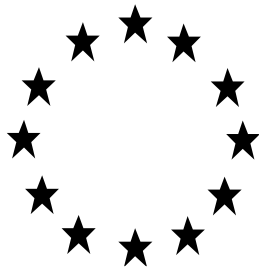
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



AOPACK 35%

Product type 04

Hydrogen peroxide as included in the Union list of approved active substances

Case Number in R4BP: BC-BG027715-51

Evaluating Competent Authority: Spain

Date: April 2024

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1 CONCLUSION

AOPACK 35% containing hydrogen peroxide, is a PT4 biocidal product intended for the disinfection of hard surfaces food and feed area (food, industrial and institutional areas) against bacteria, yeasts and fungi. The product is applied by professional users.

For disinfection in food and feed area (PT 4) the biocidal product is intended to be used for:

- aseptic packaging,
- cork stoppers disinfection,
- disinfection in enclosed spaces,
- inner surfaces in human drinking water systems
- CIP of piping and tanks beverages.

APCP

The product is a soluble concentrate (SL) containing 35.6 % pure hydrogen peroxide as active substance. The relevant physical, chemical and technical properties of the product were described adequately and in line with the related criteria as set in the BPR (for SL products). They have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.
The appearance of the product is a colourless and odourless liquid.
A shelf life of 24 months can be granted when stored in HDPE bottle (commercial packaging material), which is supported by the results of the long-term stability study.
The product may be also marketed in bulk, using 20m^3 stainless steel containers used for transport (tank trucks). Shelf-life for these containers is claimed as a maximum of 3 months, based on accelerated data. This claim is deemed acceptable as the product is not corrosive to metals and the accelerated data show no impact on the stainless steel coupons used to mimic storage in stainless steel. Since the estimated period of storage in 20 m^3 steel tanks is up to three months, this endpoint is covered by the accelerated storage in glass bottles with a steel coupon which mimics storage in stainless steel containers.

Physico chemical hazards have been assessed. The product is classified as oxidising liquid category 2.

Analytical methods for the determination of active substance in the biocidal product are validated according to guidance SANCO3030/99/rev.4.

Efficacy

The biocidal product contains hydrogen peroxide as the active substance. The product is intended for the use as disinfectant in the biocidal product type 4: Food and feed area. The product demonstrate efficacy against bacteria, yeast, fungi and bacterial spores.
It is used as a disinfectant in the food and feed industry (PT4), for aseptic packaging in close systems, surface disinfection by VHP process, disinfection of inner surfaces by CIP, disinfection of inner surfaces in human drinking water systems, and disinfection of cork stoppers.

Human health

The assessment of the risks for human health for the product was carried out for the active substance only as no substance of concern was identified.

After evaluating the exposure and characterizing the risk to human health of the biocidal product according to the pattern of use requested by the applicant, the conclusions for each scenario are:

Summary table risk assessment for human health			
Scenario	**Scenario**	**Conclusion**	**Exposed group**
Use 1: Aseptic packaging by automated immersion in closed system.			
1.	Mixing and loading	A **safe** situation has been identified for loading of the machines for aseptic packaging by immersion when PPEs and RMMs are used.	Professional users
2.	Indoor application	A **safe** situation has been identified for disinfection of food packaging by immersion into bath of hot hydrogen peroxide in aseptic filling machine when PPEs and RMMs are used.	Professional users
3.	Post-application	A **safe** situation has been identified for maintenance of the aseptic packaging plant (e.g. manual cleaning, technical incidents or repair) when PPEs and RMMs are used.	Professional users
Use 2: Aseptic packaging by automated spraying in closed system.			
4.	Mixing and loading	A **safe** situation has been identified for loading of the machines for aseptic packaging by spraying when PPEs and RMMs are used.	Professional users
5.	Indoor application	A **safe** situation has been identified for disinfection of food packaging by spraying into bath of hot hydrogen peroxide in aseptic filling machine when PPEs and RMMs are used.	Professional users
6.	Post-application	A **safe** situation has been identified for maintenance of the aseptic packaging plant (e.g. manual cleaning, technical incidents or repair) when PPEs and RMMs are used.	Professional users
Use 3: Surface disinfection by VHP process in food processing facilities.			
7.	Mixing and loading	A **safe** situation has been identified for loading of the VHP machines when PPEs and RMMs are used.	Professional users
8.	Indoor application	A **safe** situation has been identified for disinfection of dry surfaces in enclosed areas when PPEs and RMMs are used.	Professional users
9.	Post-application	A **safe** situation has been identified for maintenance of the VHP machines (e.g. manual cleaning, technical incidents or repair) when PPEs and RMMs are used.	Professional users
Use 4 – Disinfection of inner surfaces in human drinking water systems			
10.	Mixing and loading	A **safe** situation has been identified for loading of the biocidal product to obtain the diluted end-product when PPEs and RMMs are used.	Professional users
11.	Indoor application	A **safe** situation has been identified for disinfection by cleaning-in-place (CIP) process when PPEs and RMMs are used.	Professional users

Summary table risk assessment for human health			
Scenario	**Scenario**	**Conclusion**	**Exposed group**
12.	Post-application	A **safe** situation has been identified for maintenance of the CIP machines (e.g. manual cleaning, technical incidents or repair) when PPEs and RMMs are used.	Professional users
Use 5: Disinfection of inner surfaces by CIP			
13.	Mixing and loading	A **safe** situation has been identified for loading of the biocidal product to obtain the diluted end-product when PPEs and RMMs are used.	Professional users
14.	Indoor application	A **safe** situation has been identified for disinfection by cleaning-in-place (CIP) process when PPEs and RMMs are used.	Professional users
15.	Post-application	A **safe** situation has been identified for maintenance of the CIP machines (e.g. manual cleaning, technical incidents or repair) when PPEs and RMMs are used.	Professional users
Use 6: Disinfection of cork stoppers by automated spraying in closed systems			
16.	Mixing and loading	A **safe** situation has been identified for loading of the sterilization machines when PPEs and RMMs are used.	Professional users
17.	Indoor application	A **safe** situation has been identified for disinfection of corks' surfaces by spraying in closed system when PPEs and RMMs are used.	Professional users
18.	Post-application	A **safe** situation has been identified for maintenance of the sterilization machines (e.g. manual cleaning, technical incidents or repair) when PPEs and RMMs are used.	Professional users

All scenarios resulted in acceptable risk. In addition, risk assessment for consumers via residues in food and animal health is not foreseen from the intended uses of the biocidal product.

In addition, we would like to mention that the exposure assessment of the product has been carried out for the professional users. Nevertheless, in order to apply national legislation regarding users categories, an art 37 of BPR will be applied in Spain and the product will be granted for trained professional users in our country as well, taking into account the restrictions of packaging in relation to those user categories and product types.

Environment

A risk assessment for the environment has been carried out for the intended uses of the biocidal product AOPACK 35%. Based on the environmental risk assessment, the intended uses of the product as disinfectant (PT04) for aseptic packaging, cork stoppers, surfaces in food processing facilities and inner surfaces by CIP, does not result in unacceptable risks for the environment if the directions for use are to be followed.
Therefore, the approval of AOPACK 35% can be granted from an environmental perspective.

Overall conclusion

According to the assessment performed for the biocidal product AOPACK 35%, DUROX LRA, DUROX LRD, DUROX LRA TIPO S, DUROX LRA ADVANCED, the following uses are proposed for authorization, considering the appropriate risk mitigation measures indicated in the table below:

Uses	Target organisms	User categories	Authorised application rates	Use conditions: risk mitigations measures
Use # 1 – Aseptic packaging by automated immersion in closed system.	Bacteria, yeast, bacterial spores.	Professionals users	35% (w/w) hydrogen peroxide. Temperature and contact time: ≥65 °C for ≥6.6 seconds or ≥80 °C for ≥2.5 seconds. Conditions depend on the aseptic packaging machine. One application. Waiting period: until packaging material is dry.	Wear protective chemical resistant gloves meeting the requirements of European Standard EN 374 during product handling phase (glove material to be specified by the authorisation holder within the product information). Wear a protective coverall (at least type 6, EN 13034) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information). The use of eye protection during handling of the product is mandatory. Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during M&L phase. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information). Avoid contact with eyes/skin. Do not use on clothing. Avoid inhalation of vapours. Do not eat, drink or smoke while working. Operate in a well-ventilated area. Keep away from heat sources and combustible materials. <u>ONLY FOR USES 1, 2, 4, 5 & 6:</u> In case of maintenance (e.g. manual cleaning, technical incidents or repair)
Use # 2 – Aseptic packaging by automated spraying in closed system.	Bacteria, yeast, bacterial spores.	Professional users	35% (w/w) hydrogen peroxide. 0.1-1 mL/package Temperature: 75-85ºC Contact time: ≥20 seconds. Conditions depend on the aseptic packaging machine. One application. Waiting period: until packaging material is dry.	
Use # 3 – Surface disinfection by VHP process in food processing facilities.	Bacteria, yeast.	Professionals users	1092 mg/m^3 (780 ppm) hydrogen peroxide in air generated by the VHP generator. Contact time: ≥ 4 hours Daily if required Maximum 3 times per day.	
Use # 4 – Disinfection of inner surfaces in human drinking water systems	Bacteria, fungi	Professional users	4.0% (w/w) hydrogen peroxide. Contact time: 15 min (Bacteria), 180 min (Fungi). One application. Temperature: 20ºC	
Use # 5 – Disinfection of inner surfaces by CIP	Bacteria, yeast, fungi	Professional users	5.0% (w/w) hydrogen peroxide. Contact time: 15 min (Bacteria and yeast), 180 min (Fungi). One application. Temperature: 20ºC	

Uses	Target organisms	User categories	Authorised application rates	Use conditions: risk mitigations measures
Use # 6 – Disinfection of cork stoppers by automated spraying in closed systems	Bacteria, yeast, fungi.	Professional users	35% (w/w) hydrogen peroxide. 1mL/cork stopper One application. Spraying time: 20-50 seconds. Contact time: 30 minutes. Waiting period: until packaging material is dry. Temperature: 20ºC	appropriate PPE (respiratory protective equipment (APF = 10), chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required. The type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the product information. Glove material to be specified by the authorisation holder within the product information. <u>ONLY FOR USES 1 & 2:</u> Workplace release measurements with suitable measurement equipment shall be performed upon implementation of the aseptic packaging plant, at regular intervals (annual intervals recommended) and after any change in relevant boundary conditions. The national regulations for workplace measurements have to be followed. During operation, ensure adequate ventilation along the machines (LEV) and in the industrial halls (technical ventilation). The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed. Aerosolised or vaporised application should be use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Emission to air should be controlled by

Uses	Target organisms	User categories	Authorised application rates	Use conditions: risk mitigations measures
				the machine e.g. with catalytic treatment or through a gas scrubber. During manual maintenance tasks, ensure adequate ventilation inside the machine (LEV) before opening the doors of the aseptic area. <u>ONLY FOR USE 3:</u> No access of persons to the treated area is permitted during treatment. During aeration and before permitting re-entry to the treated area it should be checked that the undercut of $AEC_{inhalation}$ of 1.25 mg/m^3 or the corresponding national reference value shall be ensured with technical and organisational measures (e.g. sensor/test strip, defined ventilation period). The professional user may only enter the room in emergency situations or to reactivate the ventilation considering RPE with APF 40 against vapour (Type of RPE to be specified by the authorisation holder within the product information). The re-entry is therefore only possible when the hydrogen peroxide level has dropped below 36 ppm (50 mg/ m^3) or below 40x the national reference value.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier[1]	**Country (if relevant)**
AOPACK 35% DUROX LRA DUROX LRD DUROX LRA TIPO S DUROX LRA ADVANCED	Spain

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Evonik Operations GmbH
	Address	Rellinghauser Straße 1-11 45128 Essen Germany
Authorisation number	ES/APP(NA)-2023-04-00928	
Date of the authorisation	16/04/2024	
Expiry date of the authorisation	16/04/2034	

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer 1	Evonik Peroxide Spain s.l.u.
Address of manufacturer	Afueras s/n, 50784- La Zaida (Zaragoza) SPAIN
Location of manufacturing sites	Afueras s/n, 50784- La Zaida (Zaragoza) SPAIN
Name of manufacturer 2	Evonik Peroxid GmbH
Address of manufacturer	Industriestraße 1 AT-9721 Weißenstein - Austria
Location of manufacturing sites	Industriestraße 1 AT-9721 Weißenstein - Austria
Name of manufacturer 3	Evonik Antwerpen N.V.
Address of manufacturer	Tijsmanstunnel West 4 2040 Antwerpen - Belgium

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

Location of manufacturing sites	Tijsmanstunnel West 4 2040 Antwerpen - Belgium
Name of manufacturer 4	Evonik Operations GmbH
Address of manufacturer	Untere Kanalstraße 3 79618 Rheinfelden - Germany
Location of manufacturing sites	Untere Kanalstraße 3 79618 Rheinfelden - Germany
Name of manufacturer 5	RNM Produtos Químicos, S.A.
Address of manufacturer	Rua Da Fabrica Nº123, 4765-080 Carreira, Famalicão - Portugal
Location of manufacturing sites	Avenida das Searas, s/n. 4760-329 Landim, Vila Nova de Famalicão – Portugal

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

Active substance	Hydrogen peroxide
Name of manufacturer 1	Evonik Peroxide Spain s.l.u.
Address of manufacturer	Afueras s/n, 50784- La Zaida (Zaragoza) SPAIN
Location of manufacturing sites	Afueras s/n, 50784- La Zaida (Zaragoza) SPAIN

Active substance	Hydrogen peroxide
Name of manufacturer 2	Evonik Peroxid GmbH
Address of manufacturer	Industriestraße 1 AT-9721 Weißenstein - Austria
Location of manufacturing sites	Industriestraße 1 AT-9721 Weißenstein - Austria

Active substance	Hydrogen peroxide
Name of manufacturer 3	Evonik Antwerpen N.V.
Address of manufacturer	Tijsmanstunnel West 4 2040 Antwerpen - Belgium
Location of manufacturing sites	Tijsmanstunnel West 4 2040 Antwerpen - Belgium

Active substance	Hydrogen peroxide
Name of manufacturer 4	Evonik Operations GmbH
Address of manufacturer	Untere Kanalstraße 3 79618 Rheinfelden - Germany

Location of manufacturing sites	Untere Kanalstraße 3 79618 Rheinfelden - Germany

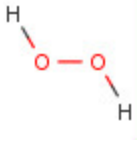
2.1.2 Product composition and formulation

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

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

Yes ☒
No ☐

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Hydrogen peroxide
IUPAC or EC name	Hydrogen peroxide
EC number	231-765-0
CAS number	7722-84-1
Index number in Annex VI of CLP	008-003-00-9
Minimum purity / content	The active substance as manufactured is an aqueous solution of 350-<700 g/kg (35-<70 %, by weight) solution of hydrogen peroxide. The theoretical (calculated) dry weight specification: minimum purity of hydrogen peroxide is 995 g/kg (99.5% by wt.).
Structural formula	

The biocidal product covered by the Hydrogen Peroxide Biocidal Product is water based liquid only containing hydrogen peroxide and water. It does not contain any other co-formulant appart from solvent (water).

Hydrogen peroxide is produced as an aqueous solution ranging from 35% to <70%.

2.1.2.2 Candidate(s) for substitution

Hydrogen peroxide does not meet the conditions laid down in Article 10 of BPR Regulation (EU) No 528/2012 and is therefore not considered as a candidate for substitution.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide	Hydrogen peroxide	Active substance	7722-84-1	231-765-0	35.6 (technical) 35.42 (pure)

*Minimum purity of hydrogen peroxide is 995 g/kg (99.5%).

2.1.2.4 Information on technical equivalence

Evonik Peroxide Spain s.l.u. – former PeroxyChem Spain, S.L.U. – was a member of CEFIC Hydrogen Peroxide Biocide Task Force and owner of data of approval active substance (CAS num. 7722-84-1) Regulation (EU) 2015/1730 of 28 September 2015 approving hydrogen peroxide as an existing active substance for use in biocidal products for product-types 1 to 6, therefore is not a technical equivalence.

2.1.2.5 Information on the substance(s) of concern

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, no co-formulant has been identified as SoC. Please refer to the confidential annex for further details.

2.1.2.6 Endocrine disruption

The biocidal product was not tested for potential endocrine disruption properties.
For the active substance, no ED assessment is required because for active substances which have been approved, the EU assessment should be followed.
The assessment of the endocrine-disrupting properties of the components in the product AOPACK 35% has been performed according to the instructions described in the document agreed in the Coordination Group.
To assess the endocrine-disrupting (ED) potential of each co-formulant in the formulation, a step-wise approach needs to be performed, which includes screening of relevant databases and searching for freely available information in reliable literature sources.
Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the components contained in the product AOPACK 35%.

2.1.2.7 Type of formulation

SL - Soluble concentrate.

2.1.3 Hazard and precautionary statements

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

Classification

2 Please delete as appropriate.

Hazard category	Ox. Liq. 2, H272 Acute Tox. 4, H302 Skin irrit. 2, H315 Eye Damage 1, H318 STOT SE 3, H335 Aquatic chronic 3
Hazard statement	H272: May intensify fire; oxidiser. H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects.
Labelling	
Signal words	Danger
Hazard statements	H272: May intensify fire; oxidiser. H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P220: Keep away from clothing and other combustible materials. P261: Avoid breathing dust/fume/gas/mist/vapours/spray. P271: Use only outdoors or in a well ventilated área. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTRE/doctor/…if you feel unwell. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P301+P312: IF SWALLOWED: Call a POISON CENTRE/doctor/…if you feel unwell. P330: Rinse mouth. P280: Wear protective gloves and eye protection P310: Immediately call to a poison centre in case of swallow/inhalation P302+P352: IF ON SKIN wash with plenty of water. P332+P313: If skin irritation occurs: Get medical advice/attention. P362+P364: Take off inmediately all contaminated clothing and wash it before reuse. P305+P351+P338: IF IN EYES rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P370 + P378: In case of fire: Use water to extinguish P403+P233: Store in a well-ventilated place. Keep container tightly closed. P273: Avoid release to the environment. P405: Store locked up. P501: Dispose of content/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations.

2.1.4 Authorised use(s)

2.1.4.1 Use description #1

Table 1. Use # 1 – Aseptic packaging by automated immersion in closed system.

Product Type	PT-04 Food and feed area disinfectants
Where relevant, an exact description of the authorised use	Not relevant.
Target organism (including development stage)	Bacteria, yeast, bacterial spores.
Field of use	Indoor
Application method(s)	Immersion. Automated immersion in closed system.
Application rate(s) and frequency	35% (w/w) hydrogen peroxide. Temperature and contact time: ≥65 °C for ≥6.6 seconds or ≥80 °C for ≥2.5 seconds Conditions depend on the aseptic packaging machine. One application. Waiting period: until packaging material is dry.
Category(ies) of users	Professional users.
Pack sizes and packaging material	Jerry can, Plastic: HDPE; 5, 20, 25, 30 and 60 L Drum, Plastic: HDPE; 220 L IBC (intermediate bulk container), Plastic: HDPE; 1000 L

2.1.4.1.1 Use-specific instructions for use

The aseptic filling systems are based on the principle of aseptically forming a tube from a sterilized sheet of package material, which is continuously filled with commercially sterile liquid food product and subsequently transversally sealed to form pouches, which in turn are folded into the final package shape. The packaging material are delivered to the aseptic filling machine either in the form of (sheet) reels or in the form of pre-formed packs, tubs and bottles. The packaging material in the form of (sheet) reels passes through a deep bath filled with hydrogen peroxide solutions by dipping. The temperature and contact time depend on the machine (usually ≥65 °C for ≥6.6 seconds or ≥80 °C for ≥2.5 seconds). After that, several stages follow to evaporate any excess hydrogen peroxide with sterile hot air. The receptacle is then filled and sealed.

Use in accordance with the instructions of the aseptic packaging machine. The user shall always carry out a microbiological validation of the disinfection, after which a protocol for disinfection of this packaging / system can be made and used thereafter.

Please refer to general direction of use for further information.

2.1.4.1.2 Use-specific risk mitigation measures

Workplace release measurements with suitable measurement equipment shall be performed upon implementation of the aseptic packaging plant, at regular intervals (annual intervals recommended) and after any change in relevant boundary conditions. The national regulations for workplace measurements have to be followed. During operation, ensure adequate ventilation along the machines (LEV) and in the industrial halls (technical ventilation). The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed. Aerosolised or vaporised application should be use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber. During manual maintenance tasks, ensure adequate ventilation inside the machine (LEV) before opening the doors of the aseptic area. In case of maintenance (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment (APF = 10), chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required. The type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the product information. Glove material to be specified by the authorisation holder within the product information. Please refer to general direction of use for further information.

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

Please see Section 2.1.5.3

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

Please see Section 2.1.5.4

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

Please see Section 2.1.5.5

2.1.4.2 Use description #2

Table 2. Use # 2 – Aseptic packaging by automated spraying in closed system.

Product Type	PT-04 Food and feed area disinfectants

Where relevant, an exact description of the authorised use	Not relevant.
Target organism (including development stage)	Bacteria, yeast, bacterial spores.
Field of use	Indoor
Application method(s)	Spraying. Automated spraying in closed system.
Application rate(s) and frequency	35% (w/w) hydrogen peroxide. 0.1-1 mL/package Temperature: 75-85ºC Contact time: ≥20 seconds. Conditions depend on the aseptic packaging machine. One application. Waiting period: until packaging material is dry.
Category(ies) of users	Professional users.
Pack sizes and packaging material	Jerry can, Plastic: HDPE; 5, 20, 25, 30 and 60 L Drum, Plastic: HDPE; 220 L IBC (intermediate bulk container), Plastic: HDPE; 1000 L

2.1.4.2.1 Use-specific instructions for use

The aseptic filling systems are based on the principle of aseptically forming a tube from a sterilized sheet of package material, which is continuously filled with commercially sterile liquid food product and subsequently transversally sealed to form pouches, which in turn are folded into the final package shape. The packaging material are delivered to the aseptic filling machine either in the form of (sheet) reels or in the form of pre-formed packs, tubs and bottles. Then, hydrogen peroxide solution is sprayed to the packaging material stepwise via a nozzle (0.1-1mL).The temperature and contact time depend on the machine (usually 75-85ºC, ≥20 seconds). After that, several stages follow to evaporate any excess hydrogen peroxide with sterile hot air. The receptacle is then filled and sealed.
Use in accordance with the instructions of the aseptic packaging machine. The user shall always carry out a microbiological validation of the disinfection, after which a protocol for disinfection of this packaging / system can be made and used thereafter.

Please refer to general direction of use for further information.

2.1.4.2.2 Use-specific risk mitigation measures

Workplace release measurements with suitable measurement equipment shall be performed upon implementation of the aseptic packaging plant, at regular intervals (annual intervals recommended) and after any change in relevant boundary conditions. The national regulations for workplace measurements have to be followed.

During operation, ensure adequate ventilation along the machines (LEV) and in the industrial halls (technical ventilation).

The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed.

Aerosolised or vaporised application should be use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber. During manual maintenance tasks, ensure adequate ventilation inside the machine (LEV) before opening the doors of the aseptic area. In case of maintenance (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment (APF = 10), chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required. The type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the product information. Glove material to be specified by the authorisation holder within the product information. Please refer to general direction of use for further information.

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

Please see Section 2.1.5.3

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

Please see Section 2.1.5.4

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

Please see Section 2.1.5.5

2.1.4.3 Use description #3

Table 3. Use # 3 –Surface disinfection by VHP process in food processing facilities.

Product Type	PT-04 Food and feed area disinfectants
Where relevant, an exact description of the authorised use	Not relevant.
Target organism (including development stage)	Bacteria, yeast.
Field of use	Indoor
Application method(s)	Vaporization. Automated disinfection with Vaporized Hydrogen Peroxide, generated with aid of a VHP generator. Main specifications of a VHP generator: Diffusion principle: vaporization, disinfection with gaseous

	hydrogen peroxide Room Volume: 30 - 150 m^3; Relative humidity: 40 - 80% Temperature: room temperature
Application rate(s) and frequency	1092 mg/m^3 (780 ppm) hydrogen peroxide in air generated by the VHP generator. Contact time: ≥ 4 hours Daily if required Maximum 3 times per day.
Category(ies) of users	Professional users.
Pack sizes and packaging material	Jerry can, Plastic: HDPE; 5, 20, 25, 30 and 60 L Drum, Plastic: HDPE; 220 L IBC (intermediate bulk container), Plastic: HDPE; 1000 L

2.1.4.3.1 Use-specific instructions for use

Prepare the area for decontamination by removing standing liquids and visible soils by wiping down. Clean the area before disinfection. Cupboard doors should be opened, surfaces should be dried and wet areas (such as sinks and toilet bowls) should be disinfected with suitable alternative products. Install biological and chemical indicators to validate the disinfection cycle.
Specially instructed users replace and seal the cap of the package as delivered by the supplier with a special cap that has a degassing valve and a fast connector. The fast connector is connected to a pipe that connects to the VHP machine. Seal the enclosed space or room and make sure that access to the vapor-treated area is denied during the whole procedure.
Efficacy of use was demonstrared by flash evaporation of hydrogen peroxide at rate of 1092 mg/m^3 for 4h.
Apply only on non-porous surfaces.
Room volume ranging from 30 up to 150 m^3. For room enclosures greater than 150 m^3 use multiple generator units to achieve the target concentration.

Diffusion speed can vary from 1.5 up to 20 g product /min.

Starting temperature of 20°C ± 2°C.

Relative humidity between 40 and 80 %.
During the desinfection cycle the VHP machine adjusts the hydrogen peroxide concentration up to the effective levels of 1092 mg/m^3 (780 ppm) and keeps it at this level for ≥ 4 hours. Concentration of hydrogen peroxide is monitored during the disinfection. After disinfection the aeration of the sealed area is required to reduce the concentration of hydrogen peroxide below 1.25 mg /m^3 before entering the area. This step can be quick but can also last several hours resulting in a total decontamination cycle of 5 – 8 hours.
The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable "standard room", if applicable) with the devices to be used, after which a protocol for disinfection of these rooms can be made and used thereafter.
In case there are methods available for chemically monitoring the active substance in the air or on surfaces, chemical validation should be performed besides biological validation, e.g. with test strips or with a device that measures ppm H_2O_2 in the air.
When it concerns a "standard room" for which a protocol is available, the validation may be limited to only a chemical validation.

Please refer to general direction of use for further information.

2.1.4.3.2 Use-specific risk mitigation measures

No access of persons to the treated area is permitted during treatment. During aeration and before permitting re-entry to the treated area it should be checked that the undercut of $AEC_{inhalation}$ of 1.25 mg/m^3 or the corresponding national reference value shall be ensured with technical and organisational measures (e.g. sensor/test strip, defined ventilation period). The professional user may only enter the room in emergency situations or to reactivate the ventilation considering RPE with APF 40 against vapour (Type of RPE to be specified by the authorisation holder within the product information). The re-entry is therefore only possible when the hydrogen peroxide level has dropped below 36 ppm (50 mg/ m^3) or below 40x the national reference value. Please refer to general direction of use for further information.

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

Please see Section 2.1.5.3

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

Please see Section 2.1.5.4

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

Please see Section 2.1.5.5

2.1.4.4 Use description #4

Table 4. Use # 4 – Disinfection of inner surfaces in human drinking water systems

Product Type	PT-04 Food and feed area disinfectants
Where relevant, an exact description of the authorised use	Not relevant.
Target organism (including development stage)	Bacteria, , fungi
Field of use	Indoor
Application method(s)	Cleaning In Place (CIP). Disinfecting the interior surfaces of closed systems by CIP.

Application rate(s) and frequency	4.0% (w/w) hydrogen peroxide. Contact time: 15 min (Bacteria), 180 min (Fungi). One application. Temperature: 20ºC
Category(ies) of users	Professional users.
Pack sizes and packaging material	Jerry can, Plastic: HDPE; 5, 20, 25, 30 and 60 L Drum, Plastic: HDPE; 220 L IBC (intermediate bulk container), Plastic: HDPE; 1000 L

2.1.4.4.1 Use-specific instructions for use

Remove the content (drinking water) before cleaning deposits and distribution systems. Clean the deposits mechanically before disinfection starts. For disinfection of bacteria and fungi the product should be diluted to 4% (w/w) of hydrogen peroxide.

A CIP machine that pumps hydrogen peroxide solution through the piping system is attached. A detector that indicates when the disinfection process is complete, is set up at the outlet. CIP machine mixes the biocidal product with water to concentration 4% of hydrogen peroxide Circulate the diluted product through the system. The process involves the jetting or spraying of surfaces or circulation of cleaning solutions through the plant under conditions of increased turbulence and flow velocity. After 15 min (Bacteria) and 180 min (Fungi) contact time, pipelines and tanks are rinsed with water before refilled with drinking water.

Please refer to general direction of use for further information.

2.1.4.4.2 Use-specific risk mitigation measures

In case of maintenance (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment (APF = 10), chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required. The type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the product information. Glove material to be specified by the authorisation holder within the product information.

Please refer to general direction of use for further information.

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

Please see Section 2.1.5.3

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

Please see Section 2.1.5.4

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

Please see Section 2.1.5.5

2.1.4.5 Use description #5

Table 5. Use # 5– Disinfection of inner surfaces by CIP

Product Type	PT-04 Food and feed area disinfectants
Where relevant, an exact description of the authorised use	Not relevant.
Target organism (including development stage)	Bacteria, yeast, fungi
Field of use	Indoor
Application method(s)	Cleaning In Place (CIP). Disinfecting the interior surfaces of closed systems by CIP.
Application rate(s) and frequency	5.0% (w/w) hydrogen peroxide. Contact time: 15 min (Bacteria and yeast), 180 min (Fungi). One application. Temperature: 20ºC
Category(ies) of users	Professional users.
Pack sizes and packaging material	Jerry can, Plastic: HDPE; 5, 20, 25, 30 and 60 L Drum, Plastic: HDPE; 220 L IBC (intermediate bulk container), Plastic: HDPE; 1000 L

2.1.4.5.1 Use-specific instructions for use

Empty the pipework and tanks, and clean tanks mechanically before disinfection starts. A CIP machine that pumps hydrogen peroxide solution through the piping system is attached. A detector that indicates when the disinfection process is complete, is set up at the outlet. CIP machine mixes the biocidal product with water to concentration 5% of hydrogen peroxide. The process is carried out by circulating the disinfection solution of 5% (w/w) hydrogen peroxide through the system under conditions of increased turbulence and flow velocity. The application is automated and a closed process. Rinse the surface with water after 15 min (Bacteria and yeast), 180 min (Fungi) contact time for deposits and pipes under closed system conditions as well. Please refer to general direction of use for further information.

2.1.4.5.2 Use-specific risk mitigation measures

In case of maintenance (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment (APF = 10), chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required. The type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the

product information. Glove material to be specified by the authorisation holder within the product information. Please refer to general direction of use for further information.

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

Please see Section 2.1.5.3

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

Please see Section 2.1.5.4

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

Please see Section 2.1.5.5

2.1.4.6 Use description #6

Table 6. Use # 6 – Disinfection of cork stoppers by automated spraying in closed systems

Product Type	PT-04 Food and feed area disinfectants
Where relevant, an exact description of the authorised use	Not relevant.
Target organism (including development stage)	Bacteria, yeast, fungi.
Field of use	Indoor
Application method(s)	Spraying. Automated spraying in closed system.
Application rate(s) and frequency	35% (w/w) hydrogen peroxide. 1mL/cork stopper One application. Spraying time: 20-50 seconds. Contact time: 30 minutes. Waiting period: until packaging material is dry. Temperature: 20ºC
Category(ies) of users	Professional users.
Pack sizes and packaging material	Jerry can, Plastic: HDPE; 5, 20, 25, 30 and 60 L Drum, Plastic: HDPE; 220 L IBC (intermediate bulk container), Plastic: HDPE; 1000 L

2.1.4.6.1 Use-specific instructions for use

Cleaning is required prior to disinfection. Use in accordance with the requirements for the disinfection machine.Load the product as received to the system (automatic process). Inject the product (1 mL/cork stopper) by spraying into the rotary drums (20-50 seconds) and assure a minimum contact time of 30 minutes. Make sure to wet surfaces completely. Then rinse the cork stoppers with water and let them dry by applying hot air. Do not open the system until the stoppers are completely dry.Make sure that the content of peroxide residues in cork is lower than 0.2 mg/stopper. Please refer to general direction of use for further information.

2.1.4.6.2 Use-specific risk mitigation measures

In case of maintenance (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment (APF = 10), chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required. The type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the product information. Glove material to be specified by the authorisation holder within the product information. Please refer to general direction of use for further information.

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

Please see Section 2.1.5.3

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

Please see Section 2.1.5.4

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

Please see Section 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

Intended only for professional use. Always read the label or leaflet before use and follow all the instructions provided.

Precleaning of surfaces required before using disinfectants. Surfaces should be meticously cleaned/rinsed/dried before the disinfection step.

Rinse treated equipment with drinking water after application.

Respect the conditions of use of the product (concentration, contact time, temperature, etc.).

Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved.

Inform the authorisation holder if the treatment is ineffective.

Further specific information for each use can be found in respective section of the use.

2.1.5.2 Risk mitigation measures

Wear protective chemical resistant gloves meeting the requirements of European Standard EN 374 during product handling phase (glove material to be specified by the authorisation holder within the product information).

Wear a protective coverall (at least type 6, EN 13034) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information).

The use of eye protection during handling of the product is mandatory.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during M&L phase. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

Avoid contact with eyes/skin.

Do not use on clothing.

Avoid inhalation of vapours.

Do not eat, drink or smoke while working.

Operate in a well-ventilated area.

Keep away from heat sources and combustible materials.

Further specific information for each use can be found in respective section of the use.

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

<u>First aid instructons</u>

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Empty containers, unused product,washing water, containers and other waste generated during application are considered hazardous waste. Deposite packaging waste at the established collection points or deliver it to a registered hazardous waste operator as agreed with the extended producer responsibility system. Deliver the other wastes to a registered establishment or undertaking for hazardous waste, in accordance with current regulations.

Code the waste according to Decision 2014/955/EU.

Do not release into soil, ground, surface water or any kind of sewer.

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

Keep only in the original container in a cool, well-ventilated place. Protect from direct sunlight.

Keep away from heat sources (e.g. hot surfaces), sparks and open flames. Keep away from combustible material.

Keep in container tightly closed, fitted with safety valve or vent. Have a ventilation system in place.

Keep away from incompatible materials: acids, bases, metals, salts of metals, reducing agents, organic materials, flammable substances. Storage area should be made of non-combustible, impermeable materials.

Shelf-life of the product under normal conditions of storage:

HDPE packagings: 24 months

Stainless steel tanks: 3 months.

2.1.6 Other information

Do not mix with other chemicals.

"Protect from direct sunlight" sentence should be added to the label.

The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).

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

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Jerry Can	5 L	HDPE	Degassing cap, HDPE	Professional	Yes
Jerry Can	20 L	HDPE	Degassing cap, HDPE	Professional	Yes
Jerry Can	25 L	HDPE	Degassing cap, HDPE	Professional	Yes
Jerry Can	30 L	HDPE	Degassing cap, HDPE	Professional	Yes
Jerry Can	60 L	HDPE	Degassing cap, HDPE	Professional	Yes
Drum	220 L	HDPE	Degassing cap, HDPE	Professional	Yes
IBC	1000 L	HDPE	Degassing cap, HDPE	Professional	Yes

*Stainless steel tank-vehicle 20-27t are containers for transport by road.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substance is generated, since the information that was presented for approval for listing of the active substance on the Union list of approved active substances under Regulation No. 528/2012 is deemed sufficient to allow the evaluation of the biocidal product. Furthermore, the data presented in connection with the approval for listing of the active substance is included in the IUCLID dossier.

The biocidal product does not contain any substances of concern.

New data for the product has been submitted, regarding analytical methods (titration, determination of heavy metals, detection in water and detection in air), appearance, acidity, relative density, accelerated storage, long term storage, low temperature stability, persistent foaming, dilution stability, surface tension, viscosity, corrosivity and efficacies. References can be found in the list of studies in the annex 3.1.

2.1.8.2 Access to documentation

The applicant Evonik Peroxide Spain s.l.u (former PeroxyChem Spain S.L.U.) is a member of the consortium of co-operating companies of the Cefic Peroxygens Sector Group, Subgroup Hydrogen Peroxide and, therefore, has access to all data submitted in the dossier for the active substance originally submitted under the Biocidal Products Directive. Even that, the letter of access from PeroxyChem Spain S.L.U. was submitted.

2.2 Assessment of the biocidal product

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

Table 2. Intended use 1 – Aseptic packaging by immersion

Product Type(s)	PT 4: food and feed area disinfectants.
Where relevant, an exact description of the authorised use	Hydrogen peroxide is used to disinfect packaging for food products by immersion into a bath containing heated hydrogen peroxide aqueous solutions.
Target organism (including development stage)	Bacteria, yeast, bacterial spores.
Field of use	Indoor
Application method(s)	Immersion. Automated immersion in closed system.
Application rate(s) and frequency	35% (w/w) hydrogen peroxide. Temperature: >=65 ºC Contact time: >=2.5 seconds Conditions depend on the aseptic packaging machine. One application. Waiting period: until packaging material is dry.
Category(ies) of user(s)	Professionals
Pack sizes and packaging material	HDPE Jerry Can 5L, 20L, 25L, 30L, 60L HDPE Drum 220L HDPE IBC 1000L Stainless steel tanks 20-27 Tn

Table 3. Intended use 2 – Aseptic packaging by automated spraying

Product Type(s)	PT 4: food and feed area disinfectants.
Where relevant, an exact description of the authorised use	Hydrogen peroxide is used to disinfect packaging for food products by spraying with hydrogen peroxide aqueous solutions.
Target organism (including development stage)	Bacteria, yeast, bacterial spores
Field of use	Indoor
Application method(s)	Spraying. Automated spraying in closed systems.
Application rate(s) and frequency	35% (w/w) hydrogen peroxide. 0.1-1 mL/package

	Temperature: 65-85 ºC Contact time: >= 20 sec Conditions depend on the aseptic packaging machine. One application. Waiting period: until packaging material is dry.
Category(ies) of user(s)	Professionals
Pack sizes and packaging material	HDPE Jerry Can 5L, 20L, 25L, 30L, 60L HDPE Drum 220L HDPE IBC 1000L Stainless steel tanks 20-27 Tn

Table 4. Intended use 3 – Surface disinfection by VHP proc. in food processing facilities

Product Type(s)	PT 4: food and feed area disinfectants.
Where relevant, an exact description of the authorised use	Hydrogen peroxide vapour decontaminates dry surfaces of food and feed areas and other enclosed spaces.
Target organism (including development stage)	Bacteria, yeasts
Field of use	Indoor
Application method(s)	Vaporization. Automated disinfection with Vaporized Hydrogen Peroxide, generated with aid of a VHP generator. Main specifications of a VHP generator: Diffusion principle: vaporization, disinfection with gaseous hydrogen peroxide Room Volume: 30 - 150 m3; Relative humidity: 40 - 80% Temperature: room temperature
Application rate(s) and frequency	1092 mg/m^3 (780 ppm) hydrogen peroxide in air generatedby the VHP generator. Contact time: ≥ 4 hours. Daily if required. Maximum 3 times per day.
Category(ies) of user(s)	Professionals
Pack sizes and packaging material	HDPE Jerry Can 5L, 20L, 25L, 30L, 60L HDPE Drum 220L HDPE IBC 1000L Stainless steel tanks 20-27 Tn

Table 5. Intended use 4 – Disinfection of distribution systems for drinking water

Product Type(s)	PT 4: food and feed area disinfectants.
Where relevant, an exact description of the authorised use	Hydrogen peroxide is used for cleaning and disinfection of distributing and storing installations for drinking water as pipes and containers.

Target organism (including development stage)	Bacteria, yeasts, fungi
Field of use	Indoor
Application method(s)	Cleaning In Place (CIP) . Disinfecting the interior surfaces of closed systems by CIP.
Application rate(s) and frequency	4.0% (w/w) hydrogen peroxide. Contact time: 15 min. One application. Frequency, as required.
Category(ies) of user(s)	Professionals
Pack sizes and packaging material	HDPE Jerry Can 5L, 20L, 25L, 30L, 60L HDPE Drum 220L HDPE IBC 1000L Stainless steel tanks 20-27 Tn

Table 6. Intended use 5 – Disinfection of inner surfaces by CIP

Product Type(s)	PT 4: food and feed area disinfectants.
Where relevant, an exact description of the authorised use	Hydrogen peroxide is used for the disinfection of installations in the food and beverage industry by circulating hydrogen peroxide through pipework and tanks (Clean-in-Place method).
Target organism (including development stage)	Bacteria, yeasts, fungi
Field of use	Indoor
Application method(s)	Cleaning In Place (CIP). Disinfecting the interior surfaces of closed systems by Cleaning In Place (CIP).
Application rate(s) and frequency	4.0% (w/w) hydrogen peroxide. Contact time: 15 min. One application. Frequency, as required.
Category(ies) of user(s)	Professionals
Pack sizes and packaging material	HDPE Jerry Can 5L, 20L, 25L, 30L, 60L HDPE Drum 220L HDPE IBC 1000L Stainless steel tanks 20-27 Tn

Table 7. Intended use 6 – Disinfection of cork stoppers

Product Type(s)	PT 4: food and feed area disinfectants.
Where relevant, an exact description of the authorised use	Hydrogen peroxide is used for the disinfection of cork stoppers in the food and beverage industry by spraying the cork surface with the undiluted product.
Target organism (including development stage)	Bacteria, yeasts, fungi

Field of use	Indoor
Application method(s)	Spraying. Automated spraying in closed systems.
Application rate(s) and frequency	35% (w/w) hydrogen peroxide. 1 mL/cork stopper One application. Spraying time: 20-50 seconds. Contact time: 5 minutes. Waiting period: until packaging material is dry.
Category(ies) of user(s)	Professionals
Pack sizes and packaging material	HDPE Jerry Can 5L, 20L, 25L, 30L, 60L HDPE Drum 220L HDPE IBC 1000L Stainless steel tanks 20-27 Tn

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	-	AOPACK 35%: 35.6% w/w	Transparent and homogeneous liquid	Final Report BT077/16 Aversa (2016a)
Colour at 20 °C and 101.3 kPa	-	AOPACK 35%: 35.6% w/w	colourless	Final Report BT077/16 Aversa (2016a)
Odour at 20 °C and 101.3 kPa	-	AOPACK 35%: 35.6% w/w	odourless	Final Report BT077/16 Aversa (2016a)
pH	CIPAC MT 75.3	AOPACK 35%: 35.6% w/w	Undiluted:2.4 1%: 6.31	Final Report BT077/16 Aversa (2016a)
Acidity/alkalinity	CIPAC MT 191	AOPACK 35%: 35.6% w/w	Acidity:0.013 % H_2SO_4 (w/w)	Final Report BT077/16 Aversa (2016a)
Relative density / bulk density	OECD 109 / EU Method A.3	AOPACK 35%: 35.6% w/w	20ºC:1.135	Final Report BT077/16 Aversa (2016a)
Storage stability test – **accelerated storage**	CIPAC MT 46.3 Validated method SANCO/3030/99	AOPACK 35%: 35.6% w/w	2 weeks at 54º±2ºC, 5 L HDPE tank Property: Appearance; T=0: Transparent and homogeneous; T=2w: Transparent and homog	Final Report BT077/16 Aversa (2016a)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	rev.4 in the Study BT079/16 CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 41		liquid, colourless, odourless / eneous liquid, colourless, odourless Weight loss: - / 0.1 % H_2O_2 content: 35.91 % w/w / 36.14 % w/w pH Undiluted: 2.41 (24.5 °C) / 2.53 (20.2 °C) Diluted 1 % w/v: 6.31 (24.6 °C) / 7.17 (20.4 °C) Acidity: 0.013 % w/w H_2SO_4 / 0.005 % w/w H_2SO_4 Dilution stability 5 % v/v: T=0 Homogeneous / After 18 hours Homogeneous	
Storage stability test – **accelerated storage**	CIPAC MT 46.3	OXTERIL® 350 SPRAY: 35,4% OXTERIL® 350 BATH: 35,4% OXTERIL® 350 COMBI: 35,4% CLARMARIN® 350: 35,1% CLARMARIN® 500: 49,5%	Stability towards stainless steel VA 1.4404 :8 weeks at 40ºC (glass flasks with steel coupon) Stable:Not significant change (appearance); decrease in hydrogen peroxide in the range of 35.0-49.9%:0.0-3.4% (acceptable limit:10%)	Imm (2016)
Storage stability test – **long term storage at ambient temperature**	CropLife International, Technical Monograph N° 17. Guidelines for Specifying the Shelf Life of Plant Protection Products/ Manual on development and use	AOPACK 35%: 35.6% w/w	Study duration: 2 years in 5 L HDPE tank packaging - Temperature: 20 ± 2ºC - Sampling times: 6 months, 12 months, 2 years (24 months). <u>Appearance:</u> T=0 , Transparent and homogeneous Liquid, colourless and odourless T=6M , Transparent and homogeneous	Final Report BT078/16 Aversa (2018a)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	of FAO and WHO specifications for pesticides		Liquid, colourless and odourless T=12M , Transparent and homogeneous Liquid, colourless and odourless T=24M , Transparent and homogeneous Liquid, colourless and odourless <u>Packaging:Weight loss (%):</u> T=0 , - T=6M , 0.04 % T=12M , 0.0 % T=24M , 0.13 % <u>Hydrogen peroxide content:</u> T=0 , 35.91% w/w T=6M , 35.91% w/w T=12M , 35.70% w/w T=24M , 35.52% w/w <u>pH values of undiluted test item:</u> T=0 , 2.41 T=6M , 2.49 T=12M , 2.57 T=24M , 2.59 <u>pH values of 1% w/v diluted test item:</u> T=0 , 6.31 T=6M , 7.35 T=12M , 7.55 T=24M , 7.57 <u>Acidity (%) value of the test item:</u> T=0 , 0.013 T=6M , 0.004 T=12M , 0.0049 T=24M , 0.0049 <u>Dilution stability :</u>Homogeneus The solution remained homogeneous after 18 hours.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			The dilution stability of the test item remained unaltered after 24 months of storage at 20 ± 2ºC. No physical changes or interactions with the packaging were observed.	
Storage stability test – **long term storage at ambient temperature**	Stainless steel packaging: Since the estimated period of storage in 20 m^3 steel tanks is up to three months, this endpoint is covered by the accelerated storage in glass bottles with a steel coupon which mimics storage in stainless steel containers (Imm,2016).			
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	AOPACK 35%: 35.6% w/w	The test item remained unaltered after cold storage at 0 ± 2ºC for 7 days. The appearance of the test item remained unaltered after cold storage at 0 ± 2ºC for one week, including the evaluation of any change in the formulation due to phase separation or precipitation No separation and precipitation was observed after cold storage.	Final Report BT077/16 Aversa (2016a)
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	No test conducted. *"Protect from direct sunlight"* sentence should be added to the label and in the storage conditions.			
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Temperature:The accelerated stability tests were conducted at 40 °C where no impact on the product stability was observed. Humidity: The effect of humidity is irrelevant because the product contains water.			
Effects on content of the active substance and technical characteristics of the biocidal product -	*The study does not need to be conducted since the no reactivity towards container materials (HDPE and stainless steel) was observed in either accelerated, low-temperature, or long-term stability tests. Thus, the selected container material is deemed suitable for the storage of the hydrogen peroxide biocidal products.*			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
reactivity towards container material				
Wettability	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Suspensibility, spontaneity and dispersion stability	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Wet sieve analysis and dry sieve test	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Emulsifiability, re-emulsifiability and emulsion stability	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Disintegration time	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Particle size distribution, content of dust/fines, attrition, friability	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Persistent foaming	CIPAC MT 47.2	AOPACK 35%: 35.6% w/w	The persistent foaming of the test item was measured in the undiluted product (as highest application rate, considering that the product is ready to use) and at 8.6 % v/v (lowest application rate, corresponding to about 3 % of hydrogen peroxide) in CIPAC Standard Water D according to CIPAC MT 47.2. The foam was measured after 10 seconds, 1, 3 and 12 minutes. No foam was produced by the test item.	Final Report BT077/16 Aversa (2016a)
Flowability/Pourability/Dustability	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Burning rate — smoke generators	*The study does not need to be conducted since the biocidal product is not a smoke generator.*			
Burning completeness — smoke generators	*The study does not need to be conducted since the biocidal product is not a smoke generator.*			
Composition of smoke — smoke generators	*The study does not need to be conducted since the biocidal product is not a smoke generator.*			
Spraying pattern — aerosols	*The study does not need to be conducted since the biocidal product is not an aerosol.*			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical compatibility	*The study does not need to be conducted since the product is not intended to be used with other products*			
Chemical compatibility	*The study does not need to be conducted since the product is not intended to be used with other products*			
Degree of dissolution and dilution stability	CIPAC MT 41	AOPACK 35%: 35.6% w/w	5 % v/v Homogeneous for 18 hours at 20°C	Aversa (2016a)
Surface tension	OECD 115 / EU Method A.5	AOPACK 35%: 35.6% w/w	67.4 mN/m at 25ºC 1 % w/v dilution:71.1 mN/m at 25ºC	Aversa (2016a)
Viscosity	OECD 114	AOPACK 35%: 35.6% w/w	0.6922 mm2/s (20ºC) 0.4803 mm2/s (40ºC) 0.7856 mPa·s (20ºC) 0.5452 mPa·s (40ºC)	Aversa (2016a)

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

The biocidal product is an aqueous solution of hydrogen peroxide, which is miscible with water in all proportions, forming colourless and odourless transparent liquids. Hydrogen peroxide is a very weak acid and aqueous solutions are slightly acidic.
The pH of the product is 2.4 when undiluted and 6.31 when diluted to 1% in water. The acidity is 0.013 H_2SO_4 % (w/w). Regarding the density, it is 1.135 g/mL.
The biocidal product does not produce persistent foaming and the solutions remain homogeneuous for at least 18 hours at 20ºC when diluted. No foaming observed in undiluted product (highest application rate).

The surface tension of the test item at 25ºC was found to be 67.4 mN/m. For a dilution at a 1% (w/v) concentration of the test item, the surface tension at 25ºC was found to be 71.1 mN/m. The product is not surface active at test item diluted 1 % w/v.

Regarding storage stability, the product remained unaltered after accelerated storage at 54 ± 2 °C for 2 weeks, in 5 L HDPE tank. The low-temperature (0ºC for 1 week) stability study confirm the stability is acceptable under tested conditions.
The product also remained stable during the long term storage stability tests for 2 years at ambient temperatures. No changes on the active substance content of the test item were observed after 2 years storage at 20 ± 2ºC. According to the results, the test item is stable up to 2 years shelf life at 20 ± 2ºC. No physical changes or interactions with the packaging were observed. The product did not react towards HDPE container, so plastic packaging material is deemed suitable for storage.The shelf-life of the product is indicated as 2 years.

The product may be also marketed in bulk, using 20-27 m^3 stainless steel containers used for transport (tank trucks). Shelf-life for these containers is claimed as a maximum of 3 months, based on accelerated data. This claim is deemed acceptable as the product is not corrosive to metals and the accelerated data show no impact on the stainlees steel coupons used to mimic storage in stainless steel.

Stainless steel packaging study: Water solution products containing between 35 and 49.9% (w/w) hydrogen peroxide. Method according CIPAC MT 46.3. 8 week storage at 40 °C in glass flasks with stainless steel coupon. No significant changes (appearance) neither interaction between product and material were observed. The decrease in hydrogen peroxide content was between 0.0 -3.4% (w/w) being the acceptable limit 10%. Thus, the product was determined to be stable under test conditions.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Differential Scanning Calorimetry (DSC) according to EN ISO 11357,DIN 51005,DIN 51077	AOPACK 35%: 35.6 % w/w hydrogen peroxide	Method description: A DSC instrument type DSC3+ from Mettler Toledo was used. The measurements were carried out with gold-plated high-pressure stainless-steel crucibles (crucible volume 20 µL) in the temperature range of 30 °C – 450 °C. The crucibles were heated to the final temperature of 450 °C with a constant gradient of 5 K/min. An empty gold-plated high-pressure stainless-steel crucible was used as reference crucible. Mass loss (back weighing of the crucible after the end of the experiment) was 0 % for all samples. The thermal stability showed an exothermic effect at 40 °C with an energy release of -50 J/g. Due to the low energy release of the exothermic effect of <-100 J/g, a critically self-accelerating decomposition reaction by the exothermic reaction	Test Report No.SPZ22-155 Imm (2022)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			does not have to be assumed. According to the TRAS 410: Texo = Tmax - 100 K = 350° C. Thus, it is assumed that the energy release is below -300 J/g up to 500 °C. According to Appendix 6 of the UN Manual of Tests and Criteria, Class 1 "explosives", the biocidal product was determined not to have explosive properties.	
Flammable gases	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Flammable aerosols	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Oxidising gases	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Gases under pressure	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Flammable liquids	*Hydrogen peroxide is an inorganic substance that cannot be oxidised but can itself act as an oxidising or reducing agent. Flammability defines the ability of a substance to become oxidised. The term "burning" describes the act of becoming oxidised. In this view, hydrogen peroxide is not flammable. Hydrogen peroxide is fully miscible with water and does not become spontaneously flammable or emits flammable gases. Hydrogen peroxide does not spontaneously ignite in contact with air. Hydrogen peroxide is thus considered as non-flammable.*			
Flammable solids	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Self-reactive substances and mixtures	Differential Scanning Calorimetry (DSC) according to EN ISO 11357,DIN 51005,DIN 51077	AOPACK 35%: 35.6 % w/w hydrogen peroxide	Method description: A DSC instrument type DSC3+ from Mettler Toledo was used. The measurements were carried out with gold-plated high-pressure stainless-steel crucibles (crucible volume 20 µL) in the temperature range of 30 °C – 450 °C. The crucibles were heated	Test Report No.SPZ22-155 Imm (2022)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			to the final temperature of 450 °C with a constant gradient of 5 K/min. An empty gold-plated high-pressure stainless-steel crucible was used as reference crucible. Mass loss (back weighing of the crucible after the end of the experiment) was 0 % for all samples. The thermal stability showed an exothermic effect at 40 °C with an energy release of -50 J/g. Due to the low energy release of the exothermic effect of <-100 J/g, a critically self-accelerating decomposition reaction by the exothermic reaction does not have to be assumed. According to the TRAS 410: Texo = Tmax - 100 K = 350° C. Thus, it is assumed that the energy release is below -300 J/g up to 500 °C. According to Appendix 6 of the UN Manual of Tests and Criteria, Class 4, Division 4.1"self-reactive substances", the biocidal product was determined not to have self-reactive properties.	
Pyrophoric liquids	*Inorganic oxidising liquids are not flammable and therefore do not have to be subjected to the classification procedures for the hazard classes flammable liquids or pyrophoric liquids.*			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Pyrophoric solids	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Self-heating substances and mixtures	Not applicable since the biocidal product is a liquid and contain a significant amount of water.Liquids are not classified as self-heating.			
Substances and mixtures which in contact with water emit flammable gases	Not applicable since the biocidal product form stable mixtures and contain a significant amount of water.			
Oxidising liquids	UN-Test O.2	AOPACK 35%: 35.6% w/w	Not oxidising. Criteria for no oxidizing liquid :any substance which , in the 1:1 mixture , by mass, of substance and cellulose tested exhibits mean pressure rise time greater than the mean pressure rise time of a 1:1 mixture, of 65% aqueous nitric acid solution and cellulose. **Results:** Reference mixture nitric acid/cellulose:2904 ms AOPACK 35%+Cellulose:4388 ms	Test Report No.: SPZ22-155.Imm (2022)
	eRemark:The test data provided by applicant showed no oxidising properties, but the evaluating Competent Authority (ES CA) decided to apply judgement based on known experience related to the application of the UN RTDG Model Regulation and classify the products in the corresponding hazard class under the CLP Regulation (Oxidising liquid Category 2) and consider that judgement based on the experience related to the application of the UN RTDG Model Regulation is to take precedence over test results.			
Oxidising solids	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Organic peroxides	*Based on its composition and the chemical structure of the components, the product is not an organic peroxide.*			
Corrosive to metals	UN Manual of Tests and Criteria: Part III, 37.4: Test methods for	Oxypure C50%: 49.4% w/w	The study on carbon steel (type: S235 JR) and alloyed aluminium (type: 7075 T6 F53) were conducted at 55ºC. 2 mm thick	Petryka (2016)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	corrosion to metals Test C.1.		metal plates were used as test specimens, one of which was completely dipped into the solution, another one only half way and a third one was hang in the vapour phase. The corrosion rate of both aluminium and steel in test item was below the threshold of 6.25mm/year. Therefore, the test item is not corrosive to metals. An aqueous solution of hydrogen peroxide 49.9% (w/w) is not corrosive to metals. Based on this result, the biocidal product, hydrogen peroxide 35% (w/w) water solution, is not corrosive to metals.	
Auto-ignition temperatures of products (liquids and gases)	*Inorganic oxidising liquids are not flammable. The test is not required for liquids not flammable in air.*			
Relative self-ignition temperature for solids	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Dust explosion hazard	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			

Conclusion on the physical hazards and respective characteristics of the product
AOPACK 35% is a liquid product containing minimum 64% (w/w) water and the active substance. Based on this composition and based on studies results the product is not expected to present a significant hazard for explosive properties, flammability, self-reactivity , pyrophoric properties and auto-flammability. The product is however classified as oxidising liquid based on known experience in the handling and use of aqueous solutions containing hydrogen peroxide, taking into account the application of the UN RTDG Model Regulation takes precedence over test results. Regarding the corrosivity to metals, since the aqueous solution containing 49.9% (w/w) hydrogen peroxide (tested product:Oxypure C50%) is not corrosive to metals, the present product (35% w/w hydrogen peroxide), do not fulfil the criteria for this classification according to the Regulation (EC) No 12727/2008 (CLP).

2.2.4 Methods for detection and identification

The hydrogen peroxide content in those aqueous solutions is determined by titration with potassium permanganate under acidic conditions. The method has been validated according to SANCO/ 3029/99 rev.4 (GLP study). The criteria for linearity, specificity, precision (repeatibility) and accuracy were met.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
A.S:Hydrogen peroxide	Titration with $KMnO_4$	The blank formulation was spiked with the technical product at two fortification levels:10% w/w-50% w/w Number of measurements:5	The method/detector response was linear (coefficient of determination, r2= > 0.98 within the range of 1.0 % w/w – 59.5 % w/w] R^2= 0.999922 r = 0.999961	specific	99.63 – 101.10	-	0.44	-	BT079/16Aversa (2016a)
A.S:Hydrogen peroxide	Titration with $KMnO_4$	5 ;3 laboratories	-	specific	-	98	0.061	-	CEFIC (2003); Crommelynk (1993); Maire (2016)*

**This method was part of the EU active substance data package (or post-approval data), evaluated by Finland.*

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

Impurity (Cd, As, Pb, Hg)	ICP-MS	5	0.5-100 µg/L; r^2 >0.99	specific	90-95	-	0.41-4.4	0.05 ppm	Maire (2016)*
Impurity (Cl^-, PO_4^{3-}, SO_4^{2-}, NO_3^-)	Ion cromato-graphic method	-		specific				-	Degusa (2005)

**This method was part of the EU active substance data package (or post-approval data), evaluated by Finland.*

Analytical methods for soil
Hydrogen peroxide is very rapidly degraded in soil, forming only water and oxygen (half-lives of a few minutes to a maximum of 15 hours. This impedes classical validation experiments (e.g. fortification). Due to its chemical structure, hydrogen peroxide is not adsorbed to soil but remains in the soil water. Soil water may be analysed for hydrogen peroxide using the methods available for water. Besides, there is no risk for relevant exposure of soil during the biocidal uses of hydrogen peroxide. In summary, no analytical method is considered to be needed.

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance	A: visible spectro-photometry	5	A: 0.03-1.5 µg/L, r^2 = 0.9997	specific	A: 103.2 – 104.5	A: 103.7	A: 0.7	LOD(A)= 0.74 µg/mL	Kligour (2001)*
Active substance	B: flow injection analysis (FIA-UV)	5	B: 0.6-6 µg/L, r^2 = 0.9991	specific	B: 88.9 – 102.9	B: 97.9	B: 8.0	LOD(B) = 2.9 µg/mL	Kligour (2001)*
Active substance	UV-Vis spectrophoto metric method	5	r^2= 0.997	specific	101-108		7.9	LOQ =139 µg/m^3	Maire (2016)*

**This method was part of the EU active substance data package (or post-approval data), evaluated by Finland.*

Analytical methods for water								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance	UPLC-FLD	5	0.01-0.1 ppm, r^2 = 0.998	specific	90 - 97	-	6.2	LOQ = 0.01 mg/L	Maire (2016)*

**This method was part of the EU active substance data package (or post-approval data), evaluated by Finland.*

Analytical methods for animal and human body fluids and tisues
Hydrogen peroxide is not classified as toxic or very toxic, and therefore no analytical method for body fluids and tissues of humans or animals is required.

Analytical methods for monitoring of active substances and residues in food and feeding stuff
There are no relevant residues of hydrogen peroxide expected in food and feeding stuff due to the rapid degradation of hydrogen peroxide to water and oxygen in the environment.

Conclusion on the methods for detection and identification of the product
The product has 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. As stated in the CAR, a large body of publicly available literature exists regarding analytical methods for hydrogen peroxide in water. In addition to the published methods, ready-to-use testing kits are commercially available, e.g. Dräger© tubes for airborne hydrogen peroxide to determine hydrogen peroxide in water down to a concentration of 0.5 mg/L. All of these published or commercially available methods have been in use for many years, have undergone scientific review and also inter-laboratory validation studies were carried out[3]. The choice of a particular method should be guided by the matrix to be analysed, the expected concentration range and potential interferences, which are discussed in the review literature[4]. Besides the information already covered in the CAR, new validated methods have been presented for the analysis of hydrogen peroxide in water and air samples, along with a validation for the titrimetric method for the analysis of the product and a method for the analysis of heavy metals in the product.

3 Gunz et al. (1990). Atmospheric chemistry of peroxides: a review. Atmospheric Environment 24A: 1601-1633.

4 Sturzenegger (1998). Wasserstoffperoxid in Oberflächengewässern: Photochemishe Production und Abbau. Dissertation an der Eidgenössischen Technischen Hochschule, Zurich, p. 144.

Analytical method for the determination of active substance in the product: The formulations of hydrogen peroxide is an aqueous solutions of a concentration of 35% (w/w). The hydrogen peroxide content is determined by titration with potassium permanganate under acidic conditions. The method has been validated according to SANCO/ 3029/99 rev.4 (GLP study).

Analytical method for hydrogen peroxide monitoring purposes in air: A UV-Vis spectrophotometric method for quantitative analysis of hydrogen peroxide in air was developed based on the OSHA method number VI-6. The analytical method was validated according to SANCO/3029/99 rev.4 (GLP study). The limit of quantification (LOQ) was assessed at 139 µg/m^3 in air.

Analytical method for hydrogen peroxide monitoring purposes in water: An ultra-performance liquid chromatographic method with fluorescence detection (UPLC-FLD) for the quantitative analysis of hydrogen peroxide in water was developed. The analytical method was validated according to SANCO/3029/99 rev.4 (GLP study). The limit of quantification (LOQ) was assessed at 0.01 mg/L in water.

Analytical method for the analysis of Cd, As, Pb, and Hg in hydrogen peroxide solutions: An inductively coupled plasma - mass spectrometric (ICP-MS) method for the quantitative analysis of Cd, As, Pb and Hg in hydrogen peroxide solution was developed and validated for the calibration range 0.5 -100 µg/L, according to SANCO/3030/99 rev.4 (GLP study). The limit of quantification (LOQ) was assessed at 0.05 mg/kg in hydrogen peroxide solution.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The biocidal product contains hydrogen peroxide as the active substance. The product is intended for the use as disinfectant in the biocidal product type 4: Food and feed area. The product demonstrate efficacy against bacteria, yeast, fungi and bacterial spores.

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

The biocidal product is effective against bacteria, yeasts, fungi and bacterial spores. It is used as a disinfectant in the food and feed industry (PT4), for aseptic packaging in close systems, surface disinfection by VHP process, disinfection of inner surfaces by CIP, and disinfection of cork stoppers.

	Use	Dose*	Claim**				
			B	Y	F	S	V
1	Aseptic packaging: immersion	35% w/w	x	x		x	
2	Aseptic packaging: spraying	35% w/w	x	x		x	
3	Surface disinfection by VHP	1092 mg/m^3	x	x			
4	Disinfection of distribution systems for drinking water	4% w/w	x		x		
5	Disinfection of inner sufaces by CIP	5% w/w	x	x	x		

6	Disinfection of cork stoppers	35% w/w	x	x	x	

*Hydrogen peroxide

**B: Bactericidal; Y: Yeasticidal; F: Fungicidal; S: Bacterial sporicidal; V: Virucidal

2.2.5.3 Effects on target organisms, including unacceptable suffering

Hidrogen peroxide is reactive and it degrades rapidly in contact with organic material. The product is able to produce, under defined conditions, a reduction in the number of:

-viable bacterial endospores (sporicidal activity),

-viable bacterial cells (bactericidal activity),

-yeast cells (yeasticidal activity) and

-mould spores (fungicidal activity).

2.2.5.4 Mode of action, including time delay

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

2.2.5.5 Efficacy data

The biocidal products tested for efficacy are hydrogen peroxide in water solutions and thus, although the products are different from the one included in the present application, the obtained results are suitable for assessment and extrapolation.

The aim of the efficacy tests is to know the effective hydrogen peroxide concentration. For a particular use and its use conditions (e.g. in-use active substance concentrations, target organisms, contact time and application method), it is considered sufficient to demonstrate efficacy with a representative biocide formulation with the minimum level of efficacy ("worst-case"). Based on this assumption, the tests can be perform with any products containing just hydrogen peroxide and water and the results can be extrapolated from product to product.

In particular, for aseptic packaging (uses 1 and 2), the doses to be applied will depend on the aseptic packaging machine being used and the user shall always carry out a microbiological validation of the disinfection, after which a protocol for disinfection of this packaging/system can be made and used thereafter.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects (H_2O_2)**	**Reference**
1: Aseptic packaging by immersion							
Sporicide	*PT4*	*Hydrogen peroxide 30%*	*Bacillus subtillis*	Field test (P3)	*Shallow bath*:	For all applied technologies, the required	[redacted]

					Hydrogen peroxide: 28% w/w; Temperature: 75ºC; Contact time: 5.8 seconds *Deep bath (1)*: Hydrogen peroxide: 29% w/w; Temperature: 64ºC; Contact time: 6.6 seconds *Deep bath (2)*: Hydrogen peroxide: 29% w/w; Temperature: 80ºC; Contact time: 2.5 seconds *2 test each, three loadings per test (10E4, 10E5 and 10E6 spores/package), 25 packages each. *Negative control*: Only water. Temperature: 90 ºC; Contact time: 5, 10, 15, 20 and 30 minutes.	log reduction was observed. Hydrogen peroxide water solutions (30% w/w) showed efficacy (LCR > 5) against bacterial spores after sterilization processes in aseptic packaging machine systems (under clean conditions, temperature ≥65 ºC, contact time ≥6.6seconds or ≥ 80ºC , contact time 2.5 seconds, by "shallow bath" and "deep bath" processes).	*Key study*
2: Aseptic packaging by spraying							
Sporicide	*PT4*	*Hydrogen peroxide 35% (B-CAP 35)*	*Bacillus subtillis, Clostridium sporogenes*	Field test (AOAC-ST, P3)	35% (w/w), 3 lots; 20s; 75ºC; clean conditions.	Biocide demonstrates sporicidal activity with 35% (w/w) hydrogen peroxide (under clean conditions, for 20 seconds contact time at 75 ºC-85 ºC).	[redacted] *A08823* *Key study*
3: Surface disinfection by VHP process in food processing facilities							

Bactericide	*PT4*	*Hydrogen peroxide 49.6% (OXYPURE C50)*	*Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae*	EN 1276: 1998 (P2/S1)	0.5, 1, 2, 4, 8, 16, 20% (v/v) of a 49.6% (w/w) solution; 5 min; 20ºC, clean conditions.	Efficacy observed with 3.97% (v/v), 4.76% (w/w) hydrogen peroxide (under clean conditions, for 5 min contact time at 20 ºC).	[redacted] *A-044635 Complementary study*
Bactericide	*PT4*	*Hydrogen peroxide 4.8% (AOFARMA 4.8)*	*Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae*	EN 1276: 2010 (P2/S1)	72, 75, 80% (v/v) of a 4.8% (w/w) solution; 1 min; 20ºC, clean conditions.	Efficacy observed with 3.93% (v/v), 4% (w/w) hydrogen peroxide (under clean conditions, for 1 min contact time at 20 ºC)	[redacted] *160043792 Key study*
Fungicide	*PT4*	*Hydrogen peroxide 49.6% (OXYPURE C50)*	*Candida albicans, Aspergillus niger*	EN 1650: 1998 (P2/S1)	0.5, 1, 2, 4, 8, 10, 15% (v/v) of a 49.6% (w/w) solution; 15 min; 20ºC, clean conditions.	Efficacy observed with 4.76% (w/w) hydrogen peroxide (under clean conditions, for 15 min contact time at 20 ºC).	[redacted] *A-043378 Key study*
Bactericide, Yeasticide	*PT4*	*Oxteril® 350 Spray (35% H2O2 (w/w))*	*Bacteria: Staphylococcus aureus, Enterococcus hirae, Escherichia coli, Pseuromonas aeruginosa* *Yeast: Candida albicans*	NF T 72-281 (P2/S2)	Test room volume: 50 m^3 (room partially furnished) Application rate: 1092 mg /m^3 (780 ppm) test concentration. Exposure: 5 h (1 h initial phase + 4 h contact time) and 280 min (40 min initial phase + 240 min contact time) at 20°C ± 2°C under clean conditions (0.3 g/L BSA) and rel. humidity: 40– 80 %	Oxteril® 350 Spray showed sufficient bactericidal and yeasticidal activitiy under test conditions. Efficacy observed with an application rate of 1092 mg/m^2 (780 ppm) hydrogen peroxide concentration generated by a generator. Test room volume was 50 m^3 and the contact time 4 hours.	[redacted] *STULV18AA2074-1 Key study*

					Assessment : Reduction in total viable counts (log reduction >5 for bacteria, > 4.0 for yeast)		
4 and 5: Disinfection of surfaces of drinking water systems and Disinfection of inner surfaces by CIP							
Bactericide	*PT4*	*Hydrogen peroxide 4.8% (AOFARMA 4.8)*	*Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae*	EN 1276: 2010 (P2/S1)	72, 75, 80% (v/v) of a 4.8% (w/w) solution; 1 min; 20ºC, clean conditions.	Efficacy observed with 3.93% (v/v), 4% (w/w) hydrogen peroxide (under clean conditions, for 1 min contact time at 20 ºC)	[redacted] *160043792 Key study*
Bactericide	*PT4*	*Hydrogen peroxide 49.6% (OXYPURE C50)*	*Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae*	EN 1276: 1998 (P2/S1)	0.5, 1, 2, 4, 8, 16, 20% (v/v) of a 49.6% (w/w) solution; 5 min; 20ºC, clean conditions.	Efficacy observed with 3.97 (v/v), 4.76% (w/w) hydrogen peroxide (under clean conditions, for 5 min contact time at 20 ºC).	[redacted] *A-044635 Complementary study*
Fungicide	*PT4*	*Hydrogen peroxide (CLARMARIN 500)*	*Aspergillus brasiliensis*	EN 1650 (2013) (P2/S1)	1, 2, 4% (v/v) of a 50% (w/w) solution; 180 min; 20ºC, clean conditions.	Efficacy observed with 1.2% (w/w) hydrogen peroxide (under clean conditions, for 180 min contact time at 20 ºC)	[redacted] *181106-0341-003 Key study*
Fungicide	*PT4*	*Hydrogen peroxide 49.6% (OXYPURE C50)*	*Candida albicans, Aspergillus niger*	EN 1650: 1998 (P2/S1)	0.5, 1, 2, 4, 8, 10, 15% (v/v) of a 49.6% (w/w) solution; 15 min; 20ºC, clean conditions.	Efficacy observed with 4.76% (w/w) hydrogen peroxide (under clean conditions, for 15 min contact time at 20 ºC).	[redacted] *A-043378 Key study*
6: Disinfection of cork stoppers							
Bactericide	*PT4*	*Hydrogen peroxide 4.8% (AOFARMA 4.8)*	*Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae*	EN 1276: 2010 (P2/S1)	25, 75, 80% (v/v) of a 4.9% (w/w) solution; 1 min; 20ºC, clean conditions.	Efficacy observed with 3.93% (v/v), 4% (w/w) hydrogen peroxide (under clean conditions, for 1 min contact time at 20 ºC)	[redacted] *160043792 Key study*

Bactericide	*PT4*	*Hydrogen peroxide 49.6% (OXYPURE C50)*	*Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae*	EN 13697: 2002 (Erratum 2007) (P2/S2)	2.5, 5, 10% (v/v) of a 49.6% (w/w) solution; 5 min; 23ºC, clean conditions.	Efficacy observed with 4.96% (v/v), 6%(w/w) hydrogen peroxide (under clean conditions, for 5 min contact time at 23 ºC).	[redacted] *110024765 Key study*
Fungicide	*PT4*	*Hydrogen peroxide 35% (OXTERIL 350 Spray)*	*Candida albicans, Aspergillus brasiliensis*	EN 1650: 2019 (P2/S1)	80%, 50, 12.5% (v/v) of a 35% (w/w) solution; 5 min; 20ºC, clean conditions.	Efficacy observed with 31.8% (w/w) hydrogen peroxide (under clean conditions, for 5 min contact time at 20 ºC).	[redacted] *211026-0002-001 Key study*
Fungicide	*PT4*	*Hydrogen peroxide 35% (OXTERIL 350 Spray)*	*Candida albicans, Aspergillus niger*	EN 13697: 2019 (P2/S2)	100, 80, 50, 12.5% (v/v) of a 35% (w/w) solution; 5 min; 23ºC, clean conditions.	Efficacy observed with 31.8% (w/w) hydrogen peroxide (under clean conditions, for 5 min contact time at 23 ºC).	[redacted] *211026-0002-002 Key study*
Bactericide, yeasticide, fungicide	*PT4*	*Hydrogen peroxide 35% (OXYPURE C35)*	*Not specified*	ISO 10718:2005 (P3)	35% (w/w) solution; 5 min; ambient temperature	The analysis performed throughout 2019 and 2020 showed 0 (or very closed to 0) values of CFUs. <10 CFU bacteria / stopper; <10 CFU yeasts and fungi / stopper	[redacted] *Complementary study*
Bactericide,	*PT4*	*Hydrogen peroxide 35% /CLARMARIN 350)*	*Bacteria: Staphylococcus aureus, Enterococcus hirae, Pseuromonas aeruginosa, Proteous vulgaris*	EN 16437: 2014 (P2S2)	100, 75, 50, 10% (v/v) of a 35% (w/w) solution; 30 min; 20ºC, clean conditions. On poplar wood strips.	Efficacy observed with 35% (w/w) hydrogen peroxide (under clean conditions, for 30 min contact time at 20 ºC).	[redacted] *170112-0015-057*

Conclusion on the efficacy of the product

Use 1: Aseptic packaging by immersion:

The biocidal product, hydrogen peroxide 35% (w/w) water solution, is used in aseptic filling applications. The packaging material in the form of (sheet) reels passes through a deep bath filled with hydrogen peroxide solutions by dipping. The temperature and contact time depend on the machine (usually ≥65 °C for ≥6.6 seconds or ≥80 °C for ≥2.5 seconds). The user shall always carry out a microbiological validation of the disinfection,

after which a protocol for disinfection of this packaging / system can be made and used thereafter.

For aseptic packaging, according to the Technical Agreements for Biocides (TAB) – EFF v.2.1 "efficacy should be demonstrated by validation of the product in the disinfection process using aseptic filling devices and packaging material that are representative for the intended use of the product. Phase 2, step 1 and phase 2, step 2 tests are not required". Moreover, "only bacterial spores survive these conditions, while vegetative bacteria and yeasts will be killed in the negative control. Therefore, demonstrating efficacy against bacterial spores is sufficient for an efficacy claim agains other groups of microorganisms for aseptic filling applications".

Aseptic packaging in food and feed industries, efficacy was demonstrated against bacterial spores by validation of the product in the process of aseptic packaging under practical conditions of use (shallow bath and deep bath technologies). Based on efficacy tests, the biocidal product is effective against bacteria, yeast and bacterial spores under use conditions.

Field test (P3, sporicidal): Hydrogen peroxide water solutions (30% w/w) showed efficacy (LCR > 5) against bacterial spores after sterilization processes in aseptic packaging machine systems (under clean conditions, temperature ≥65 ºC, contact time ≥6.6seconds or ≥ 80ºC , contact time 2.5 seconds, by "shallow bath" and "deep bath" processes).

Use 2: Aseptic packaging by spraying:

The biocidal product, hydrogen peroxide 35% (w/w) water solution, is used for aseptic packaging. The packaging material are delivered to the aseptic filling machine. Then, hydrogen peroxide solution is sprayed to the packaging material stepwise via a nozzle. The temperature and contact time depend on the machine (usually 75-85 ºC, ≥ 20 seconds). The user shall always carry out a microbiological validation of the disinfection, after which a protocol for disinfection of this packaging / system can be made and used thereafter.

For aseptic packaging, according to the Technical Agreements for Biocides (TAB) – EFF v.2.1 "efficacy should be demonstrated by validation of the product in the disinfection process using aseptic filling devices and packaging material that are representative for the intended use of the product. Phase 2, step 1 and phase 2, step 2 tests are not required". Moreover, "only bacterial spores survive these conditions, while vegetative bacteria and yeasts will be killed in the negative control. Therefore, demonstrating efficacy against bacterial spores is sufficient for an efficacy claim agains other groups of microorganisms for aseptic filling applications".

Aseptic packaging in food and feed industries, efficacy was demonstrated against bacterial spores by validation of the product in the process of aseptic packaging under practical conditions of use. Based on efficacy tests, the biocidal product is effective against bacteria, yeast and bacterial spores under use conditions.

Field test (P3, sporicidal): Sporicidal activity with 35% (w/w) hydrogen peroxide (under clean conditions, for 20 seconds contact time at 75 ºC-85 ºC).

Use 3: Room disinfection by VHP:

The biocidal product, hydrogen peroxide 35% (w/w) water solution, is used for the disinfection of surfaces by VHP process. Vaporised hydrogen peroxide decontaminates dry surfaces of food and feed areas and other enclosed spaces. During the disinfection cycle the VHP machine adjusts the hydrogen peroxide concentration up to the efficacy levels of

1092 mg/m^3 (780 ppm) and keeps it at this level for ≥ 4 hours. The product is effective against bacteria and yeasts.

EN-1276 (P2/S1, bactericidal): Efficacy observed with 4.76% (w/w) hydrogen peroxide (under clean conditions, for 5 min contact time at 20 ºC).

EN-1276 (P2/S1, bactericidal): Efficacy observed with 4% (w/w)) hydrogen peroxide (under clean conditions, for 1 min contact time at 20 ºC), with EN 1276: 2010.

EN-1650 (P2/S1, fungicidal): Efficacy observed with 4.76% (w/w) hydrogen peroxide (under clean conditions, for 15 min contact time at 20 ºC).

NF T 72 -281 (P2/S2, bactericidal, yeasticidal): Efficacy observed with an application rate of 1092 mg/m^2 (780 ppm) hydrogen peroxide concentration generated by a generator. Test room volume was 50 m^3 and the contact time 4 hours.

The product covers the minimal spectrum of target organisms (bacteria and yeast) required for the disinfection of hard surfaces in food and feed areas.

Use 4: Disinfection of surfaces of drinking water systems:

The biocidal product, hydrogen peroxide 35% (w/w) water solution, is used for cleaning and disinfection of distributing and storing installations for drinking water as pipes and container. The diluted product at 4% (w/w) hydrogen peroxide is circulated though the system (cleaning-in-place). The process involves the jetting or spraying of surfaces or circulation of cleaning solutions through the plant under conditions of increased turbulence and flow velocity. Based on efficacy tests, the biocidal products are effective against bacteria, yeasts, and fungi.

EN 1276 (1998) (P2/S1, bactericidal): Efficacy observed with 4.76% (w/w) hydrogen peroxide (under clean conditions, for 5 min contact time at 20 ºC).

EN-1276 (2010) (P2/S1, bactericidal): Efficacy observed with 4% (w/w) hydrogen peroxide (under clean conditions, for 1 min contact time at 20 ºC).

EN 1650 (1998) (P2/S1,yeasticidal, fungicidal): Efficacy observed with 4.76% (w/w) hydrogen peroxide (under clean conditions, for 15 min contact time at 20 ºC).

EN 1650 (2013) (P2/S1, fungicidal): Efficacy observed with 1.2% (w/w) hydrogen peroxide (under clean conditions, for 180 min contact time at 20 ºC).At the request of the concerned states, a new study EN 1650 (2013) was added to the studies carried out and the contact time was extended to 180 minutes to guarantee efficacy.

The product covers the minimal spectrum of target organisms required for the disinfection of drinking water systems (bacteria).

At the next renewal, in accordance with the Appendix 4 of the efficacy guidance Volume II parts B/C, which will be in force, in order to support a PT 4 use "Disinfection of inner surfaces in human drinking water systems" P2S1 and P2S2 tests must be provided. Therefore, new P2S2 tests will be expected to support the use #4.

Use 5: Disinfection of inner surfaces by CIP:

The biocidal product, hydrogen peroxide 35% (w/w) water solutions, are used for the disinfection of installations in the food and beverage industry by circulating a 5% solution of hydrogen peroxide through pipework and tanks. Based on efficacy tests, the biocidal product is effective against bacteria, yeasts and fungi.

EN 1276 (1998) (P2/S1, bactericidal): Efficacy observed with 4.76% (w/w) hydrogen peroxide (under clean conditions, for 5 min contact time at 20 ºC).

EN-1276 (2010) (P2/S1, bactericidal): Efficacy observed with 4% (w/w) hydrogen peroxide (under clean conditions, for 1 min contact time at 20 ºC).

EN 1650 (1998) (P2/S1, yeasticidal, fungicidal): Efficacy observed with 4.76% (w/w) hydrogen peroxide (under clean conditions, for 15 min contact time at 20 ºC).

EN 1650 (2013) (P2/S1, fungicidal): Efficacy observed with 1.2% (w/w) hydrogen peroxide (under clean conditions, for 180 min contact time at 20 ºC).

At the request of the concerned states, a new study EN 1650 (2013) was added to the studies carried out and the contact time was extended to 180 minutes to guarantee efficacy.

The product covers the minimal spectrum of target organisms (bacteria and yeast) required for the disinfection of hard surfaces in food and feed areas.

Use 6: Disinfection of cork stoppers:

The biocidal product, hydrogen peroxide 35% (w/w) water solutions, are used for the disinfection of cork stoppers in the food and beverage industry, by spraying the undiluted product onto the surface of the cork stoppers inside the rotary drum of the disinfection machine. Based on efficacy tests, the biocidal product is effective against bacteria yeasts and fungi.

EN 1276 (P2/S1, bactericidal): Efficacy observed with 4% (w/w)hydrogen peroxide (under clean conditions, for 1 min contact time at 20 ºC), with EN 1276: 2010.

EN 13697 (P2/S2, bactericidal): Efficacy observed with 6% (w/w) hydrogen peroxide (under clean conditions, for 5 min contact time at 23 ºC).

EN 1650 (P2/S1, fungicidal): Efficacy observed with 31.8% (w/w) hydrogen peroxide (under clean conditions, for 5 min contact time at 20 ºC).

EN 13697 (P2/S2, fungicidal): Efficacy observed with 31.8% (w/w) hydrogen peroxide (under clean conditions, for 5 min contact time at 23 ºC).

ISO 10718 (P3, bactericidal, yeasticidal, fungicidal): Efficacy observed with 35% (w/w) hydrogen peroxide (for 5 min contact time at ambient temperature).

At the request of the concerned states, a new study on porous surfaces was added to the studies carried out and the contact time was extended to 30 minutes to guarantee efficacy due to the cork stoppers' porosity.

EN 16437 (P2/S2, bactericidal): Efficacy observed with 35% (w/w) hydrogen peroxide (under clean conditions, for 30 min contact time at 20ºC) on poplar wood strips.

The product covers the minimal spectrum of target organisms (bacteria and yeast) required for the disinfection of hard surfaces in food and feed areas.

2.2.5.6 Occurrence of resistance and resistance management

Hydrogen peroxide (H_2O_2) is capable of damaging nearly every biological macromolecule as it generates reactive oxidative species (hydroxyl radicals and oxygen singlet) which can attack DNA as well as causing damage to enzymes and membrane constituents. However, the lethal effects of these oxidative species can be avoided with any damage being repaired in microorganisms such as *Escherichia coli* and *Salmonella typhimurium*.

When *E.coli* and *S. typhimurium* are exposed to low concentrations of H_2O_2, 3 µM and 60 µM respectively, cells produce enzymes and other proteins which are important for cellular defence and mitigate the toxic effects of the oxidative species. This adaptive response is triggered by nontoxic levels of the oxidative species to protect against and produce resistance to oxidative stress caused when challenged with higher concentrations, 10 mM[5].

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. There are two major temporal classes of hydrogen peroxide-inducible proteins, "early" and "late" proteins. The "early" proteins are those for which synthesis is maximal during the first 10 minutes of exposure and the "late" proteins which are synthesized at a maximal rate starting 10- 30 minutes after H_20_2 addition. Synthesis of the "early" and "late proteins return to normal with 30 minutes 60 minutes, respectively[6]. This suggests that the adaptive responses are transient rather than permanent. Therefore, resistance, as described in TNsG on Annex I inclusion (April 2002), as a genetically inherited characteristic has not been demonstrated.

Nakamura et al (2012)[21] reported that a novel disinfection method whereby hydroxyl radicals were artificially generated by photolysis of H_2O_2 had recently been developed. Hydroxyl radicals that had been generated by laser irradiation of hydrogen peroxide were found to kill pathogens of oral infectious diseases. Laser irradiation of bacterial suspensions in 1M H_2O_2 resulted in a >99.99 % reduction in the number of bacteria within 3 minutes. However, the sensitivity of the bacteria to this disinfection system varied somewhat according to the species.

Staphylococcus aureus and *Candida albicans* are frequently detected in the oral cavity and sometimes cause serious infectious diseases. 250 mM H_2O_2 was found to hardly kill any microorganisms. However, this was believed to be too low a concentration to exert a fungicidal and bactericidal effect because 3 % H_2O_2, corresponding to approximately 890 mM, is the standard concentration used in disinfection. Furthermore, besides having strong bactericidal and fungicidal effects, disinfection by reactive oxygen species (ROS), such as hydroxyl radicals, probably would not lead to development of bacterial and fungal resistance to these agents because they interact directly with several cell structures and different metabolic pathways. In particular, hydroxyl radicals and singlet oxygen are thought to be free from induction of resistance because no defence mechanisms against these ROS have been reported in living cells[7].

In addition to the findings of Nakamura et al (2012), the target organisms of biocidal products registered under product type 1, 2, 3 and 6 are *Escherichia coli*, *Staphylococcus. Aureus* and *Candida albicans*.

Hydrogen Peroxide has been intensively used as a disinfectant and preservative for more than 3 decades and has not lead to the development of significant resistance levels among field populations. Therefore, genetically inherited resistance is not expected when the product is used as recommended.

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5 Dukan and Touati (1996) Hypochlorous Acid Stress in *Escherichia coli*: Resistance, DNA Damage, and Comparison with Hydrogen Peroxide Stress. Journal of Bacteriology, 178 (21): 6145- 6150.

6 Christman et al (1985) Positive Control of a Regulon for Defences Against Oxidative Stress and Some Heat-Shock Proteins in *Salmonella typhimurium*. Cell, 41: 753-762.

7 Nakamura et al (2012) Microbial Resistance in Relation to Catalase Activity to Oxidative Stress Induced by Photolysis of Hydrogen Peroxide. Microbiol Immunol, 56: 48-55.

2.2.5.7 Known limitations

No limitations or restrictions concerning the product are known under the conditions intended for its use.

2.2.5.8 Evaluation of the label claims

The label claims for this product vary according to the use. The lowest in-use concentration in the instructions of use corresponds to the lowest effective concentration as previously demonstrated, and the conditions for application of the product correspond to the conditions tested. See section 2.2.5.5, 'Conclusion on the efficacy of the product'.

For PT4 aseptic packaging by spraying/immersion, bactericidal and sporicidal efficacies are claimed. The product is sprayed undiluted (35% (w/w) hydrogen peroxide). Conditions depend on the machine model, typically being ≥65 °C for ≥6.6 seconds or ≥80 °C for ≥2.5 seconds for immersion and 20s / 75ºC-85ºC for spraying.

For PT4 surface disinfection by VHP process, bactericidal and yeasticidal activities are claimed. The product (35% (w/w) hydrogen peroxide) is vaporised by the VHP machine.

For PT4 disinfection of distribution systems for drinking water, bactericidal, and fungicidal efficacies are claimed. The product is sprayed and/or injected through the systems at a concentration of 4% (w/w) hydrogen peroxide.

For PT4 disinfection of inner surfaces by CIP in food and beverage industry, bactericidal, yeasticidal and fungicidal efficacies are claimed. The biocidal product is circulated in a clean-in-place (CIP) system at a concentration of 5% (w/w) hydrogen peroxide.

For PT4 disinfection of cork stoppers, bactericidal, yeasticidal and fungicidal efficacies are claimed. The biocidal product is sprayed in a closed system at ambient temperature on the surface of the cork stoppers up to 30 minutes. The product is ready-to-use (35% (w/w) hydrogen peroxide).

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

The product is not intended for use with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Causes skin irritation.
Justification for the value/conclusion	Only the active substance hydrogen peroxide is classified for this health risk category.

	Hydrogen peroxide causes burns. The irritating property of hydrogen peroxide to the skin and the eye varies dramatically with its concentration. As seen in the CAR, the 35 % hydrogen peroxide caused slight to moderate reversible erythema and oedema in a skin irritation study (OECD 404, GLP study). Under CLP regulation and according to hydrogen peroxide specific concentration limit (Skin irrit. 2, H315: C ≥ 35%), AOPACK 35% must be classified as **Skin irritation 2, H315**: "Causes skin irritation".
Classification of the product according to CLP	Skin Irritant Category 2, H315: Causes skin irritation.

Data waiving	
Information requirement	Skin corrosion and irritation
Justification	In order to avoid further testing on vertebrates no studies on the skin irritation of the products were conducted as there are valid data available on each component of the mixtures sufficient to allow classification of the mixtures according to the rules laid down in the Regulation (EC) 1072/2008 (CLP) and no synergistic effects between any of the components are expected.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Causes serious eye damage.
Justification for the value/conclusion	Only the active substance hydrogen peroxide is classified for this health risk category. Hydrogen peroxide causes concentration dependent eye lesions. At higher concentrations, severe and irreversible damage to the rabbit eye has been demonstrated. In a study with 10% hydrogen peroxide, severe iritis and severe corneal opacity were observed both in washed and unwashed eyes. In addition, corneal staining was noticed in both rabbits with unwashed eyes. Severe conjunctivitis was observed in all four animals. Additionally, 3 rabbits had haemorrhagic conjunctivitis. Eyes gradually improved till day 7, at which time corneal opacity was present in all eyes, iritis was observed in one unwashed and one washed eye and conjunctivitis was observed in all eyes. Washing the eyes with tap water shortly after exposure increased the severity of the irritation (similar to OECD 405, GLP study). The effects of 10% hydrogen peroxide to the rabbit eye were severe and justify current classification with Eye damage 1, H318: "Causes serious eye damage". Specific concentration limits were established as follow:

	Eye Damage 1, H318: C ≥ 8% Eye Irritant 2, H319: 5% ≤ C ≤ 8% Therefore, AOPACK 35% must be classified as **Eye damage category 1.**
Classification of the product according to CLP	Eye Damage Category 1, H318: Causes serious eye damage.

Data waiving	
Information requirement	Eye irritation
Justification	In order to avoid further testing on vertebrates no studies on eye irritation of the products family were conducted as there are valid data available on each component of the mixtures sufficient to allow classification of the mixtures according to the rules laid down in the Regulation (EC) 1072/2008 (CLP) and no synergistic effects between any of the components are expected.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	May cause respiratory irritation.
Classification of the product according to CLP	Only the active substance hydrogen peroxide is classified for this health risk category. Both animal data and human experience indicate that hydrogen peroxide causes respiratory irritation. In a mice study an RD_{50} value of approx. 160 mg/m^3 (113 ppm) and an extrapolated (by the RMS) value RD_{10} value of 17.5 mg/m^3 (12 ppm) have been derived. According to the REACH guidance (Chapter R.8, APPENDIX R. 8-9), the RD_{10} in mice is proposed as a starting point to derive a threshold for a biologically significant sensory irritation in humans, and a candidate AEC (ca. 1.5 ppm; 2.2 mg/m^3) can be derived from RD_{10}. Such value is potentially useful in future refinements of the risk assessment, but was not used as the reference value in the risk assessment in the CAR. The evocation of respiratory irritancy in the experiments with 50% solutions of hydrogen peroxide justify the classification with "Specific target organ toxicity, single exposure 3" (H335) for mixtures containing C ≥ 35% hydrogen peroxide (Specific concentration limit). Therefore, AOPACK 35% must be classified as Specific target organ toxicity, single exposure 3 (H335).
	STOT Single Exp. 3, H335: May cause respiratory irritation.

Data waiving

Information requirement	Respiratory tract irritation
Justification	In order to avoid further testing on vertebrates no studies on respiratory tract irritation of the products were conducted as there are valid data available on each component of the mixtures sufficient to allow classification of the mixtures according to the rules laid down in the Regulation (EC) 1072/2008 (CLP) and no synergistic effects between any of the components are expected.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Non sensitising.
Justification for the value/conclusion	The product is classified following Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008. Neither the active substance nor the coformulants are classified as Skin sensitisation category. Therefore, the mixture should not be classified as Skin. Sens. category.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Skin sensitization
Justification	In order to avoid further testing on vertebrates no studies on the skin sensitization of the products were conducted as there are valid data available on each component of the mixtures sufficient to allow classification of the mixtures according to the rules laid down in the Regulation (EC) 1072/2008 (CLP) and no synergistic effects between any of the components are expected.

Respiratory sensitization

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not classified.
Justification for the value/conclusion	The product is classified following Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008. Neither the active substance nor the coformulants are classified as Respiratory sensitisation category. Therefore, the mixture should not be classified as Resp. Sens. category.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Respiratory sensitization
Justification	In order to avoid further testing on vertebrates no studies on the skin sensitization of the products were conducted as there are valid data

	available on each component of the mixtures sufficient to allow classification of the mixtures according to the rules laid down in the Regulation (EC) 1072/2008 (CLP) and no synergistic effects between any of the components are expected**.**

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Harmful if swallowed.
Justification for the selected value	Only the active substance hydrogen peroxide is classified for this health risk category. According to hydrogen peroxide active substance CAR, the a.s. was found to be acutely toxic via oral route and is classified as category 4 for acute oral toxicity. The assessment report includes information regarding several acute toxicity studies. An acute oral toxicity study with a 35 % (w/w) hydrogen peroxide aqueous solution in rats was performed according to OECD Guideline 401 (GLP study). This study was reliable without restriction and it resulted in LD_{50} values of 1193 for males and 1270 mg/kg bw for females, respectively. ATE value corrected for 100% hydrogen peroxide (worst case scenario, males) is 420 mg/kg bw. According to chapter 3.1.3.6 "Classification of mixtures based on ingredients of the mixture (Additivity formula)" of the CLP Regulation, the ATE of the mixture (ATE_{mix}) is determined by calculation from the ATE values for all relevant ingredients according to the following formula: $\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$ where: C_i = concentration of ingredient i (% w/w or % v/v) i = the individual ingredient from 1 to n n = the number of ingredients ATE_i = Acute Toxicity Estimate of ingredient i. Based on the ATE value of 420 mg/kg bw, calculated ATE_{mix} is higher than 300mg/kg bw and lower than 2000 mg/kg bw. Therefore, AOPACK 35% must be classified as **Acute Toxicity (oral) Category 4.**
Classification of the product according to CLP	Acute Toxicity Category 4, H302: Harmful if swallowed.

Data waiving

Information requirement	Acute toxicity: oral
Justification	No vertebrate studies have been performed with the formulated product in order to avoid unnecessary testing with vertebrates. Instead of that, we rely on toxicity data from the ingredients present in the formulation. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected."

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not classified.
Justification for the selected value	Only the active substance hydrogen peroxide is classified for this health risk category. The LC_{50} value for hydrogen peroxide 50% (w/w) water solution in rats was determined to be greater than 170 mg/m^3 as no mortality occurred at the highest achievable **vapour** concentration. There are no reliable acute inhalation toxicity studies available which show that hydrogen peroxide should be classified. However, based on Annex VI of the CLP Regulation, hydrogen peroxide has a minimum classification in category 4 for acute inhalation toxicity. For this reason, it is proposed to use the ATE values mentioned in Table 3.1.2 of the CLP Regulation for the classification of mixtures which contain hydrogen peroxide. For acute toxicity category 4, the ATE value is 11 mg/L for a vapour of hydrogen peroxide, while the ATE is 1.5 mg/L for a dust/mist of hydrogen peroxide. Given that exposition to vapour represents a more realistic scenario, a point estimated value of 11 mg/L for cat. 4 was used. According to chapter 3.1.3.6 "Classification of mixtures based on ingredients of the mixture (Additivity formula)" of the CLP Regulation, the ATE of the mixture (ATE_{mix}) is determined by calculation from the ATE values for all relevant ingredients according to the following formula: $\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$ where: C_i = concentration of ingredient i (% w/w or % v/v)

	i = the individual ingredient from 1 to n n = the number of ingredients ATE_i = Acute Toxicity Estimate of ingredient i. Based on the ATE value of 11 mg/L, calculated ATE_{mix} is higher than 20 mg/L. Therefore, AOPACK 35 % is not classified according to CLP Regulation (section 3.1.3.6.1).
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Acute toxicity: inhalation
Justification	No vertebrate studies have been performed with the formulated product in order to avoid unnecessary testing with vertebrates. Instead of that, we rely on toxicity data from the ingredients present in the formulation. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected."

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not classified.
Justification for the selected value	The product is classified following Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008. Neither the active substance nor the co-formulants are classified for this health risk category. Hence, AOPACK 35% is not classified for acute dermal toxicity.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Acute toxicity: dermal

Justification	No vertebrate studies have been performed with the formulated product in order to avoid unnecessary testing with vertebrates. Instead of that, we rely on toxicity data from the ingredients present in the formulation. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected."

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Hydrogen peroxide
Value(s)*	100% (default)
Justification for the selected value(s)	No standard dermal penetration studies with hydrogen peroxide have been successfully conducted. Based on the physico-chemical properties of hydrogen peroxide, 100% dermal penetration should be used in the absence of more accurate information. However, in the absence of clear systemic effects, no dermal penetration parameter was needed in order to conclude on human health risks from the presented uses of hydrogen peroxide. In rat blood diluted 1000 times, the half-life of hydrogen peroxide was less than 5 minutes for the low and intermediate concentrations of hydrogen peroxide 5 and 10 mg/L. For the high concentration (20 mg/mL) the half-life was more than 4 h. In the study, concentrations of hydrogen peroxide were far away from the range of a.s. in products or in-use concentrations. Even then the study demonstrates the high efficacy of the antioxidative system in blood. Furthermore, it supports the view that hydrogen peroxide if entering blood circulation is rapidly decomposed in blood and will not be systemically available. For this reason, the distribution of hydrogen peroxide in the body is expected to be very limited after exposure to hydrogen peroxide solutions. In conclusion, it was acceptable to waive the dermal penetration study.

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

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, no co-formulant has been identified as SoC.

Available toxicological data relating to a mixture

No toxicological studies have been performed with the formulated product. The classification of the product relies on the available toxicity studies for the active substance and co-formulants.

No further studies on the toxicity of the product are considered necessary as there are valid data available on the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) 1072/2008 (CLP) and synergistic effects between any of the components are not expected and the rest of the coformulants.

Other

Not relevant.

2.2.6.2 Exposure assessment

General Remarks

The assessment of occupational exposure towards *AOPACK 35%* as disinfectant of food and feed areas is based on information provided by the Applicant. In the absence of human exposure data, the exposure estimation to *AOPACK 35%* is based on the selected models and default values from the Biocides Human Health Exposure Methodology (BHHEM 2015) along with HEEG recommendations and the Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017.

If no appropriate models are available in the BHHEM, surrogate models are chosen and a justification is provided.

Where exposure is calculated based on empirical data (Biocides Human Health Exposure Methodology (BHHEM 2015) along with HEEG recommendations), these data are applied in agreement with the recommendations given by the guidelines as follows: In case of continuous (chronic) exposure scenarios the typical exposure is calculated based on the 75%-ile of the data. The 95%-ile is considered to represent the typical case when recommended by applicable guidelines. Where 95%-iles are not given, the maximum values are used instead.

Due to the high reactivity and rapid degradation, no systemic effects and no systemic availability could be observed for hydrogen peroxide. For this reason, only an exposure and risk assessment for local effects is performed.

The following strategy for the local effects exposure and risk assessment has been chosen:

1 Quantitative exposure and risk assessment via the inhalation route of exposure considering the inhalative AEC (1.25 mg/m^3) as derived for hydrogen peroxide in the Assessment Report (AR, 2015).
2 Qualitative risk characterization for potential local effects via the dermal route of exposure considering both the SCLs set for hydrogen peroxide in the CLP regulations as well as appropriate risk mitigation measures (i.e. gloves, coveralls, etc.) and label instructions (i.e. P-statements associated with the H-statements).

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

Summary table: relevant paths of human exposure							
Exposure path	Primary (direct) exposure			Secondary (indirect) exposure			
	Industrial use	Professional use	Non-professional use	Industrial use	Professional use	General public	Via food
Inhalation	n.a	Yes	n.a	n.a	Yes	No	n.a
Dermal	n.a	Yes	n.a	n.a	No	No	n.a
Oral	n.a	No	n.a	n.a	No	No	No
n.a. not applicable							

For disinfection in food and feed area (PT 4) the biocidal product is intended to be used for:

- aseptic packaging,
- cork stoppers disinfection,
- disinfection in enclosed spaces,
- inner surfaces in human drinking water systems,
- CIP of piping and tanks beverages.

The biocidal product containing 35.6 % of hydrogen peroxide is intended for use in aseptic packaging, disinfection of food packaging by immersion (PT4) and is identical to the representative product used for authorisation of the active substance for PT 4a, aseptic packaging. The aseptic packing operates in closed system where exposure is limited and emission to air is negligible.

The cork stoppers disinfection is performed in specially designated machines, where after cleaning with water, disinfectant is applied automatically by spraying. After disinfection, a catalysator is added for complete decay of hydrogen peroxide and additionally corks are rinsed and dried at the end, therefore no residues are expected.

Surface disinfection in enclosed spaces by VHP process the biocidal product containing 35.6 % hydrogen peroxide is used. All information on the use of hydrogen peroxide as surface disinfectant in enclosed spaces is derived from an exposure form prepared by a company specialised in disinfection via VHP machine (vaporised hydrogen peroxide). The products are intended for professional use of hydrogen peroxide as surface disinfectant in enclosed (sealed) spaces via machine based VHP (vaporised hydrogen peroxide). Emission to air is controlled by the machines and catalytic decomposition of hydrogen peroxide may take place in some machines. Machines may also have sensors to detect when safe level of hydrogen peroxide is reached for re-entry into rooms/areas. If the concentration is over the Occupational Exposure Limit (OEL) or AEC, respiratory protective equipment has to be worn when re-entering the disinfected rooms/areas e.g. for collection of indicators or the machine.

The biocidal products are intended to be used for cleaning and disinfection of distributing and storing installations for drinking water as pipes and container as well as piping and tanks for beverages.

The biocidal products are used for drinking water disinfection at the drinking water suppliers and their water distribution systems, water in reservoirs and water for animals. Primary exposure is expected for professionals only during loading since application is automated. Secondary exposure (oral, dermal) via drinking water is relevant and in practice residual hydrogen peroxide has to be checked to ensure that it is below the national limit.

In the exposure assessment presented below, the following stages have been considered.

PRIMARY EXPOSURE

- Loading of biocidal product (formulation of biocidal product into end-use applications, Professional Users Exposure).
- Application of the end-product as disinfectant (Professional Users).

SECONDARY EXPOSURE

- Secondary exposure (oral, dermal) via drinking water and in practice residual hydrogen peroxide has to be checked to ensure that it is below the national limit.
- Inhalation of volatilised residues: Inhalation exposure of general public is eliminated as re-entry is not possible before reaching the safe levels.
- Exposure of general public or secondary exposure in general is not considered as there is no residual hydrogen peroxide on treated surfaces or equipment. Volatile residues do not occur due to a rinsing step and high reactivity of the active substance.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
Use 1: Aseptic packaging by automated immersion in closed system.			
1	Loading	Primary exposure Loading of the machines for aseptic packaging	Professionals
2	Application - aseptic packaging	Primary exposure Disinfection of food packaging by immersion into bath of hot hydrogen peroxide in aseptic filling machine	Professionals
3	Post application	Primary exposure Maintenance work	Professionals
Use 2: Aseptic packaging by automated spraying in closed system.			
4	Loading	Primary exposure Loading of the machines for aseptic packaging	Professionals
5	Application - aseptic packaging	Primary exposure Disinfection of food packaging by spraying with hydrogen peroxide aqueus solutions	Professionals
6	Post application	Primary exposure Maintenance work	Professionals
Use 3: Surface disinfection by VHP process in food processing facilities.			
7	Loading	Primary exposure Loading scenario for automated applications: the VHP machine, aseptic packaging, connecting and disconnecting VHP pipelines	Professionals
8	Application - VHP process	Primary exposure	Professionals

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
		No exposure during application as no persons present in the room during application	
9	Post application - re-entry	Primary exposure Re-entry to the treated room	Professionals
Use 4: Disinfection of inner surfaces in human drinking water systems			
10	Loading	Primary exposure Loading task to dilute the product	Professionals
11	Application	Primary exposure No exposure during automated spraying with CIP technologies	Professionals
12	Post-application	Primary exposure Maintenance work.	Professionals
Use 5: Disinfection of inner surfaces by CIP			
13	Loading	Primary exposure Manual loading scenario	Professionals
14	Application	Primary exposure No exposure during automated spraying with CIP technologies	Professionals
15	Post-application	Primary exposure Maintenance work.	Professionals
Use 6: Disinfection of cork stoppers by automated spraying in closed systems			
16	Loading	Primary exposure Loading of the machine for cork stoppers disinfection	Professionals
17	Cork stoppers disinfection	Primary exposure: Disinfection of cork stoppers in the closed machine	Professionals
18	Post application – Maintenance	Primary exposure Maintenance work	Professionals

Industrial exposure

Not applicable.

Professional exposure

Scenario [1] – Loading of the machines for aseptic packaging

Description of Scenario [1]
Hydrogen peroxide is used to disinfect packaging for food products by immersion into a bath containing heated hydrogen peroxide aqueous solutions. The product at 35.6% concentration is ready-to-use. The product is loaded into the refilling tanks or refilling systems. The professional worker may be exposed during the loading of the product to the refilling tasks. It is assumed that most facilities have automated systems and therefore loading is not of concern. Automatic machines are equipped with pumps and therefore the likelihood of eye or skin contact is low. However, as a worst-case, the loading exposure to aerosols was calculated. The scenario to be modelled is using mixing and loading model 7 "Pouring liquid into systems" according to the recommendation no. 7. The tasks described in this model most accurately apply to the above procedures. The mixing and loading phase is assumed to take 10 min/day. Calculations with the Advanced REACH Tool 1.5 (ART) were provided by the Applicant. Quantitative exposure via the inhalation route of exposure is performed using the Advanced Reach Tool (ART) which takes into account both vapour and aerosols. The modelled scenario includes a 10 min exposure phase for mixing and loading activities. The 90th percentile exposure values calculated with the Advanced Reach Tool are used to take into account the variability in exposure levels. Calculated liquid mole fraction is used in the ART calculations. For activity coefficient the default of 1 is used as no real representative functional groups for hydrogen peroxide was found in the XL UNIFAC or AIOMFAC which are the software tools used specifically for activity coefficient calculation. The applicant included a non-exposure period of 470 minutes in the calculation. This value turns the output value into an 8h-time-weighted-average (8h-TWA). When assessing acute local effects, such as the corrosive effects of hydrogen peroxide, exposure should be expressed as the mean event concentration (MEC) as a reasonable worst-case, since local effects are mainly determined by peak concentration values rather than by long time-weighted mean exposure concentrations. Therefore, the non-exposure period to 0 minutes should be used to get the mean event concentration. Finally, the applicant only included the manual loading but manual (1a) and automated (1b) loading processes have been evaluated in the assessment. Detailed values used in both models are found below.

M&L model 7	**Parameters**	**Value**	**Justification / Source**
Tier 1	Weight fraction of a.s.	36%	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Expected duration of actual exposure	10 minutes	Recommendation no. 7, 2015
	Dermal exposure		
	Hand exposure without gloves	Negligible	Assumption

Description of Scenario [1]			
	Dermal Absorption	100%	Section 2.2.6.1.
	Inhalation exposure		
	Inhalation exposure	0.94 mg/min	Recommendation no. 7, 2015
	Inhalation uptake	100%	Default value
ART 1.5	**Parameters**	**Value**	
Tier 1	Duration	10 min	
	Non-exposure period	0 min	
	Product type	Liquids	
	Process temperature	Room temperature (15-25°C)	
	Vapour pressure	214 Pa (at 20°C)	
	Liquid mole fraction	36%(w/w): 0.2295	
	Activity coefficient	36%(w/w): 1	
	Emission source	Near field (i.e. the volume of air within 1 metre in any direction of the worker's head)	
	Activity class	Transfer of liquid products Falling liquids (worst case)	
	Situation	(1a) Transfer of liquid product with flow of 0 - 1 L/min (1b) Transfer of liquid product with flow of 1 - 10 L/min	
	Containment level	Open process	
	Loading type	(1a) Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely (worst case) (1b) Submerged loading, where the liquid dispenser remains below the fluid level reducing the amount of aerosol formation	
	Control measures (in close proximity of the near-field emission source)	(1a) No localised controls (1b) Containment – no extraction. Note: If this class is selected the answer to the containment question in the activity emission potential will automatically be overruled and set to 'open process' Medium level containment	
	Process fully enclosed	No	
	Effective housekeeping practices in place	Yes	
	Work area	Indoors	

Description of Scenario [1]		
	Room size of the work area	Any size workroom
	Ventilation rate	No restriction on general ventilation characteristics
Tier 2	Penetration through respiratory protection equipment (RPE with gas/vapour filter: APF = 10)	10 %

Calculations for Scenario [1]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/m³]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/m³]**
Scenario [1] – M&L 7	Tier 1 / No PPE	0.34	--	--	0.34
Scenario [1a] - ART	Tier 1 / No PPE	3.9	--	--	3.9
Scenario [1a] - ART	Tier 2 / RPE (APF = 10)	0.39	--	--	0.39
Scenario [1b] - ART	Tier 1 / No PPE	0.039	--	--	0.039

See Annex 3.2 for more information.

Further information and considerations on scenario [1]
According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as severe eye irritant (H318), irritant to skin (H315) and irritant to respiratory tract (STOT SE 3). Therefore, a qualitative assessment of local effects will be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [2] – Aseptic packaging by immersion

Description of Scenario [2]
Hydrogen peroxide is used to disinfect packaging for food products by immersion into a bath containing heated hydrogen peroxide aqueous solutions. The aseptic filling systems are based on the principle of aseptically forming a tube from a sterilized sheet of package material, which is continuously filled with commercially sterile

Description of Scenario [2]

liquid food product and subsequently transversally sealed to form pouches, which in turn are folded into the final package shape.

The packaging material are delivered to the aseptic filling machine either in the form of (sheet) reels or in the form of pre-formed packs, tubs and bottles. The packaging material in the form of (sheet) reels passes through a deep bath filled with 35 % (w/w) hydrogen peroxide by dipping. The temperature and contact time depend on the machine (usually >=65 ºC, >= 2.5 seconds). After that, several stages follow to evaporate any excess hydrogen peroxide with sterile hot air (250-300 ºC). The receptacle is then filled and sealed.

The sterilisation of the packaging sheet material through a bath filled with the product according should be adjusted to the specifications of the machine model and wait until the packaging material is completely dry. The system is closed until the forced ventilation inside the aseptic area of the machine is performed.

Since immersion is done inside the sterilization machine in closed environment, no exposure is possible during the application of the treatment at the bath.

Regarding the CAR hydrogen peroxide (PT01 - PT06, 2015), during normal process situation, inhalation exposure might be expected, since hydrogen peroxide can be emitted into the environment in vapour form through possible leakages in the chamber (CAR hydrogen peroxide, PT01 - PT06, 2015). Inhalation exposure for the application phase is assessed based on measurement data reported by Riihimäki et al. (V. Riihimäki, A. Toppila, P. Piirilä, E. Kuosma, P. Pfäffli, P. Tuomela:" Respiratory Health in Aseptic Packaging with Hydrogen Peroxide: A Report of Two Cases", J. Occup. Health, Volume 44, Issue 6, November 2002, pp. 433-438). Riihimäki et al. as well as Mastrangelo et al. (G. Mastrangelo, R. Zanibellato, E. Fadda, J.H. Lange, L. Scoizzato, R. Rylander: "Exposure to Hydrogen Peroxide and Eye and Nose Symptoms Among Workers in a Beverage Processing Plant", Ann. Occup. Hyg., Vol. 53, No. 2, pp. 161–165, 2009) reported high measured exposure levels surrounding the aseptic packaging machines (8h TWA: 1.7-3.47 mg/m^3, peak levels up to 11.3 mg/m^3). However, in both cases, the exposure could be reduced to acceptable levels after proper installation and maintenance of the machines (e.g. no open product and waste flows) and installation of appropriate ventilation systems (including LEV). Adequate ventilation systems (local exhaust ventilation (LEV) and general mechanical ventilation) can be assumed to be present in industrial working halls in food industry reducing potential inhalation exposure. Measured concentrations of the a.s. around the aseptic filling machines (CAR hydrogen peroxide, PT01 - PT06, 2015) then indicate an inhalation exposure which is below the $AEC_{inhalation}$ of 1.25 mg/m^3 (8h TWA: 0.14 - 0.7 mg/m^3, Riihimäki (2002)). Measures such as inspections by authorities or continuous monitoring of background exposure levels with direct reading instruments are common and indicate a need for regular inspection of airborne concentrations of the a.s. in the sourroundings of the aseptic packaging machines.

Calculations for Scenario [2]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/m³]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/m³]**
Scenario [2]	Tier 1 / No PPE	3.47 (max. value)	--	--	3.47 (max. value)
Scenario [2]	Tier 2 / No PPE, Yes RMMs	0.7 (max. value)	--	--	0.7 (max. value)

Further information and considerations on scenario [2]
According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as severe eye irritant (H318), irritant to skin (H315) and irritant to respiratory tract (STOT SE 3). Therefore, a qualitative assessment of local effects will be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [3] – Maintenance work

Description of Scenario [3]
In case of trouble, the operator can only access this area when the machine has stopped in order to restore the machine condition and is exposed to hydrogen peroxide only for a very limited period of time (typically less than 1 minute) and this does not happen frequently. However, it can be assumed that the hydrogen peroxide concentration drops immediately as soon as the machine is opened. As a precautionary RMM PPE (rubber boots, waterproof coverall, safety glasses with side-shields and long-sleeved gloves) and RPE (RPE with gas/vapour filter: APF = 10) have to be worn in these cases. The equipment is designed such that it cannot be opened during use. In case of routine maintenance, the machine will be turned off and vented until all vapour is exhausted and the equipment is cooled off. Regarding the CAR hydrogen peroxide (PT01 - PT06, 2015), in case of a functional disorder, the worker may only open the machine when it has stopped in order to restore the machine condition. Inhalation exposure for corrective maintenance is assessed based on measurement data reported by Schuh et al. (2016) (C.Schuh, M.Weigl, W.Wegscheider: "Simultane Bestimmung der Desinfektionsmittel Peroxyessigsäure und Wasserstoffperoxid in der Luft an Arbeitsplätzen", 76 (2016) Nr. 7/8, pp. 259-264). Inhalation exposure during corrective maintenance as an incidental event is possible and may be assumed relevant. This position is supported by data listed in the CAR of hydrogen peroxide (PT01 - PT06, 2015) and reported by Schuh (2016) for peak exposure during opening of the machines in case of maintenance (0.4 - 1.5 mg/m³).

Calculations for Scenario [3]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/m³]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/m³]**
Scenario [3]	Tier 1 / No PPE	1.5 (max. value)	--	--	1.5 (max. value)
Scenario [3]	Tier 2 / RPE (APF = 10)	0.15 (max. value)	--	--	0.15 (max. value)

Further information and considerations on scenario [3]
According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as severe eye irritant (H318), irritant to skin (H315) and irritant to respiratory tract (STOT SE 3). Therefore, a qualitative assessment of local effects will be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [4] – Loading of the machines for aseptic packaging

Description of Scenario [4]
Hydrogen peroxide up to 36% is sprayed or atomized into the container combined with hot sterile air. The professional worker may be exposed during the loading of the product to the refilling tasks. It is assumed that most facilities have automated systems and therefore loading is not of concern. Automatic machines are equipped with pumps and therefore the likelihood of eye or skin contact is low. However, as a worst-case, the loading exposure to aerosols was calculated. The scenario to be modelled is using mixing and loading model 7 "Pouring liquid into systems" according to the recommendation no. 7. The tasks described in this model most accurately apply to the above procedures. The mixing and loading phase is assumed to take 10 min/day. Calculations with the Advanced REACH Tool 1.5 (ART) were provided by the Applicant. Quantitative exposure via the inhalation route of exposure is performed using the Advanced Reach Tool (ART) which takes into account both vapour and aerosols. The modelled scenario includes a 10 min exposure phase for mixing and loading activities. The 90th percentile exposure values calculated with the Advanced Reach Tool are used to take into account the variability in exposure levels. Calculated liquid mole fraction is used in the ART calculations. For activity coefficient the default of 1 is used as no real representative functional groups for hydrogen peroxide was found in the XL UNIFAC or AIOMFAC which are the software tools used specifically for activity coefficient calculation. The applicant included a non-exposure period of 470 minutes in the calculation. This value turns the output value into an 8h-time-weighted-average (8h-TWA). When assessing acute local effects, such as the corrosive effects of hydrogen peroxide, exposure should be expressed as the mean event concentration (MEC) as a reasonable worst-case, since local effects are mainly determined by peak concentration values rather than by long time-

Description of Scenario [4]			
weighted mean exposure concentrations. Therefore, the non-exposure period to 0 minutes should be used to get the mean event concentration. Finally, the applicant only included the manual loading but manual (4a) and automated (4b) loading processes have been evaluated in the assessment. Detailed values used in both models are found below.			
M&L model 7	**Parameters**	**Value**	**Justification / Source**
Tier 1	Weight fraction of a.s.	36%	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Expected duration of actual exposure	10 minutes	Recommendation no. 7, 2015
	Dermal exposure		
	Hand exposure without gloves	Negligible	Assumption
	Dermal Absorption	100%	Section 2.2.6.1.
	Inhalation exposure		
	Inhalation exposure	0.94 mg/min	Recommendation no. 7, 2015
	Inhalation uptake	100%	Default value
ART 1.5	**Parameters**	**Value**	
Tier 1	Duration	10 min	
	Non-exposure period	0 min	
	Product type	Liquids	
	Process temperature	Room temperature (15-25°C)	
	Vapour pressure	214 Pa (at 20°C)	
	Liquid mole fraction	36%(w/w): 0.2295	
	Activity coefficient	36%(w/w): 1	
	Emission source	Near field (i.e. the volume of air within 1 metre in any direction of the worker's head)	
	Activity class	Transfer of liquid products Falling liquids (worst case)	
	Situation	(4a) Transfer of liquid product with flow of 0.1 - 1 L/min (4b) Transfer of liquid product with flow of 1 - 10 L/min	
	Containment level	Open process	

Description of Scenario [4]		
	Loading type	(4a) Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely (worst case) (4b) Submerged loading, where the liquid dispenser remains below the fluid level reducing the amount of aerosol formation
	Control measures (in close proximity of the near-field emission source)	(4a) No localised controls (4b) Containment – no extraction. Note: If this class is selected the answer to the containment question in the activity emission potential will automatically be overruled and set to 'open process' Medium level containment
	Process fully enclosed	No
	Effective housekeeping practices in place	Yes
	Work area	Indoors
	Room size of the work area	Any size workroom
	Ventilation rate	No restriction on general ventilation characteristics
Tier 2	Penetration through respiratory protection equipment (RPE with gas/vapour filter: APF = 10)	10 %

Calculations for Scenario [4]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/m³]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/m³]**
Scenario [4] – M&L 7	Tier 1 / No PPE	0.34	--	--	0.34
Scenario [4a] - ART	Tier 1 / No PPE	3.9	--	--	3.9
Scenario [4a] - ART	Tier 2 / RPE (APF = 10)	0.39	--	--	0.39
Scenario [4b] - ART	Tier 1 / No PPE	0.039	--	--	0.039

See Annex 3.2 for more information.

Further information and considerations on scenario [4]
According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as severe eye irritant (H318), irritant to skin (H315) and irritant to respiratory tract (STOT SE 3). Therefore, a qualitative assessment of local effects will be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [5] – Aseptic packaging by spraying

Description of Scenario [5]
This scenario describes the activities for the sterilization of food packaging materials prior to filling. Hydrogen peroxide up to 36% is sprayed or atomized into the container combined with hot sterile air. The system controls the amount of hydrogen peroxide to ensure that a uniform film coats the inside surface of the package. The sterilization efficacy by spraying hydrogen peroxide is enhanced by temperatures between 65-85ºC and the duration is less than 1 minute (typically 20 seconds). The conditions will depend on the aseptic packaging machine. Hydrogen peroxide decomposes to oxygen and water; as a strong oxidant reacts with cell components of microorganisms being able to kill a wide variety of organisms. It is reported that traces of hydrogen peroxide in food are less than 0.25 ppm (Hedrick, 1973; Smith & Brown, 1980). The high temperature used in the process ensures removing residual hydrogen peroxide. Relevant exposure paths are dermal and inhalatory for professionals at industrial site. Consumers may be, in theory, exposed by oral route due to the residual hydrogen peroxide in food containers; however, this is very unlikely due to the reactive nature of the chemical and the drying process that ensures very low quantities (not higher than 0.5 ppm). Furthermore, hydrogen peroxide decomposes to oxygen and water which are of no human health concern. The application phase by spraying is done inside the sterilization machine in closed environment. No involvement of workers is foreseen. Regarding the CAR hydrogen peroxide (PT01 - PT06, 2015), during normal process situation, inhalation exposure might be expected, since hydrogen peroxide can be emitted into the environment in vapour form through possible leakages in the chamber (CAR hydrogen peroxide, PT01 - PT06, 2015). Inhalation exposure for the application phase is assessed based on measurement data reported by Riihimäki et al. (V. Riihimäki, A. Toppila, P. Piirilä, E. Kuosma, P. Pfäffli, P. Tuomela:" Respiratory Health in Aseptic Packaging with Hydrogen Peroxide: A Report of Two Cases", J. Occup. Health, Volume 44, Issue 6, November 2002, pp. 433-438). Riihimäki et al. as well as Mastrangelo et al. (G. Mastrangelo, R. Zanibellato, E. Fadda, J.H. Lange, L. Scoizzato, R. Rylander: "Exposure to Hydrogen Peroxide and Eye and Nose Symptoms Among Workers in a Beverage Processing Plant", Ann. Occup. Hyg., Vol. 53, No. 2, pp. 161–165, 2009) reported high measured exposure levels surrounding the aseptic packaging machines (8h TWA: 1.7-3.47 mg/m^3, peak levels up to 11.3 mg/m^3). However, in both cases, the exposure could

Description of Scenario [5]
be reduced to acceptable levels after proper installation and maintenance of the machines (e.g. no open product and waste flows) and installation of appropriate ventilation systems (including LEV). Adequate ventilation systems (local exhaust ventilation (LEV) and general mechanical ventilation) can be assumed to be present in industrial working halls in food industry reducing potential inhalation exposure. Measured concentrations of the a.s. around the aseptic filling machines (CAR hydrogen peroxide, PT01 - PT06, 2015) then indicate an inhalation exposure which is below the $AEC_{inhalation}$ of 1.25 mg/m^3 (8h TWA: 0.14 - 0.7 mg/m^3, Riihimäki (2002)). Measures such as inspections by authorities or continuous monitoring of background exposure levels with direct reading instruments are common and indicate a need for regular inspection of airborne concentrations of the a.s. in the sourroundings of the aseptic packaging machines.

Calculations for Scenario [5]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/m^3]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/m^3]**
Scenario [5]	Tier 1 / No PPE	3.47 (max. value)	--	--	3.47 (max. value)
Scenario [5]	Tier 2 / No PPE, Yes RMMs	0.7 (max. value)	--	--	0.7 (max. value)

Further information and considerations on scenario [5]

According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as severe eye irritant (H318), irritant to skin (H315) and irritant to respiratory tract (STOT SE 3). Therefore, a qualitative assessment of local effects will be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [6] – Maintenance work

Description of Scenario [6]
In case of trouble, the operator can only access this area when the machine has stopped in order to restore the machine condition and is exposed to hydrogen peroxide only for a very limited period of time (typically less than 1 minute) and this does not happen frequently. However, it can be assumed that the hydrogen peroxide concentration drops immediately as soon as the machine is opened. As a precautionary RMM PPE (rubber boots, waterproof coverall, safety glasses with side-shields and long-sleeved gloves) and RPE (RPE with gas/vapour filter: APF = 10) have to be worn in these cases. The equipment is designed such that it cannot be opened during use. In case of routine maintenance, the machine will be turned off and vented until all vapour is exhausted and the equipment is cooled off.

Description of Scenario [6]
Regarding the hydrogen peroxide CAR/AR (PT01 - PT06, 2015), in case of a functional disorder, the worker may only open the machine when it has stopped in order to restore the machine condition. Inhalation exposure for corrective maintenance is assessed based on measurement data reported by Schuh et al. (2016) (C.Schuh, M.Weigl, W.Wegscheider: "Simultane Bestimmung der Desinfektionsmittel Peroxyessigsäure und Wasserstoffperoxid in der Luft an Arbeitsplätzen", 76 (2016) Nr. 7/8, pp. 259-264). Inhalation exposure during corrective maintenance as an incidental event is possible and may be assumed relevant. This position is supported by data listed in the CAR of hydrogen peroxide (PT01 - PT06, 2015) and reported by Schuh (2016) for peak exposure during opening of the machines in case of maintenance (0.4 - 1.5 mg/m^3).

Calculations for Scenario [6]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/m^3]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/m^3]**
Scenario [6]	Tier 1 / No PPE	1.5 (max. value)	--	--	1.5 (max. value)
Scenario [6]	Tier 2 / RPE (APF = 10)	0.15 (max. value)	--	--	0.15 (max. value)

Further information and considerations on scenario [6]
According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as severe eye irritant (H318), irritant to skin (H315) and irritant to respiratory tract (STOT SE 3). Therefore, a qualitative assessment of local effects will be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [7] – Loading the VHP machine

Description of Scenario [7]
Specially instructed users insert sealed cartridge with 35% aqueous hydrogen peroxide into a VHP machine. The sealed cartridge refers to the marketed packaging already described in section 2.1.7 of the PAR (for example 1L HEDP bottles). The packaging (cartridge) is connected to the VHP machine and sealed by changing caps. This cap has a degassing valve and a special fast connector which makes it possible to connect and seal the packaging with the VHP machine. Once properly installed, the machine sucks hydrogen peroxide from the cartridge to proceed with the VHP process.

During this task hydrogen peroxide is not set free. Therefore, exposure to hydrogen peroxide is not likely to occur. However, as a worst case, the pouring scenario can be considered with respect to worker inhalation exposure. In the exposure assessment the exposure to 36% (w/w) hydrogen peroxide (upper range value) was calculated for the mixing/loading step of the VHP process.

The scenario to be modelled is using mixing and loading model 7 "Pouring liquid into systems" according to the recommendation no. 7. The tasks described in this model most accurately apply to the above procedures. The mixing and loading phase is assumed to take 10 min/day.

Calculations with the Advanced REACH Tool 1.5 (ART) were provided by the Applicant. Quantitative exposure via the inhalation route of exposure is performed using the Advanced Reach Tool (ART) which takes into account both vapour and aerosols. The modelled scenario includes a 10 min exposure phase for mixing and loading activities. The 90th percentile exposure values calculated with the Advanced Reach Tool are used to take into account the variability in exposure levels. Calculated liquid mole fraction is used in the ART calculations. For activity coefficient the default of 1 is used as no real representative functional groups for hydrogen peroxide was found in the XL UNIFAC or AIOMFAC which are the software tools used specifically for activity coefficient calculation. The applicant included a non-exposure period of 470 minutes in the calculation. This value turns the output value into an 8h-time-weighted-average (8h-TWA). When assessing acute local effects, such as the corrosive effects of hydrogen peroxide, exposure should be expressed as the mean event concentration (MEC) as a reasonable worst-case, since local effects are mainly determined by peak concentration values rather than by long time-weighted mean exposure concentrations. Therefore, the non-exposure period to 0 minutes should be used to get the mean event concentration.
Finally, the applicant only included the manual loading but manual (7a) and automated (7b) loading processes have been evaluated in the assessment.

Detailed values used in both models are found below.

M&L model 7	**Parameters**	**Value**	**Justification / Source**
Tier 1	Weight fraction of a.s.	36%	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Expected duration of actual exposure	10 minutes	Recommendation no. 7, 2015
	Dermal exposure		
	Hand exposure without gloves	Negligible	Assumption
	Dermal Absorption	100%	Section 2.2.6.1.
	Inhalation exposure		
	Inhalation exposure	0.94 mg/min	Recommendation no. 7, 2015
	Inhalation uptake	100%	Default value
ART 1.5	**Parameter**	**Value**	

Tier 1	Duration	10 min
	Non-exposure period	0 min
	Product type	Liquids
	Process temperature	Room temperature (15-25°C)
	Vapour pressure	214 Pa (at 20°C)
	Liquid mole fraction	36%(w/w): 0.2295
	Activity coefficient	36%(w/w): 1
	Emission source	Near field (i.e. the volume of air within 1 metre in any direction of the worker's head)
	Activity class	Transfer of liquid products Falling liquids (worst case)
	Situation	(7a) Transfer of liquid product with flow of 0.1 - 1 L/min (7b) Transfer of liquid product with flow of 1 - 10 L/min
	Containment level	Open process
	Loading type	(7a) Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely (worst case) (7b) Submerged loading, where the liquid dispenser remains below the fluid level reducing the amount of aerosol formation
	Control measures (in close proximity of the near-field emission source)	(7a) No localised controls (7b) Containment – no extraction. Note: If this class is selected the answer to the containment question in the activity emission potential will automatically be overruled and set to 'open process' Medium level containment
	Process fully enclosed	No
	Effective housekeeping practices in place	Yes
	Work area	Indoors
	Room size of the work area	Any size workroom
	Ventilation rate	No restriction on general ventilation characteristics
Tier 2	Penetration through respiratory protection equipment (RPE with gas/vapour filter: APF = 10)	10 %

Calculations for Scenario [7]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/m³]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/m³]**
Scenario [7] – M&L 7	Tier 1 / No PPE	0.34	--	--	0.34
Scenario [7a] - ART	Tier 1 / No PPE	3.9	--	--	3.9
Scenario [7a] - ART	Tier 2 / RPE (APF = 10)	0.39	--	--	0.39
Scenario [7b] - ART	Tier 1 / No PPE	0.039	--	--	0.039

See Annex 3.2 for more information.

Further information and considerations on scenario [7]
According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as severe eye irritant (H318), irritant to skin (H315) and irritant to respiratory tract (STOT SE 3). Therefore, a qualitative assessment of local effects will be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [8] – Surface disinfection by VHP process

Description of Scenario [8]
Hydrogen peroxide vapour decontaminates dry surfaces of laboratory equipment, industrial pharmaceutical isolators, biological safety cabinets, hospital rooms, emergency vehicles, laboratories and other enclosed spaces. Effective application of vaporized hydrogen peroxide (VHP) requires adequate VHP concentrations and exposure times. The VHP Generator is utilized to achieve the concentration and contact time of hydrogen peroxide in the enclosed area. The process parameters are controlled through the use of the control panel on the VHP Generator. The VHP Generator uses air as a carrier to deliver hydrogen peroxide vapor to exposed surfaces inside a sealed enclosure. This allows the process to take place at, or near, atmospheric pressure. Since the VHP process relies only on the contact of the VHP with exposed surfaces, the transfer of heat and moisture required by steam or chemical processes is not necessary. This product is continuously injected for the required exposure time to maintain the desired concentration of hydrogen peroxide vapour.

Description of Scenario [8]

The main specifications of a VHP generator are:

- Diffusion principle: vaporization, disinfection with gaseous hydrogen peroxide.
- Difussion performance (pro VHP unit): max treatable volume, 500 m^3; max diffusion speed 350 m^3/h.
- The product should be applied in a hydrogen peroxide concentration of 1092 mg/m^3 (780 ppm) in air by the VHP generator).
- Contact time: >= 4 hours. The use is on daily basis, if required, with a maximum of 3 times per day.

No access of persons to the treated area is permitted during treatment. During aeration and before permitting re-entry to the treated area it should be checked that the concentration of hydrogen peroxide is below 1.25 mg/m^3 (or the corresponding national reference value), using e.g. test strip.

During the operation of the VHP machine or in case of malfunctions entering of the room is only possible by wearing chemical suits and respiratory protection equipment.

The following table gives an overview about the phases of the VHP process.

Process of surface disinfection in enclosed spaces		
	Process description	**Exposure**
Preparation of the enclosed space or room	• removing standing liquid and visible soils • installing biological and chemical indicators • insertion of sealed cartridge with 35% aqueous hydrogen peroxide into a VHP machine • sealing the space starting the machine	Hydrogen peroxide is not set free, therefore exposure is not possible. The pouring scenario can be considered as a worst case with respect to worker exposure.
Decontamination cycle	• *dehumidification phase* VHP machine removes water from the atmosphere • *conditioning phase* VHP machine injects vaporised hydrogen peroxide into the sealed area up to a hydrogen peroxide concentration of 1092 mg/m^3 (780 ppm) • *sterilisation phase* last 1 to 2 hours during which the hydrogen peroxide vapour disinfects the surfaces inside the sealed space	No risk of exposure since room is sealed for the decontamination process

Description of Scenario [8]		
Aeration cycle	• VHP machine breaks down the hydrogen peroxide in the sealed space to water and oxygen • when breakdown is complete sensors confirm the hydrogen peroxide level is below 1.25 mg/m³ (or the corresponding national reference value).	During the operation of the VHP machine or in case of malfunctions entering of the room is only possible by wearing chemical suites and respiratory protection equipment. Access of treated rooms without chemical suites and RPE is only permitted when the indicators on the VHP machine indicate a room concentration of less than 1.25 mg/m³ (or the corresponding national reference value).
Period until re-entry	• waiting period required until the concentration in air has reached safe level before entering the space	During the operation of the VHP machine or in case of malfunctions entering of the room is only permitted by wearing appropriate PPE (coverall, protective gloves, goggles, face shield and respiratory protective equipment (RPE)). Access of treated rooms without the full PPE is only permitted when the indicators on the VHP machine indicate a room concentration of less than 1.25 mg/m³ (or the corresponding national reference value).

Calculations for Scenario [8]
Not necessary. No risk of exposure since room is sealed for the decontamination process.

Further information and considerations on scenario [8]
According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as severe eye irritant (H318), irritant to skin (H315) and irritant to respiratory tract (STOT SE 3). Therefore, a qualitative assessment of local effects will be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [9] – Re-entry period

Description of Scenario [9]
After the decontamination phase the aeration cycle starts in which the VHP machine breaks down the hydrogen peroxide in the sealed space to water and oxygen. This step is

Description of Scenario [9]
short but can also last several hours resulting in a total decontamination cycle of 5 – 8 hours. When the aeration cycle is complete, sensors inform when the hydrogen peroxide level is below 1.4 mg/m^3 (1 ppm) and biological and chemical indicators can be collected to confirm the efficacy of the decontamination cycle. Although 1.4 mg/m^3 (1 ppm - the OEL-value in the current practice, according to the ECETOX Updated report on OEL (1997)) is slightly above AEC (1.25 mg/m^3), in practice the concentration of hydrogen peroxide in air will decrease rapidly after opening the doors due to the air exchange and is expected to be below 1.25 mg/ m^3 (or the corresponding national reference value). Professional users may be exposed via dermal and inhalation routes to the residual aerosols on re-entry to treated areas. During treatment, operators must not enter a target area until the concentration of H_2O_2 is below 1.25 mg/m^3 (0.9 ppm). Therefore, RMMs to be applied to ensure that the treated area is not entered before the concetration of H_2O_2 is below 1.25 mg/m^3 (0.9 ppm) are as follows: • No access of persons to the treated area is permitted during treatment. • During aeration and before permitting re-entry to the treated area it should be checked that the undercut of $AEC_{inhalation}$ of 1.25 mg/m^3 or the corresponding national reference value shall be ensured with technical and organisational measures (e.g. sensor/test strip, defined ventilation period). • The professional user may only enter the room in emergency situations or to reactivate the ventilation considering RPE with APF = 40 against vapour (Type of RPE to be specified by the authorisation holder within the product information). The re-entry is therefore only possible when the hydrogen peroxide level has dropped below 36 ppm (50 mg/ m^3) or below 40x the national reference value.

Calculations for Scenario [9]
Not necessary. The exposure during the task is negligible by applying the corresponding RMMs.

Further information and considerations on scenario [9]
According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as severe eye irritant (H318), irritant to skin (H315) and irritant to respiratory tract (STOT SE 3). Therefore, a qualitative assessment of local effects will be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [10] – Loading of the machines to dilute the product

Description of Scenario [10]
Hydrogen peroxide is used for cleaning and disinfection of distributing and storing installations for drinking water as pipes and containers. It is also used for food facilities. The in-use dose is 4%. The product is 35% (and 36% upper range). Therefore, a loading task to dilute the product should be done. The process is automated discharging the

Description of Scenario [10]

product by pumping where exposure is very limited or accidental. However, a worst-case was calculated in order to assess potential exposure to aerosols and vapours.

The scenario to be modelled is using mixing and loading model 7 "Pouring liquid into systems" according to the recommendation no. 7. The tasks described in this model most accurately apply to the above procedures. The mixing and loading phase is assumed to take 10 min/day.

Calculations with the Advanced REACH Tool 1.5 (ART) were provided by the Applicant. Quantitative exposure via the inhalation route of exposure is performed using the Advanced Reach Tool (ART) which takes into account both vapour and aerosols. The modelled scenario includes a 10 min exposure phase for mixing and loading activities. The 90th percentile exposure values calculated with the Advanced Reach Tool are used to take into account the variability in exposure levels. Calculated liquid mole fraction is used in the ART calculations. For activity coefficient the default of 1 is used as no real representative functional groups for hydrogen peroxide was found in the XL UNIFAC or AIOMFAC which are the software tools used specifically for activity coefficient calculation. The applicant included a non-exposure period of 470 minutes in the calculation. This value turns the output value into an 8h-time-weighted-average (8h-TWA). When assessing acute local effects, such as the corrosive effects of hydrogen peroxide, exposure should be expressed as the mean event concentration (MEC) as a reasonable worst-case, since local effects are mainly determined by peak concentration values rather than by long time-weighted mean exposure concentrations. Therefore, the non-exposure period to 0 minutes should be used to get the mean event concentration.

Detailed values used in both models are found below.

M&L model 7	**Parameters**	**Value**	**Justification / Source**
Tier 1	Weight fraction of a.s.	36%	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Expected duration of actual exposure	10 minutes	Recommendation no. 7, 2015
	Dermal exposure		
	Hand exposure without gloves	Negligible	Assumption
	Dermal Absorption	100%	Section 2.2.6.1.
	Inhalation exposure		
	Inhalation exposure	0.94 mg/min	Recommendation no. 7, 2015
	Inhalation uptake	100%	Default value
ART 1.5	**Parameters**	**Value**	
Tier 1	Duration	10 min	
	Non-exposure period	0 min	
	Product type	Liquids	

Description of Scenario [10]		
	Process temperature	Room temperature (15-25°C)
	Vapour pressure	214 Pa (at 20°C)
	Liquid mole fraction	36%(w/w): 0.2295
	Activity coefficient	36%(w/w): 1
	Emission source	Near field (i.e. the volume of air within 1 metre in any direction of the worker's head)
	Activity class	Transfer of liquid products Falling liquids (worst case)
	Situation	Transfer of liquid product with flow of 10 - 100 L/min
	Containment level	Handling that reduces contact between product and adjacent air.
	Loading type	Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely (worst case)
	Control measures (in close proximity of the near-field emission source)	No localised controls (0.00% reduction)
	Process fully enclosed	No
	Effective housekeeping practices in place	Yes
	Work area	Indoors
	Room size of the work area	Any size workroom
	Ventilation rate	Only good natural ventilation
Tier 2	Penetration through respiratory protection equipment (RPE with gas/vapour filter: APF = 10)	10 %

Calculations for Scenario [10]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/m³]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/m³]**
Scenario [10] – M&L 7	Tier 1 / No PPE	0.34	--	--	0.34
Scenario [10] - ART	Tier 1 / No PPE	9.9	--	--	9.9
Scenario [10] - ART	Tier 2 / RPE (APF = 10)	0.99	--	--	0.99

See Annex 3.2 for more information.

Further information and considerations on scenario [10]
According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as severe eye irritant (H318), irritant to skin (H315) and irritant to respiratory tract (STOT SE 3). Therefore, a qualitative assessment of local effects will be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [11] – Disinfection of inner surfaces by CIP

Description of Scenario [11]
Hydrogen peroxide is used for cleaning and disinfection of distributing and storing installations for drinking water as pipes and containers. It is also used for food facilities. Cleaning in place (CIP) is defined as the cleaning of complete items of plant or pipeline circuits without dismantling or opening of the equipment and with little or no manual involvement on the part of the worker. The process involves the jetting or spraying of surfaces or circulation of cleaning solutions through the plant under conditions of increased turbulence and flow velocity. The presence of worker during the cleaning/disinfection procedure of the pipeline/installation is not required. During the cleaning-in-place process, the professional is not exposed to the product. This is a closed process. Therefore, the exposure at this task is not relevant and was not assessed.

Calculations for Scenario [11]
Not necessary. No risk of exposure since CIP is a closed process.

Further information and considerations on scenario [11]
According to the criteria of the Regulation 1272/2008, the biocidal product dilution is not proposed to be classified. Therefore, a qualitative assessment of local effects will not be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [12] – Post-application and handling of empty containers

Description of Scenario [12]
After a contact time of 1-3 h, the pipeline/installation is rinsed with water under closed system conditions and the water is transferred to a STP. Therefore, worker exposure during the rinsing process with water is not relevant and not considered in the exposure estimations for this scenario. Following dosing (i.e. pouring/pumping) of the content of the containers into the CIP holding tank, empty containers are screwed down, stored and finally disposed of. During these tasks, worker exposure is unlikely to occur.

Calculations for Scenario [12]
Not necessary. The exposure during the task is negligible.

Further information and considerations on scenario [12]
According to the criteria of the Regulation 1272/2008, the biocidal product dilution is not proposed to be classified. Therefore, a qualitative assessment of local effects will not be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health-Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [13] – Loading of the machines to dilute the product

Description of Scenario [13]
The biocidal products are used for drinking water disinfection at the drinking water suppliers and their water distribution systems, water in reservoirs and water for animals. The in-use dose is 5%. The product is 35% (and 36% upper range). Therefore, a loading task to dilute the product should be done. The process is automated discharging the product by pumping where exposure is very limited or accidental. However, a worst-case was calculated in order to assess potential exposure to aerosols and vapours. The scenario to be modelled is using mixing and loading model 7 "Pouring liquid into systems" according to the recommendation no. 7. The tasks described in this model most accurately apply to the above procedures. The mixing and loading phase is assumed to take 10 min/day. Calculations with the Advanced REACH Tool 1.5 (ART) were provided by the Applicant. Quantitative exposure via the inhalation route of exposure is performed using the Advanced Reach Tool (ART) which takes into account both vapour and aerosols. The modelled scenario includes a 10 min exposure phase for mixing and loading activities. The 90th percentile exposure values calculated with the Advanced Reach Tool are used to take into account the variability in exposure levels. Calculated liquid mole fraction is used in the ART calculations. For activity coefficient the default of 1 is used as no real representative functional groups for hydrogen peroxide was found in the XL UNIFAC or AIOMFAC which are the software tools used specifically for activity coefficient calculation. The applicant included a non-exposure period of 470 minutes in the calculation. This value turns the output value into an 8h-time-weighted-average (8h-TWA). When assessing

Description of Scenario [13]			
acute local effects, such as the corrosive effects of hydrogen peroxide, exposure should be expressed as the mean event concentration (MEC) as a reasonable worst-case, since local effects are mainly determined by peak concentration values rather than by long time-weighted mean exposure concentrations. Therefore, the non-exposure period to 0 minutes should be used to get the mean event concentration. Detailed values used in both models are found below.			
M&L model 7	**Parameters**	**Value**	**Justification / Source**
Tier 1	Weight fraction of a.s.	36%	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Expected duration of actual exposure	10 minutes	Recommendation no. 7, 2015
	Dermal exposure		
	Hand exposure without gloves	Negligible	Assumption
	Dermal Absorption	100%	Section 2.2.6.1.
	Inhalation exposure		
	Inhalation exposure	0.94 mg/min	Recommendation no. 7, 2015
	Inhalation uptake	100%	Default value
ART 1.5	**Parameters**	**Value**	
Tier 1	Duration	10 min	
	Non-exposure period	0 min	
	Product type	Liquids	
	Process temperature	Room temperature (15-25°C)	
	Vapour pressure	214 Pa (at 20°C)	
	Liquid mole fraction	36%(w/w): 0.2295	
	Activity coefficient	36%(w/w): 1	
	Emission source	Near field (i.e. the volume of air within 1 metre in any direction of the worker's head)	
	Activity class	Transfer of liquid products Falling liquids (worst case)	
	Situation	Transfer of liquid product with flow of 10 - 100 L/min	
	Containment level	Handling that reduces contact between product and adjacent air.	

Description of Scenario [13]		
	Loading type	Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely (worst case)
	Control measures (in close proximity of the near-field emission source)	No localised controls (0.00% reduction)
	Process fully enclosed	No
	Effective housekeeping practices in place	Yes
	Work area	Indoors
	Room size of the work area	Any size workroom
	Ventilation rate	Only good natural ventilation
Tier 2	Penetration through respiratory protection equipment (RPE with gas/vapour filter: APF = 10)	10 %

Calculations for Scenario [13]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/m³]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/m³]**
Scenario [13] – M&L 7	Tier 1 / No PPE	0.34	--	--	0.34
Scenario [13] - ART	Tier 1 / No PPE	9.9	--	--	9.9
Scenario [10] - ART	Tier 2 / RPE (APF = 10)	0.99	--	--	0.99

See Annex 3.2 for more information.

Further information and considerations on scenario [13]
According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as severe eye irritant (H318), irritant to skin (H315) and irritant to respiratory tract (STOT SE 3). Therefore, a qualitative assessment of local effects will be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [14] – Disinfection of inner surfaces by CIP

Description of Scenario [14]
Hydrogen peroxide is used for cleaning and disinfection of distributing and storing installations for drinking water as pipes and containers. It is also used for food facilities. Cleaning in place (CIP) is defined as the cleaning of complete items of plant or pipeline circuits without dismantling or opening of the equipment and with little or no manual involvement on the part of the worker. The process involves the jetting or spraying of surfaces or circulation of cleaning solutions through the plant under conditions of increased turbulence and flow velocity. The presence of worker during the cleaning/disinfection procedure of the pipeline/installation is not required. During the cleaning-in-place process, the professional is not exposed to the product. This is a closed process. Therefore, the exposure at this task is not relevant and was not assessed.

Calculations for Scenario [14]
Not necessary. No risk of exposure since CIP is a closed process.

Further information and considerations on scenario [14]
According to the criteria of the Regulation 1272/2008, the biocidal product dilution is not proposed to be classified. Therefore, a qualitative assessment of local effects will not be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health-Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [15] – Post-application and handling of empty containers

Description of Scenario [15]
After a contact time of 1-3 h, the pipeline/installation is rinsed with water under closed system conditions and the water is transferred to a STP. Therefore, worker exposure during the rinsing process with water is not relevant and not considered in the exposure estimations for this scenario. Following dosing (i.e. pouring/pumping) of the content of the containers into the CIP holding tank, empty containers are screwed down, stored and finally disposed of. During these tasks, worker exposure is unlikely to occur.

Calculations for Scenario [15]
Not necessary. The exposure during the task is negligible.

Further information and considerations on scenario [15]
According to the criteria of the Regulation 1272/2008, the biocidal product dilution is not proposed to be classified. Therefore, a qualitative assessment of local effects will not be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health-Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [16] – Loading of the machines for cork stoppers disinfection

Description of Scenario [16]

This scenario describes the activities for the disinfection of cork stoppers by using hydrogen peroxide 35% (36% upper range) as a ready to use product.

The loading phase is considered to be automated by pumping the product directly to the sterilization machine. In order to assess a worst-case, a mixing and loading exposure was calculated for the loading of the equipment.

The scenario to be modelled is using mixing and loading model 7 "Pouring liquid into systems" according to the recommendation no. 7. The tasks described in this model most accurately apply to the above procedures. The mixing and loading phase is assumed to take 10 min/day.

Calculations with the Advanced REACH Tool 1.5 (ART) were provided by the Applicant. Quantitative exposure via the inhalation route of exposure is performed using the Advanced Reach Tool (ART) which takes into account both vapour and aerosols. The modelled scenario includes a 10 min exposure phase for mixing and loading activities. The 90th percentile exposure values calculated with the Advanced Reach Tool are used to take into account the variability in exposure levels. Calculated liquid mole fraction is used in the ART calculations. For activity coefficient the default of 1 is used as no real representative functional groups for hydrogen peroxide was found in the XL UNIFAC or AIOMFAC which are the software tools used specifically for activity coefficient calculation. The applicant included a non-exposure period of 470 minutes in the calculation. This value turns the output value into an 8h-time-weighted-average (8h-TWA). When assessing acute local effects, such as the corrosive effects of hydrogen peroxide, exposure should be expressed as the mean event concentration (MEC) as a reasonable worst-case, since local effects are mainly determined by peak concentration values rather than by long time-weighted mean exposure concentrations. Therefore, the non-exposure period to 0 minutes should be used to get the mean event concentration.
Finally, the applicant only included the manual loading but manual (16a) and automated (16b) loading processes have been evaluated in the assessment.

Detailed values used in both models are found below.

M&L model 7	**Parameters**	**Value**	**Justification / Source**
Tier 1	Weight fraction of a.s.	36%	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Expected duration of actual exposure	10 minutes	Recommendation no. 7, 2015
	Dermal exposure		
	Hand exposure without gloves	Negligible	Assumption
	Dermal Absorption	100%	Section 2.2.6.1.
	Inhalation exposure		
	Inhalation exposure	0.94 mg/min	Recommendation no. 7, 2015
	Inhalation uptake	100%	Default value
ART 1.5	**Parameters**	**Value**	

Description of Scenario [16]		
Tier 1	Duration	10 min
	Non-exposure period	0 min
	Product type	Liquids
	Process temperature	Room temperature (15-25°C)
	Vapour pressure	214 Pa (at 20°C)
	Liquid mole fraction	36%(w/w): 0.2295
	Activity coefficient	36%(w/w): 1
	Emission source	Near field (i.e. the volume of air within 1 metre in any direction of the worker's head)
	Activity class	Transfer of liquid products Falling liquids (worst case)
	Situation	(16a) Transfer of liquid product with flow of 0.1 - 1 L/min (16b) Transfer of liquid product with flow of 1 - 10 L/min
	Containment level	Open process
	Loading type	(16a) Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely (worst case) (16b) Submerged loading, where the liquid dispenser remains below the fluid level reducing the amount of aerosol formation
	Control measures (in close proximity of the near-field emission source)	(16a) No localised controls (16b) Containment – no extraction. Note: If this class is selected the answer to the containment question in the activity emission potential will automatically be overruled and set to 'open process' Medium level containment
	Process fully enclosed	No
	Effective housekeeping practices in place	Yes
	Work area	Indoors
	Room size of the work area	Any size workroom
	Ventilation rate	No restriction on general ventilation characteristics
Tier 2	Penetration through respiratory protection	10 %

Description of Scenario [16]		
	equipment (RPE with gas/vapour filter: APF = 10)	

Calculations for Scenario [16]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/m³]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/m³]**
Scenario [16] – M&L 7	Tier 1 / No PPE	0.34	--	--	0.34
Scenario [16a] - ART	Tier 1 / No PPE	3.9	--	--	3.9
Scenario [16a] - ART	Tier 2 / RPE (APF = 10)	0.39	--	--	0.39
Scenario [16b] - ART	Tier 1 / No PPE	0.039	--	--	0.039

See Annex 3.2 for more information.

Further information and considerations on scenario [16]
According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as severe eye irritant (H318), irritant to skin (H315) and irritant to respiratory tract (STOT SE 3). Therefore, a qualitative assessment of local effects will be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [17] – Disinfection of cork stoppers

Description of Scenario [17]
This scenario describes the activities for the disinfection of cork stoppers by using hydrogen peroxide 35% (36% upper range) as a ready to use product. Hydrogen peroxide is sprayed in closed system at room temperature, on to the corks' surface during approximately 1 minute (20-50 seconds) followed by a drying process by hot air. The dose used is 4 to 20 L of biocidal product per batch of approximately 20000 stoppers (45 x 24 mm). After disinfection, the moisture content of the stoppers is stabilised, ensuring optimal sealing performance while simultaneously reducing microbiological contamination. The water excess is reduced by spinning /draining the corks; the most common system for drying is by a conventional kiln with hot air circulation and a gas heater. Each production

Description of Scenario [17]
cycle may dry up to 200000 cork stoppers arranged in nets. Residual moisture should be around 7% for the right cork performance. A high level of residual peroxide may impact adversely on the level of sulphur dioxide in the wine. Therefore, the content of peroxide residues must be lower than 0.2 mg /cork. These residuals should be controlled following the method described at ISO 21128 Cork stoppers – Determination of oxidizing residues – Iodometric titration method. The application phase is in a closed system; no workers exposure is foreseen. This use is very similar to the aseptic packaging by spraying (scenario Nº 5).

Calculations for Scenario [17]
Not necessary. No risk of exposure since the disinfection process is in a closed system.

Further information and considerations on scenario [17]
According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as severe eye irritant (H318), irritant to skin (H315) and irritant to respiratory tract (STOT SE 3). Therefore, a qualitative assessment of local effects will be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [18] – Maintenance work

Description of Scenario [18]
The residuals of H_2O_2 might be considered. A maximum residual of 0.2 mg /cork is acceptable at industrial level, being exhaustively controlled. Due to the reactivity of hydrogen peroxide, and the low residual, the exposure to the product is negligible (see scenario Nº6: maintenance work of aseptic packaging by spraying).

Calculations for Scenario [18]
Not necessary.

Further information and considerations on scenario [18]
According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as severe eye irritant (H318), irritant to skin (H315) and irritant to respiratory tract (STOT SE 3). Therefore, a qualitative assessment of local effects will be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Combined scenarios

Not applicable.

Non-professional exposure

The biocidal product is only for professional use and therefore no non-professional exposure is foreseen.

Exposure of the general public

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

Monitoring data

No data is available.

Dietary exposure

Secondary oral and dermal exposure of consumers to residual hydrogen peroxide in food and drinking water is in theory possible under PT 4 (aseptic packaging, disinfection of distribution systems for drinking water).

However, hydrogen peroxide used for aseptic packaging evaporates while the wrapping material is heated before filled with food and no residues in food are expected. Furthermore, hydrogen peroxide, if present, would rapidly decompose in contact with any type of food. In the case of distribution systems for drinking water, pipes and containers disinfected with hydrogen peroxide are flushed before refilled with drinking water and relevant residual hydrogen peroxide is regarded as negligible.

Dietary exposure is covered by the EU Risk Assessment Report (2003). After H_2O_2 has been released to the environment, it rapidly decomposes in the presence of organic material. In human food, or in drinking water, no accumulation of exogenous H_2O_2 has been observed. It is estimated that dietary intake of naturally occurring hydrogen peroxide is usually below 1 mg.

<u>Justification on the lack of risk derived from any potential by-products (free radicals) of hydrogen peroxide</u>

In aerobic cells, the catabolic pathways of hydrogen peroxide (H_2O_2) are determined by catalase, peroxidases and glutathione peroxidase enzymes.

H_2O_2 undergoes decomposition to oxygen and water when in contact with mammalian tissues.

There are two main hydrogen peroxide metabolising enzymes, catalase and glutathione peroxidase, which control H_2O_2 concentration at different levels and in different parts of the cell. Catalase deals with large amounts of H_2O_2 that may be generated in peroxisomes. Glutathione peroxidase (GSH peroxidase) metabolises H_2O_2 in both the cytosolic and mitochondrial compartments (Chance et al., 1979).

However, in the presence of transition metals, H_2O_2 can be reduced to **hydroxyl radicals.**

In the organism the hydroxyl radical can be produced non enzymatically through catalysis by transition metal ions like Fe^{2+} and Cu^{+} (the so-called Haber-Weiss- and Fenton reactions):

metal ions

$H_2O_2 + O_2^{-}\bullet \rightarrow OH\bullet + OH^- + O_2$ (Haber-Weiss reaction)

$H_2O_2 + Cu^+/Fe^{2+} \rightarrow OH\bullet + OH^- + Cu^{2+}/Fe^{3+}$ (Fenton reaction)

Likely the "full" Haber-Weiss reaction (i.e., the reduction of H_2O_2 by O_2^- ▪) is as follows (showing that the Fenton reaction is representing one particular part of the Haber-Weiss reaction):

$O_2^{-}\bullet + Fe^{3+}/Cu^{2+} \rightarrow O_2 + Fe^{2+}/Cu^+$

$H_2O_2 + Fe^{2+}/Cu^+ \rightarrow OH\bullet + OH^- + Fe^{3+}/Cu^{2+}$

The rate constant for the Haber-Weiss reaction in aqueous solution has been shown to be virtually zero and it certainly could not occur at the low steady-state concentrations of H_2O_2 present in vivo. Only in the presence of ferric ions (Fe^{3+}) can hydroxyl radical occur (Halliwell and Gutteridge, 1984).

Because iron is normally bound, free iron is maintained in the plasma at a very low level, and the cellular iron is not available to mediate in iron-stimulated radical reactions (Gutteridge, 1994).

The majority of the iron in the body is bound to haemoglobin, myoglobin, cytochromes, enzymes, the transport protein transferrin, lactoferrin stored as ferritin, and hemosiderin. However, many biological reducing agents, such as ascorbate, cysteine, and reduced flavin, can promote the release of iron from ferritin. Transferritin in the blood is usually loaded to about 30% capacity so that free iron in the plasma is maintained at a very low level. A cellular store of iron is usually not available in free form to mediate oxidative damage through a Fenton reaction in vivo unless the iron is detached from protein. A drop in pH, such as that which occurs in phagocytes by the rupture of phagolysosmes, may favour the detachment of iron from protein.

Also, when proteins are loaded incorrectly or when chelating agents such as adenosine triphosphate (ATP), adenosine 5'-diphosphate (ADP), citrate, or acidic pH are present, iron will become detached and promote enhanced ▪OH radical generation.

Therefore, under normal circumstances, many endogenous ligands prevent the participation of iron and other common transition metals in the generation of reactive oxygen species (ROS) in living cells (Vallyathan and Shi, 1997).

In their study in lipid peroxidation, Aust and White (1) confirmed that the production of ▪OH radicals from H_2O_2 occurred only when xanthine oxidase was incubated with ferritin in the absence of catalase. Since lipid peroxidation was greater in the presence of catalase, it was suggested that an iron-oxygen complex rather than the ▪OH should have been involved in the initiation of lipid peroxidation.

Furthermore, due to the short half-life of hydroxyl radicals (10^{-9} s) and the short diffusion radius (2.3 nm), the hydroxyl radical will only react with a molecule when present in very close proximity to the place where the hydroxyl radical is formed whenever they meet a "spare" transition metal ion (Roots and Okada, 1975; Kappus, 1987).

Based on the above arguments, it is considered that there is no need to carry out a risk assessment of the potential by-products formed from hydrogen peroxide in the organism due to the demonstrated low probability to occur.

References:

1. Aust S D and White B C (1985). Iron Chelation Prevents Tissue Injury Following Ischemia. Adv. Free Radical Biology & Medicine, Vol. 1, pp. 1-17, 1985.

2. Chance B, Sies H, and Boveris A (1979). Hydroperoxide metabolism in mammalian organs. Physiological Reviews 59, 527-605.

3. European Union Risk Assessment Report. Hydrogen peroxide. European Chemicals Bureau 2003.

4. Gutteridge JMC (1994). Biological origin of free radicals, and mechanisms of antioxidant protection. Chem. Biol. Interact. 91, 133-140.

5. Halliwell B and Gutteridge JMC (1984). Oxygen toxicity, oxygen radicals, transition metals and disease. Biochem. J. 219, 1-14.

6. Joint Assessment of Commodity Chemicals Report Nº 22. Hydrogen peroxide. ECETOC 1992.

7. Kappus H (1987). Oxidative stress in chemical toxicity. Arch. Toxicol. 60, 144-149.

8. Roots R and Okada S (1975). Estimation of LifeTimes and Diffusion Distances of Radicals Involved in X-Ray-Induced DNA Strand Breaks or Killing of Mammalian Cells. Radiat Res (1975) 64 (2): 306–320.

9. Vallyathan V and Shi X (1997). The role of oxygen free radicals in occupational and environmental lung disease. Env. Health Perspect. 105, 165-177.

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Veterinary use	- Disinfectant in veterinary medicine - "bath" treatment for control of ectoparasites in fish	Hydrogen peroxide is permitted as a pharmacologically active substance according to Commission Regulation (EU) No 37/2010 of 22 Dec. 2009. No MRLs are required for all food producing species.
2.	Plant protection products	- Liquid for disinfection of agricultural mechanical cutting tools - - Liquid for seed treatment	Approval as basic substance in accordance with Regulation (EC) No 1107/2009. No MRLs required (included in Annex IV of Regulation (EC) No. 396/2005).
3.	Food contact materials	- production aid for polymer dispensions (coating commodities intended to come into contact with foods, e.g. adhesives or paper coatings) - catalyst for polymer dispersions (cheese coating not meant to be eaten) - catalyst for vinylidene chloride copolymers with a predominant content of	Database BfR Recommendations on Food contact materials* XIV. Polymer Dispersions XXXIV. Vinylidene Chloride Copolymers with a Predominant Content of Polyvinylidene Chloride XXXVI. Paper and Board for Food Contact XXXVI/1. Cooking Papers, Hot Filter Papers and Filter Layers

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
		polyvinylidene chloride (in total max 0.5 % based on the final product) - production aid (starch treated with hydrogen peroxide) for production of paper and board for food contact - slimicide (antimicrobial agent) for production of (1) paper/board for food contact (2) cooking papers, hot filter papers and filter layers (3) paper/paperboard for baking purposes (4) absorber pads based on cellulosic fibres for food packaging	XXXVI/2. Paper and Paperboard for Baking Purposes XXXVI/3. Absorber pads based on cellulosic fibres for food packaging
4.	Cosmetic products	Oral products, including mouth rinse, tooth paste and tooth whitening or bleaching products	Maximum concentration of 0.1 % of hydrogen peroxide present in oral products or released from other compounds or mixtures in those products is safe. (Directive 2011/84/EU)
* https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp?id4empf=007722841WASSERSTOFFPEROXID			

Estimating Livestock Exposure to Active Substances used in Biocidal Products

No exposure to livestock is foreseen for the uses claimed.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Hydrogen peroxide, if present, would rapidly decompose in contact with any type of food.

As reported in the CAR, the estimated log Kow of –1.57 indicates negligible potential of bioconcentration of hydrogen peroxide in biota. The BCFs calculated according to TGD for fish and earthworm are 1.4 and 0.84, respectively. It has no potential for bioaccumulation.

Therefore, no accumulation of hydrogen peroxide in the food chain is expected.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Not applicable.

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

Exposure during the production and formulation of the active substance should be addressed under other EU legislation (e.g. REACH) and not repeated under Regulation (EC) No. 528/2012. The Biocides Technical meeting (TMI06) agreed that a risk assessment for production and formulation of the active substance was not required, unless the active substance was totally new to the EU market and manufactured in the EU. This is not the case for hydrogen peroxide. Therefore, no exposure assessment for manufacturing and formulation is presented in this document.

Aggregated exposure

As stated in the CAR, for hydrogen peroxide it was agreed at the WG V 2014 that aggregated risk assessment is not regarded relevant due to the high reactivity of the substance.

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
AELshort-term	Assessment-Report Hydrogen peroxide PTs 1-6 (RMS Finland (2015))	--	--	--	not established, the substance is not systemically available
AELmedium-term		--	--	--	
AELlong-term		--	--	--	
ADI[2]		--	--	--	
ARfD		--	--	--	Not established.

[1] Please explain background and reason for assessment factor.

[2] If residues in food or feed.

Reference	Value	Reference
AEC inhalation long-term, medium-term, short-term	1.25 mg/m^3	NOAEC in 90-day inhalation study (rat), AF 8
Oral absorption	No significant absorption, local effects	Assessment-Report (RMS Finland (2015))--
Dermal absorption	100%	Default value for corrosive substances (EFSA Journal 2012;10(4):2665).

Maximum residue limits or equivalent

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRLs for Veterinary use	Commission Regulation (EU) No 37/2010	all food producing species	No MRL required

MRLs for Plant protection products	Regulation (EC) No. 396/2005).	all food commodities	No MRL required (basic substance)

Specific reference value for groundwater

No specific reference values for groundwater were derived.

Risk for industrial users

No industrial applications are intended.

Risk for professional users

Systemic effects
Due to the absence of systemic effects after exposure to hydrogen peroxide, potential local effects of hydrogen peroxide are considered.

Local effects

According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as severe eye irritant (H318), irritant to skin (H315) and irritant to respiratory tract (STOT SE 3). Therefore, as AEC is set, both quantitative and qualitative assessment of local effects is performed in this section for the biocidal product.
As the dilution product is not classified, qualitative local risk assessment according to the guidance on the BPR: Volume III HH part B is not performed in this section. Therefore, as AEC is set, only quantitative assessment of local effects is performed in this section for the dilution product.

Quantitative local risk assessments

Task/ Scenario	**Tier**	**Estimated uptake (mg/m^3)**	**$AEC_{inhalation}$ (mg/m^3)**	**Estimated uptake/ AEC (%)**	**Acceptable (yes/no)**
Scenario 1 – Loading of the machines for aseptic packaging (M&L 7)	1	0.34	1.25	27.2	YES
Scenario 1a – Manual Loading of the machines for aseptic packaging (ART 1.5)	1	3.9	1.25	312	**NO**
	2**	0.39	1.25	31.2	YES
Scenario 1b – Automated Loading of the machines for aseptic packaging (ART 1.5)	1	0.039	1.25	3.12	YES
Scenario 2 – Aseptic packaging by immersion	1	3.47	1.25	277.6	**NO**
	2*	0.7	1.25	56	YES
Scenario 3 – Maintenance work	1	1.5	1.25	120	**NO**
	2**	0.15	1.25	12	YES

Task/ Scenario	Tier	Estimated uptake (mg/m^3)	$AEC_{inhalation}$ (mg/m^3)	Estimated uptake/ AEC (%)	Acceptable (yes/no)
Scenario 4 – Loading of the machines for aseptic packaging (M&L 7)	1	0.34	1.25	27.2	YES
Scenario 4a – Manual Loading of the machines for aseptic packaging (ART 1.5)	1	3.9	1.25	312	**NO**
	2**	0.39	1.25	31.2	YES
Scenario 4b – Automated Loading of the machines for aseptic packaging (ART 1.5)	1	0.039	1.25	3.12	YES
Scenario 5 – Aseptic packaging by spraying	1	3.47	1.25	277.6	**NO**
	2*	0.7	1.25	56	YES
Scenario 6 – Maintenance work	1	1.5	1.25	120	**NO**
	2**	0.15	1.25	12	YES
Scenario 7 – Loading the VHP machine (M%L 7)	1	0.34	1.25	27.2	YES
Scenario 7a – Manual Loading the VHP machine (ART 1.5)	1	3.9	1.25	312	**NO**
	2**	0.39	1.25	31.2	YES
Scenario 7b – Automated Loading the VHP machine (ART 1.5)	1	0.039	1.25	3.12	YES
Scenario 8 – Surface disinfection by VHP process	1	Negligible	1.25	--	YES
Scenario 9 – Re-entry period	1	Negligible	1.25	--	YES
Scenario 10 – Loading of the machines to dilute the product (M&L 7)	1	0.34	1.25	27.2	YES
Scenario 10 – Loading of the machines to dilute the product (ART 1.5)	1	9.9	1.25	792	NO
	2**	0.99	1.25	79.2	YES
Scenario 11 – Disinfection of distribution systems of drinking water by CIP	1	Negligible	1.25	--	YES
Scenario 12 – Post-application and handling of empty containers	1	Negligible	1.25	--	YES
Scenario 13 – Loading of the machines to dilute the product (M&L 7)	1	0.34	1.25	27.2	YES
	1	9.9	1.25	792	NO

Task/ Scenario	Tier	Estimated uptake (mg/m^3)	$AEC_{inhalation}$ (mg/m^3)	Estimated uptake/ AEC (%)	Acceptable (yes/no)
Scenario 13 – Loading of the machines to dilute the product (ART 1.5)	2**	0.99	1.25	79.2	YES
Scenario 14 – Disinfection of distribution systems of drinking water by CIP	1	Negligible	1.25	--	YES
Scenario 15 – Post-application and handling of empty containers	1	Negligible	1.25	--	YES
Scenario 16 – Loading of the machines for cork stoppers disinfection (M%L 7)	1	0.34	1.25	27.2	YES
Scenario 16a – Manual Loading of the machines for cork stoppers disinfection (ART 1.5)	1	3.9	1.25	312	**NO**
	2**	0.39	1.25	31.2	YES
Scenario 16b – Automated Loading of the machines for cork stoppers disinfection (ART 1.5)	1	0.039	1.25	3.12	YES
Scenario 17 – Disinfection of cork stoppers	1	Negligible	1.25	--	YES
Scenario 18 – Maintenance work	1	Negligible	1.25	--	YES
* only RMMs but no PPEs ** only RPE (APF = 10)					

When the inhalation exposures are compared to the $AEC_{inhalation}$ of 1.25 mg/m^3, the risk is also considered acceptable for all scenarios with the exception of:

1. Scenarios 2 & 5 where the workers task is safe using only RMMs but no PPEs according the reviewed studies. These RMMs are as follows:
   - ✓ Workplace release measurements with suitable measurement equipment shall be performed upon implementation of the aseptic packaging plant, at regular intervals (annual intervals recommended) and after any change in relevant boundary conditions. The national regulations for workplace measurements have to be followed.
   - ✓ During operation, ensure adequate ventilation along the machines (LEV) and in the industrial halls (technical ventilation).
   - ✓ The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed.
   - ✓ Aerosolised or vaporised application should be use only in closed aseptic packaging machines with no emission to water and negligible emission to air.

Emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.
- ✓ During manual maintenance tasks, ensure adequate ventilation inside the machine (LEV) before opening the doors of the aseptic area.

2. Scenarios 1a, 3, 4a, 6, 7a, 10, 13, & 16a where the workers task is safe wearing a RPE with APF = 10.
3. Scenarios 1b, 4b, 7b & 16b where the workers task is safe whether the system must be fitted with a dosing pump.
4. Scenarios 12, 15 & 18 where in case of maintenance (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment (APF = 10), chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required to avoid any incidental contact with the product. The type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the product information. Glove material to be specified by the authorisation holder within the product information.
5. and, Scenario 9 where the task is safe by applying the following RMMs:
   - ✓ No access of persons to the treated area is permitted during treatment.
   - ✓ During aeration and before permitting re-entry to the treated area it should be checked that the undercut of $AEC_{inhalation}$ of 1.25 mg/m^3 or the corresponding national reference value shall be ensured with technical and organisational measures (e.g. sensor/test strip, defined ventilation period).
   - ✓ The professional user may only enter the room in emergency situations or to reactivate the ventilation considering RPE with APF 40 against vapour (Type of RPE to be specified by the authorisation holder within the product information). The re-entry is therefore only possible when the hydrogen peroxide level has dropped below 36 ppm (50 mg/ m^3) or below 40x the national reference value.

Qualitative local risk assessments

Primary Exposure / Professional use – Use of the concentrated product in all uses

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**
High hazard Low hazard	Eye Damage. 1 (H318) Skin irritant H315 STOT SE 3 H335	Concentration up to 36% classification limit: 8 ≤ C< 50 % (eye dam. 1) 35 ≤ C < 50 % (skin irrit. 2) C ≥ 35 % (STOT SE 3)	4	Professionals	Scenario 1 – Loading of the machines for aseptic packaging Scenario 2 – Aseptic packaging by immersion Scenario 3 – Maintenance work Scenario 4 – Loading of the machines for aseptic packaging Scenario 5 – Aseptic packaging by spraying Scenario 6 – Maintenance work Scenario 7 – Loading the VHP machine Scenario 8 – Surface disinfection by VHP process	Eyes Skin RT	M&L: few minutes. Application: 1. Aseptic packaging by immersion: ≥2.5 s, ≥65ºC. 2. Aseptic packaging by spraying: ≥20 s, 65-80ºC. 3. Surface disinfection by VHP: Contact time: ≥ 4 h. The use is on daily basis, if required, with a maximum of 3 times per day. 4. Disinfection of cork stoppers: spraying time 20-50	Low	**RMM Technics**: - Containment as appropriate; - Segregation of the emitting process; - Effective contaminant extraction; - Good standard of general ventilation; - Minimisation of manual phases; - Regular cleaning of equipment and work area; - Avoidance of contact with contaminated tools and objects; **RMM Organisation**: - Minimise number of staff exposed; - Management / supervision in	Exposure must be limited to brief contacts (Practically no exposure, no splashes, no hand to eye transfer, no aerosol formation). Technical RMM and PPE are required Considering that these recommendations can be followed during this task, the risk is acceptable.

					Scenario 9 – Re-entry period Scenarios 10 & 13 – Loading of the machines to dilute the product Scenario 16 – Loading of the machines for cork stoppers disinfection Scenario 17 – Disinfection of cork stoppers Scenario 18 – Maintenance work		s, contact time 5 min. Post-application: typically less than 1 minute.		place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice; - Good standard of personal hygiene **PPE** - Use appropriate gloves anr respirator - Optional face shield - Skin coverage with appropriate barrier material based on potential for contact with the chemicals - Use chemical goggles as eye protection	

The undiluted product concentrate (up to 36% a.s.) has been allocated to the "High" hazard category according to the classification as severe eye irritant (H318 - Eye Dam 1) and the "low" hazard category according to the classification as irritant to skin (H315 – Skin Irrit 2) and irritant to respiratory tract (H335 - STOT SE 3) taking into account that the hazard categories proposed in the Guidance for Human Health Risk Assessment & evaluation (Volume III – Part B + C).

In all cases the exposed population are professionals. Mixing and loading is the task identified as most important. The product is up to 36% concentrated at this step. For any subsequent task, the product would be sensibly diluted. The task is of short duration, taking only a few minutes (i.e. opening/closing valve, dilution of the product concentrate) and is expected to be performed once or twice per day by workers. The product may be used on a daily basis by these workers. The PPE which have to be used for protection from the eye, skin and respiratory tract irritant potential of the disifectant product are described as follows.

Exposure controls
Personal protective equipment:

- Face shield
- Substance/task appropriate gloves.
- Protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure).
- Substance/task appropriate respirator.
- Chemical googles.

Respiratory protection is considered necessary when mixing and loading in adequately ventilated areas due to the high vapour pressure of H_2O_2 (the vapour pressure at ambient temperature is 214 Pa). Further, airborne particles are expected to be formed during mixing and loading operations. Therefore, where ventilation is inadequate a suitable substance/task appropriate respirator is considered necessary.

Organisation:

- General safety and hygiene measures:

Do not inhale gases/vapours/aerosols. Avoid contact with skin/eyes. Do not use on clothing. Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. When using, do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift. At the end of the shift the skin should be cleaned and skin-care agents applied. Gloves must be inspected regularly and prior to each use. Replace if necessary (e.g., pinhole leaks).

Note: in case of trouble, the operator can only access this area when the machines have stopped in order to restore the machine condition and is exposed to hydrogen peroxide only for a very limited period of time (typically less than 1 minute) and this does not happen frequently. Therefore, in case of maintenance, these RMMs are required to limit exposure.

Conclusion
The risk of local dermal and respiratory effects during M&L and maintenance work into the final product is also considered to be acceptable when RMM for high hazard class chemicals are implemented and workers are wearing protective gloves, coverall, face mask (optional), RPE and chemical googles in order to prevent any contact with hydrogen peroxide.
Therefore, specific and general RMMs are needed to avoid exposure to hydrogen peroxide linked to biocidal use:
Specific RMMs:

- ✓ ONLY FOR USES 1, 2, 4, 5 & 6:

- In case of maintenance (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment (APF = 10), chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required. The type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the product information. Glove material to be specified by the authorisation holder within the product information.

✓ ONLY FOR USES 1 & 2:

- Workplace release measurements with suitable measurement equipment shall be performed upon implementation of the aseptic packaging plant, at regular intervals (annual intervals recommended) and after any change in relevant boundary conditions. The national regulations for workplace measurements have to be followed.
- During operation, ensure adequate ventilation along the machines (LEV) and in the industrial halls (technical ventilation).
- The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed.
- Aerosolised or vaporised application should be use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.
- During manual maintenance tasks, ensure adequate ventilation inside the machine (LEV) before opening the doors of the aseptic area.

✓ ONLY FOR USE 3:

- No access of persons to the treated area is permitted during treatment.
- During aeration and before permitting re-entry to the treated area it should be checked that the undercut of $AEC_{inhalation}$ of 1.25 mg/m^3 or the corresponding national reference value shall be ensured with technical and organisational measures (e.g. sensor/test strip, defined ventilation period).
- The professional user may only enter the room in emergency situations or to reactivate the ventilation considering RPE with APF 40 against vapour (Type of RPE to be specified by the authorisation holder within the product information). The re-entry is therefore only possible when the hydrogen peroxide level has dropped below 36 ppm (50 mg/ m^3) or below 40x the national reference value.

General RMMs:

- Wear protective chemical resistant gloves meeting the requirements of European Standard EN 374 during product handling phase (glove material to be specified by the authorisation holder within the product information).
- Wear a protective coverall (at least type 6, EN 13034) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information).
- Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during M&L phase. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).
- The use of eye protection during handling of the product is mandatory.
- Avoid contact with eyes/skin.
- Do not use on clothing.
- Avoid inhalation of vapours.
- Do not eat, drink or smoke while working.
- Operate in a well-ventilated area.

The PPEs proposed by the applicant are as follows:

- *Respiratory protection*

  Wear a respirator with an approved filter. Respirator with a vapour filter of the following type should be used: EN 141.

- *Hand protection for long-term exposure*

  Suitable material for gloves: Nitrile rubber

  Break through time / glove: > 480 min

  Minimal thickness / glove: 0.7 mm

  Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).

- *Hand protection for short-term exposure (e.g. accidental aerosols from splashing etc.)*

  Suitable material for gloves: Nitrile rubber

  Break through time / glove: > 30 min

  Minimal thickness / glove: 0.4 mm

  Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).

- *Eye protection*

  Tightly fitting safety goggles; Face-shield.

- *Skin and body protection*

  Choose body protection according to the amount and concentration of the product, that is, if used as undiluted or diluted.

Risk for non-professional users

Not relevant. The biocidal product is for professional use only.

Risk for the general public

Not relevant. Exposure of the general public to the biocidal product is not expected.

Risk for consumers via residues in food

Relevant residues of hydrogen peroxide in food are not expected from the intended uses. The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections

against the intended uses (i.e. aseptic packaging, clean-in-place (CIP) application, and surface disinfection via vaporisation).

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

Risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product is not required as the product contains only the active substance hydrogen peroxide and no SoC.

2.2.7 Risk assessment for animal health

As the biocidal product is applied only indoors in food-processing facilities, exposure of animals is not expected. Particularly pets have no access to such areas for hygenic reasons.

2.2.8 Risk assessment for the environment

ES-CA:

Please note that the environmental risk assessment (section 2.2.8) is reported as provided by the applicant. The ES-CA position is presented in green evaluation boxes if necessary.

The product has the same identity and composition as the product evaluated in the CAR 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.

Regarding the uses already evaluated in the CAR, no new information is deemed necessary. Accordingly, a very short summary of the risk assessment report copied from the CAR is presented. For further information, please refer to the competent authority report on the active substance.

For the new uses, a complete assessment is presented. Nevertheless, all relevant studies have been included in the dossier, for both new uses and uses already evaluated.

2.2.8.1 Effects assessment on the environment

Hydrogen peroxide is toxic or moderately toxic to aquatic organisms; the LC_{50} values in the tests with fish range from 16.4 to 37.4 mg/L, the 48-h EC_{50} for invertebrates is 2.34mg/L and the EbC_{50} for the marine diatom *Skeletonema costatum* is 2.39 mg/L. The long-term NOEC value for the reproduction of *Daphnia magna* is 0.63 mg/L representing the lowest chronic NOEC for the aquatic invertebrates and the NOEC value for *S. costatum* was 1.69 mg/L. PNECaquatic is 12.6 µg/L based on the NOEC of 0.63 mg/L for *Daphnia magna.*

The PNEC for sewage treatment plant micro-organisms is 4.66 mg/L. No data for sediment-dwelling and soil organisms is available and due to the intrinsic properties of hydrogen peroxide data is not considered necessary. $PNEC_{soil}$ was calculated to be 0.0018 mg/kg using the equilibrium partitioning method. Birds and mammals are not anticipated to be directly exposed to hydrogen peroxide, thus a risk assessment for bird and mammals is not considered necessary.

Summary table on calculated PNEC values

$PNEC_{STP}$	$PNEC_{water}$	$PNEC_{sed}$	$PNEC_{soil}$	$PNEC_{air}$
[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/m^3]
4.66	0.0126	-	1.84×10^{-3}	-

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

Testing on the product has been considered as not required since there is valid data available on the active substance sufficient to allow classification of the product according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). All the relevant studies are included in the IUCLID dossier.

The product has the same identity and composition as the example product evaluated in the CAR 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.

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	NOEC = 0.63 mg/L (chronic, *Daphnia magna*) Aquatic chronic 3, H412; C > 63% w/w hydrogen peroxide.
Justification for the value/conclusion	Existing data on chronic aquatic toxicity for hydrogen peroxide[8] (NOEC = 0.63 mg/L) indicates that the substance hydrogen peroxide should be classified as aquatic chronic category 3, H412. The biocidal products are aqueous solutions which contain only hydrogen peroxide and water. To clarify which aqueous solutions with hydrogen peroxide had to be classified with H412, this generic concentration limit of 25 % was included in the assessment report. This generic limit is based on paragraph 4.1.3.5.5.4.3 and Table 4.1.2 of Regulation (EU) Regulation 286/2011 of March 2011 (amending CLP regulation 1272/2008). It should be borne in mind that based on the ECHA guidance and on the consolidated version of the CLP Regulation, specific concentration limits should not be established for the Acquatic hazard classes. According to the previously mentioned Figure 4.1.2, when either aqueatic toxicity of classification data available for all relevant components the additivity formula according to section 4.1.3.5.2 of CLP Regulation should be used. When the additivity formula is used, the default cut off value of 25 % is not correct. The additivity formula for chronic aquatic toxicity being: $\frac{\sum Ci + \sum Cj}{EqNOECm} = \sum_n \frac{Ci}{NOECi} + \sum_n \frac{Cj}{0{,}1 \times NOECj}$

[8] Chronic toxicity of hydrogen peroxide to *Daphnia magna* in a continuous exposure, flow-through test system, Meinertz JR, et al., Science of the Total Environment 392 (2008), pp. 225-232. NOEC = 0.63 mg/L.

	Where: Ci = concentration of component i covering the rapidly degradable components; Cj = concentration of component j covering the non-rapidlydegradable components; NOECi = NOEC for component icovering the rapidly degradable components, inmg/l; NOECj = NOEC for component jcovering the non-rapidly degradable components, inmg/l; N = number of components, and i and j are running from 1 to n; EqNOECm = Equivalent NOEC of the part of the mixture with test data. Thus: To determine the concentration from which water solutions of hydrogen peroxide would classified as Aquatic Chronic Category 3, H412: $\frac{100\%}{1\ \mathrm{mg/L}} = \frac{x}{0.63\ \mathrm{mg/L}}$; x = 63% Aqueous solutions which only contain hydrogen peroxide and water should be classified with H412 (Aquatic Chronic Toxicity, Category 3) when the concentration is 63% or higher.
Classification of the product according to CLP and DSD	Not classified.

ES-CA:

Information is available on the composition of the biocidal product AOPACK 35% and on the hazards to the environment of the components of the product.

The only component of the product which is classified as being hazardous to the environment is the active substance hydrogen peroxyde, present in the BP at a concentration of 35.6 %. According to the AR (2015) of the a.s., existing data on chronic aquatic toxicity for hydrogen peroxide (NOEC = 0.63 mg/L) indicates that the substance hydrogen peroxide should be classified as Aquatic Chronic 3 (H412)
Based on the classification principles laid down in Reg. (EC) No 1272/2008, the concentration of the active substance in the product and its classification as Aquatic Chronic 3, the biocidal product should be also classified as Acuatic Chronic 3 (H412). Hence, the product has to be labelled with the hazard statement H412: Harmful to aquatic life with long lasting effects, the precautionary statements P273 Avoid release to the environment, and P501 Dispose of contents/container according to national legislation.

ES-CA:

PBT-assessment:

According to the AR (2015) of Hydrogen peroxide, this substance does not fulfil the PBT nor the vPvB criteria.

Endocrine disruption activity of non-active substances:

No further ecotoxicological studies are available for AOPACK 35%. The biocidal product was not tested for potential endocrine disruption properties.

For the active substance, no ED assessment is required because for active substances which have been approved, the EU assessment should be followed.

The assessment of the endocrine-disrupting properties of the components in the product AOPACK 35% has been performed according to the instructions described in the document agreed in the Coordination Group (CG-39-2020-11 AP 16.4 e-c ED co-formulant assessment by MS).

To assess the endocrine-disrupting (ED) potential of each co-formulant in the formulation, a step-wise approach needs to be performed, which includeds screening of relevant databases and searching for freely available information in reliable literature sources.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the components contained in the product AOPACK 35%.

Further Ecotoxicological studies

Data waiving	
Information requirement	Further ecotoxicological studies
Justification	It is proposed that data submitted for the active substance provides sufficient information for assessment of the effects on organisms and that there are no further indications of risk due to the specific properties of the biocidal product. Therefore, it is proposed that no further studies are required.

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

Data waiving	
Information requirement	Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)
Justification	In regards of the intended uses, insignificant aquatic release of hydrogen peroxide and no direct exposure of aquatic biota to the product are expected. Apart from this, hydrogen peroxide has a short half-life in natural waters due to the activity of micro-organisms, and therefore long-term exposure of aquatic biota (flora and fauna) to hydrogen peroxide originating from anthropogenic sources is considered rather improbable. Furthermore, hydrogen peroxide is continuously formed in the environment and is ubiquitous in fresh- and seawater at natural background concentrations from some micrograms to some tens of microgram per litre. Accordingly, aquatic biota can be considered evolutionary adapted to hydrogen peroxide in this range of

	concentrations. In consideration of these points, additional testing in other specific, non-target organisms is deemed not necessary.

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

Data waiving	
Information requirement	Supervised trials to assess risks to non-target organisms under field conditions
Justification	In accordance with Annex III of the BPR, if the biocidal product is in the form of bait or granules supervised trials to assess risks to non-target organisms under field conditions and studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk may be required. The biocidal product is marketed as an aqueous solution for use under PT 4. The product is not marketed in the form of bait or granules. As such, so no supervised trials to assess risks to non-target organisms under field conditions or studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk have been conducted as it is scientifically unjustified.

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

Data waiving	
Information requirement	Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk
Justification	In accordance with Annex III of the BPR, if the biocidal product is in the form of bait or granules supervised trials to assess risks to non-target organisms under field conditions and studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk may be required. The biocidal product is marketed as an aqueous solution for use under PT 4. The product is not marketed in the form of bait or granules. As such, so no supervised trials to assess risks to non-target organisms under field conditions or studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk have been conducted as it is scientifically unjustified.

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

The biocidal product is marketed for use under PT 4 and so will not be applied to large proportions of a specific habitat. As such, no secondary ecological effect is envisaged. Data on secondary ecological effect has not been generated due to exposure considerations.

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

In accordance with Annex III of the BPR and the ECHA Guidance on the Biocidal Product Regulation, Volume IV: Environment, Part A: Information Requirements, this endpoint is only applicable to relevant components of the biocidal product.

Hydrogen peroxide is always directly produced as an aqueous solution and the aqueous solutions of hydrogen peroxide are used as biocidal products. Information on how the biocidal product can be released to into the environment due to its use, sources of environmental exposure, details of aquatic recipients and information which can be used as predicted environmental concentrations in environmental compartments has already been assessed during the active substance approval and reported in Doc IIB, Appendix 2. As such, data on the foreseeable routes of entry into the environment on the basis of the use envisaged has not been presented in the biocidal product dossier as the data presented in the active substance dossier has been determined as acceptable.

According to the CAR, hydrogen peroxide decomposes rapidly in different environmental compartments. The following processes are involved in the decomposition/degradation of hydrogen peroxide in the environment:

- Biotic degradation catalysed by microbial catalase and peroxidase enzymes
- Abiotic degradation by:
- transition metal (Fe, Mn, Cu) and heavy metal catalysed decomposition
- oxidation or reduction reactions with organic compounds or formation of addition compounds with organic or inorganic substances

Hydrogen peroxide decomposes into water and oxygen ($2H_2O_2 \rightarrow 2H_2O + O_2$). The rate of this reaction depends on the contact with catalytic materials and other factors such as heat and sunlight.

Hydrogen peroxide shows a very rapid biodegradation in sewage sludge with a DT_{50} of 2 minutes (at 20°C). Ready biodegradability has not been unequivocally demonstrated as the standard ready biodegradability tests are not suitable for inorganic substances. Rapid degradation of hydrogen peroxide has also been observed in surface water and soil compartments. This degradation has been proposed to be mainly microbially derived based on the difference in degradation rates between the natural and filtered/sterilized samples.

The biotic and abiotic decomposition reactions proceed in parallel with the formation reactions and the equilibrium of these reactions depends on the environmental conditions.

The low measured value of Henry's law constant of $H = 7.5 \times 10^{-4}$ Pa × m^3/mol indicates very low volatilisation of hydrogen peroxide from water. As hydrogen peroxide is miscible with water in all proportions and taking into account that the calculated log K_{OC} is 0.2036 mL/g, it is expected that hydrogen peroxide has a low potential for adsorption to soil and for partitioning to suspended matter or sediment.

The estimated log K_{ow} of –1.57 indicates negligible potential of bioconcentration of hydrogen peroxide in biota. The BCFs calculated according to TGD for fish and earthworm are 1.4 and 0.84, respectively. Therefore, no accumulation of hydrogen peroxide in the food chain is expected either.

ES-CA:

Information on how the product is released into the environment and its potential emissions have been assessed in this PAR. Sources for emissions as well as target environmental compartments have been considered related to the intended uses, and concentrations in the concerned enviromental compartments have been calculated. For detailed information, please refer to the section 2.2.8.2 below.

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

No further data is deemed necessary.

Leaching behaviour (ADS)

No further data is deemed necessary.

Testing for distribution and dissipation in soil (ADS)

No further data is deemed necessary.

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

No further data is deemed necessary.

Testing for distribution and dissipation in air (ADS)

No further data is deemed necessary.

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)

The biocidal product is not intended for spraying near surface waters.

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)

The biocidal product is not intended for spraying outdoors.

2.2.8.2 Exposure assessment

Since the product applied for authorisation is identical to the example product in the CAR 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, and no new data is required, a very short summary of the environmental exposure assessment is presented below for the uses already covered in that evaluation. For further information on the scenarios already covered, please refer to the CAR on the active substance.

Regarding those uses not evaluated in the CAR, new information is presented.

The uses and products corresponding to the different scenarios are sumarised in the following table:

			PRODUCTS				
Nº	***Use***	***use name***	*AOPACK 35%*	*DUROX LRA*	*DUROX LRD*	*DUROX LRA TIPO S*	*DUROX LRA ADVANCED*
1	*PT4*	*Aseptic packaging: immersion*	X		X		
2	*PT4*	*Aseptic packaging: spraying*		X	X	X	X
3	*PT4*	*Surface disinfection by VHP*	X	X	X	X	X
4	*PT4*	*Disinfection of distrib. systems of drinking water*	X	X	X	X	X
5	*PT4*	*Disinfection of inner sufaces by CIP*	X	X	X	X	X
6	*PT4*	*Disinfection of cork stoppers*	X				

ES-CA:

The environmental risk assessment of the requested uses for authorization of the biocidal product includes the assessment of the following scenarios presented by the applicant:

Scenario [1]: Aseptic packaging by immersion.
Scenario [2]: Aseptic packaging by spraying.
Scenario [3]: Surface disinfection by VHP process.
Scenario [4]: Disinfection of distribution systems for drinking water.
Scenario [5]: Disinfection of inner surfaces by CIP.
Scenario [6]: Disinfection of cork stoppers.

Spanish CA agrees with the applicant that the presented scenarios are approppriate to calculate the emissions and to assess the risk for the environment due to most of the uses of the biocidal product. However, scenario 5 has been reviewed to assess the emissions of Use 5 (Disinfection of inner surfaces by CIP) according to the PT04 ESD scenario Assessment of entire plants.

2.2.8.2.1 Uses already evaluated in the CAR for the approval of active substance at different concentration in the product and/or application rate

Scenario [1] – Aseptic packaging by immersion (use #1)

General information

This use was assessed in the CAR for a product with 35% concentration of hydrogen peroxide.

The scenario assessed in the present document for this use is the same as the one assessed in the CAR but re-calculated for a concentration up to 36% in order to cover the upper range value of the assessed product.

No specific emission scenario is available for this use. Therefore, a tailored scenario was prepared at active ingredient authorisation. This assessment was based on main assumptions on production by creameries. Calculations were based on EU Risk Assessment Report (2003). This information was updated from various sources, i.e. information gathered from producers of hydrogen peroxide (Information obtained from CEFIC, 2006), from discussions with producers of machines for aseptic packaging (referenced as Machine Producer, 2006), and from the IPPC BREF document on food, drink and milk industries (EC, 2006).

Assessed PT	PT 4
Assessed scenarios	Scenario : Aseptic packaging by immersion
ESD(s) used	Emission Scenario Document for Product Type 4: tailored scenario calculations
Approach	Average consumption
Distribution in the environment	Calculated based on CAR for active ingredient; Technical guidance document (TGD) and EUSES 2.2
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: No
Remarks	Calculations are based on the active substance CAR adapted to 36% concentration of hydrogen peroxide.

Emission estimation

During the use of 35% (w/w) hydrogen peroxide solution for disinfection of packaging material, a fraction of 10% was assumed to be degraded, i.e. 90% remaining ($F_{process}$; Machine Producer, 2006).

The creamery wastewaters carry high organic loadings, with biological oxygen demand around 0.8 to 2.5 kg BOD per tonne of milk produced. When discharged into these wastewaters, hydrogen peroxide oxidises part of the organics, and is thereby degraded. The

resulting reduction in COD is a desired side effect of using hydrogen peroxide for disinfection in creameries (Machine Producer, 2006). Besides, a viable microbial population is expected to develop very rapidly in wastewaters of creameries, due to the high amount of nutrients available. These microorganisms decompose hydrogen peroxide already in the sewage and the degradation in wastewaters of creameries is expected to be rapid. Based on the half-life of 6 minutes (11.2 min transferred to 12 °C) obtained in similar media regarding microbial density (CAR, Document II A, Section 4.1.1.1, Spain et all 1989) and assuming first-order kinetics with a time period of 1 hour residence in sewage (default for residence time according to the ESD for PT5), fraction degraded was calculated as follows:

$F_{sewage} = \exp(- \ln(2)/DT_{50} * 60 \text{ min}) = 0.024$

On-site treatment of wastewater is common for creameries, including aerobic and activated sludge treatment (EC, 2006). Any elimination of hydrogen peroxide during such treatment was not taken into account ($F_{wwtp} = 1$).

To obtain a realistic worst-case scenario in terms of hydrogen peroxide use, a large-scale creamery was modelled. This was characterised by a production of 100000 t milk/year, corresponding to the largest classes of production facilities. Such high production made up for only 220 (4%) out of 5600 plants in the EU (Eurostat (2006), data from 1997).

The consumption of hydrogen peroxide at a large-scale creamery was estimated from the typical machine output of 7000 packages/hour applicable for machines producing 1 L packages (Machine Producer, 2006). The consumption of 35% (w/w) hydrogen peroxide by these machines was given as 2.5 - 4 L/hour. Dividing the highest consumption value by the packaging output resulted in a consumption rate of 0.000571 L/package, which corresponds to 0.000571 L/kg milk assuming a density of 1 kg/L.

The emission to water at the local scale was estimated by calculating the amount of hydrogen peroxide consumed at a creamery (Qa.s.) from the parameters described above, and multiplying with the emission fractions, calculations presented in the table below.

ES-CA:

At Follow up WG-IV-2019_ENV_6-3September 2020, some new endpoints were harmonized and agreed for hydrogen peroxide. The DT_{50} value in the sewer system is 6 minutes (11.4 min transferred to 12 °C). Therefore, the fraction of hydrogen peroxide remaining in the sewage after degradation has been corrected to 0.026.

At ENV WG-II-2019, it was also agreed that for rapidly reacting substances such as hydrogen peroxide no groundwater assessment is needed since it is very unlikely that this substances will reach the groundwater. For this reason, the assessment of groundwater compartment provided by the applicant is not relevant for this environmental risk assessment.

Scenario: Aseptic packaging by immersion

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
$C_{a.s}$	36	%	Concentration of hydrogen peroxide in disinfectant solution

Q_{milk}	10^8	kg/year	Amount of milk processed at a large-scale creamery (Eurostat, 2006), realistic worst-case
$T_{emission}$	231	days/year	Working days per year (Raffael and van de Plassche, 2011)
R_{disinf}	0.000571	L/kg milk	Consumption rate of disinfectant solution, based on data from Machine Producer (2006), realistic worst-case
ρ_{disinf}	1.13	kg/L	Bulk density of 35% (w/w) hydrogen peroxide disinfectant solution (Document II A 3.1.3) (assumed to be the same for 36% HP solution)
$F_{process}$	0.9		Fraction of a.s. remaining at discharge into sewage, realistic worst-case
F_{sewage}	0.024		Fraction of a.s. remaining after degradation in sewage, realistic worst-case
F_{wwtp}	1		Fraction remaining after on-site waste-water treatment (aerobic/biological), conservatively ignored here
$Q_{a.s}$		kg/kg milk	Amount of a.s. used per mass of milk packaged. Only for derivation of estimation equation.
$E_{local, water}$ (kg/day)	= Qa.s. · Fprocess · Fsewage · Fwwtp = Qmilk · Temission-1 · Rdisinf · Ca.s. · ρ disinf · Fprocess · Fsewage · Fwwtp **2.17**		

ES-CA:

The nominal declared content of hydrogen peroxide in the biocidal product is 35.6 % (w/w). The risk assessment has been performed taking into account this value. In addition, the bulk density of the biocidal product is reported to be 1.135 g/cm^3. The fraction of a.s. remaining after degradation in sewage has been corrected to 0.026 (see WG-IV-2019_ENV_6-3). Considering these values, the emission to the STP is **2.34** kg/d. Therefore, a new risk assessment is provided.

Fate and distribution in exposed environmental compartments

Direct emissions of hydrogen peroxide to surface water or soil do not occur. Hydrogen peroxide is only used in 35% aqueous solutions (up to 36% upper range). Aseptic packaging only takes place in closed systems, and hydrogen peroxide remaining in process air is washed out. Furthermore, air emissions are negligible. Possible exposures to environmental compartments are summarised in table below:

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Aseptic packaging by immersion	yes	yes	no	no	yes	no	yes	yes	-

Default values for general parameters of EUSES were used to calculate the distribution in the environment and the predicted environmental concentrations (PECs) for sewage

treatment plants, freshwater compartment, soil and groundwater. In the same line as CAR calculations, the default value for EFFLUENTstp (Total volume of wastewater treated in the STP, 2000 m^3/d) was changed to higher value of 5000 m^3/d., because the volumes of waste waters from these uses at large plants were not regarded relevant to be conducted to the standard STPs. The detailed rationale for the larger STP is explained in the emission estimation chapter at CAR.

Input parameters for calculations are summarised in table below:

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	34.01		
Boiling point	150.2	°C	
Vapour pressure (at 25°C)	299	Pa	
Water solubility	miscible	mg/L	
Log Octanol/water partition coefficient	-1.57	Log 10	
Henry's Law Constant (at 20 ºC)	7.5 x 10^{-4}	Pa/m^3/mol	
Biodegradability	Readily biodegradable		
DT_{50} for activated sludge	0.03	h (at 20ºC)	
DT_{50} for hydrolysis in surface water	5	d	
DT_{50} for degradation in soil	0.5	d	

As stated at CAR section 8.3.3 Doc-IIIB, relevant compartments after degradation at STP were calculated by using substance specific key input parameters (Doc IIA Chapter 1.3, Table 4.1.1.3-1) as follows: Henry´s law constant 7.5 · 10-4 Pa m^3/mol, log Kow -1.57, DT50 in activated sludge 0.03 h and DT50 in soil 0.5 d, EUSES 2.2 using equations form the Technical guidance document (TGD) gives following distribution of hydrogen peroxide in the STP:

Calculated fate and distribution in the STP	
Compartment	Percentage [%]
Air	1.23E-04
Water	0.376
Primary settler	0.01445
Surplus sludge	2.58E-05
Degraded in STP	99.61

ES-CA:

Distribution of substances into the STP was calculated with Simple Treat 4.0 in EUSES 2.2.0:

Calculated fate and distribution in the STP	
Compartment	Percentage [%]
Air	0.0002
Water	0.6637
Sludge	0.0145
Degraded in STP	99.32

Calculated PEC values

In line with calculations at CAR, the predicted environmental concentrations (PEC) in sewage, receiving surface water and sediment and groundwater under agricultural soil were calculated from the emission estimates following the TGD and EUSES 2.2. Exposure to groundwater is anticipated from sewage sludge application only; direct exposure to soil and thereafter to groundwater (pore water of agricultural soil) is regarded negligible.

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/l]
Aseptic packaging by immersion	1.63×10^{-3}	1.63×10^{-4}	1.33×10^{-4}	1.51×10^{-5}	1.73×10^{-5}

ES CA:

The following PEC values have been recalculated by Spanish CA:

Summary table on calculated PEC values				
PEC_{STP}	**PEC_{air}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**
[mg/L]	[mg/m^3]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]
3.10E-03	1.30E-09	3.10E-04	2.54E-04	7.04E-06

Primary and secondary poisoning

Secondary dietary exposure of consumers to residual hydrogen peroxide in food and drinking water is in theory possible under PT 4 aseptic packaging by immersion method. However, the packaging sheet material is dried to remove residual hydrogen peroxide by a combination of mechanical means (rubber rollers) and hot air and thus no residues in food are expected. Furthermore, hydrogen peroxide, if present, would rapidly decompose in contact with any type of food.
Dietary exposure is covered by the EU Risk Assessment Report (2003). After H_2O_2 has been released to the environment, it rapidly decomposes in the presence of organic material. In human food, or in drinking water, no accumulation of exogenous H_2O_2 has been observed. It is estimated that dietary intake of naturally occurring hydrogen peroxide is usually below 1 mg.

Substance is unlike to bioaccumulate in aquatic or terrestrial environment according to the TGD. It has a low log Kow (-1.57), it is not highly adsorptive, it does not belong to a class of substances known to have a potential to accumulate in living organisms, its structural features does not indicate accumulation and it is readily biodegradable and has a short degradation half-life of 5 days in the water and 12 hours in soil. No further assessment of secondary exposure via the food chain is therefore considered necessary.

Scenario [3] – Surface disinfection by VHP process (use #3)

General information

This use was assessed in the CAR at target concentrations of 350 - 560 mg/m^3 (250 - 400 ppm).

However, the product assessed in the present document is applied at 1092 mg/m^3 (780 ppm) hydrogen peroxide according to section 2.1.4. Thus, new assessment is perfomed in this document for this use.

Surfaces and rooms in food processing facilities are disinfected by vaporised hydrogen peroxide generated with aid of a VHP generator.

No official emission scenario document exists for disinfection by the VHP process in PT 4.

According to the CAR, specific routines for emission calculation were set up for surface disinfection by the VHP process in public health areas (PT 2.01), based on the information from a manufacturer of VHP-machines (Information obtained from CEFIC, 2006). The VHP process is the same for application in public health and food processing areas.

Thus, the assessment of this use is based on scenario PT 2.01 evaluated in the CAR but re-calculated for the specific application rate of the present use.

Assessed PT	PT 4
Assessed scenarios	Scenario : Surface disinfection by VHP process
ESD(s) used	No ESD used
Approach	Tailored scenario calculations for surface disinfection by the VHP process in public health areas (PT 2.01, CAR), based on the information from a manufacturer of VHP-machines (Information obtained from CEFIC, 2006)
Distribution in the environment	Calculated based on CAR for active ingredient; Technical guidance document (TGD) and EUSES 2.2
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: No
Remarks	No emission scenario is available for surface disinfection by VHP process.

	Therefore, calculations are based on scenario PT 2.01 of the active substance CAR adapted to specific application rate for the present use.

Emission estimation

Emissions from this process are low since the whole disinfection cycle is carried out in closed rooms and because treated surfaces need not be rinsed after the application. Nevertheless, residual hydrogen peroxide in the room air after the decomposition step may reach the environment by ventilation. A worst-case emission factor to air (Fair) of 0.8 % was estimated as the quotient of the maximum residual concentration in air after the decomposition step and the minimum target concentration in air, i.e. 1 ppm/780 ppm = 0.0013.

There may also be cases where treated surfaces are swept after disinfection, although cleaning is necessary already before disinfection. Residual hydrogen peroxide on surfaces may then reach the sewer with discharged cleaning water. Also, residual hydrogen peroxide solution in the cartridge may be discharged to sewage. The STP would then act as a point source for emission to the receiving river. To cover such minor losses, a worst-case emission factor to sewage (Fwater) of 5% of applied hydrogen peroxide was assumed. However, in a realistic worst-case, no relevant amounts of hydrogen peroxide would be expected to reach sewage from this application. Once reaching sewage, hydrogen peroxide will rapidly react with microbes and organic matter, and be decomposed by microbial catalase and dissolved transition metal ions such as iron. These effects were accounted for using the half-life in similar media regarding microbial density compared to raw sewage of 6 minutes (11.2 min transferred to 12 °C) from CAR, Document II A, Section 4.1.1.1 (Spain et al 1989). Assuming single first-order kinetics and a residence time in sewage of 1 hour (default according to the ESD for PT5), a fraction of 0.024 of the discharged hydrogen peroxide then reaches the STP:

$F_{sewage} = \exp(-\ln(2)/DT_{50} * 60\ min) = 0.024$

A single room of a large size (50 m^2 x 3 m = 150 m^3) was assumed to be treated at the maximum target concentration of hydrogen peroxide (1092 mg/m^3), leading to an applied amount (Mappl) of 150 m^3/appl * 1092 mg/m^3 * 10^{-6} kg/mg = 0.164 kg/appl. Up to three rooms can be treated daily with one machine (N_{appl} = 3/day; Information obtained from CEFIC, 2006). Finally it was assumed that a maximum of three machines be in operation at the same day and local scale ($N_{machines}$ = 3). For air emissions, it was conservatively assumed that emissions from all machines would go the same emission cloud.

Using the parameters derived above, the consumption of hydrogen peroxide at the local scale was calculated and emitted fractions derived based on the emission factors, results are presented in the table below.

Scenario: Surface disinfection by VHP process

Parameter	Sewage	Air	Flag	Comment, reference
M_{appl} [kg/application]	0.164		S	Amount of hydrogen peroxide used to disinfect a large room (50 m^2 · 3 m), realistic worst-case
N_{appl} [1/days]	3		S	Number of applications with one machine during one day, maximum
$N_{machines}$ [-]	3		S	Number of machines operating daily at the same local scale, realistic worst-case

F_i [-]	0.05	0.008	S	Fraction of hydrogen peroxide used that is emitted (i = sewage or air), worst cases (see text)
F_{sewage} [-]	0.024	-	S	Fraction of hydrogen peroxide remaining after degradation in sewage, realistic worst-case
$E_{local,water}$ [kg/day]	$= M_{appl} \cdot N_{appl} \cdot N_{machines} \cdot F_{water} \cdot F_{sewage}$			
	0.0018		**O**	
$E_{local,air}$ [kg/day]	$= M_{appl} \cdot N_{appl} \cdot N_{machines} \cdot F_{air}$			
	0.012		**O**	

Flags: D - default; S - specified by user; O – output

ES-CA:

The biocidal product is used as VHP to disinfect surfaces in facilities with a maximum in-use concentration of 1092 mg a.s./m³ (~ 780 ppm). According to the CAR for hydrogen peroxide (2015), no official emission scenario document exists for disinfection by the VHP process in PT 04 and this use was assessed considering the scenario for surface disinfection by the VHP process in public health areas (PT 02) as a realistic worst-case covering also the use in PT 4. However, the room volume considered in the CAR DocIIB of hydrogen peroxide was 150 m^3, but this volume was modified by TAB ENV 66 to 450000 m^3 for large slaughter house (10000 m^2 surface - 5 m height) and 6000 m^3 for large kitchen (2000 m^2 surface – 3 m height) for disinfection by fogging. Therefore, the emission has been recalculated by Spanish CA to account considering the worst case of 50000 m3 for large slaughter house. The following parameters were considered:

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Amount of hydrogen peroxide used to disinfect a large space in an industrial area (1000 m² surface - 4 m height), realistic worst-case	M_{appl}	4.37	[kg/application]	Defaults as described in CAR DocIIB considering room volume according to TAB (2017) Calculation based on 1092 mg/m^3
Number of applications with one machine during one day, maximum	N_{appl}	3	[1/d]	
Number of machines operating daily at the same local scale, realistic worst-case	$N_{machines}$	3	[-]	
Fraction of hydrogen peroxide used that is emitted to sewage	F_i	0.05	[-]	
Fraction of hydrogen peroxide used that is emitted to air	F_i	0.008	[-]	Worst-case based on maximum residual concentration in air.
Fraction of hydrogen peroxide remaining after degradation in sewage, realistic worst-case	F_{sewage}	0.026	[-]	Degradation in the sewer according to the values agreed at WG-IV_2019_ENV_6-3.
$E_{local,water}$	$= M_{appl} \cdot N_{appl} \cdot N_{machines} \cdot F_{water} \cdot F_{sewage}$			
	0.051		kg/day	O
$E_{local,air}$	$= M_{appl} \cdot N_{appl} \cdot N_{machines} \cdot F_{air}$			
	0.315		kg/day	O

Fate and distribution in exposed environmental compartments

Direct emissions of hydrogen peroxide to surface water or soil do not occur. Hydrogen peroxide is only used in 35% aqueous solutions. Vaporisation only takes place in closed systems, and hydrogen peroxide remaining in process air is decomposed afterwards. Furthermore, air emissions are negligible. Possible exposures to environmental compartments are summarised in table below:

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Surface disinfection by VHP process	yes	yes	no	no	yes	yes	yes	yes	-

Default values for general parameters of EUSES were used to calculate the distribution in the environment and the predicted environmental concentrations (PECs) for sewage treatment plants, freshwater compartment, soil and groundwater.

Input parameters for calculations are summarised in table below:

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	34		
Boiling point	150.2	°C	
Vapour pressure (at 25 °C)	299	Pa	
Water solubility	miscible	mg/L	
Log Octanol/water partition coefficient	-1.57	Log 10	
Henry's Law Constant (at 20 ºC)	7.5 x 10-4	Pa/m^3/mol	
Biodegradability	Readily biodegradable		
DT_{50} for activated sludge	0.03	h (at 20ºC)	
DT_{50} for hydrolysis in surface water	5	d	
DT_{50} for degradation in soil	0.5	d	

As stated at CAR section 8.3.3 Doc-IIIB, relevant compartments after degradation at STP were calculated by using substance specific key input parameters (Doc IIA Chapter 1.3, Table 4.1.1.3-1) as follows: Henry´s law constant 7.5 · 10-4 Pa m^3/mol, log Kow -1.57, DT50 in activated sludge 0.03 h and DT50 in soil 0.5 d, EUSES 2.2 using equations form the Technical guidance document (TGD) gives following distribution of hydrogen peroxide in the STP:

Calculated fate and distribution in the STP	
Compartment	Percentage [%]
Air	1.23E-04
Water	0.376
Primary settler	0.01445
Surplus sludge	2.58E-05
Degraded in STP	99.61

ES-CA:

Please see the new distribution values of into the STP provided in Scenario 1.

Calculated PEC values

In line with calculations at CAR, the predicted environmental concentrations (PEC) in sewage, receiving surface water and sediment and groundwater under agricultural soil were calculated from the emission estimates following the TGD and EUSES 2.2. Exposure to groundwater is anticipated from sewage sludge application only; direct exposure to soil and thereafter to groundwater (pore water of agricultural soil) is regarded negligible.

Summary table on calculated PEC values

	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/L]
Surface disinfection by VHP process	3.38 $x10^{-6}$	3.38 $x10^{-7}$	2.77 x 10^{-7}	3.13 x 10^{-8}	3.58 x 10^{-8}

The emission to air from ventilation was calculated, although vaporisation only takes place in closed systems, and hydrogen peroxide remaining in process air is decomposed afterwards. The resulting PECair can be calculated following the TGD (equation 40), i.e. by multiplying the air emission of 0.012 kg/day with the standard concentration at 100 m from the emission point calculated for a standard source of 1 kg/day (C_{stdair} = 2.78 x 10^{-4} mg x m^{-3})). The resulting PEC_{air} is 3.34 x·10^{-3} µg/m^3. This is a worst-case value, since the emission estimate is a worst-case, and since the standard concentration from the TGD is also based on worst-case assumptions.

The estimated PECair is well below the typical background concentrations of hydrogen peroxide in air of 0.14-1.4 µg/m^3 (CAR, Document II A, Section 4.1.1, Table 4.1.1-1). Therefore, the additional emissions constitute only a negligible contribution to the ambient air concentrations. Furthermore the troposphere has a buffer capacity for hydrogen peroxide, which is part of the equilibrium system of photooxidants. Potential minor air emissions of hydrogen peroxide are therefore not expected to alter the existing tropospheric background concentrations to any relevant degree.

ES CA:

The following PEC values have been recalculated by Spanish CA:

Summary table on calculated PEC values				
PEC_{STP}	**PEC_{air}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**
[mg/L]	[mg/m^3]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]
2.12E-03	1.09E-03	2.12E-04	1.74E-04	1.93E-06

Primary and secondary poisoning

After the decontamination cycle is terminated hydrogen peroxide has to be broken down to the level below 1.25 mg/m3. Access to the vapour-treated area is denied during the disinfection process. There is neither operator nor general public exposure to hydrogen peroxide as the safe level is reached before the re-entry. Sensors of the machine confirm when the safe level is reached.

Dietary exposure is covered by the EU Risk Assessment Report (2003). After H_2O_2 has been released to the environment, it rapidly decomposes in the presence of organic material. In human food, or in drinking water, no accumulation of exogenous H_2O_2 has been observed. It is estimated that dietary intake of naturally occurring hydrogen peroxide is usually below 1 mg.

Substance is unlike to bioaccumulate in aquatic or terrestrial environment according to the TGD. It has a low log Kow (-1.57), it is not highly adsorptive, it does not belong to a class of substances known to have a potential to accumulate in living organisms, its structural features does not indicate accumulation and it is readily biodegradable and has a short degradation half-life of 5 days in the water and 12 hours in soil. No further assessment of secondary exposure via the food chain is therefore considered necessary.

Scenario [4] – Disinfection of distribution systems for drinking water (use #4)

General information

This use was assessed in the CAR at concentration of 2% (w/w).

However, the product assessed in the present document is applied at 4% (w/w) hydrogen peroxide according to section 2.1.4. Thus, new assessment is perfomed in this document for this use.

Hydrogen peroxide is used to disinfect distribution systems for drinking water (pipes, tanks) after maintenance or cleaning operations. A EUBEES emission scenario document (ESD 5, Herrmann & Wagner, 2003) is available for this use, providing general information and addressing individual active substances but not hydrogen peroxide.

An emission scenario was set up in the CAR based on that document and information obtained from CEFIC.

Thus, the assessment of this use is based on scenario PT 4c evaluated in the CAR but re-calculated for the specific application rate of the present use.

Assessed PT	PT 4
Assessed scenarios	Scenario : Disinfection of distribution systems for drinking water
ESD(s) used	No ESD used
Approach	Tailored scenario calculations based on EUBEES emission scenario document (ESD 5, Herrmann & Wagner, 2003) and information obtained from CEFIC.
Distribution in the environment	Calculated based on CAR for active ingredient; Technical guidance document (TGD) and EUSES 2.2
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation: No Use: Yes

	Service life: No
Remarks	No emission scenario is available for the disinfection of distribution systems for drinking water. Scenario based on the one evaluated in the CAR adapted to specific application rate for the present use.

Emission estimation

Distribution systems for drinking water are disinfected only intermittently. Hydrogen peroxide is decomposed during the disinfection process by oxidation reactions with organic or inorganic compounds, as well as by biotic and abiotic catalysis. A conservative reduction of only 25% was assumed (Fwater = 75%). Spent disinfection solution containing hydrogen peroxide is likely to be disposed into sewage. Generally, the waterworks or service companies carrying out the disinfection are required to check the residual concentration of disinfectants before discharge, assuring that discharge limits set on national level are not exceeded (Herrmann & Wagner, 2003). Thus, residual hydrogen peroxide from the disinfection of distribution systems for drinking water is discharged to sewage, with no other relevant emission pathways.

In the sewage, residual hydrogen peroxide is decomposed further, by the same mechanisms as discussed above. However, reaction partners or catalytically active components are actually much more abundant in sewage than during the use of drinking water. The fraction of hydrogen peroxide reaching the sewage treatment plant (STP) was estimated to be 0.024 as a conservative case. Assuming 60 minutes of dwell time in sewage (default according to the ESD for PT5) and using the maximum biodegradation half-life of 6 minutes (11.2 min transferred to 12 °C) from CAR, Document II A, Section 4.1.1.1 (Spain et al 1989), a single first-order kinetics degraded fraction in the sewer is calculated as follows:

$F_{sewage} = \exp(- \ln(2)/DT_{50} * 60 \text{ min}) = 0.024$

As a realistic worst-case, it is assumed that 25 m^3 (Vdisinf) of a 4% (w/w) solution of hydrogen peroxide are used for disinfection of distribution systems for drinking water (see table below). This volume is equivalent e.g. to flooding 500 m of pipe with a diameter of 25 cm with the disinfection solution. Tanks of much larger volume can be treated with this amount, since tanks are only sprayed and not flooded.

Using the parameters derived above, the consumption of hydrogen peroxide at the local scale was calculated and emitted fractions derived based on the emission factors, results are presented in the table below.

Scenario: Disinfection of distribution systems for drinking water

Parameter	Value	Flag	Comment, reference
$C_{a.s.}$, kg/L	0.04	S	Concentration of hydrogen peroxide in the disinfection solution, maximum value
V_{disinf}, L	25,000	S	Volume of disinfection solution used, realistic worst-case

F_{water}	0.75	S	Fraction of hydrogen peroxide remaining at discharge into waste water
F_{sewage}	0.024	S	Fraction of hydrogen peroxide decomposed during transport in sewage (see text)
$E_{local,water}$ [kg/day]	$= C_{a.s.} \cdot V_{disinf} \cdot F_{water} \cdot F_{sewage}$		
	18	O	

Flags: D - default; S - specified by user; O – output

ES-CA:

The fraction of a.s. remaining after degradation in sewage has been corrected to 0.026 (see WG-IV-2019_ENV_6-3). Considering these values, the emission to the STP is **19.5** kg/d. A new risk assessment has been provided.

Fate and distribution in exposed environmental compartments

Direct emissions of hydrogen peroxide to surface water or soil do not occur. Hydrogen peroxide is only used in 35% aqueous solutions. Spraying takes place but only by airless spray. Furthermore, only closed areas are sprayed and any ventilation is turned off until the spray has settled. Therefore, no relevant air emissions occur. Furthermore, air emissions are negligible. Possible exposures to environmental compartments are summarised in table below:

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Disinfection of distribution systems for drinking water	yes	yes	no	no	yes	no	yes	yes	-

Default values for general parameters of EUSES were used to calculate the distribution in the environment and the predicted environmental concentrations (PECs) for sewage treatment plants, freshwater compartment, soil and groundwater.

Input parameters for calculations are summarised in table below:

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	34		
Boiling point	150.2	°C	
Vapour pressure (at 25°C)	299	Pa	
Water solubility	miscible	mg/L	
Log Octanol/water partition coefficient	-1.57	Log 10	

Henry's Law Constant (at 20 ºC)	7.5 x 10^{-4}	Pa/m^3/mol	
Biodegradability	Readily biodegradable		
DT_{50} for activated sludge	0.03	h (at 20ºC)	
DT_{50} for hydrolysis in surface water	5	d	
DT_{50} for degradation in soil	0.5	d	

As stated at CAR section 8.3.3 Doc-IIIB, relevant compartments after degradation at STP were calculated by using substance specific key input parameters (Doc IIA Chapter 1.3, Table 4.1.1.3-1) as follows: Henry´s law constant 7.5 · 10-4 Pa m^3/mol, log Kow -1.57, DT50 in activated sludge 0.03 h and DT50 in soil 0.5 d, EUSES 2.2 using equations form the Technical guidance document (TGD) gives following distribution of hydrogen peroxide in the STP :

Calculated fate and distribution in the STP	
Compartment	Percentage [%]
Air	1.23E-04
Water	0.376
Primary settler	0.01445
Surplus sludge	2.58E-05
Degraded in STP	99.61

ES-CA:

Please see the new distribution values of into the STP provided in Scenario 1.

Calculated PEC values

In line with calculations at CAR, the predicted environmental concentrations (PEC) in sewage, receiving surface water and sediment and groundwater under agricultural soil were calculated from the emission estimates following the TGD and EUSES 2.2. Exposure to groundwater is anticipated from sewage sludge application only; direct exposure to soil and thereafter to groundwater (pore water of agricultural soil) is regarded negligible.

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/L]
Disinfection of distribution systems for drinking water	0.0338	3.38 x10^{-3}	2.77 x 10^{-3}	3.13 x 10^{-4}	3.58 x 10^{-4}

ES CA:

The following PEC values have been recalculated by Spanish CA:

Summary table on calculated PEC values				
PEC_{STP}	**PEC_{air}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**
[mg/L]	[mg/m^3]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]
6.47E-02	1.08E-08	6.47E-03	5.29E-03	5.87E-05

Primary and secondary poisoning

The water treatment plant is signalled and closed and can only be assessed by authorised personnel. Exposure of the general public is not expected.

Dietary exposure is covered by the EU Risk Assessment Report (2003). After H_2O_2 has been released to the environment, it rapidly decomposes in the presence of organic material. In human food, or in drinking water, no accumulation of exogenous H_2O_2 has been observed. It is estimated that dietary intake of naturally occurring hydrogen peroxide is usually below 1 mg.

Substance is unlike to bioaccumulate in aquatic or terrestrial environment according to the TGD. It has a low log Kow (-1.57), it is not highly adsorptive, it does not belong to a class of substances known to have a potential to accumulate in living organisms, its structural features does not indicate accumulation and it is readily biodegradable and has a short degradation half-life of 5 days in the water and 12 hours in soil. No further assessment of secondary exposure via the food chain is therefore considered necessary.

2.2.8.2.2 Uses not evaluated in the CAR for the approval of active substance

Scenario [2] – Aseptic packaging by spraying (use #2)

General information

Hydrogen peroxide is used in aseptic packaging to sterilise packaging material. Aseptic packaging by immersion has been assessed at active ingredient authorisation phase. However, no assessment was carried out for the spraying methodology.

No specific emission scenario is available for this use. Therefore, a tailored scenario was prepared for the aseptic packaging by immersion at active ingredient authorisation. In order to be consistent with previous approach, this assessment will be based on main assumptions on production by creameries used previously at active ingredient authorisation phase. Those calculations were based on EU Risk Assessment Report (2003). This information was updated from various sources, i.e. information gathered from producers of hydrogen peroxide (Information obtained from CEFIC, 2006), from discussions with producers of machines for aseptic packaging (referenced as Machine Producer, 2006), and from the IPPC BREF document on food, drink and milk industries (EC, 2006).

Assessed PT	PT 4
Assessed scenarios	Scenario : Aseptic packaging by spraying
ESD(s) used	Emission Scenario Document for Product Type 4: tailored scenario calculations
Approach	Average consumption

Distribution in the environment	Calculated based on CAR for active ingredient; Technical guidance document (TGD) and EUSES 2.2
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: No
Remarks	No emission scenario is available for the aseptic packaging treatment by spraying. Therefore, calculations are based on the active substance CAR adapted to hydrogen peroxide consumption rate by spraying method

Emission estimation

The spraying process notably differs from the immersion method where a bath is used. The product at 35% concentration (up to 36% upper range) is loaded in the tank of filling machine. The machine is an automated system that controls that concentration does not drop down. Hydrogen peroxide is sprayed or atomized into the container. A measured amount of hydrogen peroxide is metred into each nozzle which delivers the solution into each container to ensure that a uniformly coats the inside surface of the package. Application rate of 1 mL of 35 %(w/w) hydrogen peroxide per package is considered according to section 2.2.1. According to assumptions on the immersion method, typical machine output of 7.000 packages/hour is applicable for machines producing 1 L packages. Sparing process includes a drying phase by hot sterile air. Therefore, residual hydrogen peroxide should not exceed 0.5 ppm in food.

The packaging machines are closed systems with ventilation by sterile air. The ventilation air contains hydrogen peroxide evaporated from the immersion bath and the drying process. The air is circulated internally, and hydrogen peroxide is washed by scrubbers. Scrubbing water is discharged to sewage.

CAR estimations assumed that during the use of 35% (w/w) hydrogen peroxide solution for disinfection of packaging material, a fraction of 10% was assumed to be degraded, i.e. 90% remaining for immersion process. This is very conservative for the spraying methodology. However, this figure will be used as a worst case estimation of the fraction of a.s. remaining at discharge into sewage ($F_{process}$).

For the STP degradation phase, same assumptions as CAR will be used as well, being a first order kinetics with time period of 1 hour in sewage:

$F_{sewage} = \exp(- \ln(2)/DT_{50} * 60 \text{ min}) = 0.024$

Any elimination of hydrogen peroxide during on-site wastewater treatment was not taken into account ($F_{wwtp} = 1$).

The emission to water at the local scale is estimated by calculating the amount of hydrogen peroxide consumed at a creamery (Qa.s.) from the parameters described above, and multiplying with the emission fractions, calculations presented in the table below.

Scenario: Aseptic packaging by spraying

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Application rate	1	mL/package	
$c_{a.s}$	36	%	Concentration of hydrogen peroxide in disinfectant solution (upper range value)
Q_{milk}	10^8	kg/year	Amount of milk processed at a large-scale creamery (Eurostat, 2006), realistic worst-case
$T_{emission}$	231	days/year	Working days per year (Raffael and van de Plassche, 2011)
R_{disinf}	0.001	L/kg milk	Consumption rate of disinfectant solution (1 mL of biocidal product per 1 L package). 0.001 L/package, which corresponds to 0.001 L/kg milk assuming a density of 1 kg/L.
ρ_{disinf}	1.13	kg/L	Bulk density of 35% (w/w) hydrogen peroxide disinfectant solution (Document II A 3.1.3)
$F_{process}$	0.9		Fraction of a.s. remaining at discharge into sewage, realistic worst-case
F_{sewage}	0.024		Fraction of a.s. remaining after degradation in sewage, realistic worst-case
F_{wwtp}	1		Fraction remaining after on-site waste-water treatment (aerobic/biological), conservatively ignored here
$Q_{a.s}$		kg/kg milk	Amount of a.s. used per mass of milk packaged. Only for derivation of estimation equation.
$E_{local, water}$ (kg/day)	= Qa.s. · Fprocess · Fsewage · Fwwtp = Qmilk · Temission-1 · Rdisinf · Ca.s. · □disinf · Fprocess · Fsewage · Fwwtp		
	3.80		

ES-CA:

The nominal declared content of hydrogen peroxide in the biocidal product is 35.6 % (w/w). Nevertheless, the concentration range based on specifications is 35-36 % (w/w). The risk assessment has been updated taking into account the upper range limit of 36% (w/w) in order to cover the worst case scenario. In addition, the bulk density of the biocidal product is reported to be 1.135 g/cm^3. The fraction of a.s. remaining after degradation in sewage has been corrected to 0.026 (see WG-IV-2019_ENV_6-3). Considering these values, the emission to the STP is **4.09** kg/d. Therefore, a new risk assessment is provided.

Fate and distribution in exposed environmental compartments

Direct emissions of hydrogen peroxide to surface water or soil do not occur. Hydrogen peroxide is only used in 35% aqueous solutions (up to 36% upper range). Aseptic packaging spraying takes place in closed system and the hydrogen peroxide remaining in the process air is decomposed by high temperature or washed out at scrubbers. Furthermore, air

emissions are negligible. Possible exposures to environmental compartments are summarised in table below:

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Aseptic packaging by spraying	yes	yes	no	no	yes	no	yes	yes	-

Default values for general parameters of EUSES were used to calculate the distribution in the environment and the predicted environmental concentrations (PECs) for sewage treatment plants, freshwater compartment, soil and groundwater. In the same line as CAR calculations, the default value for EFFLUENTstp (Total volume of wastewater treated in the STP, 2000 m^3/d) was changed to higher value of 5000 m^3/d., because the volumes of waste waters form these uses at large plants were not regarded relevant to be conducted to the standard STPs. The detailed rationale for the larger STP is explained in the emission estimation chapter at CAR.

Input parameters for calculations are summarised in table below:

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	34		
Boiling point	150.2	°C	
Vapour pressure (at 25°C)	299	Pa	
Water solubility	miscible	mg/L	
Log Octanol/water partition coefficient	-1.57	Log 10	
Henry's Law Constant (at 20 ºC)	7.5 x 10^{-4}	Pa/m^3/mol	
Biodegradability	Readily biodegradable		
DT_{50} for activated sludge	0.03	hr (at 20ºC)	
DT_{50} for hydrolysis in surface water	5	d	
DT_{50} for degradation in soil	0.5	d	

As stated at CAR section 8.3.3 Doc-IIIB, relevant compartments after degradation at STP were calculated by using substance specific key input parameters (Doc IIA Chapter 1.3, Table 4.1.1.3-1) as follows: Henry´s law constant 7.5 · 10-4 Pa m^3/mol, log Kow -1.57, DT50 in activated sludge 0.03 h and DT50 in soil 0.5 d, EUSES 2.2 using equations form the Technical guidance document (TGD) gives following distribution of hydrogen peroxide in the STP :

Calculated fate and distribution in the STP	
Compartment	Percentage [%]
Air	1.23E-04
Water	0.376
Primary settler	0.01445
Surplus sludge	2.58E-05

Degraded in STP	99.61

ES-CA:

Please see the new distribution values of into the STP provided in Scenario 1.

Calculated PEC values

In line with calculations at CAR, the predicted environmental concentrations (PEC) in sewage, receiving surface water and sediment and groundwater under agricultural soil were calculated from the emission estimates following the TGD and EUSES 2.2. Exposure to groundwater is anticipated from sewage sludge application only; direct exposure to soil and thereafter to groundwater (pore water of agricultural soil) is regarded negligible.

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/l]
Aseptic packaging by spraying	2.86×10^{-3}	2.86×10^{-4}	2.34×10^{-4}	2.65×10^{-5}	3.03×10^{-5}

ES CA:

The following PEC values have been recalculated by Spanish CA:

Summary table on calculated PEC values				
PEC_{STP}	**PEC_{air}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**
[mg/L]	[mg/m^3]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]
5.43E-03	2.28E-09	5.43E-04	4.44E-04	1.23E-05

Primary and secondary poisoning

Secondary dietary exposure of consumers to residual hydrogen peroxide in food and drinking water is in theory possible under PT 4 aseptic packaging by spraying method. However, hydrogen peroxide used for aseptic packaging evaporates while the wrapping material is heated before filled with food and no residues in food are expected. Furthermore, hydrogen peroxide, if present, would rapidly decompose in contact with any type of food.
Dietary exposure is covered by the EU Risk Assessment Report (2003). After H_2O_2 has been released to the environment, it rapidly decomposes in the presence of organic material. In human food, or in drinking water, no accumulation of exogenous H_2O_2 has been observed. It is estimated that dietary intake of naturally occurring hydrogen peroxide is usually below 1 mg.
Substance is unlike to bioaccumulate in aquatic or terrestrial environment according to the TGD. 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 does not indicate accumulation and it is readily biodegradable and has a short degradation half-life of 5 days in the water and 12 hours in soil. No further assessment of secondary exposure via the food chain is therefore considered necessary.

Scenario [5] – Disinfection of inner surfaces by CIP (use #5)

The scenario for PT4, Disinfection of inner surfaces by CIP is the same as in disinfection of distribution systems for drinking water, which was already evaluated in the CAR. For further information, please see section 2.2.8.2.2.

ES-CA:

Spanish CA disagrees with the applicant and considers this scenario is not similar to disinfection of distributions systems for drinking water. Therefore, scenario 5 is not covered by the assessment presented in the CAR of Hydrogen peroxide. Spanish CA considers the use Disinfection of inner surfaces by CIP should be assessed considering the ESD scenario for PT04 Assessment of entire plants, as it is stated in ESD for PT04 that this scenario covers the emissions of CIP disinfection and disinfection of storage tanks. Therefore, a new Risk assessment is provided using the following parameters:

Parameter	Unit	Symbols	S/D/O/P	Value	Remark
Amount of active substance	kg/yr	Qa.i	S	191	Table 6 ESD
Number of emission days per year	d/yr	$T_{emission}$	D	231	
Fraction released to wastewater	-	F_{water}	D	1	
Fraction of substance eliminated due to the on-site pre-treatment of the plant	-	F_{elim}	D	0	
Fraction of substance disintegrated during or after application (before release to the sewer system)	-	F_{dis}	D	0	
Capacity of the STP	l/d	$CAP_{STP\text{-}off\text{-}site}$	D	2000000	

Calculations:

	Hydrogen peroxide
DT50 (min) @12 ºC	11.4
K_{sewer} (h^{-1})	3.65
F_{sewer}	0.026

$$Elocal_{water} = (Qai/Temission) * Fwater * (1-Fdis) * (1-Felim)*Fsewage$$

$$C_{influent} = Elocal_{water} * 10^6 / CAP_{STP\text{-}off\text{-}site}$$

Results:	hydrogen peroxide
Elocal water (Ct_0) (kg/d)	0.83
Elocal water (Ct_1) (kg/d)	0.022
C influent (mg/l)*	0.011

* These value takes into account the degradation of the active substances during its stay in the sewer system.

The following PEC values have been calculated:

Summary table on calculated PEC values				
PEC_{STP}	**PEC_{air}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**
[mg/L]	[mg/m^3]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]
7.14E-05	1.20E-11	7.14E-06	5.84E-06	1.39E-07

Scenario [6] – Disinfection of Cork stoppers (use #6)

The scenario for PT4, Disinfection of cork stoppers, is very similar to the scenario [2] aseptic packaging by spraying. A dose of 4-20 L of biocidal product per batch (20000 cork stoppers per batch) is estimated to be used in the disinfection of cork stoppers. Taking the upper range value (20 L), it gives 1 mL/cork stopper which corresponds with the application rate, that is, 1 mL/package, used in scenario 2. Therefore, the same calculations apply.

ES-CA:

Spanish CA agrees with the applicant and considers this scenario is already covered by assessment presented in Scenario [2].

2.2.8.3 Risk characterisation

ES-CA:
The risk characterization performed for all the assessed scenarios by Spanish CA is presented bellow:

Atmosphere
The estimated PEC_{air} for each assessed scenario is well below the typical background concentrations of hydrogen peroxide in air that ranges from 0.14 to 1.4 µg/m^3, with a maximum concentration of 10 µg/m^3 (Document IIA, 2015). Therefore, the additional emissions constitute only a negligible contribution to the ambient air concentrations. Furthermore the troposphere has a buffer capacity for hydrogen peroxide, which is part of the equilibrium system of photooxidants. Potential minor air emissions of hydrogen peroxide are therefore not expected to alter the existing tropospheric background concentrations to any relevant degree.

In conclusion, emissions to air from the use of the BP AOPACK 35% can be regarded as negligible and probably don't alter existing background concentrations in the troposphere to any relevant degree.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
Scenario	**$PEC/PNEC_{STP}$**
• Scenario [1]: Aseptic packaging by immersion	6.66E-04
• Scenario [2]: Aseptic packaging by spraying.	1.17E-03
• Scenario [3]: Surface disinfection by VHP process.	4.56E-04
• Scenario [4]: Disinfection of distribution systems for drinking water.	1.39E-02
• Scenario [5]: Disinfection of inner surfaces by CIP.	1.53E-05
• Scenario [6]: Disinfection of cork stoppers.	1.17E-03

Conclusion: no unacceptable risks for the STP are expected. For all possible environmental exposure scenarios the PEC/PNEC ratio were calculated to be < 1.

Aquatic and sediment compartments

Summary table on calculated PEC/PNEC values		
Scenario	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**
• Scenario [1]: Aseptic packaging by immersion	2.46E-02	n.r.
• Scenario [2]: Aseptic packaging by spraying.	4.31E-02	n.r.
• Scenario [3]: Surface disinfection by VHP process.	1.69E-02	n.r.
• Scenario [4]: Disinfection of distribution systems for drinking water.	5.14E-01	n.r.
• Scenario [5]: Disinfection of inner surfaces by CIP.	5.67E-04	n.r.
• Scenario [6]: Disinfection of cork stoppers.	4.31E-02	n.r.

n.r.: not relevant

Conclusion: no unacceptable risks for the aquatic compartment are expected. For all possible environmental exposure scenarios the PEC/PNEC ratio were calculated to be < 1. Regarding sorption to sediment, it cannot be expected as hydrogen peroxide will not accumulate as it rapidly oxydizes in contact to organic matter. No unacceptable risks for benthic organisms are expected.

Terrestrial compartment

Summary table on calculated PEC/PNEC values	
Scenario	**PEC/PNEC$_{soil}$**
• Scenario [1]: Aseptic packaging by immersion	3.83E-03
• Scenario [2]: Aseptic packaging by spraying.	6.70E-03
• Scenario [3]: Surface disinfection by VHP process.	1.05E-03
• Scenario [4]: Disinfection of distribution systems for drinking water.	3.19E-02
• Scenario [5]: Disinfection of inner surfaces by CIP.	7.54E-05
• Scenario [6]: Disinfection of cork stoppers.	6.70E-03

Conclusion: no unacceptable risks for the soil compartment are expected. For all possible environmental exposure scenarios the PEC/PNEC ratio were calculated to be < 1.

Groundwater

At ENV WG-II-2019, it was agreed that for rapidly reacting substances such as hydrogen peroxide no groundwater assessment is needed since it is very unlikely that this substances will reach the groundwater. For this reason, the assessment of groundwater compartment has not been performed.

Primary and secondary poisoning

Primary poisoning
No risk is expected.

Secondary poisoning
No risk is expected.

Mixture toxicity
Mixture toxicity is not relevant for the biocidal product since the product composition comprises only one active substance and no environmentally relevant substances of concern.

Aggregated exposure (combined for relevant emission sources)

Summary table on calculated PEC/PNEC values				
ΣRQ	**PEC/PNEC$_{STP}$**	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{soil}$**
	1.74E-02	6.42E-01	6.42E-01	4.93E-02

Hydrogen peroxide is released from multiple sources simultaneously. However, aggregated emission will not result in unacceptable risks to environmental compartments the total sum of PEC:PNEC ratios remain below one in all cases.

2.2.8.3.1 Uses already evaluated in the CAR for the approval of active substance at different concentration in the product and/or application rate

Scenario [1] – Aseptic packaging by immersion (use #1)

Atmosphere
The ecotoxicological properties of the product may be derived from the properties of the active substance and other components of the product. Information on the ecotoxicity of the active substance is presented previously. There are no compounds of concern in the formulated products that adversely affect the conclusions of the risk assessment for the active substance in the product, therefore no further assessment is needed.

Conclusion: same conclusion as described at CAR applies: emissions to air from biocidal uses can be regarded negligible and they do probably not alter existing background concentrations in the troposphere to any relevant degree. Therefore, further assessment of PECs in air and rainwater from emissions due to use of biocidal products is considered to be not relevant.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
PT 4. Aseptic packaging by immersion	**PEC/PNEC$_{STP}$**
	3.50×10^{-4}

Conclusion: Risk is considered negligible.

Aquatic compartment

Summary table on calculated PEC/PNEC values				
PT 4. Aseptic packaging by immersion	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
	0.01295	0.01295	NR	NR

*NR: no PNEC derived as this is not a relevant compartment

Conclusion: Risk is considered negligible.

Terrestrial compartment

Summary table on calculated PEC/PNEC values	
PT 4. Aseptic packaging by immersion	**$PEC/PNEC_{soil}$**
	8.23×10^{-3}

At CAR document IIA, PNEC soil was calculated to be 1.84×10^{-3} mg/kg (wet weight) with:

$K_{soil\text{-}water}$ = soil-water partition coefficient (0.248 m^3/m^3)
RHO_{soil} = bulk density of (wet) soil (1700 kg/m^3)
$PNEC_{water}$ = 0.0126 mg/L

As negligible exposure of soil is to be expected following the biocidal uses of hydrogen peroxide and any traces of hydrogen peroxide reaching soil are very rapidly degraded taking into account the short half-life in soil (see CAR Section 4.1.1.1), PNEC for soil organisms is not required for the risk assessment of hydrogen peroxide under BPR Regulation.

Conclusion: Risk is considered negligible.

Groundwater

CAR document IIB, section 8.3.3.1 stated: Exposure to groundwater is anticipated from sewage sludge application only; direct exposure to soil and thereafter to groundwater (pore water of agricultural soil) is regarded negligible.

Conclusion: Risk is considered negligible.

Aggregated exposure (combined for relevant emission sources)

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

Scenario [3] – Surface disinfection by VHP process (use #3)

Atmosphere

The estimated PEC_{air} (3.34×10^{-3} µg/m^3) is well below the typical background concentrations of hydrogen peroxide in air of 0.14-1.4 µg/m^3 (CAR, Document II A, Section 4.1.1, Table 4.1.1-1). Therefore, the additional emissions constitute only a negligible contribution to the ambient air concentrations. Furthermore the troposphere has a buffer capacity for hydrogen peroxide, which is part of the equilibrium system of photooxidants. Potential minor air emissions of hydrogen peroxide are therefore not expected to alter the existing tropospheric background concentrations to any relevant degree.

Conclusion: same conclusion as described at CAR applies: emissions to air from biocidal uses can be regarded negligible and they do probably not alter existing background concentrations in the troposphere to any relevant degree. Therefore, further assessment of

PECs in air and rainwater from emissions due to use of biocidal products is considered to be not relevant.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
PT 4. Surface disinfection by VHP process	**$PEC/PNEC_{STP}$**
	$7.26x\ 10^{-7}$

Conclusion: Risk is considered negligible.

Aquatic compartment

Summary table on calculated PEC/PNEC values				
PT 4. Surface disinfection by VHP process	**$PEC/PNEC_{water}$**	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
	$2.69x\ 10^{-5}$	$2.69x\ 10^{-5}$	NR	NR

*NR: no PNEC derived as this is not a relevant compartment

Conclusion: Risk is considered negligible.

Terrestrial compartment

Summary table on calculated PEC/PNEC values	
PT 4. Surface disinfection by VHP process	**$PEC/PNEC_{soil}$**
	1.71×10^{-5}

At CAR document IIA, PNEC soil was calculated to be 1.84×10^{-3} mg/kg (wet weight) with:

$K_{soil\text{-}water}$ = soil-water partition coefficient (0.248 m^3/m^3)
RHO_{soil} = bulk density of (wet) soil (1700 kg/m^3)
$PNEC_{water}$ = 0.0126 mg/L

As negligible exposure of soil is to be expected following the biocidal uses of hydrogen peroxide and any traces of hydrogen peroxide reaching soil are very rapidly degraded taking into account the short half-life in soil (see CAR Section 4.1.1.1), PNEC for soil organisms is not required for the risk assessment of hydrogen peroxide under BPR Regulation.

Conclusion: Risk is considered negligible.

Groundwater

CAR document IIB, section 8.3.3.1 stated: Exposure to groundwater is anticipated from sewage sludge application only; direct exposure to soil and thereafter to groundwater (pore water of agricultural soil) is regarded negligible.

Conclusion: Risk is considered negligible.

Aggregated exposure (combined for relevant emission sources)

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

Scenario [4] – Disinfection of distribution systems for drinking water (use #4)

Atmosphere

The ecotoxicological properties of the product may be derived from the properties of the active substance and other components of the product. Information on the ecotoxicity of the active substance is presented previously. There are no compounds of concern in the formulated products that adversely affect the conclusions of the risk assessment for the active substance in the product, therefore no further assessment is needed.

Conclusion: same conclusion as described at CAR applies: emissions to air from biocidal uses can be regarded negligible and they do probably not alter existing background concentrations in the troposphere to any relevant degree. Therefore, further assessment of PECs in air and rainwater from emissions due to use of biocidal products is considered to be not relevant.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
PT 4. Disinfection of distribution systems for drinking water	**PEC/PNEC$_{STP}$**
	7.26×10^{-3}

Conclusion: Risk is considered negligible.

Aquatic compartment

Summary table on calculated PEC/PNEC values				
PT 4. Disinfection of distribution systems for drinking water	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
	0.268	0.268	NR	NR

*NR: no PNEC derived as this is not a relevant compartment

Conclusion: Risk is considered negligible.

Terrestrial compartment

Summary table on calculated PEC/PNEC values	
PT 4. Disinfection of distribution systems for drinking water	**PEC/PNEC$_{soil}$**
	0.17

At CAR document IIA, PNEC soil was calculated to be 1.84×10^{-3} mg/kg (wet weight) with:

$K_{soil\text{-}water}$ = soil-water partition coefficient (0.248 m^3/m^3)
RHO_{soil} = bulk density of (wet) soil (1700 kg/m^3)

$PNEC_{water}$ = 0.0126 mg/L

As negligible exposure of soil is to be expected following the biocidal uses of hydrogen peroxide and any traces of hydrogen peroxide reaching soil are very rapidly degraded taking into account the short half-life in soil (see CAR Section 4.1.1.1), PNEC for soil organisms is not required for the risk assessment of hydrogen peroxide under BPR Regulation.

Conclusion: Risk is considered negligible.

Groundwater

CAR document IIB, section 8.3.3.1 stated: Exposure to groundwater is anticipated from sewage sludge application only; direct exposure to soil and thereafter to groundwater (pore water of agricultural soil) is regarded negligible.

Conclusion: Risk is considered negligible.

Aggregated exposure (combined for relevant emission sources)

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

2.2.8.3.2 Uses not evaluated in the CAR for the approval of active substance

Scenario [2] – Aseptic packaging by spraying (use #2)

Atmosphere

The ecotoxicological properties of the product may be derived from the properties of the active substance and other components of the product. Information on the ecotoxicity of the active substance is presented previously. There are no compounds of concern in the formulated products that adversely affect the conclusions of the risk assessment for the active substance in the product, therefore no further assessment is needed.

Conclusion: same conclusion as described at CAR applies: emissions to air from biocidal uses can be regarded negligible and they do probably not alter existing background concentrations in the troposphere to any relevant degree. Therefore, further assessment of PECs in air and rainwater from emissions due to use of biocidal products is considered to be not relevant.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
PT 4. Aseptic packaging by spraying	**$PEC/PNEC_{STP}$**
	6.13×10^{-4}

Conclusion: Risk is considered negligible.

Aquatic compartment

Summary table on calculated PEC/PNEC values				
PT 4. Aseptic packaging by spraying	**$PEC/PNEC_{water}$**	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
	0.023	0.023	NR	NR

*NR: no PNEC derived as this is not a relevant compartment

Conclusion: Risk is considered negligible.

Terrestrial compartment

Summary table on calculated PEC/PNEC values	
PT 4. Aseptic packaging by spraying	**$PEC/PNEC_{soil}$**
	0.014

At CAR document IIA, PNEC soil was calculated to be 1.84×10^{-3} mg/kg (wet weight) with:

$K_{soil\text{-}water}$ = soil-water partition coefficient (0.248 m^3/m^3)
RHO_{soil} = bulk density of (wet) soil (1700 kg/m^3)
$PNEC_{water}$ = 0.0126 mg/L

As negligible exposure of soil is to be expected following the biocidal uses of hydrogen peroxide and any traces of hydrogen peroxide reaching soil are very rapidly degraded taking into account the short half-life in soil (see CAR Section 4.1.1.1), PNEC for soil organisms is not required for the risk assessment of hydrogen peroxide under BPR Regulation.

Conclusion: Risk is considered negligible.

Groundwater

CAR document IIB, section 8.3.3.1 stated: Exposure to groundwater is anticipated from sewage sludge application only; direct exposure to soil and thereafter to groundwater (pore water of agricultural soil) is regarded negligible.

Conclusion: Risk is considered negligible.

Aggregated exposure (combined for relevant emission sources)

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

Scenario [5] – Disinfection of inner surfaces by CIP (use #5)

The scenario for PT4, Disinfection of inner surfaces by CIP is the same as in disinfection of distribution systems for drinking water, which was already evaluated in the CAR. For further information, please see section 2.2.8.3.2.

Scenario [6] – Disinfection of cork stoppers (use #6)
The scenario for PT4, Disinfection of cork stoppers is the same as Aseptic packaging disinfection by spraying. See scenario [2].

ES-CA:

Overall conclusion on the risk assessment for the environment of the product
A risk assessment for the environment has been carried out for the intended uses of the biocidal product AOPACK 35%. Based on the environmental risk assessment, the intended uses of the product as disinfectant (PT04) for aseptic packaging, cork stoppers, surfaces in food processing facilities, distribution systems for drinking water and inner surfaces by CIP, do not result in unacceptable risks for the environment if the directions for use are to be followed. Therefore, the approval of AOPACK 35% can be granted from an environmental perspective.

Overall conclusion on the risk assessment for the environment of the product
Risks are considered to be acceptable according to the above presented figures.

2.2.9 Measures to protect man, animals and the environment

Please refer to summary of the product assessment (SPC) and to the relevant sections of the assessment report.

Clean-up methods:

- If possible, dam large quantities of liquid with sand or soil.
- Dilute with large quantities of water.

Waste management:

- Smaller quantities of hydrogen peroxide may be discharged immediately to the sewer. Keep concentrations in discharged water < 0.1% (w/w).
- Immediately notify the appropriate authorities in case of significant discharge.

2.2.10 Assessment of a combination of biocidal products

The biocidal product is not intended for the use with other biocidal products.

2.2.11 Comparative assessment

Not relevant

3 ANNEXES

3.1 List of studies for the biocidal product

Section No. (IUCLID dossier)	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
3.1	[redacted]	[redacted]	Certificate of Quality AOPACK 35% Study No. 201601001.2	Y	PeroxiChem Spain S.L.U
3.1, 3.2, 3.3, 3.4, 3.5.7, 3.6, 3.8, 3.9	[redacted]	[redacted]	Physical-chemical characterization and accelerated storage stability of the test item AOPACK 35% Study No. BT077/16	Y	PeroxiChem Spain S.L.U
3.4	[redacted]	[redacted]	Accelerated storage test of hydrogen peroxide containing biocidal products of the Oxteril and Clarmarin group	Y	Evonik Resource Efficiency GmbH
3.4	[redacted]	[redacted]	Physical-chemical properties of test item AOPACK 35% after two years shelf life Final report BT078/16	Y	PeroxyChem Spain, S.L.U.
3.4, 4.17	Goor G. et al.	1989	Hydrogen peroxide, In: Ullmann´s Encyclopedia of Industrial Chemistry, 5th completely revised edition, 1989, Vol. A 13. Elvers B., Hawkins S., Ravenscroft M. and Schulz G. (eds), VCH, Weinheim, 445 Non-GLP, published	N	
4.1, 4.4, 4.8	[redacted]	[redacted]	Determination of safety data according to hazardous materials legislation for a H_2O_2 containing formulation AOPACK®35% Test Report No.: SPZ22-155	Y	Evonik Operations GmbH
4.4	[redacted]	[redacted]	AOPACK 35%: Determination of oxidizing properties. Study No. BC-43/16	Y	PeroxyChem Spain, S.L.U.
4.16	[redacted]	[redacted]	Oxypure C50%. Test for corrosion to metals. Test Report BC-49/16.	Y	PeroxyChem Spain, S.L.U.
5.1	[redacted]	[redacted]	Peroxyde d'hydrogène à usage industriel. Détermination de la teneur en peroxyde d'hydrogène. Méthode titrimetrique. Chemoxal/Chalon. Controle qualité. 3 December 1993. Non-GLP, unpublished	Y	CEFIC Peroxygens Sector Group
5.1	CEFIC	2003	Hydrogen peroxide for Industrial use. Determination of hydrogen peroxide content. Titrimetric method. Method no. AM-7157. CEFIC Peroxygens Sector Group, Brussels, March 2003. http://www.cefic.org/Templates/shwAssocDetails.asp?NID=473&HID=27&ID=66 Non-GLP, published	N	CEFIC Peroxygens Sector Group
5.1	[redacted]	[redacted]	Physical-chemical characterization and accelerated storage stability of the test item OXYPURE 902 DW 50 Test Report BT079/16	Y	PeroxyChem Spain, S.L.U.
5.1	[redacted]	[redacted]	Development and validation of a titrimetric method for the determination of Hydrogen peroxide in water. Members of the Peroxygens Sector Group, Study No. 510669 GLP, unpublished	Y	Members of the Peroxygens Sector Group

Section No. (IUCLID dossier)	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
5.2	[redacted]	[redacted]	Analytical method for H_2O_2: Determination of chloride, phosphate, sulphate and nitrate. Degussa AG Dept. O2-AO-AT. January 2005 Members of the Cefic Peroxygens Sector Group Non-GLP, unpublished	Y	CEFIC Peroxygens Sector Group
5.2.2	[redacted]	[redacted]	Hydrogen peroxide: feasibility study. Members of the Cefic Peroxygens Sector Group. Study No. CTL/TZ0357/SUM/REPT GLP, unpublished	Y	Members of the Cefic Peroxygens Sector Group
5.2.2	[redacted]	[redacted]	Development and validation of an analytical method for the analysis of hydrogen peroxide in air. Study No. 510667 GLP, unpublished	Y	Members of the Cefic Peroxygens Sector Group
5.2.3	[redacted]	[redacted]	Development and validation of an analytical method for the analysis of hydrogen peroxide in water. Members of the Peroxygens Sector Group, Study No. 510666 GLP, unpublished	Y	Members of the Cefic Peroxygens Sector Group
5.2.3	[redacted]	[redacted]	Development and validation of an analytical method for the analysis of Cd, As, Pb and Hg in hydrogen peroxide in solution. Members of the Peroxygens Sector Group, Study No. 510668 GLP, unpublished	Y	Members of the Cefic Peroxygens Sector Group
6.7	[redacted]	[redacted]	Report on microbiological compliance in cork stoppers	Y	[redacted]
6.7	[redacted]	[redacted]	Modification of the AOAC Sporicidal Method to Determine Efficacy of Products Used in Aseptic Filling Applications. (B-CAP 35%) FMC Corporation. Study No. A08823 Non-GLP, unpublished.	Y	FMC Corporation (Evonik Peroxide Spain s.l.u)
6.7	[redacted]	[redacted]	Bacterial and Yeasticidal effectiveness by airborne disinfection of surfaces on OXTERIL® 350 Spray Report number: STULV18AA2074-1	Y	Evonik Resource Efficiency GmbH
6.7	[redacted]	[redacted]	Determinación de la actividad básica en antisépticos y desinfectantes químicos (norma UNE-EN 1650) (OXYPURE C50) FMC FORET, S.A. Study No. A-043378 Non-GLP, unpublished.	Y	Evonik Peroxide Spain s.l.u
6.7	[redacted]	[redacted]	Determination of Basic Bactericidal Activity of Antiseptics and Chemical Disinfectants (EU Standard UNE-EN 1276) (OXYPURE C50) FMC FORET, S.A. Study No. A-044635 Non-GLP, unpublished.	Y	Evonik Peroxide Spain s.l.u
6.7	[redacted]	[redacted]	Valoración de la actividad bactericida según norma UNE-EN 13697: ABRIL 2002 (ERRATUM: JULIO 2007) (OXYPURE C50) FMC FORET, S.A. Study No. 110024765 Non-GLP, unpublished.	Y	Evonik Peroxide Spain s.l.u

Section No. (IUCLID dossier)	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
6.7	[redacted]	[redacted]	Valoración de la actividad fungicida según norma UNE-EN 13697: ABRIL 2002 (ERRATUM: JULIO 2007) (OXYPURE C50) FMC FORET, S.A. Study No. 110024766 Non-GLP, unpublished.	Y	Evonik Peroxide Spain s.l.u
6.7	[redacted]	[redacted]	Valoración de la actividad bactericida según norma UNE-EN 1276: 2010 (ERRATUM: ENERO 2011) Study No. 160043792	Y	PeroxyChem Spain, S.L.U.
6.7	[redacted]	[redacted]	Use and efficacy of hydrogen peroxide in Tetra Pak packaging machine systems. Tetra Pak Packaging Solutions S.p.A. November 2020. Non-GLP, unpublished.	Y	[redacted]
6.7	[redacted]	[redacted]	Quantitative suspension test for the evaluation of fungicidal efficacy according to EN 1650. Study no. 211026-0002-001. Evonik Operations GmbH. November 2021. Non-GLP, unpublished.	Y	Evonik Operations GmbH
6.7	[redacted]	[redacted]	Quantitative surface test for the evaluation of fungicidal efficacy according to EN 13697. Study no. 211026-0002-002. Evonik Operations GmbH. November 2021. Non-GLP, unpublished.	Y	Evonik Operations GmbH
6.7	[redacted]	[redacted]	Quantitative surface test for the evaluation of bactericidal efficacy according to EN 16437. Study no. 170112-0015-057. Evonik Operations GmbH. December 2017.	y	Evonik Resource Efficiency GmbH
6,7	[redacted]	[redacted]	Quantitative suspension test for the evaluation of fungicidal activity according to EN 1650. Study no. 181106-0341-003. Evonik Resource Efficiency GmbH. December 2018	Y	Evonik Resource Efficiency GmbH

3.2 Output tables from exposure assessment tools

Human health assessment

Human Expoxure Calculations_AOPAC

report_AP-VHP-CSD .xls

report_AP-VHP-CSD (2).xls

report_CIP(1).xls

ENVIRONMENT ASSESSMENT

Outputs of calculations for PT4. Aseptic packaging (immersion)

EUSES-Aseptics35% _PT4-scen1_asep pa

Outputs of calculations for PT4. Aseptic packaging (spraying)

EUSES-Aseptics35%
_PT4-scen2_asep pa

Outputs of calculations for PT4. Surface disinfection by VHP process, food processing facilities

EUSES-Aseptics35%
_PT4-scen3_surface

Outputs of calculations for PT4. Disinfection of distribution systems for drinking water and disinfection of inner surfaces by CIP

EUSES-Aseptics35%
_PT4-scen4_drinking

3.3 New information on the active substance

No new information on the active substance has been presented.

3.4 Residue behaviour

No residues are expected for the uses evaluated.

As reported in the active substance CAR, any residues would rapidly decompose into water and oxygen, as the substance rapidly degrades in the environment and has no potential for bioaccumulation.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[9]

The studies are available in the IUCLID file.

3.6 Confidential annex

See PAR confidential for more information.

3.7 Other

No further information is deemed necessary

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