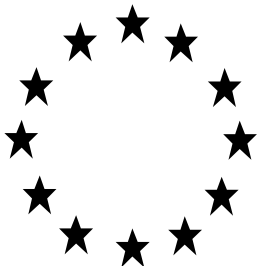
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT (FAMILY) FOR UNION AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Airedale PAA 2-15% Product Family

Product types 2, 3, 4

Peracetic acid

Case Number in R4BP: BC-EW057176-14

Evaluating Competent Authority: Belgium

Date: 04/07/2022

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1 CONCLUSION

The outcome of the assessment for the biocidal product family 'Airedale PAA 2-15% Product Family' is specified in the BPC opinion following discussions at the BPC-43 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	**Country (if relevant)**
Airedale PAA 2-15% Product Family	Union Authorisation (members states of the EEA and Switzerland)

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Rigest Trading (Ireland) Limited
	Address	Mullingar Heifer Beef Nolagh Ballinalack CO. Westmeath N91W896
Pre-submission phase started on	02 March 2017	
Pre-submission phase concluded on	01 April 2017 Decision number: UPP-D-1243542-99-00/F	
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Airedale Chemical Company Ltd
Address of manufacturer	Airedale Mills Skipton Road Cross Hills Keighley BD20 7BX
Location of manufacturing sites	Airedale Mills Skipton Road Cross Hills Keighley BD20 7BX

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

Active substance	Peracetic Acid
Name of manufacturer	Airedale Chemical Company Ltd
Address of manufacturer	Airedale Mills Skipton Road Cross Hills Keighley BD20 7BX

Location of manufacturing sites	Airedale Mills Skipton Road Cross Hills Keighley BD20 7BX

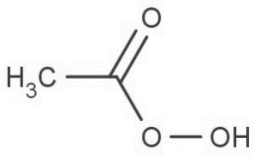
2.1.2 Product (family) composition and formulation

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	Peracetic Acid
IUPAC or EC name	Peroxyethanoic acid
EC number	201-186-8
CAS number	79-21-0
Index number in Annex VI of CLP	607-094-00-8
Minimum purity / content	Pure peracetic acid does neither exist commercially nor is it an intermediate in the production of peracetic acid products. Furthermore, any attempt to produce pure peracetic acid would be prevented by the explosion risks of such a compound. Peracetic acid is produced by reacting hydrogen peroxide (H2O2) with acetic acid in aqueous solution. In this process, peracetic acid is not obtained as a pure substance but in the form of aqueous solutions containing peracetic acid, acetic acid, hydrogen peroxide and water. The peracetic acid content in existing aqueous equilibrium solutions (products) can be as low as < 0.1% or as high as > 15% (w/w). The equilibrium solution is typically the biocidal product which is placed on the market. The component of Hydrogen Peroxide is not considered a second active substance as testing can only be completed in peracetic acid in the equilibrium form.
Structural formula	

2.1.2.2 Candidate(s) for substitution

Peracetic Acid is not a candidate for substitution in accordance with the Article 10 of the BPR.

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Peracetic acid	Peroxyethanoic acid	Active substance	79-21-0	201-186-8	1.74	15.9
Acetic acid	Acetic acid	Part of active substance equilibrium	64-19-7	200-580-7	7.7	15.9
Hydrogen peroxide	Hydrogen peroxide	Part of active substance equilibrium	7722-84-1	231-765-0	8.1	25.97
HEDP	1-hydroxyethylidene-1,1-diphosphonic acid	Stabilizer	2809-21-4	220-552-8	0.99	1.2

According to the Article 3(1)(s) of the BPR consolidated version 528/2012 a 'biocidal product family' means a group of biocidal products having:

(i) similar uses;
(ii) the same active substances;
(iii) similar composition with specified variations; and
(iv) similar levels of risk and efficacy.

Airedale PAA 2-15% Product Family is a biocidal product family with:

(i) similar uses

Each product of the biocidal product family is meant to protect animals and man by controlling spreading of infectious diseases. Most of the products in the BPF are intended for surface disinfection in industries (with contact with food or not) via CIP, spraying, wiping, disinfection can also occur via dipping. The BPF also contains products for veterinary hygiene including teat disinfection (teat disinfection use is not approved).

(ii) **the same active substances**

Each product of the BPF contains the same active substance : Peracetic acid.

(iii) **similar composition with specified variations**

Products of the biocidal product family contain 1.74% to 15.9% Peracetic acid. The family is then divided into 3 meta-SPC based on the active substance concentrations : 2% ; 5% and 15%. All the products are meant to be diluted before use. The products contain 4 different co-formulants with the following functions : stabilizer, catalyser and surfactant. All the variations in the composition are specified in the confidential annex.

(iv) **similar levels of risk and efficacy**

All the products of the BPF shows at least bactericidal & yeasticidal activity, as required by ECHA's Efficacy guidance. Fungicidal and virucidal activity is also demonstrated depending on the products.
Regarding the risks, similar levels have been demonstrated for Human Health and Environment (see conclusions of the respective sections). When necessary Risk Mitigation Measures are applied.

It is therefore concluded that the BPF Airedale PAA 2-15% Product Family complies with the definition of the Article 3(1)(s)

2.1.2.4 Information on technical equivalence

The active substance is listed on the Article 95 approved supplier list and has received technical equivalence – decision number : TAP-D-1267940-18-00/F

2.1.2.5 Information on the substance(s) of concern

HEDP is to be considered as a Substance of Concern for meta-SPC 1, where it takes part in the classification of the meta-SPC as Acute Tox 4 (oral); H302. See confidential annex for further details

2.1.2.6 Type of formulation

SL – soluble concentrate

2.1.3 Hazard and precautionary statements[1]

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

Meta-SPC 1

Classification	
Hazard category	Organic peroxide G Metal corr. 1 Oxidising liq. 2 Acute Tox 4 (Oral) Skin Corr. 1B Eye Dam. 1 STOT SE 3 Aquatic Chronic 2
Hazard statement	H272: May intensify fire; oxidiser H290: May be corrosive to metals H302: Harmful if swallowed H314: Causes severe skin burns and eye damage H318: Causes serious eye damage. H335: May cause respiratory irritation. H411: Toxic to aquatic life with long lasting effects.
Labelling	
Signal words	Danger
Hazard statements	H272: May intensify fire; oxidiser H290: May be corrosive to metals H302: Harmful if swallowed H314 : Causes severe skin burns and eye damage H411: Toxic to aquatic life with long lasting effects. EUH071: Corrosive to the respiratory tract

[1] 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).

Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P220: Keep away from clothing and other combustible materials. P234: Keep only in original packaging. P260: Do not breathe vapour/ spray. P264: Wash … thoroughly after handling. P271: Use only outdoors or in a well-ventilated area P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/ face protection. P301 + P330 + P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physican. P363: wash contaminated clothing before reuse P391: Collect spillage. P403+P233 : Store in a well-ventilated place.Keep container tightly closed. P501: Dispose of contents/container to a licensed hazardous-waste collection point.
Note	-

Meta-SPC 2

Classification	
Hazard category	Organic peroxide F Metal corr. 1 Acute Tox. 4 (oral, dermal, inhal) Skin Corr. 1A Eye Dam. 1 STOT SE 3 Aquatic Chronic 1
Hazard statement	H242: Heating may cause fire. H290: May be corrosive to metals. H302+H312+H332: Harmful if swallowed, in contact with skin or if inhaled. H314: Causes severe skin burns and eye damage H318: Causes serious eye damage. H335: May cause respiratory irritation. H410: Very toxic to aquatic life with long lasting effects.
Labelling	
Signal words	Danger

Hazard statements	H242: Heating may cause fire. H290: May be corrosive to metals. H302+H312+H332: Harmful if swallowed, in contact with skin or if inhaled. H314: Causes severe skin burns and eye damage. H410: Very toxic to aquatic life with long lasting effects. EUH071: Corrosive to the respiratory tract
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P234: Keep only in original packaging. P260: Do not breathe vapour/ spray. P264: Wash … thoroughly after handling. P271: Use only outdoors or in a well-ventilated area P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/ face protection. P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physican. P363: wash contaminated clothing before reuse P391: Collect spillage. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P411: Store at temperatures not exceeding 30°C. P501: Dispose of contents/container to a licensed hazardous-waste collection point.
Note	

Meta-SPC 3

Classification	
Hazard category	Organic peroxide F Metal corr. 1 Acute Tox. 4 (oral) Acute Tox 3 (Dermal) Acute Tox 3 (Inhal) Skin Corr. 1A Eye Dam. 1 STOT SE 3 Aquatic Chronic 1

Hazard statement	H242: Heating may cause fire. H290: May be corrosive to metals. H302: Harmful if swallowed H311: Toxic in contact with Skin H331: Toxic if inhaled H314: Causes severe skin burns and eye damage H318: Causes serious eye damage. H335: May cause respiratory irritation. H410: Very toxic to aquatic life with long lasting effects.
Labelling	
Signal words	Danger
Hazard statements	H242: Heating may cause fire. H290: May be corrosive to metals. H302: Harmful if swallowed H311: Toxic in contact with Skin H331: Toxic if inhaled H314: Causes severe skin burns and eye damage. H410: Very toxic to aquatic life with long lasting effects. EUH071: Corrosive to the respiratory tract
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P234: Keep only in original packaging. P260: Do not breathe vapour/ spray. P264: Wash … thoroughly after handling. P271: Use only outdoors or in a well-ventilated area P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/ face protection. P301 + P330 + P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physican. P361+P364: Take off immediately all contaminated clothing and wash it before reuse. P391: Collect spillage. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P411: Store at temperatures not exceeding 30°C. P501: Dispose of contents/container to a licensed hazardous-waste collection point.
Note	

2.1.4 Authorised use(s)

Meta SPC 1 (2% PAA)

2.1.4.1 Uses description

Use # 1.1 – CIP including pharmaceutical and cosmetic industry

Product Type	PT2 "Disinfectants and algaecides not intended for direct application to humans or animals"
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses
Field of use	Indoor – general (including pharmaceutical and cosmetic industry) Disinfection of hard/non-porous surfaces by CIP procedures (with circulation)
Application method(s)	The diluted product should be transferred to equipment by manual dosing or automated dosing. Final rinsing (with potable water) is mandatory : after the disinfection procedure, treated surfaces are rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	At room temperature, in 15 min CT • Active against bacteria and yeasts : **0.02% PAA** (e.g. 1% product with 2% PAA i.e. 10 mL product/L) • Active against bacteria, yeasts and fungi : **0.1% PAA** (e.g. 5% product with 2% PAA i.e. 50 mL product/L) • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (e.g. 7.5% product with 2% PAA i.e. 75 mL product/L) The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

Use # 1.2 – Surface Disinfection by spraying or pouring (followed by wiping for a homogenous distribution) including in pharmaceutical and cosmetic industries

Product Type	PT2 "Disinfectants and algaecides not intended for direct application to humans or animals"
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses
Field of use	Indoor – general (including pharmaceutical and cosmetic industry) Disinfection of hard/non-porous surfaces by spraying or pouring
Application method(s)	The diluted product should be placed in a trigger spray bottle or poured onto the equipment or surface.
Application rate(s) and frequency	At room temperature, in 15 min CT • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (e.g. 7.5% product with 2% PAA i.e. 75 mL product/L) The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

Use # 1.3 – Disinfection of inner surfaces (tanks, pipes, vessels, filling machines, …) by CIP in food and feed industry

Product Type	PT4 "Food and feed area"
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses
Field of use	Indoor – In food/feed Industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood) Disinfection of hard/non-porous surfaces by CIP procedures (with circulation)
Application method(s)	The diluted product should be transferred to equipment by manual dosing or automated dosing. For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory.

	Final rinsing (with potable water) is mandatory : after the disinfection procedure, treated surfaces are rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	At room temperature, in 15 min CT • Active against bacteria and yeasts : **0.02% PAA** (e.g. 1% product with 2% PAA i.e. 10 mL product/L) • Active against bacteria, yeasts and fungi : **0.1% PAA** (e.g. 5% product with 2% PAA i.e. 50 mL product/L) • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (e.g. 7.5% product with 2% PAA i.e. 75 mL product/L) The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

Use # 1.4 – Surface Disinfection by spraying or by pouring (followed by wiping for a homogenous distribution) in food and feed industry

Product Type	PT4 "Food and feed area"
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses
Field of use	Indoor – In food/feed Industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood) Disinfection of hard/non-porous surfaces by spraying or pouring
Application method(s)	The diluted product should be placed in a trigger spray bottle or poured onto the equipment or surface. For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory.
Application rate(s) and frequency	At room temperature, in 15 min CT • Active against bacteria, yeasts, fungi and viruses :

	0.15% PAA (e.g. 7.5% product with 2% PAA i.e. 75 mL product/L) The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

Use # 1.5 – Disinfection by dipping in food and feed industry

Product Type	PT4 "Food and feed area"
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses
Field of use	Indoor – In food/feed Industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood) Disinfection of equipment (hard/non-porous surfaces) by dipping
Application method(s)	The equipment to be disinfected should be placed in a dipping bath For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory
Application rate(s) and frequency	At room temperature, in 15 min CT • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (e.g. 7.5% product with 2% PAA i.e. 75 mL product/L) The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

META SPC 2 (5% PAA)

2.1.4.2 Uses description

Use # 2.1 – CIP including in pharmaceutical and cosmetic industry

Product Type	PT2 "Disinfectants and algaecides not intended for direct application to humans or animals"
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses
Field of use	Indoor – general (including pharmaceutical and cosmetic industry) Disinfection of hard/non-porous surfaces by CIP procedures (with circulation)
Application method(s)	The diluted product should be transferred to equipment by manual dosing or automated dosing. Final rinsing (with potable water) is mandatory : after the disinfection procedure, treated surfaces are rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	At room temperature, in 15 min CT • Active against bacteria and yeasts **0.02% PAA** (e.g. 0.4% product with 5% PAA i.e. 4 mL product/L) • Active against bacteria, yeasts and fungi : **0.1% PAA** (e.g. 2% product with 5% PAA i.e. 20 mL product/L) • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (e.g. 3% product with 5% PAA i.e. 30 mL product/L) The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

Use # 2.2 – Surface Disinfection by spraying or pouring (followed by wiping for a homogenous distribution) including in pharmaceutical and cosmetic industries

Product Type	PT2 "Disinfectants and algaecides not intended for direct application to humans or animals"

Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses
Field of use	Indoor – general (including pharmaceutical and cosmetic industry) Disinfection of hard/non-porous surfaces by spraying or pouring
Application method(s)	The diluted product should be placed in a trigger spray bottle or poured onto the equipment or surface.
Application rate(s) and frequency	At room temperature, in 15 min CT • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (e.g. 3% product with 5% PAA i.e. 30 mL product/L) The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

Use # 2.3 – Surface Disinfection by spraying or pouring (followed by wiping for a homogenous distribution) for veterinary hygiene

Product Type	PT3 "Veterinary hygiene"
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeasts Viruses
Field of use	Indoor in veterinary areas Disinfection by spraying : On hard/non-porous & porous surfaces By pouring : ONLY on hard/non-porous surfaces, WITH prior cleaning
Application method(s)	The diluted product should be placed in a trigger spray bottle or poured onto the equipment or surface. Cleaning prior to use is mandatory. Do not use equipment/surfaces or allow animals/poultry to enter until product is completely absorbed to the surface or air dried.
Application rate(s) and frequency	• Active against bacteria, yeasts and viruses : **0.2% PAA** (e.g. 4% product with 5% PAA i.e. 40 mL product/L)

	In 5 min contact time at +10°C The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA Disinfection of animal housing takes place once animals have been moved out and the building has been cleared and cleaned
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

Use # 2.4 – Disinfection by dipping for veterinary hygiene

Product Type	PT3 "Veterinary hygiene"
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Viruses
Field of use	Indoor Disinfection of equipment (hard/non-porous & porous surfaces by dipping), WITH prior cleaning
Application method(s)	The equipment to be disinfected should be placed in a dipping bath Cleaning prior to use is mandatory.
Application rate(s) and frequency	• Active against bacteria, yeasts and viruses : **0.2% PAA** (e.g. 4% product with 5% PAA i.e. 40 mL product/L) In 5 min contact time at +10°C The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

Use # 2.5 – Disinfection of inner surfaces (tanks, pipes, vessels, filling machines, …) by CIP in food and feed industry

Product Type	PT4 "Food and feed area"
Where relevant, an exact description of the authorised use	Not relevant

Target organism (including development stage)	Bacteria Yeasts Fungi Viruses
Field of use	Indoor – In food/feed Industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood) Disinfection of hard/non-porous surfaces by CIP procedures (with circulation)
Application method(s)	The diluted product should be transferred to equipment by manual dosing or automated dosing. For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory Final rinsing (with potable water) is mandatory : after the disinfection procedure, treated surfaces are rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	At room temperature, in 15 min CT • Active against bacteria and yeasts **0.02% PAA** (e.g. 0.4% product with 5% PAA i.e. 4 mL product/L) • Active against bacteria, yeasts and fungi : **0.1% PAA** (e.g. 2% product with 5% PAA i.e. 20 mL product/L) • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (e.g. 3% product with 5% PAA i.e. 30 mL product/L) The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA 1-2 applications per day
Category(ies) of users	Professional Industrial
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

Use # 2.6 – Surface Disinfection by spraying or pouring (followed by wiping for a homogenous distribution) in food and feed industry

Product Type	PT4 "Food and feed area"
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses

Field of use	Indoor – In food/feed Industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood) Disinfection of hard/non-porous surfaces by spraying or pouring
Application method(s)	The diluted product should be placed in a trigger spray bottle or poured onto the equipment or surface. For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory.
Application rate(s) and frequency	At room temperature, in 15 min CT • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (e.g. 3% product with 5% PAA i.e. 30 mL product/L) The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

Use # 2.7 – Disinfection by dipping in food and feed industry

Product Type	PT4 "Food and feed area"
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses
Field of use	Indoor – In food/feed Industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood) Disinfection of equipment (hard/non-porous surfaces) by dipping
Application method(s)	The equipment to be disinfected should be placed in a dipping bath For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory.
Application rate(s) and frequency	At room temperature, in 15 min CT • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (e.g. 3% product with 5% PAA i.e. 30 mL product/L) The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA 1-2 applications per day

Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

META SPC 3 (15% PAA)

2.1.4.3 Uses description

Use # 3.1 – CIP, including in pharmaceutical and cosmetic industry

Product Type	PT2 "Disinfectants and algaecides not intended for direct application to humans or animals"
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses
Field of use	Indoor – general (including pharmaceutical and cosmetic industry) Disinfection of hard/non-porous surfaces by CIP procedures (with circulation)
Application method(s)	The diluted product should be transferred to equipment by manual dosing or automated dosing. Final rinsing (with potable water) is mandatory : after the disinfection procedure, treated surfaces are rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	At room temperature, in 15 min CT • Active against bacteria and yeasts **0.02% PAA** (e.g. 0.135% product with 15% PAA i.e. 1.35 mL product/L) • Active against bacteria, yeasts and fungi : **0.1% PAA** (e.g. 0.675 % product with 15% PAA i.e. 6.75 mL product/L) • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (e.g. 1% product with 15% PAA i.e. 10 mL product/L) The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

Use # 3.2 – Surface Disinfection by spraying or pouring (followed by wiping for a homogenous distribution), including in pharmaceutical and cosmetic industries

Product Type	PT2 "Disinfectants and algaecides not intended for direct application to humans or animals"
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses
Field of use	Indoor – general (including pharmaceutical and cosmetic industry) Disinfection of hard/non-porous surfaces by spraying or pouring
Application method(s)	The diluted product should be placed in a trigger spray bottle or poured onto the equipment or surface.
Application rate(s) and frequency	At room temperature, in 15 min CT • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (e.g. 1% product with 15% PAA i.e. 10 mL product/L) The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

Use # 3.3 – Surface Disinfection by spraying or pouring (followed by wiping for a homogenous distribution) for veterinary hygiene

Product Type	PT3 "Veterinary hygiene"
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Viruses
Field of use	Indoor - In veterinary areas Disinfection of hard/non-porous & porous surfaces by spraying or pouring, WITH prior cleaning)
Application method(s)	Cleaning prior to use is mandatory The diluted product should be placed in a trigger spray bottle or poured onto the equipment or surface.
Application rate(s) and frequency	• Active against bacteria, yeasts and viruses : **0.2% PAA** (e.g. approximately 1.33% product with 15% PAA i.e. 13.3 mL product/L) In 5 min contact time at +10°C

	The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA Disinfection of animal housing takes place once animals have been moved out and the building has been cleared and cleaned
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

Use # 3.4 – Disinfection by dipping for veterinary hygiene

Product Type	PT3 "Veterinary hygiene"
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Viruses
Field of use	Indoor Disinfection of equipment (hard/non-porous & porous surfaces) by dipping, WITH prior cleaning
Application method(s)	The equipment to be disinfected should be placed in a dipping bath Cleaning prior to use is mandatory
Application rate(s) and frequency	• Active against bacteria, yeasts and viruses : **0.2% PAA** (e.g. approximately 1.33% product with 15% PAA i.e. 13.3 mL product/L) In 5 min contact time at +10°C The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

Use # 3.5 – Disinfection of inner surfaces (tanks, pipes, vessels, filling machines, …) by CIP in food and feed industry

Product Type	PT4 "Food and feed area"
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Fungi

	Viruses
Field of use	Indoor – In food/feed Industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood) Disinfection of hard/non-porous surfaces by CIP procedures (with circulation)
Application method(s)	The diluted product should be transferred to equipment by manual dosing or automated dosing. For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory Final rinsing (with potable water) is mandatory : after the disinfection procedure, treated surfaces are rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	At room temperature, in 15 min CT • Active against bacteria and yeasts **0.02% PAA** (e.g. 0.135% product with 15% PAA i.e. 1.35 mL product/L) • Active against bacteria, yeasts and fungi : **0.1% PAA** (e.g. 0.675 % product with 15% PAA i.e. 6.75 mL product/L) • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (e.g. 1% product with 15% PAA i.e. 10 mL product/L) The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

Use # 3.6 – Surface Disinfection by spraying or pouring (followed by wiping for a homogenous distribution) in food and feed industry

Product Type	PT4 "Food and feed area"
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses
Field of use	Indoor – In food/feed Industry including dairies, breweries, beverage and soft drinks industry, food processing and meat

	industries (except in slaughterhouses and other processes with blood) Disinfection of hard/non-porous surfaces by spraying or pouring
Application method(s)	The diluted product should be placed in a trigger spray bottle or poured onto the equipment or surface. For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory
Application rate(s) and frequency	At room temperature, in 15 min CT • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (e.g. 1% product with 15% PAA i.e. 10 mL product/L) The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

Use # 3.7 – Disinfection by dipping in food and feed industry

Product Type	PT4 "Food and feed area"
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Fungi Viruses
Field of use	Indoor – In food/feed Industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood) Disinfection of equipment (hard/non-porous surfaces) by dipping
Application method(s)	The equipment to be disinfected should be placed in a dipping bath For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory
Application rate(s) and frequency	At room temperature, in 15 min CT • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (e.g. 1% product with 15% PAA i.e. 10 mL product/L) The dilution instructions in brackets must be adapted when using a product with a different concentration in PAA 1-2 applications per day
Category(ies) of users	Industrial

	Professional
Pack sizes and packaging material	HDPE Bottle/pail with HDPE screw cap : ca 5 L, ca 25 L, ca 30 L HDPE drum with PP bung : ca 200 L HDPE IBC with HDPE screw cap : ca 1000 L

2.1.5 General directions for use

2.1.5.1 Instructions for use

Disinfection cycle (for surface disinfection ONLY):

- About the surfaces to be disinfected which must be cleaned before the disinfection procedure, the user should thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected.
- Products must be diluted in potable water before use.
  Dilution rate and contact time depends on the use considered. Please refer to the description of application method related to each use.

• Disinfection **procedures by CIP** - Final rinsing step (with potable water).
After the disinfection procedure, CIP vessels (pipework and tanks) are drained and rinsed with water under closed system conditions

• Disinfection procedures **by dipping** : The bath is not intended to be re-used.
Use the bath only once a day after work and replace it by a fresh solution daily.

• Disinfection procedures **by spraying** : Make sure to wet the surface completely (application rate > 20 mL/m^2 but maximum 100mL/m^2) in order to keep the surface wet during the required contact time.

Do not use equipment until product is completely absorbed to the surface or air dried.

For PT3 uses : Do not use equipment/surfaces or allow animals/poultry to enter until product is completely absorbed to the surface or air dried.
The products cannot be used for the disinfection of animal transport vehicles.

2.1.5.2 Risk mitigation measures

- Wear chemical goggles consistent with EN 166 or equivalent, protective clothing chemically resistant to the biocidal product, and chemical resistant gloves classified under Standard EN374 (Protective gloves against chemicals and micro-organisms), preferably butyl rubber.
- Use with adequate ventilation. Use engineering controls to maintain airborne level below exposure limit requirements or guidelines. Atmospheric levels should be maintained below the exposure guideline. For all wiping and spraying application, a ventilation rate of at least 10/h is required in the rooms where the application takes place.
- When respiratory protection is required (i.e. when the concentration of PAA and/or H2O2 are above their respective AECinhal (0.5 mg/m3 and 1.25 mg/m3 respectively), use an approved air-purifying or positive-pressure supplied-air respirator depending on the potential airborne concentration.
- Do not use equipment/surfaces or allow animals/poultry to enter until product is completely absorbed to the surface or air dried
- Keep out of reach of children and non-target animals/pets.
- Re-entrance into treated area is only allowed once the levels of peracetic acid and hydrogen peroxide in the air are below the AECinhal (respectively 0.5 mg/m3 for PAA & 1.25 mg/m3 for H2O2)
- No bystanders are allowed in treated area during the application phase.
- For PT3 uses : Animals should be removed before treatment takes place

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

- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.
- IF ON SKIN: Immediately wash skin with plenty of water. Take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. After washing the skin: Call 112/ambulance for medical assistance.
- Information to Healthcare personnel/doctor: Initiate life support measures, thereafter call a POISON CENTRE
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.
- Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.
- IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Immediately call 112/ambulance for medical assistance.
- Information to Healthcare personnel/doctor: Immediately initiate life support measures, thereafter call a POISON CENTRE.
- If symptoms: Call 112/ambulance for medical assistance.
- If no symptoms: Call a POISON CENTRE or a doctor.
- Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

2.1.5.4 Instructions for safe disposal of the product and its packaging

- This biocidal product, when being disposed of in its unused and uncontaminated state should be treated as a hazardous waste according to EC Directive 2008/98/EC. Any disposal practices must be in compliance with all national and provincial laws and any municipal or local by-laws governing hazardous waste. Do not dump into any sewers, on the ground, or into any body of water. Avoid release to the environment. High-temperature incineration is an acceptable practice.
- Containers are non-refillable. Do not reuse or refill the containers. Containers should be triple or pressure rinsed with water promptly after they are emptied. They can then be offered for recycling or reconditioning for biocidal products, or they can be punctured and disposed of in a sanitary landfill or by other procedures approved by national and local authorities. Send waste liquid from rinsing of used containers to an approved waste handling facility.

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

- Store below 30°C
- Do not store below 0°C
- Store in dark conditions
- Keep in a well-ventilated place. Keep this product in the original container when not in use. Container must be stored and transported in an upright position to prevent spilling the contents through the vent, where fitted.
- Do not store in and avoid contact with aluminium, carbon steel, copper, mild steel, iron.
- Avoid contact with amines, ammonia, strong acids, strong bases, strong oxidizers.
- Shelf-life :
    - Meta-SPC 1 (2% PAA) : 6 months

- Meta-SPC 2 (5% PAA) : 6 months
- Meta-SPC 3 (15% PAA) : 12 months

2.1.6 Other information

SL – soluble concentrate

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Other: bottle/pail	ca 5 L	Plastic: HDPE pail/drum	HDPE screw cap	Professional use only	Yes
Other: bottle/pail	ca 25 L	Plastic: HDPE pail/drum	HDPE screw cap	Professional use only	Yes
Other: bottle/pail	ca 30 L	Plastic: HDPE pail/drum	HDPE screw cap	Professional use only	Yes
Other: drum	ca 200 L	Plastic: HDPE drum	PP bung	Professional use only	Yes
Other: IBC	ca 1000 L	Plastic: HDPE drum	HDPE screw cap	Professional use only	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

New data has been generated on the product family to support product authorisation. Such studies include Physical and Chemical properties and efficacy and are listed in Annex 3.1 of this PAR.

2.1.8.2 Access to documentation

The applicant "Airedale PAA 2-15% Product Family" received a Letter of Access to the complete active substance dossier for equilibrium peracetic acid from the members of the Peracetic Acid Registration Group (PAR).

2.1.8.3 Similar conditions of use

The biocidal product family "Airedale PAA 2-15% Product Family" is deemed to be eligible for Union authorisation. Decision number: UPP-D-1243542-99-00/F.

2.2 Assessment of the biocidal product (family)

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

Use # 1 – Surface Disinfection by spray, mist, foam, wipe (pour and wipe with cloth) on general surfaces including pharmaceutical and cosmetic industry

Product Type	PT 2 - Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Surface Disinfection by spray, mist, foam, wipe (pour and wipe with cloth) on general surfaces including pharmaceutical and cosmetic industry
Target organism (including development stage)	*Bacteria Gram +ve – vegetative cells* *Bacteria Gram -ve – vegetative cells* *Fungi/yeasts – vegetative cells* Virus
Field of use	Indoor. The biocidal product is recommended for the control of bacteria, fungi, yeast and viruses on hard surfaces.
Application method(s)	The biocidal product should be diluted in water to the required ppm of peracetic acid. The diluted product should be placed in a trigger or foaming spray bottle or poured onto the equipment or surface. Uniform distribution of the biocidal product should be ensured. For heavy soiled surfaces use a cleaning product before use. Application should ensure the equipment or surface is fully saturated and left for at least 10 minutes. Do not use equipment/surfaces until product is completely absorbed to the surface or air dried. Product requires dilution prior to use from capped bottles, drum or intermediate bulk container (IBC). For capped bottles pour into a bucket or container (max 10L), via measuring cylinder (100ml). In many cases, the drum or IBC will be connected via a coupling system pipe to a container. Pails/drums for this type of product are commonly not full-aperture opening drums. Diluted product is transferred to trigger spray at point of use. Dose Rate: 200 ppm ai for antibacterial (600 ppm ai for Airocide PAAD) 700 ppm ai for virucidal 2000 ppm ai for antifungal
Application rate(s) and frequency	1-2 times a day
Category(ies) of users	Industrial/Professional use only.
Pack sizes and packaging material	HDPE 5L pail, 25L pail, 30L pail, 200L drum, 1000L container

Use # 2 – Products used for cleaning in place e.g. tanks, pipes, filling machines on general surfaces including pharmaceutical and cosmetic industry

Product Type	PT 2 - Disinfectants and algaecides not intended for direct application to humans or animals

Where relevant, an exact description of the authorised use	Products used for cleaning in place e.g. tanks, pipes, filling machines on general surfaces including pharmaceutical and cosmetic industry
Target organism (including development stage)	*Bacteria Gram +ve – vegetative cells* *Bacteria Gram -ve – vegetative cells* *Fungi/yeasts – vegetative cells* Virus
Field of use	Indoor. The biocidal product is recommended for the control of bacteria, fungi, yeast and viruses on hard surfaces.
Application method(s)	The biocidal product should be diluted in water to the required ppm of peracetic acid. The diluted product should be transferred to equipment by manual dosing or automated dosing. For heavy soiled surfaces use a cleaning product before use. Application should ensure the equipment or surface is fully saturated and left for at least 10 minutes. Equipment to be flushed with water prior to use. Product requires dilution prior to use from capped bottles, drum or intermediate bulk container (IBC). For capped bottles pour into a bucket or container (max 10L), via measuring cylinder (100ml). In many cases, the drum or IBC will be connected via a coupling system pipe to a container. Pails/drums for this type of product are commonly not full-aperture opening drums. Dose Rate: 200 ppm ai for antibacterial (600 ppm ai for Airocide PAAD) 700 ppm ai for virucidal 2000 ppm ai for antifungal
Application rate(s) and frequency	1-2 times a day
Category(ies) of users	Industrial/Professional use only.
Pack sizes and packaging material	HDPE 5L pail, 25L pail, 30L pail, 200L drum, 1000L container

Use # 3 – Surface Disinfection by spray, mist, foam, wipe (pour and wipe with cloth)

Product Type	PT 3 – Veterinary hygiene
Where relevant, an exact description of the authorised use	Surface Disinfection by spray, mist, foam, wipe (pour and wipe with cloth)
Target organism (including development stage)	*Bacteria Gram +ve – vegetative cells* *Bacteria Gram -ve – vegetative cells* *Fungi/yeasts – vegetative cells* Virus
Field of use	Indoor/Outdoor. The biocidal product is recommended for the control of bacteria, fungi, yeast and viruses on hard surfaces.
Application method(s)	The biocidal product should be diluted in water to the required ppm of peracetic acid. The diluted product should be placed in a trigger or foaming spray bottle or poured onto the

	equipment or surface. For heavy soiled surfaces use a cleaning product before use. Application should ensure the equipment or surface is fully saturated and left for at least 10 minutes. Do not use equipment/surfaces or allow animals/poultry to enter until product is completely absorbed to the surface or air dried. Product requires dilution prior to use from capped bottles, drum or intermediate bulk container (IBC). For capped bottles pour into a bucket or container (max 10L), via measuring cylinder (100ml). In many cases, the drum or IBC will be connected via a coupling system pipe to a container. Pails/drums for this type of product are commonly not full-aperture opening drums. Diluted product is transferred to trigger spray at point of use. Dose Rate: 700 ppm ai for virucidal 1500 ppm for antibacterial 2000 ppm ai for antifungal
Application rate(s) and frequency	1-2 times a day
Category(ies) of users	Industrial/Professional use only.
Pack sizes and packaging material	HDPE 5L pail, 25L pail, 30L pail, 200L drum, 1000L container

Use # 4 – Teat Disinfection

Product Type	PT 3 – Veterinary hygiene
Where relevant, an exact description of the authorised use	Teat Disinfection
Target organism (including development stage)	*Bacteria Gram +ve – vegetative cells* *Bacteria Gram -ve – vegetative cells* *Fungi/yeasts – vegetative cells* Virus
Field of use	Indoor/Outdoor. The biocidal product is recommended for the control of bacteria, fungi, yeast and viruses on teats.
Application method(s)	The biocidal product should be diluted in water to the required ppm of peracetic acid. The diluted product should be applied by manual or automatic non-medical teat disinfection. Application should ensure the equipment or surface is fully saturated and left for at least 10 minutes. Pre and Post milking. Product requires dilution prior to use from capped bottles, drum or intermediate bulk container (IBC). For capped bottles pour into a bucket or container (max 10L), via measuring cylinder (100ml). In many cases, the drum or IBC will be connected via a coupling system pipe to a container. Pails/drums for this type of product are commonly not full-aperture opening drums. Dose Rate:

	700 ppm ai for virucidal 1500 ppm for antibacterial 2000 ppm ai for antifungal
Application rate(s) and frequency	1-2 times a day
Category(ies) of users	Industrial/Professional use only.
Pack sizes and packaging material	HDPE 5L pail, 25L pail, 30L pail, 200L drum, 1000L container

Use # 5 – Disinfection of Equipment by Immersion, dipping, soaking

Product Type	PT 3 – Veterinary hygiene
Where relevant, an exact description of the authorised use	Disinfection of Equipment by Immersion, dipping, soaking
Target organism (including development stage)	*Bacteria Gram +ve – vegetative cells* *Bacteria Gram -ve – vegetative cells* *Fungi/yeasts – vegetative cells* Virus
Field of use	Indoor/Outdoor. The biocidal product is recommended for the control of bacteria, fungi, yeast and viruses on surfaces.
Application method(s)	The biocidal product should be diluted in water to the required ppm of peracetic acid. The equipment is manual or automatic. Application should ensure the equipment is fully saturated and left for at least 10 minutes. Do not use equipment until product is completely absorbed to the surface or air dried. Product requires dilution prior to use from capped bottles, drum or intermediate bulk container (IBC). For capped bottles pour into a bucket or container (max 10L), via measuring cylinder (100ml). In many cases, the drum or IBC will be connected via a coupling system pipe to a container. Pails/drums for this type of product are commonly not full-aperture opening drums. Dose Rate: 700 ppm ai for virucidal 1500 ppm for antibacterial 2000 ppm ai for antifungal
Application rate(s) and frequency	1-2 times a day
Category(ies) of users	Industrial/Professional use only.
Pack sizes and packaging material	HDPE 5L pail, 25L pail, 30L pail, 200L drum, 1000L container

Use # 6 – Surface Disinfection by spray, mist, foam, wipe (pour and wipe with cloth) in dairies, breweries, beverage and soft drinks industry and food processing

Product Type	PT 4 – Food and feed area

Where relevant, an exact description of the authorised use	Surface Disinfection by spray, mist, foam, wipe (pour and wipe with cloth) in dairies, breweries, beverage and soft drinks industry and food processing
Target organism (including development stage)	*Bacteria Gram +ve – vegetative cells* *Bacteria Gram -ve – vegetative cells* *Fungi/yeasts – vegetative cells* Virus
Field of use	Indoor. The biocidal product is recommended for the control of bacteria, fungi, yeast and viruses on surfaces.
Application method(s)	The biocidal product should be diluted in water to the required ppm of peracetic acid. The diluted product should be placed in a trigger or foaming spray bottle or poured onto the equipment or surface. For heavy soiled surfaces use a cleaning product before use. Application should ensure the equipment or surface is fully saturated and left for at least 10 minutes. Do not use equipment/surfaces until product is completely absorbed to the surface or air dried. Product requires dilution prior to use from capped bottles, drum or intermediate bulk container (IBC). For capped bottles pour into a bucket or container (max 10L), via measuring cylinder (100ml). In many cases, the drum or IBC will be connected via a coupling system pipe to a container. Pails/drums for this type of product are commonly not full-aperture opening drums. Diluted product is transferred to trigger spray at point of use. Dose Rate: 200 ppm ai for antibacterial (600 ppm ai for Airocide PAAD) 700 ppm ai for virucidal
Application rate(s) and frequency	1-2 times a day
Category(ies) of users	Industrial/Professional use only.
Pack sizes and packaging material	HDPE 5L pail, 25L pail, 30L pail, 200L drum, 1000L container

Use # 7 – Products used for cleaning in place e.g. tanks, pipes, filling machines in dairies, breweries, beverage and soft drinks industry and food processing. Automated spraying in closed system

Product Type	PT 4 – Food and feed area
Where relevant, an exact description of the authorised use	Products used for cleaning in place e.g. tanks, pipes, filling machines in dairies, breweries, beverage and soft drinks industry and food processing. Automated spraying in closed system
Target organism (including development stage)	*Bacteria Gram +ve – vegetative cells* *Bacteria Gram -ve – vegetative cells* *Fungi/yeasts – vegetative cells* Virus
Field of use	Indoor. The biocidal product is recommended for the control of bacteria, fungi, yeast and viruses on surfaces.

Application method(s)	The biocidal product should be diluted in water to the required ppm of peracetic acid. The diluted product should be transferred to equipment by manual dosing or automated dosing. For heavy soiled surfaces use a cleaning product before use. Application should ensure the equipment is fully saturated and left for at least 10 minutes. Equipment to be flushed with water prior to use. Product requires dilution prior to use from capped bottles, drum or intermediate bulk container (IBC). For capped bottles pour into a bucket or container (max 10L), via measuring cylinder (100ml). In many cases, the drum or IBC will be connected via a coupling system pipe to a container. Pails/drums for this type of product are commonly not full-aperture opening drums. Dose Rate: 200 ppm ai for antibacterial (600 ppm ai for Airocide PAAD) 700 ppm ai for virucidal
Application rate(s) and frequency	1-2 times a day
Category(ies) of users	Industrial/Professional use only.
Pack sizes and packaging material	HDPE 5L pail, 25L pail, 30L pail, 200L drum, 1000L container

Use # 8 – Products used for soaking single stage cleaning and disinfection without mechanical action in dairies, breweries, beverage and soft drinks industry and food processing

Product Type	PT 4 – Food and feed area
Where relevant, an exact description of the authorised use	Products used for soaking single stage cleaning and disinfection without mechanical action in dairies, breweries, beverage and soft drinks industry and food processing
Target organism (including development stage)	*Bacteria Gram +ve – vegetative cells* *Bacteria Gram -ve – vegetative cells* *Fungi/yeasts – vegetative cells* Virus
Field of use	Indoor. The biocidal product is recommended for the control of bacteria, fungi, yeast and viruses on surfaces.
Application method(s)	The biocidal product should be diluted in water to the required ppm of peracetic acid. The equipment is manual or automatic. Application should ensure the equipment is fully saturated and left for at least 10 minutes. Do not use equipment until product is completely absorbed to the surface or air dried. For capped bottles pour into a bucket or container (max 10L), via measuring cylinder (100ml). In many cases, the drum or IBC will be connected via a coupling system pipe to a container. Pails/drums for this type of product are commonly not full-aperture opening drums. Dose Rate: 200 ppm ai for antibacterial (600 ppm ai for Airocide PAAD) 700 ppm ai for virucidal

Application rate(s) and frequency	1-2 times a day
Category(ies) of users	Industrial/Professional use only.
Pack sizes and packaging material	HDPE 5L pail, 25L pail, 30L pail, 200L drum, 1000L container

2.2.2 Physical, chemical and technical properties

'Airedale PAA 2-15 Product Family' is composed by 3 meta-SPCs:

Meta-SPC 1 contains 2.05 and 2.0% PAA products: "Peracetic Acid 2% Foamy"[2] and "Peracetic Acid 2%"[3].

Meta-SPC 2 contains 4.5 and 5.0% PAA products: "Airocide PAAD" and "Peracetic Acid 5%"[4]

Meta-SPC 3 contains 15% PAA product: "Peracetic Acid 15%"[5]

All products are "soluble concentrates"

The physical, chemical and storage stability data submitted to support this product application are summarised in the following table.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state, colour and odour[6] at 20 °C and 101.3 kPa	Organoleptic	PAA 2% Foamy	Colourless, transparent homogenous liquid	2% Peracetic Acid + surfactant foamy: Determination of Long-Term Storage Stability", study number CP35RS, [redacted], 26/2/19
		PAA 2%	Colourless, transparent, homogenous liquid	2% Peracetic Acid: Determination of Long-Term Storage Stability", study number SL59VS, [redacted], 13/9/18
		Airocide PAAD	Colourless, transparent, homogenous liquid	5% Peracetic Acid + surfactant (Airocide PAAD): Determination of

2 Noted in this section as "PAA 2% Foamy"
3 Noted in this section as "PAA 2%"
4 Noted in this section as "PAA 5%"
5 Noted in this section as "PAA 15%"
6 Odour was not investigated for safety reasons: the products are hazardous by inhalation.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				Long-Term Storage Stability", study number HX58DF, [redacted],12/2/19
		PAA 5%	Colourless, transparent, homogenous liquid	5% Peracetic Acid: Determination of Long-Term Storage Stability", study number KD57SG, [redacted],7/3/19
		PAA 15%	Colourless, transparent, homogenous liquid	Peracetic Acid 15%: Determination of Long-Term Storage Stability", study number NM01XP, [redacted],7/11/19
Acidity / alkalinity	Procedure designed to be compatible with Method 122 of the OECD Guidelines for Testing of Chemicals and CIPAC Methods MT 75.3 and MT 191 of the CIPAC Handbook for the Analysis of Technical and Formulated Pesticides @25°C	PAA 2% Foamy	Neat item: pH = 1.24 1% dilution: pH = 2.83 % H_2SO_4 = 12.1 % w/w	2% Peracetic Acid + surfactant foamy): Determination of Long-Term Storage Stability", study number CP35RS, A. [redacted], 26/2/19
		PAA 2%	Neat item: pH <1 1% dilution: pH = 2.8 % H_2SO_4 = 12.7 % w/w	2% Peracetic Acid: Determination of Long-Term Storage Stability", study number SL59VS, A. [redacted], 13/9/18
		Airocide PAAD	Neat item: pH <1 1% dilution: pH = 2.95 % H_2SO_4 = 8.26 % w/w	5% Peracetic Acid + surfactant (Airocide PAAD): Determination of Long-Term Storage Stability", study number HX58DF, A. [redacted],12/2/19
		PAA 5%	Neat item: pH <1 1% dilution: pH = 2.88 % H_2SO_4 = 8.44 % w/w	5% Peracetic Acid: Determination of Long-Term Storage Stability", study number KD57SG, [redacted],7/3/19

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		PAA 15%	Neat item: pH <1 1% dilution: pH = 2.86 - 3 % H_2SO_4 = 28.29 % w/w	Peracetic Acid 15%: Determination of Long-Term Storage Stability", study number NM01XP, [redacted],7/11/19 "Peracetic Acid (15% in solution): Determination of Physico-Chemical Properties", study number 41303797, [redacted] 7/5/14
Relative density	Pycnometer method, designed to be compatible with Method A3 Relative Density @ 20+- 0.5°C	PAA 2% Foamy	1.06	2% Peracetic Acid + surfactant foamy): Determination of Long-Term Storage Stability", study number CP35RS, [redacted], 26/2/19
		PAA 2%	1.06	2% Peracetic Acid: Determination of Long-Term Storage Stability", study number SL59VS, [redacted], 13/9/18
		Airocide PAAD	1.12	5% Peracetic Acid + surfactant (Airocide PAAD): Determination of Long-Term Storage Stability", study number HX58DF, [redacted],12/2/19
		PAA 5%	1.12	5% Peracetic Acid: Determination of Long-Term Storage Stability", study number KD57SG, [redacted],7/3/19
		PAA 15%	1.16	Peracetic Acid 15%: Determination of Long-Term Storage Stability", study

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				number NM01XP, [redacted] [redacted],7/11/19
Storage stability test – **accelerated storage**		No data on accelerated storage stability has been submitted. The mention "STORE BELOW 30 °C" is thus mandatory on labels		
Storage stability test – **long term storage at ambient temperature**[7]	12 months 25 +- 2°C - The batch had over 1 month to stabilize before measurement of T0. - Internal data from the applicant confirms that the PAA products need a minimum of 10 days after production on the plant for the mixture to stabilise and reach equilibrium. - All products tested for shelf life had reached equilibrium.	PAA 2% Foamy 500 ml bottle: Approximately 500 mL, white, translucent plastic (HDPE) bottle with a red plastic opaque screw on lid.	PAA_{t0} = 2.35 % w/w PAA_{t6m} = 2.15% w/w Variation: 8.51% PAA_{t12m} = 2.02% w/w Variation: 14.04% AA_{t0} = 15.7 % w/w AA_{t12m} = 14.7 % w/w Variation: 6.37% $H2O2_{t0}$ = 9.26 % w/w $H2O2_{t9m}$ = 8.44 % w/w Variation: 8.85% $H2O2_{t12m}$ = 8.24 % w/w Variation: 11.01% No signs of corrosion, degradation or seepage after 12 months. Weight loss: 0.808%	"2% Peracetic Acid + surfactant foamy: Determination of Long-Term Storage Stability", study number CP35RS, [redacted] [redacted], 26/2/19

[7] Please note that the reported AA content does not reflect the actual content. It should be noted that issues with the detection of acetate are recognized, following detailed analysis of storage tests. Indeed, the method is not enough specific and detects also peracetic acid.
Additionally, dilution performed prior to the measurement of the acetic acid could have an impact on the content of AA, since water is part of the equilibrium.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Test item remains colorless, transparent, homogenous, with no sedimentation or precipitation $pH_{t0\ neat}$ =1.25 $pH_{t12m\ neat}$ =1.53 $pH_{t0\ 1\%}$ = 2.85 $pH_{t12m\ 1\%}$ = 2.73 $H_2SO_{4\ to}$ = 12.1% w/w $H_2SO_{4\ t12m}$ =12.3% w/w	
		25 kg keg : Approximately 25 litre (25 kg keg) blue, opaque, plastic (HDPE) jerry can like keg with a moulded handle on the top. The container had a black opaque plastic screw on lid with a black opaque plastic tamper proof seal.	PAA_{t0} = 2.32 % w/w PAA_{t6m} = 2.15% w/w Variation: 7.32% PAA_{t12m} = 2.03% w/w Variation: 12.5% AA_{t0} = 16.0 % w/w AA_{t12m} = 15.1 % w/w Variation: 5.63% $H2O2_{t0}$ =9.24 %w/w $H2O2_{t9m}$ = 8.27 % w/w Variation: 10.5% $H2O2_{t12m}$ = 7.88 % w/w Variation: 14.72%	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			No signs of corrosion, degradation or seepage after 12 months. Weight loss: 1.05 % Test item remains colorless, transparent, homogenous, with no sedimentation or precipitation $pH_{t0\ neat}$ =1.23 $pH_{t12m\ neat}$ =1.51 $pH_{t0\ 1\%}$ = 2.82 $pH_{t12m\ 1\%}$ = 2.80 $H_2SO_{4\ to}$ = 12.1% w/w $H_2SO_{4\ t12m}$ =12.4% w/w Dilution stability after 12 months storage for 10% v/v dilution: stable	
		PAA 2% 500 ml bottle: Approximately 500 mL, white, translucent plastic (HDPE) bottle with a red plastic opaque screw on lid.	PAA_{t0} = 2.28 % w/w PAA_{t12m} = 2.40% w/w Variation: 5.26% AA_{t0} = 16.9 % w/w AA_{t12m} = 15.1 % w/w Variation: 10.65%	2% Peracetic Acid: Determination of Long-Term Storage Stability", study number SL59VS, [redacted], 13/9/18

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			$H2O2_{t0}$ = 8.89 % w/w $H2O2_{t12m}$ = 8.82 % w/w Variation: 0.79% No signs of corrosion, degradation or seepage after 12 months. Weight loss: 0.221% Test item remains colorless, transparent, homogenous, with no sedimentation or precipitation $pH_{t0\ neat}$ <1 $pH_{t12m\ neat}$ =1.23 $pH_{t0\ 1\%}$ = 2.78 $pH_{t12m\ 1\%}$ = 2.82 $H_2SO_{4\ to}$ = 12.7% w/w $H_2SO_{4\ t12m}$ =12.8% w/w	
		25 kg keg : Approximately 25 liter (25 kg keg) blue, translucent plastic (HDPE) jerry can like keg with a moulded handle on the top. The container had a black opaque plastic screw on lid with a black opaque plastic tamper proof seal.	PAA_{t0} = 2.28 % w/w PAA_{t12m} = 2.28% w/w No variation AA_{t0} = 16.9 % w/w AA_{t12m} = 15.2 % w/w Variation: 10.06%	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			$H2O2_{t0}$ =8.67 %w/w $H2O2_{t12m}$ =8.10 % w/w Variation: 6.57% No signs of corrosion, degradation or seepage after 12 months. Weight loss: 1.26 % Test item remains colorless, transparent, homogenous, with no sedimentation or precipitation $pH_{t0\ neat}$ <1 $pH_{t12m\ neat}$ =1.27 $pH_{t0\ 1\%}$ = 2.83 $pH_{t12m\ 1\%}$ = 2.89 $H_2SO_{4\ to}$ = 12.7% w/w $H_2SO_{4\ t12m}$ =13% w/w Dilution stability after 12 months storage for 10% v/v dilution: stable Persistent foaming: no foam after 1 minute at 10% v/v and 1% v/v dilutions	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Airocide PAAD 500 ml bottle: Approximately 500 mL, white, translucent plastic (HDPE) bottle with a red plastic opaque screw on lid.	PAA_{t0} = 5.47 % w/w PAA_{t12m} = 6.01 % w/w Variation: 9.87% AA_{t0} = 12.2 % w/w AA_{t6m} = 12.5 % w/w Variation 2.46 AA_{t12m} = 10.9 % w/w Variation: 10.9% $H2O2_{t0}$ = 23 % w/w $H2O2_{t12m}$ = 21.0 % w/w Variation: 8.69% No signs of corrosion, degradation or seepage after 12 months. Weight loss: 0.857% Test item remains colorless, transparent, homogenous, with no sedimentation or precipitation $pH_{t0\ neat}$ <1 $pH_{t12m\ neat}$ =1.23 $pH_{t0\ 1\%}$ = 2.94 $pH_{t12m\ 1\%}$ = 2.84 $H_2SO_{4\ to}$ = 8.24% w/w	5% Peracetic Acid + surfactant (Airocide PAAD): Determination of Long-Term Storage Stability", study number HX58DF, [redacted],12/2/19

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		25 kg keg : Approximately 25 liter (25 kg keg) blue, translucent plastic (HDPE) jerry can like keg with a moulded handle on the top. The container had a black opaque plastic screw on lid with a black opaque plastic tamper proof seal.	$H_2SO_{4\ t12m}$ =8.75% w/w PAA_{t0} = 5.33 % w/w PAA_{t12m} = 5.06 % w/w Variation: 5.07% AA_{t0} = 12.6 % w/w AA_{t6m} = 12.7 % w/w Variation 0.79% AA_{t12m} = 11.2 % w/w Variation: 11.11% $H2O2_{t0}$ =23 %w/w $H2O2_{t12m}$ =20.7 % w/w Variation: 10% No signs of corrosion, degradation or seepage after 12 months. Weight loss: 1.40 % Test item becomes cloudy, turbid, translucent liquid after 3 months and very cloudy, turbid, homogenous liquid after 12 months. On standing the test item	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			changed to a colourless, transparent liquid with a white translucent cloudy top layer. The applicant has justified this drastic change in appearance by the surfactant. As eCA, we do not accept the shelf life of 12 months. Based on variation of concentrations of various components of the equilibrium, shelf life of 6 months is validated by eCA. $pH_{t0\ neat}$ <1 $pH_{t12m\ neat}$ =1.24 $pH_{t0\ 1\%}$ = 2.96 $pH_{t12m\ 1\%}$ = 2.76 $H_2SO_{4\ to}$ = 8.27% w/w $H_2SO_{4\ t12m}$ =8.83% w/w Dilution stability after 12 months storage for 4% v/v dilution: stable Persistent foaming: 0.4% v/v 15 ml of foam after 1 minute 2 ml of foam after 12 minutes	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			4% v/v 18 ml of foam after 1 minute 8 ml of foam after 12 minutes	
		PAA 5% 500 ml bottle: Approximately 500 mL, white, translucent plastic (HDPE) bottle with a red plastic opaque screw on lid.	PAA_{t0} = 5.27 % w/w PAA_{t12m} = 4.81% w/w Variation: 8.73% AA_{t0} = 13.7 % w/w AA_{t6m} = 12.6 % w/w Variation 8.03 AA_{t12m} = 10.7 % w/w Variation: 21.9% $H2O2_{t0}$ = 22.9 % w/w $H2O2_{t12m}$ = 21.6 % w/w Variation: 5.68% No signs of corrosion, degradation or seepage after 12 months. Weight loss: 0.221% Test item remains colorless, transparent, homogenous, with no sedimentation or precipitation $pH_{t0\ neat}$ <1	5% Peracetic Acid: Determination of Long-Term Storage Stability", study number KD57SG, [redacted] [redacted],7/3/19

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			$pH_{t12m\ neat}$ =1.20 $pH_{t0\ 1\%}$ = 2.89 $pH_{t12m\ 1\%}$ = 2.77 $H_2SO_{4\ to}$ = 8.47% w/w $H_2SO_{4\ t12m}$ =8.89% w/w	
		25 kg keg : Approximately 25 liter (25 kg keg) white, translucent plastic (HDPE) jerry can like keg with a moulded handle on the top. The container had a black opaque plastic screw on lid with a black opaque plastic tamper proof seal.	PAA_{t0} = 5.27 % w/w PAA_{t12m} = 4.81% w/w Variation: 8.73% AA_{t0} = 13.8 % w/w AA_{t6m} = 13.9 % w/w Variation 0.72% AA_{t12m} = 10.3 % w/w Variation: 25.36% $H2O2_{t0}$ =22.8 %w/w $H2O2_{t12m}$ =21.3 % w/w Variation: 6.58% No signs of corrosion, degradation or seepage after 12 months. Weight loss: 1.26 % Test item remains colorless, transparent, homogenous, with no	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			sedimentation or precipitation $pH_{t0\ neat}$ <1 $pH_{t12m\ neat}$ =1.25 $pH_{t0\ 1\%}$ = 2.86 $pH_{t12m\ 1\%}$ = 2.82 $H_2SO_{4\ to}$ = 8.40% w/w $H_2SO_{4\ t12m}$ =9.08% w/w Dilution stability after 12 months storage for 3% v/v dilution: stable Persistent foaming: no foam after 1 minute at 3% v/v and 0.4% v/v dilutions	
		PAA 15% 500 ml bottle: Approximately 500 mL, white, translucent plastic (HDPE) bottle with a red plastic opaque screw on lid.	PAA_{t0} = 15.9 % w/w PAA_{t12m} = 15.3% w/w Variation: 3.77% AA_{t0} = 22.3 % w/w AA_{t3m} = 25.5 % w/w Variation 14.35 AA_{t12m} = 29.3 % w/w Variation: 31.39% Considering that the PAA content (the active substance itself) is stable and only the AA content is	Peracetic Acid 15%: Determination of Long-Term Storage Stability", study number NM01XP, [redacted] ,7/11/19

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			higher than the admitted variation, eCA proposes to set the shelf-life to 12 months. Please note that AA is not an active substance here and is not of toxicological concern. $H2O2_{t0}$ = 24.8 % w/w $H2O2_{t12m}$ = 24.0 % w/w Variation: 3.23% No signs of corrosion, degradation or seepage after 12 months. Weight loss: 0.505% Test item remains colorless, transparent, homogenous, with no sedimentation or precipitation $pH_{t0\ neat}$ <1 $pH_{t12m\ neat}$ =1.06 $pH_{t0\ 1\%}$ = 2.98 $pH_{t12m\ 1\%}$ = 2.74 $H_2SO_{4\ to}$ = 13.2% w/w $H_2SO_{4\ t12m}$ =13.3% w/w PAA_{t0} = 15.9 % w/w	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		25 kg keg : Approximately 25 litre (25 kg keg) blue, translucent plastic (HDPE) jerry can like keg with a moulded handle on the top. The container had a blue opaque plastic screw on lid with a blue opaque plastic tamper proof seal.	PAA_{t12m} = 14.7 % w/w Variation: 7.64% AA_{t0} = 23.8 % w/w AA_{t3m} = 24.6 % w/w Variation 3.36% AA_{t12m} = 29.5 % w/w Variation: 23.95% Considering that the PAA content (the active substance itself) is stable and only the AA content is higher than the admitted variation, eCA proposes to set the shelf-life to 12 months. Please note that AA is not an active substance here and is not of toxicological concern. $H2O2_{t0}$ =24.7 %w/w $H2O2_{t12m}$ =23.5 % w/w Variation: 4.86% No signs of corrosion, degradation or seepage after 12 months. Weight loss: 0.898 % Test item remains colorless,	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			transparent, homogenous, with no sedimentation or precipitation $pH_{t0\ neat}$ <1 $pH_{t12m\ neat}$ =1.07 $pH_{t0\ 1\%}$ = 3.03 $pH_{t12m\ 1\%}$ = 2.74 $H_2SO_{4\ to}$ = 13.2% w/w $H_2SO_{4\ t12m}$ =13.7% w/w Dilution stability after 12 months storage for 1% v/v dilution: stable Persistent foaming: no foam after 1 minute at 1% v/v and 0.13% v/v dilutions	
Storage stability test – **low temperature stability test for liquids**	No data on low temperature storage stability has been submitted. The mention "DO NOT STORE BELOW 0 °C" is thus mandatory on labels			
Effects on content of the active substance and technical characteristics of the biocidal product - **light**		The product is packaged in opaque containers, therefore exposure to light is not relevant The applicant proposes to add the following storage RMM: "STORE IN DARK CONDITIONS"		
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Please see the results of long term storage tests for the effect of temperature. The products are water based formulation and water is a part of active substance equilibrium , thus the humidity is not a relevant parameter to be investigated.			
Effects on content of the active substance	Please see the results of long term storage tests for more details. There is no interaction between container material and the product.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
and technical characteristics of the biocidal product - **reactivity towards container material**				
Wettability	Waived	Not applicable for the formulation type SL		
Suspensibility, spontaneity and dispersion stability	Waived	Not applicable for the formulation type SL		
Wet sieve analysis and dry sieve test	Waived	Not applicable for the formulation type SL		
Emulsifiability, re-emulsifiability and emulsion stability	Waived	The products are not emulsifiable concentrates		
Disintegration time	Waived	Not applicable for the formulation type SL		
Particle size distribution, content of dust/fines, attrition, friability	Waived	a) the products are sold in capped containers only. a) MMAD is not used as an input parameter in the HHRA. Estimation of exposure via spray has been done using standard models which do not use this parameter as an input. c) the MMAD is not relevant for efficacy assessment.		
Persistent foaming[8]	Procedure designed to be compatible with Method MT 47.2 of the CIPAC Handbook for the Analysis of Technical and Formulated Pesticides	PAA 2% Foamy	Intended for use as a foam	
		PAA 2%	At 10% v/v dilution: Few bubbles around the periphery were produced intially. They are still present after 1 minute. This foam disappears completely after 3 minutes	2% Peracetic Acid: Determination of Long-Term Storage Stability", study number SL59VS, [redacted], 13/9/18

[8] According to the efficacy assessment, the minimum efficacious dose is 50 ppm peracetic acid, corresponding to the following dilutions of products: 0.25 % products meta-SPC1; 0.1 % products meta-SPC 2 and 0.04 % product meta-SPC 3. The highest in use dose is 1000 ppm PAA, corresponding to a dilution of 5% for products of meta-SPC1; 2000 ppm PAA, corresponding to a dilution of 4% products meta-SPC2 and 1.5% product meta-SPC3. The applicant has initially submitted data with the highest concentration than those validated by the efficacy assessment. BE eCA has accepted these data and considers that they are worst case compared to the validated dosages. For the lowest in use concentrations, data have been either measured at higher dilution. In view of absence of persistent foaming, we have also accepted these data.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			At 1% v/v dilution: Approxim. 5 ml of foam was produced intially. Few bubbles around the periphery are still present after 1 minute. This foam disappears completely after 12 minutes	
		Airocide PAAD	At 4% v/v dilution: Approximately 54 mL of foam[9] was produced intially. The amounf of foam remains unchanged after 12 minutes. At 0.4% v/v dilution: Approximately 47 mL of foam was produced intially. 27 ml of foam remains after 1 minutes, 12 ml of foam remains after 3 minutes and 4 ml of foam remains afer 12 minutes.	5% Peracetic Acid + surfactant (Airocide PAAD): Determination of Long-Term Storage Stability", study number HX58DF, [redacted],12/2/19
		PAA 5%	At 3% v/v dilution:	5% Peracetic Acid: Determination of Long-Term Storage

[9] The high amount of foam is explained by a presence of a foaming agent. It is added for detergency power and not foaming as such.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Few bubbles around the periphery were produced intially. This foam disappears completely after 10 seconds At 0.4% v/v dilution: No foam was produced intially	Stability", study number KD57SG, [redacted] 7/3/19
		PAA 15%	No foam was produced intially at both 1 % v/v and 0.13 % v/v	Peracetic Acid 15%: Determination of Long-Term Storage Stability", study number NM01XP, [redacted],7/11/19
Flowability/Pourability/Dustability	Waived	Not applicable for the formulation type SL		
Burning rate — smoke generators	Waived	Not applicable for the formulation type SL		
Burning completeness — smoke generators	Waived	Not applicable for the formulation type SL		
Composition of smoke — smoke generators	Waived	Not applicable for the formulation type SL		
Spraying pattern — aerosols	Waived	Not applicable for the formulation type SL		
Physical compatibility	Waived	Not applicable as the product is not intended to be mixed with other products		
Chemical compatibility	Waived	Not applicable as the product is not intended to be mixed with other products		
Degree of dissolution and dilution stability[10]	Procedure designed to be compatible	PAA 2% Foamy 10% v/v dilution	After 30 minutes and 24 hours:	2% Peracetic Acid + surfactant foamy): Determination of

[10] According to the efficacy assessment, the highest in use dose is 1000 ppm PAA, corresponding to a dilution of 5% for products of meta-SPC1; 2000 ppm PAA, corresponding to a dilution of 4% products meta-SPC2 and 1.5% product meta-SPC3. The applicant has initially submitted data with the highest concentration than those

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	with Method MT 41.1 of the CIPAC Handbook for the Analysis of Technical and Formulated Pesticides		Colourless transparent liquid, with no signs of precipitate, sedimentation or separation.	Long-Term Storage Stability", study number CP35RS, [redacted], 26/2/19
		PAA 2% 10% v/v dilution	After 30 minutes and 24 hours: Colourless transparent liquid, with no signs of precipitate, sedimentation or separation.	2% Peracetic Acid: Determination of Long-Term Storage Stability", study SL59VS, [redacted], 13/9/18
		Airocide PAAD 4% v/v dilution	After 30 minutes and 24 hours: Colourless transparent liquid, with no signs of precipitate, sedimentation or separation.	5% Peracetic Acid + surfactant (Airocide PAAD): Determination of Long-Term Storage Stability", study number HX58DF, [redacted],12/2/19
		PAA 5% 3% v/v dilution	After 30 minutes and 24 hours: Colourless transparent liquid, with no signs of precipitate, sedimentation or separation.	5% Peracetic Acid: Determination of Long-Term Storage Stability", study number KD57SG, [redacted] 7/3/19
		PAA 15% 1% v/v dilution	After 30 minutes and 24 hours: Colourless transparent liquid, with no	Peracetic Acid 15%: Determination of Long-Term Storage Stability", study number NM01XP,

validated by the efficacy assessment. BE eCA has accepted these data and considers that they are worst case compared to the validated dosages.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			signs of precipitate, sedimentation or separation.	[redacted] 7/11/19
Surface tension[9]	Ring method designed to be compatible with Method A5 Surface Tension and Method 115 of the OECD Guidelines for Testing of Chemicals @ 20.0 +_ 0.5 °C	PAA 2% Foamy	Undiluted: 45 mN/m 0.5% v/v : 33.5 mN/m → surface active	2% Peracetic Acid + surfactant foamy): Determination of Long-Term Storage Stability", study number CP35RS, [redacted], 26/2/19
		PAA 2% 5% v/v dilution[11]	5% v/v : 64.5 mN/m	2% Peracetic Acid: Determination of Long-Term Storage Stability", study number SL59VS, [redacted], 13/9/18
		Airocide PAAD	0.1% v/v : 38.2 mN/m 0.2% v/v : 23.8 mN/m	Physico/Chemical Testing on Samples of PAA 5% and Airocide PAAD, study number GLP3016008956R1/ 2021, [redacted], 22/3/21
		PAA 5%	0.1% v/v : 71.0 mN/m 0.2% v/v : 64.6 mN/m	Physico/Chemical Testing on Samples of PAA 5% and Airocide PAAD, study number GLP3016008956R1/ 2021, [redacted], 22/3/21
		PAA 15%	Undiluted product: 43.6 mN/m → surface active	"Peracetic Acid (15% in solution): Determination of Physico-Chemical Properties", study number 41303797, [redacted], 7/5/14
Viscosity	Capillary viscometer method, a procedure designed to be	PAA 2% Foamy	@ 20°C: 1.38 mm²/s @ 40°C: 0.902 mm²/s	2% Peracetic Acid + surfactant foamy): Determination of Long-Term Storage Stability", study

[11] This was the highest application that could be obtained without the test item reacting with the platinum surface tension ring.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	compatible with Method 114 of the OECD Guidelines for Testing of Chemicals @ 20.0 +_ 0.5 °C @ 40.0 +_ 0.5 °C			number CP35RS, [redacted], 26/2/19
		PAA 2%	@ 20°C: 1.34 mm²/s @ 40°C: 0.866 mm²/s	2% Peracetic Acid: Determination of Long-Term Storage Stability", study number SL59VS, [redacted], 13/9/18
		Airocide PAAD	@ 20°C: 1.327 mm²/s @ 40°C: 0.882 mm²/s	Physico/Chemical Testing on Samples of PAA 5% and Airocide PAAD, study number GLP3016008956R1/ 2021, [redacted], 22/3/21
		PAA 5%	@ 20°C: 1.25 mm²/s @ 40°C: 0.813 mm²/s	Physico/Chemical Testing on Samples of PAA 5% and Airocide PAAD, study number GLP3016008956R1/ 2021, [redacted], 22/3/21
		PAA 15%	@ 20°C: 1.96 mm²/s @ 40°C: 1.24 mm²/s	"Peracetic Acid (15% in solution): Determination of Physico-Chemical Properties", study number 41303797, [redacted] 7/5/14

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

All products of this BPF are colorless, transparent, homogenous SL – soluble concentrates. pH of the neat items is turning around 1, and pH of the 1% dilution is ranged from 2.8 to 3. The relative density is going from 1.06 to 1.16.

Since no tests on accelerated storage stability and low temperature stability have been performed, the following mentions have to appear mandatory on the label: "STORE BELOW 30 °C" and "DO NOT STORE BELOW 0°C". The following RMM for storage is also to be indicated: "STORE IN DARK CONDITIONS". The results from long term stability tests grants a shelflife of 6 months for the meta -SPC 1, and 2 and 12 months for the meta-SPC 3.

The characteristics of the products are provided by the applicant and are assessed as acceptable.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Waived	- In the peracetic acid assessment report it is stated: 5% and 15% equilibrium products ("PEROXYACETIC ACID 5% and 15%"): not explosive (no mechanical and thermal sensitivity). Pure or highly concentrated stabilized PAA may form explosive vapour/air mixtures above 40.5 °C. Detailed explosive limits are unknown in the literature. - Under CLP, explosive property determination as described for the hazard class 'explosives' needs not to be conducted for organic peroxides. Therefore the explosive hazard is not applicable for the products of this BPF		
Flammable gases	Waived	Not applicable for the formulation type SL		
Flammable aerosols	Waived	Not applicable for the formulation type SL		
Oxidising gases	Waived	Not applicable for the formulation type SL		
Gases under pressure	Waived	Not applicable for the formulation type SL		
Flammable liquids	Pensky – Martens closed cup apparatus	PAA 2% Foamy PAA 2% Airocide PAAD PAA 5%	No flash before boiling (boiling point = 98.5°C) No flash before boiling (boiling point = 102.2°C) No flash before boiling (boiling point = 102.8°C) No flash before boiling (boiling point = 104.4°C)	" Flash Point Analysis on Test Items: Peracetic Acid 2% (Foamy), Peracetic Acid 2% (Non-Foamy), Peracetic Acid 5%, Peracetic acid 15% and Airocide PAAD", study number GLP/3016008200R1 /2020, [redacted] 30/11/20

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		PAA 15%	Flash point = 71.5°C Based on the experimentally determined flashpoint, the products of this BPF are not flammable liquids[12]	
Flammable solids	Waived	Not applicable for the formulation type SL		
Self-reactive substances and mixtures	Waived	This hazard is covered by the hazard "Organic peroxide".		
Pyrophoric liquids	Waived	Based on experience in handling and use of the test item during testing, the result of the pyrophoric properties test has been predicted negative. Indeed, according to the Guidance on CLP Criteria: "the classification procedure for pyrophoric liquids need not be applied when experience in manufacture or handling shows that the liquid does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the liquid is known to be stable at room temperature for prolonged periods of time (days))."		
Pyrophoric solids	Waived	Not applicable for the formulation type SL		
Self-heating substances and mixtures	Waived	Not applicable for the formulation type SL		
Substances and mixtures which in contact with water emit flammable gases	Waived	The classification procedure for this class can be waived based on - the chemical structure of the substance or mixture does not contain metals or metalloids; - an experience in handling and use shows that the mixture does not react with water, - the mixture is known to form a stable mixture with water (water is part of the equilibrium).		
Oxidising liquids	Please see the explanation below this table, related to the organic peroxide hazard			
Oxidising solids	Waived	Not applicable for the formulation type SL		
Organic peroxides	Please see the explanation below this table			Peracetic Acid 15/23: Organic Peroxides

[12] It should be noted that the stability of products at temperatures higher than ambient temperature is not demonstrated. It is however of common knowledge that organic peroxide solutions are sensitive to high temperatures and can degrade before reaching the boiling point.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				Classification testing", study number J310021R1V1/2016, [redacted], 26/4/16 "Peracetic acid 15%: Adiabatic Storage Test (UN H.2)", study number J4028005883R1/2020, [redacted] 7/7/20
Corrosive to metals	UN test C.1 55 +-1°C It is normal protocol to run the test for 168 hours but due to a reaction occurring between 3 & 19 hours the test was terminated before	PAA 15%	Mass loss higher than 13.5% for steel coupons in vapour space and half submersed. Mass loss less than 13.5 % for aluminium coupons in vapour space, half submersed or fully submersed. **The item is considered as metal corrosive**. All products of the BPF are considered also as metal corrosive without further testing (see below).	Peracetic Acid 15 %: UN corrosivity testing", study number S114204R1V1/2015, [redacted], 24/9/15
	Waived	PAA 2% Foamy PAA 2% Airocide PAAD PAA 5%	According to the Guidance on the application of the CLP criteria: "experience may have proven the corrosivity of given substances	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			and mixtures. In such cases no more testing is needed." The applicant has provided a statement from the filling line at the site of manufacturing. This statement shows that peracetic acid filling line regularly breaks down due to the corrosive nature of the product (peracetic acid 2% solution). Pictures demonstrate very clearly corrosion of gears, resulting in the product leakage. Gears are composed of 316 staineless steel and the corrosion is observed after 40 hour working week (5 x 8 hours shifts). As eCA we consider that the applicant has demonstrated enough experience in handling and manufacturing allowing a classification in corrosive to metals of the more diluted product. Since the 2% solution is considered as corrosive, and 15% solution is demonstrated to be corrosive, the solutions with 5% PAA should also be considered as metal corrosive.	
Auto-ignition temperatures of products (liquids and gases)	Waived	This endpoint does not need to be determined for non flammable liquids. Moreover, the endpoint does not need to be addressed for organic peroxides. For information : The assessment report for the a.s. indicates the following endpoint: 5% equilibrium product "PEROXYACETIC ACID 5%" : Auto-ignition temperature: 435°C 15% equilibrium product "PEROXYACETIC ACID 15%" : Auto-ignition temperature: 280 °C		
Relative self-ignition temperature for solids	Waived	Not applicable for the formulation type SL		
Dust explosion hazard	Waived	Not applicable for the formulation type SL		

Organic peroxide hazard:
Because of the presence of peracetic acid, the products of this BPF need to be considered within the organic peroxide hazard class, on basis of the chemical structure of this substance.

In general, the worst case is defined as formulation containing the highest amount of PAA. However, it is important to note that the contents of hydrogen peroxide and peracetic acid have also effects on physical hazards/classification. In this family, a worst case regarding organic peroxide hazard can be reasonably defined as the formulation PAA 15 % representing meta-SPC 3.

The applicant has submitted the following tests in order to characterize the properties and attribute a category to organic peroxide hazard for this product:

- UN detonation test (A.6): detonative properties;
- time/pressure test (C.1) and deflagration test (C.2) : deflagrative properties:;
- Koenen test (E.1) and Dutch pressure vessel test (E.2): sensitivity to heating under confinement;
- modified Trauzl test (F.4): explosive power

Additionally, the self-accelerating decomposition temperature (SADT) has been determined using the Vent sizing package 2 Calorimetry.
All tests are performed according to the procedures laid down in the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, sixth revised edition.

The results of the testing are summarized here:
Does it propagate a detonation? → NO → Can it propagates a deflagration? → NO (C.1 & C.2) → What is the effect of heating it under defined confinement? → NONE (E.1 & E.2) → Packaged in packages of more than 400 kg/ 450 l or to be considered for exemption? → YES → What is its explosive power? → LOW → **Type F** .

The self-accelerated temperature of decomposition is 35°C for PAA 15% product.
The low SADT value indicates that the sample may require temperature control during transportation. The SADT for the sample as packaged for transport should be determined in order to confirm this. The applicant has indeed submitted a supplementary determination of SADT on the 25 L plastic drum and on the 1000 l plastic IBC. The SADT was estimated to be 85°C for the 25 l drum and 70°C for the 1000 l IBC, and thus exclude the necessity of temperature control during transportation.

Since the product of **meta-SPCs 3 is** classified in **organic peroxide hazard F** and in accordance with the Guidance on the Application of the CLP Criteria: "*In general, organic peroxides do not have or have only weak oxidising properties*" and "*Under CLP organic peroxides are comprised in a separate hazard class and they must not be considered according to the procedures described for oxidising liquids*".

Based on the tests results of the worst case, the rest of the meta-SPCs, containing less PAA than meta-SPC 3, should be classified in the same (type F) or less strict organic peroxide (type G) hazard class. Since the main solvent of all of these products is water, the very last bullet in the decision tree: "is a diluent with boiling point <150°C used" will automatically classify all products of this family in organic peroxide class F.

No new tests have been submitted for the meta-SPC 2. In accordance with what is said previously, BE eCA proposes to classify all products of this meta-SPC in organic peroxide type F class.

The Guidance on the application of the CLP Criteria describes a*n exceptional case in this respect is a peroxyacetic acid formulation, as currently classified in the UN RTDG Model Regulations under UN 3149, with the following description: HYDROGEN PEROXIDE AND PEROXYACETIC ACID MIXTURE with acid(s), water and not more than 5 % peroxyacetic acid, STABILISED. In the classification procedure for organic peroxides, see decision logic in Section 2.15.4.4, this formulation will be assigned to organic peroxide Type G, and consequently no label elements are allocated. In view of the above, this formulation can be classified, also in accordance with CLP, as an Oxidising liquid, Category 2.*
Based on the content in PAA, this exceptional case could be applied to the **meta-SPCs 1**, containing 2.05 % w/w PAA. Based on this exemption, the Meta-SPCs 1 is proposed to be classified as **oxidising liquid category 2** (UN 3149), and shall be labelled according the CLP as an **organic peroxide type G** (although it is a type F according to the decision tree and because of water as a diluent) to avoid duplicate labelling as oxidising liquid and organic peroxide.

Conclusion on the physical hazards and respective characteristics of the product
The classification in relation to physical hazards is: Meta-SPC 1: Metal Corr 1, Org Perox G, Ox Liq 2 Meta-SPC 2: Metal Corr 1, Org Perox F Meta-SPC 3: Metal Corr 1, Org Perox F

2.2.4 Methods for detection and identification

Method Reference: 41303798

PAA/Hydrogen Peroxide

A sample of the product was diluted with water and acidified and titrated with potassium permanganate (hydroperoxide content) and sodium thiosulphate/starch (PAA content). Acceptable validation data and chromatograms were submitted.

Acetate/Sulphate/HEDP[13]

A sample of the product was diluted in 0.01M sodium hydroxide and analysed by Ion Chromatography, using a Ion-Pack AS11-HC column.
It should be noted that issues with the detection of acetate is recognized, following detailed analysis of storage tests. Indeed, the method is not enough specific and detects not only acetate, but also peracetic acid. It results in a wrong measurement of acetic acid content.

The applicant has provided a validation of method for the product PAA 15%:

[13] 1-hydroxyethylidene-1,1-diphosphonic acid

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
PAA 15%	Titration	12-17% Level 1: 12, (n = 3) Level 2: 17, (n = 3) 80 to 113% of nominal concentration of analyte	0.8-4 g/l (n=7) [8-40% in the formulation] r^2 = 0.996	Stated to be specific to target compound	99-102 (level 1) 98-98 (level 2)	100 (level 1) 98 (level 2)	1.01 (level 1) 0.413 (level 2)	Not applicable	[redacted] 2014
Hydrogen Peroxide	Titration	Level 1: 10, (n = 3) Level 2: 14, (n = 3) 90 to 127% of nominal concentration of analyte	0.06-3 g/l (n=7) [6-30% in the formulation] r^2 = 1	Stated to be specific to target compound	101-102 (level 1) 101-101 (level 2)	101 (level 1) 101 (level 2)	1.03 (level 1) 0.481 (level 2)	10%	[redacted], 2014
Acetate	IC	Level 1: 30, (n = 5) Level 2: 60, (n = 5)	0.008-0.2 g/l (n=7)	Chromatogram of blank formulation shows interference at	93.1 – 106 (level 1)	99.7 (level 1)	5.02 (level 1)	30%	[redacted], 2014

		64 to 128% of nominal concentration of analyte	[6.67-167% in the formulation] r^2 = 0.9993	the target retention time*	96.2 - 105 (level 2)	101 (level 2)	3.31 (level 2)		
Sulphate	IC	Level 1: 0.3, (n = 5) Level 2: 0.6, (n = 5) 80 to 160% of nominal concentration of analyte	0.016-0.4 g/l (n=7) [0.053—1.33% in the formulation] r^2 = 0.9999	Chromatogram of blank formulation shows no interference at the target retention time	105-111 (level 1) 99.2-104 (level 2)	107 (level 1) 102 (level 2)	2.30 (level 1) 1.53 (level 2)	0.3%	[redacted] 2014
HEDP	IC	Level 1: 0.15% (n = 5) Level 2: 0.3% (n = 5) 69 to 139% of nominal concentration of analyte	0.008-0.2 g/l (n=7) [0.027-0.67% in the formulation] r^2 = 0.9999	Chromatogram of blank formulation shows no interference at the target retention time	104-108 (level 1) 99.4-103 (level 2)	106 (level 1) 101(level 2)	1.57 (level 1) 1.31 (level 2)	0.15%	[redacted] 2014

*Sample were diluted to minimise the effect of the interfering peak

Additional validation data for the products PAA 2%, PAA 2% Foamy, PAA 5% and AIROCIDE 5% are presented in the below table.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
PAA PAA 2%	Titration	Level 1 :1% (n=5) Level 2: 1.3% (n=5) Level 3: 2% (n=5) 50 to 100 % of nominal concentration of analyte	0.03-0.34 g/l (n=9) [1-12% in the formulation] r^2 = 0.9988	Stated to be specific to target compound	97-98 91-92 86-93	 98 91 88	 0.484 0.438 0.320	Not applicable	[redacted] 2019 NJ21XW
PAA 2% Foamy		Level 1: 0.9% (n=5) Level 2: 1.3% (n=5) Level 3: 2% (n=5) Level 4: 11% (n=5) 40 to 493% of nominal			79-94 96-98 89-97 82-83	 88 97 95 83	 8.43 0.854 3.59 0.783		

PAA 5% Airocide 5%		concentration of analyte Level 1: 1% (n=5) Level 2: 1.3% (n=5) Level 3: 2% (n=5) 21 to 41% of nominal concentration of analyte Level 1: 1% (n=5) Level 2: 1.3% (n=5) Level 3: 2% (n=5) 22 to 45% of nominal concentration of analyte			82-96 89-110 86-92 108-127 118-120 97-105	85 94 90 119 119 102	7.11 9.41 2.88 5.75 0.537 3.76		
Hydrogen Peroxide PAA 2%	Titration	Level 1: 17% (n=5)	0.18-1.56 g/l (n=9)	Stated to be specific to target compound	102-102	102 102 100	0.320 0.242 0.366	10%	[redacted] 2019 NJ21XW

		Level 2: 10% (n=5) Level 3: 21% (n=5) 115 to 230% of nominal concentration of analyte	[6-52% in the formulation] r^2 = 0.9999		102-102 100-101				
PAA 2% Foamy		Level 1: 17% (n=5) Level 2: 10% (n=5) Level 3: 21% (n=5) 113 to 268 % of nominal concentration of analyte			101-101 99-100 101-101	100 99.4 100	0.323 0.514 0.190		
PAA 5%		Level 1: 17% (n=5) Level 2: 10% (n=5) Level 3: 21% (n=5)			100-100 99-101 100-100	100 100 100	0.194 0.480 0.321		

Airocide 5%		44 to 93% of nominal concentration of analyte Level 1: 17% (n=5) Level 2: 10% (n=5) Level 3: 21% (n=5) 44 to 92% of nominal concentration of analyte			99-100 101-102 99-100	 99 102 99	0.340 0.242 0.681		
Acetate PAA 2%	IC	Level 1: 7% (n=5) Level 2: 13% (n=5) Level 3: 20% (n=5) 38 to 120% of nominal concentrate of analyte	0.002-0.1 g/l (n=10) [1.7-83% in the formulation] r^2 = 1.0	Chromatogram of blank formulation shows interference at the target retention time*	92-96 87-97 95-98	94 92 96	2.23 2.46 1.92	7%	[redacted] 2019 NJ21XW

PAA 2% Foamy		Level 1: 7% (n=5) Level 2: 13% (n=5) Level 3: 20% (n=5) 42 to 121% of nominal concentration of analyte			81-89 91-93 91-96	83 92 94	4.18 0.738 2.12		
PAA 5%		Level 1: 7% (n=5) Level 2: 13% (n=5) Level 3: 20% (n=5) 52 to 149% of nominal concentration of analyte			77-97 92-97 92-97	95 94 95	2.32 2.46 1.92		

Airocide 5%		Level 1: 7% (n=5) Level 2: 13% (n=5) Level 3: 20% (n=5) 52 to 148% of nominal concentration of analyte			91-95 92-95 94-96	93 94 95	1.52 1.40 1.34		
Sulphate PAA 2%	IC	Level 1: 0.3% (n=5) Level 2: 0.7% (n=5) Level 3: 1% (n=5) 81 to 271% of nominal concentration of analyte	0.004-0.8 g/l (n=10) [0.053-1.33% in the formulation] r^2 = 1.0	Chromatogram of blank formulation shows interference at the target retention time*	81-118 93-112 95-107	99 102 101	17.4 8.57 4.30	0.3%	[redacted], 2019 NJ21XW
PAA 2% Foamy		Level 1: 0.3% (n=5) Level 2: 0.7% (n=5)			98-106 93-102 93-103	102 99 98	3.31 3.72 3.76		

		Level 3: 1% (n=5) 89 to 297% of nominal concentration of analyte							
PAA 5%							3.72		
		Level 1: 0.3% (n=5)			95-104	99	2.44 1.21		
		Level 2: 0.7% (n=5)			97-104 98-101	101 99			
		Level 3: 1% (n=5) 89 to 296% of nominal concentration of analyte							
							5.15		
Airocide 5%							1.48 2.36		
		Level 1: 0.3% (n=5)			79-90 97-101	86 98			
		Level 2: 0.7% (n=5)			98-103	100			
		Level 3: 1% (n=4) 79 to 265% of nominal concentration of analyte							

HEDP**	IC		0.008-0.4 g/l (n=8)	Chromatogram of blank formulation shows interference at the target retention time*				0.1%	[redacted]
PAA 2%		Level 1: 0.1% (n=5)	[0.07-3.3% in the formulation]		-4-22	11	103 5.38		2019 NJ21XW
		Level 2: 0.3% (n=5)	r^2 = 1.0		56-65	61	1.69		
		Level 3: 0.5% (n=5)			72-75	74			
		7.8 to 39.1% of nominal concentration of analyte							
							48.6		
PAA 2% Foamy		Level 1: 0.1% (n=5)			-83-25	-48	8.80		
					51-64	58	6.31		
		Level 2: 0.3% (n=5)			63-74	67			
		Level 3: 0.5% (n=5)							
		8.3 to 41.3% of nominal concentration of analyte							
					-49-5		74.8		
PAA 5%		Level 1: 0.1% (n=5)			49-62	-31	9.09		

Airocide 5%		Level 2: 0.3% (n=5) Level 3: 0.5% (n=5) 8.9 to 44.6% of nominal concentration of analyte Level 1: 0.1% (n=5) Level 2: 0.3% (n=5) Level 3: 0.5% (n=5) 9.7 to 48.5% of nominal concentration of analyte			51-69 -80-5 43-53 57-61	57 61 -18 49 60	10.4 196 8.20 2.95		

*Calibration standards were matrix match to address the background interference

**Low recoveries were obtained due to HEDP being consumed by chelation during sample preparation, this was confirmed by the % recoveries increasing with concentration. To compensate for the low recoveries, the concentrations in the test samples were corrected accordingly based on the recovery at the appropriate concentration. In addition, the amounts determined in storage stability study in a few cases were just below the LOQ (0.1%), however if HEDP results are critical the method will need to be revalidated with an LOQ of 0.005% or the results less than 0.1% amended to <0.1%.

Analytical methods for soil
Because absorption to sediment/soil is not likely to occur due to the physico-chemical properties of peracetic acid and because of rapid degradation in contact with organic material, no analytical method for soil needs to be provided.

Analytical methods for air
Analytical method for detection in air was submitted in the CAR dossier.

Analytical methods for water
Analytical method for detection in water was submitted in the CAR dossier.

Analytical methods for animal and human body fluids and tissues
Analytical method for detection in blood was submitted in the CAR dossier.

Analytical methods for monitoring of active substances and residues in food and feeding stuff
The applicant has provided a justification for a non-submission of data for analytical method for residues in/on food or feedstuffs based on to the properties of peracetic acid (highly unstable and rapid degradation upon contact with organic matter).

Conclusion on the methods for detection and identification of the product
Adequate analytical methods are available to support the biocidal product family. PAA and hydrogen peroxide are analysed via titration. The rest of compounds described in the reference specification of the active substance is analysed via IC.

2.2.5 Efficacy against target organisms

2.2.5.1 Function (organisms to be controlled) and field of use (products/objects to be protected) for the products of the AIREDALE family

Main group 01: DISINFECTANTS

Product types :

- PT2 (*Disinfectants and algaecides not intended for direct applications to humans or animals*)
- PT3 (*Veterinary Hygiene*)
- PT4 (*Food & feed Area*)

The biocidal products within the ***AIREDALE family*** contain Peracetic acid (PAA - CAS N° 79-21-0) as active substance (based on the equilibrium PAA/H_2O_2, in presence of acetic acid, as defined in the CAR of the active substance) between 2 and 15% and is divided into 3 Meta SPCs :

- META SPC 1 : products with 2% PAA
- META SPC 2 : products with 5% PAA
- META SPC 3 : products with 15% PAA

NOTE from the APPLICANT : *Peracetic acid is an equilibrium reaction and cannot be tested separately from the equilibrium components hydrogen peroxide and acetic acid. The RMS for PAA approval conclude that the biocidal efficiency of the equilibrium mixture (the one to be taken into account) is mostly due to the peracetic acid content rather than the other constituents. As it is defined in the CAR of PAA, H2O2 and AA are considered as being part of the active substance PAA.*

All the biocidal products within the family are liquid concentrates that need to be diluted with tap water. They are intended to be used by professional and industrial users.

Target organisms may include (besides bacteria and yeasts as mandatory target organisms), fungi and viruses, relevant to the products' areas of use and in-use conditions.

According to the product and the intended uses, the following main use procedures are considered :

- CIP (Cleaning In Place) with circulation (PT2; PT3 & PT4)
- Disinfection of surfaces/equipment by dipping (only for PT3 and PT4 uses) or spraying (PT2; PT3 & PT4)
- Disinfection of teats before & after milking (PT3)

2.2.5.2 Mode of action and effects on target organisms, including unacceptable suffering

The mode of action of peracetic acid is very unspecific.

2.2.5.3 Efficacy data

Efficacy tests performed according to suspension and surface standards have been submitted: Phase 2/Step 1 efficacy tests as mandatory tests for products intended to be used for CIP with circulation procedures. Phase 2/Step 1 and Step 2 efficacy tests as mandatory tests for products intended to be used for soaking, spraying and teat disinfection procedures.

EFF guidance and TAB applicability :

Please note that this application was submitted in early 2017.
As the consequence, the decision made and added in the T.A.B. by the time of the initial submission of the dossier are not of application.

IMPACT of CO-FORMULANTS on efficacy of the products :

Please note that this application was submitted in early 2017.
As the consequence, the discussion about the impact of co-formulants on efficacy (started in 2017), the conclusions and the final decision (added in the 1.3 version of the T.A.B. from August 2017) applicable from Sept. 2019 are not of application.

The Applicant mentioned that the CAR/BPC opinion states "Peracetic acid contributes most to the biocidal efficacy of the application solutions. The results of tests clearly show that peracetic acid has a significantly higher biocidal activity than hydrogen peroxide. However, the synergistic effects cannot be excluded. Acetic acid at the concentrations present in the application solutions will not contribute to the efficacy as the pH is way above the one required for biocidal activity of an acid." Peracetic acid as the only component contributing to the efficacy of the peracetic acid products has been further discussed in the provided justification (reference 6.1-04). Furthermore, the submitted efficacy data demonstrated the same level of efficacy for the peracetic acid products of the Airedale PAA 2-15% Product Family regardless of the product formulation tested. This substantiates that other components present in the different formulations, including surfactants, do not impact the efficacy of the products. Therefore, this allows us to use the provided efficacy studies as bridging data to fulfil the efficacy requirements for all products in the Airedale PAA 2-15% Product Family.

Additional information provided by the Applicant about the non-influence of the catalyser on the pH of the products undiluted/in use :

The same concentration for sulphuric acid (catalyser) was used across the product range as its function is only to initiate the reaction and does not affect the end product. Efficacy is only applicable once the reaction is complete and peracetic acid has been formed. The pH of all products within the Airedale PAA 2-15% Product Family is at the same level (neat products pH <1.3, 1% solutions pH 2.8-3) and thus, the acid (catalyser) concentration has not affected the pH value of each product that would have an impact on efficacy of each product of the family.

Justification of the read-across between the 3 Meta SPC :

- The applicant has submitted a review of the biocidal efficacy of peracetic acid, hydrogen peroxide and acetic acid (Document "6.1-04"- CONFIDENTIAL DOCUMENT to be found in the confidential annex). It was concluded that the biocidal efficiency of the equilibrium mixture is mostly due to the peracetic acid content rather than the other constituents.
- Further clarification based on the submitted efficacy data is included in another document "Appendix_2_Efficacy_RCOM " (CONFIDENTIAL DOCUMENT to be found in the confidential annex). It was concluded that the presented efficacy results show the same log reduction achieved for the same microorganisms for the Airedale 2-15% PAA products tested. The efficacy data demonstrate the same level of efficacy for the peracetic acid products of the Airedale PAA 2-15% Product Family regardless of the product formulation tested. Therefore, this allows the applicant to use the provided efficacy studies as bridging data to fulfil the efficacy requirements for all products in the Airedale PAA 2-15% Product Family.

+ IMPORTANT NOTE TO MSCAs :

A lot of efficacy tests (performed according to suspension and surface EN standards) have been provided by the APP by the time of the submission of this application in UK in early 2017.

However, when this dossier has been transmitted to BE (due to Brexit), the EFF expert made the decision to take over the EFF assessment from the beginning :

About the EFF data package provided by the Applicant in 2017, a majority of tests/reports were related to efficacy of a 2% PAA representative product (About the 5% & 15% representative products, the efficacy data package was not complete & the tests have been only performed using test conditions not claimed by the APP). Among all the reports submitted, many of them were judged not reliable enough. As the consequence, in order to strengthen the PAR as much as possible, the BE EFF expert asked the Applicant to provide additional efficacy tests more reliable and more in line with the label claims.

For PT2 & PT4 intended uses, the EFF expert together with the Applicant agreed to apply a read-across from the efficacy data generated for a 2% PAA *Foamy* test-product (META SPC 1) to the 5% PAA (META SPC 2) & the 15% PAA (META SPC 3) products. For the virucidal efficacy, the Applicant have submitted additional efficacy studies performed under dirty conditions with the 5% PAA product.

However, during the commenting phase, we have no choice but to admit that the surfactants included in the formulation of the product PAA 2% *Foamy*, could impact the efficacy of the products (for example by enabling it to better stick on the surfaces to be disinfected).

Since the Applicant have none efficacy tests currently available to clearly demonstrate the non-impact of the foaming agent, the BE eCA have proposed to set effective concentrations based on the full/complete EFF data package provided for the product PAA 5%. That's why in the tables below, all the results of the Eff tests performed with the product PAA 2% *Foamy* (and the data provided for information also) have been replaced by all the results of the Eff tests performed with the product PAA 5%

For PT3 intended uses, a read-across from the efficacy data generated for a 5% PAA test-product (META SPC 2) to the 15% PAA (META SPC 3) products has been applied and does remain.

EFF tests – PT2/4 intended uses :

<table>
<tr><th colspan="5">Experimental data on the efficacy of the biocidal product against target organisms</th></tr>
<tr><th>Test product</th><th>Function & Test organisms</th><th>Test method / Test system / concentrations applied / exposure time</th><th>Test results : effects</th><th>Reference & R.I.</th></tr>
<tr>
<td>PAA 5%</td>
<td>Bactericidal activity
Enterococcus hirae
E.coli
Pseudomonas aeruginosa
Staphylococcus aureus

+ Salmonella typhimurium
Listeria monocytogenes
Yersinia enterocolitica
E. coli O157:H7
MRSA</td>
<td>EN 1276 (2009)
Quantitative suspension test

• Temperature : +20 ± 1°C
• Contact time : 5 min
• Concentrations tested : 0.4% BP
• I.S. :
0.3g/L BSA (clean conditions)
3g/L BSA (dirty conditions)</td>
<td>
<table>
<tr><th colspan="3">Products PAA 5%
Old & New formulation</th></tr>
<tr><td></td><td colspan="2">Log reduction</td></tr>
<tr><td></td><td colspan="2">0.4%</td></tr>
<tr><td></td><td>CLEAN</td><td>DIRTY</td></tr>
<tr><td>E. coli</td><td colspan="2">> 6.63</td></tr>
<tr><td>S. aureus</td><td colspan="2">> 6.61</td></tr>
<tr><td>E. hirae</td><td colspan="2">> 6.38</td></tr>
<tr><td>P. aeruginosa</td><td colspan="2">> 6.60</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td>S. typhimurium</td><td colspan="2">> 6.53</td></tr>
<tr><td>L. monocytogenes</td><td colspan="2">> 6.63</td></tr>
<tr><td>Y. enterocolitica</td><td colspan="2">> 6.64</td></tr>
<tr><td>E. coli O157:H7</td><td colspan="2">> 6.31</td></tr>
<tr><td>MRSA</td><td colspan="2">> 6.56</td></tr>
</table>

BACTERICIDAL ACTIVITY (including Salmonella typhimurium, Listeria monocytogenes, Yersinia enterocolitica, E. coli O157:H7 and MRSA)
at 0.4% dilution of product PAA 5%
in 5 min
at +20°C
in CLEAN/DIRTY conditions
</td>
<td>Docs 26 & 27
+ Docs 28 & 29</td>
</tr>
<tr>
<td></td>
<td>Fungicidal/Yeasticial activity
Aspergillus brasiliensis
Candida albicans
+ Saccharomyces cerevisiae</td>
<td>EN 1650 (2008)
Quantitative suspension test

• Temperature :+20 ± 1°C
• Contact time : 15 min
• Concentrations tested : 0.4 – 1.2 – 2 % BP
• I.S. :
0.3g/L BSA (clean conditions)</td>
<td>
<table>
<tr><td></td><td colspan="4">Product PAA 5%</td></tr>
<tr><td></td><td colspan="4">Log reduction</td></tr>
<tr><td></td><td colspan="2">0.4%</td><td colspan="2">1.2%</td></tr>
<tr><td></td><td>Clean</td><td>Dirty</td><td>Clean</td><td>Dirty</td></tr>
<tr><td>A. brasiliensis</td><td>0.15</td><td>0.1</td><td>0.57</td><td>0.62</td></tr>
<tr><td>C. albicans</td><td colspan="4">> 5.54</td></tr>
<tr><td>S. cerevisiae</td><td colspan="2">> 5.20</td><td colspan="2">nd</td></tr>
</table>
</td>
<td>Docs 34 & 38</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td>3g/L BSA (dirty conditions)</td>
<td>
<table>
<tr><td></td><td colspan="2">Product PAA 5% (new)</td></tr>
<tr><td></td><td colspan="2">Log reduction</td></tr>
<tr><td></td><td colspan="2">2%</td></tr>
<tr><td></td><td>Clean</td><td>Dirty</td></tr>
<tr><td>A. brasiliensis</td><td colspan="2">> 5.23</td></tr>
</table>
YEASTICIDAL ACTIVITY (including Saccharomyces cerevisiae) at 0.4%

FUNGICIDAL/YEASTICIDAL ACTIVITY (including Saccharomyces cerevisiae) at 2%

in 15 min
at +20°C
in CLEAN/DIRTY conditions
</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bactericidal activity
Enterococcus hirae
E.coli
Pseudomonas aeruginosa
Staphylococcus aureus

+ Salmonella typhimurium
Listeria monocytogenes
Yersinia enterocolitica
E. coli O157:H7
MRSA</td>
<td>EN 13697 (2015)
Quantitative carrier test – hard & non-porous surfaces

• Temperature :+20 ± 1°C
• Contact time : 5 min
• Concentrations tested : 0.4% BP
• I.S. : 3g/L BSA (dirty conditions)</td>
<td>
<table>
<tr><td colspan="2">Products PAA 5%
Old & New formulation</td></tr>
<tr><td></td><td>Log reduction</td></tr>
<tr><td></td><td>DIRTY</td></tr>
<tr><td></td><td>0.4%</td></tr>
<tr><td>E. coli</td><td>> 5.86</td></tr>
<tr><td>S. aureus</td><td>> 5.88</td></tr>
<tr><td>E. hirae</td><td>> 5.97</td></tr>
<tr><td>P. aeruginosa</td><td>> 6.04</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td>S. typhimurium</td><td>> 5.99</td></tr>
<tr><td>L. monocytogenes</td><td>> 6.06</td></tr>
<tr><td>Y. enterocolitica</td><td>> 5.97</td></tr>
<tr><td>E. coli O157:H7</td><td>> 5.68</td></tr>
<tr><td>MRSA</td><td>> 5.99</td></tr>
</table>
BACTERICIDAL ACTIVITY (including Salmonella typhimurium, Listeria monocytogenes, Yersinia enterocolitica, E. coli O157:H7 and MRSA) at 0.4%
in 5 min
at +20°C
</td>
<td>Doc.5 “6.7 - 05 Report IMSL2016 07 021 1F (EN 13697 Bacteria 5 mins)”</td>
</tr>
</table>

<table>
<tr><td></td><td></td><td></td><td>on hard/non-porous surfaces WO prior cleaning.</td><td></td></tr>
<tr><td></td><td>Fungicidal/Yeasticial activity
Aspergillus brasiliensis
Candida albicans
+ Saccharomyces cerevisiae</td><td>EN 13697 (2015)
Quantitative carrier test – hard & non-porous surfaces

• Temperature :+20 ± 1°C
• Contact time : 5 - 15 min
• Concentrations tested : 0.4 – 3 - 4% BP
• I.S. : 3g/L BSA (dirty conditions)</td><td>
<table>
<tr><td>PAA 5%</td><td colspan="4">Log reduction</td></tr>
<tr><td></td><td colspan="4">DIRTY</td></tr>
<tr><td></td><td colspan="2">5 min</td><td colspan="2">15 min</td></tr>
<tr><td></td><td>0.4%</td><td>3%</td><td>0.4%</td><td>3%</td></tr>
<tr><td>A. brasiliensis</td><td>nd</td><td>0.23</td><td>nd</td><td>1.10</td></tr>
<tr><td>C. albicans</td><td>> 1.63</td><td colspan="3">> 4.80</td></tr>
<tr><td>S. cerevisiae</td><td>> 3.21</td><td colspan="3">> 5.05</td></tr>
</table>
<table>
<tr><td>PAA 5% new</td><td colspan="2">Log reduction</td></tr>
<tr><td></td><td colspan="2">DIRTY</td></tr>
<tr><td></td><td colspan="2">15 min</td></tr>
<tr><td></td><td>3%</td><td>4%</td></tr>
<tr><td>A. brasiliensis</td><td>3.1</td><td>> 4.80</td></tr>
</table>
YEASTICIDAL ACTIVITY (including Saccharomyces cerevisiae)
at 3%
in 5 min
at +20°C
on hard/non-porous surfaces wo prior cleaning

FUNGICIDAL/YEASTICIDAL ACTIVITY (including Saccharomyces cerevisiae)
at 3%
in 15 min
at +20°C
on hard/non-porous surfaces WO prior cleaning.</td><td>Doc. 6 "6.7 - 06 Report IMSL2016 07 021 1G (EN 13697 Fungi)"

Doc. 42 "6.7 - 42 Report IMSL2016 07 021 1Z (EN 13697) Peracetic Acid 5% (A niger)"</td></tr>
<tr><td>PAA 5%</td><td>Virucidal activity
Adenovirus
Murine norovirus
Poliovirus</td><td>EN 14476 (2013 + AC 2019)
Quantitative suspension test

• Temperature : +20 ± 1°C
• Contact time : 15 min
• Concentrations tested : 1 – 3 – 4% BP
• I.S. : 3g/L BSA (dirty conditions)</td><td>
<table>
<tr><td></td><td colspan="3">Log reductions</td></tr>
<tr><td></td><td>1%</td><td>3 %</td><td>4%</td></tr>
<tr><td>Adenovirus</td><td>3.42</td><td colspan="2">> 4.00</td></tr>
<tr><td>Poliovirus</td><td>2.83</td><td colspan="2">> 4.00</td></tr>
<tr><td>Norovirus</td><td>4.00</td><td colspan="2">> 4.00</td></tr>
</table>
VIRUCIDAL ACTIVITY
at 3%
in 15 min
at +20°C
in DIRTY conditions.</td><td>Doc. 61 "6.7-61 EN 14476 J002352"

RI ⇔ 1</td></tr>
</table>

<table>
<tr>
<td></td>
<td>Virucidal activity
Adenovirus
Murine norovirus</td>
<td>EN 16777 (2018)
Quantitative carrier test – hard & non-porous surfaces

• Temperature : +20 ± 1°C
• Contact time : 15 min
• Concentrations tested : 0.5 – 3 – 4% BP
• I.S. : 3g/L BSA (dirty conditions)</td>
<td>
<table>
<tr><td></td><td colspan="3">Log reductions</td></tr>
<tr><td></td><td>1%</td><td>3 %</td><td>4%</td></tr>
<tr><td>Adenovirus</td><td>3.63</td><td colspan="2">> 4.00</td></tr>
<tr><td>Norovirus</td><td>3.96</td><td colspan="2">> 4.00</td></tr>
</table>
VIRUCIDAL ACTIVITY
at 3%
in 15 min
at +20°C
On hard/non-porous surfaces WO prior cleaning
</td>
<td>Doc. 62 “6.7-62 J002600 16777”

RI ⇔ 1</td>
</tr>
</table>

<table>
<tr><td colspan="4">META SPC 2 : Products with 5% PAA (new formulations) - PT2 & PT4
In PAA 5% product concentration (%)</td></tr>
<tr><td>EN 1276</td><td>0.4% - 5 min – 20°C – C & D</td><td>EN 13697</td><td>0.4% - 5 min – 20°C – D</td></tr>
<tr><td>EN 1650 - Y</td><td>0.4% - 15 min – 20°C – C & D</td><td>EN 13697 - Y</td><td>3% - 5 min – 20°C – D</td></tr>
<tr><td>EN 1650 – F/Y</td><td>2% - 15 min – 20°C – C & D</td><td>EN 13697 – F/Y</td><td>3% - 15 min – 20°C – D</td></tr>
<tr><td>EN 14476</td><td>3% - 15 min – 20°C – D</td><td>EN 16777</td><td>3% - 15 min – 20°C – D</td></tr>
<tr><td colspan="4">CIP procedures (with circulation) – with 15 min CT at 20°C WO prior cleaning
B + Y : 0.4 % PB-5% (⇔ 0.02% PAA)
B + F/Y : 2% PB-5% (⇔ 0.1% PAA)
B + F/Y + V : 3% PB-5% (⇔ 0.15% PAA)</td></tr>
<tr><td colspan="4">Surface disinfection (PT2/PT4 – “Spray” + PT4 “Dipping”)
– with 15 min CT at 20°C WO prior cleaning
B + F/Y + V : 3% PB-5% (⇔ 0.15% PAA)</td></tr>
</table>

Notes (after commenting phase):

- About uses of the products in PHARMACEUTICAL and COSMETIC INDUSTRIES, all the Efficacy tests were performed using 3 g/L BSA (⇔ dirty conditions) : Considering the EN 14885 standard from 2018, for uses in pharmaceutical/cosmetic industry, as our FR colleagues have rightly pointed out, the EN 14485 standard has been adapted i.e. for testing under dirty conditions either 3 g BSA /L or 5 g SDS /L could be used. Furthermore, when you compare both versions of the EN 1276 standard (i.e. from 2009 and 2019) and of EN 13697 standard (i.e. from 2001 and 2015), specific interfering substances for products intended to be used in pharmaceutical/cosmetic industries have been removed from the more recent versions.

  Since all the tests have been performed using 3 g BSA /L, the tests are valid and duly acceptable. As the conclusions, the requirement of a cleaning step for such applications could be removed from the use instructions.

- About uses of the products in BREWERIES, ALCOHOLIC, NON-ALCOHOLIC BEVERAGE and SOFT DRINK INDUSTRIES, all the Efficacy tests were performed using 3 g/L BSA (⇔ dirty conditions) : Considering the EN 14885 standard from 2018, for such uses, for testing under dirty conditions either 3 g BSA /L or yeasts/sucroce could be used. Furthermore, when you compare both versions of the EN 1276 standard (i.e. from 2009 and 2019) and of EN 13697 standard (i.e. from 2001 and 2015), specific interfering substances have been removed from the more recent versions.
  Since all the tests have been performed using 3 g BSA /L, the tests are valid and duly acceptable. As the conclusions, the requirement of a cleaning step for such applications could be removed from the use instructions.

- About uses of the products in DAIRIES, all the Efficacy tests were performed using 3 g/L BSA (⇔ dirty conditions) : Considering the EN 14885 standard from 2012 & 2018, for such uses, for testing under dirty conditions either 3 g BSA /L or milk could be used. However, in the more recent versions of EN 1276/EN 13697 and the ECHA Eff guidance, all the efficacy tests should be performed using skimmed milk.
  Since all the tests have been performed using 3 g BSA /L, the tests are valid and duly acceptable.

- About uses of the products in MEAT INDUSTRIES, all the Efficacy tests were performed using 3 g/L BSA (⇔ dirty conditions) : Considering the updates foreseen related to the ECHA EFF guidance, a restriction "not in Slaughterhouses and other processes with blood" as a purpose of safety is added.

EFF tests - PT3 intended uses :

<table>
<tr><th colspan="5">Experimental data on the efficacy of the biocidal product against target organisms</th></tr>
<tr><th>Test product</th><th>Function & Test organisms</th><th>Test method / Test system / concentrations applied / exposure time</th><th>Test results : effects</th><th>Reference & R.I.</th></tr>
<tr>
<td>PERASAN 0.025% PAA (dilution of the product DEOSAN ACTIV)</td>
<td>Bactericidal activity
E.coli
Staphylococcus aureus
Streptococcus uberis</td>
<td>EN 1656 (2009)
Quantitative suspension test

• Temperature :+30 ± 1°C
• Contact time : 5 min
• Concentrations tested : RTU
• I.S. : 10g/L Skimmed Milk</td>
<td>
<table>
<tr><th></th><th>Log reduction</th></tr>
<tr><td></td><td>RTU</td></tr>
<tr><td>E. coli</td><td>> 5.32</td></tr>
<tr><td>S. aureus</td><td>> 5.19</td></tr>
<tr><td>S. uberis</td><td>> 5.30</td></tr>
</table>
Bactericidal activity
at 0.025%
in 5 min
at +30°C
in MILKY conditions
</td>
<td>Doc.32a

RI ⇔ 1</td>
</tr>
<tr>
<td>DEOSAN ACTIV</td>
<td>Bactericidal activity
Enterococcus hirae</td>
<td>EN 1656 (2020)
Quantitative suspension test</td>
<td>
<table>
<tr><th></th><th>Log reduction</th></tr>
</table>
</td>
<td>Doc. 50 "6.7-50 EN 1656 B</td>
</tr>
</table>

<table>
<tr>
<td>(composition of the product PAA 5 %)</td>
<td>Proteus vulgaris
Pseudomonas aeruginosa
Staphylococcus aureus</td>
<td>• Temperature :+10 ± 1°C
• Contact time : 5 min
• Concentrations tested : 2 – 4 - 5% BP
• I.S. : 3g/L BSA (clean conditions)</td>
<td>
<table>
<tr><th></th><th>2%</th><th>4%</th><th>5%</th></tr>
<tr><td>P. aeruginosa</td><td colspan="3">> 5.21</td></tr>
<tr><td>S. aureus</td><td colspan="3">> 5.53</td></tr>
<tr><td>P. vulgaris</td><td colspan="3">> 5.31</td></tr>
<tr><td>E. hirae</td><td colspan="3">> 5.17</td></tr>
</table>
BACTERICIDAL ACTIVITY
at 2%
in 5 min
at +10°C
in clean conditions.
</td>
<td>efficacy report PAA5%”

RI ⇔ 1</td>
</tr>
<tr>
<td>DEOSAN ACTIV (composition of the product PAA 5 %)</td>
<td>Bactericidal activity
E. coli
Staphylococcus aureus
Streptococcus uberis</td>
<td>EN 1656 (2020)
Quantitative suspension test

• Temperature :+30 ± 1°C
• Contact time : 60 sec.
• Concentrations tested : 0.1 – 1 - 2% BP
• I.S. : 3g/L BSA (clean conditions)</td>
<td>
<table>
<tr><th></th><th colspan="3">Log reduction</th></tr>
<tr><th></th><th>0.1%</th><th>1%</th><th>2%</th></tr>
<tr><td>E. coli</td><td colspan="3">> 5.51</td></tr>
<tr><td>S. aureus</td><td>< 3.88</td><td colspan="2">> 5.25</td></tr>
<tr><td>S. uberis</td><td>4.29</td><td colspan="2">> 5.19</td></tr>
</table>
BACTERICIDAL ACTIVITY
at 1%
in 60 sec.
at +30°C
in CLEAN conditions.
</td>
<td>Doc. 57 « 6.7-57 Deosan Activ EN 1656-DZ-54-12-20 signed »

RI ⇔ 1</td>
</tr>
<tr>
<td>DEOSAN ACTIV (composition of the product PAA 5 %)</td>
<td>Yeasticidal activity
Candida albicans</td>
<td>EN 1657 (2016)
Quantitative suspension test

• Temperature :+10 ± 1°C
• Contact time : 5 min
• Concentrations tested : 3 – 4 - 5% BP
• I.S. : 3g/L BSA (clean conditions)</td>
<td>
<table>
<tr><th></th><th colspan="3">Log reduction</th></tr>
<tr><th></th><th>3%</th><th>4%</th><th>5%</th></tr>
<tr><td>C. albicans</td><td colspan="3">> 4.51</td></tr>
</table>
YEASTICIDAL ACTIVITY
at 3%
in 5 min
at +10°C
in CLEAN conditions.
</td>
<td>Docs 52 “6.7-52 EN 1657 Y efficacy report PAA5%”

RI ⇔ 1</td>
</tr>
<tr>
<td>DEOSAN ACTIV (composition of the product PAA 5 %)</td>
<td>Yeasticidal activity
Candida albicans</td>
<td>EN 1657 (2016)
Quantitative suspension test

• Temperature :+30 ± 1°C
• Contact time : 60 sec. - 5 min</td>
<td>
<table>
<tr><th></th><th colspan="3">Log reduction</th></tr>
<tr><th></th><th>3%</th><th>4%</th><th>5%</th></tr>
<tr><td>C. albicans</td><td colspan="3">> 4.28</td></tr>
</table>
YEASTICIDAL ACTIVITY
</td>
<td>Docs 56 ‘6.7-56 EN 1657 Y efficacy report PAA5%’

RI ⇔ 1</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td>• Concentrations tested : 2 - 3 – 4 - 5% BP
• I.S. : 3g/L BSA (clean conditions) or 10 g/L Milk</td>
<td>at 3%
in 60 sec.
at +30°C
in CLEAN conditions

<table><tr><td></td><td colspan="3">Log reduction</td></tr><tr><td></td><td>2%</td><td>4%</td><td>5%</td></tr><tr><td>C. albicans</td><td colspan="3">> 4.28</td></tr></table>
YEASTICIDAL ACTIVITY
at 2%
in 5 min
at +30°C
in MILKY conditions</td>
<td></td>
</tr>
<tr>
<td>Product PAA 5 %</td>
<td>Bactericidal activity
Enterococcus hirae
Proteus vulgaris
Pseudomonas aeruginosa
Staphylococcus aureus</td>
<td>EN 14349 (2012)
Quantitative carrier test – hard & non-porous surfaces

• Temperature :+10 ± 1°C
• Contact time : 30 min
• Concentrations tested : 0.1 – 0.4 – 1% BP
• I.S. : 3g/L BSA (clean conditions)</td>
<td><table><tr><td></td><td colspan="3">Log reduction</td></tr><tr><td></td><td>0.1%</td><td>0.4%</td><td>1%</td></tr><tr><td>P. aeruginosa</td><td>< 4</td><td colspan="2">> 4</td></tr><tr><td>S. aureus</td><td colspan="3">> 4</td></tr><tr><td>E. hirae</td><td>< 4</td><td colspan="2">> 4</td></tr><tr><td>P. vulgaris</td><td colspan="3">> 4</td></tr></table>
BACTERICIDAL ACTIVITY
at 0.4%
in 30 min
at +10°C
on hard/non-porous surfaces with prior cleaning</td>
<td>Doc. 11 « 6.7 - 11 BT-ADL-02-02 EN14349 Report SA EH PA PV 23 June 17 LM CW »

RI ⇔ 1</td>
</tr>
<tr>
<td>DEOSAN ACTIV (composition of the product PAA 5 %)</td>
<td>Bactericidal activity
Enterococcus hirae
Proteus vulgaris
Pseudomonas aeruginosa
Staphylococcus aureus</td>
<td>EN 14349 (2013)
Quantitative carrier test – hard & non-porous surfaces

• Temperature :+10 ± 1°C
• Contact time : 5 min
• Concentrations tested : 0.1 – 1 - 2% BP
• I.S. : 3g/L BSA (clean conditions)</td>
<td><table><tr><td></td><td colspan="3">Log reduction</td></tr><tr><td></td><td>0.1%</td><td>1%</td><td>2%</td></tr><tr><td>P. aeruginosa</td><td>< 2.27</td><td colspan="2">> 5.59</td></tr><tr><td>P. vulgaris</td><td>1.64</td><td colspan="2">> 4.73</td></tr><tr><td>E. hirae</td><td>< 2.36</td><td colspan="2">> 5.68</td></tr><tr><td>S. aureus</td><td>< 2.53</td><td colspan="2">> 5.85</td></tr></table>
BACTERICIDAL ACTIVITY
at 1%</td>
<td>Doc. 58 « 6.7-58 Deosan Activ EN 14349-dz-58-12-20 signed »

RI ⇔ 1</td>
</tr>
</table>

<table>
<tr><td></td><td></td><td></td><td>in 5 min
at +10°C
on hard/non-porous surfaces with prior cleaning</td><td></td></tr>
<tr><td>DEOSAN ACTIV (composition of the product PAA 5 %)</td><td>Bactericidal activity
Enterococcus hirae
Proteus vulgaris
Pseudomonas aeruginosa
Staphylococcus aureus</td><td>EN 16437 (2020)
Quantitative carrier test – hard & porous surfaces

• Temperature :+10 ± 1°C
• Contact time : 5 min
• Concentrations tested : 2 - 3 – 4 - 5% BP
• I.S. : 3g/L BSA (clean conditions)</td><td><table><tr><td></td><td colspan="4">Log reduction</td></tr><tr><td></td><td>2%</td><td>3%</td><td>4%</td><td>5%</td></tr><tr><td>S. aureus</td><td colspan="4">> 6.04</td></tr><tr><td>P. aeruginosa</td><td colspan="4">> 5.25</td></tr><tr><td>E. hirae</td><td colspan="4">> 5.57</td></tr><tr><td>P. vulgaris</td><td colspan="4">> 4.72</td></tr></table>BACTERICIDAL ACTIVITY
at 2%
in 5 min
at +10°C
on hard/porous surfaces with prior cleaning</td><td>Doc.51 « 6.7-51 EN 16437 B surface efficacy report PAA5% »

RI ⇔ 1</td></tr>
<tr><td>DEOSAN ACTIV (composition of the product PAA 5 %)</td><td>Bactericidal activity
E. coli
Staphylococcus aureus
Streptococcus uberis

Yeasticidal activity
Candida albicans</td><td>EN 16437 (2020)
Modified quantitative carrier test – <u>on synthetic skin</u>

• Temperature :+30 ± 1°C
• Contact time : 1 min / 5 min
• Concentrations tested : 2 - 4 - 5% BP
• I.S. : 3g/L BSA (clean conditions) or 10 g/L Milk</td><td><table><tr><td></td><td colspan="3">Log reduction</td></tr><tr><td></td><td>2%</td><td>4%</td><td>5%</td></tr><tr><td>S. aureus</td><td>3.78</td><td>4.58</td><td>5.15</td></tr><tr><td>E. coli</td><td colspan="3">> 5.30</td></tr><tr><td>S. uberis</td><td>4.24</td><td>5.17</td><td>> 5.55</td></tr><tr><td>C. albicans</td><td>2.67</td><td>3.82</td><td>> 4.30</td></tr></table>BACTERICIDAL & YEASTICIDAL ACTIVITY
at 4%
in 1 min
at +30°C
on “clean” skin

<table><tr><td></td><td colspan="3">Log reduction</td></tr><tr><td></td><td>2%</td><td>4%</td><td>5%</td></tr><tr><td>S. aureus</td><td>3.63</td><td>4.91</td><td>5.94</td></tr><tr><td>E. coli</td><td colspan="3">> 5.57</td></tr><tr><td>S. uberis</td><td>5.23</td><td colspan="2">> 5.73</td></tr><tr><td>C. albicans</td><td>3.23</td><td>> 4.54</td><td>> 4.57</td></tr></table>BACTERICIDAL & YEASTICIDAL ACTIVITY
at 4%
in 5 min
at +30°C
on skin in presence of milk</td><td>Doc.55 “6.7-55 EN 16437 modified B&Y efficacy report PAA5%”

RI ⇔ 1</td></tr>
</table>

<table>
<tr>
<td>DEOSAN ACTIV (composition of the product PAA 5 %)</td>
<td>Yeasticidal activity
Candida albicans</td>
<td>EN 16438 (2014)
Quantitative carrier test – hard & non-porous surfaces

• Temperature :+10 ± 1°C
• Contact time : 5 min
• Concentrations tested : 3 – 4 - 5% BP
• I.S. : 3g/L BSA (clean conditions)</td>
<td>
<table>
<tr><th></th><th colspan="3">Log reduction</th></tr>
<tr><th></th><th>3%</th><th>4%</th><th>5%</th></tr>
<tr><td>C. albicans</td><td colspan="3">> 4.29</td></tr>
</table>
YEASTICIDAL ACTIVITY
at 3%
in 5 min
at +10°C
on hard/non-porous surfaces with prior cleaning
</td>
<td>Doc. 53 « 6.7-53 EN 16438 Y efficacy report PAA5% »

RI ⇔ 1</td>
</tr>
<tr>
<td>DEOSAN ACTIV (composition of the product PAA 5 %)</td>
<td>Virucidal activity
ECBO virus</td>
<td>EN 14675 (2015)
Quantitative suspension test

• Temperature : +10 ± 1°C
• Contact time : 5 min
• Concentrations tested : 1 – 4 – 5% BP
• I.S. : 3g/L BSA (clean conditions)</td>
<td>
<table>
<tr><th></th><th colspan="3">Log reduction</th></tr>
<tr><th></th><th>1%</th><th>4%</th><th>5%</th></tr>
<tr><td>ECBO virus</td><td>3.58</td><td colspan="2">> 4.00</td></tr>
</table>
VIRUCIDAL ACTIVITY
at 4%
in 5 min
at +10°C
in clean conditions.
</td>
<td>Doc. 63 "6.7-63 EN 14675 J002352"

RI ⇔ 1</td>
</tr>
<tr>
<td>DEOSAN ACTIV (composition of the product PAA 5 %)</td>
<td>Virucidal activity
ECBO virus</td>
<td>EN 14675 (2015)
Quantitative suspension test

• Temperature : +30 ± 1°C
• Contact time : 5 min
• Concentrations tested : 0.5 – 2 – 3% BP
• I.S. : 10g/L Skimmed Milk</td>
<td>
<table>
<tr><th></th><th colspan="3">Log reduction</th></tr>
<tr><th></th><th>0.5%</th><th>2%</th><th>3%</th></tr>
<tr><td>ECBO virus</td><td>2.58</td><td>3.75</td><td>> 4</td></tr>
</table>
VIRUCIDAL ACTIVITY
at 3%
in 5 min
at +30°C
in MILKY conditions.
</td>
<td>Doc. 64 "6.7-64 J002600 14675 Report PAA 5%"

RI ⇔ 1</td>
</tr>
</table>

Summary of the validated results from the EFF studies relevant according to the claims :
In PAA 5% product concentration (%).

<table>
<tr><td rowspan="2">EN 1656</td><td></td><td rowspan="2">EN 14349 - NP</td><td>1% - 5 min – 10°C – Clean</td></tr>
<tr><td>2% - 5 min – 10°C – Clean</td><td>0.4% - 30 min – 10°C – Clean</td></tr>
<tr><td rowspan="2">1% - 1 min – 30°C – Clean</td><td>EN 16437 - P</td><td>2% - 5 min – 10°C – Clean</td></tr>
<tr><td></td><td>EN 16437 – Skin – B+Y</td><td>4% - 1 min – 30°C – Clean</td></tr>
<tr><td>EN 1657 - Y</td><td>3% - 5 min – 10°C – Clean</td><td></td><td>4% - 5 min – 30°C – MILK</td></tr>
</table>

	3% - 1 min – 30°C – Clean	**EN 16438 – NP - Y**	3% - 5 min – 10°C – Clean
	2% - 5 min – 30°C – MILK		
EN 14675	4% - 5 min – 10°C – Clean		
	3% - 5 min – 30°C – MILK		

NOTE for the MSCAs :
About disinfection of porous surfaces by spraying or dipping in PT3 applications :
By the time of the initial submission and on the date when this report was written, no requirements about EFF tests to be submitted are available. Then, the EFF expert made the decision to apply the use conditions validated for teat disinfection.

<table>
<tr><th colspan="3">Conclusion on the efficacy of the products of the AIREDALE Family
and validated label claims</th></tr>
<tr><td colspan="3">Please note that, since required by other MSs, for surface disinfection by spraying/mopping or immersion, P2S1 and all P2S2 tests are mandatory and must be taken into account and therefore the higher concentration required is the limiting one and thus be set up as the necessary concentration.
Please also note that one single use instructions (with Use concentration/Contact Time/T°C) will be validated for basic efficacy requirements.

Please note that herebelow the use concentrations are expressed in percentage of pure peracetic acid (% PAA) & in product concentration (% and ml/L).</td></tr>
<tr><th colspan="2">Meta SPC-1 (2% PAA)</th><th>Validated label claims</th></tr>
<tr><th colspan="3">For this Meta-SPC 1 (related to products containing 2% PAA), via read-across from the efficacy data generated for the PAA 5% test-product</th></tr>
<tr><td rowspan="2">PT2</td><td>Use #1.1 : CIP procedures with circulation (including pharmaceutical and cosmetic industry)</td><td>On hard/non-porous surfaces
Without prior cleaning,
In 15 min CT, at Room Temperature

• Active against bacteria and yeasts
0.02% PAA (⇔ 1% product with 2% PAA i.e. 10 mL product/L)

• Active against bacteria, yeasts and fungi :
0.1% PAA (⇔ 5% product with 2% PAA i.e. 50 mL product/L)

• Active against bacteria, yeasts, fungi and viruses :
0.15% PAA (⇔ 7.5% product with 2% PAA i.e. 75 mL product/L)</td></tr>
<tr><td>Use #1.2 : Surface Disinfection by spraying or by pouring, also in pharmaceutical and cosmetic industries</td><td>On hard/non-porous surfaces
Without prior cleaning,
In 15 min CT, at Room Temperature

• Active against bacteria, yeasts, fungi and viruses :
0.15% PAA (⇔ 7.5% product with 2% PAA i.e. 75 mL product/L)</td></tr>
<tr><td>PT4</td><td>Use #1.3 : Disinfection of inner surfaces (tanks, pipes, vessels, filling machines, …) by CIP with circulation</td><td>On hard/non-porous surfaces
Without prior cleaning,
In 15 min CT, at Room Temperature

• Active against bacteria and yeasts
0.02% PAA (⇔ 1% product with 2% PAA i.e. 10 mL product/L)</td></tr>
</table>

		• Active against bacteria, yeasts and fungi : **0.1% PAA** (⇔ 5% product with 2% PAA i.e. 50 mL product/L) • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (⇔ 7.5% product with 2% PAA i.e. 75 mL product/L) For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory.
	Use #1.4 : Surface Disinfection by spraying or by pouring	On hard/non-porous surfaces Without prior cleaning, In 15 min CT, at Room Temperature • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (⇔ 7.5% product with 2% PAA i.e. 75 mL product/L) For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. *About disinfection procedures via dipping, the precautionary sentence "the bath solution is intended to be used only once" will be included in the PAR.*
	Use #1.5 : Surface Disinfection by dipping	
***Meta SPC-2* (5% PAA)**		**Validated label claims**
For full efficacy data package provided for the product PAA 5%		
PT2	Use #2.1 : CIP procedures with circulation (including pharmaceutical and cosmetic industry)	On hard/non-porous surfaces Without prior cleaning, In 15 min CT, at Room Temperature • Active against bacteria and yeasts **0.02% PAA** (⇔ 0.4% product with 5% PAA i.e. 4 mL product/L) • Active against bacteria, yeasts and fungi : **0.1% PAA** (⇔ 2% product with 5% PAA i.e. 20 mL product/L) • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (⇔ 3% product with 5% PAA i.e. 30 mL product/L)
	Use #2.2 : Surface Disinfection by spraying or pouring, also in pharmaceutical and cosmetic industries	On hard/non-porous surfaces Without prior cleaning, In 15 min CT, at Room Temperature

		• Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (⇔ 3% product with 5% PAA i.e. 30 mL product/L)
PT3	Use #2.3 : Surface Disinfection by spraying OR pouring (followed by wiping for a homogenous distribution)	By spraying : On hard/non-porous & porous surfaces By pouring : ONLY on hard/non-porous surfaces <u>WITH</u> prior cleaning • Active against bacteria, yeasts and viruses : **0.2% PAA** (⇔ 4% product with 5% PAA i.e. 40 mL product/L) In 5 min contact time at +10°C *About PT3 disinfection procedures via dipping, the precautionary sentence "the bath solution is intended to be used only once" will be included in the PAR.*
	Use #2.4 : Surface Disinfection by dipping	
	Use #2.5 : Teat disinfection (pre-milking)	<u>WITH</u> prior cleaning • Active against bacteria and yeasts : **0.2% PAA** (⇔ 4% product with 5% PAA i.e. 40 mL product/L) In 1 min contact time at +30°C *Since the product has been tested at +30°C, if the product is stored at +4-7°C (fridge), the product must "return" to Room Temperature before use & must be diluted with potable water at Room Temperature.*
	Use #2.6 : Teat disinfection (post-milking)	• Active against bacteria, yeasts and viruses : **0.2% PAA** (⇔ 4% product with 5% PAA i.e. 40 mL product/L) In 5 min contact time at +30°C *Since the product has been tested at +30°C, if the product is stored at +4-7°C (fridge), the product must "return" to Room Temperature before use & must be diluted with potable water at Room Temperature.* Keep the animals standing for at least 5 minutes after treatment.
PT4	Use #2.7 : Disinfection of inner surfaces (tanks, pipes, vessels, filling machines, …) by CIP with circulation	On hard/non-porous surfaces Without prior cleaning, In 15 min CT, at Room Temperature • Active against bacteria and yeasts **0.02% PAA** (⇔ 0.4% product with 5% PAA i.e. 4 mL product/L)

		• Active against bacteria, yeasts and fungi : **0.1% PAA** (⇔ 2% product with 5% PAA i.e. 20 mL product/L) • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (⇔ 3% product with 5% PAA i.e. 30 mL product/L) For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory.
	Use #2.8 : Surface Disinfection by spraying or pouring	On hard/non-porous surfaces Without prior cleaning, In 15 min CT, at Room Temperature • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (⇔ 3% product with 5% PAA i.e. 30 mL product/L) For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. *About disinfection procedures via dipping, the precautionary sentence "the bath solution is intended to be used only once" will be included in the PAR.*
	Use #2.9 : Surface Disinfection by dipping	
***Meta SPC-3* (15% PAA)**		**Validated label claims**
For this Meta-SPC 3 (related to products containing 15% PAA), via read-across from the efficacy data generated for the PAA 5% test-product		
PT2	Use #3.1 : CIP procedures with circulation (including pharmaceutical and cosmetic industry)	On hard/non-porous surfaces Without prior cleaning, In 15 min CT, at Room Temperature • Active against bacteria and yeasts **0.02% PAA** (⇔ 0.135% product with 15% PAA i.e. 1.35 mL product/L) • Active against bacteria, yeasts and fungi : **0.1% PAA** (⇔ 0.675 % product with 15% PAA i.e. 6.75 mL product/L) • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (⇔ 1% product with 15% PAA i.e. 10 mL product/L)
	Use #3.2 : Surface Disinfection by spraying or pouring, also in pharmaceutical and cosmetic industries	On hard/non-porous surfaces Without prior cleaning, In 15 min CT, at Room Temperature • Active against bacteria, yeasts, fungi and viruses :

		0.15% PAA (⇔ 1% product with 15% PAA i.e. 10 mL product/L)
PT3	Use #3.3 : Surface Disinfection by spraying OR pouring (followed by wiping for a homogenous distribution)	By spraying : On hard/non-porous & porous surfaces By pouring : ONLY on hard/non-porous surfaces <u>WITH</u> prior cleaning • Active against bacteria, yeasts and viruses : **0.2% PAA** (e.g. approximately 1.33% product with 15% PAA i.e. 13.3 mL product/L) In 5 min contact time at +10°C *About PT3 disinfection procedures via dipping, the precautionary sentence "the bath solution is intended to be used only once" will be included in the PAR.*
	Use #3.4 : Surface Disinfection by dipping	
	Use #3.5 : Teat disinfection (pre-milking)	<u>WITH</u> prior cleaning • Active against bacteria and yeasts : **0.2% PAA** (e.g. approximately 1.33% product with 15% PAA i.e. 13.3 mL product/L) In 1 min contact time at +30°C *Since the product has been tested at +30°C, if the product is stored at +4-7°C (fridge), the product must "return" to Room Temperature before use & must be diluted with potable water at Room Temperature.*
	Use #3.6 : Teat disinfection (post-milking)	• Active against bacteria, yeasts and viruses : **0.2% PAA** (e.g. approximately 1.33% product with 15% PAA i.e. 13.3 mL product/L) In 5 min contact time at +30°C *Since the product has been tested at +30°C, if the product is stored at +4-7°C (fridge), the product must "return" to Room Temperature before use & must be diluted with potable water at Room Temperature.* Keep the animals standing for at least 5 minutes after treatment.
PT4	Use #3.7 : Disinfection of inner surfaces (tanks, pipes, vessels, filling machines, …) by CIP with circulation	On hard/non-porous surfaces Without prior cleaning, In 15 min CT, at Room Temperature • Active against bacteria and yeasts

		0.02% PAA (⇔ 0.135% product with 15% PAA i.e. 1.35 mL product/L) • Active against bacteria, yeasts and fungi : **0.1% PAA** (⇔ 0.675 % product with 15% PAA i.e. 6.75 mL product/L) • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (⇔ 1% product with 15% PAA i.e. 10 mL product/L) For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory.
	Use #3.8 : Surface Disinfection by spraying or pouring	On hard/non-porous surfaces Without prior cleaning, In 15 min CT, at Room Temperature • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA** (⇔ 1% product with 15% PAA i.e. 10 mL product/L) For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. *About disinfection procedures via dipping, the precautionary sentence "the bath solution is intended to be used only once" will be included in the PAR.*
	Use #3.9 : Surface Disinfection by dipping	

2.2.5.4 Occurrence of resistance and resistance management

As the mode of action of peracetic acid is very unspecific, it is very unlikely that resistance to peracetic acid can develop. The development of specific resistance management strategies for the use of peracetic acid does not seem to be an urgent task. Nevertheless, the general principle of alternating use of disinfectants with different modes of action is recommended.

2.2.5.5 Known limitations

Nothing to mention.

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

Nothing to mention, since the biocidal products within the family are not intended to be used in combination with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Data waiving	
Information requirement	No study been conducted because the classification of the product having been determined using information on the components in accordance with Regulation (EC) No 1272/2008
Justification	Peracetic acid has a harmonised classification (Index Number 607-094-00-8). There are no specific concentration limits for Skin Corr. 1A; H314 so the general limits apply : C ≥ 5% Based on the concentration of peracetic acid at 15%, 5% and 2% plus the presence of Hydrogen peroxide and acetic acid in the equilibrium, the products in the family are classified as Skin Corr: H314

Eye irritation

Data waiving	
Information requirement	No study has been conducted the classification of the product having been determined using information on the components in accordance with Regulation (EC) No 1272/2008
Justification	Peracetic acid has a harmonised classification (Index Number 607-094-00-8). There are no specific concentration limits for Eye Dam. 1; H318 so the general limits apply : C ≥ 3% Based on the concentration of peracetic acid at 15%, 5% and 2% plus the presence of Hydrogen peroxide and acetic acid in the equilibrium, the products in the family are classified as Eye Dam. 1; H318

Respiratory tract irritation

Data waiving	
Information requirement	No Study has been been conducted,the classification of the product having been determined using information on the components in accordance with Regulation (EC) No 1272/2008
Justification	Components causing Respiratory tract irritation are present in the mixture C ≥ 1% in accordance with the specific concentration limit; all products in the family are classified as STOT SE 3; H335

Skin sensitization

Data waiving	
Information requirement	No Study has been been conducted,the classification of the product having been determined using information on the components in accordance with Regulation (EC) No 1272/2008
Justification	Based on the calculation method for classification according to the rules laid down in Regulation 1272/2008, components causing skin sensitisation are not present in the mixture. Classification is not required.

Respiratory sensitization (ADS)

Data waiving	
Information requirement	No Study has been been conducted,the classification of the product having been determined using information on the components in accordance with Regulation (EC) No 1272/2008
Justification	Based on the calculation method for classification according to the rules laid down in Regulation 1272/2008, components causing respiratory sensitisation are not present in the mixture. Classification is not required.

Acute toxicity

Acute toxicity by oral route

Data waiving	
Information requirement	No Study has been been conducted,the classification of the product having been determined using information on the components in accordance with Regulation (EC) No 1272/2008
Justification	Based on the calculation method for classification according to the rules laid down in Regulation 1272/2008, the 15%, 5% and 2% peracetic acid ATE is >300 ≤ 2,000 mg/kg bw, classified as Acute Tox 4; H302.

Acute toxicity by inhalation

Data waiving	
Information requirement	No Study has been been conducted,the classification of the product having been determined using information on the components in accordance with Regulation (EC) No 1272/2008
Justification	Based on the calculation method for classification according to the rules laid down in Regulation 1272/2008, the 15% peracetic needs to be classified as Acute Tox 3; H331. The 5% peracetic acid needs to be classified as Acute Tox 4; H332. The 2% peracetic acid does not need to be classified for acute inhalation toxicity.

Acute toxicity by dermal route

Data waiving	
Information requirement	No Study has been been conducted,the classification of the product having been determined using information on the components in accordance with Regulation (EC) No 1272/2008
Justification	Based on the calculation method for classification according to the rules laid down in Regulation 1272/2008, the 15% acid ATE is >200 ≤ 1,000 mg/kg bw, classified as Acute Tox 3; H311.The 5% peracetic ATE is comprised between 1000 & 2000, therefore classified as H312 & 2% peracetic acid ATE is >2,000 mg/kg bw, classification is not required.

Information on dermal absorption

Data waiving	
Information requirement	Reference to the active substance approval.
Justification	Based on the physico-chemical properties of PAA, 100% dermal penetration should be used in the absence of more accurate information. However, in this particular case, in the absence of clear systemic effects, no dermal penetration parameter was needed in order to conclude on human health risks from the presented uses of peracetic acid. In conclusion, it was acceptable to "waive" the dermal penetration study.

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

Substances of concern are: HEDP. Further information is available in the Confidential Annex.

Available toxicological data relating to a mixture

Not applicable.

Other

Not applicable – no additional test for exposure to humans are required.

2.2.6.2 Exposure assessment

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

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	yes	yes	n.a.	yes	yes	n.a.	n.a.
Dermal	yes	yes	n.a.	yes	yes	n.a.	n.a.
Oral	no	no	n.a.	no	no	n.a.	n.a.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Mixing/ loading	PT 2/3/4 - Decanting of product concentrated and dilution with water	Professionals
2.	Application	PT 2/3/4 – Spray and wipe of disinfectant on general surfaces for surface disinfection (Use # 1.2, 2.2, 3.2 / 2.3, 3.3 / 1.4, 2.8, 3.8)	Professionals
3.	Application	PT 2/3/4 – Pour and wipe of disinfectant on general surfaces (Use # 1.2, 2.2, 3.2 / 2.3, 3.3 / 1.4, 2.8, 3.8)	Professionals
4.	Application	PT 2/4 – Disinfection of tanks, pipes, filling machines in place (Use # 1.1, 2.1, 3.1 / 1.3, 2.7, 3.7)	Professionals
5.	Application	PT 3 – Disinfection of teats (Use #2.5, 2.6, 3.5, 3.6)	Professionals
6.	Application	PT 3/4 – Disinfection of Equipment by Immersion, dipping, soaking (Use # 2.4, 3.4 / 1.5, 2.9, 3.9)	Professionals

Equilibrium peracetic acid used in a variety of different product types for disinfection purposes is composed of acetic acid, peracetic acid, hydrogen peroxide and water. After application of equilibrium peracetic acid in the intended uses within PT2 through PT4, peracetic acid and hydrogen peroxide are the relevant substances which have to be considered in the human health exposure assessment and risk characterisation. For this reason, the risk characterisation was performed for both peracetic acid and hydrogen peroxide, respectively (peracetic acid CAR, 2015).

A summary of the operations where the product is intended to be used is included below:

<u>PT2</u>
Disinfection of surfaces and equipment in industrial, public and health care areas: The product is applied by spraying, wiping, mopping, immersing or flooding.
Instrument disinfection by immersion or filling.
CIP (clean in place) in the industrial, pharma & cosmetic industry.

<u>PT3 – All possible non-rinse applications.</u>
Disinfection of animal houses and equipment by spraying, wiping or mopping.
Disinfection of animal transport vehicles by spraying.
Disinfection of equipment by dipping: Equipment is dipped into a bath which contains the treatment solutions.
Backflush (automatic sanitation of the milking cluster) and manual cluster cleaning – expected to be rinsed after disinfection.

PT4 – All possible non-rinse applications.
Cold aseptic and hygienic filling: Disinfection of bottles, caps, lids and exterior machinery surfaces. Expected to a maximum of 200ppm.
Crate and utensil washing: Disinfection of cheese moulds, food crates and other utensils used in the process in the beverage/food industry.
Disinfection of equipment in the food and beverage industry.
CIP (clean in place) in the food & beverage industry -
Disinfection of surfaces and equipment by spraying and wiping or mopping.
Disinfection of milking parlours.
Disinfection of equipment in primary fish processing.
Disinfection of surfaces and equipment in fish processing plants by spraying, wiping, mopping or immersion.

Industrial exposure

The authorised uses and therefore the exposure scenarios assessed are the same for industrial and professional users; refer to exposure for professional users. No further consideration of industrial exposure is required.

Professional exposure

Scenario 1

Description of Scenario 1		
PT 2/3/4 – Decanting of product concentrated and dilution with water This scenario covers potential worker exposure during the mixing/loading operations required in order decant the required volume of product concentrate into the relevant container, with subsequent dilution with the appropriate volume of water. This operation may take place up to 2 times per day and may occur indoors or outdoors; indoors is considered the critical scenario due to more limited ventilation. The operation is applicable to any of the products, with peracetic concentrations in the range 2-15%. A number of different pack sizes are available, and the method of decanting varies by pack volume. The 5 L and 25 kg packs are intended to be hand decanted (direct pouring). The 200 L drums are intended to be stored in a horizontal position on a drum trolley, and the contents decanted via a tap or using a hand pump. The 1000 kg intermediate bulk container (IBC) has a tap on it and would either be decanted by hand into a container or have a small pump attached. There may be few automated systems, but these are deemed to result in no worker exposure due to absence of direct liquid handling. Users are expected to be appropriately trained, to follow the product use directions and use the specified personal protective equipment. Workers are required to wear goggles, gloves and protective clothing when handling the product. Adequate ventilation should be ensured; otherwise appropriate respiratory protection will be required. Refer to Section 2.1.5.2 for details. Estimates of exposure are obtained using Mixing and Loading Model 7 (TNsG Part 2), and also ConsExpo Web v1.01 for the calculation of vapour concentration.		
	Parameters[1]	Value
Tier 1	Exposure time	<1 minute

TNsG M&L Model 7		
Tier 1 ConsExpo Web v1.0.1	Frequency	730/year (= 2/day)
	Model	Exposure to vapour
	Mode of release	Evaporation
	Exposure duration	0.75 minutes
	Product amount	12500 g (based on 25 kg pack)
	Weight fraction substance	PAA: 15% H_2O_2: 25.109%
	Room volume	1 m^3
	Ventilation rate	0.5/hour
	Inhalation rate	1.37 m^3/hr (default value for light exercise for 60 kg worker)
	Vapour pressure	PAA: 1900 Pa (CAR, 2015) H_2O_2: 214 Pa (CAR, 2015)
	Application temperature	20°C
	Molecular weight	PAA: 76 g/mol (CAR, 2015) H_2O_2: 34 g/mol (CAR, 2015)
	Mass transfer coefficient	18.6 m/hr (Thibodeaux's method)
	Release area mode	Constant
	Release area	20 cm^2
	Emission duration	0.3 minute
	Molecular weight matrix	18 g/mol (water)

[1] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.
[2] Only include the parameters changed with respect to the previous Tier.

Calculation of the exposure based on the Tier I parameters gives acceptable exposure; higher Tier assessment has not been conducted.

Calculations for Scenario 1

Exposure to workers during the mixing/loading operations that take place in order to decant the required amount of product into any relevant container can be estimated using Mixing and Loading Model 7 (*Technical Notes for Guidance, Human Exposure to Biocidal Products - Guidance on Exposure Estimation, June 2002*). Exposure in this model is based on professionals pouring and pumping liquids into systems.

Product pack sizes of 5 L, 25 kg, 200 kg and 1000 kg are available. The 5 L and 25 kg packs are intended to be hand decanted. The 200 kg drums would be horizontal on a drum trolley with a tap or using a hand pump to extract the product from the top. The 1000 kg

IBC has a tap on it and would either be decanted by hand into a container or have a small pump attached.

Dermal Exposure

No systemic dermal reference values are set for peracetic acid (CAR, Nov 2015) or hydrogen peroxide (CAR, Mar 2015), and so the risk characterisation of these components is focused on local effects and no systemic doses are estimated.

The concentration of the undiluted product is 2, 5 or 15%. This exceeds the dermal NOAEC of 0.2% PAA for short-term and medium-term exposure and the dermal NOAEC of 0.1% PAA for long-term exposure. The maximum undiluted product concentration of H_2O_2 is 23% w/w (in the 15% PAA product). This is below the 35% concentration limit for skin irritation and 5% limit for eye irritation.

The product concentration is constant during this exposure scenario. Dermal exposure can be minimised/avoided by the use of protective clothing chemically resistant to the biocidal product, and chemical resistant gloves classified under Standard EN374 (Protective gloves against chemicals and micro-organisms), preferably butyl rubber. Normal work hygiene procedures should be used following use, including washing hands. Any inadvertent dermal exposure should be removed by rinsing with water in accordance with Section 2.2.5.3. On the basis of the peracetic acid concentration in the undiluted products, it is therefore recommended that gloves are always required in order to prevent skin contact during mixing/loading operations; this is in accordance with current product use recommendations. This recommendation forms part of the normal PPE requirements for such operations, and so exposure is deemed to be acceptable.

Inhalation Exposure

Mixing and Loading Model 7 predicts a 50th percentile inhalation exposure of 0.29 mg/m^3. This is applicable to the undiluted products, the most concentrated of which contains 15% peracetic acid and 23% hydrogen peroxide. Therefore the predicted inhalation exposure for peracetic acid is (0.29 mg/m^3 x 0.15) = 0.044 mg/m^3, and for hydrogen peroxide the predicted inhalation exposure is (0.29 mg/m^3 x 0.23) = 0.0667 mg/m^3.

For peracetic acid, the 2015 peracetic acid CAR recommends a short-, medium- and long-term AEL of 0.50 mg/m^3. The potential inhalation exposure of 0.044 mg/m^3 during mixing/loading is predicted to be below the AEL and so no additional control measures are required.

For hydrogen peroxide, the 2015 peracetic acid CAR recommends a short-, medium- and long-term AEL of 1.25 mg/m^3. The potential inhalation exposure of 0.087 mg/m^3 during mixing/loading is predicted to be below the AEL and so no additional control measures are required.

It is noted that Mixing and Loading Model 7, TNsG Part 2 (2002) does not calculate the potential vapour concentration, and the CAR (Nov, 2015) noted that "*The exposure models primarily used for the estimation of inhalation exposure (TNsG models) do not take into account the volatility of the substance. The inhalation exposure to vapour in addition to aerosols has to be taken into account at product authorisation*". This can be estimated using ConsExpo Web v1.0.1.

ConsExpo has been previously agreed as an appropriate tool in the exposure assessment for professional users (HEEG Opinion 3, Agreed in TM II 08, 01/04/2008). This opinion notes that "*ConsExpo allows the adaptation of the default values to assess exposure of*

professional users", and that "*Professionals are likely to use products for longer periods and more frequently than consumers/non-professionals*". The calculation of the peracetic acid present as vapour in the air from the container from which the undiluted product is decanted uses some deviations from the default input parameters in the ConsExpo Fact Sheet (L.C.H. Prud'homme de Lodder *et al*, RIVM report 320104003/2006, Cleaning Products Fact Sheet):

- The product amount has been increased from 500 g (based on half of a 1 litre container for the consumer assessment) to 12,500 g to represent the 25 kg pack size

The calculated mean event air concentration of peracetic acid is 0.35 mg/m^3, which is below the inhalation AEC of 0.5 mg/m^3. The mean air concentration on the day of exposure and average for the year are lower and therefore not critical. Other than the normal personal protective equipment required to be used when handling this product, no additional PPE or measures are required.

The calculated mean event air concentration of hydrogen peroxide is 0.060 mg/m^3, which is below the inhalation AEC of 1.25 mg/m^3. The mean air concentration on the day of exposure and average for the year are lower and therefore not critical. Other than the normal personal protective equipment required to be used when handling this product, no additional PPE or measures are required.

In the case where the ventilation rate is not known and therefore it is not possible to determine whether ventilation is therefore adequate, a worst-case calculation has also been performed, assuming the ventilation rate = 0 air changes/hour (ACH). Note that the version of ConsExpo Web has changed since the original submission from v1.0.1 to v.1.0.3; this change had no effect on the original calculations, which means that inhalation exposure will be acceptable under all conditions of ventilation.

Refer to Annex 3.2 for copies of the ConsExpo Web v1.0.3 input parameters and output results.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated air concentration mg/m³**	**Max concn for dermal exposure**	**Estimated oral exposure**	**Estimated total uptake**
Scenario 1	1/ Std PPE	PAA: 0.044 (M&L model 7, TNsG Pt 2) + 0.35 (ConsExpo Web) = 0.394	PAA: 15%	n/a	-
		H_2O_2: 0.073 (M&L model 7, TNsG Pt 2) + 0.066 (ConsExpo Web) = 0.139	H_2O_2: 25.109%		

Std PPE = PPE required under Section 2.1.5.2 as default
n/a – oral exposure considered negligible for trained professional users

Further information and considerations on Scenario 1

On the basis that both peracetic acid and hydrogen peroxide are highly reactive and degrade rapidly at the site of first contact with organic material, no systemic exposure is anticipated and all assessments are based on local effects at the site of first contact with the body. In the case of inhalation exposure, this is based on the predicted air concentration, whereas for dermal exposure, this is based on the concentration of the product and the propensity to cause dermal corrosion and/or irritation.

The use directions for the 2/5/15% peracetic acid products include the statement "*Wear protective gloves/protective clothing/eye protection/face protection"*. Use of the recommended PPE will prevent dermal exposure during mixing/loading, and the use of eye and face protection will prevent inadvertent oral exposure and exposure to eyes.

Scenario 2

Description of Scenario 2		
PT 2/3/4 - Spraying and wiping of disinfectant on general surfaces for surface disinfection The application of the product is anticipated to be indoors. The biocidal product should be diluted in water to the required ppm of peracetic acid. The diluted product should be placed in a trigger spray bottle. Uniform distribution of the biocidal product should be ensured. Application should ensure the equipment or surface is fully saturated and left for at least 10 minutes. Do not use equipment/surfaces until product is completely absorbed to the surface or air dried. Product requires dilution prior to use from capped bottles, drum or intermediate bulk container (IBC). For capped bottles pour into a bucket or container (max 10 L), via measuring cylinder (100 mL). In many cases, the drum or IBC will be connected via a coupling system pipe to a container. Pails/drums for this type of product are commonly not full-aperture opening drums. Diluted product is transferred to trigger spray at point of use. Users are expected to be appropriately trained, to follow the product use directions and use the specified personal protective equipment. Workers are required to wear goggles, gloves and protective clothing when handling the product. Adequate ventilation should be ensured; otherwise appropriate respiratory protection will be required. Refer to Section 2.1.5.2for details. Dose Rate: Antifungal up to 2000ppm active may be required. The exposure scenario is applicable to all products, which contain peracetic acid at 2-15% and therefore require appropriate dilution to achieve the required dose rate. Estimates of exposure are obtained using Consumer Spraying & Dusting Model 2 (TNsG Part 2), and also ConsExpo Web v1.01 for the calculation of vapour concentration.		
	Parameters[1]	Value
Tier 1	Inhalation exposure (75th %ile)	10.5 mg in-use product/m^3

Consumer Spraying & Dusting Model 2 (2002)	Maximum spray concentration	2000 ppm = 0.2% w/v
Tier 1 ConsExpo Web v1.0.1 Spray model	Frequency[4]	730/year (max 2/day)
	Model	Exposure to vapour
	Mode of release	Constant rate
	Exposure duration[3]	180 mins
	Product amount[3]	48.6 g
	Weight fraction substance	PAA: 0.2 % max H_2O_2: 0.92%
	Room volume[3]	45 m^3
	Ventilation rate[3]	2.5/hour
	Inhalation rate[3]	1.37 m^3/hr (default for light exercise for a 60 kg worker)
	Emission duration[3]	30 mins
	Vapour pressure	PAA: 1900 Pa (CAR, 2015) H_2O_2: 214 Pa (CAR, 2015)
	Application temperature	20°C (room temperature)
	Molecular weight	PAA: 76 g/mol (CAR, 2015) H_2O_2: 34 g/mol (CAR, 2015)
Tier 2[2]	Ventilation rate	10/hour
	Alternative: Respiratory protection (only if ventilation rate of 10 air changes per hour cannot be provided)	APF4[5]

[1] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.
[2] Only include the parameters changed with respect to the previous Tier.
[3] Default input parameter from L.C.H. Prud'homme de Lodder *et al*, RIVM report 320104003/2006, Cleaning Products Fact Sheet (Section 5.3 – spray cleaners), except that Exposure Duration, Product Amount, Room Volume and Emission Duration are 3x larger than in the model to account for professional rather than consumer use.
[4] Parameter from description of intended uses (Section 2.2.1)
[5] HSE Guidance 'Respiratory protective equipment at work – A practical guide' (HSE, 2013, available via http://www.hse.gov.uk/pubns/books/hsg53.htm)

Calculation of the exposure based on the Tier I parameters gives acceptable exposure for PAA, but not for hydrogen peroxide.

Consumer spraying and dusting – Model 2 observe exposure for hand and forearm; legs, feet & face; and inhaled exposure. The two first are fully covered by the PPE applied to the users. Inhalatory exposure is discussed below, and was assessed following Consumer spraying and dusting – Model 2.

Calculations for Scenario 2

Summary table: estimated exposure from professional uses

Exposure scenario	**Tier/PPE**	**Estimated air concentration mg/m³**	**Max concn for dermal exposure**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 2	1/ Std PPE	PAA: 0.152 (Consumer spraying and dusting – Model 2, TNsG part 2) 0.29 + (ConsExpo Web spray model) = 0.442	PAA: 0.2%	n/a	-
		H_2O_2: 0.699 (Consumer spraying and dusting – Model 2, TNsG part 2) 1.3 + (ConsExpo Web spray model) = 1.999	H_2O_2: 0.92%	n/a	-
	2/ Higher Ventilation	PAA: 0.152 (Consumer spraying and dusting – Model 2, TNsG part 2) 0.072 + (ConsExpo Web spray model) = 0.224	PAA: 0.2%	n/a	-
		H_2O_2: 0.699 (Consumer spraying and dusting – Model 2, TNsG part 2) 0.33 + (ConsExpo Web spray model) = 1.029	H_2O_2: 0.92%	n/a	-
	Alternative: 2/ RPE	PAA: 0.152 (Consumer spraying and dusting – Model 2, TNsG part 2) 0.29 + (ConsExpo Web spray model) = 0.442 RPE with APF of 4 = 0.111	PAA: 0.2%	n/a	-

		H_2O_2: 0.699 (Consumer spraying and dusting – Model 2, TNsG part 2) 1.3 + (ConsExpo Web spray model) = 1.999 RPE with APF of 4 = 0.500	H_2O_2: 0.92%	n/a	-

Std PPE = PPE required under Section 2.1.5.2 as default
n/a – Oral exposure considered negligible for trained professional users
In the absence of a systemic endpoint for dermal exposure, the risk characterisation of peracetic acid is focused on local effects

The potential worker exposure to via inhalation of spray during the spraying phase can be estimated using Consumer spraying and dusting – Model 2, TNsG part 2. Further, an estimate of the potential exposure to vapour during the spraying, and as a consequence of evaporation from the treated surface has been estimated using ConsExpo Web v1.0.1.

Dermal Exposure

No systemic dermal reference values are set for peracetic acid (CAR, Nov 2015) or hydrogen peroxide (CAR, Mar 2015), and so the risk characterisation of these components is focused on local effects and no systemic doses are estimated.

The maximum diluted product concentration is 2000 ppm PAA = 0.2% PAA w/v. This does not exceed the dermal NOAEC of 0.2% PAA for short-term and medium-term exposure, but above the dermal NOAEC of 0.1% PAA for long-term exposure. Based on the maximum ratio of PAA: H_2O_2 of 4.6 (for the 5% PAA product) the estimated maximum diluted product concentration of H_2O_2 is 0.92% w/v. This is below the 35% concentration limit for skin irritation and 5% limit for eye irritation.

For lower concentrations of product, where the maximum concentration is not required, the concentration is considered acceptable up to 1000 ppm, which is equivalent to 0.1% PAA. Product dilutions up to this concentration require no specific additional PPE.

The product concentration is constant during this exposure scenario. Dermal exposure can be minimised/avoided by the use of protective clothing chemically resistant to the biocidal product, and chemical resistant gloves classified under Standard EN374 (Protective gloves against chemicals and micro-organisms), preferably butyl rubber. Normal work hygiene procedures should be used following use, including washing hands. Any inadvertent dermal exposure should be removed by rinsing with water in accordance with Section 2.2.5.3. Inadvertent exposure is likely to be short-term (time between exposure and rinsing of skin), and the maximum in-use spray concentration does not exceed the short-term NOAEC for peracetic acid or hydrogen peroxide, indicating acceptable exposure.

Inhalation Exposure

Exposure to workers from the inhalation of spray during the spraying phase of the exposure scenario can be estimated using Spraying model 2 TNsG part 2 (2002). The 75th percentile inhalation value from this model is 76 mg in-use product/m^3. Based on the maximum diluted product concentration of 0.2% w/v, the equivalent inhalation exposure based on active substance is (10.5 x 0.2/100) = 0.021 mg a.s./m^3. This is below the

inhalation AEC of 0.5 mg/m^3 for short-, medium- and long-term exposure (CAR, 2015), indicating an acceptable exposure.

For hydrogen peroxide, based on the maximum ratio of PAA: H_2O_2 of 4.6 (for the 5% PAA product) the estimated maximum diluted product concentration is 0.92% H_2O_2 w/v. The inhalation exposure based on hydrogen peroxide is (10.5 x 0.92/100) = 0.0966 mg a.s./m^3 This is below the inhalation AEC of 1.25 mg/m^3 for acute, medium-term and long-term exposure (CAR, 2015).

Inhalation exposure can result from direct inhalation of spray particles suspended in the air, and also from the inhalation of vapour. The CAR (Nov, 2015) noted that "*The exposure models primarily used for the estimation of inhalation exposure (TNsG models) do not take into account the volatility of the substance. The inhalation exposure to vapour in addition to aerosols has to be taken into account at product authorisation*", and so an estimate of the worker exposure to vapour generated from the evaporation of the applied spray to the treated surface has been obtained using ConsExpo Web v1.0.1.

ConsExpo has been previously agreed as an appropriate tool in the exposure assessment for professional users (HEEG Opinion 3, Agreed in TM II 08, 01/04/2008). This opinion notes that "*ConsExpo allows the adaptation of the default values to assess exposure of professional users*", and that "*Professionals are likely to use products for longer periods and more frequently than consumers/non-professionals*". On that basis the following amendments have been included:

- the Exposure Duration, Product Amount, Room Volume and Emission Duration have all been increased by a factor of 3x compared with the default values. The exposure duration is 180 minutes (3 hours), conducted twice per day, which is considered representative of a full shift, which will include other activities.
- the Frequency has been increased from the default value of 365/year to 730/year to account for the possibility of 2 operations per day.

The increased input parameters mean that the equivalent area being applied and cleaned is 5.13 m^2 up to twice per day; this is coordinated with Exposure Scenario 3 for consistency.

The maximum external concentration (mean event concentration) of peracetic acid in the air due to vapour, as calculated using ConsExpo Web v1.0.1 is 0.29 mg/m^3. The total mean event air concentration (spray + vapour) is 0.442, which is below the inhalation AEC of 0.5 mg/m^3 for short-, medium- and long-term exposure (CAR, 2015). The mean air concentration on the day of exposure and average for the year are lower and therefore not critical. No additional mitigation measures are necessary based on the parameters assessed.

The maximum external concentration (mean event concentration) of hydrogen peroxide in the air due to vapour, as calculated using ConsExpo Web v1.0.1 is 1.3 mg/m^3. The total mean event air concentration (spray + vapour) is 1.999, which is above the inhalation AEC of 1.25 mg/m^3 for short-, medium- and long-term exposure (CAR, 2015). A refined tier 2 scenario with a higher level of ventilation or RPE in case a higher ventilation rate cannot be applied is thus proposed. This one provides an acceptable level of exposure.

Further information and considerations on Scenario 2

Secondary exposure is not considered relevant for this scenario as the use direction indicate that treated surfaces should not be used until the product is completely absorbed to the surface or air dried, at which point surface residues should be minimised.

Scenario 3

Description of Scenario 3		
PT 2/3/4 – Pour and wipe of disinfectant on general surfaces for surface disinfection The application of the product can be indoors or outdoors, but the indoor use is more critical due to the more limited ventilation. The biocidal product should be diluted in water to the required ppm of peracetic acid. The diluted product should be poured onto the equipment or surface. Application should ensure the equipment or surface is fully saturated and left for at least 10 minutes. Do not use equipment/surfaces until product is completely absorbed to the surface or air dried. Product requires dilution prior to use from capped bottles, drum or intermediate bulk container (IBC). For capped bottles pour into a bucket or container (max 10 L), via measuring cylinder (100 mL). In many cases, the drum or IBC will be connected via a coupling system pipe to a container. Pails/drums for this type of product are commonly not full-aperture opening drums. Users are expected to be appropriately trained, to follow the product use directions and use the specified personal protective equipment. Workers are required to wear goggles, gloves and protective clothing when handling the product. Adequate ventilation should be ensured, otherwise appropriate respiratory protection will be required. Refer to Section 2.1.5.2for details. Dose Rate: Antifungal up to 2000ppm active may be required. The exposure scenario is applicable to all products, which contain peracetic acid at 2-15% and therefore require appropriate dilution to achieve the required dose rate. Estimates of exposure are obtained using Spraying Model 2 (TNsG Part 2), and also ConsExpo Web v1.01 for the calculation of vapour concentration.		
	Parameters[1]	Value
Tier 1 Spraying model 2 TNsG part 2 (2002) Pouring	Inhalation exposure (75th %ile)	0.29 mg in-use product/m^3
	Maximum spray concentration	2000 ppm = 0.2% w/v
Tier 1 ConsExpo Web v1.0.1 Spray model Evaporation	Frequency[4]	730/year (max 2/day)
	Model	Exposure to vapour
	Mode of release	Evaporation
	Exposure duration[3]	180 mins
	Product amount[3]	48.6 g
	Weight fraction substance	PAA: 0.2 % max H_2O_2: 0.92%

	Room volume[3]	45 m^3
	Ventilation rate[3]	2.5/hour
	Inhalation rate[3]	1.37 m^3/hr (default for light exercise for a 60 kg worker)
	Vapour pressure	1900 Pa (CAR, 2015) H_2O_2: 214 Pa (CAR, 2015)
	Application temperature	20°C (room temperature)
	Molecular weight	PAA: 76 g/mol (CAR, 2015) H_2O_2: 34 g/mol (CAR, 2015)
	Mass transfer coefficient	18.6 m/hr (Thibodeaux's method)
	Release area mode	Increasing
	Release area	5.13 m^2
	Application duration	30 minutes
	Molecular weight matrix	18 g/mol (water)
Tier 2[2]	Ventilation rate	10/hour
	Alternative: Respiratory protection (only if ventilation rate of 10 air changes per hour cannot be provided)	APF4[5]

[1] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.
[2] Only include the parameters changed with respect to the previous Tier.
[3] Default input parameter from L.C.H. Prud'homme de Lodder *et al*, RIVM report 320104003/2006, Cleaning Products Fact Sheet (Section 5.3 – spray cleaners), except that Exposure Duration, Product Amount, Room Volume and Emission Duration are 3x larger than in the model to account for professional rather than consumer use.
[4] Parameter from description of intended uses (Section 2.2.1)
[5] HSE Guidance 'Respiratory protective equipment at work – A practical guide' (HSE, 2013, available via http://www.hse.gov.uk/pubns/books/hsg53.htm)

Calculation of the exposure based on the Tier I parameters gives acceptable exposure; for PAA, but not for hydrogen peroxide. A tier 2 scenario with higher concentration has thus been performed.

Calculations for Scenario 3

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated air concentration mg/m³**	**Max concn for dermal exposure**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 3	1/ Std PPE	PAA: 0.00058 (pouring)+ 0.28 (evaporation)= 0.28058	PAA: 0.2 %	n/a	-
		H_2O_2: 0.00267 (pouring)+ 1.3 (evaporation)= 1.30267	H_2O_2: 0.92 %		

	2/ Higher ventilation rate	PAA: 0.00058 (pouring)+ 0.071 (evaporation)= 0.07158	PAA: 0.2 %	n/a	-
		H_2O_2: 0.00267 (pouring)+ 0.33 (evaporation)= 0.33267	H_2O_2: 0.92 %	n/a	-
	Alternative: 2/RPE	PAA: 0.00058 (pouring)+ 0.28 (evaporation)= 0.28058 RPE with APF of 4 = 0.070	PAA: 0.2 %	n/a	-
		H_2O_2: 0.00267 (pouring)+ 1.3 (evaporation)= 1.30267 RPE with APF of 4 = 0.326	H_2O_2: 0.92 %	n/a	-

Std PPE = PPE required under Section 2.1.5.2 as default
n/a – oral exposure considered negligible for trained professional users

Dermal Exposure

No systemic dermal reference values are set for peracetic acid (CAR, Nov 2015) or hydrogen peroxide (CAR, Mar 2015), and so the risk characterisation of these components is focused on local effects and no systemic doses are estimated.

The maximum diluted product concentration is 2000 ppm PAA = 0.2% PAA w/v. This does not exceed the dermal NOAEC of 0.2% PAA for short-term and medium-term exposure, but above the dermal NOAEC of 0.1% PAA for long-term exposure. Based on the maximum ratio of PAA:H_2O_2 of 4.6 (for the 5% PAA product) the estimated maximum diluted product concentration of H_2O_2 is 0.92% w/v. This is below the 35% concentration limit for skin irritation and 5% limit for eye irritation.

For lower concentrations of product, where the maximum concentration is not required, the concentration is considered acceptable up to 1000 ppm, which is equivalent to 0.1% PAA. Product dilutions up to this concentration require no specific additional PPE.

The product concentration is constant during this exposure scenario. Dermal exposure can be minimised/avoided by the use of protective clothing chemically resistant to the biocidal product, and chemical resistant gloves classified under Standard EN374 (Protective gloves against chemicals and micro-organisms), preferably butyl rubber. Normal work hygiene procedures should be used following use, including washing hands. Any inadvertent dermal exposure should be removed by rinsing with water in accordance with Section 2.2.5.3. Inadvertent exposure is likely to be short-term (time between exposure and rinsing of skin), and the maximum in-use spray concentration does not exceed the short-term NOAEC for peracetic acid or hydrogen peroxide, indicating acceptable exposure.

Inhalation Exposure

No single model is available to estimate the inhalation exposure from the sequential processes of pouring a diluted product on to a surface, followed by wiping with a cloth.

Therefore the two processes have been assessed separately using the most appropriate models.

(i) Pouring of liquids

Mixing and Loading Model 7, TNsG part 2 (2002), which covers the pouring of liquids into systems, predicts a 50th percentile inhalation exposure of 0.29 mg in-use product/m^3. This is applicable to the diluted products, the most concentrated of which contains 0.2% peracetic acid and 0.92% hydrogen peroxide (based on the maximum ratio of PAA:H_2O_2 of 4.6 for the 5% PAA product). Therefore the predicted inhalation exposure for peracetic acid is (0.29 mg/m^3 x 0.2/100) = 0.00058 mg/m^3, and for hydrogen peroxide the predicted inhalation exposure is (0.29 mg/m^3 x 0.92/100) = 0.00267 mg/m^3.

(ii) Evaporation of vapour from surface

The evaporation of peracetic acid from the surface following wiping with a cloth will result in the presence of vapour which can be inhaled. The CAR (Nov, 2015) noted that "*The exposure models primarily used for the estimation of inhalation exposure (TNsG models) do not take into account the volatility of the substance. The inhalation exposure to vapour in addition to aerosols has to be taken into account at product authorisation*", and so an estimate of the worker exposure to vapour generated from the evaporation of the applied spray to the treated surface has been obtained using ConsExpo Web v1.0.1.
ConsExpo has been previously agreed as an appropriate tool in the exposure assessment for professional users (HEEG Opinion 3, Agreed in TM II 08, 01/04/2008).

ConsExpo has been previously agreed as an appropriate tool in the exposure assessment for professional users (HEEG Opinion 3, Agreed in TM II 08, 01/04/2008). This opinion notes that "*ConsExpo allows the adaptation of the default values to assess exposure of professional users*", and that "*Professionals are likely to use products for longer periods and more frequently than consumers/non-professionals*". On that basis the following amendments have been included:

- the Exposure Duration, Product Amount, Room Volume and Emission Duration have all been increased by a factor of 3x compared with the default values
- the Frequency has been increased from the default value of 365/year to 730/year to account for the possibility of 2 operations per day.

The increased input parameters mean that the equivalent area being applied and cleaned is 5.13 m^2 up to twice per day; this is coordinated with Exposure Scenario 3 for consistency.

The maximum external concentration (mean event concentration) of peracetic acid in the air due to vapour, as calculated using ConsExpo Web v1.0.1 is 0.28 mg/m^3, giving a total of (0.00058 + 0.28) = 0.28058 mg/m^3, which is below the inhalation AEC of 0.5 mg/m^3 for short-, medium- and long-term exposure (CAR, 2015). The mean air concentration on the day of exposure and average for the year are lower and therefore not critical. No additional mitigation measures are necessary based on the parameters assessed.

The maximum external concentration (mean event concentration) of hydrogen peroxide in the air due to vapour, as calculated using ConsExpo Web v1.0.1 is 1.3 mg/m^3, giving a total of (0.00267 + 1.3) = 1.30267 mg/m^3, which is above the inhalation AEC of 1.25 mg/m^3 for short-, medium- and long-term exposure (CAR, 2015). A tier 2 scenario is thus proposed, with increased ventilation or RPE in case a higher ventilation rate cannot be applied, in order to obtain a concentration in the air below the AEC.

Further information and considerations on Scenario 3

Secondary exposure is not considered relevant for this scenario as the use direction indicate that treated surfaces should not be used until the product is completely absorbed to the surface or air dried, at which point surface residues should be minimised.

Scenario 4

Description of Scenario 4		
PT 2/4 – Disinfection of tanks, pipes, filling machines in place Operations take place indoors. The biocidal product should be diluted in water to the required ppm of peracetic acid. The diluted product should be transferred to equipment by manual dosing or automated dosing; manual dosing is considered to represent the critical exposure scenario (due to the increased potential for dermal exposure and proximity to vapour), which is assessed here. Manual application is assumed to be achieved by pouring the diluted product into the apparatus to be cleaned. Tanks sizes may be in the range 5 – 150,000 L, with construction primarily from stainless steel or HDPE. Application should ensure the equipment or surface is fully saturated and left for at least 10 minutes. Equipment to be flushed with water prior to use. Product requires dilution prior to use from capped bottles, drum or intermediate bulk container (IBC). For capped bottles pour into a bucket or container (max 10 L), via measuring cylinder (100 mL). In many cases, the drum or IBC will be connected via a coupling system pipe to a container. Pails/drums for this type of product are commonly not full-aperture opening drums. Dose Rate: Antifungal up to 2000ppm active may be required. The exposure scenario is applicable to all products, which contain peracetic acid at 2-15% and therefore require appropriate dilution to achieve the required dose rate. Estimates of exposure are obtained using ConsExpo Web v1.01 for the calculation of vapour concentration.		
	Parameters[1]	Value
Tier 1 ConsExpo Web v1.0.1	Frequency	730/year (= 2/day)
	Model	Exposure to vapour
	Mode of release	Evaporation
	Exposure duration[3]	0.75 minutes
	Product amount	12500 g
	Weight fraction substance	PAA: 0.2% H_2O_2: 0.92%
	Room volume[3]	1 m^2
	Ventilation rate[3]	0.5/hour
	Inhalation rate	1.37 m^3/hr (default value for light exercise for 60 kg worker)
	Vapour pressure	PAA: 1900 Pa (CAR, 2015) H_2O_2: 214 Pa (CAR, 2015)
	Application temperature	20°C

	Molecular weight	PAA: 76 g/mol (CAR, 2015) H_2O_2: 34 g/mol (CAR, 2015)
	Mass transfer coefficient	18.6 m/hr (Thibodeaux's method)
	Release area mode[3]	Constant
	Release area	706 cm^2
	Emission duration[3]	0.3 minute
	Molecular weight matrix	18 g/mol (water)
Tier 2[2]	-	-

[1] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.
[2] Only include the parameters changed with respect to the previous Tier.
[3] Default input parameter from L.C.H. Prud'homme de Lodder *et al*, RIVM report 320104003/2006, Cleaning Products Fact Sheet.

Calculation of the exposure based on the Tier I parameters gives acceptable exposure; higher Tier assessment has not been conducted.

Calculations for Scenario 4

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated air concentration mg/m³**	**Max concn for dermal exposure**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 4	1/ Std PPE	PAA: 0.15 (ConsExpo Web spray model)	PAA: 0.2%	n/a	-
		H_2O_2: 0.076 (ConsExpo Web spray model)	H_2O_2: 0.92%		

Std PPE = PPE required under Section 2.1.5.2 as default
n/a – oral exposure considered negligible for trained professional users

Dermal Exposure
No systemic dermal reference values are set for peracetic acid (CAR, Nov 2015) or hydrogen peroxide (CAR, Mar 2015), and so the risk characterisation of these components is focused on local effects and no systemic doses are estimated.

The maximum diluted product concentration is 2000 ppm PAA = 0.2% PAA w/v. This does not exceed the dermal NOAEC of 0.2% PAA for short-term and medium-term exposure, but above the dermal NOAEC of 0.1% PAA for long-term exposure. Based on the maximum ratio of PAA: H_2O_2 of 4.6 (for the 5% PAA product) the estimated maximum diluted product concentration of H_2O_2 is 0.92% w/v. This is below the 35% concentration limit for skin irritation and 5% limit for eye irritation.

For lower concentrations of product, where the maximum concentration is not required, the concentration is considered acceptable up to 1000 ppm, which is equivalent to 0.1% PAA. Product dilutions up to this concentration require no specific additional PPE.

The product concentration is constant during this exposure scenario. Dermal exposure can be minimised/avoided by the use of protective clothing chemically resistant to the biocidal product, and chemical resistant gloves classified under Standard EN374 (Protective gloves against chemicals and micro-organisms), preferably butyl rubber. Normal work hygiene procedures should be used following use, including washing hands. Any inadvertent dermal exposure should be removed by rinsing with water in accordance with Section 2.2.5.3. Inadvertent exposure is likely to be short-term (time between exposure and rinsing of skin), and the maximum in-use spray concentration does not exceed the short-term NOAEC for peracetic acid or hydrogen peroxide, indicating acceptable exposure.

Inhalation Exposure

Notes: Given the volatility of the components of the products, exposure to aerosols is not deemed relevant for this application, as the vast majority of inhalation exposure will happen through evaporation, and not the formation of aerosol, which seems unlikely for a dipping bath application.

An assessment has been conducted using the Liquid Cleaner/Mixing & Loading scenario in ConsExpo Web v1.0.1, which is detailed in L.C.H. Prud'homme de Lodder *et al*, RIVM report 320104003/2006, Cleaning Products Fact Sheet (see Section 2.2.2 for discussion of the input parameters). ConsExpo has been previously agreed as an appropriate tool in the exposure assessment for professional users (HEEG Opinion 3, Agreed in TM II 08, 01/04/2008). This opinion notes that "*ConsExpo allows the adaptation of the default values to assess exposure of professional users*", and that "*Professionals are likely to use products for longer periods and more frequently than consumers/non-professionals*". The calculation of the peracetic acid present as vapour in the air from the container from which the diluted product is decanted uses some deviations from the default input parameters in the ConsExpo Fact Sheet (L.C.H. Prud'homme de Lodder *et al*, RIVM report 320104003/2006, Cleaning Products Fact Sheet):

- The product amount has been increased from 500 g (based on half of a 1 litre container for the consumer assessment) to 12,500 g to represent the 25 kg pack size.
- The release area has been increased from 20 cm^2 (which represents the area of a 5 cm diameter pack opening) to 706 cm^2 to represent the surface area of a bucket of diameter 30 cm (which is appropriate for a container of max 10 L, as specified in the use direction), since a dilution may be carried out in an open container, rather than a container with a small aperture, and this represents the worst-case scenario.

The calculated mean event air concentration of peracetic acid is 0.15 mg/m^3, which is below the inhalation AEC of 0.5 mg/m^3. The mean air concentration on the day of exposure and average for the year are lower and therefore not critical. Other than the normal personal protective equipment required to be used when handling this product, no additional PPE or measures are required.

The calculated mean event air concentration of hydrogen peroxide is 0.076 mg/m^3, which is below the inhalation AEC of 1.25 mg/m^3. The mean air concentration on the day of exposure and average for the year are lower and therefore not critical. Other than the normal personal protective equipment required to be used when handling this product, no additional PPE or measures are required.

Further information and considerations on Scenario 4

The critical operations that occur in this exposure scenario are:

1. Decanting undiluted product into a container to allow dilution with water to the desired concentration
2. Decanting/pouring of the diluted product into the equipment that requires cleaning

Point 1, which involves the pouring of undiluted product, has been assessed under Exposure Scenario 1; please refer this assessment for details. Point 2 is similar, but occurs using diluted product.

The calculated vapour concentration in air uses the default input value for ventilation rate of 0.5/hour. However, due to the short period during which the diluted product is present in the container, the air concentration is not significantly affected by ventilation rate, and so this is not a critical factor in this calculation.

Secondary exposure is not considered relevant for this scenario as the use direction indicate that treated equipment is to be flushed with water prior to use, at which point residues should be minimised.

Scenario 5

Description of Scenario 5		
PT 3 – Disinfection of teats The biocidal product should be diluted in water to the required ppm of peracetic acid. The diluted product should be applied by manual or automatic non-medical teat disinfection; manual application is considered the critical use due to greater chance of dermal exposure and closer proximity to vapour. Application should ensure the equipment or surface is fully saturated and left for at least 10 minutes. The operation may take place indoors or outdoors up to 2 times per day. Refer to further information in this scenario for details of the input parameters used in the exposure calculations. Product requires dilution prior to use from capped bottles, drum or intermediate bulk container (IBC). For capped bottles pour into a bucket or container (max 10 L), via measuring cylinder (100 mL). In many cases, the drum or IBC will be connected via a coupling system pipe to a container. Pails/drums for this type of product are commonly not full-aperture opening drums. Users are expected to be appropriately trained, to follow the product use directions and use the specified personal protective equipment. Workers are required to wear goggles, gloves and protective clothing when handling the product. Adequate ventilation should be ensured; otherwise appropriate respiratory protection will be required. Refer to Section 2.1.5.2for details. Dose Rate: Antifungal up to 2000 ppm active may be required [250 ppm for 5 mins bacteria for Delf] Estimates of exposure are obtained using ConsExpo Web v1.01 for the calculation of vapour concentration.		
	Parameters[1]	Value

Tier 1 ConsExpo Web v1.0.1	Frequency	730/year (= 2/day)
	Model	Exposure to vapour
	Mode of release	Evaporation
	Exposure duration	65 minutes
	Product amount	32500 g (based on a flow rate of 500 mL/min)
	Weight fraction substance	PAA: 0.2% = 2000 ppm H_2O_2: 0.92%
	Room volume	1000 m^2
	Ventilation rate	0.5/hour (natural ventilation)
	Inhalation rate	1.37 m^3/hr (default value for light exercise for a 60 kg worker)
	Vapour pressure	PAA: 1900 Pa H_2O_2: 214 PA
	Application temperature	20°C
	Molecular weight	PAA: 76 g/mol H_2O_2: 34 g/mol
	Mass transfer coefficient	18.6 m/hr (Thibodeaux's method; an approximation of a two layer model describing the evaporation of a substance from water)
	Release area mode	Constant
	Release area	1.04 m^2
	Emission duration	65 minute
	Molecular weight matrix	18 g/mol (water)
Tier 2[2]	-	-

[1] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.
[2] Only include the parameters changed with respect to the previous Tier.

Calculation of the exposure based on the Tier I parameters gives acceptable exposure; higher Tier assessment has not been conducted.

Calculations for Scenario 5

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated air concentration mg/m³**	**Max concn for dermal exposure**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 5	1/ Std PPE	0.33 (ConsExpo Web)	PAA: 0.2%	n/a	-
		0.17 (ConsExpo Web)	H_2O_2: 0.92%	n/a	-

Std PPE = PPE required under Section 2.1.5.2 as default
n/a – oral exposure considered negligible for trained professional users
In the absence of a systemic endpoint for dermal exposure, the risk characterisation of peracetic acid and hydrogen peroxide is focused on local effects

Dermal Exposure

No systemic dermal reference values are set for peracetic acid (CAR, Nov 2015) or hydrogen peroxide (CAR, Mar 2015), and so the risk characterisation of these components is focused on local effects and no systemic doses are estimated.

The maximum diluted product concentration is 2000 ppm PAA = 0.2% w/v. This does not exceed the dermal NOAEC of 0.2% PAA for short-term and medium-term exposure, but above the dermal NOAEC of 0.1% PAA for long-term exposure. Based on the maximum ratio of PAA: H_2O_2 of 4.6 (for the 5% PAA product) the estimated maximum diluted product concentration is 0.92% H_2O_2 w/v. This is below the 35% concentration limit for skin irritation and 5% limit for eye irritation.

For lower concentrations of product, where the maximum concentration is not required, the concentration is considered acceptable up to 1000 ppm, which is equivalent to 0.1% PAA. Product dilutions up to this concentration require no specific additional PPE.

The product concentration is constant during this exposure scenario. Dermal exposure can be minimised/avoided by the use of protective clothing chemically resistant to the biocidal product, and chemical resistant gloves classified under Standard EN374 (Protective gloves against chemicals and micro-organisms), preferably butyl rubber. Normal work hygiene procedures should be used following use, including washing hands. Any inadvertent dermal exposure should be removed by rinsing with water in accordance with Section 2.2.5.3. Inadvertent exposure is likely to be short-term (time between exposure and rinsing of skin), and the maximum in-use spray concentration does not exceed the short-term NOAEC for peracetic acid or hydrogen peroxide, indicating acceptable exposure.

Inhalation exposure

No specific model is available to estimate the actual exposure from the teat disinfection use. In order to define a scenario that can be modelled by an existing exposure model (eg. ConsExpo Web v1.0.1), then the following logic and assumptions have been made about the processes involved:

- The application of the product to the teat is done using a hand-held device which contains enclosed rotating brushes to facilitate cleaning the teat, and a continuous flow of the diluted product which flows into the device around the brushes, and discharges from the bottom of the device on to the floor adjacent to the worker.

No details of the flow rate of product are available, but an estimate based on video footage of the operation[14] is 500 mL/min.

- Inhalation exposure will be predominantly from exposure to vapour, as the hand-held apparatus does not produce a spray or aerosol, and the internal brushes are enclosed and do not eject particles of the product.
- The device is applied to each of the four teats in turn to effectively clean them. This is estimated to take about 10 seconds per cow[14]. The operator will then move on to the next cow; this means that the treated surface on the cow is only adjacent to the worker for a maximum of 30 seconds.
- The waste product that is discharged from the hand-held device either during or between the cleaning events is assumed to fall on the floor around the worker; it is estimated that the area of the puddle formed will be approximately 1 m^2.
- While the flow of product from the hand-held device is continuous, if the worker is continuously moving on to the next cow, then this puddle will either reform in the new location, or will drain naturally away, such that the area of the puddle does not increase with time as the waste product is continually removed from the work area by drainage.
- As each cow is treated according to the specified disinfection process, it will go on to be milked, and then discharged from the milking shed. This means that treated cows will not remain in the milking shed for a significant time. It is assumed that at any point in time, 10 treated cows will be present in the milking shed.
- Therefore the area of surface (teats/udder of one cow) being treated estimated to be 20 x 20 cm = 0.04 m^2, and the waste puddle of product, estimated to be 1 m^2 will be constant for the period of milking, giving a total area of treated surface in the vicinity of the worker of (10 cows x 0.04 m^2/cow) + 1 m^2 = 1.4 m^2 from which evaporation can occur inside the milking shed.
- If it takes 30 seconds to treat one cow and move on to the next, then the total period of exposure will depend on the size of the herd being milked. An average herd size is approximately 130 cows[15], which means that it will take (130 x 0.5 mins) = 65 mins to clean the entire herd prior to milking.
- The operation may take place twice per day (at each milking). However, the key exposure is based on inhalation, which depends on the air concentration. The air concentration is assumed to dissipate to zero between milking events by ventilation and degradation. Therefore, the results for one milking session will be the same for the second session. There are no systemic endpoints for peracetic acid or hydrogen peroxide, so the events will not be additive from the workers perspective. Similarly, any dermal exposure is based on local effects driven by the concentration of the product, and any effects are not additive between milking sessions.
- The volume of the milking shed has been estimated at 1000 m^3 (based on 3 m height, and 18.25 m x 28.25 m floor area.

An estimate of the potential vapour concentration in the air during the milking process can be obtained using ConsExpo Web v1.0.1. The constant area evaporation model that describes this scenario can be derived as a modification of the mixing/loading evaporation model for liquid general purpose cleaners described in the RIVM Cleaning Products Fact Sheet[16]. Certain input parameters, e.g. exposure duration, release area, product amount

14 http://dairy-equipment.co.uk/teat-sanicleanse-system/

15 Bate, A (2016) UK Dairy Industry Statistics, House of Commons Library Briefing Paper [available online at http://researchbriefings.files.parliament.uk/documents/SN02721/SN02721.pdf]

16 L.C.H. Prud'homme de Lodder et al, Cleaning Products Fact Sheet - To assess the risks for the consumer. RIVM report 320104003/2006

and room volume have been modified from the default exposure scenario on the fact sheet to reflect the input parameters discussed above.

The calculated mean event air concentration of peracetic acid is 0.33 mg/m^3, which is below the inhalation AEC of 0.5 mg/m^3. The mean air concentration on the day of exposure and average for the year are lower and therefore not critical. Other than the normal personal protective equipment required to be used when handling this product, no additional PPE or measures are required.

The calculated mean event air concentration of hydrogen peroxide is 0.17 mg/m^3, which is below the inhalation AEC of 1.25 mg/m^3. The mean air concentration on the day of exposure and average for the year are lower and therefore not critical. Other than the normal personal protective equipment required to be used when handling this product, no additional PPE or measures are required.

Further information and considerations on Scenario 5

No secondary exposure is anticipated as a result of this exposure scenario. Both peracetic acid and hydrogen peroxide are highly reactive in contact with biological material, and so will rapidly degrade to innocuous products on the cow teats. This also means that transfer to milk is highly unlikely.

Scenario 6

Description of Scenario 6
PT 3/4 – Disinfection of Equipment by Immersion, dipping, soaking and soaking single stage cleaning and disinfection The operation can take place indoors or outdoors; indoors is considered the critical exposure scenario due to more limited ventilation, and can take place up to 2 times per day. The biocidal product should be diluted in water to the required ppm of peracetic acid. The equipment is manual or automatic. Examples of equipment intended for disinfection are small production utensils, removable machine parts – possible used for food production. Application should ensure the equipment is fully saturated and left for at least 10 minutes. Do not use equipment until product is completely absorbed to the surface or air dried. Product requires dilution prior to use from capped bottles, drum or intermediate bulk container (IBC). For capped bottles pour into a bucket or container (max 10 L), via measuring cylinder (100 mL). In many cases, the drum or IBC will be connected via a coupling system pipe to a container. Pails/drums for this type of product are commonly not full-aperture opening drums. Users are expected to be appropriately trained, to follow the product use directions and use the specified personal protective equipment. Workers are required to wear goggles, gloves and protective clothing when handling the product. Adequate ventilation should be ensured; otherwise appropriate respiratory protection will be required. Refer to Section 2.1.5.2for details. Dose Rate: Antifungal up to 2000ppm active may be required. The exposure scenario is applicable to all products, which contain peracetic acid at 2-15% and therefore require appropriate dilution to achieve the required dose rate.

Estimates of exposure are obtained using ConsExpo Web v1.01 for the calculation of vapour concentration.		
	Parameters[1]	Value
Tier 1 ConsExpo Web v1.0.1	Frequency	730/year (= 2/day)
	Model[3]	Exposure to vapour
	Mode of release[3]	Evaporation
	Exposure duration[4]	120 minutes
	Product amount[4]	12500 g
	Weight fraction substance	PAA: 0.2% H_2O_2: 0.92%
	Room volume[4]	45 m^2
	Ventilation rate[4]	2.5/hour
	Inhalation rate	1.37 m^3/hr (default value for light exercise for a 60 kg worker)
	Vapour pressure	PAA: 1900 Pa H_2O_2: 214 Pa
	Application temperature	20°C
	Molecular weight	PAA: 76 g/mol H_2O_2: 34 g/mol
	Mass transfer coefficient	18.6 m/hr (Thibodeaux's method)
	Release area mode[3]	Constant
	Release area[4]	706 cm^2
	Emission duration[4]	120 minute
	Molecular weight matrix	20 g/mol (90% water)
Tier 2[2]	-	-

[1] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.
[2] Only include the parameters changed with respect to the previous Tier.
[3] Default input parameter from L.C.H. Prud'homme de Lodder *et al*, RIVM report 320104003/2006, Cleaning Products Fact Sheet.
[4] Justification for value included in the description of the calculations

Calculation of the exposure based on the Tier I parameters gives acceptable exposure; higher Tier assessment has not been conducted.

Calculations for Scenario 6

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated air concentration mg/m³**	**Max concn for dermal exposure**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 6	1/ Std PPE	PAA: 0.29	PAA: 0.2%	n/a	-
		H_2O_2: 0.15	H_2O_2: 0.92%		

Std PPE = PPE required under Section 2.1.5.2 as default
n/a – Oral exposure considered negligible for trained professional users

Dermal Exposure
No systemic dermal reference values are set for peracetic acid (CAR, Nov 2015) or hydrogen peroxide (CAR, Mar 2015), and so the risk characterisation of these components is focused on local effects and no systemic doses are estimated.

The maximum diluted product concentration is 2000 ppm PAA = 0.2% w/v. This does not exceed the dermal NOAEC of 0.2% PAA for short-term and medium-term exposure, but above the dermal NOAEC of 0.1% PAA for long-term exposure. Based on the maximum ratio of PAA: H_2O_2 of 4.6 (for the 5% PAA product) the estimated maximum diluted product concentration is 0.92% H_2O_2 w/v. This is below the 35% concentration limit for skin irritation and 5% limit for eye irritation.

For lower concentrations of product, where the maximum concentration is not required, the concentration is considered acceptable up to 1000 ppm, which is equivalent to 0.1% PAA. Product dilutions up to this concentration require no specific additional PPE.

The product concentration is constant during this exposure scenario. Dermal exposure can be minimised/avoided by the use of protective clothing chemically resistant to the biocidal product, and chemical resistant gloves classified under Standard EN374 (Protective gloves against chemicals and micro-organisms), preferably butyl rubber. Normal work hygiene procedures should be used following use, including washing hands. Any inadvertent dermal exposure should be removed by rinsing with water in accordance with Section 2.2.5.3. Inadvertent exposure is likely to be short-term (time between exposure and rinsing of skin), and the maximum in-use spray concentration does not exceed the short-term NOAEC for peracetic acid or hydrogen peroxide, indicating acceptable exposure.

Inhalation Exposure
An assessment has been conducted using a modification of the Liquid Cleaner/Mixing & Loading scenario in ConsExpo Web v1.0.1, which is detailed in L.C.H. Prud'homme de Lodder *et al*, RIVM report 320104003/2006, Cleaning Products Fact Sheet (see Section 2.2.2 for discussion of the input parameters). ConsExpo has been previously agreed as an appropriate tool in the exposure assessment for professional users (HEEG Opinion 3, Agreed in TM II 08, 01/04/2008). This opinion notes that "*ConsExpo allows the adaptation of the default values to assess exposure of professional users*", and that "*Professionals are likely to use products for longer periods and more frequently than consumers/non-professionals*". The calculation of the peracetic acid present as vapour in the air from the container from which the diluted product is decanted uses some deviations from the default input parameters in the ConsExpo Fact Sheet (L.C.H. Prud'homme de Lodder *et al*, RIVM report 320104003/2006, Cleaning Products Fact Sheet):

- The exposure duration has been increased from 0.75 mins (for a mixing/loading scenario) to 120 min, to represent an extended period spent dipping, soaking and

removing items from a container filled with diluted product. It has been assumed that 2 such operations per day could be conducted.
- The product amount has been increased from 500 g (based on half of a 1 litre container for the consumer assessment) to 12,500 g to represent the 25 kg pack size.
- The room volume has been increased from 1 m^2 (which represented a personal body space in a mixing/loading scenario) to 45 m^2, to represent a representative indoor space. This value is also consistent with the room volume used in other exposure scenarios in this assessment.
- The ventilation rate has been increased from 0.5/hour to 2.5/hour for consistency with other exposure scenarios in this assessment.
- The release area has been increased from 20 cm^2 (which represents the area of a 5 cm diameter pack opening) to 706 cm^2 to represent the surface area of a bucket of diameter 30 cm (which is appropriate for a container of max 10 L, as specified in the use directions), since a dilution may be carried out in an open container, rather than a container with a small aperture, and this represents the worst-case scenario.
- The emission duration has been increased to 120 minutes, which represents the evaporation of peracetic acid from the solution and into the air during the entire operation.

The calculated mean event air concentration of peracetic acid is 0.29 mg/m^3, which is below the inhalation AEC of 0.5 mg/m^3. The mean air concentration on the day of exposure and average for the year are lower and therefore not critical. Other than the normal personal protective equipment required to be used when handling this product, no additional PPE or measures are required.

The calculated mean event air concentration of hydrogen peroxide is 0.15 mg/m^3, which is below the inhalation AEC of 1.25 mg/m^3. The mean air concentration on the day of exposure and average for the year are lower and therefore not critical. Other than the normal personal protective equipment required to be used when handling this product, no additional PPE or measures are required.

It is noted that the air concentration is highly dependent on the rate of ventilation used. The assessment assumes 2.5/hour, as discussed above. However, a sensitivity analysis conducted using ConsExpo demonstrates that if the rate of ventilation is below 1.05/hour, then the air concentration could exceed the inhalation AEC (refer to Annex 3.2 for additional information). The worst case occurs where the ventilation rate is 0/hour, which results in a mean event air concentration of 0.89 mg/m^3. In this case, then the options for maintaining acceptable exposure via inhalation are:
- Increase ventilation to >1.05/hour, or
- Use of RPE that is effective against peracetic acid with a Protection Factor of at least 5 would reduce the inhaled concentration to a level below the inhalation AEC, even where no ventilation is used.

Further information and considerations on Scenario 6

If manual filling of the container to be used for the dipping operations is to be carried out, then additional exposure from decanting the undiluted product into the container will need to be considered; refer to Exposure Scenario 1. Where larger containers of product are used to dispense the product (e.g. drum or IBC), then this additional exposure can be disregarded as a coupling system pipe will remove this potential exposure.

Secondary exposure is not considered relevant for this scenario as the use direction indicate that treated equipment should not be used until the product is completely absorbed to the surface or air dried, at which point surface residues should be minimised.

Combined scenarios

No systemic endpoints have been set for peracetic acid or hydrogen peroxide. Therefore it is not relevant to combine systemic exposure from the professional uses. It is concluded that in the absence of (primary) systemic adverse effects the risk characterisation is focused on local effects.

A number of the scenarios are related to other scenarios; for example in a spraying application, it is relevant to consider Exposure Scenarios 1 (mixing/loading of undiluted formulated product), 2 and 3 (initiation of spraying equipment and release into the treated area). Given that the key parameter for exposure/risk characterisation is inhalation, which depends on the event air concentration, it is not relevant to combine these exposures, as they are sequential and unlikely to be additive. This is also covered in the peracetic acid CAR (2015) which states, under Combined Exposure "*Based on the absence of systemic effects after exposure towards peracetic acid, it is important to note in this context that the inhalation AEC values are not time-dependent and relate to the concentrations of peracetic acid in the air, which do not cause sensory irritation or corrosive effects. For this reason, only the highest inhalation exposure level is relevant and the addition of exposure levels and the calculation of a combined inhalation exposure during the different tasks are not relevant*".

It is concluded that is not relevant to combine Exposure Scenarios based on air and product concentration.

Non-professional exposure

No exposure scenarios include exposure to non-professional operators. No further consideration of non-professional exposure is required.

Exposure of the general public

No exposure scenarios include exposure to the general public. No further consideration of exposure to the general public is required.

Monitoring data

No information on surveys or studies with the product or with a surrogate are available or required.

Dietary exposure

The proposed uses are in the pharmaceutical and cosmetic industries (Uses # 1.2, 2.2, 3.2 / 1.1, 2.1, 3.1) are not relevant to food and will not result in any direct or indirect exposure to food or drink. In the case of inadvertent exposure, both peracetic acid and hydrogen peroxide are known to be highly reactive and would rapidly decompose in contact with any type of food (peracetic acid and hydrogen peroxide CARs, 2015). Regarding

veterinary hygiene (Uses # 2.3, 3.3 / 2.5, 2.6, 3.5, 3.6 / 2.4, 3.4) are relevant to food and would normally lead to direct or indirect exposure though food. However, given the nature of the active substance, its high reactivity and low stability, direct or indirect exposure to livestock is negligible.

Uses # 1.4, 2.8, 3.8 / 1.3, 2.7, 3.7 / 1.5, 2.9, 3.9 are intended for use in dairies, breweries, beverage and soft drinks industry and food processing, and therefore secondary oral and dermal exposure of consumers to residual hydrogen peroxide in food and drinking water is in theory possible. However, as discussed above, both peracetic acid and hydrogen peroxide are known to be highly reactive and would rapidly decompose in contact with any type of food (peracetic acid and hydrogen peroxide CARs, 2015). MRLs are not required for peracetic acid and hydrogen peroxide, and it concluded that the dietary exposure via residues in food is negligible.

It is noted that the peracetic acid CAR (2015) stated "… *secondary human exposure to peracetic acid and hydrogen peroxide via food etc. is not considered to be relevant as both peracetic acid and hydrogen peroxide degrade rapidly following application and no residues are expected in foodstuffs*". No further consideration is necessary.

Information of non-biocidal use of the active substance

The active substance is not intended for any non-biocidal uses. No further consideration is necessary.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Exposure of livestock via the diet is considered non-relevant; refer to the discussion under Dietary Exposure above, which remains relevant for both human food and livestock feed. None of the intended uses are for the treatment of water, and so the exposure of livestock via drinking water is also considered non-relevant. Uses # 1.2, 2.2, 3.2 / 1.1, 2.1, 3.1 specifically preclude the direct treatment of livestock. . Uses # 2.5, 2,6, 3.5, 3.6 for teat disinfection have the potential for livestock exposure due to the direct treatment of teats. However, it is known that both peracetic acid and hydrogen peroxide are highly reactive and degrade rapidly on contact with biological surfaces. Neither compounds are absorbed systemically, and so exposure to livestock via uses # 2.5, 2,6, 3.5, 3.6 is considered non-relevant, and will not result in residues in animal tissues or commodities (eg. milk). Uses # 2.4, 3.4 are also veterinary uses, involving the treatment of equipment. However the use states "Do not use equipment until product is completely absorbed to the surface or air dried", at which point residues are expected to be very low and non-relevant for livestock exposure. Uses # 1.4, 2.8, 3.8 / 1.3, 2.7, 3.7 / 1.5, 2.9, 3.9 are for use in dairies, breweries, beverage and soft drinks industry and food processing where livestock are not expected to be present.

It is concluded that there is no direct or indirect exposure of livestock from the proposed uses. No further consideration is necessary.

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

Uses #1.1, 1.2, 2.1, 2.2, 3.1, 3.2 are not relevant to food will not result in any direct or indirect exposure to food or drink. Uses # 1.4, 2.8, 3.8 / 1.3, 2.7, 3.7 / 1.5, 2.9, 3.9 are intended for use in dairies, breweries, beverage and soft drinks industry and food processing, and therefore secondary oral and dermal exposure of consumers to residual

hydrogen peroxide in food and drinking water is in theory possible. However, both peracetic acid and hydrogen peroxide are known to be highly reactive and rapidly decompose in contact with any type of food (peracetic acid and hydrogen peroxide CARs, 2015). MRLs are not required for peracetic acid and hydrogen peroxide, and it concluded that the dietary exposure via residues in food is negligible.

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

No exposure scenarios include exposure to non-professional operators. No further consideration of transfer of active substances into foods as a result of non-professional exposure is required.

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

Pure peracetic acid does neither exist commercially nor is it an intermediate in the production of peracetic acid products. Furthermore, any attempt to produce pure peracetic acid would be prevented by the explosion risks of such a compound. Peracetic acid is produced by reacting hydrogen peroxide (H_2O_2) with acetic acid in aqueous solution. In this process, peracetic acid is not obtained as a pure substance but in the form of aqueous solutions containing peracetic acid, acetic acid, hydrogen peroxide and water. Therefore the production and formulation occur effectively *in-situ* for peracetic acid and no exposure is anticipated.

Instructions for disposal are included in Section 2.1.5.4. Unused formulated material must not be dumped into sewers, on to the ground or into any body of water, and release into the environment is to be avoided. Therefore secondary exposure from waste formulated material is not likely. Containers are not to be reused or refilled and therefore there is no exposure from decanting formulation into containers. Washing of empty containers with water should take place using the required PPE, including as a minimum protective gloves and eye protection in order to minimise dermal exposure. The in-use dilution does not exceed the level of dermally irritating concentrations and therefore use of PPE is not necessary to prevent skin exposure, however appropriate PPE (workwear, gloves, eye protection) is necessary when handling the undiluted formulated material. The residual volumes in 'empty' containers will be relatively low and within the volumes evaluated for exposure in Scenarios 1 and 2. Therefore the air concentration resulting from the presence of vapour will be at acceptable levels. It is therefore concluded that the risk of exposure during disposal is low and not of concern.

Aggregated exposure

The uses under consideration are for industrial/professional users only, and are assessed within this document for full shift exposures. Secondary exposure of professional users is considered non-relevant, since workers will use appropriate PPE to minimise dermal exposure. Secondary exposure to other humans is considered unlikely since both peracetic acid and hydrogen peroxide are highly unstable and will rapidly degrade at the site of first contact which effectively reduces the possibility of any residual concentrations. The high reactivity of peracetic ac id and hydrogen peroxide mean that both components rapidly degrade on contact with biological materials, and it is concluded that dietary exposure and exposure to livestock will not occur.

No systemic endpoints are set for either peracetic acid or hydrogen peroxide, and therefore only local effects are relevant. Dermal effects are dependent on product concentration and potential local effects are mitigated by the use of appropriate PPE (gloves, workwear, eye protection, RPE). Inhalation is the primary route of concern and the inhalation AEC values are not time-dependent and relate to the concentrations of peracetic acid in the air, which do not cause sensory irritation or corrosive effects. Only the highest inhalation exposure level (as calculated in the 8 Exposure Scenarios) is relevant and the addition of exposure levels and the calculation of a combined inhalation exposure during the different tasks are not relevant.

It is therefore concluded that it is not necessary to aggregate any of the assessed exposure scenarios.

Summary of exposure assessment

Scenarios and values to be used in risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated air concentration mg/m³**	**Max conc for dermal exposure**
1.	Professionals	1 / Std PPE	PAA: 0.394 H_2O_2: 0.1267	PAA: 15% H_2O_2: 23%
2.	Professionals	2 / higher ventilation	PAA: 0.224 H_2O_2: 1.029	PAA: 0.2% H_2O_2: 0.92%
2. (alternative)	Professionals	2 / RPE	PAA: 0.111 H_2O_2: 0.500	PAA: 0.2% H_2O_2: 0.92%
3.	Professionals	2 / higher ventilation	PAA: 0.07158 H_2O_2: 0.3327	PAA: 0.2% H_2O_2: 0.92%
3. (alternative)	Professionals	2 / RPE	PAA: 0.070 H_2O_2: 0.326	PAA: 0.2% H_2O_2: 0.92%
4.	Professionals	1 / Std PPE	PAA: 0.15 H_2O_2: 0.076	PAA: 0.2% H_2O_2: 0.92%
5.	Professionals	1 / Std PPE	PAA: 0.33 H_2O_2: 0.17	PAA: 0.2% H_2O_2: 0.92%
6.	Professionals	1 / Std PPE	PAA: 0.29 H_2O_2: 0.15	PAA: 0.2% H_2O_2: 0.92%

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation (peracetic acid)

Reference	**Study**	**NOAEL (LOAEL)**	**AF[1]**	**Correction for oral absorption**	**Value**
AEC short-term$_{inh}$	Human data	NOAEC 0.5 ppm)	3.16	-	0.5 mg/m³

AEC medium-term$_{inh}$	Human data	NOAEC 0.5 ppm)	3.16	-	0.5 mg/m^3
AEC long-term$_{inh}$	Human data	NOAEC 0.5 ppm)	3.16	-	0.5 mg/m^3
NOAEC short-term$_{dermal}$	Human data	LOAEC 0.2%	1	-	0.2%
NOAEC medium-term$_{dermal}$	Human data	LOAEC 0.2%	1	-	0.2%
NOAEC long-term$_{dermal}$	Rabbit one year study	LOAEC 0.2%	2	-	0.1%
ARfD	-	-	-	-	N/A; no systemic effects
ADI	-	-	-	-	N/A; no systemic effects

[1] The for assessment factor for AEL$_{inh}$ is an intraspecies dynamic factor (CAR, 2015).
No derivation of the AF of 2 for the LOAEC$_{dermal}$ is stated in the CAR 2015.

Reference values to be used in Risk Characterisation (hydrogen peroxide)

Reference	**Study**	**NOAEL (LOAEL)**	**AF[1]**	**Correction for oral absorption**	**Value**
AEC short-term$_{inh}$	NOAEC in 90-day inhalation study (rat)	NOAEC 0.5 ppm)	8	-	1.25 mg/m^3
AEC medium-term$_{inh}$					
AEC long-term$_{inh}$					
ARfD	-	-	-	-	N/A; no systemic effects
ADI	-	-	-	-	N/A; no systemic effects

[1] The for assessment factor for AEL$_{inh}$ is an intraspecies dynamic factor (CAR, 2015).
No derivation of the AF of 2 for the LOAEC$_{dermal}$ is stated in the CAR 2015.

Equilibrium peracetic acid used in a variety of different product types for disinfection purposes is composed of acetic acid, peracetic acid, hydrogen peroxide and water. After application of equilibrium peracetic acid in the intended uses within PT2 through PT4, peracetic acid and hydrogen peroxide are the relevant substances which have to be considered in the human health exposure assessment and risk characterisation. For this reason, the risk characterisation was performed for both peracetic acid and hydrogen peroxide, respectively (peracetic acid CAR, 2015).

Risk for industrial users

Exposure for industrial users is identical to that for professional users; refer to the risk characterisation for professional users below.

Systemic effects
No systemic effects are observed and therefore no systemic endpoints are set for peracetic acid or hydrogen peroxide. All risk characterisation is based on local effects. Refer to 'Risks for Professional Users'.

Local effects
All local effects for industrial users are the same as for professional users; refer to the Local Effects section under Risk for Professional Users below.

Conclusion
Refer to the Conclusions section under Risk for Professional Users below.

Risk for professional users

Systemic effects

No systemic effects are observed and therefore no systemic endpoints are set for peracetic acid or hydrogen peroxide. All risk characterisation is based on local effects.

Only local effects are considered relevant for peracetic acid and hydrogen peroxide, and an characterisation of the risk by inhalation and dermal exposure is included below. No oral exposure is anticipated for professional users.

Local effects

Task/ Scenario	Tier	Dermal Exposure			Inhalation Exposure		
		Concen-tration % w/w	Dermal NOAEC % w/w	Accept-able (y/n)	Air concen-tration; mg/m³	Inhalation AEC; mg/m³	Accept-able (y/n)
1	1	PAA: 15	0.2 (short) 0.1 (long)	No Gloves required	0.394	0.5	Yes
		HP: 23	35	Yes	0.1267	1.25	Yes
2	2	PAA: 0.2	0.2 (short) 0.1 (long)	Yes Yes	0.224 (alternative RPE: 0.111)	0.5	Yes
		HP: 0.92	35	Yes	1.029 (alternative RPE: 0.500)	1.25	Yes
3	2	PAA: 0.2	0.2 (short) 0.1 (long)	Yes Yes	0.07158 (alternative RPE: 0.070)	0.5	Yes
		HP: 0.92	35	Yes	0.3327 (alternative RPE: 0.326)	1.25	Yes
4	1	PAA: 0.2	0.2 (short) 0.1 (long)	Yes Yes	0.15	0.5	Yes
		HP: 0.92	35	Yes	0.076	1.25	Yes
5	1	PAA: 0.2	0.2 (short) 0.1 (long)	Yes Yes	0.33	0.5	Yes
		HP: 0.92	35	Yes	0.17	1.25	Yes

6	1	PAA: 0.2	0.2 (short) 0.1 (long)	Yes Yes	0.29	0.5	Yes
		HP: 0.92	35	Yes	0.15	1.25	Yes

For each scenario, a qualitative risk assessment is also performed, taking into account the eventual dilution of the product.

Scenario 1: Mixing & Loading:

Very High Hazard				
Hazard Effects	Frequency and duration of potential exposure	Degree of potential eposure	Relevant RMM	PPE
Skin Corr. 1A (H314)	15 minutes to the concentrated product (diluted product is a such concentration that the product can't be considered as being classified as H314).	Manual Mixing & Loading is the principal step with risk of exposure to the concentrated product.	- Training for staff on good practice; - Control staff entry to work area;	- RPE during M&L; - Substance/task appropriate gloves; - protection coverall; - Chemical goggles.

During the mixing and loading of the concentrated product (15 % PAA and 25 % HP), the NOECdermal is exceeded for PAA, but not for HP. As there is potential dermal contact, PPE (chemical resistant gloves, acid-proof protective coverall, safety glasses and/or face shield) are to be worn to prevent direct dermal contact. This is applicable due to the immediate and direct effect of these BP's as being corrosive in undiluted form. Accidental spillages to the bare skin should be immediately washed off and the contaminated skin rinsed with water, if this happens. Therefore, residues of spillages remaining on bare skin are not expected and the use of PPE is assumed for direct handling of the biocidal product. No local risk assessment is proposed for scenario 2-6, since the diluted products used are not classified.

Conclusion

The concentration of the formulation does not exceed the dermal NOAEL for peracetic acid or hydrogen peroxide, apart from the mixing/loading Scenario 1, where the concentration of peracetic acid does exceed the dermal NOAEL. Protective gloves, workwear and eye protection are required under all circumstances and are sufficient to avoid dermal contact.

Secondary exposure to treated surfaces is considered acceptable for Scenarios 2-6 with no additional mitigation measures as the concentrations of PAA and HP are below the dermal limit for local effects, and no systemic effects are relevant from dermal exposure. The concentrations of PAA and HP in Scenario 1 (mixing/loading concentrated product) exceed the dermal limits, but this scenario deals with the decanting and dilution of product to the concentrations used in subsequent Scenarios. Equipment and surfaces will not be treated directly with the product concentrate and so secondary exposure from Scenario 1 is considered acceptable.

Inhalation exposure is within the inhalation AEC for peracetic acid for all exposure scenarios, indicating that no adverse effects will be experienced by workers.

Inhalation exposure is within the inhalation AEC for hydrogen peroxide for all scenarios, but scenario 2 and 3. For those 2 scenarios, a higher rate of ventilation or RPE in case a higher ventilation rate cannot be applied is required to ensure an exposure below the AEC. The diluted products used in Scenario 2, 3, 4, 5 & 6 are no longer classified as H314. However, dermal exposure must still be limited using PPE such as gloves and coverall in order to remain below the dermal NOAEC of PAA, set at 0.1%.

Risk for non-professional users

The uses of the formulated products are not intended for non-professional users. No further consideration is required.

Risk for the general public

No exposure scenarios include exposure to the general public, as all scenarios are for industrial/professional users only. Exposure via food and water are not considered relevant. No systemic endpoints are set for peracetic acid or hydrogen peroxide, and all risk characterisation is on the basis of local effects. The general public are not expected to be present where non-zero air concentrations may be present, and are not expected to be in dermal contact with either the undiluted or diluted formulations. No secondary exposures are considered relevant for the general public.

It is concluded that the risk for the general public is acceptable.

Risk for consumers via residues in food

The proposed uses are in the pharmaceutical and cosmetic industries (Uses #1.1, 1.2, 2.1, 2.2, 3.1, 3.2), for veterinary hygiene (Uses # 2.3, 2.4, 3.3, 3.4) are not relevant to food and will not result in any direct or indirect exposure to food or drink. In the case of inadvertent exposure, both peracetic acid and hydrogen peroxide are known to be highly reactive and would rapidly decompose in contact with any type of food (peracetic acid and hydrogen peroxide CARs, 2015)

Uses # 1.4, 2.5, 2.6, 2.8, 3.8 / 1.3, 2.7, 3.7, 3.5, 3.6 / 1.5, 2.9, 3.9 are intended for use in dairies, breweries, beverage and soft drinks industry and food processing, and therefore secondary oral and dermal exposure of consumers to residual hydrogen peroxide in food and drinking water is in theory possible. However, as discussed above, both peracetic acid and hydrogen peroxide are known to be highly reactive and would rapidly decompose in contact with any type of food (peracetic acid and hydrogen peroxide CARs, 2015). MRLs are not required for peracetic acid and hydrogen peroxide, and it concluded that the risk for consumers via residues in food is negligible.

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

The inhalation AEC values for peracetic acid and hydrogen peroxide are not additive and have been assessed separately. Similarly, the dermal NOAEC values are not additive, and relate to the concentrations of the components in the formulated products. Therefore is it not appropriate to consider the risk from the combined exposure to the active substances in this biocidal product, and the overall risk characterisation is adequately addressed by the risk characterisation for each component.

2.2.7 Risk assessment for animal health

There is considered to be no likelihood of transfer of residues of peracetic acid to food or feed, and so there will be no exposure via the diet as feed. It is not anticipated that animals will be present during the application of the product, so no direct application to animals will occur, other than Exposure Scenario 6 (refer to position in Risk for consumers via residues in food above). Similarly, secondary exposure is considered unlikely since both peracetic acid and hydrogen peroxide are highly unstable and will rapidly degrade at the site of first contact which effectively reduces the possibility of any residual concentrations. To insure that Animals will not be exposed during application, RMM have been added to insure their removal before that treatment takes place.

However, Scenario 5 – teat disinfection, need an additional assessment as, there is a direct application to the skin of the animal for the treatment.
Seeing that the concentration of the product used during teat disinfection is set at 0.2% in PAA, and that the AEC_{dermal} long term for PAA is at 0.1%, and given that there are no proposed method to decrease the risk to the animal, this has to be considered as an unacceptable risk to the animal, and the use has to be rejected.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The product contains one active substance (peracetic acid) and one substance of concern for the environment (hydrogen peroxide). Although hydrogen peroxide is itself an approved active substance under PT 1 – 6, in accordance with the decision of the Biocidal Products Committee (BPC, Document no: BPC_20_2017_16 and as stated in the assessment report for peracetic acid under PT 2, 3 and 4, hydrogen peroxide is not classed as a second active substance in the case of a biocidal product, however it is a substance of concern (SoC) as active substances from other product types for which a draft final Competent Authority Report is available should be considered as a SoC if they are present in the biocidal product at a concentration ≥ 0.1% (Guidance on BPR Vol IV Parts B+C § 8.1.1). The PNECs for peracetic acid and hydrogen peroxide are presented below:

Source of PNEC: Assessment Report for peracetic acid (August 2016)
https://echa.europa.eu/documents/10162/3e4f6b76-dace-92fa-0d84-43a61a7274b3

Peracetic acid (active substance)	
$PNEC_{aquatic}$	0.069 µg/L
$PNEC_{marine}$	0.0069 µg/L
$PNEC_{sediment}$	0.056 µg/kg sediment
$PNEC_{stp}$	0.051 mg/L
$PNEC_{soil}$ / $PNEC_{terrestrial}$	0.282 mg/kg_{wwt} soil or 0.320 mg/kg_{dwt} soil

log P_{ow} = - 0.60 (pH 7)

PBT assessment: Not P or B is T

A secondary poisoning assessment is not necessary as the log K_{ow} for peracetic acid is <3.

Source of PNEC: Assessment Report for hydrogen peroxide (March 2015) https://echa.europa.eu/documents/10162/f4b6ac51-c4e8-b45c-f7ba-b38f48f3cf67

Hydrogen peroxide (SoC)	
$PNEC_{aquatic}$	12.6 µg/L
$PNEC_{marine}$	12.6 µg/L
$PNEC_{sediment}$*	-
$PNEC_{stp}$	4.66 mg/L
$PNEC_{soil}$ / $PNEC_{terrestrial}$	0.0018 mg/kg_{wwt}

log P_{ow} = - 1.57 (pH 7)

PBT assessment: Not P or B is T

*Not necessary according to CAR (Considering the low n-octanol/water partition coefficient of hydrogen peroxide (log Kow –1.57), the expected low adsorption to organic matter (QSAR based log Koc 0.2036) and its generally rapid abiotic and biotic degradation in surface waters, hydrogen peroxide is not expected to partition into the sediment)

A secondary poisoning assessment is not necessary as the log Kow for hydrogen peroxide is <3.

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

No additional data are required; classification is based on the components in the formulation (see confidential annex for further details).

Further Ecotoxicological studies

Data waiving	
Information requirement	Further Ecotoxicological studies
Justification	No additional data are required.

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

Data waiving	
Information requirement	Effects on other non-target organisms.
Justification	No additional data are required.

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

Data waiving	
Information requirement	Supervised trials.
Justification	No additional data are required.

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

Data waiving	
Information requirement	Acceptance by ingestion.
Justification	No additional data are required.

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

No additional data are required.

Endocrine disrupting potential of co-formulants for non-target organisms

Please refer to section 2.2.9 Assessment of ED properties

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

The products within the family contain a range of a.s. from 1.74% to 15.9% peracetic acid, which exists as an aqueous solution containing peracetic acid, acetic acid, hydrogen peroxide and water. Acetic acid is regarded as a substance of no concern, as it is an Annex I substance under BPR which can be exempted from SoC identification according to the Guidance on BPR Vol. IV Part B and C § 8.1.1 and its presence within the products does not trigger classification and labelling for the environment. In accordance with the decision of the Biocidal Products Committee (BPC, Document no: BPC-20-2017-16), hydrogen peroxide is not classed as a second active substance in the case of a biocidal product, however it is a substance of concern. Therefore, for the environmental risk assessment, both peracetic acid and hydrogen peroxide were assessed separately and the risk of the

products evaluated from the summation of the two substances (one a.s. plus one SoC). Degradation is expected to be extremely rapid for both substances and is considered to occur during transit in sewers and at STP (in line with decisions made for hydrogen peroxide and peracetic acid at EU review).

For product type 2, all products are intended for use as surface disinfection (by spraying or by pouring, followed by wiping for a homogenous distribution) and for use for cleaning in place (e.g. tanks, pipes, filling machines). Both uses include the pharmaceutical and cosmetic industry. All product uses will be indoors only, with indirect exposure to the environment occurring via release of wastewater to drains and transit to STP.

For product type 3, all products are intended for use as surface disinfection (by spraying or by pouring, followed by wiping for a homogenous distribution) and disinfection of equipment (immersion, dipping and soaking). The products are intended for indoor use only. During indoor use, indirect exposure to the environment will occur via release of wastewater to drain as treatment sites will have connection to an STP or via release to the manure/slurry storage and subsequent spreading of the manure/slurry on agricultural land. These products are not intended for use directly to the aquatic environment. The manure and slurry is applied directly to land as fertiliser and assumed to be incorporated below the soil surface. All other exposure is expected to occur via entry down the drain and via STP.

For product type 4, all products are intended for use as surface disinfection (by trigger spray bottle or by pouring (followed by wiping for a homogenous distribution)), for use for cleaning in place (e.g. tanks, pipes, vessels, filling machines), automated spraying within a closed system and for soaking single stage cleaning and disinfection without mechanical action. All uses are for dairies, breweries, beverage and soft drinks industry, and food processing and meat industries (except in slaughterhouses and other processes with blood). The product use will be indoors only, with indirect exposure to the environment occurring via release of wastewater to drains and transit to STP.

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

No new study data have been provided in support of the product application so degradation half-lives of both peracetic acid and hydrogen peroxide have been taken from their respective EU reviews.

Leaching behaviour (ADS)

No leaching study data have been considered relevant to support use of the product family - emissions modelling will follow the approach taken in the EU reviews of hydrogen peroxide and peracetic acid.

Testing for distribution and dissipation in soil (ADS)

No new study data have been provided in support of the product application so degradation half-lives of both peracetic acid and hydrogen peroxide have been taken from their respective EU reviews.

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

No new study data have been provided in support of the product application so degradation half-lives of both peracetic acid and hydrogen peroxide have been taken from their respective EU reviews.

Testing for distribution and dissipation in air (ADS)

No new study data have been provided in support of the product application so degradation half-lives of both peracetic acid and hydrogen peroxide have been taken from their respective EU reviews.

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)

Acute aquatic toxicity

Data waiving	
Information requirement	Acute aquatic toxicity
Justification	No additional data are required.

Chronic aquatic toxicity

Data waiving	
Information requirement	Chronic aquatic toxicity
Justification	No additional data are required.

Measured aquatic bioconcentration

No additional data are required.

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)

No additional data are required.

2.2.8.2 Exposure assessment

The products in the "Airedale 2-15% PAA biocidal product family" all exist as aqueous solutions containing peracetic acid, hydrogen peroxide, acetic acid and water. Peracetic acid is present as the sole active substance at concentrations of 1.74 to 15.9 % w/w. In accordance with the decision of the Biocidal Products Committee (**BPC, Document no: BPC-20-2017-16**), hydrogen peroxide (present at concentrations from 9 to 23 % w/w) is not classed as a second active substance but must be considered to be a substance of concern. No other co-formulants, including acetic acid, are considered of concern for the environment and so no only peracetic acid (a.s.) and hydrogen peroxide (SoC) are included in the environmental exposure assessment.

Products within the product family are for use in PT 2 (disinfectants and algaecides not intended for direct application to humans or animals), PT 3 (veterinary hygiene biocidal products) and PT 4 (disinfectants used in food and feed areas). Application is proposed for use on hard surfaces such as walls, floors and equipment (including clean in place (CIP) where the disinfectant is added to water circulating through pipes and vessels of machines) by trained professional operators. Only indoor use is intended.

- The intended use of the products under Product Type 2 is as surface disinfectants by spraying or by pouring (followed by wiping for a homogenous distribution) on general surfaces, and for use as cleaning in place (e.g. tanks, pipes, filling machines) on general surfaces including the pharmaceutical and cosmetic industry.

- The intended use of the products under Product Type 3 is as surface disinfectants by spraying or by pouring (followed by wiping for a homogenous distribution) on general surfaces and for disinfection of equipment by immersion, dipping and soaking.

- The intended use of the products under Product Type 4 are as surface disinfectants by spraying or by pouring (followed by wiping for a homogenous distribution) on general surfaces; for use as cleaning in place (e.g. tanks, pipes, vessels, filling machines) and for use in soaking single stage cleaning and disinfection without mechanical action, within dairies, breweries, beverage and soft drinks, and food processing and meat industries (except in slaughterhouses and other processes with blood).

General information

Assessed PT	PT 2
Assessed scenarios	Industrial and institutional areas Medical sector – disinfection of rooms, furniture and objects, instruments Chemical toilets
ESD used	ESD for PT 2: Private and public health area disinfectants and other biocidal products (2011) + Supplement (2001) ; ESD for PT 4: Disinfectants used in food and feed areas (2011) ; Relevant refinements / models taken from Technical Agreements in Biocides (TAB, Aug 2018)
Approach	Calculations performed based on the applicant's tonnage data (TONNAGE approach). Calculations performed on a maximum in-use concentration of 1500 ppm (i.e. 1.74 g/l) and a standard application rate for biocidal products (CONSUMPTION approach).
Distribution in the environment	Calculated based on the BPR, Volume IV – Part B+C (2017), (TAB Aug 2018)
Groundwater simulation	No – no groundwater assessment is needed for the rapidly reacting substances peracetic acid and hydrogen peroxide.
Confidential Annexes	Yes Tonnage based calculations are presented in the confidential Annex 1 to Part B.
Life cycle steps assessed	All scenarios Production: No – covered in the EU review Formulation: No Use: Yes Service life: No – a.s. in product is expected to degrade rapidly in service so this assessment is not required
Remarks	A consumption based approach has been used for the risk assessment, with the exception of use in medical rooms and furniture for peracetic acid, which has been performed based on tonnage data provided for Product Type 2. The local emissions to waste water have been calculated using the equations presented in the ESD for Product Type 2, which are incorporated into the ECHA spreadsheets. Additional refinement of the local emissions was performed and are presented in this document.

Assessed PT	PT 3
Assessed scenarios	Disinfection of animal housings Disinfection of vehicles used for animal transport Disinfection of footwear and animals' feet
ESD used	ESD for PT 3: Veterinary hygiene biocidal products (2011) ESD for PT 18: Insecticides for stables and manure storage systems (2006) Technical Agreements in Biocides (TAB, Aug 2018)
Approach	Calculations performed on a maximum in-use concentration of 2000 ppm (i.e. 2,32 g/l) and a standard application rate for biocidal products (CONSUMPTION approach).
Distribution in the environment	Calculated based on the BPR, Volume IV – Part B+C (2017), (TAB Aug 2018)

Groundwater simulation	No – no groundwater assessment is needed for the rapidly reacting substances peracetic acid and hydrogen peroxide.
Confidential Annexes	No
Life cycle steps assessed	All scenarios Production: No – covered in the EU review Formulation No Use: Yes Service life: No – a.s. in product is expected to degrade rapidly in service so this assessment is not required
Remarks	The local emissions to waste water have been calculated using the equations presented in the ESD for Product Type 3. Additional refinement of the local emissions, when required, were performed and are presented in this document.

Assessed PT	PT 4
Assessed scenarios	Disinfection in food, drink and milk industries Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries Disinfection of milking parlour systems
ESD used	ESD for PT 4: Disinfectants used in food and feeds areas (2011) ESD for PT 18: Insecticides for stables and manure storage systems (2006)
Approach	Calculations performed based on the applicant's tonnage data (TONNAGE approach). Calculations performed on a maximum in-use concentration of 1500 ppm (i.e. 1.74 g/l) and a standard application rate for biocidal products (CONSUMPTION approach).
Distribution in the environment	Calculated based on the BPR, Volume IV – Part B+C (2017), (TAB Aug 2018)
Groundwater simulation	No – no groundwater assessment is needed for the rapidly reacting substances peracetic acid and hydrogen peroxide.
Confidential Annexes	Yes Tonnage based calculations are presented in the confidential Annex 1 to Part B.
Life cycle steps assessed	All scenarios Production: No – covered in the EU review Formulation: No Use: Yes Service life: No – a.s. in product is expected to degrade rapidly in service so this assessment is not required
Remarks	The local emissions to waste water have been calculated using the equations presented in the ESD for Product Type 4, which are incorporated into the ECHA spreadsheets. Additional refinement of the local emissions was performed and are presented in this document.

For clarity purposes, all product uses are summarised in the table below, along with the scenarios that allow to cover their emissions to the environment and the maximal in-use concentrations from the approved uses.

Use	Use title	PT	Covered by scenario(s)	Max. in-use dilution (% v/v)
Meta SPC 1 Peracetic Acid 2% **(Max. PAA conc. 2.36% w/w, max. HP conc. 9.9% w/w, density = 1.06 g/mL)**				
1*	CIP, including in pharmaceutical and cosmetic industry	2	4a Use in food, drink and milk industry (entire plants - general scenario - additional scenario) (PT4) 2c Medical equipment (replacement of solution & once-through solution) (PT2) 2f Use in chemical toilets (PT2)	0.1%
2	Surface disinfection by spraying or by pouring (followed by wiping for a homogenous distribution), also in pharmaceutical and cosmetic industries	2	2a Use in industrial areas (application rate) (PT2) 2b Use in industrial areas (consumption based) (PT2) 2c Medical rooms and furniture (PT2)	0.1%
3	Disinfection of inner surfaces (tanks, pipes, vessels, filling machines, …) by CIP	4	4a Use in food, drink and milk industry (entire plants - general scenario - additional scenario) (PT4) 4c Use in milking parlour (PT4)	0.1%
4	Surface Disinfection by spraying or by pouring (followed by wiping for a homogenous distribution, in food/feed industry	4	4b Use in large kitchens and slaughterhouses (application to surfaces) (PT4)	0.1%
5**	Surface Disinfection by dipping in food/feed industry	4	2d Medical equipment - dipping bath (PT2) 2e Other contaminated instruments (PT2)	0.1%
Meta SPC 2 Peracetic Acid 5% **(Max. PAA conc. 5.5% w/w, max. HP conc. 24.38% w/w, density = 1.12 g/mL)**				
1*	CIP, including in pharmaceutical and cosmetic industry	2	4a Use in food, drink and milk industry (entire plants - general scenario - additional scenario) (PT4) 2c Medical equipment (replacement of solution & once-through solution) (PT2) 2f Use in chemical toilets (PT2)	0.15%
2	Surface disinfection by spraying or by pouring (followed by wiping for a homogenous distribution), also in pharmaceutical and cosmetic industries	2	2a Use in industrial areas (application rate) (PT2) 2b Use in industrial areas (consumption based) (PT2) 2c Medical rooms and furniture (PT2)	0.15%
3***	Surface disinfection by spraying or by pouring (followed by wiping for a homogenous distribution)	3	3a Use in animal housing (PT3) 3b Use in animal transport (PT3)	0.2%
4****	Surface Disinfection by dipping	3	3c Use on foot-ware (PT3) 3d Use on animals' feet (PT3)	0.2%

5	Disinfection of inner surfaces (tanks, pipes, vessels, filling machines, …) by CIP	4	4a Use in food, drink and milk industry (entire plants - general scenario - additional scenario) (PT4) 4c Use in milking parlour (PT4)	0.15%
6	Surface Disinfection by spraying or by pouring (followed by wiping for a homogenous distribution)	4	4b Use in large kitchens and slaughterhouses (application to surfaces) (PT4)	0.15%
7**	Surface Disinfection by dipping in food/feed industry	4	2d Medical equipment - dipping bath (PT2) 2e Other contaminated instruments (PT2)	0.15%
Meta SPC 3 Peracetic Acid 15% **(Max. PAA conc. 15.9% w/w, max. HP conc. 25.97% w/w, density = 1.16 g/mL)**				
1*	CIP, including in pharmaceutical and cosmetic industry	2	4a Use in food, drink and milk industry (entire plants - general scenario - additional scenario) (PT4) 2c Medical equipment (replacement of solution & once-through solution) (PT2) 2f Use in chemical toilets (PT2)	0.15%
2	Surface disinfection by spraying or by pouring (followed by wiping for a homogenous distribution), also in pharmaceutical and cosmetic industries	2	2a Use in industrial areas (application rate) (PT2) 2b Use in industrial areas (consumption based) (PT2) 2c Medical rooms and furniture (PT2)	0.15%
3***	Surface disinfection by spraying or by pouring (followed by wiping for a homogenous distribution)	3	3a Use in animal housing (PT3) 3b Use in animal transport (PT3)	0.2%
4*** *	Surface Disinfection by dipping	3	3c Use on foot-ware (PT3) 3d Use on animals' feet (PT3)	0.2%
5	Disinfection of inner surfaces (tanks, pipes, vessels, filling machines, …) by CIP	4	4a Use in food, drink and milk industry (entire plants - general scenario - additional scenario) (PT4) 4c Use in milking parlour (PT4)	0.15%
6	Surface Disinfection by spraying or by pouring (followed by wiping for a homogenous distribution)	4	4b Use in large kitchens and slaughterhouses (application to surfaces) (PT4)	0.15%
7**	Surface Disinfection by dipping in food/feed industry	4	2d Medical equipment - dipping bath (PT2) 2e Other contaminated instruments (PT2)	0.15%

* As no specific CIP scenario for PT2 is available, PT4 CIP scenarios have been assessed to cover this use. The scenario "Assessment of entire plants", based on an average amount of PAA used in a plant and considering both treatment by an on-site and an off-site STP, was also used in the CAR of PAA to cover CIP in PT2. The "General scenario is a worst-case for the off-site STP (assumes a daily use of 600L working solution, 100% to the sewer system). Furthermore, the PT2 scenarios " Use in chemical toilets" (assumes an emission of 666L diluted product a day) and "Other contaminated instruments" (assumes the use of 250kg peracetic acid per year with 1 release every 4 days) have been evaluated as well as this scenarios presume an even higher daily emission to the sewer.

** At the time this application was submitted, no PT4 scenarios for dipping were available yet. Therefore, the dipping scenarios for PT2 have been assessed to cover the use for PT4 dipping: "Medical equipment - dipping bath" (assumes a volume of 30x10L diluted product a day) and "Other contaminated instruments" (2.5kg PAA/day, diluted to max. 1.74 g/l corresponds to an emission of 1436.8l/day). Meanwhile a PT4 scenario for dipping was published (TAB ENV 217 (02.02.2021), considering an emission of 5x100L diluted product per day). Since the PT2 scenario Other contaminated instruments is worst-case, it was not deemed necessary to include this scenario.

*** This use includes surface disinfection of equipment as well, for which the scenario "Dipping of tools" (TAB ENV 55) seems most appropriate to estimate environmental emissions (scenario overlooked in the early evaluation phase). However, as the scenarios "Use in animal housing" and "Use in animal transport" were already assessed and worst case, a separate calculation for disinfection of equipment was not performed.

**** 2 PT3 dipping scenarios "Use on foot-ware" and "Use on animals' feet" were presented to cover this usage, of which Use on animals' feet represents the worst case. The intended use is disinfection of equipment to run a stable (e.g. cluster equipment for teat disinfection). However, there exists a PT3 scenario "Dipping of tools" (TAB ENV 55, presumes a daily volume of 100 L working solution to the sewer) that is specifically developed for this type of applications and has not been taken into account (overlooked in the early evaluation phase). Since the scenario Use on animals 'feet is by far the worst-case (2x 675 L, 90% reaching the sewer =1215L working solution per day), it was not considered necessary to add this scenario after all.

Emission estimation

Products within the "Airedale 2-15% PAA biocidal product family" will be supplied in pack sizes of 5 L, 25 L, 30 L, 200 L and 1000 L. For PT 2, a default application of 1000 m^2 per day was used in the environmental risk assessment for the large scale uses. For PT 3, default values are available for housing sizes for different animal categories are available, up to a maximum size of 8040 m^2. For PT 4, realistic worst case assumptions of 10,000 m^2 for the area of slaughterhouses (based on slaughterhouse size combined with the size of the areas to be disinfected) and 2000 m^2 for kitchens and canteens (area of largest example kitchen or canteen, doubled) were chosen. One application per day was assumed, unless otherwise stated. The products are intended to be diluted in water, to a maximum concentration of 1500ppm (i.e. 15ml/l, considering the maximum relative density of the products containing 15% peracetic acid (density of 1.16) this corresponds to 1.74 g/l) for PT2/PT4 and 2000 ppm (i.e. 2 ml/l, considering the relative density this corresponds to 2.32g/l) for PT3. In the absence of a specified application rate, a rate of 0.1 L/m^2 was assumed as a worst case default application rate as suggested in the TAB for PT 2 and PT 4; the same approach was taken for PT 3 products for consistency. The application rate of 0.1 L/m^2 is in line with the value recommended in the TAB for PT 2 for large scale uses where no application rate is specified. The corresponding "worst case" maximum concentration of hydrogen peroxide was calculated to be 7667ppm (i.e. 8.59 g/l) for PT2/PT4 and 10222 ppm (i.e. 11.45g/l) for PT3, which occurs on dilution of the products containing 5% peracetic acid, with a relative density of 1.12, to 1500ppm or 2000 ppm.

The air compartment is considered not to be a compartment of concern for either peracetic acid or hydrogen peroxide, when the product is used indoors as a water based solution. The ESD for PT 2 assumes that where a biocidal active substance could be released to air indoors within the industrial premises, it is likely to settle on a surface and be subject to wet cleaning. As a result, a worst case default F_{water} of 1 has been used in the assessment. It is stated in the Doc II-A of the EU review that peracetic acid has a DT_{50} of 22 minutes indoors in air and therefore is not expected to persist in air. In addition, Doc II-A and Doc II-B of the Final CAR for hydrogen peroxide concluded that emissions to air from indoor applications would be negligible in the absence of heating or pressurised spraying operations. The low Henry's Law constant of 7.5E-4 Pa/m^3/mol (at 20 °C) means that hydrogen peroxide would not be expected to evaporate from aqueous solutions. Airborne concentrations at STP will be calculated using $Fstp_{air}$ fractions derived using SimpleTreat 4.0 to calculate likely levels 100 m away from a point source.

Environmental risks to the soil compartment are considered negligible as well: due to the high reactivity of peracetic acid and hydrogen peroxide, and the high organic matter content of both STP sludge and liquid manure, PAA and HP are not expected to persist in relevant concentrations until the sludge or the manure are applied to agricultural soil. A further quantitative assessment is not deemed necessary.

As discussed in the ENV WG (WG-III-2019 for HP and WG-III-2020 for PAA), also no groundwater assessment is needed for the rapidly reacting substances PAA and HP.

Calculations

For Product Type 2, the local emissions to waste water using the annual tonnage data of the products in the EU have been calculated, in accordance with the ESD, for general purpose (tiles, floors, sinks) and lavatories uses in industrial scenarios. Tonnage based assessment has been undertaken in line with the simplistic model presented in Table 3 of section 2.1.4.2 of the 2011 ESD for PT 2 and in Table 3.5 in section 3.3.2 of the ESD for PT 2 (RIVM report 601 450 008 ([redacted], 2001)). As a worst case assumption, the amount of peracetic acid content was assumed to be 15,9% of the product tonnage, and the amount of hydrogen peroxide was assumed to be 25,97%.

The 'break even' tonnage was calculated for peracetic acid and hydrogen peroxide, based on the working concentrations of 0.00174 kg/L and 0.00859 kg/L, respectively. The calculations are presented in the confidential annex at the end of this document.

As the supplied tonnage data for the products as Product Type 2 exceeds the 'break even' tonnage, the local emissions to waste water were calculated based on both the tonnage data and the consumption data. On comparison with the local emissions to waste water values calculated based on consumption use, the values produced based on tonnage data were lower for all scenarios, except for use in medical rooms and furniture for peracetic acid. Therefore, with the exception this scenario, a consumption based approach was taken for the risk assessment.

The local emissions for the active substance peracetic acid and the substance of concern hydrogen peroxide to water and air (where applicable) before pre-treatment following use of the products as product types 2, 3 and 4 were calculated.

Degradation in the sewer system for discharges to drain

Elocal values were refined based on degradation of peracetic acid and hydrogen peroxide in the sewer system.

Studies provided in the CAR demonstrate that peracetic acid decomposes rapidly when in contact with metal cations or organic matter, both of which are considered likely to be present in high concentrations in raw sewage in the facility drain or in waste water collecting tanks. It is therefore considered that degradation of peracetic acid in raw sewage is likely to occur and that this is a suitable refinement in relevant emission estimations. In Doc II-B of the PT 1-6 review of peracetic acid (Table 8.3-1), it is reported that the DT_{50} value in the effluent stream (transferable to sewer systems) is 9.48 minutes when normalised to 12 °C, equating to a k rate of 4.38 h^{-1}. For the Product Type 2 and Product Type 4 emissions to STP, refinements of peracetic acid were performed to take into account the degradation in sewage effluent. The calculation was performed manually on the local emission to waste water for peracetic acid.

Additionally, Table 8.3.1-1 in Doc II-B of the PT 1 – 6 review for hydrogen peroxide reports a DT_{50} in effluent stream of 6 min at 20 °C (11.38 min when normalised to 12 °C) – this equates to a *k* rate of 3.65 h^{-1}.

It was further reported that normalised *k* rates (at 12 °C) were used in sewer system modelling as this was considered to best represent the likely temperature in drains during

transit to STP. Furthermore, a sewer residence time of 1 h is recommended as default value, based upon the assumptions that :

- the average distance between the point of release into the drain and local STP is approximately 4.5 km ;
- the estimated flow rate in the municipal canal sewer system is assumed to be approximately 1.5 km in 20 min (i.e. 4.5 km/h).

The amounts of peracetic acid and hydrogen peroxide that arrive at local STP after one hour residence time in the sewer system (Mt1) can be calculated assuming first order kinetics using the following equation:

$Elocal_{compartment(final)} = Elocal_{compartment(initial)} \times e^{(-kt)}$

Where:
$k = ln(2)/DT_{50}$ (degradation constant of peracetic acid in sewage effluent, DT_{50} = 9.5 min)
$k = ln(2)/DT_{50}$ (degradation constant of hydrogen peroxide in sewage effluent, DT_{50} = 11.38 min)
t = 60 minutes (1 hour – from ESD for PT 5)

$Elocal_{compartment(final)} = Elocal_{compartment(initial)} \times 0.01255$ (peracetic acid)
$Elocal_{compartment(final)} = Elocal_{compartment(initial)} \times 0.02587$ (hydrogen peroxide)

The final local emission values to water (and air) for the active substance peracetic acid and the substance of concern hydrogen peroxide have been calculated using the above equation and are presented in the following Elocal tables as 'refined'.

Calculations for each product type

A brief summary of each usage pattern and the input parameters used to calculate Elocal values are presented below.

PT 2

PT 2 biocidal products are used for disinfecting air, surfaces, materials, equipment and furniture not used for direct food or feed contact in private, public and industrial areas (including hospitals). Uses relevant to the biocidal product family include walls and floors in health and other institutions, chemical toilets, waste water and hospital waste.

It is stated in the 2011 PT 2 ESD that: "*Surface disinfection in industrial, institutional and primary health care areas is usually done on a regular basis (daily) by using a ready-for-use product (e.g. wipe, trigger spray) or using a diluted concentrate which can be applied*

by scrubbing, mopping or wiping. The post-application includes either wiping the surfaces or letting them dry." This treatment regime outlined in the ESD summarises the proposed use pattern of the "Airedale Product Family" at PT 2 industrial premises.

As indicated within section 2.1.4.1 of the PT 2 ESD (2011), "*Industrial premises such as biotechnology plants, production plants for pharmaceuticals, cosmetics or toiletries or production plants for computers are considered as local point sources which release their waste water to a local STP (Sewage Treatment Plant). Surfaces to be disinfected in such industrial premises can greatly vary. They can be surfaces of the rooms themselves (2 m² up to > 200 m²) such as floors, walls and ceilings, or smaller surfaces (< 2 m²) such as furniture, equipment, working places, isolator benches etc. The largest surface area to be disinfected in industrial premises was identified to be 1,000 m².*

Nappl: Since disinfection can take place from "after each use" to "monthly", one disinfection per day is considered a reasonable default value.

AREAsurface: The variation in the size of the surface area to be disinfected is quite high and depends on the nature and size of the industrial plant. Based on the above summarised information on sizes of treated surfaces (< 2 m² to 1,000 m²), it is assumed that a default surface area of 1,000 m² to be disinfected on a daily base in an industrial plant (including room floors and walls, furniture and working places) is a reasonable default value representing a worst case."

- **Disinfection of industrial and institutional areas**: Airedale biocide products will be applied by spraying (trigger spray and wipe) scrubbing, mopping or wiping, before rinsing the surfaces, wiping the surfaces or letting them dry post-application. As a periodic treatment, fumigation involving the evaporation of a disinfection liquid in a room can also be applied, usually in hospitals, but this is no intended use. Surfaces disinfected include floors, walls, ceilings or smaller surfaces such as furniture, equipment etc. The largest surface area to be disinfected was identified to be 1,000 m^2 (SCC, 2008) and this is assumed to be a reasonable default value representing a worst case. Since disinfection in industrial areas can take place from 'after each use' to 'monthly', one disinfection per day is considered to be a reasonable default value. The main emission pathway is to the sewer system. Degradation of the substance during disinfection is not considered in a first tier release to waste water (Fwater) giving a default of 100 %, but this can be reduced if data are available to justify a reduction. In institutional and private health areas, it is assumed that disinfection takes place only during the working week. Temission

was adapted accordingly to 260 days per year. Also for institutional areas, the factor Fdis describing the amount of substance disintegrated during or after application was included.

Parameters (Table 2 of PT 2 ESD)	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*
Application rate of biocidal product [2]	Vform	0.1	$L.m^{-2}$	S
Concentration of active substance in the product (peracetic acid)	Cform	1.74	$g.L^{-1}$	S
Concentration of substance of concern in the product (hydrogen peroxide)	Cform	8.89	$g.L^{-1}$	S
Surface area to be disinfected	$AREA_{surface}$	1000	m^2	D/P

1) S: data set; D: default; O: output; P: pick list

2) TAB, Aug 2018, ENV 26

- **Medical sector for disinfection of rooms, furniture and objects**: Before disinfection, normal domestic cleaning is always carried out with disposable cloths and soap or synthetic detergents. The surfaces are then treated with a disinfecting solution at the on-label rate so that surfaces remain wet for at least 5 minutes and then allowed to air-dry. It is assumed that any disinfectant present in the fraction of the solution remaining on the surfaces will remain there until it is degraded, transported via contact or evaporated. The rapid degradation of both peracetic acid and hydrogen peroxide means that it is unlikely that substantial amounts will remain on the surface next time it is cleaned and transferred to wastewater and subsequently to the sewer from the previous cleaning operation.

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*
Concentration at which active substance is used (peracetic acid)				
Sanitary purposes	C_{san}	0.00174	$kg.L^{-1}$	S
Brushes	C_{obj}	0.00174	$kg.L^{-1}$	S
Concentration at which substance of concern is used (hydrogen peroxide)				
Sanitary purposes	C_{san}	0.00859	$kg.L^{-1}$	S
Brushes	C_{obj}	0.00859	$kg.L^{-1}$	S

1) S: data set; D: default; O: output; P: pick list

- **Disinfectants used in the medical sector for disinfection of instruments:** Disinfecting of instruments such as endoscopes (usually referred to as scopes) is conducted in automated washers/disinfectors in most hospitals, with manual disinfection carried out where patient turnover is low. The ESD assumes use of the

automated washers as these are most common. Waste water from the washers, including the disinfectant, is released into the sewer. Washers also have exhaust hoods and ventilation systems to prevent the loss of volatile disinfectants and volatilisation processes are ignored in the model for substances with Henry coefficients <0.03 Pa m^3 mol^{-1} (noting that peracetic acid has a Henry's Law Constant of 0.217 Pa m^3 mol^{-1} at 20 °C). Other instruments are disinfected in solutions (or suspensions) of disinfectants with the baths also discarded into the sewer after use; where both washers and baths are used the emission for a single point source (one hospital) should be calculated by summing the results of both emission scenarios.

Three different scenarios are considered. A replacement system is where the disinfectant in the washer/disinfectant is replaced at regular intervals, frequently every 14 days. Disinfectant declines during use due to dilution, carry-over on scopes removed from the washer, volatilisation and decomposition. In a once-through system, a fresh disinfectant solution is applied every disinfectant operation and then discarded into the sewer after use. Due to the short residence time, degradation is ignored in the once-through system. Operation 365 days per year is assumed. A third scenario, dipping is also modelled, in which instruments are disinfected locally in baths which are then disposed of into the sewer, as occurs in out-patient departments. The dipping scenario assumes 100 replacements of 250 kg active substance per year, with negligible volatilisation and the possibility to correct for degradation if required.

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P* [1]
Disinfection system	-	Replacement/ once-through/ dipping	-	P
Working concentration of active ingredient peracetic acid	Cdisinf	0.174	%	S
Working concentration of substance of concern hydrogen peroxide	Cdisinf	0.859	%	S
Volume of solution in machine/dipping bath	Qmachine_bath	100	m^3	P/D

1) S: data set; D: default; O: output; P: pick list

Other contaminated instruments:

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P* [1]
Rate constant for chemical conversion peracetic acid	$kdeg_{disinf}$	0	d^{-1}	S

Rate constant for chemical conversion hydrogen peroxide	$kdeg_{disinf}$	0	d^{-1}	S

1) S: data set; D: default; O: output; P: pick list

- **Disinfection of chemical toilets**: Chemical toilets are installed on transport vehicles (aircraft, buses, boats, caravans, recreational vehicles) and at temporary sites where there is no direct connection to the sewer system. Waste is collected in tanks and sanitary additives containing biocides are added for disinfection and reduction of odour. The contents of the tanks may be discharged directly into the sewer system or collected by professional operators and transferred to a municipal STP. The release of disinfectant to the influent of the STP (Finfluent) is by default 100 %, but can be reduced if data are available justifying such a reduction. Disintegration (Fdis) of a substance during or after application is by default 0 %, but can be increased if data are available to justify changing this parameter.

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*
Fraction of active substance in the biocidal product (peracetic acid)	Fform	0.15	[-]	S
Fraction of substance of concern in the biocidal product (hydrogen peroxide)	Fform	0.256	[-]	S
Density of the biocidal product (peracetic acid)	RHO_{form}	1.16	$kg.L^{-1}$	S
Density of the substance of concern (hydrogen peroxide)	RHO_{form}	1.12	$kg.L^{-1}$	S
Amount of biocidal product per litre pre-charge liquid in a chemical toilet (peracetic acid)	Vform	0.01	$L.L^{-1}$	S
Amount of biocidal product per litre pre-charge liquid in a chemical toilet (hydrogen peroxide)	Vform	0.03	$L.L^{-1}$	S

1) S: data set; D: default; O: output; P: pick list

PT 3

Biocidal products in product type 3 are used for disinfection for the purpose of veterinary hygiene in areas where animals are housed, kept or transported. PT 3 products control animal pathogens, prevent animal diseases, increase production and improve the quality of animal products. The risk assessment covers the proposed normal use of the biocidal product together with a 'realistic worst case scenario'. All products are assumed to be professional use.

Only the release pathway to waste water is taken into account, as due to the high reactivity of peracetic acid and hydrogen peroxide releases to manure/slurry, air and land (from the spreading of manure/slurry) can be considered negligible.

It is generally prohibited in Europe to discharge waste water containing slurry to the public sewer, although local authorities might allow livestock farms to discharge diluted waste streams to the public sewer if they are able to treat the extra pollution load. So liquid waste containing manure is either removed to a slurry or waste water collection tank and may be subsequently applied to land or treated in a communal or on-farm waste water treatment plant (WWTP). Emission routes for the on-farm WWTP are considered the same as for direct discharge to a communal WWTP. The fraction of biocide reaching the manure/slurry storage system depends on the animal species and the category considered (i.e. the type of housing and slurry collection system).

The ESD for PT 18 Emission Scenario Document for Insecticides for Stables and Manure Storage Systems was used as a basis for the ESD for PT 3 since the scenarios are very similar and the emission paths almost identical.

Please see PT 4 for a scenario for disinfection of milking parlours.

- **Disinfection of animal housings:** after the animals have been moved out, the area is thoroughly cleaned and then disinfectants are applied by spraying surfaces with high or low pressure equipment. The main emission pathways are into the slurry/manure system and to the air; in addition 6 out of 18 animal housing types will result in a contribution to STP. The models assume that all internal surfaces could be sprayed (unless specified not to be the case at Tier 2). Default values for different animal categories and the respective data on housing sizes, animal numbers, number of disinfection events and slurry production are available.

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*
Content of active ingredient in formulation (product) (peracetic acid)	Fbioc	2.32	$g.L^{-1}$	S
Content of substance of concern in formulation (product) (hydrogen peroxide)	Fbioc	11.45	$g.L^{-1}$	S
Amount of (undiluted) product prescribed to be used per m²	$Vprodi_{1,i2,i3}$	0.1	$L.m^{-2}$	S
Dilution factor (for preparation of the working solution from the formulation (product))	Fdil	1	[-]	S
Fraction of active ingredient/SoC released to the STP	Fstp_i1,i2,i3,i4	0.2	[-]	D^2 (table 10 ESD PT3

1) S: data set; D: default; O: output; P: pick list
2) According to ESD PT18 No. 14, release fractions vary with the way of application. Default values for release to STP in table 10 in ESD PT3 are based on the estimates for application by spraying in ESD PT18 No. 14. Besides application by spraying also application by pouring is an intended application way of the Airedale product family. However, according to table 5.4 of ESD PT18 No. 14 application by pouring, which is comparable with sprinkling, results in a lower release fraction to the STP and a higher release fraction to manure/slurry compared to spraying. Consequently, the default 0.2 is the worst-case release fraction to the STP.

- **Disinfection of vehicles used for animal transport:** this may relate to either transport of animals from farm to slaughter house, or transport of animals from one farm to another. After each transport, trucks and transport boxes (for poultry) are cleaned and disinfected. Slaughter houses are normally specialised and distinction is made between mammals and poultry; additional disinfection of transport boxes should also be considered for poultry. Exposure is therefore calculated for the transport of mammals and poultry separately. Cleaning and disinfection are performed on special sites on the premises of the transport companies or slaughter houses. Disinfection is assumed to occur once per day on seven days per week (large slaughter houses slaughter every day). The main emission pathway is emission to waste water, but emission to air may also occur.

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*
Content of active ingredient in formulation (product) (peracetic acid)	Fbioc	2.32	[$g.L^{-1}$]	S
Content of substance of concern in formulation (product) (hydrogen peroxide)	Fbioc	11.45	[$g.L^{-1}$]	S
Amount of undiluted product prescribed to be used per m2	Vprod	0.1	[$L.m^{-2}$]	S
Dilution factor	Fdil	1	[-]	S

1) S: data set; D: default; O: output; P: pick list

- **Footwear:** Workers walk over a mat soaked with disinfectant solution or through a tub containing the disinfectant. The tubs have a bigger volume than the mats and therefore the tubs are considered to be more conservative (i.e. worst case). It is assumed that there is one tub located at the entrance to the animal housing containing 10 L, which is replaced once per day. The remaining solution in the

footbath is either discharged to waste water or to manure. Emission to air is considered to be negligible, taking into account the low surface area of the tub and that the solution is only stirred up a few times per day.

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*
Relevant emission stream	stream (i4)	1	[-]	P (Appendix 1: Table 7)
Content of active ingredient in formulation (product) (peracetic acid)	Fbioc	2.32	[$g.L^{-1}$]	S
Content of substance of concern in formulation (product) (hydrogen peroxide)	Fbioc	11.45	[$g.L^{-1}$]	S
Dilution factor	Fdil	1	[-]	S

1) S: data set; D: default; O: output; P: pick list

- **Disinfection of animals' feet:** the hooves of dairy cows in particular are disinfected for hygiene reasons on their way to or from the milking parlour. Hoof disinfectant is further recommended twice per week during the dry period of the cows (both disinfections may be on the same day of the week). The disinfectant is not rinsed off the hooves. It is recommended that the disinfectant in the bath is replaced following a maximum of 100 walking-through events. While the disinfection of hooves of other animals also occurs, this is less frequent than for dairy cows and therefore considered to be less worse case. A herd size of 100 dairy cows, a milking frequency of twice per day and a tub content of 675 L replaced after 100 walk-through events are assumed. Leftover disinfectant may be discharged into the slurry system or into waste water. Discharge to slurry is most common. Disinfectant occurring twice on one day per week is a worst case for STP and therefore this was chosen as the worst case in general, noting that this does not make a difference to the exposure via manure. Emission to the air may also occur.

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*
Relevant emission stream	stream (i4)	1	[-]	P (Appendix 1: Table 7)
Volume of the reservoir (tub)	Vreserv	1350[2]	[l]	D (Appendix 1: Table 7)
Content of active ingredient in formulation (product) (peracetic acid)	Fbioc	2.32	[$g.L^{-1}$]	S
Content of substance of concern in formulation (product) (hydrogen peroxide)	Fbioc	11.45	[$g.L^{-1}$]	S

Dilution factor	Fdil	1	[-]	S
Number of days with disinfectant applications in one year	Napp-bioc	104	[-]	D
Time interval between two applications (tub fillings)	Tbioc-int	7	[d]	D
Number of animals in housing for dairy cows	Nanimal	100	[-]	P (Appendix 1: Table 8)

1) S: data set; D: default; O: output; P: pick list
2) Tub size is 675 L, but hooves may be disinfected twice per week on the same day, so tub size is doubled and time interval between applications is set to 7

PT4

PT 4 biocides are used for disinfection of food and feed areas, including equipment, containers, consumption utensils, surfaces or pipework during production, storage or consumption of food, feed and rink for humans and animals. Biocides are used to reduce the level of potential food pathogens, minimise the risks of food-borne diseases and to avoid the spoilage and deterioration of food and feed. The risk assessment covers the proposed normal use of the biocidal product together with a 'realistic worst case scenario'.

As a first tier to maintain a conservative approach, degradation of the active substance is not considered and Fdis is set to 0; degradation can be considered as a higher tier approach where data is available to support this approach.

- **Disinfection in food, drink and milk industries (FDM):** this is a very diverse sector. Installations must comply with food safety and hygiene regulations, which define the frequency of biocide applications and sometimes the products used. Physical cleaning is always conducted before application of the biocide. Disinfection is typically conducted by low and high pressure spraying, soaking and brushing, clean in place (CIP) where the disinfectant is added to water circulating through pipes and vessels of machines.

  The exposure of environmental compartments to biocides depends on the method of disinfection used. Disinfectants applied by soaking, brushing or CIP are mostly discharged to a sewage treatment plant. There may also be some emission to air, although mechanisms are implemented to reduce this. Due to the high levels of fats, oil and grease the waste water is usually pre-treated before release to the environment. According to the Environment Agency of England and Wales, 2000, the main options of discharging waste water are to an off-site STP without treatment or after partial treatment, to a watercourse after full on-site STP or off-site re-use of some waste water, e.g. as a feed stream in another industry or for irrigation.

Two scenarios are assessed in the ESD: a general scenario for disinfecting milk extraction systems and one developed based on industry survey data in which the same disinfectant is used at several different points and by different application methods in a plant before being released from the same point source. In the second case, a brewery was taken to be the worst case as a lower water volume results on a higher biocide concentration; this was combined with treatment at either an on-site or off-site STP. As a refinement for the on-site STP, elimination during wastewater treatment is taken into account: a 1 hour residence time and $DT_{50\ STP}$ is assumed.

Assessment of entire plants (e.g. breweries, dairies, beverage processing plants)				
Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*
Amount of biocidal active substance used per year in the local plant (peracetic acid)	Qai	407	$kg.yr^{-1}$	P (Table 6 in ESD for PT4)
Amount of biocidal substance of concern used per year in the local plant (hydrogen peroxide)[2]	Qai	2080.1	$kg.yr^{-1}$	P

1) S: data set; D: default; O: output; P: pick list
2) Based on PAA amount, converted on equivalent content factor of 5.111 (maximum ratio of HP/PAA that occurs with products containing 5% PAA).

General scenario for drink and beverage industry, dairy industry, breweries				
Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*
Concentration of active ingredient peracetic acid	Cform	1.74	$g.L^{-1}$	S
Concentration of substance of concern hydrogen peroxide	Cform	8.59	$g.L^{-1}$	S
Volume of disinfectant used for cleaning of the installation, process lines[2]	$Vform_{inst}$	100	L	S
Volume of disinfectant used for cleaning of the mixing tanks[2]	$Vform_{mix}$	100	L	S
Volume of disinfectant used for cleaning of the storage tanks[2]	$Vform_{tank}$	100	L	S
Number of application per day	Nappl	2	d^{-1}	S

1) S: data set; D: default; O: output; P: pick list
2) $Vform_{tank}$=100 L each (value provided by the applicant). No value is given in the TAB and the ESD states that further research is needed to define a default value for Vform. For the application methods given 2x100 L is high and so this is considered to be protective of the proposed uses.

- **Disinfection in slaughterhouses and butcheries:** disinfection in slaughterhouses and butcheries occurs mainly as a surface treatment applied by high/low pressure spraying, foaming, soaking and manual brushing. CIP is used only in exception cases. The ESD differentiates between heavily and less heavily

soiled areas, which triggers the amount and frequency of disinfection. Disinfection occurs daily in some areas and weekly in other areas.

Disinfection in large scale catering kitchens and canteens: (e.g. restaurants, hotels, houses for the elderly and hospitals) disinfection is mainly performed by wiping, soaking or manual brushing. Disinfection may occur 1-2 times per day for some areas.

The main route of emission is to the sewer system. Waste water from slaughterhouses and butcheries has a high organic load and so is usually pre-treated prior to release. Waste water from large scale catering kitchens and canteens is often diluted with other waste water streams from the proximity of the kitchen or canteen and so pre-treatment is not usually required.

Local emissions are calculated based on the application rate per m^2 and the area of the treated surface. The surface area disinfected is largest in the large scale catering kitchens and slaughterhouses and is therefore considered to be the worst case. Due to the variety in frequency of application and areas treated, realistic worst case assumptions of 10,000 m^2 for the area of slaughterhouses (based on slaughterhouse size combined with the size of the areas to be disinfected) and 2000 m^2 for kitchens and canteens (area of largest example kitchen or canteen, doubled) were chosen and combined with a single application per day. The number of applications on the product label however is 2 and so 2 applications are assumed. It is assumed that only one slaughterhouse, kitchen or canteen discharges to the STP. It is also assumed that 100 % of the disinfectant is released to waste water, but factors for elimination of the substance during pre-treatment of the waste water before release to the STP or disintegration of the substance during or after application can be included if there is data to support them.

The product label states that for applications by spraying and wiping in large scale catering kitchens, canteens, slaughterhouses and butcheries, the worst case number of applications per day is 2. The TAB states that where no application rate is provided, a default of 0.1 L/m^2 should be used for large scale PT 4 uses.

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*
Type of application	[-]	spraying/wiping	[-]	P
Size of the area treated	[-]	Large scale	[-]	P
Application rate of the active substance peracetic acid[2]	Qai_{appl}	0.174	g/m^2	S
Application rate of the substance of concern hydrogen peroxide[2]	Qai_{appl}	0.859	g/m^2	S

Number of applications per day	Nappl	2	d^{-1}	S (Product label)

1) S: data set; D: default; O: output; P: pick list
2) Application rate of 0.1 L/m^2 (from TAB, Aug 2018) and working solution concentrations of 1.74 g/L for peracetic acid and 8.59 g/L hydrogen peroxide

- **Disinfection of milking parlour systems:** disinfection of milking parlours is conducted using CIP, where the disinfectant is added to the circulating water and pumped through the equipment. Emission usually occurs to the sewer system on larger or smaller, modern farms, but can occur to manure on smaller older farms; it is therefore assumed in the ESD that emission from milking parlour systems is to the sewer system. Emissions to air are considered to be negligible.

  Default volumes have been adopted of 45 L for the milk storage tank and 65 L for the milk installation. The milk installation is cleaned twice a day and the milk tank is cleaned once every 3 days. The worst case is therefore the day when both the milk installation and milking tank are cleaned.

  Fraction released to waste water was assumed to be 100 % at the first tier, with a reduction based on data, e.g. from monitoring at the higher tier, if this can be justified based on available information. Disintegration is also assumed to be 0 % at the first tier, but higher tier approaches can be used if supporting data is available. No degradation of peracetic acid or hydrogen peroxide and 100 % release to waste water were assumed in the calculation.

Variable/parameter	*Symbol*	*Value*	*Unit*	*S/D/O/P [1]*
Concentration of active ingredient peracetic acid	Cform	1.74	$g.L^{-1}$	S
Concentration of substance of concern hydrogen peroxide	Cform	8.59	$g.L^{-1}$	S

1) S: data set; D: default; O: output; P: pick list

Resulting local emission to relevant environmental compartments for the active substance peracetic acid (PAA) and substance of concern hydrogen peroxide (HP)					
Scenario	**Local emission ($Elocal_{compartment}$) to wastewater and air [kg/d]**				**Remarks**
	Default		**Refined for degradation in effluent stream**		
	PAA	**HP**	**PAA**	**HP**	
Product Type 2					
2a Use as surface disinfectant in industrial premises [ESD PT2 JRC 2011, Section 2.1.4.1, Table 2, p.12 & TAB ENV 24, Sept 2015]					Based on - working solution concentration 1500 ppm (PAA) 7667 ppm (HP) equivalent to Cform=1.74g/l (PAA) (assuming product density of 1.16) and 8.59 (HP) g/L (assuming product density of 1.12) - worst-case use rate of working solution Vform= 0.1 L/m^2 for large scale application[#]
- Large scale application	0.174 wwater	0.859 wwater	0.0022 wwater	0.0222 wwater	
- Small scale application (RTU)	-	-	-	-	Covered by worst-case use

Resulting local emission to relevant environmental compartments for the active substance peracetic acid (PAA) and substance of concern hydrogen peroxide (HP)					
Scenario	**Local emission ($Elocal_{compartment}$) to wastewater and air [kg/d]**				**Remarks**
	Default		**Refined for degradation in effluent stream**		
	PAA	**HP**	**PAA**	**HP**	
2b Use as surface disinfectant in institutional areas [ESD PT2 JRC 2011, Section 2.1.4.2, p.16 & Appendix 1]					A consumption based approach selected as it was found to be the worst case approach.
- Sanitary use/ General purpose (tiles, floors, sinks)	0.0435 wwater	0.215 wwater	-	-	Covered by worst-case combined use (below)
- Sanitary use/ Lavatory	0.0174 wwater	0.0859 wwater	-	-	Covered by worst-case combined use (below)
- Combined Sanitary use/ General purpose (tiles, floors, sinks) and Lavatory	0.0609 wwater	0.301 wwater	0.000764 wwater	0.00778 wwater	Based on - working solution concentration 1500 ppm (PAA) 7667 ppm (HP) equivalent to Cform=0.00174 (PAA) kg/l (assuming product density of 1.16) and 0.00859 (HP) kg/L (assuming product density of 1.12)
2c Disinfectant use in the medical sector for disinfection of rooms, furniture and objects [ESD PT2 RIVM 2001, § 3.3, p.17]					A tonnage based approach was selected for peracetic acid and a consumption based approach was selected for hydrogen peroxide as worst case approaches.
- Sanitary purposes	-	0.118 wwater	-	-	Covered by worst-case combined use (below)
- Objects	-	0.204 wwater	-	-	Covered by worst-case combined use (below)
- Combined Sanitary purposes and Objects	Please refer to the Confidential Annex	0.322 wwater	Please refer to the Confidential Annex	0.00833 wwater	Based on working solution concentration 1500 ppm (PAA) and 7667 ppm (HP) equivalent to C_{san} = C_{obj}=0.00174 (PAA) (assuming product density of 1.16) and 0.00859 (HP) kg/L (assuming product density of 1.12)

Resulting local emission to relevant environmental compartments for the active substance peracetic acid (PAA) and substance of concern hydrogen peroxide (HP)					
Scenario	**Local emission ($Elocal_{compartment}$) to wastewater and air [kg/d]**				**Remarks**
	Default		**Refined for degradation in effluent stream**		
	PAA	**HP**	**PAA**	**HP**	
2d Used in hospitals for disinfection of scopes and other articles in washers/disinfectors [ESD PT2 RIVM 2001, Section 3.4.1, Table 3.7, p.25 & TAB ENV 23, Sept 2015, scenario for Dipping disinfection system]					Based on - working solution concentration 1500 ppm (PAA) and 7667 ppm (HP) equivalent to C_{disinf}=0.174% (PAA) and 0.859% (HP)
- Replacement system	0.424 wwater	2.09 wwater	0.00532 wwater	0.0541 wwater	
- Once through system	0.0522 wwater	0.258 wwater	0.000655 wwater	0.00667 wwater	
- Dipping system	0.522 wwater	2.58 wwater	0.00655 wwater	0.0655 wwater	
2e Used in hospitals for disinfection of other contaminated instruments [ESD PT2 RIVM 2001, Section 3.4.2, Table 3.8, p.26]	2.5 wwater	12.778 wwater	0.0314 wwater	0.331 wwater	Based on - Amount of active substance $Qyear_{disinf}$ = 250 (PAA, default) and 1277.8 (HP converted on equivalent content factor of 5.111) kg/year

Resulting local emission to relevant environmental compartments for the active substance peracetic acid (PAA) and substance of concern hydrogen peroxide (HP)					
Scenario	**Local emission ($Elocal_{compartment}$) to wastewater and air [kg/d]**				**Remarks**
	Default		**Refined for degradation in effluent stream**		
	PAA	**HP**	**PAA**	**HP**	
2f Disinfection of chemical toilets [ESD PT2 JRC 2011, Section 2.4, Table 7, p.29]	1.16 wwater	5.73 wwater	0.0146 wwater	0.148 wwater	Based on - Fraction of active substance in the biocidal product Fform= 0.15 (PAA – 15%) , no unit, and Density of the biocidal product RHO_{form} = 1.16 kg/L (based on "Peracetic acid 15%", worst-case). Actual content of the concentrated product is 174 g PAA/L product - To obtain maximum working solution concentration 1500 ppm (PAA) in the pre-charge liquid i.e. 1.74 g PAA/L (assuming product density of 1.16, amount of biocidal product per litre pre-charge liquid in a chemical toilet Vform = 1.74/174 = 0.01 L (this was used as a refinement to the default value of 0.02 L). - For HP "Peracetic acid 5%" is worst-case, considering the equivalent content factor of 5.111 this results in Fform= 0.256, RHOform = 1.12 kg/L and Vform = 0.03 (Peracetic acid 5%" needs to be diluted 30 times to obtain maximum working solution concentration 1500 ppm PAA). - Fraction of substance disintegrated during or after application (before release to the sewage system), F_{dis} = 0 (worst-case)

Resulting local emission to relevant environmental compartments for the active substance peracetic acid (PAA) and substance of concern hydrogen peroxide (HP)					
Scenario	**Local emission ($Elocal_{compartment}$) to wastewater and air [kg/d]**				**Remarks**
	Default		**Refined for degradation in effluent stream**		
	PAA	**HP**	**PAA**	**HP**	
Product Type 3					
3a Use in disinfection of animal housing [ESD PT3 JRC 2011, Section 2.1, Tables 1a-d, p.14-19]	0.373 wwater	1.84 wwater	0.00468 wwater	0.0476 wwater	Based on worst-case working solution concentration and use application rate below (used for all PT3 uses) - working solution concentration 2000 ppm (PAA) 10222 ppm (HP) equivalent to Content of a.s. in product Fbioc = 2.32 (PAA) g/l (assuming product density of 1.16) and 11.45 (HP) g/L (assuming product density of 1.12) - Amount of product (undiluted i.e. Fdil=1) per m^2 Vprod = 0.1 L/m^2 (TAB, ENV 26) Worst-case emission to STP resulting from - Type of housing/manure storage cat-subcat (i1) = 16 Turkeys in free range with litter floor - Surface treated Combined Floor + Wall and roof and other - Waste stream (i4) waste water - Release fraction of PAA/HP to STP, Fstp=0.2, which is worst-case for emission to STP

Resulting local emission to relevant environmental compartments for the active substance peracetic acid (PAA) and substance of concern hydrogen peroxide (HP)					
Scenario	**Local emission ($Elocal_{compartment}$) to wastewater and air [kg/d]**				**Remarks**
	Default		**Refined for degradation in effluent stream**		
	PAA	**HP**	**PAA**	**HP**	
3b Use in disinfection of vehicles used for animal transport [ESD PT3 JRC 2011, Section 2.2, Table 2, p.21-22]	0.949 wwater 0.105 air	4.68 wwater 0.521 air	0.0119 wwater 0.105 air	0.121 wwater 0.521 air	Based on worst-case working solution concentration and use application rate above. Worst-case emission to STP and to air resulting from - Mammal transports
3c Use in disinfection for veterinary hygiene: footwear [ESD PT3 JRC 2011, Section 2.4.1, Tables 4a-d, p.23-27]	0.0232 wwater	0.115 wwater	0.000291 wwater	0.00296 wwater	Based on worst-case working solution concentration above Worst-case emission to STP resulting from - Type of housing/manure storage cat-subcat (i1) = all result in same emission to STP - Waste stream (i4) waste water
3d Use in disinfection for veterinary hygiene: animals' feet (dairy cows) [ESD PT3 JRC 2011, Section 2.4.2, Tables 5a-d, p.34-38]	2.82 wwater 0.313 air	13.91 wwater 1.55 air	0.0354 wwater 0.313 air	0.360 wwater 1.55 air	Based on worst-case working solution concentration above - Dilution factor of product Fdil = 1 (i.e. working solution undiluted) - all scenario defaults Worst-case emission to STP resulting from - Waste stream (i4) slurry - Fraction of a.s. released to STP Fstp = 0.9 For water, assumed tub size of twice the largest tub size (675 L), 52 times per year, 7 days apart to account of the worst case of 2 hoof disinfections per week, occurring on the same day.

Resulting local emission to relevant environmental compartments for the active substance peracetic acid (PAA) and substance of concern hydrogen peroxide (HP)					
Scenario	**Local emission ($Elocal_{compartment}$) to wastewater and air [kg/d]**				**Remarks**
	Default		**Refined for degradation in effluent stream**		
	PAA	**HP**	**PAA**	**HP**	
Product Type 4					
4a Use in food, drink and milk industries (FDM) [ESD PT4 JRC 2011, Section 2.1, p.12] ECHA spreadsheet PT4 tab PT4-FDM industries - assessment of entire plants (e.g. breweries, dairies, beverage processing plants) relevant for CIP, disinfection of storage tanks by automated spraying/foaming, disinfection of surfaces, membrane filters or bottles etc. [ESD PT4 JRC 2011, Section 2.1.4.2, Table 5, p.14-15]					Based on - Amount of biocidal active substance used per year in the local plant Qai = 407 (PAA) kg/year (default value) and 2080.2 (HP) kg/year) (HP converted on equivalent content factor of 5.111) - Number of emission days per year Temission = 231 days/year i.e. Elocal = 407/231 or 1.76 kg a.s./d (PAA) 2080.1/231 or 9.01 kg a.s./d - Fraction of substance disintegrated during or after application (before release to the sewage system) F_{dis}=0 worst-case - Tier 2: Refinement for the on-site STP assuming degradation during 1 hour using rate constant for STP aeration tank at 15°C (k=9.28h^{-1} for PAA or 13.96h^{-1} for HP), resulting in e^{-kt}=9.33E-5 for PAA or 8.65E-7 for HP. - All scenario defaults
- Off-site STP	1.76 wwater	9.01 wwater	0.0221 wwater	0.233 wwater	
- On-site STP Tier1	$C_{effluent}$ = $Clocal_{water}$ = 0.0977 mg/L)	($C_{effluent}$ = $Clocal_{water}$ = 0.499 mg/L)	-	-	
- On-site STP Tier 2 (elimination during on-site wastewater treatment)	(Clocalwater = 9.11E-6 mg/L)	(Clocalwater = 4.32E-7 mg/L))	-	-	

Resulting local emission to relevant environmental compartments for the active substance peracetic acid (PAA) and substance of concern hydrogen peroxide (HP)					
Scenario	**Local emission ($Elocal_{compartment}$) to wastewater and air [kg/d]**				**Remarks**
	Default		**Refined for degradation in effluent stream**		
	PAA	**HP**	**PAA**	**HP**	
- general scenario for drink and beverage industry, dairy industry, breweries relevant to systems processing liquids in the food and feed area [ESD PT4 JRC 2011, Section 2.1.4.1, Table 4, p.12-13]	1.04 wwater	5.15 wwater	0.0131 wwater	0.133 wwater	Based on - working solution concentration 1500 ppm (PAA) 7667 ppm (HP) equivalent to 1.74 (PAA) g/l (assuming product density of 1.16) and 8.59 (HP) g/L (assuming product density of 1.12 - Assumed worst-case volumes of disinfectant (i.e. working solution) used for cleaning of installation, process lines $Vform_{inst}$, mixing tanks $Vform_{mix}$ and storage tanks $Vform_{tank}$=100 L each (value provided by the applicant). No value is given in the TAB and the ESD states that further research is needed to define a default value for Vform. For the application methods given 2x100 L is high and so this is considered to be protective of the proposed uses. - Number of application per day Nappl= 2 per day (worst-case label use) - All scenario defaults

Resulting local emission to relevant environmental compartments for the active substance peracetic acid (PAA) and substance of concern hydrogen peroxide (HP)					
Scenario	**Local emission ($Elocal_{compartment}$) to wastewater and air [kg/d]**				**Remarks**
	Default		**Refined for degradation in effluent stream**		
	PAA	**HP**	**PAA**	**HP**	
- additional scenario for disinfection in food, drink and milk industries (FDM) [redacted] (1999) [ESD PT4 JRC 2011, Annex I, Tables 12-13, p.30]	0.0435 wwater 0.00435 air	0.215 wwater 0.0215 air	0.000546 wwater 0.00435 air	0.00556 wwater 0.0215 air	Based on - working solution concentration 1500 ppm (PAA) 7667 ppm (HP) equivalent to 0.00174 (PAA) kg/l (assuming product density of 1.16) and 0.00859 (HP) kg/L (assuming product density of 1.12) - Amount of working solution used Q_{disinf} and Q_{water}=25 L total per day (default as per PT2 scenario 2c, ESD PT2 RIVM 2001, Section 3.3, p.17) - All scenario defaults

Resulting local emission to relevant environmental compartments for the active substance peracetic acid (PAA) and substance of concern hydrogen peroxide (HP)					
Scenario	**Local emission ($Elocal_{compartment}$) to wastewater and air [kg/d]**				**Remarks**
	Default		**Refined for degradation in effluent stream**		
	PAA	**HP**	**PAA**	**HP**	
4b Disinfectants used in large scale catering kitchens, canteens, slaughterhouses and butcheries [ESD PT4 JRC 2011, Section 3.3, p.17, see Table 10 p.24]					Based on - working solution concentration 1500 ppm (PAA) 7667 ppm (HP) equivalent to 1.5 (PAA) g/l (assuming product density of 1.16) and 8.59 (HP) g/L (assuming product density of 1.12) - working solution use rate via spraying/wiping 0.1 L/m^2 (default rate for large scale PT 4 use taken from the TAB) equivalent to 0.174 (PAA) g/m2 and 0.859 (HP) g/m^2 - worst-case large scale application i.e. covers Small scale application (RTU) - All scenario defaults, except Number of applications per day Nappl=2 (worst-case label use)
i) Application by spraying/ wiping - large scale catering kitchens and canteens	0.696 wwater	3.44 wwater	0.00873 wwater	0.0889 wwater	
- slaughterhouses and butcheries	3.48 wwater	17.2 wwater	0.0437 wwater	0.444 wwater	

Resulting local emission to relevant environmental compartments for the active substance peracetic acid (PAA) and substance of concern hydrogen peroxide (HP)					
Scenario	**Local emission ($Elocal_{compartment}$) to wastewater and air [kg/d]**				**Remarks**
	Default		**Refined for degradation in effluent stream**		
	PAA	**HP**	**PAA**	**HP**	
4c Disinfectants used in milking parlour systems [ESD PT4 JRC 2011, Section 2.3, p.24, see Table 11 p.26	0.305 wwater	1.50 wwater	0.00382 wwater	0.0389 wwater	Based on - working solution concentration 1500 ppm (PAA) (assuming product density of 1.16 7667 ppm (HP) equivalent to 1.74 (PAA)g/l and 8.59 (HP) g/L (assuming product density of 1.12) - All scenario defaults

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway							
	Fresh-water	Freshwater sediment	STP	Air	Soil	Ground-water	Other
PT2	Yes	Yes	Yes	Yes	Yes	Yes	No
PT3	Yes	Yes	Yes	Yes	Yes	Yes	No
PT4	Yes	Yes	Yes	Yes	Yes	Yes	No

Y – receiving compartment; N – not a receiving compartment; NR – not relevant to use pattern or behaviour of compounds.

Environmental risks to the soil compartment and groundwater are considered negligible as well: due to the high reactivity of peracetic acid and hydrogen peroxide, and the high organic matter content of both STP sludge and liquid manure, PAA and HP are not expected to persist in relevant concentrations until the sludge or the manure are applied to agricultural soil. A further quantitative assessment is not deemed necessary.

The $Elocal_{water}$ values predicted for the tonnage based approach are in most cases lower than for the consumption based approach. Where this is the case, no further consideration has been made in relation to the tonnage based approach. Where a tonnage based approach indicates higher exposure, $Elocal_{water}$ values have been calculated with both the tonnage and consumption based approach.

An initial estimation of the PEC values for peracetic acid (active substance) and hydrogen peroxide (substance of concern) were performed based on the local emissions to wastewater, using the following input parameters. All other parameters were set to default values.

As peracetic acid and hydrogen peroxide rapidly degrade, no consideration of metabolites or degradation products is considered necessary.

Input parameters (only set values) for calculating the fate and distribution in the environment – Peracetic Acid (active substance)			
Input	Value	Unit	Remarks
Molecular weight	76.05	g/mol	-
Melting point	0	°C	-
Boiling point	110	°C	at 760 mmHg (101.325 kPa)
Vapour pressure (20°C)	1410	Pa	-
Henry's Law Constant (25 °C)	0.217	$Pa/m^3/mol$	-
pKa	8.24		
Solubility in water	1.0×10^6	mg/L	Completely miscible with water at any ratio (maximum default value selected)

Input parameters (only set values) for calculating the fate and distribution in the environment – Peracetic Acid (active substance)			
Partition coefficient n-octanol/water (at pH7)	-0.60	log P_{OW}	-
Koc	1.02	L/Kg	Doc II-A calculation
Biodegradability	Ready biodegradable	-	-

[1] Converted to 20°C using a Q10 value of 2.2 and E_A of 54000 kJ/mol.

Calculation of the fate and distribution in STP and refinement of the PEC values are based on the following input parameters for peracetic acid (active substance).

Input parameters (refined values) for calculating the fate and distribution in the environment – Peracetic Acid (active substance)			
Input	Value	Unit	Remarks
Rate constant for STP aeration tank *[if measured data available]*	7.30 9.28	h^{-1} (at 12 °C) h^{-1} (at 15 °C)	Based on DT_{50} of 5.7 min at 12 °C
Rate constant for STP-effluent stream (also transferable to the sewer system and liquid manure *[if measured data available]*	4.38	h^{-1} (at 12 °C)	Based on DT_{50} of 9.5 min at 12 °C
DT_{50} for degradation in soil	12	hr (at 12 °C)	Decision reached at ENV WG-II-2016 using hydrogen peroxide value
Organic carbon/water partition coefficient (Koc)	1.46	L/kg	AR (LoEP) of PAA (Decision reached at ENV WG-III-2020)

[1] Peracetic acid was observed to rapidly degrade in the presence of organic matter and microbial activity. In the absence of measured data for degradation in soil, the worst case default was selected.

Calculated fate and distribution of peracetic acid in the STP ***[if STP is a relevant compartment]***		
Compartment	Percentage [%]	Remarks*
	All scenarios	
Air	4.35E-2	SimpleTreat v4.0
Water	0.9903	SimpleTreat v4.0
Sludge	1.33E-2	SimpleTreat v4.0
Degraded in STP	98.95	SimpleTreat v4.0

*SimpleTreat 4.0 (method 1) for STP simulation data (Decision reached at ENV WG-III-2020)

Input parameters (only set values) for calculating the fate and distribution in the environment – Hydrogen peroxide (substance of concern)			
Input	Value	Unit	Remarks
Molecular weight	34.01	g/mol	-
Melting point	-0.43	°C	-
Boiling point	150.2	°C	at 101.325 kPa
Vapour pressure (20°C)	214	Pa	-
Henry's Law Constant (20°C)	7.5×10^{-4}	$Pa/m^3/mol$	-

Input parameters (only set values) for calculating the fate and distribution in the environment – Hydrogen peroxide (substance of concern)			
Solubility in water	1.0×10^6	mg/L	Completely miscible with water at any ratio (maximum default value selected)
Partition coefficient n-octanol/water (at pH7)	-1.57	log P_{OW}	-
Koc	1.598	L/Kg	
Biodegradability	Not relevant	-	Compound is not organic

[1] Estimated worst-case to take account for unfavourable conditions

Calculation of the fate an distribution in STP and refinement of the PEC values are based on the following input parameters for hydrogen peroxide (substance of concern).

Input parameters (refined values) for calculating the fate and distribution in the environment – Hydrogen peroxide (substance of concern)			
Input	Value	Unit	Remarks
Rate constant for STP (sewage sludge)	10.94 13.96	h^{-1} (at 12 °C) h^{-1} (at 15 °C)	Based on DT_{50} of 2 min at 20 °C
Rate constant transferable for sewer drain/liquid manure (based on the worst-case degradation rate for similar media regarding microbial density)	3.65	h^{-1} (at 12°C)	Based on DT_{50} of 6 min at 20°C (11.38 min at 12°C)
Degradation in soil (DT_{50})	12	hr	Worst case from lit. review, taken to be at 12°C
Organic carbon/water partition coefficient (Koc)	1.598	L/kg	Based on QSAR log Koc of 0.2036

Calculated fate and distribution of hydrogen peroxide in the STP *[if STP is a relevant compartment]*		
Compartment	Percentage [%]	Remarks*
	All scenarios	
Air	1.56E-4	SimpleTreat v4.0
Water	0.621	SimpleTreat v4.0
Sludge	1.45E-2	SimpleTreat v4.0
Degraded in STP	99.36	SimpleTreat v4.0

*SimpleTreat 4.0 (method 1) for STP simulation data (Decision reached at ENV WG-III-2020)

Calculated PEC values

Compartmental PECs have only been determined for discharge of waste disinfectant solution to local STP according to the proposed use patterns, with subsequent partitioning to local air and water discharge from STP to receiving watercourses. These are presented in the following tables.

Calculated PEC values for peracetic acid (active substance) and hydrogen peroxide (substance of concern)

The following tables show the PEC values in STP, freshwater and air for peracetic acid and hydrogen peroxide, based on the substance specific input parameters above and local emissions to wastewater and air.

PEC values are shown below assuming degradation in the sewers (refined values). As this is an accepted refinement, it is not considered necessary to calculate PEC values assuming no degradation in the sewer.

As peracetic acid and hydrogen peroxide rapidly degrade, no consideration of metabolites or degradation products is considered necessary.

Summary table on calculated PEC values based on refined values for peracetic acid following emission to waste water (refined based on degradation in the sewer)					
Peracetic acid			**PEC_{STP}**	**PEC_{water}**	**PEC_{air}**
			[µg/L]	[µg/L]	[mg/m^3]
Product Type 2					
2a Use in industrial areas (application rate)			1.08E-02	1.08E-03	2.64E-10
2b Use in industrial areas (consumption based)			3.78E-03	3.78E-04	9.24E-11
2c Medical rooms and furniture (tonnage based)			4.99E-03	4.99E-04	1.22E-10
2d Medical equipment	Replacement of solution		2.63E-02	2.63E-03	6.43E-10
	Once-through solution		3.24E-03	3.24E-04	7.92E-11
	Dipping bath		3.24E-02	3.24E-03	7.92E-10
2e Other contaminated instruments			1.46E-01	1.46E-02	3.77E-09
2f Use in chemical toilets			7.21E-02	7.21E-03	1.76E-09
Product Type 3					
3a Use in animal housing (turkeys in free range with litter floor)*			2.32E-02	2.32E-03	5..66E-10
3b Use in animal transport			5.90E-02	5.90E-03	2.93E-05
3c Use on foot-ware (veal calves)*			1.44E-03	1.44E-04	3.52E-11
3d Use on animal feet			1.75E-01	1.75E-02	8.71E-05
Product Type 4					
4a Use in food, drink and milk industry	Entire plants	Off-site STP	1.09E-01	1.09E-02	2.66E-09
		On-site STP Tier 1	-	97.701	-
		On-site STP Tier 2	-	9.11E-03	-
	General scenario		6.49E-02	6.49E-03	1.58E-09
	Additional scenario		2.70E-03	2.70E-04	1.21E-06

Summary table on calculated PEC values based on refined values for peracetic acid following emission to waste water (refined based on degradation in the sewer)				
Peracetic acid		**PEC_{STP}**	**PEC_{water}**	**PEC_{air}**
		[µg/L]	[µg/L]	[mg/m^3]
4b Use in large kitchens and slaughterhouses	Use in kitchens (application to surfaces)	4.33E-02	4.33E-03	1.06E-09
	Use in slaughterhouses (application to surfaces)	2.16E-01	2.16E-02	5.28E-09
4c Use in milking parlour		1.89E-02	1.89E-03	4.62E-10

* worst-case animal

Summary table on calculated PEC values based on refined values for hydrogen peroxide following emission to waste water (refined based on degradation in the sewer)				
Hydrogen peroxide		**PEC_{STP}**	**PEC_{water}**	**PEC_{air}**
		[µg/L]	[µg/L]	[mg/m^3]
Product Type 2				
2a Use in industrial areas (application rate)		7.37E-02	7.37E-03	1.24E-11
2b Use in industrial areas (consumption based)		2.58E-02	2.58E-03	4.32E-12
2c Medical rooms and furniture (consumption based)		2.77E-02	2.77E-03	4.63E-12
2d Medical equipment	Replacement of solution	1.80E-01	1.80E-02	3.01E-11
	Once-through solution	2.21E-02	2.21E-03	3.71E-12
	Dipping bath	2.21E-01	2.21E-02	3.71E-11
2e Other contaminated instruments		1.03E+00	1.03E-01	1.43E-10
2f Use in chemical toilets		4.92E-01	4.92E-02	8.25E-11

Summary table on calculated PEC values based on refined values for hydrogen peroxide following emission to waste water (refined based on degradation in the sewer)					
Hydrogen peroxide			**PEC_{STP}**	**PEC_{water}**	**PEC_{air}**
			[µg/L]	[µg/L]	[mg/m^3]
Product Type 3					
3a Use in animal housing (turkeys in free range with litter floor)*			1.58E-01	1.58E-02	2.65E-11
3b Use in animal transport			4.02E-01	4.02E-02	1.45E-04
3c Use on foot-ware (veal calves)*			9.83E-03	9.83E-04	1.65E-12
3d Use on animal feet			1.19	1.19E-01	4.30E-04
Product Type 4					
4a Use in food, drink and milk industry	Entire plants	Off-site STP	7.24E-01	7.24E-02	1.01E-10
		On-site STP Tier 1	-	499.401	-
		On-site STP Tier 2	-	4.32E-04	-
	General scenario		4.42E-01	4.42E-02	7.41E-11
	Additional scenario		1.84E-02	1.84E-03	5.97E-06
4b Use in large kitchens and slaughterhouses	Use in kitchens (application to surfaces)		2.95E-01	2.95E-02	4.94E-11
	Use in slaughterhouses (application to surfaces)		1.47	1.47E-01	2.47E-10
4c Use in milking parlour			1.29E-01	1.29E-02	2.16E-11

* worst-case anima

Calculated PEC values for peracetic acid (active substance) and hydrogen peroxide (substance of concern)

It should be noted that in relation to the "substance of concern", the EU review of hydrogen peroxide under PT 1 – 6 concluded in Doc II-A that the compound is a naturally existing substance in the environment and it is ubiquitous in air and all types of natural waters. Therefore the natural background concentrations and the natural formation and degradation pathways for each environmental compartment are presented in the following Table (originally taken from ESR risk assessment report (2003) for hydrogen peroxide):

Measured hydrogen peroxide concentrations in the environment (EU Risk Assessment Report, 2003)

Compartment	***Typical mean values***	***Highest values***	***Comments***
Air	*0.14-1.4 µg/m³ (0.1-1 ppb)*	*10 µg/m³ (7 ppb)*	
Cloud water	*50-1000 µg/L*	*> 8000 µg/L*	
Rain water, summer	*100-500 µg/L*	*> 8000 µg/L*	
Rain water, winter	*< 100 µg/L*		
Sea water	*0.5-5 µg/L*	*14 µg/L*	
Lake water	*1-30 µg/L*	*> 100 µg/L*	*Highest values: reliability poor, but probably realistic*
Groundwater	*0.7 µg/L*	*2.25 µg/L*	*Only one study referred*

As a conclusion, natural hydrogen peroxide concentrations in environmental media depend on the dynamic equilibrium of the simultaneous formation and decomposition reactions. Environmental media can therefore be expected to possess some capacities to buffer any anthropogenic emissions of hydrogen peroxide. Furthermore, the decomposition of hydrogen peroxide in air, water or soil generally cannot be investigated by standard guideline tests designed for biotic or abiotic degradation of organic compounds.

It is noted that predicted levels of hydrogen peroxide from worst case use of the product family fall within or below natural background levels in air and surface waters. Maximum levels of hydrogen peroxide from the use of the product in different compartments are given below.

	Maximum Level Predicted (µg/L)
Air	0.430
Water	0.147

2.2.8.3 Risk characterisation

PEC/PNEC Ratios

The PNECs are summarised below:

Source of PNEC: Assessment Report for peracetic acid (August 2016)
https://echa.europa.eu/documents/10162/509d2298-d477-6b7e-5b7e-a7da47c0dd47

Peracetic acid (active substance)	
$PNEC_{aquatic}$	0.069 µg/L
$PNEC_{marine}$	0.0069 µg/L
$PNEC_{sediment}$	0.056 µg/kg_t sediment
$PNEC_{stp}$	0.051 mg/L
$PNEC_{soil}$ / $PNEC_{terrestrial}$	0.282 mg/kg_{wwt} soil or 0.320 mg/kg_{dwt} soil

log P_{ow} = - 0.60 (pH 7)
PBT assessment: Not P or B is T

A secondary poisoning assessment is not necessary as the log K_{ow} for peracetic acid is <3.

Source of PNEC: Assessment Report for hydrogen peroxide (March 2015)
https://echa.europa.eu/documents/10162/2bd12686-d1ae-2096-fe9d-1ba0af019c66

Hydrogen peroxide (SoC)	
$PNEC_{aquatic}$	12.6 µg/L
$PNEC_{marine}$	12.6 µg/L
$PNEC_{sediment}$*	-
$PNEC_{stp}$	4.66 mg/L
$PNEC_{soil}$ / $PNEC_{terrestrial}$	0.0018 mg/kg_{wwt}

log P_{ow} = - 1.57 (pH 7)
PBT assessment: Not P or B is T
*Not necessary according to CAR (Considering the low n-octanol/water partition coefficient of hydrogen peroxide (log Kow –1.57), the expected low adsorption to organic matter (QSAR based log Koc 0.2036) and its generally rapid abiotic and biotic degradation in surface waters, hydrogen peroxide is not expected to partition into the sediment).

A secondary poisoning assessment is not necessary as the log Kow for hydrogen peroxide is <3.

PEC/PNEC Ratios for peracetic acid and hydrogen peroxide

The PEC and PNEC values are provided below for the STP and water compartments and compared with the relevant PNEC values.

Sediment PEC calculations have not been undertaken because the same EPM calculation is appropriate for both the water and sediment compartments. Aquatic risk and sediment risk are therefore identical and the risk to sediment is covered by calculations presented for the water compartment.

As degradation in drains is an acceptable refinement which has been agreed in the CARs for both peracetic acid and hydrogen peroxide, PEC values presented in the tables which follow consider the risks posed by these highly reactive compounds after they have been broken down in transit (refined emissions). PEC values not including degradation in drains have not been presented.

Comparison of PEC and PNEC values in the STP for **peracetic acid** using refined parameters, following degradation

STP			
PT 2			
	PEC (µg/L)	PNEC (µg/L)	PEC/PNEC
2a Use in industrial areas (application rate)	7.37E-02	51	2.12E-04
2b Use in industrial areas (consumption based)	2.58E-02		7.42E-05
2c Medical rooms and furniture	2.77E-02		9.78E-05
2c Medical equipment -replacement of solution	1.80E-01		5.16E-04
2c Medical equipment - once-through solution	2.21E-02		6.36E-05
2d Medical equipment - dipping bath	2.21E-01		6.36E-04
2e Other contaminated instruments	1.03		2.86E-03
2f Use in chemical toilets	4.92E-01		1.41E-03
PT 3			
	PEC (µg/L)	PNEC (µg/L)	PEC/PNEC
3a Use in animal housing (veal calves)	2.32E-02	51	4.55E-04
3b Use in animal transport	5.90E-02		1.16E-03
3c Use on foot-ware (veal calves)	1.44E-03		2.83E-05
3d Use on animals' feet	1.75E-01		3.43E-03
PT 4			

	PEC (µg/L)	PNEC (µg/L)	PEC/PNEC
4a Use in food, drink and milk industry - entire plants (off-site STP)	1.09E-01	51	2.14E-03
4a Use in food, drink and milk industry - general scenario	6.49E-02		1.27E-03
4a Use in food, drink and milk industry, additional scenario	2.70E-03		5.30E-05
4b Use in large kitchens and slaughterhouses - use in kitchens (application to surfaces)	4.33E-02		8.48E-04
4b Use in large kitchens and slaughterhouses - use in slaughterhouses (application to surfaces	2.16E-01		4.24E-03
4c Use in milking parlour	1.89E-02		3.71E-04

Comparison of PEC and PNEC values in water for peracetic acid using refined parameters, following degradation

PECwater				
PT 2				
		PEC (µg/L)	PNEC (µg/L)	PEC/PNEC
2a Use in industrial areas (application rate)		1.08E-03	6.90E-02	1.57E-02
2b Use in industrial areas (consumption based)		3.78E-04		5.48E-03
2c Medical rooms and furniture		4.99E-04		7.23E-03
2c Medical equipment - replacement of solution		2.63E-03		3.82E-02
2c Medical equipment - once-through solution		3.24E-04		4.70E-03
2d Medical equipment - dipping bath		3.24E-03		4.70E-02
2e Other contaminated instruments		1.46E-02		2.11E-01
2f Use in chemical toilets		7.21E-03		1.04E-01
PT 3				
		PEC (µg/L)	PNEC (µg/L)	PEC/PNEC
3a Use in animal housing (veal calves)		2.32E-03	6.90E-02	3.36E-02
3b Use in animal transport		5.90E-03		8.55E-02
3c Use on foot-ware (veal calves)		1.44E-04		2.09E-03
3d Use on animals' feet		1.75E-02		2.54E-01
PT 4				
		PEC (µg/L)	PNEC (µg/L)	PEC/PNEC
4a Use in food, drink and milk industry - entire plants	Off-site STP	1.09E-02	6.90E-02	1.59E-01
	On-site STP Tier 1	97.701		1416.085

	On-site STP Tier 2	9.11E-03		1.32E-01
4a Use in food, drink and milk industry - general scenario		6.49E-03		9.40E-02
4a Use in food, drink and milk industry, additional scenario		2.70E-04		3.92E-03
4b Use in large kitchens and slaughterhouses - use in kitchens (application to surfaces)		4.33E-03		6.27E-02
4b Use in large kitchens and slaughterhouses - use in slaughterhouses (application to surfaces		2.16E-02		3.13E-01
4c Use in milking parlour		1.89E-03		2.74E-02

No consideration of sediment risk has been undertaken for the a.s. – both PEC and PNEC have been derived by EPM from aquatic values. Therefore, sediment risk will be identical to aquatic risk presented above.

Comparison of PEC and PNEC values in STP for **hydrogen peroxide** using refined parameters, following degradation

STP			
PT 2			
	PEC (µg/L)	PNEC (µg/L)	PEC/PNEC
2a Use in industrial areas (application rate)	7.37E-02	4660	1.58E-05
2b Use in industrial areas (consumption based)	2.58E-02		5.54E-06
2c Medical rooms and furniture	2.77E-02		5.93E-06
2c Medical equipment -replacement of solution	1.80E-01		3.85E-05
2c Medical equipment - once-through solution	2.21E-02		4.75E-06
2d Medical equipment - dipping bath	2.21E-01		4.75E-05
2e Other contaminated instruments	1.03E+00		2.20E-04
2f Use in chemical toilets	4.92E-01		1.06E-04
PT 3			
	PEC (µg/L)	PNEC (µg/L)	PEC/PNEC
3a Use in animal housing (veal calves)	1.58E-01	4660	3.39E-05
3b Use in animal transport	4.02E-01		8.63E-05
3c Use on foot-ware (veal calves)	9.83E-03		2.11E-06
3d Use on animals' feet	1.19E+00		2.56E-04
PT 4			
	PEC (µg/L)	PNEC (µg/L)	PEC/PNEC
4a Use in food, drink and milk industry - entire plants	7.24E-01	4660	1.55E-04

4a Use in food, drink and milk industry - general scenario	4.42E-01		9.50E-05
4a Use in food, drink and milk industry, additional scenario	1.84E-02		3.96E-06
4b Use in large kitchens and slaughterhouses - use in kitchens (application to surfaces)	2.95E-01		6.33E-05
4b Use in large kitchens and slaughterhouses - use in slaughterhouses (application to surfaces	1.47E+00		3.17E-04
4c Use in milking parlour	1.29E-01		2.77E-05

Comparison of PEC and PNEC values in water for hydrogen peroxide using refined parameters, following degradation

PECwater				
PT 2				
		PEC (µg/L)	PNEC (µg/L)	PEC/PNEC
2a Use in industrial areas (application rate)		7.37E-03	12.6	5.85E-04
2b Use in industrial areas (consumption based)		2.58E-03		2.05E-04
2c Medical rooms and furniture		2.77E-03		2.19E-04
2c Medical equipment -replacement of solution		1.80E-02		1.43E-03
2c Medical equipment - once-through solution		2.21E-03		1.76E-04
2d Medical equipment - dipping bath		2.21E-02		1.76E-03
2e Other contaminated instruments		1.03E-01		8.15E-03
2f Use in chemical toilets		4.92E-02		3.91E-03
PT 3				
		PEC (µg/L)	PNEC (µg/L)	PEC/PNEC
3a Use in animal housing (veal calves)		1.58E-02	12.6	1.25E-03
3b Use in animal transport		4.02E-02		3.19E-03
3c Use on foot-ware (veal calves)		9.83E-04		7.80E-05
3d Use on animals' feet		1.19E-01		9.48E-03
PT 4				
		PEC (µg/L)	PNEC (µg/L)	PEC/PNEC
4a Use in food, drink and milk industry - entire plants (off-site STP)	Off-site STP	7.24E-02	12.6	5.75E-03
	On-site STP Tier 1	4.99E+02		3.96E+01
	On-site STP Tier 2	4.32E-04		3.43E-05
4a Use in food, drink and milk industry - general scenario		4.42E-02		3.51E-03
4a Use in food, drink and milk industry, additional scenario		1.84E-03		1.46E-04

4b Use in large kitchens and slaughterhouses - use in kitchens (application to surfaces)	2.95E-02		2.34E-03
4b Use in large kitchens and slaughterhouses - use in slaughterhouses (application to surfaces	1.47E-01		1.17E-02
4c Use in milking parlour	1.29E-02		1.02E-03

No consideration of sediment risk has been undertaken for the SoC since according to the CAR this is not necessary because hydrogen peroxide is not expected to partition into the sediment–(moreover, using a PNECsediment derived by EPM (as for PAA) would also lead to a sediment risk identical to the aquactic risk presented above as both PEC and PNEC would have been derived by EPM from aquatic values).

Conclusions

Risks have only been considered for emissions of PAA and HP after degradation in sewage system in line with EU agreed assumptions present in their respective CARs and discussed within this PAR.

STP

The resulting PEC/PNEC ratios at local STP indicate acceptable risks to STP micro-organisms for the proposed uses for both peracetic acid and hydrogen peroxide after degradation in the sewage system (refined values) for all scenarios.

Water

Predicted surface water concentrations (PEC values) have been calculated only for indirect exposure to water via STP discharge as direct aquatic exposure is not expected for the proposed uses.

The resulting PEC/PNEC ratios indicated an acceptable risk to aquatic organisms for the proposed uses for both peracetic acid and hydrogen peroxide after degradation in the sewage system (refined values) for all scenarios, except for discharge via the on-site STP in scenario "4a Use in food, drink and milk industry - entire plants", where no elimination (tier 1) during on-site wastewater treatment is considered. However, the risk is acceptable, if a realistic tier 2 elimination fraction is taken into account. Moreover, according to TAB ENV 2019 (published 19/12/2019) for CIP scenario evaluating breweries it is sufficient to assess only one STP including biological treatment. It is then irrelevant if

it is an on-site or off-site STP and by consequence the calculation for the off-site STP is adequate to cover CIP use.

Sediment

Sediment exposure only occurs indirectly via STP discharge as direct exposure is not expected for the proposed uses.

Sediment PEC calculations have not been undertaken because the same EPM calculation is appropriate for both the water and sediment compartments. Aquatic risk and sediment risk are therefore identical and the risk to sediment is covered by calculations presented for the water compartment. The resulting PEC/PNEC ratios indicated an acceptable risk to aquatic organisms for the proposed uses for both peracetic acid and hydrogen peroxide after degradation in the sewage system (refined values) for all scenarios.

Terrestrial Compartment

Soil exposure only occurs indirectly via land application of slurry/manure or sewage sludge. Direct exposure is not expected for the proposed uses.

A quantitative assessment has not been undertaken as due to the high reactivity of peracetic acid and hydrogen peroxide, and the high organic matter content of both STP sludge and liquid manure, PAA and HP are not expected to persist in relevant concentrations until the sludge or the manure are applied to agricultural soil.

Groundwater

As due to the high reactivity of peracetic acid and hydrogen peroxide concentrations in soil as a result of indirect exposure are expected to be negligible, no groundwater assessment was deemed necessary.

Air

It is possible that emissions of peracetic acid (PAA) and hydrogen peroxide could reach the air compartment at local STP following discharge of disinfectant solution to drains following wet cleaning of internal surfaces in treated areas. However, models presented in Annex 3.7 of this PAR predict insignificant levels of both compounds at 100 m from the point source (STP) and thus risks are acceptable.

Primary and secondary poisoning

Primary poisoning

Not required as the product is not a solid formulation used outside.

Secondary poisoning

The active substance peracetic acid has a log K_{ow} <3 (-0.60), therefore a secondary poisoning assessment is not triggered.

The substance of concern hydrogen peroxide has a log Kow <3 (-1.57), therefore a secondary poisoning assessment is not triggered.

Moreover, peracetic acid and hydrogen peroxide dissipate rapidly in the environment. This is a further indication of their low accumulation potential.

Conclusion: A primary and secondary poisoning assessment is not required for this product. No further consideration is necessary.

Mixture toxicity

A mixture assessment is required for the environment as the product contains one active substance (peracetic acid) and one substance of concern (hydrogen peroxide).

Mixture toxicity has been assessed according to the ECHA Transitional Guidance on mixture toxicity assessment for biocidal products for the environment. Peracetic acid and hydrogen peroxide have been identified as relevant substances and the tiered assessment scheme describe in the Guidance has been followed.

Tiered approach

According to the different ecotoxicological data set available for peracetic acid and hydrogen peroxide in the relevant compartments and scenarios, Tier 1 has been followed as recommended in the ECHA Transitional Guidance on mixture toxicity assessment for biocidal products for the environment. Synergistic effects of peracetic acid and hydrogen peroxide in terms of environmental toxicity are not expected due to their mode of action and readily biodegradability.

Aggregated exposure (combined for relevant emission sources)

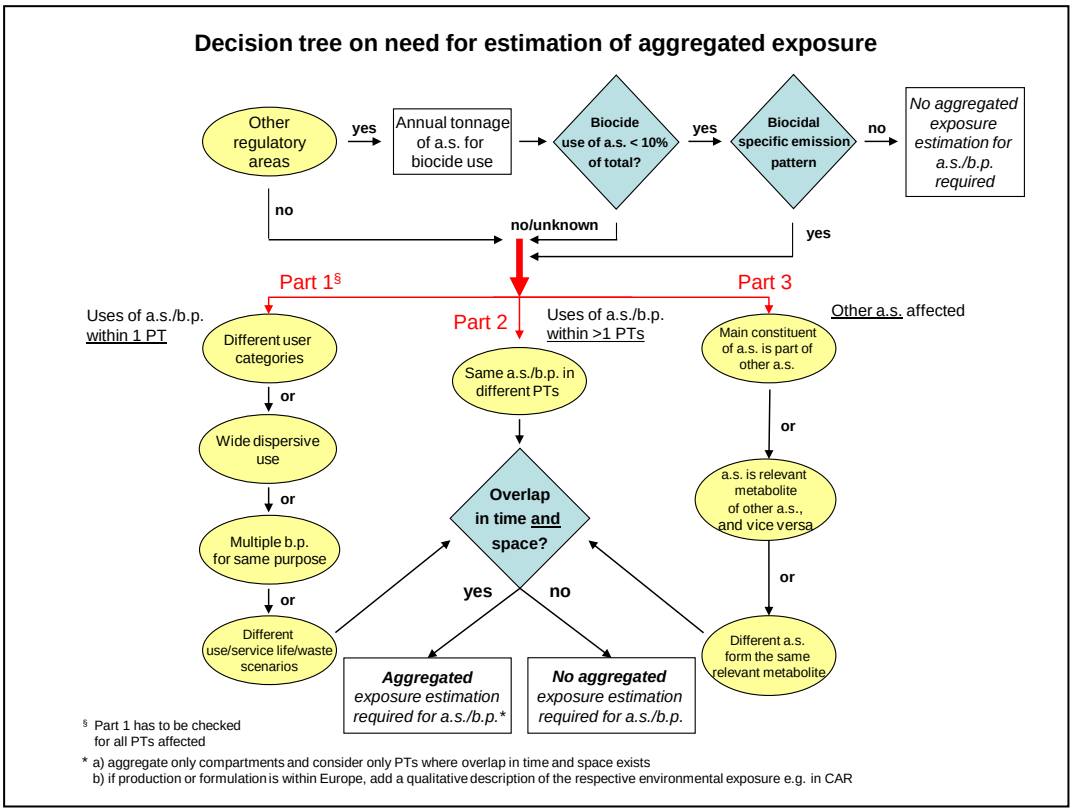


Figure 1: Decision tree on the need for estimation of aggregated exposure

At the time of product evaluation, there is no regulatory interpretation how an identified unacceptable cumulative risk should be taken into account when approving active substances, since approval of one safe use is considered sufficient. Thus, approval of an active substance cannot be based on the outcome of the aggregated risk assessment. However, it is important to indicate whether a potential cumulative risk can be identified.

Peracetic acid (PAA)

Aggregated environmental exposure assessment was performed for PAA in its review under several PT (including PT 2, 3 and 4). Cumulative assessment of emissions to local STP from wide dispersive use patterns were considered but risks were considered to fall significantly below 1 and thus be acceptable. However, it must be further noted that the CAR for PAA concluded that the compound degrades rapidly by both abiotic and biotic processes. Depending on environmental conditions, abiotic decomposition can follow three

different reactions, namely spontaneous decomposition, metal catalysed decomposition and hydrolysis. In addition, PAA degrades rapidly under conditions where organic matter and microbial activity are present and it can be considered as readily biodegradable substance. DT_{50} values for biodegradation in sewage sludge of 3 minutes (at 20°C) and in effluent water from a sewage treatment plant of 5 minutes were accepted. With >99% removal of PAA during transit in sewer systems and >99% removal within the STP itself, significant emissions to receiving surface waters or terrestrial compartment are extremely unlikely.

Public literature reports that peracetic acid has numerous "biocidal" applications, including use as a chemical disinfectant in healthcare, as a sanitizer in the food industry, and as a disinfectant during water treatment. Peracetic acid has also previously been used during the manufacture of chemical intermediates for pharmaceuticals. The compound is also stated as being very widely used for non-biocidal uses (at much higher concentrations of 35 - 40% w/w) for chemical synthesis where oxidation reactions are required, namely:

- Epoxidation of olefins;
- Selective epoxidation of various unsaturated compounds;
- Oxidation of thioethers to sulfoxides or sulfones;
- Oxidation of tertiary amines to amine oxides;
- Oxidation of pyridines to pyridine oxides;
- Oxidation of ketones to esters or lactones;
- Baeyer-Villiger oxidation of acylbenzenes to o-acylphenols.

It is extremely difficult to quantify the relationship between biocidal and non-biocidal use patterns of PAA to determine whether or not the 10% threshold is reached (see first step in the decision tree for cumulative assessment). However, non-biocidal uses appear to use concentrations of PAA that are 10 times greater than those typically indicated for biocidal concentrates. On that basis, it is likely that biocidal uses could represent only a minor fraction of the total use of PAA.

Hydrogen peroxide (same-PT active but treated as an SoC)

With regard to this compound, it was concluded in the Assessment Report for PT 1 – 6 uses) that only a minor fraction of total hydrogen peroxide manufactured in the EU is ever used as biocidal product. As this value is certainly <10 % (outlined in the Decision Tree as trigger level for the need to estimate aggregated exposure), then further consideration is not necessary.

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

Taking all of these factors into account for both PAA and hydrogen peroxide, aggregated exposure has not been taken further.

Overall conclusion on the risk assessment for the environment of the product

The PEC/PNEC values for the active substance peracetic acid and the substance of concern hydrogen peroxide were summarised and are presented in the following table. Cumulative values have not been generated for soil, groundwater or the air compartment as they are not considered relevant.

For product types 2, 3 and 4, the final mixture toxicity PEC/PNEC values in relevant compartments were less than 1, indicating an acceptable risk to the environment for all uses.

Summary table on calculated ΣPEC/PNEC values

Product type / scenario	$\Sigma PEC/PNEC_{STP}$	$\Sigma PEC/PNEC_{water}$
PT 2		
2a Use in industrial areas (application rate)	2.28E-04	1.63E-02
2b Use in industrial areas (consumption based)	7.97E-05	5.69E-03
2c Medical rooms and furniture	1.04E-04	7.45E-03
2c Medical equipment -replacement of solution	5.55E-04	3.96E-02
2c Medical equipment - once-through solution	6.84E-05	4.88E-03
2d Medical equipment - dipping bath	6.84E-04	4.88E-02
2e Other contaminated instruments	3.08E-03	2.19E-01
2f Use in chemical toilets	1.52E-03	1.08E-01
PT 3		
3a Use in animal housing (veal calves)	4.88E-04	3.49E-02
3b Use in animal transport	1.24E-03	8.87E-02
3c Use on foot-ware (veal calves)	3.04E-05	2.17E-03
3d Use on animals' feet	3.69E-03	2.63E-01

PT 4			
4a Use in food, drink and milk industry - entire plants	Off-site STP	2.30E-03	1.64E-01
	On-site STP Tier 1	-	1.46E+03
	On-site STP Tier 2	-	1.32E-01
4a Use in food, drink and milk industry - general scenario		1.37E-03	9.75E-02
4a Use in food, drink and milk industry, additional scenario		5.70E-05	4.06E-03
4b Use in large kitchens and slaughterhouses - use in kitchens (application to surfaces)		9.11E-04	6.50E-02
4b Use in large kitchens and slaughterhouses - use in slaughterhouses (application to surfaces)		4.56E-03	3.25E-01
4c Use in milking parlour		3.99E-04	2.84E-02

Based on the proposed use patterns of Airedale PAA 2-15 % Product Family for Product Types 2, 3 and 4, the cumulative PEC/PNEC values in the STP, water (and sediment as these will be identical to water) compartments were less than 1 and are therefore considered acceptable. This indicates an acceptable risk to the environment.

Based upon acceptable levels of cumulative risk being predicted in all relevant ENV receiving compartments, then all proposed uses for this biocidal product family in PT 2, 3 and 4 can be authorised. No additional mitigation measures are required.

2.2.9 Assessment of ED properties

A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the ED properties of the substances in Airedale PAA 2-15% Product Family:

1. Assessment of the ED properties of the active substances in Airedale PAA 2-15% Product Family:
   - According to section 2.1.1 of the final CA document, the assessment of ED properties of the active substances that have already been evaluated and approved will be coordinated at EU level. Hence, the rMS should not evaluate the ED properties of these substances nor request additional data on the ED properties in the context of product authorisation procedures. As Peracetic acid is not part of the list of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review.
   - Therefore, BE eCA considers that there are no concerns regarding ED properties of Peracetic acid.

2. Assessment of the ED properties of non-active substances (co-formulants) in Airedale PAA 2-15% Product Family:

- After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex - ED assessment), none of the co-formulants has been identified as having ED properties or are subject to an on-going evaluation or a decision regarding their ED properties. Based on the available information, BE eCA considers that there is no concern regarding the ED properties of these co-formulants.

Overall conclusion on the biocidal product family regarding ED properties:
Based on the existing knowledge and the data provided by the applicant, there is no indication of concern for humans and for non-target organisms regarding the ED properties of the substances used in the biocidal product family Airedale PAA 2-15% Product Family. If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product family authorisation will be revised according to CA-March18.Doc.7.b-final, section 2.3 (47).

2.2.10 Measures to protect man, animals and the environment

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

2.2.11 Assessment of a combination of biocidal products

The products of the "Airedale PAA 2-15% Product Family" are not intended to be used in combination with other biocidal products.

2.2.12 Comparative assessment

Not relevant the active substance of the "Airedale PAA 2-15% Product Family" is not a candidate for substitution.

3 Annexes

3.1 List of studies for the biocidal product family

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
3.1-01	[redacted]	2017	Peracetic Acid 5/23: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: SM49PV GLP, Unpublished	Y	AIR
3.1-02	[redacted]	2017	Airocide PAAD: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: PP66RT GLP, Unpublished	Y	AIR
3.1-03	[redacted]	2017	Peracetic Acid 15/23: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: FJ65MV GLP, Unpublished	Y	AIR
3.1-04	[redacted]	2017	Peracetic Acid 2% + detergent: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: NQ80JJ GLP, Unpublished	Y	AIR
3.1-05	[redacted]	2018	Peracetic Acid 2%: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: SL59VS GLP, Unpublished	Y	AIR
3.2-01	[redacted]	2014	Peracetic Acid (15% in solution): Determination of Physico-Chemical Properties Harlan Laboratories Ltd. Airedale Chemical Company, Report No.: 41303797 GLP, Unpublished	Y	AIR
3.2-02	[redacted]	2018	2% Peracetic Acid: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: SL59VS GLP, Unpublished	Y	AIR
3.2-03	[redacted]	2019	2% Peracetic Acid + surfactant: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: CP35RS GLP, Unpublished	Y	AIR
3.2-04	[redacted]	2019 b	5% Peracetic Acid: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: KD57SG GLP, Unpublished	Y	AIR
3.2-05	[redacted]	2019 c	5% Peracetic Acid + surfactant (Airocide PAAD): Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road,	Y	AIR

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
			Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: HX58DF GLP, Unpublished		
3.2-06	[redacted]	2019d	15% Peracetic Acid: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: NM01XP GLP, Unpublished	Y	AIR
3.2-07	[redacted]	2017a	Peracetic Acid 5/23: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: SM49PV GLP, Unpublished	Y	AIR
3.2-08	[redacted]	2017b	Airocide PAAD: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: PP66RT GLP, Unpublished	Y	AIR
3.2-09	[redacted]	2017c	Peracetic Acid 15/23: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: FJ65MV GLP, Unpublished	Y	AIR
3.2-10	[redacted]	2017d	Peracetic Acid 2% + detergent: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: NQ80JJ GLP, Unpublished	Y	AIR
3.3-01	[redacted]	2018	2% Peracetic Acid: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: SL59VS GLP, Unpublished	Y	AIR
3.3-02	[redacted]	2019a	2% Peracetic Acid + surfactant: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: CP35RS GLP, Unpublished	Y	AIR
3.3-03	[redacted]	2019b	5% Peracetic Acid: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: KD57SG GLP, Unpublished	Y	AIR
3.3-04	[redacted]	2019c	5% Peracetic Acid + surfactant (Airocide PAAD): Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: HX58DF GLP, Unpublished	Y	AIR
3.3-05	[redacted]	2019d	15% Peracetic Acid: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK	Y	AIR

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
			Airedale Chemical Company, Report No.: NM01XP GLP, Unpublished		
3.4.1-01	[redacted]	2018	2% Peracetic Acid: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: SL59VS GLP, Unpublished	Y	AIR
3.4.1-02	[redacted]	2019a	2% Peracetic Acid + surfactant: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: CP35RS GLP, Unpublished	Y	AIR
3.4.1-03	[redacted]	2019b	5% Peracetic Acid: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: KD57SG GLP, Unpublished	Y	AIR
3.4.1-04	[redacted]	2019c	5% Peracetic Acid + surfactant (Airocide PAAD): Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: HX58DF GLP, Unpublished	Y	AIR
3.4.1-05	[redacted]	2019d	15% Peracetic Acid: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: NM01XP GLP, Unpublished	Y	AIR
3.4.1-08	[redacted]	2017a	Peracetic Acid 5/23: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: SM49PV GLP, Unpublished	Y	AIR
3.4.1-09	[redacted]	2017b	Airocide PAAD: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: PP66RT GLP, Unpublished	Y	AIR
3.4.1-10	[redacted]	2017c	Peracetic Acid 15/23: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: FJ65MV GLP, Unpublished	Y	AIR
3.4.1-11	[redacted]	2017d	Peracetic Acid 2% + detergent: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: NQ80JJ GLP, Unpublished	Y	AIR
3.5.7-01	[redacted]	2018	2% Peracetic Acid: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK	Y	AIR

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
			Airedale Chemical Company, Report No.: SL59VS GLP, Unpublished		
3.5.7-02	[redacted]	2019a	2% Peracetic Acid + surfactant: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: CP35RS GLP, Unpublished	Y	AIR
3.5.7-03	[redacted]	2019b	5% Peracetic Acid: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: KD57SG GLP, Unpublished	Y	AIR
3.5.7-04	[redacted]	2019c	5% Peracetic Acid + surfactant (Airocide PAAD): Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: HX58DF GLP, Unpublished	Y	AIR
3.5.7-05	[redacted]	2019d	15% Peracetic Acid: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: NM01XP GLP, Unpublished	Y	AIR
3.7-01	[redacted]	2018	2% Peracetic Acid: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: SL59VS GLP, Unpublished	Y	AIR
3.7-02	[redacted]	2019a	2% Peracetic Acid + surfactant: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: CP35RS GLP, Unpublished	Y	AIR
3.7-03	[redacted]	2019b	5% Peracetic Acid: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: KD57SG GLP, Unpublished	Y	AIR
3.7-04	[redacted]	2019c	5% Peracetic Acid + surfactant (Airocide PAAD): Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: HX58DF GLP, Unpublished	Y	AIR
3.7-05	[redacted]	2019d	15% Peracetic Acid: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: NM01XP GLP, Unpublished	Y	AIR
3.8-01	[redacted]	2014	Peracetic Acid (15% in solution): Determination of Physico-Chemical Properties	Y	AIR

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
			Harlan Laboratories Ltd. Airedale Chemical Company, Report No.: 41303797 GLP, Unpublished		
3.8-02	[redacted]	2017	Peracetic Acid 2% + detergent: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: NQ80JJ GLP, Unpublished	Y	AIR
3.8-03	[redacted]	2018	2% Peracetic Acid: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: SL59VS GLP, Unpublished	Y	AIR
3.8-04	[redacted]	2019a	2% Peracetic Acid + surfactant: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: CP35RS GLP, Unpublished	Y	AIR
3.8-05	[redacted]	2021	Physico/ Chemical Testing on Samples of PAA 5% and Airocide PAAD DEKRA UK Ltd, Phi House, Southampton Science Park Airedale Chemical Company, Report no.: GLP3016008956R1/2021 GLP, Unpublished	Y	AIR
3.8-06	[redacted]	2021	Physico/ Chemical Testing on Samples of PAA 5% and Airocide PAAD DEKRA UK Ltd, Phi House, Southampton Science Park Airedale Chemical Company, Report no.: GLP3016008956R1/2021 GLP, Unpublished	Y	AIR
3.9-01	[redacted]	2014	Peracetic Acid (15% in solution): Determination of Physico-Chemical Properties Harlan Laboratories Ltd. Airedale Chemical Company, Report No.: 41303797 GLP, Unpublished	Y	AIR
3.9-02	[redacted]	2017	Peracetic Acid 2% + detergent: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: NQ80JJ GLP, Unpublished	Y	AIR
3.9-03	[redacted]	2018	2% Peracetic Acid: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: SL59VS GLP, Unpublished	Y	AIR
3.9-04	[redacted]	2019a	2% Peracetic Acid + surfactant: Determination of Long-Term Storage Stability Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: CP35RS GLP, Unpublished	Y	AIR
3.9-05	[redacted]	2021	Physico/ Chemical Testing on Samples of PAA 5% and Airocide PAAD DEKRA UK Ltd, Phi House, Southampton Science Park	Y	AIR

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
			Airedale Chemical Company, Report no.: GLP3016008956R1/2021 GLP, Unpublished		
3.9-06	[redacted]	2021	Physico/ Chemical Testing on Samples of PAA 5% and Airocide PAAD DEKRA UK Ltd, Phi House, Southampton Science Park Airedale Chemical Company, Report no.: GLP3016008956R1/2021 GLP, Unpublished	Y	AIR
4.6	[redacted]	2020	Flash Point Analysis on Test Items: Peracetic Acid 2% (Foamy), Peracetic Acid 2% (Non-Foamy), Peracetic Acid 5%, Peracetic Acid 15% and Airocide PAAD DEKRA Organisational and Process Safety, Phi House, Southampton Science Park Airedale Chemical Company Ltd, Report No: GLP3016008200R1/2020 GLP, Unpublished	Y	AIR
4.15-01	[redacted]	2016	Peracetic Acid 15/23. Organic Peroxides Classification Testing Chilworth Technology Ltd, DEKRA Insight Facility Airedale Chemical Company Ltd, Report No.: J310021R1V1/2016 GLP, Unpublished	Y	AIR
4.15-02	[redacted]	2020	Peracetic Acid 15%, Adiabatic Storage Test (UN H.2) DEKRA Process Safety, Phi House, Southampton Science Park Airedale Chemical Company Ltd, Report No: J4028005883R1/2020 Non-GLP, Unpublished	Y	AIR
4.16	[redacted]	2015	Peracetic Acid 15%: UN Corrosivity Testing Chilworth Technology Limited, a Dekra company Airedale Chemical Company Ltd, Report No.: S114204R1V1/2015 GLP, Unpublished	Y	AIR
5.1 5.1-06	[redacted]	2014	Peracetic Acid (15% in solution): 5-batch analysis Harlan Laboratories Ltd Airedale Chemicals Company Limited, Report No.: 41303798 GLP, Unpublished	Y	AIR
5.1-01, 5.1-02, 5.1-03, 5.1-04, 5.1-05	[redacted]	2019	Peracetic Acid (2% Peracetic Acid, 2% Peracetic Acid & Surfactant, 5% Peracetic Acid, 5% Peracetic Acid & Surfactant): Analytical Method Validation Envigo Research Limited, Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, UK Airedale Chemical Company, Report No.: NJ21XW GLP, Unpublished	Y	AIR
5.1.-07	[redacted]	2019	Confidential Information - Waiver supporting the non-inclusion of HEDP content assessment and method validation for Peracetic Acid Product Family ERM Report No. 0387741-PC1 Airedale Chemical Company, Report No.: NJ21XW Non-GLP, Unpublished	Y	AIR
6.1-04	[redacted]	2017	A review of the biocidal efficacy of peracetic acid, hydrogen peroxide and acetic acid JSC International Limited Airedale Chemical Company Ltd Review article.	Y	AIR
6.7-01	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Escherichia coli*, *Staphylococcus aureus*, *Enterococcus hirae* and *Pseudomonas aeruginosa* using the European Disinfection Test EN1276:2009. Peracetic Acid 5% (200ppm ai) - 20°C	Y	AIR

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
			Airocide PAAD (200ppm ai) - 20°C Peracetic Acid 15% (195 ppm ai)- 20°C Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report No.: IMSL2016/07/021.1A Not-GLP, Unpublished		
6.7-02	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Salmonella typhimurium, Listeria monocytogenes, Yersinia enterocolitica, Escherichia coli 0157:H7* and MRSA using the European Disinfection Test EN1276:2009. Peracetic Acid 5% (200ppm ai) - 20°C Airocide PAAD (200ppm ai) - 20°C Peracetic Acid 15% (195 ppm ai)- 20°C Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report No.: IMSL2016/07/021.1C Not-GLP, Unpublished	Y	AIR
6.7-03	[redacted]	2017	Activity of Peracetic Acid Formulation Variant against *Escherichia coli, Staphylococcus aureus, Enterococcus hirae* and *Pseudomonas aeruginosa* using the European Disinfection Test EN1276:2009. Peracetic Acid 2% Foamy (200ppm ai) - 10°C Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report No.: IMSL2016/07/021.1B Not-GLP, Unpublished	Y	AIR
6.7-04	[redacted]	2017	Activity of Peracetic Acid Formulation Variant against *Salmonella typhimurium, Listeria monocytogenes, Yersinia enterocolitica, Escherichia coli 0157:H7* and MRSA using the European Disinfection Test EN1276:2009. Peracetic Acid 2% Foamy (200ppm ai) - 10°C Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report No.: IMSL2016/07/021.1D Not-GLP, Unpublished	Y	AIR
6.7-05	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Escherichia coli, Staphylococcus aureus, Enterococcus hirae, Pseudomonas aeruginosa, Salmonella typhimurium, Listeria monocytogenes, Yersinia enterocolitica, Escherichia coli 0157:H7* and MRSA using the European Disinfection Test EN13697:2015. Peracetic Acid 2% Foamy (200ppm ai) Peracetic Acid 5% (200ppm ai) Airocide PAAD (200ppm ai) Peracetic Acid 15% (195 ppm ai) Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report No.: IMSL2016/07/021.1F Not-GLP, Unpublished	Y	AIR
6.7-06	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Aspergillus niger, Candida albicans and Saccharomyces cerevisiae* using the European Disinfection Test EN13697:2015. Peracetic Acid 2% Foamy Peracetic Acid 5% Airocide PAAD Peracetic Acid 15%	Y	AIR

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
			Industrial Microbiological Services Ltd (IMSL); Airedale Chemical Company Limited, Report No.: IMSL2016/07/021.1G Not-GLP, Unpublished		
6.7-07	[redacted]	2017	Test Report: EN 14476 2013 +A1 2015 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (Phase 2/Step 1). BluTest Laboratories Ltd Airedale Chemical Company Limited, Project No.: BT-ADL-01 Not-GLP, Unpublished	Y	AIR
6.7-08	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Aspergillus niger, Candida albicans and Saccharomyces cerevisiae* using the European Disinfection Test EN1650:2008. Peracetic Acid 2% Foamy (200ppm ai) - 20°C Peracetic Acid 5% (200ppm ai) - 20°C Airocide PAAD (200ppm ai) - 20°C Peracetic Acid 15% (195 ppm ai) - 20°C Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report No.: IMSL2016/07/021.1E Not-GLP, Unpublished	Y	AIR
6.7-09	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Staphylococcus aureus* and *Streptococcus uberis* using the European Disinfection Test EN1656:2009. Peracetic Acid 2% Foamy (200ppm ai) Peracetic Acid 5% (200ppm ai) Airocide PAAD (200ppm ai) Peracetic Acid 15% (195 ppm ai) Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report No.: IMSL2016/07/021.1H Not-GLP, Unpublished	Y	AIR
6.7-10	[redacted]	2017	Test Report: EN 14349 2012 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action – Test method and requirements (Phase 2, Step 2). BluTest Laboratories Ltd Airedale Chemical Company Limited, Project No.: BT-ADL-01 Not-GLP, Unpublished	Y	AIR
6.7-11	[redacted]	2017	Test Report: EN 14349 2012 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action — Test method and requirements (phase 2, step 2) BluTest Laboratories Ltd Airedale Chemical Company Limited, Project No.: BT-ADL-02-02 Not-GLP, Unpublished	Y	AIR
6.7-12	[redacted]	2017	Test Report: EN 14349 2012 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action — Test method and requirements (phase 2, step 2) BluTest Laboratories Ltd Airedale Chemical Company Limited, Project No.: BT-ADL-02-01 Not-GLP, Unpublished	Y	AIR

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
6.7-13	[redacted]	2017	Test Report: EN 14349 2012 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action — Test method and requirements (phase 2, step 2) BluTest Laboratories Ltd Airedale Chemical Company Limited, Project No.: BT-ADL-02-03 Not-GLP, Unpublished	Y	AIR
6.7-14	[redacted]	2017	Test Report: EN 16437 2014 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on porous surfaces without mechanical action — Test method and requirements (phase 2, step 2) BluTest Laboratories Ltd Airedale Chemical Company Limited, Project No.: BT-ADL-01 Not-GLP, Unpublished	Y	AIR
6.7-15	[redacted]	2017	Test Report: EN 16437 2014 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on porous surfaces without mechanical action — Test method and requirements (phase 2, step 2) BluTest Laboratories Ltd Airedale Chemical Company Limited, Project No.: BT-ADL-02-02 Not-GLP, Unpublished	Y	AIR
6.7-16	[redacted]	2017	Test Report: EN 16437 2014 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on porous surfaces without mechanical action — Test method and requirements (phase 2, step 2) BluTest Laboratories Ltd Airedale Chemical Company Limited, Project No.: BT-ADL-02-01 Not-GLP, Unpublished	Y	AIR
6.7-17	[redacted]	2017	Test Report: EN 16437 2014 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on porous surfaces without mechanical action — Test method and requirements (phase 2, step 2) BluTest Laboratories Ltd Airedale Chemical Company Limited, Project No.: BT-ADL-02-03 Not-GLP, Unpublished	Y	AIR
6.7-18	[redacted]	2017	Activity of Peracetic Acid Formulation Variant against *Bacillus subtilis* using the European Disinfection Test EN13704:2002. Peracetic Acid 2% Foamy (200ppm ai) - 20°C Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report No.: IMSL2016/07/021.1I Not-GLP, Unpublished	Y	AIR
6.7-19	[redacted]	2017 a	The Diseases of Animals (Approved Disinfectants) (England) Order 2007 No 448: Airocide PAAD Defra Disinfectant Approvals Bacteriology Department Airedale Chemical Company Limited, Report No.: DTA432 Not-GLP, Unpublished	Y	AIR
6.7-20	[redacted]	2017	Test Report: EN 14349 2012 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area	Y	AIR

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
			on non-porous surfaces without mechanical action — Test method and requirements (phase 2, step 2) BluTest Laboratories Ltd Airedale Chemical Company Limited, Project No.: BT-ADL-03-03 Not-GLP, Unpublished		
6.7-21	[redacted]	2017	Test Report: EN 14349 2012 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action — Test method and requirements (phase 2, step 2) BluTest Laboratories Ltd Airedale Chemical Company Limited, Project No.: BT-ADL-03-01 Not-GLP, Unpublished	Y	AIR
6.7-22	[redacted]	2017	Test Report: EN 16437 2014 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on porous surfaces without mechanical action — Test method and requirements (phase 2, step 2) BluTest Laboratories Ltd Airedale Chemical Company Limited, Project No.: BT-ADL-03-02 Not-GLP, Unpublished	Y	AIR
6.7-23	[redacted]	2017	Test Report: EN 14476 2013 + A1 2015 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of virucidal activity in the medical area — Test method and requirements (phase 2, step 1) BluTest Laboratories Ltd Airedale Chemical Company Limited, Project No.: BT-ADL-03-03 Not-GLP, Unpublished	Y	AIR
6.7-24	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Escherichia coli, Staphylococcus aureus, Enterococcus hirae* and *Pseudomonas aeruginosa* using the European Disinfection Test EN1276:2009 Peracetic Acid 2% Foamy (200ppm ai) - 10°C (Old Formulation) Peracetic Acid 2% Foamy (200ppm ai) - 10°C (New Formulation) Industrial Microbiological services Ltd (IMSL) Airedale Chemical Company Limited, Report No.: IMSL2016/07/021.1M Not-GLP, Unpublished	Y	AIR
6.7-25	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Salmonella typhimurium, Listeria monocytogenes, Yersinia enterocolitica, Escherichia coli* 0157:H7 and MRSA using the European Disinfection Test EN1276:2009 Peracetic Acid 2% Foamy (200ppm ai) - 10°C (Old Formulation) Peracetic Acid 2% Foamy (200ppm ai) - 10°C (New Formulation) Industrial Microbiological services Ltd (IMSL) Airedale Chemical Company Limited, Report No.: IMSL2016/07/021.1O Not-GLP, Unpublished	Y	AIR
6.7-26	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Escherichia coli, Staphylococcus aureus, Enterococcus hirae* and *Pseudomonas aeruginosa* using the European Disinfection Test EN1276:2009 Peracetic Acid 5% (200ppm ai) - 20°C (Old Formulation) Peracetic Acid 5% (200ppm ai) - 20°C (New Formulation) Industrial Microbiological services Ltd (IMSL) Airedale Chemical Company Limited, Report No.: IMSL2016/07/021.1J Not-GLP, Unpublished	Y	AIR

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
6.7-27	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Salmonella typhimurium, Listeria monocytogenes, Yersinia enterocolitica, Escherichia coli* 0157:H7 and MRSA using the European Disinfection Test EN1276:2009 Peracetic Acid 5% (200ppm ai) - 20°C (Old Formulation) Peracetic Acid 5% (200ppm ai) - 20°C (New Formulation) Industrial Microbiological services Ltd (IMSL) Airedale Chemical Company Limited, Report No.: IMSL2016/07/021.1N Not-GLP, Unpublished	Y	AIR
6.7-28	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Escherichia coli, Staphylococcus aureus, Enterococcus hirae* and *Pseudomonas aeruginosa* using the European Disinfection Test EN1276:2009 Airocide PAAD (200ppm ai) - 20°C (Old Formulation) Airocide PAAD (200ppm ai) - 20°C (New Formulation) Industrial Microbiological services Ltd (IMSL) Airedale Chemical Company Limited, Report No.: IMSL2016/07/021.1L Not-GLP, Unpublished	Y	AIR
6.7-29	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Salmonella typhimurium, Listeria monocytogenes, Yersinia enterocolitica, Escherichia coli* 0157:H7 and MRSA using the European Disinfection Test EN1276:2009 Airocide PAAD (200ppm ai) - 20°C (Old Formulation) Airocide PAAD (200ppm ai) - 20°C (New Formulation) Industrial Microbiological services Ltd (IMSL) Airedale Chemical Company Limited, Report No.: IMSL2016/07/021.1P Not-GLP, Unpublished	Y	AIR
6.7-30	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Escherichia coli, Staphylococcus aureus, Enterococcus hirae* and *Pseudomonas aeruginosa* using the European Disinfection Test EN1276:2009 Peracetic Acid 15% (195ppm ai) - 20°C (Old Formulation) Peracetic Acid 15% (195ppm ai) - 20°C (New Formulation) Industrial Microbiological services Ltd (IMSL) Airedale Chemical Company Limited, Report No.: IMSL2016/07/021.1K Not-GLP, Unpublished	Y	AIR
6.7-31	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Salmonella typhimurium, Listeria monocytogenes, Yersinia enterocolitica, Escherichia coli* 0157:H7 and MRSA using the European Disinfection Test EN1276:2009 Peracetic Acid 15% (195ppm ai) - 20°C (Old Formulation) Peracetic Acid 15% (195ppm ai) - 20°C (New Formulation) Industrial Microbiological services Ltd (IMSL) Airedale Chemical Company Limited, Report No.: IMSL2016/07/021.1Q Not-GLP, Unpublished	Y	AIR
6.7-32	[redacted]	2015	Certificate of Analysis: 0.025% Peracetic acid Abbot Analytical Delf (UK) Ltd, Report No.: 15D. 146VT.DEL Not-GLP, Unpublished	Y	DELF

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
6.7-33	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Aspergillus niger, Candida albicans and Saccharomyces cerevisiae* using the European Disinfection Test EN1650:2008 Peracetic Acid 2% Foamy (Old Formulation) Peracetic Acid 2% Foamy (New Formulation) Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report Number: IMSL2016/07/021.1U Not-GLP, Unpublished	Y	AIR
6.7-34	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Aspergillus niger, Candida albicans and Saccharomyces cerevisiae* using the European Disinfection Test EN1650:2008 Peracetic Acid 5% (Old Formulation) Peracetic Acid 5% (New Formulation) Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report Number: IMSL2016/07/021.1R Not-GLP, Unpublished	Y	AIR
6.7-35	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Aspergillus niger, Candida albicans and Saccharomyces cerevisiae* using the European Disinfection Test EN1650:2008 Airocide PAAD (Old Formulation) Airocide PAAD (New Formulation) Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report Number: IMSL2016/07/021.1T Not-GLP, Unpublished	Y	AIR
6.7-36	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Aspergillus niger, Candida albicans and Saccharomyces cerevisiae* using the European Disinfection Test EN1650:2008 Peracetic Acid 15% (Old Formulation) Peracetic Acid 15% (New Formulation) Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report Number: IMSL2016/07/021.1S Not-GLP, Unpublished	Y	AIR
6.7-37	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Aspergillus niger* using the European Disinfection Test EN1650:2008 Peracetic Acid 2% Foamy (New Formulation) Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report Number: IMSL2016/07/021.1X Not-GLP, Unpublished	Y	AIR
6.7-38	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Aspergillus niger* using the European Disinfection Test EN1650:2008 Peracetic Acid 5% (New Formulation) Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report Number: IMSL2016/07/021.1V Not-GLP, Unpublished	Y	AIR
6.7-39	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Aspergillus niger* using the European Disinfection Test EN1650:2008 Airocide PAAD (New Formulation) Industrial Microbiological Services Ltd (IMSL)	Y	AIR

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
			Airedale Chemical Company Limited, Report Number: IMSL2016/07/021.1Y Not-GLP, Unpublished		
6.7-40	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Aspergillus niger* using the European Disinfection Test EN1650:2008 Peracetic Acid 15% (New Formulation) Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report Number: IMSL2016/07/021.1W Not-GLP, Unpublished	Y	AIR
6.7-41	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Aspergillus niger* using the European Disinfection Test EN13697:2015 Peracetic Acid 2% Foamy (New Formulation) Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report Number: IMSL2016/07/021.1AA Not-GLP, Unpublished	Y	AIR
6.7-42	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Aspergillus niger* using the European Disinfection Test EN13697:2015 Peracetic Acid 5% (New Formulation) Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report Number: IMSL2016/07/021.1Z Not-GLP, Unpublished	Y	AIR
6.7-43	[redacted]	2017	Activity of Peracetic Acid Formulation Variants against *Aspergillus niger* using the European Disinfection Test EN13697: 2015 Airocide PAAD (New Formulation) Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report Number: IMSL2016/07/021.1AB Not-GLP, Unpublished	Y	AIR
6.7-44	[redacted]	2017	Activity of a Peracetic Acid Formulation Variant against *Staphylococcus aureus, Enterococcus hirae, Pseudomonas aeruginosa*, and *Proteus Vulgaris* using the European Disinfection Test EN1656:2009 Peracetic Acid 2% Foamy (200ppm ai) (New Formulation) Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report Number: IMSL2016/07/021.1AC Not-GLP, Unpublished	Y	AIR
6.7-45	[redacted]	2017	Activity of a Peracetic Acid Formulation Variant against *Staphylococcus aureus, Enterococcus hirae, Pseudomonas aeruginosa*, and *Proteus Vulgaris* using the European Disinfection Test EN1656:2009 Peracetic Acid 5% (200ppm ai) (New Formulation) Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report Number: IMSL2016/07/021.1AE Not-GLP, Unpublished	Y	AIR
6.7-46	[redacted]	2017	Activity of a Peracetic Acid Formulation Variant against *Staphylococcus aureus, Enterococcus hirae, Pseudomonas aeruginosa*, and *Proteus Vulgaris* using the European Disinfection Test EN1656:2009 Airocide PAAD (200ppm ai) (New Formulation) Industrial Microbiological Services Ltd (IMSL)	Y	AIR

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
			Airedale Chemical Company Limited, Report Number: IMSL2016/07/021.1AF Not-GLP, Unpublished		
6.7-47	[redacted]	2017	Activity of a Peracetic Acid Formulation Variant against *Staphylococcus aureus*, *Enterococcus hirae*, *Pseudomonas aeruginosa*, and *Proteus Vulgaris* using the European Disinfection Test EN1656:2009 Peracetic Acid 15% (195ppm ai) (New Formulation) Industrial Microbiological Services Ltd (IMSL) Airedale Chemical Company Limited, Report Number: IMSL2016/07/021.1AD Not-GLP, Unpublished	Y	AIR
6.7-48	[redacted]	2017 b	The Diseases of Animals (Approved Disinfectants) (England) Order 2007 No 448: Airocide PAAD Airedale Chemical Company Limited, Report Number: DTA432 Not-GLP, Unpublished	Y	AIR
6.7-49	[redacted]	2018	The Diseases of Animals (Approved Disinfectants) (England) Order 2007 No 448: Airocide PAAD Airedale Chemical Company Limited, Report Number: DTA432 Not-GLP, Unpublished	Y	AIR
6.7-50	[redacted]	2020	Evaluation of activity according to PN-EN 1656:2020-01 Airedale Chemical Company Limited, Report Number: DZ/38/09/20 Not-GLP, Unpublished	Y	AIR
6.7-51	[redacted]	2020	Evaluation of activity on porous surfaces test according to PN-EN 16437+A1:2020-03 Airedale Chemical Company Limited, Report Number: DZ/36/09/20 Not-GLP, Unpublished	Y	AIR
6.7-52	[redacted]	2020	Evaluation of activity according to PN-EN 1657:2016-06 Airedale Chemical Company Limited, Report Number: DZ/37/08/20 Not-GLP, Unpublished	Y	AIR
6.7-53	[redacted]	2020	Evaluation of activity according to PN-EN 16438:2014-04 Airedale Chemical Company Limited, Report Number: DZ/39/09/20 Not-GLP, Unpublished	Y	AIR
6.7-54	[redacted]	2021	Evaluation of activity according to PN-EN 13697+A1:2019-08 Airedale Chemical Company Limited, Report Number: DZ/55/12/20 Not-GLP, Unpublished	Y	AIR
6.7-55	[redacted]	2020	Evaluation of activity on porous surfaces test according to PN-EN 16437+A1:2020-03, modified Airedale Chemical Company Limited, Report Number: DZ/38/08/2020 Not-GLP, Unpublished	Y	AIR
6.7-56	[redacted]	2020	Evaluation of activity according to PN-EN 1657:2016-06 Airedale Chemical Company Limited, Report Number: DZ/37/09/20 Not-GLP, Unpublished	Y	AIR
6.7-57	[redacted]	2021	Evaluation of activity according to PN-EN 1656:2020-01 Airedale Chemical Company Limited, Report Number: DZ/54/12/20 Not-GLP, Unpublished	Y	AIR

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
6.7-58	[redacted]	2021	Evaluation of activity according to PN-EN 14349:2013-05 Airedale Chemical Company Limited, Report Number: DZ/58/12/20 Not-GLP, Unpublished	Y	AIR
6.7-59	[redacted]	2021	Evaluation of activity according to PN-EN 1650:2019-12 Airedale Chemical Company Limited, Report Number: DZ/56/12/20 Not-GLP, Unpublished	Y	AIR
6.7-60	[redacted]	2021	Evaluation of activity according to PN-EN 1276:2019-12 Airedale Chemical Company Limited, Report Number: DZ/25/02/21 Not-GLP, Unpublished	Y	AIR
6.7-61	[redacted]	2020	Quantitative suspension test for evaluation of virucidal activity in the medical area (Phase 2 Step1) EN 14476 Airedale Chemical Company Limited, Report Number: J002352 14476, Not-GLP, Unpublished	Y	AIR
6.7-62	[redacted]	2021	Chemical disinfectants and antiseptics – Quantitative nonporous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area -Test method and requirements (phase 2/step 2) EN 16777 Airedale Chemical Company Limited, Report Number: J002600 16777, Not-GLP, Unpublished	Y	AIR
6.7-63	[redacted]	2020	Quantitative suspension test for evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area (Phase 2 Step1) EN 14675 Airedale Chemical Company Limited, Report Number: J002352 14675, Not-GLP, Unpublished	Y	AIR
6.7-64	[redacted]	2021	Quantitative suspension test for evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area (Phase 2 Step1) EN 14675 Airedale Chemical Company Limited, Report Number: J002600 14675, Not-GLP, Unpublished	Y	AIR
12.3-01 to 12.3-06 12.3-12	[redacted]	-	Various packaging specification	N	-
12.3-07 to 12.3-11	[redacted]	-	Various labels Airedale Chemical Company Ltd	N	-
13a	[redacted]	2017	Confirmation letter from eCA	N	-
13b-01	ECHA	2016	ECHA decision letter on inclusion into Article 95	N	-
13b-02	[redacted]	2016	LoA to Active substance Data on PAA	Y	AIR
13c-01 to 13c-05	[redacted]	2017	Various product Safety Data Sheet Airedale Chemical Company Ltd	N	-
13d-01 to 13d-05	[redacted]	-	Various Raw Material Safety Data Sheet	N	-
13e	ECHA	2017	ECHA letter on pre-submission consultation for Union Authorisation	N	-
13f	[redacted]	-	Document: Structure of the BP family	N	-
13g	[redacted]	-	Document: Tolerance limits of the active substance content	N	-
13h	[redacted]	-	Document: Efficacy Data – Peracetic Acid Summary EN Testing	Y	AIR
13i	[redacted]	-	Document: Biocidal product family overview	Y	AIR
13j	-	-	Document: Draft Assessment Report (draft PAR)	-	-

IUCLID Section number	Author(s)	Year	Title Source (when different from company) Company, Report No. GLP (where relevant), (Un)Published or not	Data Protection Claimed Y/N	Owner
13k	-	-	Document: Responses to sift questions July 2018	-	-
13l	-	-	Document: ED assessment of co-formulants	-	-

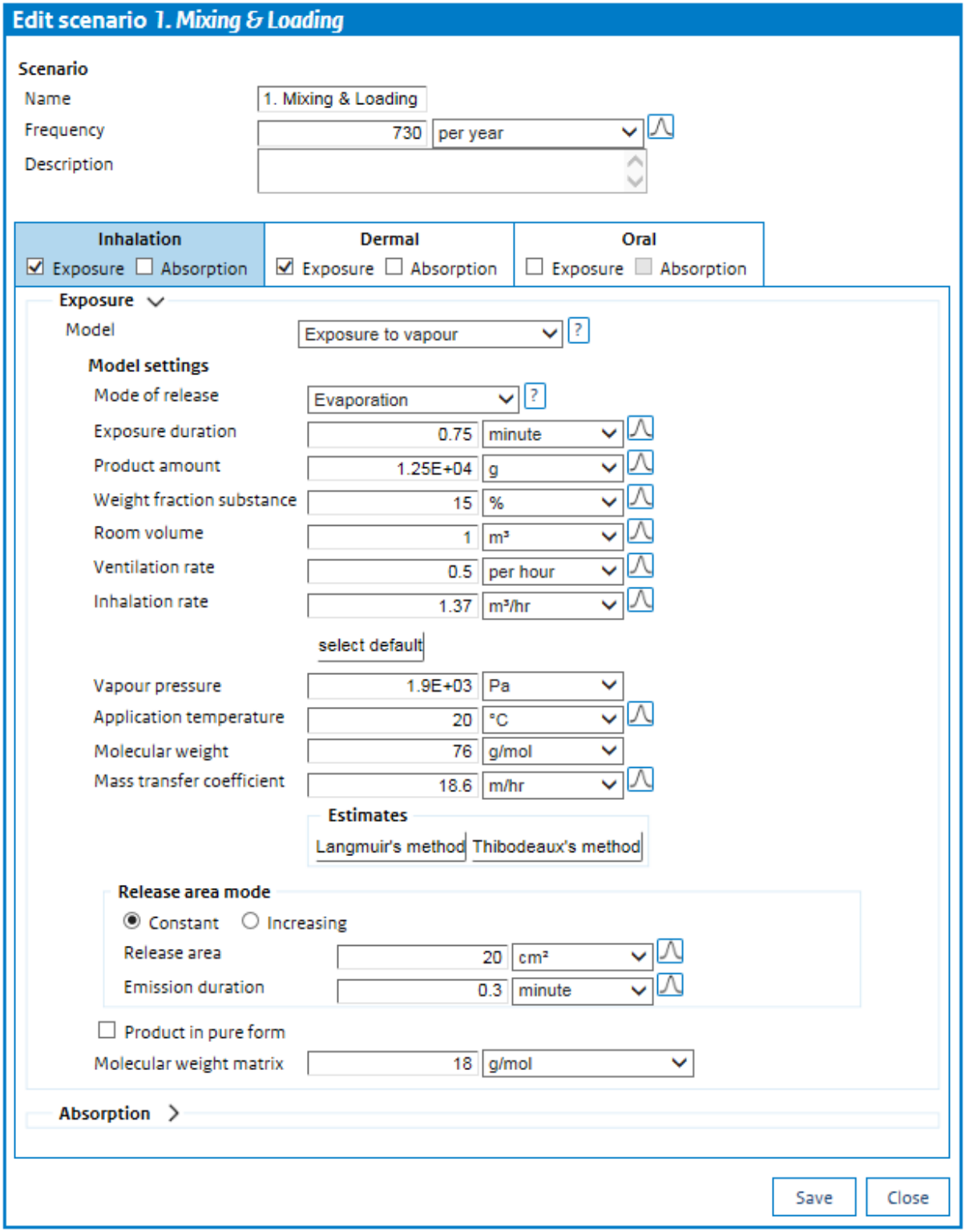
3.2 Output tables from exposure assessment tools

Worker exposure assessment – Exposure Assessment Details

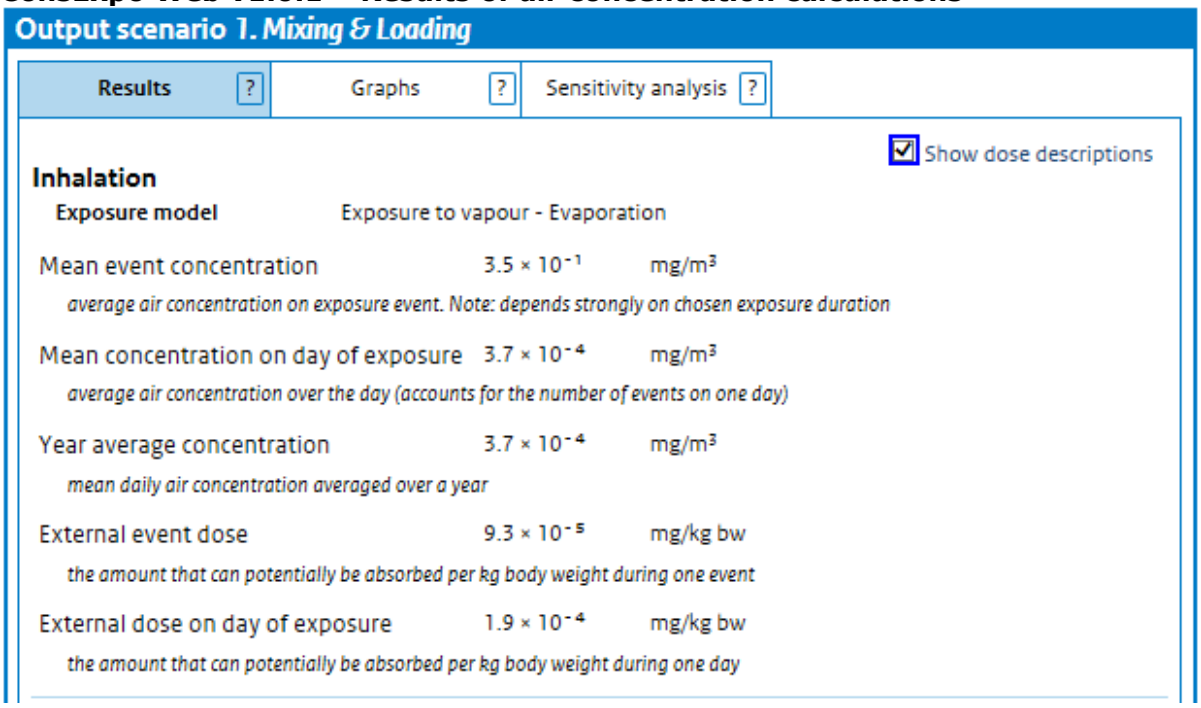
The following inputs/outputs from ConsExpo Web v1.0.1 are presented based on the peracetic acid inputs. The same calculations are valid for hydrogen peroxide, but using the compound-specific inputs specified in each exposure scenario in Section 2.2.6.2.

Exposure Scenario 1 (PT 2/3/4 – Decanting of product concentrated and dilution with water)

ConsExpo Web v1.0.1 – Input Parameters



ConsExpo Web v1.0.1 – Results of air concentration calculations



Output scenario 1. *Mixing & Loading*

Results ? | Graphs ? | Sensitivity analysis ?

☑ Show dose descriptions

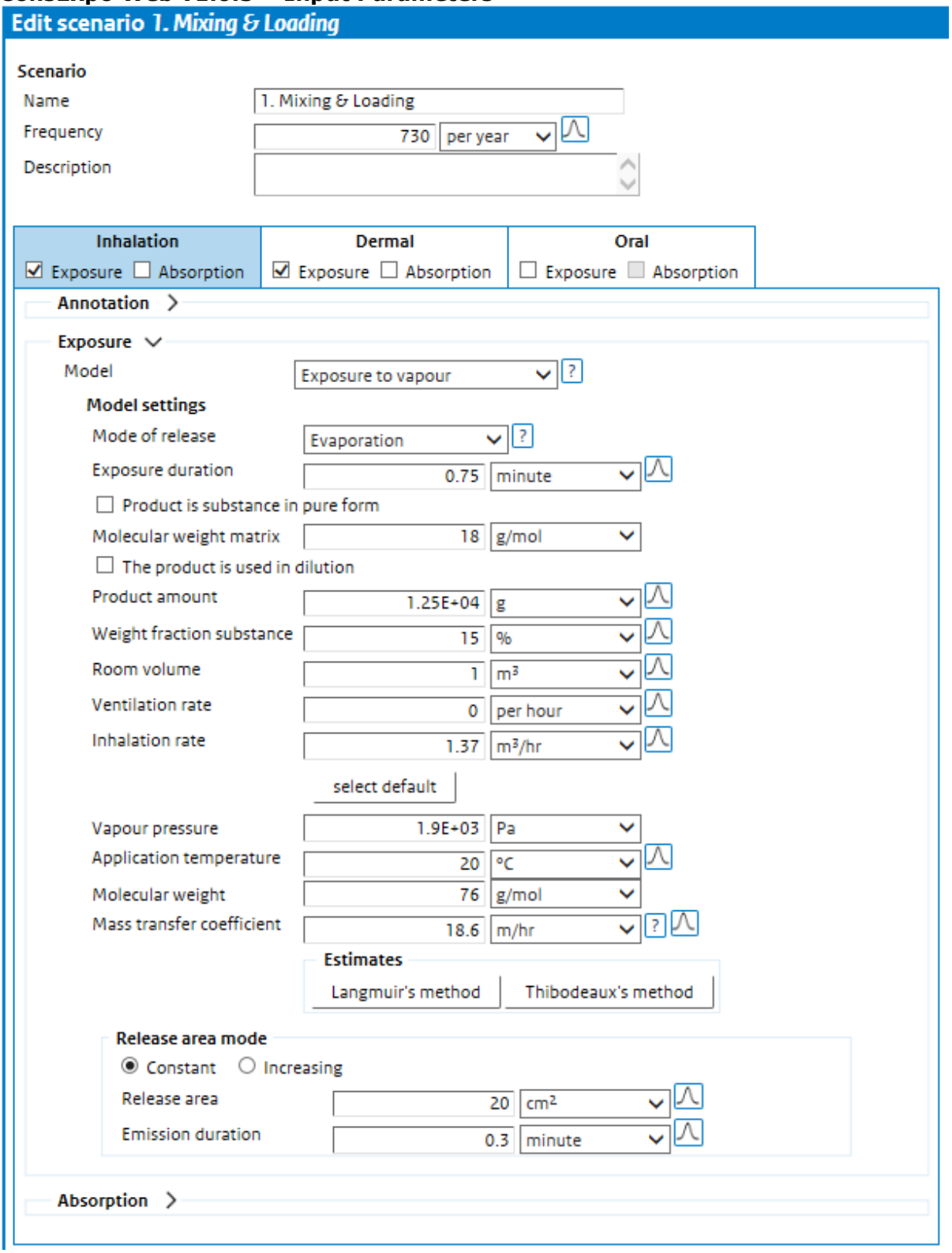
Inhalation

Exposure model Exposure to vapour - Evaporation

Mean event concentration	3.5×10^{-1}	mg/m³
average air concentration on exposure event. Note: depends strongly on chosen exposure duration		
Mean concentration on day of exposure	3.7×10^{-4}	mg/m³
average air concentration over the day (accounts for the number of events on one day)		
Year average concentration	3.7×10^{-4}	mg/m³
mean daily air concentration averaged over a year		
External event dose	9.3×10^{-5}	mg/kg bw
the amount that can potentially be absorbed per kg body weight during one event		
External dose on day of exposure	1.9×10^{-4}	mg/kg bw
the amount that can potentially be absorbed per kg body weight during one day		

Exposure Scenario 1 (PT 2/3/4 – Decanting of product concentrated and dilution with water) – Zero ventilation assumed

ConsExpo Web v1.0.3 – Input Parameters



ConsExpo Web v1.0.3 – Results of air concentration calculations (zero ventilation)

Output scenario 1. *Mixing & Loading*

Results ? | Graphs ? | Sensitivity analysis ?

☑ Show dose descriptions

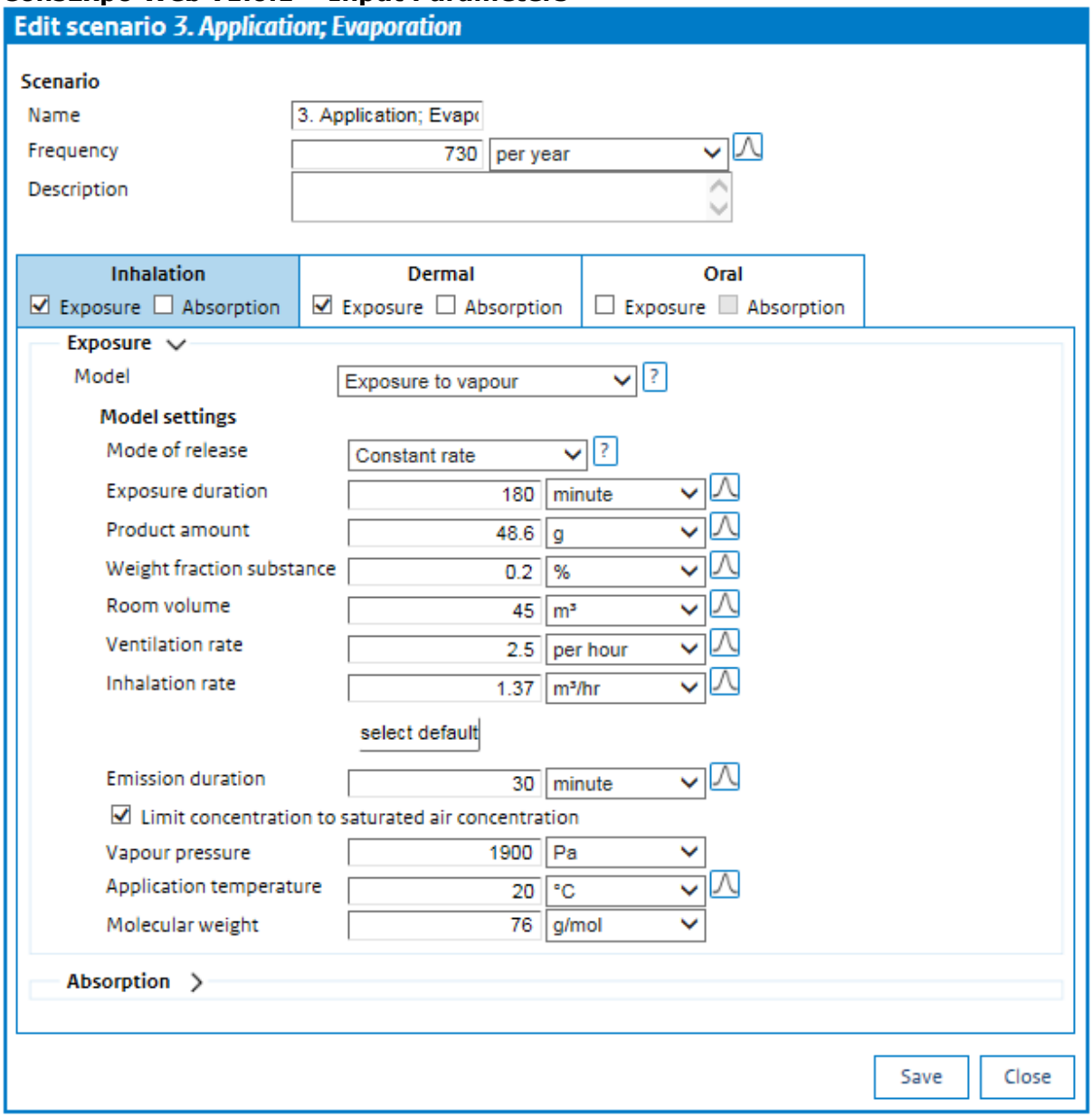
Inhalation

Exposure model Exposure to vapour - Evaporation

Mean event concentration	3.5×10^{-1}	mg/m³
average air concentration on exposure event. Note: depends strongly on chosen exposure duration		
Peak concentration (TWA 15 min)	3.5×10^{-1}	mg/m³
peak concentration (TWA 15 min) is the 15 minute time weighted average of the air concentration. In case the exposure duration is less than 15 minutes, the mean event air concentration is given instead.		
Mean concentration on day of exposure	3.7×10^{-4}	mg/m³
average air concentration over the day (accounts for the number of events on one day)		
Year average concentration	3.7×10^{-4}	mg/m³
mean daily air concentration averaged over a year		
External event dose	9.3×10^{-5}	mg/kg bw
the amount that can potentially be absorbed per kg body weight during one event		
External dose on day of exposure	1.9×10^{-4}	mg/kg bw
the amount that can potentially be absorbed per kg body weight during one day		

Exposure Scenario 2 (PT 2/3/4 - Spray and wipe of disinfectant on general surfaces for surface disinfection)

ConsExpo Web v1.0.1 – Input Parameters



ConsExpo Web v1.0.1 – Results of air concentration calculations

Output scenario 3. Application; Evaporation

Results ? | Graphs ? | Sensitivity analysis ?

☑ Show dose descriptions

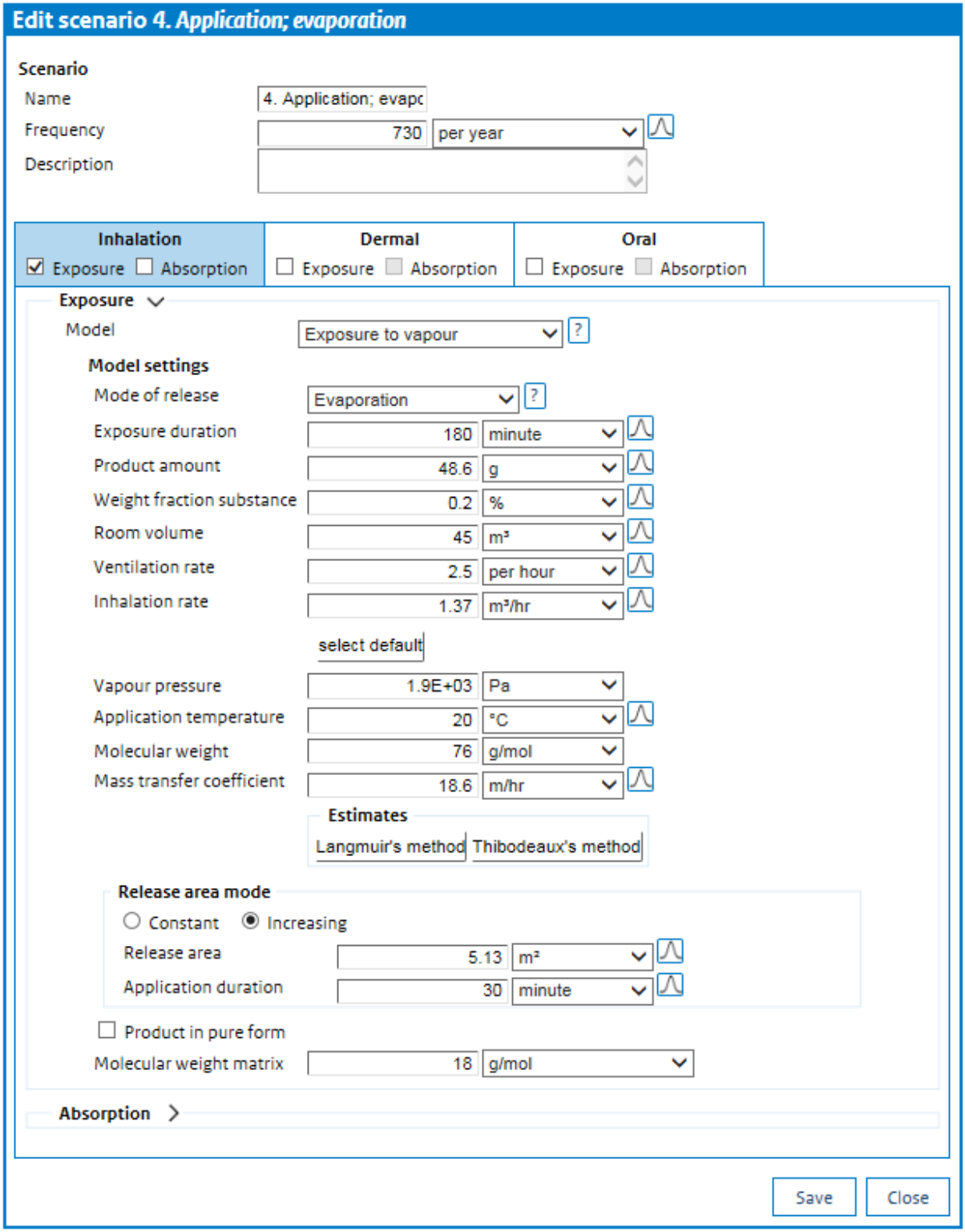
Inhalation

Exposure model Exposure to vapour - Constant rate

Mean event concentration	2.9×10^{-1}	mg/m³
average air concentration on exposure event. Note: depends strongly on chosen exposure duration		
Mean concentration on day of exposure	7.2×10^{-2}	mg/m³
average air concentration over the day (accounts for the number of events on one day)		
Year average concentration	7.2×10^{-2}	mg/m³
mean daily air concentration averaged over a year		
External event dose	1.8×10^{-2}	mg/kg bw
the amount that can potentially be absorbed per kg body weight during one event		
External dose on day of exposure	3.6×10^{-2}	mg/kg bw
the amount that can potentially be absorbed per kg body weight during one day		

Exposure Scenario 3 (PT 2/3/4 - Pour and wipe of disinfectant on general surfaces for surface disinfection)

ConsExpo Web v1.0.1 – Input Parameters



ConsExpo Web v1.0.1 – Results of air concentration calculations

Output scenario 4. *Application; evaporation*

Results ? | Graphs ? | Sensitivity analysis ?

☑ Show dose descriptions

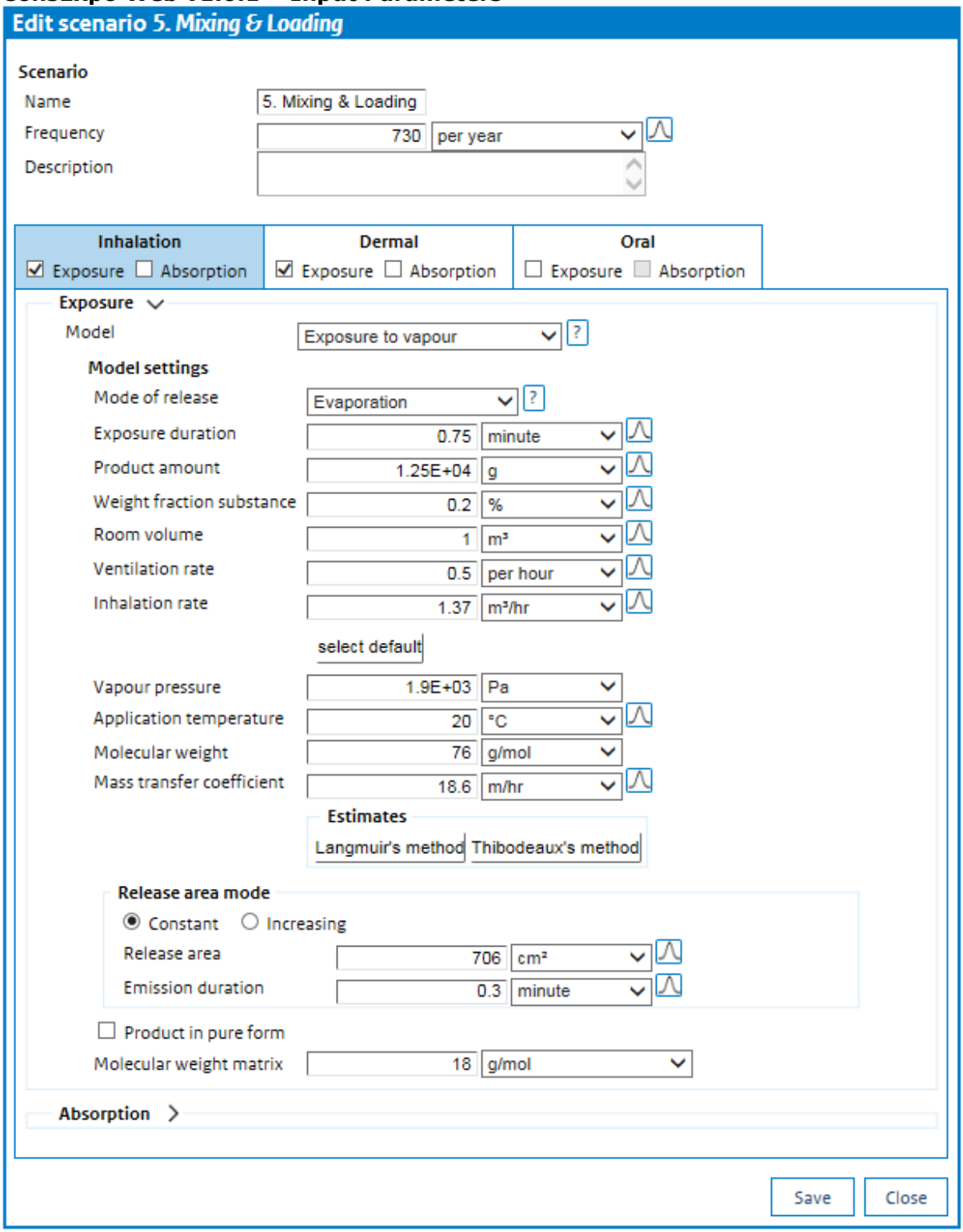
Inhalation

Exposure model Exposure to vapour - Evaporation

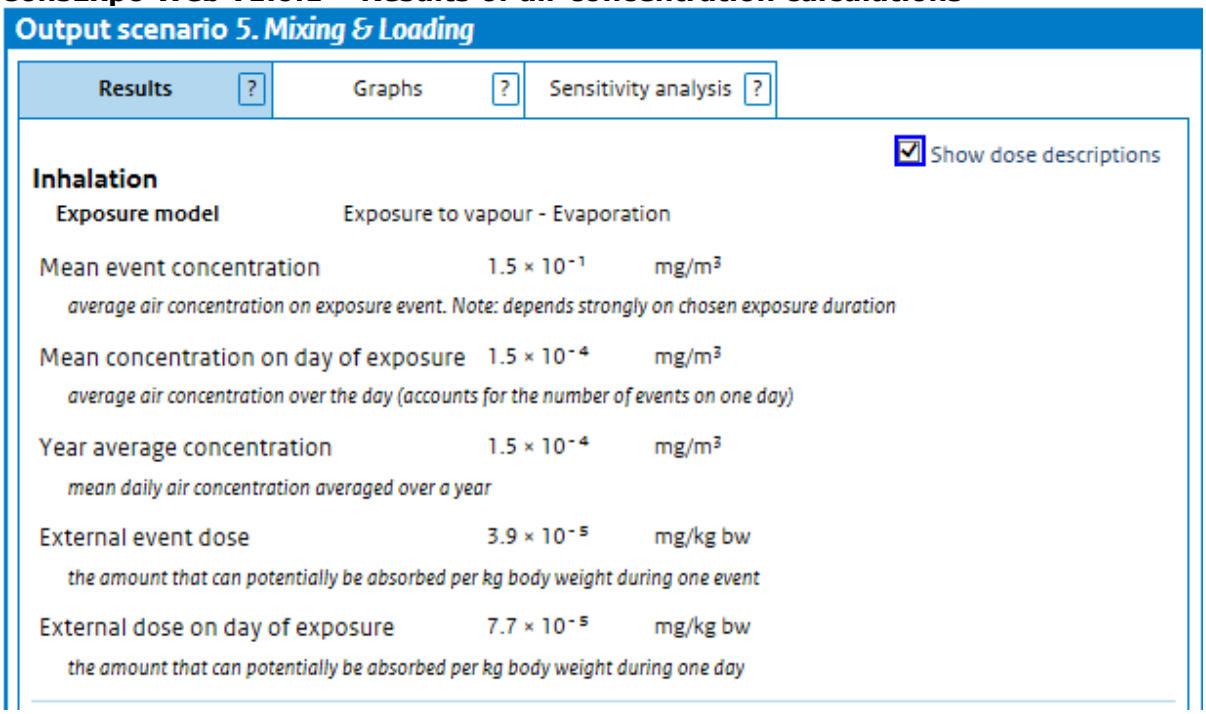
Mean event concentration	2.8×10^{-1}	mg/m³
average air concentration on exposure event. Note: depends strongly on chosen exposure duration		
Mean concentration on day of exposure	7.1×10^{-2}	mg/m³
average air concentration over the day (accounts for the number of events on one day)		
Year average concentration	7.1×10^{-2}	mg/m³
mean daily air concentration averaged over a year		
External event dose	1.9×10^{-2}	mg/kg bw
the amount that can potentially be absorbed per kg body weight during one event		
External dose on day of exposure	3.8×10^{-2}	mg/kg bw
the amount that can potentially be absorbed per kg body weight during one day		

Exposure Scenario 4 (PT 2/4 – Disinfection of tanks, pipes, filling machines in place)

ConsExpo Web v1.0.1 – Input Parameters



ConsExpo Web v1.0.1 – Results of air concentration calculations



Output scenario 5. *Mixing & Loading*

Results ? | Graphs ? | Sensitivity analysis ?

☑ Show dose descriptions

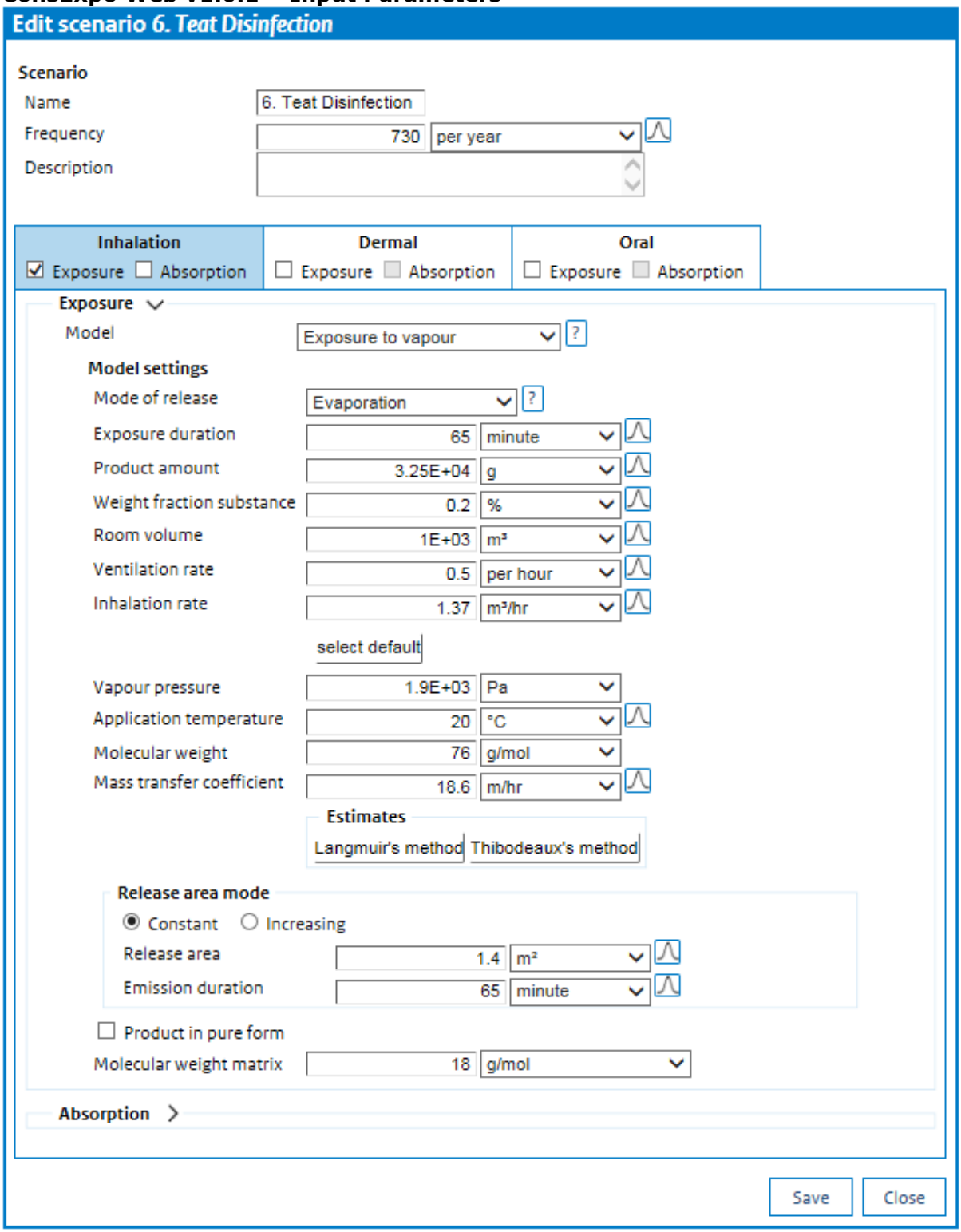
Inhalation

Exposure model Exposure to vapour - Evaporation

Mean event concentration	1.5×10^{-1}	mg/m³
average air concentration on exposure event. Note: depends strongly on chosen exposure duration		
Mean concentration on day of exposure	1.5×10^{-4}	mg/m³
average air concentration over the day (accounts for the number of events on one day)		
Year average concentration	1.5×10^{-4}	mg/m³
mean daily air concentration averaged over a year		
External event dose	3.9×10^{-5}	mg/kg bw
the amount that can potentially be absorbed per kg body weight during one event		
External dose on day of exposure	7.7×10^{-5}	mg/kg bw
the amount that can potentially be absorbed per kg body weight during one day		

Exposure Scenario 5 (PT 3 – Disinfection of teats)

ConsExpo Web v1.0.1 – Input Parameters



ConsExpo Web v1.0.1 – Results of air concentration calculations

Output scenario *Teat Disinfection*

Results ? | Graphs ? | Sensitivity analysis ?

☑ Show dose descriptions

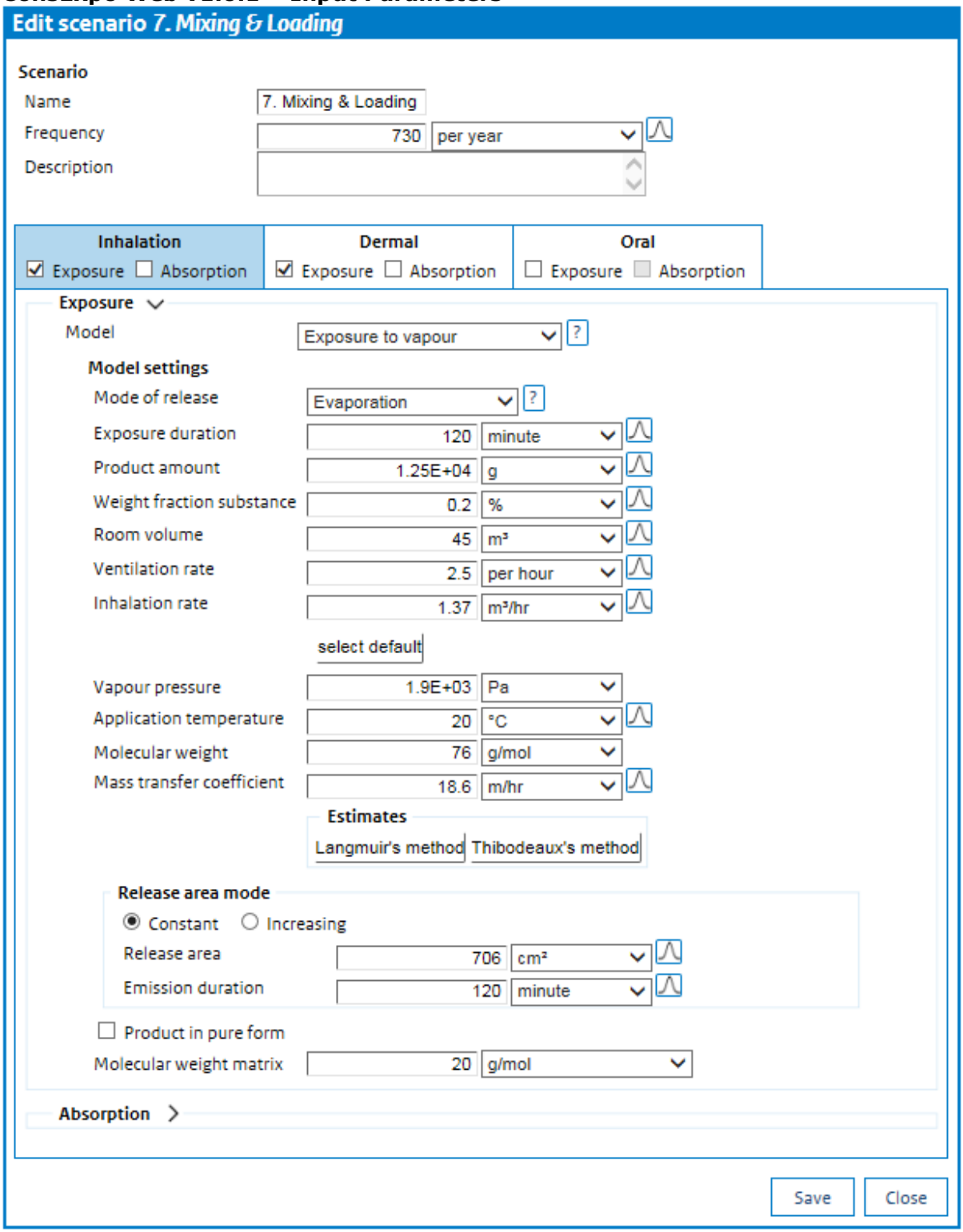
Inhalation

Exposure model Exposure to vapour - Evaporation

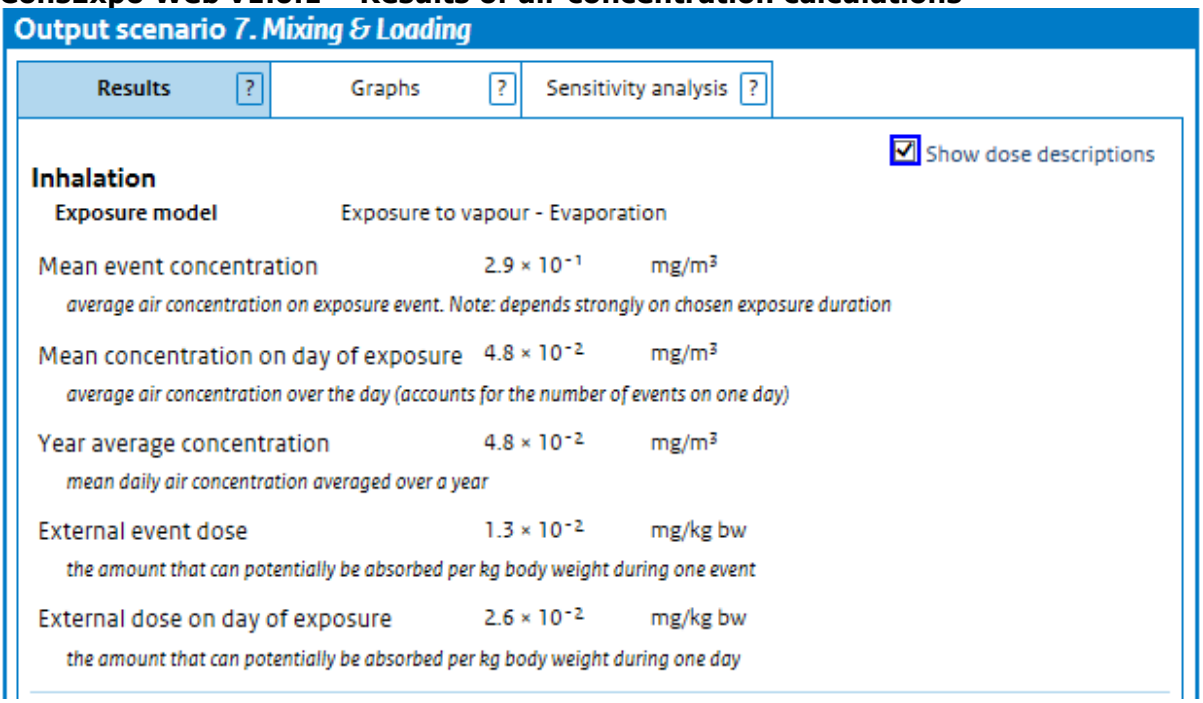
Mean event concentration	3.3×10^{-1}	mg/m³
average air concentration on exposure event. Note: depends strongly on chosen exposure duration		
Mean concentration on day of exposure	3.0×10^{-2}	mg/m³
average air concentration over the day (accounts for the number of events on one day)		
Year average concentration	3.0×10^{-2}	mg/m³
mean daily air concentration averaged over a year		
External event dose	7.9×10^{-3}	mg/kg bw
the amount that can potentially be absorbed per kg body weight during one event		
External dose on day of exposure	1.6×10^{-2}	mg/kg bw
the amount that can potentially be absorbed per kg body weight during one day		

Exposure Scenario 6 (PT 2/4 – Disinfection of Equipment by Immersion, dipping, soaking and soaking single stage cleaning and disinfection)

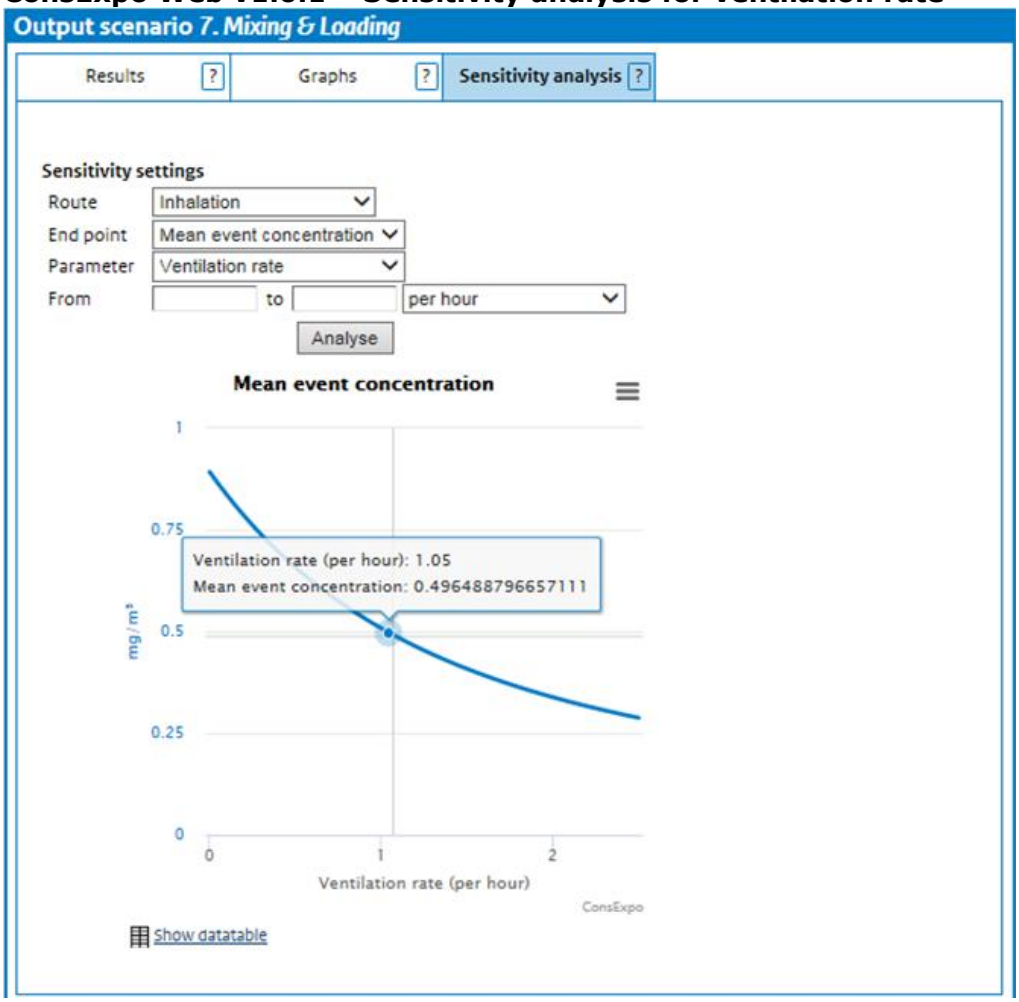
ConsExpo Web v1.0.1 – Input Parameters



ConsExpo Web v1.0.1 – Results of air concentration calculations



ConsExpo Web v1.0.1 – Sensitivity analysis for ventilation rate



3.3 Confidential annex

See separate confidential annex document