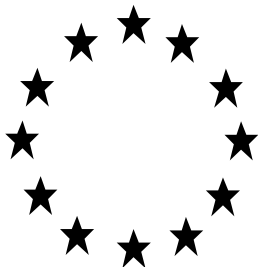
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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



Product family identifier in R4BP	ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY PT4, PT5
Product type(s):	PT 4 (Food and feed area)
Active ingredient(s):	Hydrogen peroxide
Case No. in R4BP	BC-DC029869-40
Asset No. in R4BP	DE-0017662-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/05.00002 710-05-05-00002-00-00-00-0000
Date	28.06.2021 (initial assessment)

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1 Overall conclusion

The assessment presented in this report has shown the efficacy for disinfection of food and feed areas PT 4), whereas the efficacy for the disinfection of drinking water for animals (PT 5) could not be demonstrated. Furthermore, the efficacy for the use of aseptic packaging in a closed system (immersion) was not demonstrated. No unacceptable risks were identified, if the products within the product family “Anti-Germ Hydrogen Peroxide based disinfectants product family PT 4, PT5” with the active substance hydrogen peroxide (5-35.0 % w/w, pure content) are used as an disinfectant in food and feed area (product-type 4) by professional users.

The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012 are fulfilled.

Please find detailed information on the uses appropriate for authorisation in chapter 2.3.1.4 and chapter 2.3.2.4.
General directions for use of the product family are summarised in chapter 2.3.1.5 and 2.3.2.5.

A classification according to Regulation (EC) No 1272/2008 is necessary. Detailed information on classification and labelling is provided in chapter 2.3.1.3 and 2.3.2.3.

The assessment of the intended use(s) as applied for by the applicant (see chapter 3.1) has taken the following into consideration:
1. The conclusions and recommendations of the Assessment Report by Finland for the approval of the active substance hydrogen peroxide for PT 4 and PT 5 including the “elements to be taken into account by Member States when authorising products” as requested by the Finish CA.
2. The specific provisions from the Commission Implementing Regulation (EU) No. 2015/1730 for the active substance hydrogen peroxide for PT 4 and PT 5.

Approval of the active substance
The active substance hydrogen peroxide is included in the Union list of approved active substances for PT 4 and PT 5 and the specific provisions laid down there are fulfilled:

- Authorisations of biocidal products shall be without prejudice to Regulation (EU) No 98/2013 on the marketing and use of explosive precursors.

- For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.
- For PT 4 products shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004, unless the Commission has established specific limits on the migration of hydrogen peroxide into food or it has been established pursuant to that Regulation that such limits are not necessary.

Composition and formulation

The products within the “Anti Germ Hydrogen Peroxide based product family PT4, PT5” are liquids which contain the active substance hydrogen peroxide.
For the full composition of the biocidal product family including all meta SPCs applied for, please refer to the confidential annexes.

Endocrine disrupting properties

According to the CAR for hydrogen peroxide, there is no indication for endocrine disrupting properties of the active substance. None of the co-formulants is contained in the candidate list for substances of very high concern for authorisation, the community rolling action plan (CoRAP) or the public activities coordination tool (PACT) according to Regulation (EU) 1907/2006 for potential environmental ED-hazards or ECHA’s endocrine disruptor assessment list.
In conclusion there are no indications for endocrine disrupting properties of the biocidal product family.

Physical, chemical and technical properties

The physical, chemical and technical properties have been determined and deemed acceptable (please find more information in chapter 3.2).

Physical hazards and respective characteristics

A physical hazard was identified for meta-SPC 1, which shall be classified as Oxidising liquid, Category 2, H272: May intensify fire; oxidiser. For meta-SPC 2 (originally meta-SPC 5) no physical hazards were identified (please find more information in chapter 3.3).

Methods for detection and identification

Information on the analytical methods for the active substance is provided in chapter 3.4. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms

The product has been shown to be efficacious for the uses appropriate for authorisation listed in chapter 2.3.1 and in chapter 2.3.2. The efficacy for the disinfection of drinking water for animals (PT 5) and for aseptic packaging in a closed system (immersion) (PT4) was not demonstrated.
Please find more information on efficacy of the product in chapter 3.5.

Risk assessment for human health

For this biocidal product family, two substances of concern have been identified in meta SPC 3 and 4. However meta SPC 3 and 4 were not considered appropriate for authorisation. In meta SPC 1 (appropriate for authorisation as meta SPC 1), meta SPC 2 (not appropriate for authorisation) and 5 (appropriate for authorisation as meta SPC 2) no substances of concern have been identified. Therefore the human health risk assessment for the uses appropriate for authorisation for this product is based on the active substance.

A human health risk assessment has been carried out for professional use of the products within the product family (see chapter 3.6). Secondary exposure to the general public is not expected.

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to professional users. Regarding professional users health protection, there are no objections against the intended uses if the directions for use are followed.

Risk assessment for animal health

An animal health risk assessment has not been considered necessary for the product family (see chapter 3.7).

Risk assessment for the environment

Since no relevant substance of concern has been identified the risk assessment for the environment for this product is based on the active substance.
A risk assessment for the environment has been carried out for all intended uses of the products within the product family (see chapter 3.8).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable risk for the environment if the directions for use are followed.

Comparative Assessment

A comparative assessment has not been necessary (see chapter 3.10) since no candidate for substitution were identified).

1.1 Conclusion regarding meta SPC 1 as applied for by the applicant, corresponding to meta SPC 1 as appropiate for authorisation

Sufficient efficacy could not be demonstrated for the disinfection of drinking water for animals (PT 5), therefore, these uses of this meta SPC cannot be authorised. The disinfection in food and feed areas (PT 4) in this meta SPC for aseptic packaging can be authorised against bacteria, the disinfection against yeasts was withdrawn during the authorisation process. The disinfection in food and feed areas by cleaning in place are considered appropriate for authorisation. For detailed information see 1. Overall conclusion.

1.2 Conclusion regarding meta SPC 2 as applied for by the applicant, not to be authorised

Sufficient efficacy could not be demonstrated for the disinfection of drinking water for animals (PT 5), therefore, all uses in this meta SPC cannot be authorised. For other endpoints see 1. Overall conclusion.

1.3 Conclusion regarding meta SPC 3 as applied for by the applicant, not to be authorised

Sufficient efficacy could not be demonstrated for the disinfection of drinking water for animals (PT 5), therefore, the uses in this meta SPC cannot be authorised. For other endpoints see 1. Overall conclusion.

1.4 Conclusion regarding meta SPC 4 as applied for by the applicant, not to be authorised

Sufficient efficacy could not be demonstrated for the disinfection of drinking water for animals (PT 5), therefore, the uses in this meta SPC cannot be authorised. For other endpoints see 1. Overall conclusion.

1.5 Conclusion regarding meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 as appropiate for authorisation

The use of this meta SPC for disinfection in food and feed areas (PT 4) by fogging is appropriate for authorisation, for details see 1. Overall conclusion. The use of this meta SPC for disinfection in food and feed areas (PT 4) by automatic vaporisation was withdrawn during the authorisation process.

2 Summary of the product family assessment

2.1 Administrative information (first information level)

2.1.1 Identifier in R4BP

ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY PT4, PT5

2.1.2 Product type(s)

PT 4 (Food and feed area)

2.1.3 Manufacturer(s) of the product(s)

Name of manufacturer	Kersia Deutschland GmbH
Address of manufacturer	Oberbrühlstraße 16-18 87700 Memmingen Germany
Location of manufacturing sites	Oberbrühlstraße 16-18 87700 Memmingen Germany

Name of manufacturer	HYPRED France S.A.S.
Address of manufacturer	Zone Industrielle Le Roineau 72500 Vaas France
Location of manufacturing sites	Zone Industrielle Le Roineau 72500 Vaas France

Name of manufacturer	Kersia Hungary Kft
Address of manufacturer	Rákóczi u. 98 4400 Nyíregyháza

	Hungary
Location of manufacturing sites	Rákóczi u. 98 4400 Nyíregyháza Hungary

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

Active substance	Hydrogen peroxide
Name of manufacturer	Belinka Perkemija, d.o.o.
Address of manufacturer	Zasavska cesta 95 1231 Ljubljana-Črnuče Slovenia
Location of manufacturing sites	Zasavska cesta 95 1231 Ljubljana-Črnuče Slovenia

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Resource Efficiency GmbH
Address of manufacturer	Rellinghauser Strasse 1 – 11 45128 Essen Germany
Location of manufacturing sites	Rodenbacher Chaussee 4 63457 Hanau Germany

2.2 Composition and formulation (first information level)

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Hydrogen peroxide	Hydrogen peroxide	Active substance	7722-84-1	231-765-0	5	35.0

The substance hydrogen peroxide is manufactured and supplied in different purities that are complying with the reference specification of 35 – 70%. The amount of substance added to the biocidal products depends on the supplied purity of hydrogen peroxide. Therefore, the exact dosed amount of the substance cannot be provided but only the concentrations of “pure” hydrogen peroxide present in the biocidal products.

- Hydrogen peroxide is generally placed on the market in a stabilised form, refer to Regulation (EC) No 1272/2008, Annex 6. 1.1.3.1 Note D.

- According to the information provided the products in family contain no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012.

2.2.2 Information on technical equivalence

- Is the source of the active substance(s) the same as the one 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 ☐

2.2.3 Information on the substance(s) of concern

The following substance(s) of concern were identified:

- Orthophosphoric acid (CAS-No. 7664-38-2) in meta SPC 3 and 4 (as applied for by the applicant, not authorised)
- Sulphuric acid (CAS-No. 7664-93-9) in meta SPC 4 (as applied for by the applicant, not authorised)

Orthophosphoric acid was identified as substance of concern in meta SPC 3 and meta SPC 4 since it contributes to the classification of the biocidal products as Skin Corr. 1B (H314) and Eye Dam. 1, (H318). Sulphuric acid was identified as substance of concern in meta SPC 4 since it contributes to the classification of the biocidal products as Skin Corr. 1B (H314) and Eye Dam. 1 (H318).

- (Further) information on the substance(s) of concern is provided in the confidential annex.

2.2.4 Candidate(s) for substitution

No candidate for substitution was identified.

2.2.5 Type(s) of formulation

AL (Any other liquid), SL (Soluble concentrate)

2.3 Meta SPC(s) (second information level)

2.3.1 Meta SPC No. 1 appropriate for authorisation

2.3.1.1 Administrative information

2.3.1.1.1 Meta SPC identifier

Meta SPC 1

2.3.1.1.2 Suffix to the authorisation number

01

2.3.1.1.3 Product type(s) of the products in the meta SPC

PT 4 (Food and feed area)

2.3.1.2 Composition and formulation of the products within the meta SPC

2.3.1.2.1 Qualitative and quantitative information on the composition of the products in the meta SPC

Table 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Hydrogen peroxide	Hydrogen peroxide	Active substance	7722-84-1	231-765-0	35	35

2.3.1.2.2 Type(s) of formulation of the products in the meta SPC

AL (Any other liquid), SL (Soluble concentrate)

2.3.1.3 Classification and Labelling according to the Regulation (EC) 1272/2008 [1]

Besides the a.s. hydrogen peroxide, the other components do not affect the classification of the products in the meta SPC.

A harmonised classification for the active substance Hydrogen peroxide exists, however it does not include a classification for the aquatic compartment. The CA report (RMS FI March 2015) proposes classification of hydrogen peroxide as H412 – Harmful to aquatic life with long lasting effects, according to the submitted ecotoxicological data. This classification is recorded in the list of endpoints and consequently taken into account for the classification of ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY. The active substance concentration in the products of meta SPC 1 is 35% (w/w). Therefore, a classification of the biocidal product family pursuant to the Regulation (EC) 1272/2008 is required, which results in:
H412 Harmful to aquatic life with long lasting effects

1 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.3.1.5.2.

Table 3

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Ox. Liq. 2	H272: May intensify fire; oxidiser
Acute Tox. 4 (oral)	H302: Harmful if swallowed.
Skin Irrit. 2	H315: Causes skin irritation.
Eye Dam. 1	H318: Causes serious eye damage.
STOT SE 3	H335: May cause respiratory irritation.
Aquatic Chronic 3	H412: Harmful to aquatic life with long-lasting effects

Table 4

Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS03	
	GHS05	
	GHS07	
Signal word	-	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
Supplemental hazard information	-	
Supplemental label elements	-	
Precautionary statements	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Labelling		
	Code	**Pictogram / Wording**
	P220	Keep/Store away from clothing/…/combustible materials.
	P221	Take any precaution to avoid mixing with combustibles/…
	P261	Avoid breathing dust/fume/gas/mist/vapours/ spray.
	P264	Wash … thoroughly after handling.
	P270	Do not eat, drink or smoke when using this product.
	P271	Use only outdoors or in a well-ventilated area.
	P273	Avoid release to the environment.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P301 + P312	IF SWALLOWED: Call a POISON CENTER/doctor/… if you feel unwell.
	P302 + P352	IF ON SKIN: Wash with plenty of water/…
	P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P310	Immediately call a POISON CENTER/doctor/ …
	P312	Call a POISON CENTRE/doctor/… if you feel unwell.
	P321	Specific treatment (see … on this label).
	P330	Rinse mouth.
	P332 + P313	If skin irritation occurs: Get medical advice/ attention.
	P362+ P364	Take off contaminated clothing and wash it before reuse.
	P370 + P378	In case of fire: Use … to extinguish.
	P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
	P405	Store locked up.
	P501	Dispose of contents/containers in accordance with local/regional/national/international regulation.
Note	-	

2.3.1.4 Use(s) of the products in the meta SPC appropriate for authorisation

2.3.1.4.1 Use 1 appropriate for authorisation - aseptic packaging

Product Type(s)	PT 4
Where relevant, an exact description of the use	Aseptic packaging: disinfection of packaging for food products
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor
Application method(s)	closed system: spraying
Application rate(s) and frequency	Spraying in aseptic packaging units, undiluted product, ≥200 °C, clean conditions continuous application
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan, drums, IBC made of HDPE Packaging sizes: 5 – 1100 kg

2.3.1.4.1.1 Use-specific instructions for use

1. Fill the products into storage tanks using an automated dosing system. Alternatively, connect the packaging of the product with the closed system in which the disinfection process is performed.
2. After disinfection, the disinfected packaging material is automatically blown dry with air before use.
3. The user of the biocidal product should perform biological validation with a suitable test organism (e.g. spores of *Geobacillus stearothermophilus*) at least once to ensure efficacy of the disinfection process in the respective aseptic packaging systems.

2.3.1.4.1.2 Use-specific risk mitigation measures

1. Sufficient ventilation via local exhaust ventilation (LEV) and general mechanical ventilation shall be ensured.
2. The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed.
3. 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.

4. In case of maintenance no bystanders shall be present in the vicinity of the aseptic packaging machines.

The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures for the following application methods:
Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).

5. In case of maintenance of the aseptic packaging plant (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment, 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.

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

See chapter 2.3.1.5.3

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

See chapter 2.3.1.5.4

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

See chapter 2.3.1.5.5

2.3.1.4.2 Use 2 appropriate for authorisation – disinfection in food and feed areas by cleaning in place (CIP) by filling into storage tank

Product Type(s)	PT 4
Where relevant, an exact description of the use	Disinfection in food and feed areas by cleaning in place (CIP)
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor
Application method(s)	Adding disinfectant to circulation water by filling into a storage tank.
Application rate(s) and frequency	– 15 min contact time of 2% product dilution, 60 °C, clean conditions – 6 h contact time of 0.5% product dilution, 40 °C, clean conditions regular application, if required (depending on disinfection cycles)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan, drums, IBC made of HDPE Packaging sizes: 5 – 1100 kg

2.3.1.4.2.1 Use-specific instructions for use

1. Fill the products into storage tanks using an automated dosing system. Adjust the disinfection solution into the system to an end-use concentration of of 0.20% a.s. or 0.79% a.s. (equals to 0.5 % or 2.0 % of product dilution), depending on temperature and contact time.
2. Only use in pre-cleaned systems.
3. After application of the biocidal product, rinse treated pipes and machinery with drinking water.

2.3.1.4.2.2 Use-specific risk mitigation measures

See chapter 2.3.1.5.2

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

See chapter 2.3.1.5.3

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

See chapter 2.3.1.5.4

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

See chapter 2.3.1.5.5

2.3.1.4.3 Use 3 appropriate for authorisation – disinfection in food and feed areas by cleaning in place (CIP) with automatic dosing pump

Product Type(s)	PT 4
Where relevant, an exact description of the use	Disinfection in food and feed areas by cleaning in place (CIP)
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor
Application method(s)	Adding disinfectant to circulation water automatically by a dosing pump.
Application rate(s) and frequency	– 15 min contact time of 2% product dilution, 60 °C, clean conditions – 6 h contact time of 0.5% product dilution, 40 °C, clean conditions regular application, if required (depending on disinfection cycles)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan, drums, IBC made of HDPE Packaging sizes: 5 – 1100 kg

2.3.1.4.3.1 Use-specific instructions for use

1. Connect the packaging of the product with the closed system in which the disinfection process is performed. Adjust the disinfection solution into the system to an end-use concentration of of 0.20% a.s. or 0.79% a.s. (equals to 0.5 % or 2.0 % of product dilution), depending on temperature and contact time.
2. Only use in pre-cleaned systems.
3. After application of the biocidal product, rinse treated pipes and machinery with drinking water.

2.3.1.4.3.2 Use-specific risk mitigation measures

See chapter 2.3.1.5.2

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

See chapter 2.3.1.5.3

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

See chapter 2.3.1.5.4

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

See chapter 2.3.1.5.5

2.3.1.5 General directions for use of the products in the meta SPC

2.3.1.5.1 Instructions for use

See chapters 2.3.1.4.1.1 / 2.3.1.4.2.1 / 2.3.1.4.3.1

2.3.1.5.2 Risk mitigation measures

1. The process of dilution has to be carried out using an automatic dosing system.

The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures for the following application methods:
Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).

2. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
3. The use of minimum a protective apron or a protective coverall (at least type 6, EN 13034) during handling of the product is mandatory.
4. The use of eye protection during handling of the product is mandatory.

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

1. IF SWALLOWED: Immediately call a POISON CENTER/doctor/…
2. IF ON SKIN: Wash with plenty of water/…
3. IF INHALED: Remove person to fresh air and keep comfortable for breathing.
4. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
5. Specific treatment (see … on this label).
6. Rinse mouth.
7. If skin irritation occurs: Get medical advice/ attention.
8. Take off contaminated clothing and wash it before reuse.

2.3.1.5.4 Instructions for safe disposal of the product and its packaging

1. Residues of the biocidal product must be disposed off in accordance with the Waste Framework Directive (2008/98/EG) and the European Waste Catalogue (EWC) as well as national and regional regulations.
2. Leave biocidal products in original containers. Do not mix with other wastes. Containers containing residues of the product have to be handled accordingly.
3. Waste entry on pesticides: 20 01 19*
4. Waste entry on packaging containing residues of or contaminated by dangerous substances: 15 01 10

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

1. The product should be stored below 40°C. Shelf life: 18 months

2.3.1.5.6 Other information

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 this product.

2.3.2 Meta SPC No. 2 appropriate for authorisation

2.3.2.1 Administrative information

2.3.2.1.1 Meta SPC identifier

Meta SPC 2

2.3.2.1.2 Suffix to the authorisation number

02

2.3.2.1.3 Product type(s) of the products in the meta SPC

4 (Food and feed area)

2.3.2.2 Composition and formulation of the products within the meta SPC

2.3.2.2.1 Qualitative and quantitative information on the composition of the products in the meta SPC

Table 5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Hydrogen peroxide	Hydrogen peroxide	Active substance	7722-84-1	231-765-0	5.0	5.0

2.3.2.2.2 Type(s) of formulation of the products in the meta SPC

AL (Any other liquid)

2.3.2.3 Classification and Labelling according to the Regulation (EC) 1272/2008[2]

Besides the a.s hydrogen peroxide, the other components do not affect the classification of the products in the meta SPC.
A harmonised classification for the active substance Hydrogen peroxide exists, however it does not include a classification for the aquatic compartment. The CA report (RMS FI March 2015) proposes classification of hydrogen peroxide as H412 – Harmful to aquatic life with long lasting effects, according to the submitted ecotoxicological data. This classification is recorded in the list of endpoints and consequently taken into account for the classification of ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY. The active substance concentration in the products of meta SPC 2 is 5% (w/w). Therefore, a classification of the biocidal product family pursuant to the Regulation (EC) 1272/2008 is not required.

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.3.5.5.2.

Table 6

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Eye Irrit. 2	H319: Causes serious eye irritation.

Table 7

Labelling		
	Code	**Pictogram / Wording**
	GHS07	

2 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Labelling	**Code**	**Pictogram / Wording**
Signal word	-	Warning
Hazard statements	H319	Causes serious eye irritation.
Supplemental hazard information	-	
Supplemental label elements	-	
Precautionary statements	P264	Wash … thoroughly after handling.
	P280	Wear eye protection/face protection.
	P305+ P351+ P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P337+ P313	If eye irritation persists: Get medical advice/ attention.
Note	-	

2.3.2.4 Use(s) of the products in the meta SPC appropriate for authorisation[3]

2.3.2.4.1 Use 4 appropriate for authorisation – Room disinfection by fogging in food processing facilities

Product Type(s)	PT 4
Where relevant, an exact description of the use	Disinfection of surfaces by fogging in food processing facilities
Target organism(s) (including development stage)	bacteria bacterial spores yeast fungi
Field(s) of use	Indoor
Application method(s)	fogging
Application rate(s) and frequency	12 mL/m^3, median droplet size of 1 – 15 µm diameter, undiluted product, 6 h contact time at room temperature, clean conditions regularly, if required (depending on disinfection cycles)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan, drums, IBC made of HDPE Packaging sizes: 5 – 1100 kg

3 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

2.3.2.4.1.1 Use-specific instructions for use

See chapter 2.3.2.5.1

2.3.2.4.1.2 Use-specific risk mitigation measures

See chapter 2.3.2.5.2

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

See chapter 2.3.2.5.3

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

See chapter 2.3.2.5.4

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

See chapter 2.3.2.5.5

2.3.2.5 General directions for use of the products in the meta SPC

2.3.2.5.1 Instructions for use

1. Fill the reservoir of the fogging machine with the RTU product or connect the drum with the (suction) pump of the fogging machine. 2. For use in rooms of 30 - 150 m³ volume. 3. Leave and seal the room. Do not enter the room during the fogging process. 4. For application in dry, pre-cleaned enclosures at room temperature. Before treatment, open drawers, closets, cabinet doors etc. to permit exposure to hydrogen peroxide. After distribution of 12 ml biocidal product per cubic metre, allow to act for 6 hours. 5. Biological validation shall be performed by the user of the biocidal products for each room to be disinfected by fogging (or in a suitable “standard” room in a facility, if applicable) with the devices

to be used, after which a protocol for disinfection of these rooms can be made and used thereafter.

6. After disinfection, the room needs to be ventilated several times before re-entry.
7. Remove foodstuffs prior to treatment.

2.3.2.5.2 Risk mitigation measures

1. The use of a dosage device for manual loading is recommended.
2. The disinfection shall only be started with a time delay (switch) (mobile devices) or from the outside to avoid contact with the disinfectant.
3. The room shall be sealed and re-entry prevented while disinfection takes place. It shall be indicated that a disinfection process is running (information of other workers).
4. Re-entry is only permitted once the air concentration has dropped below the reference value (AEC). After the application, the room must be ventilated, preferably by mechanical ventilation. The duration of the ventilation period has to be established by measurement with suitable measurement equipment. In cases where re-entry is required before sufficient ventilation has taken place, appropriate PPE (respiratory protective equipment, chemical protective gloves, chemical protective coverall, eye protection) may be 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>The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures for the following application methods:</u>
<u>Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).</u>

5. The use of eye protection during handling of the product is mandatory.
6. Protective chemical resistant gloves during product handling phase are recommended (glove material to be specified by the authorisation holder within the product information).

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

1. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
2. If eye irritation persists: Get medical advice/ attention.

2.3.2.5.4 Instructions for safe disposal of the product and its packaging

1. Residues of the biocidal product must be disposed off in accordance with the Waste Framework Directive (2008/98/EG) and the European Waste Catalogue (EWC) as well as national and regional regulations.
2. Leave biocidal products in original containers. Do not mix with other wastes. Containers containing residues of the product have to be handled accordingly.
3. Waste entry on pesticides: 20 01 19*
4. Waste entry on packaging containing residues of or contaminated by dangerous substances: 15 01 10

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

1. The product should be stored below 40°C.Shelf life: 18 month

2.3.2.5.6 Other information

1. 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 this product. 2. Efficacy was demonstrated with a flow rate of 2.7 ml/min/m³ according to the norm NF T72-281 used in the provided efficacy study.

2.4 Individual products in the meta SPC(s) (third information level)

- Information on the specific composition of each individual product is provided in the confidential annex (chapter 5).

2.5 Packaging

Table 8

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Jerrycan	5-25 kg (e.g. 5, 6, 20, 25 kg)	HDPE	HDPE	Professional	Yes
Drums	60-230 kg (e.g. 60, 65, 70, 200, 230 kg)	HDPE	HDPE	Professional	Yes
IBC	1000-1100 kg (e.g. 1000, 1100 kg)	HDPE	HDPE	Professional	Yes

3 Assessment of the biocidal product family

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

Meta SPC	Use	PT	Where relevant, an exact description of the use	Target organism(s) (including development stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category(ies) of users	Pack sizes and packaging material
1	01	5	disinfection of drinking water for animals	gram-positive bacteria: Staphylococcus aureus (vegetative cells) Enterococcus hirae (vegetative cells) gram-negative bacteria: Escherichia coli (vegetative cells) Pseudomonas aeruginosa (vegetative cells)	Indoor	Continuous dosing using an automatic dosing pump	continuous application or if required (depending on disinfection cycles) 0,01 - 0,1 % (aq)	Professional user	jerrycan, HDPE, 5-25 kg, drum, HDPE, 60-230 kg, IBC, HDPE, 1000-1100 kg

1	02	5	disinfection of drinking water for animals	gram-positive bacteria: Staphylococcus aureus (vegetative cells) Enterococcus hirae (vegetative cells) gram-negative bacteria: Escherichia coli (vegetative cells) Pseudomonas aeruginosa (vegetative cells)	Indoor	manual filling into a water storage tank	continuous application or if required (depending on disinfection cycles) 0,005 - 0,1 % (aq)	Professional user	jerrycan, HDPE, 5-25 kg, drum, HDPE, 60-230 kg, IBC, HDPE, 1000-1100 kg
1	03	4	aseptic packaging: disinfection of packaging for food products	gram-positive bacteria: Staphylococcus aureus (vegetative cells) Enterococcus hirae (vegetative cells) gram-negative bacteria: Escherichia coli (vegetative cells)	Indoor	closed system: immersion	continuous application 1,5 - 100 % (aq)	Professional user	jerrycan, HDPE, 5-25 kg, drum, HDPE, 60-230 kg, IBC, HDPE, 1000-1100 kg

				Pseudomonas aeruginosa (vegetative cells) Yeasts: candida albicans (vegetative cells)					
1	04	4	aseptic packaging: disinfection of packaging for food products	gram-positive bacteria: Staphylococcus aureus (vegetative cells) Enterococcus hirae (vegetative cells) gram-negative bacteria: Escherichia coli (vegetative cells) Pseudomonas aeruginosa (vegetative cells) Yeasts: candida albicans (vegetative cells)	Indoor	closed system: spraying	continuous application 1,5 - 100 % (aq)	Professional user	jerrycan, HDPE, 5-25 kg, drum, HDPE, 60-230 kg, IBC, HDPE, 1000-1100 kg
1	05	4	disinfection in food and feed areas by cleaning in place (CIP)	gram-positive bacteria: Staphylococcus aureus (vegetative cells)	Indoor	adding disinfectant to circulation water manually	regular application, if required (depending on	Professional user	jerrycan, HDPE, 5-25 kg, drum, HDPE, 60-230 kg,

				Enterococcus hirae (vegetative cells) <u>gram-negative bacteria:</u> Escherichia coli (vegetative cells) Pseudomonas aeruginosa (vegetative cells) <u>Yeasts:</u> candida albicans (vegetative cells)		by filling into a storage tank	disinfection cycles) 0,25 - 2 % (aq)		IBC, HDPE, 1000-1100 kg
1	06	4	disinfection in food and feed areas by cleaning in place (CIP)	<u>gram-positive bacteria:</u> Staphylococcus aureus (vegetative cells) Enterococcus hirae (vegetative cells) <u>gram-negative bacteria:</u> Escherichia coli (vegetative cells) Pseudomonas aeruginosa (vegetative cells) <u>Yeasts:</u>	Indoor	adding disinfectant to circulation water automatically by a dosing pump	regular application, if required (depending on disinfection cycles) 0,25 - 2 % (aq)	Professional user	jerrycan, HDPE, 5-25 kg, drum, HDPE, 60-230 kg, IBC, HDPE, 1000-1100 kg

				candida albicans (vegetative cells)					
2	07	5	disinfection of drinking water for animals	<u>gram-positive bacteria:</u> Staphylococcus aureus (vegetative cells) Enterococcus hirae (vegetative cells) <u>gram-negative bacteria:</u> Escherichia coli (vegetative cells) Pseudomonas aeruginosa (vegetative cells)	Indoor	Continuous dosing using an automatic dosing pump	continuous application or if required (depending on disinfection cycles) 0,007 - 0,07 % (aq)	Professional user	jerrycan, HDPE, 5-25 kg, drum, HDPE, 60-230 kg, IBC, HDPE, 1000-1100 kg
2	08	5	disinfection of drinking water for animals	<u>gram-positive bacteria:</u> Staphylococcus aureus (vegetative cells) Enterococcus hirae (vegetative cells) <u>gram-negative bacteria:</u> Escherichia coli (vegetative cells)	Indoor	manual filling into a water storage tank	continuous application or if required (depending on disinfection cycles) 0,007 - 0,07 % (aq)	Professional user	jerrycan, HDPE, 5-25 kg, drum, HDPE, 60-230 kg, IBC, HDPE, 1000-1100 kg

				Pseudomonas aeruginosa (vegetative cells)					
3	09	5	disinfection of drinking water for animals	<u>gram-positive bacteria:</u> Staphylococcus aureus (vegetative cells) Enterococcus hirae (vegetative cells) <u>gram-negative bacteria:</u> Escherichia coli (vegetative cells) Pseudomonas aeruginosa (vegetative cells)	Indoor	Continuous dosing using an automatic dosing pump	continuous application or if required (depending on disinfection cycles) 0,01 - 0,1 % (aq)	Professional user	jerrycan, HDPE, 5-25 kg, drum, HDPE, 60-230 kg, IBC, HDPE, 1000-1100 kg
3	10	5	disinfection of drinking water for animals	<u>gram-positive bacteria:</u> Staphylococcus aureus (vegetative cells) Enterococcus hirae (vegetative cells) <u>gram-negative bacteria:</u>	Indoor	manual filling into a water storage tank	continuous application or if required (depending on disinfection cycles) 0,01 - 0,1 % (aq)	Professional user	jerrycan, HDPE, 5-25 kg, drum, HDPE, 60-230 kg, IBC, HDPE, 1000-1100 kg

				Escherichia coli (vegetative cells) Pseudomonas aeruginosa (vegetative cells)					
4	11	5	disinfection of drinking water for animals	<u>gram-positive bacteria:</u> Staphylococcus aureus (vegetative cells) Enterococcus hirae (vegetative cells) <u>gram-negative bacteria:</u> Escherichia coli (vegetative cells) Pseudomonas aeruginosa (vegetative cells)	Indoor	Continuous dosing using an automatic dosing pump	continuous application or if required (depending on disinfection cycles) 0,005 - 0,1 % (aq)	Professional user	jerrycan, HDPE, 5-25 kg, drum, HDPE, 60-230 kg, IBC, HDPE, 1000-1100 kg
4	12	5	disinfection of drinking water for animals	<u>gram-positive bacteria:</u> Staphylococcus aureus (vegetative cells) Enterococcus hirae (vegetative cells)	Indoor	manual filling into a water storage tank	continuous application or if required (depending on disinfection cycles) 0,005 - 0,1 % (aq)	Professional user	jerrycan, HDPE, 5-25 kg, drum, HDPE, 60-230 kg, IBC, HDPE, 1000-1100 kg

				gram-negative bacteria: Escherichia coli (vegetative cells) Pseudomonas aeruginosa (vegetative cells)					
5	13	4	disinfection of surfaces by vaporisation in food processing facilities	gram-positive bacteria: Staphylococcus aureus (vegetative cells) Enterococcus hirae (vegetative cells) Bacillus subtilis (spores) gram-negative bacteria: Escherichia coli (vegetative cells) Pseudomonas aeruginosa (vegetative cells) Yeasts: candida albicans (vegetative cells) Fungi:	Indoor	fogging and fumigation	regularly, if required (depending on disinfection cycles) 6 mL/m^3	Professional user	jerrycan, HDPE, 5-25 kg, drum, HDPE, 60-230 kg, IBC, HDPE, 1000-1100 kg

				Aspergillus brasiliensis (vegetative cells)					
5	14	4	disinfection of surfaces by vaporisation in food processing facilities	<u>gram-positive bacteria:</u> Staphylococcus aureus (vegetative cells) Enterococcus hirae (vegetative cells) Bacillus subtilis (spores) <u>gram-negative bacteria:</u> Escherichia coli (vegetative cells) Pseudomonas aeruginosa (vegetative cells) <u>Yeasts:</u> candida albicans (vegetative cells) <u>Fungi:</u> Aspergillus brasiliensis (vegetative cells)	Indoor	automatic vaporisation with an evaporation unit	regularly, if required (depending on disinfection cycles) 6 mL/m^3	Professional user	jerrycan, HDPE, 5-25 kg, drum, HDPE, 60-230 kg, IBC, HDPE, 1000-1100 kg

3.2 Physical, chemical and technical properties

General information: ANTI-GERM H2O.NET is another trade name for ANTI-GERM WP 35 (meta SPC-1)

Table 9: Physical, chemical and technical properties of the Biocidal product

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	ANTI-GERM H2O.NET (Meta SPC 1); Lot number: ANTI-GERM H2O.NET-02/11/2016; 35% H_2O_2	liquid	Waiving[4] Lehmann, R. (2017); Report no. AT 11.03.04
		ANTI-GERM OXID'O (Meta SPC 2, not appropriate for authorisation); Lot number: ANTI-GERM OXID'O-02/11/2016; 49.6 % (w/w)	liquid	Lehmann, R. (2017); Report no. AT 11.04.04
Physical state at 20 °C and 101.3 kPa		ANTI-GERM AQUA	liquid	Lehmann, R. (2017); Report no. AT 11.01.04

[4] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

		(Meta SPC 3, not appropriate for authorisation); Lot number: ANTI-GERM AQUA 03/11/2017; 20.4%)		
Physical state at 20 °C and 101.3 kPa		ANTI-GERM'O (Meta SPC 4, not appropriate for authorisation); Lot number: ANTI-GERM 'O-04/11/2016; 32.4%(w/w) H_2O_2	liquid	Lehmann, R. (2017); Report no. AT 11.02.04
Physical state at 20 °C and 101.3 kPa		ANTI-GERM DES OXI AIR (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-14/03/2017 5.1 % (w/w) H_2O_2	liquid	Lehmann, R. (2017); Report no. AT 11.29.04
Physical state at 20 °C and 101.3 kPa		ANTI-GERM DES OXI AIR-S (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-S-15/03/2017 5.2 % (w/w) H_2O_2	liquid	Lehmann, R. (2017); Report no. AT 11.30.04
Colour at 20 °C and 101.3 kPa	Visual inspection	ANTI-GERM H2O.NET (Meta SPC 1);	clear, homogenous	Lehmann, R. (2017); Report no. AT 11.03.04

		Lot number: ANTI-GERM H2O.NET-02/11/2016; 35% H_2O_2		
Colour at 20 °C and 101.3 kPa		ANTI-GERM OXID'O (Meta SPC 2, not appropriate for authorisation); Lot number: ANTI-GERM OXID'O-02/11/2016; 49.6 % (w/w) H_2O_2	clear, homogenous	Lehmann, R. (2017); Report no. AT 11.04.04
Colour at 20 °C and 101.3 kPa		ANTI-GERM AQUA (Meta SPC 3, not appropriate for authorisation) Lot number: ANTI-GERM AQUA 03/11/2017; 20.4%) H_2O_2	clear, slightly yellowish	Lehmann, R. (2017); Report no. AT 11.01.04
Colour at 20 °C and 101.3 kPa		ANTI-GERM'O (Meta SPC 4, not appropriate for authorisation) Lot number: ANTI-GERM 'O-04/11/2016; 32.4%(w/w) H_2O_2	clear, homogenous, slightly yellowish	Lehmann, R. (2017); Report no. AT 11.02.04
Colour at 20 °C and 101.3 kPa		ANTI-GERM DES OXI AIR (Meta SPC 5, corresponding to Meta SPC 2 in SPC);	clear, homogenous, slightly yellowish	Lehmann, R. (2017); Report no. AT 11.29.04

		Lot number: ANTI-GERM DES OXI AIR-14/03/2017 5.1 % (w/w) H_2O_2		
Colour at 20 °C and 101.3 kPa		ANTI-GERM DES OXI AIR-S (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-S-15/03/2017 5.2 % (w/w) H_2O_2	clear, homogenous, slightly yellowish	Lehmann, R. (2017); Report no. AT 11.30.04
Odour at 20 °C and 101.3 kPa	Olfactory inspection	ANTI-GERM H2O.NET (Meta SPC 1); Lot number: ANTI-GERM H2O.NET-02/11/2016; 35% % (w/w) H_2O_2	faint	Lehmann, R. (2017); Report no. AT 11.03.04
Odour at 20 °C and 101.3 kPa		ANTI-GERM OXID'O (Meta SPC 2, not appropriate for authorisation); Lot number: ANTI-GERM OXID'O-02/11/2016; 49.6 % (w/w) H_2O_2	faint	Lehmann, R. (2017); Report no. AT 11.04.04
Odour at 20 °C and 101.3 kPa		ANTI-GERM AQUA (Meta SPC 3, not appropriate for authorisation) Lot number: ANTI-GERM AQUA 03/11/2017; 20.4%) H_2O_2	faint	Lehmann, R. (2017); Report no. AT 11.01.04

Odour at 20 °C and 101.3 kPa		ANTI-GERM'O (Meta SPC 4, not appropriate for authorisation) Lot number: ANTI-GERM 'O-04/11/2016; 32.4%(w/w) H_2O_2	faint	Lehmann, R. (2017); Report no. AT 11.02.04
Odour at 20 °C and 101.3 kPa		ANTI-GERM DES OXI AIR (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-14/03/2017 5.1 % (w/w) H_2O_2	faint	Lehmann, R. (2017); Report no. AT 11.29.04
Odour at 20 °C and 101.3 kPa		ANTI-GERM DES OXI AIR-S (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-S-15/03/2017 5.2 % (w/w) H_2O_2	faint	Lehmann, R. (2017); Report no. AT 11.30.04
Acidity / alkalinity	CIPAC MT 75	ANTI-GERM H2O.NET (Meta SPC 1); Lot number: ANTI-GERM H2O.NET-02/11/2016; 35% % (w/w) H_2O_2	1% aqueous solution: pH = 4.95 Neat formulation: pH = 2.2	Lehmann, R. (2017); Report no. AT 11.03.04 COA attached to the study report of the long-term storage stability test

Acidity / alkalinity	CIPAC MT 75	ANTI-GERM OXID'O (Meta SPC 2, not appropriate for authorisation); Lot number: ANTI-GERM OXID'O-02/11/2016; 49.6 % (w/w) H_2O_2	1% aqueous solution: pH = 4.82 Neat formulation: pH = 2.2	Lehmann, R. (2017); Report no. AT 11.04.04 COA attached to the study report of the long-term storage stability test
Acidity / alkalinity	CIPAC MT 75 CIPAC MT 191	ANTI-GERM AQUA (Meta SPC 3, not appropriate for authorisation) Lot number: ANTI-GERM AQUA 03/11/2017; 20.4%) H_2O_2	1% aqueous solution: pH = 1.97 Acidity (calculated as H2SO4) = 27.65 %w/w in a 0.4% dilution	Lehmann, R. (2017); Report no. AT 11.01.04
Acidity / alkalinity	CIPAC MT 75 CIPAC MT 191	ANTI-GERM'O (Meta SPC 4, not appropriate for authorisation) Lot number: ANTI-GERM 'O-04/11/2016; 32.4%(w/w) H_2O_2	1% aqueous solution: pH = 1.99 Acidity (calculated as H2SO4) = 8.01 %w/w in a 0.18% dilution Due to the presence of two acids in the test item two Equivalence-Points (EP) of the titration-curves were found. EP 2 is used to define the acidity, because at EP 1 the pH-value of 7 is not reached yet.	Lehmann, R. (2017); Report no. AT 11.02.04
Acidity / alkalinity	CIPAC MT 75 CIPAC MT 191	ANTI-GERM DES OXI AIR	1% aqueous solution: pH = 4.36	Lehmann, R. (2017); Report no. AT 11.29.04

		(Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-14/03/2017 5.1 % (w/w) H_2O_2	Acidity (calculated as H2SO4) = 0.066 % w/w in a 0.4% dilution Neat formulation: pH = 2.31	COA attached to the study report of the long-term storage stability test
Acidity / alkalinity	CIPAC MT 75 CIPAC MT 191	ANTI-GERM DES OXI AIR-S (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-S-15/03/2017 5.2 % (w/w) H_2O_2	1% aqueous solution: pH = 4.0 Acidity (calculated as H2SO4) = 0.134 % w/w in a 0.4% dilution	Lehmann, R. (2017); Report no. AT 11.30.04
Relative density / bulk density	OECD Guideline 109 oscillating-tube densitometer	ANTI-GERM H2O.NET (Meta SPC 1); Lot number: ANTI-GERM H2O.NET-02/11/2016; 35% (w/w) H_2O_2	D_4^{20} = 1.132	Lehmann, R. (2017); Report no. AT 11.03.05
Relative density / bulk density	OECD Guideline 109 oscillating-tube densitometer	Anti-Germ ODXID'O (Meta SPC 2, not appropriate for authorisation); Lot number: ANTI-GERM ODXID'O-03/11/2016; 49.6% (w/w) H_2O_2	D_4^{20} = 1.190	Lehmann, R. (2017); Report no. AT 11.04.05
Relative density / bulk density	OECD Guideline 109 oscillating-tube densitometer	Anti-Germ AQUA	D_4^{20} = 1.255	Lehmann, R. (2017); Report no. AT 11.01.05

		(Meta SPC 3, not appropriate for authorisation); Lot number: ANTI-GERM AQUA-03/11/2016; 20.4% (w/w) H_2O_2		
Relative density / bulk density	OECD Guideline 109 oscillating-tube densitometer	Anti-Germ'O (Meta SPC 4, not appropriate for authorisation); Lot number: ANTI-GERM'O-04/11/2016; 32.4% (w/w) H_2O_2	D_4^{20} = 1.179	Lehmann, R. (2017); Report no. AT 11.02.05
Relative density / bulk density	OECD Guideline 109 oscillating-tube densitometer	Anti-Germ DES OXI AIR (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-14/03/2017; 5.1% (w/w) H_2O_2	D_4^{20} = 1.017	Lehmann, R. (2017); Report no. AT 11.29.05

Relative density / bulk density	OECD Guideline 109 oscillating-tube densitometer	Anti-Germ DES OXI AIR-S (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-S-15/03/2017; 5.2% (w/w) H_2O_2	D_4^{20} = 1.018	Lehmann, R. (2017); Report no. AT 11.30.05
Storage stability test – **accelerated storage**	CIPAC MT 46.3 8 weeks storage at 40 °C Analytical method presented in chapter 3.4 was used	ANTI-GERM H2O.NET (Meta SPC 1); Lot number: ANTI-GERM H2O.NET-02/11/2016; 35% (w/w) H_2O_2	No significant change in content of active substance, appearance, pH, packaging and dilution stability after 8 weeks storage at 40 °C. Active substance: 34.928% (before storage) to 34.994% (after storage), i.e. -0.07% At the start of the test, the test item was a clear, homogeneous liquid with a typical odor. The aspect and the odor of the test item were considered to be stable after an accelerated temperature stability test at 40°C ± 2°C for 4 and for 8 weeks. The inspection of the packaging and the cap gave no indications for destructive effects of the test item	Lehmann, R. (2017); Report no. AT 11.03.04

<table>
<tr>
<td></td>
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<td>towards the material of the packaging. No changes happened.

No significant changes in the aspect and weight of the packaging were observed:
t_0: 1192.58 and 1183.17 g
t_{4weeks}: 1189.45 and 1180.19 g (before measurement)
1185.91 and 1180.19 g (after measurement)
t_{8weeks}: 1183.19 and 1177.60 g

<table>
<tr><th>Time [weeks]</th><th>Bottle 1 Loss of mass [%]</th><th>Bottle 2 Loss of mass [%]</th></tr>
<tr><td>4</td><td>0.287</td><td>0.276</td></tr>
<tr><td>8</td><td>0.251</td><td>0.240</td></tr>
</table>

pH:
t_0: 4.95
t_{4weeks}: 5.25
t_{8weeks}: 5.16

There were no effects on the dilution stability of the test item during the accelerated storage stability procedure. At any time the 1 % dilutions stayed stable for 24 hours.</td>
<td></td>
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</table>

Storage stability test – **accelerated storage**	CIPAC MT 46.3 8 weeks storage at 40 °C Analytical method presented in chapter 3.4 was used	ANTI-GERM OXID'O (Meta SPC 2, not appropriate for authorisation); Lot number: ANTI-GERM OXID'O-02/11/2016; 49.6 % (w/w) H_2O_2	No significant change in content of active substance, appearance, pH, packaging and dilution stability after 8 weeks storage at 40 °C. Active substance: 49.549% (before storage) to 49.433% (after storage), i.e. -0.234% At the start of the test, the test item was a clear, homogeneous liquid with a typical odor. The aspect and the odor of the test item were considered to be stable after an accelerated temperature stability test at 40°C ± 2°C for 4 and for 8 weeks. The inspection of the packaging and the cap gave no indications for destructive effects of the test item towards the material of the packaging. No changes happened. No significant changes in the aspect and weight of the packaging were observed: t_0: 1297.88 and 1294.75 g t_{4weeks}: 1295.30 and 1291.94 g (before measurement)	Lehmann, R. (2017); Report no. AT 11.04.04

<table>
<tr>
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<td></td>
<td>1292.82 and 1291.94 g (after measurement)
t_{8weeks}: 1290.08 and 1288.77 g

<table><tr><td>Time [weeks]</td><td>Bottle 1 Loss of mass [%]</td><td>Bottle 2 Loss of mass [%]</td></tr><tr><td>4</td><td>0.216</td><td>0.236</td></tr><tr><td>8</td><td>0.230</td><td>0.267</td></tr></table>
pH:
t_0: 4.82
t_{4weeks}: 5.01
t_{8weeks}: 5.08

There were no effects on the dilution stability of the test item during the accelerated storage stability procedure. At any time the 1 % dilutions stayed stable for 24 hours.</td>
<td></td>
</tr>
<tr>
<td>Storage stability test – accelerated storage</td>
<td>CIPAC MT 46.3
8 weeks storage at 40 °C

Analytical method presented in chapter 3.4 was used</td>
<td>ANTI-GERM AQUA
(Meta SPC 3, not appropriate for authorisation)
Lot number: ANTI-GERM AQUA 03/11/2017;
20.4%(w/w) H_2O_2</td>
<td>No significant change in content of active substance, appearance, pH, packaging and dilution stability after 8 weeks storage at 40 °C.
Active substance: 20.093% (before storage) to 19.111% (after storage), i.e. -4.88%
Colour: vanishing of yellow colour</td>
<td>Lehmann, R. (2017); Report no. AT 11.01.04</td>
</tr>
</table>

			At the start of the test: Homogeneous clear, slightly yellowish liquid with a typical odor. After 4 weeks at 40°C: Homogeneous clear liquid with a typical odor. It could be seen that the yellowish color disappeared after 4 weeks at 40°C. The inspection of the packaging and the cap gave no indications for destructive effects of the test item towards the material of the packaging After 8 weeks at 40°C: Homogeneous clear liquid with a typical odor. Between 4 and 8 weeks at 40°C no more changes happened. The inspection of the packaging and the cap gave no indications for destructive effects of the test item towards the material of the packaging. No significant changes in the aspect and weight of the packaging were observed: t_0: 1303.41 and 1176.62 g	

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<td>t_{4weeks}: 1298.58 and 1172.14 g (before measurement)
1291.25 and 1172.14 g (after measurement)
t_{8weeks}: 1285.28 and 1166.6 g

<table><tr><th>Time [week]</th><th>Bottle1 Loss [%]</th><th>Bottle2 Loss [%]</th></tr><tr><td>4</td><td>0.402</td><td>0.417</td></tr><tr><td>8</td><td>0.502</td><td>0.518</td></tr></table>
pH:
t_0: 1.97
t_{4weeks}: 1.89
t_{8weeks}: 1.87

There were no effects on the dilution stability of the test item during the accelerated storage stability procedure. At any time the 1 % dilutions stayed stable for 24 hours.</td>
<td></td>
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<tr>
<td>Storage stability test – accelerated storage</td>
<td>CIPAC MT 46.3
8 weeks storage at 40 °C

Analytical method presented in chapter 3.4 was used</td>
<td>ANTI-GERM’O
(Meta SPC 4, not appropriate for authorisation)
Lot number: ANTI-GERM ‘O-04/11/2016;
32.4%(w/w) H_2O_2</td>
<td>No significant change in content of active substance, appearance, pH, packaging and dilution stability after 8 weeks storage at 40 °C.
Active substance: 32.170% (before storage) to 31.603% (after storage), i.e. -1.76%</td>
<td>Lehmann, R. (2017); Report no. AT 11.02.04</td>
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<td>Colour: vanishing of yellowish colour

At the start of the test, the test item was a clear, homogeneous, slightly yellowish liquid with faint odor. The aspect and the odor of the test item were considered to be stable after an accelerated temperature stability test at 40°C ± 2°C for 4 and for 8 weeks. The only change that happened was the vanishing of the yellowish color after four weeks. Between 4 and 8 weeks no more changes happened.

No significant changes in the aspect and weight of the packaging were observed:
t_0: 1149.74 and 1171.65 g
t_{4weeks}: 1145.62 and 1167.52 g
t_{8weeks}: 1139.90 g after measurement in the 4th week to 1135.87 g and 1163.57 g

<table>
<tr><td>Time [weeks]</td><td>Bottle 1 Loss of mass [%]</td><td>Bottle 2 Loss of mass [%]</td></tr>
<tr><td>4</td><td>0.393</td><td>0.386</td></tr>
</table>
</td>
<td></td>
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</table>

			<table><tr><td>8</td><td>0.389</td><td>0.371</td></tr></table> pH: t_0: 1.99 t_{4weeks}: 2.07 t_{8weeks}: 1.94 There were no effects on the dilution stability of the test item during the accelerated storage stability procedure. At any time the 1 % dilutions stayed stable for 24 hours.	
Storage stability test – **accelerated storage**	CIPAC MT 46.3 8 weeks storage at 40 °C Analytical method presented in chapter 3.4 was used	ANTI-GERM DES OXI AIR (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-14/03/2017 5.1 % (w/w) H_2O_2	No significant change in content of active substance, appearance, pH, packaging and dilution stability after 8 weeks storage at 40 °C. Active substance: 4.870% (before storage) to 4.641% (after storage), i.e. -4.70% At the start of the test: Homogeneous clear, slightly yellowish liquid with a typical odor. After 4 weeks at 40°C: Homogeneous clear liquid with a typical odor. The inspection of the packaging and the cap gave no indications for	Lehmann, R. (2017); Report no. AT 11.29.04

			destructive effects of the test item towards the material of the packaging After 8 weeks at 40°C: Homogeneous clear liquid with a typical odor. Between 4 and 8 weeks at 40°C no more changes happened. The inspection of the packaging and the cap gave no indications for destructive effects of the test item towards the material of the packaging. No significant changes in the aspect and weight of the packaging were observed: t_0: 1086.26, 1102.35 and 1103.77 g t_{4weeks}: 1083.99, 1100.20 and 1101.74 g (before measurement) 1083.99, 1100.20 and 1043.94 g (after measurement) t_{8weeks}: 1081.74, 1098.04 and 1041.69 g Time [week] / Bottle1 Loss [%] / Bottle2 Loss [%] / Bottle3 Loss [%]	

			<table><tr><td>4</td><td>0.22</td><td>0.21</td><td>0.20</td></tr><tr><td>8</td><td>0.22</td><td>0.21</td><td>0.23</td></tr></table> pH: t_0: 4.36 t_{4weeks}: 4.11 t_{8weeks}: 4.27	
Storage stability test – **accelerated storage**	CIPAC MT 46.3 8 weeks storage at 40 °C Analytical method presented in chapter 3.4 was used	ANTI-GERM DES OXI AIR-S (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-S-15/03/2017 5.2 % (w/w) H_2O_2	No significant change in content of active substance, appearance, pH, packaging and dilution stability after 8 weeks storage at 40 °C. Active substance: 4.812% (before storage) to 4.558% (after storage), i.e. -5.28% Colour: vanishing of yellowish colour At the start of the test: Homogeneous clear, slightly yellowish liquid with a typical odor. After 4 weeks at 40°C: Homogeneous clear liquid with a typical odor. The inspection of the packaging and the cap gave no indications for destructive effects of the test item towards the material of the packaging	Lehmann, R. (2017); Report no. AT 11.30.04

			After 8 weeks at 40°C: Homogeneous clear liquid with a typical odor. Between 4 and 8 weeks at 40°C no more changes happened. The inspection of the packaging and the cap gave no indications for destructive effects of the test item towards the material of the packaging. No significant changes in the aspect and weight of the packaging were observed: t_0: 1083.77, 1078.92 and 1099.28 g t_{4weeks}: 1081.38, 1076.55 and 1097.02 g (before measurement) 1081.38, 1076.55 and 1049.13 g (after measurement) t_{8weeks}: 1079.25, 1074.09 and 1046.94 g Time [week] / Bottle1 Loss [%] / Bottle2 Loss [%] / Bottle3 Loss [%] 4 / 0.24 / 0.23 / 0.22 8 / 0.21 / 0.24 / 0.22	

			pH: t_0: 4.00 t_{4weeks}: 3.75 t_{8weeks}: 3.81	
Storage stability test – **long term storage at ambient temperature**	GIFAP No. 17 CIPAC MT 75.3 CIPAC MT 41.1 Analytical method presented in chapter 3.4 was used	ANTI-GERM H2O.NET (Meta SPC 1); Lot number: H2O NET – 02/11/2016; 35% (w/w) H_2O_2 White HDPE-bottle with vented screw-top	Results after 18 month : No significant change in appearance and packaging after storage at ambient temperature. The test item was a clear, homogeneous liquid with typical odor at all time points of the 18 months storage. <u>Active substance content</u>: start: 34.92% 18 month: 34.74% (-0.53%) <u>pH (1% solution)</u> start: 4.96 18 month: 6.33 <u>Weight loss</u> of 0.95% after 18 month.	Lehmann, R. (2018); Report no. AT 11.03.03 Lehmann, R. (2020); Report no. AT 20.38

			Dilution stability (after 46 month[5]): The clear solution (0.5%, 2%, 5%) did not show any separation effects after 30 minutes and after 24 hours.	
Storage stability test – **long term storage at ambient temperature**	GIFAP No. 17 CIPAC MT 75.3 Analytical method presented in chapter 3.4 was used	ANTI-GERM OXID'O (Meta SPC 2, not appropriate for authorisation); Lot number: ANTI-GERM OXID'O-03/11/2016; 49.6 % (w/w) H_2O_2 white HDPE-bottle with vented screw-top	Results after 18 month : No significant change in appearance and packaging after storage at ambient temperature. Active substance content: start: 49.55% 18 month: 48.97% (-1.17%) pH (1% solution) start: 4.84 18 month: 6.44 Weight loss of 0.73% after 18 month.	Lehmann, R. (2018); Report no. AT 11.04.03
Remark:	The pH values of the two products ANTI-GERM H2O.NET (ANTI-GERM WP 35) and ANTI-GERM OXID'O vary considerably during storage: **Start** **3 Monate** **6 Monate** **12 Monate** **18 Monate**			

[5] Measurement of dilution stability was not included in first report. The measurent was now done with the 46 month old test item stored in the laboratory. As the same batch is tested for accelerated (dilution stability included) and long term storage also the start value is given for comparison.

	ANTI-GERM WP 35 4,96 7,27 6,15 6,25 6,33 **ANTI-GERM OXID'O** 4,83 7,48 3,78 4,80 6,44 The two products are aquoeus solutions of the active susbstance hydrogen peroxide (including stablizers) but without further constituents (e.g. acidic buffering substances). The pH- values are measured as 1% aquoeus solutions of the products in demineralized water. Such solutions show sightly acidic pH due to the reaction  Electrochemical pH determination is based on low voltage potentials that need a basic conductivity of the solvent medium. Due to the high purity of the water used for dilution and the lack of buffering substances in the products diluted this conductivity is not provided. As a consequence, varying and shifting pH values are observed in these measurements.				
Storage stability test – **long term storage at ambient temperature**	GIFAP No. 17 CIPAC MT 75.3 CIPAC MT 191 Analytical method presented in chapter 3.4 was used	ANTI-GERM AQUA (Meta SPC 3, not appropriate for authorisation) Lot number: ANTI-GERM AQUA 03/11/2016; 20.4%(w/w) H_2O_2 White HDPE-bottle with vented screw-top	Results after 18 month: No significant change in appearance and packaging after storage at ambient temperature. <u>Active substance content</u>: start: 20.093% 12 month: 18.088% (-9.98%) 18 month: 15.347% (-23.62%) <u>pH (1% solution)</u> start: 1.97 18 month: 1.78 <u>Acidity/Alkalinity:</u> Start: 22.28% w/w 18 month: 22.78% w/w <u>Weight loss</u> of 2.58% after 18 month.	Lehmann, R. (2018); Report no. AT 11.01.03

Storage stability test – **long term storage at ambient temperature**	GIFAP No. 17 CIPAC MT 75.3 CIPAC MT 191 Analytical method presented in chapter 3.4 was used	ANTI-GERM'O (Meta SPC 4, not appropriate for authorisation) Lot number: ANTI-GERM 'O-04/11/2016; 32.4%(w/w) H_2O_2 White HDPE-bottle with with vented screw-top	Results after 18 month: No significant change in appearance and packaging after storage at ambient temperature. Active substance content: start: 32.17% 18 month: 30.95% (-3.80%) pH (1% solution) start: 2.00 18 month: 1.88 Acidity/Alkalinity: Start: 7.43% w/w 18 month: 7.48% w/w Weight loss of 1.4% after 18 month.	Lehmann, R. (2018); Report no. AT 11.02.03
Storage stability test – **long term storage at ambient temperature**	GIFAP No. 17 CIPAC MT 75.3 CIPAC MT 191 Analytical method presented in chapter 3.4 was used	ANTI-GERM DES OXI AIR (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-15/03/2017 5.1 % (w/w) H_2O_2 White HDPE-bottle with vented screw-top	Results after 18 month: No significant change in appearance and packaging after storage at ambient temperature. Active substance content: start: 4.87% 18 month: 4.88% (+0.27%) pH (1% solution) start: 4.36 18 month: 4.09	Lehmann, R. (2018); Report no. AT 11.29.03

			Acidity/Alkalinity: Start: 0.07% w/w 18 month: 0.07% w/w Weight loss of 1.1% after 18 month.	
Storage stability test – **long term storage at ambient temperature**	GIFAP No. 17 CIPAC MT 75.3 CIPAC MT 191 Analytical method presented in chapter 3.4 was used	ANTI-GERM DES OXI AIR-S (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-S-15/03/2017 5.2 % (w/w) H_2O_2 White HDPE-bottle with vented screw-top	Results after 18 month: No significant change in appearance and packaging after storage at ambient temperature. Active substance content: start: 4.806% 18 month: 4.845% (+0.81%) pH (1% solution) start: 4.00 18 month: 3.81 Acidity/Alkalinity: Start: 0.13% w/w 18 month: 0.14% w/w Weight loss of 1.1% after 18 month.	Lehmann, R. (2018); Report no. AT 11.30.03
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3 CIPAC MT 75.3	ANTI-GERM H2O.NET (Meta SPC 1); Lot number: H2O NET – 02/11/2016;	At the start of the test: Homogeneous, clear, slightly yellowish liquid with a characteristic odor. pH=4.95 (1 % solution)	Lehmann, R. (2017); Report no. AT 11.03.02

		35% (w/w) H_2O_2 blue HDPE-bottle	After 7 days at 0°C to 1”C: Homogeneous, clear, slightly yellowish liquid with a characteristic odor. pH=4.82 (1 % solution) No precipitate was to be found on the filter.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3 CIPAC MT 75.3	ANTI-GERM OXID’O (Meta SPC 2, not appropriate for authorisation); Lot number: ANTI-GERM OXID’O-03/11/2016; 49.6 % (w/w) H_2O_2 blue HDPE-bottle	At the start of the test: Homogeneous, clear, slightly yellowish liquid with a characteristic odor. pH=4.82 (1 % solution) After 7 days at 0°C to 1”C: Homogeneous, clear, colorless liquid with a characteristic odor. pH=4.70 (1 % solution) No precipitate was to be found on the filter. No formation of oily phases could be observed.	Lehmann, R. (2017); Report no. AT 11.04.02
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3 CIPAC MT 75.3	ANTI-GERM AQUA (Meta SPC 3, not appropriate for authorisation) Lot number: ANTI-GERM AQUA 03/11/2016; 20.4%(w/w) H_2O_2 blue HDPE-bottle	At the start of the test: Homogeneous, clear, yellowish liquid with a characteristic odor. pH=1.97 (1 % solution) After 7 days at 0°C to 1”C: Homogeneous, clear, yellowish liquid with a	Lehmann, R. (2017); Report no. AT 11.01.02

			characteristic odor. pH=1.95 (1 % solution) No precipitate was to be found on the filter. No formation of oily phases could be observed.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3 CIPAC MT 75.3	ANTI-GERM'O (Meta SPC 4, not appropriate for authorisation) Lot number: ANTI-GERM 'O-04/11/2016; 32.4%(w/w) H_2O_2 blue HDPE-bottle	At the start of the test: Homogeneous, clear, slightly yellowish liquid with a characteristic odor. pH=1.99 (1 % solution) After 7 days at 0°C to 1"C: Homogeneous, clear, slightly yellowish liquid with a characteristic odor. pH=2.04 (1 % solution) No precipitate was to be found on the filter. No formation of oily phases could be observed.	Lehmann, R. (2017); Report no. AT 11.02.02
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3 CIPAC MT 75.3	ANTI-GERM DES OXI AIR (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-14/03/2017 5.1 % (w/w) H_2O_2 black HDPE-bottle	At the start of the test: Homogeneous, clear, slightly yellowish liquid with a characteristic odor. pH=4.39 (1 % solution) After 7 days at 0°C to 1"C: Homogeneous, clear, slightly yellowish liquid with a characteristic odor. pH=4.17 (1 % solution)	Lehmann, R. (2017); Report no. AT 11.29.02

			No precipitate was to be found on the filter. No formation of oily phases could be observed.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3 CIPAC MT 75.3	ANTI-GERM DES OXI AIR-S (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-S-15/03/2017 5.2 % (w/w) H_2O_2 black HDPE-bottle	At the start of the test: Homogeneous, clear, slightly yellowish liquid with a characteristic odor. pH=4.0 (1 % solution) After 7 days at 0°C to 1”C: Homogeneous, clear, slightly yellowish liquid with a characteristic odor. pH=3.78 (1 % solution) No precipitate was to be found on the filter. No formation of oily phases could be observed.	Lehmann, R. (2017); Report no. AT 11.30.02
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Impact on light can be excluded due to lightproof packaging.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			The effects of temperature on the content of the active substance and on technical characteristics of the biocidal products are addressed in the studies on accelerated storage. Humidity: The products are	

			packaged in sealed containers which do not allow access of humidity. Furthermore, since the products are water-based, access of humidity would be irrelevant.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			**HDPE is resistant to aqueous hydroxide peroxide solutions**	Dangerous Goods Database http://www.dgg.bam.de/en/ Wässrige H_2O_2 < 8% : BAM-Nr.: 3833;W Wässrige H_2O_2 8% - 20 % (stabil) BAM-Nr.: 882 Wässrige H_2O_2 20% - 40% (stabil) BAMNr.:881 Wässrige H_2O_2 40% - 60% (stabil) BAM-Nr.:7894
Wettability			Not applicable, liquid formulation.	
Suspensibility, spontaneity and dispersion stability			Not applicable, liquid formulation, no suspension.	
Wet sieve analysis and dry sieve test			Not applicable, liquid formulation.	
Emulsifiability, re-emulsifiability and emulsion stability			Not applicable, liquid formulation, no emulsion.	
Disintegration time			Not applicable, liquid formulation.	

Particle size distribution, content of dust/fines, attrition, friability			Not applicable, liquid formulation.	
Persistent foaming	CIPAC MT 47.2	ANTI-GERM H2O.NET (Meta SPC 1); Lot number: ANTI-GERM H2O.NET-02/11/2016; 35% (w/w) H_2O_2 Dilution: 2.24 g in 220 mL	Volume of foam: 10 sec.: < 1 mL 1 min.: 0 mL 12 min: 0 mL	Lehmann, R. (2017); Report no. AT 11.03.05
Persistent foaming	CIPAC MT 47.2	Anti-Germ ODXID'O (Meta SPC 2, not appropriate for authorisation); Lot number: ANTI-GERM ODXID'O-03/11/2016; 49.6% (w/w) H_2O_2 Dilution: 2.24 g in 220 mL	Volume of foam: 10 sec.: 0 mL 1 min.: 0 mL 12 min: 0 mL	Lehmann, R. (2017); Report no. AT 11.04.05
Persistent foaming	CIPAC MT 47.2	Anti-Germ AQUA (Meta SPC 3, not appropriate for authorisation); Lot number: ANTI-GERM AQUA-03/11/2016; 20.4% (w/w) H_2O_2 Dilution: 2.24 g in 220 mL	Volume of foam: 10 sec.: 0 mL 1 min.: 0 mL 12 min: 0 mL	Lehmann, R. (2017); Report no. AT 11.01.05
Persistent foaming	CIPAC MT 47.2	Anti-Germ'O	Volume of foam: 10 sec.: 0 mL 1 min.: 0 mL	Lehmann, R. (2017); Report no. AT 11.02.05

		(Meta SPC 4, not appropriate for authorisation); Lot number: ANTI-GERM'O-04/11/2016; 32.4% (w/w) H_2O_2 Dilution: 2.24 g in 220 mL	12 min: 0 mL	
Persistent foaming	CIPAC MT 47.2	Anti-Germ DES OXI AIR (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-14/03/2017; 5.1% (w/w) H_2O_2 Dilution: 2.24 g in 220 mL	Volume of foam: 10 sec.: 0 mL 1 min.: 0 mL 12 min: 0 mL	Lehmann, R. (2017); Report no. AT 11.29.05
Persistent foaming	CIPAC MT 47.2	Anti-Germ DES OXI AIR-S (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-S-15/03/2017; 5.2% (w/w) H_2O_2 Dilution: 2.24 g in 220 mL	Volume of foam: 10 sec.: 0 mL 1 min.: 0 mL 12 min: 0 mL	Lehmann, R. (2017); Report no. AT 11.30.05
Persistent foaming	The determination of persistent foaming was done for the unstored test item and is not part of any storage test. However, according to the Manual on development and use of FAO and WHO specifications for pesticides, first edition – third edition, March 2016, section 7.1.5, page 127 we are of the opinion that the determination of persistent foaming is not a requirement as part of the storage stability studies.			

	Furthermore, the determination of persistent foaming of the not stored test items gives in all cases a volume of foam less than 1 mL. This result is far away from the limit of 60 mL. It is expected that the volume of foam for a stored item will not reach the limit of 60 mL. We therefore have the opinion that the endpoint persistent foam is addressed in a sufficient way.			
Flowability/Pourability/Dustability			Not applicable, liquid formulation.	
Burning rate — smoke generators			Not applicable, liquid formulation, will not be used in smoke generators.	
Burning completeness — smoke generators			Not applicable, liquid formulation, will not be used in smoke generators.	
Composition of smoke — smoke generators			Not applicable, liquid formulation, will not be used in smoke generators.	
Spraying pattern — aerosols			Not applicable, no aerosol	
Physical compatibility			Not applicable, liquid formulation, not to be mixed with other products.	
Chemical compatibility			Not applicable, liquid formulation, not to be mixed with other products.	
Degree of dissolution and dilution stability	CIPAC MT 41.1	ANTI-GERM H2O.NET (Meta SPC 1); Lot number: ANTI-GERM H2O.NET-02/11/2016; 35% % (w/w) H_2O_2	The clear solution did not show any separation effects after 30 minutes and after 24 hours.	Lehmann, R. (2017); Report no. AT 11.03.04

Degree of dissolution and dilution stability	CIPAC MT 41.1	ANTI-GERM OXID'O (Meta SPC 2, not appropriate for authorisation); Lot number: ANTI-GERM OXID'O-02/11/2016; 49.6 % (w/w) H_2O_2	The clear solution did not show any separation effects after 30 minutes and after 24 hours.	Lehmann, R. (2017); Report no. AT 11.04.04
Degree of dissolution and dilution stability	CIPAC MT 41.1	ANTI-GERM AQUA (Meta SPC 3, not appropriate for authorisation) Lot number: ANTI-GERM AQUA 03/11/2017; 20.4%) H_2O_2	The clear solution did not show any separation effects after 30 minutes and after 24 hours.	Lehmann, R. (2017); Report no. AT 11.01.04
Degree of dissolution and dilution stability	CIPAC MT 41.1	ANTI-GERM'O (Meta SPC 4, not appropriate for authorisation) Lot number: ANTI-GERM 'O-04/11/2016; 32.4%(w/w) H_2O_2	The clear solution did not show any separation effects after 30 minutes and after 24 hours.	Lehmann, R. (2017); Report no. AT 11.02.04
Degree of dissolution and dilution stability	CIPAC MT 41.1	ANTI-GERM DES OXI AIR (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-14/03/2017 5.1 % (w/w) H_2O_2	The clear solution did not show any separation effects after 30 minutes and after 24 hours.	Lehmann, R. (2017); Report no. AT 11.29.04

Degree of dissolution and dilution stability	CIPAC MT 41.1	ANTI-GERM DES OXI AIR-S (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-S-15/03/2017 5.2 % (w/w) H_2O_2	The clear solution did not show any separation effects after 30 minutes and after 24 hours.	Lehmann, R. (2017); Report no. AT 11.30.04
Surface tension	OECD Guideline 115 Wilhelmy-plate-method	ANTI-GERM H2O.NET (Meta SPC 1); Lot number: ANTI-GERM H2O.NET-02/11/2016; 35% (w/w) H_2O_2	34.1 mN/m at 20°C, pure product 51.7 mN/m at 20°C, 1 % w/w solution	Lehmann, R. (2017); Report no. AT 11.03.05
Surface tension	OECD Guideline 115 Wilhelmy-plate-method	Anti-Germ ODXID'O (Meta SPC 2, not appropriate for authorisation); Lot number: ANTI-GERM ODXID'O-03/11/2016; 49.6% (w/w) H_2O_2	48.8 mN/m at 20°C, pure product 62.4 mN/m at 20°C, 1 % w/w solution	Lehmann, R. (2017); Report no. AT 11.04.05
Surface tension	OECD Guideline 115 Wilhelmy-plate-method	Anti-Germ AQUA (Meta SPC 3, not appropriate for authorisation); Lot number: ANTI-GERM AQUA-03/11/2016; 20.4% (w/w) H_2O_2	48.8 mN/m at 20°C, pure product 70.8 mN/m at 20°C, 1 % w/w solution	Lehmann, R. (2017); Report no. AT 11.01.05

Surface tension	OECD Guideline 115 Wilhelmy-plate-method	Anti-Germ'O (Meta SPC 4, not appropriate for authorisation); Lot number: ANTI-GERM'O-04/11/2016; 32.4% (w/w) H_2O_2	43.8 mN/m at 20°C, pure product 68.5 mN/m at 20°C, 1 % w/w solution	Lehmann, R. (2017); Report no. AT 11.02.05
Surface tension	OECD Guideline 115 Wilhelmy-plate-method	Anti-Germ DES OXI AIR (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-14/03/2017; 5.1% (w/w) H_2O_2	58.1 mN/m at 20°C, pure product 65.9 mN/m at 20°C, 1 % w/w solution	Lehmann, R. (2017); Report no. AT 11.29.05
Surface tension	OECD Guideline 115 Wilhelmy-plate-method	Anti-Germ DES OXI AIR-S (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-S-15/03/2017; 5.2% (w/w) H_2O_2	65.2 mN/m at 20°C, pure product 64.8 mN/m at 20°C, 1 % w/w solution	Lehmann, R. (2017); Report no. AT 11.30.05
Viscosity	OECD Guideline 114 Rotational viscometer	ANTI-GERM H2O.NET (Meta SPC 1); Lot number: ANTI-GERM H2O.NET-02/11/2016; 35% (w/w) H_2O_2	dynamic viscosity varied as follows: 20.0 C, from 2.0 mPa*s at 10.0 s^{-1} to 1.4 mPa*s at 50.0 s^{-1}	Lehmann, R. (2017); Report no. AT 11.03.05

			40.0 °C, from 1.2 mPa*s at 10.0 s^{-1} to 0.9 mPa*s at 50.0 s^{-1}	
Viscosity	OECD Guideline 114 Rotational viscometer	Anti-Germ ODXID'O (Meta SPC 2, not appropriate for authorisation); Lot number: ANTI-GERM ODXID'O-03/11/2016; 49.6% (w/w) H_2O_2	dynamic viscosity varied as follows: 20.0 C, from 1.8 mPa*s at 10.0 s^{-1} to 1.3 mPa*s at 50.0 s^{-1} 40.0 °C, from 1.5 mPa*s at 10.0 s^{-1} to 1.0 mPa*s at 50.0 s^{-1}	Lehmann, R. (2017); Report no. AT 11.04.05
Viscosity	OECD Guideline 114 Rotational viscometer	Anti-Germ AQUA (Meta SPC 3, not appropriate for authorisation); Lot number: ANTI-GERM AQUA-03/11/2016; 20.4% (w/w) H_2O_2	dynamic viscosity varied as follows: 20.0 C, from 3.0 mPa*s at 10.0 s^{-1} to 2.7 mPa*s at 50.0 s^{-1} 40.0 °C, from 2.0 mPa*s at 10.0 s^{-1} to 2.3 mPa*s at 50.0 s^{-1}	Lehmann, R. (2017); Report no. AT 11.01.05
Viscosity	OECD Guideline 114 Rotational viscometer	Anti-Germ'O (Meta SPC 4, not appropriate for authorisation); Lot number: ANTI-GERM'O-04/11/2016; 32.4% (w/w) H_2O_2	dynamic viscosity varied as follows: 20.0 C, from 2.3 mPa*s at 10.0 s^{-1} to 1.3 mPa*s at 50.0 s^{-1} 40.0 °C, from 1.3 mPa*s at 10.0 s^{-1} to 1.1 mPa*s at 50.0 s^{-1}	Lehmann, R. (2017); Report no. AT 11.02.05
Viscosity	OECD Guideline 114 Rotational viscometer	Anti-Germ DES OXI AIR	dynamic viscosity varied as follows:	Lehmann, R. (2017); Report no. AT 11.29.05

		(Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-14/03/2017; 5.1% (w/w) H_2O_2	20.0 C, from 0.9 mPa*s at 10.0 s^{-1} to 1.4 mPa*s at 50.0 s^{-1} 40.0 °C, from 18.3 mPa*s at 10.0 s^{-1} to 1.5 mPa*s at 50.0 s^{-1}	

Viscosity	OECD Guideline 114 Rotational viscometer	Anti-Germ DES OXI AIR-S (Meta SPC 5, corresponding to Meta SPC 2 in SPC); Lot number: ANTI-GERM DES OXI AIR-S-15/03/2017; 5.2% (w/w) H_2O_2	dynamic viscosity varied as follows: 20.0 C, from 0.9 mPa*s at 10.0 s^{-1} to 1.6 mPa*s at 50.0 s^{-1} 40.0 °C, from 12.3 mPa*s at 10.0 s^{-1} to 1.4 mPa*s at 50.0 s^{-1}	Lehmann, R. (2017); Report no. AT 11.30.05

Table 10

Conclusion on the physical, chemical and technical properties
The BPF Anti-Germ Hydrogen Peroxide based desinfectants applied for consisted of 5 meta SPC. For each meta SPC at least the full physico chemical properties of one product are tested. The products are all clear homogenous liquids with a faint odour beside ANTI-GERM H2O.NET (ANTI-GERM WP 35) and ANTI-GERM ODXID'O there are slightly yellowish. The provided stability tests for meta SPC 1 and 2 (ANTI-GERM H2O.NET (ANTI-GERM WP 35) and ANTI-GERM ODXID'O) show no significant change in active substance content (-0.53% resp. -1.17%), appearance and packaging after storage. However, the measured pH values are not meaningfull as they vary considerably during storage (differences > 2) which is caused by the low conductivity of the measured solution. As all other proporties show no significant change and the active substance does not decrease a shelf life of 18 month can be granted. The product ANTI-GERM AQUA (meta-SPC 3) shows an active substance decrease of 9.98 after 12 and 23.62% after 18 month. Therefore, a shelf life of 12 months is granted. The three products tested for meta SPC 4 and 5 applied for (meta SPC 5 applied for corresponds to meta SPC 2 appropriate for authorisation) shows a maximum decrease of 3.80% and no significant change in appearance and packaging after storage. Furthermore, the accelerated and low temperature storage tests are also acceptable. Therefore, a shelf life of 18 month can be granted for meta-SPC 4 and 5 applied for (meta SPC 5 applied for corresponds to meta SPC 2 appropriate for authorisation).

Conclusion on the physical, chemical and technical properties
The technical characteristica persistent of foaming and dilution stability are acceptable tested for all products.

3.3 Physical hazards and respective characteristics

Table 11: Physical hazards and respective characteristics of the product

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	study scientifically not necessary			Waiver: The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive properties.	IUCLID[6]
Flammable gases	study scientifically unjustified			Waiver[7]	IUCLID[6]
Flammable aerosols	study scientifically unjustified			Waiver[7]	IUCLID[6]
Oxidising gases	study scientifically unjustified			Waiver[7]	IUCLID[6]

[6] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

[7] The applicant doesn't need to provide data in accordance with Article 21(1c) and (2) of Regulation (EU) No 528/2012 as the hazard class is not applicable: The product is not in the applicable physical state for the hazard class.

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Gases under pressure	study scientifically unjustified			Waiver[7]	IUCLID[6]
Flammable liquids	study scientifically not necessary			Waiver: The study does not need to be conducted because the products almost completly contain inorganics.	IUCLID[6]
Flammable solids	study scientifically unjustified			Waiver[7]	IUCLID[6]
Self-reactive substances and mixtures	study scientifically not necessary			Waiver: According to Regulation (EU) 1272/2008 (CLP), Annex I, Point 2.8.4.2 (a) there is no need for classification procedures for self-reactive substances if there are no chemical groups present in the molecules associated with explosive or self-reactive properties. None of the components of the formulation is known to be explosive. It is not to be expected that an interaction between the different components will occur resulting in a self-reactive chemical.	IUCLID[6]
Pyrophoric liquids	study scientifically not necessary			Waiver: The study does not need to be conducted because the substance is known to be stable in contact with air at room temperature for prolonged periods of time (days) and hence, the classification procedure does not need to be applied..	IUCLID[6]
Pyrophoric solids	study scientifically unjustified			Waiver[7]	IUCLID[6]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Self-heating substances and mixtures	study scientifically unjustified			Waiver[7]	IUCLID[6]
Substances and mixtures which in contact with water emit flammable gases	study scientifically not necessary			Waiver: The study does not need to be conducted because the experience in production or handling shows that the substance does not react with water, e.g. the substance is manufactured with water or washed with water.	IUCLID[6]
Oxidising liquids	UN Test O.2 (in Part III of the UN-MTC)	ANTI-GERM WP 35; 35% (w/w) H_2O_2 ANTI-GERM OXID'O; 49.6 % (w/w)		Meta SPC 1 and 2) as applied for: No experimental data were provided for the biocidal products ANTI-GERM WP 35 and ANTI-GERM OXID'O. But the given waiver can't be used caused by misinterpretation of Annex 6 of Regulation (EC) No. 1272/2008. Respecting the fact that GHS/CLP classification criteria for physical hazards are related to international transport regulations (the United Nations Recommendations on the Transport of Dangerous Goods) data already exist for hydrogen peroxide. According to UN Recommendations on the Transport of Dangerous Goods (Vol.1, 20th rev. ed. 2017) Hydogen peroxide is classified in Class 5.1, UN packing group II with UN number 2014 as „HYDROGEN PEROXIDE, AQUEOUS SOLUTION	

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
				with not less than 20% but not more than 60% hydrogen peroxide (stabilized as necessary)". Consequential for SPC 1 + 2: Oxidising liquid, Category 2 based on GHS/CLP criteria	
		ANTI-GERM AQUA sample reference 400008749, 20.4%(w/w) H_2O_2	Mean pressure rise time: 9.030 s (Anti-germ Aqua: Cellulose (1:1)) 3.461 s (65% nitric acid : Cellulose (1:1))	Meta SPC 3 as applied for: Study cannot be used for classification. The study results are not reliable in comparison. to the experience on the transport of dangerous goods Consequential for SPC 3 as applied for: Oxidising liquid, Category 2 based on GHS/CLP criteria	Siusiene, E. (2018) Report no. S3016002985R1 V1/2018
		ANTI-GERM'O sample reference 400008748, 32.4%(w/w) H_2O_2	Mean pressure rise time: 2.135 s (Anti-germ'O: Cellulose (1:1)) 3.461 s (65% nitric acid : Cellulose (1:1))	Meta SPC 4 as applied for: Study cannot be used for classification. The study results are not reliable in comparison. to the experience on the transport of dangerous goods. Consequential for SPC 4 as applied for: Oxidising liquid, Category 2 based on GHS/CLP criteria	

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
		ANTI-GERM DES OXI AIR sample reference 400008747, 5.0 % (w/w) H_2O_2	1.102 s (Sodium Chlorate (40%) : Cellulose (1:1)) Mean pressure rise time: 110.608 s (Anti-germ Des Oxi Air : Cellulose (1:1)) 3.461 s (65% nitric acid : Cellulose (1:1)) This result is considered transferrable to the product ANTI-GERM DES OXI AIR S, 5.2 % (w/w) H_2O_2	Meta SPC 5 as applied for, corresponding to meta SPC 2 as appropriate for authorisation: Not classified based on GHS/CLP criteria	
Oxidising solids	study scientifically unjustified			Waiver[7]	IUCLID[6]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Organic peroxides	study scientifically not necessary			Waiver: The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	IUCLID[6]
Corrosive to metals	UN Test in Part III of the UN-MTC, 37.4	ANTI-GERM H2O.NET; Batch no ANTI-GERM H2O.NET-02/11/2016; 35% (w/w) H_2O_2	No mass loss was observed on steel (1.0037) and aluminium (7075-T6) plates after 28 days. No localised corrosion attack was observed on neither steel (1.0037) nor aluminium (7075-T6) plates after 28 days.	SPC1: Not classified based on GHS/CLP criteria	Lehmann, R. (2018); Report no. AT 13.22.01
		ANTI-GERM OXID'O;	No mass loss was observed on steel (1.0037) and aluminium (7075-T6) plates after 28 days.	SPC2: Not classified based on GHS/CLP criteria	Lehmann, R. (2018); Report no. AT 13.22.02

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
		Batch no: ANTI-GERM OXID'O-03/11/2016; 49.6 % (w/w)	No localised corrosion attack was observed on neither steel (1.0037) nor aluminium (7075-T6) plates after 28 days.		
		ANTI-GERM AQUA Batch no. ANTI-GERM AQUA 03/11/2017; 20.4%(w/w) H_2O_2	uniform corrosion (exposure time: 3 days): mass loss: 30.6 % (Steel 1.0037) mass loss: 22.8 % (aluminium 7075-T6)	SPC 3: Substance or mixture corrosive to metals, Category 1 based on GHS/CLP criteria	Lehmann, R. (2018); Report no. AT 13.22.00

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
		ANTI-GERM'O Batch no. ANTI-GERM 'O-04/11/2016; 32.4%(w/w) H_2O_2	uniform corrosion (exposure time: 3 days): mass loss: 29.3 % (Steel 1.0037) mass loss: 2.4 % (aluminium 7075-T6)	SPC 4: Substance or mixture corrosive to metals, Category 1 based on GHS/CLP criteria .	Lehmann, R. (2018); Report no. AT 13.22.00
		ANTI-GERM DES OXI AIR S Batch no. ANTI-GERM DES OXI AIR-S-15/03/2017 5.2 % (w/w) H_2O_2	No mass loss higher than 51.5% was observed on steel (1.0037) and aluminium (7075-T6) plates after 28 days (highest mass loss found for steel: 5.17 %; highest mass loss found for aluminium: 2.21 %). No localised corrosion attack higher than 450 µm was observed on steel (1.0037) plates after 28 days (highest	SPC5: Not classified based on GHS/CLP criteria	Lehmann, R. (2018); Report no. AT 13.22.03

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
			localised corrosion found for steel: 240 µm). No localised corrosion attack was observed on aluminium (7075-T6) plates after 28 days. This result is considered transferrable to the product ANTI-GERM DES OXI AIR, 5.0 % (w/w) H_2O_2		
Auto-ignition temperature (liquids and gases)	study scientifically not necessary			Waiver: The study does not need to be conducted because the products almost completly contain inorganics.	IUCLID[6]
Relative self-ignition temperature for solids	study scientifically unjustified			Waiver[7]	IUCLID[6]
Dust explosion hazard	study scientifically unjustified			Waiver[7]	IUCLID[6]

Table 12

Conclusion on the physical hazards and respective characteristics
Not all data provided by the applicant were acceptable. BPF is not considered to be explosive. Due to the composition of the products flammable properties can be exclude. No experimental data for oxidising properties were provided for the biocidal products ANTI-GERM WP 35 (Meta SPC 1 as applied for) and ANTI-GERM OXID'O (Meta SPC 2 as applied for). Studies were provided for the oxidising properties of the biocidal products ANTI-GERM AQUA (Meta SPC 3 as applied for), ANTI-GERM'O (Meta SPC 4 as applied for) and ANTI-GERM DES OXI AIR (Meta SPC 5 as applied for, corresponding to Meta SPC 2 as appropriate for authorisation). But the study results of the biocidal products ANTI-GERM AQUA and ANTI-GERM'O are not reliable in comparison to the experience on the transport of dangerous goods. Therefore, the biocidal products of the meta-SPCs 1, 2, 3 and 4 as applied for have to be classified as Oxidising liquid, Category 2 (see UN Recommendations on the Transport of Dangerous Goods (Vol.1, 20th rev. ed. 2017) UN no. 2014, „HYDROGEN PEROXIDE, AQUEOUS SOLUTION with not less than 20% but not more than 60% hydrogen peroxide (stabilized as necessary), Class 5.1, UN packing group II). Based on negative test results for the biocidal product ANTI-GERM DES OXI AIR, which can be assigned to biocidal product ANTI-GERM DES OXI AIR S of meta-SPC 5 as applied for, corresponding to meta SPC 2 as appropriate for auhorisation, classification is not required. Corrosive properties were tested for the biocidal products ANTI-GERM WP 35, ANTI-GERM OXID'O, ANTI-GERM AQUA, ANTI-GERM'O and ANTI-GERM DES OXI AIR S. Based on the experimental data the biocidal products ANTI-GERM AQUA (Meta SPC3 as applied for) and ANTI-GERM'O' (Meta SPC 4 as applied for) have to be classified as corrosive to metals in Category 1. For the biocidal products ANTI-GERM WP 35 (Metra SPC 1), ANTI-GERM OXID'O (Metra SPC 2) and ANTI-GERM DES OXI AIR S (Metra SPC 5) classification is not required.

Conclusion on the physical hazards and respective characteristics
Based on negative test results for the biocidal product ANTI-GERM DES OXI AIR S, which can be assigned to biocidal product ANTI-GERM DES OXI AIR of meta-SPC 5, classification is not required.

3.4 Methods for detection and identification

Hydrogen Peroxide content of the products ANTI-GERM OXID'O and ANTI-GERM H2O.NET was determined by reaction of the peroxide with Iodide to Iodine and quantification of the Iodine by titration with Sodium Thiosulfate.
The Titration was carried with ca. 20 mg H_20_2 in the test solution in all studies. This was ensured with different amounts of tests items within this studies. Based on this, the linearity validated in study Lehmann, R. (2017); Report no. AT 11.04.01 is acceptable for all studies.

Table 13

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**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Hydrogenperoxide (active substance) in ANTI-GERM WP 35 und ANTI-GERM OXID'O	Titration	A solvent blank were analysed by titration. The blank was colourless at the initial point.	50 to 150 % of titrated amount (7.737 – 30.136 mg H_20_2) R^2: 1	32 mg Test item (ca. 49.5 mg H_20_2)			0.080	Not available	Lehmann, R. (2017); Report no. AT 11.04.01

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**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Hydrogen peroxide in ANTI-GERM AQUA	Titration	A solvent blank were analysed by titration. The blank was colourless at the initial point.	See Report no. AT 11.04.01	94 mg Test item net (ca. 20.0 mg H_20_2)			0.083		Lehmann, R. (2017), Report no. AT 11.01.01
				Fortification: about 20 % available H_20_2 (17.850 – 18.761 mg H_20_2)/ 3 samples	99.97 – 100.12	100.05	0.079		
				Fortification of the nominal content of hydrogen peroxide: 50%, 75%, 125% and 150% / 1 sample per fortification level	50%: 100.38% 75%:99.96% 125%:99.74% 150%: 100.14%	100.05	0.270 (of the four measurements)		
Hydrogen peroxide in ANTI-GERM'O	Titration		See Report no. AT 11.04.01	55 mg Test item net (ca. 32% H_20_2)			0.049	Not available	

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**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
		A solvent blank were analysed by titration. The blank was colourless at the initial point.		Fortification: about 32% available H_20_2 (17.850 – 18.761 mg H_20_2)/ 3 samples	99.81% - 100.13%	99.96	0.158		Lehmann, R. (2017), Report no. AT 11.02.01
				Fortification of the nominal content of hydrogen peroxide: 50%, 75%, 125% and 150% / 1 sample per fortification level	50%: 100.37% 75%:99.98 125%:100.35% 150%: 100.23%	100.23	0.180 (of the four measurements)		
Hydrogen peroxide in ANTI-GERM DES OXI AIR	Titration	A solvent blank were analysed by titration. The blank was colourless at the initial point.	See Report no. AT 11.04.01	370 mg Test item net (ca. 4.9% H_20_2)			0.127	Not available	Lehmann, R. (2017), Report no. AT 11.29.01
				Fortification: about 5% available H_20_2 (17.056 – 19.733 mg H_20_2)/ 3 samples	99.89% - 100.21%	100.06	0.125		

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**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
				Fortification of the nominal content of hydrogen peroxide: 50%, 75%, 125% and 150% / 1 sample per fortification level	50%: 100.35% 75%:99.92 125%:100.19% 150%: 100.07%	100.103	0.152		
Hydrogen peroxide in ANTI-GERM DES OXI AIR-S	Titration	A solvent blank were analysed by titration. The blank was colourless at the initial point.	See Report no. AT 11.04.01	375 mg Test item net (ca. 4.8% H_20_2)			0.108	Not available	Lehmann, R. (2017), Report no. AT 11.30.01
				Fortification: about 5% available H_20_2 (18.562 – 19.963 mg H_20_2)/ 3 samples	99.71% - 99.90%	99.78	0.101		

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**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
				Fortification of the nominal content of hydrogen peroxide: 50%, 75%, 125% and 150% / 1 sample per fortification level	50%: 99.62% 75%:99.69 125%:100.22% 150%: 100.00%	99.84	0.213		

The contents of the SoC phosphoric and sulfuric acid in the products are not expected to change during storage of the products. Therefore no analytical method to quantify the content of these substances is necessary. Consequently, a validation of such analytical methods as well is not required.

Table 14

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	no relevant residues expected	-	AR PT 1-6, LoEP, March 2015
Drinking water	hydrogen peroxide	drinking water limit of 0.1 µg/L is not applicable to hydrogen peroxide, since it is formed naturally in water at concentration	AR PT 1-6, LoEP, March 2015

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
		levels up to 30 µg/L or even above 100 µg/L in specific situations	
Surface water	hydrogen peroxide	12.6 µg/L	$PNEC_{water}$ based on NOEC *Daphnia magna* of 0.63 mg/L, AR PT 1-6, LoEP, March 2015
Air	hydrogen peroxide	1.25 mg/m³	$AEC_{inhalation}$: 1.25 mg/m³, AR PT 1-6, LoEP, March 2015
Animal and human body fluids and tissues	not residue relevant	-	not classified as T / T+ AR PT 1-6, LoEP, March 2015
Food of plant origin	no relevant residues expected	-	AR PT 1-6, LoEP, March 2015 EC, Basis substance application, March 2016
Food of animal origin	no relevant residues expected	-	AR PT 1-6, LoEP, March 2015 EC, Basis substance application, March 2016

Table 15

Analytical methods for drinking and surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
hydrogen peroxide	UPLC/FLD system using Acquity UPLC HSS	no confirmation	0.008 – 0.12 mg/L R=0.998	0.01 mg/L/5 0.1 mg/L/5	84-98 96-98	90 97	6.2 0.62	10 µg/L	Maire (2016) CAR PT 1-6, Doc IIIA 4.2(c), 2017;

Analytical methods for drinking and surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
	T3 Column; 285 nm								post approval data

Table 16:

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
hydrogen peroxide	Instrument: Cary 60 UV/Vis, UV-Vis absorption spectra between 200 and 900 nm	no confirmation	1.6 – 7.5 mg/L $R \geq 0.997$	139 µg/m³/5 1400 µg/m³/5	87-111 95-115	101 108	10 7.9	139 µg/m³	Maire (2016) CAR PT 1-6, Doc IIIA 4.2(b), 2017; post approval data

Table 17

Data waiving was acceptable for the following information requirements	
Information requirement	1. Analytical methods for determining active substance concentration were submitted. For the analytical methods for SOCs the applicant explained that the contents of the SoC phosphoric and sulfuric acid in the products are not expected to change during storage of the products. Therefore, an additional analytical method to quantify the content of SOcs is scientiffically not necessary. 2. 5.2.1. Soil: Data waving was accepted. 3. 5.2.2. Air: No data waiving. For analytical methods for air, the applicant refers to the CAR for the active substance hydrogen peroxide. However, the BPC opinions Hydrogen peroxide PT04 and PT05 (2015) call for a new analytical method for the determination of the a.s. in air. This information has been submitted 2016 as post-approval data. A review of the method presented results in an agreement of acceptability. Due to the expected exposure level (below 1% of the corresponding reference values) determined from quantitative local risk assessment for the SoC orthophosphoric acid, an additional analytical method for air is not considered to be essential for occupational safety. An analytical method for air for sulphuric acid is not considered to be essential for occupational safety, due to aerosol formation is expected to be negligible during mixing and loading and the vapour pressure of sulphuric acid is low and thus exposure to vapour is also not expected. Moreover SoCs orthophosphoric acid and sulfuric acid are not present in the mSPCs appropriate for authorisation. They are only part of the mSPCs that will not be authorised. 4. 5.2.3. Water (including drinking water) and sediment: No data waiving. 5. 5.2.4 Body fluids and tissues: Data waving was accepted. 6. 5.3. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant: Data waving was accepted
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 18

Conclusion on the methods for detection and identification
The method(s) provided regarding the active substance(s), residues and substances of concern was/were acceptable The methods provided regarding the residues of the active substance hydrogen peroxide were acceptable. The presented methods were accepted as post approval data. Methods regarding residues of substances of concern were not necessary.

3.5 Efficacy against target organisms

3.5.1 Function and field of use

The biocidal product family “ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY PT4, PT5” is composed of disinfectants for PT 4 (Food and feed area) and PT 5 (Drinking water for animals). In PT 4, the uses are aseptic packaging (disinfection of packaging for food products), disinfection in food and feed areas by cleaning in place (CIP) and room disinfection by fogging in food processing facilities. In PT 5, the intended use is disinfection of drinking water for animals. The products are either ready-to-use products or concentrates of hydrogen peroxide. Product application is limited to professionals.

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

The biocidal product family “ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY PT4, PT5” is intended to have bactericidal and yeasticidal activity in the uses:
- aseptic packaging
- cleaning in place (CIP)
- disinfection of drinking water for animals

Room disinfection is intended to have bactericidal, yeasticidal, fungicidal and sporicidal activity.

3.5.3 Effects on target organisms, including unacceptable suffering

Application of biocidal products with the active substance hydrogen peroxide leads to reduction in the number of target organisms by irreversible inactivation of cells. Suffering is not relevant when microorganisms are concerned.

3.5.4 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 cause irreversible damage to a number of cell components such as enzymes, membrane constituents and DNA, resulting in a reduction of cell viability of target microorganisms.

3.5.5 Efficacy data

Disinfection of drinking water for animals (former uses 1, 2, 7, 8, 9, 10, 11, 12, meta-SPCs 1, 2, 3, 4 as applied for by the applicant)

For meta-SPCs 1, 3 and 4, disinfection of drinking water for animals was intended for up to 0.1% product dilution. For meta-SPC 2, the upper limit of the intended dose range is 0.07% product dilution.
The applicant submitted several studies according to EN 1276 to demonstrate efficacy. The German CA considers none of these studies acceptable for demonstrating efficacy for the intended uses, as they did not demonstrate efficacy at appropriate temperatures, within the dose ranges applied for (i.e. too high doses) or within the contact time applied for.
Despite repeated requests from the evaluating German CA, the applicant did not submit a simulated use test or a field test for the disinfection of drinking water for animals.
To conclude, neither data from phase 2, step 1 tests nor a simulated use test nor a field test demonstrating efficacy for the disinfection of drinking water for animals has been submitted. Thus, the respective uses in meta-SPCs 1, 2, 3 and 4 cannot be authorised.

Aseptic packaging: disinfection of packaging for food products (former uses 3 and 4, meta-SPC 1 as applied for by the applicant, former use 4 corresponds to use 1 appropriate for authorisation)
Efficacy against bacteria at phase 2, step 1 level was demonstrated by an EN 1276 study performed at 60 °C (for details see section on CIP). With regard to yeast, an EN 1650:2013 study demonstrated efficacy of 0.5% biocidal product at 60 °C within 5 min unter clean conditions.
To further substantiate the efficacy of meta-SPC 1 products for disinfection of packaging for food products, the applicant submitted a simulated use test done according to VDMA guidelines. In this study, food cartons were artificially inoculated with spores of *Bacillus atrophaeus* and treated in an industrial aseptic packaging unit. Controls were run through the entire process without addition of the biocidal product. Log reduction rates of >4 were obtained with the biocidal product, while no effect was observed in the controls.
As endospores of Firmicutes can be considered as worst case due to their increased biocide tolerance when compared to vegetative bacteria and yeasts, efficacy in the simulated use test against *B. atrophaeus* spores covers claims against bacteria and yeasts.
In conclusion, disinfection of packaging for food products by spraying can be authorised with the target organisms bacteria and yeasts. Concerning the intended application method of immersion at ≥70 °C (former use 3 as applied for by the applicant), no suitable efficacy studies at these temperatures have been submitted by the applicant. Therefore, this application method cannot be authorised. Thus, the authorised use (former use 4 as applied for by the applicant; use 1 appropriate for authorisation) is:
- Aseptic packaging by spraying: ≥200 °C, clean conditions

In any case a validation step should be undertaken by the user, in which the respective aseptic filling system and the biocidal product undergo biological validation of disinfection efficacy once.

Disinfection in food and feed areas by cleaning in place (CIP) (former uses 5 and 6, meta-SPC 1 as applied for by the applicant, corresponding to use 2 and 3 appropriate for authorisation)
To demonstrate efficacy against bacteria, two EN 1276 studies are available, which demonstrate efficacy within the intended dose range of 0.25-2% biocidal product. The first study demonstrates efficacy at 20 °C under clean conditions for a product concentration of 0.29% within 6 h. The other study was performed at 60 °C under clean conditions. Most controls A did not pass as valid due to thermal effects. The German CA accepts this study as proof of efficacy based on expert judgement. Another EN 1276 study done at the same laboratory at the same time contained fully valid controls for 20 °C. Furthermore, for *E. hirae* (most tolerant of the four standard bacterial strains) controls remained valid up to 15 minutes at 60 °C. Thus, for bacteria the combination of 15 min contact time with 2% biocidal product under clean conditions can be accepted as efficacious.
As proof of yeasticidal action, the applicant submitted three EN 1650:2013 studies with *C. albicans* at 40, 50 and 60 °C, respectively. At 40 °C, 0.5% dilution of the biocidal product was efficacious under clean

conditions with 30 min contact time. In the study done at 60 °C, 0.5% biocidal product were deemed efficacious within 5 min under clean conditions. No EN 1650 study with a meta-SPC 1 product is available at 20 °C.
Taken together, CIP uses can be authorised with the following parameters:
- 2% product concentration and 15 min contact time at 60 °C in clean conditions.
- 0.5% product concentration and 6 h contact time at 40 °C in clean conditions.

Room disinfection in food processing facilities (former uses 13 and 14, meta-SPC 5 as applied for by the applicant, use 13 to be authorised as use 4 appropriate for authorisation)
To demonstrate efficacy of meta-SPC 5 products when the biocidal products are fogged, several phase 2, step 1 EN tests in clean conditions were submitted. An EN 1276:2010 test demonstrated efficacy against bacteria after 30 min contact time. Two EN 1650:2013 tests demonstrated efficacy against yeast and fungi within 60 and 90 min, respectively. Efficacy against spores was supported by an EN 13704:2002 test with a contact time of 120 min.
Furthermore, the applicant submitted a NF T72-281 test report as simulated use test. Relevant parameters of the test setup are listed in Table 19. This test demonstrates efficacy with a contact time of 6 h against bacteria, yeasts, fungi and bacterial spores when a biocidal product of meta-SPC 5 is fogged at an application rate of 12 ml/m³. Although humidity was slightly below the parameters prescribed in the standard (32% vs. 40-80%), the German CA considers the test as acceptable in conjunction with a validation requirement. Biological validation shall be performed by the user of the biocidal products for each room to be disinfected by fogging (or in a suitable “standard” room in a facility, if applicable) with the devices to be used, after which a protocol for disinfection of these rooms can be made and used thereafter.
In conclusion, disinfection of surfaces by fogging can be authorised with the following parameters:
- 12 ml/m³ of undiluted product for 6 h contact time at room temperature in clean conditions.

Table 19

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**	**Reference**
PT 5 Bactericidal	Disinfection of drinking water for animals	Anti-Germ Aqua (199 g/kg hydrogen peroxide) Meta-SPC 3	*P. aeruginosa* *E. coli* *S. aureus* *E. hirae*	EN 1276:2010	Suspension test Product concentrations tested: 0.01%; 0.05%; 0.1%; 0.2% T: 20±1 °C clean conditions (0.3 g/l BSA) 120 & 360 min	The required log reduction of ≥5 was achieved for all test species after 360 min for 0.1% product dilution and after 120 min for 0.2% product dilution under clean conditions. Remark: Test temperature too high and either contact time (360 min) not representative or product dilution (0.2%) higher than applied for.	Forest, 2017a
PT 4 Bactericidal	Room disinfection by fogging	Anti-Germ Des Oxi Air (50 g/kg hydrogen peroxide) Meta-SPC 5	*P. aeruginosa* *E. coli* *S. aureus* *E. hirae*	EN 1276:2010	Suspension test Product concentrations tested: 0.1%; 50%; 80% T: 20±1 °C Clean conditions (0.3 g/l BSA) 30 min	The required log reduction of ≥5 was achieved for all test species at a product dilution of 80% under clean conditions.	Carré, 2017a N°RE-1176/0417 **Key study**
PT 4, 5 Bactericidal	Cleaning in place (CIP) Disinfection of drinking water for animals	Anti-Germ Des Oxi-35 (350 g/kg hydrogen peroxide) Meta-SPC 1	*P. aeruginosa* *E. coli* *S. aureus* *E. hirae*	EN 1276:2010	Suspension test Product concentrations tested: 0.01%; 0.05%; 0.1%; 0.29%	The required log reduction of ≥5 was achieved for all test organisms at a product dilution of 0.29% under	Forest, 2017b **Key study**

Experimental data on the efficacy of the biocidal product against target organism(s)							
					T: 20±1 °C Clean conditions (0.3 g/l BSA) 360 min	clean conditions. Remark: Test temperature too high for PT 5.	
PT 4, 5 Bactericidal	Cleaning in place (CIP) Disinfection of drinking water for animals	Anti-Germ Des Oxi-35 Meta-SPC 1	*P. aeruginosa* *E. coli* *S. aureus* *E. hirae*	EN 1276:2009	Suspension test Product concentrations tested: 0.25%; 0.5%; 1% (*E. hirae* only) 2.5%; 5%, 10% (all test species) T: 20±1 °C Clean conditions (0.3 g/l BSA) 60; 120; 240 min	The required log reduction of ≥5 was achieved for all test organisms at either 60 min contact time and 10% product dilution or at 240 min contect time and 5% product dilution under clean conditions. Remark: Efficacious product concentrations higher than applied for.	Kampe, 2017a L16/0709.10
PT 4 Bactericidal	Cleaning in place (CIP) Aseptic filling	Anti-Germ Des Oxi-35 Meta-SPC 1	*P. aeruginosa* *E. coli* *S. aureus* *E. hirae*	EN 1276:2009	Suspension test Product concentrations tested: 0.5%, 1%; 2% T: 60±1 °C Clean conditions (0.3 g/l BSA) 5; 15; 30 min	The required log reduction of ≥5 was achieved at either 15 min contact time and 2% product dilution or 30 min contact time and 0.5% product dilution under clean conditions. Due to the high test temperature, Control A (control of test conditions) in many cases was not valid. Only *E. hirae* passed Control A at 5	Kampe, 2017b L16/0709.6 **Key study**

Experimental data on the efficacy of the biocidal product against target organism(s)							
						and 15 min contact time.	
PT 5 Bactericidal	Disinfection of drinking water for animals	Anti-Germ Aqua Meta-SPC 3	*P. aeruginosa* *E. coli* *S. aureus* *E. hirae*	EN 1276:2010	Suspension test Product concentrations tested: 0.01%; 0.1%; 0.5% T: 15±1 °C dirty PT 5 (>15 mg DOC/l, adjusted with YE) 30 min	The required log reduction of ≥5 was achieved only for *P. aeruginosa* at 0.5% product dilution under dirty conditions. All other combinations of test species and product dilution failed to clear the threshold of 5 logR.	Klock, 2018a L18/0647.1
PT 5 Bactericidal	Disinfection of drinking water for animals	Anti-Germ Aqua Meta-SPC 3	*P. aeruginosa* *E. coli* *S. aureus* *E. hirae*	EN 1276:2010	Suspension test Product concentrations tested: 0.01%; 0.1%; 0.5% T: 15±1 °C clean PT 5 (>2 mg DOC/l, adjusted with YE) 30 min	The required log reduction of ≥5 was **not** achieved for any combination of test species and product dilution under clean conditions.	Klock, 2018b L18/0647.2
PT 5 Bactericidal	Disinfection of drinking water for animals	Anti-Germ Oxid'O (500 g/kg hydrogen peroxide) Meta-SPC 2	*P. aeruginosa* *E. coli* *S. aureus* *E. hirae*	EN 1276:2010	Suspension test Product concentrations tested: 0.01%; 0.1%; 0.5% T: 15±1 °C dirty PT 5 (>15 mg DOC/l, adjusted with YE) 30 min Required logR: ≥5	The required log reduction of ≥5 was **not** achieved for any combination of test species and product dilution under dirty conditions.	Klock, 2018c L18/0648.1
PT 5 Bactericidal	Disinfection of drinking water for animals	Anti-Germ Oxid'O Meta-SPC 2	*P. aeruginosa* *E. coli* *S. aureus* *E. hirae*	EN 1276:2010	Suspension test Product concentrations tested: 0.01%; 0.1%; 0.5%	The required log reduction of ≥5 was **not** achieved for any combination of	Klock, 2018d L18/0648.2

Experimental data on the efficacy of the biocidal product against target organism(s)							
					T: 15±1 °C clean PT 5 (>2 mg DOC/l, adjusted with YE) 30 min	test species and product dilution under clean conditions.	
PT 4 Yeasticidal	Room disinfection by fogging	Anti-Germ Des Oxi Air Meta-SPC 5	*C. albicans*	EN 1650:2013	Suspension test Product concentrations tested: 0.1%; 50%; 80% T: 20±1 °C Clean conditions (0.3 g/l BSA) 60 min	The required log reduction of ≥4 was achieved for a product dilution of 80% at 60 min contact time under clean conditions.	Carré, 2017b N°RE-1183/0417 **Key study**
PT 4 Yeasticidal	Cleaning in place (CIP)	Anti-Germ Des Oxi-35 Meta-SPC 1	*C. albicans*	EN 1650:2013	Suspension test Product concentrations tested: 0.5%; 1%; 2% T: 40±1 °C Clean conditions (0.3 g/l BSA) 5; 15; 30 min Required logR: ≥4	The required log reduction of ≥4 was achieved either for a product dilution of 1% at 5 min contact time or for a product dilution of 0.5% at 30 min contact time under clean conditions.	Kampe, 2017c L16/0709.7 **Key study**
PT 4 Yeasticidal	Cleaning in place (CIP)	Anti-Germ Des Oxi-35 Meta-SPC 1	*C. albicans*	EN 1650:2013	Suspension test Product concentrations tested: 0.5%; 1%; 2% T: 50±1 °C Clean conditions (0.3 g/l BSA) 5; 15; 30 min	The required log reduction of ≥4 was achieved either for a product dilution of 2% at 5 min contact time or for a product dilution of 0.5% at 15 min contact time under clean conditions.	Kampe, 2017d L16/0709.8

Experimental data on the efficacy of the biocidal product against target organism(s)							
PT 4 Yeasticidal	Cleaning in place (CIP) Aseptic filling	Anti-Germ Des Oxi-35 Meta-SPC 1	*C. albicans*	EN 1650:2013	Suspension test Product concentrations tested: 0.5%; 1%; 2% T: 60±1 °C Clean conditions (0.3 g/l BSA) 5; 15; 30 min	The required log reduction of ≥4 was achieved for a product dilution of 0.5% at 5 min contact time under clean conditions.	Kampe, 2017e L16/0709.9 **Key study**
PT 4 Fungicidal	Room disinfection by fogging	Anti-Germ Des Oxi Air Meta-SPC 5	*A. brasiliensis*	EN 1650:2013	Suspension test Product concentrations tested: 0.1%; 50%; 80% T: 20±1 °C Clean conditions (0.3 g/l BSA) 90 min	The required log reduction of ≥4 was achieved for a product dilution of 50% and 80% at 90 min contact time under clean conditions.	Carré, 2017c N°RE-1303/0617 **Key study**
PT 4 Sporicidal	Room disinfection by fogging	Anti-Germ Des Oxi Air Meta-SPC 5	*B. subtilis (spores)*	EN 13704:2002	Suspension test Product concentrations tested: 0.1%; 50%; 80% T: 20±1 °C Clean conditions (0.3 g/l BSA) 120 min	The required log reduction of ≥3 was achieved for a product dilution of 50% and 80% at 120 min contact time under clean conditions.	Carré, 2017d N°RE-1209/0417 **Key study**
PT 4 bactericidal, fungicidal, sporicidal	Room disinfection by fogging	Anti-Germ Des Oxi Air Meta-SPC 5	*P. aeruginosa* *E. coli* *S. aureus* *E. hirae* *C. albicans* *A. brasiliensis* *B. subtilis (spores)*	NF T72-281:2014	Fogging test (room disinfection) Product concentrations tested: 100%, 12 ml/m³ Tested device: Technifogger 40 (Auratech)	The required log reductions (≥5 bacteria, ≥4 yeast/fungi, ≥3 bacterial spores) were achieved for all test species at 6 h contact time. Humidity in the test room was slightly below the	Moulès, 2017 R-DSVAANT002 **Key study**

Experimental data on the efficacy of the biocidal product against target organism(s)							
					T: 21-22 °C IS: 20 g/l milk (P. aeruginosa); 5 g/l milk (all other test species) CT: 360 min Room volume: 55 m^3 Flow rate: 150 ml product /min Diffusion time: 4:24 min Humidity: 32% Distance fogger-carriers: 3.3 m	range prescribed by NF T72-281 (32% vs 40-80%). However, this was deemed acceptable by the eCA, as validation by the user will be required.	
PT 4 sporicidal	Aseptic filling	Anti-Germ Des Oxi-35 Spray (350 g/kg hydrogen peroxide) Meta-SPC 1	*Bacillus atrophaeus (spores)*	VDMA document/Code of Practice no.6/2002, rev 2008 *Filling Machines of VDMA Hygiene Class V: Testing the Effectiveness of Packaging Sterilization Devices*	Simulated use test for aseptic filling Product concentrations tested: 100%, 1100 ml/h T: 220±20 °C (product vapour T) Air flow: 8±2 m^3/h per vapourizer Performance: 12000 drink cartons/h *B. atrophaeus* spores were applied directly by spray inoculation on drink cartons for three runs. $2.28*10^4$ CFU/carton (log 4.36; n=16) $2.28*10^5$ CFU/carton (log 5.36; n=18) $2.28*10^6$ CFU/carton (log 6.36; n=17) Controls were tested with	Depending on the initial level of inoculation, the following average log reductions were achieved: Log 4.36 → 4.36 log reduction Log 5.36 → 4.84 log reduction Log 6.36 → 5.55 log reduction According to VDMA, a log reduction of ≥4 is required. Thus, the test was passed at all tested inoculation levels. On the control cartons, an average of $2.28*10^2$ CFU/carton survived. Thus, temperature alone had no effect on the test spores.	Andal & Gunnæs, 2018 EDMS-112-1151 **Key study**

Experimental data on the efficacy of the biocidal product against target organism(s)							
					temperature active, but no product applied. $2.28*10^2$ CFU/carton (n=4) Surviving spores were quantified by agar overlay.		

3.5.6 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 (Dukan and Touati (1996), Christman et al (1985)).
The resistance to oxidative stress that *E. coli* develops when exposed to H202, 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 H202 addition. Synthesis of the “early” and “late proteins return to normal with 30 minutes 60 minutes, respectively (Christman et al (1985)). 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) 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 1 M 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. 250mM 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 (Nakamura et al (2012)).
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.

3.5.7 Known limitations

No limitations and no undesirable or unintended side-effects have been observed during the studies on the efficacy against the target organisms of this biocidal product family.

3.5.8 Evaluation of the label claims

The following label claims are supported by the efficacy data that were provided:

Meta-SPC 1:
- Bactericidal, yeasticidal
- CIP at 40 °C in clean conditions, 0.5% product concentration, 6 h contact time
- CIP at 60 °C in clean conditions, 2% product concentration, 15 min contact time
- Aseptic packaging by spraying at ≥200 °C in clean conditions, undiluted product

Meta-SPC 5:
- Bactericidal, yeasticidal, fungicidal, sporicidal
- Room disinfection by fogging at room temperature in clean conditions, undiluted product, 12 ml/m³, 6 h contact time

In general, the required contact times should be mentioned on the product label.

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

The biocidal products of this biocidal product family are not intended to be authorised for use in combination with other biocidal products.

3.5.10 Data waiving and conclusion

Table 20

Conclusion on the efficacy
It can be concluded that products of the biocidal product family "ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY PT4, PT5" demonstrated sufficient biocidal activity to be authorised for the following uses in PT 4: Meta-SPC 1:

Conclusion on the efficacy
- Cleaning in place (CIP): 2% product dilution, 15 min contact time, 60 °C, clean conditions - Cleaning in place (CIP): 0.5% product dilution, 6 h contact time, 40 °C, clean conditions - Aseptic packaging by spraying: undiluted product, ≥200 °C, clean conditions, validation required Meta-SPC 5: - Room disinfection by fogging: undiluted product, 12 ml/m³, 6 h contact time, clean conditions, validation required Efficacy of the uses "Disinfection of drinking water for animals" in meta-SPCs 1, 2, 3 and 4 has not been demonstrated. Likewise, efficacy of aseptic packaging by immersion at ≥70 °C has not been demonstrated. Consequently, these uses cannot be authorised. Resistance is not reported or known at the time being.

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Table 21

Hydrogen peroxide	Value	Study	Safety factor
AEL long-term	not established, the substance is not systemically available	Assessment-Report (RMS Finland (2015))	-
AEL medium-term	not established, the substance is not systemically available	Assessment-Report (RMS Finland (2015))	-
AEL acute	not established, the substance is not systemically available	Assessment-Report (RMS Finland (2015))	-

Table 22

Hydrogen peroxide	Value	Reference
AEC inhalation long-term, medium-term, acute	1.25 mg/m^3	NOAEC in 90-day inhalation study (rat), AF 8
Oral absorptionOral 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).

3.6.2 Assessment of effects of the product on human health

3.6.2.1 Skin corrosion and irritation

Table 23

Data waiving was acceptable for the following information requirements	
Information requirement	8.1. Skin corrosion or skin irritation
Justification	All meta SPC:

Data waiving was acceptable for the following information requirements	
	Studies on potential skin corrosive or skin irritating properties of the biocidal product family are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.1 "Skin irritation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected." The composition of the biocidal product family is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no information on synergistic effects between any of the components. Consequently, classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

Table 24

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Meta SPC 1, 2 as applied for by the applicant, meta SPC 1 also appropriate for authorisation: Irritating to the skin Meta SPC 3, 4 as applied for by the applicant, but not authorised: Corrossive to the skin Meta SPC 5 as applied for by the applicant, corresponds to meta SPC 2 appropriate for authorisation: Not corrosive and irritating to the skin
Justification for the value/conclusion	Meta SPC 1 as applied for by the applicant and also appropriate for authorisation: H_2O_2 (max. 35 %): Skin Corr. 1A[1)], SCL: Skin Irrit. 2; H315: 35 % ≤ C < 50 %[1)]; Resulting classification: Skin Irrit. 2, H315 Meta SPC 2 as applied for by the applicant, but not authorised: H_2O_2 (max. 49.9 %): Skin Corr. 1A[1)], SCL: Skin Irrit. 2; H315: 35 % ≤ C < 50 %[1)]; Resulting classification: Skin Irrit. 2, H315 Meta SPC 3 as applied for by the applicant, but not authorised: Orthophosphoric acid (max. 28.35 %): Skin Corr. 1B[1)], SCL: Skin Corr. 1B; H314: C ≥ 25 %[1)]; Resulting classification: Skin Corr. 1B; H314; Hydrogen peroxide also contributes to this classification. Meta SPC 4 as applied for by the applicant, but not authorised: H_2O_2 (max. 32.43 %): Skin Corr. 1A[1)], SCL: Skin Corr.1B; H314: 50 % ≤ C < 70 %[1)] Orthophosphoric acid (max. 3.6 %): Skin Corr. 1B[1)], SCL: Skin Corr. 1B; H314: C ≥ 25 %[1)] Sulphuric acid (max. 5.76 %): Skin Corr. 1A[1)], SCL: Skin Corr. 1A; H314: C ≥ 15 %[1)] According to Regulation (EC) No. 1272/2008 the generic concentration limit for the classification of corrosive substances in a mixture is C ≥ 5 %. The specific concentration limits of the three components above are higher. Therefore, their concentrations were adapted to this concentration limit. The actual concentrations were multiplied with the quotient of the GCL and the SCL. Resulting in following concentration levels: H_2O_2: 32.43 x (5 %/50 %)

Conclusion used in Risk Assessment – Skin corrosion and irritation	
	= 3.24 %; Orthophosphoric acid: 3.6 % x (5 %/25 %) = 0.72 %; Sulphuric acid: 5.76 % x (5 %/15 %) = 1.92 %; The total concentration of these components is 5.91 %: This is above the GCL of 5 %. Hence classification as Skin Corr. 1B is required. Meta SPC 5 as applied for by the applicant, corresponds to meta SPC 2 appropriate for authorisation: The biocidal product does not contain components classified for skin irritation and corrosion in relevant concentrations.
Classification of the product according to CLP	Meta SPC 1, 2 as applied for by the applicant, meta SPC 1 also appropriate for authorisation: Skin Irrit. 2, H315 Meta SPC 3, 4 as applied for by the applicant, but not authorised: Skin Corr. 1B Meta SPC 5 as applied for by the applicant, corresponds to meta SPC 2 appropriate for authorisation: Not classified for skin irritation/corrosion

[1)] According to Regulation (EC) No. 1272/2008

3.6.2.2 Eye irritation

Table 25

Data waiving was acceptable for the following information requirements	
Information requirement	8.2. Eye irritation
Justification	All meta SPC: Studies on potential eye damaging or eye irritating properties of the biocidal product family are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.2 “Eye irritation” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), “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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” The composition of the biocidal product family is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no information on synergistic effects between any of the components. Consequently, classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

Table 26

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Meta SPC 1, 2, 3, 4 as applied for by the applicant, meta SPC 1 also appropriate for authorisation: Causes serious eye damage. Meta SPC 5 as applied for by the applicant, corresponds to meta SPC 2 appropriate for authorisation: Causes serious eye irritation.
Justification for the value/conclusion	Meta SPC 1 as applied for by the applicant and also appropriate for authorisation: H_2O_2 (max. 35 %): Skin Corr. 1A[1)], SCL: Eye Dam. 1; H318: 8 % ≤ C < 50 %[1)]; Resulting classification: Eye Dam. 1; H318 Meta SPC 2 as applied for by the applicant, but not authorised: H_2O_2 (max. 49.9 %): Skin Corr. 1A[1)], SCL: Eye Dam. 1; H318: 8 % ≤ C < 50 %[1)]; Resulting classification: Eye Dam. 1; H318 Meta SPC 3 as applied for by the applicant, but not authorised: Orthophosphoric acid (max. 28.35 %): Skin Corr. 1B[1)], SCL: Skin Corr. 1B; H314: C ≥ 25 %[1)]; Resulting classification: Eye Dam. 1; H318; Hydrogen peroxide also contributes to this classification. Classification as Skin Corr. 1 implies classification as Eye Dam. 1 Meta SPC 4 as applied for by the applicant, but not authorised: H_2O_2 (max. 32.43 %): Skin Corr. 1A[1)], SCL: Eye Dam.1; H318: 8 % ≤ C < 50 %[1)] Resulting classification: Eye Dam. 1; H318 Orthophosphoric acid and sulfuric acid may contribute to this classification. Meta SPC 5 as applied for by the applicant, corresponds to meta SPC 2 appropriate for authorisation: H_2O_2 (max. 5.0015 %): Skin Corr. 1A[1)], SCL: Eye Irrit. 2; H319: 5 % ≤ C < 8 %[1)]; Resulting classification: Eye Irrit. 2; H319
Classification of the product according to CLP	Meta SPC 1, 2, 3, 4 as applied for by the applicant, meta SPC 1 also appropriate for authorisation: Eye Dam.1, H318 Meta SPC 5 as applied for by the applicant, corresponds to meta SPC 2 appropriate for authorisation: Eye Irrit. 2. H319

[1)] According to Regulation (EC) No. 1272/2008

3.6.2.3 Respiratory tract irritation

Table 27

Data waiving was acceptable for the following information requirements	
Information requirement	Annex III of BPR, point 8.7.1, “other endpoints”
Justification	All meta SPC: There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the biocidal product family has to be made according to the rules of the Regulation (EC) No 1272/2008. The biocidal products do not contain components classified for respiratory irritation in relevant concentrations.

Table 28

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Meta SPC 1, 2 as applied for by the applicant, meta SPC 1 also appropriate for authorisation: Irritating to the respiratory tract. Meta SPC 3, 4, 5 as applied for by the applicant, meta SPC 5 as applied for corresponds to meta SPC 2 appropriate for authorisation: Not irritating to the respiratory tract.
Justification for the value/conclusion	Meta SPC 1, 2 as applied for by the applicant, meta SPC 1 also appropriate for authorisation: H_2O_2 (max. 35 %, and max. 49.9 %): Skin Corr. 1A[1)], SCL: STOT SE 3, H335: C ≥ 35 %[1)]; Resulting classification: STOT SE 3, H335 Meta SPC 3, 4, 5 as applied for by the applicant, meta SPC 5 as applied for corresponds to meta SPC 2 appropriate for authorisation: Concentration of relevant components is below the limits for classification.
Classification of the product according to CLP	Meta SPC 1, 2 as applied for by the applicant, meta SPC 1 also appropriate to be authorised: STOT SE 3, H335 Meta SPC 3, 4, 5 as applied for by the applicant, meta SPC 5 as applied for corresponds to meta SPC 2 appropriate for authorisation: Not classified for respiratory tract irritation.

3.6.2.4 Skin sensitisation

Table 29

Data waiving was acceptable for the following information requirements	
Information requirement	8.3. Skin sensitisation
Justification	All meta SPC: Studies on potential skin-sensitising properties of the biocidal products are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8 Skin sensitisation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected." The composition of the biocidal product family is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no information on synergistic effects between any of the components. Consequently, classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

Table 30

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	All Meta-SPC: Not sensitising to the skin.
Justification for the value/conclusion	The biocidal products do not contain components classified for skin sensitisation in relevant concentrations.
Classification of the product according to CLP	All Meta-SPC: Not classified for skin sensitisation.

3.6.2.5 Respiratory sensitisation (ADS)

Table 31

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. Data on respiratory sensitisation for the biocidal products or their components are not available.

Table 32

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	All Meta-SPC: Not sensitising to the respiratory tract.
Justification for the value/conclusion	The biocidal products do not contain components classified for respiratory sensitisation.
Classification of the product according to CLP	All Meta-SPC: Not classified for respiratotory sensitisation.

3.6.2.6 Acute toxicity

3.6.2.6.1 Acute toxicity by oral route

Table 33

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.1. By oral route
Justification	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 (2017), “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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” The composition of the biocidal product family is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no information on synergistic effects between any of the components. Consequently, classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

Table 34

Value used in the Risk Assessment – Acute oral toxicity	
Value	Meta SPC 1, 2, 3, 4 as applied for by the applicant, meta SPC 1 also appropriate for authorisation: Harmful if swallowed. Meta SPC 5 as applied for by the applicant, corresponds to meta SPC 2 appropriate for authorisation: Not harmful if swallowed.
Justification for the selected value	Oral LD_{50} calculated from all relevant components: Meta SPC 1 as applied for by the applicant and as authorised: 1232 mg/kg bw Meta SPC 2 as applied for by the applicant, not authorised: 842 mg/kg bw Meta SPC 3 as applied for by the applicant, not authorised: 2050 mg/kg bw Meta SPC 4 as applied for by the applicant, not authorised: 1295 mg/kg bw Meta SPC 5 authorised as meta SPC 2: 8397 mg/kg bw
Classification of the product according to CLP	Meta SPC 1, 2, 4 as applied for by the applicant, meta SPC 1 also appropriate for authorisation: Acute Tox. 4, H302 Meta SPC 3, 5 as applied for by the applicant, meta SPC 5 as applied for corresponds to meta SPC 2 appropriate for authorisation: Not classified for acute oral toxicity.

3.6.2.6.2 Acute toxicity by inhalation

Table 35

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation
Justification	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 (2017), “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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” The composition of the biocidal product family is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no information on synergistic effects between any of the components. Consequently, classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required

Table 36

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	All Meta SPC: Not harmful if inhaled.
Justification for the selected value	Inhalation LD_{50} (aerosol) calculated from all relevant components: Meta SPC 1 as applied for by the applicant and as authorised: 4.29 mg/L Meta SPC 2 as applied for by the applicant, not authorised: 3.00 mg/L Meta SPC 3 as applied for by the applicant, not authorised: 7.35 mg/L Meta SPC 4 as applied for by the applicant, not authorised: 2.70 mg/L Meta SPC 5 as applied for, authorised as meta SPC 2: 29.99 mg/L Inhalation LD_{50} (vapour) calculated from all relevant components: Meta SPC 1 as applied for by the applicant and as authorised: 31.43 mg/L Meta SPC 2 as applied for by the applicant, not authorised: 22.04 mg/L Meta SPC 3 as applied for by the applicant, not authorised: 53.92 mg/L Meta SPC 4 as applied for by the applicant, not authorised: 33.92 mg/L Meta SPC 5 as applied for, authorised as meta SPC 2: 219.9 mg/L Using the converted acute toxicity point estimate (ATE) for aerosol (1.5 mg/L) would lead for Meta SPC 1, 2, 4 as applied for by the applicant, meta SPC 1 also appropriate for authorisation to an estimaed LC_{50} below 5 mg/L. This would result in a classification with Acute Tox. 4, H332. Using the converted acute toxicity point estimate (ATE) for vapour (11 mg/L) would lead for all Meta SPC to an estimaed LC_{50} above 20 mg/L. Hence, classification for none of the Meta-SPC is required. For a similar product family the us of the correct acute toxicity point estimate for acute inhalation toxicity classification was reviewed and discussed during the BPC-WG-II-2019 and an adhoc follow-up. This discusion was summarised in the corresponding PAR as followed. At TOX WG-II-2019 on 27 March 2019 (item #2) acute toxicity point estimate for acute inhalation toxicity classification point was reviewed and the following was discussed: *"The applicant informed that in spray application no aerosol is formed and exposure to vapours is expected. The WG members asked information on the basis of the harmonised classification of the active substance as Acute Tox. 4, H332 and indicated that the eCA should use the converted acute toxicity point estimate that corresponds to the state of the active substance originally tested for the harmonised classification. It was also noted that in the acute toxicity study in the CAR no mortality was reported. The eCA explained that vapour form is the dominant form in occupational setting and therefore the acute toxicity of the product was calculated considering the acute toxicity estimate of vapours instead of dust/mist. The eCA concluded that the products containing H_2O_2 should not be classified for acute inhalation toxicity."* After WG-II-2019 meeting, ECHA shared the conclusions of the CMR September 2001 meeting informing on the basis for the harmonised acute inhalation toxicity classification of

Value used in the Risk Assessment – Acute inhalation toxicity	
	hydrogen peroxide (CAS No 7722-84-1; EC No 231-765-0): The Acute Tox. 4 inhalation classification has been derived based on rat studies with vapours of hydrogen peroxide. Acute toxicity point estimatation for acute inhalation toxicity classification has further been discussed in an ad hoc follow-up (AHFU of item # 2 of WG-II-2019). Most of the members agreed with the eCA proposal to use the converted acute toxicity point estimate of vapours to calculate the acute inhalation toxicity classification. The related discussion and considerations of member states are reflected in the following: ”The members agreed with the eCA proposal to use the converted acute toxicity point estimate (ATE) for vapours (i.e. 11 mg/L) since the H_2O_2 harmonized classification was based on a rat study using vapour. This would be in line with the Guidance on the Application of the CLP Criteria, indicating that the ATE corresponding to the physical form of the active substance in the study(ies) used as the basis for the classification, should be applied. Using the ATE of 11 mg/L, the products in the biocidal product family do not require the classification for Acute Tox. 4, H332. The eCA indicated that the determined MMAD is >50 µm for the tested products with trigger sprayers in the HP Family 1; furthermore, the applicant clarified that the MMAD is in fact >100 µm. One member considered that this information further supports the eCA approach since the risk related to exposure to the aerosol is low (generally, particles with aerodynamic diameters <50 µm may reach the thoracic region and those <15 µm the alveolar region of the respiratory tract). One member noted that different views on the classification for acute inhalation toxicity are presented in applications for H_2O_2 product authorisation and suggested to add further argumentation to support the use of the ATE for vapour, for e.g. by referring to the saturated vapour concentration (SVC) (see Guidance on the Application of the CLP Criteria, Chapter 3.1.2.3.2. (p241)). Another member argued that classification for human health effects is normally based on intrinsic properties of the substance (not on exposure considerations). Based on the composition of the products in meta SPC 3, the member considered that the ATE for mists should in principle be applied and the products classified for Acute Tox 4, H332. The member, however, considered that classification of the products for inhalation toxicity is not essential in light of the new information submitted since: - the classification for Acute Tox. 4, H332 is not required for H_2O_2 concentrations below 50 %; - deaths are linked to secondary effects caused by a highly concentrated corrosive solution, while the H_2O_2 concentrations in the products are below the Skin Corr. 1B concentration limit of 50 % (Annex VI of Regulation (EC) No 1272/2008). Corrosive effects, which may induce secondary acute toxicity, are therefore not expected and classification not required. The member also noted that inhalation hazards are already addressed by the STOT SE 3, H335 classification of meta SPC 3.”
Classification of the product according to CLP	All Meta SPC: Not classified for acute inhalation toxicity.

3.6.2.6.3 Acute toxicity by dermal route

Table 37

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.3. By dermal route
Justification	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 (2017), “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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” The composition of the biocidal product family is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no information on synergistic effects between any of the components. Consequently, classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

Table 38

Value used in the Risk Assessment – Acute dermal toxicity	
Value	All Meta-SPC: Not harmful in contact with skin.
Justification for the selected value	The biocidal products do not contain components classified for acute dermal toxicity.
Classification of the product according to CLP	All Meta-SPC: Not classified acute dermal toxicity.

3.6.2.7 Information on dermal absorption

Table 39

Data waiving was acceptable for the following information requirements	
Information requirement	8.6. Information on dermal absorption
Justification	Dermal absorption is considered not relevant for the products pertaining to the BPF (all meta SPC), since hydrogen peroxide toxicity is based on local effects only. The same applies for phosphoric acid (meta SPC 3 and meta SPC 4) and sulphuric acid (meta SPC 4). In the absence of clear systemic effects, setting of dermal absorption values is not deemed necessary; however, a default value of 100 % was set for hydrogen peroxide in the Assessment Report on Hydrogen peroxide in PT1-6.

Table 40

Value(s) used in the Risk Assessment – Dermal absorption	
Value(s)	100%
Justification for the selected value(s)	Default acc. to the CAR (2015)

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

None.

3.6.2.9 Available toxicological data relating to a mixture

Not relevant.

3.6.2.10 Other

Not relevant.

3.6.2.11 Endocrine disrupting properties

The biocidal product family does not contain any components, listed for ED properties on the SVHC list or the Endocrine disruptor assessment list of the ECHA. Members of this product family may contain a co-formulant classified with Repr. 1B, H360D in non-relevant concentrations below 0.1%.

3.6.2.12 Summary of effects assessment

Table 41

Endpoint	Brief description
Skin corrosion and irritation	Based on the known toxicological properties of the single components: Meta SPC 1, 2 as applied for by the applicant, meta SPC 1 also appropriate for authorisation: Skin Irrit. 2, H315 Meta SPC 3, 4 as applied for by the applicant, but not authorised: Skin Corr. 1B Meta SPC 5 as applied for by the applicant, corresponds to meta SPC 2 appropriate for authorisation: Not classified for skin irritation/corrosion.
Eye irritation	Based on the known toxicological properties of the single components: Meta SPC 1, 2, 3, 4 as applied for by the applicant, meta SPC 1 also appropriate for authorisation: Eye Dam.1, H318

Endpoint	Brief description
	Meta SPC 5 as applied for by the applicant, corresponds to meta SPC 2 appropriate for authorisation: Eye Irrit. 2. H319
Respiratory tract irritation	Based on the known toxicological properties of the single components: Meta SPC 1, 2 as applied for by the applicant, meta SPC 1 also appropriate for authorisation: STOT SE 3, H335 Meta SPC 3, 4, 5 as applied for by the applicant, meta SPC 5 as applied for by the applicant corresponds to meta SPC 2 appropriate for authorisation: Not classified for respiratory tract irritation.
Skin sensitisation	Based on the known toxicological properties of the single components: All meta SPC: Not classified for skin sensitisation.
Respiratory sensitization (ADS)	Based on the known toxicological properties of the single components: All meta SPC: Not classified for respiratory sensitisation.
Acute toxicity by oral route	Based on the known toxicological properties of the single components: All Meta SPC: Not classified for acute oral toxicity.
Acute toxicity by inhalation	Based on the known toxicological properties of the single components: Meta SPC 1, 2, 4 as applied for by the applicant, meta SPC 1 also appropriate for authorisation: Acute Tox. 4, H332 Meta SPC 3, 5 as applied for by the applicant, meta SPC 5 applied for by the applicant corresponds to meta SPC 2 appropriate for authorisation: Not classified for acute inhalation toxicity.
Acute toxicity by dermal route	Based on the known toxicological properties of the single components: All meta SPC: Not classified acute dermal toxicity.
Information on dermal absorption	Based on the CAR (2015): 100 % (default)
Available toxicological data relating to non-active substance(s)	Refer to section 3.6.2.8.
Available toxicological data relating to a mixture	Not relevant
Other relevant information	Not available.

3.6.3 Exposure assessment

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

Table 42

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

n.a.: not applicable

List of scenarios

Table 43

Summary table: scenarios				
Scenario No.	**Scenario**	**Use No. (Product type)**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1	PT05: Disinfection of drinking water for animals – manual	2, 8, 10, 12 (PT05)	Primary exposure of workers resulting from manual mixing and loading of b.p. into water storage tank or product reservoir; no relevant application or post-application activities Secondary exposure of workers to disinfected animal drinking water (applies to meta SPC 1, 2, 3, 4 as applied for by the applicant)	professional
2	PT05: Disinfection of drinking water for animals – automated	1, 7, 9, 11 (PT05)	Primary exposure of workers resulting from automated mixing and loading of b.p.by connecting of transfer lines; no relevant application or post-application activities Secondary exposure of workers to disinfected animal drinking water (applies to meta SPC 1, 2, 3, 4 as applied for by the applicant)	professional
3	PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying	3, 4 (PT04)	Primary exposure of workers resulting from manual or automated mixing and loading of b.p. into the circuit of the application system; primary exposure to inhalation of workers being in the vicinity of the automated aseptic packaging unit and during maintenance Secondary exposure of a professional bystander who is present in the working hall (applies to meta SPC 1)	professional
4	PT04: Disinfection in food and feed areas by cleaning in place (CIP)	5, 6 (PT04)	Primary exposure of workers resulting from manual or automated mixing and loading of b.p. into the circuit of the application system; no relevant application or post-application activities No secondary exposure of a professional bystander (applies to meta SPC 1)	professional
5	PT04: Disinfection by vaporisation in food processing facilities	13 (PT04)	Primary exposure of workers resulting from manual or automated mixing and loading of b.p. into the circuit of the vaporisation unit; no relevant application or post-application activities Secondary exposure of a professional bystander after re-entry of the room (applies to meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation)	professional

Professional exposure

ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY PT4, PT5 is a biocidal product family (BPF) of hydrogen peroxide based disinfectants for which five meta SPCs were applied for by the applicant.

Within PT04 the products of meta SPC 1 applied for (ANTI-GERM WP 35) are used for disinfection of packaging for food products (aseptic packaging) and for disinfection in food and feed areas by cleaning in place (CIP); the products of meta SPC 5 (ANTI-GERM DES OXI AIR and ANTI-GERM DES OXI AIR-S) as applied for by the applicant and corresponding to meta SPC 2 appropriate for authorisation, are used for disinfection by vaporisation in food processing facilities.
Within PT05 the products of meta SPC 1 (ANTI-GERM WP 35), meta-SPC 2 (ANTI-GERM OXID'O), meta SPC 3 (ANTI-GERM AQUA) and meta SPC 4 (ANTI-GERM'O) as applied for by the applicant are used for disinfection of drinking water for animals.

All members of meta SPC 1 - 4 as applied for by the applicant are concentrates containing the a.s. hydrogen peroxide (CAS-No.: 7722-84-1) in different concentrations (w/w):

- meta SPC 1 as applied for by the applicant 0 - 35.0%
- meta SPC 2 as applied for by the applicant 0 - 49.9%
- meta SPC 3 as applied for by the applicant 0 - 20.279%
- meta SPC 4 as applied for by the applicant 0 - 31.78%.

The products of meta SPC 5 as applied for by the applicant and corresponding to meta SPC 2 appropriate for authorisation are ready to use products containing the a.s. hydrogen peroxide in a concentration of 0 - 5.0 % (w/w).

Products of meta SPC 3 and meta SPC 4 as applied for by the applicant also contain the substance of concern (SoC) orthophosphoric acid (CAS-No.: 7664-38-2, meta SPC 3: 25.65 - 28.35% (w/w), meta SPC 4: 2.4 - 3.6% (w/w)).

Products of meta SPC 4 as applied for by the applicant contain the SoC sulfuric acid (CAS-No.: 7664-93-9, 3.84 - 5.76% (w/w)).
In the following section five different scenarios are described. Therein, a *quantitative* exposure assessment for the inhalation pathway has been performed for the a.s. hydrogen peroxide and the SoC orthophosphoric acid, but not for the SoC sulfuric acid. For details of the underlying selection criteria and the risk assessment refer to chapter 3.6.4.5.

In addition, a *qualitative* local risk assessment is performed for the a.s. and is also described in chapter 3.6.4.5. The qualitative local risk assessment covers also the assessment of the SoC. The following table clarifies the assessments performed for the a.s. and the SoC.

Table 44

	Exposure (and risk) assessment			
	quantitative		***qualitative***	
	inhalation	dermal	inhalation	dermal
a.s. hydrogen peroxide	**+**	**-**	**+**	**+**
SoC orthophosphoric acid	**+**	**-**	**+**	**+**
SoC sulfuric acid	**-**	**-**	**+**	**+**

As a matter of lucidity, in the following summary table the five scenarios are assigned to the different meta SPCs of ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY PT4, PT5 as applied for by the applicant. In addition, concentrations of a.s. and relevant SoCs (see quantitative exposure assessment in the table above and chapter 3.6.4.5) are listed for the different meta SPCs.
For concentrates (meta SPC 1 – 4 as applied for by the applicant) the b.p. has to be diluted to an application solution. Therefore, the concentration of b.p. in each application solution is assigned to the different application methods (scenarios) and meta SPCs.

Table 45

Summary table: Presentation of the exposure assessment in the different meta SPCs of this PAR Words in bold are explained in the text below.						
No. meta SPC as applied for	**Use No.**	**Scenario**		**Max. conc. a.s. in b.p. [%]**	**Max. conc. SoC* in b.p. [%]**	**Conc. b.p. in application solution [%]**
		No.	**Intended application**			
1	2, 8, 10, 12 as applied for by the applicant	1	PT05: Disinfection of drinking water for animals – manual	35.0	-	0.01-0.1
	1, 7, 9, 11 as applied for by the applicant	2	PT05: Disinfection of drinking water for animals – automated			
	3, 4 as applied for by the applicant	3	PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying			1.5-100
	5, 6 as applied for by the applicant	4	PT04: Disinfection in food and feed areas by cleaning in place (CIP)			0.25-2

2	2, 8, 10, 12 as applied for by the applicant	**1**	**PT05: Disinfection of drinking water for animals – manual**	**49.9**	-	0.007-0.07
	1, 7, 9, 11 as applied for by the applicant	**2**	**PT05: Disinfection of drinking water for animals – automated**			
3	2, 8, 10, 12 as applied for by the applicant	1	PT05: Disinfection of drinking water for animals – manual	20.279	**28.35**	0.01-0.1
	1, 7, 9, 11 as applied for by the applicant	2	PT05: Disinfection of drinking water for animals – automated			
4	2, 8, 10, 12 as applied for by the applicant	1	PT05: Disinfection of drinking water for animals – manual	31.78	3.6	0.005-0.1
	1, 7, 9, 11 as applied for by the applicant	2	PT05: Disinfection of drinking water for animals – automated			
5	13, 14 as applied for by the applicant	**5**	**PT04: Disinfection by vaporisation in food processing facilities**	**5.0**	-	12 mL/m^3**

* orthophosphoric acid
** ready to use products

Regarding the table above, scenario 1 - 5 are described in detail, but only for scenarios listed in bold a quantitative calculation for inhalation exposure (a.s. ± SoC) has been performed with the highest concentration applicable:

- For scenario 1 and 2 the highest concentration of the a.s. is listed in meta SPC 2 as applied for by the applicant. Therefore, these concentrations represent a worst case for scenario 1 and 2.
- The highest concentration of the SoC orthophosphoric acid is assigned to meta SPC 3 as applied for by the applicant and is used for exposure calculation within scenario 1 and 2.
- The mixing and loading phase of scenario 3 is also valid for disinfection via CIP (scenario 4) as the highest concentration of the a.s. is the same for both scenarios.
- To represent ready to use products with a significant lower concentration of a.s. (meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation), inhalation exposure for scenario 5 is also calculated.

General Information

The products of all meta SPCs are marketed in different package sizes in jerry cans, drums or IBCs (material HDPE, packaging sizes 5 - 1100 kg).

In accordance with the CAR for hydrogen peroxide PT01 - PT06 and PT11 + PT12 (2015 and 2017) the ART tool has been used to quantitatively calculate inhalation exposure. In Annex 4.3.1, the details of the exposure calculations for the professional user are laid out.

- **Scenario 1 - PT05: Disinfection of drinking water for animals – manual**

Table 46

Description of Scenario
The products of **meta SPC 1 - 4** as applied for by the applicant are used for disinfection of drinking water for animals. The exposure assessment of disinfection of drinking water for animals is based on the approach for manual mixing and loading agreed upon in WG HH VII 2018. For the mixing and loading phase, small containers (e.g. jerry cans) of concentrated b.p. are manually emptied into a product reservoir from which the product is automatically dosed into the water stream. Alternatively, the concentrate is manually dosed by adding the b.p. into a water tank to archieve the target concentration. In both cases, exposure is likely. The hydrogen peroxide application itself (application phase) is an automated process without worker involvement (CAR hydrogen peroxide, PT01 - PT06, 2015). Therefore, exposure is not expected. During post-application empty containers have to be disposed. Exposure is already covered by the calculation of the mixing and loading phase. *Dermal exposure* Dermal exposure to hands and body (area around the belly) during mixing and loading of the b.p. is incidental, but splashes are likely to occur. No quantitative dermal exposure assessment is performed, but a qualitative local risk assessment is provided. For details refer to chapter 3.6.4.5. *Inhalation exposure* Inhalation exposure for manual mixing and loading of the a.s. hydrogen peroxide and the SoC orthophosphoric acid are estimated using the Advanced Reach Tool 1.5 (ART). The modelled scenario includes a 10 min exposure phase for mixing and loading activities. In order to estimate the short-term exposure level (STEL), the non-exposure period was considered to be 0 min. *Exposure to the eyes* During the mixing and loading phase of the b.p. splashes are likely to occur. Eye contact in consequence of splashes cannot be excluded. *Secondary exposure* Secondary inhalation and dermal exposure of a professional bystander to disinfected animal drinking water is possible, but negligible due to the high dilution of the b.p. as wells as the rapid decomposition of the a.s. (CAR hydrogen peroxide, PT01 - PT06, 2015).

Summary of exposure assessment

No risk is identified resulting from the quantitative risk assessment in Tier 1. A refined exposure assessment (Tier 2) is not required but has been performed for informational purposes only.

Details of Scenario 1 - PT05: Disinfection of drinking water for animals – manual	
Parameters	**Value**
Concentration of a.s. hydrogen peroxide in b.p.	49.9% (w/w) – worst case: meta SPC 2 as applied for by the applicant
Concentration of SoC orthophosphoric acid in b.p.	28.35% (w/w) – worst case: meta SPC 3 as applied for by the applicant
Frequency per day	1
ART 1.5 parameters	
Room volume	Any size workroom
Ventilation rate	Only good natural ventilation
Exposure duration per day	10 min
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 0.1 - 1 l/minute
Containment level	Handling that reduces contact between product and adjacent air
Loading type	Splash loading

Calculations for Scenario 1 - PT05: Disinfection of drinking water for animals – manual

The results of the calculation for potential and actual inhalation exposure (Tier 1 and Tier 2) are summarised in the summary Table 51.
For details of the calculation of inhalation exposure, please refer to Annex 4.3.1 of this PAR. For risk characterisation, see chapter 3.6.4.5.

Further information and considerations

As described before, the highest concentration of a.s. in the b.p. is listed in meta SPC 2 as applied for by the applicant, the highest concentration of relevant SoC in meta SPC 3 as applied for by the applicant. Using these concentrations for exposure assessment for a.s. and SoC, a worst case assessment is performed.

The classification of the b.p requires additional assessment of local risks (see chapter 3.6.4.5). Local risk assessment indicated a risk for skin, eyes and respiratory system during mixing and loading activities:

- SKIN:
  Incidental contact to hands and body is possible during short-term manual mixing and loading activities. Thus, protective chemical resistant gloves and a chemical protective coverall are

necessary. However, due to the short-term activity, the type of work and the better compliance, instead of a protective coverall an apron might be considered alternatively. As aerosol formation is expected to not be particularly high during mixing and loading, a type 6 coverall (EN 13034) is considered to be sufficient. Due to the classification H314, chemical protective footwear (EN 13832) is necessary for meta SPC 3 and 4.

- EYES:
  Incidental contact to eyes is possible due to splashes during mixing and loading. Therefore, eye protection (e.g. chemical goggles or face shield) is necessary.

Furthermore the following technical and organisational measures shall be considered for the mixing and loading phase:

- The use of automatic dosage equipment is obligatory
- Sufficient ventilation or LEV

- **Scenario 2 - PT05: Disinfection of drinking water for animals – automated**

Table 47

Description of Scenario
The products of **meta SPC 1 - 4** as applied for by the applicant are used for disinfection of drinking water for animals. The exposure assessment of disinfection of drinking water for animals is based on the approach for mixing and loading described in the assessment report for hydrogen peroxide (CAR hydrogen peroxide, PT01 - PT06, 2015; PT11 + PT12, 2017). For the mixing and loading phase, larger packages (e.g. drums and IBCs) of concentrated b.p. are connected to a suction pump by connecting transfer lines. The b.p. is then automatically dosed into the water stream or a buffer tank. During this procedure exposure is likely and is therefore, calculated. The hydrogen peroxide application itself (application phase) is an automated process without worker involvement (CAR hydrogen peroxide, PT01 - PT06, 2015). Therefore, exposure is not expected. During post-application empty containers have to be disposed. Exposure is already covered by the calculation of the mixing and loading phase. *Dermal exposure* Dermal exposure to hands and body (area around the belly) during mixing and loading of the b.p. is incidental, but splashes are likely to occur. No quantitative dermal exposure assessment is performed, but a qualitative local risk assessment is provided. For details refer to chapter 3.6.4.5. *Inhalation exposure* Inhalation exposure for automated mixing and loading of the a.s. hydrogen peroxide and the SoC orthophosphoric acid are estimated using the Advanced Reach Tool 1.5 (ART). The modelled scenario includes a 10 min exposure phase for mixing and loading activities. In order to estimate the short-term exposure level (STEL), the non-exposure period was considered to be 0 min. *Exposure to the eyes* During the mixing and loading phase of the b.p. splashes are likely to occur. Eye contact in consequence of splashes cannot be excluded. *Secondary exposure* Secondary inhalation and dermal exposure of a professional bystander to disinfected animal drinking water is possible, but negligible due to the high dilution of the b.p. as wells as the rapid decomposition of the a.s. (CAR hydrogen peroxide, PT01 - PT06, 2015).

Summary of exposure assessment

Since no risk is identified resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is not required (Tier 2) but has been performed for informational purposes only.

Details of Scenario 2 - PT05: Disinfection of drinking water for animals – automated	
Parameters	**Value**
Concentration of a.s. hydrogen peroxide in b.p.	49.9% (w/w) – worst case: meta SPC 2 as applied for by the applicant
Concentration of SoC orthophosphoric acid in b.p.	28.35% (w/w) – worst case: meta SPC 3 as applied for by the applicant
Frequency per day	1
ART 1.5 parameters	
Room volume	Any size workroom
Ventilation rate	Only good natural ventilation
Exposure duration per day	10 min
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 10 - 100 l/minute
Containment level	Open process
Loading type	Submerged loading
Localised controls	Medium level containment (99.00% reduction)

Calculations for Scenario 2 - PT05: Disinfection of drinking water for animals – automated

The results of the calculation for potential and actual inhalation exposure (Tier 1 and Tier 2) are summarised in the summary Table 51.
For details of the calculation of inhalation exposure, please refer to Annex 4.3.1 of this PAR. For risk characterisation, see chapter 3.6.4.5.

Further information and considerations

As described before, the highest concentration of a.s. in the b.p. is listed in meta SPC 2 as applied for by the applicant, the highest concentration of relevant SoC in meta SPC 3 as applied for by the applicant. Using these concentrations for exposure assessment for a.s. and SoC, a worst case assessment is performed.
The classification of the b.p requires an assessment of local risks (see chapter 3.6.4.5). Local risk assessment indicated a risk for skin, eyes and respiratory system during mixing and loading activities:

- SKIN:
  Incidental contact to hands and body is possible during short-term mixing and loading activities in case open handling of concentrated product is unavoidable. Thus, protective chemical resistant gloves and a chemical protective coverall are necessary. However, due to the short-term activity, the type of work and the better compliance, instead of a protective coverall an apron might be worn alternatively. As aerosol formation is expected to not be particularly high during mixing and loading, a type 6 coverall (EN 13034) is considered to be sufficient. Due to the classification H314, chemical protective footwear (EN 13832) is necessary for meta SPC 3 and 4.

- EYES:
  Incidental contact to eyes is possible due to splashes in case open handling of concentrated product is unavoidable. Therefore, eye protection (e.g. chemical goggles or face shield) is necessary.

- RESPIRATORY SYSTEM:
  Exposure to the respiratory system of workers seems possible in case open handling of concentrated product is unavoidable. Under unfavourable conditions, e.g. in very small rooms with insufficient ventilation, the air concentration of hydrogen peroxide may exceed the reference value of 1.25 mg/m^3 ($AEC_{inhalation}$) and require the use of RPE. The Type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the product information

Furthermore, the following technical and organisational measures shall be considered for the mixing and loading phase:

- use of automatic dosage equipment is foreseen
- Sufficient ventilation or LEV

- **Scenario 3 - PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying**

Table 48

Description of Scenario
Meta SPC 1 as applied for by the applicant, corresponding to meta SPC 1 appropriate for authorisation In **meta SPC 1** as applied for by the applicant the disinfectants are used for disinfection of packages for food products in e.g. aseptic filling machines. The products of meta SPC 1 as applied for by the applicant are concentrated disinfectant solutions which may directly be applied or may be diluted manually or automated prior to application. For manual mixing and loading, smaller packages/containers (e.g. jerry cans kg) are manually emptied into a product reservoir from which the b.p. is automatically dosed into the circuit of the application system. When performing an automated mixing and loading phase, larger packages (e.g. drums or IBCs) are connected to a suction pump by connection of transfer lines and the product is than automatically transported into the circuit. Often mixing and loading is performed separately, not in direct proximity to the filling machines (segregation of the process). During application phase the packaging material is automatically inserted and disinfected inside the machine prior to rinsing with water and/or filling with food products. The material is either immersed briefly into a bath containing heated hydrogen peroxide solution or is disinfected by spraying of the application solution. During application and normal process situation workers do not have to be present permanently in the proximity of the facility. In order to guarantee product hygiene, aseptic filling machines usually shall have a certain degree of containment by default. The post-application consists of handling of empty containers; exposure is already covered by the calculation of the mixing and loading phase. *Dermal exposure* Dermal exposure to hands and body (area around the belly) during mixing and loading of the b.p. is incidental, but splashes are likely to occur. The disinfection process itself takes place in a containment area inside the aseptic packaging machine. Access to the disinfection area of the machine is restricted during operation due to product hygiene reasons. Thus, dermal exposure is not expected during normal operation. However, dermal contact to hands may be possible while restoring the filling machine (corrective maintenance). No quantitative dermal exposure assessment is performed, but a qualitative local risk assessment is provided. For details refer to chapter 3.6.4.5. *Inhalation exposure* Exposure to vapour occurs during a) *Mixing and loading activities*: In contrast to automated mixing and loading, manual activities during mixing and loading represent the worst case scenario and an assessment for the a.s. hydrogen peroxide has been performed using the

Advanced Reach Tool 1.5 (ART). The modelled scenario includes a 10 min exposure phase for mixing and loading activities. In order to estimate the short-term exposure level (STEL), the non-exposure period was considered to be 0 min.

b) application phase (normal process situation (I) - and corrective maintenance/restoring (II)):

(I) 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.

(II) In case of a functional disorder, the worker may only open the machine when it has stopped in order to restore the machine condition (CAR hydrogen peroxide, PT01 - PT06, 2015). 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). They indicate a short-term exceedance of the $AEC_{inhalation}$ of 1.25 mg/m^3.

A qualitative local risk assessment is provided in chapter 3.6.4.5 due to the local effects of hydrogen peroxide.

Exposure to the eyes

During the mixing and loading and the corrective maintenance/restoring phase of the b.p. splashes are likely to occur. Eye contact in consequence of splashes cannot be excluded.

Secondary exposure

Secondary dermal exposure of a professional bystander is not expected. Secondary inhalation exposure to workers in the same room is assumed to be in the same order of magnitude or lower as for the operator.

Summary of exposure assessment

Details of Scenario 3 - PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying	
Parameters	**Value**
Concentration of a.s. hydrogen peroxide in b.p.	35% (w/w)
ART 1.5 parameters for mixing and loading phase	
Room volume	Any size workroom
Ventilation rate	Only good natural ventilation
Exposure duration per day	10 min
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 0.1 - 1 l/minute
Containment level	Handling that reduces contact between product and adjacent air.
Loading type	Splash loading

Calculations for Scenario 3 - PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying

The results of the calculation for potential and actual inhalation exposure (Tier 1 and Tier 2) are summarised in the summary Table 51.
For details of the calculation of inhalation exposure, please refer to Annex 4.3.1 of this PAR. For risk characterisation, see chapter 3.6.4.5.

Further information and considerations

The classification of the b.p requires an assessment of local risks (see chapter 3.6.4.5). Local risk assessment indicated a risk for skin, eyes and respiratory system during (manual or automated) mixing and loading activities and corrective maintenance:

- SKIN:
  Incidental contact to hands and body is possible during short-term (manual and automated) mixing and loading activities and during maintenance. Thus, protective chemical resistant gloves and a chemical protective coverall are necessary. However, due to the short-term activity, the type of work and the better compliance, instead of a protective coverall an apron might be worn alternatively. As aerosol formation is expected to not be particularly high during mixing and loading, a type 6 coverall (EN 13034) is considered to be sufficient.

- EYES:
  Incidental contact to eyes is possible due to splashes during mixing and loading and corrective maintenance. Therefore, eye protection (e.g. chemical goggles or face shield) is necessary.

- RESPIRATORY SYSTEM:
  Exposure to the respiratory system of workers seems possible during corrective maintenance. Under unfavourable conditions the air concentration of hydrogen peroxide may exceed the reference value of 1.25 mg/m^3 ($AEC_{inhalation}$) and require the use of RPE. The Type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the product information

Furthermore, the following technical and organisational measures shall be considered.

- The use of automatic dosage equipment is obligatory
- Enhanced ventilation (general mechanical ventilation and LEV)
- Product and waste water transfer in closed pipes
- Workplace release measurements with suitable measurement equipment upon implementation of the aseptic packaging plant, at regular intervals (annual intervals recommended) and after any change in relevant boundary conditions (normal process situation)
- In case of maintenance no bystanders shall be present in the vicinity of the aseptic packaging machines.

- **Scenario 4 - PT04: Disinfection in food and feed areas by cleaning in place (CIP) – manual or automated**

Table 49

Description of Scenario
Meta SPC 1 as applied for by the applicant, corresponding to meta SPC 1 appropriate for authorisation The products of **meta SPC 1** are concentrated disinfectant solutions used for disinfection of storage tanks, heaters, containers, apparatus, pipelines, machinery and equipment in dairy, beverage and food industry. For manual mixing and loading phase, small packages (e.g. jerry cans) are manually emptied into a CIP holding tank (product reservoir) from which the b.p. is automatically dosed into the circuit of the application system. When performing an automated mixing and loading, larger packages (e.g. drums or IBCs) are connected to a suction pump by connection of transfer lines and the product is than automatically transported into the circuit. Manual mixing and loading is linked to higher exposure in comparison to automated activities. The application phase (disinfection) takes place in a closed process where the disinfection solution is automatically circulated through pipework and tanks. Afterwards, the system is emptied and rinsed with water in order to remove residues of disinfectant solution. Exposure to professionals during application can be excluded. The post-application consists of handling of empty containers; exposure is already covered by the calculation of the mixing and loading phase. *Dermal exposure* Dermal exposure to hands and body (area around the belly) during mixing and loading of the b.p. is incidental, but splashes are likely to occur. No quantitative dermal exposure assessment is performed, but a qualitative local risk assessment is provided. For details refer to chapter 3.6.4.5. *Inhalation exposure* For mixing and loading, manual activities represent the worst case scenario. A calculation for mixing and loading has been performed for scenario 3 with the same a.s. concentration as applicable for this scenario. Details are listed in Annex 4.3.1. Therefore, no additional calculation has been performed. Since the application phase (disinfection) takes place in a closed system, no inhalation exposure is expected. *Exposure to the eyes* During the mixing and loading phase of the b.p. splashes are likely to occur. Eye contact in consequence of splashes cannot be excluded. *Secondary exposure* Secondary dermal and inhalation exposure of a professional bystander is not expected.

Calculations for Scenario 4 - PT04: Disinfection in food and feed areas by cleaning in place (CIP) – manual or automated

The calculations for mixing and loading for scenario 3 (manual mixing and loading) which covers also the mixing and loading for scenario 4 is are described in Annex 4.3.1 of this PAR - for justification see explanation above. For risk characterisation, see chapter 3.6.4.5.

Further information and considerations

Since the assessment of local risks for mixing and loading activities for this scenario (see chapter 3.6.4.5) results in the same outcome in terms of risk mitigation measures described for scenario 3, they are not mentioned here. Please refer to the heading *further information and considerations* listed within the description of scenario 3.

- **Scenario 5 - PT04: Disinfection by vaporisation in food processing facilities**

Table 50

Description of Scenario
Meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation- PT04: Disinfection by vaporisation in food processing facilities The exposure assessment of disinfection by vaporisation is based on the approach described in the assessment report for hydrogen peroxide (CAR hydrogen peroxide, PT11 + PT12, 2017). The products of **meta SPC 5** as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation are ready to use disinfectant solutions and are used for disinfection of surfaces by vaporisation in food processing facilities. For loading activities with smaller packages (e.g. jerry cans), the containers are manually emptied into a product reservoir from which the b.p. is automatically dosed into the circuit of the vaporisation unit. Larger packages (e.g. drums or IBCs) are connected to a suction pump by connection of transfer lines and the product is automatically transported into the circuit. According to the applicant, the application (surface disinfection) can either be performed with a mobile or a stationary (installed in the room) vaporisation unit and is achieved by vaporisation of the solution containing hydrogen peroxide or by producing a mist by cold fogging. First, the room shall be emptied and cleaned. Subsequently, in case of mobile devices, the operator places the vaporisation unit into the room. In the next step, the unit is loaded with the b.p. (manually or automated) and the application phase is started. In case of mobile devices, the operator has to leave the room immediately after starting the time switch (prior to release of the a.s.); stationary units are usually started from the outside. During disinfection, the room is sealed and re-entry prevented. According to the applicant, after the surface disinfection has been performed, ventilation in the disinfected room is turned on (from the outside). The uncertainty when simulating a re-entry time is high for a number of reasons (e.g. see Recommendation no. 16 of the BPC Ad hoc Working Group on Human Exposure: Applicability of ConsExpo for water based disinfectants, 2019). In order to demonstrate that with the room and ventilation conditions claimed by the applicant, the air concentrations of the a.s. hydrogen peroxide decrease below the reference value within a decent time (289.8 min in our example), we have conducted an exemplifiying calculation (please refer to Annex 4.3.1). As the calculation of a re-entry time is associated with high uncertainties, re-entry may only be permitted until sensors give signal that the hydrogen peroxide concentration in the area has dropped below the reference value (CAR hydrogen peroxide PT01 - PT06, 2015). Alternatively, a defined waiting period (e.g. in combination with a heating period for drying of the surfaces) may ensure decrease of the hydrogen peroxide concentration. In the latter case, the duration of the ventilation period shall be established by measurement, so that the undercut of the $AEC_{inhalation}$ of 1.25 mg/m^3 is ensured. *Dermal exposure* Dermal exposure to hands during mixing and loading of the b.p. is incidental, but splashes are likely to occur. No quantitative dermal exposure assessment is performed, but a qualitative local risk assessment is provided. For details refer to chapter 3.6.4.5.

Inhalation exposure

Inhalation exposure for disinfection by vaporisation of the a.s. hydrogen peroxide is estimated using the Advanced Reach Tool 1.5 (ART). The modelled scenario includes a 10 min exposure phase for mixing and loading activities. In order to estimate the short-term exposure level (STEL), the non-exposure period was considered to be 0 min..

As the simulation of re-entry is connected to high uncertainties (e.g. see Recommendation no. 16 of the BPC Ad hoc Working Group on Human Exposure: Applicability of ConsExpo for water based disinfectants, 2019), inhalation exposure and measures to ensure a safe re-entry are determined qualitatively (see further information and considerations below).

Exposure to the eyes

During the loading phase of the b.p. splashes are likely to occur. Eye contact in consequence of splashes cannot be excluded.

Secondary exposure

Secondary dermal exposure of a professional bystander is not expected. Secondary inhalation exposure to workers in the same room is assumed to be in the same order of magnitude or lower as for the operator.

Summary of exposure assessment

Details of Scenario 5 - PT04: Disinfection by vaporisation in food processing facilities	
Parameters	**Value**
Concentration of a.s. hydrogen peroxide in b.p.	5.0% (w/w)
ART 1.5 parameters for mixing and loading phase	
Room volume	Any size workroom
Ventilation rate	Only good natural ventilation
Exposure duration per day	10 min
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 0.1 - 1 l/minute
Containment level	Handling that reduces contact between product and adjacent air
Loading type	Splash loading

Calculations for Scenario 5 - PT04: Disinfection by vaporisation in food processing facilities

The results of the calculation for potential and actual inhalation exposure (Tier 1 and Tier 2) are summarised in the summary Table 51.
For details of the calculation of inhalation exposure, please refer to Annex 4.3.1 of this PAR. For risk characterisation, see chapter 3.6.4.5.

Further information and considerations

The classification of the b.p requires an assessment of local risks (see chapter 3.6.4.5). Local risk assessment indicated possible exposure to skin and eyes and a risk for eyes during mixing and loading activities:

- SKIN:
  Incidental contact to hands is possible during mixing and loading activities. Since no classification for local dermal effects is applicable, dermal protection can only be recommended.

- EYES:
  Incidental contact to eyes is possible due to splashes during mixing and loading. Therefore, eye protection (e.g. chemical goggles or face shield) is necessary.

Furthermore, the following technical and organisational measures shall be considered for the mixing and loading and re-entry phase:

- Minimisation of splashes and spills (the use of a dosage device is recommended for manual loading phase)
- Start of the disinfection with a time delay (switchmobile devices) or from outside (stationary devices).
- Sealing of the room while disinfection takes place.
- Ventilation of the room preferably with technical ventilation before re-entry
- Re-entry only once the air concentration has dropped below the reference value (measurement before each disinfection or establishment of a ventilation period by measurement)

Summary of exposure assessment Scenario 1-5 (Meta SPC 1-5 as applied for by the applicant)

Quantitative inhalation exposure is calculated for manual (scenario 1, 3 and scenario 5) and automated mixing and loading (see scenario 2) and for aseptic packaging (scenario 3) with the details listed in Annex 4.3.1. Scenario 3 covers the quantitative inhalation exposure for professional users for scenario 4 (worst case: manual mixing and loading) – in this case no assessment has been performed separately.
No quantitative dermal exposure assessment is performed. A qualitative local risk assessment is provided and described in chapter 3.6.4.5. Therefore, no estimated dermal uptake can be indicated here.

Table 51

	Summary table: estimated exposure from professional uses				
Scenario	**Use No.**	**Phase**	**Tier/PPE**	**Estimated external inhalation uptake [mg/m³]**	
				a.s. Hydrogen peroxide	**SoC** Orthophosphoric acid
Scenario 1 PT05: Disinfection of drinking water for animals – manual	2, 8, 10, 12 as applied for by the applicant	Mixing and loading	10 min: Tier 1	0.880	2.20E-03
Scenario 2 PT05: Disinfection of drinking water for animals – automated	1, 7, 9, 11 as applied for by the applicant	Mixing and loading	15 min: Tier 1	0.170	5.50E-04
Scenario 3 PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying	3,4 as applied for by the applicant	Mixing and loading (covers also scenario 4 (use no. 5, 6 as applied by the applicant))	10 min: Tier 1	0.570	-
		Normal process situation	8h TWA: Tier 1	3.400	-
			8h TWA: Tier 2*	0.700	-

		Corrective maintenance	2 min: Tier 1	1.5	-
			2 min: Tier 2**	Qualitative assignment of measures assigned to ensure safe use	-
Scenario 5 PT04: Disinfection by vaporisation in food processing facilities	13, 14 as applied for by the applicant	Mixing and loading	10 min: Tier 1	0.069	-
		Re-entry	Tier 2***	Qualitative assignment of measures assigned to ensure safe use	

* Measures taken into account in Tier 2 for normal process situation: enhanced ventilation (general mechanical ventilation and LEV), product and waste water transfer in closed pipes, workplace release measurements upon implementation and at regular intervals
** Measures taken into account in Tier 2 for corrective maintenance: appropriate PPE (respiratory protective equipment, chemical protective gloves, chemical protective coverall, eye protection)
*** Measures taken into account in Tier 2 during and after fogging: start of the disinfection with a time delay (switch; mobile devices) or from outside (stationary devices), sealing of the room while disinfection takes place. ventilation of the room preferably with technical ventilation before re-entry and re-entry only once the air concentration has dropped below the reference value (measurement before each disinfection or establishment of a ventilation period by measurement)

- **Combined scenarios**

Not applicable.

3.6.3.1.1 Non-professional exposure

The biocidal product family is for professional use only. Hence, non-professional use is not relevant.

3.6.3.1.2 Secondary exposure of the general public

The biocidal products of this family are only applied indoors in food processing facilities. The general public has no access to such areas. Hence, exposure of the general public is not relevant.
Use as animal drinking water disinfectant was not authorised and therefore not evaluated.

3.6.3.2 Dietary exposure

Table 52

Intended use(s) (critical application with regard to dietary exposure)	
Meta SPC as applied for by the applicant	1 (uses1&2), 2 (uses 6&7), 3 (uses 8&9), 4 (uses 10&11)
Active substance(s)	Hydrogen peroxide
Type of formulation	AL (Any other liquid)
Substance(s) of concern	- Orthophosphoric acid, CAS-No. 7664-38-2 (Meta SPC 3&4 as applied for by the applicant) - Sulphuric acid, CAS-No. 7664-93-9 (Meta SPC 4 as applied for by the applicant)
Field(s) of use	Disinfection of drinking water for animals (PT5)
Target organism(s)	gram-positive bacteria: *Staphylococcus aureus* (vegetative cells) *Enterococcus hirae* (vegetative cells) gram-negative bacteria: *Escherichia coli* (vegetative cells) *Pseudomonas* aeruginosa (vegetative cells)
Application rate(s) and frequency	- application rate: 0,01 - 0,1 % (aq) - continuous application or application if required (depending on disinfection cycles) Meta SPC 1 use 1, Meta-SPC 2 use 6, Meta-SPC 3 use 8, Meta-SPC 4 use 10 as applied for by the applicant but not appropriate for authorisation, continuous dosing using an automatic dosing pump Meta-SPC 1 use 2, Meta-SPC 2 use 7, Meta-SPC 3 use 9, Meta-SPC 4 use 11 as applied for by the applicant but not appropriate for authorisation, manual filling into a water storage tank
Category(ies) of users	professional
Waiting periods after treatment	none
Further information	/
Meta SPC	1 (use 3) as applied for by the applicant
Active substance(s)	Hydrogen peroxide
Type of formulation	AL (Any other liquid
Substance(s) of concern	none
Field(s) of use	Aseptic packaging (PT4)
Target organism(s)	gram-positive bacteria: *Staphylococcus aureus* (vegetative cells) *Enterococcus hirae* (vegetative cells) gram-negative bacteria: *Escherichia coli* (vegetative cells) *Pseudomonas* aeruginosa (vegetative cells)

	Yeasts: *candida albicans* (vegetative cells)
Application rate(s) and frequency	- application rate: 1,5 - 100 % (aq) - continuous application - disinfection of packaging for food products in closed system by immersion or spraying
Category(ies) of users	professional
Waiting periods after treatment	none
Further information	/
Meta SPC	1 (uses 4&5) as applied for by the applicant and appropriate for authorisation
Active substance(s)	Hydrogen peroxide
Type of formulation	AL (Any other liquid
Substance(s) of concern	none
Field(s) of use	Disinfection in food and feed areas by cleaning in place (CIP) (PT4)
Target organism(s)	gram-positive bacteria: *Staphylococcus aureus* (vegetative cells) *Enterococcus hirae* (vegetative cells) gram-negative bacteria: *Escherichia coli* (vegetative cells) *Pseudomonas aeruginosa* (vegetative cells) Yeasts: *candida albicans* (vegetative cells)
Application rate(s) and frequency	- application rate: 0,25 - 2 % (aq) - regular application, if required (depending on disinfection cycles) Meta-SPC 1 use 4 as applied for by the applicant and appropriate for authorisation manual application of disinfectant to circulation water by filling into a storage tank Meta-SPC 1 use 5 as applied for by the applicant and appropriate for authorisation automatic application of disinfectant to circulation water by a dosing pump
Category(ies) of users	professional
Waiting periods after treatment	none
Further information	/
Meta SPC	5 (uses 13&14) as applied for by the applicant corresponds to meta-SPC 2 appropriate for authorisation
Active substance(s)	Hydrogen peroxide
Type of formulation	AL (Any other liquid
Substance(s) of concern	none

Field(s) of use	Surface disinfection (PT4)
Target organism(s)	gram-positive bacteria: *Staphylococcus aureus* (vegetative cells) *Enterococcus hirae* (vegetative cells) *Bacillus subtilis* (spores) gram-negative bacteria: *Escherichia coli* (vegetative cells) *Pseudomonas aeruginosa* (vegetative cells) Yeasts: *candida albicans* (vegetative cells) Fungi: *Aspergillus brasiliensis* (vegetative cells)
Application rate(s) and frequency	- application rate: 6 mL/m3 - regularly application, if required (depending on disinfection cycles) Meta-SPC 5 use 13 as applied for by the applicant corresponds to meta-SPC 2 appropriate for authorisation fogging and fumigation Meta-SPC 5 use 14 as applied for by the applicant corresponds to meta-SPC 2 appropriate for authorisation automatic vaporisation with an evaporation unit
Category(ies) of users	professional
Waiting periods after treatment	none
Further information	/

Representative dietary exposure scenarios

Critical scenarios with respect to consumer dietary intake for the biocidal product family ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY PT4, PT5 are presented in the following table. They have been selected based on the information on the intended uses given in Table 52.

Table 53

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use**	**Description of scenario**	**Subject of exposure**
Livestock exposure			
1.	animal husbandry	disinfection of animal drinking water	livestock animals
Transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)			
2.	food industry	aseptic packaging	packaged food
3.	food industry	CIP	food
4.	food processing facilities	surface disinfection	food

3.6.3.2.1 General information on active substance(s)

Table 54

Active substance (Common Name)	Hydrogen peroxide
CAS number	7722-84-1
Chemical structure	
Molecular formular	H_2O_2
Molar mass	34.01 g/mol
Log Po/w	-1.57 (calculated value)
Active substance approval	PT: 1-6; RMS: FI
Restrictions	BPC-Opinion (PT4, 2015) 2.3. No. 4 Products containing hydrogen peroxide shall not be incorporated in materials and articles

	intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004, unless the Commission has established specific limits on the migration of hydrogen peroxide into food or it has been established pursuant to that Regulation that such limits are not necessary. 2.4 No. 4 A robust justification should be provided that residues will be removed from the treated surfaces or packaging materials.
Current regulations on MRLs	No MRLs required according to Regulation (EC) No 37/2010 Reg. (EU) 2017/1777 (inclusion in Annex IV of Reg. (EC) No. 396/2005) Drinking water limit of 0.1 µg/L acc. to Drinking Water Directive 98/83/EC

3.6.3.2.1.1 Information of non-biocidal use of the active substance

Table 55

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)	Database BfR Recommendations on Food contact materials* XIV. Polymer Dispersions XXXIV. Vinylidene Chloride Copolymers with a Predominant Content of Polyvinylidene Chloride

		- catalyst for vinylidene chloride copolymers with a predominant content of 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. Paper and Board for Food Contact XXXVI/1. Cooking Papers, Hot Filter Papers and Filter Layers 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

3.6.3.2.2 Nature of residues

- **Information on active substance**

Table 56

Summary on the nature of residues	
Stability of hydrogen peroxide	hydrolysis CAR (AR, (Hydrogen Peroxide, PT1-6, eCA: FI, 2015) LOEP, p. 36) No hydrolysis because of the chemical nature of the compound. However, decomposition of hydrogen peroxide is catalysed abiotically by transition metal ions. The half-life in surface water (see below) includes abiotic catalysis, next to biotic degradation. thermal stability (CAR (Hydrogen Peroxide, PT1-6, eCA: FI, 2015), Doc IIA 1.3, p. 4) - strong oxidizer - thermodynamically unstable: decomposition into breakdown products water and oxygen.

Summary on the nature of residues	
	degradation in environment (CAR (Hydrogen Peroxide, PT1-6, eCA: FI, 2015), Doc IIA 4.1.1.3, p. 52) rapid decomposition in different environmental compartments, i.e. in surface water (5d, estimated based on literature data), soil (12 h, , estimated based on literature data), active sludge (DT50 2 min at 20C) and air (2h, estimated based on literature data).
Animal metabolism	CAR Doc IIA 3.1, p. 21-22 (quoting EU Risk Assessment Report (2003) pp. 104-105)) Hydrogen peroxide is a normal metabolite in the aerobic cell (…). There are two hydrogen peroxide metabolising enzymes, catalase and glutathione peroxidase, which control the H_2O_2 concentration at different levels and in different parts of the cell as well as in the blood. Due to the high efficacy of the antioxidative system in blood hydrogen peroxide is rapidly decomposed and will not be systemically available. In biological systems, hydrogen peroxide may also undergo iron-catalysed reactions (Fenton reaction, Haber-Weiss reaction) resulting in the formation of hydroxyl radicals.
Potential for accumulation	(AR, (Hydrogen Peroxide, PT1-6, eCA: FI, 2015) LOEP, p. 30) None
Existing plant residue definitions	not applicable
Existing animal residue definitions	not applicable
Conclusion on degradation of active substance under use conditions	rapid degradation of hydrogen peroxide under use conditions

- **Disinfection by-products**

"*Most of hydrogen peroxide decomposes to water and oxygen. The antimicrobial action of hydrogen peroxide stems from its ability to form powerful oxidants such as the hydroxyl radical and singlet oxygen. These reactive oxygen species cause irreversible damage to cellular components such as enzymes, membrane constituents and DNA. The range of by-products is considered wide and not well characterized at detailed level. …. At a level of practical concentrations, no disinfection by-products (DBPs) with (eco)-toxicological relevance have been identified.*" (CAR IIA 1.4.3 (Hydrogen Peroxide, PT1-6, eCA: FI, 2015))

3.6.3.2.3 Estimating Livestock Exposure to Active Substances used in Biocidal Products

Table 57

Scenario: Disinfection of animal drinking water as applied for by the applicant but not appropriate for authorisation	
Description of scenario	Livestock animals drink water that has been disinfected with hydrogen peroxide.
Application of biocidal product	Continuous dosing using an automatic dosing pump or manual filling into a water storage tank max. application rate: 0.1 % bp in water (corresponding to 0.035 % hydrogen peroxide) application frequency: continuous application of if required (depending on disinfection cycles) (description of intended use acc. to applicant´s dossier, pp. 73-74
Estimated residues in drinking water/ livestock exposure	Residue levels in animal drinking water: The biocidal product (concentrated aqueous solution of hydrogen peroxide) is added to drinking water at the application rate indicated above. The aim is to maintain a concentration of 5 mg/L residual hydrogen peroxide at the final point in order to maintain the quality of drinking water (CAR (Hydrogen Peroxide, PT1-6, eCA: FI, 2015) IIB 8.2.2.8, p. 40) Livestock exposure During uptake of drinking water by livestock animals residual hydrogen peroxide will rapidly degrade upon contact with organic material (e.g. drinking trough surfaces, animal tissues). Moreover even if hydrogen peroxide would enter the blood circulation it is rapidly decomposed in blood and will not be systemically available. (CAR (Hydrogen Peroxide, PT1-6, eCA: FI, 2015) IIA 3.1, p. 22). Consequently relevant residues in livestock edible tissues are not expected.
Conclusion on consumer exposure via residues in food	Relevant residues in livestock edible tissues are not expected.

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

Table 58

Scenario: Aseptic packaging	
Description of scenario	Disinfection of packaging material for food products
Application of biocidal product	- application in a closed system (e.g. in aseptic filling machines) - packaging material is either immersed briefly into a bath containing heated hydrogen peroxide solution or the packaging material is disinfected by spraying the application solution - max. application rate: 1.5 % – 100.0 % biocidal product (corresponding to 0.525 % - 35 % hydrogen peroxide) (description of intended use acc. to applicant´s dossier, pp. 97-98
Estimated transfer of residues into food	Theoretically oral exposure of consumers to residual hydrogen peroxide in food is possible. However, hydrogen peroxide evaporates while the wrapping material is heated before filling with food and no residues in food are expected. Furthermore, hydrogen peroxide, if present would rapidly decompose upon contact with any type of food. (see also AR (Hydrogen Peroxide, PT1-6, eCA: FI, 2015) 2.2.1.3, p. 18; BPC-Opinion (Hydrogen Peroxide, PT4) 2.1 c), p. 7)
Conclusion on consumer exposure via residues in food	Relevant residues in food and feedstuff are not expected.

Table 59

Scenario: Clean-in-place (CIP)	
Description of scenario	Disinfection in food and feed areas by cleaning in place
Application of biocidal product	- application in a closed system (e.g. disinfection of storage tanks, heaters, containers, apparatus, pipelines, machinery and equipment in dairy, beverage and food industry) - after disinfection, the system is emptied and rinsed with water to remove any residues - max. application rate: 0.25 % – 2.0 % biocidal product (corresponding to 0.088 % - 0.7 % hydrogen peroxide) (description of intended use acc. to applicant´s dossier, pp. 110-111&115
Estimated transfer of residues into food	Theoretically oral exposure of consumers to residual hydrogen peroxide in food is possible. However, in clean-in-place systems the disinfection step with hydrogen peroxide is followed by flushing pipes and containers of food processing machinery with drinking water before being refilled with food. Therefore in CIP systems transfer of residual hydrogen peroxide into food is not expected. Furthermore, residual hydrogen peroxide, if present would rapidly decompose upon contact with any type of food. (see also evaluation for disinfection of water distribution systems in AR (Hydrogen Peroxide, PT1-6, eCA: FI, 2015) 2.2.1.3, p. 18; BPC-Opinion (Hydrogen Peroxide, PT4) 2.1 c), p. 7)

Conclusion on consumer exposure via residues in food	Relevant residues in food and feedstuff are not expected.

Table 60

Scenario: Surface disinfection	
Description of scenario	Disinfection of surfaces by vaporisation in food processing facilities
Application of biocidal product	- ready-to-use biocidal products - disinfection of surfaces by vaporisation in food processing facilities - max. application rate: in-use concentration of 5 % hydrogen peroxide (description of intended use acc. to applicant´s dossier, pp. 123-124
Estimated transfer of residues into food	Theoretically oral exposure of consumers to residual hydrogen peroxide in food is possible. It is assumed that food is not present during the vaporisation procedure as this may affect the quality of food items (e.g. via oxidation of fatty acids). Only after the re-entry period contact of treated surfaces with food/feed may occur. However, due to rapid degradation of hydrogen peroxide, transfer of relevant residues from treated surfaces onto food/feed items is not expected. Furthermore, residual hydrogen peroxide, if present on treated surfaces would rapidly decompose upon contact with any type of food.
Conclusion on consumer exposure via residues in food	Relevant residues in food and feedstuff are not expected.

3.6.3.2.5 Substances of concern

For meta SPCs 1 and 2 as applied for by the applicant, meta SPC 1 also appropriate for authorisation, no substances of concern (SoC) have been identified. The same is valid for meta SPC 5 as applied for by the applicant corresponding to meta SPC 2 appropriate for authorisation. For the biocidal products of meta SPCs 3 and 4 as applied for by the applicant not appropriate for authorisation used for disinfection of drinking water for animals, the following substances of concern (SoC) have to be considered:

Table 61

SPC No. as applied for	Substance(s) of concern	CAS No.	Classification	Qualitative assessment
3, 4	Orthophosphoric acid	7664-38-2	Skin Corr. 1B	Substance induces local effects like skin corrosion. It is not considered to be systemically available after dermal or oral exposure and therefore no accumulation into animal tissues is expected. Due to the low vapour pressure inhalation exposure is not relevant.
4	Sulphuric acid	7664-93-9	Skin Corr. 1A	Substance induces local effects like skin corrosion. It is not considered to be systemically available after dermal or oral exposure and therefore no accumulation into animal tissues is expected. Due to the low vapour pressure inhalation exposure is not relevant.

Conclusion

Relevant residues from SoC in livestock edible tissues are not expected.

3.6.3.2.6 Overall conclusion for dietary exposure

The products of the biocidal product family are intended to be used for animal drinking water disinfection as applied for by the applicant but not appropriate for authorisation, aseptic packaging, clean-in-place (CIP) application, and surface disinfection via vaporisation. Due to rapid degradation of hydrogen peroxide relevant residues of hydrogen peroxide in food or feed are not expected.

Similar to the CAR (Hydrogen Peroxide, PT1-6, eCA: FI, 2015) Doc IIC 12.5, p. 18) an assessment of cumulative exposure has not been performed due to the lack of guidance. Additional non-biocidal sources of consumer exposure, that should be included in a cumulative assessment, include drinking water for humans, natural hydrogen peroxide in food, and hydrogen peroxide contained in tooth and mouth care products.

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

- **Scenario**

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR.

3.6.3.4 Summary of exposure assessment

Table 62

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
Scen. 1 PT05: Disinfection of drinking water for animals – manual	Professional user	Tier 2: protective gloves, coverall (at least an apron), eye protection, automatic dosing system, chemical protective footwear (meta SPC 3 & 4)	Acceptable

Scen. 2 PT05: Disinfection of drinking water for animals – automated	Professional user	Tier 2: protective gloves, coverall (at least an apron), eye protection, chemical protective footwear (meta SPC 3 & 4)	Acceptable
Scen. 3 PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying	Professional user	Tier 2: protective gloves (product handling phase), coverall (at least an apron; product handling phase), eye protection (product handling phase), automatic dosing system, enhanced ventilation (LEV and general mechanical ventilation), product and waste water transfer in closed pipes, workplace release measurements upon implementation and at regular intervals, RPE (corrective maintenance)	Acceptable
Scen. 4 PT04: Disinfection in food and feed areas by cleaning in place (CIP)	Professional user	Tier 2: protective gloves, coverall (at least an apron), eye protection, automatic dosing system,	Acceptable
Scen. 5 PT04: Disinfection by vaporisation in food processing facilities	Professional user	Tier 2: eye protection start of the disinfection with a time delay (switch; mobile devices) or from outside (stationary devices), sealing of the room while disinfection takes place, ventilation of the room preferably with technical ventilation before re-entry, re-entry only once the air concentration has dropped below the reference value (measurement before each disinfection or establishment of a ventilation period by measurement)	Acceptable

3.6.4 Risk characterisation for human health

3.6.4.1 Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report(s) as see in 3.6.1 Assessment of effects of the active substance on human health.

3.6.4.2 Maximum residue limits or equivalent

Table 63

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)

3.6.4.3 Specific reference value for groundwater

No specific reference values for groundwater were derived.

3.6.4.4 Risk for industrial users

No industrial applications are intended.

3.6.4.5 Risk for professional users

The biocidal product family ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY PT4, PT5 originally comprises five meta SPCs as applied for by the applicant. An overview of the applications applied for the five meta SPCs is given in Table 43. All members of the biocidal product family ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY PT4, PT5 contain hydrogen peroxide (CAS No.: 7722-84-1) as active substance.

Presentation of risk assessment results for the professional user
In the following the composition of section 3.6.4.5 is outlined to provide easier access to the relevant results.

Quantitative local risk assessments for the active substance hydrogen peroxide and the substance of concern orthophosphoric acid (concentration > 10%)

Due to the absence of systemic effects after exposure to hydrogen peroxide, potential local effects of hydrogen peroxide are considered. The quantitative local risk assessment for professional users for biocidal products of meta SPC 1 - 4 as applied for by the applicant for the active substance hydrogen peroxide is covered by the risk assessment for meta SPC 2 as applied for by the applicant, while the quantitative local risk assessment for professional users for biocidal products of meta SPC 5 as applied for by the applicant for the active substance hydrogen peroxide is presented in meta SPC 5 (see Table 64).
The quantitative local risk assessment for professional users for biocidal products of meta SPC 3 as applied for by the applicant for the substance of concern orthophosphoric acid (CAS No.: 7664-38-2) is presented in meta SPC 3 (see Table 64).

Qualitative risk assessments for the active substance hydrogen peroxide and the substances of concern orthophosphoric acid and sulphuric acid

The qualitative local risk assessments for professional users for biocidal products of meta SPC 1 – 5 as applied for by the applicant for the active substance hydrogen peroxide as well as the substances of concern orthophosphoric acid and sulphuric acid (CAS No.: 7664-93-9) are presented separately in each meta SPC (see Table 64) since the classifications and/or the relevant substances of concern and/or the concentrations in application solutions and/or the intended scenarios differ between meta SPC 1, 2, 3, 4 and 5 (see Table 65) as applied for by the applicant.

Table 64: Overview of presentation of risk assessments (local-quantitative/local-qualitative) for the professional user for the active substance hydrogen peroxide and the substances of concern orthophosphoric acid and sulphuric acid for biocidal products covered by meta SPCs 1-5 as applied for by the applicant

	Quantitative local risk assessment			Qualitative local risk assessment	
Meta SPC as applied for	**Substance**	**RA presented in meta SPC?**	**Remark**	**RA presented in meta SPC?**	**Contributing substance(s)**
1	H_2O_2	Partly	2 uses covered by meta SPC 2 1 use (Aseptic packaging) assessed in meta SPC 1	Yes	H_2O_2
2	H_2O_2	Yes	Covers meta SPC 1 - 4	No (presented in meta SPC 1)	H_2O_2
3	H_2O_2	No	Covered by meta SPC 2	Yes	H_2O_2, H_3PO_4
	H_3PO_4	Yes	-		
4	H_2O_2	No	Covered by meta SPC 2	No (presented in meta SPC 3)	H_2O_2, H_3PO_4, H_2SO_4
5	H_2O_2	Yes	-	Yes	H_2O_2

RA: risk assessment; a.s.: active substance: H_2O_2: hydrogen peroxide; H_3PO_4: orthophosphoric acid; H_2SO_4: sulphuric acid

Table 65: Overview of differences in classification and/or substances of concern and/or concentrations in the application solutions and/or the intended scenarios that affect the qualitative local risk assessment for biocidal products covered by meta SPCs 1-5 as applied for by the applicant

Differences affecting qualitative local risk assessment				
Meta SPC	**Classification for concentrated b.p.**	**SoC**	**Concentration**	**Intended scenarios***
1	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT-SE 3, H335	-	100% 0.1 % - 2%	1, 2, 3, 4
2		-	100% 0.07 %	1, 2
3	Skin Corr. 1B, H314 Eye Dam. 1, H318	H_3PO_4	100% 0.1%	1, 2
4		H_3PO_4 H_2SO_4	100% 0.1%	1, 2
5	-	-	5%	5

b.p.: biocidal product; SoC: Substance of concern; H_3PO_4: orthophosphoric acid; H_2SO_4: sulphuric acid

* 1: 'PT05: Disinfection of drinking water for animals – manual'; 2: 'PT05: Disinfection of drinking water for animals – automated'; 3: 'PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying'; 4: 'PT04: Disinfection in food and feed areas by cleaning in place (CIP)'; 5: PT04: Disinfection by vaporisation in food processing facilities

Exposure of professional users to biocidal products generally takes place via the inhalation and/or dermal route and is assessed by means of external inhalation and/or dermal exposure values. The occupational risk characterisation for the biocidal product family ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY PT4, PT5 is carried out with external reference values.

3.7.4.5.1 Risk for professional users for meta SPC 1 (also appropriate for authorisation)

Details of risk characterisation for the active substance hydrogen peroxide

Reference values

For the purpose of risk characterisation resulting from inhalation exposure of professional users to hydrogen peroxide from the biocidal products covered by meta SPC 2 as applied for by the applicant, inhalation exposure to hydrogen peroxide is assessed. For this, the local reference value $AEC_{inhalative}$ (1.25 mg/m^3) of hydrogen peroxide, that covers all durations of exposure, is used as external inhalation reference value and directly compared with airborne concentrations of hydrogen peroxide.

Calculation of substance specific risk index (RI)

The substance specific risk index (RI) referring to the active substance hydrogen peroxide resulting from use of the biocidal products covered by meta SPC 2 as applied for by the applicant is determined according to the equation:

> RI = inhalation exposure to hydrogen peroxide (in mg/m^3) / $AEC_{inhalative}$ of hydrogen peroxide (in mg/m^3).

Table 66 gives a detailed overview of the local risk assessment results for inhalation route referring to the active substance hydrogen peroxide for the biocidal products covered by meta SPC 1 for the use 'PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying' as applied for by the applicant. It is noted that for clarity reasons exposure values and risk indices are rounded to two decimal places in Table 66. However, the underlying calculations are based on unrounded exposure values.

A risk for professional users referring to the active substance hydrogen peroxide resulting from the use of the biocidal products covered by meta SPC 1 as applied for by the applicant is unlikely if the risk characterisation for the scenario yields a risk index (RI) of less than 1.
Table 72 gives a detailed overview of the risk assessment results referring to the active substance hydrogen peroxide. It is noted that for clarity reasons all values are rounded to an appropriate number of decimal places in Table 72. However, the underlying calculations are based on unrounded values.

As shown in Table 72, for the scenario 'PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying (10 min STEL)' a risk for the professional user is unlikely already in Tier 1. By contrast, for the scenarios 'PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying (8 h TWA)' and 'PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying (2 min STEL, corrective maintenance)' inacceptable risks are identified after Tier 1 consideration. However, when additional risk mitigation measures are implemented a risk for the professional user is unlikely in Tier 2.The risk assessment result for the scenario shown in Table 66 is regarded as a worst case assumption for risk assessment of the respective secondary exposure. As it is assumed to be in the same order of magnitude or lower than exposure of the operator for the aforementioned scenarios.

Table 66: Overview of detailed local risk assessment results for inhalation route referring to the substance of concern hydrogen peroxide for the biocidal products covered by the use 'PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying' in meta SPC 1 as applied for by the applicant

Scenario		external inhalation		RI	Acceptable
		potential/ actual exposure mg/m³	external reference value $AEC_{inhalative}$ mg/m³		
PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying (8 h TWA)	Tier 1	3.40	1.25	2.72	no
	Tier 2	0.70	1.25	0.56	**yes**
PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying (10 min STEL)	Tier 1	0.57	1.25	0.46	**yes**
PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying (2 min STEL, corrective maintenance)	Tier 1	1.50	1.25	1.20	no
	Tier 2	assessed qualitatively see Local risks			
PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying (2 min STEL,post-application)	Tier 1	not applicable			

RI: substance specific risk index;

Conclusion

Based on the risk assessment of the active substance hydrogen peroxide via the inhalation route, a risk for professional users resulting from the intended use ('PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying') with the biocidal products covered by meta SPC 1 as applied for by the applicant regarding an 8-hour day, 10 min peak exposure and 2 min peak exposure is unlikely since the respective risk characterisation consistently yields risk indices of less than 1 at least after TIER 2 consideration or risks can be covered qualitatively . Regarding occupational safety, there are no objections against the intended uses taking into account the provisions described in chapter 2.3 of this PAR.

Local effects - quantitative

The quantitative local risk assessment for professional users for biocidal products of meta SPC 1 as applied for and appropriate for authorisation is covered by the risk assessment for the intended applications 'PT05: Disinfection of drinking water for animals – manual' and 'PT05: Disinfection of drinking water for animals – automated' as presented for biocidal products of meta SPC 2 as applied for by the applicant. For details refer to section 3.6.4.5.2 below. The risk assessment for the aforementioned two intended applications also covers the risk assessment for biocidal products of meta SPC 1 for the intended applications 'PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying' and 'PT04: Disinfection in food and feed areas by cleaning in place (CIP)' that is not presented in detail in this PAR.

Local effects – qualitative

The active substance hydrogen peroxide contributes to the classification of the biocidal products covered by meta SPC 1 applied for by the applicant and also appropriate for authorisation (with H315 (Causes skin irritation), H318 (Causes serious eye damage) and H335 (May cause respiratory irritation). Therefore a qualitative risk assessment for local effects regarding contact with the skin, eye and respiratory tract is necessary. The qualitative local risk assessment takes into account the concentrated biocidal products covered by meta SPC 1 as well as the different dilutions thereof. The Table 67 gives an overview of the relevant classifications for the qualitative local risk assessment of biocidal products covered by meta SPC 1. Furthermore, the allocated hazard category according to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2017) covered by meta SPC 1 is plotted against the respective classification.

Table 67: Relevant classification and resulting hazard categories in meta SPC 1

b.p. concen-tration (max.) in application solution [%]	Resulting classification according to Regulation (EC) No. 1272/2008	Resulting hazard category according to Guidance on the Biocidal products Regulation Volume III Human Health – Part B Risk Assessment (2017)	Contributing substances (active substance and substances of concern)
100	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT-SE 3, H335	High	Hydrogen peroxide
0.1 - 2	-	-	Hydrogen peroxide

For the concentrated biocidal products covered by meta SPC 1 local risk assessment is triggered by the corrosive properties (Eye Dam. 1, H318) as this classification is allocated to the hazard category ‘high’ (Table 67). The classification for irritative properties (Skin Irrit. 2, H315 and STOT-SE 3, H335) is allocated to the hazard category ‘low’.
For the diluted biocidal products covered by meta SPC 1 no classification is applicable and therefore no local risk assessment is triggered (Table 67).

Concluding qualitatively on the acceptability of risk, the acceptable maximum frequency and duration of potential exposure as well as potential degree of exposure for the particular hazard category is taken into account. According to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2017) the following tables are prepared to carry out the qualitative risk assessment for local effects regarding contact with the skin, eye and respiratory tract of the biocidal products covered by meta SPC 1 for the intended uses ‘PT05: Disinfection of drinking water for animals – manual’, ‘PT05: Disinfection of drinking water for animals – automated’, ‘PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying’ and ‘PT04: Disinfection in food and feed areas by cleaning in place (CIP)’. With the proposed protection measures the reduction of dermal and/or eye contact minimizes the anticipated health risk to an acceptable level for the intended uses and for secondary exposure.

Table 68: Summary of qualitative conclusions for local risk assessment for scenario 'PT05: Disinfection of drinking water for animals – manual' in meta SPC 1 (covers meta SPC 2)

Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Mixing/Loading: manual filling of b.p. into a water storage tank from which the bp is automatically dosed into the water stream	meta SPC 1: 100% (concentrate) meta SPC 2: 100% (concentrate)	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT-SE 3, H335	High	10 min/day	SKIN: Incidental contact possible EYES: Incidental contact possible RESPIRATORY SYSTEM: possible	**Technics**: - the use of automatic dosage equipment is obligatory - Sufficient ventilation or LEV **Organisation**: - Avoidance of contact with contaminated tools and objects - Regular cleaning of equipment and work area - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE**: - protective coverall (at least an apron, type 6) - protective chemical resistant gloves - chemical goggles or face shield	**YES**
Application	meta SPC 1: 0.1% meta SPC 2: 0.07%	-	-	n.a.	n.a.	n.a.	-
Post-application	meta SPC 1: 0.1% meta SPC 2: 0.07%	-	-	n.a.	n.a.	n.a.	-

Table 69: Summary of qualitative conclusions for local risk assessment for scenario 'PT05: Disinfection of drinking water for animals-automated' in meta SPC 1 (covers meta SPC 2)

Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Mixing/Loading: continuous dosing of b.p. using an automatic dosing pump (connecting transfer lines), automated dosing into water stream	meta SPC 1: 100% (concentrate) meta SPC 2: 100% (concentrate)	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT-SE 3, H335	High	10 min/day	SKIN: Incidental contact possible EYES: Incidental contact possible RESPIRATORY SYSTEM: possible	**Technics:** - use of automatic dosage equipment is foreseen - Sufficient ventilation or LEV **Organisation:** - Avoidance of contact with contaminated tools and objects - Regular cleaning of equipment and work area - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE:** - protective coverall (at least an apron, type 6) - protective chemical resistant gloves - chemical goggles or face shield	**YES**
Application	meta SPC 1: 0.1% meta SPC 2: 0.07%	-	-	n.a.	n.a.	n.a.	-
Post-application	meta SPC 1: 0.1% meta SPC 2: 0.07%	-	-	n.a.	n.a.	n.a.	-

Table 70: Summary of qualitative conclusions for local risk assessment for scenario 'PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying - manual Mixing and Loading' in meta SPC 1

Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Mixing/Loading: manual mixing and loading of product revervoir	100%	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT-SE 3, H335	High	10 min/day	SKIN: Incidental contact possible EYES: Incidental contact possible RESPIRATORY SYSTEM: possible	**Technics:** - the use of automatic dosage equipment is obligatory - use expected to be in mechanical ventilated rooms only[1)] **Organisation:** - Avoidance of contact with contaminated tools and objects - Regular cleaning of equipment and work area - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE:** - protective coverall (at least an apron, type 6) - protective chemical resistant gloves - chemical goggles or face shield	**YES**

Tasks, uses, processes	**Concentration b.p. (max.) in application solution**	**Local effects in terms of C&L**	**Hazard category**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM & PPE**	**Acceptability**
Mixing/Loading: automated mixing and loading by connecting transfers lines	100%	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT-SE 3, H335	High	10 min/day	SKIN: Incidental contact possible EYES: Incidental contact possible RESPIRATORY SYSTEM: possible	**Technics:** - use of automatic dosage equipment is foreseen - use expected to be in mechanical ventilated rooms only [1)] **Organisation:** - Avoidance of contact with contaminated tools and objects - Regular cleaning of equipment and work area - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE:** - protective coverall (at least an apron, type 6) - protective chemical resistant gloves - chemical goggles or face shield	**YES**

Tasks, uses, processes	**Concentration b.p. (max.) in application solution**	**Local effects in terms of C&L**	**Hazard category**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM & PPE**	**Acceptability**
Application: spraying/immersion in closed system	100%	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT-SE 3, H335	High	**Normal process situation:** exposure not assessed **Corrective maintenance:** incidental event	**Normal process situation:** RESPIRATORY SYSTEM: possible **Corrective maintenance:** SKIN: Incidental contact possible EYES: Incidental contact possible RESPIRATORY SYSTEM: possible	**Normal process situation:** Measures to control exposure: Technics: - Sufficient ventilation (LEV) - Containment as appropriate - Segregation of the emitting process - use expected to be in mechanical ventilated rooms only 1) **Corrective maintenance:** Measures to control exposure: Technics: - Sufficient ventilation (LEV) if possible - use expected to be in mechanical ventilated rooms only 1) Organisation: - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly PPE: - protective coverall (at least type 6) - protective chemical resistant gloves - chemical goggles - RPE (if insufficient ventilation): substance/task appropriate respirator	**YES**

Tasks, uses, processes	**Concentration b.p. (max.) in application solution**	**Local effects in terms of C&L**	**Hazard category**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM & PPE**	**Acceptability**
Post-application	100%	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT-SE 3, H335	High	negligible	negligible	-	**YES**

1) Aseptic packaging machines are expected to be positioned in a technical ventilated room. Under these conditions, it can be expected that approporiate technical ventilation is also feasable for the mixing & loading step.

Table 71: Summary of qualitative conclusions for local risk assessment for scenario 'PT04: Disinfection in food and feed areas by cleaning in place (CIP)- manual mixing and loading' in meta SPC 1

Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Mixing/Loading: manual mixing and loading of product revervoir	100%	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT-SE 3, H335	High	10 min/day	SKIN: Incidental contact possible EYES: Incidental contact possible RESPIRATORY SYSTEM: possible	Technics: - the use of automatic dosage equipment is obligatory - use expected to be in mechanical ventilated rooms only 1) Organisation: - Avoidance of contact with contaminated tools and objects - Regular cleaning of equipment and work area - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene PPE: - protective coverall (at least an apron, type 6) - protective chemical resistant gloves - chemical goggles or face shield	**YES**

Tasks, uses, processes	**Concentration b.p. (max.) in application solution**	**Local effects in terms of C&L**	**Hazard category**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM & PPE**	**Acceptability**
Mixing/Loading: automated mixing and loading by connecting transfers lines	100%	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT-SE 3, H335	High	10 min/day	SKIN: Incidental contact possible EYES: Incidental contact possible RESPIRATORY SYSTEM: possible	Technics: - use of automatic dosage equipment is foreseen - use expected to be in mechanical ventilated rooms only 1) Organisation: - Avoidance of contact with contaminated tools and objects - Regular cleaning of equipment and work area - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene PPE: - protective coverall (at least an apron, type 6) - protective chemical resistant gloves - chemical goggles or face shield	**YES**
Application: spraying/immersion in closed system	2%	-	-	n.a.	n.a.	n.a.	-
Post-application	2%	-	-	n.a.	n.a.	n.a.	-

1) Cleaning in place (CIP) are expected to be positioned in a technical ventilated room. Under these conditions, it can be expected that approporiate technical ventilation is also feasable for the mixing & loading step.

Conclusion

Concerning the irritating/corrosive properties of biocidal products covered by meta SPC 1 as applied for by the applicant exposure should be minimized with protection measures. If the proposed protection measures are implemented, the intended uses ('PT05: Disinfection of drinking water for animals – manual', 'PT05: Disinfection of drinking water for animals – automated', 'PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying' and 'PT04: Disinfection in food and feed areas by cleaning in place (CIP)') do not lead to concern for professional users.

Overall conclusion

In summary, a risk for professional users resulting from the use of the biocidal products covered by meta SPC 1 as applied for by the applicant is unlikely for the intended uses 'PT05: Disinfection of drinking water for animals – manual', 'PT05: Disinfection of drinking water for animals – automated', 'PT04: Aseptic packaging (disinfection of packaging for food products) by immersion or spraying' and 'PT04: Disinfection in food and feed areas by cleaning in place (CIP)'. Risk mitigation measures described in chapter 2.3 have to be taken into account in order to ensure safe use of the biocidal products covered by meta SPC 1 as applied for by the applicant. The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.7.4.5.2 Risk for professional users for meta SPC 2 as applied for by the applicant

General considerations

In the absence of primary systemic adverse effects of the active substance hydrogen peroxide the risk characterisation is focused on local effects. The systemic effects are considered to be secondary to the local irritation/corrosion. Therefore only external exposure limits are relevant to account for the potential local effects of hydrogen peroxide.

The occupational risk assessment for biocidal products covered by meta SPC 2 as applied for by the applicant takes into account local effects of the active substance hydrogen peroxide. The risk assessment is carried out for a concentration of 49.9 % hydrogen peroxide which is applicable for the biocidal products covered by meta SPC 2 as applied for by the applicant and therefore represents worst case for meta SPC 1 (except for the use 'Aseptic packaging') as applied for by the applicant (35.0 % hydrogen peroxide), meta SPC 3 as applied for by the applicant (20.279 % hydrogen peroxide) and meta SPC 4 as applied for by the applicant (31.78 % hydrogen peroxide).

Local effects

The local toxicity profile of the active substance hydrogen peroxide is considered. Hydrogen peroxide has irritating (and corrosive) properties (skin, eyes and respiratory tract, i.e. sites of first contact). The content of hydrogen peroxide in the formulation contributes to the classification of the biocidal products in meta SPC 2 as applied for by the applicant with H315 (Causes skin irritation), H318 (Causes serious eye damage) and H335 (May cause respiratory irritation).Therefore a qualitative risk characterisation for the professional user is performed. Since there is an $AEC_{inhalative}$ (respiratory tract irritation) for the active substance hydrogen peroxide available a quantitative risk characterisation for the professional user is also carried out. The quantitative assessment for local effects after exposure via inhalation takes into account the classification of the biocidal products covered by meta SPC 2 as applied for by the applicant with H335. Since no AECdermal for the active substance hydrogen peroxide is available a qualitative risk assessment is performed for the local dermal effects taking into account the classification of the product.

Local effects- quantitative

Details of risk characterisation for the active substance hydrogen peroxide

For consideration of reference values and the calculation of the substance specific risk index (RI) see chapter 3.6.4.5.1.

Table 72 gives a detailed overview of the local risk assessment results for inhalation route referring to the active substance hydrogen peroxide for the biocidal products covered by meta SPC 2 as applied for by the applicant. It is noted that for clarity reasons exposure values and risk indices are rounded to two decimal places in Table 72. However, the underlying calculations are based on unrounded exposure values.

A risk for professional users referring to the active substance hydrogen peroxide resulting from the use of the biocidal products covered by meta SPC 2 as applied for by the applicant is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 72, no exposure is expected in the scenarios “PT05: Disinfection of drinking water for animals – manual (8 h TWA)”, as well as “PT05: Disinfection of drinking water for animals – automated (8 h TWA)” and the scenarios “PT05: Disinfection of drinking water for animals – manual (10 min STEL)” and “PT05: Disinfection of drinking water for animals – automated (10 min STEL)” “PT05: Disinfection of drinking

water for animals – automated (10 min STEL)" and "PT05: Disinfection of drinking water for animals – automated (8 h TWA)" yield RIs of less than 1 already in TIER 1.

Risk assessment results for the scenarios that are shown in Table 72 are regarded as worst case assumptions for risk assessment of the respective secondary exposure. As mentioned in chapter 3.6.3 dermal exposure of the bystander, i.e. secondary dermal exposure, is expected to be negligible for the following scenarios: "PT05: Disinfection of drinking water for animals – manual (8 h TWA)", "PT05: Disinfection of drinking water for animals – automated (10 min STEL)" and "PT05: Disinfection of drinking water for animals – automated (8 h TWA)", "PT05: Disinfection of drinking water for animals – manual (10 min STEL)". Inhalation exposure of the bystander, i.e. secondary inhalation exposure, is assumed to be in the same order of magnitude or lower than exposure of the operator for the aforementioned scenarios.

Table 72: Overview of detailed local risk assessment results for inhalation route referring to the substance of concern hydrogen peroxide for the biocidal products covered by meta SPC 2 as applied for by the applicant

Scenario		external inhalation		RI	Acceptable
		potential/ actual exposure mg/m³	external reference value $AEC_{inhalative}$ mg/m³		
PT05: Disinfection of drinking water for animals – manual (8 h TWA)	Tier 1	not expected			**yes**
PT05: Disinfection of drinking water for animals – manual (10 min STEL)	Tier 1	0.88	1.25	0.70	**yes**
PT05: Disinfection of drinking water for animals – automated (8 h TWA)	Tier 1	not expected			**yes**
PT05: Disinfection of drinking water for animals – automated (10 min STEL)	Tier 1	0.17	1.25	0.14	**yes**

RI: substance specific risk index;

Conclusion

Based on the risk assessment of the active substance hydrogen peroxide via the inhalation route, a risk for professional users resulting from the intended uses ('PT05: Disinfection of drinking water for animals – manual (8 h TWA)', 'PT05: Disinfection of drinking water for animals – automated (10 min STEL)', 'PT05: Disinfection of drinking water for animals – automated (8 h TWA)' and 'PT05: Disinfection of drinking water for animals – manual (10 min STEL)') with the biocidal products covered by meta SPC 2 as applied for by the applicant regarding an 8-hour day and 10 min peak exposure is unlikely since no exposure is expected or the respective risk characterisation consistently yields risk indices of less than 1 already at

least after TIER 1 consideration. Regarding occupational safety, there are no objections against the intended uses taking into account the provisions described in chapter 2.3 of this PAR.

Local effects – qualitative

The local toxicity profile of the active substance hydrogen peroxide is considered.
Qualitative local risk characterisation

The active substance hydrogen peroxide contributes to the classification of the biocidal products covered by meta SPC 2 as applied for by the applicant with H315 (Causes skin irritation), H318 (Causes serious eye damage) and H335 (May cause respiratory irritation). Therefore a qualitative risk assessment for local effects regarding contact with the skin, eye and respiratory tract is necessary. The qualitative local risk assessment takes into account the concentrated biocidal products covered by meta SPC 2 as applied for by the applicant as well as the different dilutions thereof. The Table 73 gives an overview of the relevant classifications for the qualitative local risk assessment of biocidal products covered by meta SPC 2 as applied for by the applicant. Furthermore, the allocated hazard categories according to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2017) covered by meta SPC 2 as applied for by the applicant are plotted against the respective classification.

Table 73: Relevant classification and resulting hazard categories in meta SPC 2 as applied for by the applicant

b.p. concen-tration (max.) in application solution [%]	Resulting classification according to Regulation (EC) No. 1272/2008	Resulting hazard category according to Guidance on the Biocidal products Regulation Volume III Human Health – Part B Risk Assessment (2017)	Contributing substances (active substance and substances of concern)
100	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT-SE 3, H335	High	Hydrogen peroxide
0.07	-	-	Hydrogen peroxide

For the concentrated biocidal products covered by meta SPC 2 as applied for by the applicant local risk assessment is triggered by the corrosive properties (Eye Dam. 1, H318) as this classification is allocated to the hazard category ‘high’ (Table 73). The classification for irritative properties (Skin Irrit. 2, H315 and STOT-SE 3, H335) is allocated to the hazard category ‘low’.
For the diluted biocidal products covered by meta SPC 2 as applied for by the applicant no classification is applicable and therefore no local risk assessment is triggered (Table 73).

Concluding qualitatively on the acceptability of risk, the acceptable maximum frequency and duration of potential exposure as well as potential degree of exposure for the particular hazard category is taken into account. According to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2017) the tables as presented in meta SPC 1 are prepared to carry out the qualitative risk assessment for local effects regarding contact with the skin, eye and respiratory tract of the biocidal products covered by meta SPC 2 as applied for by the applicant for the intended uses ‘PT05: Disinfection of drinking water for animals – manual’, ‘PT05: Disinfection of drinking water for animals – automated’. With the proposed protection measures the reduction of dermal and/or eye contact minimizes the anticipated health risk to an acceptable level for the intended uses and for secondary exposure.

Conclusion

Concerning the irritating/corrosive properties of biocidal products covered by meta SPC 2 as applied for by the applicant exposure should be minimized with protection measures. If the proposed protection measures are implemented, the intended uses (‘PT05: Disinfection of drinking water for animals – manual’, ‘PT05: Disinfection of drinking water for animals – automated’) do not lead to concern for professional users.

Overall conclusion

In summary, a risk for professional users resulting from the use of the biocidal products covered by meta SPC 2 as applied for by the applicant is unlikely for the intended uses ‘PT05: Disinfection of drinking water for animals – manual’, ‘PT05: Disinfection of drinking water for animals – automated’. Risk mitigation measures described in chapter 2.3 have to be taken into account in order to ensure safe use of the biocidal products covered by meta SPC 2 as applied for by the applicant. The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.7.4.5.3 Risk for professional users for meta SPC 3 as applied for by the applicant

General considerations

The following substance is identified as substance of concern regarding biocidal products covered by meta SPC 3 as applied for by the applicant based on classification with H314 (Causes severe skin burns and eye damage): orthophosphoric acid (CAS No.: 7664-38-2).

The occupational risk assessment for biocidal products covered by meta SPC 3 as applied for by the applicant takes into account local effects of the active substance hydrogen peroxide as well as local effects of the substance of concern orthophosphoric acid.

Local effects - quantitative

Details of risk characterisation for the active substance hydrogen peroxide

The risk assessment for professional users for biocidal products of meta SPC 3 as applied for by the applicant is covered by the risk assessment for the intended applications 'PT05: Disinfection of drinking water for animals – manual' and 'PT05: Disinfection of drinking water for animals – automated' as presented in section 3.6.4.5.2 for biocidal products of meta SPC 2 as applied for by the applicant. For details refer to this section.

Details of risk characterisation for the substance of concern orthophosphoric acid

For the substance of concern orthophosphoric acid local irritation is considered as critical effect with respect to inhalation exposure. A quantitative risk characterisation for professional users is carried out since there is an Indicative Occupational Exposure Limit Value (IOELV) and furthermore a German OEL for orthophosphoric acid available. Additionally the substance of concern fulfils German criteria (OEL + relevant classification + >10 % concentration) set for consideration of a full quantitative occupational risk characterisation for inhalation exposure.

Reference values

For the purpose of risk characterisation resulting from inhalation exposure of professional users to orthophosphoric acid from the biocidal products covered by meta SPC 3 as applied for by the applicant, inhalation exposure to orthophosphoric acid is assessed. For this, the German OEL (2 mg/m³ (8 h TWA) and 4 mg/m³ (15 min STEL)) for aerosol of orthophosphoric acid is used as external inhalation reference value and directly compared with airborne concentrations of orthophosphoric acid. Since no dermal reference value for the substance of concern orthophosphoric acid is available a qualitative risk assessment is performed for the local dermal effects taking into account the classification of the product.

Calculation of substance specific risk index (RI)

The substance specific risk index (RI) referring to the substance of concern orthophosphoric acid resulting from use of the biocidal products covered by meta SPC 3 as applied for by the applicant is determined according to the equation:

RI = inhalation exposure to orthophosphoric acid (in mg/m³) / German OEL of orthophosphoric acid (in mg/m³).

gives a detailed overview of the local risk assessment results for inhalation route referring to the substance of concern orthophosphoric acid for the biocidal products covered by meta SPC 3 as applied for by the applicant. It is noted that for clarity reasons exposure values and risk indices are rounded to two decimal places in. However, the underlying calculations are based on unrounded exposure values.

A risk for professional users referring to the substance of concern orthophosphoric acid resulting from the use of the biocidal products covered by meta SPC 3 as applied for by the applicant is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in **Table 74** no exposure is expected in the scenarios 'PT05: Disinfection of drinking water for animals – manual (8 h TWA)', as well as 'PT05: Disinfection of drinking water for animals – automated (8 h TWA)' and the scenarios 'PT05: Disinfection of drinking water for animals – manual (10 min STEL)', 'PT05: Disinfection of drinking water for animals – automated (8 h TWA)' and 'PT05: Disinfection of drinking water for animals – automated (10 min STEL)' yield RIs of far less than 1 after TIER 1 consideration.

Risk assessment results for the scenarios that are shown in **Table 74** are regarded as worst case assumptions for risk assessment of the respective secondary exposure. As mentioned in chapter 3.6.3 dermal exposure of the bystander, i.e. secondary dermal exposure, is expected to be negligible for the following scenarios: 'PT05: Disinfection of drinking water for animals – manual (8 h TWA)', 'PT05: Disinfection of drinking water for animals – manual (10 min STEL)', 'PT05: Disinfection of drinking water for animals – automated (8 h TWA)' and 'PT05: Disinfection of drinking water for animals – automated (10 min STEL) '. Inhalation exposure of the bystander, i.e. secondary inhalation exposure, is assumed to be in the same order of magnitude or lower than exposure of the operator for the aforementioned scenarios.

Table 74: Overview of detailed local risk assessment results for inhalation route referring to the substance of concern orthophosphoric acid for the biocidal products covered by meta SPC 3 as applied for by the applicant

Scenario		external inhalation		RI	Acceptable
		potential/ actual exposure mg/m³	OEL mg/m³		(yes/no)
PT05: Disinfection of drinking water for animals – manual (8 h TWA)	Tier 1	not expected			**yes**
PT05: Disinfection of drinking water for animals – manual (10 min STEL)	Tier 1	2.20×10^{-3}	4	5.50×10^{-4}	**yes**
PT05: Disinfection of drinking water for animals – automated (8 h TWA)	Tier 1	Not expected			**yes**
PT05: Disinfection of drinking water for animals – automated (10 min STEL)	Tier 1	5.50×10^{-4}	4	1.38×10^{-4}	**yes**

RI: substance specific risk index

Conclusion

Based on the risk assessment of the substance of concern orthophosphoric acid via the inhalation route, a risk for professional users resulting from the intended uses ('PT05: Disinfection of drinking water for animals – manual (8 h TWA)', 'PT05: Disinfection of drinking water for animals – manual (10 min STEL)', 'PT05: Disinfection of drinking water for animals – automated (8 h TWA)', 'PT05: Disinfection of drinking water for animals – automated (10 min STEL)') with the biocidal products of the biocidal family ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY PT4, PT5 regarding an 8-hour day and 10 min peak exposure as well as from secondary exposure of the bystander is unlikely since no exposure is expected or the respective risk characterisation yields risk indices of less than 1 already after TIER 1 consideration. The risk characterisation shows that the German OEL and German short-term OEL of orthophosphoric acid can be met.

Local effects – qualitative

The local toxicity profiles of the active substance hydrogen peroxide as well as the substance of concern orthophosphoric acid are considered.

Qualitative local risk characterisation

The active substance hydrogen peroxide as well as the substance of concern orthophosphoric acid contribute to the classification of the biocidal products covered by meta SPC 3 as applied for by the applicant with H314 *(*Causes severe skin burns and eye damage) and H318 (Causes serious eye damage). Therefore a qualitative risk assessment for local effects regarding contact with the skin, eye and respiratory tract is necessary. The qualitative local risk assessment takes into account the concentrated biocidal products covered by meta SPC 3 as applied for by the applicant as well as the different dilutions thereof. The Table 75 gives an overview of the relevant classifications for the qualitative local risk assessment of biocidal products covered by meta SPC 3 as applied for by the applicant. Furthermore, the allocated hazard categories according to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2017) covered by meta SPC 3 as applied for by the applicant are plotted against the respective classification.

Table 75: Relevant classification and resulting hazard categories in meta SPC 3 as applied for by the applicant

b.p. concen-tration (max.) in application solution [%]	Resulting classification according to Regulation (EC) No. 1272/2008	Resulting hazard category according to Guidance on the Biocidal products Regulation Volume III Human Health – Part B Risk Assessment (2017)	Contributing substances (active substance and substances of concern)
100	Skin Corr. 1B, H314 Eye Dam. 1, H318	High	Hydrogen peroxide Orthophosphoric acid
0.1	-	-	Hydrogen peroxide Orthophosphoric acid

For the concentrated biocidal products covered by meta SPC 3 as applied for by the applicant local risk assessment is triggered by the corrosive properties (Skin Corr. 1B, H314 and Eye Dam. 1, H318) as this classification is allocated to the hazard category ‘high’ (Table 75).
For the diluted biocidal products covered by meta SPC 3 as applied for by the applicant no classification is applicable and therefore no local risk assessment is triggered (Table 75).

Concluding qualitatively on the acceptability of risk, the acceptable maximum frequency and duration of potential exposure as well as potential degree of exposure for the particular hazard category is taken into account. According to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2017) the following tables are prepared to carry out the qualitative risk

assessment for local effects regarding contact with the skin, eye and respiratory tract of the biocidal products covered by meta SPC 3 as applied for by the applicant for the intended uses ‘PT05: Disinfection of drinking water for animals – manual’, ‘PT05: Disinfection of drinking water for animals – automated’. With the proposed protection measures the reduction of dermal and/or eye contact minimizes the anticipated health risk to an acceptable level for the intended uses and for secondary exposure.

Table 76: Summary of qualitative conclusions for local risk assessment for scenario 'PT05: Disinfection of drinking water for animals – manual' in meta SPC 3 as applied for by the applicant (covers meta SPC 4)

Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Mixing/Loading: manual filling of b.p. into a water storage tank from which the bp is automatically dosed into the water stream	meta SPC 3: 100% (concentrate) meta SPC 4: 100 % (concentrate)	SkinCorr. 1B, H314 Eye Dam. 1, H318	High	10 min/day	SKIN: Incidental contact possible EYES: Incidental contact possible RESPIRATORY SYSTEM: possible	**Technics:** - the use of automatic dosage equipment is obligatory - Sufficient ventilation or LEV **Organisation:** - Avoidance of contact with contaminated tools and objects - Regular cleaning of equipment and work area - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE:** - protective coverall (at least an apron, type 6) - protective chemical resistant gloves - chemical goggles or face shield - protective footwear	**YES**
Application	meta SPC 3: 0.1% meta SPC 4: 0.1%	-	-	n.a.	n.a.	n.a.	-
Post-application	meta SPC 3: 0.1%	-	-	n.a.	n.a.	n.a.	-

	meta SPC 4: 0.1%						

Table 77: Summary of qualitative conclusions for local risk assessment for scenario 'PT05: Disinfection of drinking water for animals-automated' in meta SPC 3 as applied for by the applicant (covers meta SPC 4)

Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Mixing/Loading: continuous dosing of b.p. using an automatic dosing pump (connecting transfer lines), automated dosing into water stream	meta SPC 3: 100% (concentrate) meta SPC 4: 100 % (concentrate)	SkinCorr. 1B, H314 Eye Dam. 1, H318	High	10 min/day	SKIN: Incidental contact possible EYES: Incidental contact possible RESPIRATORY SYSTEM: possible	**Technics:** - use of automatic dosage equipment is foreseen - Sufficient ventilation or LEV **Organisation:** - Avoidance of contact with contaminated tools and objects - Regular cleaning of equipment and work area - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE:** - protective coverall (at least an apron, type 6) - protective chemical resistant gloves - chemical goggles or face shield - protective footwear	**YES**
Application	meta SPC 3: 0.1% meta SPC 4: 0.1%	-	-	n.a.	n.a.	n.a.	-
Post-application	meta SPC 3: 0.1% meta SPC 4: 0.1%	-	-	n.a.	n.a.	n.a.	-

Conclusion

Concerning the irritating/corrosive properties of biocidal products covered by meta SPC 3 as applied for by the applicant exposure should be minimized with protection measures. If the proposed protection measures are implemented, the intended uses ('PT05: Disinfection of drinking water for animals – manual', 'PT05: Disinfection of drinking water for animals – automated') do not lead to concern for professional users.

Overall conclusion

In summary, a risk for professional users resulting from the use of the biocidal products covered by meta SPC 3 as applied for by the applicant is unlikely for the intended uses 'PT05: Disinfection of drinking water for animals – manual', 'PT05: Disinfection of drinking water for animals – automated'. Risk mitigation measures described in chapter 2.3 have to be taken into account in order to ensure safe use of the biocidal products covered by meta SPC 3 as applied for by the applicant. The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.7.4.5.4 Risk for professional users for meta SPC 4 as applied for by the applicant

General considerations

The following substances are identified as substances of concern regarding biocidal products covered by meta SPC 4 as applied for by the applicant based on classification with H314 (Causes severe skin burns and eye damage): orthophosphoric acid and sulphuric acid.

The occupational risk assessment for biocidal products covered by meta SPC 4 as applied for by the applicant takes into account local effects of the active substance hydrogen peroxide as well as local effects of the substances of concern.

Local effects- quantitative

Details of risk characterisation for the active substance hydrogen peroxide

The risk assessment for professional users for biocidal products of meta SPC 4 as applied for by the applicant is covered by the risk assessment for the intended applications 'PT05: Disinfection of drinking

water for animals – manual' and 'PT05: Disinfection of drinking water for animals – automated' as presented in section 3.6.4.5.2 for biocidal products of meta SPC 2 as applied for by the applicant. For details refer to this section.

Details of risk characterisation for the substances of concern orthophosphoric acid and sulphuric acid

No quantitative risk characterisation for professional users is carried out although there are Indicative Occupational Exposure Limit Values (IOELV) and furthermore German OELs for orthophosphoric acid and sulphuric acid available. Justification: The substances of concern do not fulfil German criteria (OEL + relevant classification + > 10% concentration) set for consideration of a full quantitative occupational risk characterisation for inhalation exposure.

Local effects – qualitative

The local toxicity profiles of the active substance hydrogen peroxide as well as the substances of concern orthophosphoric acid and sulphuric acid are considered.

Qualitative local risk characterisation

The active substance hydrogen peroxide as well as the substances of concern orthophosphoric acid and sulfuric acid contribute to the classification of the biocidal products covered by meta SPC 4 as applied for by the applicant with H314 *(*Causes severe skin burns and eye damage) and H318 (Causes serious eye damage). Therefore a qualitative risk assessment for local effects regarding contact with the skin, eye and respiratory tract is necessary. The qualitative local risk assessment takes into account the concentrated biocidal products covered by meta SPC 4 as applied for by the applicant as well as the different dilutions thereof. The Table 78 gives an overview of the relevant classifications for the qualitative local risk assessment of biocidal products covered by meta SPC 4 as applied for by the applicant. Furthermore, the allocated hazard category according to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2017) covered by meta SPC 4 as applied for by the applicant is plotted against the respective classification.

Table 78: Relevant classification and resulting hazard categories in meta SPC 4 as applied for by the applicant

b.p. concen-tration (max.) in application solution [%]	Resulting classification according to Regulation (EC) No. 1272/2008	Resulting hazard category according to Guidance on the Biocidal products Regulation Volume III Human Health – Part B Risk Assessment (2017)	Contributing substances (active substance and substances of concern)
100	SkinCorr. 1B, H314 Eye Dam. 1, H318	High	Hydrogen peroxide Orthophosphoric acid Sulphuric acid
0.1	-	-	Hydrogen peroxide Orthophosphoric acid Sulphuric acid

For the concentrated biocidal products covered by meta SPC 4 as applied for by the applicant local risk assessment is triggered by the corrosive properties (Skin Corr. 1B, H314 and Eye Dam. 1, H318) as this classification is allocated to the hazard category 'high' (Table 78).
For the diluted biocidal products covered by meta SPC 4 as applied for by the applicant no classification is applicable and therefore no local risk assessment is triggered (Table 78).

Concluding qualitatively on the acceptability of risk, the acceptable maximum frequency and duration of potential exposure as well as potential degree of exposure for the particular hazard category is taken into account. According to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2017) the tables as presented in meta SPC 3 are prepared to carry out the qualitative risk assessment for local effects regarding contact with the skin, eye and respiratory tract of the biocidal products covered by meta SPC 4 as applied for by the applicant for the intended uses 'PT05: Disinfection of drinking water for animals – manual', 'PT05: Disinfection of drinking water for animals – automated'. With the proposed protection measures the reduction of dermal and/or eye contact minimizes the anticipated health risk to an acceptable level for the intended uses and for secondary exposure.

Conclusion

Concerning the irritating/corrosive properties of biocidal products covered by meta SPC 4 as applied for by the applicant exposure should be minimized with protection measures. If the proposed protection measures are implemented, the intended uses ('PT05: Disinfection of drinking water for animals – manual', 'PT05: Disinfection of drinking water for animals – automated') do not lead to concern for professional users.

Overall conclusion

In summary, a risk for professional users resulting from the use of the biocidal products covered by meta SPC 4 as applied for by the applicant is unlikely for the intended uses 'PT05: Disinfection of drinking water for animals – manual', 'PT05: Disinfection of drinking water for animals – automated'. Risk mitigation measures described in chapter 2.3 have to be taken into account in order to ensure safe use of the biocidal products covered by meta SPC 4 as applied for by the applicant. The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.7.4.5.5 Risk for professional users for meta SPC 5 as applied for by the applicant

General considerations
In the absence of primary systemic adverse effects the risk characterisation is focused on local effects. The systemic effects are considered to be secondary to the local irritation/corrosion. Therefore only external exposure limits are relevant to account for the potential local effects of hydrogen peroxide.

The occupational risk assessment for biocidal products covered by meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation takes into account local effects of the active substance hydrogen peroxide.

Local effects

The local toxicity profile of the active substance hydrogen peroxide is considered. Hydrogen peroxide has irritating (and corrosive) properties (skin, eyes and respiratory tract, i.e. sites of first contact). The content of the formulation contributes to the classification of the biocidal products in meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation with H319 (Causes serious eye irritation). Therefore a qualitative risk characterisation for the professional user is performed. Since there is an $AEC_{inhalative}$ (respiratory tract irritation) for the active substance hydrogen peroxide available a quantitative risk characterisation for the professional user is also carried out. Since no AECdermal for the active substance hydrogen peroxide is available a qualitative risk assessment is performed for the local dermal effects taking into account the classification of the product.

Local effects- quantitative

Details of risk characterisation for the active substance hydrogen peroxide

For consideration of reference values and the calculation of the substance specific risk index (RI) see chapter 3.6.4.5.1.

Table 79 gives a detailed overview of the local risk assessment results for inhalation route referring to the active substance hydrogen peroxide for the biocidal products covered by meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation. It is noted that for clarity reasons exposure values and risk indices are rounded to two decimal places in Table 79. However, the underlying calculations are based on unrounded exposure values.

A risk for professional users referring to the active substance hydrogen peroxide resulting from the use of the biocidal products covered by meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 79, for the scenario “PT04: Disinfection by vaporisation in food processing facilities (8 h TWA)” no exposure is expected, the scenario “PT04: Disinfection by vaporisation in food processing facilities (10 min STEL)” yields RIs of less than 1 already in TIER 1 while the scenario “PT04: Disinfection by vaporisation in food processing facilities (post application, re-entry) is assessed qualitatively.

Table 79: Overview of detailed local risk assessment results for inhalation route referring to the substance of concern hydrogen peroxide for the biocidal products covered by meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation

Scenario		**external inhalation**		**RI**	**Acceptable**
		potential/ actual exposure mg/m³	**external reference value $AEC_{inhalative}$** mg/m³		
PT04: Disinfection by vaporisation in food processing facilities (8 h TWA)	Tier 1	Not expected			**yes**
PT04: Disinfection by vaporisation in food processing facilities (10 min STEL)	Tier 1	0,07	1,25	0,06	**yes**
PT04: Disinfection by vaporisation in food processing facilities (post-application, re-entry)		Assessed qualitatively			**yes**

RI: substance specific risk index

Conclusion

Based on the risk assessment of the active substance hydrogen peroxide via the inhalation route, a risk for professional users resulting from the intended uses (“PT04: Disinfection by vaporisation in food processing facilities (8 h TWA)”, “PT04: Disinfection by vaporisation in food processing facilities (10 min STEL)”) and “PT04: Disinfection by vaporisation in food processing facilities (post-application, re-entry)” with the biocidal products covered by meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation regarding an 8-hour day, 10 min peak exposure and re-entry after application is unlikely since no exposure is expected, the respective risk characterisation consistently yields risk indices of less than 1 already after TIER 1 consideration or the risk is assessed qualitatively. Regarding occupational safety, there are no objections against the intended uses taking into account the provisions described in chapter 2.3 of this PAR.

Local effects – qualitative

The local toxicity profiles of the active substance hydrogen peroxide is considered. This substance contributes to the classification of the biocidal products covered by meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation with H319 (Causes eye irritation).

Qualitative local risk characterisation

The active substance hydrogen peroxide contributes to the classification of the biocidal products covered by meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation with H319 (Causes eye irritation). Therefore a qualitative risk assessment for local effects regarding eye contact is necessary. The qualitative local risk assessment takes into account the ready-to-use (rtu) biocidal products covered by meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation. The Table 80 gives an overview of the relevant classifications for the qualitative local risk assessment of biocidal products covered by meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation. Furthermore, the allocated hazard categories according to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2017) are plotted against the respective classification.

Table 80: Relevant classification and resulting hazard categories (meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation)

b.p. concentration (max.) in application solution [%]	Resulting classification according to Regulation (EC) No. 1272/2008	Resulting hazard category according to Guidance on the Biocidal products Regulation Volume III Human Health – Part B Risk Assessment (2017)	Contributing substances (active substance and substances of concern)
5	Eye Irrit. 2, H319	Low	Hydrogen peroxide

For the rtu biocidal products covered by meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation local risk assessment is triggered by irritation to the eyes (Eye Irrit. 2, H319) as this classification is allocated to the hazard category “low” (Table 80).

Concluding qualitatively on the acceptability of risk, the acceptable maximum frequency and duration of potential exposure as well as potential degree of exposure for the particular hazard category is taken into account. According to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2017) the following table is prepared to carry out the qualitative risk assessment for local effects regarding eye contact of the biocidal products covered by meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation for the intended use PT04: Disinfection by vaporisation in food processing facilities (Table 80). With the proposed protection measures the reduction of dermal and/or eye contact minimizes the anticipated health risk to an acceptable level for the intended use.

Table 81: Summary of qualitative conclusions for local risk assessment for scenario 'PT04: Disinfection by vaporisation in food processing facilities' in meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation

Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptable
Mixing/Loading: manual mixing and loading of product revervoir or automated loading by connecting transfers lines; product is automatically pumped into the circuit of the fogger	5%	Eye Irrit. 2, H319	Low	10 min/day	SKIN: Incidental contact possible EYES: Incidental contact possible	**Technics**: - Minimisation of splashes and spills (if manual: the use of a dosage device is recommended) **Organisation**: - Avoidance of contact with contaminated tools and objects - Regular cleaning of equipment and work area - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE**: - chemical goggles	**YES**

Application	5%	Eye Irrit. 2, H319	Low	exposure not expected	no exposure since sealed room and entry not permitted	-	**YES**
Post-application	5%	Eye Irrit. 2, H319	Low	negligible	negligible	-	**YES**

Conclusion

Concerning the irritating properties of biocidal products covered by meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation, exposure should be minimized with protection measures. If the proposed protection measures are implemented, the intended use 'PT04: Disinfection by vaporisation in food processing facilities' does not lead to concern for professional users.

Overall conclusion

In summary, a risk for professional users resulting from the use of the biocidal products covered by meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation is unlikely for the intended use 'PT04: Disinfection by vaporisation in food processing facilities'. Risk mitigation measures described in chapter 2.3 have to be taken into account in order to ensure safe use of the biocidal products covered by meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation.
The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.6.4.6 Risk for non-professional users

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

3.6.4.7 Risk for the general public

Not relevant. Exposure of the general public to the biocidal products of this family is not expected.

3.6.4.8 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. .animal drinking water disinfection as applied for by the applicant but not appropriate for authorisation, aseptic packaging, clean-in-place (CIP) application, and surface disinfection via vaporisation).

3.6.4.9 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 in Meta SPC 1, 2 and 5 is not required as the products contain only the active substance hydrogen peroxide and no SoC.

For MetaSPC 3 and MetaSPC4 a risk assessment including the mixture toxiciy of the active substance hydrogen peroxide and substances of concern orthophosphoric acid (in MetaSPC 3 and 4) and sulphuric acid (in MetaSPC4) is not applicable according to the Guidance Volume III Human Health - Assessment & Evaluation (Parts B+C) (Version 4). The methodology of cumulative risk assessment can be applied only in order to assess systemic effects. Since the active substance as well as the substances of concern are not systemically available the risk charakterisation from combined exposure to the active substance and substances of concern is not applicable.

3.6.4.10 Summary of risk characterisation

3.6.4.10.1 Summary of risk characterisation for industrial user

No industrial applications are intended.

3.6.4.10.2 Summary of risk characterisation for professional user

For summary of the quantitative risk characterisation of the a.s. for professional user please refer to Table 72 (summary of scenario 1-4 in meta SPC 1-4 as applied for by the applicant) and to Table 79 (summary of scenario 5 in meta SPC 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation). For summary of the quantitative risk characterisation of the SoC orthophosphoric acid for the professional user please refer to

Table **74** (summary of scenarios 1 and 2 in meta SPC 3 as applied for by the applicant).
In summary, a risk for professional users resulting from the use of the biocidal product family is unlikely for the intended uses in meta SPC 1-5 as applied for by the applicant. Risk mitigation measures described in chapter 2.3 have to be taken into account in order to ensure safe use of the biocidal product family.
The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.6.4.10.3 Summary of risk characterisation for non-professional user

Not relevant.

3.6.4.10.4 Summary of risk characterisation for indirect exposure

Not relevant.

3.7 Risk assessment for animal health[8]

As the biocidal products of this family are applied only indoors in food-processing facilities, exposure of animals is not expected. Particularly pets have no access to such areas for hygenic reasons. Use as animal drinking water disinfectant was not authorised.

8 Pets and domestic animals.

3.8 Risk assessment for the environment

3.8.1 General information

The biocidal product family ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS for use in PT 4 and 5 contains the active substance hydrogen peroxide at a maximum content of 49.9 % (w/w). No substances of concern were identified. No ecotoxicological studies were submitted for the products, the environmental risk assessment is thus based on data from the active substance AR (FI, 2015).

3.8.2 Effects assessment

Effect data is taken from the active substance AR (FI, 2015).

3.8.2.1 Mixture toxicity

Screening step

- **Screening Step 1:**

For the uses in PT4, exposure of environmental compartments via STP is likely. Consequently, risk assessment is required for STP, surface water as receiving compartment of STP run off and soil as receiving compartment after application of STP sludge. For detailed information please also see the explanations in chapter 3.8.4.2.

- **Screening Step 2:**

The products contain only one active substance and no substances of concern with regard to the environment. The SoCs identified in the risk assessment for human health are not classified as hazardous for the environment and thus are not considered here. Therefore, mixture toxicity assessment is not required.

- **Screening Step 3: Screen on synergistic interactions**

Not required.

Table 82

Screening step	
Y	Significant exposure of environmental compartments? (Y/N)
N	Number of relevant substances >1? (Y/N)

Screening step	
	Indication for synergistic effects for the product or its constituents in the literature not required.

3.8.2.2 Aquatic compartment (including sediment and STP)

- **Acute aquatic toxicity**

No new data was provided for the product authorisation.
PNECaqua as derived in the active substance AR (FI, 2015) for H_2O_2 is **0.0126 mg/L**. As hydrogen peroxide does not partition from the water phase, adsorption to sediment is negligible. PNECsed was consequently not derived.

- **Inhibition of microbial activity (STP)**

The effect of hydrogen peroxide on aerobic biological sewage treatment processes was assessed according to OECD 209 by determining respiration inhibition of the micro-organisms present in activated sludge following 0.5 and 3 hours contact. The EC_{50} values were determined to be 466 mg/L after 0.5 h and >1000 mg/L after 3 h based on nominal concentrations. For the risk assessment the EC_{50} value after 0.5 h contact time is used. Applying an assessment factor of 100 to the EC_{50} of the respiration inhibition test a **$PNEC_{STP}$ of 4.66 mg a.s./L** was derived.

3.8.2.3 Terrestrial compartment (including groundwater)

No new data was provided for the product authorisation.
PNECsoil as derived in the active substance AR (FI, 2015) for H_2O_2 is **0.0018 mg/kg wwt** based on EPM.

Contamination of groundwater
According to BPR Annex VI, point 68, the reference value for groundwater is 0.1 µg/L.

3.8.2.4 Atmosphere

Hydrogen peroxide is present at natural background concentrations of 0.14 to 10 µg/m³ in the atmosphere, according to evaluation in the active substance AR (FI, 2015). Emissions from the proposed use are considered negligible.

3.8.2.5 Non-compartment specific effects

The estimated log Kow for hydrogen peroxide is as low as -1.57 and calculated BCF values are 1.4 for fish and 0.84 for earthworm according to the active substance AR (FI, 2015). Hence, bioconcentration in biota is considered negligible.

3.8.2.6 Summary of effects assessment

In Table 83 the PNEC values for environmental compartments, which need to be considered for environmental risk assessment of ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY, are summarised. Please note that seawater and sea sediment are not assumed to be receiving compartments for hydrogen peroxide from the uses proposed for ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCTS FAMILY and thus environmental risk assessment was not carried out for the marine environment.

Table 83

Summary table on calculated PNEC values	
Compartment	**PNEC**
aquatic	0.0126 mg/L
soil	0.0018 mg/kg wwt
STP	4.66 mg/L

3.8.3 Fate and behaviour

According to AR (FI, 2015), hydrogen peroxide decomposes rapidly in different environment 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 ($2\ H_2O_2 \rightarrow 2\ H_2O + O_2$). The rate of this reaction depends on the contact with catalytic materials and other factors such as heat and sunlight.

Standard ready biodegradability test are not suitable for inorganic substances. Nevertheless, hydrogen peroxide shows a very rapid degradation with organic matter in sewage sludge (DT_{50} = 2 min, 20° C). Rapid degradation of hydrogen peroxide has also been observed in surface water and soil compartments. This degradation has been considered to be mainly microbial derived based on the difference in degradation rates between the natural and filtered/sterilised 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 measured/estimated representative half-lives for different environmental compartments are shown in Table 84.

Table 84

Summary table on half-lives of hydrogen peroxide			
Compartment	**DT50 measured/ estimated in tests**	**Remarks**	**Reference**
Sewage sludge	2 min	Measured at 20° C	AR
Raw sewage, manure	6 min	Measured at 20° C	CAR
Surface water	5 days	Estimated (an extreme worst case DT_{50} estimate to take account for unfavourable conditions)	AR
Soil	12 hrs	Estimated (worst case DT_{50} estimate vased in literature sources)	AR
Air	24 hrs	Estimated (worst case DT_{50} estimate vased in literature sources)	AR

The low measured value of Henry's law constant ($H = 7.5 \times 10^{-4}$ Pa.m³/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 estimated log K_{OC} is 0.2036 (QSAR), it is expected that hydrogen peroxide has a low potential for adsorption to soil and for partitioning to suspended matter or sediment.

3.8.4 Exposure assessment

3.8.4.1 General information

The Anti-Germ hydrogen peroxide based disinfectants product family is used in product type 4 (meta SPC 1 & 5 as applied for by the applicant) for disinfection in food and feed area and product type 5 (meta SPC 1-4 as applied for by the applicant) for disinfection of animal drinking water. The products within the BPF have an a.s. content of 5 - 49.9 % (w/w).

Table 85

Assessed PT	PT 4
Assessed scenarios	Scenario 4a: Aseptic packaging (ASP) Scenario 4b: Cleaning in place (CIP) Scenario 4c: Disinfection of surfaces by vaporisation (VHP)
ESD(s) used	Emission Scenario Document for Product Type 4, Disinfectants used in food and feed areas, JRC 2011 Technical Agreements for Biocides (TAB) – ENV v. 2.0 (August, 2018)
Approach	Scenario 4a: consumption based Scenario 4b: consumption based Scenario 4c: consumption based
Distribution in the environment	Calculated based on Guidance BPR IV ENV B + C (2017)
Groundwater simulation	No higher tier model was performed
Confidential Annexes	No
Life cycle steps assessed	Scenario 4a-4c: Production: No Formulation No Use: Yes Service life: No
Remarks	

Table 86 Intended uses in PT 5

Assessed PT	PT 5
Assessed scenarios	Scenario 5a: Automatic pumping for continuous treatment and direct use of the water Scenario 5b: Automatic pumping for continuous treatment for storage of treated water in a buffer tank

	Scenario 5c: Automatic dosing of a diluted solution to be introduced in a buffer tank Scenario 5d: Manual dosing of a diluted solution to be introduced in a buffer tank
ESD(s) used	Emission Scenario Document for Product Type 5: drinking water disinfectants, August 2003 Emission Scenario Document for Product Type 18, No. 14: insecticides for stables and manure storage systems
Approach	All intended uses: Qualitative assessment
Distribution in the environment	No calculations were performed due to qualitative assessment
Groundwater simulation	No higher tier model was performed
Confidential Annexes	No
Life cycle steps assessed	All intended uses: Production: No Formulation: No Use: Yes Service life: No
Remarks	

3.8.4.2 Fate and distribution in exposed environmental compartments

3.8.4.2.1 Environmental Exposure Assessment of PT 4

The biocidal products within meta SPCs 1 and 5 as applied for by the applicant used as disinfectant of antiseptic packaging, CIP (cleaning in place) and disinfection of surfaces by vaporisation in food processing facilities contain 5 - 35 % (w/w) hydrogen peroxide as a.s.. All uses comply with professional uses in closed systems.

The first use mentioned in Meta-SPC 1 is the antiseptic packaging (ASP). It describes a disinfection of packaging for food products by immersion or spraying. In the first case the packaging material is put into a bath with a heated hydrogen peroxide solution. In the second case the solution is directly sprayed on the material. Subsequently the packagings are blown dry with air before use.
The biocidal product contains 35% (w/w) hydrogen peroxide as active substance. The maximum product dilution is 2% (w/w) with 0.79% in-use concentration of hydrogen peroxide. The second use mentioned in Meta-SPC 1 describes a biocidal product which contains 35% (w/w) hydrogen peroxide as active substance and is used for the disinfection in food and feed areas by cleaning in place (CIP). The maximum product dilution is 2% (w/w) with 0.79% in-use concentration of hydrogen peroxide. While this

application method the solution of hydrogen peroxide circulates in a closed system for a certain period of time. Afterwards the system is emptied and rinsing with water to remove any residues.
The third use of PT4 the disinfection by vaporisation is mentioned in meta-SPC 5. For the disinfection of surfaces by vaporisation in food processing facilities a ready-to-use product is used. This product contains 5% (w/w) of hydrogen peroxide as active substance with an application rate of 12 mL/m³.

Emission pathways

Application 4a and 4b are closed systems, no emission to the environment is likely to occur. The only possible emission to the environment is via STP. According to the hydrogen peroxide Assessment Report for PT1-6 (Finland, March 2015) emissions to air from biocidal uses of hydrogen peroxide are negligible. Thus, this environmental emission pathway is not assessed further. To show worst cases of the two mentioned uses a 100% assumption of emitting in the sewer system are considered.

The vaporisation of hydrogen peroxide (use 4c) is applied in closed rooms where the solution is released to air. Afterwards the rooms have to be ventilated well, therefore, residues of the disinfectant may be emitted to air. According to the CAR (2007) of hydrogen peroxide a worst-case emission factor to air (Fair) of 0.4% was considered and the remaining part is emitted to STP.

In the sewer system degradation could be assumed because hydrogen peroxide is a very reactive substance and degrades rapidly in contact with organic material. According to the TAB ENV 39 ‘Degradation in the sewer system before release to STP’ and the ESD PT 5 Drinking Water Disinfectants (August 2003) following equation to perform a degradation in the sewer is used:

$F_{sewage} = \exp(- \ln(2)/DT50 * 60 \text{ min})$

Assuming a residence time of 60 minutes in the municipal canal system (default according to the ESD for PT5) and using the maximum biodegradation half-life of 6 minutes (11.2 min transferred to 12 °C), see section 3.8.3 Fate and behaviour, and single first-order kinetics degraded fraction in the sewer is calculated. This results in a fraction of $F_{sewage} = 0.024$ and is considered in following emission estimations.
Hence, no relevant amounts of the a.s. will be expected in the STP and further receiving compartments.

3.8.4.2.2 Environmental Exposure Assessment of PT 5

The biocidal products within meta SPCs 1-4 used as disinfectant of animal drinking water (Scenarios 5a-5d) contain 20.28 - 49.90 % (w/w) hydrogen peroxide as a.s.. The highest in-use concentrations and thus the worst cases represent the b.p. applications in meta SPC 1 and meta SPC 2 with a product application rate of 0.01 % - 0.1 % (w/w) and 0.007 % - 0.07 % (w/w) respectively. For both, this results in a hydrogen peroxide in-use concentration of 0.0035 - 0.035 % (w/w).
The products for the disinfection of animal drinking water can either be applied by continuous dosing using an automatic dosing pump or by manual filling into a water storage tank. According to information by the applicant, three different situations of disinfection can occur:

- Automatic dosing by pump for continuous treatment and direct use of the water
- Automatic dosing by pump for continuous treatment for storage of treated water in a buffer tank
- Automatic or manual dosing of a diluted solution to be introduced in a buffer tank

In case of continuous dosing, the product will be directly dosed into the water lines. Therefore, an internal valve is installed in the water tube system, where the dosage pump is connected.
In case of manual filling into the water storage tank, the product is filled in manually into the water to reach the final in-use concentration.
Contact times in accordance to the user instructions have to be ensured.

The applicant states that any hydrogen peroxide residues in the drinking water taken up by the animal will degrade to water and oxygen already immediately after uptake, i.e. when getting in contact with the mucous membranes of the oral cavity of the animals and when being transported through the gastrointestinal tract (GIT). Experts of the German Federal Institute for Risk Assessment (BfR) confirmed this statement in frame of the exposure assessment for the biocidal product authorisation in 2017. Therefore, the RefMS concludes that no residues of hydrogen peroxide are expected in urine and faeces of the animals. Thus, for the release pathway of intake and excretion of hydrogen peroxide treated waters by animals, no quantitative environmental exposure assessment was performed.
Another path of exposure would be the mixing and loading step in case of manual dosing of a diluted solution. Nevertheless, neither for PT 5 nor for PT 18 (i.e. insecticides used in animal housings) on which the environmental exposure assessment for disinfectants of animal drinking water is based, a mixing/loading step is taken into account. At PT 18 expert group meeting in January 2017 it was explicitly stated that mixing and loading step has not to be considered in the assessment for PT 18 in case of insecticides/larvicides applied in animal housings. Accordingly, no quantitative environmental exposure assessment was performed for that potential release pathway.
Furthermore, hydrogen peroxide is applied to the drinking water of animals in animal houses and can be released by spilled water. Any spillage would end up either in bedding material or other organic matter, respectively, on floor/soil surface or directly in slurry/manure tanks in case of slatted floors. In AR for

hydrogen peroxide (FI, 2015) a worst case DT_{50} of 6 min (20° C, equal to 11.4 min at 12 ° C) in manure and raw sewage was reported. Furthermore, one hour residence time in municipal sewer system according to ESD PT 5 (EUBEES, 2003) has to be considered, in case that due to cleaning procedure any residual hydrogen peroxide will end up in the sewer system. In STP, the relevant DT_{50} in sewage sludge is 2 min (20° C, equal to 3.8 min at 12 ° C). Due to the fast reaction of hydrogen peroxide with organic matter and the assumed low amount of spilled water due to drinking behaviour of the animals, the environmental exposure for both, release via manure and via STP, has to be considered as negligible. Thus, no quantitative environmental exposure assessment was performed for spillage of treated water.

Table 87

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	**Freshwater sediment**	**Sea-water**	**Seawater sediment**	**STP**	**Soil**	**Ground-water**	**Air**	**Other**
PT4									
Scenario 4a ASP on-site ASP off-site	+ +	- +	- -	- -	- +	- +	- +	- -*	- -
Scenario 4b (CIP)	+	+	-	-	+	+	+	-*	-
Scenario 4c Vaporisation	+	+	-	-	+	+	+	(+)*	-
PT5									
Scenario 5a-d	-	-	-	-	-	-	-	-	-

*According to the AR of H_2O_2 PT1-6 (Finland, March 2015) emissions to air are negligible.

Table 88

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	34.01	g/Mol	LOEP
Melting point	-0.43	°C	LOEP
Boiling point	150.2	°C	LOEP
Vapour pressure (at 20°C)	214	Pa	LOEP
Water solubility	miscible	mg/l	LOEP
Log Octanol/water partition coefficient	-1.57	Log 10	LOEP
Organic carbon/water partition coefficient (Koc)	1.598	L/kg	LOEP

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Henry's Law Constant (at 20°C)	7.5 x 10^{-4}	Pa m^3/mol	LOEP
Biodegradability	Ready biodegradable		
Rate constant for STP	20.79	h^{-1}	
DT_{50} for biodegradation in surface water	5	d (at 12ºC)	LOEP
DT_{50} for degradation in soil	12	hr (at 12ºC)	LOEP

3.8.4.3 Aquatic compartment (including sediment and STP)

The distribution and degradation of the a.s. in the STP was simulated using the model SimpleTreat (version 4.0):

Table 89

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
	Scenario 4a - c	
Air	0.0001567	Model used Simple Treat 4.0
Water	0.658	
Sludge	0.01449	
Degraded in STP	99.33	

- **Emission estimation**

- **Scenario 4a: Antiseptic packaging**

The ESD PT4 (JRC, 2011) provides an emission scenario for the releases of disinfectants used in entire plants (ESD PT 4, JRC, 2011, chapter 2.1.4.2, p. 15). An amount of active substances (100%) used in a model plant (Q_{ai}) is provided in a pick list of the ESD PT4, table 6, p. 16, and mentioned an average annual amount of 191 kg/yr for hydrogen peroxide. This amount is related to a mean emission time value of 231 days per year ($T_{emission}$). The fraction of emitted a.s. to water is assumed to be 100% as default value from the ESD PT4.The emission scenario distinguishes between two cases: the release to an on-site STP, with a capacity of 112.7 m^3, and the release to an off-site STP, with the standard default values according to the Guidance BPR Vol. IV B+C ENV (2017) (daily capacity of 2000 m^3).
The input parameter for calculating the releases are summarised in Table 90.

Table 90 Input parameters for calculating the local emission

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 4a: Antiseptic packaging			
Amount of biocidal a.s. used in local plant (Q_{ai})	191	kg/yr	P
Number of emission days per year ($T_{emission}$)	231	d/yr	D
Fraction released to wastewater (F_{water})	1		D
Degradation factor in the sewer (F_{sewage})	0.024		CAR Hydrogen peroxide (2007)
Capacitiy of the STP On-site Off-site	 112.7 2000	 m³/d	 D
Dilution factor in surface water	160		D

Calculations for Scenario4a: Antiseptic packaging

On-site treatment of waste water and direct release to surface water
Effluent concentration of a.s. in the effluent of the on-site STP

$$C_{effluent} = (Q_{ai}/T_{emission}) * F_{water}/(CAP_{STP\_onsite}*DIL)*F_{sewage}$$

Off-site treatment of waste waster
Influent concentration of a.s. in the off-site STP

$$C_{influent} = (Q_{ai}/T_{emission}) * F_{water}/CAP_{STP\_offsite}$$

$$Elocal_{water} = c_{influent} * CAP_{STP\_offsite} * F_{sewage}$$

Table 91 Resulting local emission to relevant environmental compartment

Resulting local emission to relevant environmental compartment:			
	Value	**Unit**	**Remarks**
$C_{effluent}$ on-site STP	0.001	mg/L	$PEClocal_{surface\ water}$
$Elocal_{water}$ off-site STP	0.020	kg/d	

The calculation of $C_{effluent}$ according to the on-site STP, which is equal to PEC surface water, is only mentioned for completeness and will not be considered in the further environmental risk assessment. Since there is no unacceptable risk for the surface water if a PNEC aquatic of 1.26 x 10^{-2} mg/L is taken into account.

The application of the b.p. by immersion or spraying results in a release of **0.020 kg/d** hydrogen peroxide to the sewer treatment plant.

- **Scenario 4b: Cleaning in Place (CIP)**

For the estimation of local emission to waste water the emission scenario for disinfection of milking parlour systems from ESD PT4, chapter 2.3, table 11 is used. As this scenario is performed of disinfection of milking parlours by CIP the disinfectant is added to the circulating water and pumped through the equipment. Regarding a density of b.p.of 1.13 g/cm³ and a concentration of 35% of a.s.the application rate of a.s. is about 7.9 g/L. This is equal to 0.79% in-use concentration of hydrogen peroxide in a product dilution of 2% (w/w). The size of plant installations and the assumption of fraction released to waste water (100%) have been adopted from the ESD PT 4.
The input parameter for calculating the releases are summarised in Table 92.

Table 92 Input parameters for calculating the local emission

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 4b: Cleaning in Place			
Concentration of a.s. (c_{form})	7.9	g/L	S
Amount of disinfectant used for cleaning of the milkin installation ($Vform_{inst}$)	130	L/d	D
Amount of disinfectant used for claening of the milk storage tank ($Vform_{tank}$)	45	L/d	D
Fraction of the emission to waste water (F_{water})	1		D
Degradation factor in the sewer (F_{sewage})	0.024		CAR Hydrogen peroxide (2007)

Calculations for Scenario 4b: Cleaning in Place

$Q_{ai} = c_{form} * (Vform_{inst} + Vform_{tank})$

$Elocal_{water} = Q_{ai} * (1-F_{dis}) * F_{water} * F_{sewage}$

Table 93 Resulting local emission to relevant environmental compartment: STP

Resulting local emission to relevant environmental compartment: STP		
	$Elocal_{water}$[kg/d]	Remark
Cleaning in Place	0.033	

The application of the b.p. by cleaning in place of tanks and installations results in a release of **0.033 kg/d** hydrogen peroxide to the sewer treatment plant.

Scenario 4c: Disinfection of surfaces by vaporisation

The ESD PT4 (JRC, 2011), table 10, provides an emission scenario for calculating the releases of disinfectants used in large scale catering kitchens, canteens, slaughterhouses and butcheries. According to TAB ENV 66 (TAB ENV 2.0, August 2018) default values for room volumes of slaughterhouse and large scale catering kitchens were performed. It is assumed that one application per day and an application rate about 12 mL/m³ is applied. Regarding a density of b.p.of 1.0 g/cm³ and a concentration of 5 % of a.s.the application rate of a.s. is about 0.6 g/m³.
The input parameter for calculating the releases are summarised in Table 94.

Table 94 Input parameters for calculating the local emission

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 4c: Disinfection of surfaces by vaporisation			
Application rate of the active substance (Qai_{appl})	0.6	g/m³	S
Room volume to be disinfected Slaughterhouse Large scale catering kitchens	 50000 6000	m³	TAB ENV 66 August 2018
Number of applications per day (N_{appl})	1	d	D
Fraction of the emission to waste water (F_{water})	1		D
Degradation factor in the sewer (F_{sewage})	0.024		CAR Hydrogen peroxide (2007)

Calculations for Scenario 4c: Disinfection of surfaces by vaporisation

$Elocal_{water} = Qai_{appl} * Area_{volume} * Nappl * F_{water} * F_{sewage}$

Table 95 Resulting local emission to relevant environmental compartment: STP

Resulting local emission to relevant environmental compartment: STP		
	$Elocal_{water}$ [kg/d]	Remark
Scenario 4c: Slaughterhouse Large scale catering kitchens	 0.720 0.086	

The application of the b.p. by vaporisation of surfaces result in a release of **0.720 kg/d** hydrogen peroxide for slaughterhouses and **0.086 kg/d** for large scale catering kitchens to the sewer treatment plant .

According to the intended uses of 'Anti-Germ hydrogen peroxide based disinfectants product family ` indirect emissions to surface water and sediment via output of the effluent from STP occurs. The predicted environmental concentrations for STP, surface water and sediment are estimated as follows and are summarised in Table 96 :

PEC_{STP} (=$Clocal_{eff}$) and $Clocal_{inf}$ according to equation 35, 36 and 41, chapter 2.3.6.7, Guidance BPR Vol. IV B+C ENV (2017)

$PEClocal_{surfacewater}$ according to equation 51, chapter 2.3.7.3.1, Guidance BPR Vol. IV B+C ENV (2017)

$PEClocal_{sediment}$ according to equation 53, chapter 2.3.7.3.2, Guidance BPR Vol. IV B+C ENV (2017)

Table 96 Summary of STP influent ($Clocal_{inf}$) and effluent ($Clocal_{eff}$), PEC_{STP}, $PEClocal_{surface\ water}$ and $PEClocal_{sediment}$

	$Clocal_{inf}$ [mg/L]	**$Clocal_{eff}$** [mg/L]	**PEC_{STP}** [mg/L]	**$PEClocal_{surface\ water}$** [mg/L]	**$PEClocal_{sediment}$** [mg/kg]
Scenario 4a (off-site)	0.010	6.580×10^{-5}	6.580×10^{-5}	6.580×10^{-6}	5.380×10^{-6}
Scenario 4b	0.016	1.053×10^{-4}	1.053×10^{-4}	1.03×10^{-5}	8.61×10^{-6}
Scenario 4c Slaughterhouse Large scale kitchen	 0.360 0.043	 2.369×10^{-3} 2.829×10^{-4}	 2.369×10^{-3} 2.829×10^{-4}	 2.369×10^{-4} 2.829×10^{-5}	 1.940×10^{-4} 2.310×10^{-5}

3.8.4.4 Terrestrial compartment (including groundwater)

- **<u>Emission estimation</u>**

The three applications of 'Anti-Germ hydrogen peroxide based disinfectants product family' in the following scenarios:

- Scenario 4a: Antiseptic packaging
- Scenario 4b: Cleaning in place (CIP) and
- Scenario 4c: Disinfection of surfaces by vaporisation (VHP)

are assumed to lead to indirect emission to the terrestrial compartment via sewage sludge application on agricultural land. The release estimation for STP is already presented in chapter 3.9.4.3. Aquatic compartment (including sediment and STP). The concentrations in dry sewage sludge is equal to:

- 3.677 x 10^{-3} mg/kg for antiseptic packaging,
- 5.869 x 10^{-3} mg/kg for cleaning in place and
- 0.132 mg/kg for vaporisation in slaughterhouses and 0.016 for large scale catering kitchens, respectively.

The PEC_{soil} is estimated according to equation 69, chapter 2.3.7.5.1, Guidance BPR Vol. IV B +C ENV (2017) and the $PEC_{groundwater}$ is calculated according to equation 71, chapter 2.3.7.6, Guidance BPR Vol. IV Part B + C ENV (2017). The PEC`s of soil and groundwater are summarised in Table 97.

Table 97 Calculated PEC values of the terrestrial compartment

Calculated PEC values		
	PEC_{soil} (mg/kg)	**PEC_{GW}** (µg/L)
Scenario 4a (off-site)	1.288 x 10^{-7}	1.472 x 10^{-4}
Scenario 4b	2.060 x 10^{-7}	2.354 x 10^{-4}
Scenario 4c Slaughterhouse Large scale kitchen	 4.760 x 10^{-6} 5.764 x 10^{-7}	 6.160 x 10^{-3} 7.427 x 10^{-4}

3.8.4.5 Atmosphere

The three applications of ‘Anti-Germ hydrogen peroxide based disinfectants product family’ in the following scenarios:

- Scenario 4a: Antiseptic packaging
- Scenario 4b: Cleaning in place (CIP) and
- Scenario 4c: Disinfection of surfaces by vaporisation (VHP)

are assumed to lead to indirect emission to the air compartment via STP. The release estimation for STP is already presented in chapter 3.9.4.3. Aquatic compartment (including sediment and STP). Scenario 4c is the only application where an emission direct to air is also possible as the room have to be well ventilated before entering. According to the description mentioned in 3.9.4.3 Aquatic compartment (including sediment and STP) the emission of scenario 4c ‘VHP’ to air is calculated as shown in table Table 98.

A worst-case emission factor to air (F_{air}) of 0.4 % was estimated as the quotient of the maximum residual concentration in air after the decomposition step and the minimum target concentration in air (CAR hydrogen peroxide DOC IIB).

Table 98 Input parameters for calculating the local emission

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 4c: Disinfection of surfaces by vaporisation			
Application rate of the active substance (Qai_{appl})	0.6	g/m³	S
Room volume to be disinfected Slaughterhouse Large scale catering kitchens	 50000 6000	m³	TAB ENV 66 August 2018
Number of applications per day (N_{appl})	1	d	D
Fraction of the emission to air (F_{air})	0.004		CAR (2007)

$Elocal_{air} = Q_{appl} * Room_{volume} * N_{appl} * F_{air}$

Table 99 Resulting local emission to relevant environmental compartment: Air

Resulting local emission to relevant environmental compartment: Air		
	Elocalair [kg/d]	Remark
Scenario 4c: Slaughterhouse Large scale catering kitchens	 0.120 0.014	

The application of the b.p. by vaporisation result in a release of **0.120 kg/d** hydrogen peroxide for slaughterhouses and **0.014 kg/d** for large scale catering kitchens to the air.

The PEC_{air} for all scenarios are estimated according to equation 45, chapter 2.3.7.2, Guidance BPR Vol. IV B +C ENV (2017) and are summarised in Table 100.

Table 100 Calculated PEC values of the air compartment

Calculated PEC values	
	PEC_{air} (mg/m³)
Scenario 4a (off-site)	5.514×10^{-12}
Scenario 4b	1.394×10^{-11}
Scenario 4c Slaughterhouse Large scale kitchen	 3.336×10^{-5} 3.892×10^{-6}

As stated in the AR for hydrogen peroxide (FI, 2015), emissions to air from biocidal uses of the a. s. are negligible and do not relevantly alter existing background concentrations in the troposphere.

3.8.4.6 Non-compartment specific effects relevant for the food chain

- **Primary poisoning**

Not applicable.

- **Secondary poisoning**

The estimated log Kow of hydrogen peroxide is –1.57 indicating a negligible potential for bioconcentration in biota. Therefore, it is justified that accumulation of hydrogen peroxide in the food chain is not expected, and the risk of secondary poisoning in aquatic and terrestrial predators is negligible.

3.8.4.7 Calculated PEC values

Summary table on calculated PEC values						
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/L]	**[mg/L]**	**[mg/kg_{wwt}]**	**[mg/kg]**	**[µg/l]**	**[mg/m^3]**
Scenario 4a off-site	6.580×10^{-5}	6.580×10^{-6}	5.380×10^{-6}	1.288×10^{-7}	1.472×10^{-4}	5.514×10^{-12}
Scenario 4b	1.053×10^{-4}	1.053×10^{-5}	8.610×10^{-6}	2.060×10^{-7}	2.354×10^{-4}	1.394×10^{-11}
Scenario 4c Slaughterhouse Large scale kitchen	 2.369×10^{-3} 2.829×10^{-4}	 2.369×10^{-4} 2.829×10^{-5}	 1.940×10^{-4} 2.310×10^{-5}	 4.760×10^{-6} 5.764×10^{-7}	 6.160×10^{-3} 7.427×10^{-4}	 3.336×10^{-5} 3.892×10^{-6}

3.8.4.8 Aggregated exposure (combined for relevant emission sources)

At the time of preparation of the environmental assessment for this PAR, no EU agreed guidance was available on how to perform a full aggregated exposure assessment. Therefore, no detailed assessment has been made at this stage. This area may need to be re-assessed in the future once agreed guidance has been made available.

3.8.5 Risk characterisation

The PT4 uses for the BPF in antiseptic packaging (ASP), cleaning in place (CIP) and room disinfection in food processing facilities (VHP), as well as the PT 5 use for disinfection of animal drinking water were evaluated concerning their emissions to the environment.
PECs for the PT 4 uses of scenario 4a and 4b were calculated assuming 100% emission of active substance via water. Only for the use of the products in room disinfection in food processing facilities, PECs considering the direct air path were used for risk assessment, since the products are applied through vaporisation and subsequent ventilation of treated rooms is required.
For the use in PT5 (Meta SPCs 1, 2, 3 and 4 as applied for by the applicant) negligible exposure was assumed. Thus, a quantitative environmental risk assessment is not required for the requested use of ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY in PT5.

3.8.5.1 Aquatic compartment (sediment and STP)

The PEC values used for calculation of the PEC/PNEC ratios in surface water were determined considering 100% emission of active substance via water for scenario 4a and b, while PECs for scenario 4c considering 0.4% emission to the exterior via air path. Resulting PEC/PNEC ratios are given in Table 101.
$PEC/PNEC_{water}$ for on-site STP (scenario 4a) is only mentioned for completeness and will not be considered in the further environmental risk assessment.
As adsorption potential for hydrogen peroxide to sediment is low, an assessment of the sediment was not undertaken.

Table 101

Calculated PEC/PNEC values	
	$PEC/PNEC_{water}$
Scenario 4a ASP (off-site)	5.22×10^{-4}
Scenario 4b CIP	8.36×10^{-4}
Scenario 4c VHP Slaughter house Large scale kitchen	 1.880×10^{-2} 2.25×10^{-3}

- **STP**

As explained above in this chapter the calculation of the PEC/PNEC ratios in STPs were determined considering 100% emission via water for scenario 4a and b and only for scenario 4c an emission of 0.4% of active substance via air is assumed. Resulting risk quotients are given in Table 102.

Table 102

Calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 4a ASP (off-site)	 1.41×10^{-5}
Scenario 4b CIP	2.26×10^{-5}
Scenario 4c VHP Slaughter house Large scale kitchen	 5.08×10^{-4} 6.07×10^{-5}

Conclusion

For the aquatic compartment including STP, no unacceptable risks were identified for the PT 4 uses. According to the negligible exposure resulting from the use in animal drinking water in PT 5, risks for the aquatic environment resulting from this use are considered acceptable.

3.8.5.2 Terrestrial compartment (Soil/Groundwater)

The only environmentally relevant emission pathway to soil results from the proposed uses in PT4 for this product family, namely via application of sludge from STPs on agricultural soil.
Resulting PEC/PNEC ratios are given in Table 103.

Table 103

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Scenario 4a ASP (off-site)	 7.00×10^{-5}
Scenario 4b CIP	1.12×10^{-4}
Scenario 4c VHP Slaughter house Large scale kitchen	 2.64×10^{-3} 3.20×10^{-4}

- **Groundwater**

Calculated groundwater concentrations resulting from the proposed uses of the product family in PT4 are 1.47×10^{-4} µg/L for antiseptic packaging, 2.35×10^{-4} µg/L for cleaning in place, as well as 6.16×10^{-3} µg/L for room disinfection in slaughter houses and 7.43×10^{-4} µg/L in large scale kitchens. The maximum permissible concentration by directive 2006/18/EC is 0.1 µg/L. As all calculated concentrations are below this threshold, the environmental risks for groundwater contamination are considered acceptable.

Conclusion

PEC/PNEC ratios for soil are below 1 and calculated groundwater concentrations do not exceed the threshold of 0.1 µg/L for all PT4 uses assessed here. Thus, environmental risks are considered acceptable for the terrestrial compartment including groundwater for the product family.

3.8.5.3 Atmosphere

Conclusion

As stated in the AR for hydrogen peroxide (FI, 2015), emissions to air from biocidal uses of this substance are negligible and do not relevantly alter existing background concentrations in the troposphere. A risk assessment of the PECs in air and rainwater is thus not necessary.

3.8.5.4 Non-compartment specific effects relevant for the food chain

- **Primary poisoning**

Not applicable.

- **Secondary poisoning**

Due to the low potential of the active substance to bioaccumulate in biota, accumulation in the food chain is not expected. The risk of secondary poisoning in aquatic and terrestrial food chains is hence considered negligible.

3.8.5.5 PBT assessment

According to the active substance AR (FI, 2015), hydrogen peroxide does not fulfil any of the PBT criteria, nor the POP criteria. As no substances of concern were identified for the ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY, it is assumed that PBT criteria are not fulfilled for the biocidal product family.

3.8.5.6 Endocrine disrupting properties

Active substance

As stated in the active substance AR (FI, 2015), hydrogen peroxide is not suspected to interfere with the hormone systems of human and wildlife according to COM (1999)706 and no evidence was shown for endocrine disruption potential according to the studies submitted for active substance approval.

Non-active substances

The full composition of the BPF is listed in the Chapter **Fehler! Verweisquelle konnte nicht gefunden werden. Fehler! Verweisquelle konnte nicht gefunden werden.**. There are no indications that a non-active substance of the product may have endocrine disrupting properties on environmental non-target organisms based on the data provided by the applicant. Nonetheless, the eCA considered in its evaluation further information available on the non-active substances: None of the co-formulants is contained in the candidate list for substances of very high concern for authorisation, the community rolling action plan (CoRAP) or the public activities coordination tool (PACT) according to Regulation (EU) 1907/2006 for potential environmental ED-hazards or ECHA's endocrine disruptor assessment list. For none of the co-formulants indications on potential ED effects on environmental non-target organisms were found in scientific literature.

3.8.5.7 Summary of risk characterisation

In Table 104 PEC/PNEC ratios for the proposed uses of the BPF in PT 4 are summarised.

Table 104

	PEC/ $PNEC_{STP}$	**PEC/ $PNEC_{water}$**	**PEC/ $PNEC_{soil}$**
Scenario 4a ASP On-site Off-site	 1.41×10^{-5}	 8.73×10^{-2} 5.22×10^{-4}	 7.00×10^{-5}
Scenario 4b CIP	2.26×10^{-5}	8.36×10^{-4}	1.12×10^{-4}
Scenario 4c VHP slaughter house large scale kitchen	 5.08×10^{-4} 6.07×10^{-5}	 1.88×10^{-2} 2.25×10^{-3}	 2.64×10^{-3} 3.20×10^{-4}

As all relevant PEC/PNEC ratios for the proposed uses of ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY in PT4 are below 1, risks for the environment are considered acceptable. For the proposed use in PT5, negligible exposure of environmental compartments is considered and the determination of PEC/PNEC ratios is not required. Consequently, no unacceptable risks were identified for the environmental compartments and all uses of ANTI-GERM HYDROGEN PEROXIDE BASED DISINFECTANTS PRODUCT FAMILY, which were assessed in this report.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

No candidate for substitution was identified (see chapter 2.2.4), hence a comparative assessment is not necessary.

4 Annexes

4.1 List of studies for the biocidal product family

4.1.1 List of studies for the products in meta SPC No. 1

Table 105

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	3.1. Appearance (at 20 °C and 101,3 kPa) 3.2. Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1 %) is outside the pH range 4-10 3.4.1.1. Accelerated storage test 3.4.2.3. Reactivity towards container material 3.7. Degree of dissolution and dilution stability	Accelerated storage stability test at 40°C +- 2°C for 8 weeks on ANTI-GERM H2O.NET Synonyms: ANTI-GERM WP 35 ANTI-GERM DES OXI 35-SPRAY ANTI-GERM DES OXI 35-BATH	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH
2	3.3. Relative density (liquids) and bulk, tap density (solids) 3.4.1.3. Low temperature stability test (liquids) 3.5.7. Persistent foaming 3.8. Surface tension 3.9. Viscosity	Physico-chemical tests on Anti-Germ H2O.NET	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH
3	3.4.1.2. Long term storage test at ambient temperature	Long term storage stability test at ambient temperature for 18 months on ANTI-GERM H2O.NET, Synonyms: ANTI-GERM WP 35, ANTI-GERM DES OXI 35-SPRAY, ANTI-GERM DES OXI 35-BATH	Dr. Lehmann, R.	2018	ANTI-GERM International GmbH

4	3.4.1.2. Long term storage test at ambient temperature	Long term storage stability test - Addendum – on ANTI-GERM H2O.NET, Synonyms: ANTI-GERM WP 35, ANTI-GERM DES OXI 35-SPRAY, ANTI-GERM DES OXI 35-BATH	Dr. Lehmann, R.	2020	Kersia Deutschland GmbH
5	4.13 Oxidising liquids	Anti-germ Des Oxi Air, Anti-germ'O & Anti-germ Aqua Oxidising Liquids Testing	Siusiene, E.	2018	ANTI-GERM International GmbH
6	4.16. Corrosive to metals	Determination of the corrosion of metals by ANTI-GERM H2O.NET ANTI-GERM OXID'O ANTI-GERM DES OXI AIR S following method 37.4 C.1 of the UN Handbook ANTI-GERM AQUA and ANTI-GERM 'O, Screening test	Lehmann, R.	2018	ANTI-GERM International GmbH
7	5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product	Validation of the analytical method for the determination of Hydrogen Peroxide in aqueous solution (ANTI-GERM OXID'O and ANTI-GERM H2O.NET)	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH
8	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	TEST REPORT EN 1276: 2010, BACTERICIDAL ACTIVITY	Forest, A.	2017	ANTI-GERM International GmbH

9	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Bactericidal Activity of ANTI-GERM DES OXI-35 in the quantitative suspension test according to DIN EN 1276:2009 (Phase 2, Step 1) Report-No: L16/0709.10	Kampe, A.; Klock, J.-H.	2017	ANTI-GERM International GmbH
10	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Bactericidal Activity of ANTI-GERM DES OXI-35 in the quantitative suspension test according to DIN EN 1276:2009 (Phase 2, Step 1) Report-No: L16/0709.6	Kampe, A.; Klock, J.-H.	2017	ANTI-GERM International GmbH
11	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Yeasticidal Activity of ANTI-GERM DES OXI-35 in the quantitative suspension test according to DIN EN 1650:2013 (Phase 2, Step 1) Report-No: L16/0709.7	Kampe, A.; Gabriel, H.	2017	ANTI-GERM International GmbH
12	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Yeasticidal Activity of ANTI-GERM DES OXI-35 in the quantitative suspension test according to DIN EN 1650:2013 (Phase 2, Step 1) Report-No: L16/0709.8	Kampe, A.; Klock, J.-H.	2017	ANTI-GERM International GmbH
13	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Yeasticidal Activity of ANTI-GERM DES OXI-35 in the quantitative suspension test according to DIN EN 1650:2013 (Phase 2, Step 1) Report-No: L16/0709.9	Kampe, A.; Gabriel, H.	2017	ANTI-GERM International GmbH
14	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Carton sterilization effect on E-PS120A with 35 % hydrogen peroxide “ANTI-GERM DES OXI-35 SPRAY” from KERSIA	Andal, H.; Gunnæs, A.	2018	ANTI-GERM International GmbH

4.1.2 List of studies for the products in meta SPC No. 2 as applied for by the applicant, not to be authorised

Table 106

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	3.1. Appearance (at 20 °C and 101,3 kPa) 3.2. Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1 %) is outside the pH range 4-10 3.4.1.1. Accelerated storage test 3.4.2.3. Reactivity towards container material 3.7. Degree of dissolution and dilution stability	Accelerated storage stability test at 40°C +- 2°C for 8 weeks on ANTI-GERM OXID'O	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH
2	3.3. Relative density (liquids) and bulk, tap density (solids) 3.4.1.3. Low temperature stability test (liquids) 3.5.7. Persistent foaming 3.8. Surface tension 3.9. Viscosity	Physico-chemical tests on Anti-Germ ODXID'O	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH
3	3.4.1.2. Long term storage test at ambient temperature	Long term storage stability test at ambient temperature for 18 months on ANTI-GERM OXID'O	Dr. Lehmann, R.	2018	ANTI-GERM International GmbH

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
4	4.16. Corrosive to metals	Determination of the corrosion of metals by ANTI-GERM OXID'O following method 37.4 C.1 of the UN Handbook	Lehmann, R.	2018	ANTI-GERM International GmbH
5	5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product	Validation of the analytical method for the determination of Hydrogen Peroxide in aqueous solution (ANTI-GERM OXID'O and ANTI-GERM H2O.NET)	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH
6	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Quantitative suspension test for the evaluation of bactericidal activity of ANTI-GERM Oxid'O in Food, Industrial, Domestic and Institutional Areas (DIN EN 1276 Ber 1:2010; Phase 2, Step 1) - Test report L18/0648.1	Klock, J.-H.; Gabriel, H.	2018	ANTI-GERM International GmbH
7	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Quantitative suspension test for the evaluation of bactericidal activity of ANTI-GERM Oxid'O in Food, Industrial, Domestic and Institutional Areas (DIN EN 1276 Ber 1:2010; Phase 2, Step 1) - Test report L18/0648.2	Klock, J.-H.; Gabriel, H.	2018	ANTI-GERM International GmbH

4.1.3 List of studies for the products in meta SPC No. 3 as applied for by the applicant, not to be authorised

Table 107

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	3.1. Appearance (at 20 °C and 101,3 kPa) 3.2. Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1 %) is outside the pH range 4-10 3.4.1.1. Accelerated storage test 3.4.2.3. Reactivity towards container material 3.7. Degree of dissolution and dilution stability	Accelerated storage stability test at 40°C +-2°C for 8 weeks on ANTI-GERM AQUA	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH
2	3.3. Relative density (liquids) and bulk, tap density (solids) 3.4.1.3. Low temperature stability test (liquids) 3.5.7. Persistent foaming 3.8. Surface tension 3.9. Viscosity	Physico-chemical tests on Anti-Germ AQUA	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH
3	3.4.1.2. Long term storage test at ambient temperature	Long term storage stability test at ambient temperature for 18 months on ANTI-GERM AQUA	Dr. Lehmann, R.	2018	ANTI-GERM International GmbH
4	4.13 Oxidising liquids	Anti-germ Des Oxi Air, Anti-germ'O & Anti-germ Aqua	Siusiene, E.	2018	ANTI-GERM International GmbH

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
		Oxidising Liquids Testing			
5	4.16. Corrosive to metals	Determination of the corrosion of metals by ANTI-GERM AQUA and ANTI-GERM ‘O Screening test	Lehmann, R.	2018	ANTI-GERM International GmbH
6	5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product	Validation of the analytical method for the determination of Hydrogen Peroxide in ANTI-GERM AQUA	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH
7	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Quantitative suspension test for the evaluation of bactericidal activity of ANTI-GERM Aqua in Food, Industrial, Domestic and Institutional Areas (DIN EN 1276 Ber 1:2010; Phase 2, Step 1) - Test report L18/0647.1	Klock, J.-H.; Gabriel, H.	2018	ANTI-GERM International GmbH
8	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Quantitative suspension test for the evaluation of bactericidal activity of ANTI-GERM Aqua in Food, Industrial, Domestic and Institutional Areas (DIN EN 1276 Ber 1:2010; Phase 2, Step 1) - Test report L18/0647.2	Klock, J.-H.; Gabriel, H.	2018	ANTI-GERM International GmbH

4.1.4 List of studies for the products in meta SPC No. 4 as applied for by the applicant, not to be authorised

Table 108

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	3.1. Appearance (at 20 °C and 101,3 kPa) 3.2. Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1 %) is outside the pH range 4-10 3.4.1.1. Accelerated storage test 3.4.2.3. Reactivity towards container material 3.7. Degree of dissolution and dilution stability	Accelerated storage stability test at 40°C +- 2°C for 8 weeks on ANTI-GERM ‘O	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH
2	3.3. Relative density (liquids) and bulk, tap density (solids) 3.4.1.3. Low temperature stability test (liquids) 3.5.7. Persistent foaming 3.8. Surface tension 3.9. Viscosity	Physico-chemical tests on Anti-Germ’O	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH
3	3.4.1.2. Long term storage test at ambient temperature	Long term storage stability test at ambient temperature for 18 months on ANTI-GERM'O	Dr. Lehmann, R.	2018	ANTI-GERM International GmbH
4	4.13 Oxidising liquids	Anti-germ Des Oxi Air, Anti-germ'O & Anti-germ Aqua	Siusiene, E.	2018	ANTI-GERM International GmbH

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
		Oxidising Liquids Testing			
5	4.16. Corrosive to metals	Determination of the corrosion of metals by ANTI-GERM AQUA and ANTI-GERM 'O Screening test	Lehmann, R.	2018	ANTI-GERM International GmbH
6	5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product	Validation of the analytical method for the determination of Hydrogen Peroxide in ANTI-GERM'O	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH

4.1.5 List of studies for the products in meta SPC No. 5 as applied for by the applicant, corresponding to meta SPC 2 appropriate for authorisation

Table 109

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	3.1. Appearance (at 20 °C and 101,3 kPa) 3.2. Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1 %) is outside the pH range 4-10	Accelerated storage stability test at 40°C ± 2°C for 8 weeks on ANTI-GERM DES OXI AIR	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
	3.4.1.1. Accelerated storage test 3.4.2.3. Reactivity towards container material 3.7. Degree of dissolution and dilution stability				
2	3.1. Appearance (at 20 °C and 101,3 kPa) 3.2. Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1 %) is outside the pH range 4-10 3.4.1.1. Accelerated storage test 3.4.2.3. Reactivity towards container material 3.7. Degree of dissolution and dilution stability	Accelerated storage stability test at 40°C ± 2°C for 8 weeks on ANTI-GERM DES OXI AIR-S	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH
3	3.3. Relative density (liquids) and bulk, tap density (solids) 3.4.1.3. Low temperature stability test (liquids) 3.5.7. Persistent foaming 3.8. Surface tension 3.9. Viscosity	Physico-chemical tests on Anti-Germ DES OXI AIR	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH
4	3.3. Relative density (liquids) and bulk, tap density (solids) 3.4.1.3. Low temperature stability test (liquids)	Physico-chemical tests on Anti-Germ DES OXI AIR-S	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
	3.5.7. Persistent foaming 3.8. Surface tension 3.9. Viscosity				
5	3.4.1.2. Long term storage test at ambient temperature	Long term storage stability test at ambient temperature for 18 months on ANTI-GERM DES OXI AIR	Dr. Lehmann, R.	2018	ANTI-GERM International GmbH
6	3.4.1.2. Long term storage test at ambient temperature	Long term storage stability test at ambient temperature for 18 months on ANTI-GERM DES OXI AIR-S	Dr. Lehmann, R.	2018	ANTI-GERM International GmbH
7	4.13 Oxidising liquids	Anti-germ Des Oxi Air, Anti-germ'O & Anti-germ Aqua Oxidising Liquids Testing	Siusiene, E.	2018	ANTI-GERM International GmbH
8	4.16. Corrosive to metals	Determination of the corrosion of metals by ANTI-GERM DES OXI AIR S following method 37.4 C.1 of the UN Handbook	Lehmann, R.	2018	ANTI-GERM International GmbH
9	5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product	Validation of the analytical method for the determination of Hydrogen Peroxide in ANTI-GERM DES OXI AIR	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH
10	5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and	Validation of the analytical method for the determination of Hydrogen Peroxide in ANTI-GERM DES OXI AIR-S	Dr. Lehmann, R.	2017	ANTI-GERM International GmbH

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
	substances of concern in the biocidal product				
11	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	TEST REPORT N°RE-1176/0417	Strohl, P.; Carré, A.	2017	ANTI-GERM International GmbH
12	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	TEST REPORT N°RE-1183/0417	Strohl, P.; Carré, A.	2017	ANTI-GERM International GmbH
13	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	TEST REPORT N°RE-1209/0417	Strohl, P.; Carré, A.	2017	ANTI-GERM International GmbH
14	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Determination of bactericidal, sporicidal, fungicidal and yeasticidal activity of airborne-based surface cleaning and disinfection process ANTI-GERM DES OXI AIR (ANTI-GERM) / TECHNIFOGGER 40 (AURATECH) according to NF T72-281 (food and industrial areas)	Moulès, V.	2017	ANTI-GERM International GmbH

4.2 List of studies for the active substance(s)

4.2.1 Hydrogen peroxide

- The applicant has access to the data from the active substance approval (see chapter 4.2.1.1 for details).

4.2.1.1 Access to data from active substance approval

The applicant provided a letter of access to the dossier assessed for the approval of the active substance Hydrogen peroxide for use in food and feed area disinfectants (product-type 4) and drinking water disinfectants (product-type 5). Please, refer to the corresponding Assessment Report for a reference list.

4.3 Output tables from exposure assessment tools

Output tables from <u>human health</u> exposure assessment tools

4.3.1 Safety for professional users

Risk and exposure and risk assessment for professional users:

exposure assessment professi

5 Confidential annex (Access level: “Restricted” to applicant and authority)

See separate document.

6 Confidential annex – MS only (Access level: “Restricted - Authority”)

See separate document.