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)

AEROCLEAN

Product types 2, 3 & 4

L-(+)-lactic acid and Hydrogen Peroxide

Case Number in R4BP: BC-ND051407-48

Evaluating Competent Authority: FR

Date: July 2023

Table of Contents

1 CONCLUSION

AEROCLEAN is a soluble concentrate biocidal product containing L-(+)-lactic acid and hydrogen peroxide as active substances. The product is used as PT2, PT3 and PT4 disinfectants of surfaces and equipments by professional users.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore may be authorised for the following uses:

- Airborne disinfection of empty greenhouses and empty material shelters
- Airborne disinfection of eggs storage rooms (not intended for human consumption)
- Airborne disinfection of empty buildings (livestock buildings, veterinary clinic and adjoining animal rooms) and materials
- Airborne disinfection of breeding premises in the presence of animals
- Airborne disinfection of empty buildings and materials on surfaces in contact with food or feed

as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

Detailed information on the intended use(s) of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

The biocidal product does not contain any non-active substance (so called "co-formulant(s)") which is considered as a substance of concern.

The biocidal product should be considered not to have endocrine-disrupting properties.

The biocidal product does not contain any active substances having endocrine-disrupting properties.

Based on the available information, none of the non-active substances contained in the biocidal product is identified as having endocrine-disrupting properties according to Regulation (EU) 2017/2100. Any indications or alerts of co-formulants having ED properties should be further assessed in the frame of REACH Regulation. More detailed information is available in the confidential annex of the PAR.

Composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer of the biocidal product is listed in section 1.4 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substances in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturers of the active substances are listed in section 1.5 of the SPC.

Conclusions of the assessments for each area

The intended uses as applied for by the applicant have been assessed and the conclusions of the assessments for each area are summarised below.

Physico-chemical properties

Physical and chemical properties of the product AEROCLEAN have been described and are considered acceptable for a soluble concentrate for the intended uses.
A decrease of 58% of the content of L-(+)-lactic acid and 56% of the content of hydrogen peroxide are observed after 12 months of storage. An (eco)toxicological assessment of the degradation products formed during storage and an assessment of the efficacy of the aged product have been performed. No (eco)toxicological concern was identified for the formed degradation products and the aged product after a storage period of 17 months was still efficacious. Based on that, the shelf-life of the product has been set at 17 months.

The product should be protected away from direct sunlight and stored at a temperature below 25°C. It should be reported on the label "Foaming product: Do not agitate during mixing and loading to avoid foaming".

The product is neither flammable nor auto-flammable. It has no explosive, self-reactive and no oxidizing properties. It is classified as corrosive to metals Cat. 1 (H290).

The analytical methods for the determination of hydrogen peroxide and L-(+)-lactic acid in the product are considered acceptable.

Efficacy

Efficacy of the product AEROCLEAN has been demonstrated against bacteria, yeasts, fungi, enveloped viruses (PT2 and PT4) and viruses (PT3) in the conditions of use detailed in the SPC.

Efficacy is not demonstrated for the use #3 (PT3 – Airborne disinfection of incubators and hatcheries (including eggs) by natural evaporation) and for the mode of application by thermonebulisation for the uses # 1, #4 and #6.

Human health

Classification:

Classification is summarised in the following table:

Classification	Labelling specification/other information
Skin Corr. 1C	H314
Serious eye damage cat. 1	H318

The risk is acceptable for all uses for professional users considering the risk mitigation measures (RMM) and the use of personal/respiratory protective equipment (PPE/RPE) and for the general public considering the use of risk mitigation measures (RMM) listed below.

For uses of product AEROCLEAN by nebulization (uses 1, 2, 4, 5, 6), RMMs are the following

- To apply the product, use only automated nebulizer.
- Seal the treatment enclosure (e.g. with tape) to ensure that hydrogen peroxide levels outside the enclosure are kept at acceptable levels.
- During mixing, loading and cleaning of the device, the user has to wear gloves (EN 374), coverall (at least category III type 4, EN 14605+A1) and goggles.
- In case of skin contact, wash skin exposed.
- During the nebulization (treatment time), contact time (one hour) and during ventilation time, no person (operator, by-stander etc.) is allowed to be present within the treated area.
- After nebulisation and contact time, the room must be ventilated, preferably by mechanical ventilation. The duration of the ventilation period has to be established by measurement with suitable measurement equipment. Re-entry is only permitted once the hydrogen peroxide air concentration has dropped below 0,9ppm (1.25 mg/m3) or the corresponding national reference value.
- Use a calibrated sensor to confirm the hydrogen peroxide air concentration is ≤0.9 ppm (1.25 mg/m3) or below the corresponding national reference value prior to re-entry.
- The professional user may only enter the room in emergency situations or to reactivate the ventilation considering RPE with APF 40 against vapour (Type of RPE to be specified by the authorisation holder within the product information). The re-entry is therefore only possible when the hydrogen peroxide level has dropped below 36 ppm (50 mg/ m3) or below 40x the national reference value.
- Do not touch the surface until it is dried.

For use # 3 (Airborne disinfection of incubators and hatcheries by evaporation), RMM are the following

- During mixing and loading, the user has to wear gloves (EN 374), coverall (at least category III type 4, EN 14605+A1), goggles and a respiratory protective equipment min APF 4
- Do not open the hatchery / incubator after treatment and contact time before a ventilation period of:
    - 3h20 at ventilation rate of 2/h,
    - 50min at a ventilation rate of 8/h,
    - 23min at a ventilation rate of 18/h.
- Do not touch the surface until it is dried.

Animal health

Regarding the use in PT3 for the disinfection of breeding premises in presence of animals, the risk for animal health is not acceptable when the animals are present in the room/buildings during application. Therefore the following RMM is proposed in SPC for use # 5: "Only use in empty animal housing".

Moreover for this use and for airborne disinfection of empty buildings and materials (PT3) by cold or thermo nebulization, the risk for animal health is acceptable considering the same

re-entry period for animals than for people without RPE. The following RMM is proposed: Re-entry is only permitted for animals once the hydrogen peroxide air concentration has dropped below 0.9 ppm (1.25 mg/m^3) or the corresponding national reference value.

Indirect exposure via food

No specific residue data were submitted in the context of this dossier.
Regarding the intended uses of AEROCLEAN for the disinfection of empty buildings and materials on surfaces in contact with food or feed (PT4), the disinfection of eggs storage rooms, empty buildings (livestock buildings, veterinary clinic and adjoining animal rooms) and materials and the disinfection of breeding premises in the presence of animals (PT3), residues in food, feed, eggs, milk or drinking water might be expected.
Nevertheless, based on the low concentration of L-(+)-lactic acid, the endogenous production, and compared to naturally occurring levels in food, significant indirect exposure via the intended uses is not expected.
Considering the properties of hydrogen peroxide, no significant exposure via food is expected.

Environment

Following the application of the product AEROCLEAN by professional users for airborne disinfection for PT2, 3 and 4, risks are acceptable for all the environmental compartments and for all the uses presented in SPC.

Overall conclusion

According to the assessment performed for the biocidal product AEROCLEAN, conclusions are given for the following uses considering the appropriate instruction of uses and risk mitigation measures, as indicated in the SPC and summarized above in the dedicated section.
Lines highlighted in grey correspond to the uses that are not proposed for authorisation:

Uses		Physical hazard properties	Efficacy	Human health	Animal health	Indirect exposure via food	Environment
1	Airborne disinfection of empty greenhouses and empty material shelters Application by professional users - by cold nebulisation - by thermonebulisation	**Acceptable**	**Acceptable** Except for application by thermonebulisation	**Acceptable**	**Acceptable**	**Acceptable**	**Acceptable**
2	Airborne disinfection of eggs storage rooms (not intended for human consumption) Application by professional users by cold nebulisation	**Acceptable**	**Acceptable** Only in the absence of eggs during treatment	**Acceptable**	**Acceptable**	**Acceptable**	**Acceptable**
3	Airborne disinfection of incubators and hatcheries Application by professional users by evaporation	**Acceptable**	**Non acceptable** Efficacy was not demonstrated	**Acceptable**	**Acceptable**	**Acceptable**	**Acceptable**
4	Airborne disinfection of empty buildings (livestock buildings, veterinary clinic, adjoining animal rooms) and materials Application by professional users - by cold nebulisation - by thermonebulisation	**Acceptable**	**Acceptable** Except for application by thermonebulisation	**Acceptable**	**Acceptable**	**Acceptable**	**Acceptable**

5[1]	Airborne disinfection of breeding premises in presence of animals Application by professional users - by cold nebulization	**Acceptable**	**Acceptable**	**Acceptable**	**Acceptable** Only in the absence of animals during treatment	**Acceptable**	**Acceptable**
6	Airborne disinfection of empty buildings and materials on surfaces in contact with food or feed Application by professional users - by cold nebulisation - by thermonebulisation	**Acceptable**	**Acceptable** Except for application by thermonebulisation	**Acceptable**	**Acceptable**	**Acceptable**	**Acceptable**

[1] As use 5 becomes similar to use 4 considering the required restriction for the application of the product i.e. the treatment shall only be performed in the absence of animal, use 5 will be deleted from the SPC

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)**
AEROCLEAN	European Union
AIRNAPUR	European Union
EGGOA	European Union
FUMICLEAN	European Union
FOGAIR	European Union
ASEPTOL AIR	European Union
SEPTOKAIR	European Union
NEBULAIR	European Union
OXIR	European Union
KLEANSAIR	European Union

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	HUVEPHARMA SA
	Address	34, rue Jean Monnet ZI d'Etriché 49500 Segré-en-Anjou Bleu France
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer	HUVEPHARMA SA
Address of manufacturer	12 rue de Malacussy 42100 Saint Etienne France
Location of manufacturing sites	12 rue de Malacussy 42100 Saint Etienne France

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

Active substance	L-(+)-lactic acid
Name of manufacturer	Jungbunzlauer S.A.
Address of manufacturer	Z.I. et Portuaire BP 32 67390 Mackolsheim France
Location of manufacturing sites	Z.I. et Portuaire BP 32 67390 Mackolsheim France

Active substance	L-(+)-lactic acid
Name of manufacturer	PURAC Biochem
Address of manufacturer	Arkelsedijk 46, 4206 AC Gorinchem P.O. Box 21, 4200 AA Gorinchem Netherlands
Location of manufacturing sites	Arkelsedijk 46, 4206 AC Gorinchem P.O. Box 21, 4200 AA Gorinchem Netherlands

Active substance	Hydrogen peroxide
Name of manufacturer	ARKEMA France
Address of manufacturer	420 rue d'Estienne d'Orves 92705 Colombes FRANCE
Location of manufacturing sites	RN 85, BP1 38560 Jarrie FRANCE

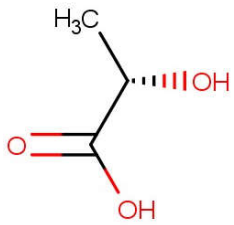
2.1.2 Product composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	L-(+)-lactic acid
IUPAC or EC name	(*S*)-2-Hydroxypropionic acid
EC number	201-196-2
CAS number	79-33-4
Index number in Annex VI of CLP	607-743-00-5
Minimum purity / content	95,5 %
Structural formula	

Main constituent(s)	
ISO name	Hydrogen peroxide
IUPAC or EC name	hydrogen peroxide
EC number	231-765-0
CAS number	7722-84-1
Index number in Annex VI of CLP	008-003-00-9
Minimum purity / content	99,5%
Structural formula	

2.1.2.2 Candidate(s) for substitution

Not relevant

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 (%)
L-(+)-lactic acid	2-Hydroxypropanoic acid	Technical active substance*	79-33-4	201-196-2	5,23
Content in the biocidal product of the TK containing the active substance					6,25
Hydrogen peroxide H_2O_2	Hydrogen peroxide	Technical active substance*	7722-84-1	231-765-0	7,54
Content in the biocidal product of the TK containing the active substance					15,0

* Based on the minimum purity of active substance: 95,5% w/w for L (+) Lactic acid (dry weight basis) and 99,5% for Hydrogen peroxide (dry weight basis).

2.1.2.4 Information on technical equivalence

The three active substance suppliers are listed in the Union list of approved active substances under Regulation No. 585/2012.

L-(+)-lactic acid from PURAC Biochem and Hydrogen peroxide from ARKEMA France do not need technical equivalence as these two suppliers were participant in the review program of the substances.

L-(+)-lactic acid from Jungbunzlauer S.A. was considered as technically equivalent to the European reference source for this active substance (decision n° TAP-D-1403137-31-00/F).

2.1.2.5 Information on the substance(s) of concern

Please see the confidential annex for further details.

2.1.2.6 Assessment of endocrine disruption (ED) properties of the biocidal product

The biocidal product contains the active substance L-(+)-lactic acid, which is not considered to have endocrine disrupting properties and the active substance Hydrogen peroxide which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

Based on the available information, no significant indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.
Please refer to the Confidential Annex for further details.

2.1.2.7 Type of formulation

SL: Soluble Concentrate

2.1.3 Hazard and precautionary statements[2]

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

Classification	
Hazard category	Met. Corr. 1 Skin corr.1C Serious eye damage cat.1
Hazard statement	H290: Corrosive to metals H314: Causes severe skin burns and eye damage H318: Causes serious eye damage
Labelling	
Signal words	Danger
Hazard statements	H290: Corrosive to metals H314: Causes severe skin burns and eye damage EUH 071: corrosive to the respiratory tract
Precautionary statements	P234: Keep only in original packaging P260: Do not breathe vapours/spray. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331+P310: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a Poison Centre/Doctor. P303+P361+P353+P310: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower. Immediately call a Poison Centre/Doctor. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing P305+P351+P338+P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. Immediately call a Poison Centre/Doctor. P321: Specific treatment (see ... on this label). P363: Wash contaminated clothing before reuse P390: Absorb spillage to prevent material damage. P405: Store locked up. P406: Store in a corrosion-resistant container. P501: Dispose of contents/container in accordance with local regulation
Note	-

2 For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Airborne disinfection of empty greenhouses and empty material shelters

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeasts Fungi Enveloped viruses
Field of use	Indoor, Disinfection of non-porous surfaces of empty visibly clean greenhouses and empty material shelters.
Application method(s)	Cold nebulization in large enclosures (> 4 m^3) up to 300m^3
Application rate(s) and frequency	Dose of pure product to be used: • Bacteria, yeasts : 5 ml/m^3 • Enveloped viruses : 5,2 ml/m^3 • Fungi: 10 ml/m^3 Before application, the product needs to be diluted in water at a concentration ranged from 25% to 100% v/v of pure AEROCLEAN depending on the volume to be treated. To reach the required dose (e.g. 5 ml pure product /m^3 for bacteria and yeasts), the application rate of the diluted product has to be adapted according to the dilution factor (e.g. for a solution of 25 %v/v AEROCLEAN, 20 ml of diluted product/m^3 have to be applied against bacteria and yeast)*. Temperature: room temperature Minimum contact time[3]: 1 hour Range of median droplet diameters: 7 to 30 µm One application to be done at each sanitation period of empty buildings.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE (High Density Polyethylene) can of 1 litre with degassing cap HDPE can of 5 litres with degassing cap HDPE can of 20 litres with degassing cap HDPE drum of 200 litres with degassing cap

2.1.4.2 Use-specific instructions for use

- The product should only be used on visually clean surfaces when applied in greenhouses.

[3] Corresponds to the dwell phase defined as the contact time required to obtain the expected level of efficacy (vol II parts B&C: November 2022, §5.4.2.5.2).

- The contact time starts when the required total volume of pure product (see application rate) is nebulized.
- Efficacy on porous surfaces has not been demonstrated.
- As an example, the product has been demonstrated as efficacious against fungi (via efficacy studies performed according to the EN17272 standard) with a flow rate of 293,3 ml/min (i.e. 17,6 litre/hour) and at 38,8 ml diluted product (at 25% v/v) per cubic meter of room volume at room temperature.

2.1.4.3 Use-specific risk mitigation measures

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

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

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

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2.1.4.7 Use description

Table 2. Use # 2 – Airborne disinfection of eggs storage rooms (not intended for human consumption)

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses
Field of use	Indoor Disinfection of non-porous surfaces of empty eggs storage rooms (not intended for human consumption)
Application method(s)	Cold nebulization in large enclosure (> 4 m^3) up to 150m^3
Application rate(s) and frequency	Dose of pure product to be used: Bacteria, yeasts, fungi, viruses : 13,2 ml/m^3 Before application, the product needs to be diluted in water at a concentration of 33% v/v of pure AEROCLEAN in order to apply 40 ml of diluted product/m^3*.

	Minimum contact time: 1 hour Temperature: 20°C Range of median droplet diameters: 7 to 30 µm Repeat before each new egg arrival in the room.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE can of 1 litre with degassing cap HDPE can of 5 litres with degassing cap HDPE can of 20 litres with degassing cap HDPE drum of 200 litres with degassing cap

2.1.4.8 Use-specific instructions for use

- Efficacy on porous surfaces has not been demonstrated.
- The product is not intended to disinfect eggs.
- The contact time starts when the required total volume of pure product (see application rate) is nebulized.
- As an example, the product has been demonstrated as efficacious against fungi (via efficacy studies performed according to the EN17272 standard) with a flow rate of 298,8 ml/min (i.e. 17,93 litre/hour) and at 40 ml diluted product (at 33% v/v) per cubic meter of room volume at room temperature.

2.1.4.9 Use-specific risk mitigation measures

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

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

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

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2.1.4.13 Use description

Use # 3 is not proposed for authorisation

2.1.4.14 Use description

Table 4. Use # 4 – Airborne disinfection of empty buildings (livestock buildings, veterinary clinic and adjoining animal rooms) and materials

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses
Field of use	Indoor, Disinfection of non-porous surfaces of empty buildings (livestock buildings, veterinary clinic, adjoining animal rooms) and materials.
Application method(s)	Cold nebulization in large enclosures (> 4 m^3) up to 300m^3
Application rate(s) and frequency	Dose of pure product to be used: • Bacteria and yeasts: 5 ml/m^3 • Viruses: 5,2 ml/m^3 • Fungi: 10 ml/m^3 Before application, the product needs to be diluted in water at a concentration ranged from 25% to 100% v/v of pure AEROCLEAN depending on the volume to be treated. To reach the required dose (e.g. 5 ml pure product / m^3 for bacteria and yeasts) the application rate of the diluted product has to be adapted according to the dilution factor (e.g. for a solution of 25% v/v AEROCLEAN, 20 ml diluted product/m^3 have to be applied against bacteria and yeast)*. Minimum contact time: 1 hour Temperature: 20°C Range of median droplet diameters: 7 to 30 µm One application to be done at each sanitation period of empty buildings.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE can of 1 litre with degassing cap HDPE can of 5 litres with degassing cap HDPE can of 20 litres with degassing cap HDPE drum of 200 litres with degassing cap

2.1.4.15 Use-specific instructions for use

- Clean surfaces before disinfection.
- Efficacy on porous surfaces has not been demonstrated.
- The contact time starts when the required total volume of pure product (see application rate) is nebulized.
- As an example, the product has been demonstrated as efficacious against fungi (via efficacy studies performed according to the EN17272 standard) with a flow rate of 293,3 ml/min (i.e. 17,07 litre/hour) and at 40 ml diluted product (at 25% v/v) per cubic meter of room volume at room temperature.
- Only use in empty animal housing.

2.1.4.16 Use-specific risk mitigation measures

- Re-entry is only permitted for animals once the hydrogen peroxide air concentration has dropped below 0.9 ppm (1.25 mg/m^3) or the corresponding national reference value.

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

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

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

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2.1.4.20 Use description

Table 5. Use # 5 – Airborne disinfection of breeding premises[4]

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeasts Viruses
Field of use	Indoor, Disinfection of non-porous surfaces of buildings
Application method(s)	Cold nebulization in large enclosures (> 4 m^3) up to 300m^3
Application rate(s) and frequency	Dose of pure product : • Bacteria, yeasts and viruses: 8,2 ml/m^3 Before application, the product needs to be diluted in water at a concentration of 23% v/v of pure AEROCLEAN, in order to apply 35,7 ml diluted product/m³*. Shut the building and stop air extraction. Apply the solution and let it act for 1 hour. Then open ventilation hatches and restart air extraction. Minimum contact time: 1 hour Temperature: 20°C

[4] As use 5 becomes similar to use 4 considering the required restriction for the application of the product i.e. the treatment shall only be performed in the absence of animal, use 5 will be deleted from the SPC

	Range of median droplet diameters: 7 to 30 µmRepeat operation once a day maximum and not more than 2 days per week.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE can of 1 litre with degassing cap HDPE can of 5 litres with degassing cap HDPE can of 20 litres with degassing cap HDPE drum of 200 litres with degassing cap

2.1.4.21 Use-specific instructions for use

- Efficacy on porous surfaces has not been demonstrated.
- The contact time starts when the required total volume of pure product (see application rate) is nebulized.
- As an example, the product has been demonstrated as efficacious against bacteria (via efficacy studies performed according to the EN17272 standard) with a flow rate of 320,3 ml/min (i.e. 19,22 litre/hour) and at 35.7 ml diluted product (at 23% v/v) per cubic meter of room volume at room temperature.

2.1.4.22 Use-specific risk mitigation measures

- Only use in empty animal housing.
- Re-entry is only permitted for animals once the hydrogen peroxide air concentration has dropped below 0.9 ppm (1.25 mg/m^3) or the corresponding national reference value.

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

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

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

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2.1.4.26 Use description

Table 6. Use # 6 – Airborne disinfection of empty buildings and materials on surfaces in contact with food or feed

Product Type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	

Target organism (including development stage)	Bacteria Yeasts Fungi Enveloped viruses only
Field of use	Indoor, Disinfection of non-porous surfaces of empty buildings and materials in feed or food industries
Application method(s)	Cold nebulization in large enclosures (> 4 m^3) up to 300m^3
Application rate(s) and frequency	Dose of pure product to be used: • Bacteria, yeasts : 5 ml/m^3 • Enveloped viruses : 5,2 ml/m^3 • Fungi: 10 ml/m^3 Before application, the product needs to be diluted in water at a concentration ranged from 25% to 100% v/v of pure AEROCLEAN depending on the volume to be treated. To reach the required dose (e.g. 5 ml pure product/m^3 for bacteria and yeasts) the application rate of the diluted product has to be adapted according to the dilution factor (e.g. for a solution of 25% v/v AEROCLEAN, 20 ml diluted product/m^3 have to be applied against bacteria and yeast)*. Minimum contact time: 1 hour Temperature: room temperature Range of median droplet diameters: 7 to 30 µm One application to be done at each sanitation period of empty buildings.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE can of 1 litre with degassing cap HDPE can of 5 litres with degassing cap HDPE can of 20 litres with degassing cap HDPE drum of 200 litres with degassing cap

2.1.4.27 Use-specific instructions for use

- Efficacy on porous surfaces has not been demonstrated.
- The contact time starts when the required total volume of pure product (see application rate) is nebulized.
- As an example, the product has been demonstrated as efficacious against fungi (via efficacy studies performed according to the EN17272 standard) with a flow rate of 293,3 ml/min (i.e. 17,6 litre/hour) and at 38,8 ml diluted product (at 25% v/v) per cubic meter of room volume at room temperature.

2.1.4.28 Use-specific risk mitigation measures

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

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

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

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2.1.5 General directions for use

2.1.5.1 Instructions for use

- Follow the instructions of the equipment suppliers to obtain a sufficient diffusion time. - The users should inform if the treatment is ineffective and report straightforward to the registration holder. - The product has been demonstrated as efficacious (via efficacy studies performed according to the EN17272 standard) with a flow rate of 268,3 to 340 ml/min (i.e. 16,1-20,4 L/H). - Biological validation shall be performed for each room to be disinfected (or in a suitable "standard" room in a facility, if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter.

2.1.5.2 Risk mitigation measures

- To apply the product, use only automated nebulizer. - Seal the treatment enclosure (e.g. with tape) to ensure that hydrogen peroxide levels outside the enclosure are kept at acceptable levels. - During mixing and loading and cleaning of the device, the user has to wear gloves (EN 374), coverall (at least category III type 4, EN 14605+A1) and goggles. - In case of skin contact, wash skin exposed. - During the nebulization (treatment time), contact time (one hour) and during ventilation time, no person (operator, by-stander etc.) is allowed to be present within the treated area. - After nebulisation and contact time, the room must be ventilated, preferably by mechanical ventilation. The duration of the ventilation period has to be established by measurement with suitable measurement equipment. Re-entry is only permitted once the hydrogen peroxide air concentration has dropped below 0,9ppm (1,25 mg/m^3) or the corresponding national reference value. - Use a calibrated sensor to confirm the hydrogen peroxide air concentration is ≤0,9 ppm (1,25 mg/m^3) or below the corresponding national reference value prior to re-entry. - The professional user may only enter the room in emergency situations or to reactivate the ventilation considering RPE with APF 40 against vapour (Type of RPE to be specified by the authorisation holder within the product information). The re-entry is therefore only possible when the hydrogen peroxide level has dropped below 36 ppm (50 mg/ m^3) or below 40x the national reference value.

- Do not touch the surface until it is dried.

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

- IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.
- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.
- IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.
- In case of impaired consciousness place in recovery position and seek medial advice immediately.

2.1.5.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
- Dispose of unused product, its packaging and all other waste in accordance with local regulations.

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

- Protect from direct sunlight
- Do not store above 25°C
- Shelf life: 17 months

2.1.6 Other information

- Foaming product: Do not agitate during mixing and loading to avoid foaming.

Full titles of EN standards and legislation referred to in section 5.2:
EN 374 – Protective gloves against dangerous chemicals and micro-organisms.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional,	Compatibility of the product with the proposed

				non-professional)	**packaging materials (Yes/No)**
Jerry can	1 litre, 5 litres, 20 litres	Opaque HDPE (High Density Polyethylene)	Degassing HDPE cap	Professional	Yes
Drum	200 litres	Opaque HDPE (High Density Polyethylene)	Degassing HDPE cap	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Physico-chemical properties studies and analytical methods on the biocidal product AEROCLEAN are provided in the application dossier by Laboratoire MERIEL.
Studies submitted to demonstrate the efficacy of the product AEROCLEAN are listed in the reference list in section 3.1.
Studies submitted for the human health classification of the product AEROCLEAN are listed in the reference list in section 3.1.

2.1.8.2 Access to documentation

For the L-(+)-lactic acid active substance, the analytical method belongs to an external laboratory named CHELAB. The method has been provided directly to the authorities.

2.2 Assessment of the biocidal product

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

Table 7. Intended use # 1 – Airborne disinfection of empty buildings, empty rooms, and equipment for industries, amenities, sanitation facilities, greenhouses and storage buildings

Product Type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Disinfection of empty buildings, empty rooms, and equipment for industries, amenities, sanitation facilities, greenhouses and storage buildings.
Target organism (including development stage)	Scientific name: Enterococcus hirae Common name: Bacteria aerobic Gram positive Development stage: Scientific name: Pseudomonas aeruginosa Common name: Bacteria, aerobic Gram-negative Development stage: Scientific name: Escherichia coli Common name: Bacteria aerobic Gram-negative Development stage: no Scientific name: Staphylococcus aureus Common name: Bacteria aerobic Gram positive Development stage: Scientific name: Aspergillus brasiliensis Common name: Fungi Development stage: Scientific name: Candida albicans Common name: Yeast Development stage: Scientific name: Vaccinia Ankara virus Common name: Enveloped viruses Development stage:
Field of use	Indoor
Application method(s)	Nebulization for building up to 300m^3 and thermonebulisation for buildings up to 1000m^3 (per application device) Dose to be used: • For bacteria, yeast and enveloped viruses: 5 ml of pure product per cubic meter. • For fungi: 10 ml of pure product per cubic meter. Prepare a solution in water at a concentration between 25% up to 100% of pure AEROCLEAN, depending on the volume to be treated*. One application to be done at each sanitation period of empty buildings.

<table>
<tr><td></td><td>
Respect a contact time of minimum 1 hour for cold nebulization and 3 hours for thermonebulisation at 18 to 20°C

Before entering the disinfected room/building respect a waiting time depending of active ventilation of the building after treatment–see table below:
<table>
<tr><td>Air renewal rate</td><td>Waiting time before entering after treatment – without PPE</td><td>Waiting time before entering after treatment – with PPE = FFP2 mask</td></tr>
<tr><td>>2.5 volumes per hour</td><td>2h40</td><td>1h</td></tr>
<tr><td>>10 volumes per hour</td><td>40 minutes</td><td>25 minutes</td></tr>
<tr><td>>20 volumes per hour</td><td>20 minutes</td><td>12 minutes</td></tr>
</table>

Example of dilution for a dose of 5ml/m3 using one application device:
<table>
<tr><td>way to apply</td><td>Nebuli-zation</td><td>Nebuli-zation</td><td>thermo fogging</td><td>thermo fogging</td></tr>
<tr><td>volume to treat in m3</td><td>100 m3</td><td>300 m3</td><td>600 m3</td><td>1000 m3</td></tr>
<tr><td>dilution of product</td><td>33%</td><td>50%</td><td>50%</td><td>80%</td></tr>
<tr><td>quantity of pure product needed at 5ml/m3</td><td>0.5 L</td><td>1.5 L</td><td>3 L</td><td>5 L</td></tr>
<tr><td>quantity of water</td><td>1 L</td><td>1.5 L</td><td>3 L</td><td>1.25 L</td></tr>
<tr><td>total quantity of solution to apply</td><td>1.5 L</td><td>3 L</td><td>6 L</td><td>6.25 L</td></tr>
</table>

*biological validation shall be performed for each room to be disinfected (or in a suitable "standard" room in a facility, if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter.
</td></tr>
<tr><td>Application rate(s) and frequency</td><td>5 or 10 ml of pure product per cubic meter depending on the target – with a minimum contact time of 1 hour by nebulization and 3h by thermonebulisation
One application to be done at each sanitation period of empty buildings/ rooms.</td></tr>
<tr><td>Category(ies) of user(s)</td><td>Professional</td></tr>
<tr><td>Pack sizes and packaging material</td><td>HDPE can of 1 L with degassing cap
HDPE can of 5 L with degassing cap
HDPE can of 20 L with degassing cap
HDPE drum of 200 L with degassing cap</td></tr>
</table>

Table 8. Intended use # 2 – Airborne disinfection of eggs storage rooms

Product Type(s)	PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use	Disinfection of eggs storage rooms.
Target organism (including development stage)	Scientific name: Enterococcus hirae Common name: Bacteria aerobic Gram positive Development stage: Scientific name: Proteus vulgaris Common name: Bacteria aerobic Gram-negative Development stage: Scientific name: Escherichia coli Common name: Bacteria aerobic Gram-negative Development stage: Scientific name: Pseudomonas aeruginosa Common name: Bacteria, aerobic Gram-negative Development stage: Scientific name: Staphylococcus aureus Common name: Bacteria aerobic Gram positive Development stage: Scientific name: Candida albicans Common name: Yeast Development stage: Scientific name: Bovine Enterovirus type 1 (ECBO) Common name: entero Virus Development stage: Scientific name: Aspergillus brasiliensis Common name: Fungi Development stage:
Field of use	Indoor
Application method(s)	Nebulization for buildings up to 150m3 (per application device) Dose to be used: • 8 ml of pure product per cubic meter for bactericidal yeasticidal and virucidal activity • 13ml/m3 for fungicidal activity Prepare a 20% to 33% solution concentration of AEROCLEAN in water and apply the solution*. Example : nebulise 50 ml/ m3 of a 20% solution nebulise 25 ml/m3 of a 33% solution Apply the product* and let it act for 1 hour minimum at 20°C. Before entering the disinfected rooms, ventilate the room actively respecting a flow greater than 20 air volumes renewal per hour and respect a waiting time of 20 minutes

	*biological validation shall be performed for each room to be disinfected (or in a suitable "standard" room in a facility, if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter.
Application rate(s) and frequency	8 ml of pure product per cubic meter for bactericidal yeasticidal and virucidal activity and 13ml/m3 for fungicidal activity with a minimum contact time of 1 hour. Repeat at each new egg arrival in the room.
Category(ies) of user(s)	Professional
Pack sizes and packaging material	HDPE can of 1 L with degassing cap HDPE can of 5 L with degassing cap HDPE can of 20 L with degassing cap HDPE drum of 200 L with degassing cap

Table 9. Intended use # 3 – Airborne disinfection of incubators and hatcheries

Product Type(s)	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Disinfection of hatching eggs, incubators and hatcheries
Target organism (including development stage)	Scientific name: Enterococcus hirae Common name: Bacteria aerobic Gram positive Development stage: Scientific name: Proteus vulgaris Common name: Bacteria aerobic Gram-negative Development stage: Scientific name: Staphylococcus aureus Common name: Bacteria aerobic Gram positive Development stage: Scientific name: Escherichia coli Common name: Bacteria Development stage: Scientific name: Pseudomonas aeruginosa Common name: Bacteria, aerobic Gram-negative Development stage: Scientific name: Candida albicans Common name: Yeast Development stage: Scientific name: Aspergillus brasiliensis Common name: Fungi Development stage: Scientific name: Bovine Enterovirus type 1 (ECBO) Common name: entero Virus Development stage:

Field of use	Indoor
Application method(s)	Evaporation in buildings up to 30m3 Dose to be used: 13 ml of pure product per cubic meter. Put 13 ml per cubic meter of pure product in a large opening plate on the ground of incubator/hatchery* Let the product evaporates totally at 35°C to 38°C. Respect a contact time of 4 hours as a minimum. Before entering the disinfected rooms, ventilate the room actively respecting a flow greater than 20 air volumes renewal per hour and respect a waiting time of 20 minutes *biological validation shall be performed for each room to be disinfected (or in a suitable "standard" room in a facility, if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter.
Application rate(s) and frequency	13 ml of pure product per cubic meter. – 4h contact time Once at each loading eggs
Category(ies) of user(s)	Professional
Pack sizes and packaging material	HDPE can of 1 L with degassing cap HDPE can of 5 L with degassing cap HDPE can of 20 L with degassing cap HDPE drum of 200 L with degassing cap

Table 10. Intended use # 4 – Airborne disinfection of empty buildings and materials

Product Type(s)	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Disinfection of empty buildings (livestock buildings, veterinary clinic, adjoining animal rooms) and material.
Target organism (including development stage)	Scientific name: Proteus vulgaris Common name: Bacteria aerobic Gram negative Development stage: Scientific name: Pseudomonas aeruginosa Common name: Bacteria, aerobic Gram-negative Development stage: Scientific name: Enterococcus hirae Common name: Bacteria aerobic Gram-positive Development stage: Scientific name: Escherichia coli Common name: Bacteria, aerobic Gram-negative Development stage: Scientific name: Staphylococcus aureus Common name: Bacteria aerobic Gram-positive Development stage: Scientific name: Candida albicans Common name: Yeast

<table>
<tr><td></td><td>Development stage:

Scientific name: Aspergillus brasiliensis
Common name: Fungi
Development stage:

Scientific name: Bovine Enterovirus type 1 (ECBO)
Common name: entero -Virus
Development stage:</td></tr>
<tr><td>Field of use</td><td>Indoor</td></tr>
<tr><td>Application method(s)</td><td>Nebulization for buildings up to 300m3 and thermonebulisation for buildings up to 1000m3 (per application device)

Buildings must be cleaned before disinfection.
Dose to be used:
• For bacteria, yeast and viruses: 5 ml of pure product per cubic meter.
• For fungi: 10 ml of pure product per cubic meter.

Prepare a solution in water at a concentration between 25% up to 100% of pure AEROCLEAN, depending on the volume to be treated*, and apply the solution on already cleaned surfaces. One application to be done at each sanitation period of empty buildings.
Respect a contact time of minimum 1 hour for cold nebulization and 3 hours for thermonebulisation at 18 to 20°C.

After treatment, with a standard active ventilation allowing 20 volumes of air renewal per hour, wait for 20 minutes before entering the disinfected building.

Example of dilution for a dose of 5ml/m3 using one application device:
<table><tr><td>way to apply</td><td>Nebuli-zation</td><td>Nebuli-zation</td><td>thermo fogging</td><td>thermo fogging</td></tr><tr><td>volume to treat in m3</td><td>100 m3</td><td>300 m3</td><td>600 m3</td><td>1000 m3</td></tr><tr><td>dilution of product</td><td>33%</td><td>50%</td><td>50%</td><td>80%</td></tr><tr><td>quantity of pure product needed at 5ml/m3</td><td>0.5 L</td><td>1.5 L</td><td>3 L</td><td>5 L</td></tr><tr><td>quantity of water</td><td>1 L</td><td>1.5 L</td><td>3 L</td><td>1.25 L</td></tr><tr><td>total quantity of solution to apply</td><td>1.5 L</td><td>3 L</td><td>6 L</td><td>6.25 L</td></tr></table>
*biological validation shall be performed for each room to be disinfected (or in a suitable "standard" room in a facility, if applicable) with the devices to be used after which a protocol</td></tr>
</table>

	for disinfection of these rooms can be made and used thereafter.
Application rate(s) and frequency	5 or 10 ml of pure product per cubic meter depending on the target. Once at each sanitation period.
Category(ies) of user(s)	Professional
Pack sizes and packaging material	HDPE 1 L can with a degassing cap HDPE 5 L can with a degassing cap HDPE 20 L can with a degassing cap HDPE 200 L drum with a degassing cap

Table 11. Intended use # 5 – Airborne disinfection of breeding premises in presence of animals

Product Type(s)	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Disinfection buildings in the presence of animals
Target organism (including development stage)	Scientific name: Enterococcus hirae Common name: Bacteria Development stage: Scientific name: Proteus vulgaris Common name: Bacteria Development stage: Scientific name: Escherichia coli Common name: Bacteria, aerobic Gram-negative Development stage: Scientific name: Pseudomonas aeruginosa Common name: Bacteria, aerobic Gram-negative Development stage: Scientific name: Staphylococcus aureus Common name: Bacteria Development stage: Scientific name: Candida albicans Common name: Yeasts Development stage: Scientific name: Bovine Enterovirus type 1 (ECBO) Common name: entero -Virus Development stage:
Field of use	Indoor
Application method(s)	Nebulization for buildings up to 300m3 (per application device) Dose to be used: 8 ml of pure product per cubic meter. Prepare a solution of AEROCLEAN concentrated at a maximum of 10% in water. Shut the building and stop air extraction.

	Apply the solution and let it act for 1 hour. Then open ventilation hatches and restart air extraction. Example : For a building of 400m² ground surface – i.e. 1200m3 - use 4 nebulizing devices. In total for the whole volume nebulize 96 Litres of a 10% solution. *biological validation shall be performed for each room to be disinfected (or in a suitable "standard" room in a facility, if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter.
Application rate(s) and frequency	8 ml of pure product per cubic meter. - Repeat operation once a day maximum and not more than 2 days per week.
Category(ies) of user(s)	Professional
Pack sizes and packaging material	HDPE can of 1 L with degassing cap HDPE can of 5 L with degassing cap HDPE can of 20 L with degassing cap HDPE drum of 200 L with degassing cap

Table 12. Intended use # 6 – Airborne disinfection of empty buildings and materials on surfaces in contact with food or feed

Product Type(s)	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Disinfection of empty buildings and materials in Feed or Food industries
Target organism (including development stage)	Scientific name: Pseudomonas aeruginosa Common name: Bacteria, aerobic Gram-negative Development stage: Scientific name: Enterococcus hirae Common name: Bacteria aerobic Gram-positive Development stage: Scientific name: Escherichia coli Common name: Bacteria aerobic Gram-negative Development stage: Scientific name: Staphylococcus aureus Common name: Bacteria aerobic Gram-positive Development stage: Scientific name: Candida albicans Common name: Yeast Development stage: Scientific name: Aspergillus brasiliensis Common name: Fungi Development stage:

<table>
<tr><td></td><td>Scientific name: Vaccinia virus
Common name: Poxvirus - Enveloped Virus
Development stage:</td></tr>
<tr><td>Field of use</td><td>Indoor</td></tr>
<tr><td>Application method(s)</td><td>Nebulization for buildings up to 300m3 and
Thermonebulisation for buildings up to 1000m3 (per application device)
Dose to be used:
• For bacteria, yeast and enveloped viruses: 5 ml of pure product per cubic meter.
• For fungi: 10 ml of pure product per cubic meter.

Prepare a solution in water at a concentration between 25% up to 100% of pure AEROCLEAN, depending on the volume to be treated, and apply the solution*.
Respect a contact time of minimum 1 hour for nebulization and 3 hours for thermonebulisation at 18 to 20°C.

Before entering the disinfected room/building respect a waiting time depending of active ventilation of the building after treatment –see table below:

<table>
<tr><td>Air renewal rate</td><td>Waiting time before entering after treatment – without PPE</td><td>Waiting time before entering after treatment – with PPE = FFP2 mask + protective goggles</td></tr>
<tr><td>>2.5 volumes per hour</td><td>2h40</td><td>1h40</td></tr>
<tr><td>>10 volumes per hour</td><td>40 minutes</td><td>25 minutes</td></tr>
<tr><td>>20 volumes per hour</td><td>20 minutes</td><td>12 minutes</td></tr>
</table>

Rinse surfaces with drinkable water is compulsory.

Example of dilution for a dose of 5ml/m3 using one application device:
<table>
<tr><td>way to apply</td><td>Nebuli-zation</td><td>Nebuli-zation</td><td>thermo fogging</td><td>thermo fogging</td></tr>
<tr><td>volume to treat in m3</td><td>100 m3</td><td>300 m3</td><td>600 m3</td><td>1000 m3</td></tr>
<tr><td>dilution of product</td><td>33%</td><td>50%</td><td>50%</td><td>80%</td></tr>
<tr><td>quantity of pure product needed at 5ml/m3</td><td>0.5 L</td><td>1.5 L</td><td>3 L</td><td>5 L</td></tr>
<tr><td>quantity of water</td><td>1 L</td><td>1.5 L</td><td>3 L</td><td>1.25 L</td></tr>
<tr><td>total quantity of solution to apply</td><td>1.5 L</td><td>3 L</td><td>6 L</td><td>6.25 L</td></tr>
</table>
</td></tr>
</table>

	*biological validation shall be performed for each room to be disinfected (or in a suitable "standard" room in a facility, if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter.
Application rate(s) and frequency	5 or 10 ml of pure product per cubic meter depending on the target. One application to be done at each sanitation period of empty buildings.
Category(ies) of user(s)	Professional
Pack sizes and packaging material	HDPE 1 L can with a degassing cap HDPE 5 L can with a degassing cap HDPE 20 L can with a degassing cap HDPE 200 L drum with a degassing cap

2.2.2 Physical, chemical and technical properties

AEROCLEAN is a soluble concentrate (SL) formulation containing L-(+)-lactic acid (5.0% w/w pure content) and hydrogen peroxide (7.5% w/w pure content). Products do not contain hydrocarbons or H304 co-formulant content above 10% w/w.

Use concentrations:
- Maximum use concentration: 100.0 % (v/v)
- Minimum use concentration: 23.0 % (v/v)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR-CA assessment
Physical state at 20 °C and 101.3 kPa	Visual observation	AEROCLEAN 5.0% w/w L-(+)-lactic acid 7.5% w/w hydrogen peroxide Batch n° 051218-1	Limpid clear and homogeneous liquid with menthol smell	[redacted] (2019) Stability study of AEROCLEAN Date: 24/04/19	Acceptable
Colour at 20 °C and 101.3 kPa	Visual observation				
Odour at 20 °C and 101.3 kPa	Olfactory test				
Acidity / alkalinity	CIPAC MT 75.3 CIPAC MT 31 and MT 191	AEROCLEAN 5.0% w/w L-(+)-lactic acid7.5% w/w hydrogen peroxide Batch n° 051218-1	Acidity: 2.08% as H_2SO_4	[redacted] (2019) Stability study of AEROCLEAN Date: 24/04/19	Acceptable
pH value	CIPAC MT 75.3	AEROCLEAN 5.0% w/w L-(+)-lactic acid 7.5% w/w hydrogen peroxide Batch n° 051218-1	pH of neat formulation at rt: 2.63 pH of 1% dilution at rt: 3.75	[redacted] (2019) Stability study of AEROCLEAN Date: 24/04/19	Acceptable

Relative density	OECD test guideline 109 – Densimeter Gibertini n°70259	AEROCLEAN 5.0% w/w L-(+)-lactic acid 7.5% w/w hydrogen peroxide Batch n° 051218-1	Relative density: D^{20}_4 = 1.042 ± 0.01 at 20 °C	[redacted] (2019) Stability study of AEROCLEAN Date: 24/04/19	Acceptable

<table>
<tr>
<td>Storage stability test – accelerated storage</td>
<td>CIPAC method MT46.3

Validated analytical method:
- $\underline{H_2O_2}$: Labo1006
- <u>Lactic acid:</u> AP-LABCHI-945</td>
<td>AEROCLEAN 5.0% w/w L-(+)-lactic acid 7.5% w/w hydrogen peroxide Batch n° 051218-1</td>
<td>AEROCLEAN was stored in 150 mL HDPE drums during 2 weeks at 54 °C:
<table>
<tr><th></th><th>Initial</th><th>After 2 weeks at 54°C</th></tr>
<tr><td>Colour and aspect</td><td>Limpid clear and homogeneous liquid with menthol smell</td><td>Cloudy liquid with menthol smell</td></tr>
<tr><td>Packaging</td><td colspan="2">150 mL HDPE drums with degassing cap with no crackle, leakage or ballooning</td></tr>
<tr><td>Packaging weight variation</td><td>-</td><td>No loss</td></tr>
<tr><td>pH of neat</td><td>2.6</td><td>2.5</td></tr>
<tr><td>pH of 1% dilution</td><td>3.747</td><td>3.65</td></tr>
<tr><td>Acidity (as H_2SO_4)</td><td>2.08%</td><td>2.42%</td></tr>
<tr><td>Relative density</td><td>1.042</td><td>1.031</td></tr>
<tr><td colspan="3">Active Substances</td></tr>
<tr><td>Lactic acid content (% w/w)</td><td>4.06%</td><td>2.44%</td></tr>
<tr><td>Lactate ion content (% w/w)*</td><td>0.69%</td><td>0.31%</td></tr>
<tr><td>Lactic acid eq content (% w/w)*</td><td>4.75%</td><td>2.75%</td></tr>
<tr><td>Lactic acid variation</td><td>-</td><td>- 39.9%</td></tr>
<tr><td>Lactic acid eq variation*</td><td>-</td><td>- 42.1%</td></tr>
<tr><td>H_2O_2 content (% w/w)</td><td>7.80% w/w</td><td>5.00% w/w</td></tr>
<tr><td>H_2O_2 variation</td><td>-</td><td>- 35.9%</td></tr>
<tr><td colspan="3">Co-formulant</td></tr>
<tr><td colspan="3">See Conf Annex</td></tr>
<tr><td colspan="3">Degradation product</td></tr>
<tr><td colspan="3">See Conf Annex</td></tr>
</table>
* Due to low pH value of the formulation (2.6), an equilibrium is formed between lactic acid and lactate (pka =3.90). The analytical method (AP-LABCHI-945) can only quantify the lactic acid content. However based on the dissociation constant definition, lactate ion content can be calculated. Lactic acid eq content is corresponding of the addition of the measured content in lactic acid and the calculated content in lactate ion.</td>
<td>(1) [redacted] (2019) Stability study of AEROCLEAN Date: 24/04/19

(2) [redacted] (2021) Stability study of AEROCLEAN Date: 22/06/2021</td>
<td>Non acceptable

A significant reduction in both active substances content is observed.

The product is not considered stable after 2 weeks at 54°C.

According to accelerated storage stability data, the product should not be stored at temperature higher than 30°C.</td>
</tr>
</table>

			Conclusion: Significant decrease (> 10%) for both active substances is observed. The product is not considered stable after a storage of 2 weeks at 54 °C. Therefore, the product should not be stored above 30°C.		

<table>
<tr>
<td>Storage stability test – long term storage at ambient temperature</td>
<td>Validated analytical method:
- H_2O_2: Labo1006
- Lactic acid: AP-LABCHI-945</td>
<td>AEROCLEAN 5.0% w/w L-(+)-lactic acid 7.5% w/w hydrogen peroxide Batch n° 051218-1</td>
<td>AEROCLEAN was stored in the commercial packaging (1 L HDPE drum) during 18 months at 20 °C. The study will be carried out until 2 years. The study is conducted under GLP.
<table>
<tr><th></th><th>Initial</th><th>T12 months</th><th>T18 months</th></tr>
<tr><td>Colour and aspect</td><td>Limpid clear and homogeneous liquid with menthol smell</td><td colspan="2">Cloudy liquid with menthol smell</td></tr>
<tr><td>Packaging</td><td colspan="3">1 L HDPE drums with degassing cap with no crackle, leakage or ballooning</td></tr>
<tr><td>Packaging weight variation</td><td>-</td><td colspan="2">No loss</td></tr>
<tr><td>pH of neat</td><td>2.6</td><td>2.7</td><td>2.8</td></tr>
<tr><td>pH of 1% dilution</td><td>3.75</td><td>3.90</td><td>3.61</td></tr>
<tr><td>Acidity (as H_2SO_4)</td><td>2.08%</td><td>2.59%</td><td>2.60%</td></tr>
<tr><td>Relative density</td><td>1.042</td><td>1.026</td><td>1.023</td></tr>
<tr><td colspan="4">Active Substances</td></tr>
<tr><td>Lactic acid content (% w/w)</td><td>4.06%</td><td>1.67%</td><td>1.19%</td></tr>
<tr><td>Lactate ion content (% w/w)*</td><td>0.69%</td><td>0.30%</td><td>0.31%</td></tr>
<tr><td>Lactic acid eq content (% w/w)*</td><td>4.75%</td><td>1.97%</td><td>1.50%</td></tr>
<tr><td>Lactic acid variation</td><td>-</td><td>- 58.9%</td><td>- 70.7%</td></tr>
<tr><td>Lactic acid eq variation*</td><td>-</td><td>- 58.5%</td><td>- 68.4%</td></tr>
<tr><td>H_2O_2 content (% w/w)</td><td>7.80%</td><td>3.40%</td><td>2.70%</td></tr>
<tr><td>H_2O_2 variation</td><td>-</td><td>- 56.4%</td><td>- 65.4%</td></tr>
<tr><td colspan="4">Co-formulant</td></tr>
<tr><td colspan="4">See Conf Annex</td></tr>
<tr><td colspan="4">Degradation product</td></tr>
</table>
</td>
<td>(1) [redacted] (2019) Stability study of AEROCLEAN Date: 24/04/19

(2) [redacted] (2021) Stability study of AEROCLEAN Date: 22/06/2021</td>
<td>Non acceptable

A significant decrease of both active substances is observed from 12 months of storage. The product AEROCLEAN is not considered stable after 12 months nor 18 months.

Two degradation products have been identified: See Conf Annex.

According to the decision tree accepted during BPC 31 (June 2019, Doc n° BPC-31-2019-13), acceptable information on efficacy after storage, on degradation byproducts and on the toxicity and eco-toxicity of these byproducts should be available to support the claimed shelf life.

An assessment of these degradation products on the ecotoxicological and</td>
</tr>
</table>

			See Conf Annex **Dilution Stability -** at 33% v/v - at 84% v/v: No sediment even after 18 hours / No deposit after 30min **Persistent foaming (**after 1 min**) -** at 33% v/v: 214 mL / 218 mL / 205 mL - at 100% v/v: 218 mL / 221 mL / 207 mL ** Due to low pH value of the formulation (2.6), an equilibrium is formed between lactic acid and lactate (pka = 3.90). The analytical method (AP-LABCHI-945) can only quantify the lactic acid content. However based on the dissociation constant definition, lactate ion content can be calculated. Lactic acid eq content is corresponding of the addition of the measured content in lactic acid and the calculated content in lactate ion.* <u>Conclusion:</u> Significant decrease (> 10%) for both active substances is observed. Based on the significant decrease (> 50% after 12 months) of both active substances, the stability of the product is not considered demonstrated. There is no significant change in the physical and chemical properties of the formulation. Due to the presence of hydrogen peroxide, the apparition of peracids could occur. A study has been made in order to determine the real composition of AEROCLEAN formulation at the end of its shelf life. The detail of the study is reported in Annex Confidential. According to the decision tree accepted during BPC 31 (June 2019, Doc n° BPC-31-2019-13), acceptable information on efficacy after storage, on degradation byproduct(s) and on the toxicity and eco-toxicity of these byproduct(s) should be available to support the claimed shelf life.		toxicological risk assessments has been performed (See Conf Annex). Furthermore, efficacy tests have been performed with an 17 months aged formulation (See 2.2.5.5. Efficacy data). Based on these efficacy results and on the (eco)toxicological assessments, a shelf life of 17 months can be granted.

Storage stability test – **low temperature stability test for liquids**	CIPAC MT39.3	AEROCLEAN 5.0% w/w L-(+)-lactic acid 7.5% w/w hydrogen peroxide Batch n° 051218-1	Tested packaging: 150 mL HDPE drums After 7 days at 0°C, the product is frozen. Once at ambient temperature, there was no presence of sediments, phase differentiation nor crystallisation.	(1) [redacted] (2019) Stability study of AEROCLEAN Date: 24/04/19 (2) [redacted] (2021) Stability study of AEROCLEAN Date: 22/06/2021	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	The active substance, L-(+)-lactic acid, is not light sensitive. However, hydrogen peroxide decomposes into water and oxygen. The rate of this reaction depends on the contact with catalytic materials and other factors such as heat and sunlight.	-	Acceptable Due to the chemical sensitivity of hydrogen peroxide, the mitigation measure "store away from light" is stated on the label.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	Based on the results of the accelerated storage study, the product should not be stored above 30°C. Moreover as the product is aqueous, it is not expected that humidity would have an effect on the product.	-	Acceptable The product should not be stored above 30°C.
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	AEROCLEAN 5.0% w/w L-(+)-lactic acid 7.5% w/w hydrogen peroxide Batch n° 051218-1	See "Storage stability test – long term storage at ambient temperature" Visual aspect of containers after storage: no crackle, leakage or ballooning Weight variation on storage after storage: +2.5%	(1) [redacted] (2019) Stability study of AEROCLEAN Date: 24/04/19 (2) [redacted] (2021) Stability study of AEROCLEAN Date: 22/06/2021	Acceptable
Wettability	-	-	Not relevant for a liquid formulation.	-	-
Suspensibility, spontaneity and dispersion stability	-	-	Not relevant. AEROCLEAN do not form a suspension.	-	-

Wet sieve analysis and dry sieve test	-	-	Not relevant for an aqueous solution.	-	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not relevant. AEROCLEAN do not form an emulsion.	-	-
Disintegration time	-	-	Not relevant. Data required for tablets only.	-	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not relevant for a liquid formulation.	-	*Please note that based on the HH assessment currently proposed in the PAR, MMAD (mass medium aerodynamic diameter) does not need to be determine as AEROCLEAN utilisation is only for empty room. Moreover MMAD was not relevant to demonstrate efficacy of the product.*

Persistent foaming	CIPAC MT 47.2	AEROCLEAN 5.0% w/w L-(+)-lactic acid 7.5% w/w hydrogen peroxide Batch n° 051218-1	Foam volume at a concentration of 33% v/v: - 0 s: 236.0 mL - 1 min: 214.0 mL - 3 min: 212.0 mL - 12min: 210.0 mL Foam volume at a concentration of 100% v/v: - 0 s: 234.0 mL - 1 min: 218.0 mL - 3 min: 214.0 mL - 12 min: 213.5 mL The measured foam is superior to 60 mL at maximum use and minimum use concentrations. AEROCLEAN is a foaming product.	(1) [redacted] (2019) Stability study of AEROCLEAN Date: 24/04/19 (2) [redacted] (2021) Stability study of AEROCLEAN Date: 22/06/2021	Acceptable Level of foams are outside acceptable limits (max 60 mL) at maximum use concentration and at 33.0% v/v. Even if the test was not carried out at the minimum use concentration (23.0% v/v), FR-CA do not expect significant variation between 23.0% v/v and 33.0% v/v. AEROCLEAN is a foaming product. The mention of "Foaming product: Do not agitate during mixing and loading to avoid foaming" should be stated on the label.
Flowability/Pourability/Dustability	-	-	Not relevant for aqueous solutions.	-	-
Burning rate — smoke generators	-	-	Not relevant. AEROCLEAN is not a smoke generator.	-	-
Burning completeness — smoke generators	-	-	Not relevant. AEROCLEAN is not a smoke generator.	-	-
Composition of smoke — smoke generators	-	-	Not relevant. AEROCLEAN is not a smoke generator.	-	-
Spraying pattern — aerosols	-	-	Not relevant	-	-
Physical compatibility	-	-	Not relevant. AEROCLEAN is not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products.	-	-
Chemical compatibility	-	-	Not relevant. AEROCLEAN is not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products.	-	-

Degree of dissolution and dilution stability	CIPAC MT 41	AEROCLEAN 5.0% w/w L-(+)-lactic acid 7.5% w/w hydrogen peroxide Batch n° 051218-1	<table><tr><th></th><th>Initial</th><th>T12 months</th><th>T18 months</th></tr><tr><td>At 33% v/v</td><td colspan="3">No sediment even after 18 hours</td></tr><tr><td>At 84% v/v</td><td colspan="3">No deposit after 30 min</td></tr></table> Conclusion: The test was performed at the maximum in use concentration 84.0% v/v. There is no residue retained on the 75 µm sieve (below the acceptable limit (2%)).	(1) [redacted] (2019) Stability study of AEROCLEAN Date: 24/04/19 (2) [redacted] (2021) Stability study of AEROCLEAN Date: 22/06/2021	Acceptable It was agreed during WG I 2023 APCP The test has not been carried out at the maximum and minimum use concentration. However, these results can be extrapolated as there is no effect of the concentration on the results (no residue retained on the 75 µm sieve).
Surface tension	DIN 14370:2004 (Ring method)	AEROCLEAN 5.0% w/w L-(+)-lactic acid 7.5% w/w hydrogen peroxide Batch n° JH051218-1	At a concentration of 100% v/v: 29.3 mN/m	[redacted] [redacted] (2019) [redacted] Non GLP	Acceptable AEROCLEAN is surface active.
Viscosity	CIPAC MT 22.1 (HB F) (Capillary viscometer method)	AEROCLEAN 5.0% w/w L-(+)-lactic acid 7.5% w/w hydrogen peroxide Batch n° JH051218-1	At 20 °C: 1.2 mm^2/s At 40 °C: 0.9 mm^2/s	[redacted] [redacted] (2019) [redacted] Non GLP	Acceptable

Conclusion on the physical, chemical and technical properties of the product
The product AEROCLEAN is a soluble concentrate (SL) formulation. All studies have been performed in accordance with the current requirements. The product is a colorless liquid, with a peppermint odour. The physico-chemical characteristics of the soluble concentrate (SL) formulation have been correctly described.

Both accelerated stability study (after 2 weeks at 54°C) and long term storage study show a significant decrease in both active substances content. This decrease is superior to the 10% acceptable limit, and superior to 50% after 12 months of storage. Two degradation products have been identified by the applicant (See Conf Annex).
According to the technical agreements for biocides (v 2.0, Feb 2020), acceptable information on efficacy after storage, on degradation by-products and on the toxicity and eco-toxicity of these by-products should be available to support the claimed shelf life. An assessment of these degradation products on the ecotoxicological and toxicological risk assessments has been performed (See Conf Annex). Furthermore, efficacy tests have been performed with a 17 months aged formulation (See 2.2.5.5. Efficacy data). Based on these efficacy results and on the (eco)toxicological assessments, a shelf-life of 17 months can be granted.
As accelerated and long term storage stability data show significant decrease in both active substance contents, it is recommended to store the products at a temperature below 25 °C.

Level of foams are outside acceptable limits (max 60 mL) at maximum use and minimum use concentrations. AEROCLEAN is a foaming product. The mention of "Foaming product: Do not agitate during mixing and loading to avoid foaming" should be stated on the label.

Due to the chemical sensitivity of hydrogen peroxide, the mitigation measure "store away from light" is stated on the label.

Its technical characteristics are acceptable for a soluble concentrate (SL) formulation.

Labelling mention: Store at temperature below 25 °C, Store away from light, Foaming product: Do not agitate during mixing and loading to avoid foaming.

Shelf-life: 17 months

Post authorization data: None

2.2.3 Physical hazards and respective characteristics

Please note that the hazard classes which are not relevant based on physical state of the product AEROCLEAN, have been removed from the below table.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR Evaluation
Explosives	Statement Method EC A14 (using DSC) UN Test N.1 to 3	AEROCLEAN 5.0% w/w L-(+)-lactic acid 7.5% w/w hydrogen peroxide	Differential Scanning Calorimetry (DSC) graphs were provided of 2 samples (AEROCLEAN fresh sample and sample after 14 days at 54°C). Differential Scanning Calorimetry (DSC) graphs provided do not show any exothermic decomposition up to 600°C, what demonstrates that the product AEROCLEAN is unlikely to be explosive. *DSC conditions:* Gas used: Nitrogen Ventilation: Yes Atmospheric pressure: 1.5 bar Crucible used: Steel (Incoloy). 30 µL. with crimped lid Programmation: Phase No. 3: Isotherm at about 25 °C for 5 min Heating phase from 25 °C to 600 °C at 5 °C/min Moreover, based on the composition of the product, no explosive properties is expected (See confidential PAR)	[redacted]	Acceptable The product is not classified as explosive solid according to CLP regulation.
Flammable liquids	Statement	AEROCLEAN 5.0% w/w L-(+)-lactic acid 7.5% w/w hydrogen peroxide Batch n°051218-1	AEROCLEAN is not expected to present a significant hazard for flammability. Test is not required as it contains more than 99% of non-flammable substances, among them more than 80% of water (See Conf Annex).	[redacted]	Acceptable The product is not classified as flammable according to CLP regulation.
	Method ASTM D93-16a (closed cup)		Method ASTM D93-16a (closed cup) cover the determination of the flash point of products in the temperature range from 40 °C to 370 °C. In the case of AEROCLEAN, the analysis of the flash point was ended at the boiling temperature (100 °C) of the sample under analysis.	CoA_AEROCLEAN SAS LABORATOIRE MERIEL (2019) Report n° 19/000152799	
Self-reactive substances and mixtures	Statement Method EC A14 (using DSC)	AEROCLEAN 5.0% w/w L-(+)-lactic acid	Differential Scanning Calorimetry (DSC) graphs were provided of 2 samples (AEROCLEAN fresh sample and sample after 14 days at 54°C).	[redacted]	Acceptable

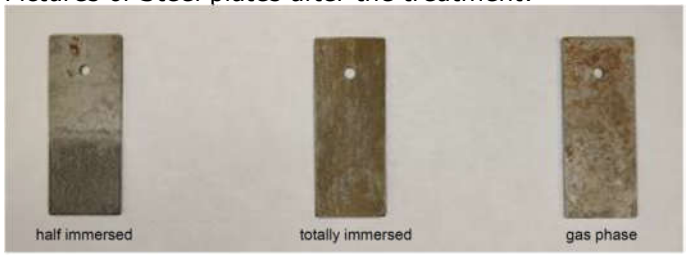
Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR Evaluation
	UN Test N.1 to 3	7.5% w/w hydrogen peroxide	Neither endothermic nor exothermic peak was observed up to 600°C under the experimental conditions for both samples. Therefore, the product is not considered as self-reactive. *DSC condition:* Gas used: Nitrogen Ventilation: Yes Atmospheric pressure: 1.5 bar Crucible used: Steel (Incoloy), 30 µL, with crimped lid Programmation: Phase No. 3: Isotherm at about 25 °C for 5 min Heating phase from 25 °C to 600 °C at 5 °C/min Moreover, based on the composition of the product, no self-reactive properties is expected (See Conf Annex)	[redacted]	
Pyrophoric liquids	-	-	AEROCLEAN does not contain components that ignite spontaneously on coming into contact with air at normal temperatures. Moreover, the experience and handling do not show any ignition of the product in contact with air at ambient temperature.	-	Acceptable The product is not pyrophoric
Self-heating substances and mixtures	-	-	AEROCLEAN do not contain components that ignite spontaneously on coming into contact with air at normal temperatures.	-	Acceptable
Substances and mixtures which in contact with water emit flammable gases	-	-	Water is used as solvent for active substances. These aqueous solutions are stable and do not emit flammable gasses.	-	Acceptable
Oxidising liquids	Statement	AEROCLEAN 5.0% w/w L-(+)-lactic acid 7.5% w/w hydrogen	According to the evaluation of L-(+)-lactic acid under Biocidal Products Regulation, this active substance (5% w/w) has no oxidizing properties. According to the evaluation of hydrogen peroxide under Biocidal Products Regulation, this active substance (7.5% w/w) is a strong oxidizer which justifies its biocidal properties. However according to decision (CG-54-2022-07 AP 14.1_Final), it has been agreed, that the concentration limits of UN TDGR Model Regulations should be used for hydrogen peroxide. Concentration	[redacted]	Acceptable The product does not possess oxidizing properties.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR Evaluation
			limits for classification as oxidizing liquid are: - Content in H_2O_2 <8% w/w: Not Oxidising Liquid - Content in H_2O_2 8% to <20%: Oxidising Liquid, Packing Group III, UN2984 - Content in H_2O_2 20% to 60%: Oxidising Liquid, Packing Group II, UN2014 - Content in H_2O_2 >60%: Oxidising Liquid, Packing Group I, UN2015 The concentration of hydrogen peroxide in AEROCLEAN is <8% w/w. Moreover, based on the composition of the co-formulants, no oxidizing properties is expected (See Conf Annex). In conclusion, AEROCLEAN is not classified as oxidising liquid.		
Organic peroxides	Chromatography and mass spectrometry studies	(**1**) AEROCLEAN 5.0% w/w L-(+)-lactic acid 7.5% w/w hydrogen peroxide Batch n° JC050220-1 (**2**) AEROCLEAN 5.0% w/w L-(+)-lactic acid 7.5% w/w hydrogen peroxide Batch n° JC050220-1 (**3**) AEROCLEAN 5.0% w/w L-(+)-lactic acid	Several studies were launched by the applicant in order to identify the different degradation products in AEROCLEAN (see 2.2.2 Storage stability test). All the potential new components have been identified and quantified. Based on the results, two degradation products have been identified, but no peak corresponding to peracids or organic peroxides have been found. Therefore, no further investigation has been performed.	(**1**) [redacted] (2020) [redacted] (**2**) [redacted] (2020) [redacted] (**3**) [redacted] (2020) [redacted] (**4**) [redacted] (2021) [redacted]	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR Evaluation
		7.5% w/w hydrogen peroxide Batch n° JC050220-1 (**4**) AEROCLEAN 5.0% w/w L-(+)-lactic acid 7.5% w/w hydrogen peroxide Batch n° JC050220-1			

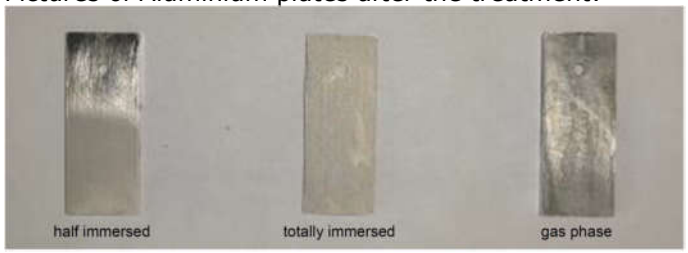
Corrosive to metals	Method 37.4 C.1 (UN Handbook)				According to accelerated and long term storage stability data, a significant decrease in both active substance contents is observed. It can therefore be concluded that the composition of the liquid in the reaction vessel during the corrosive test period is not similar to the product AEROCLEAN when the solution is not refreshed. Hence, the test in which the test solution is refreshed has been furnished. In Nieddu (report n° 23/000151552), a corrosion phenomena (mass loss more than 13.5% for an exposure time of 7 days) was observed (totally immersed plate): 17.8% of mass loss on steel plates. AEROCLEAN is then classified as corrosive to metals Cat. 1 (H290).

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>FR Evaluation</th></tr>
<tr><td></td><td></td><td>AEROCLEAN
5.0% w/w L-(+)-lactic acid
7.5% w/w hydrogen peroxide
Batch n° JH051219-1</td><td>Corrosive test to metals was performed on a fresh product AEROCLEAN. The complete refresh of the product was carried out every 2/3 days.

Data measured for Steel (ISO 3574) plates after storage time of 7 days:
Table 2 - Results obtained for steel plates
<table>
<tr><th>Operating condition</th><th>Initial weight g</th><th>Final weight g</th><th>Weight loss %</th></tr>
<tr><td>Totally immersed plate</td><td>15.1244</td><td>12.4340</td><td>17.8</td></tr>
<tr><td>50% immersed plate</td><td>14.6727</td><td>13.3141</td><td>9.3</td></tr>
<tr><td>gas phase plate</td><td>15.0355</td><td>14.7237</td><td>2.1</td></tr>
</table>
Pictures of Steel plates after the treatment:
 

Data measured for Aluminium (7075-T6) plates after storage time of 7 days:
Table 1 - Results obtained for aluminium plates
<table>
<tr><th>Operating condition</th><th>Initial weight g</th><th>Final weight g</th><th>Weight loss %</th></tr>
<tr><td>Totally immersed plate</td><td>5.4626</td><td>5.3395</td><td>2.3</td></tr>
<tr><td>50% immersed plate</td><td>5.4413</td><td>5.3752</td><td>1.2</td></tr>
<tr><td>gas phase plate</td><td>5.4746</td><td>5.4537</td><td>0.4</td></tr>
</table></td><td>[redacted] (2023)
[redacted]

Non GLP</td><td></td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR Evaluation
			Pictures of Aluminium plates after the treatment:  After the treatment with the test item, steel and aluminium metal plates were cleaned with a brush with synthetic bristles, then cleaned with ethanol in ultrasonic bath and then degreased with acetone in ultrasonic bath. Pictures of Steel plates after brushing and cleaning:  Pictures of Aluminium plates after brushing and cleaning:		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR Evaluation
			 Conclusion: The corrosion of the Aluminum plates was uniform. % weight changes obtained were lower than 13.5% after 7 days (acceptable criterion). Concerning Steel plates, it can be assessed that a remarkable corrosion phenomena (mass loss more than 13.5% for an exposure time of 7 days) was observed (totally immersed plate): 17.8% of mass loss. Moreover, localised corrosion occurred. The metallographic measurement of the deepest hole (for totally immersed, half immersed and gas phase plates) is not considered necessary because for the totally immersed sample the mass loss is more than 13.5%. Considering results obtained (as reported in Subsection 37.4 of UN-MTC and sections 2.8.1 and 2.8.2 of the Model Regulations and Chapter 2.16 of the GHS) it can be assessed that the corrosion rate on steel plate (totally immersed specimen) exceeds 6.25 mm a year at a test temperature of 55 °C and that the product under examination belongs to Class 8 - Corrosive substances. Since the product under examination was found to be corrosive to metals based on the test described in part III, subsection 37.4 of the Nations RTDG Unite, Manual of tests and criteria, then the H290 hazard statement has to be assigned to the mixture, according to the		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR Evaluation
			classification criteria defined by CLP regulation for the hazard class "Corrosive to metals".		
Auto-ignition temperatures of products (liquids and gases)	Not relevant	Not relevant	Not relevant for testing as AEROCLEAN contains more than 80% of water (See Conf Annex) and the analysis of the flash point was ended at the boiling temperature (100 °C) of the sample under analysis.	Not relevant	Acceptable

Conclusion on the physical hazards and respective characteristics of the product
The biocidal product AEROCLEAN is a soluble concentrate (SL) formulation. The product is neither flammable nor auto-flammable. It has no explosive or oxidizing properties. It is classified as corrosive to metals Cat. 1 (H290). **Classification related to physical hazards and respective characteristics of the product:** H290 as mentioned in CLP regulation

2.2.4 Methods for detection and identification

Determination of the active substances Hydrogen peroxide and L (+) Lactic acid in AEROCLEAN

Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)	Repeatability / Precision	Reference
Active substance Hydrogen peroxide	Volumetric redox titration	6 levels for linearity (0.15 to 0.2 g of product titrated)	Calibration solutions of the reference items at six concentrations were analysed. Calibration solutions prepared from 0.15 to 0.2 g of product titrated. y = 87.611x + 0.0852 Linear regression coefficient (R^2) is > 0.99	Different preparations were tested: - A hydrogen peroxide standard of known concentration - A control solution containing only the co-formulant of hydrogen peroxide (See Conf Annex for composition details) - A batch of product with peroxide hydrogen known concentration Results show that the method is specific to the detection and titration of Hydrogen peroxide.	The accuracy was tested on two different batches (product and standard), The accuracy results were in conformity with SANCO/3030/99 rev. 4 requirements. Indeed, the recovery results should be in the range 97%-103%. Recoveries were experimentally equal to 99.9% (product) and 99.6% (standard).	RSD = 0.22% for precision (n=6) at a concentration of 7.5% w/w in Hydrogen peroxide. The precision was acceptable as the RSD was lower than the result of the modified Horwitz equation: 0.99.	Analytical method Labo1006 [redacted] (2020)

Active substance L (+) lactic acid	Ion chromatography with conductimetric detection	6 levels for linearity (21%, to 134% of the theoretical amount of L (+) lactic acid in the test item)	Calibration solutions of the reference items at six concentrations were analysed. Calibration solutions prepared from 10 mg/L in solution corresponding to 1.0 g/100 g (21% of target concentration) to 67 mg/L in solution corresponding to 6.7 g/100 g (134% of target concentration) y = 1348126x R^2 = 0.998	Analysis of solvent blank, formulation blank, reference item and test item. No interference from other substances present in the solvent blank, formulation blank and test item. Therefore, the analytical method showed a good specificity for L (+) lactic acid analysis in AEROCLEAN.	Accuracy was checked by analysis of three reconstituted samples with known amounts of L (+) lactic acid at 70%, 100% and 130% of the theoretical nominal content. The accuracy results were in conformity with SANCO/3030/99 rev. 4 requirements. Indeed, the recovery results should be in the range 97%-103% (formulations containing more than 10% w/w) and they were experimentally equal to 102.7% (mean of 3 injections of the same sample), 97.7% (mean of 6 injections of the same sample), and 100.3% (mean of 3 injections of the same sample).	RSD = 0.5% for precision (n=6) at a concentration of 5.0% w/w in L (+) lactic acid The precision was acceptable as the RSD was lower than the result of the modified Horwitz equation: 2.1.	Analytical method [redacted] (2021)

Determination of the co-formulants and impurity in AEROCLEAN: see Conf Annex

Analytical methods for soil								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Residues in Hydrogen peroxide	<u>According to the CAR of Hydrogen peroxide:</u> Not applicable, because hydrogen peroxide is rapidly decomposed in soil and does not adsorb to soil matrix. Trace amounts of hydrogen peroxide in soil water may be analysed by the method for water.								
Residues in L-(+)-lactic acid	<u>According to the CAR of Lactic acid:</u> This is not applicable as no relevant residues are expected.								

Analytical methods for air								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Residues in Hydrogen peroxide	<u>According to the CAR of Hydrogen peroxide:</u> Spectrometric determination.								
Residues in L-(+)-lactic acid	<u>According to the CAR of Lactic acid:</u> This is not applicable as no relevant residues are expected.								

Analytical methods for water								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Residues in Hydrogen peroxide	<u>According to the CAR of Hydrogen peroxide:</u> Spectrometric determination.								
Residues in L-(+)-lactic acid	<u>According to the CAR of Lactic acid:</u> This is not applicable as no relevant residues are expected.								

Analytical methods for animal and human body fluids and tissues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Residues in Hydrogen peroxide	<u>According to the CAR of Hydrogen peroxide:</u> Not required as the substance is not acutely toxic (T) or very toxic (T+).								
Residues in L-(+)-lactic acid	<u>According to the CAR of Lactic acid:</u> This is not applicable as no relevant residues are expected.								

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Residues in Hydrogen peroxide	<u>According to the CAR of Hydrogen peroxide:</u> Not required as not expected in food/feed of plant origin.								
Residues in L-(+)-lactic acid	<u>According to the CAR of Lactic acid:</u> This is not applicable as no relevant residues are expected.								

Conclusion on the methods for detection and identification of the product

An analytical method using volumetric redox titration for the determination of hydrogen peroxide in AEROCLEAN has been provided and is considered as validated according to SANCO/3030/99 rev. 4 requirements.

An analytical method using ion chromatography with conductimetric detection for the determination of L-(+)-lactic acid in AEROCLEAN has been provided and is considered as validated according to SANCO/3030/99 rev. 4 requirements.

Limited validation data have been provided for the determination of co-formulants and degradation product in AEROCLEAN (See Conf Annex).

The applicant has a letter of access for analytical methods for hydrogen peroxide and L-(+)-lactic acid residues.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

AEROCLEAN is intended to be used indoor by professional users for the disinfection:
- of empty buildings/rooms and equipment of empty greenhouses and empty material shelters (PT2);
- of breeding premises in presence of animals, eggs storage rooms (including eggs), incubators and hatcheries (including eggs), empty buildings (livestock buildings, veterinary clinic, adjoining animal rooms) and material (PT3);
- of empty buildings and material in feed and food industry (PT4).

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

AEROCLEAN is used to disinfect surfaces for the purpose of the protection of human and animal health.

Target organisms claimed by the applicant are:
- For uses #1 (PT02) and #6 (PT04): bacteria, yeasts, fungi and enveloped viruses;
- For use #2 and #3 (PT03): bacteria, yeasts, fungi and viruses;
- For use #4 (PT03): bacteria, yeasts, fungi and viruses.
- For use #5 (PT03): bacteria, yeasts and viruses;

2.2.5.3 Effects on target organisms, including unacceptable suffering

The product is able to produce a reduction in the number of viable bacterial cells (bactericidal activity), of yeast cells (yeasticidal activity), of fungal cells (fungicidal activity), and of infectious virus particles (virucidal activity) of relevant test organisms under defined conditions.

2.2.5.4 Mode of action, including time delay

- L-(+)-lactic acid:
  - In solution, L-(+)-lactic acid exists in a pH-dependent equilibrium between the undissociated and dissociated form. Only in its undissociated state, the acid is able to pass the cell membrane.
  - At a relatively low pH, the uncharged acid enters the cell. Inside the cell, the L-(+)-lactic acid dissociates due to the higher pH.
  - The molecules remain inside the cell, because the resulting ions cannot pass the membrane.
  - The pH inside the cell is lowered and metabolic reactions are inhibited.
  - Further effects are also reported: decrease of the membrane permeability for amino acids, organic acids, phosphates resulting in uncoupling of both substrate transport and oxidative phosphorylation from the electron transport system. Furthermore, an inhibition of the glycolysis by the lactate ion is observed.

- Hydrogen peroxide:
  - Hydrogen peroxide is reactive and it degrades rapidly in contact with organic material. A significant proportion of hydrogen peroxide decomposes to water and oxygen.

- The antimicrobial action of hydrogen peroxide stems from its ability to form powerful oxidants such as the hydroxyl radical and singlet oxygen. These reactive oxygen species cause irreversible damage to cellular components such as enzymes, membrane constituents and DNA.

Contact times for the different activities claimed are determined in the efficacy tests (see table on section 2.2.5.5).

2.2.5.5 Efficacy data

1) Efficacy data relevant for PT2 and PT4 uses:

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	Disinfection of empty greenhouses and empty material shelters (PT2) – Use#1 Disinfection of empty buildings and material of food industry (PT4) – Use #6	AEROCLEAN (1 year old aged product)	*P. aeruginosa* *E. coli* *S. aureus* *E. hirae*	EN1276:2019 Phase 2 step 1 (suspension test)	Concentration tested (% v/v): 0.5, 1, 1.5 and 2. Temperature: 20°C Contact time: 5 min Clean conditions (0.3 g/L BSA) Criteria: ≥5 log reduction	Bactericidal activity demonstrated at 1.5% v/v	Test report 2020-MER-014 Supportive data (clean conditions)
Fungicidal Yeasticidal		AEROCLEAN (1 year old aged product)	*A. brasiliensis* *C. albicans*	EN1650:2019 Phase 2 step 1 (suspension test)	Concentration tested (% v/v): -*A. brasiliensis*: 10, 20 and 30 -*C. albicans*: 2, 5 and 9 Temperature: 20°C Contact time: 15 min Clean conditions (0.3 g/L BSA) Criteria: ≥4 log reduction	Fungicidal activity demonstrated at 30% v/v Yeasticidal activity demonstrated at 9% v/v	Test report 2020-MER-017 Supportive data (clean conditions)
Enveloped virus		AEROCLEAN (3 months old aged product)	Vaccinia Virus Ankara (MVA)	EN 14476+A2 (2019) Phase 2 step 1 (suspension test)	Concentration tested (% v/v): 10, 50 and 80 Temperature: 20°C Contact time: 15 min Clean conditions (0.3 g/L BSA) Criteria: ≥4 log reduction	Virucidal activity demonstrated at 50%	Study R20/07LVMER001 Supportive data (clean conditions)
Virucidal	Disinfection of empty greenhouses and empty material shelters (PT2) – use #1 Disinfection of empty buildings and material of food industry (PT4) – use #6	AEROCLEAN (fresh product)	Murine Norovirus strain S99 Berlin Adenovirus type 5	EN17272:2020 Phase 2 Step 2	Semi-field trial using an electrical aerosol applicator Cold nebulisation OCENE (Hurricane model) Concentration of pure product tested : 4.96 to 5.06 ml/m^3 Dilution: 12.5% v/v pure product in hard water. Temperature: 20°C	Norovirus : Product diluted at 12.5 % v/v in hard water, 1225 mL dispersed in 4min24s i.e. 16,70L/h, CT=1h, 20°C/60%, dose: 4,96 mL pure product/m^3 => ≥ 4,00 log	Study MIC.20/11-021.EV/V RI = 1

					Contact time: 60 min Dirty conditions (3 g/L BSA) Particle size: 7 to 30 µm Counted flow: 16.7 to 16.9 L/h On the floor / nozzle at 30 cm of the floor Dimension : 30.87 m^3 (6.10 x 2.30 x 2.20 m) R.H.: 50-75% (at test begin) <u>Criteria</u>: Virus: ≥4 log reduction	Product diluted at 12.5 % v/v in hard water, 1250 mL dispersed in 4min27s i.e. 16,85L/h, CT=1h, 19,5°C/60%, dose: 5,06 mL pure product/m^3 => ≥ 5,79 log Adenovirus : Product diluted at 12.5 % v/v in hard water, 1210 mL dispersed in 4min20s i.e. 16,75L/h, CT=1h, 21°C/57%, dose: 4,90 mL pure product/m^3 => >5,13 log	
	Disinfection of empty greenhouses and empty material shelters (PT2) – use #1 Disinfection of empty buildings and material of food industry (PT4) – use #6	AEROCLEAN (age not known)	*S. aureus*	EN17272:2020 Phase 2 Step 2 Efficacy and distribution test	Semi-field trial using an electrical aerosol applicator Cold nebulisation OCENE (Hurricane model) <u>Concentration of pure product tested</u>: 4.92 mL/m^3. Dilution: 12.5% pure product in hard water. Temperature: 20°C Contact time: 60 min Dirty conditions (3 g/L BSA) Particle size: 7 to 30 µm Counted flow: 17.5 L/h On the floor / nozzle at 30 cm of the floor Dimension : 30.87 m^3 (6.10 x 2.30 x 2.20 m) R.H.: 50-75% (at test begin) The distribution test was performed in parallel with the efficacy test.	<u>Efficacy test:</u> Bactericidal activity demonstrated against *S. aureus* at 4.92 mL pure product /m^3 (12.5% pure product diluted in hard water, 1215 mL dispersed in 4min10s i.e. 17.50 L/h, TC=1h, 19.5°C / 58% R.H.). <u>Distribution test:</u> The distribution test is valid: ≥ 5 log of reduction is obtained on each carrier performed at 4.9 mL/m^3 of the pure product.	Study MIC.20/10-051.EVSa RI = 1

					Criteria: Bacteria: ≥5 log reduction		
Bactericidal Fungicidal Virucidal	Disinfection of empty greenhouses and empty material shelters (PT2) – use #1 Disinfection of empty buildings and material of food industry (PT4) – use #6	AEROCLEAN (17 months old aged product)	*P. aeruginosa* *P. hauseri* *S. aureus* *E. hirae* *E. coli* *ECBO Virus* *A. brasiliensis* *C. albicans*	EN17272:2020 Phase 2 step 2	Semi-field trial using an electrical aerosol applicator Cold nebulisation OCENE (Hurricane model) Concentration of pure product tested : 4 to 10ml/m^3 Temperature: 20°C Contact time: 60 min Dirty conditions (3 g/L BSA) R.H.: 50-75% (at test begin) Counted flow: 16.1 to 17.8 L/h On the floor / nozzle at 35 cm of the floor Particle size: 7 to 30 µm Dimension : 30.87 m^3 (6.10 x 2.30 x 2.20 m) Criteria: Bacteria: ≥5 log reduction Fungi: ≥4 log reduction Virus: ≥4 log reduction	Bactericidal activity at 4.9 mL pure product /m^3 (1/8th pure product diluted in hard water, 1210 mL dispersed in 4min 05s thus 17.78 L/h, contact time =1h, 21°C / 50% R.H.). Yeasticidal activity at 3.87 mL pure product /m^3 (1/10th pure product diluted in hard water, 1195 mL dispersed in 4min 10s thus 17.21 L/h, contact time =1h, 22°C / 52% R.H.). Fungicidal activity at 9.7 mL pure product /m^3 (1/4th pure product diluted in hard water, 1198 mL dispersed in 4min 05s thus 17.60 L/h, contact time =1h, 21°C / 55% R.H.). Virucidal activity on ECBO virus at 5.1 mL pure product /m^3 (1/8th pure product diluted in hard water, 1265 mL dispersed in 4min 35s thus 16.56 L/h, contact time =1h, 22°C / 63% R.H.).	Test report MIC.20/05-291.EV/B-F-V HPA RI = 1 (bacteria and fungi) RI = 3 (virus strain not expected by the norm)
Fungicidal	Disinfection of empty greenhouses and empty	AEROCLEAN	*A. brasiliensis*	Field test-Phase 3 following the	Electrical nebuliser (ZEPHIRE) – 2 devices	Mean global log reduction: 2.68	Study R1907MER001

	material shelters (PT2) – use #1 Disinfection of empty buildings and material of food industry (PT4) – use #6	(6 months old aged product)		method of the EN 17272 Preliminary testing of performance qualification of 2 systems of airborne ZEPHIRE of surface disinfection in real use conditions. Cold nebulisation	Assessment of the fungicidal activity in 10 areas of a building of 620 m^3 i.e. 310 m^3 per device. <u>Concentration tested</u> : 9.42 mL pure product /m^3 Concentration of AEROCLEAN: 73% in water of distribution network Volume of the dilution in the tanks at T0: 5.5 litres Residual volume after 33 minutes of running: ZEPHIRE A: 1,8 L ZEPHIRE B: 1,2 L Particle size: 5 à 80 µm Operating time: 33 minutes Contact time: 60 min Low level soiling (3 g/L BSA) Temperature: 28.7°C R.H.: 42.5% Distance between 2 ZEPHIRES: 1.5 m <u>Criteria</u>: ≥4-5 log reduction	Efficacy criteria has not been fulfilled. Fungicidal activity is not demonstrated.	RI = 1
Bactericidal	Disinfection of empty greenhouses and empty material shelters (PT2) – use #1 Disinfection of empty buildings and material of food industry (PT4) – use #6	AEROCLEAN (8 months old aged product)	*E. hirae*	Field test-Phase 3 following the method of the EN 17272 Preliminary testing of performance qualification of 2 systems of airborne ZEPHIRE of surface disinfection in	Electrical nebuliser (ZEPHIRE) – 2 devices Assessment of bactericidal activity in 10 areas of a building of 620 m^3 i.e. 310 m^3 per device. <u>Concentration tested</u> : 4.23 mL pure product /m^3 Conc. of AEROCLEAN: 36.4% in water of distribution network. Volume of the dilution in the tanks at T0: 5.5 litres Residual volume after 66 minutes of running:	Mean global log reduction: 3.04 Efficacy criteria is not been fulfilled. Bactericidal activity is not demonstrated.	Study R1909MER001 RI = 3 (only one strain tested, concentration tested not claimed)

				real use conditions. Cold nebulisation	ZEPHIRE A: 2.2 L ZEPHIRE B: 1,6 L Particle size: 5 à 80 µm Operating time: 66 minutes Contact time: 60 min Low level soiling (3 g/L BSA) Temperature : 23.5°C R.H.: 39.9% Distance between 2 ZEPHIRES: 1.5 m. Criteria: ≥5-6 log reduction		
Bactericidal Fungicidal	Disinfection of empty greenhouses and empty material shelters (PT2) – use #1 Disinfection of empty buildings and material of food industry (PT4) – use #6	AEROCLEAN (9 months old aged product)	*E. hirae* *A. brasiliensis*	Field test- Phase 3 following the method of the EN 17272 Disinfection of a building of 1053m^3 per device - with thermo-nebulisation, in real use conditions.	Electrical nebuliser One device (No information on the test device) Assessment of bactericidal and fungicidal activity in 10 areas of a building of 1053 m^3. Concentration tested : Bacteria: final volume 6 L (5L AEROCLEAN + 1L raw water) Fungi: final volume 12 L (10L AEROCLEAN + 2L raw water) Residual volume after running time: not mentioned. Contact time: 180 min Low level soiling (3 g/L BSA) Operating time: Bacteria: 21 minutes Fungi: 34 minutes Temperature : 13.4 to 16.6°C R.H.: 59.4 to 65.4% Criteria: Bacteria: ≥ 5-6 log reduction Fungi: ≥ 4-5 log reduction	Bactericidal activity: Mean reduction: 4.84 Log Fungicidal activity: Mean reduction: 3.46 Log	Study R1912MER004 RI = 3 (only *E. hirae* and *A. brasiliensis* tested, no information on the test device, residual volume not reported)

Claimed Use #1: *PT2 – Airborne disinfection of empty greenhouses and empty material shelters against bacteria, yeasts, fungi and enveloped viruses by cold nebulization and thermonebulisation, at 20°C in dirty conditions.*
Claimed Use #6: *PT4 – Airborne disinfection of empty buildings and materials in Feed or Food industries against bacteria, yeasts, fungi and enveloped viruses only by cold nebulization for buildings up to 300 m^3 and thermonebulisation* for buildings up to 1000 m^3 *(per device), at 20°C, in dirty conditions*

Following studies have been submitted:

To support bactericidal claims:

- A test according to EN 1276. The product AEROCLEAN (1 year aged) passed the test at 1.5% (v/v) under clean conditions (0.3 g/L bovine albumin) at 5 minutes contact time and 20°C. This test is considered as supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.
- A test according to EN 17272. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test at 4.90 mL pure product /m^3 i.e. 1/8th pure product diluted in raw water, 1210 mL dispersed in 4min 05s (i.e. 17.78L/H), under dirty conditions (3 g/L bovine albumin), at 1 hour contact time, at 21°C and 52% R.H.
- A field-test following the method of the EN 17272 in order to support the efficacy of AEROCLEAN by cold nebulization in large enclosures (310 m^3 per device, electrical nebulizer with 5 to 80 particle size). This test did not pass the criteria of the standard. Furthermore, the test was performed only on *E. Hirae*, at 23.5°C and 39.9% RH.
- A field-test following the method of the EN 17272 in order to support the efficacy of AEROCLEAN by thermonebulisation in in large enclosures (1053 m^3 per device). This test did not pass the criteria of the standard. Furthermore, the test was performed only on *E. hirae* and no information has been given on the thermonebulisation device in the test report.
- No further test according to EN 17272 has been performed to support thermonebulisation application.

Therefore, based on the data provided, bactericidal activity of AEROCLEAN, is demonstrated for an application, by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room (large enclosure), at 4.9 mL pure product/m^3 diluted at 1/8th in raw water, 1210 mL dilution dispersed in 4min 05s (i.e. 17.78 L/H or 296.3 mL/min), with a contact time of one hour at 20°C and 50-75% RH, under dirty conditions. Efficacy of thermonebulisation application is not demonstrated.

To support yeasticidal claims:

- A test according to EN 1650. The product AEROCLEAN (1 year aged) passed the test, against yeast, at 9% (v/v) under clean conditions (0.3 g/l bovine albumin) at 15 minutes contact time and 20°C. This test is considered supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.
- A test according to EN 17272 against yeasts. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test at 3.87 mL pure product /m^3 diluted at 1/10th in raw water, 1195 mL dilution dispersed in 4min 10s (i.e. 17.21L/H), under dirty conditions (3 g/L bovine albumin), at 1 hour contact time, at 22°C and 52% R.H.
- No further test according to EN 17272 has been performed to support thermonebulisation application.

Therefore, based on the data provided, yeasticidal activity of AEROCLEAN, is demonstrated for an application by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room (large enclosure), at 3.87 mL pure product /m^3 diluted at 1/10th in raw water, 1195 mL dilution dispersed in 4min 10s (i.e. 17.21L/H or 286.8 mL/min), with a contact time of one hour at 20°C and 50-75% RH, under dirty conditions. Efficacy of thermonebulisation application is not demonstrated.

To support fungicidal claims:

- A test according to EN 1650. The product AEROCLEAN (1 year aged) passed the test at 30% (v/v) under clean conditions (0.3 g/l bovine albumin) at 15 minutes contact time and 20°C. This test is considered supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.
- A test according to EN 17272. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test at 9.70 mL pure product /m^3 diluted at 1/4th in raw water, 1198 mL dilution dispersed in 4min 05s (i.e. 17.60L/H), under dirty conditions (3 g/L bovine albumin), at 1 hour contact time, at 21°C and 55% R.H.
- A field-test following the method of the EN 17272 in order to support the efficacy of AEROCLEAN by cold nebulization in large enclosures (310 m^3 per device, electrical nebulizer with 5 to 80 particle size). This test did not pass the criteria of the standard. Furthermore, the test was performed only on *A. brasiliensis*, at 28.7°C and 42.5% RH.
- A field-test following the method of the EN 17272 in order to support the efficacy of AEROCLEAN by thermonebulisation in large enclosures (1053 m^3 per device). This test did not pass the criteria of the standard. Furthermore, the test was performed only on *A. brasiliensis* and no information has been given on the thermonebulisation device in the test report.
- No further test according to EN 17272 has been performed to support thermonebulisation application.

Therefore, based on the data provided, the fungicidal activity of AEROCLEAN is demonstrated for an application by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room (large enclosure), at 9.70 mL pure product /m^3 diluted at 1/4th in raw water, 1198 mL dilution dispersed in 4min 05s (i.e. 17.6 L/H or 293.3 mL/min), with a contact time of one hour at 20°C and 50-75% RH, under dirty conditions. Efficacy of thermonebulisation application is not demonstrated.

To support virucidal claims:

- A test according to EN 14476. This test has been performed on the Modified Vaccinia Virus Ankara because the applicant claims a virucidal activity against enveloped viruses for this use. The product AEROCLEAN (3 months aged) passed the test at 50% (v/v) under clean conditions (0.3 g/L bovine albumin) at 15 minutes contact time and 20°C. This test is considered supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.
- A test according to EN 17272 (17 months aged) performed on ECBO virus. However, the test organism is not relevant for this use; this test is not acceptable.
- A test according to EN 17272 performed on the Murine Norovirus and the Adenovirus. The product AEROCLEAN (fresh product) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test:
    - for Norovirus at 4.96 mL pure product /m^3 diluted at 12.5% v/v in hard water, 1225 mL dilution dispersed in 4min 24s (i.e. 16.7 L/H), under dirty

conditions (3 g/L bovine albumin), at 1 hour contact time, at 20°C and 60% R.H.

- for Adenovirus at 4.90 mL pure product /m^3 diluted at 12.5% v/v in hard water, 1210 mL dilution dispersed in 4min 20s (i.e. 16.75 L/H), under dirty conditions (3 g/L bovine albumin), at 1 hour contact time, at 21°C and 57% R.H.

- A test according to EN 17272 performed on porcine parvovirus. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test at 5.18 mL pure product /m^3 diluted at 1/8th in hard water, 1280 mL dilution dispersed in 4min 30s (i.e. 17.07L/H), under low-level soiling conditions (3 g/L BSA), at 1 hour contact time, at 18°C and 70% R.H. This test has been submitted to support the virucidal activity for use #4, it has been considered sufficient to support the efficacy of the aged product against enveloped viruses but not sufficient to substantiate a full virucidal activity for PT2 and PT4.
- No data has been submitted to support thermonebulisation.

Therefore, based on the data provided, the virucidal activity against enveloped viruses of AEROCLEAN is demonstrated for an application by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room (large enclosure), at 5.18 mL pure product /m^3 diluted at 12.5% v/v in raw water, 1280 mL dilution dispersed in 4min 30 s (i.e. 17.07 L/H or 284.5 mL/min), with a contact time of one hour at 20°C and 50-75% RH, under dirty conditions. Efficacy of thermonebulisation application is not demonstrated.

Use #1 (PT 2) includes the application in empty greenhouses in dirty conditions. However, according to Appendix 4 of the ECHA efficacy guidance the higher soiling of PT 3 should be tested for uses in PT 2 agricultural areas. Therefore, as the relevant efficacy tests listed for the PT 2 use have been performed with 3 g/L BSA, which corresponds to low level soiling for PT 3, the product should only be used on visually clean surfaces when applied in greenhouses.

To conclude on use #1 and #6, efficacy is demonstrated for :

- Use 1: Airborne disinfection of empty greenhouses and empty material shelters (PT 02) by cold nebulization (particle size: 7 to 30 µm), in large enclosures, in dirty conditions (except for greenhouses where product has to be applied on visibly clean surfaces), on non-porous surfaces:
  - Mandatory target organisms:
    - Bacteria, yeasts: at 4.9 mL pure product /m^3 diluted at 12.5% v/v in raw water, 1210 mL dilution dispersed in 4min 05s (i.e. 17.78L/H or 296.3 mL/min), 1h, 20°C, 50-75% RH.
  - Other target organisms:
    - Fungi : 9.7 mL pure product /m^3 diluted at 25% v/v in raw water, 1198 mL dilution dispersed in 4min 05s (i.e. 17.60L/H or 293.3 mL/min), 1h, 20°C, 50-75% RH.
    - Enveloped viruses: 5.2 mL/m^3 diluted at 12.5% v/v in raw water, 1280 mL dispersed in 4min 30s (i.e. 17.07L/H or 284.5 mL/min), 1h, 20°C and 50-75% RH.
- Use 6: Airborne disinfection of empty buildings and materials in food and feed industries (PT 04) by cold nebulization (particle size: 7 to 30 µm), in large enclosures, in dirty conditions, on non-porous surfaces:
  - Mandatory target organisms:
    - Bacteria, yeasts: at 4.90 mL pure product /m^3 diluted at 12.5% v/v in hard water, 1210 mL dilution dispersed in 4min 05s (i.e. 17.78L/H or 296.3 mL/min), 1h, 20°C, 50-75% RH.
  - Other target organisms:

- Fungi : 9.70 mL pure product /m^3 diluted at 25% v/v in hard water, 1198 mL dispersed in 4min 05s (i.e. 17.60L/H or 293.3 mL/min), 1h, 20°C, 50-75% RH.
- Enveloped viruses only: 5.2 mL pure product /m^3 diluted at 12.5% v/v in raw water, 1280 mL dispersed in 4min 30s (i.e. 17.07L/H or 284.5 mL/min), 1h, 20°C and 50-75% RH.

Efficacy of thermonebulisation application is not demonstrated for both use #1 and use #6.

2) Efficacy data relevant for PT3 uses:

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**
PT3							
Bactericidal	Disinfection of eggs storage rooms (use #2); incubators and hatcheries (use #3); empty building and materials (use #4); breeding premises in presence of animals (use #5) (PT3)	AEROCLEAN (1 year old aged product)	*P. aeruginosa* *P. vulgaris* *S. aureus* *E. hirae*	EN1656:2019 Phase 2 step 1 (suspension test)	Concentration tested (% v/v): 10, 12, 14 and 16. Temperature: 10°C Contact time: 30 min Low level soiling (3 g/L BSA) Criteria: ≥5 log reduction	Bactericidal activity demonstrated at 14% v/v.	Test report 2020-MER-015 Supportive data (temperature and soiling not relevant with the claims)
Bactericidal		AEROCLEAN (11 months old aged product)	*P. aeruginosa* *P. vulgaris* *S. aureus* *E. hirae*	EN16437:2014 Phase 2 step 2 (porous surface test)	Concentration tested (% v/v): 20, 50 and 100 Temperature: 10°C Contact time: 60 min Low level soiling (3 g/L BSA) Criteria: ≥4 log reduction	Bactericidal activity demonstrated at 100%	Test report 2020-MER-022 Supportive data (not relevant for room disinfection)
Fungicidal Yeasticidal		AEROCLEAN (1 year old aged product)	*A. brasiliensis* *C. albicans*	EN1657:2016 Phase 2 step 1 (suspension test)	Concentration tested (% v/v): -*A. brasiliensis*: 20, 30 and 40 -*C. albicans*: 16, 18 and 20 Temperature: 10°C Contact time: 30 min Low level soiling (3 g/L BSA) Criteria: ≥4 log reduction	Fungicidal activity demonstrated at 40% v/v. Yeasticidal activity demonstrated at 18% v/v.	Test report 2020-MER-016 Supportive data (temperature and soiling not relevant with the claims)
Virucidal		AEROCLEAN (fresh product)	*ECBO virus*	EN 14675:2015 Phase 2 step 1 (suspension test)	Concentration tested (% v/v): 40, 50, 60, 70 and 80. Temperature: 10°C Contact time: 30 min High level soiling (10 g/L BSA + 10.0g/L yeast extract) Criteria: ≥4 log reduction	Virucidal activity demonstrated at 80% v/v.	Test report MIC.2002-181 Supportive data (temperature and soiling not

							relevant with the claims, presence of a precipitate)
Bactericidal Fungicidal Yeasticidal Virucidal	Disinfection in incubators and hatcheries (use #3) (PT3) by passiv evaporation	AEROCLEAN (fresh product)	*E. hirae* *A. brasiliensis*	Field test- Phase 3 Disinfection by evaporation at 37°C	Assay premises: 584 L incubator (59x66x150 cm) Concentration of pure product tested: 13 mL/m^3 Temperature: 37°C Contact time: 1.5 hours (bacteria) and 4 hours (fungi) High level soiling (10 g/L BSA + 10g/L yeast extract) Surface type: inox Bacteria: No ventilation Fungi: No ventilation up to 120 min then ventilation during 4.4 min to stabilize the temperature to 37°C then no ventilation until the end of the test. Product volume: 7.6 mL <u>Criteria</u>: Bacteria: ≥5 log reduction Fungi: ≥4 log reduction	Bactericidal activity against E. hirae: 3.55 log reduction for a contact time of 90 minutes. Residual product volume: 2.2 mL => insufficient efficacy (Probably due to a too short contact time). Fungicidal activity demonstrated : 5.28 log reduction at 13 mL/m^3 (No residual product at the end of the test) and 4 hours contact time and high level soiling conditions	Test report R2008SMER001 RI = 3 (only one bacterial strain, absence of eggs in the incubator to simulate the real use)
Bactericidal Fungicidal Virucidal	Disinfection of empty building and materials (PT3) – use #4	AEROCLEAN (17 months old aged product)	*P. aeruginosa* *P. hauseri* *S. aureus* *E. hirae* *E. coli* *ECBO Virus* *A. brasiliensis* *C. albicans*	EN17272:2020 Phase 2 step 2	Semi-field trial using an electrical aerosol applicator Cold nebulisation OCENE (Hurricane model) <u>Concentration of pure product tested</u> : 4 to 10 mL/m^3 Temperature: 20°C Contact time: 60 min Low level soiling (3 g/L BSA) R.H.: 50-75% (at test begin) Counted flow: 16.1 to 17.8 L/h	Bactericidal activity at 4.9 mL pure product /m^3 (1/8th pure product diluted in hard water, 1210 mL dispersed in 4min 05s thus 17.78 L/h, contact time =1h, 21°C / 50% R.H.). Yeasticidal activity at 3.9 mL pure product /m^3 (1/10th pure product diluted in hard water, 1195 mL dispersed in 4min 10s thus 17.21 L/h, contact time =1h, 22°C / 52% R.H.).	Test report MIC.20/05-291.EV/B-F-V HPA RI = 2 (bacteria, yeast, fungi) RI = 3 (virus strain not expected by the norm)

					On the floor / nozzle at 35 cm of the floor Particle size: 7 to 30 µm Dimension : 30.87 m^3 (6.10 x 2.30 x 2.20 m) Criteria: Bacteria: ≥5 log reduction Fungi: ≥4 log reduction Virus: ≥4 log reduction	Fungicidal activity at 9.7 mL pure product /m^3 (1/4th pure product diluted in hard water, 1198 mL dispersed in 4min 05s thus 17.60 L/h, contact time =1h, 21°C / 55% R.H.). Virucidal activity on ECBO virus at 5.1 mL pure product /m^3 (1/8th pure product diluted in hard water, 1265 mL dispersed in 4min 35s thus 16.56 L/h, contact time =1h, 22°C / 63% R.H.).	
Bactericidal Fungicidal Virucidal	Disinfection of eggs storage rooms (use #2); breeding premises in presence of animals (use #5) (PT3)	AEROCLEAN (accelerated aging of 2 weeks at 54°C in the same packaging material to be marketed (PEHD))	*E. hirae* *ECBO Virus* *A. brasiliensis*	NF T 72-281:2014 Phase 2 step 2	Semi-field trial using an electrical aerosol applicator Cold nebulisation OCENE (Hurricane model) Concentration of pure product tested: 7 to 13 mL/m^3 Temperature: 18-20°C Contact time: 60 min High level soiling (10 g/L BSA + 10 g/L yeast extract) R.H.: 40-80% (at test begin) Counted flow: 16.7 to 19.5 L/h On the floor / nozzle at 35 cm of the floor Particle size: 7 to 30 µm Dimension : 30.87 m^3 (6.10 x 2.30 x 2.20 m) Criteria: Bacteria: ≥5 log reduction Fungi: ≥4 log reduction Virus: ≥4 log reduction	Bactericidal activity demonstrated at 7.8 mL pure product /m^3 (1/4th pure product diluted in hard water, 965 mL dispersed in 3 min 09 s thus 18.38L/h, contact time =1h, 18.5°C / 44% R.H.). Fungicidal activity demonstrated at 13.8 mL pure product /m^3 (1/2 pure product diluted in hard water, 850 mL dispersed in 3 min 03 s thus 16.72L/h, contact time =1h, 19°C / 55% R.H.). Virucidal activity against ECBO virus demonstrated at 7.6 mL pure product /m^3 (1/4th pure product diluted in hard water, 940 mL, dispersed in 3 min thus 18.8 L/h, contact time =1h, 18°C / 55% R.H.).	Test report MIC.19/03-251.EV/B-F-V HPA RI = 2 (only one bacterial strain tested and yeasts not tested)

Bactericidal Fungicidal Virucidal	Disinfection of eggs storage rooms (use #2); incubators and hatcheries (use #3); breeding premises in presence of animals (use #5) (PT3)	AEROCLEAN (17 months old aged product)	*P. aeruginosa* *P. hauseri* *S. aureus* *E. hirae* *E. coli* *ECBO Virus* *A. brasiliensis* *C. albicans*	EN17272:2020 (NF T 72-281:2014) Phase 2 step 2	Semi-field trial using an electrical aerosol applicator Cold nebulisation OCENE (Hurricane model) <u>Concentration of pure product tested</u>: 7 to 13 mL/m^3 Temperature: 18-20°C Contact time: 60 min High level soiling (10 g/L BSA + 10g/L yeast extract) R.H.: 50-75% (at test begin) Counted flow: 16.9 to 20.4 L/h On the floor / nozzle at 35 cm of the floor Particle size: 7 to 30 µm Dimension : 30.87 m^3 (6.10 x 2.30 x 2.20 m) <u>Criteria</u>: Bacteria: ≥5 log reduction Fungi: ≥4 log reduction Virus: ≥4 log reduction	Bactericidal activity demonstrated at 8.15 mL pure product /m^3 (1/4.5th pure product diluted in hard water, 1132 mL dispersed in 3 min 32s thus 19.22L/h, contact time =1h, 19°C / 52% R.H.). Fungicidal activity demonstrated at 13.17 mL pure product /m^3 (1/3rd pure product diluted in hard water, 1220 mL dispersed in 4min 05s thus 17.93 L/h, contact time =1h, 20.5°C / 52% R.H.). Yeasticidal activity demonstrated at 4.94 mL pure product /m^3 (1/8th pure product diluted in hard water, 1220 mL dispersed in 4min thus 18.30L/h, contact time =1h, 21°C / 56% R.H.). Virucidal activity demonstrated at 7.76 mL pure product /m^3 (1/5th pure product diluted in hard water, 1198 mL dispersed in 4min 15s thus 16.91L/h, contact time =1h, 22°C / 51% R.H.).	Test report MIC.20/03-091.EV/B-F-V HPA RI = 2 for the uses #2 and #5 (temperature, absence of eggs) RI = 3 for use #3 (application by evaporation)
Virucidal	Disinfection of empty building and materials (PT3) – use #4	AEROCLEAN (17 months old aged product)	Porcine parvovirus	EN17272:2020 Phase 2 step 2	Semi-field trial using an electrical aerosol applicator Cold nebulisation OCENE (Hurricane model) <u>Concentration of pure product tested</u>: 5.18 mL/m^3 Temperature: 18°C Contact time: 60 min	Virucidal activity demonstrated at 5.18 mL pure product /m^3 (1/8th pure product diluted in hard water, 1280 mL dispersed in 4min 30s thus 17.07L/h, contact time =1h, 18°C / 70% R.H.).	Test report MIC.22/10-121.EV/V HPA RI = 1

					Low level soiling (3 g/L BSA) R.H.: 70% (at test begin) Counted flow: 17.1 L/h On the floor / nozzle at 35 cm of the floor Particle size: 7 to 30 µm Dimension : 30.87 m^3 (6.10 x 2.30 x 2.20 m) Criteria: ≥4 log reduction		
Virucidal	Disinfection of eggs storage rooms (use #2); incubators and hatcheries (use #3); breeding premises in presence of animals (use #5) (PT3)	AEROCLEAN (17 months old aged product)	Porcine parvovirus	EN17272:2020 Phase 2 step 2	Semi-field trial using an electrical aerosol applicator Cold nebulisation OCENE (Hurricane model) Concentration of pure product tested: 7.81 mL/m^3 Temperature: 19°C Contact time: 60 min High level soiling (10 g/L BSA + 10 g/L yeast extract) R.H.: 67% (at test begin) Counted flow: 17.7 L/h On the floor / nozzle at 35 cm of the floor Particle size: 7 to 30 µm Dimension : 30.87 m^3 (6.10 x 2.30 x 2.20 m) Criteria: ≥4 log reduction	Virucidal activity demonstrated at 7.81 mL pure product /m^3 (1/5th pure product diluted in hard water, 1205 mL dispersed in 4min 05s thus 17.71L/h, contact time =1h, 19°C / 67% R.H.).	Test report MIC.22/10-171.EV/V HPA RI = 1 for the uses #2 and #5 (temperature, absence of eggs) RI = 3 for use #3 (application by evaporation)
Fungicidal	Disinfection of empty building and materials (PT3) – use #4	AEROCLEAN (6 months old aged product)	*A. brasiliensis*	Field test-Phase 3 according to EN17272:2020 Preliminary testing of performance qualification of 2 systems of airborne	Electrical nebuliser (ZEPHIRE) – 2 devices Assessment of the fungicidal activity in 10 areas of a building of 620 m^3 i.e. 310 m^3 per device. Concentration of pure product tested : 9.42 mL/m^3	Mean global reduction: 2.68 Efficacy criteria has not been fulfilled. Fungicidal activity is not demonstrated.	Study R1907MER001 RI = 2

				ZEPHIRE of surface disinfection in real use conditions. Cold nebulisation	Concentration of AEROCLEAN: 73% in water of distribution network Volume of the dilution in the tanks at T0: 5.5 litres Residual volume after 33 minutes of running: ZEPHIRE A: 1,8 L ZEPHIRE B: 1,2 L Particle size: 5 à 80 µm Operating time: 33 minutes Contact time: 60 min Low level soiling (3 g/L BSA) Temperature: 28.7°C R.H.: 42.5% Distance between 2 ZEPHIRES: 1.5 m <u>Criteria</u>: ≥4-5 log reduction		
Bactericidal	Disinfection of empty building and materials (PT3) – use #4	AEROCLEAN (8 months old aged product)	*E. hirae*	Field test-Phase 3 according to EN17272:2020 Preliminary testing of performance qualification of 2 systems of airborne ZEPHIRE of surface disinfection in real use conditions. Cold nebulisation	Electrical nebuliser (ZEPHIRE) – 2 devices Assessment of bactericidal activity in 10 areas of a building of 620 m^3 i.e. 310 m^3 per device. <u>Concentration of pure product tested</u> : 4.23 mL/m^3 Conc. of AEROCLEAN: 36.4% in water of distribution network. Volume of the dilution in the tanks at T0: 5.5 litres Residual volume after 66 minutes of running: ZEPHIRE A: 2.2 L ZEPHIRE B: 1,6 L Particle size: 5 à 80 µm	Mean global reduction: 3.04 Efficacy criteria is not been fulfilled. Bactericidal activity is not demonstrated.	Study R1909MER001 RI = 3 (only one bacterial strain)

					Operating time: 66 minutes Contact time: 60 min Low level soiling (3 g/L BSA) Temperature : 23.5°C R.H.: 39.9% Distance between 2 ZEPHIRES: 1.5 m. <u>Criteria</u>: ≥5-6 log reduction		
Bactericidal Fungicidal	Disinfection of empty building and materials (PT3) – use #4	AEROCLEAN (9 months old aged product)	*E. hirae* *A. brasiliensis*	Field test-Phase 3 according to EN17272:2020 Disinfection of a building of 1053m^3 per device - with thermo-nebulisation, in real use conditions.	Electrical nebuliser One device (No information on the test device) Assessment of bactericidal and fungicidal activity in 10 areas of a building of 1053 m^3. <u>Concentration tested</u> : Bacteria: final volume 6 L (5L AEROCLEAN + 1 L raw water) Fungi: final volume 12 L (10L AEROCLEAN + 2 L raw water) Residual volume after running time: not mentioned. Contact time: 180 min Low level soiling (3 g/L BSA) Operating time: Bacteria: 21 minutes Fungi: 34 minutes Temperature : 13.4 to 16.6°C R.H.: 59.4 to 65.4% <u>Criteria</u>: Bacteria: ≥ 5-6 log reduction Fungi: ≥ 4-5 log reduction	Bactericidal activity: Mean reduction: 4.84 Log Fungicidal activity: Mean reduction: 3.46 Log => Insufficient bactericidal and fungicidal activity.	Study R1912MER004 RI = 3 (only *E. hirae* and *A. brasiliensis* tested, no information on the test device, residual volume not reported)

It has to be noted that according to the applicant, semi-field tests and field tests for TP3 could not be performed at 10°C as the climate was not sufficiently cold when the test was performed (the lowest temperature was reached for a thermo-nebulisation test at 13°C). Thereby, on SPC and label, the contact times are indicated for a temperature of 20°C.

Claimed Use #2: *PT3 – Airborne disinfection of eggs storage rooms (including eggs) against bacteria, yeasts, fungi and viruses by cold nebulization for buildings up to 150 m³ (per device), at 20°C in high level soiling conditions.*

Following studies have been submitted:

To support bactericidal claims:

- A test according to EN 1656. The product AEROCLEAN (1 year aged) passed the test at 14% (v/v) under low-level soiling conditions (3 g/l bovine albumin) at 30 minutes contact time and 10°C. This test is considered supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.
- A test according to EN 16437 to support bactericidal efficacy on porous surfaces. The product AEROCLEAN (11 months aged) passed the test at 100% (v/v) under low-level soiling conditions (3 g/l bovine albumin) at 60 minutes contact time and 10°C. However, the test and the low-level soiling conditions are not relevant for this use.
- A test according to NF T72-281. The product AEROCLEAN (aged 2 weeks at 54°C) applied by cold nebulization (particle size: 7 to 30 µm), in a 30.87 m^3 room, passed the test at 7.82 mL pure product /m^3 diluted at 1/4th in hard water, 965 mL dilution dispersed in 3min 09s (i.e. 18.38L/H), under high-level soiling conditions (10 g/L BSA+10 g/L yeast extracts), at 1 hour contact time, at 18.5°C and 44% R.H. However, this test was only performed on *E. hirae*.
- A test according to EN 17272. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a >4 m^3 room, passed the test at 8.15 mL pure product /m^3 diluted at 1/4.5th in hard water, 1132 mL dilution dispersed in 3min 32s (i.e. 19.22L/H), under high-level soiling conditions (10 g/L BSA+10 g/L yeast extracts), at 1 hour contact time, at 22°C and 52% R.H.

The bactericidal activity of AEROCLEAN is demonstrated for an application by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room (large enclosure), at 8.15 mL pure product /m^3 diluted at 1/4.5th in hard water, 1132 mL dilution dispersed in 3min 32s (i.e. 19.22L/H or 320.3 ml/min), with a contact time of one hour at 20°C and 50-75% RH, under high-level soiling conditions, on non-porous surfaces only, and in absence of eggs as the provided data does not permit to conclude on this use. Indeed, the presence of eggs could lead to a consumption of product (egg shell = porous surface) and thus tests performed in absence of eggs could overestimate the efficacy of the product.

To support yeasticidal claims:

- A test according to EN 1657. The product AEROCLEAN (1 year aged) passed the test at 18% v/v under low-level soiling conditions (3 g/L bovine albumin) at 30 minutes contact time and 10°C. This test is considered supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.
- A test according to EN 17272. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room (large room), passed the test at 4.94 mL pure product /m^3 diluted at 1/8th in hard water, 1220 mL dilution

dispersed in 4min (i.e. 18.3L/H), under high-level soiling conditions (10 g/L BSA+10 g/L yeast extracts), at 1 hour contact time, at 21°C and 56% R.H.

The yeasticidal activity of AEROCLEAN is demonstrated for an application by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room (large enclosure), at 4.94 mL pure product /m^3 diluted at 1/8th in hard water, 1220 mL dilution dispersed in 4min (i.e. 18.3L/H or 305 ml/min), with a contact time of one hour at 20°C and 50-75% RH, under high-level soiling conditions and in absence of eggs as the provided data does not permit to conclude on this use (for the same reason as mentioned above).

To support fungicidal claims:

- A test according to EN 1657. The product AEROCLEAN (1 year aged) passed the test at 40% v/v under low-level soiling conditions (3 g/L bovine albumin) at 30 minutes contact time and 10°C. This test is considered supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.
- A test according to NF T72-281. The product AEROCLEAN (aged 2 weeks at 54°C) applied by cold nebulization (particle size: 7 to 30 µm), in a 30.87 m^3 room, passed the test at 13.77 mL pure product /m^3 diluted at 50% v/v in hard water, 850 mL dilution dispersed in 3min 03s (i.e. 16.72L/H), under high-level soiling conditions (10 g/L BSA+10 g/L yeast extracts), at 1 hour contact time, at 19°C and 55% R.H. However, this test was only performed on *A. brasiliensis*.
- A test according to EN 17272. The product AEROCLEAN (18 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test at 13.17 mL pure product /m^3 diluted at 1/3rd in hard water, 1220 mL dilution dispersed in 4min 05s (i.e. 17.93L/H), under high-level soiling conditions (10 g/L BSA+10 g/L yeast extracts), at 1 hour contact time, at 20.5°C and 52% R.H.

The fungicidal activity of AEROCLEAN is demonstrated for an application by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room (large enclosure), at 13.17 mL pure product /m^3 diluted at 1/3rd in hard water, 1220 mL dilution dispersed in 4min 05s (i.e. 17.93L/H or 298.8 ml/min), with a contact time of one hour at 20°C and 50-75% RH, under high-level soiling conditions and in absence of eggs as the provided data does not permit to conclude on this use (for the same reason as mentioned above).

To support virucidal claims:

- A test according to EN 14675. This test has been performed on ECBO Virus. The product AEROCLEAN (fresh) passed the test at 80% (v/v) under high-level soiling conditions (10 g/l BSA + 10 g/L yeast extract) at 30 minutes contact time and 10°C. This test is considered supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.
- A test according to NF T72-281 on ECBO virus. The product AEROCLEAN (aged 2 weeks at 54°C) applied by cold nebulization (particle size: 7 to 30 µm), in a 30.87 m^3 room, passed the test at 7.61 mL pure product /m^3 diluted at 1/4th in hard water, 940 mL dilution dispersed in 3 min (i.e. 18.8L/H), under high-level soiling conditions (10 g/L BSA+10 g/L yeast extracts), at 1 hour contact time, at 18°C and 55% R.H.

A test according to EN 17272 performed on porcine parvovirus. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test at 7.81 mL pure product /m^3 diluted at 1/5th in hard water, 1205 mL dilution dispersed in 4min 05s (i.e. 17.71L/H), under high-level soiling conditions (10 g/L BSA+10 g/L yeast extracts), at 1 hour contact time, at 19°C and 67% R.H.

The virucidal activity of AEROCLEAN is demonstrated for an application by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room (large enclosure), at 7.81 mL pure product /m^3 diluted at 1/5th in hard water, 1205 mL dilution dispersed in 4min 05s (i.e. 17.71 L/H or 295.2 mL/min), with a contact time of one hour at 19 °C and 67% RH, under high-level soiling conditions and in absence of eggs as the provided data does not permit to conclude on this use (for the same reason as mentioned above).

Claimed Use #3: *PT3 – Airborne disinfection of incubators and hatcheries (including eggs) against bacteria, yeasts, fungi and viruses by natural evaporation in buildings up to 30m^3, at 35-38°C in high level soiling conditions.*

Following studies have been submitted:

To support bactericidal claims:

- A test according to EN 1656. The product AEROCLEAN (1 year aged) passed the test at 14% (v/v) under low-level soiling conditions (3 g/L bovine albumin) at 30 minutes contact time and 10°C. This test is considered supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.
- A test according to EN 16437 to support bactericidal efficacy on porous surfaces. The product AEROCLEAN (11 months aged) passed the test at 100% v/v under low-level soiling conditions (3 g/L bovine albumin) at 60 minutes contact time and 10°C. However, this test and the low-level soiling conditions are not relevant for this use.
- A test according to EN 17272. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test at 8.15 mL pure product /m^3 diluted at 1/4.5th in hard water, 1132 mL dilution dispersed in 3min 32s (i.e. 19.22L/H), under high-level soiling conditions (10 g/L BSA+10 g/L yeast extracts), at 1 hour contact time, at 22°C and 52% R.H. However, the application method is not relevant for this use; this is test is not acceptable.
- A semi-field test with an application by natural evaporation has been submitted. However, this test has only been performed on *E. hirae* and demonstrates insufficient efficacy on this target organisms with a contact time of 90 minutes instead of the claimed 240 minutes. Furthermore, no eggs have been included in the test system.

The bactericidal activity of AEROCLEAN is not demonstrated for this use.

To support yeasticidal claims:

- A test according to EN 1657. The product AEROCLEAN (1 year aged) passed the test at 18% (v/v) under low-level soiling conditions (3 g/L bovine albumin) at 30 minutes contact time and 10°C. This test is considered supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.
- A test according to EN 17272. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test at 4.94 mL pure product /m^3 diluted at 1/8th in hard water, 1220 mL dilution dispersed in 4min (i.e. 18.3 L/H), under high-level soiling conditions (10 g/L BSA+10 g/L yeast extracts), at 1 hour contact time, at 21°C and 56% R.H. However, the application method is not relevant for this use; this is test is not acceptable.
- No test with an application by natural evaporation has been submitted.

The yeasticidal activity of AEROCLEAN is not demonstrated for this use.

To support fungicidal claims:

- A test according to EN 1657. The product AEROCLEAN (1 year aged) passed the test at 40% v/v under low-level soiling conditions (3 g/L bovine albumin) at 30 minutes contact time and 10°C. This test is considered supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.
- A test according to EN 17272. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test at 13.17 mL pure product /m^3 diluted at 1/3rd in hard water, 1220 mL dilution dispersed in 4min 05s (i.e. 17.93L/H), under high-level soiling conditions (10 g/L BSA+10 g/L yeast extracts), at 1 hour contact time, at 20.5°C and 52% R.H. However, the application method is not relevant for this use; this is test is not acceptable.
- A semi-field test with an application by natural evaporation has been submitted. Fungicidal activity on *A. brasiliensis* has been demonstrated in high level soiling conditions, with a contact time of 240 minutes, at 37°C and 50% RH, for a volume of 584L. However, no eggs have been included in the test system, and yeast have not been tests.

The fungicidal activity of AEROCLEAN is not demonstrated.

To support virucidal claims:

- A test according to EN 14675. This test has been performed on ECBO Virus. The product AEROCLEAN (fresh) passed the test at 80% v/v under high level soiling conditions (10 g/L BSA + 10 g/L yeast extract) at 30 minutes contact time and 10°C. This test is considered supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.
- A test according to EN 17272 performed on porcine parvovirus. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test at 7.81 mL pure product /m^3 diluted at 1/5th in hard water, 1205 mL dilution dispersed in 4min 05s (i.e. 17.71L/H), under high-level soiling conditions (10 g/L BSA+10 g/L yeast extracts), at 1 hour contact time, at 19°C and 67% R.H.
- No test with an application by natural evaporation has been submitted.

The virucidal activity of AEROCLEAN is not demonstrated for this use.

Claimed Use #4: *PT3 – Airborne disinfection of empty buildings and materials against bacteria, yeasts, fungi and viruses by cold nebulization for buildings up to 300m^3 and thermonebulisation for buildings up to 1000m^3 (per application device), at 18-20°C in low level soiling conditions.*

Following studies have been submitted:

To support bactericidal claims:

- A test according to EN 1656. The product AEROCLEAN (1 year aged) passed the test at 14% v/v under low-level soiling conditions (3 g/L bovine albumin) at 30 minutes contact time and 10°C. This test is considered supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.

- A test according to EN 16437 to support bactericidal efficacy on porous surfaces. The product AEROCLEAN (11 months aged) passed the test at 100% v/v under low-level soiling conditions (3 g/L bovine albumin) at 60 minutes contact time and 10°C. However, the test is not relevant for this use.
- A test according to EN 17272. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test at 4.90 mL pure product /m^3 diluted at 1/8th in hard water, 1210 mL dilution dispersed in 4min 05s (i.e. 17.78 L/H), under low-level soiling conditions (3 g/l bovine albumin), at 1 hour contact time, at 21°C and 52% RH.
- A field-test following the methods of the EN 17272 in order to support the efficacy of AEROCLEAN by cold nebulization in large enclosures (310 m^3 per device, electrical nebulizer with 5 to 80 particle size). This test did not pass the criteria of the standard. Furthermore, the test was performed only on *E. Hirae*, at 23.5°C and 39.9% RH.
- A field-test following the methods of the EN 17272 in order to support the efficacy of AEROCLEAN by thermonebulisation in large enclosures (1053 m^3 per device). This test did not pass the criteria of the standard. Furthermore, the test was performed only on *E. Hirae* and no information has been given on the thermonebulisation device in the test report.
- No further test has been submitted to support thermonebulisation application.

The bactericidal activity of AEROCLEAN is demonstrated for an application by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room (large enclosure), at 4.9 mL pure product /m^3 diluted at 1/8th in hard water, 1210 mL dilution dispersed in 4min 05s (i.e. 17.78 L/H or 296.3 ml/min), with a contact time of one hour at 20°C and 50-75% RH, under low-level soiling conditions, on non-porous surfaces. Provided data do not permit to demonstrate the efficacy of thermonebulisation application.

To support yeasticidal claims:

- A test according to EN 1657. The product AEROCLEAN (1 year aged) passed the test at 18% v/v under low-level soiling conditions (3 g/L bovine albumin) at 30 minutes contact time and 10°C. This test is considered supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.
- A test according to EN 17272. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test at 3.9 mL pure product /m^3 diluted at 1/10th in raw water, 1195 mL dilution dispersed in 4min 10s (i.e. 17.21L/H), under low-level soiling conditions (3 g/L bovine albumin), at 1 hour contact time, at 22°C and 52% R.H.
- No further test has been submitted to support thermonebulisation application.

The yeasticidal activity of AEROCLEAN is demonstrated for an application by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room (large enclosure), at 3.87 mL pure product /m^3 diluted at 1/10th in hard water, 1195 mL dilution dispersed in 4min 10s (i.e. 17.21 L/H or 286.8 mL/min), with a contact time of one hour at 20°C and 50-75% RH, under low-level soiling conditions. Provided data do not permit to demonstrate the efficacy of thermonebulisation application.

To support fungicidal claims:

- A test according to EN 1657. The product AEROCLEAN (1 year aged) passed the test at 40% v/v under low-level soiling conditions (3 g/L bovine albumin) at 30 minutes contact time and 10°C. This test is considered supportive data, only phase 2 step 2

tests are taken into consideration as requested in the updated version for the efficacy guidance.

- A test according to EN 17272. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test at 9.70 mL pure product /m^3 diluted at 1/4th in raw water, 1198 mL dilution dispersed in 4min 05s (i.e. 17.60 L/H), under low-level soiling conditions (3 g/L bovine albumin), at 1 hour contact time, at 21°C and 55% RH.
- A field-test following the method of the EN 17272 in order to support the efficacy of AEROCLEAN by cold nebulization in large enclosures (310 m^3 per device, electrical nebulizer with 5 to 80 particle size). This test did not pass the criteria of the standard. Furthermore, the test was performed only on *A. brasiliensis*, at 28.7°C and 42.5% RH.
- A field-test following the method of the EN 17272 in order to support the efficacy of AEROCLEAN by thermonebulisation in large enclosures (1053 m^3 per device). This test did not pass the criteria of the standard. Furthermore, the test was performed only on *A. brasiliensis* and no information has been given on the thermonebulisation device in the test report.
- No further test has been submitted to support thermonebulisation application.

The fungicidal activity of AEROCLEAN is demonstrated for an application by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room (large enclosure), at 9.7 mL pure product /m^3 diluted at 1/4th in hard water, 1198 mL dilution dispersed in 4min 05s (i.e. 17.60 L/H or 293.3 ml/min), with a contact time of one hour at 20°C and 50-75% RH, under low-level soiling conditions.

To support virucidal claims:

- A test according to EN 14675. This test has been performed on ECBO Virus. The product AEROCLEAN (fresh) passed the test at 80% v/v under high-level soiling conditions (10 g/L BSA + 10 g/L yeast extract) at 30 minutes contact time and 10°C. This test is considered supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.
- A test according to EN 17272 performed on porcine parvovirus. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test at 5.18 mL pure product /m^3 diluted at 1/8th in hard water, 1280 mL dilution dispersed in 4min 30s (i.e. 17.07L/H), under low-level soiling conditions (3 g/L BSA), at 1 hour contact time, at 18°C and 70% R.H.
- No field test has been submitted for application by cold nebulization and thermonebulisation in > 150m^3 buildings.

The virucidal activity is demonstrated for an application by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room (large enclosure), at 5.18 mL pure product /m^3 diluted at 1/8th in hard water, 1280 mL dilution dispersed in 4min 30s (i.e. 17.07L/H or 284.5 mL/min), with a contact time of one hour at 18°C and 70% RH, under low-level soiling conditions.

Claimed Use #5: *PT3 – Airborne disinfection of breeding premises in presence of animals against bacteria, yeasts and viruses by cold nebulization for buildings up to 300m^3 (per device), at 20°C in high level soiling conditions.*

Following studies have been submitted:

To support bactericidal claims:

- A test according to EN 1656. The product AEROCLEAN (1 year aged) passed the test at 14% v/v under low-level soiling conditions (3 g/L bovine albumin) at 30 minutes contact time and 10°C. This test is considered supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.
- A test according to EN 16437 to support bactericidal efficacy on porous surfaces. The product AEROCLEAN (11 months aged) passed the test at 100% v/v under low-level soiling conditions (3 g/L bovine albumin) at 60 minutes contact time and 10°C. However, this test and the low-level soiling conditions are not relevant for this use.
- A test according to NF T72-281. The product AEROCLEAN (aged 2 weeks at 54°C) applied by cold nebulization (particle size: 7 to 30 µm), in a 30.87 m^3 room, passed the test at 7.82 mL pure product /m^3 diluted at 1/4th in hard water, 965 mL dilution dispersed in 3min 09s (i.e. 18.38L/H), under high-level soiling conditions (10 g/L BSA+10 g/L yeast extracts), at 1 hour contact time, at 18.5°C and 44% R.H. However, this test was only performed on *E. hirae*.
- A test according to EN 17272. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test at 8.15 mL pure product /m^3 diluted at 1/4.5th in hard water, 1132 mL dilution dispersed in 3min 32s (i.e. 19.22L/H), under high-level soiling conditions (10 g/L BSA+10 g/L yeast extracts), at 1 hour contact time, at 22°C and 52% R.H.
- A field-test following the method of the EN 17272 in order to support the efficacy of AEROCLEAN by cold nebulization in > 150 m^3 buildings. This test did not pass the criteria of the standard. Furthermore, the test was performed only on *E. hirae*, at 23.5°C and 39.9% RH.

The bactericidal activity of AEROCLEAN is demonstrated for an application by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room (large enclosure), at 8.15 mL pure product /m^3 diluted at 1/4.5th in hard water, 1132 mL dilution dispersed in 3min 32s (i.e. 19.22 L/H or 320.3 mL/min), with a contact time of one hour at 20°C and 50-75% RH, under high-level soiling conditions, on non-porous surfaces only.

To support yeasticidal claims:

- A test according to EN 1657. The product AEROCLEAN (1 year aged) passed the test at 18% v/v under low-level soiling conditions (3 g/L bovine albumin) at 30 minutes contact time and 10°C. This test is considered supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.
- A test according to EN 17272. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test at 4.94 mL pure product /m^3 diluted at 1/8th in hard water, 1220 mL dilution dispersed in 4 min (i.e. 18.3 L/H), under high-level soiling conditions (10 g/L BSA+10 g/L yeast extracts), at 1 hour contact time, at 21°C and 56% R.H.

The yeasticidal activity of AEROCLEAN is demonstrated for an application by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room (large enclosure), at 4.94 mL pure product /m^3 diluted at 1/8th in hard water, 1220 mL dilution dispersed in 4min (i.e. 18.3 L/H or 305 mL/min), with a contact time of one hour at 20°C and 50-75% RH, under high-level soiling conditions.

To support virucidal claims:

- A test according to EN 14675. This test has been performed on ECBO Virus. The product AEROCLEAN (fresh) passed the test at 80% v/v under high-level soiling conditions (10 g/L BSA + 10 g/L yeast extract) at 30 minutes contact time and 10°C. This test is considered supportive data, only phase 2 step 2 tests are taken into consideration as requested in the updated version for the efficacy guidance.
- A test according to NF T72-281 on ECBO virus. The product AEROCLEAN (aged 2 weeks at 54°C) applied by cold nebulization (particle size: 7 to 30 µm), in a 30.87 m^3 room, passed the test at 7.61 mL pure product /m^3 diluted at 1/4th in hard water, 940 mL dilution dispersed in 3 min (i.e. 18.8 L/H), under high-level soiling conditions (10 g/L BSA+10 g/L yeast extracts), at 1 hour contact time, at 18 °C and 55% R.H.
- A test according to EN 17272 performed on porcine parvovirus. The product AEROCLEAN (17 months aged) applied by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room, passed the test at 7.81 mL pure product /m^3 diluted at 1/5th in hard water, 1205 mL dilution dispersed in 4min 05s (i.e. 17.71L/H), under high-level soiling conditions (10 g/L BSA+10 g/L yeast extracts), at 1 hour contact time, at 19°C and 67% R.H.

The virucidal activity is demonstrated for an application by cold nebulization (particle size: 7 to 30 µm), in a > 4 m^3 room (large enclosure), at 7.81 mL pure product /m^3 diluted at 1/5th in hard water, 1205 mL dilution dispersed in 4min 05s (i.e. 17.71 L/H or 295.2 mL/min), with a contact time of one hour at 19°C and 67% RH, under high-level soiling conditions.

To conclude on use #2, #3, #4 and #5, efficacy is demonstrated for:

- Use 2: Airborne disinfection of eggs storage rooms (excluding eggs) (PT 03) by cold nebulization in large enclosures, in high-level soiling conditions on non-porous surfaces:
  - Mandatory target organisms:
    - Bacteria, yeasts and fungi: at 13.17 mL pure product /m^3 diluted at 1/3rd in hard water, 1220 mL dilution dispersed in 4min 05s (i.e. 17.93L/H or 298.8 mL/min), 1h, 20°C and 50-75% RH.
  - Other target organisms:
    - Viruses: at 7.81 mL pure product /m^3 diluted at 1/5th in hard water, 1205 mL dilution dispersed in 4min 05s (i.e. 17.71L/H or 295.2 mL/min), 1h, 19°C and 67% RH.
- Use 4: Airborne disinfection of empty buildings and materials (PT3) by cold nebulization in large enclosures in low-level soiling conditions:
  - Mandatory target organisms:
    - Bacteria, yeasts: at 4.9 mL pure product /m^3 diluted at 1/8^{th} in hard water, 1210 mL dilution dispersed in 4min 05s (i.e. 17,78L/H or 296.3 mL/min), 1h, 20°C, 50-75% RH.
  - Other target organisms:
    - Fungi: at 9.7 mL pure product /m^3 diluted at 1/4^{th} in hard water, 1198 mL dilution dispersed in 4min 05s (i.e. 17,93L/H or 293.3 mL/min), 1h, 20°C, 50-75% RH.
    - Viruses: at 5.18 mL pure product /m^3 diluted at 1/8th in hard water, 1280 mL dilution dispersed in 4min 30s (i.e. 17.07L/H or 284.5 mL/min), 1h, 18°C and 70% RH.
- Use 5: Airborne disinfection of breeding premises in presence of animals (PT 03) by cold nebulization (particle size: 7 to 30 µm), in large enclosures, in high-level soiling conditions, on non-porous surfaces:
  - Mandatory target organisms:
    - Bacteria, yeasts: at 8.15 mL pure product /m^3 diluted at 1/4.5^{th} in hard water, 1132 mL dilution dispersed in 3min 32s (i.e. 19.22 L/H or 320.3 mL/min), 1h, 20°C, 50-75% RH.
  - Other target organisms:
    - Viruses: at 7.81 mL pure product /m^3 diluted at 1/5th in hard water, 1205 mL dilution dispersed in 4min 05s (i.e. 17.71L/H or 295.2 mL/min), 1h, 19°C and 67% RH.

Efficacy is not demonstrated for use #3 (PT3 – Airborne disinfection of incubators and hatcheries (including eggs) by natural evaporation). Efficacy for thermonebulisation is also not demonstrated.

Conclusion on the efficacy of the product

The biocidal product AEROCLEAN, has shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C), for the following uses claimed:

- Use 1: Airborne disinfection of empty greenhouses and empty material shelters (PT 02) by cold nebulization (particle size: 7 to 30 µm), in large enclosures, in dirty conditions (except for greenhouses), on non-porous surfaces:
  - Mandatory target organisms:
    - Bacteria, yeasts: at 5 mL pure product /m^3 diluted at 12.5% v/v in hard water, 1210 mL dilution dispersed at 17.78L/H (i.e. 296.3 ml/min), 1h, 20°C, 50-75% RH.
  - Other target organisms:
    - Fungi : 10 mL pure product /m^3 diluted at 25% in hard water, 1198 mL dilution dispersed at 17.60L/H (i.e. 293.3 ml/min), 1h, 20°C, 50-75% RH.
    - Enveloped viruses: 5.2 mL pure product /m^3 diluted at 12.5% v/v in raw water, 1280 mL dilution dispersed in 4min 30s (i.e. 17.07L/H or 284.5 mL/min), 1h, 20°C and 50-75% RH..

Following use instruction will be added in the SPC: "The product should only be used on visually clean surfaces when applied in greenhouses".

- Use 2: Airborne disinfection of eggs storage rooms (not including eggs) (PT3) by cold nebulization (particle size: 7 to 30 µm) in large enclosures, in high-level soiling conditions, on non-porous surfaces.
  - Mandatory target organisms:
    - Bacteria, yeasts, fungi: at 13.2 mL pure product /m^3 diluted at 33% v/v in hard water, 1220 mL dilution dispersed at 17.93L/H (i.e. 298.8 mL/min), 1h, 20°C, 50-75% RH.
  - Other target organisms:
    - Viruses: at 8 mL pure product /m^3 diluted at 20% v/v in hard water, 1205 mL dilution dispersed in 4min 05s (i.e. 17.71L/H or 295.2 ml/min), 1h, 20°C and 50-75% RH.

- Use 3: Airborne disinfection of incubators and hatcheries (including eggs) (PT3) by natural evaporation for buildings up to 30m^3, at 37°C in high-level soiling conditions is not validated.

- Use 4: Airborne disinfection of empty buildings and materials by cold nebulization (particle size: 7 to 30 µm) in large enclosures, in low-level soiling conditions, on non-porous.
  - Mandatory target organisms:
    - Bacteria, yeasts: at 5 mL pure product /m^3 diluted at 12.5% v/v in hard water, 1210 mL dilution dispersed at 17,78L/H (i.e. 296.3 mL/min), 1h, 20°C, 50-75% RH.
  - Other target organisms:
    - Fungi: at 10 mL pure product /m^3 diluted at 25% v/v in hard water, 1198 mL dilution dispersed at 17,93L/H (i.e. 293.3 mL/min), 1h, 20°C, 50-75% RH.

- Viruses: at 5.2 mL pure product /m^3 diluted at 25% v/v pure product diluted in hard water, 1280 mL dilution dispersed in 4min 30s (i.e. 17.07L/H or 284.5 mL/min), 1h, 20°C and 50-75% RH.

- Use 5[5]: Airborne disinfection of breeding premises in presence of animals by cold nebulization (particle size: 7 to 30 µm) for buildings up to 300 m^3 (per application device), in high-level soiling conditions, on non-porous surfaces.
  - Mandatory target organisms:
    - Bacteria, yeast: at 8.2 mL pure product /m^3 diluted at 23% v/v in hard water, 1132 mL dilution dispersed at 19.22L/H (i.e. 320.3 ml/min), 1h, 20°C, 50-75% RH.
  - Other target organisms:
    - Viruses: at 8 mL pure product /m^3 diluted at 20% in hard water, 1205 mL dilution dispersed in 4min 05s (i.e. 17.71L/H or 295.2 ml/min), 1h, 20°C and 50-75% RH.

- Use 6: Airborne disinfection of empty buildings and materials in food and feed industries (PT 04) by cold nebulization (particle size: 7 to 30 µm), in large enclosures, in dirty conditions, on non-porous surfaces:
  - Mandatory target organisms:
    - Bacteria, yeasts: at 5 mL pure product /m^3 diluted at 12.5% v/v in hard water, 1210 mL dilution dispersed at 17.78L/H (i.e. 296.3 mL/min), 1h, 20°C, 50-75% RH.
  - Other target organisms:
    - Fungi : 10 mL pure product /m^3 diluted at 25% v/v in hard water, 1198 mL dilution dispersed at 17.60L/H (i.e. 293.3 mL/min), 1h, 20°C, 50-75% RH.
    - Enveloped viruses only: 5.2 mL pure product /m^3 diluted at 12.5% v/v in raw water, 1280 mL dilution dispersed in 4min 30s (i.e. 17.07L/H or 284.5 mL/min), 1h, 20°C and 50-75% RH.

It has to be noted that the contact time corresponds to the dwell phase defined as the contact time required to obtain the expected level of efficacy (vol II parts B&C: November 2022, §5.4.2.5.2).

In order to validate the efficacy of the product AEROCLEAN until the end of its shelf life (18 months), the applicant has provided semi-field test performed according to EN 17272 with a 17-month-aged product for the uses #1, #2, #4, #5, and #6. Efficacy is therefore demonstrated for these uses until a shelf-life of 17 months.

2.2.5.6 Occurrence of resistance and resistance management

- According to the assessment report of L-(+)-lactic acid:
There is no known resistance reported for PT 2, 3 and 4 applications. Taking into account the mode of action of L-(+)-lactic acid which is no-specific, development of resistance against L-(+)-lactic acid is unlikely.

- According to the assessment report of Hydrogen peroxide:

[5] Use 5 "Airborne disinfection of breeding premises in presence of animals […]." corresponds to use 4 "Airborne disinfection of breeding premises" in the SPC.

The lethal effects of oxidative molecular species generated from hydrogen peroxide can be avoided with any damage being repaired in microorganisms such as *Escherichia coli* and *Salmonella typhimurium*. When *E.coli* and *S.typhimurium* are exposed to low concentrations of H_2O_2, 3 µM and 60 µM respectively, cells produce enzymes and other proteins, which are important for cellular defence and mitigate the toxic effects of the oxidative species. This adaptive response is triggered by non-toxic levels of the oxidative species to protect against and produce resistance to oxidative stress caused when challenged with higher concentrations, 10 mM (Dukan and Touati (1996), Christman *et al.* (1985)). The resistance to oxidative stress that *E.coli* develops when exposed to H_20_2, as reported in literature papers, demonstrates an adaptive response only. Hydrogen peroxide has been intensively used as a disinfectant and preservative for more than 3 decades and has not lead to the development of significant resistance levels among field populations. Genetically inherited resistance is not expected when the products are used as recommended.

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

2.2.5.7 Known limitations

None.

2.2.5.8 Evaluation of the label claims

Please refer above to the conclusion on the efficacy of the product.

Biological validation shall be performed for each room to be disinfected (or in a suitable "standard" room in a facility, if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter.

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

Not applicable

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

No eye irritation study, no acute inhalation, oral and dermal toxicity study and no skin sensitisation study performed on the product AEROCLEAN have been provided. A classification by calculation according to the CLP Regulation n°1272/2008 rules is performed for these end-points. The harmonised classification (when available) and classification proposed in the provided MSDS have been used for active substances and co-formulants.
An eye irritation study has been performed on dilutions of the product AEROCLEAN, the study has been assessed and data have been reported in the PAR (see below).

No human data is available.

Skin corrosion and irritation

Summary table of in vitro studies on skin corrosion/irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 435 Corrositex RI 1 but not relevant for the classification	Aeroclean Batch No JH051218-1-V8S40C corresponding to Aeroclean batch No. JH051218-1 incubated 8 weeks at 40°C Hydrogen peroxide (4%), lactic acid (2%) Dose: 500µL 4 synthetic proteinaceous bio-barrier	GLP	Negative control (propionic acid 6%v/v): not disrupt the membrane → not corrosive Positive control (sodium hydroxide): disrupt the membrane after 11min 47s → skin corr 1B Test item: not disrupt the membrane after 1 hour (four replicate) → not corrosive	Active substances content in the tested material is lower than the content which is claimed in the product as the tested material is aged product: 4% instead of 7.5% for Hydrogen peroxide and 2% instead of 5% for lactic acid	[redacted] 2019 ; In Vitro Membrane Barrier Test Method for skin Corrosion [redacted]

Summary table of in vitro studies on skin corrosion/irritation					
OECD 439 Epidermis Test Method RI 1	Aeroclean Batch No JH051218-1 Hydrogen peroxide (7.55%), lactic acid (5%) Dose: 16µL 3 living Reconstructed Human epidermis (Batch No. 19-RHE-004) during 42min	GLP After application, rinsing with 25mL DPBS and a 41h 25min post-incubation period at 37°C, 5% CO_2 Cell viability measured by enzymatic conversion of vital dye MTT into a blue formazan salt quantitatively measured after extraction from tissues	Mean percent viability of treated tissues: 1.2% (test item) 1.1% (positive control, 5% Sodium dodecyl Sulfate) (negative control: distilled water) → skin irr category 2 or Skin corr category 1		[redacted] 2019 ; In Vitro skin irritation: Reconstructed Human Epidermis Test Method [redacted]

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The product AEROCLEAN is corrosive.
Justification for the value/conclusion	Taking into account the lower concentration of active substances in the tested material of the study OECD 435 (4% instead of 7.5% for Hydrogen peroxide and 2% instead of 5% for lactic acid), it is not possible to conclude that the product AEROCLEAN is not corrosive based on this study. Based on the Epidermis Test, the product AEROCLEAN is classified skin irritant category 2 or skin corrosive category 1. The product is therefore classified based on available data on the composition of the product and according to the classification rules laid down in the CLP Regulation.
Classification of the product according to CLP and DSD	Skin corr. 1C – H314

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The product AEROCLEAN is serious eye damaging
Justification for the value/conclusion	Based on available data on the composition of the product and according to the classification rules laid down in the CLP Regulation, the product AEROCLEAN is classified severe eye damage H318.
Classification of the product according to CLP and DSD	Eye Dam. 1 – H318

A study has been provided for the eye irritation of dilutions of the product AEROCLEAN at 10%, 8% and 5%:

Summary table of in vitro studies on skin corrosion/irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 492 RI 2	Dilution at 10%, 8% and 5% of the product Aeroclean old sample Batch No JH260319-1 Hydrogen peroxide (7.35%), lactic acid (5.0%) Dose: 50µL RhCE EpiOcular OCL-212-ver2.0 (MatTek Corporation, batch No. 30668) RhCE tissue viability measured by enzymatic conversion of the vital dye MTT [3-(4,5-Dimethylthiazol-2-yl)-2,5-	Non-GLP	Tissue viability of the RhCE replicates treated with AEROCLEAN diluted at: 10%: 78.39% viability 8%: 81.00% viability 5%: 93.80% viability Vs 37.40% viability for the positive control (Methyl acetate) → the dilutions at 10%, 8% and 5% of AEROCLEAN are not classified for eye irritation		[redacted] 2021 ; Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage [redacted]

Summary table of in vitro studies on skin corrosion/irritation					
	diphenyltetrazolium bromide; Thiazolyl blue tetrazolium bromide; CAS number 298-93-1] by the viable cells of the tissue into a blue MTT formazan salt (quantitatively measured after extraction from tissue) OD at 570nm				

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Based on available data on the composition of the product and according to the classification rules laid down in the CLP Regulation, a classification for corrosivity is considered to implicitly cover the potential to cause respiratory tract irritation. The labelling EUH071 is required as an exposure to aerosols is expected.
Classification of the product according to CLP and DSD	Not classified The labelling will mention the following statement: EUH 071 : corrosive to the respiratory tract

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitization	
Value/conclusion	The product AEROCLEAN is not skin sensitizer
Justification for the value/conclusion	Based on available data on the composition of the product and according to the classification rules laid down in the CLP Regulation, no classification for the skin sensitisation is required for the product AEROCLEAN. Regarding the mention EUH208, none component classified Skin Sens 1A or 1B are present at a content equal to or superior to 1/10th of the GCL in the product. No mention EUH 208 is required.
Classification of the product according to CLP and DSD	Not classified

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitization	
Value/conclusion	The product AEROCLEAN is not sensitizer for the respiratory track.
Justification for the value/conclusion	Based on available data on the composition of the product and according to the classification rules laid down in the CLP Regulation, no classification for the respiratory sensitisation is required for the product AEROCLEAN.
Classification of the product according to CLP and DSD	Not classified

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	The product AEROCLEAN is not toxic by oral route
Justification for the selected value	According to the formulation, only the active substance hydrogen peroxide is classified Acute toxicity cat. 4 - H302. Based on LD_{50} available in the CAR of the active substance, ATEmix calculation has been done (see confidential annex for details). ATEmix is higher than 2000 mg/kg bw leading to no classification of the product AEROCLEAN for oral acute toxicity.
Classification of the product according to CLP and DSD	Not classified

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	The product AEROCLEAN is not toxic by inhalation
Justification for the selected value	The active substance hydrogen peroxide is classified Acute toxicity cat. 4 - H332. Information on LC_{50} is available in the CAR of the active substance. But based on previous AMM UE with hydrogen peroxide, the default value for Acute toxicity cat. 4 is used for ATEmix calculation. Another ingredient in the product is classified Acute toxicity cat. 4 - H332 based on MSDS information. As the product is used by nebulization, ATEmix calculation has been done for vapour and for mist. (see confidential annex for details). ATEmix is higher than 20 mg/L (vapour) and 5 mg/L (mist) leading to no classification of the product AEROCLEAN for acute toxicity by inhalation.
Classification of the product according to CLP and DSD	Not classified

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	The product AEROCLEAN is not toxic by dermal route
Justification for the selected value	Based on available data on the composition of the products and according to the classification rules laid down in the CLP Regulation, no classification is required for acute toxicity by dermal route for the product AEROCLEAN.
Classification of the product according to CLP and DSD	Not classified

Available toxicological data relating to a mixture

Not relevant

2.2.6.2 Information on dermal absorption

No dermal absorption study has been submitted by the applicant on the product AEROCLEAN. However taking into account that only local risk assessment is performed, dermal absorption value is not relevant.

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

No SOC is identified linked to the classification of the product.

None of ingredients of the composition have an European IOELV.
One co-formulant is an active substance. However, it is listed on the annex I, therefore it is not considered as a SOC.

2.2.6.4 Other

As the two active substances degrade by more than 10% in the stability study, degradation products have been identified and quantified in the stability study. A toxicological risk assessment is needed regarding these degradation products. Please see confidential PAR for further details.

2.2.6.5 Exposure assessment and risk characterization for human health

Following the WG TOX I - 2021 that took place on March 2021 and in the frame of the discussion of the CAR of Lactic Acid TP6, it has been agreed to not perform the comparison of endogenous L-(+)-lactic acid with systemic exposure levels at product authorization. Consequently, no calculation regarding the estimation of level of exposure of lactic acid is performed.

Therefore, since the product AEROCLEAN is classified Skin corr. 1C (H314) and Eye Dam. 1 (H318), only a qualitative local risk assessment is performed for the exposure to L-(+)-lactic.

For hydrogen peroxide, dermal and inhalation exposure assessment is addressed. For dermal exposure, only a qualitative local risk assessment is performed. For inhalation exposure, a quantitative local risk assessment is performed.

Primary exposure will be assessed for professional users only, as the product Aeroclean is intended to be used only by professionals.
Secondary exposure for professional and general public will also be assessed.

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

Reference values to be used in Risk Characterization

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AEC inhalation (hydrogen peroxide)	NOAEC in 90-day inhalation study (rat)				1.25 mg/m^3
NOAEC dermal* (Lactic acid)					10%
ARfD					-
ADI					-

* The dermal NOEC value of lactic acid will not be used in the assessment as the product is classified for local effects. Dermal effect will be covered by the qualitative assessment.

List of scenarios

Summary table: exposure scenarios		
Scenario and task number	**Description of scenario and tasks**	**Exposed group**
Uses # 1, 4 and 6: Airborne disinfection of empty buildings / material by nebulisation (cold or thermo) **Uses # 2 and 5: Airborne disinfection of egg storage rooms or in presence of animals by nebulisation**		
[Scenario 1]	***Airborne disinfection by nebulisation***	

Task [1.1]	Mixing and loading of the product	Professional
Task [1.2]	Application of the product and re-entry in the room	Professional (primary exposure) Professional and general public (secondary exposure)
Task [1.3]	Cleaning nebulising device	Professional
Use # 3: Airborne disinfection of incubators and hatcheries (PT3) by evaporation		
[Scenario 2]	***Airborne disinfection by evaporation***	
Task [2.1]	Loading of the product in the plate	Professional
Task [2.2]	Application of the product	Professional
Task [2.3]	Re-entry in the room / opening the incubator and removing / cleaning of the plate	Professional (primary exposure) Professional and general public (secondary exposure)

For secondary exposure, no specific scenario is developed, only a re-entry time is determined based on the scenario assessed for the primary exposure.

Uses # 1, 4 and 6: Airborne disinfection of empty buildings / material by nebulisation (cold or thermo) - PT2, 3 and 4
Uses # 2 and 5: Airborne disinfection of egg storage rooms or in presence of animals by nebulization – PT3

The product is used to disinfect empty buildings and materials by nebulisation. The maximum claimed used concentration is 10mL of pure product per cubic meter for uses 1, 4 and 6 and 13mL of pure product per cubic meter for uses 2 and 8mL for use 5. The maximum volume to be disinfected is 300m^3 for cold nebulisation (uses 1, 4 and 6) and nebulisation (use 5), 1000m^3 for thermo nebulisation (uses 1, 4 and 6) and 150m^3 for nebulisation (use 2).
Regarding the claimed dose for uses 2 and 5, the efficacy has validated a dose of 13.2mL of pure product per cubic meter for use 2 and 8.2mL of pure product per cubic meter for use 5. The validated dose of 13.2mL/m3 has been use in the risk assessment instead of 13mL/m3 for use 2. Use 5 is covered by uses 1, 4 and 6 - cold nebulisation, assessment has been performed at 10mL/m3 for max 300m3 for these 4 uses.

The product is diluted in water and put in the nebulising device.
For thermo and cold nebulisation (use 1, 4 and 6), the dilution rate is between 25% v/v and 100% v/v (equivalent to pure product) depending on the size of the building and the nebulising device. For nebulisation (use 5), the maximum dilution rate is 10% v/v and for nebulisation (use 2), the dilution rate is between 20% and 33% v/v.
Regarding the maximum dilution rate claimed for use 5, the efficacy has validated a dilution rate at 23%. This dilution rate of 23% has therefore been used for use 5 instead of 10% in the risk assessment.

The ventilation should be stopped only for use 5. The contact time ranges between 1 hour minimum for cold nebulisation (uses 1, 4 and 6) and nebulisation (uses 2 and 5) to 3 hours

minimum for thermo-nebulisation (uses 1, 4 and 6) at 18-20°C. After application, the nebulising device is cleaned.

This is summarized in the table below:

Use	**1**	**4**	**6**	**2**	**5**
	Airborne disinfection of empty buildings, empty rooms, and equipment for industries, amenities, sanitation facilities, greenhouses and storage buildings	Airborne disinfection of empty buildings and materials	Airborne disinfection of empty buildings and materials on surfaces in contact with food or feed	Airborne disinfection of eggs storage rooms	Airborne disinfection of breeding premises in presence of animals
Application rate (pure product)	10mL/m3	10mL/m3	10mL/m3	13mL/m3	8mL/m3
Maximum volume to be disinfected	Up to 300 m3 Cold nebulisation	Up to 300 m3 Cold nebulisation	Up to 300 m3 Cold nebulisation	Up to 150 m3 Nebulisation	Up to 300 m3 Nebulisation
	Up to 1000 m3 Thermo nebulisation	Up to 1000 m3 Thermo nebulisation	Up to 1000 m3 Thermo nebulisation		
Efficacy validation (if > to claimed use)	-	-	-	13.2ml/m3	8.2ml/m3
Dilution (v/v)	25-100%	25-100%	25-100%	20-33%	Max 10%
Efficacy validation (if > to claimed use)	-	-	-	-	23%
Contact time	1h (cold nebulisation) 3h (thermo nebulisation)	1h (cold nebulisation) 3h (thermo nebulisation)	1h (cold nebulisation) 3h (thermo nebulisation)	1h	1h
Remark					Ventilation stopped

Dermal and inhalation exposure is expected during the mixing and loading of the product and during the nebulisation.

The pure product is classified H314/ H318, a qualitative assessment is performed for dermal exposure.
Regarding the classification of the dilution, for thermo and cold nebulisation (uses 1, 4 and 6), as the dilution rate could be up to 100% v/v (equivalent to pure product) the dilutions have been considered classified as the pure product as a worst-case.
For uses 2 and 5, classification of the dilution has been performed for 20%, 23% and 33% v/v dilution rate. The dilutions at 20% and 23% are classified skin irrit. 2 - H315, Eye irrit.

2 - H319 and the dilution at 33% is classified skin irrit. 2 - H315, Eye Dam. 1 - H318. (See excel file and confidential annex for further information)

Primary exposure

Scenario 1: Airborne disinfection by nebulization

Task [1.1]: Mixing and Loading of the product

Description of Task [1.1]
The professional user dilutes the product and put the dilution in the nebulising device. Exposure by inhalation to aerosol is considered negligible, only exposure by inhalation to vapour is expected during the task. Taking into account the different packaging size, the dilution can be done manually or automatically. Manual mixing and loading is assessed and will cover automatic mixing and loading. Inhalation exposure to vapour has been assessed using **ConsExpo – Exposure to vapour – Evaporation from constant surface**. A duration of 10 min has been considered for this task. Half of the packaging is considered for the exposure to vapour from the bottle during mixing and loading task in ConsExpo. Taking into account the maximum packaging size of 20L which can be manually poured, the quantity of product used in the model is half of the packaging size: 10L which corresponds to 10420g with the density of 1.042 for the evaporation from the bottle. Regarding the release area, as no information is available for the opening of the bottle, a circular opening of 5 cm diameter has been used.

Input parameters for Task [1.1]

	Parameters[6]	Value	Reference and justification[7]
Tier 1 (no RPE)	Concentration of hydrogen peroxide in the product	7.5%	Applicant's data
	Exposure duration	10min	See explanation above
	Molecular weight matrix (water)	18 g/mol	
	Room volume	1 m3	User breathing zone
	Ventilation rate	0.6/h	Unknown room
	Product amount (in bottle)	10420g	See explanation above
	Release area (opening of the bottle)	20 cm2	See explanation above
	Release area (plate)	572cm2	See explanation above
	Application duration	10min	See explanation above
	Mass transfer rate	10m/h	ConsExpo
	Vapour pressure	214 Pa	
	Temperature	20°C	

Calculations for Task [1.1]

Local effects

Summary table: estimated local exposure and risk characterisation for professional users				
Exposure scenario	**Tier/PPE**	**Estimated dermal exposure [%]**	**Estimated inhalation exposure [mg/m³]**	**Estimated total exposure [mg/m³ or %]**
Task [1.1]	1/no RPE	nr	0.2	nr

Task [1.2]: Application of the product and re-entry in the room

Description of Task [1.2] – exposure to aerosol

For cold nebulization and nebulization, to assess inhalation exposure to aerosol during the nebulisation, the **Spraying model 1**, from BHHEM (p.281), is used. This model covers the mixing and loading and the application tasks. As exposure to aerosol is not expected during mixing and loading, the concentration of active substance in the diluted product is used for calculation.

The exposure value from the model is as follow:

- 104 mg/m³ (inhalation)

Calculation for inhalation exposure is made with 7.5% hydrogen peroxide for cold nebulization (uses 1, 4 and 6 as a worst-case, calculation is made with 1.81% hydrogen peroxide for nebulization for use 5 and calculation is made with 2.59% hydrogen peroxide for nebulization for use 2 (concentration ranges between 1.57% and 2.59% in the different dilutions).

For thermo nebulization as the diluted product under the form of vapour is vaporized in the rooms/buildings, no exposure to aerosol is considered.

Tier	Parameters	Value	Source
1	Max hydrogen peroxide for uses 1, 4 and 6	7.5%	Applicant's data
	Max hydrogen peroxide for use 2	2.59%	Applicant's data
	Max hydrogen peroxide for use 5	1.81%	Applicant's data
	Inhalation exposure value (mg/m3)	104 mg/m³	Spraying model 1
2	Respiratory protective equipment	APF 4 (uses 2 and 5) APF 10 (uses 1, 4 and 6)	

Calculations for Task [1.2] – exposure to aerosol

[6] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE.

[7] Include the source of information (e.g. product information, recommendations, guidance documents, exposure models) and justification (where needed).

Local effects

Summary table: estimated local exposure and risk characterisation for professional users				
Exposure scenario	**Tier/PPE**	**Estimated dermal exposure [%]**	**Estimated inhalation exposure [mg/m³]**	**Estimated total exposure [mg/m³ or %]**
Task [1.2]	**Uses 1, 4 and 6 – cold nebulisation**			
	1/no RPE	nr	7.8	nr
	2/APF 10	nr	0.78	nr
	Use 2 - nebulisation			
	1/no RPE	nr	2.7	nr
	2/APF 4	nr	0.67	nr
	Use 5 - nebulisation			
	1/no RPE	nr	1.88	nr
	2/APF 4	nr	0.47	nr

Description of Task [1.2] - exposure to vapour

During the nebulisation and contact time (minimum 1-3h depending on the nebulisation type), the user can be exposed by inhalation to vapour.

The concentration of active substance in the air has not to exceed the AEC (1.25 mg/m^3). If the air concentration of the active substance exceeds the AEC, the user has not be present during the nebulisation and contact time and a re-entry period has to be calculated.

For this task, two steps are assessed:
- First determination of the air concentration of the active substance at the end of the contact time
- Then from this air concentration and considering the ventilation rate, determination of the re-entry time

a) Determination of the air concentration of the substance at the end of the contact time

For nebulisation and cold nebulisation:
It is considered that the aerosol of the diluted product will deposit on all the surfaces of the rooms/buildings (floor, wall and ceiling) after the nebulisation and evaporation from the surfaces will occur.

The concentration of the substance in the air at the end of the application has been modelised with **ConsExpo – Exposure to vapour – Evaporation from constant surface** following the recommendation 16 (a). The release surface area has been calculated considering a height of 2.5m for building of max 150m3 and 3m for building up to 300m3. By default a ventilation rate of 0.6/h has been chosen. This is also relevant for use 5 where the ventilation is stopped in the building considering that the building is not hermetically closed (natural ventilation, door, window and additional ventilation openings closed) cf. ConsExpo general Factsheet p 26.

For thermo nebulisation:
The diluted product under the form of vapour is vaporized in the rooms/buildings.

The concentration of the substance in the air at the end of the application has been modelised with **ConsExpo – Exposure to vapour – Instantaneous release** (a). By default a ventilation rate of 0.6/h has been chosen considering that the building is not hermetically closed (natural ventilation, door, window and additional ventilation openings closed) cf. ConsExpo general Factsheet p 26.

b) Determination of the re-entry time

After the application by nebulisation, the professional has to re-activate the ventilation in the treated room (for use 5). Thus, another ConsExpo model **ConsExpo – Exposure to vapour – Instantaneous release** has been chosen to modelise the air concentration of substance when the ventilation rate of treated room is re-activated to its initial value in order to determine a re-entry time in the building (b). Different ventilation rates have been chosen to cover the different uses (2/h, 8/h or 20/h).

Input parameters for Task [1.2]

	Parameters[8]	Value	Reference and justification[9]
a) Concentration in the air at the end of the contact time			
Common parameter	Concentration of hydrogen peroxide in the product	7.5%	Applicant's data
	Product amount (uses 1, 4 and 6) – thermo nebulisation	10420g	Applicant's data 10mL/m^3 x 1000m^3 x1.042
	Room volume – thermo nebulisation	1000m3	Applicant's data

[8] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE.

[9] Include the source of information (e.g. product information, recommendations, guidance documents, exposure models) and justification (where needed).

	Product amount (uses 1, 4 and 6) – cold nebulisation / (use 5) - nebulisation	3126g	Applicant's data 10mL/m^3 x 300m^3 x1.042
	Room volume – cold nebulisation / nebulisation	300m3	Applicant's data
	Release area – cold nebulisation / nebulisation	320m2	Considering a building of 3m high
	Product amount (use 2) - nebulisation	2063g	Applicant's data 13.2mL/m^3 x 150m^3 x1.042
	Room volume (use 2)	150m3	Applicant's data
	Release area (use 2)	200m2	Considering a building of 2.5m high
	Ventilation rate	0.6/h	Default value
	Mass transfer rate	10m/h	ConsExpo
	Vapour pressure	214 Pa	CAR data
	Temperature	20°C	CAR data
	Emission duration (uses 1, 4 and 6) – thermo nebulisation	3h	Applicant's data
	Emission duration (uses 1, 4 and 6) – cold nebulisation / (use 5) - nebulisation	1h	Applicant's data
	Emission duration (use 2)	1h	Applicant's data
Tier 1	No RPE	-	
Tier 2	RPE	APF 40	
b) Air concentration when the ventilation of treated room is re-activated			
Common parameter	Concentration of hydrogen peroxide in the product	100%	The modelisation in ConsExpo (a) give a value for the active substance
	Product amount (uses 1, 4 and 6) – thermo nebulisation	130g	1.3x10^2 mg/m^3 (result obtain in a) see below) x1000 m^3
	Room volume – thermo nebulisation	1000m3	Applicant's data
	Product amount (uses 1, 4 and 6) – cold nebulisation / (use 5) - nebulisation	129g	4.3x10^2 mg/m^3 (result obtain in a) see below) x300 m^3
	Room volume – cold nebulisation	300m3	Applicant's data
	Product amount (use 2) - nebulisation	85.5g	5.7x10^2 mg/m^3 (result obtain in a) see below) x150m^3
	Room volume (use 2)	150m3	Applicant's data
	Ventilation rates	2/h 8/h 20/h	Default value

	Mass transfer rate	10m/h	ConsExpo
	Vapour pressure	214 Pa	CAR data
	Temperature	20°C	CAR data
Tier 1	No RPE	-	
Tier 2	RPE	APF 40	

Calculations for Task [1.2] – Exposure to vapour

Local effects

a) Concentration of substance in the air at the end of the application

Summary table: estimated local exposure and risk characterisation for professional users				
Exposure scenario	**Tier/PPE**	**Estimated dermal exposure [%]**	**Estimated air concentration [mg/m³]**	**Estimated total exposure [mg/m³ or %]**
Task [1.2]	Uses 1, 4 and 6 – cold nebulisation / Use 5 - nebulisation			
	Tier 1/no RPE	nr	$4.3x10^2$	nr
	Tier 2/APF 40	nr	11	nr
	Use 2 - nebulisation			
	Tier 1/no RPE	nr	$5.7x10^2$	nr
	Tier 2/APF 40	nr	14	nr
	Uses 1, 4 and 6 – thermo nebulisation			
	Tier 1/no RPE	nr	$1.3x10^2$	nr
	Tier 2/APF 40	nr	3.3	nr

b) Air concentration of substance when the ventilation of treated room is re-activated – calculation of the re-entry time

Ventilation rate: 2/h

Cold nebulisation (Uses 1, 4 and 6) – Nebulisation (use 5)

RPE	**Air concentration (mg/m3)**	**Time (h)**
Without RPE	1.2	2.96
APF 4	4.9	2.24
APF 10	12	1.80
APF 40	50	1.08

Nebulisation (use 2)

RPE	Air concentration (mg/m3)	Time (h)
Without RPE	1.2	3.08
APF 4	4.7	2.40
APF 10	12	1.92
APF 40	48	1.24

Thermo nebulisation (Uses 1, 4 and 6)

RPE	Air concentration (mg/m3)	Time (h)
Without RPE	1.2	2.36
APF 4	4.9	1.64
APF 10	12	1.20
APF 40	50	0.48

Ventilation rate: 8/h

Cold nebulisation (Uses 1, 4 and 6) – Nebulisation (use 5)

RPE	Air concentration (mg/m3)	Time (min)
Without RPE	1.2	44
APF 4	4.9	34
APF 10	12	27
APF 40	50	16

Nebulisation (use 2)

RPE	Air concentration (mg/m3)	Time (min)
Without RPE	1.2	46
APF 4	4.7	36
APF 10	12	29
APF 40	48	19

Thermo nebulisation (Uses 1, 4 and 6)

RPE	Air concentration (mg/m3)	Time (min)
Without RPE	1.2	35
APF 4	4.9	25
APF 10	12	18
APF 40	50	7

Ventilation rate: 20/h

Cold nebulisation (Uses 1, 4 and 6) – Nebulisation (use 5)

RPE	Air concentration (mg/m3)	Time (min)
Without RPE	1.1	18
APF 4	4.3	14
APF 10	12	11
APF 40	48	7

Nebulisation (use 2)

RPE	Air concentration (mg/m3)	Time (min)
Without RPE	1.2	19
APF 4	4.7	14
APF 10	10	12
APF 40	42	8

Thermo nebulisation (Uses 1, 4 and 6)

RPE	Air concentration (mg/m3)	Time (min)
Without RPE	1.1	14
APF 4	4.3	10
APF 10	12	7
APF 40	48	3

Task [1.3]: Cleaning nebulizing device

Description of Task [1.3]
After the treatment, the nebulizing device should be cleaned. The BEAT model - cleaning of the spray equipment is used to assess this exposure. Only dermal exposure is considered and will be assessed in the local risk assessment. Inhalation exposure to aerosol is considered negligible and inhalation exposure to vapour is also considered negligible taking into account that only few amount of product remains in the device and the product will be diluted during the cleaning.

Combined exposure

Combined exposure is not relevant based on the absence of systemic effects after exposure towards hydrogen peroxide and L-(+)-lactic acid. The addition of exposure levels and the calculation of combined exposure during the different tasks (e.g. mixing and loading, application and post-application) is not relevant.

Outcome of quantitative local exposure and risk characterisation

Summary table: estimated local exposure and risk characterisation for professional users

Summary table: estimated local exposure and risk characterisation for professional users				
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure [mg/m³]**	**Estimated exposure / AEC (%)** AECinhalation = 1.25 mg/m³	**Acceptable (yes/no)**
Scenario [1]				
Task[1.1]	1/no RPE	0.2	16%	yes
Task[1.2] Exposure to aerosol	Uses 1, 4 and 6 – cold nebulisation			
	1/no RPE	7.8	627%	no
	2/APF 10	0.78	63%	yes
	Use 2 - nebulisation			
	1/no RPE	2.7	215%	no
	2/APF 4	0.67	54%	yes
	Use 5 - nebulisation			
	1/no RPE	1.88	151%	no
	2/APF 4	0.47	38%	yes
Task[1.2] Exposure to vapour	Uses 1, 4 and 6 – cold nebulisation / Use 5 - nebulisation			
	a) Tier 1/no RPE	$4.3x10^2$	34400%	no
	a) Tier 2/APF 40	11	860%	no
	b) Tier 1/no RPE	1.2 After 3h at 2/h After 44min at 8/h After 18min at 20/h	96%	yes
	b) Tier 2/APF 40	1.25 After 1h05 at 2/h After 16min at 8/h After 7min at 20/h	100%	yes
	Use 2 - nebulisation			
	a) Tier 1/no RPE	$5.7x10^2$	45600%	no
	a) Tier 2/APF 40	14	1140%	no
	b) Tier 1/no RPE	1.2 After 3h05 at 2/h After 46min at 8/h After 19min at 20/h	96%	yes
	b) Tier 2/APF 40	1.2 After 1h14 at 2/h After 19min at 8/h After 8min at 20/h	94%	yes
	Uses 1, 4 and 6 – thermo nebulisation			
	a) Tier 1/no RPE	$1.3x10^2$	10400%	no
	a) Tier 2/APF 40	3.3	260%	no
	b) Tier 1/no RPE	1.2 After 2h22 at 2/h After 35min at 8/h After 14min at 20/h	96%	yes

	b) Tier 2/APF 40	1.25 After 29 min at 2/h After 7min at 8/h After 3min at 20/h	100%	yes
Task[1.3]	nr			

As the air concentration at the end of the treatment (nebulisation and contact time) exceeds the AEC even with a RPE with APF 40 (task [1.2] – exposure to vapour a)), the user has not to be present during the nebulisation and contact time. The following RMM is therefore added:
"During the nebulization (treatment time), contact time (one hour / three hours) and during ventilation time, no person (operator, by-stander etc.) is allowed to be present within the treated area"

Moreover a re-entry period has been calculated depending on the ventilation rate (task [1.2] – exposure to vapour b)).

For simplicity and comprehensiveness of the RMM, it is proposed to round the re-entry delays whatever the use and the type of nebulisation. Hence for all uses 1, 2, 4, 5 and 6, the following RMM is proposed:

"The re-entry with a respiratory protective equipment min APF 40 is possible after treatment and contact time and a ventilation period of:

- 1h15 at ventilation rate of 2/h,
- 20min at ventilation rate of 8/h,
- 10min at ventilation rate of 20/h."

"The re-entry without RPE is possible after treatment and contact time and a ventilation period of:

- 3h at ventilation rate of 2/h,
- 45min at a ventilation rate of 8/h,
- 20min at a ventilation rate of 20/h."

After trilateral discussions with other member states, it has been agreed to amend the RMM as follow to have an easier practical use and also to be in line with the previous H2O2 dossiers:

"Seal the treatment enclosure (e.g. with tape) to ensure that hydrogen peroxide levels outside the enclosure are kept at acceptable health and safety levels."

"After nebulisation and contact time, the room must be ventilated, preferably by mechanical ventilation. The duration of the ventilation period has to be established by measurement with suitable measurement equipment. Re-entry is only permitted once the H2O2 air concentration has dropped below 0,9ppm (1.25 mg/m3) or the corresponding national reference value."

"Use a calibrated sensor to confirm the H2O2 air concentration is ≤0.9 ppm (1.25 mg/m3) or below the corresponding national reference value prior to re-entry."

"The professional user may only enter the room in emergency situations or to reactivate

the ventilation considering RPE with APF 40 against vapour (Type of RPE to be specified by the authorisation holder within the product information). The re-entry is therefore only possible when the hydrogen peroxide level has dropped below 36 ppm (50 mg/ m3) or below 40x the national reference value."

Outcome of qualitative local risk assessment

The product is intended to be applied by professionals. It is classified H314/ H318.
Dermal exposure is expected during the mixing and loading of the product. No aerosol exposure is expected.

The professional is using the product for the mixing & loading for a low duration per day and with PPE. Considering this, the risk is deemed acceptable. See table below.

Hazard			Exposure information							Risk	
Hazard category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE**	**Relevant RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
High	H314		2, 3 4	Mixing and loading	Skin	Few minutes per day Frequency: no data	Dermal contact	Gloves Skin coverage	Labelling • Labelling according to CLP Trained personnel • Professional workers RMM • In case of skin contact, wash skin exposed	Acceptable	(↑) High hazard category (↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low exposure duration (few min per day)
					Inhalation		No aerosol expected	None			
High	H318				Eye		Eye exposure through potential splashes or hand to eye transfer	Chemical goggles			

For thermo and cold nebulisation (uses 1, 4 and 6), as a worst-case, the dilution are classified H314 / H318 as the pure product.

For uses 2 and 5, the dilutions are classified H315 / H318 or H315/H319. (See excel file and confidential annex for further information)

During the cleaning of the nebulising device, the professional will be exposed for a low duration per day and with PPE. Considering this, the risk is deemed acceptable (see table below).

Dermal and inhalation exposure is possible during nebulization, however considering that due to inhalation exposure to vapour, the user has not to be present during nebulization, no further assessment is needed for dermal and aerosol exposure.

Hazard			Exposure information							Risk	
Hazard category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE**	**Relevant RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
High	H314		2, 3 4	Cleaning device	Skin	Few minutes per day Frequency: no data	Dermal contact	Gloves Skin coverage	Labelling • Labelling according to CLP Trained personnel • Professional workers RMM • In case of skin contact, wash skin exposed	Acceptable	(↑) High hazard category (↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low exposure duration (few min per day)
					Inhalation		No aerosol expected	none			
Low	H315				Skin		Dermal contact	Gloves Protective coverall			
High	H318				Eye		Eye exposure through aerosols or hand to eye transfer	Chemical goggles			
Low	H319				Eye		Eye exposure through aerosols or hand to eye transfer	Chemical goggles			

For contact with the cleaned surfaces, as the different dilutions are classified, risk is considered acceptable with the RMM: "Do not touch the surface until it is dried."

Secondary exposure

Inhalation and dermal exposure

Depending on the use, secondary exposure is possible after the disinfection during entry in a treated area and when touching treated surfaces.
For inhalation, the re-entry time calculated in scenario 1 task [1.3] without RPE depending on the ventilation rate used in the room is also applicable for secondary exposure.

For Uses 1, 4 and 6 – cold nebulisation / Use 5 – nebulisation, "The re-entry without RPE is possible after treatment, contact time and a ventilation period of:

- 3h at ventilation rate of 2/h,
- 44min at a ventilation rate of 8/h,
- 18min at a ventilation rate of 20/h."

For Use 2 – cold nebulisation, "The re-entry is possible after treatment and contact time without RPE after a ventilation period of:

- 3h05 at ventilation rate of 2/h,
- 46min at a ventilation rate of 8/h,
- 19min at a ventilation rate of 20/h"

For Uses 1, 4 and 6 by thermo nebulisation, "The re-entry is possible after treatment and contact time without RPE after a ventilation period of:

- 2h22 at ventilation rate of 2/h,
- 35min at a ventilation rate of 8/h,
- 14min at a ventilation rate of 20/h."

For simplicity and comprehensiveness of the RMM, it is proposed to round the re-entry delays whatever the use and the type of nebulisation. Hence for all uses 1, 2, 4, 5 and 6, the following RMM is proposed:
"The re-entry without RPE is possible after treatment and contact time and a ventilation period of:

- 3h at ventilation rate of 2/h,
- 45min at a ventilation rate of 8/h,
- 20min at a ventilation rate of 20/h."

After trilateral discussions with other member states, it has been agreed to amend the RMM as follow to have an easier practical use and also to be in line with the previous H2O2 dossiers:

"After nebulisation and contact time, the room must be ventilated, preferably by mechanical ventilation. The duration of the ventilation period has to be established by measurement with suitable measurement equipment. Re-entry is only permitted once the H2O2 air

concentration has dropped below 0,9ppm (1.25 mg/m3) or the corresponding national reference value."

"Use a calibrated sensor to confirm the H2O2 air concentration is ≤0.9 ppm (1.25 mg/m3) or below the corresponding national reference value prior to re-entry."

For contact with the cleaned surfaces, as the different dilutions are classified, risk is considered acceptable with the RMM: "Don't allow to touch the surface until it is dried".

Exposure of animals

For use 5, where animals are present during the treatment, inhalation and dermal exposure is expected during the nebulization of the product.

The dilution which is nebulized is classified H315 / H319. The nebulization occur in all directions and a contact time of minimum 1 hour is required. Moreover, estimated inhalation concentration of hydrogen peroxide is very high (34 400% of AEC, see task1.2).
Considering this, the risk is not considered as acceptable for animals present during the nebulization.
The use 5 can be acceptable only if the disinfection is performed in absence of animals.

Moreover animals have to wait before re-entering in the treated room.

For use 4, buildings are empty during the treatment, however inhalation and dermal exposure is also possible for animal during re-entry in the treated buildings. Therefore the animals have also to wait before re-entering in the treated room.

To conclude the following RMM are necessary for uses 4 and 5:

"Only use in empty animal housing" (only use 5)

"The re-entry is possible after treatment and contact time and a ventilation period of:
- 3h at ventilation rate of 2/h,
- 45min at a ventilation rate of 8/h,
- 20min at a ventilation rate of 20/h."

(uses 4 and 5)

After trilateral discussions with other member states, it has been agreed to amend the RMM as follow to have an easier practical use and also to be in line with the previous H2O2 dossiers:

"After nebulisation and contact time, the room must be ventilated, preferably by mechanical ventilation. The duration of the ventilation period has to be established by measurement with suitable measurement equipment. Re-entry is only permitted once the H2O2 air concentration has dropped below 0,9ppm (1.25 mg/m3) or the corresponding national reference value."

"Use a calibrated sensor to confirm the H2O2 air concentration is ≤0.9 ppm (1.25 mg/m3) or below the corresponding national reference value prior to re-entry."

"Don't allow to touch the surface until it is dried" (uses 4 and 5)

Conclusion for Uses # 1, 4 and 6: Airborne disinfection of empty buildings / material by nebulisation (cold or thermo) - PT2, 3 and 4 and Uses # 2 and 5: Airborne disinfection of egg storage rooms or in presence of animals by nebulization – PT3

For all uses: Uses 1, 4 and 6 - cold or thermo nebulisation and uses 2 and 5 - nebulisation

The risk is considered as acceptable considering local effects if the following PPE are worn:

During mixing and loading and cleaning of the device:

- ✓ Gloves
- ✓ Coverall
- ✓ Goggles

And with the following RMM

- "During the nebulization (treatment time), contact time (one hour or three hours) and during ventilation time, no person (operator, by-stander etc.) is allowed to be present within the treated area"
- "Seal the treatment enclosure (e.g. with tape) to ensure that hydrogen peroxide levels outside the enclosure are kept at acceptable health and safety levels
- "In case of skin contact, wash skin exposed"
- "During the nebulization (treatment time), contact time (one hour) and during ventilation time, no person (operator, by-stander etc.) is allowed to be present within the treated area"
- "After nebulisation and contact time, the room must be ventilated, preferably by mechanical ventilation. The duration of the ventilation period has to be established by measurement with suitable measurement equipment. Re-entry is only permitted once the H2O2 air concentration has dropped below 0,9ppm (1.25 mg/m3) or the corresponding national reference value."
- "Use a calibrated sensor to confirm the H2O2 air concentration is ≤0.9 ppm (1.25 mg/m3) or below the corresponding national reference value prior to re-entry."
- "The professional user may only enter the room in emergency situations or to reactivate the ventilation considering RPE with APF 40 against vapour (Type of RPE to be specified by the authorisation holder within the product information). The re-entry is therefore only possible when the hydrogen peroxide level has dropped below 36 ppm (50 mg/ m3) or below 40x the national reference value."
- "Do not allow to touch the surface until it is dried"

Risk is not acceptable for animals for use 5 if present during nebulization. The use 5 can be acceptable only if the disinfection is performed in absence of animals. Risk is therefore acceptable with the following additional RMM:

- "Only use in empty animal housing"

Use # 3: Airborne disinfection of incubators and hatcheries (PT3)

The product is used to disinfect incubators and hatcheries by evaporation. The claimed used concentration is 13mL of pure product per cubic meter. The maximum volume to be disinfected is 30m3.

The product is put in a large plate on the ground of incubator or hatchery. The product is allowed to evaporate totally at 35-38°C. Minimum 4 hours of contact time is recommended.

Dermal and inhalation exposure is expected during the loading of the product in the plate. Inhalation exposure is expected during the opening of the incubator / hatchery. Moreover dermal exposure is expected in the incubator / hatchery after disinfection.

Primary exposure

Scenario 2: Airborne disinfection by evaporation

Task [2.1]: Loading of the product in the plate

Description of Task [2.1]

The professional user pours manually the product in a large plate and put it on the ground of the incubator / hatchery.

Exposure by inhalation to aerosol is considered negligible, only exposure by inhalation to vapour is expected during the task. Product will evaporate from the opening of the bottle and from the plate after it is poured.

Inhalation exposure to vapour has been assessed using **ConsExpo – Exposure to vapour – Evaporation from constant surface**.

A duration of 10 min has been considered for this task distributed in 5min for the evaporation from the bottle and 5 min for the evaporation of the plate.
Half of the packaging is considered for the exposure to vapour from the bottle during mixing and loading task in ConsExpo. Also half of the plate has been considered for the evaporation from the plate.

Taking into account the maximum packaging size of 20L which can be manually poured, the quantity of product used in the model is half of the packaging size: 10L which corresponds to 10420g with the density of 1.042 for the evaporation from the bottle.
For the evaporation of the plate, as the claimed dose is 13mL/m3, for the maximum room size of 30m3, a maximum of 390mL of product can be used. Therefore 195mL of product is used in the model which corresponds to 203g with the density of 1.042.

Regarding the release area, as no information is available for the opening of the bottle, a circular opening of 5 cm diameter has been used. For the plate, applicant has considered a cup of 10x10cm however it is not in accordance with the description of the use where a large opening plate is specified and taking into account that all the product has to evaporate from the plate. Therefore it is considered the standard size of a plate: 27cm of diameter which corresponds at a around 1cm liquid height.

Input parameters for Task [2.1]

	Parameters[10]	Value	Reference and justification[11]
Tier 1 (no PPE)	Concentration of hydrogen peroxide in the product	7.5%	Applicant's data
	Exposure duration	5min	See explanation above
	Molecular weight matrix (water)	18 g/mol	
	Room volume	1 m3	User breathing zone
	Ventilation rate	0.6/h	Unknown room
	Product amount (in bottle)	10420g	See explanation above
	Product amount (in plate)	203g	See explanation above
	Release area (opening of the bottle)	20 cm2	See explanation above
	Release area (plate)	572cm2	See explanation above
	Application duration	5min	See explanation above
	Mass transfer rate	10m/h	ConsExpo
	Vapour pressure	214 Pa	

	Temperature	20°C	
Tier 2	Respiratory protective equipment	APF 4	

Calculations for Task [2.1]

Local effects

Summary table: estimated local exposure and risk characterisation for professional users				
Exposure scenario	**Tier/PPE**	**Estimated dermal exposure [%]**	**Estimated inhalation exposure [mg/m³]**	**Estimated total exposure [mg/m³ or %]**
Task [2.1]	1/no RPE	nr	2.9 (0.1 bottle + 2.8 plate)	nr
	3/APF 4	nr	0.73 (bottle + plate)	nr

Task [2.2]: Application of the product

Description of Task [2.2]
No exposure of the user is expected during the evaporation of the product in incubator / hatchery as the user is not present.

Task [2.3]: Opening the incubator and removing / cleaning of the plate

[10] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE.

[11] Include the source of information (e.g. product information, recommendations, guidance documents, exposure models) and justification (where needed).

Description of Task [2.3]

After the contact time (minimum 4h), the user opens the incubator / hatchery and removes the plate.

The product should evaporate totally. No dermal exposure is expected as no more liquid product should be present in the plate. Therefore only inhalation exposure is expected.

No data is provided regarding the ventilation rate in incubator / hatchery. It is considered that the ventilation will be stopped during the evaporation. As a worst-case it has been considered at 0/h taking into account that these apparatus can be closed hermetically. This is a worst-case taking into account that the eggs are present in the incubator / hatchery and that ventilation is necessary.

Regarding the opening of the incubator / hatchery. Data have required to the applicant regarding the design of incubator / hatchery and ventilation. Applicant specified that incubators and hatching rooms are like big closets that are shut with hermetic doors; access is done through a corridor. Moreover these facilities have ventilation system connected with the exterior through pipes containing filters. There is no communication of ventilation system with any other room of the hatchery farm.

This data has been considered in the exposure assessment and will be specified in the SPC.

Therefore, exposure assessment has been performed considering that hatchery/incubator has its own ventilation system which can be activated without opening the door. In that case, a hatchery/ incubator of 30m^3 has been considered as a worst-case.

Taking into account that all the product is in the air because the product should evaporate totally, as a worst-case, the user will be exposed at the concentration of 13mL/m3 of product (a).

Then we have calculated a time period before opening the door of the incubator / hatchery. Different ventilation rate have been used as no well supported information is available on ventilation rate in incubator / hatchery: 2/h, 8/h, 18/h. (b)

Concentration of the substance in the air has been modelised with **ConsExpo – Exposure to vapour – Instantaneous release**

Input parameters for Task [2.3]

	Parameters[12]	Value	Reference and justification[13]
a) Air concentration of substance before the ventilation is re-activated			
Tier 1	Concentration of hydrogen peroxide in the product	7.5%	Applicant's data
	Content of product	406g	13mL/m^{3}x30m^{3}x1.042
	Ventilation rate	0/h	Default value
	Room volume	30 m3	Applicant's data
	Vapour pressure	800Pa	Handbook data / literature data
	Temperature	40°C	Handbook data / literature data
b) Air concentration of substance when the ventilation is re-activated – calculation of the time to open the incubator/hatchery			
Tier 1	Concentration of hydrogen peroxide in the product	7.5%	Applicant's data
	Content of product	406g	13mL/m^{3}x30m^{3}x1.042

	Ventilation rate	2/h 8/h 18/h	Default value
	Room volume	30 m3	Applicant's data
	Vapour pressure	800Pa	Handbook data / literature data
	Temperature	40°C	Handbook data / literature data

Calculations for Task [2.3]

Local effects

a) Air concentration of substance before the ventilation is re-activated

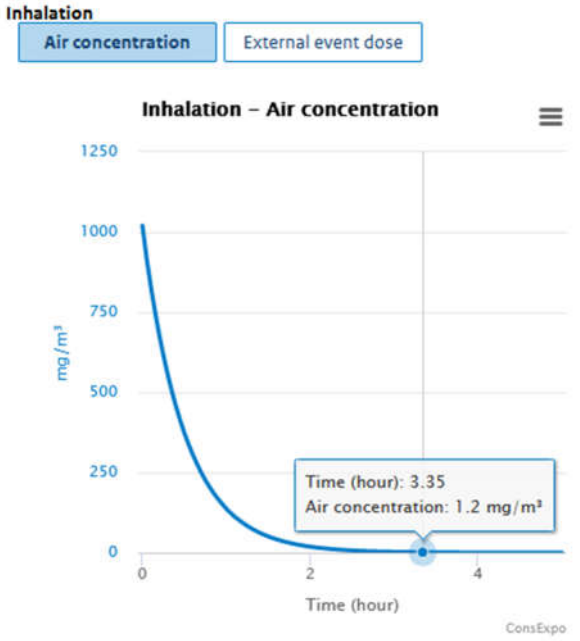
Summary table: estimated local exposure and risk characterisation for professional users				
Exposure scenario	**Tier/PPE**	**Estimated dermal exposure [%]**	**Estimated inhalation exposure [mg/m³]**	**Estimated total exposure [mg/m³ or %]**
Task [2.3]	1/no RPE	nr	$1x10^3$	nr

b) Air concentration of substance when the ventilation is re-activated – calculation of the time to open the incubator/hatchery

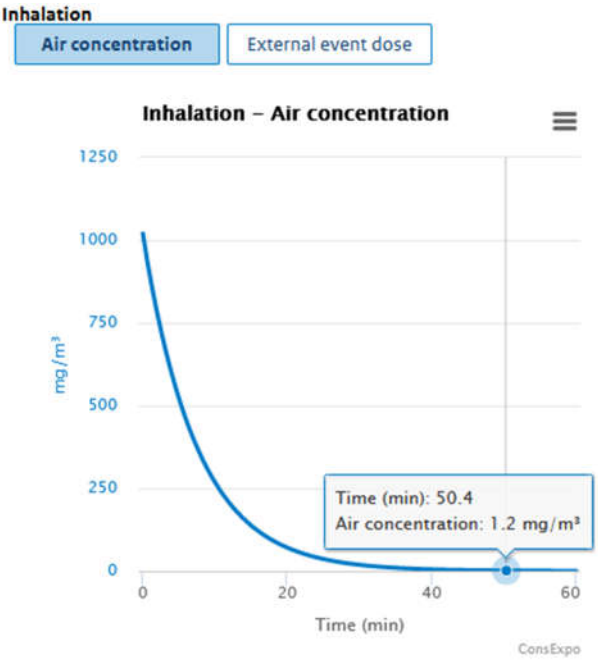
Ventilation rate: 2/h

[12] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE.

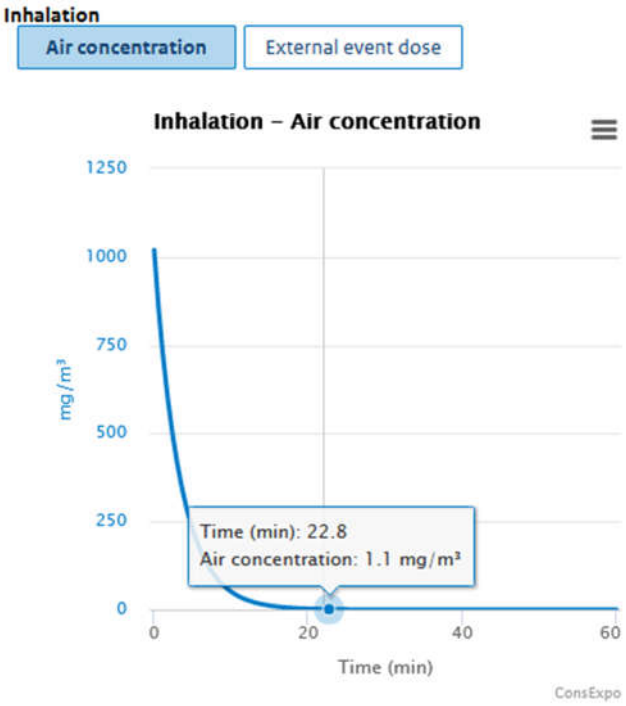
[13] Include the source of information (e.g. product information, recommendations, guidance documents, exposure models) and justification (where needed).



Ventilation rate: 8/h



Ventilation rate: 18/h



Outcome of quantitative local exposure and risk characterisation

Summary table: estimated local exposure and risk characterisation for professional users

Summary table: estimated local exposure and risk characterisation for professional users				
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure [mg/m³]**	**Estimated exposure / AEC (%)** AECinhalation = 1.25 mg/m³	**Acceptable (yes/no)**

Outcome of quantitative local exposure and risk characterisation

Summary table: estimated local exposure and risk characterisation for professional users

Summary table: estimated local exposure and risk characterisation for professional users				
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure [mg/m³]**	**Estimated exposure / AEC (%)** AECinhalation = 1.25 mg/m³	**Acceptable (yes/no)**
Scenario [2]				
Task[2.1]	1/no RPE	2.9	234%	no
	2/APF 4	0.73	59%	yes
Task[2.2]	1/no RPE	nr	nr	yes
Task[2.3]	a) 1/no RPE	1x10³	81276%	no
	b) 1/no RPE	1.2 After 3.35h at 2/h After 50min at 8/h After 23min at 18/h	96%	yes

Outcome of qualitative local risk assessment

The product is intended to be applied by professionals. It is classified H314 / H318.

Dermal exposure is expected during the mixing and loading of the product. No aerosol exposure is expected.

The professional is using the product for the mixing & loading for a low duration per day and with PPE. Considering this, the risk is deemed acceptable. See table below.

Hazard			**Exposure information**							**Risk**	
Hazard category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE**	**Relevant RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
High	H314		2, 3 4	Mixing and loading	Skin	Few minutes per day Frequency: no data	Dermal contact	Gloves Skin coverage	Labelling • Labelling according to CLP Trained personnel • Professional workers	Acceptable	(↑) High hazard category (↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low exposure duration (few min per day)
					Inhalation		No aerosol expected	none			
High	H318				Eye		Eye exposure through potential splashes or hand to eye transfer	Chemical goggles			

During the cleaning of the plate, as the product should evaporate totally during the application, no residue on the surface is expected therefore no acceptable risk is expected.

For contact with the disinfected surfaces, taking into account that the application is done at 40°C and taking into account the contact time of minimum 4h, the surfaces are expected to be dried after the disinfection leading to no unacceptable risk. Nevertheless as the product is classified, the RMM: "Do not touch the surface until it is dried" is added.

Secondary exposure

Inhalation and dermal exposure

Secondary exposure is possible after the disinfection during entry in the room after opening of the hatchery / incubator and when touching treated surfaces after disinfection.

For hatchery/incubator with their own ventilation, the door will be opened only after the time period calculated in scenario 2 task [2.3] depending on the ventilation rate used. Therefore the risk is acceptable when entering in the room.

For contact with the disinfected surfaces, as the product is classified H314/H318, risk is considered acceptable with the RMM: "Don't allow to touch the surface until it is dried".

Conclusion for Use # 3: Airborne disinfection of incubators and hatcheries (PT3)

The risk is considered as acceptable considering local effects if the following PPE and RPE are worn:

During mixing and loading:

- ✓ Gloves
- ✓ Coverall
- ✓ Goggles
- ✓ Respiratory protective equipment min APF 4

And with the following RMM

- "Do not open the hatchery / incubator after treatment and contact time before a ventilation period of:
  - 3h21 at ventilation rate of 2/h,
  - 50min at a ventilation rate of 8/h,
  - 23min at a ventilation rate of 18/h."

- "Don't allow to touch the surface until it is dried"

Monitoring data

Not relevant

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

Not relevant

Aggregated exposure

Not relevant

Summary of exposure assessment

Not relevant

2.2.6.6 Dietary risk assessment

Dietary exposure

By definition, PT 2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore, residue in food or fed are not expected for AEROCLEAN PT2 uses.

As PT3 and 4 uses, AEROCLEAN is intended to be used as veterinary hygiene biocidal products and food and feed area disinfectants. Therefore, residues in food or feed might be expected based on intended uses.

Lactic acid

For L-(+)-lactic acid data the following evaluation was provided in the Assessment Report, 2007:

"L(+) lactic acid is a naturally occurring alpha-hydroxy acid found in plants, animals and humans. Major sources of L(+) lactic acid in the human organism are endogenous production (e.g. via anaerobic catabolism of glycogen and glucose) production by gastro intestinal microorganisms and uptake via food. The production of L(+) lactic acid as an intermediary metabolite in a 70 kg resting man is estimated to be in the range of 117-230 g/d but can be much higher during exercise. The mean daily per capita intake of L(+) lactic acid and D(-) lactic acid from milk and milk products has been estimated to be approximately 1g in Switzerland (Walther, 2006). The estimated overall intake via food in the EU and the USA is estimated to be 1.65-2.76 g/person/day.

L(+) lactic acid has been approved in the EU as a food additive without an ADI or upper limit (quantum satis; Dir. 95/2/EC), as a cosmetics ingredient, and as veterinary medicinal product without the requirement for MRL setting (EMEA 2008). "

Moreover, *"because of the very low systemic toxicity of L(+) lactic acid, derivation of any systemic toxicological reference dose was regarded unnecessary. Considering the intended uses, exposure is estimated to be clearly below endogenous production (<100g/person/day) and dietary exposure (<1 g/person/day). Therefore, neither an ADI nor an ARfD has been set."*

Hydrogen peroxide

For hydrogen peroxide the following evaluation was provided in the Assessment Report, 2015:
"*Secondary oral and dermal exposure of consumers to residual hydrogen peroxide in food and drinking water is in theory possible under PT 4 (aseptic packaging, disinfection of distribution systems for drinking water) and PT 5 (disinfection of drinking water). However, hydrogen peroxide used for aseptic packaging evaporates while the wrapping material is heated before filled with food and no residues in food are expected. Furthermore, hydrogen peroxide, if present, would rapidly decompose in contact with any type of food.*
Secondary oral exposure of consumers to hydrogen peroxide is possible via disinfection of distribution system for drinking water as well as via disinfected drinking water. Pipes and containers disinfected with hydrogen peroxide are flushed before refilled with drinking water and relevant residual hydrogen peroxide is regarded as negligible under disinfection of distribution systems for drinking water (PT 4)".

Considering the disinfection by-products (DBPs),"*hydrogen peroxide is reactive and it degrades rapidly in contact with organic material. A significant proportion of hydrogen peroxide decomposes to water and oxygen. The antimicrobial action of hydrogen peroxide stems from its ability to form powerful oxidants such as the hydroxyl radical and singlet oxygen. These reactive oxygen species cause DNA. The range of by-products is considered wide and not well characterized at detailed level. It would be very difficult to provide analytical methodology to verify the low level concentrations of the enormous variety of molecular structures including breakdown products. At a level of practical concentrations, no disinfection by-products (DBPs) with (eco)toxicological relevance have been identified. No methods for DBPs is required."*
Moreover, European guidance on the assessment of DBPs is finalised and available[14]. Nevertheless, this guidance was *'developed to be applicable to biocides in PT 2 (…) for the other PTs future development of an adapted guidance is needed to ensure a harmonized approach across the EU"* (ECHA, 2017). Therefore, in the frame of this dossier, in order to assess consumer risk assessment, no finalized or draft guidance is available.
Without any indication on how to perform an exposure assessment of the DPB formed during H_2O_2 application, no proposal has been made.

For Substances of Concern
No SoCs are relevant for dietary exposure assessment (see paragraph "available toxicological data relating to non-active substance(s) (i.e. substance(s) of concern) above).

Information of non-biocidal use of the active substance

- Lactic acid

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s) [2]**
1.	Food	Lactic Acid (E 270) – Food additive	Quantum satis (Regulation (EU) 1129/2011)
2.	Veterinary	Lactic Acid - All food producing species	No MRL required (Regulation (EC) No 37/2010)
3.	Cosmetic	Lactic Acid – Used as buffering humectant or skin conditioning	Up to a maximum level of 2.5% and a pH ≥ 5 (SCCBFP, 2000)

[1] e.g. plant protection products, veterinary use, food or feed additives

[14] ECHA (European Chemicals Agency) - Guidance on the Biocidal Products Regulation – Volume V, guidance on disinfection by-products – Version 1.0 – January 2017.

[2] e.g. MRLs. Use footnotes for references.

- Hydrogen peroxide

- **Summary table of other (non-biocidal) uses**			
	Sector of use[1]	**Intended use**	**Reference value(s) [2]**
1.	Plant protection product	Hydrogen peroxide (basic substance – approved on 29/03/2017)	No MRLs required (Reg 396/2005)
2.	Veterinary use	Hydrogen peroxide: all food producing species	No MRL required (Reg 37/2010)
3.	Processing aid – National regulation in France	Hydrogen peroxide – directly used on food or in rinsing water for food[3]	Maximum concentration of H_2O_2 in washing solution for salads: 2mM (68 ppm), Remaining level: Technically unavoidable content

[1] e.g. plant protection products. veterinary use. food or feed additives
[2] e.g. MRLs. Use footnotes for references.
[3] Arrêté du 19 octobre 2006 relatif à l'emploi d'auxiliaires technologiques dans la fabrication de certaines denrées alimentaires
[4] EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2014. Scientific Opinion on the evaluation of the safety and efficacy of peroxyacetic acid solutions for reduction of pathogens on poultry carcasses and meat. EFSA Journal 2014;12(3):3599, 60 pp. doi:10.2903/j.efsa.2014.3599
[5] Council Directive 2011/84/EU of 20 September 2011 amending Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress – Official Journal of The European Union - L 283/36

Estimating Livestock Exposure to Active Substances used in Biocidal Products

See above

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

Not relevant

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

Not relevant

Risk for consumers via residues in food

By definition, PT2 biocidal product is not intended for direct application to humans or animals and is not used for direct contact with food or feedingstuffs.
Regarding PT 3 and PT 4 uses, considering properties of L-(+)-lactic acid and hydrogen peroxide, no significant exposure via food is expected.
See details in § "Dietary exposure".

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

Not relevant

2.2.7.1 Risk assessment for animal health

The risk assessment is detailed in the human health part.

2.2.8 Risk assessment for the environment

AEROCLEAN product is a PT2, PT3, and PT4 disinfectant containing L-(+)-lactic acid and hydrogen peroxide that is applied for the disinfection of hard surfaces not intended for direct application to humans or animals (PT2), disinfection for veterinary hygiene (PT3) and disinfectants in food and feed area (TP4). The data on active substances are provided by the assessment report of L-(+)-lactic acid for PT2, 3, 4 (Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, Assessment Report L-(+)-lactic acid Product-type 2, 3 and 4, June 2017) and assessment report of hydrogen peroxide for PT 1-6 (Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, Assessment Report hydrogen peroxide Product-type 1-6, March 2015). The available ecotoxicological information and e-fate data are used for risk assessment for the environment.

Please note that for Lactic acid, the TAB ENV 249 (version from October 2022) states that a qualitative assessment is sufficient for direct and indirect releases to soil as well as for indirect releases to surface water (via STP and via manure). Nevertheless as this dossier was finalized before this date, a complete risk assessment we provided for Lactic acid.

Details about the non-classification of co-formulants as substance of concern (SoC) can be found in the confidential PAR.

2.2.8.1 Effects assessment on the environment

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 new environmental studies have been carried out with the AEROCLEAN product. All data pertaining to the active substances are therefore derived from the L-(+)-lactic acid assessment report (PT2, 3, 4, June 2017) and the hydrogen peroxide assessment report (PT1-6, March 2015). The product is not classified for the environment as there is no substance of concern and considering the proposed classification H412 for Hydrogen peroxide (CAR) and the non-classification of Lactic acid.

Further Ecotoxicological studies

No new data is available

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

No new data is available

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

No new data is available

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

No new data is available

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

No new data is available

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

Please refer to the exposure assessment below.

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

At WGII2020, it was stated that L-(+)-lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. It is an endogenous metabolite in many organisms, a common naturally occurring food constituent and also a growth regulator intended to increase nut and fruit set. Furthermore, the environment is exposed to Lactic acid via the excretion of faeces and urine by humans (and their subsequent release from the STPs), as well as the direct disposal of excreta by other mammals. In soils, L-(+)-lactic acid naturally occurs as a fermentation by-product of anaerobic degradation of organic matter. This substance may covalent bind with organic material in sewage sludge, manure, and soils. In microorganisms, lactate formation is one of the usual pathways for NAD+ regeneration and when formed, lactate can be further metabolized through the pathway of pyruvate metabolism. As lactate is metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge as well as transformation and dilution in deeper soil layers is not be taken into account in soil concentration calculations – and thus in subsequent groundwater concentrations (Tier 1). Modelling of groundwater exposure in case of Lactic acid largely overestimates concentrations and is considered unrealistic.

For all these reasons, it can be stated that L-(+)-lactic acid does not cause unacceptable risk for groundwater, without need for further calculations.

For soil calculations, a DT50 of 30 days was stated without the need of further studies.

At ENV WG-IV-2019, it was agreed that no groundwater assessment is needed for hydrogen peroxide since it is a rapidly reacting substance and it is very unlikely that this substance will reach the groundwater. Therefore, PEC calculation and the following risk ratio calculation for groundwater will not be presented in this AEROCLEAN product assessment.

Leaching behaviour (ADS)

No new data is available

Testing for distribution and dissipation in soil (ADS)

No new data is available

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

No new data is available

Testing for distribution and dissipation in air (ADS)

No new data is available

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

Not relevant

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

Not relevant

Based on the L-(+)-lactic acid and hydrogen peroxide assessment reports, the relevant PNECs for the environmental risk characterisation are reported below:

Summary table on PNEC values				
Active substance	**$PNEC_{STP}$**	**$PNEC_{water}$**	**$PNEC_{sed}$**	**$PNEC_{soil}$**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]
L-(+)-lactic acid	10	3.9	4.8*	1.9*

Hydrogen peroxide	4.66	1.26E-02	n.r.**	1.80E-03*

* The PNECsoil and the PNECsediment are derived using the equilibrium partitioning method (ECHA Guidance on BPR Vol IV, Part B, v2.0, 2017, equations 89 and 91).
** n.r. (not relevant). Considering the low n-octanol/water partition coefficient of hydrogen peroxide (log K_{ow} –1.57), the expected low adsorption to organic matter (QSAR based log K_{OC} 0.2036) and its generally rapid abiotic and biotic degradation in surface waters […], hydrogen peroxide is not expected to partition into the sediment. Because of the lack of exposure, a proposal for a PNEC for sediment-dwelling organisms is not considered necessary. Furthermore, any potential risk to sediment dwelling organisms is considered to be adequately covered by using the PNEC for the water phase (Hydrogen peroxide PT 1-6, Document IIA, 2015). Therefore, no risk assessment for the sediment has to be carried out.

2.2.8.2 Exposure assessment

The claimed uses and the scenarios covering each of them are presented in the following table:

Claimed use from SPC	PT	Description of use	Covered by
1	2	Airborne disinfection of empty greenhouses and empty material shelters*	Scenario 1: Disinfection of industrial areas
2	3	Airborne disinfection of eggs storage rooms**	Scenario 3: Disinfection of surfaces of livestock animal housing and equipment
3	3	Airborne disinfection of incubators and hatcheries	Scenario 2: Disinfection of hatcheries
4	3	Airborne disinfection of empty buildings and materials	Scenario 3: Disinfection of surfaces of livestock animal housing and equipment
5	3	Airborne disinfection of breeding premises in presence of animals	Scenario 3: Disinfection of surfaces of livestock animal housing and equipment

6	4	Airborne disinfection of empty buildings and materials on surfaces in contact with food or feed	Scenario 4: Disinfection of large scale food and feed areas (slaughterhouses)

* Use 1 was initially described as the disinfection of empty buildings, empty rooms, and equipment for industries, amenities, sanitation facilities, greenhouses and storage buildings that justified the use of the scenario for the disinfection of industrial areas. As the initial places to disinfect covered the new description of use 1, the industrial scenario was still considered relevant.
** This use is also covered by scenario 4, especially for the STP emission pathway. In fact, considering the very large volume (50 000 m^3) used in scenario 4, this scenario covers the egg storage rooms that is restricted by the applicant for a disinfection of spaces not larger than 150 m^3. The higher application rate for use 2 (13.2 ml/m^3) compared to the one used in scenario 4 (10 ml/m^3) is compensated by the very high volume used in scenario 4. Eggs are not for consumption.

All intended application methods are either by nebulization or by evaporation.

General information

Assessed PT	PT 2
Assessed scenarios	Scenario 1: Disinfection of industrial areas
ESD(s) used	Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), 2011
Approach	Average consumption
Distribution in the environment	Calculated based on Guidance for BPR IV Part B+C (2017). Assessment report: L-(+)-lactic acid Product-type 02, 03 and 04, June 2017 and hydrogen peroxide Product-type 1-6, March 2015 Technical Agreements for Biocides v2.1, December 2019
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	/

Assessed PT	PT 3

Assessed scenarios	Scenario 2: Disinfection of hatcheries Scenario 3: Disinfection of surfaces of livestock animal housing and equipment - Scenario 3-a: Emission to the STP via wastewater - Scenario 3-b: Emission to soil via manure/slurry
ESD(s) used	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, 2011 OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage systems ENV/JM/MONO(2006)4 Technical Agreements for Biocides v2.1, December 2019
Approach	Average consumption
Distribution in the environment	Calculated based on Guidance for BPR IV Part B+C (2017). Assessment report: L-(+)-lactic acid Product-type 02, 03 and 04, June 2017 and hydrogen peroxide Product-type 1-6, March 2015 Technical Agreements for Biocides v2.1, December 2019
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	/

Assessed PT	PT 4
Assessed scenarios	Scenario 4: Disinfection of large scale food and feed areas (slaughterhouses)
ESD(s) used	Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas, 2011
Approach	Average consumption
Distribution in the environment	Calculated based on Guidance for BPR IV Part B+C (2017). Assessment report: L-(+)-lactic acid Product-type 02, 03 and 04, June 2017 and hydrogen peroxide Product-type 1-6, March 2015 Technical Agreements for Biocides v2.1, December 2019

Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	/

According to TAB ENV-189 (version October 2022) the density of the b.p. should be included in emission scenarios where density is not already indicated as an input parameter. The correct product density is 1.042 kg/L. The presented emission calculation in all 5 scenarios are done with the rounded value of 1. Since applying the correct b.p. density value has no impact on the general outcome of the environmental risk assessment the emission calculations were not corrected.

Emission estimation

Scenario 1: Disinfection of industrial areas

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: Disinfection of industrial areas			
Application rate of biocidal product V_{form}	0.01	l/m^3	S
Concentration of active substance in the product (technical concentration) C_{form} L-(+)-lactic acid Hydrogen peroxide	 50 75	 g/l g/l	S - Considering a product density around 1
Volume to be disinfected Volume	4000	m^3	D - TAB ENV 52
Number of applications per day Nappl	1	d^{-1}	D
Fraction of substance disintegrated during or after application F_{dis}	0	[-]	D
Fraction released to wastewater F_{water}	1	[-]	D

Calculations for Scenario 1

$Elocalwater = V_{form} * C_{form} * Volume * Nappl * (1-F_{dis}) * F_{water} / 1000$

It should be noted that no degradation of hydrogen peroxide during disinfection process is taken into account in a first approach and therefore overestimate the actual discharge of this active substance into sewer system as this substance is highly reactive to the organic matter and metal cations. Consequently, degradation in the sewer system is considered in this assessment. The degradation of active substance in the sewer system is calculated assuming first order kinetic using the following equation:

Elocal waste water DEG t1 = E local waste water t0* EXP(-k * t1)

Elocal waste water DEG t1 = Emission to the STP after degradation in sewer [$kg.d^{-1}$]
E local waste water t0 = Emission to sewer [$kg.d^{-1}$]
t1 = residence time in sewer system [h]
k = reaction rate constant in sewer system [h^{-1}]

A sewer residence time of 1 h before the STP, proposed as default value in the ESD for PT5, is used for the calculation. The value of 1 hour is based upon an average distance of 4.5 km

from the point of release to the STP and an estimated flow rate of 1.5 km in 20 minutes in the municipal canal sewer system.

As agreed at WGIV2019 a k value of 3.65 h^{-1} (12°C) is used for the calculation

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission ($Elocal_{compartment}$) [kg/d^{-1}]**	**Remarks**
L-(+)-lactic acid	STP	2.00	
Hydrogen peroxide	STP	3.00	
Hydrogen peroxide (after degradation in sewer)	STP	7.80E-02	

Scenario 2 : Disinfection of hatcheries

Two main emission pathways are possible depending on the way of application: either discharge to wastewater after spraying or fogging, or release to air after fumigation or fogging. For the sake of completeness the emission to air was considered in ESD TP3 (2011), but usually hatcheries are equipped with air filter systems to prevent release of odour and microbes to the outside air. Thus, the biocide emission to outside air is limited. Moreover, the emissions to the atmosphere are unlikely to occur due to the low vapour pressure of L-(+)-lactic acid (0.4 Pa) and the low estimated half-life (24h) of hydrogen peroxide in atmosphere. Therefore, air is not a compartment of concern for these active substances and no PEC value is presented for this compartment.

The proposed application method for AEROCLEAN product in hatcheries is by evaporation and in order to cover the emissions, the worst case scenario (spraying/fogging or fumigation) was applied to calculate the releases to wastewater.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 2 : Disinfection of hatcheries			
Quantity of disinfectant used per cubic meter (technical concentration) *Qa.i.appl*			S - Considering a product density around 1
L-(+)-lactic acid	0.65	g/m^3	13 mL product/m^3 @ 5%
Hydrogen peroxide	0.975	g/m^3	13mL product/m^3 @ 7.5%
Application stages:			
Stage 1 – eggs in fumigation sluice:			
Volume of the fumigation sluice	49	m^3	D

Vsluice			
Number of fumigation sluices *Nsluice*	1	-	D
Number of disinfection events *Napplsluice*	7	d^{-1}	D
Stage 2 – eggs in hatcher:			
Volume of the hatcher *Vhatcher*	9.73	m^3	D
Number of hatchers *Nhatcher*	27	-	D
Number of disinfection events *Napplhatcher*	0.57	d^{-1}	D
Stage 3 – rooms and equipment:			
Volume of the setter *Vsetter*	9.73	m^3	D
Number of setters *Nsetter*	162	-	D
Number of disinfection events (single-stage setter) *Napplsetter*	0.06	d^{-1}	D
Volume of the hatcher *Vhatcher*	9.73	m^3	D
Number of hatchers *Nhatcher*	27	-	D
Number of disinfection events *Napplhatcher*	0.57	d^{-1}	D
Fraction released to air after aerosol or fogging treatment *Fair_fog*	0.1	-	D
Fraction released to wastewater *Fwater*	(1 - *Fair_fog*)	-	Calculation as a worst case fraction for release to wastewater

Calculations for Scenario 2

$$Elocalwater = Qa.i._{appl} \bullet 10^{-3} \bullet F_{water} [(V_{sluice} \bullet N_{sluice} \bullet N_{applsluice}) + (V_{hatcher} \bullet N_{hatcher} \bullet N_{applhatcher}) \bullet 2 + (V_{setter} \bullet N_{setter} \bullet N_{applsetter})]$$

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission ($Elocal_{compartment}$) [kg/d^{-1}]**	**Remarks**
L-(+)-lactic acid	STP	0.43	
Hydrogen peroxide	STP	0.65	
Hydrogen peroxide (after degradation in sewer; cf. scenario 1)	STP	1.69E-02	

Scenario 3: Disinfection of surfaces of livestock animal housing and equipment of animal housings

Please note that for this scenario in PT03, the assessment does not represent the up-to-date way to calculate the PEC values for the different compartments. In fact recent TAB entries (for instance ENV 233 and ENV 245) must be considered at the renewal of this product.

Animal Subcategory:

The main emission pathway for poultry's housing types is releases to wastewater via the sewer system and STP (scenario 3-a). In other situations, the main emission pathway is to the terrestrial compartment via the slurry/manure system (scenario 3-b).

For an easier reading of the PAR, only worst-case situations are presented:
- For emissions to wastewater: Turkey's emissions
- For emissions to soil via slurry/manure: Ducks emissions

In fact, these two animal categories are worst case considering the number of applications during the storage period and the dimension of the treated volumes compared to the other animal categories.

Worst-case application rate:

Three different uses are covered by this scenario:

Claimed use from SPC	PT	Description of use	Application rate	Covered by
2	3	Airborne disinfection of eggs storage rooms	13.2 mL/m^3	Scenario 3: Disinfection of surfaces of livestock animal housing and equipment
4	3	Airborne disinfection of empty buildings and materials	10 mL/m^3	

5	3	Airborne disinfection of breeding premises in presence of animals	8 mL/m^3	

The application rate of 13.2 mL/m^3 was chosen as a worst case scenario even if it is considered overly conservative.
The application method for this scenario is by nebulization. However, spraying application fraction to wasterwater and slurry/manure was used as a worst case.

Scenario 3-a – Emissions to wastewater via the STP

Scenario 3-a: Emissions to wastewater via the STP					
Parameter	**Symbol**	**Value**		**Unit**	**S/D/O**
		Hydrogen peroxide	**L-(+)-lactic acid**		**Remarks**
Input					
Type of House	cat-subcat (i1)	Turkey in free range – litter floor		[-]	Worst case for releases to the STP
Type of biocide	bioctype (i2)	Disinfectant		[-]	S
Type of application	appway (i3)	Spraying		[-]	S
Relevant emission stream	stream (i4)	Wastewater		[-]	-
Volume of the housing	VOLUME (i1)	12500		[m^3]	D – ESD PT18 No.14
Content of active ingredient in formulation (product)	Fbioc	7.5	5	%w/w	S – Considering a product density around 1
Amount of product prescribed to be used per m²	Vprod$_{i1,i2,i3}$	0.0132		[L/m^3]	S
Dilution factor (for preparation of the working solution from the formulation (product))	Fdil	-		[-]	S – RTU
Fraction of a.s released to wastewater	F_{ww}	0.2			D
Intermediate calculations					
Amount of active ingredient to be used for one application	Qai-prescr$_{i1,i2,i3}$	1.24E+01	8.25	[kg]	O

Calculations for Scenario 3a

Elocalwater = Fstp• Qai-prescr i1,i2,i3

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission (Elocal$_{compartment}$) [kg/d^{-1}]**	**Remarks**
L-(+)-lactic acid	STP	1.65	
Hydrogen peroxide	STP	2.48	
Hydrogen peroxide (after degradation in sewer; cf. scenario 1)	STP	6.43E-02	

Scenario 3-b – Emissions to soil via slurry/manure

Scenario 3-b: Emission to soil via slurry/manure					
Parameter	**Symbol**	**Value**		**Unit**	**S/D/O**
		Hydrogen peroxide	**L-(+)-lactic acid**		
Input					
Type of House	cat-subcat (i1)	Ducks in free range – litter floor		[-]	Worst case for releases to slurry/manure
Type of biocide	bioctype (i2)	Disinfectant		[-]	S
Type of application	appway (i3)	Spraying		[-]	S
Relevant emission stream	stream (i4)	Slurry/manure		[-]	-
Volume of the housing	VOLUME (i1)	7500		[m^3]	D
Content of active ingredient in formulation (product)	Fbioc	7.5	5	%w/w	S – Considering a product density of 1
Amount of product prescribed to be used per m^3	$Vprod_{i1,i2,i3}$	0.0132		[L/m^3]	S
Dilution factor (for preparation of the working solution from the formulation (product))	Fdil	-		[-]	S – RTU
Fraction of a.s released to slurry	$F_{slurry/manure}$	0.3		[-]	D
Number of disinfectant applications in one year	Napp-bioc	13		[-]	D
Biocide application interval	Tbioc-int	28		[d]	D
Number of manure applications for grassland	Nlapp-grass	4		[-]	D TAB ENV 62
Number of manure applications for arable land	Nlapp-arab	1		[-]	D
Manure application time interval for grassland	Tgr-int	53		[d]	D
Manure application time interval for arable land	Tar-int	212		[d]	D
Land application interval for manure application on arable land	Tar-int,10	365		[d]	D
Number of animal in housing	$Nanimal_{i1}$	10 000		[-]	D
Amount of nitrogen per animal	$Qnitrog_{i1}$	0.00274		[kg/d]	D
If nitrogen emission applied					
Nitrogen emission standard for one year on grassland	$QN_{, grassland}$	170		[kg/ha]	D TAB ENV 160
Nitrogen emission standard for one year on arable land	$QN_{, arable\ land}$	170		[kg/ha]	D TAB ENV 160
Mixing depth with soil, grassland	$DEPTH_{,grassland}$	0.05		[m]	D
Mixing depth with soil, arable land	$DEPTH_{,arable\ land}$	0.2		[m]	D
Density of wet bulk soil	$RHOsoil_{wet}$	1700		[kg/m^3]	D
Intermediate calculations					
Number of biocides applications during storage period for application on grassland	$Napp\text{-}manure_{gr}$	1*	1.9	[-]	O
Number of biocides applications during storage period for application on arable land	$Napp\text{-}manure_{ar}$	1*	7.6	[-]	O

Scenario 3-b: Emission to soil via slurry/manure					
Parameter	**Symbol**	**Value**		**Unit**	**S/D/O**
		Hydrogen peroxide	**L-(+)-lactic acid**		
Amount of active ingredient to be used for one application	Qai-prescr$_{i1,i2,i3}$	7.31	4.88	[kg]	o
Amount of active ingredient in relevant stream i4 after one application	Qai $_{i1,i2,i3,i4}$ slurry/manure t0	2.23	1.49	[kg]	o
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland	Qai-grass$_{i1,i2,i3,i4}$ (manure/slurry)	2.23	2.82	[kg]	o
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to arable land	Qai-arab$_{i1,i2,i3,i4}$ (manure/slurry)	2.23	1.13E+01	[kg]	o

* Due to the strong degradation kinetics (DT_{50} of 6 min at 20°C), it can be assumed that residues of hydrogen peroxide resulting from former applications during the manure storage period are negligible. In fact, the shortest period between two applications within the manure storage period considered in the ESD is at least 7 days. In this case, only the last application is considered.

Hydrogen peroxide degradation in manure:

Hydrogen peroxide is highly reactive to the organic matter and metal cations which are present in abundant amounts in manure. Therefore, degradation of H_2O_2 in manure is taken into account in the exposure assessment. Nevertheless, the DT_{50} used are not harmonized to an environmental temperature of 12°C since it is stated in the OECD series on Emission Scenario Documents No 14 (Emission Scenario Document for Insecticides for Stables and Manure Storage Systems – page 69) that in farmyard manure typical temperatures are ambient to greater than ambient.

The degradation of hydrogen peroxide in the manure before land application is calculated, assuming first order kinetic, using the following equation:

$$Qai_{\text{slurry/manure DEG t1}} = Qai_{\text{slurry/manure t0}} * EXP(-k * t1)$$

$Qai_{\text{slurry/manure DEG t1}}$ = total amount of substance in manure at time 1 with degradation [kg]
$Qai_{\text{slurry/manure t0}}$ = total amount of substance at time 0 [kg]
t_1 = residence time in slurry/manure [h]
k = reaction rate constant in slurry/manure [h^{-1}]

A slurry/manure residence time of 2 h is proposed for the calculation. It is assumed that the last application takes place two hours before the manure is applied to agricultural land and this assumption is a worst case since the maximum time span between the disinfection process and the application of manure to agricultural land is up to 6 months.
A DT_{50} of 1.00E-01 h (6 min at 20°C, Final CAR H_2O_2 PT1-6) is used for calculation, corresponding to a reaction rate constant in slurry/manure of 6.93 h^{-1}.

Parameter	Symbol	Value		Unit	S/D/O
		Hydrogen peroxide	L-(+)-lactic acid		
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland (after degradation in manure)	$Qai\text{-}grass_{i1,i2,i3,i4}$ (manure/slurry)	2.12E-06	2.82	[kg]	o
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to arable land (after degradation in manure)	$Qai\text{-}arab_{i1,i2,i3,i4}$ (manure/slurry)	2.12E-06	1.13E+01	[kg]	o
Amount of nitrogen produced during the relevant period for every relevant(sub)category of animal/housing i1 and application to grassland	$Qnitrog\text{-}grass_{i1,i4}$	5809		[kg]	o
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to arable land	$Qnitrog\text{-}arab_{i1,i4}$	1452		[kg]	o
End calculations					
SOIL					
Initial concentration in grassland soil (after the last of four manure applications per year), after 10 years of manure application	PIECgrs10_DEG–Ni1,i2,i3,i4	7.31E-08	1.15E-01	[mg/kg_{wwt}]	o*
Initial concentration in soil of arable land after 10 years of manure application	PIECars 10 DEG-$N_{i1,i2,i3,i4}$	1.83E-08	9.72E-02	[mg/kg_{wwt}]	o*

*Please refer to Input parameters table below for DT50soil and k values.

For L-(+)-lactic acid and hydrogen peroxide, the above general justification for groundwater (section 2.2.8.1 "Further studies on fate and behaviour in the environment") is sufficient to consider that these substances do not cause unacceptable risk for water bodies (groundwater and surface water) for the AEROCLEAN product and no further calculations are needed.

Scenario 4 : Disinfection of large scale food and feed areas (slaughterhouses)

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 4 : Disinfection of large scale food and feed areas (slaughterhouses)			
Application rate of biocidal product V_{form}	0.01	l/m^3	S

Concentration of active substance in the product C_{form} L-(+)-lactic acid Hydrogen peroxide	 50 75	 g/l g/l	S - Considering a product density around 1
Volume to be disinfected Volume	50 000	m^3	TAB ENV 66
Number of applications per day Nappl	1	d^{-1}	D
Fraction of substance disintegrated during or after application F_{dis}	0	[-]	D
Fraction released to wastewater F_{water}	1	[-]	D

Calculations for Scenario 4

Elocalwater = V_{form} * C_{form} * Volume* Nappl * (1-F_{dis}) * F_{water} / 1000

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission ($Elocal_{compartment}$) [kg/d^{-1}]**	**Remarks**
L-(+)-lactic acid	STP	2.50E+01	
Hydrogen peroxide	STP	3.75E+01	
Hydrogen peroxide (after degradation in sewer; cf. scenario 1)	STP	9.75E-01	

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway								
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water
Scenario 1 – PT02 Industrial areas	Yes	Yes	n.r.	n.r.	Yes	n.r.	Yes	Yes
Scenario 2 – PT03 Hatcheries	Yes	Yes	n.r.	n.r.	Yes	n.r.	Yes	Yes
Scenario 3a – PT03 Surfaces of livestock animal housing and equipment via STP	Yes	Yes	n.r.	n.r.	Yes	n.r.	Yes	Yes

Identification of relevant receiving compartments based on the exposure pathway								
Scenario 3b – PT03 Surfaces of livestock animal housing and equipment via slurry/manure	No	No	n.r.	n.r.	No	n.r.	Yes	Yes
Scenario 4 – PT04 Disinfection in food and feed areas (Slaughterhouses)	Yes	Yes	n.r.	n.r.	Yes	n.r.	Yes	Yes

Input parameters (only set values) for calculating the fate and distribution in the environment of L(+) Lactic acid			
Input	Value	Unit	Remarks
Molecular weight	90.08	$g.mol^{-1}$	Assessment Report L-(+)-lactic acid Product-type 02, 03 and 04, June 2017
Vapour pressure (at 20°C)	0.4	Pa	
Water solubility (at 12°C)	1.00E+06	mg/l	Completely miscible with water
Henry's Law Constant (at 20°C)	3.60E-05	$Pa/m^3/mol$	-
Log Octanol/water partition coefficient	-0.74	Log 10	Assessment Report L-(+)-lactic acid Product-type 02, 03 and 04, June 2017
Organic carbon/water partition coefficient (Koc)	20	l/kg	
Biodegradability	Readily biodegradable failing the 10-days window criterion	-	
DT_{50} for degradation in soil (at 12ºC)	30	d	30d as refinement for 90d value in AR (WGII2020)
ktotal (0.2 m relevant for STP and slurry/manure arable land)	2.61E-02	d^{-1}	Calculated
ktotal (0.05 m relevant for slurry/manure grass land)	3.51E-02	d^{-1}	Calculated

Calculated fate and distribution in the STP of L-(+)-lactic acid		
Compartment	Percentage [%]	Remarks
Air	2.50E-05	Simple treat v4.0
Water	22.5	
Sludge	0.20	
Degraded in STP	77.3	

Input parameters (only set values) for calculating the fate and distribution in the environment of Hydrogen peroxide			
Input	Value	Unit	Remarks
Molecular weight	3.40E+01	$g.mol^{-1}$	Assessment Report Hydrogen peroxide, TP1-6 March 2015
Vapour pressure (at 20°C)	2.14E+02	Pa	
Water solubility (at 12°C)	1000 (for risk assessment)	mg/l	Completely miscible with water
Henry's Law Constant	0.00075 (at 20°C)	$Pa/m^3/mol$	-
Log Octanol/water partition coefficient	-1.57	Log 10	Assessment Report Hydrogen peroxide, TP1-6 March 2015
Organic carbon/water partition coefficient (Koc)	1.598	l/kg	
Biodegradability	Readily biodegradable	-	
DT_{50} for degradation in soil (at 12ºC)	0.5	d	
DT_{50} for degradation in STP (at 20°C)	2	min	
k reaction rate constant in sewer system and for liquid manure (12°C)	3.65	h^{-1}	Calculated
ktotal (0.2 m relevant for STP)	1.59	d^{-1}	Calculated
ktotal (0.05 m relevant for slurry/manure grass land)	2.21	d^{-1}	Calculated

Calculated fate and distribution in the STP of Hydrogen peroxide		
Compartment	Percentage [%]	Remarks
Air	2.00E-04	Simple treat v4.0
Water	6.20E-01	
Sludge	1.50E-02	
Degraded in STP	99.3	

Calculated PEC values

Summary table on calculated PEC values of L-(+)-lactic acid					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}** (EPM covered by water)	**PEC_{soil}** (twa)	**PEC_{GW}***
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]
Scenario 1 – PT02 Industrial areas	2.25E-01	2.25E-02	n.r.	5.16E-03	n.r.
Scenario 2 – PT03	4.84E-02	4.84E-03	n.r.	1.11E-03	n.r.

Hatcheries					
Scenario 3a – PT03 Surfaces of livestock animal housing and equipment via STP	1.86E-01	1.86E-02	n.r.	4.26E-03	n.r.
Scenario 3b – PT03 Surfaces of livestock animal housing and equipment via slurry					
Grassland	n.r.	n.r.	n.r.	1.13E-01	n.r.
Arable Land	n.r.	n.r.	n.r.	9.57E-02	n.r.
Scenario 4 – PT04 Disinfection in food and feed areas (Slaughterhouses)	2.81	2.81E-01	n.r.	6.45E-02	n.r.

***** As explained in section "2.2.8.1 - Effects assessment on the environment", there is no need for further calculation in groundwater risk assessment for active substance L-(+)-lactic acid. Therefore, a Tier 2 assessment using Focus Pearl model is not required.

Summary table on calculated PEC values of Hydrogen peroxide					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed} (not relevant for hydrogen peroxide)**	**PEC_{soil} (initial)**	**PEC_{GW}***
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]
Scenario 1 – PT02 Industrial areas	2.42E-04	2.42E-05	n.r.	2.18E-05	n.r.
Scenario 2 – PT03 Hatcheries	5.24E-05	5.24E-06	n.r.	4.72E-06	n.r.
Scenario 3a – PT03 Surfaces of livestock animal housing and equipment via STP	1.99E-04	1.99E-05	n.r.	1.80E-05	n.r.
Scenario 3b – PT03 Surfaces of livestock animal housing and equipment via slurry					
Grassland	n.r.	n.r.	n.r.	7.22E-08	n.r.
Arable Land	n.r.	n.r.	n.r.	1.81E-08	n.r.
Scenario 4 – PT04 Disinfection in food and feed areas (Slaughterhouses)	3.02E-03	3.02E-04	n.r.	2.72E-04	n.r.

* At ENV WG-IV-2019, it was agreed that no groundwater assessment is needed for hydrogen peroxide since it is a rapidly reacting substance and it is very unlikely that this substance will reach the groundwater. Therefore, PEC calculation and the following risk ratio calculation for groundwater will not be presented in this AEROCLEAN product assessment.

Primary and secondary poisoning

Primary poisoning

Primary poisoning via the direct consumption of the products by wild birds and mammals is unlikely. Therefore, primary poisoning is not considered relevant for this evaluation.

Secondary poisoning

The secondary poisoning assessment is not relevant for the active substances L-(+)-lactic acid and hydrogen peroxide. These substances are unlikely to bioaccumulate in aquatic or terrestrial environment according to the ECHA Guidance Vol IV Part B+C. They have a low Log Kow (<3) and a BCF <100 (see table below). These values indicate a negligible potential for bioconcentration in biota and no accumulation of this substance in the food chain is expected.

Summary table on Log K_{ow} and BCF values			
	Log K_{ow}	**BCF $_{fish}$**	**BCF $_{earthworm}$**
L-(+)-lactic acid	-0.74	4.80E-02	6.78
Hydrogen peroxide	-1.57	1.4	0.84

2.2.8.3 Risk characterisation

Atmosphere

Emissions and PECs in air are considered as negligible. Furthermore, hydrogen peroxide is rapidly decomposed in air. It can be concluded that the use of the AEROCLEAN product will not pose a significant risk to the atmospheric compartment.

Sewage treatment plant (STP), Aquatic compartment, Terrestrial compartment and Groundwater

A summary of the calculated PEC/PNEC values for each scenario and all the relevant environmental compartments are indicated in the following table:

Summary table on calculated PEC/PNEC values of L-(+)-lactic acid					
	PEC/PNEC$_{STP}$	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{soil}$**	**GW (µg/L)**

			PNEC EPM: covered by surface water		
Scenario 1 – PT02 Industrial areas	2.25E-02	5.77E-03	n.r.	2.72E-03	n.r.
Scenario 2 – PT03 Hatcheries	4.84E-03	1.24E-03	n.r.	5.84E-04	n.r.
Scenario 3a – PT03 Surfaces of livestock animal housing and equipment via STP	1.86E-02	4.76E-03	n.r.	2.24E-03	n.r.
Scenario 3b – PT03* Surfaces of livestock animal housing and equipment via slurry					
Grassland	n.r.	n.r.	n.r.	5.95E-02	n.r.
Arable Land	n.r.	n.r.	n.r.	5.04E-02	n.r.
Scenario 4 – PT04 Disinfection in food and feed areas (Slaughterhouses)	2.81E-01	7.21E-02	n.r.	3.40E-02	n.r.

* According to the TAB entry 168, to cover sites not connected to the local drainage system, releases to waste water and to slurry/manure must be cumulated to carry out the risk assessment *via* slurry/manure. For this product, risks remains acceptable in this situation.

Conclusion:
For the active substance L-(+)-lactic acid, risks to the STP, aquatic and terrestrial compartments are acceptable for the use of the AEROCLEAN product.

Summary table on calculated PEC/PNEC values of Hydrogen peroxide					
	$PEC/PNEC_{STP}$	**$PEC/PNEC_{water}$**	**$PEC/PNEC_{sed}$ PNEC: not relevant for hydrogen peroxide**	**$PEC/PNEC_{soil}$**	**GW (µg/L)**
Scenario 1 – PT02 Industrial areas	5.19E-05	1.92E-03	n.r.	1.21E-02	n.r.
Scenario 2 – PT03 Hatcheries	1.12E-05	4.16E-04	n.r.	2.62E-03	n.r.
Scenario 3a – PT03 Surfaces of livestock animal housing and equipment via STP	4.28E-05	1.58E-03	n.r.	9.98E-03	n.r.
Scenario 3b – PT03*					

Surfaces of livestock animal housing and equipment via slurry Grassland Arable Land	n.r. n.r.	n.r. n.r.	n.r. n.r.	4.01E-05 1.01E-05	n.r. n.r.
Scenario 4 – PT04 Disinfection in food and feed areas (Slaughterhouses)	6.49E-04	2.40E-02	n.r.	1.51E-01	n.r.

* According to the TAB entry 168, to cover sites not connected to the local drainage system, releases to waste water and to slurry/manure must be cumulated to carry out the risk assessment *via* slurry/manure. For this product, risks remains acceptable in this situation.

Conclusion:

For the active substance hydrogen peroxide, risks are acceptable for all compartments under all the scenarios for the use of the AEROCLEAN product.

Primary and secondary poisoning

Conclusion:

For active substances L-(+)-lactic acid and hydrogen peroxide, risks of primary and secondary poisoning are acceptable for the uses of the AEROCLEAN product.

Mixture toxicity

Mixture toxicity of the two active substances L(+) Lactic acid and hydrogen peroxide was performed. STP, aquatic (surface water) and terrestrial compartments are concerned for this assessment.

Considering that only a qualitative assessment is required for active substance L-(+)-lactic acid and no groundwater is required for hydrogen peroxide, groundwater has not been included in the mixture risk assessment calculation.

No synergistic interaction is foreseen between L-(+)-lactic acid and hydrogen peroxide.

Summary table on calculated ΣPEC/PNEC values			
	$\Sigma PEC/PNEC_{STP}$	**$\Sigma PEC/PNEC_{water}$**	**$\Sigma PEC/PNEC_{Soil}$**
Scenario 1 – PT02 Industrial areas	2.26E-02	7.69E-03	1.48E-02
Scenario 2 – PT03 Hatcheries	4.85E-03	1.66E-03	3.21E-03
Scenario 3a – PT03 Surfaces of livestock animal housing and equipment via STP	1.86E-02	6.34E-03	1.22E-02

Scenario 3b – PT03 * Surfaces of livestock animal housing and equipment via slurry			
Grassland	n.r.	n.r.	5.95E-02
Arable Land	n.r.	n.r.	5.04E-02
Scenario 4 – PT04 Disinfection in food and feed areas (Slaughterhouses)	2.82E-01	9.61E-02	1.85E-01

* According to the TAB entry 168, to cover sites not connected to the local drainage system, releases to waste water and to slurry/manure must be cumulated to carry out the risk assessment *via* slurry/manure. For this product, risks remains acceptable in this situation.

Conclusion:

It can be concluded that the mixture toxicity assessment show acceptable risks for all the compartments for the use of the AEROCLEAN product.

Aggregated exposure (combined for relevant emmission sources)

According to Article 10(1) of BPD a cumulative risk assessment shall be performed where relevant. The decision tree above was used to evaluate the need for estimation of aggregated exposure.

Since the amount of L-(+)-lactic acid that is used annually in biocidal products accounts for less than 10% compared to the annual production and import volume of L-(+)-lactic acid in the EU, no aggregated risk assessment was performed.

For hydrogen peroxide it was agreed at the WG V 2014 that no aggregate risk assessment was deemed necessary due to the high reactivity of the substance.

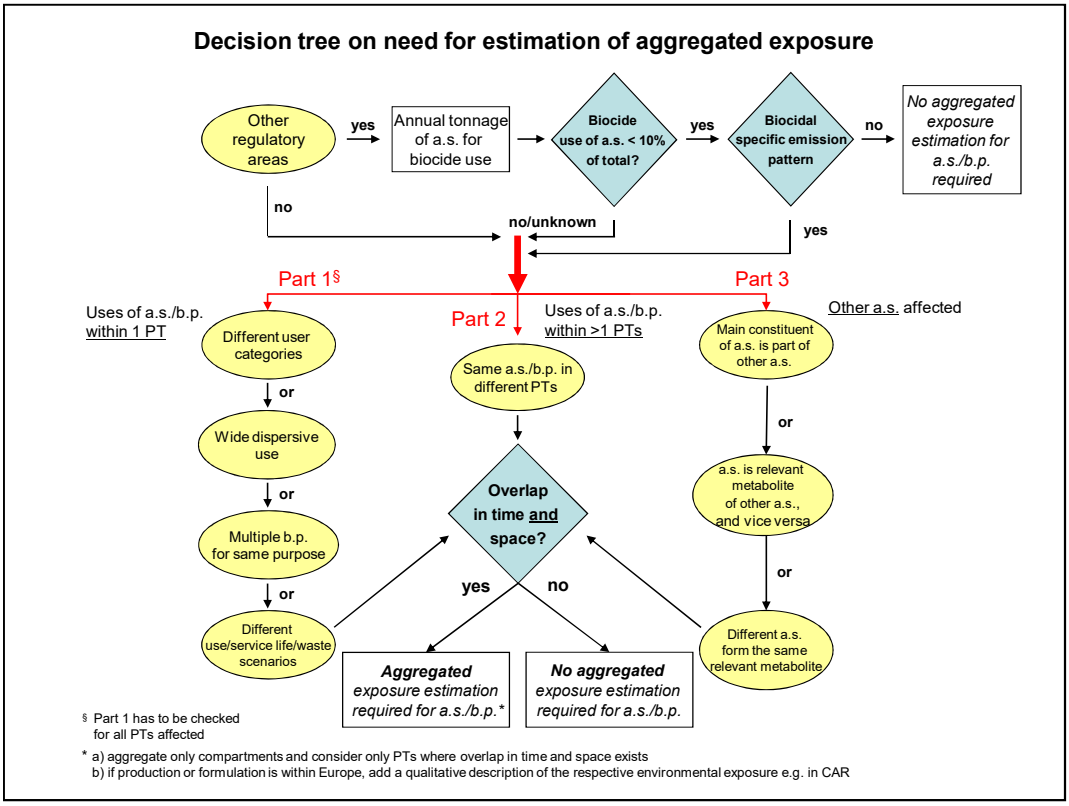


Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product
Following the application of the AEROCLEAN product by professional users in airborne disinfection for PT2, 3 and 4, acceptable risks are reached for all the environmental compartments and for all the uses presented in SPC.

2.2.9 Measures to protect man, animals and the environment

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

2.2.10 Assessment of a combination of biocidal products

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

2.2.11 Comparative assessment

Not relevant

3 ANNEXES

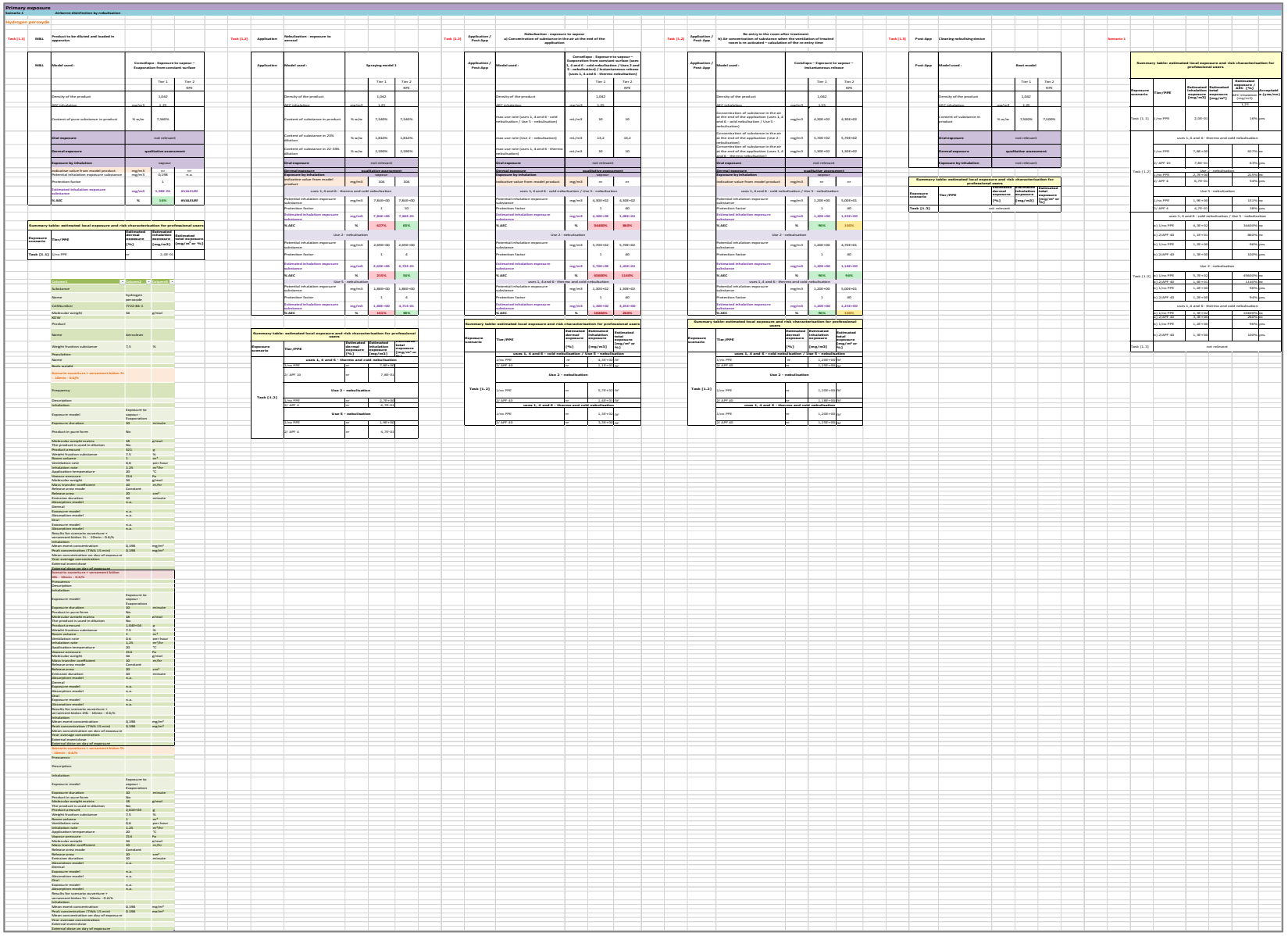
3.1 List of studies for the biocidal product

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)
[redacted]	2019	Stability study of AEROCLEAN Date: 24/04/19 GLP Unpublished	Yes	LABORATOIRE MERIEL S.A.S. / Huvepharma SA
[redacted]	2021	Stability study of AEROCLEAN Date: 22/06/2021 GLP Unpublished	Yes	LABORATOIRE MERIEL S.A.S. / Huvepharma SA
[redacted]	2020	Quantitative analysis of water and residual counter-ions in two batch of double-viologene [redacted] GLP Unpublished	Yes	LABORATOIRE MERIEL S.A.S. / Huvepharma SA
[redacted]	2020	Identification of a degradation product by LC-QTOF [redacted] GLP Unpublished	Yes	LABORATOIRE MERIEL S.A.S. / Huvepharma SA
[redacted]	2020	Identification confirmation of a degradation product by LC-QTOF [redacted] GLP Unpublished	Yes	LABORATOIRE MERIEL S.A.S. / Huvepharma SA
[redacted]	2021	[redacted] GLP Unpublished	Yes	LABORATOIRE MERIEL S.A.S. / Huvepharma SA
[redacted]	2019	Literature review on explosive properties and oxidizing properties of the ingredients of the product AEROCLEAN [redacted]	Yes	LABORATOIRE MERIEL S.A.S. / Huvepharma SA

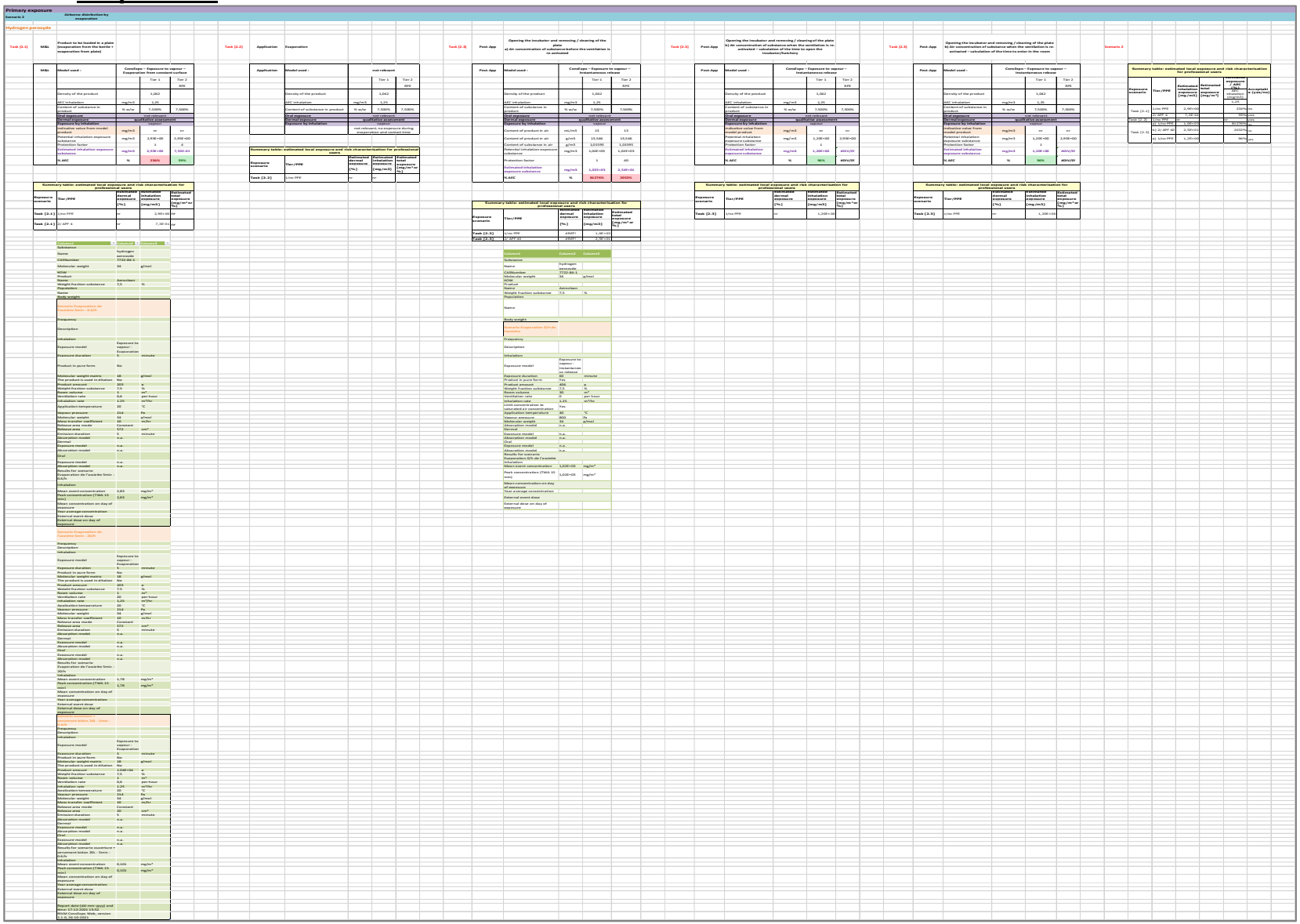
		Unpublished		
[redacted]	2019	In Vitro Membrane Barrier Test Method for skin Corrosion [redacted]	Yes	Huvepharma SA
[redacted]	2019	In Vitro skin irritation: Reconstructed Human Epidermis Test Method [redacted]	Yes	Huvepharma SA

3.2 Output tables from exposure assessment tools

- **Nebulization**



- **Evaporation**



3.3 New information on the active substance

Not relevant

3.4 Residue behaviour

Not relevant

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

Please refer to the IUCLID file

3.6 Confidential annex

Please refer to the confidential annex