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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR UNION AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

WESSOCLEAN GOLD LINE

Product type(s) 3, 4

Peracetic acid

Case Number in R4BP: BC-QN034236-29

Evaluating Competent Authority: DE

Date: 11/10/2022

Table of Contents

1 CONCLUSION

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
WESSOCLEAN GOLD LINE	-

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	WESSO AG
	Address	Wacholderweg 6 90518 Altdorf b. Nürnberg Germany
Pre-submission phase started on	29.05.2017	
Pre-submission phase concluded on	13.07.2017	
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	WESSO AG
Address of manufacturer	Wacholderweg 6 90518 Altdorf b. Nürnberg Germany
Location of manufacturing sites	Wacholderweg 6 90518 Altdorf b. Nürnberg Germany

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

Active substance	Peracetic acid
Name of manufacturer	Evonik Resource Efficiency GmbH
Address of manufacturer	Postfach 1345 63403 Hanau Germany
Location of manufacturing sites	Evonik Peroxid GmbH Industriestraße 11 9721 Weissenstein Austria

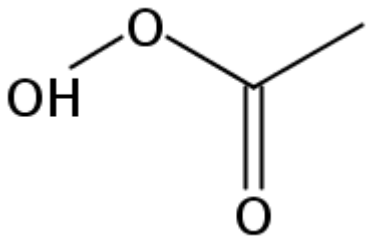
2.1.2 Product composition and formulation

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

Yes ☐
No ☒

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

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Peracetic acid
IUPAC or EC name	Ethaneperoxoic 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	100 %
Structural formula	

2.1.2.2 Candidate(s) for substitution

No candidate for substitution was identified.

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	Ethaneperoxoic acid	Active substance	79-21-0	201-186-8	0.03
Hydrogen peroxide	-	Non-active substance[1]	7722-84-1	231-765-0	3.15
Acetic acid	-		64-19-7	200-580-7	0.06
Propan-2-ol	-		67-63-0	200-661-7	2.52
Ethanol	-		64-17-5	200-578-6	1.61
Sulphuric acid	-		7664-93-9	231-639-5	0.01

Information on the full composition is provided in the confidential[2] annex.

2.1.2.4 Information on technical equivalence

Is the source of the active substance(s) the same as the one evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☒
No ☐

2.1.2.5 Information on the substance(s) of concern

The following substance(s) of concern was/were identified:

- Hydrogen peroxide (CAS No 7722-84-1)
- Propan-2-ol (CAS-No 67-63-0)
- Ethanol (CAS No 64-17-5)
- Sulphuric acid (CAS No 7664-93-9)

Hydrogen peroxide, propan-2-ol, ethanol and sulphuric acid are identified as substances of concern because of their contribution to the classification of the biocidal product with Eye Irrit. 2 and Met. Corr. 1. In addition, the co-formulant propan-2-ol is also considered a substance of concern, since it is an approved biocidal active substance with derived reference values and present in the product at a concentration ≥ 0.1 %.

➢ (Further) information on the substance(s) of concern is provided in the confidential annex (chapter 3.6.2).

2.1.2.6 Type of formulation

AL – any other liquid

[1] Non-active substance(s), of which knowledge is essential for proper use of the product. In the SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of non-active substance.

[2] Access level: "Restricted" to applicant and authority

2.1.3 Classification and Labelling according to the Regulation (EC) 1272/2008 [3]

Besides the active substance Peracetic acid and the substances of concern, the other components do not affect the classification of the product.
A harmonised classification for the active substance Peracetic acid does exist, but will be revised according to the AR (2015). Thus, the classification from the CA report (RMS FI November 2015) was taken into account.

The current harmonised classification of the active substance Peracetic acid is based Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation).[4]

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.1.3.2 and if applicable to chapter 2.1.3.1.

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

4 See: http://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/cl-inventory/view-notification-summary/105223

Table 1

Classification Hazard classes, Hazard categories	**Hazard statements**	
Met. Corr. 1	H290	
Eye Irrit. 2	H319	
Harmful to aquatic life with long lasting effects	H412	
Labelling	**Code**	**Pictogram / Wording**
Hazard pictogram	GHS05	
Signal word	-	Danger
Hazard statements	H290	May be corrosive to metals
	H319	Causes serious eye irritation.
	H412	Harmful to aquatic life with long lasting effects
Supplemental hazard information	-	-
Supplemental label elements	-	-
Precautionary statements	P234	Keep only in original packaging.
	P264	Wash hands thoroughly after handling.
	P273	Avoid release to the environment
	P280	Wear eye protection.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P337 + P313	If eye irritation persists: Get medical advice/attention.
	P390	Absorb spillage to prevent material damage.
	P501	Dispose of contents and container to an approved waste disposal plant in accordance with national regulations.
Note	-	

Note that P-phrases listed were selected based on existing CLP preference rules for selecting P- phrases.
P406 may be omitted if P234 is given on the label.

2.1.3.1 Use(s) appropriate for authorisation[5]

2.1.3.1.1 Use 1 appropriate for authorisation – Disinfection of hatching eggs at room temperature in the sluice

Product Type(s)	3
Where relevant, an exact description of the use	
Target organism(s) (including development stage)	*bacteria* *yeast* *fungi*
Field(s) of use	Indoor, hatcheries (sluice), disinfection of hatching eggs
Application method(s)	Closed system: cold fogging
Application rate(s) and frequency	1 L undiluted product per 15 m^3 (= 0.067 L/m^3); median droplet size ≤ 15 µm
Category(ies) of users	professional
Pack sizes and packaging material	1L bottle (PE) 20L can (HDPE) 220L drum (HDPE) 1.000L IBC container (PE)

2.1.3.1.1.1 Use-specific instructions for use

1) 1 L product per 15 m^3 (= 0.067 L/m^3) must be distributed for a period of at least 30 minutes. When an application rate of 0.067 L/m^3 is achieved the contact time starts.

   For bactericidal, yeasticidal and fungicidal efficacy let take effect at 20 °C for 60 minute contact time. Afterwards the air in the chamber is replaced by means of an exhaust system.
2) The product is used as ready-to-use solution.
3) Disinfection after every new refilling of the disinfection chamber with eggs.
4) Only for use in dry enclosures of 4 -150 m^3.
5) Biological validation shall be performed by the user of the biocidal products for each room setup (including e.g. hatching eggs, equipment) to be disinfected by fogging (or in a suitable "standard" room in a facility, if applicable) with the devices to be used, after which a protocol for disinfection processes in these rooms can be made and used thereafter.

2.1.3.1.1.2 Use-specific risk mitigation measures

See chapter 2.1.3.2.2

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

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

See chapter 2.1.3.2.3

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

See chapter 2.1.3.2.4

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

See chapter 2.1.3.2.5

2.1.3.1.2 Use 2 appropriate for authorisation – Disinfection of hatching eggs at 36 °C e.g. in the hatcher

Product Type(s)	3
Where relevant, an exact description of the use	
Target organism(s) (including development stage)	*bacteria* *yeast* *fungi*
Field(s) of use	Indoor, hatcheries (hatcher), disinfection of hatching eggs
Application method(s)	Closed system: cold fogging
Application rate(s) and frequency	1 L undiluted product per 15 m^3 (= 0.067 L/m^3); median droplet size ≤ 15 µm
Category(ies) of users	professional
Pack sizes and packaging material	1L bottle (PE) 20L can (HDPE) 220L drum (HDPE) 1.000L IBC container (PE)

2.1.3.1.2.1 Use-specific instructions for use

1) 1 L product per 15 m^3 (= 0.067 L/m^3) must be distributed for a period of at least 30 minutes. When an application rate of 0.067 L/m^3 is achieved the contact time starts.

   For bactericidal, yeasticidal and fungicidal efficacy let take effect at 36 °C for 60 minute contact time. Afterwards the air in the chamber is replaced by means of an exhaust system.
2) The product is used as ready-to-use solution.
3) Disinfection after every new refilling of the disinfection chamber with eggs.
4) Only for use in dry enclosures of 4 -150 m^3.

5) Biological validation shall be performed by the user of the biocidal products for each room setup (including e.g. hatching eggs, equipment) to be disinfected by fogging (or in a suitable "standard" room in a facility, if applicable) with the devices to be used, after which a protocol for disinfection processes in these rooms can be made and used thereafter.

2.1.3.1.2.2 Use-specific risk mitigation measures

See chapter 2.1.3.2.2

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

See chapter 2.1.3.2.3

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

See chapter 2.1.3.2.4

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

See chapter 2.1.3.2.5

2.1.3.1.3 Use 3 appropriate for authorisation – Disinfection of surfaces in the vegetable/fruit/plants packaging industry by airborne diffusion

Product Type(s)	4
Where relevant, an exact description of the use	
Target organism(s) (including development stage)	*bacteria* *yeast* *fungi*
Field(s) of use	Indoor Non-porous surfaces of transport and storage equipment for potatoes, fruits, vegetables and plants without direct contact to potatoes, fruits, vegetables or plants.
Application method(s)	Closed system: cold fogging
Application rate(s) and frequency	40 mL product per 1 m^3 (0.04 L/m^3) room air; median droplet size ≤ 15 µm
Category(ies) of users	professional
Pack sizes and packaging material	1L bottle (PE) 20L can (HDPE) 220L drum (HDPE)

	1.000L IBC container (PE)

2.1.3.1.3.1 Use-specific instructions for use

1) 40 mL ready to use product per 1 m^3 room air (0.04 L/m^3) is distributed for a period of at least 30 min. When an application rate of 0.04 L/m^3 is achieved, the contact time starts.
2) For bactericidal, yeasticidal and fungicidal efficacy let take effect at room temperature for a contact time of 30 minutes. Afterwards, the room is intensively aerated.
3) The product is a ready-to-use solution that must not be diluted with water.
4) Disinfecting before placing new items in the packaging line.
5) Only for use in dry enclosures of 3 – 5 m^3
6) Biological validation shall be performed by the user of the biocidal products for each installation to be used for disinfection by fogging (or in a suitable "standard" installation in a facility, if applicable) with the devices to be used, after which a protocol for disinfection in these installations can be made and used thereafter.

2.1.3.1.3.2 Use-specific risk mitigation measures

See chapter 2.1.3.2.2

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

See chapter 2.1.3.2.3

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

See chapter 2.1.3.2.4

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

See chapter 2.1.3.2.5

2.1.3.2 General directions for use of the products

2.1.3.2.1 Instructions for use

<u>For loading the product:</u>
The product may only be transferred/loaded with automatic pumps.

2.1.3.2.2 Risk mitigation measures

For loading the product:

1) The use of eye protection during handling of the product is recommended.

For application of the product:

2) Application of the product is only permitted in closed, airtight disinfection systems. Workers must not be present during disinfection process./ No workers are allowed in the disinfection chamber during application.
3) The disinfection shall only be started from the outside to avoid contact with the disinfectant.
4) The chamber must remain hermetically sealed during disinfection and re-entry must be prevented. It shall be indicated that a disinfection process is running.
5) After application, the chamber must be completely ventilated by a technical ventilation system.
6) Re-entry is only permitted once the product has dried from all surfaces and the air concentrations of peracetic acid and hydrogen peroxide have dropped below the respective reference values (AECs). To ensure sufficient ventilation, either a disinfection system with sensors indicating when the relevant concentrations have dropped below the reference values has to be used, or the required duration of the technical ventilation has to be established by measurement with suitable measurement equipment for each technical installation and after any change in relevant boundary conditions.

For repair or maintenance of dosing pumps:

7) Prior to intervention in the pumps, existing product residues must be largely removed by flushing the pumps.

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

First aid

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

Environment:

5) Avoid direct release of the undiluted product to the environment and sewage system.
6) Large spills: Cover the liquid with absorbent material. Contain and collect for disposal.

2.1.3.2.4 Instructions for safe disposal of the product and its packaging

1) Residues of the biocidal product must be disposed off in accordance with the Waste Framework Directive (2008/98/EG) and the European Waste Catalogue (EWC) as well as national and regional regulations.
2) Do not empty into drains.
3) Dispose of contents/container to an authorised waste collection point.
4) Leave biocidal products in original containers. Do not mix with other wastes.
5) When totally empty, containers are recyclable.

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

1) Shelf life: 12 months.
2) Protect from frost.
3) Store at temperatures below 30°C.

2.1.3.2.6 Other information

1) Please be aware of the EU reference value of 0.5 mg/m³ for the active substance peracetic acid (CAS No.: 79-21-0) which was used for the risk assessment for this product.
2) Please be aware of the EU reference value of 1.25 mg/m³ for the substance of concern hydrogen peroxide (CAS No.: 7722-84-1) which was used for the risk assessment for this product.
3) Please be aware of the EU reference value of 17.9 mg/kg bw/d for the substance of concern propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for this product.
4) For orientation: relative humidity as tested in adapted EN 17272 for efficacy: 33 - 53 %.

2.1.4 Packaging

Table 2

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Bottle	1 L	PE	Closure PE	professional	Yes
Can	20 L	HDPE	Closure HDPE	professional	Yes
Drum	220 L	HDPE	Closure HDPE	professional	Yes
Container	1000 L	PE	-	professional	Yes

2.1.5 Documentation

2.1.5.1 Data submitted in relation to product application

Please refer to the reference list in Annex 3.1 of this PAR.

2.1.5.2 Access to documentation

The applicant provided a letter of access to the dossier for the active substance "peracetic acid" in chapter 13 of the IUCLID-dossier. This dossier is satisfying the requirements set out in Annex II of Regulation (EU) No 528/2012 for use in PT 3 (Veterinary hygiene) and PT4 (Food and feed area).

2.1.5.3 Similar conditions of use

Decision Number UPP-D-1257074-87-00/F, dated 13.07.2017 from ECHA and addressed to WESSO AG states the following:

The biocidal product WESSOCLEAN GOLD LINE is deemed to be eligible for Union authorisation.
Based on the information provided by the applicant, it appears that the application could meet the basic requirements of Article 42(1) of the Biocidal Products Regulation.
No objections were raised from either the Commission or the Member States Competent Authorities (MSCAs) as regards the eligibility of the prospective application for Union authorisation on the grounds that the biocidal product WESSOCLEAN GOLD LINE falls outside of the scope of the Biocidal Products Regulation, or had been attributed the wrong product type, or that it would have non-similar conditions of use across the Union.

2.2 Assessment of the biocidal product

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

Table 3. Intended use # 1 – Disinfection of hatching eggs

Product Type(s)	3
Where relevant, an exact description of the authorised use	Disinfection takes place in a closed disinfection chamber. The product is automatically sprayed into the disinfection chamber by means of a cold sprayer with compressed air.
Target organism (including development stage)	*Pseudomonas aeroginosa*-vegetative cell *Enterococcus hirae*-vegetative cell *Staphylococcus aureus*-vegetative cell *Proteus vulgaris*-vegetative cell *Candida albicans*-Spores and spore producing structures *Aspergillus brasiliensis*-Spores and spore producing structures
Field of use	Indoor
Application method(s)	Closed system: spraying
Application rate(s) and frequency	1 L ready to use product (GOLD LINE) per 15 m^3 for a period of at least 30 minutes
Category(ies) of user(s)	professional
Pack sizes and packaging material	1L bottle (PE) 20L can (HDPE) 220L drum (HDPE) 1.000L IBC container

Table 4. Intended use # 2 – Disinfection of surfaces in the vegetable/fruit/plants packaging industry

Product Type(s)	4
Where relevant, an exact description of the authorised use	Liquid for the surface disinfection of transport and storage equipment for potatoes, fruits, vegetables and plants. The disinfection takes place in closed room. Direct contact to potatoes, fruits, vegetables or plants is excluded.
Target organism (including development stage)	*Pseudomonas aeroginosa*-vegetative cell *Enterococcus hirae*-vegetative cell *Staphylococcus aureus*-vegetative cell *Escherichia coli*-vegetative cell *Candida albicans*-Spores and spore producing structures *Aspergillus brasiliensis*-Spores and spore producing structures
Field of use	Indoor
Application method(s)	Closed system: spraying
Application rate(s) and frequency	40 mL ready to use product per 1 m^3 room air or 1,5 L ready to use product per 0,5 h for a period of at least 30 min.

Category(ies) of user(s)	professional
Pack sizes and packaging material	1L bottle (PE) 20L can (HDPE) 220L drum (HDPE) 1.000L IBC container

2.2.2 Physical, chemical and technical properties

Table 5.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Organoleptical analysis.	Charge: 070.717/WGL.EU/T1M	liquid	[redacted], 2017
Colour at 20 °C and 101.3 kPa	Organoleptical analysis.	Charge: 070.717/WGL.EU/T1M	clear, colorless to light yellow	[redacted], 2017
Odour at 20 °C and 101.3 kPa	Organoleptical analysis.	Charge: 070.717/WGL.EU/T1M	characteristic (tartish, fruity) odor	[redacted], 2017
Acidity / alkalinity	CIPAC MT 191, CIPAC MT 75.3	Batch No.: Lot 300.617	Start of Storage pH= 3.24 Acidity H2SO4 0.63 g/100g	[redacted], 2017
Relative density / bulk density	OECD 109 - oscillating densitimeter	Batch No.: Lot 300.617	1.0046 at 20°C	[redacted], 2017
Storage stability test – **accelerated storage**			Study was not conducted; "store below 30 °C" will be added to the label claim.	
Storage stability test – **long term storage at ambient temperature**		Batch No.: Lot 300.617	Wessoclean Gold Line is stored in 20 L HDPE for 12 month at ambient temperature. The content of peracetic acid rises in 12 month (% w/w): t=0, 0.006 t=3, 0.007 t=6, 0.008 t=9, 0.008 t=12, 0.009	[redacted], 2017 [redacted], 2018

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			H_2O_2 stays almost constant over 12 months (% w/w): t=0, 3.3 t=3, 3.0 t=6, 3.1 t=9, 3.2 t=12, 3.1 ethanol and 2-propanol were detected over 12 months (% w/w): ethanol t=0, 1.6 t=3, 1.4 t=6, 1.3 t=9-12, 1.4 2-propanol t=0, 2.7 t=3-12, 2.3 The pH is stable for 6 month. t=0, pH=3.24 t=3, pH=3.23 t=6, pH=3.20 t=9, pH=3.12 t=12, pH=3.06 The relative density (D_4^{20}) decreased over 12 months: t=0, 1.0046 t=3, 1.0044 t=6, 1.0042 t=9, 1.0040 t=12, 1.0037	
	eCA: The weight change was not addressed during the storage stability studies. However, volatilization is not expected to occur over the storage period as the amount of the volatile species ethanol and 2-propanol did not change dramatically (< 0.5 % w/w). Further, the amount of the unstable species (which may form volatile species by decomposition, namely hydrogen peroxide and peracetic acid) showed only a slight decrease (≤ 0.3 % w/w). As the containers were tightly closed evaporation is not expected to			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	occur. Therefore, the stability is shown even without addressing the weight change during the storage stability studies.			
Storage stability test – **low temperature stability test for liquids**			Study was not conducted; protect from frost will be added to the label claim	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			The product was stored in the commercial HDPE packaging under normal light conditions during long term storage stability tests. Further, the blue HDPE and white PE-IBC container are light proof. The white 20 L container is off-white opaque.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			The products comprises water therefore no impact of humidity is expected; requirements on the storage temperature will be added to the label claim	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			**Waiver**: Data on reactivity towards container material are not required if a lack of extreme pH or alternatively, if information from experience in use and/or	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			chemical structure indicate that testing is unnecessary. The biocidal product WESSOCLEAN GOLD LINE has a pH of about 3.2, which is only moderately acidic. The chemical structures indicate no signs that testing is necessary and long term marketing experience shows that the used packaging materials made of HDPE or PE are suitable and compatible with the biocidal product. The materials constituting the packaging are not expected to be susceptible to damage by the contents, or liable to form hazardous compounds with the contents. Therefore, further data is not required.	
Wettability			Not applicable - product is a RTU liquid product.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Suspensibility, spontaneity and dispersion stability			Not applicable - product is a RTU liquid product.	
Wet sieve analysis and dry sieve test			Not applicable - product is a RTU liquid product.	
Emulsifiability, re-emulsifiability and emulsion stability			Not applicable - product is a RTU liquid product.	
Disintegration time			Not applicable - product is a RTU liquid product.	
Particle size distribution, content of dust/fines, attrition, friability			Not applicable - product is a RTU liquid product.	
Persistent foaming			Not applicable - product is a RTU liquid product.	
Flowability/Pourability/Dustability			Not applicable - product is a RTU liquid product.	
Burning rate — smoke generators			Not applicable - the product is not intended to be used as smoke generator	
Burning completeness — smoke generators			Not applicable - the product is not intended to be used as smoke generator	
Composition of smoke — smoke generators			Not applicable - the product is not intended to be used as smoke generator	
Spraying pattern — aerosols			Not applicable - the product will not be applied as a spray	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical compatibility			Not applicable - product is not intended to be used in combination with other substances, mixtures or biocidal or non-biocidal products	
Chemical compatibility			Not applicable - product is not intended to be used in combination with other substances, mixtures or biocidal or non-biocidal products	
Degree of dissolution and dilution stability			Not applicable - product is RTU and further dilution is not foreseen	
Surface tension	OECD 115, ring method	Batch No.: Lot 300.617	23,2 mN/m (20°C)	[redacted], 2017
Viscosity	OECD 114, rotational viscometer (dynamic)	Batch No.: Lot 300.617	1.37 mPa/s (20°C) 1.28 mPa/s (40°C) The biocidal product Wessoclean Gold Line is a Newtonian liquid.	[redacted], 2017

Conclusion on the physical, chemical and technical properties of the product
Wessoclean Gold Line is a clear, colourless to light yellow liquid with a characteristic (tartish, fruity) odour. The pH of the product is pH= 3.24, a test of acidity showed 0.63 g H_2SO_4/100g solution. A Storage stability test – accelerated storage is waived. The long term storage stability study showed an increase of PAA during storage. This could be explained by the sensitive equilibrium, the measurement inaccuracy or also generous rounding of determined values. Taking all available data into account (please refer also to the confidential annex) a shelf life of 12 month can be granted.

2.2.3 Physical hazards and respective characteristics

Table 6.

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	study scientifically not necessary	Expert statement: Hydrogen peroxide and peracetic acid of the biocidal product WESSOCLEAN GOLD LINE are present in very low concentrations. Explosive properties are not expected. The other components in the product are not associated with possible explosive properties. (see below)			IUCLID[6]
Flammable gases	study scientifically unjustified				Regulation (EU) No 528/2012[7]
Flammable aerosols	study scientifically unjustified				Regulation (EU) No 528/2012
Oxidising gases	study scientifically unjustified				Regulation (EU) No 528/2012
Gases under pressure	study scientifically unjustified				Regulation (EU) No 528/2012
Flammable liquids	EU method A.9, DIN EN ISO 3679, Setaflash	WESSOCLEAN GOLD LINE / WESSOCLEAN GREEN LINE; Lot 300.617, Charge	Flash point: 56 °C	Expert statement: As the biocidal product consists of more than 90 % of water, a classification as flammable liquid is not	[redacted], 2017

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

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

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
		WGL.EU, Batch T1M		considered necessary, as miscible solutions with water content of more than 90 % by mass are considered to be unable to sustain combustion (cf. Section 32.2.5 of the UN RTDG, Manual of Tests and Criteria (ST/SG/AC.10/11/Rev. 7). (see below)	
Flammable solids	study scientifically unjustified				Regulation (EU) No 528/2012
Self-reactive substances and mixtures	study scientifically not necessary	Expert statement: According to Section 2.8.4.2 in Annex I to CLP the classification procedures for self-reactive substances and mixtures need not be applied if there are no chemical groups present in the molecule associated with explosive or self-reactive properties. Examples of such groups are given in Tables A6.1 and A6.3 in Appendix 6 of the UN RTDG, Manual of Tests and Criteria (ST/SG/AC.10/11/Rev.7). As the biocidal product WESSOCLEAN GOLD LINE contains none of these chemical groups, self-reactive properties are not expected. (see below)			IUCLID
Pyrophoric liquids	study scientifically not necessary	Expert statement: As the biocidal product WESSOCLEAN GOLD LINE consists of more than 90 % of water and no component is known as pyrophoric, a classification as pyrophoric liquid is considered not necessary.			IUCLID

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Pyrophoric solids	study scientifically unjustified				Regulation (EU) No 528/2012
Self-heating substances and mixtures	study scientifically not necessary	Expert statement: According to the guidance on the application of the CLP criteria, 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 adsorbed on a large surface (e.g. on powder particles), a self-heating hazard should be considered. The biocidal product WESSOCLEAN GOLD LINE is a liquid with a water content >90 %. Adsorption on large surfaces like powder particles is not foreseen. (see below)			IUCLID
Substances and mixtures which in contact with water emit flammable gases	study scientifically not necessary	Expert statement: The biocidal product is an aqueous solution (> 90% water) and does not contain metals or metalloids. Testing is therefore not necessary.			IUCLID
Oxidising liquids	study scientifically not necessary	Expert statement: The biocidal product contains hydrogen peroxide as relevant possible oxidising compound. However, the concentration of hydrogen peroxide in the biocidal product is below the specific concentration limit of 8 %, therefore classification as oxidising liquid is not considered. (see below)			IUCLID
Oxidising solids	study scientifically unjustified				Regulation (EU) No 528/2012

<table>
<tr><th>Hazard class / characteristics</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Parameter</th><th>Results</th><th>Reference</th></tr>
<tr><td>Organic peroxides</td><td>study scientifically not necessary</td><td colspan="3">Expert statement:
Any organic peroxide shall be considered for classification in this class, unless it contains: a) not more than 1,0 % available oxygen from the organic peroxides when containing not more than 1,0 % hydrogen peroxide; or b) not more than 0,5 % available oxygen from the organic peroxides when containing more than 1,0 % but not more than 7,0 % hydrogen peroxide.
The biocidal product contains hydrogen peroxide in the range between 1 and 7 % as well as peracetic acid. However, a study does not need to be conducted because the available oxygen from the organic peroxide is less than 0.5% and a classification is not considered necessary. (see below)</td><td>IUCLID</td></tr>
<tr><td>Corrosive to metals</td><td>UN Test C.1 in Part III of the UN-MTC, 37.4 (2009)</td><td colspan="3"><table>
<tr><td>Test Item</td><td>Wessoclean Gold Line EU</td><td>Batch No. 040.918/WGL.EU /T1M</td></tr>
<tr><td>Type of material</td><td>Aluminium (7075)</td><td>Steel (S235JRG)</td></tr>
<tr><td>Exposure time (days)</td><td>28</td><td>28</td></tr>
<tr><td>Temperature during exposure (°C)</td><td>48 – 56</td><td>48 – 56</td></tr>
<tr><td>Mass loss of the most corroded sample (%)</td><td>90.2</td><td>100 (completely dissolved)</td></tr>
<tr><td colspan="3">The test is considered positive if for any specimen the mass loss on the metal specimen is more than 51.5 % after 28 days.</td></tr>
<tr><td>Test result</td><td>Positive</td><td>Positive</td></tr>
<tr><td>Classification</td><td>Corrosive</td><td>Corrosive</td></tr>
</table></td><td>[redacted], 2018</td></tr>
</table>

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Auto-ignition temperature (liquids and gases)	study scientifically not necessary	Expert statement: The auto-ignition temperatures of relevant components are: propan-2-ol = 399 °C; Ethanol = 365 °C; 5% peracetic acid solution = 435 °C. As the b. p. is an aqueous solution with > 90% water, the auto-ignition temperature of 365 °C can be regarded as worst case. (cf. see below)			IUCLID
Relative self-ignition temperature for solids	study scientifically unjustified				Regulation (EU) No 528/2012
Dust explosion hazard	study scientifically unjustified				Regulation (EU) No 528/2012

Explosives:

The biocidal product WESSOCLEAN GOLD LINE contains hydrogen peroxide and peracetic acid with contiguous oxygen atoms. The other components in the product are not associated with possible explosive properties. However, the concentrations of hydrogen peroxide and peracetic acid are comparably low in the biocidal product and the content of water is >90 %. According to the Assessment report on the active substance hydrogen peroxide, the explosive limit is ≥40 % (wt) as vapour and ≥86 % (wt) in aqueous liquid. It is further mentioned that explosive vapour phases can only be formed of aqueous hydrogen peroxide solutions with concentrations higher than 70 % (w/w) at temperatures above 110 °C.

According to the Assessment report on the active substance peracetic acid 5 % and 15 % equilibrium products ("PEROXYACETIC ACID 5 % and 15 %") are reported to be not explosive (no mechanical and thermal sensitivity). Pure or highly concentrated stabilized PAA may form explosive vapour/air mixtures above 40.5 °C. As the concentrations of the active substances hydrogen peroxide and peracetic acid in WESSOCLEAN GOLD LINE are far below the values mentioned in the Assessment reports and the content of water is >90 %, explosive properties of the biocidal product can be excluded and further testing is scientifically unjustified.

Flammable liquids:

The flash point of WESSOCLEAN GOLD LINE was determined to be 56 °C according to EU method A.9. According to the Guidance on the Application of the CLP Criteria this value is generally in the range for classification in category 3 for flammable liquids (Flash point ≥

23 °C and ≤ 60 °C). However, according to section 2.6.4.5 of the CLP regulation (REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures) liquids with a flash point of more than 35 °C need not be classified in Category 3 if negative results have been obtained in the sustained combustibility test L.2 (Part III, section 32 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria). This test is used to determine if a substance sustains combustion when heated under the test conditions and exposed to a flame.
According to section 32.2.5 of the UN Recommendation liquids are considered to be unable to sustain combustion if they are miscible solutions with a water content of more than 90 % by mass. As the biocidal product consists of more than 90 % of water, a classification as flammable liquid is not considered necessary.

Self-reactive substances and mixtures:
The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.
According to the Guidance of the application of the CLP criteria (version 5.0) substances or mixtures classified as self-reactive substances and mixtures can decompose strongly exothermically when 50 kg are exposed to temperatures of 75 °C or lower depending on the Self-Accelerating Decomposition Temperature (SADT) of the substance or mixture. Chemical groups indicating self-reactive properties are:
a. Aliphatic azo compounds (-C-N=N-C-)
b. Organic azides (-C-N_3)
c. Diazonium salts (-CN_2+Z^-)
d. N-nitroso compounds (-N-N=O)
e. Aromatic sulfohydrazides (-SO_2-NH-NH_2).
As the biocidal product WESSOCLEAN GOLD LINE contains none of these substances mentioned above, self-reactive properties are not expected and further studies are scientifically unjustified.
Chemical groups indicating self-reactive properties and explosive properties refer to organic materials (see titles of Table A6.1 and A6.3). However, hydrogen peroxide and sulphuric acid are inorganic materials.
Since no explosive properties are to be expected due to the very low PAA concentration and the biocidal product is not to be regarded as an organic peroxide and consequently it is also not self-reactive. This conclusion can be drawn as the classification of a self-reactive substance or mixture shall be performed in accordance with test series A to H as described in Part II of the UN Manual of Tests and Criteria. The same tests apply to organic peroxides. However, the test were waived based on the hydrogen peroxide content < 8 %.
Additionally, the biocidal product does not meet the criteria according to CLP Annex I 2.8.2.2, for which the classification procedure should apply: "Mixtures of oxidising substances, meeting the criteria for classification as oxidizing substances, which contain 5 % or more of combustible organic substances and which do not meet the criteria mentioned in (a), (c), (d) or (e) in 2.8.2.1, shall be subjected to the self-reactive substances classification procedure;"

The biocidal product does not meet the criteria for an oxidizing liquid (due to the content of 3.15 % Hydrogen peroxide) and does not contain 5 % or more of combustible organic substances.
Considering the classification criteria and the composition of the product, self-reactive properties can be excluded without requesting further information and test results."

Self-heating substances and mixtures:
According to the guidance on the application of the CLP criteria (Version 5.0), 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 adsorbed on a large surface (e.g. on powder particles), a self-heating hazard should be considered. The biocidal product WESSOCLEAN GOLD LINE is a liquid with a water content >90 %. Adsorption on large surfaces like powder particles is not foreseen. Therefore, a study on this endpoint is scientifically not necessary.

Oxidising liquids:
According to the Guidance on the Application of the CLP Criteria (Version 5.0, section 2.13) the classification procedure and criteria for oxidising substances or mixtures is not applicable for organic peroxides. Thus, hydrogen peroxide is considered as the only compound with possible oxidising properties. However, according to the assessment report on the active substance hydrogen peroxide specific concentration limits are available and classification is only necessary in concentrations >8 % (according to UN TDGR). As the concentration of hydrogen peroxide in the biocidal product WESSOCLEAN GOLD LINE is far below this specific concentration limit, classification of the biocidal product is not considered necessary.

Organic peroxides:
The study does not need to be conducted because the organic peroxide formulation substance contains not more than 0.5 % available oxygen from the organic peroxide when containing more than 1.0 % but not more than 7.0 % hydrogen peroxide.
According to REGULATION (EC) No 1272/2008, the available oxygen content (%) of an organic peroxide mixture is given by the formula: 16*(n*c/m) where n is the number of peroxygen groups per molecule of organic peroxide (1 for PAA in WESSOCLEAN GOLD LINE); c is the concentration (mass %) of organic peroxide (0.0302 % PAA in WESSOCLEAN GOLD LINE); m is the molecular mass of organic peroxide (76.05 g/mol for PAA). The concentration 0.03002 % is the upper limit of the nominal concentration and can be regarded as worst case. Based on this concentration the active oxygen content is 0.0064 %. As the upper limit of the hydrogen peroxide concentration is 2.975 % and the active oxygen content derived from PAA is far below 0.5 %, a study does not need to be conducted and classification is not necessary.

Auto-ignition temperature (liquids and gases):
A study addressing the auto ignition temperature for the biocidal product is not available. The auto-ignition of propan-2-ol is 399 °C. Ethanol has an auto-ignition temperature of 365 °C. According to the Assessment report the auto-ignition temperature of a 5 % peracetic

acid solution is 435 °C. As the biocidal product is an aqueous solution with > 90 % water, the auto-ignition temperature of 365 °C can be regarded as a worst case.

Conclusion on the physical hazards and respective characteristics of the product
The biocidal products WESSOCLEAN GOLD LINE and WESSOCLEAN GREEN LINE are considered as not explosive and they do not have pyrophoric, self-reactive or self-heating properties. The flash point is 56°C, but classification as flammable liquid category 3 is not considered necessary as the biocidal product consists of >90% of water and miscible solutions with water content of more than 90 % by mass are considered to be unable to sustain combustion. As the active substances hydrogen peroxide and peracetic acid are present in low concentrations a classification as oxidising liquid or as organic peroxide is not considered necessary. Based on the results of UN Test C.1 the product is classified as corrosive to metals, category 1; H290 May be corrosive to metals.

2.2.4 Methods for detection and identification

Table 7.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Peracetic acid Batch 100.417	two subsequent iodometric titrations	First determination of the total active oxygen equivalents. Secondly determination of hydrogen peroxide which was selectively removed by manganometric titration. Due to the alcohols present in the sample the equivalence point could not be assigned properly, therefore the result of this	Titration methods are direct methods. The consumed volume in titration is directly related to the amount of analyte in the test solution. A calibration where a technical signal is related to a concentration is not applicable for titration methods.	Hydrogen peroxide and peroxoacetic acid could not be spiked separately for recovery experiments N=6 on 2 different spiking levels (120% and 140%)	99.9-100.6	100.3	0.24	LOQ (PAA): 2.5 g/kg LOQ (H2O2): 3.4 g/kg (Source: Biocidal active substance:Document IIIA, Section A4.1/01 Annex Point IIA IV.4.1)	[redacted], 2017
Hydrogen peroxide Batch 100.417	two subsequent iodometric titrations								

		titration was not used. Instead of this, the remaining peroxoacetic acid was titrated with a second iodometric titration.	(Source: Biocidal active substance: Document IIIA, Section A4.1/01 Annex Point IIA IV.4.1)						

Information on the analytical method validation for the SoCs are given in the confidential annex.

Table 8.

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	no relevant residues expected	-	AR for PT 1-6, LoEP, chapter 2, 03/2015
Drinking water	peracetic acid	0.1 µg/L	minimal requirement of the Drinking Water Act
Surface water	peracetic acid	0.069 µg/L	$PNEC_{aquatic}$ based on NOEC *Danio rerio* (AF 10), AR for PT 1-6, chapter 2.2.2.2, 03/2015
Air	peracetic acid	0.5 mg/m³ (0.16 ppm)	AEC inhalation, AR for PT 1-6, LoEP, chapter 2, 03/2015
	hydrogen peroxide	1.25 mg/m³ (0.88 ppm)	AEC inhalation, AR for PT 1-6, LoEP, chapter 2, 03/2015
Animal and human body fluids and tissues	no relevant residues expected	-	not classified as T/T+ AR for PT 1-6, chapter 2.1.3., 03/2015
Food of plant origin	no relevant residues expected	-	AR for PT 1-6, LoEP, chapter 2, 03/2015
Food of animal origin	no relevant residues expected	-	AR for PT 1-6, LoEP, chapter 2, 03/2015

Table 9.

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R²)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Peracetic acid (PAA)	Determination as MTSO per LC-UV at 225 nm using Inertsil ODS-3 column	No interference	0.2 – 20 mg/L (MTSO) that means 0.1 – 10 mg/L PAA R² 1.0000	0.1 – 5 mg/L	-	105	2.4	reported LOQ: 0.02 mg/L	CAR, doc IIIA, 4.2 c (01), [redacted] (2006)

Table 10.

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R²)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Peracetic acid (PAA)	Determination as MTSOO per LC-UV at 224 nm using C18 column	No interference	NA	1.61 ppm / 4 2.99 ppm / 4 0.23 ppm / 4 0.23 ppm / 4 0.47 ppm / 4	-	95 96 97 94 95	2.6 1.6 5.3 5.1 1.1	0.23 ppm	CAR, doc IIIA, 4.2 b (01), [redacted] (2004)
Hydrogen peroxide	Determination as titanium peroxysulfate per absorption spectro-	No interference	NA	2.09 ppm / 4 3.75 ppm / 4 0.42 ppm / 4 0.32 ppm / 4 0.59 ppm / 4	-	93 95 87 93 92	4.2 8.0 9.0 7.2 3.5	0.32 ppm	CAR, doc IIIA, 4.2 b (01), [redacted] (2004)

	metry at 410 nm								

Table 11.

Analytical methods for animal and human body fluids (blood)									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R²)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Peracetic acid (PAA)	Determination as MTSO per LC-UV at 225 nm using Inertsil ODS-3 column	No interference	0.2 – 20 mg/L (MTSO) that means 0.1 – 10 mg/L PAA R² 1.0000	0.1 – 5 mg/L	-	105	2.4	reported LOQ: 0.02 mg/L	CAR, doc IIIA, 4.2 c (01), [redacted] (2006)

Table 12.

Data waiving was acceptable for the following information requirements	
Information requirement	1. Analytical methods for the SoC Ethanol and Propan-2-ol are given in the conf. Annex. For the analytical method for SOCs the applicant explained that the contents of the SoC sulfuric acid in the products are not expected to change during storage of the products. Therefore, an additional analytical method to quantify the content of sulphuric acid is scientifically not necessary. For the SoCs Ethanol and Propan-2-ol analytical methods are given in the conf. Annex. The one for hydrogen peroxide is stated in table 7. 2. 5.2.1. Soil 3. 5.2.2. Air: Analytical methods for determination of the a.s. peracetic acid and and the SoC hydrogen peroxide in air have already been provided in the CAR for peracetic acid. For the SoCs propan-2-ol and ethanol, no analytical method for determination in air has been provided by the applicant, but a reference to [redacted] (2012, published by the German MAK Commission for monitoring purposes at workplaces) was given. However, the quantitative exposure assessment has indicated air concentrations which are significantly below the respective German OELs. Consequently, the provision of analytical methods for determination of this compound in air was waived. 4. 5.3. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for

	the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant[8]
Justification	Analytical methods for monitoring purposes in soil and in/on food of plant and animal origin or feeding stuffs are not necessary since no relevant residues of peracetic acid are expected.

Conclusion on the methods for detection and identification of the product
The methods provided regarding the residues of peracetic acid (and hydrogen peroxide) in water, air and blood were acceptable even if the LOQ of the methods is not sufficiently low in comparison to the current lowest limits. In the respective AR for peracetic acid PT 1-6 the methods are accepted despite these deficiencies. The provided method regarding the residues of hydrogen peroxide (substance of concern) in air is accepted.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

In PT 3 the product is intended to be used for the disinfection of hatching eggs (porous surface) at different stages in the hatchery. This includes the disinfection in the sluice at 20 °C in chambers of approximately 50 m³ where the eggs are disinfected upon their arrival in the hatchery after a rough cleaning. Further disinfection can take place in e.g the hatcher (approx. 10 m³) where the eggs are incubated at 36 °C.
In PT 4 the product is intended for disinfection of non-porous surfaces of transport and storage equipment in the vegetable, fruit and plants packaging industry. Disinfection takes place at room temperature in small chambers in the range of 3 - 5 m³.
For all intended uses in PT 3 and PT 4 the product is applied by cold fogging.

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

The product is intended to have bactericidal, yeasticidal and fungicidal activity.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Application of the product leads to damage of cellular components that leads to irreversible inactivation of the target organisms.

[8] Not necessary if neither the active substance nor the material treated with it come into contact with food- producing animals, food of plant and animal origin or feeding stuffs

2.2.5.4 Mode of action, including time delay

As stated in the respective BPC opinion "[…] the primary mode of action of peracetic acid is oxidation. It denatures proteins, disrupts cell wall permeability, and oxidizes sulfhydr[y]l groups and sulfur bonds in proteins, enzymes, and other metabolites."

2.2.5.5 Efficacy data

The product is applied by cold fogging and was tested in a tiered approach with phase 2 step 1 tests (quantitative suspension tests) and standardized simulated use tests (fogging tests) as well as a field study that was performed in the sluice of a hatchery.
Additionally, standardized phase 2 step 2 surface tests (EN 13697, EN 14349, EN 16438) were submitted but were not taken into account and not listed in the table of key studies (table 13) as they are not relevant to prove efficacy for disinfection by fogging.
EN 13697 was passed with 100 % of the ready-to-use product at 20 °C under high soiling conditions of PT 4 in 30 min for bacteria, yeast and fungi. EN 14349 was passed for bacteria with 100 % of the ready-to-use product at 36 °C under high soiling conditions for PT 3 in 30 min. EN 16438 was passed for yeast with 100 % of the ready-to-use product at 36 °C under high soiling conditions for PT 3 in 30 min but is not valid for fungi due to invalid controls B and C for *Aspergillus brasiliensis*.

Use 1: Disinfection of hatching eggs in PT 3
To prove bactericidal, yeasticidal and fungicidal efficacy of the product for disinfection in the sluice at 20 °C in a volume of approximately 50 m³ phase 2, step 1 studies (EN 1656, EN 1657) at 20 °C were submitted as well as a fogging test according to an adapted protocol of EN 17272 at 20 °C. In addition a field study in the sluice of a hatchery was performed. The phase 2, step 1 studies were passed under high soiling conditions with 80 % of the product within 60 min at 20 °C and within 30 min at 36 °C for bacteria, yeast and fungi.
The adapted fogging test was performed at 20 °C in a volume of 75 m³ with a lower application rate (40 ml/m³) than intended (67 ml/m³) and a contact time of 60 min. The room size of 75 m³ was suitable to prove efficacy in the intended volume of approximately 50 m³ in accordance with EN 17272 as well as NF T72-281.
In the adapted fogging test Proteus vulgaris, which usually is one of the standard test bacteria for PT 3 applications, was replaced by Escherichia coli. This was deemed acceptable as in this case neither E. coli nor P. vulgaris are the limiting test organisms according to an expert statement by the test laboratory and the results of a phase 2 step 1 test.
As discussed at WG-EFF-II-2019 the fogging test was performed in presence of trolleys and hatching eggs according to the intended use. In total, 9600 unfertilized eggs (approx. 130 eggs/m³) were added that derived from production rejects. Therefore, the number of available eggs was limited and not further increased due to ethical reasons (avoidance of food waste). Therefore, although the number of eggs per m³ is lower than intended (approx. 1000 eggs/m³) it was accepted as representative number in the efficacy test. Additional carriers were placed between the eggs and the trolleys to prove that efficacy was also achieved in less accessible areas in accordance with the intended use. The test was passed for yeast and fungi under high soiling conditions on carriers in the standard position as well as on additional carriers between the eggs and trolleys. Likewise, the test was passed for *E. coli*, *P. aeruginosa* and *E. hirae* in both positions. However, during the main efficacy test with *S. aureus* a significant reduction was neither observed on standard carriers nor on additional carriers placed within the egg trolleys. For *S. aureus* the test

was repeated in an empty room. In the empty room a sufficient lg reduction was achieved for *S. aureus* at 20 °C in a volume of 75 m³ with a lower application rate (40 ml/m³) than intended (67 ml/m³) and a contact time of 60 min. As efficacy against *S. aureus* was only sufficiently demonstrated in the empty room but not in the loaded room bactericidal efficacy was not sufficiently demonstrated for the disinfection of hatching eggs by the simulated use test according to adapted EN 17272.
Taking into account that a lower application rate than intended was tested in the simulated use test a field study was performed to further substantiate bactericidal efficacy. The field study was performed with the intended application rate of 67 ml/m³ in a sluice of 60 m³ including 12 trolleys with trays containing 4800 hatching eggs per trolley leading to a total of 57.600 hatching eggs in the room. Twelve samples (each before and after disinfection) at varying positions within the disinfection chamber were collected from the egg surface by contact plates and analysed for aerobic microorganisms. For evaluation of the resulting cfu counts a two-step ranking system was used. First a ranking factor for the cfu count of each individual plate was assigned (from 0 => good quality / low microbial contamination (< 3 cfu) to 4 => poor quality / very high microbial contamination (> 90 cfu)). The ranking factors of all plates were then summed up and divided by the number of plates to determine the average quality / microbial contamination of the eggs (from average quality < 0.5 => very good quality / lowest microbial contamination to average quality > 2.5 => very poor quality / highest microbial contamination).
In the control samples before disinfection between 118 and > 380 colonies were detected per plate ranking in the category of highest microbial contamination / very poor egg quality. After disinfection ten out of twelve samples showed no growth of colonies on the plates and for two samples 2 cfu/plate were observed which corresponds to an average reduction of 2.9 lg and ranking in the category of lowest microbial contamination / very good egg quality. Together with the bactericidal phase 2 step 1 test and the adapted EN 17272 at a lower application rate the results of the field study are deemed sufficient to prove bactericidal efficacy.

For disinfection at 36 °C in chambers of approximately 10 m³ phase 2, step 1 studies (EN 1656, EN 1657) at 36 °C were provided that were passed under high soiling conditions with 80 % of the product within 30 min at 36 °C for bacteria, yeast and fungi. Justifications for read-across to the adapted fogging test at 20 °C in 75 m³ were provided with regard to room size and temperature.
Regarding the room size it was justified that according to EN 17272 a study in a volume of 30 – 150 m³ is suitable to prove efficacy for large enclosures > 4 m³ which also includes the intended chambers with 10 m³. Moreover, the applicant referred to the fogging test provided for the use in PT 4 that was performed at the same application rate in a smaller room (4 m³). However, the fogging tests for PT 3 and PT 4 were not directly comparable, e.g. with regard to soiling and loading of eggs. Nonetheless the transferability of the test results in 75 m³ to the smaller chamber with 10 m³ was accepted in accordance with EN 17272.
With respect to the test temperature it was justified that the requested test laboratories did not have the technical possibilities to control the temperature of the test room. In addition it was argued that the fogging study at 20 °C represents the worst case mainly based on the results of the phase 2 step 1 tests at 20 °C and 36 °C. Therefore, read-across to the fogging test at 20 °C in a room with 75 m³ was accepted for the use at 36 °C in 10 m³ e.g. in the hatcher.

Taken together bactericidal yeasticidal and fungicidal efficacy have been demonstrated for the product when applied with 67 ml/m³ at 20 °C and 36 °C for enclosures of 4 m³ to 150 m³ under PT3 high soiling conditions with 60 min contact time.

Use 2: Disinfection of surfaces in the vegetable/fruit/plants packaging industry

To prove bactericidal, yeasticidal and fungicidal efficacy of the product for disinfection of non-porous transport and storage equipment in small enclosures (3 – 5 m³) at 20 °C phase 2 step 1 tests (EN 1276, EN 1650) and a fogging test according to an adapted protocol of EN 17272 were provided. The phase 2, step 1 studies were passed under high soiling conditions with 80 % of the product within 30 min at 20 °C for bacteria, yeast and fungi.

The adapted fogging study was performed at 20 °C in a volume of 4 m³ with the intended application rate (40 ml/m³) and was passed by all tested organisms. Therefore bactericidal, yeasticidal and fungicidal efficacy has been sufficiently demonstrated for the product when applied with 40 ml/m³ at 20 °C for enclosures 3 - 5 m³ under PT 4 high soiling conditions with 30 min contact time.

Key studies are listed in the table below.

Table 13.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
bactericidal	PT3 Use 1 - Disinfection of hatching eggs	Wessoclean Gold Line	*P. aeruginosa* *S. aureus* *E. hirae* *P. vulgaris*	DIN EN 1656:2009 + correction 2010	Product concentration: 50 %, 80 %; additionally 10 % for *P. aeruginosa* and *P. vulgaris* Contact time: 45 min, 60 min Soiling: dirty; 10,0 g/l BSA and 10 g/l yeast extract Temperature: 20 °C	Results show a > 5 lg reduction for bacteria under dirty conditions at 80 % at 20 °C within 60 min.	[redacted] 2019-a Report 19-01154-1
yeasticidal, fungicidal	PT3 Use 1 - Disinfection of hatching eggs	Wessoclean Gold Line	*C. albicans* *A. brasiliensis*	DIN EN 1657:2016	Product concentration: 10 %, 50 %, 80 % 	Results show a > 4 lg reduction for yeast and fungi under dirty conditions at 80 % at 20 °C within 45 min.	[redacted]2019-b Report 19-01154-2

					dirty; 10,0 g/l BSA and 10 g/l yeast extract Temperature: 20 °C		
bactericidal	PT3 Use 1 - Disinfection of hatching eggs	Wessoclean Gold Line	*P. aeruginosa* *S. aureus* *E. hirae* *P. vulgaris*	DIN EN 1656:2009 + correction 2010	Product concentration: 80 %; additionally 10 % and 50 % for *E. hirae* Contact time: 30 min; additionally 45 min and 60 min for *E. hirae* Soiling: dirty; 10,0 g/l BSA and 10 g/l yeast extract Temperature: 36 °C	Results show a > 5 lg reduction for bacteria under dirty conditions at 80 % at 36 °C within 30 min.	[redacted] 2017-c Report 17-01086-3
yeasticidal, fungicidal	PT3 Use 1 - Disinfection of hatching eggs	Wessoclean Gold Line	*C. albicans* *A. brasiliensis*	DIN EN 1657:2016	Product concentration: 80 % Contact time: 30 min, 45 min, 60 min	Results show a > 4 lg reduction for yeast and fungi under dirty conditions at 80 % at 36 °C within 30 min.	[redacted] 2017-d Report 17-01086-4

					Soiling: dirty; 10,0 g/l BSA and 10 g/l yeast extract Temperature: 36 °C		
bactericidal, yeasticidal, fungicidal	PT3 Use 1 - Disinfection of hatching eggs	Wessoclean Gold Line	*S. aureus* *E. hirae* *P. aeruginosa* *E. coli* *C. albicans* *A. brasiliensis*	Adapted EN 17272:2020	<u>Product concentration:</u> 100 % <u>Device:</u> air pressure fogging device connected to five nozzles in the room Median droplet size ≤ 8 µm <u>Application rate:</u> 40 ml/m³ <u>Contact time:</u> 60 min <u>Soiling:</u> Dirty 10 g/l BSA and 10 g/l yeast extract <u>Temperature:</u> 20 °C	Adaptations in the protocol were accepted in this specific case. a) Loaded room (trolleys and eggs) with standard and additional carrier positions: Results show a > 4 lg reduction for yeast and fungi under dirty conditions when applied with 40 ml/m³ at 20 °C in a volume of 75 m³. Results show a > 5 lg reduction for *E. hirae*, *P. aeruginosa* and *E. coli* under dirty conditions when applied with 40 ml/m³ at 20 °C in a volume of 75 m³. The distribution test with *S. aureus* demonstrated sufficient lg reduction at standard carrier positions (> 5 lg) but not at the additional carrier position (0.89 lg). In the main efficacy test no sufficient lg reduction was demonstrated for S. aureus at standard and additional carrier positions (< 2.19 lg). b) Empty Room: Combined distribution and main test for S. aureus	[redacted] 2021a PB2020-2990_PB2020-2991

					<u>Room Size:</u> 75 m³ <u>Test setup</u>: Test was performed in a room loaded with trolleys and eggs (see adaptations below) for all target organisms with carriers at standard positions as well as additional positions according to the use. Distribution test: 1 additional carrier between the trolleys. Main test: 3 additional carriers between the trolleys / between the eggs.	Results show a > 5 lg reduction for S. aureus under dirty conditions when applied with 40 ml/m³ at 20 °C in an empty room of 75 m³.	

					For *S. aureus* the test was repeated in an empty room with carriers for the distribution and the main test (combined in one test run). <u>Humidity:</u> <u>Loaded room:</u> Distribution test: 51.9 % Main test: 53.4 % <u>Empty room:</u> 45.0 % Main adaptations: - loading with trolleys and 9,600 eggs - additional carriers between the eggs / the trolleys - elution volume for carriers reduced to 10 ml for better resolution		

					- qualitative assessment of residual organisms in surplus elution medium including carriers (e.g. no quantitative n'2) - test of inhibitory activity (n1) only for *S.aureus* - n1 was not repeated for the additional test with S. aureus in an empty room		
bactericidal	PT3 Use 1 - Disinfection of hatching eggs	Wesso Gold-Line	Total aerobic microorganisms	Field study in the sluice of a hatchery (performed in the course of mandatory hygiene monitoring)	<u>Product concentration:</u> 100 % <u>Device:</u> 2 sprayers in the sluice (BTS Resonator atomiser from Besteman	In the control samples before disinfection between 118 up to > 380 colonies were detected per plate ranked as "very poor" [10] with regard to bacterial contamination. After disinfection 10 of 12 samples showed no growth of colonies on the plates, on two plates 2 cfu/plate were observed which leads to a ranking of "very good" [10] with regard to bacterial	[redacted] 2021 bioclean-2021-03

[10] "very poor" refers to the egg quality and thus represents the category of highest microbial contamination in the study; „very good" refers to the egg quality and thus represents the category of lowest microbial contamination in the study.

					Techno Support) Median droplet size ≤ 8 µm <u>Application rate</u>: 67 ml/m³ <u>Contact time (=duration of nebulization)</u> [9]<u>:</u>: 60 min <u>Ventilation time:</u> 10 min <u>Soiling:</u> naturally occurring Temperature: not specified <u>Room Size:</u> 60 m³ including 12 trolleys with trays containing 4800 hatching eggs per trolley (in total 57.600	contamination. This corresponds to an average reduction of at least 2.9 lg.	

[9] As the product was continually diffused for 60 min, the contact time and the diffusion time are indistinguishable.

					hatching eggs in the room) <u>Samples:</u> 12 samples before and 12 samples after disinfection. Each sample consisted of a contact plate (PCA with neutraliser) for surface sampling directly from the egg shell. Sampling after disinfection was performed on an egg adjacent to the egg tested before disinfection at each of the 12 tested positions. <u>Sampling positions:</u> Each sample was taken from the middle position of the respective tray		

					in the following trolleys: 3 samples from the middle trolley (lower, middle, upper tray); 4 samples from the trolleys at the corners (middle tray); 4 samples from trolleys at the edges close to the wall (middle tray); 1 random position <u>Humidity:</u> not specified <u>Readout:</u> cfu per plate; quality ranking from very poor to very good based on the number of cfu/plate and the number of plates		

bactericidal	PT4 Use 2 - Disinfection of surfaces in the vegetable / fruit / plants packaging industry	Wessoclean Gold Line	*P. aeruginosa* *S. aureus* *E. hirae* *E. coli*	DIN EN 1276:2009 + correction 2010	Product concentration: 80 %, additionally 10 % and 50 % for *E. hirae* Contact time: 30 min; additionally 45 min and 60 min for *E. hirae* Soiling: dirty; 3 g/l BSA Temperature: 20 °C	Results show a > 5 lg reduction for bacteria under dirty conditions at 80 % at 20 °C within 30 min.	[redacted] 2017-a Report 17-01086-1
yeasticidal, fungicidal	PT4 Use 2 - Disinfection of surfaces in the vegetable / fruit / plants packaging industry	Wessoclean Gold Line	*C. albicans* *A. brasiliensis*	DIN EN 1650:2008+A1 2013	Product concentration: 80 % Contact time: 30 min, 45 min, 60 min Soiling: dirty; 3 g/l BSA Temperature: 20 °C	Results show a > 4 lg reduction for yeast and fungi under dirty conditions at 80 % at 20 °C within 30 min.	[redacted] 2017-b Report 17-01086-2

bactericidal, yeasticidal, fungicidal	PT4 Use 2 - Disinfection of surfaces in the vegetable / fruit / plants packaging industry	Wessoclean Green Line	*S. aureus* *E. hirae* *P. aeruginosa* *E. coli* *C. albicans* *A. brasiliensis*	Adapted EN 17272:2020	Product concentration: 100 % Device: ultrasonic precision nebulizer raX Median droplet size ≤ 8 µm Application rate: 40 ml/m³ Contact time: 30 min Soiling: Dirty 3 g/l BSA Temperature: 20 °C Room Size: 4 m³ Humidity: 33 % Main adaptations: - all test organisms,	Drying controls of *S. aureus* and *P. aeruginosa* were slightly too low, but lg reduction could still be demonstrated. Adaptations in the protocol were accepted in this specific case. Results show a >5 lg reduction for bacteria and a > 4 lg reduction for yeast and fungi under dirty conditions when applied with 40 ml/m³ at 20 °C in a volume of 4 m³.	[redacted]2021b PB2021-0332

					distribution test and efficacy test performed in one test run - elution volume for carriers reduced to 10 ml for better resolution - qualitative assessment of residual organisms in surplus elution medium including carriers (e.g. no quantitative n'2) - test of inhibitory activity (n1) only for *S.aureus*		

Conclusion on the efficacy of the product
All efficacy tests were performed with the intended product which was either named Wessoclean Gold Line or Wessoclean Green Line. The product demonstrated bactericidal, yeasticidal and fungicidal efficacy according to EN 1276, EN 1650, EN 1656, EN 1657, adapted EN 17272 and a field study in a hatchery when applied by cold fogging for the following uses in PT 3 and PT 4 under the following conditions: PT 3: Disinfection of hatching eggs Bactericidal, yeasticidal and fungicidal efficacy under high soiling conditions at 20 °C (sluice) and 36 °C (e.g. hatcher) with an application rate of 0,067 l/m³ for a contact time of 60 min. Contact time starts after the application rate has been achieved. Only for use in dry enclosures between 4 – 150 m³. Biological validation shall be performed by the user of the biocidal products for each room setup (including e.g. hatching eggs, equipment) to be disinfected by fogging (or in a suitable "standard" room in a facility, if applicable) with the devices to be used, after which a protocol for disinfection processes in these rooms can be made and used thereafter. PT 4: Disinfection of surfaces in the vegetable / fruit / plants packaging industry Bactericidal, yeasticidal and fungicidal efficacy under high soiling conditions at room temperature with an application rate of 0.04 l/m³ for a contact time of 30 min. Contact time starts after the application rate has been achieved. Only for use in dry enclosures between 3 – 5 m³ in size. Only for disinfection of non-porous surfaces. Biological validation shall be performed by the user of the biocidal products for each installation to be used for disinfection by fogging (or in a suitable "standard" installation in a facility, if applicable) with the devices to be used, after which a protocol for disinfection in these installations can be made and used thereafter.

2.2.5.6 Occurrence of resistance and resistance management

According to the assessment report of the active substance peracetic acid the development of resistance is not likely due to the unspecific mode of action.

2.2.5.7 Known limitations

No limitations are known.

2.2.5.8 Evaluation of the label claims

The label claims have to reflect the use conditions as specified in the SPC.

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

The product is not intended to be authorized for use in combination with other biocidal products.

2.2.5.10 Data waiving and conclusion

Table 14.

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.
Justification	No justifications necessary.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects of the active substance on human health

Table 15.

Peracetic acid	Value	Study	Safety factor
AEL long-term	n.a.; PAA does not cause systemic effects[1]	-	-
AEL medium-term	n.a.; PAA does not cause systemic effects[1]	-	-
AEL acute	n.a.; PAA does not cause systemic effects[1]	-	-
NOAEC dermal medium/short-term	0.2 %	Human Volunteer Study	Assessment-Report (RMS Finland (2015)
NOAEC dermal long-term	0.1 %	Rabbit one year study	Assessment-Report (RMS Finland (2015)
AEC inhalation	0.5 mg/m^3	Human data (NOAEC 0.5 ppm)	Assessment-Report (RMS Finland (2015)
ARfD	n.a.; PAA does not cause systemic effects[1]		

[1] Assessment-Report (RMS Finland (2015)

Table 16.

Peracetic acid	Value	Reference
Oral absorption	Not determined, 100% as a default	Assessment-Report (RMS Finland (2015)
Dermal absorption	100 %	Assessment-Report (RMS Finland (2015)

2.2.6.2 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to the skin
Justification for the value/conclusion	Based on the additivity approach the biocidal product does not need to be classified for skin irritation/corrosion. The content of components classified for skin irritation and corrosion is below the concentration relevant for classification. For some co-formulants specific concentration limits are assigned. Therefore, the additivity approach is performed according to the Guidance on the Application of the CLP Criteria (Version 5.0 – July 2017) section Guidance on the Application of the CLP Criteria

	Version 5.0 – July 2017 section 3.2.3.2.3.2. "Application of SCLs when applying the additivity approach".
Classification of the product according to CLP	Not classified for skin corrosion/irritation.

Data waiving	
Information requirement	8.1. Skin corrosion or skin irritation
Justification	Studies on potential skin corrosive or skin irritating properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.1 "Skin irritation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Data on the intrinsic properties are available through safety data sheets and other information for every single component in the product are provided. There is no information on synergistic effects between any of the components (e.g. surfactants). Consequently, classification of the mixture was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Irritating to the eyes
Justification for the value/conclusion	The following components contribute to the classification of the biocidal products with Eye Irrit. 2: Hydrogen peroxide (3.143 %): Skin Corr. 1A [1)]; SCL for Eye Irrit. 2: 5 % [1)] Propan-2-ol (min. 2.36 %): Eye Irrit. 2, H319 [1)]; GCL for Eye Irrit. 2: 10 % [2)] Ethanol (1.61 %): Eye Irrit. 2, H319 [3)]; GCL for Eye Irrit. 2: 10 % [2)] Application of the additivity approach according to Guidance on the Application of the CLP Criteria (2017) section 3.2.3.2.3.2. C hydrogen peroxide/SCL + C propan-2-ol/GCL + C ethanol/GCL ≥ 1 Eye Irrit. 2: 3.143 %/5 % + 2.36 %/10 % + 1.61 %/10 % = 1.03 ≥ 1
Classification of the product according to CLP	Eye Irrit. 2, H319

[1)] acc. to Annex VI of Regulation (EC) No 1272/2008

[2)] acc. to Regulation (EC) No 1272/2008
[3)] acc. to SDS submitted by the applicant

Data waiving	
Information requirement	8.2. Eye irritation
Justification	Studies on potential eye damaging or eye irritating properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.2 "Eye irritation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected." The compositions of the biocidal product is known. Data on the intrinsic properties are available through safety data sheets and other information for every single component in the product are provided. There is no information on synergistic effects between any of the components. Consequently, classification of the mixture was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	The biocidal product is considered as non-irritating to the respiratory tract. It does not contain components classified for respiratory irritation in relevant concentration.
Classification of the product according to CLP	Not classified for respiratory irritation.

Data waiving	
Information requirement	Annex III of BPR, point 8.7.1, "other endpoints"
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the biocidal product has to be made according to the rules of the Regulation (EC) No 1272/2008. The biocidal product does not contain components classified for respiratory irritation in relevant concentrations.

Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin-sensitising
Justification for the value/conclusion	The biocidal product does not contain any components, which are known to have sensitising properties. Hence classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Not classified for skin sensitisation.

Data waiving	
Information requirement	8.3. Skin sensitisation
Justification	Studies on potential skin-sensitising properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.3 Skin sensitisation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected." The compositions of the biocidal product is known. Data on the intrinsic properties are available through safety data sheets and other information for every single component in the product are provided. There is no information on synergistic effects between any of the components. Consequently, classification of the mixture was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Respiratory sensitisation (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to the respiratory tract
Justification for the value/conclusion	The biocidal product does not contain any components, which are known to have sensitising properties. Hence classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Not classified for respiratory sensitisation.

Data waiving	
Information requirement	8.4. Respiratory sensitisation
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. Data on respiratory sensitisation for the biocidal product or its components are not available.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50} (oral): > 2000 mg/kg bw
Justification for the selected value	Peracetic acid (0.0302 %), LD_{50} (oral): 85 mg/kg bw (Assessment report) Hydrogen peroxide (3.143 %), LD_{50} (oral): 563.5 mg/kg bw All other components are not classified for acute oral toxicity. LD_{50} (oral) is estimated according to the equation given in Regulation (EC) No 1272/2008: 16855 mg/kg bw
Classification of the product according to CLP	Not classified for acute oral toxicity

Data waiving	
Information requirement	8.5.1. By oral route
Justification	According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected." The compositions of the biocidal product is known. Data on the intrinsic properties are available through safety data sheets and other information for every single component in the product is provided. There is no information on synergistic effects between any of the components (e.g. surfactants). Consequently, classification of the product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	LC_{50} (inhalation): > 20 mg/L
Justification for the selected value	Peracetic acid (0.0302 %), LC_{50} (inhal.): 0.204 mg/L (dust/mist; Assessment report, 2015) Hydrogen peroxide (3.143 %), LC50 (inhal.): 11 mg/L (vapour, converted acute toxicity point estimate according to Regulation (EC) No 1272/2008) The equation as provided in the Guidance on the Application of the CLP Criteria (2017) on page 269 for application of the additivity method for mixtures with ingredient substances in different physical forms is applied:(limit / ATE) * concentration / 100)mist + (limit / ATE) x concentration / 100)vapour Limit: the upper border of ATE value for the relevant hazard category Category 4: (5 / 0.204 * 0.0302 / 100) + (20 / 11 * 3.143 / 100) = 0.065 < 1 As the value is below 1, classification for acute inhalation toxicity is not required. All other components are not classified for acute inhalation toxicity.
Classification of the product according to CLP	Not classified for acute inhalation toxicity

Data waiving	
Information requirement	8.5.2. By inhalation
Justification	According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Data on the intrinsic properties are available through safety data sheets and other information for every single component in the product are provided. There is no information on synergistic effects between any of the components (e.g. surfactants). Consequently, classification of the mixture was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD_{50} (dermal): > 2000 mg/kg bw
Justification for the selected value	Peracetic acid (0.0302 %), LD_{50} (dermal): 56.1mg/kg bw (Assessment report) All other components are not classified for acute dermal toxicity or not relevant due to their low concentration. LD_{50} (dermal) is estimated according to the equation given in Regulation (EC) No 1272/2008: 186000 mg/kg bw.
Classification of the product according to CLP	Not classified for acute dermal toxicity.

Data waiving	
Information requirement	8.5.3. By dermal route
Justification	According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Data on the intrinsic properties are available through safety data sheets and other information for every single component in the product are provided. There is no information on synergistic effects between any of the components. Consequently, classification of the mixture was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	Peracetic acid	Hydrogen peroxide
Value(s)	100 %	100 %
Justification for the selected value(s)	Default according to the CAR for PT 1 to 6 (2015) and for PT 11 and 12 (2016)	Default according to the CAR for PT 1 to 6 (2015) and for PT 11 and 12 (2016)

Data waiving	
Information requirement	8.6 Dermal absorption
Justification	Dermal absorption studies with the biocidal product is not required. The following justification for dermal penetration is extracted from the CAR Doc. IIB (2016) for PT 11 and 12: ***Peracetic acid*** *No standard dermal penetration studies with equilibrium peracetic acid have been successfully conducted. Basically it is acceptable to use default values instead of a test result to describe dermal penetration for the purpose of risk characterisation. Other available studies do provide the overall information that dermally applied peracetic acid penetrates the skin. It was also demonstrated with human skin (penetration of tritiated water through human skin in vitro) that concentrations of up to 1 % peracetic acid did not to impair the skin barrier function (refer to Doc. IIIB, 6.04/01).* *Based on the physico-chemical properties (molecular weight not >500 and logPow not <-1 or >3) of PAA, 100 % dermal penetration should be used in the absence of more accurate information. However, in this particular case, in the absence of clear systemic effects, no dermal penetration parameter is needed in order to conclude on human health risks from the presented uses of peracetic acid.*

	Peracetic acid is believed not to penetrate skin and dermal absorption is therefore considered to be not relevant at non-irritant/non-corrosive concentrations, i.e. when the integrity of the skin is kept intact. During mixing/loading operations and during application, no damage to the skin is anticipated as well since appropriate protective equipment such as gloves and coverall are considered to be used consistently during these procedures especially when handling the concentrated products. In addition, in-use concentrations during application processes are below the irritation threshold of about 0.2 % peracetic acid (for details please refer to Document IIA and IIC). ***Hydrogen peroxide*** *The limitation of dermal exposure is triggered by the hydrogen peroxide concentration, since hydrogen peroxide is recognized as skin irritant and therefore skin contact should be avoided. Hydrogen peroxide has been shown not to exert systemic effects in repeated dose toxicity studies and for this reason, a dermal penetration of hydrogen peroxide after dermal exposure is not considered to be relevant in the exposure and risk assessment.* Summarised it can be concluded for both substances that in the absence of systemic effects and corresponding reference values dermal penetration data are not necessary. If required a default of 100 % can be used.

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

For the toxicology of the substances of concern hydrogen peroxide, propan-2-ol and ethanol following data are available.

Hydrogen peroxide (CAS.-No.: 7722-84-1)

Threshold Limits and other Values for Human Health Risk Assessment

Summary		
	Value	Source
AEC inhalation long-term	1.25 mg/m^3	Assessment-Report (RMS FI (2015))
AEC inhalation medium-term	1.25 mg/m^3	Assessment-Report (RMS FI (2015))
AEC inhalation acute	1.25 mg/m^3	Assessment-Report (RMS FI (2015))
ADI	Not established, substance systemically not available	Assessment-Report (RMS FI (2015))
ARfD	Not established	Assessment-Report (RMS FI (2015))
Inhalative absorption	100 %	Default value
Oral absorption	No significant absorption, local effects	Assessment-Report (RMS FI (2015))

Summary		
	Value	Source
Dermal absorption	100 %	Default value

Classification	
Current, according to Annex VI of Reg. 1272/2008	Acute Tox. 4, H302 Acute Tox. 4, H332 (STOT SE 3; H335; C ≥ 35 %) Skin Corr. 1A, H314 (Skin Corr. 1A; H314: C ≥ 70 %, Skin Corr. 1B; H314: 50 % ≤ C < 70 %, Skin Irrit. 2; H315: 35 % ≤ C < 50 %, Eye Dam. 1; H318: 8 % ≤ C < 50 %, Eye Irrit. 2; H319: 5 % ≤ C < 8 %)

Propan-2-ol (CAS.-No.: 67-63-0)

Threshold Limits and other Values for Human Health Risk Assessment

Summary		
	Value	Source
AEL acute/medium/long-term General population	10.7 mg/kg bw/d (31.25 ppm for 8 hours/d)	Assessment-Report (RMS DE (2014))
AEL acute/medium/long-term Professional workers	17.9 mg/kg bw/d (52.6 ppm for 8 hours/d)	Assessment-Report (RMS DE (2014))
Inhalative absorption	100 %	Assessment-Report (RMS DE (2014))
Oral absorption	Nearly complete following oral, inhalation and intravenous exposure	Assessment-Report (RMS DE (2014))
Dermal absorption	75 % / 25 %	Default value, value depends on concentration of the a.s. in the products (EFSA Journal 2012;10(4):2665)

Classification	
Current, according to Annex VI of Reg. 1272/2008	Eye Irrit. 2, H319, STOT SE 3, H336

Ethanol (CAS.-No.: 64-17-5)

Classification	
Current, as listed in Safety data sheet according to Annex VI Table 3.1 of Reg. 1272/2008	Not available
Proposed (notified from manufacturers), with regard to toxicological data according to the criteria in Reg. 1272/2008 based on Assessment-Report	Eye Irrit. 2, H319 (3534/9615; notifiers / total number of notifiers)

Available toxicological data relating to a mixture

Not relevant

Other

Not available

Endocrine disrupting properties

According to the assessment report (FI, 2015), the active substance peracetic acid is not considered to have endocrine disrupting properties. There are no data indicating that any of the co-formulants may have endocrine disrupting properties regarding human health, based on the existing knowledge and the available scientific information. Therefore, the biocidal product is not considered to have endocrine disrupting properties.
For further details, please refer to chapter 3.7 in the Confid. Annex and chapter 3.9 of the MS Only Confid. Annex.

2.2.6.3 Exposure assessment

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	yes	No	yes	yes	No	No
Dermal	yes	yes	No	yes	yes	No	No
Oral	n.a.	n.a.	No	n.a.	n.a.	No	Yes

[Please indicate the main paths of human exposure by stating "yes","no" or "n.a." (not applicable) for each cell.]

List of scenarios

Table 17.

Summary table: scenarios				
Scenario number	**Scenario** (e.g. mixing/ loading)	**applied use no.**	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
FB4-1	Automated loading	1, 2	Primary exposure, Automated loading Exposure of workers during connecting/disconnecting the b.p. containers and during transfer („pumping") of the b.p. is expected	Industrial, professional
FB4-2	Re-entry after process operation	1a, 1b	Primary exposure, PT3,_Re-entry after process operation (disinfection of hatching eggs and related equipment (hard surfaces) Exposure of workers during this process is not expected, as the disinfection chamber is not opened before appropriate ventilation time, after which the product is completely evaporated and removed from the chamber.	Industrial, professional
FB4-3	Re-entry after process operation	2	Primary exposure, PT4,_Re-entry after process operation (disinfection of surfaces in the vegetable/fruit/plants packaging industry) Exposure of workers during this process is not expected, as the airtight fogging enclosure is not opened before appropriate ventilation time, after which the disinfected equipment has completely dried and the product is removed from the enclosure.	Industrial, professional
FB4-4	Maintenance/repair of dosing pumps	1, 2	Secondary exposure, Maintenance/repair of dosing pumps Exposure of workers occurring during maintenance or repair of dosing pumps and transfer pipes.	Industrial, professional

Industrial exposure

Please refer to the chapter on professional exposure below.

Professional exposure

- **General considerations**

The biocidal product WESSOCLEAN GOLD LINE is formulated as a ready to use (RTU) solution containing the a.s.

- peracetic acid 0.03% (w/w)

In addition, the following substances of concern (SoC) have been identified:

- hydrogen peroxide up to 3.15% (w/w)
- propan-2-ol up to 2.52% (w/w)
- ethanol up to 1.61% (w/w)

The product is used in PT3 in closed systems for disinfection of hatching eggs and related equipment.
In PT4 the product is used in closed systems for disinfection of hard, non-porous surfaces of transport and storage equipment for potatoes, fruits, vegetables and plants.
In contact with organic material, the components peracetic acid and hydrogen peroxide rapidly degrade. However, as there are no data about the amount of degradation during application available, degradation is not considered as a worst case assumption.
The product is pumped into the sealed disinfection chamber by an automated dosing system. Application is started from outside. No worker is present in the disinfection chamber during application.

The biocidal product is usually delivered in 220 L drums (HDPE) or 1000 L IBCs. For testing purposes, the product is available in 1 L bottles (PE) and 20 L cans (HDPE).
Manual loading of the product is not foreseen.

- **Scenario FB4-1: Primary exposure, Automated loading**

Table 18.

Description of Scenario FB4-1: Primary exposure, Automated loading		
This scenario applies to all uses of this biocidal product, constituting the major path of primary worker exposure. The b.p. is delivered in 220 L drums (HDPE) or 1000 L IBC containers. Smaller containers (1 L bottle (PE), 20 L can (HDPE)) are traded for test purposes. For disinfection, the product is automatically pumped and misted into a separate disinfection enclosure. Due to the high level of automation, exposure of workers is expected during connecting and disconnecting of storage tanks to the pumping system, only. Inhalation exposure to aerosols and vapour: In accordance with the CAR for hydrogen peroxide PT01 - PT06 (2015), inhalation exposure was quantitatively calculated with the Advanced REACH Tool (ART) version 1.5 using the parameters shown below. Activity coefficients of the a.s. peracetic acid and the SoCs hydrogen peroxide and propan-2-ol were calculated using AIOMFAC (http://www.aiomfac.caltech.edu/). To do so, all major compounds were considered. Parameters used for quantitative risk assessment of inhalation exposure are provided below. The results are summarised in Table "Summary of exposure assessment". Details on the risk assessment can be found in section 0 of this PAR. For details on the calculations of the activity coefficients and the ART calculations, see documents attached to the annex (section 3.4) of this PAR. Dermal exposure Dermal exposure for the a.s. peracetic acid and the SoC hydrogen peroxide is not assessed quantitatively but rather semi-quantitative and qualitative. For the SoC propan-2-ol dermal exposure is assessed using Human Exposure Export Group (HEEG) opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale, 2008. Exposure of the eyes Accidental exposure of the eyes may occur in rare cases due to splashes occurring during handling of the lines used to attach the product container. *Summary of exposure assessment* No unacceptable risks were identified in the quantitative Tier 1 assessment of inhalation exposure. However, local risk assessment has indicated a potential risk for the eyes, thus eye protection is recommended.		
PT3 and PT4: Primary exposure, Automated loading		
	Parameters*	**Value**

Tier 1	<u>peracetic acid</u> concentration molar fraction activity coefficient vapour pressure	 0.03% 0.0000743 1.914 1410 Pa
	<u>hydrogen peroxide</u> concentration molar fraction activity coefficient vapour pressure	 3.15% 0.01744 1.172 214 Pa
	<u>propan-2-ol</u> concentration weight fraction activity coefficient (calculated for meta SPC 1) vapour pressure	 2.52% 0.0079 7.213 4260 Pa
	<u>ART scenario parameters</u> Emissions sources Duration Process temperature	 near field 15 min (time for automated mixing and loading taken from the CAR PAA) 293 K
	Activity class	Falling liquids
	Situation	Transfer of liquid product with flow of 100 - 1000 l/minute
	Containment level	Open process
	Loading type	Submerged loading, where the liquid dispenser remains below the fluid level reducing the amount of aerosol formation
	Process fully enclosed?	No
	Effective housekeeping practices in place?	Yes
	Work area	Indoors
	Room size	Any size workroom
	Localised controls: Primary	Medium level containment (99% reduction)
	Localised controls: Secondary	No localized controls (0% reduction)

	Ventilation rate	Only good natural ventilation

*for further details and parameters refer to Annex (Section 3.4)

- **Scenario FB4-2: Primary exposure, PT3, Re-entry after process operation (disinfection of hatching eggs and related equipment (hard surfaces))**

Table 19.

Description of Scenario FB4-2: PT3, Re-entry after process operation (disinfection of hatching eggs and related equipment (hard surfaces))
The product is a ready to use disinfectant solution and is used for disinfection of hatching eggs and related equipment (hard surfaces), without exception in closed disinfection chambers. The applicant has applied for authorisation of two sub-uses which basically differ in the application temperature and the drying time. This scenario covers both sub-uses within Use 1. The fogging is started from outside the disinfection chamber. During disinfection, the room is sealed and re-entry prevented. According to the applicant, after the surface disinfection has been performed, ventilation in the disinfection chamber is turned on (from the outside). Re-entry may only be permitted when the air concentrations of the a.s. peracetic acid and the SoC hydrogen peroxide have dropped below the respective reference values. Thus, unacceptable exposure when entering the room after the disinfection process is prevented. Sufficient ventilation durations can be secured by two means: 1) A disinfection system with sensors indicating when the relevant concentrations have dropped below the reference values can be used. 2) The required duration of the technical ventilation is established by measurement with suitable measurement equipment for the individual technical installation. This must be done for each technical installation and after any change in relevant boundary conditions. <u>Inhalation exposure</u> The ventilation period is highly dependent on external parameters as for example size of the disinfection chamber, temperature, size of the treated surface, air change rates and humidity of the air supply. However, examples have been calculated in order to demonstrate that re-entry is possible after sufficient ventilation, within a reasonable time and without PPE. The ventilation period was calculated with ConsExpoWeb as a Tier 1 estimation. A more realistic ventilation time was calculated as a Tier 2 estimate with a 2-compound model (please see HEAdhoc Recommendation 16 for details). The "drying periods" have not been taken into account, as there is currently no possibility to model a delayed ventilation period in ConsExpoWeb, i.e. the ventilation is always on or off in the ConsExpoWeb simulation. Thus, the scenario was modelled assuming an almost instantaneous application of a liquid layer on the surfaces, immediately followed by the ventilation period. The resulting duration therefore refers to the sole ventilation duration, excluding the drying periods. The parameters used for the exemplary calculations are shown below. They are chosen to represent Use 1a, which is considered to be the worst-case within this Use, due to the lower temperature, and thus to cover both sub uses. <u>Exposure of the eyes</u>

Exposure of the eyes is not expected when the technical measures outlined in this PAR are obeyed.

Post-application:
All material has to be fully dry before leaving the disinfection chamber. By this, any exposure to the b.p while handling the disinfected eggs or equipment is prevented.

Summary of exposure assessment

During the disinfection process, professionals are not exposed to the biocidal product, as the process takes place in a tightly sealed room, which is not allowed to be entered. To ensure this, the technical equipment described above is defined as necessary RMM in the SPC.

PT3: Disinfection of hatching eggs and related equipment (hard surfaces)		
Parameters*	**Value**	**Unit**
concentration a.s. no. 1: peracetic acid	0.030	% (w/w)
concentration SoC no. 1: hydrogen peroxide	3.150	% (w/w)
concentration SoC no. 2: propan-2-ol	2.520	% (w/w)
vapour pressure a.s. no. 1: peracetic acid	1410	Pa
vapour pressure SoC no. 1: hydrogen peroxide	214	Pa
vapour pressure SoC no. 2: propan-2-ol	4260	Pa
Molecular weight a.s. no. 1: peracetic acid	76.05	g/mol
Molecular weight SoC no. 1: hydrogen peroxide	34.01	g/mol
Molecular weight SoC no. 2: propan-2-ol	60.1	g/mol

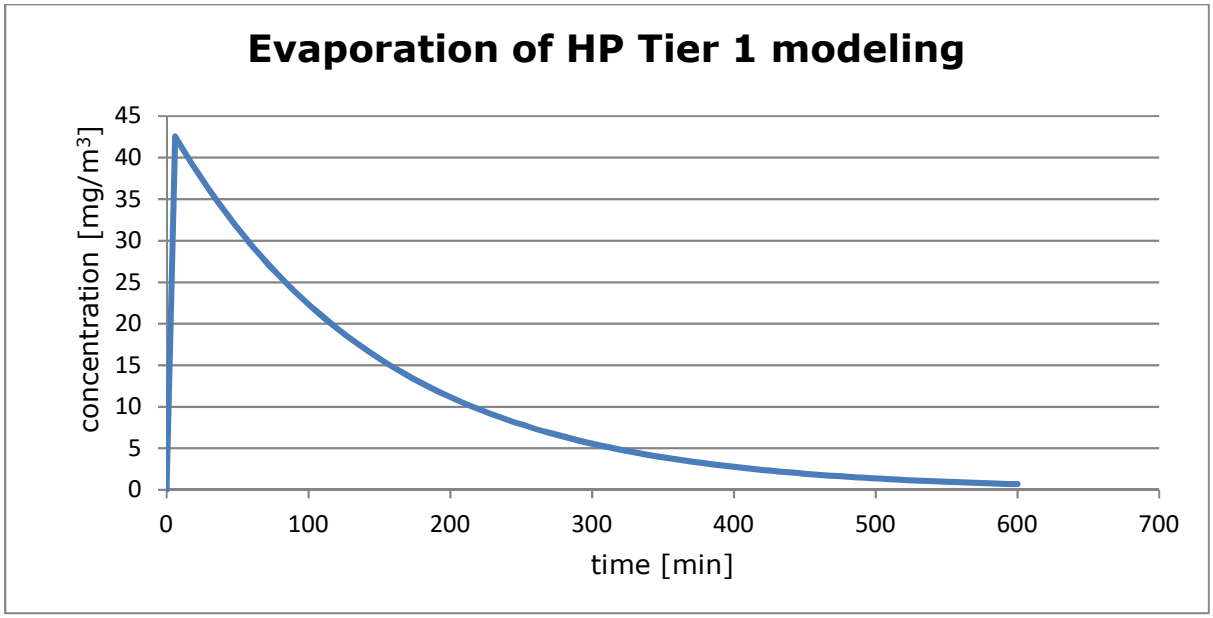
Parameters*	**Value**	**Unit**	**Reference**
density of product	1.0046	g/cm³	
concentration b.p. in application solution	100	% (w/w)	Ready to use product
application rate	0.067	l/m³	Information provided by applicant
application temperature	20	°C	The application temperatures are found to be 18-37 °C for different applications. The applicant provided 20 °C for disinfection of heatching eggs in sluice (use 1a)
Molecular weight matrix	18	g/mol	Approximately as water is main component
Product amount	3.28	kg	Application rate 0.067 l/m³ x density 1.0046 g/l x chamber volume 49 m³
Room Volume	49	m³	ESD PT3; chapter 2.5 Disinfection of eggs
Ventilation rate	20	/h	Expert judgement
Application temperature	20	°C	The application temperarues are found to be 18-37 °C for different applications. The applicant provided 20°C

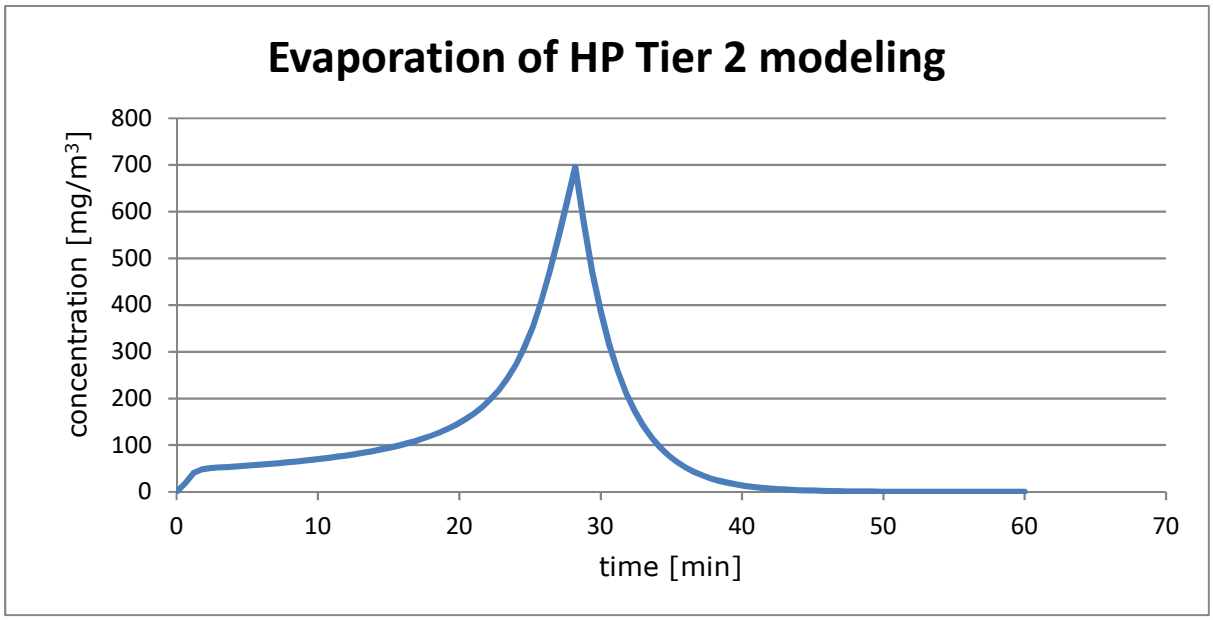
Release Area	720	m²	Expert judgement: on average a sluice is expected to have a capacity of 1490 eggs per m^3. The estimated evaporation area was calculated for a 49 m^3 sluice. It results from the surfaces of the sluice ((2 · 3 m · 6 m) + (2 · 2.7 m · 6 m) + (2 · 2.7 m · 3 m) = 85 m^2) plus the surface of the treated eggs (49 m^3 · 1490 · 87 cm^2 / 10000 = 635 m^2), in total 720 m^2.
Mass Transfer Coefficient	10	m/h	Default value in ConsExpoWeb
Application Duration	1	min	If a non-increasing surface area is selected in ConsExpo, the model assumes that the source is eliminated after the application time. In order to simulate evaporation of the applied liquid layer, it was here assumed that the layer is applied almost instantaneously, i.e., within 1 min, with increasing area.
Does area increase?	YES		

*for further details and parameters refer to the Annex (Section 3.4)

Calculations for Scenario FB4-2

The exemplified calculations are shown in detail in the annex (section 3.4). These calculations demonstrate that regarding the ventilation durations, the SoC hydrogen peroxide is more critical than the a.s. peracetic acid, i.e. longer ventilation is required until air concentrations of hydrogen peroxide are below the AEC than it takes for peracetic acid. Thus, the necessary ventilation time is determined by the rate of removal of hydrogen peroxide from the air.
The following figures show the time dependence of hydrogen peroxide (HP) air concentrations resulting from the exemplified calculations performed for Tier 1 and Tier 2.





- **<u>Scenario FB4-3: Primary exposure, PT4, Re-entry after process operation (disinfection of surfaces in the vegetable/fruit/plants packaging industry)</u>**

Table 20.

Description of Scenario FB4-3: PT4, Re-entry after process operation (disinfection of surfaces in the vegetable/fruit/plants packaging industry)

This scenario applies to Use 2. The product is a ready to use disinfectant solution and is used for disinfection of surfaces by vaporisation in food vegetable/fruit/plants packaging, without exception in closed disinfection chambers.

The applicant has described a system consisting of one or more disinfection chambers and a drying room. The material to be disinfected, e.g. storage boxes, is transported into the disinfection chamber and automatically transferred into the drying room. The disinfection is started from outside the chamber. During disinfection, the disinfection chamber and the attached drying room are sealed and re-entry is prevented. The drying room is mechanically ventilated until the disinfected equipment has dried and the air concentrations of the a.s. peracetic acid and the SoC hydrogen peroxide have dropped below the respective reference values. Thus, unacceptable exposure when entering the room after the disinfection process is prevented. Sufficient ventilation durations can be secured by two means:

1) A disinfection system with sensors indicating when the relevant concentrations have dropped below the reference values can be used.
2) The required duration of the technical ventilation is established by measurement with suitable measurement equipment for the individual technical installation. This must be done for each technical installation and after any change in relevant boundary conditions.

Inhalation exposure

The ventilation period is highly dependent on external parameters as for example size of the disinfection chamber, temperature, size of the treated surface, air change rates and humidity of the air supply. However, examples have been calculated in order to demonstrate that re-entry is possible after sufficient ventilation, within a reasonable time and without PPE. The ventilation period was calculated with ConsExpoWeb as a Tier 1 estimation. A more realistic ventilation time was calculated as a Tier 2 estimate with a 2-compound model (please see HEAdhoc Recommendation 16 for details). As for Scenario FB4-2, it was not possible to simulate the drying period due to limitations in ConsExpoWeb, so the resulting durations refer to the ventilation period only.
The parameters used for the exemplary calculations are shown in the table below. They were chosen to represent the scenario as described by the applicant.

Exposure of the eyes

Exposure of the eyes is not expected when the technical measures outlined in this PAR are obeyed.

Post-application:

All material has to be fully dry before leaving the disinfection chamber. By this, any exposure to the b.p while handling the disinfected equipment is prevented.

Summary of exposure assessment

During the disinfection process, professionals are not exposed to the biocidal product, as the process takes place in a tightly sealed room, which is not allowed to be entered. To ensure this, the technical equipment described above is defined as necessary RMM in the SPC.

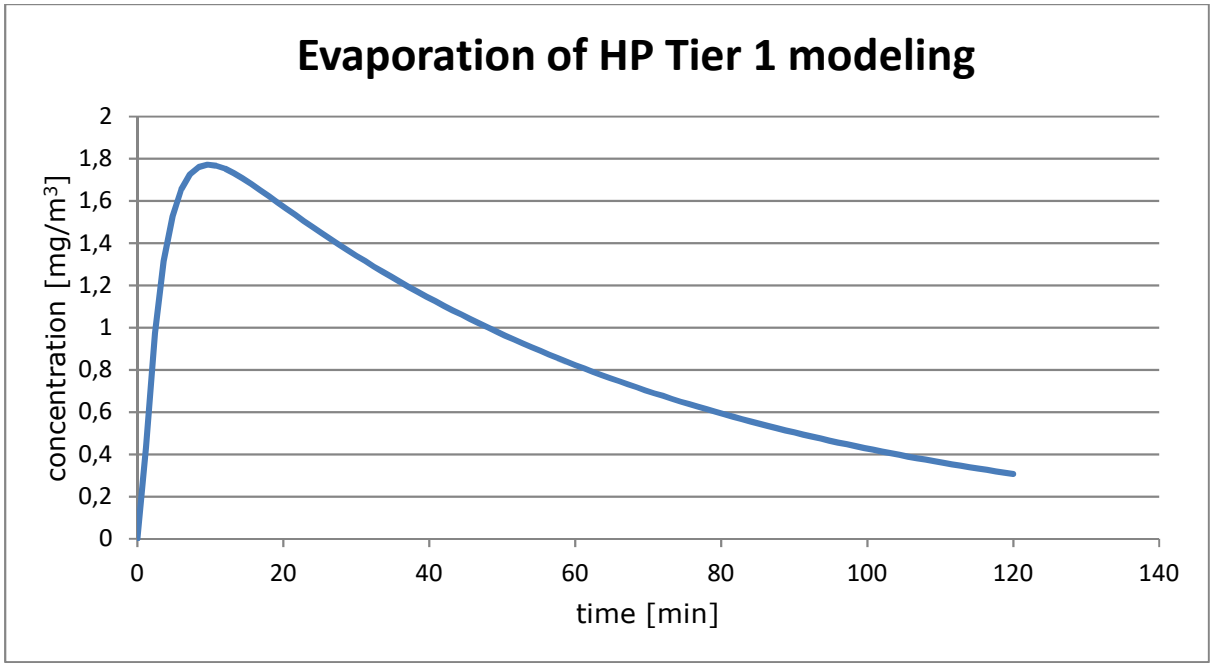
FB4-3: PT4, Re-entry after process operation (disinfection of surfaces in the vegetable/fruit/plants packaging industry)		
Parameters*	**Value**	**Unit**
concentration a.s. no. 1: peracetic acid	0.030	% (w/w)
concentration SoC no. 1: hydrogen peroxide	3.150	% (w/w)
concentration SoC no. 2: propan-2-ol	2.520	% (w/w)
vapour pressure a.s. no. 1: peracetic acid	1410	Pa
vapour pressure SoC no. 1: hydrogen peroxide	214	Pa
vapour pressure SoC no. 2: propan-2-ol	4260	Pa
Molecular weight a.s. no. 1: peracetic acid	76.05	g/mol
Molecular weight SoC no. 1: hydrogen peroxide	34.01	g/mol
Molecular weight SoC no. 2: propan-2-ol	60.1	g/mol

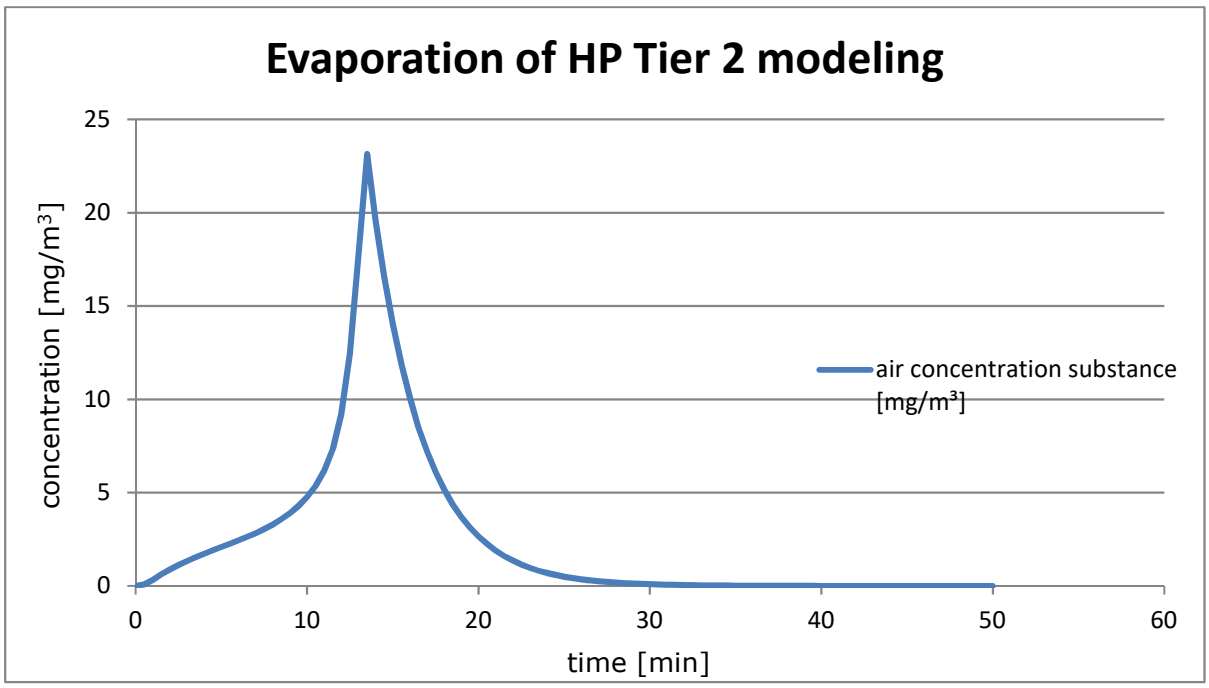
Parameters*	**Value**	**Unit**	**Reference**
density of product	1.0046	g/cm³	
concentration b.p. in application solution	100	% (w/w)	Ready to use product
application rate	0.04	l/m³	Information provided by applicant
application temperature	20	°C	The application temperatures are found to be 18-37 °C for different applications. The applicant provided 20 °C for disinfection of heatching eggs in sluice (use 1a)
Molecular weight matrix	18	g/mol	Approximately as water is main component
Product amount	0.402	kg	Application rate 0.04 l/m³ · density 1.0046 g/l · chamber volume 49 m³
Room Volume	300	m³	Applicants information regarding the dryin room
Ventilation rate	20	/h	Applicant’s information.
Application temperature	20	°C	Applicant’s information.
Release Area	25.56	m²	Applicants information: surface of two storage boxes
Mass Transfer Coefficient	10	m/h	Default value in ConsExpoWeb
Application Duration	1	min	If a non-increasing surface area is selected in ConsExpo, the model assumes that the source is eliminated after the application time. In order to simulate evaporation of the applied liquid layer, it was here assumed that the layer is applied almost instantaneously, i.e., within 1 min, assuming an increasing area.
Does area increase?	YES		

*for further details and parameters refer to Annex (Section 3.4)

Calculations for Scenario FB4-3

The exemplified calculations are shown in detail in the annex (section 3.4). These calculations demonstrate that regarding the ventilation durations, the SoC hydrogen peroxide is more critical than the a.s. peracetic acid, i.e. longer ventilation is required until air concentrations of hydrogen peroxide are below the AEC than it takes for peracetic acid. Thus, the necessary ventilation time is determined by the rate of removal of hydrogen peroxide from the air.
The following figures show the time dependence of hydrogen peroxide (HP) air concentrations resulting from the exemplified calculations performed for Tier 1 and Tier 2.





- **Scenario FB4-4: Secondary exposure, Maintenance/repair of dosing pumps**

Table 21.

Description of Scenario FB4-4: Secondary exposure, Maintenance/repair of dosing pumps
This scenario applies to all applied uses of this biocidal product. All uses applied for employ dosing pumps which automatically pump the b.p. into the respective fogging systems. While no direct exposure of workers is expected to occur from this automated pumping process during regular operation, exposure may occur when work at these pumps and pipes is required, i.e. maintenance or repair of the dosing pumps. The pump may contain the b.p, however, according to the pattern of use for PT 12 described in the biocides human health exposure methodology (BHHEM) document, version 1, p. 65, "*maintenance and repair of dosing pumps require decontamination before handling as protective equipment is not practicable for this task"*. While the requirements regarding risk mitigation measures are subject to the risk assessment, this note underlines that decontamination of the pumps and the pipes is common practice. For refinement of the exposure estimation in Tier 2 it is therefore assumed that the pumps are flushed with water prior to maintenance/repair. After decontamination, some diluted product may be left in the pumps and/or pipes. As a worst case, a dilution factor of 100 is assumed, which might represent a rather conservative figure if thorough decontamination and/or flushing of the system is expected. Inhalation exposure The inhalation exposure of workers resulting from this task was assessed using the ART model. The chosen activity class (handling of contaminated objects) and the situation (activities with treated/contaminated objects (surface 1-3 m²) are representative for "maintenance of fuel pumps" in ART. In order to have a conservative approach, a contamination of 10-90% of the surface was chosen. Activity coefficients of the a.s. peracetic acid and the SoCs hydrogen peroxide and propan-2-ol were calculated using AIOMFAC (http://www.aiomfac.caltech.edu/). For calculation of the activity coefficients for the b.p and the diluted b.p., the major compounds were considered. For details on the calculations of the activity coefficients and the ART calculations, see documents attached to the annex (section 3.4) of this PAR. Dermal exposure Dermal exposure for the a.s. peracetic acid and the SoC hydrogen peroxide is not assessed quantitatively but rather semi-quantitative and qualitative. For the SoC propan-2-ol dermal exposure is assessed using Human Exposure Export Group (HEEG) opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale, 2008. Exposure of the eyes Accidental exposure of the eyes may occur in rare cases due to splashes occurring during handling of the pumps and lines.

Summary of exposure assessment For Tier 1, the quantitative risk assessment has indicated risks resulting from inhalation exposure. As an organisational measure, flushing of the pumps prior to maintenance and/or repair is therefore required, which is assessed in Tier 2. For Tier 2, the quantitative risk assessment indicated no risk resulting from inhalation exposure.		
	Parameters*	**Value**
Tier 1	peracetic acid concentration molar fraction activity coefficient vapour pressure	 0.03% 0.0000743 1.914 1410 Pa
	hydrogen peroxide concentration molar fraction activity coefficient vapour pressure	 3.15% 0.01744 1.172 214 Pa
	propan-2-ol concentration weight fraction activity coefficient vapour pressure	 2.52% 0.0079 7.213 4260 Pa
	ART scenario parameters Emissions sources Duration Process temperature	 near field 120 min 293 K
	Activity class	Handling of contaminated objects
	Situation	Activities with treated/contaminated objects (surface 1-3 m²)
	Contamination level	Contamination 10-90 % of surface
	Process fully enclosed?	No
	Effective housekeeping practices in place?	Yes
	Work area	Indoors
	Room size	Any size workroom
	Localised controls: Primary	No localized controls (0.00 % reduction)

	Localised controls: Secondary	No localized controls (0.00 % reduction)
	Ventilation rate	Only good natural ventilation
Tier 2	<u>peracetic acid</u> concentration molar fraction activity coefficient vapour pressure	 0.0003% 0.00000071 2.47 1410 Pa
	<u>hydrogen peroxide</u> concentration molar fraction activity coefficient vapour pressure	 0.0315% 0.0001669 1.2 214 Pa
	<u>propan-2-ol</u> concentration weight fraction activity coefficient vapour pressure	 0.0252% 0.0000756 8.5 4260 Pa

*for further details and parameters refer to Annex (Section 3.4)

Calculations for Scenario [FB4-1, FB4-2, FB4-3 and FB4-4]

Table 22.

Scenario no.	**Scenario name**	**use no**	**Tier/PPE**	**Ventilation time**	**Inhalation exposure**			**Dermal exposure**
					a.s.: peracetic acid [mg/m³]	**SoC.: hydrogen peroxide [mg/m³]**	**SoC.: propan-2-ol [mg/m³]**	**SoC.: propan-2-ol [mg/day]**
					Considering the duration of a single task		**Considering entire work shift**	
FB4-1	Automated M&L	1, 2	Tier 1	n.a.	$1.30 \cdot 10^{-3}$	$3.00 \cdot 10^{-2}$	$5.00 \cdot 10^{-2}$	0.349
FB4-2	Disinfection of hatching eggs and related equipment (hard surfaces)	1a, 1b	TIER 1/ ConsExpo	516	$1.98 \cdot 10^{-9}$	1.23	$2.40 \cdot 10^{-21}$	not expected
			TIER 2/ 2-compound recom 16	48	$6.39 \cdot 10^{-4}$	0.96	$2.24 \cdot 10^{-3}$	not expected
FB4-3	Disinfection of surfaces in the vegetable/	2	TIER 1/ ConsExpo	36	$4.47 \cdot 10^{-3}$	1.23	$2.71 \cdot 10^{-3}$	not expected
			TIER 2/ 2-	23	$2.04 \cdot 10^{-3}$	0.975	$4.00 \cdot 10^{-2}$	not expected

	fruit/plants packaging industry		compound recom 16					
FB4-4	Maintenance/repair of dosing pumps	1, 2	Tier 1	n.a.	0.130	2.90	40	2.795
			TIER 2 no PPE, RMM: flushing pumps and pipes	n.a.	$1.60 \cdot 10^{-3}$	$2.90 \cdot 10^{-2}$	0.45	$2.78 \cdot 10^{-2}$

Combined scenarios

An assessment of exposure resulting from combined scenarios is only required for the SoC propan-2-ol. It is expected that mixing and loading (Scenario FB4-1) together with process operation (either Scenario FB4-2 or FB4-3) could be done by the same person. Maintenance and repair of dosing pumps, in contrast, is expected to be done by another professional.

Table 23.

Scenarios combined	**Estimated inhalation exposure 8h TWA [mg/m³]**	**Estimated dermal exposure 8h TWA [mg/d]**
Scenarios [FB4-1+ FB4-2]	$5.22 \cdot 10^{-2}$	$3.49 \cdot 10^{-1}$
Scenarios [FB4-1+ FB4-3]	$9.00 \cdot 10^{-2}$	$3.49 \cdot 10^{-1}$

Non-professional exposure

The biocidal product is not intended for non-professional use. An exposure assessment is not required.

Exposure of the general public

The biocidal product is applied as disinfectant in egg hatcheries (PT 3) and the surface disinfection of transport and storage boxes for potatoes, fruits, vegetables and plants (PT4). Both applications take place indoors in an industrial context in closed rooms and chambers. The general public has normally no access to such facilities. Also outside in the surrounding of these facilities relevant exposure is not expected since the rooms are closed and the active substance is very unstable.

Dietary exposure

List of scenarios

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use[1]**	**Description of scenario**	**Subject of exposure[2]**
1.	animal husbandry	**PT3: Use 1** disinfection of hatching eggs and related equipment with hard surfaces	eggs, chicken
2.	food industry	**PT4: Use 2** surface disinfection of transport and storage equipment for potatoes, fruits, vegetables and plants	food of plant origin

[1] e.g. animal husbandry, food industry, professional use, residential use.
[2] e.g. chicken, milk, beer

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	veterinary use	uterus disinfectant and control of foot-rot in ruminants	no MRL required[a]
2.	plant protection products	not approved as active substance, however national authorisations apply in individual MS[c] - disinfection of glasshouses, warehouses, agricultural equipment/tools and irrigation pipes (FR, PL, UK) - treatment of flower bulbs (NL, UK)	default MRL of 0.01 mg/kg[b]
	food contact materials	(1) slimicide in food packaging paper and board, and cooking papers (2) preservative for artificial sausage casings	(1) max 0.1 % based on dry fibers[d] (2) 0.5 % aqueous solution (no preserving effect on foodstuff)[e]

[a] CVMP summary report EMEA/MRL/060/96-FINAL, February 1996, https://www.ema.europa.eu/documents/mrl-report/peracetic-acid-summary-report-committee-veterinary-medicinal-products_en.pdf
[b] according to Art 18 (1) (b) Regulation (EC) No. 396/2005
[c] Commission Decision 2007/442/EC
[d] Database BfR Recommendations on Food Contact Materials: No. XXXVI. Paper and Board for Food Contact and XXXVI/1. Cooking Papers, Hot Filter Papers and Filter Layers
[e] Database BfR Recommendations on Food Contact Materials: XLIV. Artificial Sausage Casings

Conclusion on dietary exposure to active substance

The biocidal product "Wessoclean Gold Line" is intended to be used for surface disinfection in food industry (transport and storage of food of plant origin) (PT4) as well as for disinfection of hatching eggs and related equipment (PT3). While no direct treatment of food, feed and livestock animals with peracetic acid is intended, food and feed items and livestock animals may get in contact with disinfected surfaces. Therefore the possibility of residues being transferred from treated surfaces onto food items and livestock animals should be addressed in dietary exposure assessment.

At active substance approval is was noticed that equilibrium peracetic acid, as used in disinfectants, is composed of acetic acid, peracetic acid, hydrogen peroxide and water. Moreover after application of equilibrium peracetic acid the relevant substances, which have to be considered in human health exposure assessment, are peracetic acid and hydrogen peroxide. Both are highly reactive and degrade rapidly at the site of first contact with organic material. Therefore the application of disinfectant solutions containing peracetic acid and hydrogen peroxide (e.g. on surfaces, equipment, pipes, installations) in veterinary hygiene (PT3) and food and feed areas (PT4) is not expected to lead to the formation of residues in food items (AR section 2.2.1.4, Peracetic acid, PT 1-6, eCA: FI, 2015).

Consequently for the intended uses of "Wessoclean Gold Line" no relevant residues of peracetic acid and hydrogen peroxide residues in food are anticipated.

In conclusion human dietary exposure to peracetic acid and hydrogen peroxide from the intended uses is not considered to be relevant.

Conclusion on dietary exposure to substances of concern

Three substances of concern have been identified for "Wessoclean Gold Line": (1) **hydrogen peroxide**, (2) **propan-2-ol** and (3) **ethanol** (see section 2.1.2.5). For an overview and a qualitative residue evaluation for these substances please see the table below.

For hydrogen peroxide, propan-2-ol, and ethanol human exposure via food and feed is considered not to be relevant for the intended uses in egg hatching operations (PT3) and surface disinfection in food industry (PT4).

Summary table on dietary risk assessment of substances of concern (SoC)			
SoC Name (CAS-No.)	**Classification of BP due to classified SoC**	**Band (acc. to Guidance on BPR[a])**	**Evaluation of SoC**
Hydrogen peroxide (7722-84-1)	all meta-SPCs Eye Irrit 2	A	Hydrogen peroxide is evaluated above together with the active substance peracetic acid.
propan-2-ol (67-63-0)	all meta-SPCs Eye Irrit 2	A	Due to its high vapour pressure (5780 Pa, 25°C)[b], propan-2-ol will evaporate completely before food, feed or livestock animal will get into contact with disinfected surfaces, so that no transfer from treated surfaces to food should occur. In the unlikely event

			that residue transfer does occur, the active substance will evaporate from the food before it is eaten.
Ethanol (64-17-5)	all meta-SPCs Eye Irrit 2	A	Due to its high vapour pressure (5903 Pa, 25°C)[c], ethanol will evaporate completely before food, feed or livestock animal will get into contact with disinfected surfaces, so that no transfer from treated surfaces to food should occur. In the unlikely event that residue transfer does occur, the active substance will evaporate from the food before it is eaten.

[a] Guidance on the BPR: Vol. III Parts B+C, Version 4.0, December 2017, Annex A: Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products
[b] AR Propan-2-ol (2015, eCA: DE)
[c] First draft CAR Ethanol (2013, eCA: EL)

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

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

Summary of exposure assessment

Table 24:

Scenarios and values to be used in risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated inhalation exposure a.s. peracetic acid [mg/m³]**	**Estimated inhalation exposure SoC hydrogen peroxide [mg/m³]**
FB4-1	Professional, industrial	Tier 1: no PPE	1.30×10^{-3}	3.00×10^{-2}
FB4-2	Professional, industrial	Tier 1: no PPE	1.98×10^{-9}	1.23
FB4-3	Professional, industrial	Tier 1: no PPE	4.47×10^{-3}	1.23
FB4-4	Professional, industrial	Tier 1: no PPE Tier 2: no PPE, RMM: flushing of the pumps prior to maintenance and/or repair	0.13 1.6×10^{-3}	2.90 2.9×10^{-2}

Table 25:

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake SoC propan-2-ol [mg/kg bw/d]**
FB4-1	Professional, industrial	Tier 1: No PPE	0.01
FB4-2	Professional, industrial	Tier 1: No PPE	4.01×10^{-22}
FB4-3	Professional, industrial	Tier 1: No PPE	4.51×10^{-4}
FB4-4	Professional, industrial	Tier 1: No PPE	6.70

2.2.6.4 Risk characterisation for human health

Maximum residue limits or equivalent

Residue definitions

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRLs	CVMP summary report EMEA/MRL/060/96-FINAL, February 1996, https://www.ema.europa.eu/documents/mrl-report/peracetic-acid-summary-report-committee-veterinary-medicinal-products_en.pdf	food of animal origin (all food producing species)	no MRL required
MRLs	Regulation (EC) No. 396/2005	all food commodities	default MRL of 0.01 mg/kg

Specific reference value for groundwater

No specific reference values for groundwater were derived.

Risk for industrial users

The risk characterisation for industrial users is described in chapter 'Risk for professional users'.

Risk for professional users

The occupational risk assessment for the biocidal product (BP) WESSOCLEAN GOLD LINE takes into account local effects of the active substance (a.s.) peracetic acid as well as systemic and local effects of the substances of concern (SoC) propan-2-ol and hydrogen peroxide. The SoC ethanol is not assessed due to the fact that an Acceptable exposure level (AEL) is currently not available (still under review within BPR). Also, for ethanol there is no EU Occupational exposure level currently available.

Local effects - quantitative

The local toxicity profiles of the a.s. peracetic acid as well as the SoC hydrogen peroxide are considered. For both substances there is an AEC available so that a quantitative risk characterisation for professional users is carried out regarding the inhalation route.

Active substance peracetic acid

Details of risk characterisation
Reference values
The local reference value AEC 0.5 mg/m^3 of peracetic acid derived for respiratory tract irritation is used as external inhalation reference value and directly compared with airborne concentrations of peracetic acid.

Calculation of AEC exhaustion (%)
The exposure-to-AEC ratio (%) referring to the a.s. peracetic acid resulting from use of the biocidal product WESSOCLEAN GOLD LINE is determined according to the equation:

Exposure-to-AEC ratio (%) = inhalation exposure to peracetic acid (in mg/m^3) / AEC of peracetic acid (in mg/m3) x 100 %.

A risk for professional users referring to the a.s. peracetic acid resulting from the use of the biocidal product WESSOCLEAN GOLD LINE or resulting from the secondary exposure is unlikely if the AEC exhaustion (%) is below the value of 100 %.

Results
Table 26 gives a detailed overview of the risk characterisation results referring to the a.s. peracetic acid in the biocidal product WESSOCLEAN GOLD LINE. As the primary health effects associated with exposure to peracetic acid are local effects, assessment of combined scenarios is considered not relevant.

As shown in Table 26, for the scenario ‚Mixing and loading' and the secondary exposure ‚Maintenance/repair of dosing pumps' a risk for the professional user is unlikely already in Tier 1.

Also, as demonstrated in Table 26 for the exemplary calculations of re-entry after egg fogging in a disinfection chamber (‚PT3, disinfection of hatching eggs and related equipment (hard surfaces)') and re-entry after equipment fogging in a disinfection chamber (‚PT4, disinfection of surfaces in the vegetable/fruit/plants packaging industry') a risk for the professional user is unlikely for each calculation model used („Tier 1/ConsExpo", „Tier 2/2-compound recom 16") provided the required ventilation time is observed (for details see chapter Professional exposure).

Table 26: Overview of detailed local risk assessment results for inhalation route referring to the active substance peracetic acid in the biocidal product WESSOCLEAN GOLD LINE

Scenario		**Reference value inhalative $AEC_{long-term}$** mg/m³	**Estimated inhalation exposure** mg/m³	**Estimated inhalation exposure / AEC** AEC exhaustion %	**Acceptable** (yes/no)
Mixing and loading (15 min)	Tier 1	0.5	$1.30x10^{-3}$	0.26	yes
Re-entry after process operation: PT3, (disinfection of hatching eggs and related equipment (hard surfaces)(15 min))	Tier 1/ConsExpo	0.5	$1.98x10^{-9}$	$3.95x10^{-7}$	yes
	Tier 2/2-compound recom 16	0.5	$6.39x10^{-4}$	0.13	yes
Re-entry after process operation: PT4, (disinfection of surfaces in the vegetable/fruit/plants packaging industry (15 min))	Tier 1/ConsExpo	0.5	$4.47x10^{-3}$	0.89	yes
	Tier 2/2-compound recom 16	0.5	$2.04x10^{-3}$	0.41	yes
Secondary exposure: Maintenance/repair of dosing pumps (2h)	Tier 1	0.5	0.13	26	yes
	Tier 2	0.5	$1.60x10^{-3}$	0.32	yes

Conclusion

Based on the risk assessment of the a.s. peracetic acid via the inhalation route, a risk for professional users resulting from the use ‚Mixing and loading' and the secondary exposure ‚Maintenance/repair of dosing pumps' with the biocidal product WESSOCLEAN GOLD LINE is unlikely after Tier 1 consideration. Moreover, a safe re-entry after egg or equipment fogging in a disinfection chamber (‚PT3, disinfection of hatching eggs and related equipment (hard surfaces)' and ‚PT4, disinfection of surfaces in the vegetable/fruit/plants packaging industry') is possible, as exemplary calculated, provided the required ventilation time is observed (for details see chapter Professional exposure). Thus, regarding occupational safety, there are no objections against the uses.

Substance of concern hydrogen peroxide

Details of risk characterisation

Reference values

The local reference value AEC 1.25 mg/m³ of hydrogen peroxide derived for respiratory tract irritation is used as external inhalation reference value and directly compared with airborne concentrations of hydrogen peroxide.

Calculation of AEC exhaustion (%)

The exposure-to-AEC ratio (%) referring to the SoC hydrogen peroxide resulting from use of the biocidal product WESSOCLEAN GOLD LINE is determined according to the equation:

Exposure-to-AEC ratio (%) = inhalation exposure to hydrogen peroxide (in mg/m³) / AEC of hydrogen peroxide (in mg/m³) x 100 %.

A risk for professional users referring to the SoC hydrogen peroxide resulting from the use of the biocidal product WESSOCLEAN GOLD LINE or resulting from the secondary exposure is unlikely if the AEC exhaustion (%) is below the value of 100 %.

Results

Table 27 gives a detailed overview of the risk characterisation results referring to the SoC hydrogen peroxide in the biocidal product WESSOCLEAN GOLD LINE e. As the primary health effects associated with exposure to hydrogen peroxide acid are local effects, assessment of combined scenarios is considered not relevant.

As shown in Table 27, for the scenario ‚Mixing and loading' a risk for the professional user is unlikely already in Tier 1. In contrast, for the secondary exposure ‚Maintenance/repair of dosing pumps' inacceptable risks are identified after Tier 1 consideration. However, when additional risk mitigation measures are implemented a risk for the professional user is unlikely in Tier 2.

Also, as demonstrated in Table 27, for the exemplary calculations of re-entry after egg fogging in a disinfection chamber (‚PT3, disinfection of hatching eggs and related equipment (hard surfaces)') and re-entry after equipment fogging in a disinfection chamber (‚PT4, disinfection of surfaces in the vegetable/fruit/plants packaging industry') a risk for the professional user is unlikely for each calculation model used („Tier 1/ConsExpo", „Tier 2/2-compound recom 16") provided the required ventilation time is observed (for details see chapter Professional exposure).

Table 27: Overview of detailed local risk assessment results for inhalation route referring to the substance of concern hydrogen peroxide in the biocidal product WESSOCLEAN GOLD LINE

Scenario		**Reference value inhalative $AEC_{long-term}$** mg/m³	**Estimated inhalation exposure** mg/m³	**Estimated inhalation exposure / AEC** AEC exhaustion %	**Acceptable** (yes/no)
Mixing and loading (15 min)	Tier 1	1.25	$3.0x10^{-2}$	2	yes
Re-entry after process operation: PT3, (disinfection of hatching eggs and related equipment (hard surfaces)(15 min))	Tier 1/ConsExpo	1.25	1.23	98	yes
	Tier 2/2-compound recom 16	1.25	0.96	77	yes
Re-entry after process operation: PT4, (disinfection of surfaces in the vegetable/fruit/plants packaging industry (15 min))	Tier 1/ConsExpo	1.25	1.23	99	yes
	Tier 2/2-compound recom 16	1.25	0.98	78	yes
Secondary exposure: Maintenance/repair of dosing pumps (2h)	Tier 1	1.25	2.90	232	no
	Tier 2	1.25	$2.9x10^{-2}$	2	yes

Conclusion

Based on the risk assessment of the SoC hydrogen peroxide via the inhalation route, a risk for professional users resulting from the use ‚Mixing and loading' and the secondary exposure ‚Maintenance/repair of dosing pumps' with the biocidal product WESSOCLEAN GOLD LINE is unlikely at the latest after Tier 2 consideration. Moreover, a safe re-entry after egg or equipment fogging in a disinfection chamber (‚PT3, disinfection of hatching eggs and related equipment (hard surfaces)' and ‚PT4, disinfection of surfaces in the vegetable/fruit/plants packaging industry') is possible, as exemplary calculated, provided the required ventilation time is observed (for details see chapter Professional exposure).

Thus, regarding occupational safety, there are no objections against the uses as well as secondary exposure taking into account the provisions described in chapter 2.1.3.1.3.2 of this PAR.

Local effects – semi-quantitative

Active substance peracetic acid

The a.s. peracetic acid causes irreversible damage of the skin even in the respiratory tract due to its corrosive effects. Thus, the semi-quantitative risk characterisation for professional users takes into account the dermal exposure concentration of peracetic acid resulting from use of the biocidal product WESSOCLEAN GOLD LINE. For the assessment the dermal 'No observed adverse effect concentration' (NOAEC) of 0.1 % peracetic acid is used.

Details of risk characterisation
Dermal effect concentration
For the purpose of risk characterisation for professional users the dermal exposure concentration of peracetic acid is compared with the dermal NOAEC of 0.1 % peracetic acid.
If the dermal exposure concentration exceeds the NOAEC, appropriate RMM have to be applied to avoid skin contact with the biocidal product WESSOCLEAN GOLD LINE.

Table 28 gives a detailed overview of the semi-quantitative risk assessment results referring to the a.s. peracetic acid in the biocidal product WESSOCLEAN GOLD LINE. However, the re-entry after ‚PT3, disinfection of hatching eggs and related equipment (hard surfaces)' and ‚PT4, disinfection of surfaces in the vegetable/fruit/plants packaging industry' is not considered because it is assumed that surfaces have been dried completely by the ventilation system before the chamber is opened.

As shown in Table 28, for the scenarios ‚Mixing and loading' and the secondary exposure ‚Maintenance/repair of dosing pumps' as well as for the intended uses ‚PT3, disinfection of hatching eggs and related equipment (hard surfaces)' and ‚PT4, disinfection of surfaces in the vegetable/fruit/plants packaging industry' the dermal exposure concentration is each below the NOAEC. RMMs (skin protection) are thus not considered regarding the a.s. peracetic acid in the biocidal product WESSOCLEAN GOLD LINE.

Table 28: Overview of semi-quantitative risk assessment results for dermal route and the active substance peracetic acid in the biocidal product WESSOCLEAN GOLD LINE based on dermal NOAEC 0.1 %

Task/scenario	Dermal NOAEC [%]	Concentration peracetic acid (max.) in application solution [%]	Concentration peracetic acid higher/lower than dermal NOAEC?	RMM
Mixing and loading	0.1	0.03	lower	Not considered
Application: PT3, Disinfection of hatching eggs and related equipment (hard surfaces)	0.1	0.03	lower	Not considered
Application: PT4, Disinfection of surfaces in the vegetable/fruit/plants packaging industry	0.1	0.03	lower	Not considered

Secondary exposure: Maintenance/repair of dosing pumps	0.1	0.03	lower	Not considered

Conclusion
Based on the semi-quantitative risk assessment of the local effects of the a.s. peracetic acid via the dermal route, a risk for professional users resulting from the scenario ‚Mixing and loading' and the secondary exposure ‚Maintenance/repair of dosing pumps' as well as for the intended uses ‚PT3, disinfection of hatching eggs and related equipment (hard surfaces)' and ‚PT4, disinfection of surfaces in the vegetable/fruit/plants packaging industry' is unlikely. RMMs are not considered. For information: As the application scenarios take place in a closed system the semi-quantitative risk assessment for these is rather of a theoretic nature.

Systemic effects - quantitative

Substance of concern propan-2-ol

The primary toxic effect of the SoC propan-2-ol is neurotoxicity. The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to propan-2-ol resulting from use of the BP.

Details of risk characterisation
Reference values
The systemic reference value $AEL_{long\text{-}term}$ of 17.9 mg propan-2-ol/kg bw/d is used in the risk characterisation.

Calculation of total uptake and AEL exhaustion (%)
For inhalation route 100 % is assumed as default absorption for the SoC propan-2-ol. The calculation of the dermal uptake significantly depends on the methodology used for the calculation of dermal absorption. Valid data are not available for propan-2-ol. Therefore, a default value of 75 % for a.s. concentration below 5 % (according to the EFSA Guidance on Dermal Absorption, 2012) is taken into consideration for the risk characterisation.

The inhalation uptake and dermal uptake referring to the SoC propan-2-ol resulting from use of the biocidal product WESSOCLEAN GOLD LINE are determined according to the following equations:

Inhalation uptake (mg/kg bw/d) = inhalation exposure to propan-2-ol (mg/m^3) x 10 m^3/d breathing volume / 60 kg body weight / 100 % x 100 % inhalation absorption;

Dermal uptake (mg/kg bw/d) = dermal exposure to propan-2-ol (mg/kg bw/d) / 100 % x 75 %-dermal absorption.

Dermal exposure to propan-2-ol given in mg/kg bw/d is calculated from dermal exposure to propan-2-ol given in mg/person through division by 60 kg/person.
The summation of inhalation uptake and dermal uptake within a scenario gives the total uptake.

The AEL exhaustion of propan-2-ol is determined by calculating the ratio of the total uptake of propan-2-ol to the AEL as a percentage (%).

Results
Table 29 gives a detailed overview of the risk characterisation results referring to the SoC propan-2-ol in the biocidal product WESSOCLEAN GOLD LINE. It is noted that for clarity reasons all values are rounded to an appropriate number of decimal places in Table 29. However, the underlying calculations are based on unrounded values.

A risk for professional users referring to the SoC propan-2-ol resulting from the use of the biocidal product WESSOCLEAN GOLD LINE or resulting from the secondary exposure is unlikely if the AEL exhaustion (%) is below the value of 100 %.

As shown in Table 28, for the scenario ‚Mixing and loading' and the secondary exposure ‚Maintenance/repair of dosing pumps' a risk for the professional user is unlikely already in Tier 1.

Also, as demonstrated in Table 29, for the exemplary calculations of re-entry after egg fogging in a disinfection chamber (‚PT3, disinfection of hatching eggs and related equipment (hard surfaces)') and re-entry after equipment fogging in a disinfection chamber (‚PT4, disinfection of surfaces in the vegetable/fruit/plants packaging industry') a risk for the professional user is unlikely in each calculation model used („Tier 1/ConsExpo", „Tier 2/2-compound recom 16") provided the required ventilation time is observed (for details see chapter Professional exposure).

Combined scenarios

Also, shown in Table 29, for the combined scenarios ‚Mixing and loading/Re-entry afterprocess operation: PT3, (disinfection of hatching eggs and related equipment (hard surfaces))' and ‚Mixing and loading/Re-entry after process operation: PT4, (disinfection of surfaces in the vegetable/fruit/plants packaging industry)' a risk for the professional user is unlikely for both combinations of Tier 1 ‚Mixing and loading' with "Tier 1/ConsExpo" and Tier 1 ‚Mixing and loading' with "Tier 2/2-compound recom 16" provided the required ventilation time is observed (for details see chapter Professional exposure.

Table 29: Overview of detailed risk assessment results referring to the substance of concern propan-2-ol in the biocidal product WESSOCLEAN GOLD LINE

Scenario		**$AEL_{long-term}$** mg /kg bw/d	**Estimated inhalation uptake** mg /kg bw/d	**Inhalation uptake / AEL** %	**Estimated dermal uptake** mg /kg bw/d	**Dermal uptake / AEL** %	**Estimated total uptake** mg /kg bw/d	**Estimated total uptake / AEL** (AEL exhaustion) %	**Acceptable** (yes/no)
Mixing and loading	Tier 1	17.9	$8.33x10^{-3}$	0.05	$4.37x10^{-3}$	0.02	0.01	0.07	Yes
Re-entry after process operation PT3, (disinfection of hatching eggs and related equipment (hard surfaces))	Tier 1/ConsExpo	17.9	$4.01x10^{-22}$	$2.24x10^{-21}$	Not expected		$4.01x10^{-22}$	$2.24x10^{-21}$	Yes
	Tier 2/2-compound recom 16	17.9	$3.73x10^{-4}$	$2.08x10^{-3}$	Not expected		$3.73x10^{-4}$	$2.08x10^{-3}$	Yes
Re-entry after process operation: PT4, (disinfection of surfaces in the vegetable/fruit/plants packaging industry)	Tier 1/ConsExpo	17.9	$4.51x10^{-4}$	$2.52x10^{-3}$	Not expected		$4.51x10^{-4}$	$2.52x10^{-3}$	Yes
	Tier 2/2-compound recom 16	17.9	$6.66x10^{-3}$	$3.72x10^{-2}$	Not expected		$6.66x10^{-3}$	$3.72x10^{-2}$	Yes
Secondary exposure: Maintenance/repair of dosing pumps	Tier 1	17.9	6.67	37.2	0.03	0.2	6.70	37.4	Yes
	Tier 2	17.9	0.08	0.42	$3.48x10^{-4}$	$1.9x10^{-3}$	0.08	0.42	Yes

Combined: Mixing and loading + Re-entry after process operation: PT3, (disinfection of hatching eggs and related equipment (hard surfaces))	Tier 1/(Tier1/ConsExpo)	17.9	$8.33x10^{-3}$	0.05	$4.37x10^{-3}$	0.02	0.01	0.07	Yes
	Tier 1/(Tier 2/2-compound recom 16)	17.9	$8.71x10^{-3}$	0.05	$4.37x10^{-3}$	0.02	0.01	0.07	Yes
Combined: Mixing and loading + Re-entry after process operation: PT4, (disinfection of surfaces in the vegetable/fruit/plants packaging industry)	Tier 1/(Tier1/ConsExpo)	17.9	$8.78x10^{-3}$	0.05	$4.37x10^{-3}$	0.02	0.01	0.07	Yes
	Tier 1/(Tier 2/2-compound recom 16)	17.9	0.015	0.09	$4.37x10^{-3}$	0.02	0.02	0.11	Yes

Conclusion
Based on the risk assessment of the SoC propan-2-ol via the inhalation and dermal route, a risk for professional users resulting from the use ‚Mixing and loading' and the secondary exposure ‚Maintenance/repair of dosing pumps' with the biocidal product WESSOCLEAN GOLD LINE is unlikely after Tier 1 consideration. Moreover, a safe re-entry after egg or equipment fogging in a disinfection chamber (‚PT3, disinfection of hatching eggs and related equipment (hard surfaces)' and ‚PT4, disinfection of surfaces in the vegetable/fruit/plants packaging industry') as well as their combination each with the scenario ‚Mixing and loading' is possible, as exemplarily calculated, provided the required ventilation time is observed (for details see chapter Professional exposure). Thus, regarding occupational safety, there are no objections against the uses.

Local effects – qualitative

The SoCs ethanol, propan-2-ol and hydrogen peroxide trigger the classification and labelling, respectively, of the biocidal product WESSOCLEAN GOLD LINE with Eye Irrit. 2, H319 (Causes serious eye irritation).

Therefore a qualitative risk assessment for local effects regarding contact with the eyes is conducted. The qualitative risk assessment for local effects takes into account the concentrated biocidal product as well as the different dilutions thereof. The Table 30 gives an overview of the relevant classifications and the allocated hazard categories according to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017).

Table 30: Relevant classification and resulting hazard categories

b.p. concentration in application solution [%]	Resulting classification according to Regulation (EC) No. 1272/2008	Resulting hazard category according to Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017)
100%	Eye Irrit. 2, H319	LOW
1%	-	-

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

For the scenarios 'Mixing and loading', 'PT3, disinfection of hatching eggs and related equipment (hard surfaces) and ‚PT4, disinfection of surfaces in the vegetable/fruit/plants packaging industry' (Table 31), with the proposed risk mitigation measures the reduction of eye contact with the concentrated biocidal product minimises the anticipated health risk to an acceptable level. However, the secondary exposure 'Maintenance/repair of dosing pumps' is not considered because contact may only occur with the 1 %-dilution that is not classified and thus not part of the qualitative risk assessment. For details about the secondary exposure see chapter Professional exposure.

Table 31: Summary of qualitative conclusions for local risk assessment for 'Mixing and loading', 'PT3, disinfection of hatching eggs and related equipment (hard surfaces)', 'PT4, disinfection of surfaces in the vegetable/fruit/plants packaging industry')'

Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local Effects in terms of C&L	Hazard Category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Mixing and loading	100%	Eye Irrit. 2, H319	LOW	15 mins, daily	Accidental skin and eye contact possible, splashes	Technical RMM: An automatic dosing device is used to charge the system. PPE: Eye protection recommended	Acceptable
Application incl. re-entry: PT3, disinfection of hatching eggs and related equipment (hard surfaces)	100%	Eye Irrit. 2, H319	LOW	Re-entry: 20 min each, several times per day	No contact to wet surfaces	Technical RMM: Application only in closed disinfection chambers, controlled from outside. Surfaces have been dried completely by the ventilation system before the chamber is opened. PPE: None	Acceptable
Application incl. re-entry: PT4, disinfection of surfaces in the vegetable/fruit/plants packaging industry	100%	Eye Irrit. 2, H319	LOW	Re-entry: 15 min each, several times per day	No contact to wet surfaces	Technical RMM: Application only in closed disinfection chambers, controlled from outside. Surfaces have been dried completely by the ventilation system before the chamber is opened. PPE: None	Acceptable

Conclusion
Concerning the eye irritating properties of biocidal product WESSOCLEAN GOLD LINE, exposure should be minimised with risk mitigation measures. If the proposed risk mitigation measures are implemented, the scenarios 'Mixing and loading', 'PT3, disinfection of hatching eggs and related equipment (hard surfaces)' and ‚PT4, disinfection of surfaces in the vegetable/fruit/plants packaging industry' do not lead to concern for professional users.

Conclusion

In summary, a risk for professional users resulting from the use of the biocidal product WESSOCLEAN GOLD LINE and for the intended uses 'PT3, disinfection of hatching eggs and related equipment (hard surfaces)' and ‚PT4, disinfection of surfaces in the vegetable/fruit/plants packaging industry' as well as from secondary exposure ('Maintenance/repair of dosing pumps') is unlikely at the latest after Tier 2 consideration. Risk mitigation measures described in chapter 2.1.3.1.3.2 have to be taken into account in order to ensure safe use of the biocidal product WESSOCLEAN GOLD LINE.
The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

Risk for non-professional users

Exposure and risk assessment for non-professional use is not relevant since the biocidal product is for professional application only.

Risk for the general public

Exposure of the general public (e.g. bystanders, residents) is not expected. Hence, a corresponding risk assessment is not required.

Risk for consumers via residues in food

As residues in food or feed from the intended uses are not expected, human exposure to peracetic acid and hydrogen peroxide via food and feed is not considered to be relevant.

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

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

Professional user
The risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product WESSOCLEAN GOLD LINE is not carried out because in the risk characterisation only one systemically acting substance, the SoC propan-2-ol, is considered.

Summary of risk characterisation

Summary of risk characterisation for industrial user

The summary of risk characterisation for industrial users is described in chapter Summary of risk characterisation for professional users.

Summary of risk characterisation for professional user

In summary, a risk for professional users resulting from the use of the biocidal product WESSOCLEAN GOLD LINE for the intended uses ‘PT3, disinfection of hatching eggs and related equipment (hard surfaces)‘ and ‚PT4, disinfection of surfaces in the vegetable/fruit/plants packaging industry‘ as well as from secondary exposure (‘Maintenance/repair of dosing pumps’) is unlikely at the latest after Tier 2 consideration. Risk mitigation measures described in chapter 2.1.3.1.3.2 have to be taken into account in order to ensure safe use of the biocidal product WESSOCLEAN GOLD LINE.

For details see Table 26 to Table 31.

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

Summary of risk characterisation for non-professional user

Not relevant.

Summary of risk characterisation for indirect exposure

Not relevant.

2.2.7 Risk assessment for animal health

The biocidal product is applied in closed rooms and systems, where pets and domestic animal are normally not present. Hence, a risk assessment for these animals is not required.
In addition, the equilibrium substances peracetic acid and hydrogen peroxide are both highly reactive and degrade rapidly after contact with organic material. Thus, no risk for chicks, hatching from disinfected eggs, is expected.

2.2.8 Risk assessment for the environment

2.2.8.1 General information

For the biocidal product WESSOCLEAN GOLD LINE (PT 3 and PT 4) with the a.s. peracetic acid, no new studies were provided. However, the exact composition of the product is known as described in the confidential annex to this PAR and two substances of concern for the environment are contained in the product, which are propan-2-ol and hydrogen peroxide as active substance authorised in other PTs (see 2.2.8.1.1).

2.2.8.1.1 Mixture toxicity

Screening step

Screening Step 1: Identification of the concerned environmental compartments

The biocidal product WESSOCLEAN GOLD LINE affects both, aquatic and terrestrial environment. For further information on the release pathway and the relevant compartments for the assessment of the product, see chapter 2.2.8.3.2 and Table 42.

Screening Step 2: Identification of relevant substances

The biocidal product WESSOCLEAN GOLD LINE is composed of peracetic acid which is the active substance, and hydrogen peroxide and acetic acid, which are considered as parts of the active substance equilibrium mixture. Peracetic acid and hydrogen peroxide are relevant substances for the mixture toxicity assessment. Besides the active substance, the product contains no substances, which would lead to a classification of the product according to (CLP), but one further active substance in other PTs (propan-2-ol). Thus, propan-2-ol is identified as substance of concern in the product and needs to be considered in mixture toxicity assessment as well.

Screening Step 3: Screen on synergistic interactions

Synergistic interactions between the components of the product are not expected according to current knowledge.

Screening step	
Y	Significant exposure of environmental compartments? (Y/N)
Y	Number of relevant substances >1? (Y/N)
N	Indication for synergistic effects for the product or its constituents in the literature? (Y/N)

Tiered approach

According to the available data for the relevant substances identified above, tier 1 of the mixture toxicity assessment has to be followed.

2.2.8.2 Effects assessment

The effects assessment for environment is based on sufficient data available from the active substance Assessment Reports (PAA: FI, November 2015, Hydrogen peroxide: FI, January 2015 and propan-2-ol: DE, July 2014).

2.2.8.2.1 Aquatic compartment (including sediment and STP)

Available PNEC values for surface water and STP from the respective AR's of active substances are summarised in the following tables.

Table 32

Summary table PNEC values surface water		
Substance	**PNEC**	**Based on**
PAA	0.069 µg/L	NOEC for *D. rerio* 0.69 µg/L, AF 10
H_2O_2	12.6 µg/L	NOEC for *D. magna* 0.63 mg/L, AF 50
Propan-2-ol	2.82 mg/L	NOEC for *D. magna* 141 mg/L, AF 50

A PNECsediment for PAA and H_2O_2 was derived by equilibrium partitioning method in the active substance ARs. However, a separate risk assessment for sediment is not necessary, as adsorption potential of PAA, H_2O_2 and propan-2-ol are very low, the substances degrade rapidly and the risk assessment for freshwater is considered to cover the risks for sediment.

PNECSTP is 0.051 mg/L according to the active substance AR for PAA (FI, 2015).
PNECSTP is 4.66 mg/L according to the active substance AR for H_2O_2 (FI, 2015).
PNECSTP is 10 mg/L according to the active substance AR for Propan-2-ol (DE, 2014).

2.2.8.2.2 Terrestrial compartment (including groundwater)

Available PNEC values for soil from the respective AR's of active substances are summarised in the following tables.

Table 33

Summary table PNEC values for soil		
Substance	**PNEC**	**Based on**
PAA	0.282 mg/kg_{ww}	seedling emergence test with non-target plants (*Brassica napus*), AF 1000
H2O2	0.0018 mg/kg_{ww}	EPM
Propan-2-ol	0.496 mg/kg_{ww}	EPM

Birds and mammals are not anticipated to be directly exposed to peracetic acid, hydrogen peroxide, or propan-2-ol. Thus, risk assessment for bird and mammals is not considered necessary according to the respective ARs.

2.2.8.2.3 Atmosphere

The measured Henry's Law constant of 0.217 Pa m³ mol^{-1} indicates that volatilisation of peracetic acid from surface water into atmosphere is not expected to be an important process. Therefore, air is not an environmental compartment of concern.
Hydrogen peroxide is present at natural background concentrations of 0.14 to 10 µg m^{-3} in the atmosphere, according to evaluation in the active substance AR (FI, 2015). The low measured value of Henry's law constant (H = 7.5 × 10^{-4} Pa.m³ mol^{-1}) indicates very low volatilisation of hydrogen peroxide from water and therefore, air is not an environmental compartment of concern.
For the air compartment no ecotoxicological data for propan-2-ol are available. Therefore, no quantitative estimation of PNECair for this substance of concern is possible.

2.2.8.2.4 Non-compartment specific effects

According to the active substance AR (FI, 2015) peracetic acid is not expected to accumulate in organisms because the measured log P_{ow} value of -0.60 at pH 7 indicates that peracetic acid has a low potential for bioaccumulation.
The estimated log Kow for hydrogen peroxide is as low as -1.57 and calculated BCF values are 1.4 for fish and 0.84 for earthworm according to the active substance AR (FI, 2015). Propan-2-ol was found to have a low bioaccumulation potential with a log Kow as low as 0.05 and thus, secondary poisoning is considered negligible for this substance according to AR (DE, 2014). Hence, bioconcentration in biota is considered negligible.

2.2.8.2.5 Summary of effects assessment

Table 34

Summary table on calculated PNEC values			
Compartment	**PNEC PAA**	**PNEC H_2O_2**	**PNECpropan-2-ol**
Surface water	0.069 µg/L	12.6 µg/L	2820 µg/L
STP	0.051 mg/L	4.66 mg/L	10 mg/L
Soil	0.282 mg/kg_{ww}	0.0018 mg/kg_{ww}	0.496 mg/kg_{ww}

2.2.8.2.6 Fate and behaviour

Peracetic acid decomposes rapidly in all environmental compartments, i.e. in surface water, soil, air and active sludge. The following processes are involved in the decomposition/degradation of peracetic acid in the environment:

- Abiotic degradation:
  - hydrolysis
  - spontaneous decomposition

  - metal (Fe, Cr, Mn) catalysed decomposition
  - oxidation of organic substance
- Biotic degradation by micro-organisms.

Resulting degradation products of peracetic acid are oxygen, acetic acid and hydrogen peroxide. Spontaneous decomposition results in the formation of acetic acid and oxygen, while hydrolysis yields acetic acid and hydrogen peroxide. The degradation pathway by which hydrogen peroxide can be formed from peracetic acid is by hydrolysis ($CH_3C(O)OOH + H_2O \rightarrow CH_3COOH + H_2O_2$). However, this reaction is negligible in aquatic ecosystems. The predominant degradation pathway in aquatic ecosystems, which are loaded with organic matter, is the reaction of peracetic acid with organic matter and metal cations, leading to the formation of acetic acid and oxygen. Acetic acid and hydrogen peroxide are further degraded to H_2O, CO_2 and oxygen.

Hydrogen peroxide decomposes rapidly in different environmental compartments, i.e. in surface water, soil, active sludge and air. The following processes are involved in the decomposition/degradation of hydrogen peroxide in the environment:

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

Hydrogen peroxide decomposes into water and oxygen ($2H_2O_2 \rightarrow 2H_2O + O_2$). The rate of this reaction depends on the contact with catalytic materials and other factors such as heat and sunlight.
Standard ready biodegradability tests are not suitable for inorganic substances. Nevertheless, hydrogen peroxide shows a very rapid degradation with organic matter in sewage sludge (DT_{50} = 2 min, 20° C). Rapid degradation of hydrogen peroxide has also been observed in surface water and soil compartments. This degradation has been considered to be mainly microbial derived based on the difference in degradation rates between the natural and filtered/sterilised samples.
The biotic and abiotic decomposition reactions proceed in parallel with the formation reactions and the equilibrium of these reactions depends on the environmental conditions.

At WG-III-2020 the following half-lives for peracetic acid and hydrogen peroxide for the environmental exposure assessment were agreed (document WGIII2020_ENV_8-3a):

Table 35 Summary table on half-lives of peracetic acid

Compartment	DT50 measured/ estimated in tests	Remarks	Reference
STP – effluent stream (also transferable to sewer system and liquid manure)	<< 5 min (<< 9.5 min at 12°C)	Measured at 20° C, pH 7.03	AR for PAA (PT 1-6, Nov 2015 p. 18) (PT 11 & 12, Aug 2016 p.17)
STP – aeration tank	< 3 min	Measured at 20° C, pH 7	
Surface water (hydrolysis)	31.7 hours	Measured at 25° C, pH 7	AR for PAA (PT 1-6, Nov 2015, LoEP) (PT 11 & 12, Aug 2016, LoEP)

Compartment	DT50 measured/ estimated in tests	Remarks	Reference
Seawater	50 % degradation within 2 minutes		AR for PAA (PT 1-6, Nov 2015, LoEP) (PT 11 & 12, Aug 2016, LoEP)
Soil	12 hrs	Peracetic acid degrades rapidly when in contact with organic matter. This has been shown in the activated sludge test. Thus, peracetic acid is not expected to be persistent in soil. It was agreed in the BPC WG ENV II-2016 to use the DT50 from hydrogen peroxide of 12 hrs in the absence of a DT50 for PAA.	AR for PAA (PT 11 & 12, Aug 2016, LoEP)
Air	DT50 of 3.969 days (based on a 24-hour day), corresponding to 95.26 hours	According to an Atkinson calculation of the atmospheric residence time, peracetic acid degrades in the atmosphere with a DT50 of 3.969 days (based on a 24-hour day), corresponding to 95.26 hours. As the molecule does not contain olefin carbon-carbon double or acetylic triple bonds, peracetic acid is not expected to react with ozone.	AR for PAA (PT 1-6, Nov 2015, LoEP) (PT 11 & 12, Aug 2016, LoEP)

The adsorption of peracetic acid to aerosol particles, the volatilisation from water into air and the adsorption of peracetic acid to soil (K_{OC} is 1.46 L kg^{-1} (QSAR)) can be considered to be very low. Thus, peracetic acid mainly distributes in the aqueous phase if released into the environment.

Table 36: Summary table on half-lives of hydrogen peroxide

Compartment	DT50 measured/ estimated in tests	Remarks	Reference
activated sludge stage of sewage treatment plants	2 min	Measured at 20° C, pH 7.8	AR of H_2O_2 (PT 1-6, Jan 2015, LoEP) (PT 11 & 12, Oct 2017, LoEP)
Raw sewage (also transferable to sewer system), liquid manure	6 min (11.4 min at 12°C)	Measured at 20° C, pH not reported; Worst-case DT50 determinate for hydrogen peroxide in microbial communities present in an infiltration gallery of a contaminated soil remediation site.	CAR II-A of H_2O_2 (PT 1-6, July 2013, Table 4.1.1-2) (PT 11 & 12, Oct 2017, Table 4.1.1-2) https://ngwa.onlinelibrary.wiley.com/doi/epdf/10.1111/j.1745-6584.1989.tb00436.x
Surface water (hydrolysis)	Hydrolysis is not applicable based on the nature of the compound.		AR of H_2O_2 (PT 1-6, Jan 2015, LoEP) (PT 11 & 12, Oct 2017, LoEP)

Compartment	DT50 measured/ estimated in tests	Remarks	Reference
Surface water (abiotic catalysis and biotic degradation)	5 days	Estimated (an extreme worst case DT_{50} estimate to take account for unfavourable conditions, i.e. oligotrophic cold waters with low microbial density and low transition metal concentration)	AR of H_2O_2 (PT 1-6, Jan 2015, LoEP) (PT 11 & 12, Oct 2017, LoEP)
Soil	12 hrs	Rapidly decomposed in soil to water and oxygen. Worst case DT50 estimate based on literature sources.	AR of H_2O_2 (PT 1-6, Jan 2015, LoEP) (PT 11 & 12, Oct 2017, LoEP)
Air	24 hrs	Estimated (worst case DT_{50} estimate based on literature sources)	AR of H_2O_2 (PT 1-6, Jan 2015, LoEP) (PT 11 & 12, Oct 2017, LoEP)

As hydrogen peroxide is miscible with water in all proportions and taking into account that the estimated log K_{OC} is 0.2036 (QSAR, corresponds to K_{OC} of 1.598 L kg^{-1}), it is expected that hydrogen peroxide has a low potential for adsorption to soil and for partitioning to suspended matter or sediment (AR of H_2O_2 PT 1-6, Jan 2015 and PT 11 & 12, Oct 2017).

Propan-2-ol is classified as readily biodegradable, 10-day window fulfilled. No data on biodegradation in soil, water/sediment or sewage treatment plants are available as in light of the screening test result no further studies were deemed necessary. The environmental exposure assessment is based on default assumptions as provided by the Guidance on the BPR, Vol. IV, Part B+C (2017).
Propan-2-ol is also stable to hydrolysis and photolysis in water is not applicable due to no absorption maximum above 290 nm. As it has a relatively high vapour pressure, direct evaporation is expected. Nevertheless, the Henry's Law constant indicates that propan-2-ol is moderately volatile. The DT50 in the atmosphere is estimated to be 3.1 d. For further details, please refer to CAR and AR on propan-2-ol, (2015).
Based on a log KOW of 0.05 and the QSAR for alcohols, the K_{OC} was estimated as 3.3 L/kg. Therefore, propan-2-ol is expected to exhibit only a weak adsorption in soils and sediments indicating a very high mobility of propan-2-ol in soil and a very low geo-accumulation potential.

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

No further data are available.

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

No data available.

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

No data available.

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

Not required.

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

Not required.

2.2.8.3 Exposure assessment

The biocidal product WESSOCLEAN GOLD LINE is a RTU product containing peracetic acid as active substance and hydrogen peroxide, as well as propan-2-ol as substances of concern.

The biocidal product is intended to be used for disinfection of eggs in sluice to ensure veterinary hygiene (PT3). The applicant describes the use more specific as disinfection of hatching eggs and related equipment (hard surfaces) at room temperature or at 36 °C. The product is used as ready-to-use solution.

The biocidal product in PT 4 is used for disinfection of hard surfaces in the food and feed industry, more specific: for disinfection of surfaces in the vegetable/fruit/plants packaging industry by airborne diffusion.

Table 37: General information to Use 1+2

Assessed PT	PT 3
Assessed scenarios	Use 1+2: Disinfection of hatching eggs (sluice, hatcher, of rooms and equipment)
ESD(s) used	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, EN 2011 Technical Agreements for Biocides (TAB) – ENV, February 2021; ENV-188 ENV-39 and ENV-189
Approach	Use 1+2: Average consumption-based approach
Distribution in the environment	Calculated based on Guidance BPR IV - Part B+C (ECHA, 2017) Technical Agreements for Biocides (TAB) – ENV, February 2021; ENV-188 WGIII2020_ENV_8-3a _Harmonisation of UA cases_PAA.docx
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Use 1+2: Production: No

	Formulation No Use: Yes Service life: No
Remarks	

Table 38 General information to Use 3

Assessed PT	PT 4
Assessed scenarios	Use 3: Disinfection of surfaces in the vegetable/fruits/plants packaging industry (transport and storage equipment)
ESD(s) used	Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas (EN 2011, Table 10) and Technical Agreements for Biocides (TAB) – ENV, February 2021; ENV-39, ENV-177 and ENV-198
Approach	Use 3: Average consumption based approach
Distribution in the environment	Calculated based on Guidance BPR IV - Part B+C (ECHA, 2017) Technical Agreements for Biocides (TAB) – ENV, February 2021; ENV-188 WGIII2020_ENV_8-3a_ Harmonisation of assessment for PAA.docx
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Use 3: Production: No Formulation No Use: Yes Service life: No
Remarks	

2.2.8.3.1 Fate and distribution in exposed environmental compartments

Parameters according to AR (LoEP) of PAA and H_2O_2 which describe the fate and distribution of peracetic acid and hydrogen peroxide in the environment are summarised in the following table. The partitioning coefficients for the aquatic and terrestrial compartments, which are relevant for the environmental emission estimation and exposure assessment are based on these input values. Further relevant input parameters (which have been harmonised at BPC WGIII2020_ENV_8-3a) are presented in Table 39 and Table 40.

Table 39: Input parameters (only set values) for calculating the fate and distribution in the environment of peracetic acid and hydrogen peroxide

Input	PAA	H_2O_2	Unit	Remarks
Molecular weight	76.05	34.01	g/mol	
Boiling point			°C	
Vapour pressure at 20°C (at 12°C)	1410 (793)	214 (120)	Pa	
Water solubility	1.0E+06	1.0E+06	mg/L	complete miscible; without temperature correction
pKa	8.24	---		
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 (at 25°C)	0.00075 (at 20°C)	Pa × m3/mol	
Biodegradability	ready biodegradable	ready biodegradable		
Rate constant for STP	13.86 (DT50=3 min)	20.79 (DT50=2 min)	h^{-1} (at 20°C)	
DT_{50} for biodegradation in surface water	---	5	d (at 12ºC)	
DT_{50} for hydrolysis in surface water	31.7 (89.7 (at 12°C))	---	hr (at 25°C/ pH 7)	
DT_{50} for photolysis in surface water	---	---		
DT_{50} for degradation in soil	12	12	hr	without temperature correction
DT_{50} for degradation in air	95.26	24	hr	without temperature correction

Table 40: Input parameters (only set values) for calculating the fate and distribution in the environment of propan-2-ol

Input	Value	Unit	Remarks
Molecular weight	60.09	g/mol	
Vapour pressure (at 12°C)	2304	Pa	

Water solubility (at 12°C)	1.0E+06	mg/L	complete miscible with water
Log Octanol/water partition coefficient	0.05	Log 10	
Organic carbon/water partition coefficient (Koc)	3.3	L/kg	
Henry's Law Constant (at 12°C)	0.383	Pa × m^3/mol	Temperature corrected from measured Henry's Law constant of 0.80 Pa × m³/mol at 25°C
Soil water partition coefficient	0.299	m³/m³	
Suspended matter-water partition coefficient	0.982	m³/m³	
Biodegradability	ready biodegradable		10-day window fulfilled
Rate constant for STP	1	h^{-1}	Default value, BPR Guidance Vol. IV Part B + C (2017), chapter 2.3.6.4, table 4
DT_{50} for degradation in soil	30	d (at 12°C)	Default value, BPR Guidance Vol. IV Part B + C (2017), chapter 2.3.6.5, table 6

Following the Technical Agreements for Biocides (TAB) – ENV, February 2021; ENV-208 as well as the ENV WG-IV-2019 and WG-III-2020 (agreed documents of WGIV2019_ENV_6-3_Harmonisation of UA cases_PAA and WGIII2020_ENV_8-3a_Harmonisation of assessment for PAA) no groundwater assessment is needed for the rapidly reacting substances PAA and hydrogen peroxide.
Following the ENV WG-III-2020 (agreed document WGIII2020_ENV_8-3a_Harmonisation of assessment for PAA) the following distribution for peracetic acid and hydrogen peroxide in the STP was calculated by SimpleTreat 4.0 (Method 1). The distribution for propan-2-ol in the sewage treatment plant is calculated using also SimpleTreat v.4.0.

Table 41: Calculated distribution in the STP

Compartment	Percentage [%]		
	PAA	H_2O_2	propan-2-ol
Air	0.0435	0.0002	0.273
Water	0.9903	0.6637	7.956
Sludge	0.0133	0.0145	0.0309
Degraded in STP	98.95	99.32	91.74

As the distribution in sewage sludge for propan-2-ol is < 0.1 % further environmental exposure assessment via sludge application on agricultural land was considered not relevant for several biocidal products containing propan-2-ol as a.s. This was already equally considered for propan-2-ol as SoC.
For the a.s. PAA and H_2O_2 the same value for distribution in sewage sludge is estimated by SimpleTreat v. 4.0 (below 0.1 %) and therefore further environmental exposure via sludge application on agricultural land can also be considered not relevant. Furthermore, due to the high reactivity of PAA and hydrogen peroxide, and the high organic matter content of STP sludge, PAA and H_2O_2 are not expected to persist in relevant concentrations until the sludge is applied on agricultural land. A further quantitative assessment is not deemed necessary.

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

The use of the product WESSOCLEAN GOLD LINE as a disinfectant results in exposure of the environment indirectly via STP to water and sediment.

Table 42: Identification of relevant receiving compartments based on the exposure pathway

	Wastewater (STP)	Surface water and Sediment	Soil and Groundwater	Air
Use 1+2 (PT3)	yes	yes (indirect)	not relevant	yes
Use 3 (PT4)	yes	yes (indirect)	not relevant	no (for both a.s.) yes (for SoC)

2.2.8.3.3 Local emission estimation for relevant environmental compartments

a) Use1+2 [disinfection of hatching eggs and related equipment (hard surfaces)]

Two comparable uses have been indicated by the applicant: the b.p. WESSOCLEAN GOLD LINE is used as ready-to-use solution and automatically sprayed into the closed disinfection chamber by means of a cold sprayer with compressed air (working pressure 4 – 5 bar). The application amount is indicated with 1 L b.p. per 15 m³, i.e. 0.067 L b.p./m³. The b.p. is sprayed for at least 30 minutes. In case of disinfection at room temperature after 60 minutes drying period, the air in the chamber is released by means of exhaust system, whereas in case of disinfection at 36°C the drying period decreases to 20 minutes. Disinfections are carried out after every new refilling of the disinfection chamber with eggs. No differentiation between the two uses is required for the environmental exposure assessment. Thus, both application scenarios can be described by the same environmental emission scenario. The environmental emission estimation is based on Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, chapter 2.5 "Disinfection in hatcheries" (EN 2011). According to this emission model, two emission

pathways of a.s. into the environment are possible: emission to waste water and emission to air. The product specific input parameters which are relevant for the environmental emission estimation and exposure assessment are summarised in Table 43. In the ESD the quantity of disinfectant used per cubic meter Qa.i.appl has to be chosen via a picklist, but in case of b.p. WESSOCLEAN GOLD LINE, the applicant describes more specifically how the product is to be used. Thus, this value has been overwritten by the realistic value.

During the environmental risk assessment of the active substance propan-2-ol, it was assumed that 90 % of propan-2-ol is released to air and 10 % of the substance is released to water. According to the BPC opinion of propan-2-ol, the distribution between water and air should be re-evaluated in the frame of product authorisation. In case of propan-2-ol the evaporation of the SoC is facilitated by the relatively high vapour pressure. In the AR of propan-2-ol as well as in several PARs it is stated, that nearly the whole amount of the SoC applied is released to indoor air, which is emitted to the local outside air without deposition indoors. However, partial releases to sewer systems cannot be completely excluded for liquid products. Therefore, for the environmental risk assessment of the b.p. WESSOCLEAN GOLD LINE the propan-2-ol distribution to air (90 %) and waste water (10 %) used during the assessment of the active substance is maintained.

Table 43: **Input values for assessment of local emissions following use 1+2 (PT3)**

Input	**Symbol**	**Value**	**Unit**	**Remarks**
Use 1+2: PT3: disinfection of hatching eggs and related equipment (hard surfaces)				
Quantity of disinfectant (b.p.) used per cubic meter	$Qb.p._{appl}$	0.067	L/m³	specific information on intended use by applicant
Fraction a.s. in b.p.	F_{PAA}	0.00030		a.s.
Fraction SoC in b.p.	F_{H2O2}	0.0314		according to SPC
Fraction SoC in b.p.	$F_{propan-2-ol}$	0.0252		according to SPC
Density b.p.	$RHO_{b.p.}$	1.0046	kg/L	
Quantity of a.s. used per cubic meter	$Q_{H2O2.appl}$	2.105	g/m³	$Q_{a.s.} = Q_{b.p.} \times RHO_{b.p.} \times f_{a.s.}$
Quantity of a.s. used per cubic meter	$Q_{PAA.appl}$	0.002	g/m³	
Quantity of SoC used per cubic meter	$Q_{propan-2-ol.appl}$	1.688	g/m³	$Q_{SoC} = Q_{b.p.} \times RHO_{b.p.} \times f_{SoC}$
Application stages:	Stage 1 – eggs in fumigation sluice			
Volume of the fumigation sluice	V_{sluice}	49	m³	Default
Number of fumigation sluices	N_{sluice}	1		Default

Number of disinfection events	$Nappl_{sluice}$	7	d^{-1}	Default
	Stage 2 – eggs in hatcher			
Volume of the hatcher	$V_{hatcher}$	9.73	m³	Default
Number of hatchers	$N_{hatcher}$	27		Default
Number of disinfection events	$Nappl_{hatcher}$	0.57	d^{-1}	Default
	Stage 3 – rooms and equipment			
Volume of the (single-stage) setter	V_{setter}	9.73	m³	Default
Number of (single-stage) setter	N_{setter}	162		Default
Number of disinfection events (single-stage) setter	$Nappl_{setter}$	0.06	d^{-1}	Default
Fraction of a.s. released to air after aerosol or fogging treatment	$F_{air\_fog\_a.s.}$	0.1		Default
Fraction of a.s. released to waste water	$F_{water\_a.s.}$	0.9		Default

Fraction of propan-2-ol released to air after aerosol or fogging treatment	$F_{air\_fog\_SoC}$	0.9		According to AR propan-2-ol
Fraction of propan-2-ol released to waste water	F_{water_SoC}	0.1		According to AR propan-2-ol

According to ESD PT3 the following equations have to be used for calculation of local emissions to waste water and to air:

$$Elocal_{water} = Qa.i._{appl} \cdot 10^{-3} \cdot F_{water} ((V_{sluice} \cdot N_{sluice} \cdot Nappl_{sluice}) + (V_{hatcher} \cdot N_{hatcher} \cdot Nappl_{hatcher}) \cdot 2 + (V_{\mathrm{setter}} \cdot N_{\mathrm{setter}} \cdot Nappl_{\mathrm{setter}}))$$

$$Elocal_{air} = Qa.i._{appl} \cdot 10^{-3} \cdot F_{air} ((V_{sluice} \cdot N_{sluice} \cdot Nappl_{sluice}) + (V_{hatcher} \cdot N_{hatcher} \cdot Nappl_{hatcher}) \cdot 2 + (V_{\mathrm{setter}} \cdot N_{\mathrm{setter}} \cdot Nappl_{\mathrm{setter}}))$$

According to the AR of peracetic acid rapid degradation processes of active substances peracetic acid and hydrogen peroxide in the sewer system have to be considered. It has to be assumed, that the residence time of substances in the sewer system between source (exhaust system of disinfection chamber) and STP influent is 1 hour. Thus, the amounts of active substances emitted to the STP via sewer system have to be recalculated by

considering degradation processes for 1 hour. The following SFO equation can be used for recalculation:

$M_{t1} = M_{t0} * \exp^{(- k * t1)}$

where M_{t1} = total amount of substances present at t1 (kg)
M_{t0} = total amount of substance at t0 (kg)
k = rate constant (ln2 / DT_{50})
t1 = time (h) = 1 hour residence time in the sewer system

At WG-III-2020 the relevant rate constants have been discussed and the following values have been concluded:

Peracetic acid:
k = 4.38 h^{-1}, calculated from the DT_{50} of 9.5 min at 12°C (refer to **Table 35**)

Hydrogen peroxide:
k = 3.65 h^{-1}, calculated from the DT_{50} of 11.4 min at 12°C (refer to **Table 36**)

Calculations for Use 1+2

Table 44: Resulting local emission to relevant environmental compartments

Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Waste water	PAA: 1.333 x 10^{-2} kg/d H_2O_2: 1.396 kg/d SoC Propan-2-ol: 1.244 x 10^{-1} kg/d	
Air	PAA: 1.481 x 10^{-3} kg/d H_2O_2: 1.522 x 10^{-1} kg/d SoC: Propan-2-ol: 1.12 kg/d	
STP	PAA: 1.669 x 10^{-4} kg/d H_2O_2: 3.629 x 10^{-2} kg/d SoC Propan-2-ol: 1.244 x 10^{-1} kg/d	Degradation processes in sewer system have been considered for the active substances PAA and H_2O_2.

b) Use 3 [Disinfection of surfaces in the vegetable/fruits/plants packaging industry]

The following use description and emission estimation was provided by the applicant:
The biocidal product WESSOCLEAN GOLD LINE is intended to be used for the surface disinfection of conveyor lines, transport and storage boxes for potatoes, fruits, vegetables and plants. Direct contact to potatoes, fruits, vegetables or plants is excluded. The disinfection of storage boxes is carried out in disinfection and storage halls. The halls are individual plants which stand separately. In general, a hall is divided into separated cells (max. 300 m³), which have different capacities. The disinfection is carried out in a separate disinfection enclosure/ chamber (3 - 5 m³) in such a cell of the hall (see Figure 1). For the disinfection, the conveyor lines, transport and storage boxes are transported

into the disinfection enclosure/ chamber, where the biocidal product is sprayed via a misting nozzle using compressed air (working pressure 4 - 5 bar) on the equipment for a period of 30 minutes. After the disinfection process, the wet transport equipment is transferred further into the cell and is left to dry. After that, the ventilation is started and the air in this room is replaced by means of an exhaust system. As worst case the rapid degradation of the substances is not considered in the calculation of the ventilation time.

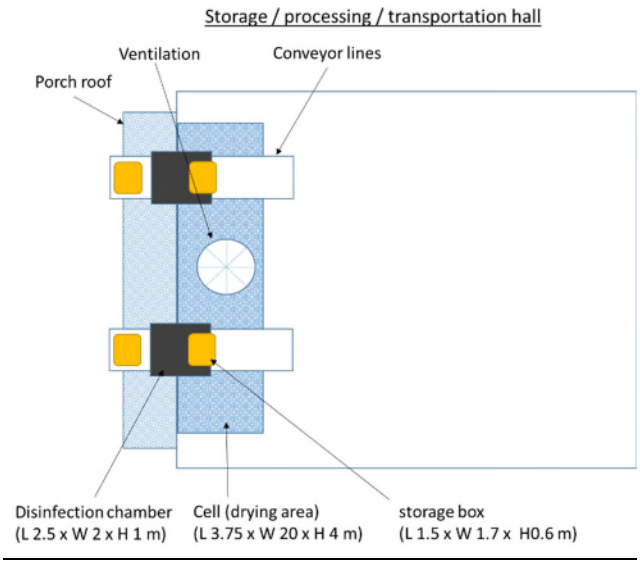


Figure 1: Structure of a hall which disinfection of storage boxes is carried out

The following two pictures shows the disinfection enclosures/ chambers.

Picture 1: **fixed disinfection enclosure (open) in the disinfection cell**

Picture 2: **mobile disinfection enclosure (closed)**

The environmental emission estimation is based on Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas, chapter 2.2 "Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries", Table 10 (EN 2011) and TAB – ENV (February 2021) ENV-177. According to this emission model, the only emission pathways of a.s. into the environment is via waste water. The estimations are presented in the following table.

During the environmental risk assessment of the active substance propan-2-ol, it was assumed that 90 % of propan-2-ol is released to air and 10 % of the substance is released to water (AR 2014, eCA DE). According to the BPC opinion of propan-2-ol, the distribution between water and air should be re-evaluated in the frame of product authorisation. In case of propan-2-ol the evaporation of the SoC is facilitated by the relatively high vapour pressure. In the AR of propan-2-ol as well as in several PARs it is stated, that nearly the whole amount of the SoC applied is released to indoor air, which is emitted to the local outside air without deposition indoors. However, partial releases to sewer systems cannot be completely excluded for liquid products. Therefore, for the environmental risk assessment of the b.p. WESSOCLEAN GOLD LINE the propan-2-ol distribution to air (90 %) and waste water (10 %) used during the assessment of the active substance is maintained.

Table 45: Input and output values for local emissions of Use 3 – according to ESD for PT 4, Table 10, 2011 and TAB – ENV (Feb. 2021) ENV-177

Input	Symbol	Value	Unit	Remarks
Use 3: PT4: disinfection of surfaces in the vegetable/fruits/plants packaging industry				
Application rate of biocidal product	Vform	0.04	L/m³	according to SPC
Density of biocidal product	$RHO_{b.p.}$	1.0046	kg/L	according to chapter 2.2.2
Fraction of active substance or	F_{PAA}	0.0003		0.03 % w/w (according to SPC)

Substance of Concern in the biocidal product	F_{H2O2} $F_{propan-2-ol}$	0.0314 0.0252		3.143 % w/w (according to SPC) 2.52 % w/w (according to SPC)
Room volume to be disinfected	VOLUMEroom	150	m³	Default according TAB (Feb. 2021) – ENV-177
Fraction of substance disintegrated during or after application (before release to the sewage system)	Fdis	0	-	Default according ESD PT 4, Tab. 10
Fraction of substance eliminated due to on-site pre-treatment of the plant waste water	Felim	0	-	Default according ESD PT 4, Tab. 10
Fraction active substance (PAA and H_2O_2) released to waste water	$Fwater_{a.s.}$	1	-	Default according ESD PT 4, Tab. 10
Fraction of Substance of Concern (propan-2-ol) released to waste water	$Fwater_{SoC}$	0.1	-	(according to AR propan-2-ol (eCA DE, 2014))
Fraction of Substance of Concern (propan-2-ol) released to air	$Fair_{SoC}$	0.9	-	(according to AR propan-2-ol (eCA DE, 2014))
Output				
Concentration of active substance or Substance of Concern in the biocidal product: Peracetic acid Hydrogen peroxide Propan-2-ol	Cform	 0.3014 31.575 25.316	g/L	
Application rate of the active substance or Substance of Concern: Peracetic acid Hydrogen peroxide Propan-2-ol	Q_{appl}	 0.0121 1.2630 1.0126	g/m³	
Calculations				
Cform = $RHO_{b.p.}$ ● Fsubstance				
Q_{appl} = Vform ● Cform				

$Elocal_{water} = Q_{appl} \bullet VOLUMEroom \bullet (1-Fdis) \bullet (1-Felim) \bullet Fwater$
$Elocal_{air} = Q_{appl} \bullet VOLUMEroom \bullet (1-Fdis) \bullet Fair$

According to TAB – ENV (February 2021) ENV-39 ENV 39 and CAR Doc. II-B of PAA (eCA FI, 2015) the degradation in the sewer system should be considered and the following calculations based on assumption made in CAR:

$$M_{t1} = M_{t0} * EXP^{(-k * t1)}$$

M_{t1} = total amount of substance present at t 1 [kg]
M_{t0} = total amount of substance at t 0 [kg] (= $Elocal_{water}$)
k = rate constant ($ln2/DT_{50}$)
t 1 = time [h] = 1 hour residence time in the sewer system

At WG-III-2020 the relevant rate constants have been discussed and the following values have been concluded:

Peracetic acid:
k = 4.38 h^{-1}, calculated from the DT_{50} of 9.5 min at 12°C (refer to **Table 35**)

Hydrogen peroxide
k = 3.65 h^{-1}, calculated from the DT_{50} of 11.4 min at 12°C (refer to **Table 36**)

Calculations for Use 3

Table 46: Resulting local emission to relevant environmental compartments

Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Waste water	PAA: 1.808 x 10^{-3} kg/d SoC H_2O_2: 1.894 x 10^{-1} kg/d SoC Propan-2-ol: 1.519 x 10^{-2} kg/d	
Air	SoC Propan-2-ol: 1.367 x 10^{-1} kg/d	
STP	PAA: 2.265 x 10^{-5} kg/d SoC H_2O_2: 4.924 x 10^{-3} kg/d SoC Propan-2-ol: 1.519 x 10^{-2} kg/d	Degradation processes in sewer system have been considered for the active substances PAA and H_2O_2.

2.2.8.3.4 Calculated PEC values

As continuous release of waste water is assumed to the municipal STP, the effluent concentration is representative for the exposure of microorganisms in STP. Thus, PEC_{STP} (= $Clocal_{eff}$) according to equation 41, chapter 2.3.6.7, Guidance on the BPR, Vol. IV, Part B+C (2017). The estimation of the local PECs for the aquatic compartment includes PECs for surface water and sediment: $PEC_{local\_surfacewater}$ has been calculated according to equation 51, chapter 2.3.8.3, Guidance on the BPR, Vol. IV, Part B+C (2017) and as the PNEC values for sediment were calculated by the equilibrium partitioning method, the risk assessment for surface water and sediment will be equal. Thus, $PEC_{local\_sediment}$ according

to equation 53, chapter 2.3.7.4, Guidance on the BPR, Vol. IV, Part B+C (2017) has not been summarised in the following table.

According to the explanations in chapter 2.2.8.3.1 no estimation of the local PECs for the terrestrial compartment (includes PECs for soil and groundwater) are done.

Table 47: Overview of calculated PECvalues for application of WESSOCLEAN GOLD LINE (PT3 and PT4)

Summary table on calculated PEC values			
	PEC_{STP}	**PEC_{water}**	**PEC_{air}**
	[µg/L]	[µg/L]	[mg/m³]
Use 1+2 (PT3)			
PAA	8.27E-4	8.27E-5	4.12E-7
SoC H_2O_2	1.20E-1	1.20E-2	4.31E-5
SoC Propan-2-ol	4.95E0	4.95E-1	3.14E-4
Use 3 (PT4)			
PAA	1.12E-4	1.12E-5	-
SoC H_2O_2	1.63E-2	1.63E-3	-
SoC Propan-2-ol	6.05E-1	6.05E-2	3.80E-5

2.2.8.3.5 Non-compartment specific effects

Primary poisoning

Not relevant.

Secondary poisoning

Due to the hydrophilicity, negligible bioconcentration potential and rapid dissipation behaviour of the active substance and SoC, the risk of secondary poisoning is considered negligible in the aquatic and terrestrial compartment.

2.2.8.3.6 Aggregated exposure (combined for relevant emission sources)

An agreed guidance document for aggregated exposure assessment is not available, yet. Therefore, such an assessment was not conducted.

2.2.8.4 Risk characterisation

2.2.8.4.1 Aquatic compartment (including STP)

- ***Surface water***

The PEC/PNEC values for surface water are given in the table below for the active substances and SoC, as well as the summation for mixture toxicity assessment.

A separate risk assessment for sediment is not necessary, as adsorption potential of both active substances is very low, both substances were shown to degrade rapidly and the risk assessment for freshwater is considered to cover the risks for sediment.

Summary table on calculated PEC/PNEC values aquatic				
	PEC/PNEC PAA	**PEC/PNEC H_2O_2**	**PEC/PNEC Propan-2-ol**	**∑PEC/PNEC**
Scenario Use 1+2	1.20E-03	9.56E-04	1.75E-04	2.33E-03
Scenario Use 3	1.62E-04	1.30-E04	2.14E-05	3.13E-04

Conclusion: No unacceptable risks were identified for the aquatic compartment for the assessed uses of the b.p. WESSOCLEAN GOLD LINE.

- ***STP***

Summary table on calculated PEC/PNEC values				
	$PEC/PNEC_{STP}$ PAA	**$PEC/PNEC_{STP}$ H_2O_2**	**$PEC/PNEC_{STP}$ Propan-2-ol**	**∑$PEC/PNEC_{STP}$**
Scenario Use 1+2	1.62E-05	2.58E-05	4.95E-04	5.37E-04
Scenario Use 3	2.20E-06	3.50E-06	6.05-E05	6.62E-05

Conclusion: No unacceptable risks were identified for STP for the assessed uses of the b.p. WESSOCLEAN GOLD LINE.

2.2.8.4.2 Terrestrial compartment (Soil/Groundwater)

Risk assessment for the terrestrial compartment of active substance and SoCs was considered not to be necessary due to their distribution in sewage sludge below 0.1 % (see chapter 2.2.8.2.2).

2.2.8.4.3 Non-compartment specific effects

Primary poisoning
Not relevant.

Secondary poisoning
Not relevant.

Summary of environmental risk assessment

Tier 1. PEC/PNEC summation
In the table below the results of PEC/PNEC summation of the active substance and SoCs are given for all assessed environmental compartments.

Compartment	Sum of PEC/PNECs Use 1+2	Sum of PEC/PNECs Use 3
Aquatic (surface water)	2.33E-03	3.13E-04
STP	5.37E-04	6.62E-05

Conclusion:
According to tier 1 of mixture toxicity assessment, risks to the environment from the product are considered acceptable for all uses and all relevant environmental compartments.

2.2.8.4.4 PBT assessment

According to the active substance ARs peracetic acid (FI, 2016), hydrogen peroxide (FI, 2015) and propan-2-ol (DE, 2014) do not fulfil any of the PBT criteria, nor the POP criteria.

2.2.8.4.5 Endocrine disrupting properties

There are no indications for endocrine disrupting properties of the active substance or the SoCs.
The full composition of the product/BPF is listed in the Confidential Annex chapter 3.6 in the confidential annex. There are no indications that a non-active substance of the product may have endocrine disrupting properties on environmental non-target organisms based on the data provided by the applicant. Nonetheless, the eCA considered in its evaluation further information available on the non-active substances: None of the co-formulants is contained in the candidate list for substances of very high concern for authorisation (SVHC), the community rolling action plan (CoRAP) or the public activities coordination tool (PACT) according to Regulation (EU) 1907/2006 for potential environmental ED-hazards or ECHA's endocrine disruptor assessment list.

2.2.8.4.6 Summary of risk characterisation

Overall conclusion on the risk assessment for the environment of the product
The expected risks to the environment from the use of the product WESSOCLEAN GOLD LINE are considered acceptable for all uses and all relevant environmental compartments.

2.2.9 Measures to protect man, animals and the environment

Please see the relevant chapters of the product evaluation and the Summary of Product Characteristics (SPC).

2.2.10 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

2.2.11 Comparative assessment

No candidate for substitution was identified (see chapter 2.1.2.2), hence a comparative assessment is not necessary.

3 Annexes[11]

3.1 List of studies for the biocidal product

Table 48

11 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	3.1	Appearance of WESSOCLEAN GOLD LINE	[redacted]	2017	WESSO AG
2	3.3	WESSOCLEAN GOLD LINE / WESSOCLEAN GREEN LINE, T=0 Determination of Relative Density (L 142 A/21-25 (A.3.)) Report-No.: 17-13244	[redacted]	2017	WESSO AG
3	3.4.1.2	Biocidal products WESSOCLEAN GOLD LINE and WESSOCLEAN GREEN LINE Study outline: Determination of Physico-chemical properties and Long term storage test at ambient temperature in commercial packaging	[redacted]	2017	WESSO AG
4	3.4.1.2	Preliminary report of analysis Report-No.: 17-13244	[redacted]	2017	WESSO AG
5	3.4.1.2	Vorläufiges Analysenergebnis Report-No.: 17-13244	[redacted]	2017	WESSO AG
6	3.4.1.2	Preliminary report of analysis (t=3 months) Report-No.: 17-13244	[redacted]	2017	WESSO AG
7	3.4.1.2	Preliminary report of analysis (t=6 months) Report-No.: 18-00531	[redacted]	2018	WESSO AG
8	3.4.1.2	Final report_ Report on the results of stability study of the test item GOLD LINE/GREEN LINE of analysis Report-No.: 18-00531	[redacted]	2018	WESSO AG
9	3.8	Determination of the Surface Tension (EEC A.5) of the test item WESSOCLEAN GOLD LINE / WESSOCLEAN GREEN LINE, T=0	[redacted]	2017	WESSO AG

10	3.9	WESSOCLEAN GOLD LINE / WESSOCLEAN GREEN LINE, T=0 Determination of Viscosity (OECD Guideline 114)	[redacted]	2017	WESSO AG
11	4.6	Determination of the Flash Point (EEC A.9.) of the test item WESSOCLEAN GOLD LINE / WESSOCLEAN GREEN LINE	[redacted]	2017	WESSO AG
12	4.16	Determination of Corrosion to Metals for WESSOCLEAN GOLD LINE EU Report-No.: Mo6329	[redacted]	2018	WESSO AG
13	5.1	Determination of Hydrogen Peroxide and Peroxoacetic Acid via Iodometrie Titration in GOLD LINE/GREEN LINE according to SANCO 3030/99 rev. 4 Report-No.: 32MV17001.01	[redacted]	2017	WESSO AG
14	5.1	Determination of Ethanol and 2-Propanol in GOLD LINE I GREEN LINE via Gas Chromatography according SANC0/3030/99 rev. 4 Report-No.: 21 MV17001.E1	[redacted]	2017	WESSO AG
15	6.7	Test report 19-01154-2 on the fungicidal efficacy of Wessoclean Gold Line Report-No.: 19-01154-2	[redacted]	2019	WESSO AG

3.2 List of studies for the active substance(s)

Peracetic acid

- The applicant has access to the data from the active substance approval (see chapter 2.1.5.2 for details).

Access to data from active substance approval

The applicant provided a letter of access to the dossier assessed for the approval of the active substance Peracetic acid for use in Veterinary Hygiene (product-type 3)and food and feed area (product-type 4) disinfectants. Please, refer to the corresponding Assessment Report for a reference list.

3.3 New information on the active substance

New information on the active substance were not provided.

3.4 Output tables from exposure assessment tools

Output tables from human health exposure assessment tools

Safety for professional users

The following file is containing all relevant parameter for exposure assessment, the activity coefficients calculated with AIOMFAC and the results of exposure assessment.

Output exposure assessment.xlsx

Confidential annex

Refer to separate document.