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

DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the eCA)

PHASE VTA

Product type(s) 4

Peracetic acid

Case Number in R4BP: BC-HV033131-35

Evaluating Competent Authority: Spain

Date: April 2023

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1 CONCLUSION

The overall conclusion is that the biocidal product PHASE VTA meets the conditions laid down in article 19 (1) of regulation EU No 528/2012 and therefore can be authorised for the uses specified in the Summary of Product Characteristics (SPC).

The use of Peracetic acid as active biocidal substance in product formulations to act as PT04 food a feed area disinfectant is limited to aseptic food packaging sterilization and for industrial use only.

Explanatory note (only for Spain authorisation):
The conclusions reached in this PAR, which affect the category of "Industrial", will be applicable to Industrial (Trained profesional and Professional) users at the Spanish level. Therefore, **ES CA will apply article 37 according to BPR in the authorisation of this product, for users and packaging sections.**

Physical-chemical properties and Analytical Methods

PHASE VTA is a clear and homogeneous colourless liquid with an intense pungent vinager type odour. The density of the product is 1.14g/ml and the acidity is in the range of 30.86% and 31.26% calculated as H_2SO_4 (w/w).
The formulation was found to be stable up to 6 months at ambient temperatures and at least for 7 days at low temperatures (0 ºC).
The rest of physical properties such as persistent foaming, dilution stability, surface tension and viscosity are within specifications.
PHASE VTA is classified as organic peroxide liquid , type F (H242) and as corrosive to metals (H290).
Regarding analytical method, the content of the active ingredient (peracetic acid) , hydrogen peroxide and acetic acid in the test item were determined by titration and validated according to SANCO/3030/99 Rev. 4

Efficacy

Phase VTA is used to disinfect food packaging materials by vaporization of peracetic acid with hot air. The semi-field trials demonstrate the sporicidal activity of the biocidal product on packaging in aseptic packaging systems. Because of the great variety in packaging and aseptic packaging systems, for each packaging/system combination, the conditions need to be adapted to optimise the rapid disinfection of packaging materials.

This claim is supported by the semi-field efficacy tests performed on *Bacillus atrophaeus*. Diluted disinfectant is vaporized with hot air and used for food packaging disinfection in aseptic packaging systems. Commonly the disinfection takes place at short contact times, high product concentrations and high temperatures. Under these conditions it is not possible to perform the standard EN suspension and surface tests with bacteria, yeasts, and moulds. Therefore, efficacy tests in semi-field trials against the most difficult organism, heat resistant bacterial spores, are more appropriate. Two semi-field tests were performed. The chosen spore forming bacterial strain, *Bacillus atrophaeus*, although different from the strains describes in the BPR efficacy guidance, has been used extensively in biomedicine as indicator strain for heat- and chemical-based decontamination regimens. The semi-field trials demonstrate the sporicidal effect of biocidal product on packaging in aseptic packaging systems.

Human Health

A classification according to Regulation (EC) No 1272/2008 is necessary. Detailed information on classification and labelling is provided in section 2.1.3 of the PAR.
Two substances of concern in the biocidal product have been identified.
According to our assessment, none of the components contained in the product are identified as endocrine disruptors and none of them are subject to an on-going evaluation or a decision regarding their ED properties Hence, ES CA considers that PHASE VTA contains no substances suspected of having endocrine disrupting properties. If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.
According to the document agreed at the CG-49 meeting on Criteria – significant indications of ED properties for non-active substances, none co-formulant is considered to have significant indication of ED properties.

Regarding Exposure assessment and Risk characterisation:
After evaluating the exposure and characterizing the risk to human health of the PHASE VTA product according to the pattern of use requested by the applicant, the conclusions for each scanario are:

Summary table: scenarios		
Scenario number	**Scenario and Users (e.g. mixing/ loading)**	**Conclusion**
1.a	Manual loading Industrial	A **safe** situation has been identified for the industrial manual loading of the product when PPEs (chemical-resistant: gloves, protective coverall, footwear; full-face mask APF10) are worn and LEV APF20 integrated in the vaporization PAA machine is working, therefore **the uses of which this scenario is part will be authorized.**
1.b	Automatic Loading Industrial	A **safe** situation has been identified for the industrial automatic loading of the product when PPEs (chemical-resistant: gloves, protective coverall, footwear and full-face mask APF10) are worn and LEV APF20 integrated in the vaporization PAA machine is working, therefore **the uses of which this scenario is part will be authorized.**

Explanatory note (only for Spain authorisation):
According to national legislation, in Spain there are three user categories:

- Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
- Professional users (P): professionals that use the biocidal products in the context of their profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills

handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.
- Non-professional users (NP): users who are not professionals and that apply the biocidal product in the context of their private life.

The conclusions reached in this PAR, which affect the category of "Industrial", will be applicable to Industrial (Trained profesional and Professional) users at the Spanish level.

Therefore, **ES CA will apply article 37 according to BPR in the authorisation of this product, for users and packaging sections.**

Environment

A risk assessment for the environment has been carried out for the intended use of the biocidal product PHASE VTA as an industrial disinfectant of aseptic packaging applied in closed systems indoors. Based on the environmental risk assessment, it is unlikely that assessed use cause any unacceptable risk for the environment if the directions for use are to be followed. Therefore, risks are acceptable to all environmental compartments and the approval of PHASE VTA can be granted from an environmental perspective.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	Country (if relevant)
PHASE VTA	Spain, .

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Evonik Peroxide Spain s.l.u.
	Address	c/ Afueras s/n 50784 La Zaida (Zaragoza) – Spain
Authorisation number	ES/APP(NA)-2023-04-00864	
Date of the authorisation	19/04/2023	
Expiry date of the authorisation	19/04/2033	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer 1	Evonik Peroxide Spain s.l.u.
Address of manufacturer	c/ Afueras s/n 50784 La Zaida (Zaragoza) – Spain.
Location of manufacturing sites	c/ Afueras s/n 50784 La Zaida (Zaragoza) – Spain.
Name of manufacturer 2	Evonik Operations GmbH (Acting for Evonik Active Oxygens, LLC (US))
Address of manufacturer	One Commerce Square 2005 Market Street Suite 3200 Philadelphia, PA 19103 – USA
Location of manufacturing sites	35 Sawyer Avenue Tonawanda, NY 14150 – USA
Name of manufacturer 3	Evonik Peroxid GmbH
Address of manufacturer	Industriestraße 1 Weißenstein AT-9721 – Austria
Location of manufacturing sites	Industriestraße 1 Weißenstein AT-9721 – Austria

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

Active substance	Peracetic acid
Name of manufacturer 1	**Evonik Peroxide Spain s.l.u.**
Address of manufacturer	c/ Afueras s/n 50784 La Zaida (Zaragoza) – Spain

Location of manufacturing sites	c/ Afueras s/n 50784 La Zaida (Zaragoza) – Spain

Active substance	Peracetic acid
Name of manufacturer 2	Evonik Operations GmbH (Acting for Evonik Active Oxygens, LLC (US))
Address of manufacturer	One Commerce Square 2005 Market Street Suite 3200 Philadelphia, PA 19103 – USA
Location of manufacturing sites	35 Sawyer Avenue Tonawanda, NY 14150 – USA

Active substance	Peracetic acid
Name of manufacturer	**Evonik Peroxid GmbH**
Address of manufacturer	Industriestraße 1 Weißenstein AT-9721 – Austria
Location of manufacturing sites	Industriestraße 1 Weißenstein AT-9721 – Austria

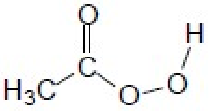
2.1.2 Product composition and formulation

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
IUPAC	Peroxyethanoic acid
Common name	Peracetic acid
EC number	201-186-8
CAS number	79-21-0
Index number in Annex VI of CLP	607-094-00-8
Minimum purity / content	The active substance is peracetic acid in an aqueous solution containing acetic acid, hydrogen peroxide and water. Pure peracetic acid does neither exist commercially nor is it an intermediate in the production of peracetic acid products. Furthermore, any attempt to produce pure peracetic acid would be prevented by the explosion risks of such a compound. Peracetic acid is produced by reacting hydrogen peroxide (HP) with acetic acid in aqueous solution. In this process,

	peracetic acid is not obtained as a pure substance but in the form of aqueous solutions containing peracetic acid, acetic acid, hydrogen peroxide and water. The peracetic acid content in existing aqueous equilibrium solutions (products) can be as low as < 0.1% or as high as > 15% (w/w). The equilibrium solution is typically the biocidal product which is placed on the market. The specifications are based on the starting materials acetic acid and hydrogen peroxide. The specification of (starting material) acetic acid is as in accordance to Regulation 231/2012. The minimum purity of acetic acid is >99.8% For (starting material) hydrogen peroxide the specification is as in the Hydrogen peroxide CAR in PTs 1-6, and the purity/contents in aqueous solution is 35% – 69.9%, as in Regulation (EU) 2015/1730
Structural formula	

2.1.2.2 Candidate(s) for substitution

Peracetic acid does not meet the conditions laid down in Article 10 of BPR Regulation (EU) No 528/2012 and is therefore not considered as a candidate for substitution. A comparative assessment is therefore not required under Article 23 of Regulation (EU) 528/2012.

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Peracetic acid	Peroxyethanoic acid	Active substance	79-21-0	201-186-8	15
Hydrogen peroxide	Hydrogen peroxide	Non-active substance: Precursor – Equilibrium partner	7722-84-1	231-765-0	10
Acetic acid	Acetic acid	Non-active substance: Precursor – Equilibrium partner	64-19-7	200-580-7	35

2.1.2.4 Information on technical equivalence

The applicant Evonik Peroxide Spain s.l.u., as the manufacturer of the active substance, and Evonik Peroxid GmbH, as the manufacturer of the active substance as well, were participants in the review programme and member of the CEFIC Peracetic Acid Registration (PAR) Group which submitted and defended the active substance dossier on peracetic acid

(PAA) as submitted to the RMS Finland. As the source and, thus, the specification of the active substance PAA as contained in Phase VTA is identical to the reference as defined by the Biocidal Product Committee for the decision on the approval of the active substance and as listed in the Union list of approved active substances under Regulation No. 528/2012, the technical equivalence is not applicable.

The source of the present active substance was included in the Union list of approved active substances. Therefore, technical equivalence is not applicable

2.1.2.5 Information on the substance(s) of concern

According to the Guidance on the BPR, Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 3.0, November 2017, two substances of concern, acetic acid and hydrogen peroxide, were identified.
Please see the confidential annex for further details.

2.1.2.6 Type of formulation

SL-Soluble concentrate.

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Org. Perox. Type F, H242 Met. Corr. 1, H290 Acute tox 3 (dermal); H311 Acute Tox. 4 (oral); H302 Acute Tox. 4 (inhalation); H332 Skin Corr. 1, H314 Eye Damage 1, H318 STOT SE 3, H335 Aquatic Chronic 1, H410
Hazard statement	H242: Heating may cause a fire. H290: May be corrosive to metals. H311: Toxic in contact with skin. H302: Harmful if swallowed. H332: Harmful if inhaled. H314: Causes severe skin burns and eye damage. H318: Causes serious eye damage. H335: May cause respiratory irritation. H410: Very toxic to aquatic life with long lasting effects.
Labelling	
Pictogram	GHS02, GHS05, GHS06, GHS09
Signal words	Danger

Hazard statements	H242: Heating may cause a fire. H290: May be corrosive to metals. H311: Toxic in contact with skin. H302+H332: Harmful if swallowed or if inhaled H314: Causes severe skin burns and eye damage. H410: Very toxic to aquatic life with long lasting effects. EUH071: Corrosive to the respiratory tract.
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking. P234: Keep only in original container. P260: Do not breathe 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. P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/… P301+P330+P331+P310: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician. P303+P361+P353+P310: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. Immediately call a POISON CENTER or doctor/physician. P305+P351+P338+P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P361+P364: Take off immediately all contaminated clothing and wash it before reuse. P403: Store in a well-ventilated place. P405: Store locked up. P273: Avoid release to the environment P391: Collect spillage. P501: Dispose of the content and/or its container as hazardous waste according to regulation in force
Notes	The following P-statements were triggered by the included H-statements, but not included: • P261 is triggered by H332, however, not assigned as covered by the included P260. • P301+P312 and P330 triggered by H302 is not assigned, as considered covered by the assigned P301+P330+P331 and P310 triggered by H314. • P302+P352 and P312 triggered by H311 is not assigned, as considered covered by the assigned P303+P361+P353 and P310 triggered by H314. • P321 is triggered by H314. However, this P-statement is highly recommended only in exceptional cases where specific treatment is known and required. No specific treatment is known, therefore P321 is not assigned. • P363 triggered by H314 is not assigned as considered covered by P361+P364 as triggered by H311.

*ES CA will apply article 37 according to BPR in the authorisation of this product including in this section the P statements that are recommended and highly recommended according to the result of the risk assessment of the product and considering the Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 (Version 4.2 March 2021).

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Industrial. Aseptic packaging: Disinfection by peracetic acid vaporization with hot air.

Product Type	PT4 – Food and feed area disinfectant
Where relevant, an exact description of the authorised use	The biocidal product is for use in aseptic food processing on food packaging materials to achieve commercial sterility.
Target organism (including development stage)	Bacterial spores
Field of use	Indoor
Application method(s)	Closed system: Vaporization by hot air. The product is diluted in an automated process and applied in a closed system (i.e. in aseptic filling machines). The biocidal product is diluted with deionized water to a targeted peracetic acid concentration and fed into the vaporizing unit at a certain flow rate becoming a vapour. The vapour is carried by heated (vaporization temperature) air into a package that needs to be sterilized. The vapour condensates inside the package during a certain time (seconds) to form a thin uniform layer. The sterilization is achieved by peracetic acid inside the condensate. Finally, ambient air is fed (drying temperature) into the treated package to remove the condensate and to dry out the package. For packaging form 5 to 30kg manual loading is authorised.
Application rate(s) and frequency	For each aseptic packaging system, the biocidal product contact time, vapour temperature, the air flow and drying air temperature need to be determined. Application dose range: 20000 - 150000 ppm peracetic acid. Final concentration on packaging: 60mgPAA/m^2 Contact time: 2.8-20 seconds Vaporization Temperature: 85ºC Drying Temperature: > 60 ºC
Category(ies) of users	Industrial.
Pack sizes and packaging material	Jerry can / 5, 20, 25 and 30 kg / HDPE

2.1.4.2 Use-specific instructions for use

See 2.1.5.1 Section

2.1.4.3 Use-specific risk mitigation measures

See 2.1.5.2 section

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

See 2.1.5.3 section

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

See 2.1.5.4 section

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

See 2.1.5.5 section

2.1.5 General directions for use

2.1.5.1 Instructions for use

Intended only for Industrial users.

For industrial users: the user of the product must have received adequate training within the framework of that industry, in a way that allows him to have the knowledge and skills in handling chemical products and in the correct use of the necessary personal protective equipment for the safe performance of his work.

Use in accordance with the requirements for aseptic packaging machines.

Read the label carefully before using.

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

Aerosolised or vaporised application should be use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.

Load manually or automaticlly the product into the machine depending on packaging:
- For packaging form 5 to 30kg manual loading is authorised.

Efficacy was demonstrated against bacterial spores at the achieve target concentration of 60 mg PAA/m2 were 3% VTA (as PAA), 3.8 sec and 85ºC vapour temperature and 7g/min of flow rate. The optimization of conditions in the machines is case by case.

The machine dilute automatically the product with deionized water to a targeted peracetic acid concentration of 60 mg PAA/m2, fed the biocidal product into the vaporizing unit at a certain flow and temperature (vaporization temperature) and let the product condensates inside the package during the stablished contact time (seconds) to form a thin uniform layer. Finally, fed ambient air (drying temperature) into the treated package to remove the condensate and to dry out the package.

For each aseptic packaging system, the biocidal product contact time, vapour temperature, the air flow and drying air temperature need to be determined.

Application dose range: 20000 - 150000 ppm peracetic acid

Final concentration on packaging: 60mgPAA/m2

The user of the biocidal product shall always carry out a microbiological 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, after which a protocol for disinfection of these packagings can be made and use thereafter.

In case there are methods available for chemically monitoring the active substance on surfaces, chemical validation should be performed besides biological validation.

When it concerns a “standard packaging” for which a protocol is available, the validation may be limited to only a chemical validation.

The product is intended to be used for didinfecting PET and HDPE bottles and cartons.

Inform the registration holder if the treatment is ineffective.

Pre-clean and dry surfaces prior to disinfection.

2.1.5.2 Risk mitigation measures

Wear protective chemical-resistant gloves, protective coverall, footwearand and full-face mask APF10 (materials and types of personal protective equipment will be specified in the product information by the authorization holder).

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

During manual maintenance tasks, ensure adequate ventilation inside the machine (LEV) before opening the doors of the aseptic area.

1. The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed.
2. Workplace release measurements with suitable measurement equipment shall be performed upon implementation of the aseptic packaging plant, at regular intervals (annual intervals recommended) and after any change in relevant boundary conditions. The national regulations for workplace measurements have to be followed.
3. 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.

Aerosolised or vaporised application should be used only in closed aseptic packaging machines with no emission to water and negligible emission to air. Emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.

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

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.
Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.
IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.
Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.
IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes After washing the skin:Call 112/ambulance for medical assistance.
Information to Healthcare personnel/doctor: Initiate life support measures, thereafter call a POISON CENTRE.
IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.
Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor.

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER

Emergency measured to protect environment in case of accident:
Prevent spillage from reaching soil, ground, surface water or any kind of sewer.
Dike to collect large liquid spills.
Contain spills with earth or sand or inert absorbent.
Stop leak and contain spill if this can be done safely.
If safe to do so, move product to secure area.
Control runoff and isolate discharged material for proper disposal.
Do not seal waste material, do not use textiles, tissues, saw dust or combustible materials to clean the spill.
Do not return product to the original storage container/tank due to risk of decomposition.
Residual hydrogen peroxide, if allowed to dry on combustible materials such as paper, fabrics, leather, or wood can cause the material to ignite and result in a fire.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Empty containers, unused product, washing water, containers and other waste generated during the treatment are considered hazardous waste. Deliver those wastes to a registered establishment or undertaking, in accordance with current regulations.
Do not release to soil, ground, surface water or any kind of sewer.

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

Keep in a dry, cool, and well-ventilated place. Containers must be vented.
Keep at temperatures below 30°C. Temperatures above 35ºC will accelerate decomposition resulting in loss of assay.
Protect the product from light.
Do not store near combustible materials.
Packaging material:. High density polyethylene. Avoid any other material.
Materials to avoid: Oxidizing agents; Strong reducing agents; Combustible materials; Heavy metals.
Shelf-life: 6 months.

2.1.6 Other information

Definitions:

- <u>Industrial users</u>:

Industrial factory workers.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Jerry can	5, 20, 25 and 30 kg	HDPE	Degassing cap, HDPE	Industrial	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

According to the previous section 2.1.2, no new data/information on human health and environment neither for the product nor the active substance(s) is deemed necessary, and therefore a very short summary of the human health and environmental assessment are presented. The present assessment report contains new data for the biocidal product regarding specific physical, chemical, and technical properties, storage stability, analytical methods, and efficacies. Moreover, a complete exposure assessment and risk characterisation is presented.

2.1.8.2 Access to documentation

The applicant, Evonik Peroxide Spain S.l.u (former PeroxyChem Spain s.l.u.), is a member of the consortium of the Cefic Peracetic Acid Registration Group and therefore, and has access to all data submitted in the dossier for the active substance originally submitted under the Biocidal Products Directive.
The applicant, Evonik Peroxide Spain S.l.u (former PeroxyChem Spain s.l.u.) and Evonik Peroxid GmbH (former Evonik Resource Efficiency GmbH), are included in Appendix 1 – Members of PAR (Paracetic Acid Registration Group) of Letter of access (LoA) submitted by Cefic Peracetic Acid Registration Group.

2.2 Assessment of the biocidal product

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

Table 2. Intended use # 1 – Aseptic packaging: Disinfection by vaporization with hot air.

Product Type(s)	SL – Soluble concentrate
Where relevant, an exact description of the authorised use	The biocidal product is for use in aseptic food processing on food packaging materials to achieve commercial sterility. The product is diluted in an automated process and applied in a closed system (i.e. in aseptic filling machines). The biocidal product is diluted with deionized water to a targeted peracetic acid concentration and fed into the vaporizing unit at a certain flow rate becoming a vapour. The vapour is carried by heated air into a package that needs to be sterilized. The vapor condensates inside the package during a certain time (seconds) to form a thin uniform layer. The sterilization is achieved by peracetic acid inside the condensate. Finally, ambient air is fed into the treated package to remove the condensate and to dry out the package.
Target organism (including development stage)	Bacteria, yeast, bacterial spores
Field of use	PT4 – Food and feed area disinfectant
Application method(s)	Vaporization by hot air
Application rate(s) and frequency	Feeding dose: 170000 ppm PAA (product as such) Disinfection dose range: 4000 - 170000 ppm PAA (depending on the machine) Final concentration on packaging: 60 mg PAA/m^2 Contact time: 2-20 seconds (depending on the machine) Temperature: > 60 ºC (depending on the machine)
Category(ies) of user(s)	Industrial users.
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
Physical state at 20 °C and 101.3 kPa	Visual method	15% PAA, 10% HP, 35% AAC	Liquid	Aversa (2017)
Colour at 20 °C and 101.3 kPa	Visual	15% PAA, 10% HP, 35% AAC	Colourless	Aversa (2017)
Odour at 20 °C and 101.3 kPa	visual	15% PAA, 10% HP, 35% AAC	Intense, pungent, vinegar type	Aversa, S (2017)

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td>pH</td><td>CIPAC MT 75.3</td><td>15% PAA, 10% HP, 35% AAC</td><td>Undiluted: 0.87
Diluted 1% w/v:2.93

At initial time
Undiluted: 0.87
Diluted 1% w/v:2.93
After accelerated storage
Undiluted: 0.96
Diluted 1% w/v:2.88</td><td>Aversa, S. 2017</td></tr>
<tr><td>Acidity / alkalinity</td><td>CIPAC MT 191</td><td>15% PAA, 10% HP, 35% AAC</td><td>31.26% H_2SO_4</td><td>Al Amin,I. 2016</td></tr>
<tr><td></td><td>CIPAC MT 191</td><td>15% PAA, 10% HP, 35% AAC</td><td>At initial time 30.86% H_2SO_4</td><td>Aversa, S. 2017</td></tr>
<tr><td>Relative density / bulk density</td><td>EU A.3</td><td>15% PAA, 10% HP, 35% AAC</td><td>$D^{20}{}_4$ =1.114</td><td>Al Amin, I . (2016)</td></tr>
<tr><td>Storage stability test – accelerated storage</td><td colspan="3">Accelerated storage at 35 ± 2 °C for 12 weeks.
The product was stored in 5 L HDPE tank.
Test item was determined by titration and Validated method SANCO/3030/99 rev.4 in Study BT221/16.
<table>
<tr><th></th><th>T0</th><th>After accelerated storage:12 weeks</th></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td>Aspect</td><td>Clear and homogeneous liquid,colourless. Intense, punget,vinegra type.</td><td>Clear and homogeneous liquid,colourless. Intense, punget,vinegra type.</td></tr>
<tr><td>AScontent (PAA% w/w)</td><td>14.81</td><td>6.83</td></tr>
<tr><td>Variation of AScontent</td><td>-</td><td>-53.88</td></tr>
<tr><td>H_2O_2 content %</td><td>9.97</td><td>6.55</td></tr>
<tr><td>Variation of H_2O_2 content</td><td>-</td><td>-34.30</td></tr>
<tr><td>Other component (equilibrium</td><td>35.94</td><td>42.43</td></tr>
</table>
</td><td>Aversa, S. (2017)</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td colspan="3">
<table>
<tr><td>partner)
Acetic acid</td><td></td><td></td></tr>
<tr><td>Variation of AA content</td><td>-</td><td>18.05</td></tr>
<tr><td>pH
undiluted
diluted 1%w/v</td><td>0.87(24.5 °C)
2.93(20.5°C)</td><td>0.96(20.5°C)
2.88(20.5°C)</td></tr>
<tr><td>Acidity expressed as H2SO4</td><td>30.858% w/w</td><td>35.085%w/w</td></tr>
<tr><td>Dilution stbility 5%v/v
Initial
After 18 hours</td><td>Homogeneous
Homogeneous</td><td>Homogeneous
Homogeneous</td></tr>
<tr><td>Packaging
Weight loss</td><td>-</td><td>-3.88%</td></tr>
<tr><td>Container observation</td><td>- (5L HDPE tank -)</td><td>No modification observed.</td></tr>
</table>
According to the results, the test item is not stable after accelerated storage at 35 ± 2 °C for 12 weeks.
The hydrogen peroxide and the peracetic acid content is decreased of about 34.3 and 53.9, while the content of acetic acid is increased about 18.1%. Temperatures above 35ºC should be avoided since peracetic acid decomposes on heating.
</td><td></td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>OPPTS 830.6317 and OPPTS 830.6320</td><td>15% PAA, 10% HP, 35% AAC</td><td>Storage at ambient temperature for 6 months.
The product was stored in 0.47 L HDPE cans.
Test item was determined by titration and validated according to SANCO/3030/99 Rev. 4.</td><td>Ciemnolonski,L. (2017)</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><th></th><th>T0</th><th>T3months</th><th>T6mont s</th></tr>
<tr><td>Aspect</td><td>Sampled liquids are clear with water like consistency</td><td>Sampled liquids are clear with water like consistency</td><td>Samplec liquids a clear wi water lil consiste cy</td></tr>
<tr><td>AScontent (PAA% w/w)</td><td>15.34</td><td>15.77</td><td>14.52</td></tr>
<tr><td>Variation of AScontent</td><td>-</td><td>2.8%</td><td>-5.3%</td></tr>
<tr><td>H_2O_2 content %</td><td>11.67</td><td>10.45</td><td>9.88</td></tr>
<tr><td>Variation of H_2O_2 content</td><td>-</td><td>-10.45%</td><td>-15.33</td></tr>
<tr><td>Container observation</td><td>No leaking, discoloration or cracking observed of sample bottles.</td><td>No leaking, discoloration or cracking observed of sample bottles.</td><td>No leaking, discolora on cracking observe of samp bottles.</td></tr>
</table>
Conclusion:PHASE VTA was found to be stable in HDPE containers up to 6 months at ambient temperature. A smaller packaging is regarded as the worst-case packaging size in terms of the surface to volume ratio. Accordingly, 0.47L HDPE can can be considered as representative of the commercial packaging (e.g. ≥ 5 kg) included in the present application and thus, claiming 6- month shelf life is justified for the commercial packaging.
</td><td></td></tr>
<tr><td>Storage stability test – low temperature stability test for liquids</td><td>CIPAC MT 39.3</td><td>15% PAA, 10% HP, 35% AAC</td><td>The test item remained unaltered after cold storage at 0 C±2 °C for 7 days,the product has not suffered changes in colour, odour, clarity, texture and separation or precipitation after cold storage.</td><td>Aversa, S. (2017)</td></tr>
</table>

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	*Stability to sunlight is not considered relevant for peracetic acid nor hydrogen peroxide when stored as recommended.* Store protected from light.			
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	• Temperature effects: See results from storage stability test. • Humidity effects: Not considered relevant for a liquid formulation.			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	OPPTS 830.6317 and OPPTS 830.6320	15% PAA, 10% HP, 35% AAC	The long-term stability study demonstrate that the plastic (HEDP) packaging material has not reacted with the product. No visible changes were observed in the appearance of the product and the packaging of the test item during the study. No reactivity towards container material was found.	Ciemnolonski,L. (2017)
Wettability	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Suspensibility, spontaneity and dispersion stability	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Wet sieve analysis and dry sieve test	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Emulsifiability, re-emulsifiability and emulsion stability	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Disintegration time	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Particle size distribution, content of dust/fines, attrition, friability	*The request is not applicable.Once vaporized the product is in the form of gas and has no particles.*			
Persistent foaming	CIPAC MT 47.2	15% PAA, 10% HP, 35% AAC	The persistent foaming of the test ítem was measured in the undiluted product (as highest application rate, considering that the product is ready	Aversa, S. (2017)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			to use) and at 0.013% (lowest application rate) Results for undiluted product: Test n / Sample weight (g) / Foam 10s (mL) / Foam 1 min 1 / undiluted / 0 / 0 2 / undiluted / 0 / 0 Results at 0.013% v/v Test n / Sample volume (µL) / Foam 10s (mL) / Foam 1 min 1 / 2 / 0 / 0 2 / 2 / 0 / 0 Conclusion: No foam was produced by the test item. eCA remark: In the "persistent foaming" study , the undiluted product was used as the highest concentration to be applied and the concentration of 0.013% v/v as the lowest concentration. It should be clarified that these doses were selected when it was intended to request the authorization of the product for different uses that were not finally included in the dossier. The lowest dose it refers to one of the uses that was finally eliminated, so it does not apply to the aseptic packaging of containers that is defended in this file. Due to the great variety of systems of aseptic packaging existing in the market, for each combination of packaging/system of packaging, it will be necessary to adapt the conditions to be applied (dose, contact time, temperature of steam, air flow and the temperature of the drying air). the product is applied undiluted in the packaging process and it is diluted to the PAA	

Results for undiluted product:

Test n	Sample weight (g)	Foam 10s (mL)	Foam 1 min
1	undiluted	0	0
2	undiluted	0	0

Results at 0.013% v/v

Test n	Sample volume (µL)	Foam 10s (mL)	Foam 1 min
1	2	0	0
2	2	0	0

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			concentration required, which can vary between 20000 ppm to 150000 ppm(2%PAA-15%PAA) depending on the system, to obtain a final concentration in the container of about 60 mg PAA/m^2. The process is automatic, so the range of concentrations, contact times and temperatures of the process or drying process are regulated by an analytical mathematical model in the machine. Therefore, the highest concentration of PAA is 15% (RTU product) and the lowest is 2%PAA.	
Flowability/Pourability/Dustability	*The study does not need to be conducted since the biocidal product is a water based liquid formulation.*			
Burning rate — smoke generators	*The study does not need to be conducted since the biocidal product is not a smoke generator.*			
Burning completeness — smoke generators	*The study does not need to be conducted since the biocidal product is not a smoke generator.*			
Composition of smoke — smoke generators	*The study does not need to be conducted since the biocidal product is not a smoke generator.*			
Spraying pattern — aerosols	*The study does not need to be conducted since the biocidal product is not an aerosol.*			
Physical compatibility	*The study does not need to be conducted since the product is not intended to be used with other products.*			
Chemical compatibility	*The study does not need to be conducted since the product is not intended to be used with other products.*			
Degree of dissolution	*The study does not need to be conducted since the product is not used in water soluble bags or tablets.*			
Dilution stability	CIPAC MT 41	15% PAA, 10% HP, 35% AAC	5% dilution The solution remained homogeneous after 18 hours.	Aversa, S. (2017).
Surface tension	EU A.5 OECD 115	15% PAA, 10% HP, 35% AAC	34.8 mN/m	Al Amin. (2016).
Viscosity	OECD 114	15% PAA, 10% HP, 35% AAC	2.00 mm^2/s (20ºC) 1.27 mm^2/s (40ºC)	Al Amin. (2016).

*PAA: peracetic acid, HP: Hydrogen peroxide, AAC: Acetic acid

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

PHASE VTA is a clear and homogeneous, colourless liquid, with an intense, pungent, vinegar type odour. The pH is 0.87 for the neat product and 2.93 for the 1% dilution. The acidity of the product was found to be in the range of 30.86% and 31.26% calculated as H_2SO_4 (w/w).
The density of the product is 1.114 g/ml at 2OºC (relative density value 1.114). The biocidal product has a surface tension of 34.8 mN/m and its viscosity is 2.00 mm^2/s at 20 ºC and 1.27 mm^2/s at 40 ºC.

Regarding the storage stability, it was found to be stable in HDPE containers up to 6 months at ambient temperature and at least for 7 days at low temperatures (0 ºC). Temperatures above 35ºC should be avoided since peracetic acid decomposes on heating and in the presence of traces of heavy metal ions. The product is not intended to be used with other products.

2.2.3 Physical hazards and respective characteristics

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
Explosives	Data waiving: *"The explosive properties do not have to be determined according to the CLP Annex I, Chapter 2.1, because explosive properties are incorporated in the decision logic for organic peroxides. Note that organic peroxides may have explosive properties when handled under higher confinement."*			
Flammable gases	*The study does not to be conducted since the biocidal product is a liquid.*			
Flammable aerosols	*The study does not to be conducted since the biocidal product is a liquid.*			
Oxidising gases	*The study does not to be conducted since the biocidal product is a liquid.*			
Gases under pressure	*The study does not to be conducted since the biocidal product is a liquid.*			
Flammable liquids	EU A.9	15% PAA, 10% HP, 36% AAC	Flash point: 71.0 ºC.	Flasińska,P.(2016)
Flammable solids	*The study does not to be conducted since the biocidal product is a liquid.*			
Self-reactive substances and mixtures	*The testing has been carried out following the classification procedure for organic peroxides since the decision logic and the corresponding tests for organic peroxides and self-reactiveness are exactly the same.The same flow chart scheme for self-reactive substances and organic peroxides.*			
Pyrophoric liquids	The mixture is known to be stable at room temperature for prolonged periods of time.			
Pyrophoric solids	*The study does not need to be performed since the biocidal product is a liquid.*			
Self-heating substances and mixtures	Waiving of the testing based on Guidance on the application of the CLP criteria: *In general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore liquids are not classified as self-heating. However, if liquids are*			

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
	adsorbed on a large surface (e.g. on powder particles), a self-heating hazard should be considered.			
Substances and mixtures which in contact with water emit flammable gases	Experience in handling and use shows the biocidal product does not react with water.Moreover, the formulation contains at least 30% water .			
Oxidising liquids	*According to* Guidance on Information Requirements and Chemical Safety Assessment chapter R.7ª v.6.0:*The third indent states that organic peroxides should not be tested for oxidising properties. Organic peroxides are distinguished by their chemical structure, and should be treated according to the procedures for the hazard class Organic Peroxides of the CLP Regulation.* *According to the Guidance on the Application of the CLP criteria:"In general, organic peroxides do not have or have only weak oxidising properties".*			
Oxidising solids	*The study does not to be conducted since the biocidal product is a liquid.*			
Organic peroxides	UN Manual of Test and Criteria 5.2 , Part II,Organic Peroxide Test Series A to H 1)Detonation (test series A,UN Test A.1 steel tube test) 2)Deflagration (test series C, C1 and C2)	16.8% PAA 23.1% HP	1)The average fragmentation length is 165 mm (reference value :115 mm) the average tube fragmentation length (over two tests) is not more than 1.5 times the average fragmentation length found with an inert material →**NO DETONATION** 2)Deflagration tests were performed under confinement:a).time/pressure test (UN Test C.1).**Result:YES, slowly.** and under atmospheric pressure b 9.deflagration test (UN Test C.2).**Result:NO.** According to the results of the tests C.1 and C.2 the material is not able to propagate a deflagration. **The conclusion is the sample does not deflagrate** since the deflagration test (C.2)	Vorwinkel (2017)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			result is “No” and the time/pressure test (C.1) result is not “Yes, rapidly”.	
	3)Heating under confinement (test series E, E1 and E2)		3) a. Koenen test (test E.1) It was found that the limiting diameter is less than 1.0 mm and the effect in any tests (1 mm orifice) was different from type “O” (tubes unchanged). **Concluding result: "No"** b. Dutch pressure vessel test (test E.2) Orifice diameter:The limiting diameter is < 1.0 mm. Concluding result: "No" According to the results of the tests E.1 and E.2 the concluding assessment of the effect under defined confinement is: **NONE EFFECT OF HEATING UNDER DEFINED CONFINEMENT.**	
	4)Explosive powder (test series F)		4) BAM Trauzl test (test F.3) Test 1: 10.8 cm^3 expansion per 10 g of sample Test 2: 10.6 cm^3 expansion per 10 g of sample In both cases the volume expansion of the lead block was more than 10 cm^3 per 10 g of sample. Therefore it can be stated that the sample showed a **low explosive power.** As the answer "Low" (assessment of the effect under defined confinement). Therefore Exit F had to be selected.	
	Classification:Org.Perox. type F liquid; H242			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	UN 5.2 Organic Peroxide Test Series UN Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria, 2009 Test 1(a) UN Gap Test. **UN Test Series 1, Test 1(a) UN (Zero Card) Gap Test/UN Test A.5 USA Gap Test** **UN Test Series 2 Test 2(a) UN Gap Test** **SERIE C TESTS:UN Test**	**22/10 Peracetic Acid PAA)** 22.1% PAA 10% HP,	- **Series 1, Test 1(a):**1) Shock sensitivity and detonation propagationResults: The liquid material tested in confined in a steel tube did not propagate a detonation when initiated by an intense stimulus (provided by a booster). The result for UN test 1 (a) is considered "Negative". *The tube was not fragmented over its entire length and the average tube fragmentation was not more than 1.5 times the average fragmentations length found with an inert water material.* The result for UN test A.5 with respect to water as inert material is considered "No". 2)Since with zero Gap the test result for duplicated test trials was "Negative", by analogy, the result for UN test 2 (a) with 50mm PMMA Gap should also be considered "Negative". **Test C.1:**The Deflagration pressures of **22/10 Peracetic Acid PAA** in	Final report PC16329AR. **Ricky Mittiga September 9, 2015**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	C.1; Time/Pressure Test and Test C.2: UN Deflagration Test		Time/Pressure vessel did not exceed 2070 kPa. *The overall test result is considered "No".* **Test C.2:** UN Deflagration Test:The sample in 300-ml Dewar glass vessel *did ignited/deflagrate while the gas flame was present for 5-minutes. The deflagration did not propagate to the upper or lower marks.* The overall test result is considered "No".	
	TESTS SERIES E		**1)UN Test E.1 Koenen Test:**The *material did not exhibit an explosion with a 1.0-mm diameter orifice. The effect on heating under confinement for all trials with a 1.0-mm diameter orifice was type "O". The limiting orifice diameter is less than the 1-mm.* The overall test result is considered "No." **2) UN Test E.3 United States Pressure Vessel Test:**The *material did not exhibit an explosion with a 1.0-mm diameter orifice. The effect on heating under confinement for all trials with a 1.0-mm* ***diameter orifice was type "O". The limiting orifice diameter is less than the 1-mm***. Concluding result: "No".→**As Packaged in packages of more than 400kg/450l→TESTS SERIES F**	

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
	TEST SERIE F		*SERIES F TEST:1)UN Test F.4 Modified Trauzl Test*: *The sample tested three times using Modified Trauzl apparatus. The average net block expansion was less than 12 cm3. Water was tested as reference material**.** The net expansion for sample with respect to water was 9.1 ml.*Result:Low **As the answer "Low" (assessment of the effect under defined confinement). Therefore Exit F had to be selected.**	
	Classification:Org.Perox. type F liquid; H242			
	UN Test H.2 ADIABATIC DEWAR STORAGE TEST (SADT Test)UN H.3	22% PAA, 10% HP,35% AAC	SADT(Calculated SADT Based on ARC Data):60ºC for a 50 kg package (liquid product)	Final report PC16329AR. **Ricky Mittiga September 9, 2015**
Corrosive to metals	Recommendations on the Transport of Dangerous Goods, Manual UN Test C.1	15% PAA, 10.% HP, 36% AAC	The test for determination of corrosive properties on metals was performed on carbon steel (type: S235 JR) and alloyed aluminium (type: 7075 T6 F53), applying weight loss method. For each type of metal, one metal specimen was completely dipped into the solution, another one only half way and a third one was hang in the	Petryka, M. (2016)

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>vapour phase (2 mm thick metal plates). The distance between the upper edge of the completely inserted specimen and the surface of the liquid was 10 mm. A temperature of 55± 1ºC was maintained throughout the test, and fresh solution was provided to ensure enough reactive agent during the course of test. The metal sheets should have been exposed in these stable conditions for one week (168hours), but for the steel test they were only 16 hours due to the violent reaction that took place. The mass loss was then determined.
Results: Corrosion rate of aluminium in Phase VTA was below the threshold of 6.25mm/year but corrosion rate of steel was above the threshold of 6.25mm/year.
<table>
<tr><td>Results of test</td><td>Aluminium</td><td>Steel</td></tr>
<tr><td>time of exposure</td><td>168 h</td><td>168 h</td></tr>
<tr><td>mass loss threshold</td><td>13.5%</td><td>2.21% *</td></tr>
<tr><td>most corroded sample mass loss</td><td>0.93%</td><td>6.27%</td></tr>
<tr><td>corrosion rate</td><td><6.25 mm/year</td><td>>6.25 mm/year</td></tr>
</table>
*value calculated</td><td></td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Conclusions: According to UN test C.1 criteria, the test material was considered to be corrosive to metals.	
Auto-ignition temperatures of products (liquids and gases)	EU A.15	15% PAA, 10% HP, 36% AAC	285ºC.	Flasińska ,P. (2016)
Relative self-ignition temperature for solids	*The study does not need to be conducted since the biocidal product is a liquid.*			
Dust explosion hazard	*The study does not need to be conducted since the biocidal product is a liquid.*			

Conclusion on the physical hazards and respective characteristics of the product
PHASE VTA is classified as organic peroxide liquid type F and considering the additional data provided by the applicant, the read-across with the product "22/10 Peracetic Acid PAA" is acceptable for packaging up to 50 kg and sufficiently proves that the product PHASE VTA in packaging up to 50 kg is an organic peroxide type F. For packaging up to 50 kg the SADT is 60°C, so no temperature control is necessary. PHASE VTA is corrosive to metals. The product was found to be corrosive to metals since the corrosion rate of steel was higher than 6.25 mm/year. Decomposition of peracetic acid produces oxygen and the oxygen released could initiate or promote combustion of other materials. The flash point of the biocidal product was determined to be 71.0 ºC and the auto-ignition temperature was of 285 ºC. Auto-ignition measured temperature may not correspond to the auto-ignition temperature of the product as it presumably degraded itself .

2.2.4 Methods for detection and identification

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

Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Peracetic acid	Titration	Fortification levels: 12% peracetic acid in	r = 0.999584	No interference	Low level :98.19-100.15	-Low level:99.17 at 12% w/w level	0.75	-	BIOTECNOLOGIE BT Final Report BT225/16 Aversa

		the blank formulation 18% peracetic acid in the blank formulation Two replicates were prepared for each fortification level.			High level: 100.36-101.50	-High level:100.93 at 18% w/w level -			(2017); BIOTECNOLOGIE BT Final Report BT221/16 Aversa (2017);
Hydrogen peroxide	Titration	Fortification levels: 8% hydrogen peroxide in the blank formulation 12% hydrogen peroxide in the blank formulation Two replicates were prepared for each fortification level.	r = 0.999392	No interferences	Low level :98.84-101.54 High level: 101.56-101.85	-Low level:100.19 at 8% w/w -High level:101.71 at 12% w/w-	0.49	-	BIOTECNOLOGIE BT Final Report BT225/16 Aversa (2017); BIOTECNOLOGIE BT Final Report BT221/16 Aversa (2017);
Acetic acid	Titration	Fortification levels: 28% acetic acid in the blank formulation 42% acetic acid in the blank formulation Two replicate	r = 0.999994	No interferences	Low level :98.45-98.61 High level: 101.78-101.88	--Low level:98.53 at 28% w/w -High level:101.83 at 42% w/w	0.73	-	BIOTECNOLOGIE BT Final Report BT225/16 Aversa (2017); BIOTECNOLOGIE BT Final Report BT221/16 Aversa (2017);

		s were prepared for each fortification level.							

eCA Remark
The total active oxygen (formed by reaction of peracetic acid with iron and hydrogen peroxide) was determined by titration with sodium thiosulfate. Hydrogen peroxide was instead determined by titration with cerium sulphate. Peracetic acid content was calculated by the difference between the two methods.

Analytical method validation – Acetic Acid

The content of the equilibrium partner (acetic acid) in the test item was determined by a titration analytical method validated in this study according to SANCO/3030/99 Rev. 4 Guidance Document .

The test item was titrated with a standard volumetric solution of sodium hydroxide until about pH 7.00.

In order to demonstrate the validity of the analytical method, the following parameters were evaluated:

Linearity test :5 different solutions were prepared by diluting the analytical standard (named SS_AcH) with ultrapure water, in order to obtain 5 different concentrations of acetic acid. Linearity was addressed using 5 calibration solutions over an appropriate range. About 1.5 g of each linearity solution were titrated with a standard volumetric solution of sodium hydroxide.

The validity criterion of $R^2 > 0.98$ was satisfied and the response was linear in the acetic acid concentration range of 1.0% w/w-50.019%w/w.

Precision: Five aliquot of about 1.5 g of test item were titrated by single determination with the sodium hydroxide 0.1 M solution. The titration solution volume was registered.

The % Relative Standard Deviation (% RSD), the mean of the five determinations RSD was compared with the value based on the modified Horwitz equation. The RSD values were < of 1.76 % (0.73 %) and the acceptability criterion was matched.

Accuracy (Recovery): The blank formulation was spiked with the analytical standard at two fortification levels at a concentration of about 80 % and 120 % respect to nominal values. Two replicates were prepared for each fortification level.

Recovery level solutions (low rec/high rec) were prepared with blank formulation and were spiked with peracetic acid standard, hydrogen peroxide technical product and acetic acid standard. About 1.5 g of test item solution were added to a 100 mL graduated flask and made up to volume with ultrapure water. 25 mL of the solution were transferred in a 250 mL beacker, 50 mL of ultrapure water were added and titrated with the sodium hydroxide 0.1 M solution.

The mean recovery, the standard deviation (SD) and the relative standard deviation (RSD %) for each fortification level were calculated.

The mean recovery is in the range required by the SANCO/3030/99 guideline for both fortification levels (98 – 102 %). The validity criterion of mean recovery was satisfied.

Specificity test and interference check: The interferences were evaluated analysing the blank formulation spiked with peracetic acid and hydrogen peroxide at the nominal concentration of the test item. Two aliquot of about 1.5 g of this solution were titrated .

No interferences was measured in the specificity solution. In fact the content of acetic acid measured was the same coming from the analitical standard of peracetic acid (mean recovery 98.58 %).

Analytical method validation – Hydrogen peroxide and peracetic acid

The content of the two active ingredients (hydrogen peroxide and peracetic acid) in the test item was determined by a titration analytical method, provided by the Sponsor and validated in this study according to SANCO/3030/99 Rev. 4 Guidance Document.
The total active oxygen (formed by reaction of peracetic acid with iron and hydrogen peroxide) was determined by titration with sodium thiosulfate. Hydrogen peroxide was instead determined by titration with cerium sulphate. Peracetic acid content was calculated by the difference between the two methods. The results reports the content of total active oxygen, hydrogen peroxide and peracetic acid.

In order to demonstrate the validity of the analytical method, the following parameters were evaluated:
Linearity test : 6 different solutions were prepared by diluting the analytical standards (named SS_HP and named SS_PAA) with ultrapure water.Linearity was addressed using 5 calibration solutions over an appropriate range.
The validity criterion of R2 > 0.98 was satisfied and the response was linear in the Hydrogen peroxide concentration range of 1.5 % w/w – 50.6 % w/w.
The validity criterion of R2 > 0.98 was satisfied and the response was linear in the peracetic acid concentration range of 1.1 % w/w – 25.1 % w/w.
Precision: Five aliquot of about 0.15 g of test item were titrated by single determination, in order to obtain the total oxygen content.
Five aliquot of about 0.20 g of test item were titrated by single determination, in order to obtain the hydrogen peroxide content.
The % Relative Standard Deviation (% RSD), the mean of the five determinations RSD was compared with the value based on the modified Horwitz equation.
The RSD values for precisión of hydrogen peroxide were < of 1.66 % (0.49 %) and the acceptability criterion was matched.
The RSD values for precisión of peracetic acid were < of 1.79 % (0.75 %) and the acceptability criterion was matched.
Accuracy (Recovery): The blank formulation was spiked with the analytical standard at two fortification levels at a concentration of about 80 % and 120 % respect to nominal values.Two replicates were prepared for each fortification level.
Recovery low level solutions (low rec) were prepared with about 4.4 g of blank formulation blank formulation and were spiked with about 3 g of peracetic acid standard ,about 1.15 g of hydrogen peroxide technical product and about 1.5 g of acetic acid standard .
Recovery high level solutions (high rec) were prepared with about 1.4 g of blank formulation blank formulation and were spiked with about 4.5 g of peracetic acid standard, about 1.8 g of hydrogen peroxide technical product and about 2.3 g of acetic acid standard .
The total active oxygen (formed by reaction of peracetic acid with iron and hydrogen peroxide) was determined by titration with sodium thiosulfate. Hydrogen peroxide was instead determined by titration with cerium sulphate. Peracetic acid content was calculated by the difference between the two methods.
Hidrogen peroxide content:About 0.2 g of test item solution were weighted and transferred in a 500 mL flask filled with 150 mL of Sulfuric acid solution, 3 drops of ferroine indicator and 1 drop of cerium sulphate solution 0.1 N. The solution was then titrated with cerium sulphate 0.1 N.
The peracetic acid content is given by the difference between the total oxygen content and the hydrogen peroxyde content.
The mean recovery, the standard deviation (SD) and the relative standard deviation (RSD %) for each fortification level were calculated.
Hydrogen peroxide: The mean recovery is in the range required by the SANCO/3030/99 guideline for low fortification levels (97 – 103 %) and for high fortification level (98 – 102 %). The validity criterion of mean recovery was satisfied.

Peracetic acid: The mean recovery is in the range required by the SANCO/3030/99 guideline for both fortification levels (98 – 102 %). The validity criterion of mean recovery was satisfied.

Specificity test and interference check:
Peracetic acid :The interferences were evaluated analysing the blank formulation spiked with acetic acid and hydrogen peroxide at the nominal concentration of the test item. Two aliquot of about 0.15 g of this solution were titrated
No interferences of peracetic acid was measured in the specificity solution.
Hyrogen peroxide :The interferences were evaluated analysing the blank formulation spiked with acetic acid and peracetic acid at the nominal concentration of the test item. Two aliquot of about 0.20 g of this solution were titrated .
No interferences was measured in the specificity solution. In fact the content of hydrogen peroxide measured was the same coming from the analitical standard of peracetic acid (mean recovery 100.91 %).

Conclusion on the methods for detection and identificationof the product
The analytical methods used for the determination of hydrogen peroxide, peracetic acid and acetic acid were validated according to SANCO/3030/99 rev.4 guidance documented in the Study BT221/16 “Physical-chemical characterization and accelerated storage stability of test item OXYPURE BIO 15%”. However the accuracy test was performed considering the different concentration of the analytes in the test item in the Study BT225/16. The RSD reported is not that of the accuracy determinations, but of the precision of 5 independently prepared samples. Considering the method showed to be accurate, it is not expected there is any interference from other components in the products. Please refer to the monitoring methods (for air, water, animal and human body fluids and tissues) and justification of non-submission (for soil) provided in the active substance dossier/CAR. The provided information and justifications for non-submission were accepted by the evaluating competent authority.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Disinfection in food and feed industry: The biocidal product is for use in aseptic food processing on food packaging materials to achieve commercial sterility. The aseptic packaging is a fully automatic disinfection system of a close VHP machine (refer to section 2.2.6.2 for further information). Organisms to be controlled and products, organisms or objects to be protected.
The organisms to be protected are man and animals. The aim of the treatments is to control infectious diseases and to avoid contamination of food or feed.

2.2.5.2 Effects on target organisms, including unacceptable suffering

As stated in the active substance dossier/CAR, peracetic acid exerts toxic (bactericidal, fungicidal, etc.) rather than bacteriostatic, fungistatic effects on target organisms.

2.2.5.3 Mode of action, including time delay

BIOCHEMICAL AND PHYSIOLOGICAL MECHANISMS
As stated in the Document IIA, chapter 2 of the active substance dossier, the following three mechanisms lead to a destruction of microbial cells:

- Denaturation of cell proteins and interruption of cell transport
- Inactivation of enzymes essential to cell metabolism, and
- Disruption of cell membranes and their permeability.

In the newer literature, additional explanations are provided on the mode of action:

- It is claimed that the hydroxyl radical is the lethal species and that iron species are also involved in the mechanism of action.
- It is speculated that organic (oxygen) radicals formed from peracetic acid such as $CH_3C(=O)O.$ or $CH_3C(=O).$, because of their greater longevity than the hydroxyl radical, are involved in the sporicidal action of PAA.
- Organic radicals formed from PAA are claimed to be sporicidal and to act as reducing agents for spores that are normally in a highly oxidised state.

TIME DELAY
Peracetic acid is fast acting. The contact time and the concentration depend on the organisms to be controlled, the pH, the temperature, and the growth media.

2.2.5.4 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use**	**Test substance**	**Test organism**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects***	**Reference**
Bacterial sporicide	*PT4*	*Clarity VTA*	*Bacillus atrophaeus*	semi-field	Bottles of 8 oz PET 1) 12000 ppm PAA 8.4 ml/min 3.8-7.6 s 2) 8000-25000 ppm PAA 7.0-10.7 ml/min 3.8 s 3) 20000 ppm PAA 8.4 ml/min 3.8 s 25-150 ºC (drying) Optimisation: Applied boundary conditions: Bottles: 8 oz PET Inoculation: 3E6/bottle PAA mass in condensate: 1.33 mg for total kill Treatment time: 2.8-7.6 s Feed flow: 7.0–10.9 ml/min Feed PAA concentration: 8000 – 25000 ppm	D-value: 0.64 s Minimum of 1.33 mg peracetic acid in the condensate is needed to accomplish a total kill of 6.48 Log10 A total kill was attained (25-90 ºC) at a modelled PAA in condensate >1.33 mg. Optimisation: A total kill can be achieved at a minimum usage of 44 mg/bottle of the concentrated Clarity VTA under the following conditions: Diluted PAA feed concentration: 20078 ppm, Diluted PAA feed flow rate: 7.0 ml/min and	 Weidong, A. (2014)

						Treatment time: 2.8 s.	
Bacterial sporicide	*PT4*	*Clarity VTA*	*Bacillus atrophaeus*	semi-field	Bottles: 8 oz PET, 8 oz HDPE, 24 oz PET. Inoculum: 2.1E3, 2.1E4, 2.1E5 cfu Flow rate: 7 g/min. Treatment time: 3.8 s Concentration: 3% wt. PAA Target concentration: 60 mg PAA/m^2	A Mean Log Cycle Reduction (MLCR) > 6 Log10 for three types of bottles of different sizes/dimensions and materials of construction with two different inoculation points under test conditions. Residues of PAA and HP < 0.5 ppm.	Weidong, A. (2015)

Conclusion on the efficacy of the product

The biocidal product is used to disinfect food packaging materials. Diluted disinfectant is vaporised with hot air and used for food packaging disinfection in aseptic packaging systems. Commonly the disinfection takes place at short contact times and high temperatures. Under these conditions it is not possible to perform the standard EN suspension and surface tests with bacteria, yeasts, and moulds. As stated in the Technical Agreements for Biocides (TAB – EFF v.2.1), efficacy should be demonstrated by validation of the product in the disinfection process using aseptic filling devices and packaging material that are representative for the intended use of the product. Phase 2, step 1 and phase 2, step 2 tests are not required.

Two semi-field trials on *Bacillus atrophaeus* (hot resistant bacterial spore) demonstrate the sporicidal activity of the biocidal product on packaging in aseptic packaging systems. These trials applied 'in house' methodology.

As stated in the TAB- EFF v.2.1: Generally, only bacterial spores survive these conditions, while vegetative bacteria and yeasts will be killed in the negative control. Therefore, demonstrating efficacy against bacterial spores (e.g. *Geobacillus stearothermophilus*) is sufficient for an efficacy claim against other groups of microorganisms for aseptic filling applications. However, when the negative control shows survival of any other target organisms (e.g. fungal spores) these should also be tested by validation of the product in the disinfection process.

A negative control with all claimed target organisms should be performed to demonstrate that the high temperature alone is insufficient to achieve sufficient control of microorganisms.

The absence of negative controls in the studies carried out does not allow authorizing the claims bactericide and yeasticide. But since it might be expected that bacterial spores survive the use conditions, it can be possible to exclude a negative control for bacterial spores if sufficient justification is provided.

Furthermore, as indicated in BPR: "most yeast and fungal spores are already irreversibly inactivated by high temperature (40º) in the control without active substance. However, ascospores of several fungi can become heat resistant and can cause problems in the food industry. When standard tests with relevant temperature resistant strains become available for yeast and fungal spores, these should be used".

The semi-field trials on *Bacillus atrophaeus* (hot resistant bacterial spore) demonstrate the sporicidal activity of the biocidal product on packaging in aseptic packaging systems.

Two semi-field tests were performed. The chosen spore forming bacterial strain, *Bacillus atrophaeus* (FDA approved), although different from the strains described in the BPR efficacy guidance, has been used extensively in biomedicine as indicator strain for heat- and chemical-based decontamination regimens. The semi-field trials demonstrate the sporicidal effect of biocidal product on packaging in aseptic packaging systems.

The efficacy of the biocidal product was evaluated with a series of microbiological tests, and total kills of initial loading of 3 x 10^6/bottle FDA-approved *Bacillus atrophaeus* spores were successfully accomplished through a combination of parameters under "COMPANY"s standard HPV settings and with some variations.
According to the Technical Report of Efficacy: "Test of PeroxyChem's Clarity® VTA Vapor PAA Technology at "*COMPANY*",. the minimum amount for a "total kill" was 1.33 mg PAA in the condensate. By optimising the conditions, it was determined that about 44 mg PAA/bottle would be required (20078 ppm PAA, 7 ml/min, 2.8 s). Considering that not all PAA is condensed on the surface of bottle, plus there is some degradation in the vaporiser and during transport in pipeline to the bottles, the final PAA on the surface is much smaller than that being fed to the process.
Two mathematical models were developed to correlate two performance parameters critical to the efficacy with operating conditions of "COMPANY's test system. The models were intended to be used for optimizing the operating conditions in order to accomplish certain objectives. As an example, minimization of biocidal product usage per bottle, while maintaining an efficacy of the total kill, is found to be achievable under a set of operating conditions through a mathematical optimization study from the models.

In a second study "Trial of PeroxyChem's Clarity® VTA Vapor Technology using Typical Validation Method at ccoperation companythe parameters applied to achieve the target of 60 mg PAA / m^2 were 3% VTA (as PAA), 3.8 sec, 85 ºC and 7 g/min. A Mean Log Cycle Reduction (MLCR) > 6 Log10 was obtained for three types of bottles (8 oz PEC, 8 oz HEDP and 24 oz PEC) of different sizes/dimensions and materials of construction with two different inoculation points under test conditions.
The effective dose was established at about 60 mg PAA/m^2

The trials were performed with Clarity VTA, based on the clarifications from the applicant, CLARITY VTA and PHASE VTA are identical. Clarity VTA was just an early, temporary brand name for the same product as Phase VTA. According to the applicant the confidential stabilizeris the coformulant in the biocidal product. The confidential stabilizer in the product can be between 0.5 and 1% w/w, being 0.75% w/w the nominal concentration. There have been no changes to the certified limits of the product formulation. In addition, confidential stabilizer functions as a stabilizer and does not contribute to the efficacy of the product at such a low level.
Peracetic acid is much stronger disinfectant than the confidential stabilizer, being sporicidal, bactericidal, virucidal and fungicidal at low concentration (<0.3%) (Block, S. S. 1991)[1]. Thus, the efficacy of the product will depend on the peracetic acid content, being the effect of confidential stabilizerirrelevant at such a low concentration (<1% w/w). As mentioned above, the function of confidential stabilizeris as a stabilizer.

It could be mentioned that the activity of efficacy of acidic disinfectants, is linked to the concentration of hydrogen (H+) and hydroxyl (OH-) ions and function by destroying the bonds of nucleic acids and precipitating proteins. They also change the pH of the micro-organisms environment. As citric acid gives away protons in solution, there is a decrease in the pH of the solution, which directly co-relates with the antimicrobial properties of the biocide agent (confidential stabilizer CAR, 2016). Both Clarity VTA and Phase VTA have identical pH, i.e. there is no significant change on protons in the solution (no decrease of pH).

Accordingly, the efficacy of both products is considered identical since the difference of 0.25% of confidential stabilizer does not have any impact.

Determination of the worst set conditions is a set of realistic operative conditions under which the sterilization process is expected to be the best. Note that this may not necessarily be the minimum/maximum allowed condition for all critical factors in the machine.

There are two kind of temperatures: temperature of steam air and temperature of drying air. The two are eligibles to optimize the process and are expressed as a range.
Temperature is a factor that makes PAA more effective, after defining the minimum PAA mass in the concentrate to achieve total kill, the optimization has the objective of minimizing the use of concentated biocidal product per bottle, under certain conditions.
The machines offer a range of temperaturas 25-60-90-150ºC. In the tests, total kill was attained for all the cases, ever under the lower drying air temperatures. The higher drying air temperature itself, is not a factor for efficacy, controls demonstrate full spore recovery without PAA treatment.
The optimization of conditions in the machines is case by case.

From the test data analyses and discussions, the following conclusions and recommendations were drawn:
-The efficacy of Phase VTA was successfully confirmed under a challenge protocol that was based on the endpoint test of a typical validation.
- PeroxyChem's correlations of chemistry and efficacy were shown to be very useful tools to design operating parameters to meet efficacy goals. Those tools also make it much easier to choose parameters for bottles with different sizes and dimensions.
-The residues of HP and PAA were confirmed to be minimal after air drying steps. The residues remained lower than the critical limit of 0.5 ppm for HP and PAA after 48 hours of storage.

[1]Block, S. S. 1991. Peroxygen compounds, p. 167–181. In S. S. Block (ed.), Disinfection, sterilization, and preservation, 4th ed. Lea & Febiger, Philadelphia,Pa.

*The confidential stabilizer is notified in the confidential annex.

2.2.5.5 Occurrence of resistance and resistance management

The mode of action of peracetic acid is very unspecific. Consequently, it is very unlikely that resistance to peracetic acid can develop.

2.2.5.6 Known limitations

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

2.2.5.7 Evaluation of the label claims

Label claim: bacterial sporicide.
This claim is supported by the semi-field efficacy tests performed on *Bacillus atrophaeus*.

It is important to point out that because of the great variety in packaging and aseptic packaging systems, for each packaging/system combination, the conditions need to be adapted to optimise the rapid disinfection of packaging materials.

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

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

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Skin corrosive.
Justification for the value/conclusion	Classification was done according to criteria laid down by Regulation (EC) No.1272/2008 (CLP). PHASE VTA has an extreme pH value ≤ 2 (pH: 0.87).
Classification of the product according to CLP	Skin Corrosive Category 1 H314: Causes severe skin burns and eye damage.

Data waiving	
Information requirement	Skin corrosion/irritation
Justification	The study is scientifically unjustified, as mixtures with extreme pH, the assessment is based on pH. In the absence of any other information, a mixture is considered corrosive to skin (Skin Corrosion Category 1) if it has a pH ≤ 2 or a pH ≥ 11,5. Where it is decided to base the classification of a mixture upon consideration of pH alone, Skin Corrosion Category 1 should be applied.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Serious eye damage
Justification for the value/conclusion	Classification was done according to criteria laid down by Regulation (EC) No.1272/2008 (CLP). PHASE VTA has an extreme pH ≤ 2 (pH: 0.87).
Classification of the product according to CLP	Eye Damage Category 1, H318: Causes serious eye damage. It should be noted that if a mixture is classified as Skin corrosion Category 1 then serious damage to eyes is implicit as reflected in the hazard statement for skin corrosion (H314: Causes severe skin burns and eye damage). Thus, the corrosive mixture is also classified, but the corresponding hazard statement (H318: Causes serious eye damage) is not indicated on the label to avoid redundancy.

Data waiving	
Information requirement	Eye irritation study
Justification	The study is scientifically unjustified, as mixtures with extreme pH, the assessment is based on pH. In the absence of any other information, a mixture is considered to cause serious eye damage (Category 1) if it has a pH ≤ 2 or ≥ 11,5.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value	Causes respiratory irritation.
Justification for the conclusion	Both peracetic acid and hydrogen peroxide are classified as STOT SE 3 (respiratory tract irritation). Peracetic acid being present at a concentration higher than the specific concentration limit of 1%. Therefore, PHASE VTA should be classified as STOT SE 3, H335. Furthermore, the biocide is classified for acute inhalation toxicity due to its peracetic acid content. Due to the known mode of action of peracetic acid, which is characterised by local irritation/corrosion at the site of first contact, the acute inhalation toxicity of peracetic acid is expected to be a consequence of the primary local irritation/corrosion. Therefore, whenever equilibrium mixtures of peracetic acid are to be classified with respect to acute inhalation toxicity, an additional classification with EUH071 is necessary.
Classification of the product according to CLP	STOT SE 3; H335: May cause respiratory irritation. EUH071: Corrosive to the respiratory tract. Duplication or redundancy should also be avoided for a substance or mixture that is assigned the supplemental hazard statement EUH071 In this case, the hazard statement H335 for STOT SE category 3 (respiratory tract irritation) should be omitted from the label.

Data waiving	
Information requirement	Respiratory tract irritation data.
Justification	No data on respiratory tract irritation have been submitted. Furthermore, this data is not required under Biocides Regulation. However, the composition of the product is known and 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 (CLP Regulation).

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitizer
Justification for the value/conclusion	None of the components is classified for skin sensitization. Therefore, the mixture should not be classified as skin sensitizer.
Classification of the product according to CLP	No classification for skin sensitization is required.

Data waiving	
Information requirement	Skin sensitization study

Justification	The composition of the product 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 product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the product can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not respiratory sensitizer
Justification for the value/conclusion	None of the components are classified for for respiratory sensitization. Therefore, the product does not meet the criteria for classification for respiratory sensitization according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification for respiratory sensitizer is required.

Data waiving	
Information requirement	Rspiratory sensitization data
Justification	No data on respiratory sensitization have been submitted. However, the composition of the product is known and 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 (CLP Regulation).

Acute toxicity

The assessment of all acute toxicological properties of PHASE VTA is derived from the classification of the active substance and co-formulants as agreed in the Annex VI of the CLP regulation or, when not available, as agreed in the Classification and Labelling notification at ECHA. This information is included in their safety data sheets.

According to Regulation (EC) No 1272/2008 classification of mixtures based on ingredients of the mixture is determined by calculation from the ATE values (ATEmix):

$$\frac{100}{ATE_{mix}} = \sum_{r} \frac{C_i}{ATE_i}$$

or

$$\frac{100 - (\sum C_{unknown} if > 10\%)}{ATE_{mix}} = \sum_{r} \frac{C_i}{ATE_i}$$

where:

where:

Ci = concentration of ingredient i (% w/w or % v/v)

i = the individual ingredient from 1 to n
n = the number of ingredients
ATEi = Acute Toxicity Estimate of ingredient i.

For further details please refer to the Confidential Annex.

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	ATE_{mix}:300 < ATE ≤2000
Justification for the selected value	Classification was done according to criteria laid down by Regulation (EC) No.1272/2008 (CLP). Based on component information (additivity formula), the biocidal product is classified for Acute (oral) Toxicity Category 4, H302 since ATE_{mix} is between 300 and 2000 mg/kg bw. DL_{50} (peracetic acid.-.oral): 85mg/PAA/kg (calculated) DL_{50} (hydrogen peroxide –oral): 420mg/kg (calculated)
Classification of the product according to CLP	Acute oral toxicity Category 4; H302: Harmful if swallowed.

Data waiving	
Information requirement	Acute oral toxicity study.
Justification	Study scientifically unjustified. No studies have been performed with the product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and 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 (CLP Regulation), and synergistic effects between any of the components are not expected Therefore, this study does not need to be conducted.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Acute tox 4; H332
Justification for the selected value	The product contains percacetic acid classified as Acute Tox*. 4 (H332) and hydrogen peroxide (non-active substance: Precursor – Equilibrium partner) classified as Acute Tox. 4* (H332) which are ≥1% w/w. According to Assessment Report of peracetic acid (November 2015, Finland), the acute inhalation LC_{50} value for the test substance containing 5% peracetic acid was 4.08 mg/l/4 h (0.204 mg PAA/l). On the other hand, hydrogen peroxide has harmonized classification as Acute Tox. 4* (H332). The route of administration by inhalation is vapour, hence a acute toxicity estimate (ATE) value of 11mg/l is appropriate. For mixtures containing some substance(s) tested for inhalation toxicity as vapours and others as dust/mist or gas, the additivity formula cannot be used directly as the ATE ranges are different.(Guidance on the Application of the CLP Criteria, Ver.5.0, July 2017, pag.247)

	Therefore for acute inhalation toxicity additivity has initially to be used separately for each relevant physical form (i.e. gas, vapour and/or dust/mist), using the appropriate category limit in CLP Annex I, Table 3.1.1. As a first step, the fraction of toxicity is calculated for each form/state: fraction = Σ (limit / ATE) x concentrations /100 Where limit = the upper border of the range of ATE values of a hazard category (Table 3.1.1 of CLP) for the state/form in question and concentrations = the concentration (%) of components tested for this state/form. The most severe category where the sum of fractions is ≥ 1 that category is applicable to the mixture. Therefore: -Category 4: (5/0.204) x 15/100 (peracetic acid) + (20/11) x 10/100 (hydrogen peroxide) = 3.67 + 0.18 = 3.85 which is above 1 meaning category 4 Thus PHASE VTA is classified as Acute Tox. 4 (H332).
Classification of the product according to CLP	Acute inhalation toxicity Category 4; H332: Harmful if inhaled.

Data waiving	
Information requirement	Acute inhalation toxicity study
Justification	Study scientifically unjustified. No studies have been performed with the product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and 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 (CLP Regulation), and synergistic effects between any of the components are not expected Therefore, this study does not need to be conducted.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	ATE_{mix}:200 < ATE ≤1000
Justification for the selected value	Classification was done according to criteria laid down by Regulation (EC) No.1272/2008 (CLP). Based on component information (additivity formula), the biocidal product is classified for Acute (dermal) Toxicity Category 3, H311 since ATE_{mix} is between 200 and 1000 mg/kg bw. DL_{50} (peracetic acid.-.dermal): 56.1mg/PAA/kg (calculated)
Classification of the product according to CLP	Acute Tox. (dermal) category 3; H311: Toxic in contact with skin.

Data waiving	
Information requirement	Acute dermal toxicity study
Justification	Study scientifically unjustified. No studies have been performed with the product in order to avoid unnecessary testing with vertebrates. The

	composition of the product is known and 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 (CLP Regulation), and synergistic effects between any of the components are not expected Therefore, this study does not need to be conducted.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Peracetic acid
Value(s)	100% (default)
Justification for the selected value(s)	According to the Assessment of the active substance, based on the physico-chemical properties of peracetic acid (Skin corrosive category 1A), 100% dermal penetration should be used in the absence of more accurate information.

Data waiving	
Information requirement	Dermal absorption study
Justification	No standard dermal penetration studies with aqueous peracetic acid have been successfully conducted. Because of the absence of clear systemic effects of the active substance, no dermal penetration parameter is needed in order to conclude on human health risks from the presented uses. The biocidal products based on peracetic acid only induce local effects at the first site of contact. In conclusion, it was acceptable to "waive" the dermal penetration study.

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

Peracetic acid is not a pure active substance but is in the form of an aqueous solution containing peracetic acid, acetic acid and hydrogen peroxide. Both acetic acid and hydrogen peroxide are components of active substance and were considered during the evaluation of peracetic acid.
The toxicity of acetic acid was reviewed during the evaluation of peracetic acid. Hydrogen peroxide is in itself a biocidal active substance.
Both acetic acid and hydrogen peroxide have harmonised classifications under Annex VI of the CLP Regulation, including specific concentration limits for some endpoints. Furthermore, an indicative occupational exposure limit (IOELV) is in place for acetic acid (a 8-hour-TWA of 25 mg/m3 (10ppm and short-term exposure level STEL (15 mins) of 50 mg/m3 (20ppm)).
According to Annex A of the document "Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 2.1 February 2017": For SoCs for which Community workplace exposure limits (IOELVs – Indicative Occupational Exposure Limit Values) have been set, a quantitative inhalation risk assessment for the professional operator against the IOELV should always be conducted
For further details please refer to the Confidential Annex.

Available toxicological data relating to a mixture

The data available on each of the components of PHASE VTA are 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.

Other

No other relevant information.

Endocrine disruption assessment

Since 7 June 2018, date when the Regulation (EU) 2017/2100 came into force, endocrine disrupting properties assessment of active substance and co-formulants is mandatory according to the article 19 of BPR.

Assessment of the ED properties of the active substances:

According to Assessment Report of Peracetic acid (November 2015, Finland) and BPC Opinion (ECHA/BPC/070/2015, September 2015), peracetic acid is not included in the Commission Staff Working Document on implementation of the 'Community Strategy for Endocrine Disrupters' - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706)). There is no evidence of any endocrine disruption potential in the human health or ecotoxicological studies presented in the dossier.Therefore, peracetic acid is not considered to have endocrine disrupting properties.

Assessment of the ED properties of non-active substances (co-formulants):

After reviewing the potential ED properties of co-formulants, none of them are subject to an on-going evaluation or a decision regarding their ED properties. Based on the available information, ES CA considers that PHASE VTA contains no substances suspected of having endocrine disrupting properties.
Several sources were considered to check the potential endocrine disrupting properties of the co-formulants contained in the biocidal product.

Overall conclusion on the biocidal product regarding ED properties:

According to our assessment, none of the components contained in the product are identified as endocrine disruptors and none of them are subject to an on-going evaluation or a decision regarding their ED properties Hence, ES CA considers that PHASE VTA contains no substances suspected of having endocrine disrupting properties. If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.
According to the document agreed at the CG-49 meeting on Criteria – significant indications of ED properties for non-active substances, none co-formulant is considered to have significant indication of ED properties.
For further details please refer to the Confidential Annex.

2.2.6.2 Exposure assessment

The biocidal product is for use in aseptic food processing on food packaging materials to achieve commercial sterility. The product is diluted in an automated VPAA (vaporized peracetic acid) process and applied in a closed system (i.e. in aseptic filling machines). The biocidal product is diluted with deionised water to a targeted peracetic acid concentration and fed into the vaporising unit at a certain flow rate becoming a vapour. The vapour is carried by heated air into a package that needs to be sterilised. The vapor condensates inside the package during a certain time (seconds) to form a thin uniform layer. The sterilisation is achieved by peracetic acid inside the condensate. Finally, ambient air is fed into the treated package to remove the condensate and to dry out the package.

The product PHASE VTA contains **one active substance**, peracetic acid (PAA), and, according to Annex A of Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) (Version 4.0 December 2017), **two substances of concern**, hydrogen peroxide (HP) and acetic acid (AA).

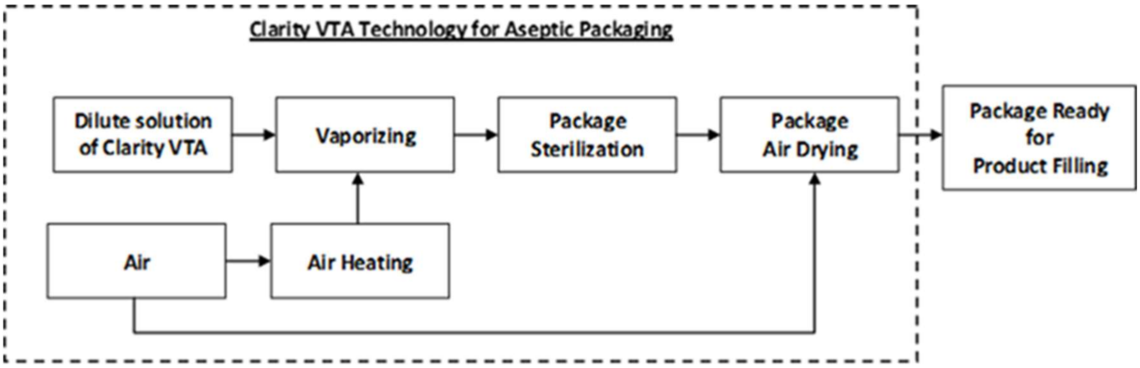
The three substances have been taken into account for exposure assessment calculations.

This use describes the activities for the sterilisation of food packaging materials prior to filling. The product is vaporised into the container combined with hot sterile air. The system controls the amount of the product to ensure that a uniform film coats the inside surface of the package.

The sterilisation efficacy is enhanced by temperatures >60ºC, and the duration is less than 1 minute (typically 2-20 seconds). The final step is filing with ambient air into the treated package to remove the condensate and to dry out the package.

The aseptic packaging is a **fully automatic disinfection system of a close VPAA machine with integrated LEV**. The biocidal product (as such) is loaded and diluted with deionised water to the required peracetic acid concentration (60 mg PAA/m2). Subsequently, it is introduced into the vaporisation unit at a certain flow rate and becomes steam. Said steam is introduced into the container to be sterilised by hot air. The vapour condenses inside the container and forms a uniform layer during a set contact time. Subsequently, air is introduced to eliminate the condensate and dry the container. The container would be ready for filling.

All aseptic packaging machines have a special protocol for sterilisation. When new packaging are used, the machine is validated accordingly.



* Clarity VTA = Phase VTA

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

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	Yes	N.A.	N.A.	N.A	N.A.	No	No
Dermal	Yes	N.A.	N.A.	N.A.	N.A.	No	No
Oral	No	N.A.	N.A.	N.A.	N.A.	No	No

N.A. Not applicable.

Primary exposure:
The relevant paths of human exposure that apply to PHASE VTA are also described here below. This analysis is made taking into account the active substance characteristics, but also the physical and chemical properties of two important ingredients that take part of the equilibrium reaction that produces peracetic acid, hydrogen peroxide an acetic acid (SoCs).

These three substances have local effects at the site of first contact. The skin and eyes exposures are assessed by a concentration comparison of these substances to each threshold concentration that triggers effects to the eyes or/and to the skin.

To assess the inhalation exposure, local effects to the respiratory tract are assessed for the three substances by quantitative estimation of the exposure to aerosols and also to vapours due to their high vapour pressures 0.1Pa.
The oral exposure route is not assessed in this risk assessment. Indeed, the product is used by trained professionals and this user category is not supposed to be exposed orally.
The inhalation exposure is quantitatively assessed by considering exposure to aerosol and also exposure to vapour.
To assess the skin and eye exposures a qualitative approach is conducted.

Secondary (indirect) exposure:

According to the active substance dossier/CAR, after application of aqueous peracetic acid solutions, secondary exposure of humans upon dermal or oral contact with treated surfaces or equipment is considered to be non-relevant. The range of in-use dilutions is below the level of dermally irritating concentrations and therefore no skin damage is possible.
Secondly both peracetic acid and hydrogen peroxide are highly unstable and will rapidly degrade at the site of first contact which effectively reduces the possibility of any residual concentrations. Additionally, in applications of peracetic acid solutions as a disinfectant in food and feeding areas (PT4), treated materials are eitherair-dried with a powered air stream or left to dry prior to further operations. Therefore, secondary human exposure to peracetic acid and hydrogen peroxide via food etc. is not considered to be relevant as both peracetic acid and hydrogen peroxide degrade rapidly following application and no residues are expected in foodstuffs. Subsequently, no MRL setting is required as peracetic acid is not persistent, no systemic effects are observed and because of its high reactivity.

In respect to acetic acid, this substance is a component naturally present in many foods and it is also used as a flavouring agent in the food industry. Minor residues of acetic acid, that could remain in packaging treated with the product, would lead to exposures that are negligible compared to the amounts ingested in the consumption of foods that contain this substance naturally or as an added flavouring agent.

List of scenarios

Due to the use in closed system VPAA machine, only exposure on loading phase is expected. As there is such a big difference in the size of packaging, we will assume that containers up to 30kg are loaded into the system manually, while for those of 200 kg (drum) and 1100kg (IBC) we will assume an automatic load.

Summary table: scenarios				
Scenario number	**Scenario**	**Description of scenario**	**Primary or secondary exposure**	**Exposed group**
1.a	Mixing/loading	Manual	Primary exposure	Industrial use
1.b		Automated		
2	Cleaning/maintenance	Cleaning/maintenance	Primary exposure	Industrial use

Industrial exposure

Local effects:
Three substances have dermal and inhalation local effects at the site of first contact, PAA, HP and AA, and one of them has also eye damage effects, HP.
The presence of these substances in product is the reason for its toxicological classification for local effects.
To assess the exposure for local effects of product, a semi-quantitative/quanlitative approach was performed, as indicated in the introduction and following Guidance on the BPR: Volume III Parts B+C , section 4.3.2 Local effects (irritation/corrosion, sensitisation) – Qualitative and semi-quantitative risk characterisation.

Reference	**Value**
Peracetic acid	
Dermal NOAEC short/medium term	0.2%
Dermal NOAEC long term	0.1%
Inhalation AEC short/medium/long-term	0.5 mg/m^3 (0.16 ppm)
Hydrogen peroxide	
Dermal Skin irritating threshold	35%
Local effect –Eye damage	8%
Inhalation AEC short/medium/long-term	1.25 mg/m^3
Acetic acid	
Dermal Skin irritating threshold	10%
Inhalation AEC (8h, long-term)	25 mg/m^3

Exposure calculations have been carried out taking into account that the fully automatic disinfection system of a close VPAA machine has integrated LEV, therefore, tier1 is calculated without any protection and a Tier2 with LEV (PF20) before to use in Tier3 the mask (FP10).

Scenario [1.a]: Manual loading

The product is loaded manually. This manual application occurs before each use as a pre-application step and only with packaging from 5 to 30 kg. Indeed, with higher volume packaging, only automatic pumping and transfer is feasible.

Dermal exposure

For the biocidal product, the PAA, HP and AA concentrations are 15% w/w, 10% w/w and 35% respectively, therefore, these are the concentrations to which users can be exposed by dermal route

Inhalation exposure

For local effects to respiratory tract, exposure to aerosol is taken into account and also exposure to vapour is also considered for the highly volatile substances (PAA, HP and acetic acid).

To assess the exposure to aerosol, the Mixing and Loading model 7, pouring liquid from TNsG 2002[1], with an indicative value of 0.94 mg/m³ for inhalation exposure is used. This inhalation indicative value is in accordance with ECHA recommendation N°6 (updated version of February 2017- version 3)[2].

To assess the exposure to vapour, the model "Exposure to vapour – Evaporation" of the scenario "Mixing and loading" of the "Disinfectant products fact sheet" of the online program ConsExpo Web is applied[3].

Description of Scenario 1a: Manual Loading

Exposure to aerosol – Mixing and Loading Model 7; TNsG 2002
Tier1:
The product is mixed and loaded manually. This manual application occurs before each use as a pre-application step and only with packaging from 5 to 30 kg.
Indicative value inhalatory exposure to aerosol from mixing&loading model 7 TNsG 2002: 0.94 mg product/m^3.
Taking into account product composition:

Common name	Content (% w/w)
Peracetic acid	15
Hydrogen peroxide	10
Acetic acid	35

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[1] Working Group. Technical notes for guidance. Human exposure to biocidal products – Guidance on exposure estimation. June 2002

[2] BPC Ad hoc Working Group on Human Exposure. ECHA Recommandation N°6 – Methods and models to assess exposure to biocidal products in different product types versio 3. 2017

[3] L.C.H. Prud'homme de Lodder, H.J. Bremmer, S.M.G.J. Pelgrom, M.V.D.Z. Park, J.G.M. van Engelen. Disinfectant Products Fact Sheet to assess the risks fort he consumer. RIVM report 320005003/2006, 2006. P22.

Tier1 : No protections
PAA exposure : 0.15*0.94 mg/m^3= 0.141 mg/m^3
HP exposure : 0.10*0.94 mg/m^3 =0.094 mg/m^3
Acetic acid exposure: 0.35*0.94 mg/m^3 = 0.329 mg/m^3

Tier2: Integrated LEV in the VPAA machine APF20
PAA exposure : 0.15*0.94mg/m^3*0.2 = 0.0282 mg/m^3
HP exposure : 0.10*0.94mg/m^3*0.2 =0.0188 mg/m^3
Acetic acid exposure: 0.35*0.94mg/m^3 *02 = 0.0658 mg/m^3

Tier3: PPE, mask for aerosols and vapours APF10
PAA exposure : 0.0282 mg/m^3*0.1= 0.00282 mg/m^3
HP exposure : 0.0188 mg/m^3*0.1 =0.00188 mg/m^3
Acetic acid exposure: 0.0658 mg/m^3*0.1 = 0.00658 mg/m^3

Exposure to vapour - ConsExpo Web Exposure to vapour – "Evaporation" of the scenario "Mixing and loading" of the "Disinfectant products fact sheet".

	Parameters	Value	Reference
Tier 1	Exposure duration	10 minutes	This is the default exposure for mixing and loading application duration that is used according to the CAR on PAA PT1-6.
	Product amount	Worst-case packaging volume for manual application: 30kg	Applicant's information. But, it is considered as a default value that the user is exposed to the half of the packaging content during inhalation exposure: evaporation from constant surface of the mixing and loading applications of a liquid (Default value from ConsExpo, Disinfectant products fact sheet).
	Weight fraction substance	a) PAA: 0.15 b) HP: 0.10 c) CH3COOH: 0.35	Applicant's information.
	Room volume	1 m^3	Personal volume, default value from ConsExpo, Disinfectant products fact sheet used for phase liquid
	Ventilation rate	0.6/hour	Default value for non-specified room (ConsExpo, Disinfectant products fact sheet, mixing and loading of e liquid, p 22)
	Inhalation rate	1.25 m^3/hr	Default inhalation rate for an adult EU Biocides (ConsExpo).
	Vapour pressure	For PAA: 1410 Pa For HP: 214 Pa For CH3COOH: 2079 Pa	PAA and HP (physical and chemical data on vapour pressure from their respective active substance CAR) CH3COOH: information taken on the ingredient's suppliers (please refer to

			SDS documents provided in the dossier)
	Application temperature	20°C	Application temperature given by the applicant (ambient temperature)
	Molecular weight	For PAA: 76.05 g/mol For HP: 34.01 g/mol For CH_3COOH: 60.05 g/mol	PAA and HP (physical and chemical data on molecular weight from their respective active substance CAR) CH_3COOH: no information in the SDS or in the REACH dossier. So the value was calculated based on the molecular formula.
Tier 2	Local exhaust ventilation (LEV) Integrated LEV	APF 20 (Aprox)	Biocides Human Health Exposure Methodology. Section3.3.1 3.3.1. Exposure Controls. Engineering control of exposure. Table pg 150.
Tier 3	PPE mask for aerosols and vapours	APF10	
ConsExpo Results for scenario PHASE VTA manual loading			
Tier 1	**Mean event concentration:** **PAA:** 2.8mg/m^3 **HP:** 0.27mg/m^3 **AA:** 11mg/m^3		
Tier 2 Integrated LEV APF20	**Mean event concentration:** **PAA:** 2.8mg/m^3 x 0.2= 0.56 mg/m^3 **HP:** 0.27mg/m^3 x 0.2= 0,054mg/m^3 **AA:** 11mg/m^3 x 0.2= 0.22mg/m^3		
Tier 3 Mask APF10	**Mean event concentration:** **PAA:** 0.56×10^{-1} mg/m^3 **HP:** 0.54×10^{-2} mg/m^3 **AA:** 0.22×10^{-1}mg/m^3		

See ConsExpo files in Annex 3.2.

Calculations for Scenario [1.a]

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier/PPE**	**Substances**	**Estimated inhalation due to exposure to aerosol mg/m³**	**Estimated inhalation due to exposure to vapour mg/m³**	**Estimated total exposure mg/m³**
Scenario [1.a]	1	PAA	1,410E-01	2,800E+00	2,941E+00
		HP	9,400E-02	2,700E-01	3,640E-01
		AA	3,290E-01	1,100E+01	1,133E+01
	2	PAA	2,820E-02	5,600E-01	5,882E-01
		HP	1,880E-02	5,400E-02	7,280E-02
		AA	6,580E-02	2,200E-01	2,858E-01
	3	PAA	2,820E-03	5,600E-02	5,882E-02
		HP	1,880E-03	5,400E-03	7,280E-03
		AA	6,580E-03	2,200E-02	2,858E-02

Scenario [1.b]: Automatic loading

The product is automatic loaded. This automatic application occurs before each use as a pre-application step and only with packaging of 200 kg (drum) and 1100kg (IBC).

Local effects:

Dermal exposure

For the biocidal product, the PAA, HP and AA concentrations are 15% w/w, 10% w/w and 35% respectively, therefore, these are the concentrations to which users can be exposed by dermal route

.

Inhalation exposure

For local effects to respiratory tract, only the exposure to aerosol is taken into account.
No exposure to vapour is assessed because:

- 1° the dosing systems for all applications occur in closed systems
- 2° the exposure duration is assumed to be negligeable

As a worst-case approach, only the exposure to aerosol, assessed by the Mixing and loading model 7, liquid pumping from the HEEG Opinion 1[4], with an indicative value of 22 mg/m³, for inhalation exposure is used.

Description of Scenario 1b: Automatic Loading
Exposure to aerosol – Mixing and Loading Model 7; TNsG 2002 Tier 1: The product is mixed and loaded automatically. This automatic application occurs before each use as a pre-application step and only with packaging from 5 to 30 kg.

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[4] HEEG Opinion on the use of available data and models fort he assessment oft he exposure of operators during the loading of products into vessels or systems in industrial scale. Mixing & loading model 7; TNsG part 2 p.142 (corrected) 2008. P 7-8

As a worst-case approach, only the exposure to aerosol, assessed by the Mixing and loading model 7, liquid pumping from the HEEG Opinion 15, with an indicative value of 22 mg/m³, for inhalation exposure is used.
Taking into account product composition:

Common name	Content (% w/w)
Peracetic acid	15
Hydrogen peroxide	10
Acetic acid	35

Tier1 : No protections
PAA exposure : 0.15*22 mg/m³ = 3.3 mg/m³
HP exposure : 0.10*22 mg/m³ =2.2 mg/m³
Acetic acid exposure: 0.35*22 mg/m³ = 7.7 mg/m³

Tie2 : Integrated LEV APF20
PAA exposure : 3.3 mg/m³*0.2 = 0.66 mg/m³
HP exposure : 2.2 mg/m³ *0.2=0.44 mg/m³
Acetic acid exposure: 7.7 mg/m³ *0.2= 1.54 mg/m³

Tier3: PPE, mask for aerosols and vapours APF10
PAA exposure : 0.66 mg/m³ *0.1= 0.066 mg/m³
HP exposure : 0.44 mg/m³ *0.1=0.044 mg/m³
Acetic acid exposure: 1.54 mg/m³ *0.1= 0.154 mg/m³

Calculations for Scenario [1.b]

Exposure scenario	**Tier/PPE**	**Substances**	**Estimated inhalation due to exposure to aerosol mg/m³**
Scenario [1.b]	1	PAA	3.300
		HP	2.200
		AA	7.700
	2	PAA	0.600
		HP	0.440
		AA	1.540
	3	PAA	0.066
		HP	0.044
		AA	0.154

Scenario [2]: Cleaning and maintenance of VPAA machines

The applicant has not included in the dossier any information on the cleaning and maintenance of the VPAA machines.

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[5] HEEG Opinion on the use of available data and models fort he assessment oft he exposure of operators during the loading of products into vessels or systems in industrial scale. Mixing & loading model 7; TNsG part 2 p.142 (corrected) 2008. P 7-8

Taking into account the characteristics of the VPAA machines, it can be assumed that the exposure during these tasks is equal to or lower than the exposure assessed for the mixing and loading phase.
Then, for this scenario, the exposures obtained from the previous scenario have been extrapolated.

Monitoring data

Dietary exposure

The intended applications of peracetic acid solutions relate only industrial uses and no professional nor non-professional uses are foreseen.

In accordance with the active substance dossier/CAR, peracetic acid and hydrogen peroxide degrade very rapidly after application on surfaces and equipment and a secondary human exposure via food etc. is not considered to be relevant as both peracetic acid and hydrogen peroxide are not expected to be prone to residue formation following application. Due to the known high reactivity of the substances and also taking into account that equipment, surfaces etc. are air-dried after completion of the disinfection procedure, no residues are, thus, expected in foodstuffs. Furthermore, peracetic acid and hydrogen peroxide will be rapidly degraded by the efficient detoxification mechanism of the organism even in the unlikely case that residues of both substances would be orally ingested. Thus, a chronic secondary exposure towards peracetic acid and hydrogen peroxide via the oral route is therefore considered not to be relevant following industrial use of peracetic acid solutions.

In respect to acetic acid, this substance is a component naturally present in many foods and is also used as a flavouring agent in the food industry. Minor residues of acetic acid, that could remain in foods treated with the product, would lead to exposures that are negligible compared to the amounts ingested in the consumption of foods that contain this substance naturally or as an added flavouring agent.

<u>Justification on the lack of risk derived from any potential by-products (free radicals) of hydrogen peroxide</u>
In aerobic cells, the catabolic pathways of hydrogen peroxide (HP) are determined by catalase, peroxidases and glutathione peroxidase enzymes.
HP undergoes decomposition to oxygen and water when in contact with mammalian tissues. There are two main hydrogen peroxide metabolising enzymes, catalase and glutathione peroxidase, which control HP concentration at different levels and in different parts of the cell. Catalase deals with large amounts of HP that may be generated in peroxisomes. Glutathione peroxidase (GSH peroxidase) metabolises HP in both the cytosolic and mitochondrial compartments (Chance et al., 1979).
However, in the presence of transition metals, HP can be reduced to **hydroxyl radicals.**
In the organism the hydroxyl radical can be produced non enzymatically through catalysis by transition metal ions like Fe^{2+} and Cu^{+} (the so-called Haber-Weiss- and Fenton reactions):

metal ions

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

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

Likely the "full" Haber-Weiss reaction (i.e., the reduction of HP by O2^{-} ▪) is as follows (showing that the Fenton reaction is representing one particular part of the Haber-Weiss reaction):

$$O_2^{-}\bullet + Fe^{3+}/Cu^{2+} \rightarrow O_2 + Fe^{2+}/Cu^{+}$$
$$H_2O_2 + Fe^{2+}/Cu^{+} \rightarrow OH\bullet + OH^{-} + Fe^{3+}/Cu^{2+}$$

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

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

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

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

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

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

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

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

References:

1. Aust S D and White B C (1985). Iron Chelation Prevents Tissue Injury Following Ischemia. Adv. Free Radical Biology & Medicine, Vol. 1, pp. 1-17, 1985.
2. Chance B, Sies H, and Boveris A (1979). Hydroperoxide metabolism in mammalian organs. Physiological Reviews 59, 527-605.
3. European Union Risk Assessment Report. Hydrogen peroxide. European Chemicals Bureau 2003.
4. Gutteridge JMC (1994). Biological origin of free radicals, and mechanisms of antioxidant protection. Chem. Biol. Interact. 91, 133-140.
5. Halliwell B and Gutteridge JMC (1984). Oxygen toxicity, oxygen radicals, transition metals and disease. Biochem. J. 219, 1-14.
6. Joint Assessment of Commodity Chemicals Report Nº 22. Hydrogen peroxide. ECETOC 1992.
7. Kappus H (1987). Oxidative stress in chemical toxicity. Arch. Toxicol. 60, 144-149.
8. Roots R and Okada S (1975). Estimation of Life Times and Diffusion Distances of Radicals Involved in X-Ray-Induced DNA Strand Breaks or Killing of Mammalian Cells. Radiat Res (1975) 64 (2): 306–320.

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

Information of non-biocidal use of the active substance

Peractic acid

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Plant protection products	Not approved	(1)
2.	Veterinary use	NO ENTRY	(2)

(1) Default MRL of 0.01 mg/kg according to Art 18(1)(b) of REGULATION (EC) NO 396/2005 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.

(2) COMMISSION REGULATION (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

No exposure to livestock is foreseen for the uses claimed.

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

No residues in food are expected. Peracetic acid and hydrogen peroxide are highly unstable and will rapidly degrade at the site of first contact which effectively reduces the possibility of any residual concentrations. Additionally, treated packaging materials are left to dry prior to further operations. Therefore, secondary human exposure to peracetic acid and hydrogen peroxide via food is not considered to be relevant.

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

The biocidal product is only used by Industrial users.

Combined scenarios

No combined scenarios are expected.

Aggregated exposure

[Template structure to be further developed once the methodology has been developed.]

Summary of exposure assessment

Scenarios and values to be used in risk assessment				
DERMAL				
Scenario number	**Exposed group**	**Tier/PPE**	**Substances**	**Concentration**

1.a 1.b	Industrial	-	PAA	15%
			HP	10%
			AA	35%
INHALATION				
Scenario number	**Exposed group**	**Tier/PPE**	**Substances**	**Estimated total exposure mg/m³**
1.a	Industrial	1	PAA	2,941E+00
			HP	3,640E-01
			AA	1,133E+01
		2	PAA	5,882E-01
			HP	7,280E-02
			AA	2,858E-01
		3	PAA	5,882E-02
			HP	7,280E-03
			AA	2,858E-02
1.b	Industrial	1	PAA	3,300E+00
			HP	2,200E+00
			AA	7,700E+00
		2	PAA	6,600E-01
			HP	4,400E-01
			AA	1,540E+00
		3	PAA	6,600E-02
			HP	4,400E-02
			AA	1,540E-01

2.2.6.3 Risk characterization

Reference values to be used in Risk Characterisation

Reference	**Study**	**NOAEL (LOAEL)**	**AF[1]**	**Value**
Peracetic acid				
Dermal NOAEC short/medium term	Human volunteer study	0.2%	-	0.2%
Dermal NOAEC long term	Rabbit one year study	0.2%	2	0.1%
Inhalation AEC short/medium/ long-term	Human data	0.5 ppm	3.16	0.5 mg/m^3 (0.16 ppm)
AEL short-term/medium-term/long-term	n.a.; PAA does not cause systemic effects			
ARfD	n.a.; PAA does not cause systemic effects			
ADI	n.a.; PAA does not cause systemic effects			
Hydrogen peroxide				
Dermal Skin irritating threshold	Classification limit for irritation	-	-	35%
Local effect –Eye damage	Classification limit for irritation			8%
Inhalation AEC short/medium/ long-term	90-day inhalation rat study	10 mg/m^3	8	1.25 mg/m^3
ARfD	not established			
ADI	ADI not established, the substance is not systemically available. The agreed acceptable max concentration is 0.1 mg/L in human drinking water. In the main use in PT 5, drinking water of chicken, max concentration: 5 mg/L			
Acetic acid				
Dermal Skin irritating threshold	Classification limit for irritation	-	-	10%
Inhalation AEC (8h, long-term)	-	-	-	25 mg/m^3

Maximum residue limits or equivalent

Not relevant

Risk for industrial users

Scenario [1.a and 1.b]:Manual and Automatic loading

Effects by dermal route

For the biocidal product, the PAA, HP and AA concentrations are 15% w/w, 10% w/w and 35% respectively, therefore, these are the concentrations to which users can be exposed by dermal route

This means that its PAA content is higher than the skin irritation threshold of 0.2% for the short-term, medium and long term exposure.
For the HP content, the 10% w/w concentration is lower than the skin irritation threshold of 35% w/w but in the range of concentrations 8% w/w to 50% w/w that triggers an Eye damage 1 classification.
For AA content, the 35% w/w concentration is higher than dermal skin iiritation threshold of 10%.

Task/ Scenario	**Tier**	**Substance**	**Value treshold**	**Concentration in product**	**Conc. in product/ Value treshold**	**Acceptable (yes/no)**
1.a 1.b	Dermal	PAA	0.2%	15%	>1	NO
		HP	35%	10%	<1	YES
		AA	10%	35%	>1	NO
	Eyes	PAA	-		-	-
		HP	8%	10%	>1	NO
		AA	-		-	-

Qualitative RC for local effects:

According to Guidance on the BPR: Volume III Parts B+C, section 4.3.2.5, a Qualitative RC for local effects has been developed.

- Local hazards (that lead to classification under CLP Regulation) of the biocidal product:

H314: Causes severe skin burns and eye damage.

H318: Causes serious eye damage.

H335: May cause respiratory irritation. Hazard category

- Assignment of hazard categories:

CLP hazar classification assigned to the product	**Relevant local effects**	**Hazar category**
Skin Corr 1A[1] (H314)	Strong corrosive	Very high
Skin Corr 1B/1C[1] (H314)	Corrosive	High
Eye Dam 1 (H318)	Severe eye irritant	High
STOT SE 3 (H335)	Irritant to respiratory tract	Low

[1] Category of skin corrosivity is not known.

- Concluding qualitatively on the acceptability of risk:

Hazard Effects	**Frequency and duration of potential exposure**	**Degree of potential exposure under best practice conditions**	**Relevant RMM**	**PPE**

Skin corr. 1A, H314	few minutes per day or less	Very high level of containment, practically no exposure;	Technical (containement, design…) and organisational measures (Entry control, training…)	- Face shield; -Substance/task appropriate gloves; - Protection coverall; - Chemical goggles
Skin corr. 1B,C, H314	few minutes per day or less	High level of containment, practically no exposure; no splashes, no hand to eye transfer, no (liquid or solid) aerosol formation.	Technical (containement, design…) and organisational measures (Entry control, training…)	- Substance/task appropriate gloves; - Skin coverage with appropriate barrier material based on potential for contact with the chemicals; - Substance/task appropriate respirator; - Optional face shield; - Eye protection
Eye dam. 1, H318	few minutes per day or less	High level of containment, practically no exposure; no splashes, no hand to eye transfer, no (liquid or solid) aerosol formation.	Technical (containement, design…) and organisational measures (Entry control, training…)	- Chemical goggles
STOT SE 3, H335 (may cause respiratory irritation)	More than few minutes but equal to or less than few hours per day	Controlled exposure	Technical and organisational measures.	- Substance/task appropriate respirator.

Therefore, local skin irritation and eye damage effects are expected when the product is handled during loading application. To protect the user, the risk related to dermal and eye exposures is only acceptable with the wearing of chemical-resistant gloves, protective skin coverage (face shield, coverall and footwear), appropriate respirator and also goggles during this application.

Effects by inhalation

Task/ Scenario	**Tier**	**Substance**	**AEC mg/m^3**	**Estimated exposure mg/m^3**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
1.a	1	PAA	5.000E-01	2,941E+00	5,882E+02	NO
		HP	1.250E+00	3,640E-01	2,912E+01	YES

		AA	2.500E+01	1,133E+01	4,532E+01	YES
	2	PAA	5.000E-01	5,882E-01	1,176E+02	NO
		HP	1.250E+00	7,280E-02	5,824E+00	YES
		AA	2.500E+01	2,858E-01	1,143E+00	YES
	3	PAA	5.000E-01	5,882E-02	1,176E+01	YES
		HP	1.250E+00	7,280E-03	5,824E-01	YES
		AA	2.500E+01	2,858E-02	1,143E-01	YES
1.b	1	PAA	5.000E-01	3,300E+00	6,600E+02	NO
		HP	1.250E+00	2,200E+00	1,760E+02	NO
		AA	2.500E+01	7,700E+00	3,080E+01	YES
	2	PAA	5.000E-01	6,600E-01	1,320E+02	NO
		HP	1.250E+00	4,400E-01	3,520E+01	YES
		AA	2.500E+01	1,540E+00	6,160E+00	YES
	3	PAA	5.000E-01	6.600E-02	1.320E+01	YES
		HP	1.250E+00	4.400E-02	3.520E+00	YES
		AA	2.500E+01	1.540E-01	6.160E-01	YES

Therefore, local inhalation effects are expected when the product is handled during loading application. <u>To protect the user, the risk related to inhalation exposures is only acceptable when LEV PF20 is working and mask PF10 is worn during this application.</u>

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

<u>Scenario [2]: Cleaning and maintenance of VPAA machines</u>

The applicant has not included in the dossier any information on the cleaning and maintenance of the VPAA machines.
Taking into account the characteristics of the VPAA machines, it can be assumed that the exposure during these tasks is equal to or lower than the exposure assessed for the mixing and loading phase.
Then, for this scenario, the conclusions for the risk characterisation obtained in the previous scenario have to be implemented.

During manual maintenance tasks, ensure adequate ventilation inside the machine (LEV) before opening the doors of the aseptic area.

Conclusions

Summary table: scenarios		
Scenario number	**Scenario and Users (e.g. mixing/ loading)**	**Conclusion**

1.a	Manual loading Industrial	A **safe** situation has been identified for the industrial manual loading of the product when PPEs (chemical-resistant: gloves, protective coverall, footwear; full-face mask APF10 and goggles) are worn and LEV APF20 integrated in the vaporization PAA machine is working, therefore **the uses of which this scenario is part will be authorized.**
1.b	Automatic Loading Industrial	A **safe** situation has been identified for the industrial automatic loading of the product when PPEs (chemical-resistant: gloves, protective coverall, footwear; full-face mask APF10 and goggles) are worn and LEV APF20 integrated in the vaporization PAA machine is working, therefore **the uses of which this scenario is part will be authorized.**
2	Cleaning / maintenance Industrial	A **safe** situation has been identified for the industrial cleaning and maintenance of VPAA machines when PPEs (chemical-resistant: gloves, protective coverall, footwear; full-face mask APF10 and goggles) are worn and LEV APF20 integrated in the vaporization PAA machine is working, therefore **the uses of which this scenario is part will be authorized.**

Risk for consumers via residues in food

No residues in food are expected. Peracetic acid and hydrogen peroxide are highly unstable and will rapidly degrade at the site of first contact which effectively reduces the possibility of any residual concentrations. Additionally, treated packaging materials are left to dry prior to further operations. Therefore, secondary human exposure to peracetic acid and hydrogen peroxide via food is not considered to be relevant.

2.2.7 Risk assessment for animal health

Not relevant for the present application.

2.2.8 Risk assessment for the environment

The active substance dossier/CAR on peracetic acid addresses the environmental exposure assessment on peracetic acid and the corresponding hydrogen peroxide.

No new data/information on environment neither for the product nor the active substance is deemed necessary, and therefore a very short summary of the environmental assessment is presented. For further details please refer to the active substance dossier/CAR.

A complete environmental exposure assessment and risk characterization is presented in the following sections.

2.2.8.1 Effects assessment on the environment

Based on previous statements, the information within the active substance dossier/CAR is found to be suitable for the biocidal product assessment. Accordingly, a very short summary copied from the CAR is presented. For further information, please refer to the active substance dossier/CAR.

Peracetic acid

In the acute aquatic tests, algae were found to be the most sensitive species with 72-h EC50 of 0.16 mg PAA/L. Fish with the lowest 96-h LC50 of 1.1 mg PAA/L and daphnia with the lowest 48-h EC50 of 0.73 mg PAA/L were less susceptible. The lowest available NOEC of 0.00069 mg PAA/L is for Zebra fish (*Danio rerio*) based on initial test concentrations, NOEC for daphnia is 0.0121 mg PAA/L. $PNEC_{aquatic}$ is 0.069 µg PAA/L and $PNEC_{marine}$ 0.0069 µg PAA/L based on NOEC for fish. The assessment factors for $PNEC_{aquatic}$ and $PNEC_{marine}$ are 10 and 100, respectively.

The PNEC for sewage treatment plant micro-organisms is 0.051 mg/l based on an assessment factor of 100. Acute terrestrial toxicity tests are available for earthworm, nontarget plants and soil micro-organisms. $PNEC_{terrestrial}$ is 0.282 mg PAA/kgwwt based on the seedling emergence test with non-target plants (*Brassica napus*) with an assessment factor of 1000. Birds and mammals are not anticipated to be directly exposed to peracetic acid, thus risk assessment for bird and mammals is not considered necessary.

Summary table on calculated PNEC values						
PNEC STP	**PNEC freshwater**	**PNEC marine water**	**PNEC sed freshwater**	**PNEC sed marine water**	**PNEC soil**	**PNEC air**
[mg/L]	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/m^3]
0.051	0.000069	0.0000069	0.000056	0.0000056	0.282	-

Hydrogen peroxide:

Hydrogen peroxide is toxic or moderately toxic to aquatic organisms; the LC50 values in the tests with fish range from 16.4 to 37.4 mg/L, the 48-h EC50 for invertebrates is 2.34mg/L and the EbC50 for the marine diatom *Skeletonema costatum* is 2.39 mg/L. The long-term NOEC value for the reproduction of *Daphnia magna* is 0.63 mg/L representing the lowest chronic NOEC for the aquatic invertebrates and the NOEC value for *S. costatum* was 1.69 mg/L. $PNEC_{aquatic}$ is 12.6 µg/L based on the NOEC of 0.63 mg/L for *Daphnia magna*.

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

Summary table on calculated PNEC values				
$PNEC_{STP}$	**$PNEC_{water}$**	**$PNEC_{sed}$**	**$PNEC_{soil}$**	**$PNEC_{air}$**
[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/m^3]
4.66	0.0126	0.0103	1.84×10^{-3}	-

Endocrine disruption activity of non-active substances

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides. These ED criteria with respect to humans establishes that a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

A. it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
B. it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;
C. the adverse effect is a consequence of the endocrine mode of action.

No further ecotoxicological studies are available for PHASE VTA. The biocidal product was not tested for potential endocrine disruption properties. PHASE VTA contains the active substance PERACETIC ACID and various co-formulants (see confidential annex 3.6).

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

The assessment of the endocrine-disrupting (ED) potential of each co-formulant in the biocidal product PHASE VTA is provided in the PAR confidential.

During screening performance none of the co-formulants triggered an alert for ED property.

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

For all components of the product valid data are available. Synergistic effects between the components are not expected. This also applies to hydrogen peroxide and peracetic acid, which have both an oxidative mode of action and are regarded to act in an additive way rather than synergistically. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal product itself is not necessary.

Composition of the biocidal product:
15% Peracetic acid CAS nº 79-21-0. Aquatic acute 1, H400 (M-factor = 1), Chronic toxicity 1, H410 (M-factor = 10).
10% Hydrogen peroxide CAS nº 7722-84-1. Aquatic chronic 3, H412.

The following formula is to be applied:
Acute category: Concentration Acute 1 x M-factor = 15% x 1 = 15%
Chronic category: Concentration Chronic 1 x M-factor = 15% x 10 = 150%

According to the Regulation (EC) No 1272/2008 (CLP), the biocidal product is not classified for Aquatic Acute Toxicity since the obtained value is less than 25%. Nevertheless, it is classified for Aquatic Chronic Toxicity Category 1, H410, since the value obtained is greater than 25%.

For further information on aquatic toxicity tests, please refer to the active substance dossier/CAR.

Further Ecotoxicological studies

Further studies for relevant components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal products. These conditions do not apply; the information on the active substance and the other components of the product allows the performance of valid environmental exposure and risk assessments and there are no indications of risk due to specific properties of the product.

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

No further studies are deemed necessary since no other specific, non-target organisms are believed to be at risk or for which the environmental risk assessment would have indicated specific potential risk. Accordingly, no further testing is required in the active substance dossier/CAR.

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

The study does not need to be conducted since the biocidal product is not in the form of bait or granules. The biocidal product is marketed as an aqueous solution and as such, no supervised trials to assess risks to non-target organisms under field conditions or studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk have been conducted as it is scientifically unjustified.

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

The study does not need to be conducted since the biocidal product is not in the form of bait or granules. The biocidal product is marketed as an aqueous solution and as such, no supervised trials to assess risks to non-target organisms under field conditions or studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk have been conducted as it is scientifically unjustified.

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

The study does not need to be conducted since the biocidal product is not intended to be applied to large proportions of a specific habitat. As such, no secondary ecological effect is envisaged.

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

The product is intended for use as disinfectant in aseptic food processing on food packaging materials in closed systems to achieve commercial sterility. As the product is applied in closed systems, no emission to the environment is likely to occur. The only possible emission to the environment is via STP.

During the industrial uses of disinfectants in food and feed areas, the active substances hydrogen peroxide and peracetic acid are released into the environment through STP into surface water. In the sewer system degradation could be assumed because peracetic acid and hydrogen peroxide are very reactive substances and degrade rapidly in contact with organic material.

Therefore, the main recipient in the environment is the STP. Subsequently, surface water is also exposed due to the indirect release via STP and fresh-water sediment. Soil and groundwater are also exposed via STP sludge spreading onto agricultural soil.

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

No further tests are deemed necessary since there is sufficient information on the components of the product to enable an environmental fate and behaviour assessment.

Leaching behaviour (ADS)

The biocidal product is applied as food and feed area disinfectant indoor. No leaching behaviour is applicable for the current use.

Testing for distribution and dissipation in soil (ADS)

Testing of the products concerning the distribution and dissipation in soil is not required because the composition and application technique of the products are not suspected to influence the degradation and transformation or mobility and adsorption properties of the active substance in a way that may considerably alter the conclusions of the risk assessments.

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

Testing of the products concerning the distribution and dissipation in water and sediment is not required because the composition and application technique of the products are not suspected to influence the degradation and transformation or mobility and adsorption properties of the active substance in a way that may considerably alter the conclusions of the risk assessments.

Testing for distribution and dissipation in air (ADS)

Testing of the products concerning the distribution and dissipation in air is not required because the composition and application technique of the products are not suspected to influence the degradation and transformation or mobility and adsorption properties of the active substance in a way that may considerably alter the conclusions of the risk assessments.

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

This endpoint is only applicable for products if the biocidal product is to be sprayed near to surface waters. The biocidal product is used as a disinfectant in food and feed industry indoors. Therefore, no overspray studies are deemed necessary.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

This endpoint is only applicable for products if the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given. The biocidal product is used as a disinfectant in food and feed industry indoors. Therefore, no data on overspray behaviour is deemed necessary.

2.2.8.2 Exposure assessment

General information

In order to be consistent with calculations already presented at active biocidal substance authorisation phase, the emission estimation is based on the ESD for PT4 for disinfectants in food and feed area (JRC Scientific and Technical Reports, 2011). The model Assessment of entire plants (e.g. breweries, dairies, beverage processing plants) (IHO 2006) (ESD Table 5, p.14-15) was used.

Assessed PT	PT 4
Assessed scenarios	Scenario: Aseptic packaging by spraying in closed systems.
ESD(s) used	Emission Scenario Document for Product Type 4: Assessment of entire plants (e.g. breweries, dairies, beverage processing plants) (IHO 2006) (ESD Table 5, p.14-15).
Approach	Average consumption
Distribution in the environment	Calculated based on Guidance BPR IV ENV B + C (2017). **Via STP:** Wastewater with the residues of the applied products is sent to the STP and then distributed to the surface water. Sludge generated in the STP is applied to agricultural land, reaching soil and groundwater.
Groundwater simulation	The calculation of the concentrations in groundwater was performed according to the approach described in the Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C) (2017).
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: No

ES CA:

The assessment has been performed considering the harmonised endpoints for peracetic acid and hydrogen peroxide (Harmonisation of assessment for PAA, Follow up ENV WG-IV-2019 September 2020) to derive emissions and distribution in the exposed environmental compartments.

Emission estimation

Input parameters for the emission calculation were based on the ESD. In order to be consistent with CAR calculations, the amount of active substance for peracetic acid of 288 kg/a, was used. The hydrogen peroxide was then adjusted to 192 kg/a (15% peracetic acid and 10% hydrogen peroxide).

Parameter	**Unit**	**Symbols**	**S/D/O/P**	**Value**	**Remark**
Amount of active substance	kg/a	$Q_{a.i}$	S	288 (PAA) 192 (H_2O_2)	according to CAR (PAA) Recalculated for H_2O_2
Number of emission days per year	d/a	$T_{emission}$	S	217	

Fraction of substance eliminated due to the on-site pre-treatment of the plant		F_{elim}	D	0	
Fraction of substance disintegrated during or after application (before release to the sewer system)		F_{dis}	D	0	
capacity of the STP	l/d	CAP $_{STP\text{-}off\text{-}site}$	D	$2E10^{6}$	

Output:
Elocal $_{water}$= Local release to wastewater(without pre-treatment) (kg/d)
C $i_{nfluent}$ = Daily influent concentration of disinfectant in STP on days where disinfection takes place (mg/l)

Calculations:
Clocalwater = (Qai/Temission) * 1000 * (1-Fdis) * (1-Felim) * Fwater / (CAPSTP_on-site * DIL)
Cinfluent = (Qai/Temission) * 1000 * (1-Fdis) * (1-Felim) * Fwater / CAPSTP_off-site

Results:	**peracetic acid**	**hydrogen peroxide**
Elocal water (kg/d)	1.05	0.884
C influent (mg/l)	0.53	0.444

Degradation of peracetic acid and hydrogen peroxide in the sewer system is assumed to follow single first-order kinetics a residence time of 1 hour in sewage (default according to the ESD for PT5), a fraction of the discharged substances reaching the STP is calculated as follows: :

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

$\mathbf{C_{t1} = C_{to} * EXP^{(-k*t1)}}$

C_{t1}= total concentration of the substance at time 1 (mg/l)

C_{to} = total concentration of the substance at time 0 (mg/l)

K= rate constant (DT$_{50}$ at 12ºC: ln2/DT$_{50}$)

T1 = time (h) = 1 hour

	peracetic acid	**hydrogen peroxide**
k (h^{-1})	4.47	0.25
C_{to} (mg/l)	0.53	0.444
C_{t1} (mg/l)	**0.006**	**0.344**

Degradation during the treatment is not considered in calculations; therefore, these are very conservative figures.

The packaging machines are closed systems with ventilation by sterile air. The ventilation air contains the active ingredients evaporated from the spraying phase and the drying process. The air is circulated internally and peracetic acid and hydrogen peroxide are washed by scrubbers. Scrubbing water is discharged to sewage

ES CA:

Spanish CA considers that the amount of active substance used into the Risk assessment for the environment of the biocidal product PHASE VTA is not correct. In order to be consistent with CAR of Peracetic acid and the Emission Scenario Document for Product Type 4, the default value for Qa.i of 407 kg·yr-1 should be used for Peracetic acid (see Table 6 ESD). Therefore, a new Risk assessment is provided, using the following parameters:
NOTE: the harmonised endpoints for peracetic acid and hydrogen peroxide (Harmonisation of assessment for PAA, Follow up ENV WG-IV-2019 September 2020) have been used.

Parameter	Unit	Symbols	S/D/O/P	Value	Remark
Amount of active substance	kg/a	Qa.i	S	407 (PAA) 271.3 (H_2O_2)	according to CAR (PAA) Recalculated for H_2O_2
Number of emission days per year	d/a	$T_{emission}$	D	231	
Fraction released to wastewater	-	F_{water}	D	1	
Fraction of substance eliminated due to the on-site pre-treatment of the plant	-	F_{elim}	D	0	
Fraction of substance disintegrated during or after application (before release to the sewer system)	-	F_{dis}	D	0	
capacity of the STP	l/d	$CAP_{STP-off-site}$	D	2000000	

Calculations:

	peracetic acid	**hydrogen peroxide**
DT50 (min) @12 ºC	9.5	11.4
K_{sewer} (h^{-1})	4.38	3.65
F_{sewer}	0.013	0.026

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

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

Results:	**peracetic acid**	**hydrogen peroxide**
Elocal water (Ct_0) (kg/d)	1.76	1.17
Elocal water (Ct_1) (kg/d)	0.0221	0.031
C influent (mg/l)*	0.011	0.015

* These values take into account a degradation of the active substances during their stay in the sewer system.

Fate and distribution in exposed environmental compartments

Direct emissions of the biocidal product to surface water or soil do not occur. Aseptic packaging spraying takes place in closed system and the peracetic acid and hydrogen peroxide remaining in the process air is decomposed by high temperature or washed out at scrubbers. Furthermore, air emissions are negligible.

The exposed environmental compartments are summarised in table below:

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario	yes	yes	n.r.	n.r.	yes	n.r.	yes	yes	no

Input parameters

Input parameters for calculating the fate and distribution in the environment			
	Peracetic acid	**Hydrogen peroxide**	
Input	*Value*	*Value*	*Unit*
Molecular weight	76.05	34.01	g/mol
Boiling point	105	150.2	°C
Vapour pressure (at 20ºC)	1410	214	Pa
Water solubility (at 20°C)	Completely miscible	Completely miscible	mg/l
Log Octanol/water partition coefficient	-0.6	-1.57	Log 10
Organic carbon/water partition coefficient (Koc)	1.46	1.598	l/kg
Henry's Law Constant	0.217 (25°C)	7.5 x 10^{-4} (20°C)	Pa.m^3/mol
Biodegradability	Readily biodegradable	Readily biodegradable	
DT_{50} for activated sludge	< 0.05	0.03	h
DT_{50} for biodegradation in surface water	-	5	d (at 12ºC /pH)
DT_{50} for degradation in soil	-	0.5	d (at 12ºC)

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

Calculated fate and distribution in the STP		
Active substance	Peracetic acid	hydrogen peroxide
Compartment	Percentage [%]	
Air	0.04657	0.0001568
Water	0.9891	0.6643
Sludge	0.0132	0.0132
Degraded in STP	98.95	99.32

ES CA:

The input parameters for calculating the distribution of peracetic acid and hydrogen perxyde in the environment were agreed at WG-IV_2019. The distribution in the STP has also been obtained with Simple Treat v4.0 (method 1) in line with the WG-IV-2019:

Input parameters for calculating the fate and distribution in the environment				
Input	**PAA**	**HP**	**Unit**	**Remarks**
Molecular weight	76.05	34.01	g/mol	
Melting point	0	-0.43	°C	
Boiling point	105	150.2	°C	
Vapour pressure	1410	214	Pa	At 20°C
Water solubility	Completely miscible	Completely miscible	mg/l	
Log Octanol/water partition coefficient	-0.6	-1.57	Log 10	At pH 7
Organic carbon/water partition coefficient (Koc)	1.46	1.598	l/kg	
Henry's Law Constant	0.217 (25°C)	7.5×10^{-4} (20°C)	Pa/m³ /mol	
Biodegradability	Ready biodegradable	Ready biodegradable		
DT_{50} for biodegradation in surface water	-	5	days	
DT_{50} for hydrolysis in surface water	89.7	-	Hour	At 12ºC
DT_{50} for degradation in soil	12	12	Hour	
DT_{50} for degradation in air	95.26	24	Hour	
DT_{50} for STP	<3	<2	Min	At 20°C
DT_{50} for biodegradation in effluent stream	<9.5	169	Min	At 12°C
DT_{50} for biodegradation in sewer	<9.5	11.4	Min	At 12°C

Calculated fate and distribution in the STP		
Active substance	Peracetic acid	hydrogen peroxide
Compartment	Percentage [%]	
Air	0.0435	0.0002
Water	0.9903	0.6637
Sludge	0.0133	0.0145
Degraded in STP	98.95	99.32

Calculated PEC values

Based on the high reactivity of both peracetic acid and hydrogen peroxide, and the high organic matter content of STP sludge, PEC values and subsequent risk characterization for soil and groundwater are expected to be negligible. However, they are presented for completeness. The predicted environmental concentrations (PEC) in sewage, receiving surface water and sediment and groundwater under agricultural soil were calculated from the emission estimates following the TGD and EUSES 2.1. Exposure to groundwater is anticipated from sewage sludge application only; direct exposure to soil and thereafter to groundwater (pore water of agricultural soil) is regarded negligible.

Summary table on calculated PEC values					
	PEC$_{STP}$	**PEC**$_{water}$	**PEC**$_{sed}$	**PEC**$_{soil}$	**PEC**$_{GW}$
	[mg/L]	[mg/L]	[mg/kg$_{wwt}$]	[mg/kg$_{wwt}$]	[mg/l]
Peracetic acid	0.062 x 10^{-3}	6.2 x 10^{-6}	5.04 x 10^{-6}	1.65 x 10^{-6}	2.65 x 10^{-6}
hydrogen peroxide	2.36 x 10^{-3}	5.9 x10^{-4}	1.92x 10^{-4}	8.3 x 10^{-6}	1 x 10^{-5}

ES CA:

The following PEC values have been recalculated:

Summary table on calculated PEC values						
	PEC$_{STP}$	**PEC**$_{air}$	**PEC**$_{water}$	**PEC**$_{sed}$	**PEC**$_{soil}$	**PEC**$_{GW}$
	[mg/L]	[mg/m^3]	[mg/L]	[mg/kg$_{wwt}$]	[mg/kg$_{wwt}$]	[µg/l]
PAA	1.10E-04	2.67E-09	1.10E-05	8.92E-06	1.30E-07	1.51E-04
H2O2	1.01E-04	1.7E-11	1.01E-05	8.30E-06	1.97E-07	2.52E-04

Primary and secondary poisoning

Primary poisoning

No data available.

Secondary poisoning

Secondary dietary exposure of consumers to residual peracetic acid and hydrogen peroxide in food and drinking water is in theory possible under PT 4 aseptic packaging by spraying method. However, these active substances used for aseptic packaging evaporates while the wrapping material is heated before filled with food and no residues in food are expected. Furthermore, if present, would rapidly decompose in contact with any type of food.

Peracetic acid and hydrogen peroxide are unlike to bioaccumulate in aquatic or terrestrial environment. Peracetic acid and hydrogen peroxide have a low log Kow (-0.26 and -1.57, respectively), are not highly adsorptive, do not belong to a class of substances known to have a potential to accumulate in living organisms, their structural features do not indicate accumulation and are readily biodegradable and have a short degradation half-life. Moreover, peracetic acid and hydrogen peroxide dissipate rapidly in the environment which is a further indication of their low accumulation potential. No further assessment of secondary exposure via the food chain is therefore considered necessary.

2.2.8.3 Risk characterisation

Atmosphere

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

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

ES CA:

Based on the physico-chemical properties of the active substance and substance of concern and on the intended use, the emissions to air due to the application of the product can be considered as negligible.

Conclusion: emissions to air from biocidal use can be regarded as negligible and no threat to the atmosphere is expected.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC $_{STP}$ values	
Peracetic acid	1,22X 10^{-3}
hydrogen peroxide	5,06X 10^{-4}

ES CA:

The following PEC/PNEC values have been recalculated:

Summary table on calculated PEC/PNEC $_{STP}$ values	
PAA	2.15E-03
H2O2	2.18E-05

Conclusion: There is no unacceptable risk to the relevant compartment for the proposed use.

Aquatic compartment

Summary table on calculated PEC/PNEC values		
Active substance	**$PEC/PNEC_{water}$**	**$PEC/PNEC_{sed}$**
Peracetic acid	$8{,}99X\ 10^{-2}$	$9{,}00X\ 10^{-2}$
hydrogen peroxide	$4{,}68X\ 10^{-2}$	-

ES CA:

The following PEC/PNEC values have been recalculated:

Summary table on calculated PEC/PNEC values		
Active substance	**$PEC/PNEC_{water}$**	**$PEC/PNEC_{sed}$**
PAA	1.59E-01	1.59E-01
H2O2	8.05E-04	8.05E-04

Conclusion: There is no unacceptable risk to the relevant compartments for the proposed use.

Terrestrial compartment

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Peracetic acid	$5{,}85X\ 10^{-6}$
hydrogen peroxide	$4{,}51X\ 10^{-3}$

ES CA:

The following PEC/PNEC values have been recalculated:

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
PAA	4.61E-07
H2O2	1.07E-04

As negligible exposure of soil is to be expected following the biocidal uses and any traces of peracetic acid and/or hydrogen peroxide reaching soil are very rapidly degraded taking into account the short half-life in soil.

Conclusion: There is no unacceptable risk to the relevant compartment for the proposed use.

Groundwater

Exposure to groundwater is anticipated from sewage sludge application only; direct exposure to soil and thereafter to groundwater (pore water of agricultural soil) is regarded negligible.

Conclusion: There is no unacceptable risk to the relevant compartment for the proposed use.

Primary and secondary poisoning

Primary poisoning

No data available.

Secondary poisoning

The log Kow of -0.60 (at pH 7) for peracetic acid and the log Kow of -1.57 for hydrogen peroxide indicate that both substances have a low potential for bioconcentration and bioaccumulation. Moreover, peracetic acid and hydrogen peroxide dissipate rapidly in the environment which is a further indication of their low accumulation potential.

Mixture toxicity

Tiered approach

Tier 1. PEC/PNEC summation

Risk quotients for assessed compartment was estimated as follows:

Summary table on calculated PEC/PNEC values				
	PEC/PNEC$_{STP}$ [mg/L]	**PEC/PNEC$_{water}$** [mg/L]	**PEC/PNEC$_{sed}$** [mg/kg$_{wwt}$]	**PEC/PNEC$_{soil}$** [mg/kg$_{wwt}$]
Peracetic acid	1,22E-03	8,99E-02	9,00E-02	5,85E-06
hydrogen peroxide	5,06E-04	4,68E-02	0,00E+00	4,51E-03
ΣRQ	**1,72E-03**	**1,37E-01**	**9,00E-02**	**4,52E-03**

ES CA:
Considering the new PEC/PNECS:

Summary table on calculated PEC/PNEC values				
	PEC/PNEC$_{STP}$	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{soil}$**
	[mg/L]	[mg/L]	[mg/kg$_{wwt}$]	[mg/kg$_{wwt}$]
PAA	2.15E-03	1.59E-01	1.59E-01	4.61E-07
H2O2	2.18E-05	8.05E-04	8.05E-04	1.07E-04
ΣRQ	**2.17E-03**	**1.60E-01**	**1.59E-01**	**1.08E-04**

Tier 1		
RQ product	Acceptable risk for the environment? yes	Remarks

PEC/PNEC sums are derived from a set of different species and endpoints. Therefore, this approach is only recommended for first-tier. This is a highly conservative approach and moreover estimated values are very low. Therefore, it is considered acceptable risk for environment. No further assessment (tiers 2-4) are needed

Aggregated exposure (combined for relevant emmission sources)

No information is available about other uses of active substances and/or the tonnage band of these potential uses. The biocidal product Phase-VTA is to be used for PT4 in a non-wide dispersive pattern of use. No other product types are intended. No overlap in time and space is expected. Therefore, no aggregate exposure estimation is required for Phase-VTA.

2.2.9 Measures to protect man, animals and the environment

Recommended methods and precautions concerning storage of active substance/biocidal product, shelf-life of biocidal product:

Keep in a dry, cool, and well-ventilated place. Containers must be vented.
Keep at temperatures below 30°C. Higher temperatures will accelerate decomposition resulting in loss of assay.
Do not store near combustible materials.
Packaging material: Passivated grade L304 or L316 stainless steel. Passivated aluminium. High density polyethylene. Avoid any other material.
Materials to avoid: Oxidizing agents; Strong reducing agents; Combustible materials; Heavy metals.
Shelf-life: 6 months.

Recommended methods and precautions concerning handling and transport:
Avoid contact with skin and eyes.
Do not breathe vapours or spray mist.
Use only in well-ventilated areas.
Wear personal protective equipment.
Do not confine material between two valves.

Recommended methods and precautions concerning fire; in case of fire nature of reaction products, combustion gases etc.:
Suitable Extinguishing Media: Water. Water spray. Carbon dioxide (CO_2).
Extinguishing media - small fires: Dry powder. Cool containers with flooding quantities of water until well after fire is out.
Extinguishing media which shall not be used for safety reasons: Do NOT use water jet.
Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases: FLAMMABLE. Risk of explosion in closed, unventilated containers due to increased pressure from decomposition gases. Decomposes under fire conditions to release oxygen that intensifies the fire. When heated beyond its flashpoint, it gives off vapours which, when mixed with air, may burn, or explode.

Particulars of likely direct or indirect adverse effects:
This product is irritating to the respiratory system and can cause pulmonary inflammation and oedema, especially if it is inhaled in the aerosol form.
In case of accidental ingestion, necrosis may result from mucous membrane burns (mouth, esophagus and stomach). Oxygen rapid release may cause stomach swelling and haemorrhaging, which may product major, or even fatal, injury to organs if a large amount has been ingested.
Corneal lesions and irreversible damage if contact with the eyes.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.
If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.
Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.
IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.
IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes After washing the skin:Call 112/ambulance for medical assistance.
Information to Healthcare personnel/doctor: Initiate life support measures, thereafter call a POISON CENTRE.
IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.
Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor.

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER

Emergency measured to protect environment in case of accident:
Prevent spillage from reaching soil, ground, surface water or any kind of sewer.
Dike to collect large liquid spills.
Contain spills with earth or sand or inert absorbent.
Stop leak and contain spill if this can be done safely.
If safe to do so, move product to secure area.
Control runoff and isolate discharged material for proper disposal.
Do not seal waste material, do not use textiles, tissues, saw dust or combustible materials to clean the spill.
Do not return product to the original storage container/tank due to risk of decomposition.
Residual hydrogen peroxide, if allowed to dry on combustible materials such as paper, fabrics, leather, or wood can cause the material to ignite and result in a fire.

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

2.2.11 Comparative assessment

Not applicable

3 ANNEXES

3.1 List of studies for the biocidal product

See confidential annex

3.2 Output tables from exposure assessment tools

Phase VTA
ConsExpo Results.xl

Phase VTA Risk
characterization.xlsx

3.3 New information on the active substance

Non applicable

3.4 Residue behaviour

-

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

All efficacy tests information is summarizad in the efficacy table. Section 2.2.5.

3.6 Confidential annex

See PAR Confidential.

3.7 Other

No further data available.