional bystander during application of product is acceptable under the same conditions as for operator. All personnel must leave the room after mopping. Re-entry without RPE is possible when concentration of hydrogen peroxide is under 1.25 mg/m³.

The risk to professional users is demonstrated to be acceptable for the application through isolators and RABS for which there is no inhalation exposure.

Qualitative risk assessment for local effects

Hazard	**Exposure**								**Risk**		
Hazard category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk	Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)
Low	Eye irrit. Cat. 2, H319	Concentration: 6.67 % Classification limit: 5 % ≤ C < 8 % (eye irritation)	2	Professional user	Pouring of the product from a 0.5 L, 1 L or 5 L container (Scenario 1)	Eye: - hand to eye transfer - splashing into eye	Few minutes per day or less	6.67 % hydrogen peroxide	**RMM** Labelling according to CLP. Organisational RMM such as training for staff on good practice, good standard of personal hygiene. Minimisation of splashes and spills. Avoidance of contact with contaminated tools and objects. Management and supervision in place to check that the RMMs in place are being used correctly and organisational controls followed. **PPE** Eye protection (chemical googles or face protection)	Acceptable + Used with low frequency + Only used by trained professionals + Used in areas with ventilation + Detailed instructions for use and training provided to end users (beyond label content) + Professionals using PPE where required	Frequency of use may be higher than recommended (↑) Instructions for use and adherence to it, may vary (↑↓)
Low	Eye irrit. Cat. 2, H319	Concentration: 6.67 % Classification limit: 5 % ≤ C < 8 % (eye irritation)	2	Professional user	Application inside cleanrooms: - wiping (Scenario 2a) - mopping (Scenario 2b)	Eye: - hand to eye transfer - splashing into eye	Few minutes per day or less	6.67 % hydrogen peroxide	**RMM** Labelling according to CLP. Organisational RMM such as training for staff on good practice, good standard of personal hygiene. Minimisation of splashes	Acceptable + Used with low frequency + Used in areas of high ventilation	Frequency of use may be higher than recommended (↑) Instructions

Hazard	Exposure								Risk		
Hazard category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk	Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)
					- spraying (Scenario 3)				and spills. Avoidance of contact with contaminated tools and objects. Very high standard of ventilation (For use in cleanrooms, adequate technical/engineering controls to remove airborne residues is mandatory e.g. room ventilation or LEV.) Management and supervision in place to check that the RMMs in place are being used correctly and organisational controls followed. **PPE** Eye protection (chemical googles or face protection)	+ Only used by trained professionals + Only used in cleanrooms where full PPE is worn by default + High degree of operational RMM in place (LEV and high ventilation) + Detailed instructions for use and training provided to end users (beyond label content) + Professionals using PPE where required	for use and adherence to it, may vary (↑↓)

Hazard	Exposure								Risk		
Hazard category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk	Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)
Low	Eye irrit. Cat. 2, H319	Concentration: 6.67 % Classification limit: 5 % ≤ C < 8 % (eye irritation)	2	Professional user	Application inside isolators and Restricted Access Barrier Systems) – Scenario 6	Eye: - hand to eye transfer - splashing into eye	Few minutes per day or less	Negligible – isolators and RABS are closed systems with a barrier between the user and the product	**RMM** Labelling according to CLP. Organisational RMM such as training for staff on good practice, good standard of personal hygiene. Minimisation of splashes and spills. Avoidance of contact with contaminated tools and objects. Very high standard of ventilation. Management and supervision in place to check that the RMMs in place are being used correctly and organisational controls followed. **PPE** Due to negligible exposure, PPE is not required during application of product inside isolators and RABS.	Acceptable + Used with low frequency + No exposure is expected + Used in areas of high ventilation + Only used by trained professionals + Used in isolators and RABS in cleanrooms where full PPE is worn by default + High degree of operational RMM in place – isolators and RABS are closed systems with a physical barrier for the user + Detailed	Frequency of use may be higher than recommended (↑) Instructions for use and adherence to it, may vary (↑↓)

Hazard	Exposure								Risk		
Hazard category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk	Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)
										instructions for use and training provided to end users (beyond label content)	

Exposure towards the active substance hydrogen peroxide results in acceptable risk for the professional user. A detailed conclusion on the risk is provided in the respective columns of the table above.

Conclusion

The risk to professional users when products are used for disinfection in isolators and RABS is demonstrated to be acceptable (Use #1, Use #2). No exposure to active substance hydrogen peroxide is expected, since isolators and RABS are closed systems with a barrier between the user and the product. To additionally reduce the risk the following RMM are proposed:

- Avoid hand to eye transfer.
- Used wipes must be disposed in a closed container.

The risk to professional users when products are used in cleanrooms is demonstrated to be acceptable with the following risk mitigation measure and use-specific description:

- For Use #4 professional pouring product into a container and wiping small areas or mopping large areas:
  - Pouring of product shall be done in ventilated rooms only (with min. 3 air changes/h).
- For Use #3 professional spaying into cleanroom wipe and wiping and Use #4 professional pouring product into a container and wiping small areas:
  - The use of eye protection during handling of the product is mandatory.
  - For use in cleanrooms, adequate technical/engineering controls to remove airborne residues is mandatory e.g. room ventilation or LEV. A minimum ventilation rate of 360/hr is mandatory for cleanrooms where the product is applied.
- For Use #4 professional pouring product into a container and mopping large areas:
  - The use of eye protection during handling of the product is mandatory.
  - For use in cleanrooms, adequate technical/engineering controls to remove airborne residues is mandatory e.g. room ventilation or LEV. A minimum ventilation rate of 360/hr is mandatory for cleanrooms where the product is applied.
  - Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory for the professional user and all other personnel within the room. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).
  - All personnel must leave the room after mopping.
  - Technical or engineering controls to remove airborne residues is mandatory (e.g. ventilation or LEV) before personnel are permitted to enter into treated areas after large surface disinfection. Monitor the air concentration and ensure that the limit value (1.25 mg/m^3) is not exceeded when personnel re-enter the area.

To further reduce the possibility of inhalation exposure the following risk mitigation measure is proposed:

- Used wipes must be disposed in a closed container.

Risk for non-professional users

The product family is not intended for non-professional use.

Risk for the general public

The general public have no access to cleanrooms.

Risk for consumers via residues in food

Exposure to hydrogen peroxide via the diet is not expected from the proposed use of Contec Hydrogen Peroxide Biocidal Product Family in cleanrooms.

Overall conclusion on risk assessment for human health

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
1 (meta SPC 1)	Application by trigger spray onto a suitable cleanroom wipe to distribute onto the inner surface of isolators and Restricted Access Barrier Systems (RABS)	Acceptable with RMM	Avoid hand to eye transfer. Used wipes must be disposed in a closed container.
2 (meta SPC 1)	Application by pouring into a container and using a suitable cleanroom wipe or mop to distribute onto the inner surface of isolators and Restricted Access Barrier Systems (RABS)	Acceptable with RMM	Avoid hand to eye transfer. Used wipes must be disposed in a closed container.
3 (meta SPC 1)	Application by trigger spray onto a suitable cleanroom wipe to distribute onto the surface of cleanrooms	Acceptable with RMM	The use of eye protection during handling of the product is mandatory. For use in cleanrooms, adequate technical/engineering controls to remove airborne residues is mandatory e.g. room ventilation or LEV. A minimum ventilation rate of 360/hr is mandatory for cleanrooms where the product is applied. Used wipes must be disposed in a closed container.
4 (meta SPC 1)	Application by pouring into a container and using a suitable cleanroom wipe or mop to distribute onto the surface of cleanrooms	Acceptable with RMM	*Pouring of the product from a container only:* Pouring of product shall be done in ventilated rooms only (with min. 3 air changes/h). *Small and large scale application:* The use of eye protection during handling of the product is mandatory. For use in cleanrooms, adequate technical/engineering controls to remove airborne residues is mandatory e.g. room ventilation or LEV. A minimum ventilation rate of 360/hr is mandatory for cleanrooms where the product is applied. Used wipes must be disposed

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
			in a closed container. *Large scale application:* Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory for the professional user and all other personnel within the room. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information). All personnel must leave the room after mopping. Technical or engineering controls to remove airborne residues is mandatory (e.g. ventilation or LEV) before personnel are permitted to enter into treated areas after large surface disinfection. Monitor the air concentration and ensure that the limit value (1.25 mg/m^3) is not exceeded when personnel re-enter the area.

2.2.7 Risk assessment for animal health

Animals will not be present in cleanrooms.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The products of the biocidal product family contain only one active substance and no substances of concern. Therefore, all toxicity data can be obtained from the active substance Assessment Report (2015):

$PNEC_{aquatic}$ = 12.6 µg/L
$PNEC_{STP}$ = 4.66 mg/L
$PNEC_{soil}$ = 0.0018 mg/kg ww soil

Considering the low log K_{OW} of −1.57, the expected low adsorption to organic matter (log K_{OC} is 0.2036 mL/g) and its generally rapid abiotic degradation in surface waters, hydrogen peroxide is not expected to partition into the sediment. Because of the lack of exposure, a proposal for a PNEC for sediment-dwelling organisms is not considered necessary and the ratio PEC/PNEC for freshwater covers that of sediment as well.

The log K_{OW} of −1.57 is indicating no potential for bioaccumulation. Therefore, hydrogen peroxide has only low potential to accumulate in living organisms and effect assessment through primary/secondary poisoning has not been carried out.

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

The active substance hydrogen peroxide is the only substance of environmental concern among the components in the Contec Hydrogen Peroxide Biocidal Product Family. Therefore, additional ecotoxicological studies are not required for product authorisation and the classification of the BPF can be based on the active substance only.

The a.s. does not have a harmonised environmental hazard classification. An environmental hazard classification Aquatic Chronic 3 (H412) was proposed in the Assessment Report for the a.s. As the a.s. is only present at a maximum of 6.67 %, no environmental hazard classification (under Reg. (EC) 1272/2008) is required for the Contec Hydrogen Peroxide Biocidal Product Family.

Further Ecotoxicological studies

No further data are available other than the studies presented in the dossier of hydrogen peroxide. The ecotoxicity of the BPF can be assessed on the basis of the active substance as no other ecotoxicologically relevant components are present in the Contec Hydrogen Peroxide Biocidal Product Family.

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)

No further data are available other than the studies presented in the dossier of hydrogen

peroxide. The ecotoxicity of the BPF can be assessed on the basis of the active substance as no other ecotoxicologically relevant components are present in the Contec Hydrogen Peroxide Biocidal Product Family.

Data waiving	
Information requirement	Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk
Justification	No additional data are required.

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

No further trials have been conducted with the BPF. The ecotoxicity of the BPF can be assessed on the basis of the active substance as no other ecotoxicologically relevant components are present in the Contec Hydrogen Peroxide Biocidal Product Family.

Data waiving	
Information requirement	Supervised trials to assess risks to non-target organisms under field conditions
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

No further studies on acceptance by ingestion of the biocidal product by any non-target organisms have been conducted with the BPF. The ecotoxicity of the product can be assessed on the basis of the active substance as no other ecotoxicologically relevant components are present in the Contec Hydrogen Peroxide Biocidal Product Family.

Data waiving	
Information requirement	Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk
Justification	No additional data are required.

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

Secondary ecological effect studies may be required when a habitat such as a water body, wetland, forest or field is treated. No testing on secondary ecological effect is needed, as products within the Contec Hydrogen Peroxide Biocidal Product Family will not be applied to large proportions of a specific habitat.

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

The products within the Contec Hydrogen Peroxide Biocidal Product Family contain 6.67 % hydrogen peroxide as the active substance. Products are ready to use disinfectants in PT 2 for application by spraying onto a suitable cleanroom wipe and applying to the surface, or by pouring the product into a suitable container and applying to the surface using a cleanroom wipe or mop.

It is expected that emissions into air are considered to be negligible and do not alter

existing background concentrations in the troposphere to any relevant degree. Conversely, (wet) cleaning of treated surfaces within industrial and institutional areas of up to 1000 m^2 per day per site can lead to significant losses to drains, which will then arrive at local STP and have the potential to reach surface waters, sediment, agricultural soil and groundwater at concentrations that require consideration.

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

Based upon the PT 2 use pattern of the Contec Hydrogen Peroxide Biocidal Product Family and information contained in the AR for hydrogen peroxide (including rapid degradation in soil, air, water and at STP), no further testing is deemed necessary.

Leaching behaviour (ADS)

The performance of a study on leaching (e.g. from treated surfaces) is neither applicable nor relevant for intended uses within PT 1-5.

Testing for distribution and dissipation in soil (ADS)

No further studies for distribution and dissipation in soil have been conducted with the BPF. The ecotoxicity of the BPF can be assessed on the basis of the active substance as no other ecotoxicologically relevant components are present in the Contec Hydrogen Peroxide Biocidal Product Family.

Data waiving	
Information requirement	Testing for distribution and dissipation in soil
Justification	No further distribution and dissipation studies in soil are required as the information on distribution and degradation for the active substance present in the BPF is sufficient.

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

No further studies for distribution and dissipation in water and sediment have been conducted with the BPF. The ecotoxicity of the BPF can be assessed on the basis of the active substance as no other ecotoxicologically relevant components are present in the Contec Hydrogen Peroxide Biocidal Product Family.

Data waiving	
Information requirement	Testing for distribution and dissipation in water and sediment
Justification	No further distribution and dissipation studies in water and sediment are required as the information on distribution and degradation for the active substance present in the BPF is sufficient.

Testing for distribution and dissipation in air (ADS)

No further studies for distribution and dissipation in air have been conducted with the BPF. The ecotoxicity of the BPF can be assessed on the basis of the active substance as no other ecotoxicologically relevant components are present in the Contec Hydrogen Peroxide Biocidal Product Family.

Data waiving	
Information requirement	Testing for distribution and dissipation in air
Justification	Due to the low Henry's law constant of 7.5E-04 Pa m^3/mol (at 20°C) and short DT_{50} in air (24 h), emissions into air are considered to be negligible. No other ecotoxicologically relevant components are present in the BPF. Testing for distribution and dissipation in air is therefore not considered relevant.

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)

No spray application near surface waters is foreseen and therefore further studies to assess the risk to aquatic organisms or plants under field conditions are not 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 (over)spray application is foreseen and therefore further studies to assess the risk to bees and other non-target arthropods under field conditions are not required.

2.2.8.2 Exposure assessment

Products are ready to use disinfectants in PT 2 (Disinfectants and algaecides not intended for direct application to humans or animals) for application by spraying onto a suitable cleanroom wipe and applying to the surface, or by pouring the product into a suitable container and applying to the surface using a cleanroom wipe or mop. The product may also be applied using pre-saturated cleanroom wipes. The products are only to be used by professionals, indoors for the disinfection of cleanroom surfaces or inside isolators and Restricted Access Barrier Systems (RABS).

General information

Assessed PT	PT 2
Assessed scenarios	Scenario 1: Disinfectants for industrial and institutional areas – small scale application (Chapter 2.1, PT 2 ESD; 2011) Scenario 2: Disinfectants for industrial and institutional areas – large scale application (Chapter 2.1, PT 2 ESD; 2011) Scenario 3: Disinfectants for industrial and institutional areas – tonnage based approach (Chapter 2.1, PT 2 ESD; 2011)
ESD(s) used	Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products, 2011
Approach	Scenario 1: Average-consumption Scenario 2: Average-consumption Scenario 3: Tonnage approach
Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulation, vol. IV – Parts B + C (2017)

Groundwater simulation	No
Confidential Annexes	Yes, applicant's own tonnage information and related input parameters for tonnage based $Elocal_{water}$ determination can be found in confidential annex
Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: No
Remarks	None

Emission estimation

Scenario 1, 2 & 3

The consumption of hydrogen peroxide can be calculated as follows:

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: Disinfectants for industrial and institutional areas – small scale application			
Application rate of biocidal product	0.04	L/m²	*c.f.* 2.2.1
Concentration of active substance in the product	66.7	g/L	6.67% (w/w)
Surface area to be disinfected per day (with an Nappl of 1)	25	m²	ENV 46 (TAB 2.1): small scale application (RTU)
Local release to wastewater (assuming an F_{water} fraction of 1)	6.67E-02	kg/d	
Scenario 2: Disinfectants for industrial and institutional areas – large scale application			
Application rate of biocidal product	0.05	L/m²	*c.f.* 2.2.1
Concentration of active substance in the product	66.7	g/L	6.67% (w/w)
Surface area to be disinfected per day (with an Nappl of 1)	1000	m²	Default ESD PT02
Local release to wastewater (assuming an F_{water} fraction of 1)	3.34E+00	kg/d	
Scenario 3: Disinfectants for industrial and institutional areas – tonnage*			
Annual tonnage	*confidential*	tonnes/year	Provided by the applicant
Local release to wastewater	*confidential*	kg/d	See confidential annex
* For reasons of confidentiality, the actual value for annual tonnage given by the applicant and all relevant input values to derive $Elocal_{water}$ and final daily discharge value can be found in the confidential annex to this PAR			

It is noted that the PT 2 CAR for hydrogen peroxide takes a different approach to emission assessment to local drain, as losses are only based upon the amount of hydrogen peroxide used to disinfect a large room that deposits on surfaces and could be released to drains from wet cleaning. To cover such minor losses, a worst case emission

factor to sewage (F_{water}) of 5% of applied hydrogen peroxide was assumed. However, as this product application differs from the representative product, a worst case assessment for spray and cleanroom wipe application of 100% release to wastewater (F_{water} = 1) has been assumed (representing wet cleaning of the treated surfaces immediately following application).

Calculations for Scenario 1, 2 & 3

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

Resulting local emission to relevant environmental compartments (considering degradation in sewer)		
Scenario	**Local emission ($Elocal_{water}$) [kg/d]**	**Remarks**
Scenario 1	1.60E-03	
Scenario 2	8.02E-02	
Scenario 3	*Confidential*	See confidential annex

It is evident from calculations and discussion in confidential annex that an assessment using a consumption-based approach offers greater protection to environmental compartments and a more precautionary approach than one using applicant's confidential tonnage data averaged across the EU. Assessment will continue on the basis of scenario 1 (small scale consumption) and scenario 2 (large scale consumption). No further assessment of Scenario 3 (tonnage approach) will be undertaken.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway							
	Freshwater	**Freshwater sediment**	**STP**	**Air**	**Soil**	**Groundwater**	**Other**
Scenario 1	Y	Y	Y	N	Y	Y	N/A
Scenario 2	Y	Y	Y	N	Y	Y	N/A

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	34.01	g/mol	
Melting point	-0.43	°C	
Boiling point	150.2	°C	
Vapour pressure (at 20°C)	214	Pa	
Water solubility (at 20°C)	1.0E+05	mg/L	Maximum EUSES value available
Log Octanol/water partition coefficient	−1.57	Log 10	

Input parameters (only set values) for calculating the fate and distribution in the environment			
Organic carbon/water partition coefficient (K_{OC})	1.598	L/kg	Based on calculated log Koc of 0.2036
Henry's Law Constant (at 20°C)	7.5E-04	Pa m^3/mol	
Biodegradability	Not relevant		Compound is not organic
Rate constant for STP	21	h^{-1}	
DT_{50} for biodegradation in surface water	5	d	Estimated value
DT_{50} for degradation in soil	12	h	Estimated value
DT_{50} for degradation in air	24	h	Estimated value

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
Air	1.66E-4	SimpleTreat 3.1
Water	0.687	
Sludge	0.0145	
Degraded in STP	99.3	

Please note that according to the ENV 9 (TAB 2.1), SimpleTreat 4.0 should have been used for the calculations. Nevertheless, calculations as performed were not corrected as the overall outcome of the risk assessment does not change.

Calculated PEC values

Please refer to Annex 3.2 for further details on the PEC calculations.

Summary table on calculated PEC values			
	PEC_{STP}	**PEC_{water}**	**PEC_{soil}**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]
Scenario 1	5.50E-06	5.50E-07	1.04E-08
Scenario 2	2.75E-04	2.75E-05	5.20E-07

Primary and secondary poisoning

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

Secondary poisoning
Substance is unlikely to bioaccumulate in aquatic or terrestrial environment. It has a low log K_{ow} (−1.57), it is not highly adsorptive, it does not belong to a class of substances known to have a potential to accumulate in living organisms, its structural features do not indicate accumulation and has a short degradation half-life of 5 days in the surface water test. The low accumulation potential is supported by low BCF and BMF for fish and earthworms of 1.4 and 0.84, respectively (AR 2015). No further assessment of

secondary exposure via the food chain is therefore considered necessary.

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: The physical properties of hydrogen peroxide do not suggest that the use of the Contec Hydrogen Peroxide Biocidal Product Family applied by trigger spray, mop or cleanroom wipe will pose a risk to the atmospheric environment. Therefore, no further assessment for this compartment is required.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{STP}$
Scenario 1	1.18E-06
Scenario 2	5.91E-05

Conclusion: The resulting PEC/PNEC ratios at local STP indicate acceptable risks to STP micro-organisms.

Aquatic compartment

Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{water}$
Scenario 1	4.37E-05
Scenario 2	2.19E-03

As there are no measured effects data for hydrogen peroxide in the sediment compartment, PEC$_{sediment}$ were not calculated, and the risk to sediment is considered to be identical to the risk posed to the aquatic compartment.

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.

Terrestrial compartment

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
Scenario 1	5.77E-06
Scenario 2	5.19E-07

Conclusion: Predicted soil concentrations (PECs) have been calculated only from the indirect exposure to soil via sewage sludge application, as direct soil exposure is not

expected from the proposed biocidal uses. The resulting PEC/PNEC ratios in receiving compartment indicate acceptable risks to terrestrial organisms.

Groundwater

At the ENV WG-II-2019 it was agreed that for rapidly reacting substances (e.g. substances reacting with organic matter) no groundwater assessment is needed since it is very unlikely that substance will reach the groundwater. For this reason, no groundwater assessment for hydrogen peroxide is considered necessary.

Primary and secondary poisoning

Primary poisoning
Not relevant

Secondary poisoning
As stated within the PT 1 – 6 review document, "the estimated log K_{ow} of hydrogen peroxide is –1.57 indicating a negligible potential of the compound to bioconcentrate in biota. The BCFs calculated according to TGD (EUSES 2.1) for fish and earthworm are 1.4 and 0.84, respectively. The accumulation of hydrogen peroxide in the food chain is not expected and the risk of secondary poisoning in aquatic and terrestrial biota is considered negligible." Therefore, no further assessment is considered necessary.

Endocrine disruption

The Assessment Report for hydrogen Peroxide states that:

> *Hydrogen peroxide is not included in the Commission staff working document on implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706)). There is no evidence of any endocrine disruption potential in the human health or ecotoxicological studies presented in the dossier.*

An endocrine disruption assessment for the formulation of the product family is provided within the Member State Confidential Annex to this PAR. Based on the considered data, neither the active substance, nor the co-formulants of these BPs have shown endocrine disrupting properties for the non-target organisms. Therefore, in line with document CA-MARC18-Doc.7.3.b-final, it could be concluded that the BPF has no ED potential either.

Mixture toxicity

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

However, it is noted that the active substance itself is highly reactive and requires the presence of several stabilisers and passivators as part of the manufacturing process (as outlined in the hydrogen peroxide CAR) to prevent rapid breakdown during storage. When considering both the classification of these additives under latest CLH regulations and maximum concentrations likely to be present within Contec Hydrogen Peroxide Biocidal Product Family, none of the compounds can be considered as environmental

"Substances of Concern" within formulations containing up to 6.67% (w/w) hydrogen peroxide. Again, no mixture toxicity has been considered relevant.

Aggregated exposure (combined for relevant emission sources)

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

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

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

Overall conclusion on the risk assessment for the environment of the product
Based upon the proposed use patterns in PT 2 whereby Contec Hydrogen Peroxide Biocidal Product Family will be applied indoors by professionals, then all risks to environmental compartments resulting from potential emissions during application and cleaning events have been shown to be acceptable. Authorisation of this biocidal product family at 6.67% (w/w) a.s. may therefore be granted in line with directions for use and instructions stated in the SPC and proposed product labelling. No further restrictions or mitigation measures are considered necessary from an environmental fate and behaviour perspective.

2.2.9 Measures to protect man, animals and the environment

Please see section 2.1.4 and 2.1.5 of this PAR and the SPC for information.

2.2.10 Assessment of a combination of biocidal products

Not applicable: this product family is not intended to be authorised for the use with other biocidal products.

3 Annexes

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, 3.2-01, 3.3, 3.9	[redacted]	2016a	Chemical and Physical Characterization on test item 'Contec HydroPure SBT16PW' [redacted] Contec Cleanroom (UK) Ltd. [redacted] GLP, Unpublished	Y	CON
3.2-02	[redacted]	2018a	pH and Acidity/Alkalinity Determination on the Test Item "CONTEC HYDROPURE" [redacted] Contec Cleanroom (UK) Ltd. [redacted] GLP, Unpublished	Y	CON
3.2-03	[redacted]	2018b	pH and Acidity/Alkalinity Determination on the Test Item "CONTEC HYDROKLEAN" [redacted] Contec Cleanroom (UK) Ltd. [redacted] GLP, Unpublished	Y	CON
3.4.1	[redacted]	2016	Biocide Product Regulation: Method for analytical support [redacted] Contec Cleanroom (UK) Ltd. [redacted] Non-GLP, Unpublished	Y	CON
3.4.1-01	[redacted]	2017	Accelerated Stability Study at 30°C/65%RH for 18 weeks on the test item Contec HydroPure SBT16HPW [redacted] Contec Cleanroom (UK) Ltd. [redacted] GLP, Unpublished	Y	CON
3.5-13	[redacted]	2018	CONTROL OF CRITICAL PARAMETERS UNDER STABILITY CONDITIONS - Ambient [redacted] Contec Cleanroom (UK) Ltd. [redacted] 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
3.5.12	[redacted]	2016	Contec HydroPure - Spray Pattern Investigation [redacted] Contec Cleanroom (UK) Ltd. Non-GLP , Unpublished	Y	CON
3.8	[redacted]	2016	Surface Tension on the sample Contec HydroPure SBT16HPW [redacted] Contec Cleanroom (UK) Ltd. [redacted] GLP, Unpublished	Y	CON
4.1, 4.6, 4.17.1	[redacted]	2021	Contec HydroPure: Determination of the Physico-chemical properties [redacted] No GLP unpublished	Y	CON
4.4	[redacted]	2014	Division 5.1 Oxidizer Testing [redacted] Contec Cleanroom (UK) Ltd. [redacted] Not-GLP, Unpublished	Y	CON
4.16	[redacted]	2020	Immersion Testing to UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part III sub-section 37 [redacted] Contec Cleanroom (UK) Ltd. [redacted] GLP, Unpublished	Y	CON
4.16	[redacted]	2020	Active ingredient determination of Contec HydroPure at set intervals during storage at 55°C [redacted] Contec Cleanroom (UK) Ltd. [redacted]	Y	CON
4.16	[redacted]	2020	Hydrogen Peroxide Corrosion to Metals Testing [redacted] Contec Cleanroom (UK) Ltd. [redacted]	Y	CON
5.1	[redacted]	2016b	Validation of an HPLC-UV	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
			method for the quantification of the active ingredient hydrogen peroxide in the test item Contec HydroPure SBT16HPW [redacted] Contec Cleanroom (UK) Ltd. [redacted] GLP, Unpublished		
6.7-01	[redacted]	2020	Microbiological Analysis Based on EN 1276 (2019) Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics (Phase 2 / Step 1) [redacted] Contec Cleanroom (UK) Ltd. [redacted]	Y	CON
6.7-02	[redacted]	2020	EN 1276:2019 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas [redacted] Contec Cleanroom (UK) Ltd. [redacted]	Y	CON
6.7-03, 6.7-06	[redacted]	2020	Microbiological analysis based on EN13697(2015)+A1:2019 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 [redacted] Contec Cleanroom (UK) Ltd. [redacted]	Y	CON
6.7-04	[redacted]	2020	EN 1650:2019 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial,	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
			domestic and institutional areas [redacted] Contec Cleanroom (UK) Ltd. [redacted]		
6.7-05	[redacted]	2020	Microbiological analysis based on EN1650(2019) Chemical disinfectants and antiseptics Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics [redacted] Contec Cleanroom (UK) Ltd. [redacted]	Y	CON
6.7-07	[redacted]	2021	Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical (4- field test) – (Phase 2/Step2) [redacted] Contec Cleanroom (UK) Ltd. [redacted]	Y	CON
6.7-08	[redacted]	2021	Microbiological Analysis Based on EN 16615 (2015) Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area. (Phase 2 / Step 2) [redacted] Contec Cleanroom (UK) Ltd. [redacted]	Y	CON
6.7-09	[redacted]	2021	Microbiological Analysis Based on EN 1650 (2019) Chemical disinfectants and antiseptics- Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food,	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
			industrial, domestic and institutional areas- Test method and requirements (Phase 2 / Step 1) [redacted] Contec Cleanroom (UK) Ltd. [redacted]		
6.7-10	[redacted]	2021	Microbiological Analysis Based on EN 13697 (2015) +A1:2019 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) [redacted] Contec Cleanroom (UK) Ltd. [redacted]	Y	CON

3.2 Output tables from exposure assessment tools

3.2.1 Human Exposure Assessment

Scenario 1 (Tier 1)

Details for Activity Scenario 1

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

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	293 K
Vapour pressure	214 Pa
Liquid mole fraction	0.04
Activity coefficient	0.8
Activity emission potential	
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 1 - 10 l/minute
Containment level	Open process
Loading type	Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely
Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes
Dispersion	
Work area	Indoors
Room size	Any size workroom

Risk Management Measures

Localised controls	
Primary	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 1.4 mg/m³.

The inter-quartile confidence interval is 0.68 mg/m³ to 2.9 mg/m³.

Scenario 1 (Tier 2)

Details for Activity Scenario 1

Emission sources: Near field ✓ Far field

Duration (mins): 10

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	293 K
Vapour pressure	214 Pa
Liquid mole fraction	0.04
Activity coefficient	0.8
Activity emission potential	
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 1 - 10 l/minute
Containment level	Open process
Loading type	Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely
Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes
Dispersion	
Work area	Indoors
Room size	Any size workroom

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)
Dispersion	
Ventilation rate	3 air changes per hour (ACH)

Predicted exposure levels

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

Mechanistic model results

The predicted 90th percentile full-shift exposure is 0.66 mg/m³.

The inter-quartile confidence interval is 0.33 mg/m³ to 1.4 mg/m³.

Scenario 2a

Scenarios

> Scenario *Scenario 2*

Scenario *Scenario 2*

Frequency	8	per day
Description	wiping small scale	

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	60	minute
Product is substance in pure form	Yes	
Amount of solution used	25	g
Weight fraction substance	6.67	%
Room volume	55	m³
Ventilation rate	360	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	1	minute
Absorption model	n.a.	

Results for scenario *Scenario 2*

☐ Show dose descriptions

Inhalation

Mean event concentration	8.3×10^{-2}	mg/m³
Peak concentration (TWA 15 min)	3.2×10^{-1}	mg/m³

Scenario 2 b (Tier 1)

Scenarios

> Scenario *Scenario 2b*

Scenario *Scenario 2b*

Frequency	1	per day
Description	mopping large area	

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	5	minute
Product is substance in pure form	Yes	
Amount of solution used	1100	g
Weight fraction substance	6.67	%
Room volume	55	m^3
Ventilation rate	360	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	20	°C
Vapour pressure	214	Pa
Molecular weight	34	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Increasing	
Release area	22	m^2
Application duration	5	minute
Absorption model	n.a.	

Results for scenario *Scenario 2b*

☐ Show dose descriptions

Inhalation

Mean event concentration	1.5×10^1	mg/m^3
Peak concentration (TWA 15 min)	1.5×10^1	mg/m^3

Scenario 2b (Tier 2)

Evaporation Model

General parameters used for all models

Exposure Duration	5	min
Molecular weight matrix	18	g/mol
Product amount	1,1	kg
Weight Fraction	6,67%	
Room Volume	55	m^3
Ventilation rate	360	/h
Vapour pressure	214	Pa
Application temperature	20	°C
Molecular weight	34	g/mol
Release Area	22	m^2
Mass Transfer Coefficient	10	m/h
Application Duration	5	min
Does area increase?	TRUE	
Number of iterations	10000	
Result Lines	100	
Duration of calculated STEL	15	min

calculate 1-compound model

calculate 2-compound model

Parameters used for 2 compound simulation

vapour pressure solvent	2338	Pa
air humidity at start & in ventillation air	50,00 %	% - Please enter 0, if solvent is NOT WATER

Results

	from shown table	from internally calculated values	
Mean Event concentration [mg/m^3]	0,5831	0,5828	
Max [mg/m^3]	1,223	1,223	at 5 min
5 min STEL [mg/m^3]		0,5828	between 0 and 5 min

Scenario 3 (Tier 1)

Scenarios

> Scenario *Scenario 3*

Scenario *Scenario 3*

Frequency	1	per day
Description	spray application using a trigger spray bottle	

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	30	minute
Product is substance in pure form	Yes	
Amount of solution used	25	g
Weight fraction substance	6.67	%
Room volume	55	m^3
Ventilation rate	20	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	20	°C
Vapour pressure	214	Pa
Molecular weight	34	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Increasing	
Release area	0.5	m^2
Application duration	1	minute
Absorption model	n.a.	

Results for scenario *Scenario 3*

☐ Show dose descriptions

Inhalation

Mean event concentration	3.0	mg/m^3
Peak concentration (TWA 15 min)	5.8	mg/m^3

Scenario 3 (Tier 2)

Evaporation Model

General parameters used for all models

Exposure Duration	45	min
Molecular weight matrix	18	g/mol
Product amount	0,025	kg
Weight Fraction	6,67%	
Room Volume	55	m^3
Ventilation rate	20	/h
Vapour pressure	214	Pa
Application temperature	20	°C
Molecular weight	34	g/mol
Release Area	0,5	m^2
Mass Transfer Coefficient	10	m/h
Application Duration	1	min
Does area increase?	TRUE	
Number of iterations	10000	
Result Lines	100	
Duration of calculated STEL	15	min

calculate 1-compound model

calculate 2-compound model

Parameters used for 2 compound simulation

vapour pressure solvent	2338	Pa
air humidity at start & in ventillation air	50,00 %	% - Please enter 0, if solvent is NOT WATER

Results

	from shown table	from internally calculated values	
Mean Event concentration [mg/m^3]	1,465	1,452	
Max [mg/m^3]	5,453	5,453	at 45 min
14,9985 min STEL [mg/m^3]		2,989	between 30,0015 and 45 min

Scenario 3 (Tier3)

Evaporation Model

General parameters used for all models

Exposure Duration	45	min
Molecular weight matrix	18	g/mol
Product amount	0,025	kg
Weight Fraction	6,67%	
Room Volume	55	m^3
Ventilation rate	360	/h
Vapour pressure	214	Pa
Application temperature	20	°C
Molecular weight	34	g/mol
Release Area	0,5	m^2
Mass Transfer Coefficient	10	m/h
Application Duration	1	min
Does area increase?	TRUE	
Number of iterations	10000	
Result Lines	100	
Duration of calculated STEL	15	min

calculate 1-compound model

calculate 2-compound model

Parameters used for 2 compound simulation

vapour pressure solvent	2338	Pa
air humidity at start & in ventillation air	50,00 %	% - Please enter 0, if solvent is NOT WATER

Results

	from shown table	from internally calculated values	
Mean Event concentration [mg/m^3]	0,1016	0,1010	
Max [mg/m^3]	0,3387	0,3387	at 45 min
14,9985 min STEL [mg/m^3]		0,2124	between 30,0015 and 45 min

3.2.2 Environmental Exposure Assessment

The section contains calculation that supplement the environmental exposure assessment presented within Section 2.2.8.2.

Contec Hydrogen Peroxide Biocidal Product Family is based on hydrogen peroxide as single a.s. for professional use only in isolators, cleanrooms and restricted barrier systems within an industrial environment. Emissions modelling based on use in industrial / institutional areas from Chapter 2.1 of the PT 2 ESD (2011) have been followed.

Calculation of PEC_{STP} and PEC_{water} (and $PEC_{sediment}$)

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.

$$Clocal_{inf} = \frac{Elocal_{water} \times 10^{6}}{EFLUENT_{stp}} \qquad (35)$$

$$Clocal_{eff} = Clocal_{inf} \times Fstp_{water} \qquad (36)$$

$$Clocal_{water} = \frac{Clocal_{eff}}{\left(1 + Kp_{susp} \times SUSP_{water} \times 10^{-6}\right) \times DILUTION} \qquad (48)$$

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 application

Parameters	Nomenclature	Scenario 1	Scenario 2	Unit
Local emission rate to (waste)water	$Elocal_{water}$	1.60E-03	8.02E-02	kg/d
Effluent discharge rate of STP	$EFFLUENT_{stp}$	2.00E+06	2.00E+06	L/d
Concentration in untreated water	$Clocal_{inf}$	8.00E-04	4.01E-02	mg/L
Fraction of emission directed to water by STP	$Fstp_{water}$	6.87E-03	6.87E-03	-
Concentration of substance in the STP effluent	$Clocal_{eff}$ **(PEC_{STP})**	5.50E-06	2.75E-04	mg/L

Calculation of PEC_{water} following application

Parameters	Nomenclature	Scenario 1	Scenario 2	Unit
Weight fraction of organic carbon in suspended solids	Foc_{susp}	0.1	0.1	kg_{oc}/kg_{solid}
Partition coefficient organic carbon-water	Koc	1.598	1.598	L/kg
Solids-water partition coefficient of suspended matter	Kp_{susp}	0.16	0.16	L/kg
Concentration of suspended matter in the river	$SUSP_{water}$	15	15	mg/L

Dilution factor	DILUTION	10	10	-
Local concentration in surface water	$Clocal_{water}$ **(PEC_{water})**	5.50E-07	2.75E-05	mg/L

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

Calculation of PEC_{soil}

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

The concentration of any active substance in dry sewage sludge can be calculated using Guidance on the Biocidal Products Regulation, vol. IV – Parts B + C (2017) as follows:

$$C_{sludge} = \frac{Fstp_{sludge} \times Elocal_{water} \times 10^6}{SLUDGERATE} \quad (39)$$

Where

$$SLUDGERATE = \frac{2}{3} \times SUSPCONC_{inf} \times EFFLUENT_{stp} + SURPLUS_{sludge} \times CAPACITY_{stp} \quad (40)$$

$$EFFLUENT_{stp} = CAPACITY_{stp} \times WASTEW_{inhab} \quad (37)$$

Calculation of PEC_{soil} following indoor application

Parameters	Nomenclature	Scenario 1	Scenario 2	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+06	2.0E+06	L/d
Surplus sludge per inhabitant	$SURPLUS_{sludge}$	0.019	0.019	kg/d eq
Capacity of the STP	$CAPACITY_{stp}$	10000	10000	eq
Sewage flow per inhabitant	$WASTEW_{inhab}$	200	200	L/d eq
Rate of sewage sludge production	SLUDGERATE	790	790	kg/d
Local emission rate to water	$Elocal_{water}$	1.60E-03	8.02E-02	kg/d
Fraction of emission directed to sludge by STP	$Fstp_{sludge}$	1.45E-04	1.45E-04	-
Concentration in dry sewage sludge	C_{sludge}	2.94E-04	1.47E-02	mg/kg_{dwt}

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

$$Facc = e^{-365\,k} \quad (62)$$

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

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

The concentration of a.s. in soil (represented as $Csludge_{soil\ 1}$ (0)) after the first year of manure application is calculated as:

$$Csludge_{soil\ 1}(0) = \frac{C_{sludge} \times APPL_{sludge}}{DEPTH_{soil} \times RHO_{soil}} \qquad (61)$$

Where:
C_{sludge}: concentration in dry sewage sludge (mg/kg_{dwt})
$APPL_{sludge}$: dry sludge application rate (0.5 kg_{dwt}/m^2 yr)
$DEPTH_{soil}$: mixing depth of soil (0.2 m)
RHO_{soil}: bulk density (wet) of soil (1700 kg/m^3)
$Csludge_{soil\ 1}$ (0): concentration in soil due to sludge in first year at t = 0 and is identical to $Csludge_{soil\ 10}$ (0)

Scenario	**C_{sludge} (mg/kg_{dwt})**	**$Csludge_{soil\ 1}$ (0) (mg/kg_{wwt})**
Scenario 1	2.94E-04	4.32E-07
Scenario 2	1.47E-02	2.16E-05

The PEC for local soil (referred to as $Clocal_{soil}$) is calculated as:

$$Clocal_{soil} = \frac{D_{air}}{k} + \frac{1}{kT}\left[C_{soil}(0) - \frac{D_{air}}{k}\right] \times \left[1 - e^{-kT}\right] \qquad (66)$$

Where:
D_{air}: aerial deposition flux per kg of soil (taken to be zero)
T: averaging time (30 d)
k: first order rate constant for removal from top soil (1.386 d^{-1})
C_{soil} (0): initial concentration in soil after sludge application (mg/kg)
$Clocal_{soil}$: average concentration in soil over T days (mg/kg)

Scenario	**$PEClocal_{soil}$ [mg/kg_{wwt}]**
Scenario 1	1.04E-08
Scenario 2	5.20E-07

3.3 New information on the active substance

No new information on the active substance was submitted as part of the Contec Hydrogen Peroxide Biocidal Product Family application.

3.4 Residue behaviour

Section 2.2.3 of the Assessment Report for Hydrogen Peroxide provides an assessment of the stability of the active substance and its breakdown to water and oxygen.

3.5 Summaries of the efficacy studies

The efficacy studies can be found in the IUCLID dossier (section 6.7) and are listed in the PAR both in the efficacy section and Annex 3.1 above.

3.6 Confidential annex

See confidential annex and Member State Confidential Annex to this document.

3.7 Other

None