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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

ARVO XY PE

Product types [2 and 4]

Hydrogen peroxide

Case Number in R4BP: BC-JC075621-52

Evaluating Competent Authority: France

Date: 30/09/2021
Revised: July 2024

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Note to the reader

The product ARVO XY PE is a same product as PEROXYDE D'HYDROGENE SOLUTION 7,4% PRÊTE A L'EMPLOI.
Thus, this document is based on the PAR of the first authorisation for PEROXYDE D'HYDROGENE SOLUTION 7,4% PRÊTE A L'EMPLOI. Only the administrative sections were adapted in this document to be in line with the information provided for ARVO XY PE.
Besides the initial evaluation for ARVO XY PE has been updated following mutual recognition in sequence applications.

In part 2.1 of the updated PAR the "proposal for decision" corresponds to the summary of product characteristics related to the updated decision.

Note that in the whole document the name of the product is still PEROXYDE D'HYDROGENE SOLUTION 7,4% PRÊTE A L'EMPLOI as it is the reference product for the same application.

History of the dossier

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-APP	*FR*	*BC-XA029665-36*	06.06.2019	Initial assessment PEROXYDE D'HYDROGENE SOLUTION 7,4% PRÊTE A L'EMPLOI
NA-BBP	*FR*	*BC-YJ029729-11*	01.07.2029	Same biocidal product assessment ARVO XY PE
NA-AAT	*FR*			Following to a referral in the frame of mutual recognition in sequence
NA-MAC	*FR*	*BC-JC075621-52*	03.05.2024	Major change assessment (addition of new targets, addition of packagings, addition of a non-active substance, addition of use conditions, addition of new dosage)

1 CONCLUSION

PEROXYDE D'HYDROGENE SOLUTION 7,4% PRÊTE A L'EMPLOI is a hydrogen peroxide PT2 and PT4 biocidal product to be used by professional users for surface disinfection (sanitary, surfaces, equipment, and furniture).
Claimed uses are

- for PT2, the disinfection in the medical sector, and institutional buildings (hotels, sport halls),
- for PT4, the disinfection in the food industry, kitchens and canteens.

The product is applied either with a trigger spray or via airbone diffusion (fogging).

- ***Physico-chemical properties and analytical methods***

Regarding the physico-chemical properties for the product PEROXYDE D' HYDROGENE SOLUTION 7,4 % PRÊTE A L'EMPLOI, all studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The appearance of product a translucent colorless liquid. There is no effect of high temperature on the stability of the formulation, since after 2 weeks at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of 2 years at ambient temperature (protect from frost) when stored in trigger spray HDPE bottle and a HDPE jerrycan (commercial packaging materials). The long-term storage stability study is on-going and the final report of this study in commercial packaging at ambient temperature should be provided in post-authorisation within two years.
The analytical methods for the product is fully validated.

- **Post-authorisation 2020**

The long-term storage stability studies in commercial packaging at ambient temperature have been provided and are acceptable. The product is stable 2 years at ambient temperature.

- **Major change 2023**

The major change (addition of packaging and of a co-formulant) does not affect significantly the assessement of physico-chemical properties. Therefore, the physico-chemical properties were not reviewed in the framework of this dossier.

The change of composition does not affect the classification for physical hazards.

- ***Efficacy assessment***

French competent authorities (FR CA) assessed that the product PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI, as a ready-to-use, has shown a sufficient efficacy, for the following uses:

- Surface disinfection for PT2 uses in the medical area (clean conditions), at room temperature, by spraying against:
  - bacteria (including Listeria, Salmonella), yeasts and fungi, with a contact time of 15 minutes;
  - bacterial spores (including *B.cereus* and *C.sporogenes*) and mycobacteria (*M.terrae* only), with a contact time of 60 min.

- Surface disinfection for PT2 uses in collectivities, at room temperature, by spraying:
  - with dirty conditions against bacteria, yeasts and fungi, with a contact time of 15 minutes;
  - with clean conditions against bacterial spores (including *B.cereus* and *C.sporogenes*) and mycobacteria (*M.terrae* only) with a contact time of 60 min.

- Surface disinfection for PT4 uses in food and feed areas, at room temperature, by spraying:
  - with dirty conditions against bacteria, yeasts, fungi, with a contact time of 15 minutes;
  - with clean conditions against bacterial spores (including *B.cereus* and *C.sporogenes*) with a contact time of 60 min.

For legionella, FR CA estimated that the standard used (EN 13623) is not adapted to surface

disinfection (the scope of the norm refers to product used in aqueous systems) and a surface test would have been submitted in order to demonstrate this claim.

- Room disinfection by airborne diffusion in the medical area (clean conditions), in collectivities and food and feed areas (dirty conditions), at room temperature, with a diffuser equipment (technical characteristics specified in the SPC) against:
  - bacteria, yeasts, fungi (2 hours of contact time), 3 hours for the additional bacteria (Listeria, salmonella) and;
  - bacterial spores (3 hours of contact time), at 12 ml of product / m^3.

For malodour control, e-CA is of the opinion that contact time claimed (2 hours) for malodour control is not consistent with regards to the uses claimed.

- **Major change 2023**

The product ARVO XY PE, as a ready-to-use, has shown a sufficient efficacy, for the following claimed uses:

- **Use #1**

Hard surface disinfection for PT2 uses in healthcare area and institutions area, at room temperature, by spraying, in clean conditions (healthcare area) and dirty conditions (institutions areas) against:

- *Legionella*, with a contact time of 15 minutes ;
- Virus (including additional strains Influenza H1N1, MVA virus, Human Coronavirus, Pseudorabies virus) with a contact time of 60 min.

Soft surface disinfection for PT2 uses in healthcare area and institutions area, at room temperature, by spraying, in clean conditions, against:

- bacteria and yeasts with a contact time of 15 minutes.

- **Use #2**

Hard surface disinfection for PT4 uses in food and feed areas, at room temperature, by spraying against:

- *Legionella*, with a contact time of 15 min in dirty condition;
- Virus, with a contact time of 60 min in clean condition.

Activity against additional virucidal strains (Influenza H1N1, MVA virus, Human Coronavirus, Pseudorabies virus) has been also demonstrated.

Soft surface disinfection for PT4 uses in food and feed area, at room temperature, by spraying, in clean conditions, against:

- Bacteria and yeasts with a contact time of 15 minutes.

It has to be noted that for uses #1 and #2:

- Additionnal virucidal strain ECBO has not been validated as no P2S1 test has been provided.
- The disinfection of soft surfaces (Uses #1 and #2), bactericidal and yeasticidal activities were demonstrated only in clean conditions, whereas the applicant claimed dirty conditions.

- **Use #3**

Room disinfection by airborne diffusion for PT2 uses in health care and institutions areas at room temperature, with a fogger equipment, in clean conditions:
At the application rate of 6.5 mL of product/m^3, against:

- Bacteria, mycobacteria, yeasts, fungi, bacterial spores, mycobacteria and virus with 3H

contact time.
Activity against additional virucidal strain Human coronavirus has been also demonstrated.

Room disinfection by airborne diffusion for PT2 uses in healthcare area, at room temperature, with a fogger equipment, with clean conditions:
At the application rate of 12 mL of product/m^3, against:
- Virus with 3H contact time.
Activity against additional virucidal strain ECBO has been also demonstrated.

Room disinfection by airborne diffusion for PT2 uses in institutions area, at room temperature, with a fogger equipment, in dirty conditions:
At the application rate of 12 mL of product/m^3, against:
- Virus with 3H contact time
Activity against additional virucidal strain ECBO has been also demonstrated.

Room disinfection by airborne diffusion for PT2 uses in health care and institutions areas at room temperature, with a fogger equipment, in clean conditions:
At the application rate of 12 mL of product/m^3, against:
- Mycobacteria and virus with 4H contact time
Activity against additional virucidal strains Influenza H1N1, Herpes Simplex, MVA virus, Human Coronavirus, Rotavirus and Pseudorabies virus has been also demonstrated.

➢ **Use #4**

Room disinfection by airborne diffusion for PT4 uses in food and feed areas at room temperature, with a fogger equipment , in clean conditions:
At the application rate of 6.5 mL of product/m^3, against:
- Bacteria, mycobacteria, yeasts, fungi, bacterial spores, mycobacteria and virus with 3H contact time.

Activity against additional strain Human coronavirus has been also demonstrated.

Room disinfection by airborne diffusion for PT4 uses in in food and feed areas, at room temperature, with a fogger equipment, in dirty conditions:
At the application rate of 12 mL of product/m^3, against:
- Virus with 3H contact time.
Activity against additional virucidal strain ECBO has been also demonstrated.

Room disinfection by airborne diffusion for PT4 uses in in food and feed areas, at room temperature, with a fogger equipment, in clean conditions:
At the application rate of 12 mL of product/m^3, against:
- Mycobacteria and virus with 4H contact time
Activity against additional virucidal strains Influenza H1N1, Herpes Simplex, MVA virus, Human Coronavirus, Rotavirus and Pseudorabies virus has been also demonstrated.

- ***Risk assessment for human health***

Primary exposure:

The risk is considered acceptable for professional users during the application of the product by spraying, considering the wear of a respiratory equipment with an APF of 4 for PT2 Hospitals, PT2 Medical practices and PT4 Food Processing Industry, an APF of 10 for PT4 Small kitchens and PT4 Canteens and an APF of 40 for PT2 Hotels and nurseries.

For the fogger application, the risk is considered acceptable for professionals considering an automatic device (the operator is not present in the room during the treatment) and a re-entry period of:

- a minimum of 3h09 for PT2 and PT4 "kitchens and canteens" and 3h30 for PT4 "food processing industry" (after the product contact time) if the ventilation system cannot be re-activated without entering the treated room;
- a minimum of 2h37 for PT2, 20 min for PT4 "kitchens and canteens" and 6 min for PT4 "food processing industry" (after the product contact time) if the ventilation system can be re-activated without entering the treated room.

Secondary exposure:

The risk is considered acceptable for bystanders entering a room with freshly treated surfaces (spraying or fogging), provided a re-entry period to respect:

- for spray application:

after the end of the rinsing or the wiping step, a minimum of 58 min for PT2 Medical practices, 125 min for PT2 Hotels and nurseries, 29 min for PT4 Small kitchens, 39 min for PT4 Canteens and 15 min for PT4 Food Processing Industry. No re-entry period is foreseen for PT2 Hospitals.

- for fogger application:
  - ✓ a minimum of 3h09 for PT2 and PT4 "kitchens and canteens" and 3h30 for PT4 "food processing industry" (after the product contact time) if the ventilation system cannot be re-activated without entering the treated room;
  - ✓ a minimum of 2h37 for PT2, 20 min for PT4 "kitchens and canteens" and 6 min for PT4 "food processing industry" (after the product contact time) if the ventilation system can be re-activated without entering the treated room.

For spray and fogger application, due to the classification of product, facial exposure to generated aerosols has to be limited by the use of PPE (goggles) and application of technical and organisational RMMs for both application.

➢ **Major change 2023**

The major change has no impact on the human health risk assessment. Therefore, the conclusions remain unchanged.

- ***Risk for consumers via residues***

By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residue in food or feed are not expected for PEROXYDE D'HYDROGENE SOLUTION 7.4% PRETE A L'EMPLOI PT 2 uses.

For PT 4 uses, residues in food, feed or drinking water might be expected based on intended uses.
Biocidal product PEROXYDE D'HYDROGENE SOLUTION 7.4% PRETE A L'EMPLOI is composed of hydrogen peroxyde and does not contain substance of concern.
For hydrogen peroxide, no dietary exposure is foreseen.
Nevertheless, hydrogen peroxyde degradation can also lead to the formation of a wide range Disinfection By Products (DBP). In the frame of this dossier, post application methods (rinsing, drying or wiping treated surfaces) are necessary to prevent food, feed or drinking water contamination. Consequently, the following risk mitigation measure is proposed "After required contact time, wipe treated surfaces or rinse treated surfaces with potable water or

let the surfaces dry well, before reusing the surfaces".

➢ **Major change 2023**

The major change does not affects significantly the assessment performed for the dietary exposure. Therefore, the dietary exposure assessment was not reviewed in the framework of this dossier.

- ***Risk assessment for environment***

Based on this risk assessment and on available data, no unacceptable risk to the environment has been identified for the product "PEROXYDE D'HYDROGÈNE SOLUTION 7,4% PRÊT À L'EMPLOI", when applied according to the intended uses, even when all the uses are aggregated.

➢ **Major change 2023**

The major change does not impact the previous risk assessment or the classification of the product.

- ***General conclusion***

According to the assessment performed for the product PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE À L'EMPLOI, the following uses are proposed for authorization considering the appropriate risk mitigation measures:

- Surface disinfection for PT2 uses (medical area and collectivities) by spraying
- Surface disinfection for PT4 uses in food and feed areas by spraying
- Room disinfection by airborne diffusion (fogging) in the medical area (clean conditions), in collectivities and food and feed areas (dirty conditions) considering an automatic device (PT2 and PT4 uses).
-

➢ **Major change 2023**

- ***General conclusion***

According to the assessment performed for the major change application, the following uses are proposed for authorization considering the appropriate risk mitigation measures:

- Hard surface disinfection for PT2 and PT4 uses by spraying against Legionella and Virus (including additional strains Influenza H1N1, MVA virus, Human Coronavirus, Pseudorabies virus).
- Soft surface disinfection for PT2 and PT4 uses by spraying against bacteria and yeast.
- Room disinfection by airborne diffusion (fogging) for PT2 and PT4 uses at the application rate of 6.5 mL of product/m^3, against bacteria, mycobacteria, yeasts, fungi, bacterial spores, virus and against additional virucidal strain Human coronavirus.
- Room disinfection by airborne diffusion (fogging) for PT2 and PT4 uses at the application rate of 12 mL of product/m^3 and contact time of 3H, in dirty conditions, against virus and against additional virucidal strain ECBO.
- Room disinfection by airborne diffusion (fogging) for PT2 and PT4 at the application rate of 12 mL of product/m^3 and contact time of 4H, in clean conditions, against mycobacteria, virus and against additional virucidal strains Influenza H1N1, Herpes Simplex, MVA virus, Human Coronavirus, Rotavirus and Pseudorabies virus.

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)
ARVO XY PE INDAL OXY SPE RC SANIT OXY PE OXY SURFACE PE PEROXY PE O2 SAFE 7.4 SPRAY OXY PAE INDAL OXY DVA KALI CHEM OXY FOG 7,4% SANISWISS SANITIZER AUTOMATE ASEPTOXY SURFACE EQQO PEROXY EQQO XY DES SPRAY EQQO XY DESINF EQQO XY SURFACE H2O2-DESINF H2O2-DSVA H2O2-PAE H2O2-SPRAY H2O2-SURFACE PEROXY DSVA PEROXY SPRAY PEROXY SURFACE SANITOXY SURFACE WPB-7	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	STOCKMEIER FRANCE SAS
	Address	3 rue de la Buhotière Saint-Jacques de la Lande BP 89152 35091 Rennes CEDEX 9 France
Authorisation number	**FR-2019-0071**	
Date of the authorisation	**01/07/2019**	
Expiry date of the authorisation	**05/06/2029**	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	STOCKMEIER FRANCE SAS
Address of manufacturer	3 rue de la Buhotière Saint-Jacques de la Lande BP 89152 35091 Rennes CEDEX 9 France
Location of manufacturing sites	3 rue de la Buhotière Saint-Jacques de la Lande BP 89152 35136 RENNES France

	Rue des Criquiers 60220 FORMERIE France

Name of manufacturer	STOCKMEIER CHEMIE EILENBURG
Address of manufacturer	GUSTAV-ADOLF-RING 5 04838 EILENBURG GERMANY
Location of manufacturing sites	GUSTAV-ADOLF-RING 5 04838 EILENBURG GERMANY

Name of manufacturer	STOCKMEIER CHEMIE GMBH & CO. KG
Address of manufacturer	AM STADTHOLZ 37 33609 BIELEFELD GERMANY
Location of manufacturing sites	AM STADTHOLZ 37 33609 BIELEFELD GERMANY

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

Active substance	Hydrogen peroxide
Name of manufacturer	SOLVAY CHEMICALS INTERNATIONAL SA
Address of manufacturer	Rue de Ransbeek 310 1120 BRUXELLES Belgium
Location of manufacturing sites	SOLVAY INTEROX LIMITED Baronnet Road , Solvay House WA4 6HA Warrington, Cheshire United-Kingdom
	SOLVAY CHEMICALS FINLAND OY Yrjonojantier 2 45910 VOIKKAA Finland
	SOLVAY CHEMICALS GMBH GERMANY Koethensche Strasse 13 06406 BERNBURG Germany
	SOLVAY CHIMICA ITALIA SPA ITALY Via Piave 6 57013 ROSIGNANO SOLVAY LI Italy
	SOLVAY CHEMIE SA BELGIUM Rue Solvay 39 5190 JEMEPPE SUR SAMBRE Belgium
	SOLVAY CHEMIE SA BELGIUM Scheldelaan 600 Haven 725 2040 ANTWERPEN Belgium
	SOLVAY INTEROX PRODUTOS PEROXIDADOS SA Rua Eng, Clement Dumoulin

	2625106 POVOA DE SANTA IRIA Portugal

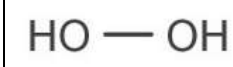
2.1.2 Product composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Hydrogen peroxide
IUPAC or EC name	-
EC number	231-765-0
CAS number	7722-84-1
Index number in Annex VI of CLP	008-003-00-9
Minimum purity / content	99.5% % w/w (dry weight) 35.0% - 70.0% w/w (technical concentrate)
Structural formula	

2.1.2.2 Candidate(s) for substitution

Not relevant

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide	-	Active substance (technical)	7722-84-1	231-765-0	7.44%

2.1.2.4 Information on technical equivalence

Not relevant

2.1.2.5 Information on the substance(s) of concern

Not relevant

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

According to our assessment, none of the co-formulants contained in the product PEROXYDE D'HYDROGENE SOLUTION 7,4% PRÊTE A L'EMPLOI, are regulatory identified as endocrine disruptors.

2.1.2.7 Type of formulation

AL - all other liquid

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Eye Irrit 2
Hazard statement	H319: Causes serious eye irritation
Labelling	
Signal words	Warning
Hazard statements	H319: Causes serious eye irritation
Precautionary statements	P264: Wash hands thoroughly after handling P280: Wear protective gloves/protective clothing/eye protection/face protection P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. P337 + P313: If eye irritation persists get medical advice/attention P501: Dispose of contents and container to be in accordance with local/regional/national/international regulations
Note	**-**

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Spray disinfectant, PT2

Product Type	PT2, Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Disinfectants for sanitary, surfaces, equipment and furniture without direct contact with food or feedstuff in medical and hospital environments, paramedical, institutional, tertiary sector, hotels, sports halls and changing rooms, etc. Disinfectants for sanitaries, bathrooms, etc.

<table>
<tr><td>Target organism (including development stage)</td><td>Bacteria
Bacterial spores
Yeasts
Fungi
Tuberculosis bacilli
Virus</td></tr>
<tr><td>Field of use</td><td>Medical sector and institutions (no food contact)</td></tr>
<tr><td>Application method(s)</td><td>Surface spraying</td></tr>
<tr><td>Application rate(s) and frequency</td><td>Ready for use (100 % v/v)
Hard surfaces:
<table>
<tr><td>Target organism(s)</td><td>Healthcare area</td><td>Institutions area</td></tr>
<tr><td>Bacteria, yeast</td><td>Clean conditions, 15 min contact time</td><td>Dirty conditions, 15 min contact time</td></tr>
<tr><td>Fungi</td><td>Clean conditions, 15 min contact time</td><td>Dirty conditions, 15 min contact time</td></tr>
<tr><td>Bacterial spores, tuberculosis bacilli, virus</td><td>Clean conditions, 60 min contact time</td><td>Clean conditions, 60 min contact time</td></tr>
</table>
Soft surfaces
<table>
<tr><td>Target organism(s)</td><td>Healthcare area</td><td>Institutions area</td></tr>
<tr><td>Bacteria, yeast</td><td>Clean conditions, 15 min contact time</td><td>Clean conditions, 15 min contact time</td></tr>
</table>
Room temperature

Application rate: max 50 ml/m^2</td></tr>
<tr><td>Category(ies) of users</td><td>Professional users</td></tr>
<tr><td>Pack sizes and packaging material</td><td>- 500mL, 750mL or 1L HDPE Prefilled trigger spray opaque bottle
- 1L Opaque bottle with nebulization equipment
- 2L, 5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment
- 2.5L PE pouch (smart bag)
- 220L barrels and 1000L IBC HDPE with filling kit</td></tr>
</table>

2.1.4.1.1 Use-specific instructions for use

- Apply the product uniformly by spraying (if needed spread with a wipe/soaked cloth on the entire surfaces to be treated) in sufficient quantity so that the surface remains wet during during the requested contact time.
- The product is not intended to be used in dirty conditions for health care area (medical / dental / veterinary hospitals equipments) therefore clean carefully the surfaces, followed by a rincing step with drinking water before application of the product in this area.
- For medical area, due to the contact time superior to 5 minutes, do not use this product for surfaces that are likely to come into contact with the patient and/or the medical

staff and surfaces which are frequently touched by different people.
- Only clean conditions are validated for virucidal, sporicidal and tuberculocidal activities, therefore clean carefully the surfaces, followed by a rincing step with drinking water before application of the product both in health care and institutions areas.
- For hard surfaces only, the product has been tested against additional bactericidal strains Listeria, Salmonella and Legionella, and additional virucidal strains Influenza H1N1, MVA virus, Human Coronavirus and Pseudorabies virus.

2.1.4.1.2 Use-specific risk mitigation measures

During the spray application, facial exposure to generated aerosols has to be limited by the use of PPE and application of technical and organisational RMM such as:
- Minimisation of splashes and spills (during loading of the product);
- Eye protection (chemical goggles);
- Training for staff on good practice.

Prohibit access to the general public during the application.
After required contact time, wipe treated surfaces or rinse treated surfaces with potable water or let the surfaces dry well.

For hospitals:

Wear respiratory protective equipment (minimum **APF 4**, type of equipment to be specified by the applicant) during the application of the product including the rinsing or wiping step.

For the general public

Access to treated area is not restricted after the end of the rinsing, wiping or drying step.

For medical practices:

Wear respiratory protective equipment (minimum **APF 4**, type of equipment to be specified by the applicant) during the application of the product including the rinsing or wiping step.

For the general public

Observe a re-entry time of minimum 58 min in the treated room after the end of the rinsing, wiping or drying step.
Or
Ensure that the ambient air concentration is below 1.25 mg / m^3 by using an H_2O_2 detector before allowing re-entry in the room.

For hotels and nurseries:

Wear respiratory protective equipment (minimum **APF 40**, type of equipment to be specified by the applicant) during the application of the product including the rinsing or wiping step.

For the general public

Observe a re-entry time of minimum 125 min in the treated room after the end of the rinsing, wiping or drying step. Or Ensure that the ambient air concentration is below 1.25 mg/ m^3 by using an H_2O_2 detector before allowing re-entry in the room.

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

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

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

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2.1.4.2 Use description

Table 2. Use # 2 – Spray disinfectant, PT4

Product Type	PT4 Food and feed area
Where relevant, an exact description of the authorised use	Disinfectants of rooms (including collective central kitchens) and equipments for the production of food and feedstuff (including drinking water) for human and animal consumption.
Target organism (including development stage)	Bacteria Bacterial spores Yeasts Fungi Virus
Field of use	Professional use in agro-food industry and collective central kitchens (food contact)
Application method(s)	Surface spraying
Application rate(s) and frequency	Ready for use (100 % v/v)

Target organism(s)	**Hard surfaces**	**Soft surfaces**
Bacteria, yeast	Dirty conditions, 15 min contact time	Clean conditions, 15 min contact time
Fungi	Dirty conditions, 15 min contact time	/
Bacterial	Clean conditions,	/

	<table><tr><td>spores, virus</td><td>60 min contact time</td><td></td></tr></table> Room temperature Application rate: max 50 ml/m^2
Category(ies) of users	Professional users
Pack sizes and packaging material	- 500mL, 750mL or 1L HDPE Prefilled trigger spray opaque bottle - 1L Opaque bottle with nebulization equipment - 2L, 5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment - 2.5L PE pouch (smart bag) - 220L barrels and 1000L IBC HDPE with filling kit

2.1.4.2.1 Use-specific instructions for use

- Apply the product uniformly by spraying (and if needed spread the product with a wipe/soaked cloth on the entire surfaces to be treated) in sufficient quantity so that the surface remains wet during at during the requested contact time.
- Only clean conditions are validated for sporicidal and virucidal activities, therefore clean carefully the surfaces before application of the product.
- The product has been tested against additional bactericidal strains Listeria, Salmonella and Legionella, and additional virucidal strains Influenza H1N1, MVA virus, Human Coronavirus, Pseudorabies virus.

2.1.4.2.2 Use-specific risk mitigation measures

During the spray application, facial exposure to generated aerosols has to be limited by the use of PPE and application of technical and organisational RMM such as:

- Minimisation of spills and splashes (during loading of the product);
- Eye protection (chemical goggles);
- Training for staff on good practice.

Prohibit access to the general public during the application.

After required contact time, wipe treated surfaces or rinse treated surfaces with potable water or let the surfaces dry well.

For small kitchens:

Wear respiratory protective equipment (minimum **APF 10**, type of equipment to be specified by the applicant) during the application of the product including the rinsing or wiping step.

For the general public

Observe a re-entry time of minimum 29 min in the treated room after the end of the rinsing, wiping or drying step.
Or
Ensure that the ambient air concentration is below 1.25 mg/ m^3 by using an H_2O_2 detector before allowing re-entry in the room.

For canteens:

Wear respiratory protective equipment (minimum **APF 10**, type of equipment to be specified by the applicant) during the application of the product including the rinsing or wiping step.

For the general public

Observe a re-entry time of minimum 39 min in the treated room after the end of the rinsing or wiping or drying step.
Or
Ensure that the ambient air concentration is below 1.25 mg/ m^3 by using an H_2O_2 detector before allowing re-entry in the room.

For food processing industry:

Wear respiratory protective equipment (minimum **APF 4**, type of equipment to be specified by the applicant) during the application of the product including the rinsing or wiping step.

For the general public

Observe a re-entry time of minimum 15 min in the treated room after the end of the rinsing or wiping or drying step.
Or
Ensure that the ambient air concentration is below 1.25 mg/ m^3 by using an H_2O_2 detector before allowing re-entry in the room.

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

-

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

-

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

-

2.1.4.3 Use description

Table 1. Use # 3 – Fogger disinfectant, PT2

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

<table>
<tr><td>Where relevant, an exact description of the authorised use</td><td></td></tr>
<tr><td>Target organism (including development stage)</td><td>Bacteria
Bacterial spores
Yeasts
Fungi
Mycobacteria
Virus</td></tr>
<tr><td>Field of use</td><td>Healthcare and institutions areas</td></tr>
<tr><td>Application method(s)</td><td>Airborne diffusion</td></tr>
<tr><td>Application rate(s) and frequency</td><td>❖ <u>12 mL of product /m³ in combination with a fogger equipment with the following characteristics</u>:
Cold nebulisation
Range of median droplet diameters: 5-10 µm

Room volume between 30 and 150 m^3

<table>
<tr><td>Target organism(s)</td><td>Healthcare area</td><td>Institutions area</td></tr>
<tr><td>Bacteria, yeasts</td><td>Clean conditions
Contact time 2H</td><td>Dirty conditions
Contact time 2H</td></tr>
<tr><td>Fungi</td><td>Clean conditions
Contact time 2H</td><td>Dirty conditions
Contact time 2H</td></tr>
<tr><td>Bacterial spores, virus</td><td>Clean conditions
Contact time 3H</td><td>Dirty conditions
Contact time 3H</td></tr>
<tr><td>Mycobacteria, virus</td><td>Clean conditions
Contact time 4H</td><td>Clean conditions
Contact time 4H</td></tr>
</table>
Room temperature
Humidity: 50-75%

❖ <u>6.5 mL of product /m³ in combination with a fogger equipment with the following characteristics:</u>
Cold nebulisation
Range of median droplet diameters: 5-10 µm

Room volume between 4 and 150 m^3
Contact time: 3H for bacteria, bacterial spores, yeasts, fungi, mycobacteria and virus
Room temperature
Humidity: 50-75%
Clean conditions</td></tr>
<tr><td>Category(ies) of users</td><td>Professional users</td></tr>
<tr><td>Pack sizes and packaging material</td><td>- 1L Opaque bottle with nebulization equipment
- 2L, 5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment
- 2.5L PE pouch (smart bag)
- 220L barrels and 1000L IBC HDPE with filling kit</td></tr>
</table>

2.1.4.3.1 Use-specific instructions for use

- The product is not intended to be used in dirty conditions for health care area (medical

/ dental / veterinary hospitals equipments), therefore clean carefully the surfaces, followed by a rincing step with drinking water before application of the product in this area.

- For the application rate of 6.5 ml/m^3, clean carefully the surfaces before application of the product followed by a rincing step with drinking water before application of the product in this area.
- The contact time starts when the required total volume of product (see application rate) is nebulized.
- At the application rate of 6.5 ml/m^3 (contact time 3H;clean conditions), the product has been tested against additional virucidal strain Human Coronavirus.
- At the application rate of 12 ml/m^3 (contact time 3H; clean conditions for healthcare/dirty conditions for institutions), the product has been tested against additional virucidal strain ECBO.
- At the application rate of 12 ml/m^3 (contact time 3H ; clean conditions for healthcare/dirty conditions for institutions), the product has been tested against additional bacterial strains Listeria and Salmonella.
- At the application rate of 12 ml/m^3 (contact time 4H ; healthcare&institutions areas/clean conditions), the product has been tested against additional virucidal strains Human Influenza H1N1, Rotavirus A, Herpes Simplex Type 1, Pseudorabies virus, and Human Coronavirus and MVA virus.
- Biological validation shall be performed for each room to be disinfected (or in a suitable "standard" room in a facility, if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter.
  As an example, at application rate of 6,5 ml/m^3 of room volume, at room temperature, the product has been demonstrated as efficacious via efficacy study performed according to EN17272 standard with a flow rate of 1,2 litre/hour.

2.1.4.3.2 Use-specific risk mitigation measures

During the loading of the fogger device, facial exposure to generated aerosols has to be limited by the use of PPE and application of technical and organisational RMM such as:

- Minimisation of spills and splashes;
- Eye protection (chemical goggles);
- Training for staff on good practice;
- Good standard of personal hygiene.

Prohibit access to the general public during the application.
Apply the product in rooms made airtight.

A re-entry period is required for professionals and for general public entering the treated room:

- a minimum of 3h09 (after the product contact time) if the ventilation system cannot be re-activated without entering the treated room;
- a minimum of 2h37 (after the product contact time) if the ventilation system can be re-activated without entering the treated room.

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

-

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

-

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

-

2.1.4.4 Use description

Table 2. Use # 4 – Fogger disinfectant, PT4

<table>
<tr><td>Product Type</td><td>PT4 Food and feed area</td></tr>
<tr><td>Where relevant, an exact description of the authorised use</td><td>Room disinfection</td></tr>
<tr><td>Target organism (including development stage)</td><td>Bacteria
Bacterial spores
Yeasts
Fungi
Mycobacteria
Virus</td></tr>
<tr><td>Field of use</td><td>Professional use in agro-food industry and collective central kitchens (food contact)</td></tr>
<tr><td>Application method(s)</td><td>Airbone diffusion</td></tr>
<tr><td>Application rate(s) and frequency</td><td>❖ <u>12 ml of product /m³ in combination with a fogger equipment with the following characteristics:</u>
Cold nebulisation
Range median droplet size: 5-10 µm

Room volume between 30 and 150 m³
<table>
<tr><th>Target organism(s)</th><th>Conditions of use</th></tr>
<tr><td>Bacteria, yeasts</td><td>Dirty conditions
Contact time 2H</td></tr>
<tr><td>Fungi</td><td>Dirty conditions
Contact time 2H</td></tr>
<tr><td>Bacterial spores, virus</td><td>Dirty conditions
Contact time 3H</td></tr>
<tr><td>Mycobacteria and virus</td><td>Clean conditions
Contact time 4H</td></tr>
</table>
Room temperature
Humidity: 50-75%

❖ <u>6.5 mL of product /m³ in combination with a fogger</u></td></tr>
</table>

	<u>equipment with the following characteristics:</u> Cold nebulisation Range of median droplet size: 5-10 µm Room volume between 4 and 150 m^3 Contact time: 3h for bacteria, bacterial spores, yeasts, fungi, mycobacteria and virus Room temperature Humidity: 50-75% Clean conditions
Category(ies) of users	Professional users
Pack sizes and packaging material	- 1L Opaque bottle with nebulization equipment - 2L, 5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment - 2.5L PE pouch (smart bag) - 220L barrels and 1000L IBC HDPE with filling kit

2.1.4.4.1 Use-specific instructions for use

- For the application rate of 6.5 ml/m^3, clean carefully the surfaces before application of the product followed by a rincing step with drinking water before application of the product in this area.
- The contact time starts when the required total volume of product (see application rate) is nebulized.
- At the application rate of 6.5 ml/m^3 (contact time 3H;clean conditions), the product has been tested against against additional virucidal strain Human Coronavirus.
- At the application rate of 12 ml/m^3 (contact time 3H;dirty conditions), the product has been tested against against additional virucidal strain ECBO.
- At the application rate of 12 ml/m^3 (contact time 3H; dirty conditions), the product has been tested against against additional bactericidal strains Listeria and Salmonella.
- At the application rate of 12 ml/m^3 (contact time 4H ; clean conditions), the product has been tested against additional virucidal strains Human Influenza H1N1, Rotavirus A, Herpes Simplex Type 1, Pseudorabies Human Coronavirus and MVA virus.
- Biological validation shall be performed for each room to be disinfected (or in a suitable "standard" room in a facility, if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter.
  As an example, at application rate of 6,5 ml/m^3 of room volume, at room temperature, the product has been demonstrated as efficacious via efficacy study performed according to EN17272 standard with a flow rate of 1,2 litre/hour.

2.1.4.4.2 Use-specific risk mitigation measures

To prevent food, feed or drinking water contamination, after required contact time, wipe treated surfaces or rinse treated surfaces with potable water well , before reusing the surfaces.

During the loading of the fogger device, facial exposure to generated aerosols has to be limited by the use of PPE and application of technical and organisational RMM such as:

- Minimisation of spills and splashes;
- Eye protection (chemical goggles);
- Training for staff on good practice;

- Good standard of personal hygiene.

Prohibit access to the general public during the application.
Apply the product in rooms made airtight.

A re-entry period is required for professionals and for general public entering the treated room:

- a minimum of 3h09 for "kitchens and canteens" uses and 3h30 "food processing industry" uses (after the product contact time) if the ventilation system cannot be re-activated without entering the treated room;
- a minimum of 20 min for "kitchens and canteens" uses and 6 min for "food processing industry" uses (after the product contact time) if the ventilation system can be re-activated without entering the treated room.

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

-

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

-

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

-

2.1.4.5 General directions for use

2.1.4.5.1 Instructions for use

- Always read the label or leaflet before use and respect follow all the instructions provided.
- Respect the conditions of use of the product (concentration, contact time, temperature, etc.).
- Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved.
- Inform the registration holder if the treatment is ineffective.

2.1.4.5.2 Risk mitigation measures

-

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

- Inhalation (spray mist): Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.
- Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur.
- Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.
- Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested
- In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting.
- Keep the container or label available.

2.1.4.5.4 Instructions for safe disposal of the product and its packaging

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

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

2 years at ambient temperature.
Mitigation measure to be added: Protect from frost.

2.1.4.6 Other information

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

2.1.5 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)
Prefilled trigger spray opaque bottle	500mL, 750mL or 1L	HDPE	Trigger spray types: -Canyon T95 Trigger spray venting -Guala TS3 Dexter	Professional	Yes

			spray degassing		
Opaque bottle	1L	HDPE	Degassing cap	Professional	Yes
Opaque Jerrycan	5L, 10L or 20L	HDPE	Degassing cap	Professional	Yes
Opaque Jerrycan	2L	HDPE	Degassing cap	Professional	Yes
Pouch (smart bag)	2.5L	PE	Sealed opening	Professional	Yes
IBC*	220L, 1000L	HDPE	Degassing cap	Professional	Yes

* IBC are used exclusively with filling kit called "kit de soutirage"

2.1.6 Documentation

2.1.6.1 Data submitted in relation to product application

Physico-chemical

Physico-chemical properties studies and analytical methods on the biocidal product PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE-A-L'EMPLOI were provided by GFB.

Efficacy

New data with the product PEROXYDE D'HYDROGENE SOLUTION 7,4% PRÊTE A L'EMPLOI are submitted for the demonstration of the efficacy. Please refer to the list of references.

Human Health

One study was provided to demonstrate post application method efficiencies (rinsing, drying, wiping) on remaining residues on treated surfaces. Moreover, the applicant provided an argumentation to explain that intended H_2O_2 biocidal use would not raise any risk for the consumer.

2.1.6.2 Access to documentation

GFB has access to data on the active substance hydrogen peroxide with a Letter of Access of Solvay SA., one applicant of the active substance Solvay SA.

2.2 Assessment of the biocidal product

The biocidal product is not the same as the one assessed for the approbation of the active substance. The composition of the product is confidential and is presented in a confidential annex. The product contains 7.44% of technical active substance hydrogen peroxyde and 7.4% of pure active substance hydrogen peroxyde.

The product does not contain PT6 preservative.

The product is not diluted for use. It is a ready-to-use.
Formulation type: AL all other liquid.

Hydrocarbon and H304 co-formulant content < 10%.

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

Table 5. Use # 1 – Spray disinfectant, PT2

Product Type	PT2, Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Disinfectants for sanitary, surfaces, equipment and furniture without direct contact with food or feedstuff in medical and hospital environments, paramedical, institutional, tertiary sector, hotels, sports halls and changing rooms, etc. Disinfectants for sanitaries, bathrooms, etc. and malodour control for humidity and garbage smells.
Target organism (including development stage)	Bacteria (including Legionella, Listeria, Salmonella) and bacterial spores, yeasts, fungi, mycobacteria (*M. terrae*), malodour control.
Field of use	Professional use in medical sector and collectivities (no food contact)
Application method(s)	surface spraying
Application rate(s) and frequency	30 to 50 ml/m² Apply at an adequate frequency based on the hygiene plan in place
Category(ies) of users	Surface spraying
Pack sizes and packaging material	500mL, 750mL or 1L HDPE Prefilled trigger spray opaque bottle (Trigger spray types: Canyon T95 Trigger spray venting or Guala TS3 Dexter spray degassing) 1L Opaque bottle with nebulization equipment, 5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment

Table 6. Use # 2 – Spray disinfectant, PT4

Product Type	PT4 Food and feed area
Where relevant, an exact description of the authorised use	Disinfectants of rooms (including collective central kitchens) and equipment for the production of food and feed stuff (including drinking water) for human and animal consumption.
Target organism (including development stage)	Bacteria (including Legionella, Listeria, Salmonella) and bacterial spores (*M.terrae*), yeasts, fungi.
Field of use	Professional use in agro-food industry and collective central kitchens (food contact)
Application method(s)	surface spraying
Application rate(s) and frequency	30 to 50 ml/m² Apply at an adequate frequency based on the hygiene plan in place
Category(ies) of users	Professional users

Pack sizes and packaging material	500mL, 750mL or 1L HDPE Prefilled trigger spray opaque bottle (Trigger spray types: Canyon T95 Trigger spray venting or Guala TS3 Dexter spray degassing) 1L Opaque bottle with nebulization equipment, 5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment

Table 73. Use # 3 – Fogger disinfectant, PT2

Product Type	PT2, Disinfectants and algaecides not intended for direct application to humans or animals.
Where relevant, an exact description of the authorised use	Disinfectants for sanitary, surfaces, equipment and furniture without direct contact with food or feedstuff in medical and hospital environments, paramedical, institutional, tertiary sector, hotels, sports halls and changing rooms, etc. Disinfectants for sanitaries, bathrooms, etc. and malodour control for humidity and garbage smells.
Target organism (including development stage)	Bacteria (including Listeria, Salmonella) and bacterial spores, yeasts and fungi.
Field of use	Professional use in medical sector and collectivities (no food contact).
Application method(s)	Airbone diffusion (fogging).
Application rate(s) and frequency	12 ml/m³ Apply at an adequate frequency based on the hygiene plan in place.
Category(ies) of users	Professional users
Pack sizes and packaging material	1L Opaque bottle with nebulization equipment 5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment

Table 84. Use # 4 – Fogger disinfectant, PT4

Product Type	PT4 Food and feed area
Where relevant, an exact description of the authorised use	Disinfectants of rooms (including collective central kitchens) and equipment for the production of food and feed stuff (including drinking water) for human and animal consumption.
Target organism (including development stage)	Bacteria (including Listeria, Salmonella) and bacterial spores, yeasts and fungi.
Field of use	Professional use in agro-food industry and collective central kitchens (food contact)
Application method(s)	Airbone diffusion (fogging)
Application rate(s) and frequency	12 ml/m³ Apply at an adequate frequency based on the hygiene plan in place
Category(ies) of users	Professional users
Pack sizes and packaging material	1L Opaque bottle with nebulization equipment, 5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment

- **Major change 2023**

Use # 1 – Spray disinfectant, PT2

Product Type	PT2, Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Disinfectants for sanitary, surfaces, equipment and furniture without direct contact with food or feedstuff in medical and hospital environments, paramedical, institutional, tertiary sector, hotels, sports halls and changing rooms, etc. Disinfectants for sanitaries, bathrooms, etc. Desinfectants for soft surfaces (textile).
Target organism (including development stage)	- Bacteria (including Legionella, Listeria, Salmonella) - Bacterial spores - Yeasts - Fungi - Mycobacteria (M. terrae) - Virus (including additional strains Influenza H1N1, Enterovirus E (ECBO), MVA virus, Human Coronavirus, Pseudorabies virus)
Field of use	Professional use in medical sector and collectivities (no food contact)
Application method(s)	Surface spraying
Application rate(s) and frequency	Application Rate Dilution (%): 0 Number and timing of application: Ready to use (100 % v/v) **Hard Surface** Contact time Bacteria, yeasts and fungi : 15 min Bacterial spores : 60 min Mycobacteria (M. terrae) : 60 min Virus : 60min **Soft Surfaces (Textile)** Contact time Bacteria and yeasts : 15 min Room temperature Medical sector : clean conditions Collectivities : dirty conditions except sporicidal and tuberculocidal activities and virus.
Category(ies) of users	Surface spraying

Pack sizes and packaging material	500mL, 750mL or 1L HDPE Prefilled trigger spray opaque bottle (Trigger spray types: Canyon T95 Trigger spray venting or Guala TS3 Dexter spray degassing) 1L Opaque bottle with nebulization equipment, 2L, 5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment Pouch (Smart bag) of 2.5L : PE HDPE IBC: 220L and 1000L

Use # 2 – Spray disinfectant, PT4

Product Type	PT4 Food and feed area
Where relevant, an exact description of the authorised use	Disinfectants of rooms (including collective central kitchens) and equipment for the production of food and feed stuff (including drinking water) for human and animal consumption.
Target organism (including development stage)	- Bacteria (including Legionella, Listeria, Salmonella) - Bacterial spores - Yeasts - Fungi - Mycobacteria (M. terrae) - Virus (including additional strains Influenza H1N1, Enterovirus E (ECBO), MVA virus, Human Coronavirus, Pseudorabies virus)
Field of use	Professional use in agro-food industry and collective central kitchens (food contact)
Application method(s)	Surface spraying
Application rate(s) and frequency	Application Rate: Dilution (%): 0 Number and timing of application: Ready to use (100 % v/v) **Hard surfaces** Contact time Bacteria, yeasts and fungi : 15 min Bacterial spores : 60 min Virus : 60 min **Soft surfaces** Contact time Bacteria and yeasts : 15 min Room temperature Clean conditions Dirty conditions except sporicidal and virucidal activities
Category(ies) of users	Professional users

Pack sizes and packaging material	500mL, 750mL or 1L HDPE Prefilled trigger spray opaque bottle (Trigger spray types: Canyon T95 Trigger spray venting or Guala TS3 Dexter spray degassing) 1L Opaque bottle with nebulization equipment, 2L, 5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment Pouch (Smart bag) of 2.5L : PE HDPE IBC: 220L and 1000L

Use # 3 – Fogger disinfectant, PT2

Product Type	PT2, Disinfectants and algaecides not intended for direct application to humans or animals.
Where relevant, an exact description of the authorised use	Room disinfection
Target organism (including development stage)	- Bacteria - Bacterial spores - Yeasts - Fungi - Mycobacteria - Virus
Field of use	Professional use in medical sector and collectivities (no food contact).
Application method(s)	Airbone diffusion (fogging).
Application rate(s) and frequency	**Application Rate** **12 mL of product /m³** Dilution (%): 0 Number and timing of application 12 mL of product /m³ in combination with a fogger equipment with the following characteristics: Droplet size: 5-10 µm Pump speed: 1.2 L/h Room volume between 30 and 150 m³ (diffusion time between 18 and 90 min) Contact time 2H for bacteria, yeasts and fungi 3H for additionnal bacteria (L.monocytogenes and S.Thyphimurium), bacterial spores, mycobacterium and virus. Medical sector: clean conditions Collectivities: dirty conditions **6.5 mL of product / m³ with a fogger equipment with the following characteristics :** Droplet size : 5-10 µm Pump speed : 1.2 L/h Room volume between 30 and 150 m³

	Contact time 3h for bacteria (including Acinetobacter), yeasts, fungi, bacterial spores, Mycobacterium (M. terrae and M. avium) and viruses (including coronavirus). Room temperature Humidity: 40 -80 % Medical sector : clean conditions Collectivities : clean conditions
Category(ies) of users	Professional users
Pack sizes and packaging material	1L Opaque bottle with nebulization equipment 2L, 5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment Pouch (Smart bag) of 2.5L : PE HDPE IBC: 220L and 1000L

Use # 4 – Fogger disinfectant, PT4

Product Type	PT4 Food and feed area
Where relevant, an exact description of the authorised use	Room disinfection
Target organism (including development stage)	- Bacteria - Bacterial spores - Yeasts - Fungi - Mycobacteria - Virus
Field of use	Professional use in agro-food industry and collective central kitchens (food contact)
Application method(s)	Airbone diffusion (fogging)
Application rate(s) and frequency	**Application Rate** **12 mL of product /m³** Dilution (%): 0 Number and timing of application 12 ml of product /m³ in combination with a fogger equipment with the following characteristics: Droplet size: 5-10 µm Pump speed: 1.2 L/h Room volume between 30 and 150 m3 (diffusion time between 18 and 90 min) Contact time 2H for bacteria, yeasts and fungi 3H for additionnal bacteria (L.monocytogenes and S.Thyphimurium), bacterial spores and virus. Room temperature Humidity: 40 -80 % Dirty conditions

	<u>6.5 mL of product / m3 with a fogger equipment with the following characteristics :</u> Droplet size : 5-10 µm Pump speed : 1.2 L/h Room volume between 30 and 150 m3 <u>Contact time</u> 3h for bacteria (including Acinetobacter), yeasts, fungi, bacterial spores, Mycobacterium (M.terrae and M.avium) and viruses (including coronavirus). Clean conditions.
Category(ies) of users	Professional users
Pack sizes and packaging material	1L Opaque bottle with nebulization equipment, 2L, 5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment Pouch (Smart bag) of 2.5L : PE HDPE IBC: 220L and 1000L

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR Evaluation	Reference
Physical state at 20 °C and 101.3 kPa	standardized internal method	Peroxyde d'hydrogene solution 7.4% PAE	Translucent colorless liquid	Acceptable	[redacted]
Colour at 20 °C and 101.3 kPa	standardized internal method	Batch QUA-ML-HD10072	Translucent colorless liquid	Acceptable	[redacted]
Odour at 20 °C and 101.3 kPa	standardized internal method	Peroxyde d'hydrogene solution 7.4% PAE	Odorless liquid	Acceptable	[redacted]
Acidity / alkalinity	CIPAC method MT 75.3. CIPAC method MT 191	Peroxyde d'hydrogene solution 7.4% PAE Batch QUA-ML-HD10072	Upon receipt, the pH of the neat formulation is 3.5 and the pH of a dilution at 1 % in water is 5.4 at ambient temperature. After the 2 weeks of accelerated storage at 54°C, the pH of the formulation does not change (pH on neat item 3.5) and the pH of a dilution at 1% in water is 5.5 at ambient temperature. Free acidity = 0.001% w/w H2SO4 for the sample upon receipt at ambient temperature. Free acidity = 0.002% w/w H2SO4 after accelerated storage (14 days at 54°C) at ambient temperature.	Acceptable	[redacted]
Relative density / bulk density	OECD method 109	Peroxyde d'hydrogene solution 7.4% PAE Batch QUA-ML-	The density of the formulation is 1.024 g/mL. The relative density is 1.025	Acceptable	[redacted]

<table>
<tr><td></td><td></td><td>HD10072</td><td></td><td></td><td></td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC MT 46.3. (30 °C ± 2 °C for 18 weeks)
Method to quantify the AS is validated in section 2.2.4</td><td>Peroxyde d’hydrogene solution 7.4% PAE
Batch QUA-ML-HD10072</td><td>The product including its packaging (bottle of 1L in HDPE), is stable after an accelerated storage procedure at 54 °C ± 2 °C for 2 weeks. No significant change of active substance content, appearance or physicochemical parameters was observed.
<table>
<tr><th>Results</th><th>Method</th><th>Upon receipt</th><th>Aged sample</th></tr>
<tr><td>Hydrogen peroxide</td><td>HPLC</td><td>73.7 ± 0.9 g/kg</td><td>71.4 ± 0.4 g/kg</td></tr>
<tr><td>Appearance</td><td>-</td><td>Colourless translucent liquid</td><td>Colourless translucent liquid</td></tr>
<tr><td>Flash point</td><td>EEC A9</td><td>> 120°C</td><td></td></tr>
<tr><td>Kinematic viscosity at 20°C</td><td>OECD 114</td><td>0.98 ± 0.00 mm^2/s</td><td></td></tr>
<tr><td>Kinematic viscosity at 40°C</td><td>OECD 114</td><td>0.66 ± 0.00 mm^2/s</td><td></td></tr>
<tr><td>Surface tension</td><td>OECD 115</td><td>70.1 mN/m</td><td></td></tr>
<tr><td>Specific gravity and density at 20°C</td><td>OECD 109</td><td>D^{20}_4 = 1.025
1.024 ± 0.000 kg/L</td><td></td></tr>
<tr><td>pH on neat item</td><td>CIPAC MT 75.3</td><td>3.5</td><td>3.5</td></tr>
<tr><td>pH of a 1% w/v dilution</td><td>CIPAC MT 75.3</td><td>5.4</td><td>5.5</td></tr>
<tr><td>Free acidity</td><td>CIPAC MT 191</td><td>0.001 % H_2SO_4 w/w</td><td>0.002 % H_2SO_4 w/w</td></tr>
<tr><td>Persistent foaming</td><td>CIPAC MT 47.3</td><td>No foam after 1 min</td><td>No foam after 1 min</td></tr>
</table></td><td>Acceptable,

The preparation is stable 14 days at 54°C.</td><td>[redacted]</td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>Gifap Monography n°17</td><td>Peroxyde d’hydrogene solution 7.4% PAE
Batch QUA-ML-HD10857</td><td>Interim report</td><td>The final report of the long-term storage study in commercial packaging at ambient temperature is required in post-authorisation.</td><td>[redacted]</td></tr>
</table>

			<table><tr><th>Results</th><th>Method</th><th colspan="2">Canyon T95 Trigger Spray Venting</th><th colspan="2">Guala TS3 Dexter Spray Degassing</th></tr><tr><td colspan="6">Initial samples</td></tr><tr><td>Hydrogen peroxide, upon priming</td><td>HPLC</td><td>75.6 ± 0.3 g/kg</td><td>75.6 ± 0.5 g/kg</td><td>75.4 ± 0.4 g/kg</td><td>75.5 ± 0.1 g/kg</td></tr><tr><td>Priming</td><td>-</td><td>Stabilized on 6th stroke 1.07 g/stroke</td><td>Stabilized on 5th stroke 1.05 g/stroke</td><td>Stabilized on 6th stroke 1.17 g/stroke</td><td>Stabilized on 6th stroke 1.07 g/stroke</td></tr><tr><td>Discharge rate (n=25)</td><td>-</td><td>1.06 g/stroke S.D.% = 1.9</td><td>1.06 g/stroke S.D.% = 4.0</td><td>1.34 g/stroke S.D.% = 3.3</td><td>1.29 g/stroke S.D.% = 7.6</td></tr><tr><td>Spray pattern</td><td>-</td><td>Homogeneous circular impact</td><td>Round shape with empty centre</td><td>Homogeneous circular impact</td><td>Homogeneous circular impact</td></tr><tr><td>Hydrogen peroxide, 6 months after priming</td><td>HPLC</td><td>73.0 ± 0.3 g/kg</td><td>73.2 ± 0.2 g/kg</td><td>73.6 ± 0.2 g/kg</td><td>73.6 ± 0.3 g/kg</td></tr><tr><td>Discharge rate (n=25)</td><td>-</td><td>1.09 g/stroke S.D.% = 2.2</td><td>1.08 g/stroke S.D.% = 1.2</td><td>1.18 g/stroke S.D.% = 10.9</td><td>1.28 g/stroke S.D.% = 6.4</td></tr><tr><td>Spray pattern</td><td>-</td><td>Homogeneous circular impact</td><td>Homogeneous circular impact</td><td>Homogeneous circular impact</td><td>Homogeneous circular impact</td></tr><tr><td colspan="6">6-month stored samples</td></tr><tr><td>Hydrogen peroxide, upon priming</td><td>HPLC</td><td>73.8 ± 0.2 g/kg</td><td>(1)</td><td>73.7 ± 0.4 g/kg</td><td>(1)</td></tr><tr><td>Priming</td><td>-</td><td>Stabilized on 6th stroke 1.08 g/stroke</td><td>(1)</td><td>Stabilized on 8th stroke 1.03 g/stroke</td><td>(1)</td></tr><tr><td>Discharge rate (n=25)</td><td>-</td><td>1.07 g/stroke S.D.% = 2.3</td><td>(1)</td><td>1.26 g/stroke S.D.% = 7.1</td><td>(1)</td></tr><tr><td>Spray pattern</td><td>-</td><td>Homogeneous circular impact</td><td>(1)</td><td>Homogeneous circular impact</td><td>(1)</td></tr></table>	This study should include determination of active substance content with validated method, following properties: H_2O_2.	
			➢ **Post-authorisation 2020** Final results: Long term stability study in 1L PEHD packaging with two different triggers Canyon T95 Trigger Sparay Venting and Guala TS3 Dexter Sparay Degassing.	The long term stability study is	[redacted]

			A - Hydrogen peroxide concentration g/kg Sprayers Canyon — H_2O_2 g/kg Opened at / Assessed at: 0 month; 6 months; 12 months; 18 months; 24 months 0 month: 75.6 ± 0.3 / 75.6 ± 0.5; 73.0 ± 0.3 / 73.2 ± 0.2; 70.2 ± 0.7 / 71.6 ± 1.0; 71.2 ± 1.0 / 68.1 ± 0.9; 71.7 ± 0.7 / 73.2 ± 1.0 6 months: 73.8 ± 0.2; 73.3 ± 0.3; 69.6 ± 6.0; 75.1 ± 0.1 12 months: 72.9 ± 0.8 / 71.9 ± 1.3; 73.3 ± 1.5 / 67.5 ± 1.5; 76.3 ± 0.7 / 75.7 ± 0.6 18 months: 74.1 ± 1.9 / 72.4 ± 1.5; 75.5 ± 0.5 / 74.9 ± 0.5 24 months: 71.1 ± 1.4 / 69.2 ± 1.4 Sprayers Guala — H_2O_2 g/kg Opened at / Assessed at: 0 month; 6 months; 12 months; 18 months; 24 months 0 month: 75.4 ± 0.4 / 75.5 ± 0.1; 73.6 ± 0.2 / 73.6 ± 0.3; 73.0 ± 1.0 / 73.1 ± 1.3; 71.9 ± 1.4 / 72.4 ± 0.7; 75.4 ± 2.0 / 74.6 ± 0.6 6 months: 73.7 ± 0.4; 74.3 ± 0.9; 74.3 ± 0.5; 74.0 ± 1.0 12 months: 73.1 ± 1.1 / 72.0 ± 0.9; 72.7 ± 1.1 / 72.5 ± 0.3; 74.7 ± 0.6 / 73.9 ± 0.5 18 months: 74.1 ± 1.3 / 71.3 ± 1.8; 74.5 ± 0.6 / 73.8 ± 2.0 24 months: 75.6 ± 1.1 / 75.7 ± 0.6 **B - Numbers of strokes for priming** Sprayers Canyon — Number of strokes for priming Opened at / Initial; 6 months; 12 months; 18 months; 24 months Initial: 6 / 5 6 months: 6 12 months: 5 / 7 18 months: 6 / 6 24 months: 3 / 3 Sprayers Guala — Number of strokes for priming Opened at / Initial; 6 months; 12 months; 18 months; 24 months Initial: 6 / 6 6 months: 8 12 months: 7 / 6 18 months: 12 / 12 24 months: 14 / 7	acceptable. The product is stable 24 months at ambient temperature .	

C - Discharge rates

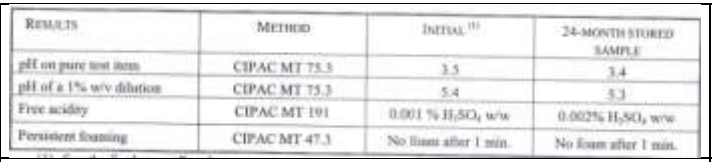
Sprayers Canyon Opened at	Discharge rates, g Assessed at 0 month	6 months	12 months	18 months	24 months
0 month	1.06 ± 1.9% 1.06 ± 4.0%	1.09 ± 2.2% 1.08 ± 1.2%	1.08 ± 8.2% 1.06 ± 8.8%	1.01 ± 8.6% 1.05 ± 8.2%	1.04 ± 8.4% 1.06 ± 8.9%
6 months		1.07 ± 2.3%	1.06 ± 10.4%	1.03 ± 4.1%	1.05 ± 4.8%
12 months			1.09 ± 1.6% 1.07 ± 2.0%	1.04 ± 7.2% 1.05 ± 6.6%	1.05 ± 6.8% 1.05 ± 3.0%
18 months				1.04 ± 3.1% 1.05 ± 1.8%	1.06 ± 5.3% 1.06 ± 6.0%
24 months					1.05 ± 3.3% 1.05 ± 2.1%

Sprayers Guala Opened at	Discharge rates, g Assessed at 0 month	6 months	12 months	18 months	24 months
0 month	1.34 ± 3.3% 1.29 ± 7.6%	1.18 ± 10.9% 1.28 ± 6.4%	1.10 ± 24.0% 1.08 ± 25.2%	1.09 ± 26.8% 1.23 ± 13.7%	1.06 ± 27.4% 1.20 ± 9.0%
6 months		1.26 ± 7.1%	1.11 ± 18.4%	1.13 ± 16.1%	1.17 ± 15.6%
12 months			1.31 ± 5.6% 1.32 ± 3.9%	1.10 ± 25.1% 1.16 ± 18.0%	1.22 ± 11.0% 1.15 ± 13.5%
18 months				1.30 ± 3.8% 1.29 ± 4.6%	1.12 ± 14.7% 1.16 ± 12.2%
24 months					1.21 ± 7.8% 1.25 ± 6.1%

Long term stability study in 1L PEHD packaging:

Storage duration	Hydrogen peroxide content	Weight of the filled commercial packaging	Appearance of the test item and packaging
Initial [1]	73.7 ± 0.9 g/kg	1079.66 g	Colourless translucent liquid No deformation, alteration or leakage of the 1L HDPE bottle
3 months	72.9 ± 1.0 g/kg (-1.1% vs initial value)	1021.45 g (-0.11%) vs. 1022.62 g (initial value)	Colourless translucent liquid No deformation, alteration or leakage of the 1L HDPE bottle
6 months	74.0 ± 0.1 g/kg (+0.4% vs initial value)	1034.78 g (-0.22%) vs. 1037.06 g (initial value)	Colourless translucent liquid No deformation, alteration or leakage of the 1L HDPE bottle
9 months	76.7 ± 0.4 g/kg (+4.0% vs initial value)	1081.45 g (-0.27%) vs. 1084.33 g (initial value)	Colourless translucent liquid No deformation, alteration or leakage of the 1L HDPE bottle
12 months	75.4 ± 0.2 g/kg (+2.3% vs initial value)	1058.92 g (-0.37%) vs. 1062.83 g (initial value)	Colourless translucent liquid No deformation, alteration or leakage of the 1L HDPE bottle
18 months	70.9 ± 0.7 g/kg (-3.9% vs initial value)	1067.95 g (-0.52%) vs. 1073.53 g (initial value)	Colourless translucent liquid No deformation, alteration or leakage of the 1L HDPE bottle
24 months	72.0 ± 0.8 g/kg (-2.3% vs initial value)	1048.74 g (-0.72%) vs. 1056.37 g (initial value)	Colourless translucent liquid No deformation, alteration or leakage of the 1L HDPE bottle

[redacted]

					
Storage stability test – **low temperature stability test for liquids**	Gifap Monography n°17	/	Cold storage study is not tested. This product is not intended to be stored at low temperatures. This information is indicated on the label available in section 12 of the IUCLUD dossier. No data provided.	Acceptable Mitigation measure to be added : Protect from frost.	/
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Statement	/	All product will be sold in opaque packages. Thus, the light sensitivity during storage was not addressed.	Acceptable	/
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Statement	/	Effect of higher temperature then recommended storage temperature is addressed in accelerated storage. Effect of humidity is not applicable for the concerned type of formulation and packaging	Acceptable	/
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container**	/	/	Addressed by accelerated and long term storage in commercial packaging.	Acceptable. Considering the composition of the product, compatibility of the product with PE can be	/

material				extrapolated to stability data in HDPE	
Wettability	/	/	No data provided.	Acceptable Not relevant for an AL formulation	/
Suspensibility, spontaneity and dispersion stability	/	/	No data provided.	Acceptable Not relevant for an AL formulation	/
Wet sieve analysis and dry sieve test	/	/	No data provided.	Acceptable Not relevant for an AL formulation	/
Emulsifiability, re-emulsifiability and emulsion stability	/	/	No data provided.	Acceptable Not relevant for an AL formulation	/
Disintegration time	/	/	No data provided.	Acceptable Not relevant for an AL formulation	/
Particle size distribution, content of dust/fines, attrition, friability	/	/	No data provided.	Acceptable Not relevant for an AL formulation	/
Persistent foaming	CIPAC method MT 47.3	Peroxyde d'hydrogene solution 7.4% PAE Batch QUA-ML-HD10072	No foam is generated when assessed according to the standardized procedure, for both the test substance upon receipt and the aged substance.	Acceptable	[redacted]
Flowability/Pourabil	/	/	No data provided.	Acceptable	/

ity/Dustability				Not relevant for an AL formulation	
Burning rate — smoke generators	/	/	No data provided.	Acceptable Not relevant for an AL formulation	/
Burning completeness — smoke generators	/	/	No data provided.	Acceptable Not relevant for an AL formulation	/
Composition of smoke — smoke generators	/	/	No data provided.	Acceptable Not relevant for an AL formulation	/
Spraying pattern	/	Peroxyde d'hydrogene solution 7.4% PAE Batch QUA-ML-HD10857 Trigger spray types: -Canyon T95 Trigger spray venting -Guala TS3 Dexter spray degassing	Interim report	The final report of the long-term storage study in commercial packaging at ambient temperature is required in post-authorisation. This study should include determination of active substance content with validated	[redacted]

			<table><tr><th>Results</th><th>Method</th><th colspan="2">Canyon T95 Trigger Spray Venting</th><th colspan="2">Guala TS3 Dexter Spray Degassing</th></tr><tr><td colspan="6">Initial samples</td></tr><tr><td>Hydrogen peroxide, upon priming</td><td>HPLC</td><td>75.6 ± 0.3 g/kg</td><td>75.6 ± 0.5 g/kg</td><td>75.4 ± 0.4 g/kg</td><td>75.5 ± 0.1 g/kg</td></tr><tr><td>Priming</td><td>-</td><td>Stabilized on 6th stroke 1.07 g/stroke</td><td>Stabilized on 5th stroke 1.05 g/stroke</td><td>Stabilized on 6th stroke 1.17 g/stroke</td><td>Stabilized on 6th stroke 1.07 g/stroke</td></tr><tr><td>Discharge rate (n=25)</td><td>-</td><td>1.06 g/stroke S.D.% = 1.9</td><td>1.06 g/stroke S.D.% = 4.0</td><td>1.34 g/stroke S.D.% = 3.3</td><td>1.29 g/stroke S.D.% = 7.6</td></tr><tr><td>Spray pattern</td><td>-</td><td>Homogeneous circular impact</td><td>Round shape with empty centre</td><td>Homogeneous circular impact</td><td>Homogeneous circular impact</td></tr><tr><td>Hydrogen peroxide, 6 months after priming</td><td>HPLC</td><td>73.0 ± 0.3 g/kg</td><td>73.2 ± 0.2 g/kg</td><td>73.6 ± 0.2 g/kg</td><td>73.6 ± 0.3 g/kg</td></tr><tr><td>Discharge rate (n=25)</td><td>-</td><td>1.09 g/stroke S.D.% = 2.2</td><td>1.08 g/stroke S.D.% = 1.2</td><td>1.18 g/stroke S.D.% = 10.9</td><td>1.28 g/stroke S.D.% = 6.4</td></tr><tr><td>Spray pattern</td><td>-</td><td>Homogeneous circular impact</td><td>Homogeneous circular impact</td><td>Homogeneous circular impact</td><td>Homogeneous circular impact</td></tr><tr><td colspan="6">6-month stored samples</td></tr><tr><td>Hydrogen peroxide, upon priming</td><td>HPLC</td><td>73.8 ± 0.2 g/kg</td><td>(1)</td><td>73.7 ± 0.4 g/kg</td><td>(1)</td></tr><tr><td>Priming</td><td>-</td><td>Stabilized on 6th stroke 1.08 g/stroke</td><td>(1)</td><td>Stabilized on 8th stroke 1.03 g/stroke</td><td>(1)</td></tr><tr><td>Discharge rate (n=25)</td><td>-</td><td>1.07 g/stroke S.D.% = 2.3</td><td>(1)</td><td>1.26 g/stroke S.D.% = 7.1</td><td>(1)</td></tr><tr><td>Spray pattern</td><td>-</td><td>Homogeneous circular impact</td><td>(1)</td><td>Homogeneous circular impact</td><td>(1)</td></tr></table>	method, following properties: H_2O_2.	
			For application by fogger, (nebulization equipment ([redacted] only technical information have been provided but as droplet size is not necessary for the risk assessment, no more data required.	Acceptable	Technical sheet: [redacted]

			<table><tr><th></th><th>Philéas Genius</th><th>Philéas 25</th><th>Philéas 75</th><th>Philéas 250</th></tr><tr><td>Treatment capacity</td><td>0,2 – 9 m²</td><td>1 – 40 m²</td><td>10 – 160 m²</td><td>50 – 600 m²</td></tr><tr><td>Droplet size</td><td>5 – 10 µm</td><td>5 – 10 µm</td><td>5 – 10 µm</td><td>5 – 10 µm</td></tr><tr><td>Pump speed</td><td>0,3 litre/h</td><td>0,5 litre/h</td><td>1,2 litres/h</td><td>3 litres/h</td></tr></table>		
Physical compatibility	/	/	No data provided. This parameter is not required as a combined application with another product is not recommended or foreseen by the applicant	Acceptable	/
Chemical compatibility	Statement	/	This parameter is not required as a combined application with another product is not recommended or foreseen by the applicant	Acceptable	/
Degree of dissolution and dilution stability	/	/	No data provided.	Acceptable Not relevant for an AL formulation ready to use	/
Surface tension	OECD method 115.		The surface tension of the formulation is 70.1 mN/m.	Acceptable	[redacted]
Viscosity	OECD method 114		The kinematic viscosity of the formulation is 0.98 mm²/s at 20°C and 0.66 mm²/s at 40°C	Acceptable	[redacted]

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

The product PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE À L'EMPLOI is an all other liquids (AL) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The appearance of the product is a translucent colorless liquid. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in bottle or jerry can in HDPE packaging material (commercial packaging material). The long-term storage stability study is on-going and final study is requested in post-registration.
A storage stability test at low temperature is not provided, therefore, the mitigation measure "the product should be protected from frost" should be added to the label.

Its technical characteristics are acceptable for an AL formulation.

- **Post-authorisation 2020**

The long-term storage stability studies in commercial packaging at ambient temperature have been provided and are acceptable. The product is stable 2 years at ambient temperature.

- **Major change 2023**

The modification does not have impact on technical properties of the product. New claimed packaging are covered by the initial assessment.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
Explosives	Statement + EEC A9	/	The formulation is predominantly composed of water. In addition, no explosive compounds are used in the formulation. In addition, the measured flash point is higher than 120°C.	Acceptable The formulation has no explosive properties. Please refer to confidential PAR for further justifications.	/
Flammable gases	/	/	/	Not relevant as the product is a liquid	/
Flammable aerosols	/	/	/	Not relevant as the product is a liquid	/
Oxidising gases	/	/	/	Not relevant as the product is a liquid	/
Gases under pressure	/	/	/	Not relevant as the product is a liquid	/
Flammable liquids	EEC A9 method.		As the flash point is higher than 120°C (>60°C), the boiling point does not have to be determined. Based on this value, the product is not considered as flammable.	Acceptable	[redacted]
Flammable solids	/	/	/	Not relevant as the product is a liquid	/
Self-reactive substances and mixtures	Statement + EEC A9	/	The formulation is predominantly composed of water. In addition, the mixture is not classified as an oxidizer and has a measured flash point superior to 120°C. Moreover, as the biocidal product is a dilution of active substance in water and that the active substance is not classify itself for self-reactive properties, it can be concluded that the product does not have self-reactive properties.	Acceptable	/
Pyrophoric liquids	Statement	/	Experience in manufacture or handling shows that the liquid does not ignite	Acceptable	/

			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)). Thus, based on the guidance on the application of the CLP criteria (Guidance to Regulation (EC) No 1272/2008, 2015, version 4.1), this classification can be excluded without further testing.		
Pyrophoric solids	/	/	/	Not relevant as the product is a liquid	/
Self-heating substances and mixtures	Statement	/	Not applicable for the formulations. In general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore, liquids are not classified as self-heating.	Acceptable	/
Substances and mixtures which in contact with water emit flammable gases	Statement	/	Experience in handling and use shows that the mixture does not react with water. The formulation contains water and can be mixed with water to form a stable mixture. Thus, based on the guidance on the application of the CLP criteria (Guidance to Regulation (EC) No 1272/2008, 2015, version 4.1), this classification can be excluded without further testing.	Acceptable	/
Oxidising liquids	Statement		The evaluated product is composed mostly of inert material from the perspective of oxidising properties. Only one component is classified as oxidising: •Hydrogen peroxide (CAS 7722-84-1) present in the product at 7.4%. The SCL for Hydrogen peroxide is defined as follows: - H_2O_2 <8% Not Oxidising Liquid	Acceptable	/

			- H_2O_2 8% to <20% Oxidising Liquid, Packing Group III, UN2984 - H_2O_2 20% to 60% Oxidising Liquid, Packing Group II, UN2014 H_2O_2 >60% Oxidising Liquid, Packing Group I, UN2015 Consequently, the product is not classified as oxidising		
Oxidising solids	/	/	/	Not relevant as the product is a liquid	/
Organic peroxides	Statement	/	The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	Acceptable	/
Corrosive to metals	UN Manual of Tests and Criteria, Part III, 37.4	Peroxyde d'hydrogene solution 7.4% PAE Batch QUA-ML-HD10914	As the mass loss of the carbon steel (2.46%) and aluminium (3.56%) materials was smaller than the trigger value of 13.5% defined in the UN Manual of Tests and Criteria for an exposure time to the product sample of seven days. Moreover, only uniform corrosion (without pitting) is observed. It was concluded that the product "Peroxyde d'hydrogène solution 7,4% prête à l'emploi" does not meet the criteria for classification as corrosive to metals Category 1 of the UN GHS. The product should therefore not be classified as potentially corrosive to metals.	Acceptable The product is not classified as corrosive to metals	[redacted] METAL CORROSION TEST FOR THE PRODUCT PEROXYDE D'HYDROGENE SOLUTION 7,4% PAE (CAS N° 7722-84-1) Report : [redacted]
		ARVO XY PE Batch FR2200012228 (new formulation)	2 mm thickness aluminium and steel plates 7 days at 55°C ± 1°C ; test solution was refreshed on day 3.5 No localised corrosion was observed after the test on any sample.	Not acceptable. No conclusion can be made on the classification of the product as a major	Lefeuvre M. 2023 Defitraces report No. 22S-0200

			Uniform corrosion was evaluated by the measure of the mass loss at the end of the test (-0.37% to -0.14% on steel, -0.11% to -0.0% on aluminium). Steel : AS content on Day 0 : 7.56% w/w AS content on Day 3.5 : 1.18% (-84.5%) AS content on Day 7 : 0.48% (-93.6%) Aluminium : AS content on Day 0 : 7.56% w/w AS content on Day 3.5 : 5.82% (-23.0%) AS content on Day 7 : 6.15% (-18.7%)	degradation occurred during the test.	
			2 mm thickness aluminium and steel plates 7 days at 55°C ± 1°C ; solution was refreshed on day 3, 4, 5 and 6. No localised corrosion was observed after the test on any sample. Uniform corrosion was evaluated by the measure of the mass loss at the end of the test (-0.84% to -0.08% on steel, -0.20% to -0.0% on aluminium). Steel : AS content on Day 0 : 7.16% w/w AS content on Day 7 : 4.86% (-32.1%) Aluminium : AS content on Day 0 : 7.16% w/w AS content on Day 7 : 7.18% (+0.3%)	Acceptable. Degradation of the test item in the presence of steel is still considered significant but the test protocole was adjusted to compensate any effect on the result of the test. As neither uniform nor localized corrosion was observed, the product is considered not classified for this hazard.	Lefeuvre M. 2023 Defitraces report No. 23S-0112
Auto-ignition	Statement	/	The formulation is predominantly composed	Acceptable	/

temperatures of products (liquids and gases)			of water. In addition, no flammable compounds are used in the formulation. Lastly, the measured flash point is superior to 120°C. A test should be performerd nevertheless, as the biocidal product is a dilution of active substance in water and that the active substance is not classify itself for self-ignition properties, it can be concluded that the product does not have self-ignition properties and no other data is required.		
Relative self-ignition temperature for solids	/	/	/	Not relevant as the product is a liquid	/
Dust explosion hazard	/	/	/	Not relevant as the product is a liquid	/

Conclusion on the physical hazards and respective characteristics of the product
The product is neither flammable, nor auto-flammable. It has no explosive and no oxidizing properties, nor corrosive to metal.
➢ **Major change 2023**
The modification does not have a significantly impact on physical hazard properties of the product.

2.2.4 Methods for detection and identification

Report: [redacted]
Report no 16-35-083-ES
Test facilities: PHYTOSAFE S .a .r .l
2 rue Marx Dormoy
64000 PAU

Principle of the method:
Hydrogen peroxide was assessed by HPLC-UV and external calibration. Detection 228 nm.

The validation of this method was considered in compliance with SANCO/3030/99 rev.4.

Validation data:

<table>
<tr><td>Specificity</td><td colspan="2">To demonstrate the specificity of the method, several solution are analyzed:
- Reference item of the active substance
- Test item of the product
No interference was found: no peak appears in the solvent blank and in the formulation blank, one peak is observed at the same retention time for the reference item and test item.
All chromatograms were available.</td></tr>
<tr><td rowspan="3">Linearity</td><td colspan="2">Linearity was studied by carrying out 11 levels of concentrations (n=1) between 1.1-268.2 mg/L of H_2O_2. The equation of the curve should have been of the form y = ax + b.
Calibration curve has been provided with a R^2 higher than 0.99.</td></tr>
<tr><td>Compound</td><td>Linearity %</td></tr>
<tr><td>Active substance</td><td>$Log(H_2O_2) = 0.975xLog(Area) - 0.326$
$R^2 = 0.9999$</td></tr>
<tr><td rowspan="3">Precision</td><td colspan="2">Repeatability was evaluated by analyzing 6 times test item solutions at 2 levels of concentration.</td></tr>
<tr><td>Compound</td><td>Repeatability (RSD)</td></tr>
<tr><td>Active substance</td><td>RSD = 1.30% % for 0.18 g/L
<table>
<tr><th>Concentration level, item/L</th><th>Sample solution</th><th>Sample weight, mg</th><th>H_2O_2 g/kg</th></tr>
<tr><td>0.18 g/L</td><td>1</td><td>461.9</td><td>73.9</td></tr>
<tr><td></td><td>2</td><td>452.3</td><td>75.5</td></tr>
<tr><td></td><td>3</td><td>456.4</td><td>73.1</td></tr>
<tr><td></td><td>4</td><td>457.3</td><td>75.5</td></tr>
<tr><td></td><td>5</td><td>461.0</td><td>73.9</td></tr>
<tr><td></td><td>6</td><td>456.8</td><td>74.1</td></tr>
<tr><td>Mean (± S.D.)</td><td></td><td></td><td>74.3 ± 1.0</td></tr>
</table>
RSD = 0.32% % for 1.8 g/L
<table>
<tr><th>Concentration level, item/L</th><th>Sample solution</th><th>Sample weight, mg</th><th>H_2O_2 g/kg</th></tr>
<tr><td>1.8 g/L</td><td>1</td><td>461.9</td><td>72.8</td></tr>
<tr><td></td><td>2</td><td>452.3</td><td>72.9</td></tr>
<tr><td></td><td>3</td><td>456.4</td><td>73.0</td></tr>
<tr><td></td><td>4</td><td>457.3</td><td>73.4</td></tr>
<tr><td></td><td>5</td><td>461.0</td><td>73.2</td></tr>
<tr><td></td><td>6</td><td>456.8</td><td>73.3</td></tr>
<tr><td>Mean (± S.D.)</td><td></td><td></td><td>73.1 ± 0.2</td></tr>
</table></td></tr>
</table>

Accuracy	Accuracy was determined by analysis of 2 reconstituted samples. The accuracy results are expressed as the recovery rate.

Fortification level	Recovery rate	Mean recovery rate	n
0.277mg	101.1; 101	101	2
2.77 mg	98.2; 98.4	98.3	2

The analytical method is fully validated for the determination of the active substance H_2O_2 in the product.

Analytical methods for H_2O_2 residues in soil, air, water (drinking water) and sediment are available in Assessment Report of active substance Product-type 1-6, March 2015. The applicant GFB has a Letter of Access from Solvay SA for these data.

As the active substance H_2O_2 is not classified Toxic or Very Toxic, an analytical method for the determination of H_2O_2 residue in human body fluids and tissues is unnecessary.

No analytical method in soil is required according to the Assessment report of hydrogen peroxide.

Regarding PT 4 uses, given the reactivity of the active substance, residue in food, feed and drink are expected to be negligible. Analytical method for the determination of hydrogen peroxide in food/feed of plant and animal origin is not required.

Conclusion on the methods for detection and identification of the product

The analytical method is fully validated for the determination of the active substance H_2O_2 in the product.

Analytical methods were provided at EU level for the determination of active substance residue in water with LOQ = 740 µg/L.

Active substance H_2O_2 is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in biological matrices is not required.

No analytical method in soil is required.

Regarding PT4 uses, given the reactivity of the active substance, residue in food, feed and drink are expected to be negligible. Analytical method for the determination of hydrogen peroxide in food/feed of plant and animal origin is not required.

Chapter 2:Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	Titrimetric determination with potassium permanganate under acidic conditions
Impurities in technical active substance (principle of method)	Not applicable, no relevant impurities

Analytical methods for residues

Soil (principle of method and LOQ)	Not applicable, because hydrogen peroxide is rapidly decomposed in soil and does not adsorb to soil matrix. Trace amounts of hydrogen peroxide in soil water may be analysed by the method for water.
Air (principle of method and LOQ)	Spectrometric determination using cobalt-bicarbonate indicator, after absorption into water.New method must be submitted before product authorisation, or the existing validated.
Water (principle of method and LOQ)	Spectrometric determination using cobalt-bicarbonate indicator, after absorption into water. (LOQ: 740 µg/L, in aqueous solution, but the study is not sufficiently validated). New method must be submitted before product authorisation, or the existing validated.
Body fluids and tissues (principle of method and LOQ)	Not required as the substance is not acutely toxic (T) or very toxic (T+)
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required as not expected in food/feed of plant origin
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required as not expected in food/feed of animal origin

Validation of the method 18-35-001-ES used in the [redacted], Determination of hydroxyl residues of "Peroxyde d'hydrogene solution 7,4% PAE Com18 after rinsing and/or wiping and/or soaking" report no: 18-35-007-ES

Report: [redacted], Validation of analytical methods for the determination of hydroxyl radicals formed from hydrogen peroxide in water, and peroxyl radicals formed from peroxoacids in water - Application to the determination of residues in water for hydrogen peroxide and/or peroxoacid containing biocidal products. Part 1: Determination of hydroxyl radiacals formed from hydrogen peroxide in water
Report no 18-35-001-ES
Test facilities: PHYTOSAFE S .a .r .l
2 rue Marx Dormoy
64000 PAU

Principle of the method:
Hydrogen peroxide reacts for the determination with DMSO (dimethylsulfoxide) in water at the neutral pH, using FeSO4 as catalyst. The oxidation product is methanesulfinic acid.
Under conditions of excess DMSO, the concentration of produced methanesulfinic acid is used for back determination of native hydrogen peroxide. Methanesulfinic acid was assessed by HPLC-MS (SIM: one transition *m/z*=79>64) and external calibration

The validation of this method was considered in compliance with SANCO/3029/99 rev.4.

Validation data:

<table>
<tr><td>Specificity</td><td colspan="3">To demonstrate the specificity of the method, several solution are analyzed:
- Methanesulfinic acid produced from oxidation of DMSO by H_2Ov
- Bank matrix: water
- Hydrogen peroxide
No interference was found: no peak appears in the reaction blank and in the, one peak is observed at the same retention time for the reference item and test item.
All chromatograms were available.</td></tr>
<tr><td rowspan="5">Linearity</td><td colspan="3">Linearity was studied by carrying out 10 levels of concentrations (n=1) between 0.006-5.787 mg/L of methanesulfinic acid.
Calibration curve has been provided with a r higher than 0.99.</td></tr>
<tr><td>Compound</td><td colspan="2">Linearity %</td></tr>
<tr><td>methanesulfinic acid</td><td colspan="2">Log(methanesulfinic acid)) = 1.009xLog(Area) – 4.828
R^2 = 0.9999</td></tr>
<tr><td colspan="3">Linearity was studied by carrying out 10 levels of concentrations (n=1) between 2.6 – 26.0 µg/L of hydrogen peroxide. The equation of the curve should have been of the form y = ax + b.
Calibration curve has been provided with a r higher than 0.99.</td></tr>
<tr><td>Compound</td><td colspan="2">Linearity %</td></tr>
<tr><td>Active substance</td><td colspan="2">Log(methanesulfinic acid)) = 1.009xLog(Area) – 4.828
R^2 = 0.9999</td></tr>
<tr><td rowspan="5">Precision</td><td colspan="3">Repeatability was evaluated by analyzing 5 times test item solutions at 1 level of concentration for Methanesulfinic acid.</td></tr>
<tr><td>Compound</td><td colspan="2">Repeatability (RSD)</td></tr>
<tr><td>Methanesulfinic acid</td><td colspan="2">RSD = 1.80% % for 0.014 mg/L
<table>
<tr><th>Nominal value</th><th>Replicate injection</th><th>Area</th><th>Methanesulfinic acid Measured value mg/L</th><th>% Error</th></tr>
<tr><td rowspan="5">0.014 mg/L
LOQ</td><td>1</td><td>858.0</td><td>0.014</td><td>+0.7 %</td></tr>
<tr><td>2</td><td>840.8</td><td>0.013</td><td>-1.3 %</td></tr>
<tr><td>3</td><td>866.0</td><td>0.014</td><td>+1.7 %</td></tr>
<tr><td>4</td><td>858.3</td><td>0.014</td><td>+0.8 %</td></tr>
<tr><td>5</td><td>829.0</td><td>0.013</td><td>-2.7 %</td></tr>
</table></td></tr>
<tr><td colspan="3">Repeatability was evaluated by analyzing 6 times test item solutions at 3 levels of concentration for H_2O_2 alone.</td></tr>
<tr><td>Compound</td><td colspan="2">Repeatability (RSD)</td></tr>
</table>

	Hydrogen peroxide	At 2.6µg/L: RSD = 1.14% At 25.5 µg/L: RSD = 1.81% At 255.1 µg/L: RSD = 3.32 %
	Repeatability was evaluated by analyzing 6 times test item solutions at 3 levels of concentration for **Peroxyde d'hydrogene solution 7,4% PAE.**	
	Compound	Repeatability (RSD)
	Hydrogen peroxide	At 48.0 µg/L of biocidal product (3.8 µg H_2O_2/L) : RSD = 3.38%

Accuracy

Matrix	*fortification level*	*n*	*recovery range (%)*		*mean recovery (%)*	*RSD (%)*
H_2O_2 alone	2.6 µg/L	6	93,6	96,8	94,8	1,14
	25.5 µg/L	6	97,4	102,6	100,1	1,81
	255.1 µg/L	6	65,8	70,7	68,4	3,32
Methanesulfinic acid	0.014 mg/L	5	97,3	101,7	99,8	1,80
Peroxyde d'hydrogene solution 7,4% PAE	3.8µg H H_2O_2/L	6	94,2	103,7	98,2	3,88

The analytical method is validated for the determination of the active substance H_2O_2 in water at traces level.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

MG 01: Disinfectants

PT2: Disinfectants and algaecides not intended for direct application to humans or animals
PT4: Food and feed area

The product PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI is a ready–to-use disinfectant. According to the applicant, the product is intended to be used as follow:

Application by spraying: The product is applied as a ready-to-use spray for the disinfection of small surfaces in the medical and institutional sectors (PT2 application) as well as food and feed areas (PT4 application). A claim for malodour control (humidity, garbage odours) is also made.

Application by fogging: The product is applied by airbone diffusion with an appropriate device, in the medical and institutional sectors (PT2 application) as well as food and feed areas (PT4 application).

The product is used by professional users.

- **Major change 2023**

This major change is intended to support new additional claims:

Spraying application (Uses # 1 and 2)

- Addition of target organisms for PT2 and PT4 hard surface disinfection by spraying: virus (including additional strains Influenza H1N1, Enterovirus E (ECBO), MVA virus, Human Coronavirus, Pseudorabies virus) and Legionella.
- Addition of soft furnishing and fabrics for PT2 and PT4 disinfection against bacteria and yeasts.

Fogging application (Uses # 3 and 4)

- Addition of a new application rate (6.5 mL/m³) with a contact time of 3H under clean conditions for bacteria, mycobacteria, bacterial spores, yeasts, fungi, virus (including additional strain Human Coronavirus) in PT2 and PT4 (Uses # 3 and 4).

For the application rate of 12 mL/m³ already authorised:
- Addition of target organism virus, for a contact time of 3H in PT2 (use # 3) and in PT 4 (use # 4).
- Addition of target organisms virus (including additional strains Influenza H1N1, Herpes Simplex, Enterovirus E (ECBO), MVA virus, Human Coronavirus, Rotavirus, Pseudorabies virus) and mycobacteria, for a contact time of 4H, in PT2 (uses # 3) and in PT4 (uses # 4).

The composition of the product is also slightly changed with the addition of a new co-formulant acting as a sequestrant. Please refer to the confidential annex for detailed information about updated composition of the biocidal product.

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

The product PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI is intended to be used for PT2 and PT4 surfaces and room disinfection. Surfaces to be disinfected by direct application or fogging include sanitaries, bathrooms, surfaces in the medical, paramedical and hospital sector, surfaces in institutions such as hotels, sports halls, changing rooms, etc. (PT2 application), as well as surfaces and equipment in contact with food- and feedstuffs in central kitchens and food processing sectors (PT4 applications).
It irreversibly inactivates vegetative bacteria, bacterial spores, mycobacteria, yeasts and fungi.

The product is used for the purpose of the protection of human health.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The product is able to produce, under defined conditions, a reduction in the number of
- viable bacterial cells (bactericidal activity),
- viable mycobacterial cells (mycobactericidal activity),
- viable bacterial endospores (sporicidal activity),
- yeast cells (yeasticidal activity), and
- moulds spores (fungicidal activity).

- **Major change 2023**

Virucidal activity is also claimed in the frame of this major change.

2.2.5.4 Mode of action, including time delay

Hydrogen peroxide is reactive and it degrades rapidly in contact with organic material. A significant proportion of hydrogen peroxide decomposes to water and oxygen. The antimicrobial action of hydrogen peroxide stems from its ability to form powerful oxidants such as the hydroxyl radical and singlet oxygen. These reactive oxygen species cause irreversible damage to cellular components such as enzymes, membrane constituents and DNA.

2.2.5.5 Efficacy data

Laboratory studies were conducted with the product PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI according to the Transitional Guidance on Efficacy Assessment for Product Types 1-5, Disinfectants (2016) and EN 14885:2015 standard.
The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

- ✓ **<u>Application by spraying</u>:**

Both quantitative suspension tests and quantitative surface tests were carried out to demonstrate the product efficacy when applied as a trigger spray.

The product is intended for use in both collectivities/food areas and medical areas.
Note that as the product is not intended for use in dirty conditions in the health area (medical / dental / veterinary hospitals equipment's), soiling conditions of CEN standards for institutional/food areas are also applicable for medical uses.

Following efficacy results have been obtained in the studies submitted:

- Bactericidal activity (with additional strains *L. monocytogenes* and *S.* Thyphimurium) is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 18-25 °C, with a contact time of 15 minutes, in clean (0.3 g/L BSA) and dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 100 % v/v.

- Sporicidal activity (including *B.cereus* and *C.sporogenes*) is demonstrated both in phase 2, steps 1 and 2 tests (EN 13704 and EN13697 modified) at 20 °C, with a contact time of 60 minutes, in clean conditions (0.3 g/L BSA). In these conditions, sporicidal activity is shown at the in-use concentration of 80 % v/v.

- Tuberculocidal activity (*M. terrae*) is demonstrated in phase 2, step 2 test (EN14563) at 20 °C, with a contact time of 60 minutes, in clean conditions (0.3 g/L BSA). Phase 2 step 1 test (EN 14348) cannot be performed at 100% v/v due to the methodology of the test and showed a log reduction of 3,41 at 80% v/v, with a contact time of 60 min. In these conditions, tuberculocidal activity is shown at the in-use concentration of 100 % v/v. However, a new P2S1 test, adapted in such a way that the product can be tested at 97% or 100%, should be provided at the renewal of the authorisation in order to confirm that the pass criteria for tuberculocidal activity is achieved.

- Fungicidal activity is demonstrated in phase 2, step 2 test (EN 13697), at 18-25 °C, with a contact time of 15 minutes, in clean (0.3 g/L BSA) and dirty conditions (3.0 g/L BSA). In these conditions, fungicidal activity is shown at the in-use concentration of 80 % v/v.
  Note that in the phase 2, step 1 test (EN 1650), at 80 % v/v, efficacy against *C. albicans* is not proven (log R < 4) and efficacy against *A. brasiliensis* is demonstrated in one out of the two trials carried out with this strain. Fungicidal efficacy is however fully supported by the phase 2, step 2 efficacy trial (EN 13697), where efficacy against both *C. albicans* and *A. brasiliensis* is demonstrated at 100 % v/v. As phase 2, step 2 tests most accurately represent product use as a surface disinfectant, and fungicide efficacy was also demonstrated according to other specific application tests (according to EN16615 and N FT 72-81 standards), it is

considered that the efficacy data sufficiently supports the product's fungicidal claim. Nevertheless, at the renewal of the authorisation, a new P2S1 test against C.albicans should be provided based on EN 13727 methodology (the product at 97% v/v can be tested) according the conditions of uses claimed in order to achieve the pass criteria.

Bactericidal (with additional strains *L. monocytogenes* and *S.* Thyphimurium) and fungicidal activities are also demonstrated according to EN 16615 standard at 20 °C, with a contact time of 15 minutes, in clean conditions (0.3 g/L BSA). Nevertheless, as the product is not intended to be used by wiping (as ready-to-use wipes or wipes to be impregnated), results and conditions of use in these tests were not taken into account.

An efficacy against *L.pneumophila* is also claimed and EN 13623 standard has been performed, demonstrating the efficacy of the product PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI, at 5 % v/v, at 20 °C, with a contact time of 15 minutes, in presence of interfering substance (0,05 % yeast extract solution). However, FR CA considers that this standard is not adapted to surface disinfection (the scope of the norm refers to products used in aqueous systems) and a surface test would have been submitted in order to demonstrate this claim.

- ✓ **<u>Malodour control</u>**

For malodour control, phase 2 step 2 test (EN 13697 modified) has been performed on 2 representative bacteria (*S.epidermidis* and *C.xerosis*), which are malodour producing bacteria. Bactericidal activity against both *S.epidermidis* and *C.xerosis* has been demonstrated at 80 % v/v, at 20 °C, with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA).

Moreover, odour test has been carried out on the smells "garbage" and "humidity", according to the criteria of norms EN 13725 and VDI 3382. The product showed a reduction of odour perception and olfactory disturbance 2 hours after application applied on non-porous carriers.

The applicant has provided the following justification:
S. epidermidis and *C. xerosis*, were specifically tested as they are listed in the Efficacy guidance document (Section 5.5.7.5 Prevention of Odour by odour-producing micro-organisms, Volume II Efficacy - Assessment and Evaluation (Parts B+C); Version 3.0; April 2018) as being responsible of malodour and are potentially present in sports hall, sport equipments and locker rooms, where body odours can remain important.

Malodour as generally described as "humidity", "garbage", "perspiration",… is also generally produced by more than one strain of microorganism. Among the bacterial strains that have been tested in this dossier, several are known to be responsible for malodour:

- *Pseudomonas aeruginosa* is associated to fruity odour
- *E. coli* is associated to floral odour,
- *Candida* is associated to yeast odour,
- *Aspergillus* is associated to earthy odour,
- *Bacillus subtilis* is associated to feet odour.

Sprocidal activity has also been demonstrated against one strain of anaerobic bacterial spore, *Clostridium sporogenes*, which is known to present putrid odour and representative of a family of bacteria for which malodour emission is also known.

Moreover, it is quite obvious that any malodour as globally described on a label as "humidity", "garbage", "perspiration",… remains an olfactory sensation more or less complex which is impossible to reduce to one chemical molecule. Once such odour is produced by a microorganism, a complex combination of volatile organic compounds is metabolized and is causing the maloudor. Several chemical functions are also associated to malodour (amines, organic acids, sulphides,…) and efficacy of the product PEROXYDE D'HYDROGENE SOLUTION 7,4% PAE to reduce such smells has been proven with the EN norms EN 13725 et VDI 3382, with 2 hours contact time.

Nevertheless eCA considers that the contact time of 2 hours performed in the odour test is not consistent with the mode of application with regard to the use of the product (surfaces should remain wet during the contact time) as, the product will disappear from the surfaces well before the end of 2 hours.

- ✓ **Application by fogger :**

The product is also intended for room disinfection for medical areas and collectivities (PT2) and for food area (PT4).

Note that as the product is not intended for uses in dirty conditions in the health area (medical / dental / veterinary hospitals equipment's), soiling conditions of the CEN standards of institutional/food areas are applicable for these uses.

Testing was carried out according to the norm NF T 72-281 to demonstrate product efficacy when applied by fogger.
Trials have been performed with the product PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI as a ready-to-use, with the diffuser equipment '[redacted] Efficacy by fogging is demonstrated at 12 mL of product / m^3, at room temperature in dirty conditions (3.0 g/L BSA), against bacteria and fungi, with a contact time of 2 hours and, against additional bacteria (*L.monocytogenes* and S.Thyphimurium) and bacterial spores with a contact time of 3 hours.

Room volumes tested (55 and 140 m^3) allow of a use for rooms between 30 and 150 m^3, according to NF T 72-281 norm.

The applicant recommends a room disinfection use with named-diffuser '[redacted] that are declined in four devices adapted to the room volume to be treated. According to the minute of CG-27 meeting, it is important to reflect in the SPC the parameters of the application device under the Section of the SPC - Application methods, but not restrict the authorisation to the tested devices only. Any device could be used as long as it fulfils the requirements in terms of the parameters defined in the SPC.
According to the document provided by the applicant below, principle diffusion of all devices is fogging with the same droplet size (5-10 µm). Nevertheless, treatment capacity, pump speed and then time for diffusion are not the same between the different equipments. Therefore except the equipment '[redacted] the others don't fulfil the main parameters droplet size, treatment capacity and pump speed defined in the SPC. The technical characteristics (droplet size, treatment capacity and, pump speed and time for diffusion) of the fogger [redacted] has been taken up in the SPC.

It has to be noted that the applicant argued that pump speed has no influence on the efficacy of the product, it varies depending on the diffuser equipment only in order to ensure a suitable and realistic diffusion time depending on the room volume and this parameter should thus not be retained as a device characteristic in the SPC. Nevertheless, E-CA still consider that it is an important parameter as it depends on the diffuser equipment and determine the time of diffusion of the product before the contact time. With the same way, the treatment capacity is clearly framed by the norm NF T 72281.

Experimental data on the efficacy of the biocidal product against target organism(s) - PT2&PT4 Surface disinfection by spraying							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide	Disinfection of PT2&PT4 surfaces	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*S.aureus* *P.aeruginosa* *E.hirae* *E.coli* *L.monocytogenes* S.Typhimurium	EN1276:2010	Phase 2 step 1 test (suspension test) Temperature: 20°C Contact time: 15 min Clean conditions (0.3 g/L BSA)	Bactericidal activity demonstrated at 80% v/v	3951-2m1 R.I=1
Bactericide	Disinfection of PT2&PT4 surfaces	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*S.aureus* *P.aeruginosa* *E.hirae* *E.coli* *L.monocytogenes* S.Typhimurium	EN13697:2015	Phase 2 step 2 test (surface test) Temperature: 18-25°C Contact time: 15 min Clean conditions (0.3 g/L BSA)	Bactericidal activity demonstrated at 100% v/v	3894-2m1 R.I=1
Bactericide	Disinfection of PT2&PT4 surfaces	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*P.aeruginosa*	EN13697:2015	Phase 2 step 2 test (surface test) Temperature: 18-25°C Contact time: 5 min Clean conditions (8,5 g/L skimmed milk)	Activity against P.aeruginosa demonstrated at 80% v/v	RE-2008/0218 R.I=1
Bactericide	Disinfection of PT2&PT4 surfaces	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*S.aureus* *P.aeruginosa* *E.hirae* *E.coli* *L.monocytogenes* S.Typhimurium	EN13697:2015	Phase 2 step 2 test (surface test) Temperature: 18-25°C Contact time: 15 min Dirty conditions (3 g/L BSA)	Bactericidal activity demonstrated at 100% v/v	Merieux 17/000247032 R.I=1
Bactericide	Disinfection of PT2&PT4 surfaces	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*S.aureus* *P.aeruginosa* *E.hirae* *E.coli* *L.monocytogenes* S.Typhimurium	EN16615 :2015	Phase 2 step 2 test (surface test) Temperature: 20°C Contact time: 15 min Clean conditions (0.3 g/L BSA)	Bactericidal activity demonstrated at 100% v/v	Merieux 17/000247760 R.I=1
Bactericide	PT2&PT4 Malodour control	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*C.xerosis* *S.epidermidis*	EN13697:2015	Phase 2 step 2 test (surface test) Temperature: 18-25°C Contact time: 15 min Dirty conditions (3 g/L BSA)	Activity against *C.xerosis and S.epidermidis* demonstrated at 80 % v/v	LMH 4758-1 R.I=1
Bactericide	PT2&PT4 Malodour control	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	smells "garbage" and "humidity"	Criteria of EN 13725 and VDI 3882 part 2	Panel of 6 people Odour and product applied on non-porous carriers, inserted in a Nalophane chamber (1m3) Samples at T0, T+30 min and T+2H	Reduction of odour perception and olfactory disturbance 2 hours after application	ODOURNET PM-2017-014 R.I=2

					Observations on odour concentration, intensity and characteritics		
Legionella	Disinfection of PT2&PT4 surfaces	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*L.pneumophila*	EN13623:2010	Phase 2 step 1 test (suspension test) Temperature: 20°C Contact time: 15 min Soiling: 0.005 g/L yeast extract	Activity against *L.pneumophila* demonstrated at 5 % v/v	Merieux 17/000247032 R.I= 3
Mycobactericide	Disinfection of PT2&PT4 surfaces	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*M.terrae*	EN14348:2005	Phase 2 step 1 test (suspension test) Temperature: 20°C Contact time:60 min and 120 min Clean conditions (0.3 g/L BSA)	Mycobactericidal activity demonstrated at 80 % v/v with 120 min (log reduction of 3,41 at 60 min)	MERIEUX 18/000126334 R.I=1
Mycobactericide	Disinfection of PT2&PT4 surfaces	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*M.terrae*	EN14563:2009	Phase 2 step 2 test (surface test) Temperature: 20°C Contact time: 60 min Clean conditions (0.3 g/L BSA)	Mycobactericidal activity demonstrated at 100 % v/v	MERIEUX 18/000005596 R.I=1
Sporicide	Disinfection of PT2&PT4 surfaces	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	Spores of *B.subtilis*	EN13704:2002	Phase 2 step 1 test (suspension test) Temperature: 20°C Contact time: 60 min Clean conditions (0.3 g/L BSA)	Sporicidal activity demonstrated at 50 % v/v	Merieux 17/000247032 R.I=1
Sporicide	Disinfection of PT2&PT4 surfaces	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	Spores of *B.subtilis* Spores of *B. cereus* Spores of *C.sporogenes*	EN13697:2015 modified	Phase 2 step 2 test (surface test) Temperature: 18-25°C Contact time: 30 min Clean conditions (0.3 g/L BSA)	Activity against spores of *B.subtilis* and *C.sporogenes* demonstrated at 80 % v/v Activity against spores of *B. cereus* has not been demonstrated in the conditions of the test.	LMH 4816-1 R.I=2
Sporicide	Disinfection of PT2&PT4 surfaces	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	Spores of *B.cereus*	EN13697:2015 modified	Phase 2 step 2 test (surface test) Temperature: 18-25°C Contact time: 60 min Clean conditions (0.3 g/L BSA)	Activity against spores of *B.cereus* demonstrated at 80% v/v	LMH 4887-1 R.I=2
Fungicide	Disinfection of PT2&PT4 surfaces	PEROXYDE D'HYDROGENE	*C.albicans* *A.brasiliensis*	EN1650+A1:2008	Phase 2 step 1 test (suspension test)	No yeasticidal activity	3952-2m1 R.I=3

		SOLUTION 7.4% PRÊTE A L'EMPLOI			Temperature: 18-25°C Contact time: 15 min Clean conditions: 0.3 g/L BSA)	demonstrated at 80 % v/v Activity againt *A.brasiliensis* demonstrated at 80 % v/v (trial n°1)	
Fungicide	Disinfection of PT2&PT4 surfaces	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*C.albicans* *A.brasiliensis*	EN13697:2015	Phase 2 step 2 test (surface test) Temperature: 18-25°C Contact time: 15 min Clean conditions (0.3 g/L BSA)	Fungicidal activity demonstrated at 80 % v/v	3917-2m1 R.I=1
Fungicide	Disinfection of PT2&PT4 surfaces	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*C.albicans* *A.brasiliensis*	EN13697:2015	Phase 2 step 2 test (surface test) Temperature: 18-25°C Contact time: 15 min Dirty conditions (3 g/L BSA)	Fungicidal activity demonstrated at 100 % v/v	Merieux 17/000247032 R.I=1
Fungicide	Disinfection of PT2&PT4 surfaces	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*C.albicans*	EN16615:2015	Phase 2 step 2 test (surface test) Temperature: 20°C Contact time: 15 min Clean conditions (0.3 g/L BSA)	Yeasticidal activity demonstrated at 100 % v/v	Merieux 18/000278130 R.I=1
Fungicide	Disinfection of PT2&PT4 surfaces	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*A.brasiliensis*	EN16615:2015 modified	Phase 2 step 2 test (surface test) Temperature: 20°C Contact time: 15 min Clean conditions (0.3 g/L BSA)	Activity against A.brasiliensis demonstrated at 100 % v/v	Merieux 17/000370019 R.I=2

Experimental data on the efficacy of the biocidal product against target organism(s) - PT2&PT4 Fogging							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide	PT2&PT4 Room disinfection	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*S.aureus* *P.aeruginosa* *E.hirae* *E.coli*	NF T 72-281:2014	Phase 2 step 2 test (surface test) Room volume: 55 m^3 Temperature: 20°C Humidity: 45 % Contact time: 120 min Dirty conditions: 3 g/L BSA	Efficacy demonstrated at 12 ml/m^3 (Diffusion time 27 min)	VIRHEALTH R-DSVADEV002-2 R.I=1
Fungicide	PT2&PT4 Room disinfection	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*C.albicans* *A.brasiliensis*	NF T 72-281:2014	Phase 2 step 2 test (surface test) Room volume: 55 m^3 Temperature: 20°C Humidity: 45 % Contact time: 120 min Dirty conditions: 3 g/L BSA	Efficacy demonstrated at 12 ml/m^3 (Diffusion time 27 min)	VIRHEALTH R-DSVADEV002-2 R.I=1
Bactericide Additional strains	PT2&PT4 Room disinfection	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*L.monocytogenes* S.Typhimurium	NF T 72-281:2014	Phase 2 step 2 test (surface test) Room volume: 140 m^3 Temperature: 20°C Humidity: 65-79 % Contact time: 180 min Dirty conditions: 3 g/L BSA	Efficacy demonstrated at 12 ml/m^3 (Diffusion time 1H20)	ACTALIA SAP0211-SMI2018.039.1 R.I=1
Sporicide	PT2&PT4 Room disinfection	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*B.subtilis* *G.stearothermophilus*	NF T 72-281:2014	Phase 2 step 2 test (surface test) Room volume: 140 m^3 Temperature: 20°C Humidity: 65-79 % Contact time: 180 min Dirty conditions: 3 g/L BSA	Efficacy demonstrated at 12 ml/m^3 against *B.subtilis* (Diffusion time 1H20) *Note that only 2 carriers (instead of 3 expected) have been tested for G.staerothermophilus, therefore this additional strain is not taking into account*	ACTALIA SAP0211-SMI2018.039.1 R.I=1

Conclusion on the efficacy of the product

French competent authorities (FR CA) assessed that the product PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI, as a ready-to-use, has shown a sufficient efficacy, for the following claimed uses:

Surface disinfection for PT2 uses in the medical area (clean conditions), at room temperature, by spraying against:
- bacteria (including Listeria, Salmonella), yeasts and fungi, with a contact time of 15 minutes;
- bacterial spores and mycobacteria (*M.terrae*), with a contact time of 60 min.

Surface disinfection for PT2 uses in institutional sector, at room temperature, by spraying:
- with clean and dirty conditions against bacteria, yeasts and fungi, with a contact time of 15 minutes;
- with clean conditions against bacterial spores and mycobacteria (*M.terrae*) with a contact time of 60 min.

Surface disinfection for PT4 uses in food and feed areas, at room temperature, by spraying:
- with clean and dirty conditions against bacteria, yeasts, fungi, with a contact time of 15 minutes;
- with clean conditions against bacterial spores with a contact time of 60 min.

For legionella, FR CA estimated that the standard used (EN 13623) is not adapted to surface disinfection (the scope of the norm refers to product used in aqueous systems) and a surface test would have been submitted in order to demonstrate this claim. Hence, efficacy against legionella is not demonstrated for the intended use.
Note that at the renewal of the authorisation, a new P2S1 test against C.albicans should be provided based on EN 13727 methodology (the product at 97% v/v can be tested) according the conditions of uses claimed in order to achieve the pass criteria. Furthermore, a new P2S1 test, adapted in such a way that the product can be tested at 97% or 100%, should be provided at the renewal of the authorisation in order to confirm that the pass criteria for tuberculocidal activity is achieved.

Room disinfection by airborne diffusion for PT2 uses in the medical area (clean conditions), at room temperature, with a fogger equipment (technical characteristics specified in the SPC) against:
- bacteria, yeasts, fungi (2 hours of contact time), 3 hours for the additional bacteria (Listeria, Salmonella) and ;
- bacterial spores (3 hours of contact time), at 12 mL of product / m^3.

Room disinfection by airborne diffusion for PT2 uses in institutional sector (dirty conditions), at room temperature, with a fogger equipment (technical characteristics specified in the SPC) against:
- bacteria, yeasts, fungi (2 hours of contact time), 3 hours for the additional bacteria (Listeria, Salmonella) and;
- bacterial spores (3 hours of contact time), at 12 mL of product / m^3

Room disinfection by airborne diffusion for PT4 uses in the food and feed areas (dirty conditions), at room temperature, with a fogger equipment (technical characteristics specified in the SPC) against:
- bacteria, yeasts, fungi (2 hours of contact time), 3 hours for the additional bacteria (Listeria, Salmonella) and ;
- bacterial spores (3 hours of contact time), at 12 mL of product / m^3.

For malodour control, efficacy against micro-organisms has been demonstrated in lab and a reduction of odour perception and olfactory disturbance is shown 2 hours after

application of the product PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI. E-CA is of the opinion that that the contact time of 2 hours performed in the odour test is not consistent with the mode of application with regard to the use of the product (surfaces should remain wet during the contact time)

- **Major change 2023**

Regarding the change of composition (addition of sequestrant agent), according to the applicant, this co-formulant is not supposed to influence efficacy. Based on the very low concentration of this co-formulant in the composition of the product (see confidential annex), eCA considers that it is not expected to have a biocidal effect or even impact the efficacy obtained with the old formulation without this co-formulant. Therefore efficacy studies performed with the old formulation are still acceptable.

To support the additional claims, additionnal efficacy data were provided for the following uses with the old formulation PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI, same of the products INDAL OXY DVA and O2SAFE 7,4:

Spraying application (Uses # 1 and 2)

- **Addition of target organism virus (including additional strains Influenza H1N1, Enterovirus E (ECBO), MVA virus, Human Coronavirus and Pseudorabies) and addition of target organism legionella for hard surface disinfection in PT2 and PT4:**
  - Virucidal activity including additional strains (Rotavirus, Pseudorabies virus, Influenza H1N1, Herpes Simplex Type 1, MVA virus, Human Coronavirus), is demonstrated in phase 2 step 1 test (EN 14476) at 20°C, under clean condition (0.3 g/L BSA) within 60 min contact time. In these conditions, virucidal activity is shown at the in-use concentration of 100 % v/v.
  - Virucidal activity including additional strains (Pseudorabies virus, Influenza H1N1, Enterovirus E (ECBO), MVA virus, Human Coronavirus,), is demonstrated in phase 2 step 2 test (EN 16777) at 20°C, under clean condition (0.3 g/L BSA) within 60 min contact time. In these conditions, virucidal activity is shown at the in-use concentration of 100 % v/v.
  - Activity against *Legionella pneumophila* is demonstrated both in phase 2 step 1 and step 2 tests (EN 1276 and EN 13697) at 20°C, under clean (PT2 - healthcare) / dirty (PT2-institutions and PT4) condition (3.0 g/L BSA), with 15 min contact time. In these conditions, activity against *Legionella pneumophila* is shown at the in-use concentration of 80 % v/v.

Additional strains are claimed and complete efficacy data package (P2S1 and P2S2 tests) have been provided by the applicant for some of them, in order to justify the efficacy of the product, even if covered by the mandatory strains implemented in the standards. Indeed, the applicant highlighted that: "Some users emphasize their need for validation of efficacy against strains that may have been involved in past or present sanitary crises (Influenza H1N1, Coronavirus for PT2, Rotavirus for PT4), that may have caused problems in their specific activity (Herpesvirus for PT2), or for which they fear having to deal with future problems (Enterovirus as emerging diarrhea agent in collective food poisoning,)".
It has to be noted that some additional strains (Rotavirus, Herpes Simplex Type 1) are not tested both in phase 2 steps 1 and 2 tests, and the applicant has withdrawn these target organisms from the dossier during the assessment. No phase 2 step 1 test has been provided for the additional strain ECBO.

Therefore, information to the users for Legionella and virucidal activity against additional strains Pseudorabies virus, Influenza H1N1, MVA virus and Human Coronavirus have been added in the SPC at the sections 4.1.1 and 4.2.1.

- **Addition of soft furnishing and fabrics for PT2 and PT4 disinfection against bacteria and yeasts:**

For the disinfection of soft furnishing, P2S2 tests submitted have been modified with the inclusion of pulp+PET based carriers. According to the applicant, as a blend of nearly half part of natural fibers (cellulose pulp) and half part of synthetic polymers (PET polyethylene terephthalate resin), these carriers look representative of the diversity of soft furnishings that can be encountered in institutional environment, healthcare facilities, transports (wool, polyamide, polyester, viscose, cotton, etc.). Indeed, in EN13697 standard, stainless steel is the representative carrier that fit for applications on metals, glass, non-porous plastics and others undefined non-porous hard surfaces. In EN16437 standard, poplar wood is the representative carrier that fit for applications on wood, concrete, cement, and others undefined non-porous hard surfaces. The applicant therefore assume that a 55 % pulp and 45 % PET wipe can also be the carrier that fits for tests in order to claim efficacies on various soft furnishings as it is quite representative of such surfaces. The eCA agree with this argumentation and have considered these studies acceptable, since also all the controls and parameters of the norm EN 16437 are fulfilled.

- Bactericidal activity is demonstrated in phase 2 step 1 (EN 1276 – see first application) under clean conditions (0.3 g/L BSA), and in modified phase 2 step 2 test (EN 16437 modified with pulp+PET based carrier) under dirty conditions (3.0 g/L BSA), both with 15 min contact time, at 20°C. In these conditions, bactericidal activity is shown at the in-use concentration of 100 % v/v, in clean conditions.
- Yeasticidal activity is demonstrated in phase 2 step 1 test (EN 13624) under clean conditions (0.3 g/L BSA), and in modified phase 2 step 2 test (EN 16437 modified with pulp+PET based carrier) under dirty conditions, both with 15 min contact time at 20°C. In these conditions, yeasticidal activity is shown at the in-use concentration of 80% v/v, in clean conditions.

The applicant claimed dirty conditions, nevertheless as P2S1 tests have been performed in clean conditions and ECHA Efficacy guidance is now applicable for this MAC application, therefore only clean conditions are validated for soft disinfection.

<u>Airborne disinfection (Uses # 3 and 4)</u>

- **Addition of a new application rate (6.5 mL/m³) with a contact time of 3h under clean condition for bacteria, mycobacteria, bacterial spores, yeasts, fungi, virus (including additional strain Human Coronavirus) for airborne disinfection in PT2 and PT4 (Uses # 3 and 4):**

- Bactericidal, mycobactericidal, sporicidal, fungicidal, yeasticidal and virucidal (including additional strain Human Coronavirus) activities have been demonstrated according to EN 17272, with the diffuser equipement ' [redacted] at room temperature, at the application rate of 6.5 mL/m^3 and with a contact time of 3H under clean conditions (0,3 g/L BSA).

- **Addition of target organism virus for the application rate of 12 mL/m³ with a contact time of 3H, in PT2 (use # 3), and in PT4 (use # 4):**

- Virucidal activity has been demonstrated according to NFT 72-281 norm, with the diffuser equipement ' [redacted] at room temperature, at the application rate of 12 ml/m^3 and a contact time of 3H, under dirty conditions (3 g/L BSA) – (clean conditions for healthcare area).

As the MAC dossier was submitted in May 2022, EN 17272 standard (June 2020) was not in force, therefore studies according to NF T 72-281 norm are acceptable to demonstrate efficacy against virus.

- **Addition of target organisms virus and mycobacteria for the application rate of 12 mL/m³ with a contact time of 4H, in PT2 and PT4 (Uses # 3 and 4).**

  - Mycobactericidal and virucidal activities (including additional strains Influenza H1N1, Herpes Simplex, MVA virus, Human Coronavirus, Rotavirus, Pseudorabies virus) have been demonstrated according to EN 17272, with the diffuser equipements [redacted] and [redacted] at room temperature, at the application rate of 12 ml/m³ and with a contact time of 4H under clean conditions (0,3 g/L BSA).

Experimental data on the efficacy of the biocidal product against target organism(s) - PT2&PT4 Surface disinfection by spraying							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Major changes - 2023							
Bactericide Legionella (additional target organism)	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*L. pneumophila*	EN1276 (2019)	Phase 2 step 1 test (suspension test) Temperature: 20°C Contact time: 15 min Dirty conditions (3 g/L BSA)	Bactericidal activity demonstrated at 50%	MIDAC RE21-0908-1 R.I=1
Bactericide Legionella (additional target organism)	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*L. pneumophila*	EN 13697 +A1:2019	Phase 2 step 2 test (surface test) Temperature: 18-25°C Contact time: 15 min Dirty conditions (3 g/L BSA)	Bactericidal activity demonstrated at 80%	MIDAC RE21-0909-1 R.I=1
Bactericide / Soft surfaces	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE	*E. hirae* *E. coli* *P. aeruginosa* *S. aureus*	EN 16437+A1 : 2019 modified (pulp+PET based-carrier)	Phase 2 step 2 test (porous surface test) Temperature: 20°C Contact time: 15 min Dirty conditions (3 g/L BSA)	Bactericidal activity demonstrated at 100% v/v	MIDAC RE21-0825-3 R.I=2
Yeasticide / Soft surfaces	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE	*Candida albicans*	EN 13624 (November 2021)	Phase 2 step 1 test (suspension test) Temperature: 20°C Contact time: 15 min Clean conditions (0.3 g/L BSA)	Yeastidal activity demonsated at 80% v/v	Apex Biosolutions Study n°074D22-2023 R.I=1
Yeasticide / Soft surfaces	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE	*Candida albicans*	EN 16437+A1 : 2019 Modified (pulp+PET based-carrier)	Phase 2 step 2 test (porous surface test) Temperature: 20°C Contact time: 15 min Dirty conditions (3 g/L BSA)	Yeastidal activity demonsated at 80% v/v	MIDAC RE21-0826-3 R.I=2
Virucidal (additional target organism)	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*Poliovirus*	EN 14476 + A1 / October 2015	Phase 2 step 1 test (suspension test) Temperature: 20°C Contact time: 15 min Clean conditions (0.3 g/L BSA)	Activity against Poliovirus demonstrated at 80% v/v	IRM 1405-1017-1/A R.I=1
Virucidal (additional target organism)	Uses 1 & 2	PEROXYDE D'HYDROGENE	*Norovirus*	EN 14476 + A1 / October	Phase 2 step 1 test (suspension test)	Activity against Norovirus Murin	IRM N°RE-1071/0218-2/A

		SOLUTION 7.4% PRÊTE A L'EMPLOI		2015	Temperature: 20°C Contact time: 30 min Clean conditions (0.3 g/L BSA)	demonstrated at 80% v/v	R.I=1
Virucidal (additional target organism)	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*Adenovirus*	EN 14476 + A1 / October 2019	Phase 2 step 1 test (suspension test) Temperature: 20°C Contact time: 60 min Clean conditions (0.3 g/L BSA)	Activity against Adenovirus demonstrated at 97% v/v	VirHealth R2304GFB1054LV-01-V1 R.I=1
Virucidal (additional strain)	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*Rotavirus*	EN 14476 + A2 / July 2019	Phase 2 step 1 test (suspension test) Temperature: 20°C Contact time: 60 min Clean conditions (0.3 g/L BSA)	Activity against Rotavirus demonstrated at 97% v/v	IRM N°RE-1139/0421 R.I=1 Withdrawn by the applicant
Virucidal (additional strain)	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	Pseudorabies virus	EN 14476 + A2 / July 2019	Phase 2 step 1 test (suspension test) Temperature: 20°C Contact time: 30 min Clean conditions (0.3 g/L BSA)	Activity against Pseudorabies virus demonstrated at 80% v/v	IRM N°RE-1170/0421 R.I=1
Virucidal (additional strain)	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*Influenza A* (H1N1)	EN 14476 + A2 / July 2019	Phase 2 step 1 test (suspension test) Temperature: 20°C Contact time: 15 min Clean conditions (0.3 g/L BSA)	Activity against Influenza A (H1N1) demonstrated at 80% v/v	IRM N°RE-1285/0620-1/A R.I=1
Virucidal (additional strain)	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	Herpes Simplex Type 1 (HSV-1)	EN 14476 + A2 / July 2019	Phase 2 step 1 test (suspension test) Temperature: 20°C Contact time: 15 min Clean conditions (0.3 g/L BSA)	Activity against Influenza A (H1N1) demonstrated at 80% v/v	IRM N°RE-1285/0620-3/A R.I=1 Withdrawn by the applicant
Virucidal (enveloped virus)	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	Modified Vaccinia Virus Ankara (MVA)	EN 14476 + A2 / July 2019	Phase 2 step 1 test (suspension test) Temperature: 20°C Contact time: 10 min Clean conditions (0.3 g/L BSA)	Activity against Influenza A (H1N1) demonstrated at 97% v/v	VirHealth N°R2004LVOBI001-1 R.I=1
Virucidal (additional strain)	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	Human Coronavirus HCoV-229E	EN 14476 + A2 / July 2019	Phase 2 step 1 test (suspension test) Temperature: 20°C Contact time: 15 min Clean conditions (0.3 g/L BSA)	Activity against Human Coronavirus demonstrated at 97% v/v	VirHealth N°R2103LVGFB001 R.I=1

Virucidal (additional target organism)	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	Norovirus and Adenovirus	EN 16777 / December 2018	Phase 2 step 2 test (surface test) Temperature: 20°C Contact time: 60 min Clean conditions (0.3 g/L BSA)	Activity against Norovirus and Adenovirus demonstrated at 80% v/v	IRM N°RE-1284/0620/A R.I=1
Virucidal (additional strain)	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	Bovine Enterovirus Type 1	EN 16777 / December 2018	Phase 2 step 2 test (surface test) Temperature: 20°C Contact time: 60 min Clean conditions (0.3 g/L BSA)	Efficacy against Bovine Enterovirus Type 1 demonstrated at 100% v/v	VirHealth R2304GFB1054-2SV-01-V1 R.I=1 No P2S1 test submitted
Virucidal (additional strain)	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	Human Influenza H1N1	EN 16777 / December 2018	Phase 2 step 2 test (surface test) Temperature: 20°C Contact time: 30 min Clean conditions (0.3 g/L BSA)	Efficacy against Human Influenza H1N1 demonstrated at 100% v/v	VirHealth R2304GFB1054SV-01-V1 R.I=1
Virucidal (additional strain)	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	Vaccinia Virus	EN 16777 / December 2018	Phase 2 step 2 test (surface test) Temperature: 20°C Contact time: 30 min Clean conditions (0.3 g/L BSA)	Efficacy against Human Vaccinia Virus demonstrated at 100% v/v	VirHealth R2304GFB1054SV-03-V1 R.I=1
Virucidal (additional strain)	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	Human Coronavirus 229E	EN 16777 / December 2018	Phase 2 step 2 test (surface test) Temperature: 20°C Contact time: 30 min Clean conditions (0.3 g/L BSA)	Efficacy against Human Coronavirus 229E demonstrated at 80% v/v	VirHealth R2304GFB1054SV-04-V1 R.I=1
Virucidal (additional strain)	Uses 1 & 2	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	Pseudorabies virus	EN 16777 / December 2018	Phase 2 step 2 test (surface test) Temperature: 20°C Contact time: 60 min Clean conditions (0.3 g/L BSA)	Efficacy against Pseudorabies virus demonstrated at 80% v/v	VirHealth R2304GFB1054SV-06-V1 R.I=1
Bactericide (new application rate)	Uses 3 & 4	INDAL OXY DVA	*S. aureus* *P. aeruginosa* *E. hirae* *E. coli* *A. baumanii*	EN 17272 (2020)	Phase 2 step 2 test (surface test) Room volume: 50 m^3 Temperature: 20°C Humidity: 51-53% Contact time: 180 min Clean conditions (0.3 g/L BSA) Device: [redacted]	Efficacy demonstrated at 6.5 mL/m^3 against bacteria (Diffusion time 17 - 18 min)	VIRHEALTH R2112DSVADEP005-1 R.I=1

Yeasticide (new application rate)	Uses 3 & 4	INDAL OXY DVA	*A. brasiliensis* *C. albicans*	EN 17272 (2020)	Phase 2 step 2 test (surface test) Room volume: 50 m^3 Temperature: 20°C Humidity: 51-53% Contact time: 180 min Clean conditions (0.3 g/L BSA) Device: [redacted]	Efficacy demonstrated at 6.5 mL/m^3 against yeasts and fungi (Diffusion time 17 - 18 min)	VIRHEALTH R2112DSVADEP005-1 R.I=1
Sporicide (new application rate)	Uses 3 & 4	INDAL OXY DVA	*B.subtilis*	EN 17272 (2020)	Phase 2 step 2 test (surface test) Room volume: 50 m^3 Temperature: 20°C Humidity: 51-53% Contact time: 180 min Clean conditions (0.3 g/L BSA) Device: [redacted]	Efficacy demonstrated at 6.5 mL/m^3 against *B. subtilis* (Diffusion time 17 - 18 min)	VIRHEALTH R2112DSVADEP005-1 R.I=1
Mycobactericidal (new application rate)	Use 3	INDAL OXY DVA	*M. terrae* *M. avium*	EN 17272 (2020)	Phase 2 step 2 test (surface test) Room volume: 50 m^3 Temperature: 20°C Humidity: 51-53% Contact time: 180 min Clean conditions (0.3 g/L BSA) Device: [redacted]	Efficacy demonstrated at 6.5 mL/m^3 against *M. terrae* and *M. avium* (Diffusion time 17 - 18 min)	VIRHEALTH R2112DSVADEP005-1 R.I=1
Virucide (new application rate)	Uses 3 & 4	INDAL OXY DVA	Norovirus Adenovirus Coronavirus HCoV-229E	EN 17272 (2020)	Phase 2 step 2 test (surface test) Room volume: 50 m^3 Temperature: 20°C Humidity: 51-53% Contact time: 180 min Clean conditions (0.3 g/L BSA) Device: [redacted]	Efficacy demonstrated at 6.5 mL/m^3 against virus strains tested (Diffusion time 17 - 18 min)	VIRHEALTH R2112DSVADEP005-1 R.I=1
Virucide (new target organism for the application rate 12 ml/m3 and CT 3H)	Uses 3 & 4	O2SAFE 7.4	Murine Type 1 Norovirus ECBO	NF T 72 281 (2014)	Phase 2 step 2 test (surface test) Room volume: 55 m^3 Temperature: 20°C Humidity: 45% Contact time: 120 min	Efficacy demonstrated at 12 mL/m^3 against virus strains tested (Diffusion time 27 min)	VIRHEALTH R-DSVADEV002_3 R.I=1

					Dirty conditions (3 g/L BSA) Device: [redacted]		
Virucide (new target organism for the application rate 12 ml/m3 and CT 3H)	Uses 3 & 4	O2SAFE 7.4	Adenovirus Poliovirus	NF T 72 281 (2014)	Phase 2 step 2 test (surface test) Room volume: 55 m^3 Temperature: 20°C Humidity: 45% Contact time: 180 min Dirty conditions (3 g/L BSA Device: [redacted]	Efficacy demonstrated at 12 mL/m^3 against virus strains tested (Diffusion time 17 - 18 min)	VIRHEALTH R-DSVADEV003 R.I=1
Virucide (new target organisms at the application rate of 12 ml/m3 and CT 4H)	Uses 3 & 4	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	Norovirus Adenovirus Vaccina virus Coronavirus 229E Herpes Simplex Type 1 Pseudorabies Virus Rotavirus A Human Influenza H1N1	EN 17272 (2020)	Phase 2 step 2 test (surface test) Room volume: 50 m^3 Temperature: 20°C Humidity: 58% Contact time: 240 min Clean conditions (0.3 g/L BSA) Device: [redacted]	Efficacy demonstrated at 12 mL/m^3 against virus strains tested (Diffusion time 31 min)	VIRHEALTH R2304GFB1053DSVA-01-V2 R.I=1
Mycobactericidal (new target organisms at the application rate of 12 ml/m3 and CT 4H)	Use 3	PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	*M. terrae* *M. avium*	EN 17272 (2020)	Phase 2 step 2 test (surface test) Room volume: 50 m^3 Temperature: 20°C Humidity: 43% Contact time: 240 min Clean conditions (0.3 g/L BSA) Device: [redacted]	Efficacy demonstrated at 12 mL/m^3 against *M. terrae* and *M. avium* (Diffusion time 31 min)	VIRHEALTH R2304GFB1053DSVA-02-V1 R.I=1

Conclusion on the efficacy of the product (MAJOR CHANGE 2023)

The product ARVO XY PE, as a ready-to-use, has shown a sufficient efficacy, for the following claimed uses:

- **Use #1**

1-Hard surface disinfection for PT2 uses in healthcare area and institutions area, at room temperature, by spraying, in clean conditions (healthcare area) and dirty conditions (institutions areas) against:
- *Legionella*, with a contact time of 15 minutes ;
- Virus, with a contact time of 60 min.
  Activity against additional virucidal strains (Influenza H1N1, MVA virus, Human Coronavirus, Pseudorabies virus) has been also demonstrated.

2-Soft surface disinfection for PT2 uses in healthcare and institutions area, at room temperature, by spraying, in clean conditions, against:
- bacteria and yeasts with a contact time of 15 minutes.

- **Use #2**

1-Hard surface disinfection for PT4 uses in food and feed areas, at room temperature, by spraying against:
- *Legionella*, with a contact time of 15 min in dirty condition;
- Virus, with a contact time of 60 min in clean condition.
  Activity against additional virucidal strains (Influenza H1N1, MVA virus, Human Coronavirus, Pseudorabies virus) has been also demonstrated.

2-Soft surface disinfection for PT4 uses in food and feed area, at room temperature, by spraying, in clean conditions, against:
- Bacteria and yeasts with a contact time of 15 minutes.

It has to be noted that for uses #1 and #2:
- Additionnal virucidal strain ECBO has not been validated as no P2S1 test has been provided.
- For the disinfection of soft surfaces (Uses #1 and #2), bactericidal and yeasticidal activities were demonstrated only in clean conditions, whereas the applicant claimed dirty conditions.

- **Use #3**

Room disinfection by airborne diffusion for PT2 uses in health care and institutions areas at room temperature, with a fogger equipment, in clean conditions:
At the application rate of 6.5 mL of product/m^3, against:
- Bacteria, mycobacteria, yeasts, fungi, bacterial spores, and virus with 3H contact time.
  Activity against additional virucidal strain Human coronavirus has been also demonstrated.

Room disinfection by airborne diffusion for PT2 uses in healthcare area, at room temperature, with a fogger equipment, with clean conditions:
At the application rate of 12 mL of product/m^3, against:
- Virus with 3H contact time.
  Activity against additional virucidal strain ECBO has been also demonstrated.

Room disinfection by airborne diffusion for PT2 uses in institutions area, at room temperature, with a fogger equipment, in dirty conditions:
At the application rate of 12 mL of product/m^3, against:

- Virus with 3H contact time
  Activity against additional virucidal strain ECBO has been also demonstrated.

Room disinfection by airborne diffusion for PT2 uses in health care and institutions areas at room temperature, with a fogger equipment, in clean conditions:
At the application rate of 12 mL of product/m^3, against:
- Mycobacteria and virus with 4H contact time

Activity against additional virucidal strains Influenza H1N1, Herpes Simplex, MVA virus, Human Coronavirus, Rotavirus and Pseudorabies virus has been also demonstrated.

- **Use #4**

Room disinfection by airborne diffusion for PT4 uses in food and feed areas at room temperature, with a fogger equipment , in clean conditions:
At the application rate of 6.5 mL of product/m^3, against:
- Bacteria, mycobacteria, yeasts, fungi, bacterial spores, and virus with 3H contact time.

Activity against additional virucidal strain Human coronavirus has been also demonstrated.

Room disinfection by airborne diffusion for PT4 uses in in food and feed areas, at room temperature, with a fogger equipment, in dirty conditions:
At the application rate of 12 mL of product/m^3, against:
- Virus with 3H contact time.
  Activity against additional virucidal strain ECBO has been also demonstrated.

Room disinfection by airborne diffusion for PT4 uses in in food and feed areas, at room temperature, with a fogger equipment, in clean conditions:
At the application rate of 12 mL of product/m^3, against:
- Mycobacteria and virus with 4H contact time

Activity against additional virucidal strains Influenza H1N1, Herpes Simplex, MVA virus, Human Coronavirus, Rotavirus and Pseudorabies virus has been also demonstrated.

2.2.5.6 Occurrence of resistance and resistance management

According to the assessment report of the active substance: "the lethal effects of oxidative molecular species generated from hydrogen peroxide can be avoided with any damage being repaired in microorganisms such as *Escherichia coli* and *Salmonella* Typhimurium".
When *E.coli* and S.Typhimurium are exposed to low concentrations of H_2O_2, 3 µM and 60 µM respectively, cells produce enzymes and other proteins which are important for cellular defence and mitigate the toxic effects of the oxidative species. This adaptive response is triggered by nontoxic levels of the oxidative species to protect against and produce resistance to oxidative stress caused when challenged with higher concentrations, 10 mM (Dukan and Touati (1996), Christman et al. (1985)). The resistance to oxidative stress that E.coli develops when exposed to H202, as reported in literature papers, demonstrates an adaptive response only. Hydrogen peroxide has been intensively used as a disinfectant and preservative for more than 3 decades and has not lead to the development of significant resistance levels among field populations. Genetically inherited resistance is not expected when the products are used as recommended".

According to the applicant, no incidence of resistance to hydrogen peroxide has been recorded until now.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

2.2.5.7 Known limitations

There are no known limitations for the product PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI.

2.2.5.8 Evaluation of the label claims

First Authorisation

French competent authorities (FR CA) assessed that the product PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI, as a ready-to-use, has shown a sufficient efficacy, for the following uses claimed:

- Spraying disinfection

Surface disinfection for PT2 uses in the medical area (clean conditions), at room temperature:

- by spraying against bacteria, yeasts and fungi, with a contact time of 15 minutes ; bacterial spores (including *B.cereus* and *C.sporogenes*) and mycobacteria (*M.terrae*) with a contact time of 60 min ;

The product is not intended to be used in dirty conditions for health area (medical / dental / veterinary hospitals equipment's.
For the health care use, as the contact time is higher than 5 minutes, surfaces that are likely to come into contact with the patient and/or the medical staff and surfaces which are frequently touched by different people leading to the transmission of microorganisms to the patient, mustn't be disinfect with this product.

Surface disinfection for PT2 uses in collectivities, at room temperature:

- by spraying: with dirty conditions, against bacteria, yeasts, fungi, with a contact time of 15 minutes ; with clean conditions against bacterial spores (including *B.cereus* and *C.sporogenes*) and mycobacteria (*M.terrae*) with a contact time of 60 min.

Surface disinfection for PT4 uses in food and feed areas, at room temperature:

- by spraying: with dirty conditions, against bacteria, yeasts, fungi, with a contact time of 15 minutes ; with clean conditions against bacterial spores (including *B.cereus* and *C.sporogenes*) with a contact time of 60 min.

- Room disinfection

Room disinfection by airborne diffusion uses in the medical area (clean conditions), in collectivities and in the food and feed areas (dirty conditions), at room temperature with a fogger equipment (technical characteristics specified in the SPC) against:

- bacteria, yeasts, fungi (2 hours of contact time), 3 hours for the additional bacteria (Listeria, Salmonella) and ;
- bacterial spores (3 hours of contact time), at 12 ml of product / m^3.

Room volume validated is comprised between 30 and 150 m^3 (i.e diffusion time between 18 and 90 min with regards to the technical parameters tested).

- Malodour control is insufficiently proven with regard to the claim uses then this claim is rejected.

- Efficacy against legionella is not demonstrated because the study performed was not appropriate with the intended uses (surface disinfection).

- **Major change 2023**

See Efficacy conclusion

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

Not applicable, the product PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI is not intended for use with other biocidal products.

2.2.6 Risk assessment for human health

"PEROXYDE D'HYDROGÈNE SOLUTION 7,4% PRÊTE À L'EMPLOI" is a ready-to-use disinfectant (PT2 and PT4) containing 7.44% w/w (technical a.s) hydrogen peroxyde (H_2O_2). It is intended to be applied for the disinfection of surfaces. These treatments are done by professionals by spraying or fogging.

The product is applied indoors at the following application dose (claimed by the applicant):
- 30 to 50 ml/m^2 for spray application;
- 12 mL/m^3 for fogger application.

➢ **Major change 2023**

For this demand, major and minor changes are claimed.

Major changes are the following:
- addition of targets for spraying application: virus+Legionella
- addition of bulk packagings with filling kit (220L barrel and 1000L IBC).

Minor changes are the following:
- addition of a non-active substance intentionally incorporated in the product: sequestering agent
- addition of soft furnishing surfaces disinfection (spraying)
- addition of a new dosage (6.5ML/m³) for clean conditions and single contact time (3h) for all targets with room disinfection (VHP)
-addition of new contact time of 4h for mycobacteria and viruses with room disinfection (VHP) (12mL/m²)
- addition of clean conditions
- addition of new packagings : bottle of 2L and soft pouch of 2.5L

Major changes (addition of targets for spraying application: virus+Legionella and addition of new packagings (60L and 220L barrel, 1000L IBC)), modification of composition and addition of new dosage can have an impact on the human health risk assessement. Please see 2.2.6.1 Assessment of effects on Human Health and 2.2.6.2 exposure assessement sections.

2.2.6.1 Assessment of effects on Human Health

No acute toxicity study (oral, dermal and inhalation), nor skin and eye irritation study neither skin sensitisation study has been performed on the product "PEROXYDE D'HYDROGÈNE SOLUTION 7,4% PRÊTE À L'EMPLOI".
Classification of the product has been carried out according to the calculation rules laid down in the CLP regulation.

➢ **Major change 2023**

The modification of composition of the product has no impact on its classification. The conclusions remain unchanged. Please see the confidential PAR for further details.

Skin corrosion and irritation

Data waiving	
Information requirement	Skin corrosion and irritation

Justification	The active substance H_2O_2 is present at 7.44% in the product. As it has a specific concentration limit for skin irritation which is >35%, **no classification is triggered** for skin irritation. Please refer to the Confidential Annex for further details.

Eye irritation

Data waiving	
Information requirement	Eye irritation
Justification	A specific concentration limit for eye irritation of >5% (H319) is available for H_2O_2. Considering the content of the a.s in the product, a **classification H319 is required**. Please refer to the Confidential Annex for further details.

Respiratory tract irritation

Data waiving	
Information requirement	Respiratory tract irritation
Justification	According to the classification rules laid down in the CLP regulation, **no classification is required** for respiratory tract irritation. Please refer to the Confidential Annex for further details.

Skin sensitization

Data waiving	
Information requirement	Skin sensitization
Justification	According to the classification rules laid down in the CLP regulation, **no classification is required** for respiratory tract irritation. Please refer to the Confidential Annex for further details.

Respiratory sensitization (ADS)

Data waiving	
Information requirement	Respiratory sensitization
Justification	According to the classification rules laid down in the CLP regulation, **no classification is required** for respiratory sensitization. Please refer to the Confidential Annex for further details.

Acute toxicity

Acute toxicity by oral route

Data waiving	
Information requirement	Oral acute toxicity
Justification	According to the classification rules laid down in the CLP regulation, **no classification is required** for oral acute toxicity. Please refer to the Confidential Annex for the calculation of ATEmix and further details.

Acute toxicity by inhalation

Data waiving	
Information requirement	Inhalation acute toxicity
Justification	According to the classification rules laid down in the CLP regulation, **no classification is required** for inhalation acute toxicity. Please refer to the Confidential Annex for the calculation of ATEmix and further details.

Acute toxicity by dermal route

Data waiving	
Information requirement	Dermal acute toxicity
Justification	According to the classification rules laid down in the CLP regulation, **no classification is required** for dermal acute toxicity. Please refer to the Confidential Annex for further details

Information on dermal absorption

Data waiving	
Information requirement	Dermal absorption
Justification	The AR of hydrogen peroxide (FI, 2015) proposes a 100 % default value for dermal absorption to be used in risk assessment. No systemic availability has been stated for H_2O_2. Therefore, only quantitative local risk assessment is performed for H_2O_2.

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

Considering the detailed formulation of the product "PEROXYDE D'HYDROGENE SOLUTION 7,4% PRÊTE À L'EMPLOI", no substance of concern has been identified.

Available toxicological data relating to a mixture

Not relevant.

Other

Not relevant.

2.2.6.2 Exposure assessment

Identification of main paths of human exposure towards active substance(s) 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**
Inhalation	n.a	yes	n.a	n.a	yes	yes
Dermal	n.a	yes	n.a	n.a	yes	yes
Oral	n.a	n.a	n.a	n.a	no	n.a

n.a. not applicable

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group**
1	**Spray application**		
1a.	Mixing and Loading	**Primary Exposure - Dermal and inhalation routes (aerosols)** Mixing and loading of the ready-to-use product from jerrycan to trigger spray.	Professionals
1b.	Spray application	**Primary Exposure - Dermal and inhalation routes (aerosols)** Product is sprayed for disinfection of surfaces using a ready-to-use trigger spray.	Professionals
1c.	Wiping the treated surfaces after spraying	**Primary exposure – Dermal and inhalation routes** After application of the product by spraying, the treated surfaces are wiped to spread out the product.	Professionals
1d.	Exposure to volatilized residues during application (mixing and loading + spraying + wiping)	**Primary exposure – Inhalation exposure (evaporation)** Due to the high volatility of the active substance (H_2O_2), exposure to volatilized residues occurs during the handling and application of the product (mixing and loading, spraying and wiping).	Professionals
2	**Application by fogger**		
2a.	Mixing and loading	**Primary Exposure - Dermal and inhalation routes (aerosols)** Mixing and loading of the ready-to-use product from jerrycan to bottle that is inserted in the fogger automatic device.	Professionals
2b.	Fogger application	**Primary exposure – Dermal and inhalation exposure** Product is diffused with a suitable automatic device in a hermetically closed room (no ventilation) and in the absence of personnel.	Professionals
2c.	Wiping	**Primary exposure – Dermal and inhalation exposure** Wiping of treated surfaces after advised contact time.	Professionals
2d.	Cleaning of fogger equipment	**Primary exposure – Dermal exposure** Cleaning of fogger equipment after fogger application.	Professionals
2e.	Exposure to volatilized residues after fogger application	**Secondary exposure – Inhalation exposure (evaporation)** Due to the high volatility of the active substance, exposure to volatilized residues occurs if persons enter rooms after the use of the product.	Professionals

3.	Exposure to volatilized residues after spraying application	**Secondary exposure – Inhalation exposure (evaporation)** Due to the high volatility of the active substance, exposure to volatilized residues occurs if persons enter rooms after spraying of the product.	Bystanders
4.	Exposure to treated surfaces	**Secondary exposure – Dermal exposure** After the application of the product by spraying or fogger on surfaces, secondary dermal exposure may occur during the contact with the treated surfaces.	Bystanders

- **Major change 2023**

For the major change some modifications are claimed which could have impact on the Human Health exposure assessment:

- Addition of target organisms virus and legionella
- Addition of soft furnishing surfaces disinfection (spraying)
- New packaging sizes: 2L bottle, 2.5L pouch, 220L barrel and 1000L IBC
- Addition of a new dosage (6.5ML/m³) for clean conditions and single contact time (3h) for all targets with room disinfection (VHP)
- Addition of new contact time of 4h for mycobacteria and viruses with room disinfection (VHP) (12mL/m²)

Addition of target organisms virus and legionella will have no impact on the human health risk assessment as the product is ready-to-use.

Addition of soft furnishing surfaces disinfection (spraying) is covered by the assessement already done and the RMM already proposed.

The addition of the new dosage (6.5ML/m³) is covered by the assessement already performed at 12mL/m^3. No further assessment is needed. The conclusions remain unchanged.

The addition of new contact time of 4h for mycobacteria and viruses with room disinfection (VHP) (12mL/m²) will have no impact on the human health risk assessment. The assessment has been performed considering a contact time of 3 hours. After a contact time of 4 hours, the air concentration will be lower than after 3 hours conctact time as the air concentration begins to decrease during the 3 hours period. Therefore the re-entry time calculated for 3 hours contact time will cover 4 hours contact time. No further assessment is needed. The conclusions remain unchanged

Regarding the new packaging size:
The addition of 2L bottle and 2.5L pouch will have no impact on the HH exposure assessment as packaging size up to 20L are already authorised. The assessment already performed for barrels up to 20L through manual M&L covers these new packaging sizes,
Regarding the 220L barrel and 1000L IBC as explained by the applicant, the 220L barrel and 1000L IBC are exclusively used with a filling kit ("kit de soutirage") which connects direclty to the opening of the large containers without exposure of the user. Considering this, the assessment already performed for barrels up to 20L through manual M&L covers these new packaging sizes.
Therefore no further assessment is needed. The conclusions remain unchanged.

Industrial exposure

Not applicable.

Professional exposure

It has to be noted that, since no systemic effect has been identified for hydrogen peroxide and that only toxicological reference values for inhalation exposure (mg/m^3) are available for this, exposure assessment for the dermal and oral route are not considered.

A local risk assessment will be performed for the dermal route.

- **Major change 2023**

Regarding the new packaging size:
The addition of 2L bottle and 2.5L pouch will have no impact on the human health exposure assessment as packaging size up to 20L are already authorised. The assessment already performed for barrels up to 20L through manual M&L covers these new packaging sizes (scenarios 1a and 2a),

Regarding the 220L barrel and 1000L IBC as explained by the applicant, the 220L barrel and 1000L IBC are exclusively used with a filling kit ("kit de soutirage"). The filling kit is screwed directly to the sealed opening of IBC and 220L drum. The smaller containers are filled with the trigger gun which is introduced into the opening of smaller container.

Figure 1. Filling kit called "kit de soutirage"

Figure 2. Sealed openings on the bottom of bulk packaging

We consider that inhalation exposure to aerosols generated during mixing and loading for these new packaging is still negligible as the extremity of the gun is fully introduced into the jerrycan when the gun is on open-position. Inhalation exposure to vapour is still expected during the filling. Exposure will be at the maximum volume of the trigger spray bottle (1L) or the maximum volume in the fogging device (up to 1.8L). Therefore we consider that the assessment performed using a maximum volume of 20L (scenario 1d M&L and 2a) will cover. No further assessment is needed. The conclusion remains unchanged.

Scenario [1] – Spray application

The product is applied by spraying on surfaces at an application rate between 30 and 50 mL/m^2. After spraying, the product can be wiped or rinsed on hard surfaces to disinfect. Considering this mode of application, professionals are exposed to the product *via* dermal and inhalation routes simultaneously during the application of the product. The different phases of exposure have been split in four different scenarios in order to clarify the assessment:

- Scenario [1a] → professional exposure during mixing and loading (dermal exposure + inhalation exposure to aerosols);
- Scenario [1b] → professional exposure during spray application (dermal exposure + inhalation exposure to generated aerosols);
- Scenario [1c] → professional exposure during wiping (dermal exposure);
- Scenario [1d] → professional exposure to volatilized residues generated due to the

high volatility of H_2O_2 during mixing and loading, spraying and wiping (inhalation to generated vapors).

It should be noted that the ventilation rate and the treated surface area for the different PTs are different. Therefore, the exposure calculations for the different scenarios were carried out to cover the intended use of the trigger spray in the relevant sectors of activities. Besides in ordre to be consistent with the intended uses, only exposition regarding small surfaces' disinfection was performed.

Spray application PT2

- PT2 Hospitals
- PT2 Medical practices
- PT2 Hotels and nurseries

Spray application PT4

- PT4 Small kitchens
- PT4 Canteens
- PT4 Food processing industry

Scenario [1a] – Primary exposure during mixing and loading

Inhalation exposure to aerosols generated during mixing and loading is considered negligible. However, inhalation exposure to vapors generated during mixing and loading is expected. This scenario will be taken into account below (scenario 1d).

Exposure assessment for the dermal route is not considered since no toxicological reference value for systemic effects have been identified. A local RA will be performed for the dermal route.

Scenario [1b] – Primary exposure during spray application (using a trigger spray)

Description of Scenario [1b]
The product is applied by indoor spraying to surfaces to disinfect using a trigger spray. The application rate claimed by the applicant for application with a trigger spray is maximum 50 mL/m^2. To assess the exposure during the spray application with a trigger spray, the "Consumer Spraying and Dusting model 2 (hand held trigger spray)" from the TNsG 2008 has been used according to the Recommendation 6 of HEAd Hoc. The indicative exposure values from the model are as follows: - 36.1 mg pb/min (hands/forearms); - 9.7 mg pb/min (feet/legs/face); - **10.5 mg/m^3 (inhalation).** It has to be noted that, since no systemic effect has been identified for hydrogen peroxide and that only toxicological reference values for inhalation exposure (mg/m^3) are available for this, exposure assessment for the dermal route is not considered. A local risk assessment will be performed for the dermal route. In this context, only the indicative exposure value for inhalation is used.

	Parameters	**Value**	**Source**
Tier 1	Concentration of a.s in the product	7.44%	Applicant's data
	Task duration (min)	30	HEAd Hoc Recommendation 6

Calculations for Scenario [1b]
PT2 Hospitals

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (mg/m³)**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total exposure (mg/m³)**
Scenario [1b]	Tier 1/no RPE	0.781	-	-	0.781
	Tier 2a/RPE (APF 4)	0.195	-	-	0.195
	Tier 2b/ RPE (APF 10)	0.078	-	-	0.078
	Tier 2c/ RPE (APF 40)	0.02	-	-	0.02

PT2 Medical practices

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (mg/m³)**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total exposure (mg/m³)**
Scenario [1b]	Tier 1/no RPE	0.781	-	-	0.781
	Tier 2a/RPE (APF 4)	0.195	-	-	0.195
	Tier 2b/ RPE (APF 10)	0.078	-	-	0.078
	Tier 2c/ RPE (APF 40)	0.02	-	-	0.02

PT2 Hotels and nurseries

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (mg/m³)**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total exposure (mg/m³)**
Scenario [1b]	Tier 1/no RPE	0.781	-	-	0.781
	Tier 2a/RPE (APF 4)	0.195	-	-	0.195
	Tier 2b/ RPE (APF 10)	0.078	-	-	0.078
	Tier 2c/ RPE (APF 40)	0.02	-	-	0.02

PT4 Small kitchens

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (mg/m³)**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total exposure (mg/m³)**
Scenario [1b]	Tier 1/no RPE	0.781	-	-	0.781
	Tier 2a/RPE (APF 4)	0.195	-	-	0.195
	Tier 2b/ RPE (APF 10)	0.078	-	-	0.078
	Tier 2c/ RPE (APF 40)	0.02	-	-	0.02

PT4 Canteens

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (mg/m³)**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total exposure (mg/m³)**
Scenario [1b]	Tier 1/no RPE	0.781	-	-	0.781
	Tier 2a/RPE (APF 4)	0.195	-	-	0.195
	Tier 2b/ RPE (APF 10)	0.078	-	-	0.078
	Tier 2c/ RPE (APF 40)	0.02	-	-	0.02

PT4 Food processing industry

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (mg/m³)**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total exposure (mg/m³)**
Scenario [1b]	Tier 1/no RPE	0.781	-	-	0.781
	Tier 2a/RPE (APF 4)	0.195	-	-	0.195
	Tier 2b/ RPE (APF 10)	0.078	-	-	0.078
	Tier 2c/ RPE (APF 40)	0.02	-	-	0.02

Scenario [1c] – Primary exposure during wiping hard surfaces

According to applicant's data, after application of the product by spraying, the treated surfaces are wiped to spread out the product.

As already mentioned above, no systemic effect has been identified for hydrogen peroxide and only toxicological reference values for inhalation exposure (1.25 mg/m^3) is available. A systemic exposure assessment for the dermal route is therefore not considered. A local risk assessment will be performed for the dermal route.

Scenario [1d] – Primary exposure to volatilized residues during a spray application

Due to the high volatility of the active substance, exposure to volatilized residues occurs during mixing and loading, spraying and wiping.

Knowing that the value of parameters as release area, room volume and product amount are different during the mixing and loading phase and the other phases, the exposure estimate has been split in two sub-scenarios: an evaluation of exposure to volatilized residues during mixing and loading and another evaluation during spraying and wiping.

Description of Scenario [1d] – M&L			
Due to the high volatility of the active substance, the inhalation exposure during mixing and loading has been assessed using ConsExpo Web evaporation model and parameters from the WGVII2018_TOX_8-2 document on harmonisation of PT2 exposure scenarios. The jerrycan during the loading being of a volume of maximum 20L, the maximum amount of product handled is half of the amount of the container content (10L equivalent to 10240 g with a density of 1.024 (Cleaning fact sheet)). Considering that exposure by inhalation during mixing and loading takes place in a perimeter around the professional user, a room volume of 1 m^3 has been chosen, which is equivalent to the user breathing zone. The WG documents recommend using the same ventilation rate as used for the application scenario. Therefore, the M/L scenario has been calculated for all relevant ventilation rates.			
	Parameters	**Value**	**Source**
Tier 1	Concentration of a.s in the product	7.44%	Applicant's data
	Exposureduration (min)	0.75	WGVII2018_TOX_8-2
	Release area (cm^2) (circular opening of 5 cm diameter for a 20 L container)	20	Expert judgement
	Room volume (m^3)	1	Cleaning fact sheet
	Vapor pressure (Pa) of a.s	214	Substance data
	Application duration (min)	0.25	WGVII2018_TOX_8-2
	Ventilation rate	Situation-of-use specific	Same ventilation rate as used for the application scenario
	PT2 Hospitals **PT2 Medical practices**	1.5	WGVII2018_TOX_8-2
	PT2 Hotels and nurseries	0.6*	UA discussions on propan-2-ol
	PT4 Small kitchens **PT4 Canteens**	5	UA discussions on propan-2-ol
	PT4 Food processing industry	20	UA discussions on propan-2-ol

* Consexpo general Fact Sheet (default value of unspecified room)

Calculations for Scenario [1d] – M&L

PT2 Hospitals
PT2 Medical practices

Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (mg/m^3)**	**Estimated total exposure (mg/m^3)**
Scenario [1d]	Tier 1/no RPE	0.0107	0.0107
	Tier 2a/ RPE (APF 4)	0.003	0.003
	Tier 2b/ RPE (APF 10)	0.001	0.001
	Tier 2c/ RPE (APF 40)	0.0003	0.0003

PT2 Hotels and nurseriesExposure scenario	Tier/PPE	Estimated inhalation exposure (mg/m³)	Estimated total exposure (mg/m³)
Scenario [1d]	Tier 1/no RPE	0.0107	0.0107
	Tier 2a/ RPE (APF 4)	0.003	0.003
	Tier 2b/ RPE (APF 10)	0.001	0.001
	Tier 2c/ RPE (APF 40)	0.0003	0.0003

PT4 Small kitchens
PT4 Canteens

Exposure scenario	Tier/PPE	Estimated inhalation exposure (mg/m³)	Estimated total exposure (mg/m³)
Scenario [1d]	Tier 1/no RPE	0.0105	0.0105
	Tier 2a/ RPE (APF 4)	0.003	0.003
	Tier 2b/ RPE (APF 10)	0.001	0.001
	Tier 2c/ RPE (APF 40)	0.0003	0.0003

PT 4 Food processing industry

Exposure scenario	Tier/PPE	Estimated inhalation exposure (mg/m³)	Estimated total exposure (mg/m³)
Scenario [1d]	Tier 1/no RPE	0.01	0.01
	Tier 2a/ RPE (APF 4)	0.003	0.003
	Tier 2b/ RPE (APF 10)	0.001	0.001
	Tier 2c/ RPE (APF 40)	0.0003	0.0003

Description of Scenario [1d] – spraying + wiping - PT2 Hospitals

Due to the high volatility of the active substance, the inhalation exposure during spraying and wiping has been assessed using ConsExpo Web evaporation model.

The application rate claimed by the applicant for application with a trigger spray is maximum 50 mL/m^2.

Considering the following parameters:

- a product density of 1.024;
- a treated surface of 0.5 m^2;

the amount of product deposited on the treated surface is maximum of **25.6 g** for **PT2 Hospitals** (50 mL/m^2 x 0.5 m^2 x 1.024 = 25.6 g)

An exposure duration of **20 min** is considered in order to take into account the time duration of the spraying and the wiping of **1 min** and the time spent in the room performing other duties.

A room volume of **80 m^3** is considered for hospital rooms in line with the HEAdhoc recommendation no 9 and 15.

Hydrogen peroxide acts by a local mode of action. Based on the absence of clear systemic effects after exposure towards hydrogen peroxide, only the inhalation exposure level (i.e. the mean event concentration) is relevant.

	Parameters	**Value**	**Source**
Tier 1	Concentration of a.s in the product	7.44%	Applicant's data
	Exposure duration (min)	20	HEAd Hoc recommendation 9 and 15)
	Release area (m^2)	0.5	HEAd Hoc recommendation 15
	Room volume (m^3)	80	HEAd Hoc recommendation 9 and 15
	Vapor pressure (Pa) of a.s	214	Substance data
	Application duration (min)	1	HEAd Hoc recommendation 15
	Ventilation rate - **PT2 Hospitals**	1.5	HEAd Hoc recommendation 9 and 15)

Calculations for Scenario [1d] - spraying + wiping

PT 2 Hospitals

Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (mg/m^3)**	**Estimated total exposure (mg/m^3)**
Scenario [1d]	Tier 1/no RPE	0.975	0.975
	Tier 2a/ RPE (APF 4)	0.2438	0.2438
	Tier 2b/ RPE (APF 10)	0.0975	0.0975
	Tier 2c/ RPE (APF 40)	0.02	0.02

Description of Scenario [1d] – spraying + wiping – PT2 Medical practices

Due to the high volatility of the active substance, the inhalation exposure during spraying and wiping has been assessed using ConsExpo Web evaporation model.

The application rate claimed by the applicant for application with a trigger spray is maximum 50 mL/m^2.

Considering the following parameters:

- a product density of 1.024;
- a treated surface of 0.5 m^2;

the amount of product deposited on the treated surface is maximum of **25.6 g** for **PT2 Medical practices** (50 mL/m^2 x 0.5 m^2 x 1.024 = 25.6 g)

An exposure duration of **20 min** is considered in order to take into account the time duration of the spraying and the wiping of **1 min** and the time spent in the room performing other duties.

A room volume of **20 m^3** is considered for medical practices in line with the HEAdhoc recommendation no 9 and 15.

Hydrogen peroxide acts by a local mode of action. Based on the absence of clear systemic effects after exposure towards hydrogen peroxide, only the inhalation exposure level (i.e. the mean event concentration) is relevant.

	Parameters	**Value**	**Source**
Tier 1	Concentration of a.s. in the product	7.44%	Applicant's data
	Vapor pressure (Pa) of a.s.	214	Substance data
	Molecular weight matrix (g/mol)	18	Applicant's data
	Event exposure duration (min)	20	HEAd Hoc recommendation 9 and 15
	Product amount (g)	25.6	Applicant's data
	Room volume (m^3)	20	HEAd Hoc recommendation 15
	Ventilation rate (/h) - **PT2 Medical practices**	1.5	HEAd Hoc recommendation 9 and 15
	Release area (m^2) - small surface	0.5	HEAd Hoc recommendation 15
	Application duration (min)	1	HEAd Hoc recommendation 9 and 15
	Mass transfer rate (m/hr)	10	New default value in ConsExpo Web

Calculations for Scenario [1d] - spraying + wiping

PT 2 Medical practices

Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (mg/m^3)**	**Estimated total exposure (mg/m^3)**
Scenario [1d]	Tier 1/no RPE	3.83	3.83
	Tier 2a/ RPE (APF 4)	0.9575	0.9575
	Tier 2b/ RPE (APF 10)	0.383	0.383
	Tier 2c/ RPE (APF 40)	0.1	0.1

Description of Scenario [1d] – spraying + wiping – PT2 Hotels and nurseries

Due to the high volatility of the active substance, the inhalation exposure during spraying and wiping has been assessed using ConsExpo Web evaporation model.

A worst-case room volume of **20 m³** has been combined with worst-case parameters from the ConsExpo General Fact Sheet (**0.6/hr** ventilation rate) considering in addition a longer exposure duration (**120 min** assumed).

The application rate claimed by the applicant for application with a trigger spray is maximum 50 mL/m^2.

Considering the following parameters:

- a product density of 1.024;
- a treated surface of 0.5 m^2;

the amount of product deposited on the treated surface is maximum of **25.6 g** for **PT2 Hotels and nurseries** (50 mL/m^2 x 0.5 m^2 x 1.024 = 25.6 g)

An exposure duration of **120 min** is considered in order to take into account the time duration of the spraying and the wiping of **1 min** and the time spent in the room performing other duties.

The release area of **0.5 m²** corresponds to the the treatment of small surfaces for a room volume of 20 m³.

Hydrogen peroxide acts by a local mode of action. Based on the absence of clear systemic effects after exposure towards hydrogen peroxide, only the inhalation exposure level (i.e. the mean event concentration) is relevant.

	Parameters	**Value**	**Source**
Tier 1	Concentration of a.s. in the product	7.44%	Applicant's data
	Vapor pressure (Pa) of a.s.	214	Substance data
	Molecular weight matrix (g/mol)	18	Applicant's data
	Exposure duration (min)	120	Expert judgement
	Product amount (g)	25.6	Applicant's data
	Room volume (m^3)	20	ConsExpo General Fact Sheet (default value of unspecified room) Applicant's data
	Ventilation rate (/h) - **PT2 Hotels and nurseries**	0.6	ConsExpo General Fact Sheet (default value of unspecified room)
	Release area (m^2) - small surface	0.5	UA on Pal IPA (propan-2-ol)
	Application duration (min)	1	WGVII2018_TOX_8-2 UA on Pal IPA (propan-2-ol)
	Mass transfer rate (m/hr)	10	New default value in ConsExpo Web

Calculations for Scenario [1d] - spraying + wiping

PT2 Hotels and nurseries

Exposure scenario	Tier/PPE	Estimated inhalation exposure (mg/m^3)	Estimated total exposure (mg/m^3)
Scenario [1d]	Tier 1/no RPE	14.9	14.9
	Tier 2a/ RPE (APF 4)	3.725	3.725
	Tier 2b/ RPE (APF 10)	1.49	1.49
	Tier 2c/ RPE (APF 40)	0.37	0.37

Description of Scenario [1d] – spraying + wiping – PT4 Small kitchens

Due to the high volatility of the active substance, the inhalation exposure during spraying and wiping has been assessed using ConsExpo Web evaporation model.

A room volume value of **25 m³** has been combined with harmonised parameters from the UA discussions on propane-2-ol (**5/hr** ventilation rate) considering in addition a longer exposure duration (**120 min** assumed).

The application rate claimed by the applicant for application with a trigger spray is maximum 50 mL/m².

Considering the following parameters:

- a product density of 1.024;
- a treated surface of 1 m²;

the amount of product deposited on the treated surface is maximum of **51.2 g** for **PT4 Small kitchens** (50 mL/m² x 1 m² x 1.024 = 51.2 g)

An exposure duration of **120 min** is considered in order to take into account the time duration of the spraying and the wiping of **2 min** and the time spent in the room performing other duties.

A room volume of **25 m³** is considered for small kitchens. The release area of **1 m²** corresponds to the treatment of small surfaces for a room volume of 25 m³ (e.g. little kitchen from restaurant, kitchen counter for kooking,…).

Hydrogen peroxide acts by a local mode of action. Based on the absence of clear systemic effects after exposure towards hydrogen peroxide, only the inhalation exposure level (i.e. the mean event concentration) is relevant.

	Parameters	**Value**	**Source**
Tier 1	Concentration of a.s. in the product	7.44%	Applicant's data
	Vapor pressure (Pa) of a.s.	214	Substance data
	Molecular weight matrix (g/mol)	18	Applicant's data
	Exposure duration (min)	120	Expert judgement
	Product amount (g)	51.2	Applicant's data
	Room volume (m³)	25	CAR propan-2-ol UA CVAS (propan-2-ol) UA Pal IPA (propan-2-ol)
	Ventilation rate (/h) – **PT4 Small kitchens**	5	UA discussions on propan-2-ol: 5/h for **PT4 "kitchens and canteens"**
	Release area (m²) - small surface	1	CAR propan-2-ol UA CVAS (propan-2-ol) UA Pal IPA (propan-2-ol)
	Application duration (min)	2	CAR propan-2-ol UA CVAS (propan-2-ol) UA Pal IPA (propan-2-ol)
	Mass transfer rate (m/hr)	10	New default value in ConsExpo Web

Calculations for Scenario [1d] - spraying + wiping

PT4 Small kitchens

Exposure scenario	Tier/PPE	Estimated inhalation exposure (mg/m^3)	Estimated total exposure (mg/m^3)
Scenario [1d]	Tier 1/no RPE	6.19	6.19
	Tier 2a/ RPE (APF 4)	1.5475	1.5475
	Tier 2b/ RPE (APF 10)	0.619	0.619
	Tier 2c/ RPE (APF 40)	0.15475	0.15475

Description of Scenario [1d] – spraying + wiping – PT4 Canteens

Due to the high volatility of the active substance, the inhalation exposure during spraying and wiping has been assessed using ConsExpo Web evaporation model.

Parameters from PT2 Hospitals (**80 m³** room volume) have been combined with harmonised parameters from the UA discussions on propan-2-ol, the CAR of propan-2-ol and UA on propan-2-ol products (**5/hr** ventilation rate, **5 m²** release area for PT4 "kitchens and canteens") considering in addition a longer exposure duration (**120 min** assumed).

The application rate claimed by the applicant for application with a trigger spray is maximum 50 mL/m^2.

Considering the following parameters:

- a product density of 1.024;
- a treated surface of 5 m^2;

the amount of product deposited on the treated surface is maximum of **256 g** for **PT4 Canteens** (50 mL/m^2 x 5 m^2 x 1.024 = 256 g)

An exposure duration of **120 min** is considered in order to take into account the time duration of the spraying and the wiping of **2 min** and the time spent in the room performing other duties.

The spraying and wiping time (application duration) has been increased to 2 minutes, considering a higher surface of 5 m². However, such application duration still remains worst case as a 1 minute application duration also allows to treat a small surface of 5 m².

The release area of **5 m²** corresponds to the treatment of small surfaces for a room volume of 80 m³.

Hydrogen peroxide acts by a local mode of action. Based on the absence of clear systemic effects after exposure towards hydrogen peroxide, only the inhalation exposure level (i.e. the mean event concentration) is relevant.

	Parameters	**Value**	**Source**
Tier 1	Concentration of a.s. in the product	7.44%	Applicant's data
	Vapor pressure (Pa) of a.s.	214	Substance data
	Molecular weight matrix (g/mol)	18	Applicant's data
	Exposure duration (min)	120	Expert judgement
	Product amount (g)	256	Applicant's data
	Room volume (m^3)	80	Applicant's data
	Ventilation rate (/h) – **PT4 Canteens**	5	UA discussions on propan-2-ol: 5/h for **PT4 "kitchens and canteens"**
	Release area (m^2) - small surface	5	Applicant's data
	Application duration (min)	2	CAR propan-2-ol UA CVAS (propan-2-ol) UA Pal IPA (propan-2-ol)
	Mass transfer rate (m/hr)	10	New default value in ConsExpo Web

Calculations for Scenario [1d] - spraying + wiping

PT4 Canteens

Exposure scenario	Tier/PPE	Estimated inhalation exposure (mg/m^3)	Estimated total exposure (mg/m^3)
Scenario [1d]	Tier 1/no RPE	9.39	9.39
	Tier 2a/ RPE (APF 4)	2.3475	2.3475
	Tier 2b/ RPE (APF 10)	0.939	0.939
	Tier 2c/ RPE (APF 40)	0.23475	0.23475

Description of Scenario [1d] – spraying + wiping – PT4 Food processing industry

Due to the high volatility of the active substance, the inhalation exposure during spraying and wiping has been assessed using ConsExpo Web evaporation model. Parameters from PT2 Hospitals (**80 m³** room volume) have been combined with harmonised parameters from the CAR of propan-2-ol and UA for propan-2-ol products (**20/hr** ventilation rate for PT4 "food processing industry") considering in addition a longer exposure duration (**120 min** assumed).

The application rate claimed by the applicant for application with a trigger spray is maximum 50 mL/m².

Considering the following parameters:

- a product density of 1.024;
- a treated surface of 5 m²;

the amount of product deposited on the treated surface is maximum of **256 g** for **PT4 Canteens** (50 mL/m² x 5 m² x 1.024 = 256 g)

An exposure duration of **120 min** is considered in order to take into account the time duration of the spraying and the wiping of **5 min** and the time spent in the room performing other duties.

A room volume of **80 m³** is considered for canteens in line with scenario C. The release area of **5 m²** corresponds to the the treatment of small surfaces for a room volume of 80 m³. These surfaces will not exceed 5 m² for room spaces of 80 m³.

Hydrogen peroxide acts by a local mode of action. Based on the absence of clear systemic effects after exposure towards hydrogen peroxide, only the inhalation exposure level (i.e. the mean event concentration) is relevant.

	Parameters	**Value**	**Source**
Tier 1	Concentration of a.s. in the product	7.44%	Applicant's data
	Vapor pressure (Pa) of a.s.	214	Substance data
	Molecular weight matrix (g/mol)	18	Applicant's data
	Exposure duration (min)	120	Expert judgement
	Product amount (g)	256	Applicant's data
	Room volume (m³)	80	Applicant's data
	Ventilation rate (/h) – **PT4 Food processing industry**	20	CAR propan-2-ol UA for propan-2-ol products (Contec IPA, CVAS, Pal IPA)
	Release area (m²) - small surface	5	Applicant's data
	Application duration (min)	5	CAR propan-2-ol UA for propan-2-ol products (Contec IPA, CVAS, Pal IPA)
	Mass transfer rate (m/hr)	10	New default value in ConsExpo Web

Calculations for Scenario [1d] - spraying + wiping

PT4 Canteens

Exposure scenario	Tier/PPE	Estimated inhalation exposure (mg/m³)	Estimated total exposure (mg/m³)
Scenario [1d]	Tier 1/no RPE	2.63	2.63
	Tier 2a/ RPE (APF 4)	0.6575	0.6575
	Tier 2b/ RPE (APF 10)	0.263	0.263
	Tier 2c/ RPE (APF 40)	0.06575	0.06575

Combined exposure - Scenario [1d]: M&L + spraying + wiping

PT 2 Hospitals

Exposure scenario	Tier/PPE	Estimated inhalation exposure during M&L (mg/m³)	Estimated inhalation exposure during spraying and wiping (mg/m³)	Estimated total exposure (mg/m³)
Scenario [1d]	Tier 1/no RPE	0.0107	0.975	0.99
	Tier 2a/ RPE (APF 4)	0.003	0.2438	0.25
	Tier 2b/ RPE (APF 10)	0.001	0.0975	0.10
	Tier 2c/ RPE (APF 40)	0.0003	0.02	0.02

PT 2 Medical practices

Exposure scenario	Tier/PPE	Estimated inhalation exposure during M&L (mg/m³)	Estimated inhalation exposure during spraying and wiping (mg/m³)	Estimated total exposure (mg/m³)
Scenario [1d]	Tier 1/no RPE	0.0107	3.83	3.84
	Tier 2a/ RPE (APF 4)	0.003	0.9575	0.96
	Tier 2b/ RPE (APF 10)	0.001	0.383	0.38
	Tier 2c/ RPE (APF 40)	0.0003	0.1	0.10

PT 2 Hotels and nurseries

Exposure scenario	Tier/PPE	Estimated inhalation exposure during M&L (mg/m³)	Estimated inhalation exposure during spraying and wiping (mg/m³)	Estimated total exposure (mg/m³)
Scenario [1d]	Tier 1/no RPE	0.0107	14.9	14.91
	Tier 2a/ RPE (APF 4)	0.003	3.725	3.73
	Tier 2b/ RPE (APF 10)	0.001	1.49	1.49
	Tier 2c/ RPE (APF 40)	0.0003	0.37	0.37

PT 4 Small kitchens

Exposure scenario	Tier/PPE	Estimated inhalation exposure during M&L (mg/m³)	Estimated inhalation exposure during spraying and wiping (mg/m³)	Estimated total exposure (mg/m³)
Scenario [1d]	Tier 1/no RPE	0.0105	6.19	6.20
	Tier 2a/ RPE (APF 4)	0.003	1.5475	1.559
	Tier 2b/ RPE (APF 10)	0.001	0.619	0.621
	Tier 2c/ RPE (APF 40)	0.0003	0.15475	0.16

PT 4 Canteens

Exposure scenario	Tier/PPE	Estimated inhalation exposure during M&L (mg/m³)	Estimated inhalation exposure during spraying and wiping (mg/m³)	Estimated total exposure (mg/m³)
Scenario [1d]	Tier 1/no RPE	0.0105	9.39	9.40
	Tier 2a/ RPE (APF 4)	0.003	2.3475	2.35
	Tier 2b/ RPE (APF 10)	0.001	0.939	0.94
	Tier 2c/ RPE (APF 40)	0.0003	0.23475	0.24

PT 4 Food processing industry

Exposure scenario	Tier/PPE	Estimated inhalation exposure during M&L (mg/m³)	Estimated inhalation exposure during Spraying and wiping (mg/m³)	Estimated total exposure (mg/m³)
Scenario [1d]	Tier 1/no RPE	0.01	2.63	2.64
	Tier 2a/ RPE (APF 4)	0.003	0.6575	0.663
	Tier 2b/ RPE (APF 10)	0.001	0.263	0.26
	Tier 2c/ RPE (APF 40)	0.0003	0.06575	0.07

Combined exposure - Scenario [1]: Total exposure during spray application [1a + 1b + 1c+ 1d]

PT 2 Hospitals

Exposure scenario	Tier/PPE	Estimated inhalation exposure during M&L (aerosols) (mg/m3)	Estimated inhalation exposure during spray application (aerosols) (mg/m3)	Estimated inhalation exposure during wiping (mg/m3)*	Estimated inhalation exposure during M&L , spaying and wiping (evaporation) (mg/m3)	Estimated total exposure (mg/m³)
Scenario [1a,b,c,d]	Tier 1/no RPE	negligible	0.781	-	0.99	1.77
	Tier 2a/ RPE (APF 4)	negligible	0.195	-	0.25	0.44
	Tier 2b/ RPE (APF 10)	negligible	0.078	-	0.10	0.18
	Tier 2c/ RPE (APF 40)	negligible	0.02	-	0.02	0.04

* No inhalation exposure to aerosols is expected during this task

PT 2 Medical Practices

Exposure scenario	Tier/PPE	Estimated inhalation exposure during M&L (aerosols) (mg/m3)	Estimated inhalation exposure during spray application (aerosols) (mg/m3)	Estimated inhalation exposure during wiping (mg/m3)*	Estimated inhalation exposure during M&L , spaying and wiping (evaporation) (mg/m3)	Estimated total exposure (mg/m³)
Scenario [1a,b,c,d]	Tier 1/no RPE	negligible	0.781	-	3.84	4.62
	Tier 2a/ RPE (APF 4)	negligible	0.195	-	0.96	1.16
	Tier 2b/ RPE (APF 10)	negligible	0.078	-	0.38	0.46
	Tier 2c/ RPE (APF 40)	negligible	0.02	-	0.10	0.12

* No inhalation exposure to aerosols is expected during this task

PT 2 Hotels and nurseries

Exposure scenario	Tier/PPE	Estimated inhalation exposure during M&L (aerosols) (mg/m3)	Estimated inhalation exposure during spray application (aerosols) (mg/m3)	Estimated inhalation exposure during wiping (mg/m3)*	Estimated inhalation exposure during M&L , spaying and wiping (evaporation) (mg/m3)	Estimated total exposure (mg/m³)
Scenario [1a,b,c,d]	Tier 1/no RPE	negligible	0.781	-	14.91	15.69
	Tier 2a/ RPE (APF 4)	negligible	0.195	-	3.73	3.92
	Tier 2b/ RPE (APF 10)	negligible	0.078	-	1.49	1.57
	Tier 2c/ RPE (APF 40)	negligible	0.02	-	0.37	0.39

* No inhalation exposure to aerosols is expected during this task

PT 4 Small kitchens

Exposure scenario	Tier/PPE	Estimated inhalation exposure during M&L (aerosols) (mg/m3)	Estimated inhalation exposure during spray application (aerosols) (mg/m3)	Estimated inhalation exposure during wiping (mg/m3)*	Estimated inhalation exposure during M&L , spaying and wiping (evaporation) (mg/m3)	Estimated total exposure (mg/m³)
Scenario [1a,b,c,d]	Tier 1/no RPE	negligible	0.781	-	6.20	6.98
	Tier 2a/ RPE (APF 4)	negligible	0.195	-	1.559	1.75
	Tier 2b/ RPE (APF 10)	negligible	0.078	-	0.621	0.70
	Tier 2c/ RPE (APF 40)	negligible	0.02	-	0.16	0.17

* No inhalation exposure to aerosols is expected during this task

PT 4 Canteens

Exposure scenario	Tier/PPE	Estimated inhalation exposure during M&L (aerosols) (mg/m3)	Estimated inhalation exposure during spray application (aerosols) (mg/m3)	Estimated inhalation exposure during wiping (mg/m3)*	Estimated inhalation exposure during M&L , spaying and wiping (evaporation) (mg/m3)	Estimated total exposure (mg/m³)
Scenario [1a,b,c,d]	Tier 1/no RPE	negligible	0.781	-	9.40	10.18
	Tier 2a/ RPE (APF 4)	negligible	0.195	-	2.35	2.55
	Tier 2b/ RPE (APF 10)	negligible	0.078	-	0.94	1.02
	Tier 2c/ RPE (APF 40)	negligible	0.02	-	0.24	0.25

* No inhalation exposure to aerosols is expected during this task

PT 4 Food processing industry

Exposure scenario	Tier/PPE	Estimated inhalation exposure during M&L (aerosols) (mg/m3)	Estimated inhalation exposure during spray application (aerosols) (mg/m3)	Estimated inhalation exposure during wiping (mg/m3)*	Estimated inhalation exposure during M&L , spaying and wiping (evaporation) (mg/m3)	Estimated total exposure (mg/m³)
Scenario [1a,b,c,d]	Tier 1/no RPE	negligible	0.781	-	2.64	3.42
	Tier 2a/ RPE (APF 4)	negligible	0.195	-	0.663	0.86
	Tier 2b/ RPE (APF 10)	negligible	0.078	-	0.26	0.34
	Tier 2c/ RPE (APF 40)	negligible	0.02	-	0.07	0.09

* No inhalation exposure to aerosols is expected during this task

Scenario [2] – Fogger application

The product is applied by fogging on surfaces at an application rate of 12 mL/m³. After application, the fogger equipment is cleaned.

Considering this mode of application, professionals are exposed to the product *via* dermal and inhalation routes simultaneously during the application of the product. The different phases of exposure have been split in four different scenarios in order to clarify the assessment:

- Scenario [2a] → professional exposure during mixing and loading (dermal exposure

+ inhalation exposure to aerosols)
- Scenario [2b] → professional exposure during fogger application (dermal exposure + inhalation exposure to generated aerosols);
- Scenario [2c] → professional exposure during wiping (dermal exposure);
- Scenario [2d] → professional exposure during cleaning of the fogger equipment (dermal exposure);
- Scenario [2e] → professional exposure to volatilized residues generated due to the high volatility of H_2O_2 after fogger application.

It should be noted that the ventilation rate and the treated surface area for the different PTs are different. Therefore, the exposure calculations for the different scenarios were carried out for PT2, PT 4 "kitchens and canteens" and for PT4 "food processing industry".

Scenario [2a] – Primary exposure during mixing and loading

Inhalation exposure to aerosols generated during mixing and loading is considered negligible.
However, inhalation exposure to vapours generated during mixing and loading is expected. Exposure assessment for the dermal route is not considered since no toxicological reference value for systemic effects have been identified. A local RA will be performed for the dermal route.

Description of Scenario [2a]			
The bottle of 0.25 to 10L inserted in the automatic fogging device can be refilled by manual mixing and loading of the ready-to-use disinfectant (7.44% w/w of hydrogen peroxide) that is packaged in cans of 1, 5, 10 or 20L. This application takes place indoors. The inhalation exposure during mixing and loading has been assessed using ConsExpo web and the model for pest control products (mixing and loading). A task duration of 10 minutes has been considered. The jerrycan during the loading being of a volume of maximum 20L, the maximum amount of product handled is half of the amount of the container content (10L equivalent to 10240 g with a density of 1.024 (Cleaning fact sheet) Considering that exposure by inhalation takes place around the professional, a room volume of 1 m^3 has been choosen equivalent to the user breathing zone. In the absence of clear systemic adverse effects, the risk characterisation of hydrogen peroxide is focused on local effects and no systemic doses are estimated.			
	Parameters	**Value**	**Source**
Tier 1	Concentration of a.s in the product	7.44%	Applicant's data
	Task duration (min)	10	Expert jugement
	Product amount (g)	10240	Applicant's data
	Release area (cm^2) (circular opening of 5 cm diameter for a 20 L container)	20	Expert jugement
	Room volume (m^3)	1	Cleaning fect sheet
	Vapor pressure of a.s (Pa)	214	Substance data
	Emission duration (hours)	24	Expert judgement
	Ventilation rate	**PT2:** 0.6/h* **PT4 "kitchens and canteens"** : 5/h **PT4 "food processing industry)**: 20/h	UA discussions on propane-2-ol

* Consexpo general Fact Sheet (default value of unspecified room)

Calculations for Scenario [2a]

PT 2

Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (mg/m^3)**	**Estimated total exposure (mg/m^3)**
Scenario [1d]	Tier 1/no RPE	0.196	0.196
	Tier 2a/ RPE (APF 4)	0.049	0.049
	Tier 2b/ RPE (APF 10)	0.02	0.02
	Tier 2c/ RPE (APF 40)	0.005	0.005

PT 4 "kitchens and canteens"

Exposure scenario	Tier/PPE	Estimated inhalation exposure (mg/m^3)	Estimated total exposure (mg/m^3)
Scenario [1d]	Tier 1/no RPE	0.16	0.16
	Tier 2a/ RPE (APF 4)	0.04	0.04
	Tier 2b/ RPE (APF 10)	0.016	0.016
	Tier 2c/ RPE (APF 40)	0.004	0.004

PT 4 "food processing industry"

Exposure scenario	Tier/PPE	Estimated inhalation exposure (mg/m^3)	Estimated total exposure (mg/m^3)
Scenario [1d]	Tier 1/no RPE	0.086	0.086
	Tier 2a/ RPE (APF 4)	0.022	0.022
	Tier 2b/ RPE (APF 10)	0.009	0.009
	Tier 2c/ RPE (APF 40)	0.002	0.002

Scenario [2b] – Primary exposure during fogger application (using an automatic device)

With an automatic device, professional users are absent from the treated room during the fogger application; therefore, no primary exposure is expected.

Scenario [2c] – Primary exposure during wiping hard surfaces

After fogger application, the treated surfaces are wiped to spread out the product.

As already mentioned above, no systemic effect has been identified for hydrogen peroxide and only toxicological reference values for inhalation exposure (1.25 mg/m^3) are available for both substances. A systemic exposure assessement for the dermal route is therefore not considered.

Scenario [2d] – Cleaning of the fogger equipment

After the fogger application, the automatic spraying device must be cleaned.

As already mentioned above, no systemic effect has been identified for hydrogen peroxide and only toxicological reference values for inhalation exposure (1.25 mg/m^3) are available. A systemic exposure assessment for the dermal route is therefore not considered.

For scenarios [2c and 2d], a local risk assessment will be performed for the dermal route.

Combined exposure - Scenario [2]: Total exposure during fogger application [2a+ 2b+ 2c+2d]

PT 2

Summary table: combined systemic exposure from professional uses						
Scenarios combined	**Estimated inhalation (generated aerosols) exposure (mg/m³)**		**Estimated dermal uptake (mg/kg bw/d)**		**Estimated inhalation (evaporation) exposure (mg/m³)**	**Estimated total exposure (mg/m³)**
Scenario [2a,2b,2c,2d] **Tier 1**	**-**	**-**	-	-	0.02	0.02

PT 4 "kitchens and canteens"

Summary table: combined systemic exposure from professional uses						
Scenarios combined	**Estimated inhalation (generated aerosols) exposure (mg/m³)**		**Estimated dermal uptake (mg/kg bw/d)**		**Estimated inhalation (evaporation) exposure (mg/m³)**	**Estimated total exposure (mg/m³)**
Scenario [2a,2b,2c,2d] **Tier 1**	**-**	**-**	-	-	0.016	0.016

PT 4 "food processing industry"

Summary table: combined systemic exposure from professional uses						
Scenarios combined	**Estimated inhalation (generated aerosols) exposure (mg/m³)**		**Estimated dermal uptake (mg/kg bw/d)**		**Estimated inhalation (evaporation) exposure (mg/m³)**	**Estimated total exposure (mg/m³)**
Scenario [2a,2b,2c,2d] **Tier 1**	**-**	**-**	-	-	0.086	0.086

Scenario [2e] – Primary exposure during re-entry of professionals in the treated room

Description of Scenario [2e] - Evaporation

The concentration of active substance in the air has not to exceed the AEC (1.25 mg/m^3) for the re-entry of professional users in the treated room. Therefore, a re-entry period has to be calculated.

Consexpo web was used to model this re-entry period following these parameters:

- Product amount: 12 ml/m^3 × 25 m^3 × 1.024 = **307g**

A first sub-scenario was modelled to establish the concentration in the air at the end of fogger application.

	Parameters	**Value**	**Source**
Tier 1	Model	Exposure to vapour	Expert judgment
	Mode of release	Evaporation	Expert judgement
	Exposure duration (min)	180	Applicant's data
	Molecular weight matrix (g/mol)	18	Applicant's data
	Product amount (g)	307	Applicant's data
	Concentration of a.s in the product	7.44%	Applicant's data
	Room volume (m^3)	25	Expert jugement
	Vapor pressure of a.s (Pa)	214	Substance data
	Molecular weight (g/mol)	34	Applicant's data
	Release area (m^2)	**PT2 and PT4 "kitchen and canteens":** 5 **PT4 "food processing industry":** 18.4	Expert jugement
	Emission duration (hours)	24	Expert judgement
	Ventilation rate (volume/hour)	0.5*	Consexpo value

* during the application by fogging, it is considered that the ventilation system is not activated.

Figure 1: air concentration of product during fogger application for PT2 and PT4 "kitchens and canteens"

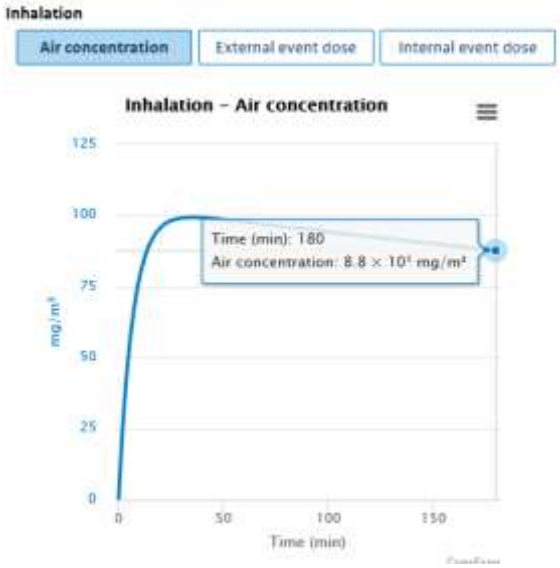


Figure 2: air concentration of product during fogger application for PT4 "food processing industry"

Considering the graph presented above (from ConsExpo) and representing the evaporation kinetic of the active substance when the ventilation system is not activated, it is assumed that, after 180 minutes (product contact time), the active substance's air concentration is beginning to decrease and is of 79 mg/m^3 for PT2 and PT4 "kitchens and canteens" and 88 mg/m3 for PT4 "food processing industry".

Description of Scenario [2e] – Instantaneous release

After the application by fogger, the professional has to re-activate the ventilation in the treated room from 0.5/hr to 0.6/hr for PT2, to 5/hr for PT4 "kitchens and canteens" and to 20/hr for PT4 "food processing industry".

Thus, another ConsExpo model has been chosen to modelize the air concentration of product when the ventilation rate of treated room is re-activated to its initial value.

Same settings were chosen than scenario [2d] except for:

- **Mode of release**: it is assumed that all the product on surfaces evaporates at once
  ➔ Instantaneous release

- **Product amount** :
  - ✓ PT2 and PT4 " kitchens and canteens": **79** mg/m^3 *(see scenario [2e]*)* × 25 m^3 = **1975** mg
  - ✓ PT4 "food processing industry": **88** mg/m^3 *(see scenario [2e]*)* × 25 m^3 = **2200** mg

- **Ventilation rate**

Consexpo web was used to model this re-entry period following these parameters.

	Parameters	**Value**	**Source**
Tier 1	Model	Exposure to vapour	Expert judgment
	Mode of release	Instantaneous release	Expert judgement
	Exposure duration (min)	180	Applicant's data
	Product amount (g)	PT2 and PT4 " kitchens and canteens": 1975 mg PT4 "food processing industry": 2200 mg	Applicant's data
	Concentration of a.s in the product	7.44%	Applicant's data
	Room volume (m^3)	25	Expert jugement
	Ventilation rate (ventilation is not re-activated)	**PT2 and PT4 "kitchens and canteens"** : 0.5/h **PT4 "food processing industry)"**: 0.5/h	UA discussions on propane-2-ol
Tier 2	Ventilation rate (ventilation re-activated)	**PT2**: 0.6/h** **PT4 "kitchens and canteens"** : 5/h **PT4 "food processing industry)"**: 20/h	UA discussions on propane-2-ol

* In the scenario [2e] presented above, the air concentration of H_2O_2 in the treated room after 180 min (equivalent to the time duration claimed for fogger application) is of 79 mg/m^3 for PT 2 and 4 " kitchens and canteens" and 88 mg/m^3 for PT4 "food processing industry".
** Consexpo general Fact Sheet (default value of unspecified room)

The rest of the evaluation (re-entry time graphs) for this scenario will be done in the risk assessment part.

Non-professional exposure

The product being only intended for professional use, non-professional exposure during the application of the product by spraying or fogger is not expected.

Exposure of the general public

Scenario [3] – Exposure to volatilized residues after spraying application

Description of Scenario [3]
"PEROXYDE D'HYDROGÈNE SOLUTION 7.4% PRETE À L'EMPLOI" product is intended for use as surface disinfectants. Inhalation of volatilized residues (H_2O_2) after indoor application by spraying is considered possible and, regarding the intended uses, this exposure takes place to bystanders entering a room with freshly treated surfaces. Therefore, a re-entry time must be evaluated for bystanders. The same parameters and the same Consexpo model as scenario 1d are applied for evaporation of residues. Only the duration of the exposure has been changed: - **for PT4**: 8 hours representing a typical working day for a bystander staying in the room for the whole day. - **for PT2**: 24 hours for a toddler (worst case). In addition, a rinsing step will be considered to decrease the amount of active substance (a wiping step can also be considered but a worst-case approach considering the amount remaining on surfaces has been applied here).

Inhalation exposure - Spraying application

The concentration of active substance in the air has not to exceed the AEC (1.25 mg/m^3) for the re-entry of non-professional users in the treated room. Therefore, a re-entry period has to be calculated.

A rinsing step is assumed after the end of spraying application. The worst-case measured hydrogen peroxide residue in the study provided by the Applicant about the efficacy of post application methods is 156.32 mg/m^2 after rinsing (material: aluminium).

PT2 Hospitals, PT2 Medical practices, PT2 Hotels and nurseries

Considering a release area of 0.5 m^2, the product amount in the room after rinsing is 156.32 mg/m^2 × 0.5 m^2 = 78.16 mg. This product amount corresponds to a product with 7.44% of hydrogen peroxide.

In ConsExpo model, we have to inform the product amount and concentration of a.s. in the product. Thus, a calculation has to be realized to fill in the parameters in ConsExpo:

(78.16 mg × 100)/7.44 = 1050 mg = **1.05 g**

PT4 Small kitchens

Considering a release area of 1 m^2, the product amount in the room after rinsing is 156.32 mg/m^2 × 1 m^2 = 156.32 mg. This product amount corresponds to a product with 7.44% of hydrogen peroxide.

In ConsExpo model, we have to inform the product amount and concentration of a.s. in the product. Thus, a calculation has to be realized to fill in the parameters in ConsExpo:

(156.32 mg × 100)/7.44 = 2101 mg = **2.1 g**

PT4 Canteens, PT4 Food processing industry

Considering a release area of 5 m^2, the product amount in the room after rinsing is 156.32 mg/m^2 × 5 m^2 = 781.6 mg. This product amount corresponds to a product with 7.44% of hydrogen peroxide.

In ConsExpo model, the product amount and concentration of a.s. in the product have to be documented. Thus, a calculation has to be realized to fill in the parameters in ConsExpo:

(781.6 mg × 100)/7.44 = 10 505 mg = **10.5 g**

For PT2, a worst-case approach has been realised considering a toddler exposition (1.26 m^3/h for inhalation rate and 10 kg for body weight). For PT4, an adult exposure is expected.

	Parameters	**Value**	**Source**
Tier 1	Concentration of a.s. in the product	7.44%	Applicant's data
	Vapor pressure (Pa) of a.s.	214	Substance data
	Molecular weight matrix (g/mol)	18	Applicant's data
	Exposure duration (min)	480	Expert judgement
	Product amount (g)	1.05	**PT2 Hospitals** **PT2 Medical practices** **PT2 Hotels and nurseries**
		2.1	**PT4 Small kitchens**
		10.5	**PT4 Canteens** **PT4 Food processing industry**

	Room volume (m^3)	80	**PT2 Hospitals** **PT4 Canteens** **PT4 Food processing industry**
		25	**PT4 Small kitchens**
		20	**PT2 Hotels and nurseries** **PT2 Medical practices**
	Ventilation rate (/h)	0.6	**PT2 Hotels and nurseries**
		1.5	**PT2 Hospitals** **PT2 Medical practices**
		5	**PT4 Small kitchens** **PT4 Canteens**
		20	**PT4 Food processing industry**
	Release area (m^2)	0.5	**PT2 Hospitals** **PT2 Medical practices** **PT2 Hotels and nurseries**
		1	**PT4 Small kitchens**
		5	**PT4 Canteens** **PT4 Food processing industry**
	Application duration (min)	1	**PT2 Hospitals** **PT2 Medical practices** **PT2 Hotels and nurseries**
		2	**PT4 Small kitchens** **PT4 Canteens**
		5	**PT4 Food processing industry**
	Mass transfer rate (m/hr)	10	New default value in ConsExpo Web

The rest of the evaluation (re-entry time graphs) for this scenario will be done in the risk assessment part.

Scenario [4] – Exposure to treated surfaces

Description of Scenario [4]
"PEROXYDE D'HYDROGÈNE SOLUTION 7.4% PRETE À L'EMPLOI" product is intended for use as surface disinfectants. Because of the high volatility of the a.s containing in the product, dermal exposure to H_2O_2 applied on surfaces is considered negligible. However, H_2O_2 is a highly reactive active substance that will react with organic matter present on the surfaces to be treated (hard) leading to the formation of Disinfectant By-Product (DBP). The number of possible DBP formed is very high and no identification neither quantification is possible. Currently, no indications on how to perform an exposure assessment of the DBP formed during H_2O_2 application with PT2 and PT 4 are available. Therefore, the applicant provided the following study: "Determination of hydroxyl residues of PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE after rinsing and/or wiping and/or drying and /or soaking". This study was performed in order to determinate residues of PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE after rinsing and/or wiping and/or drying and/or soaking. A short summary of this study is detailed in the dietary exposure section and a full description of this study is provided in Annex 3.4. The submitted study demonstrates that post application methods (wiping, rinsing or drying) are efficient and allow to lower hydroxyl residues exposure on treated surfaces. However, although hydroxyl residues are good markers of DBP synthesis, DBP in this study are not directly measured. Moreover, in the absence of validated methodology to identify, measure and evaluate DBP, they are not taken into account in the risk assessment.

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

Not relevant

Aggregated exposure

None

Summary of exposure assessment

	Scenarios and values to be used in risk assessment				
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total exposure (mg/m³)**		
			PT2	PT4 "kitchens and canteens"	PT4 "food processing industry"
1. Spray application	Professionals	Tier 1/No RPE	46.98	26.44	29.47
		Tier 2a/RPE factor 4	11.74	6.61	7.37
		Tier 2b/RPE factor 10	4.7	2.64	2.95
		Tier 2c/RPE factor 40	1.17	0.66	0.74
2. Fogger application	Professionals	Tier 1/No RPE	0.196	0.16	0.086

Dietary exposure

By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore, residue in food or feed are not expected for PEROXYDE D'HYDROGENE SOLUTION 7.4% PRETE A L'EMPLOI PT 2 uses.

As PT4, PEROXYDE D'HYDROGENE SOLUTION 7.4% PRETE A L'EMPLOI is intended to be used as disinfectants of rooms (including collective central kitchens) and equipment for the production of food and feed stuff (including drinking water) for human and animal consumption. Therefore, residues in food, feed or drinking water might be expected based on intended uses. Two ways of application are intended: surface spraying and fogging.

Biocidal product PEROXYDE D'HYDROGENE SOLUTION 7.4% PRETE A L'EMPLOI is composed of hydrogen peroxyde only.
For hydrogen peroxide, no dietary exposure is foreseen. Indeed, "*hydrogen peroxide is reactive and it degrades rapidly in contact with organic material. A significant proportion of hydrogen peroxide decomposes to water and oxygen*" (Finland, 2015). Therefore, this active substance is not expected to remain on surfaces, and no residues in food which may enter into contact with treated surface are expected.

Nevertheless, in the assessment report (Finland, 2015), it is also stated: "*The antimicrobial action of hydrogen peroxide stems from its ability to form powerful oxidants such as the hydroxyl radical and singlet oxygen. These reactive oxygen species cause irreversible damage to cellular components such as enzymes, membrane constituents and DNA. The range of by-products is considered wide and not well characterise*d*"*. Therefore, hydrogen peroxyde degradation can also lead to the formation of free radicals which are highly reactive components. Free radicals can therefore react with (in)organic components present on surfaces and lead to the formation of a wide range of by-products, potentially toxic (Disinfection By Products (DBP)). The range of DBP is considered wide and not well characterised. Therefore, it would be very difficult to provide analytical methods and toxicological data to cover the low level concentrations of the enormous variety of DBP.

European guidance on the assessment of Disinfection by products is finalised and available[1]. Nevertheless, this guidance was "*developed to be applicable to biocides in PT 2 (…) for the other PTs future development of an adapted guidance is needed to ensure a harmonised approach across the EU*" (ECHA, 2017). Therefore, in the frame of this dossier, in order to assess consumer risk assessment via DBP, no finalised or draft guidance is available.

Without any indication on how to perform an exposure assessment of the DBP formed during H_2O_2 application, the applicant provided a reliable argumentation to explain that intended H_2O_2 biocidal use would not raise any risk for the consumer:

"*So, if we also refer to other legislation as PPP and veterinary regulations, the next information is also found:*

- *According to the EFSA report on the outcome of the consultation with Member States and EFSA on the basic substance application for hydrogen peroxide for use in plant protection as fungicide and bactericide in seed treatment and for disinfecting cutting tool (EFSA Technical report, 2016), it is indicated that expected residue of hydrogen peroxide are only water and oxygen. So, EFSA set no MRL for this substance stating it was not required.*
- *« The European Agency for the Evaluation of Medicinal Products Veterinary Medicines Evaluation Unite – Committee for veterinary medicinal products – hydrogen peroxide (1) and (2) – summary report » (EMEA, 1996) also provides the following observations:*
    - *"Following treatment with H_2O_2, residues in fish and other products of animal*

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

origin cannot distinguished from the endogenous levels. Spectrophotometric methods are available for the determination of residues of H_2O_2 down to 0.01 mg/l (0.01mg/kg).

- *Although H_2O_2 is toxic to some aquatic organisms including marine phytoplankton and crustacea, the rated of dilution and dissociation encountered on fish farms ensure that harmful effects on the environment are minimized.*
- *For reasons stated in the preceding paragraphs, the Working Group on the Safety of Residues agreed that it was not necessary to set MRLs for hydrogen peroxide and agreed that the substance should be included in Annex II of Regulation N°2377/90.*
- *Therefore, the Committee for Veterinary Medicinal Products considers that there is no need to establish MRL for H_2O_2 for animal species other than fish and recommends its inclusion into Annex II of Council Regulation (EEC) No 2377/90 in accordance with the following table: H_2O_2 pharmacologically active substance is authorized in all food producing animal species".*

Besides this, literature research on the possible toxicity of hydrogen peroxide in food and feed reveals the following information in the EFSA Scientific opinion on the evaluation of the safety and efficacy of peroxyacetic acid solutions for reduction of pathogens on poultry carcasses and meat (EFSA Journal, 2014)[2].

- *"On the basis of the previous EFSA exposure scenarios including short term baths that were not evaluated previously, it was concluded no toxicity concerns were identified with regards to residues of peroxyacids, to HEDP and to possible reaction products of hydrogen peroxide and peroxyacids with lipids and proteins of the poultry carcasses."*

If we extrapolate this observation and conclusion, it can be assumed that hydrogen peroxide, even in the case it would be present at a sufficient level to lead to food exposure, would not raise any level of toxicity for the consumer.
(…)
And finally, in the Council Directive 2011/84/EU[3], amending Directive 76/768/EEC concerning cosmetic products, also referenced in the Assessment report of hydrogen peroxide (Official Journal of the European Union, 2011), the Scientific Committee on Consumer Products (SCCS) has confirmed that a maximum concentration of 0,1 % of hydrogen peroxide present in oral products or released from other compounds or mixtures in those products is safe."
Moreover, hydrogen peroxide is also authorised in France as processing aid (i.e. components of washing solution for vegetables)[4] and no risk for consumer was identified. In those kind of H_2O_2 application, a rinsing step has to be done after washing.
Based on this argumentation, FR is of opinion that PEROXYDE D'HYDROGENE SOLUTION 7.4% intended use would not raise any risk for the consumer.

Moreover, some post application methods are intended by the applicant : "*Apply the pure product (without dilution) by spraying the surfaces until they are completely covered and/or by wet cleaning with a wipe or a soaked cloth. After required contact time,* ***wipe the surfaces with a single use absorbant paper*** *or* ***rinse the surfaces with water (by spray or by dipping)*** *or* ***let the surfaces dry completely by evaporation****, before*

[2] EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2014. Scientific Opinion on the evaluation of the safety and efficacy of peroxyacetic acid solutions for reduction of pathogens on poultry carcasses and meat. EFSA Journal 2014;12(3):3599, 60 pp. doi:10.2903/j.efsa.2014.3599

[3] Council Directive 2011/84/EU of 20 September 2011 amending Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress – Official Journal of The European Union - L 283/36

[4] Arrêté du 19 octobre 2006 relatif à l'emploi d'auxiliaires technologiques dans la fabrication de certaines denrées alimentaires

reusing the surfaces."

To demonstrate the efficacy of post application methods on remaining DBP residues on surfaces, the applicant provided the following study: "*Determination of hydroxyl residues of PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE Com18 after rinsing and/or wiping and/or drying and /or soaking*.". This study was aimed at the determination of residues for PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE COM18 after rinsing and/or wiping and/or drying and/or soaking. A short summary of this study is detailed below and a full description of this study is provided in Annex 3.4.

In this study, hydrogen peroxyde was sprayed at 50 mL/m^2 (representative of highest intended application rate) onto different materials representative of surfaces commonly present in food and feed industries: glass, aluminium and polypropylene. It has to be noted that, in the frame of this dossier, biocidal product is also intended to be applied by fogging but no fogging application was investigated in this study. Nevertheless, this deviation is considered as minor.
Determination of hydroxyl residues, that could be in contact with organic matter or food and so could lead to the possible production of DBP, was performed on treated surfaces after drying, wiping, rinsing and soaking surfaces. No measurement of residue in rinsing water took place in this study.
Post application method efficacies were calculated:
- For drying: lowest efficacy was calculated for glass (99.60 %) and highest efficacy was found for aluminium and Polypropylene (> 99.99%);
- For wiping, efficacy was upper than 99.99% for all kind of tested surfaces;
- For rinsing, lowest efficacy was of 95.70% for aluminium and upper than 99.90% for glass and polypropylene;
- For soaking, lowest efficacy was calculated for aluminium (99.77 %) and highest efficacy was found for glass and Polypropylene (> 99.90%).
As a conclusion, wiping was the most universal and efficient procedure wich resulted in less than 0.01% of residual hydroxyl residues whatever the materials.

The submitted study demonstrates that post application methods are efficient and allow to lower hydroxyl residues on treated surfaces.

Therefore, in the frame of this dossier, post application methods (drying or rinsing or wiping treated surfaces) are necessary to prevent food, feed or drinking water contamination. As a conclusion, after required contact time, wipe treated surfaces or rinse treated surfaces with potable water or let the surfaces dry well, before reusing the surfaces.

List of scenarios

Not relevant.

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s) [2]**
1.	Plant protection product	Hydrogen peroxide (basic substance – approved on 29/03/2017)	No MRLs required (Reg 396/2005)
2.	Veterinary use	Hydrogen peroxide: all food producing species	No MRL required (Reg 37/2010)
3.	Processing aid – National regulation in France	Hydrogen peroxide – directly used on food or in rinsing water for food[3]	Maximum concentration of H_2O_2 in washing solution for salads: 2mM (68 ppm), Remaining level: Technically unavoidable content
4.	Processing aid	Solutions of peroxyacetic acid, acid acetic, hydrogen peroxide and 1-hydroxyethylidene-1,1-diphosphonic acid for reduction of pathogens on poultry carcasses and meat[4]	None
5.	Para-pharmaceutical product	Hydrogen peroxide in oral dental products (Council Directive 2011/84/EU)[5]	Maximum concentration of 0,1 % of hydrogen peroxide present in oral products

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

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

[3] Arrêté du 19 octobre 2006 relatif à l'emploi d'auxiliaires technologiques dans la fabrication de certaines denrées alimentaires

[4] EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2014. Scientific Opinion on the evaluation of the safety and efficacy of peroxyacetic acid solutions for reduction of pathogens on poultry carcasses and meat. EFSA Journal 2014;12(3):3599, 60 pp. doi:10.2903/j.efsa.2014.3599

[5] Council Directive 2011/84/EU of 20 September 2011 amending Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress – Official Journal of The European Union - L 283/36

- **Major change 2022**

The major change does not affects significantly the assessement performed for the dietary exposure. Therefore, the dietary exposure assessment was not reviewed in the framework of this dossier.

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AECshort-term	90 d study in rats	10 mg/m³	8	n.r	1.25 mg/m³
AECmedium-term				n.r	
AEClong-term				n.r	
ARfD	n.a				
ADI					

Risk for industrial users

Not applicable

Risk for professional users

PT2 Hospitals:

Scenarios combined	Tier	AEL mg/m³	Estimated exposure mg/m³	Estimated exposure / AEL (%)	Acceptable (yes/no)
Scenario [1] – Spray application/ wiping of surfaces	Tier 1/No RPE	1.25	1.77	141	No
	Tier 2a/RPE factor 4	1.25	0.44	35	Yes
	Tier 2b/RPE factor 10	1.25	0.18	14	Yes
	Tier 2c/RPE factor 40	1.25	0.04	4	Yes
Scenario [2] – Fogger application	Tier 1/No RPE	1.25	0.196	15.7	Yes

PT2 Medical practices:

Scenarios combined	Tier	AEL mg/m³	Estimated exposure mg/m³	Estimated exposure / AEL (%)	Acceptable (yes/no)
Scenario [1] – Spray application/ wiping of surfaces	Tier 1/No RPE	1.25	4.62	370	No
	Tier 2a/RPE factor 4	1.25	1.16	92	Yes
	Tier 2b/RPE factor 10	1.25	0.46	37	Yes
	Tier 2c/RPE factor 40	1.25	0.12	9	Yes
Scenario [2] – Fogger application	Tier 1/No RPE	1.25	0.196	15.7	Yes

PT2 Hotels and nurseries:

Scenarios combined	Tier	AEL mg/m³	Estimated exposure mg/m³	Estimated exposure / AEL (%)	Acceptable (yes/no)
Scenario [1] – Spray application/ wiping of surfaces	Tier 1/No RPE	1.25	15.69	1255	No
	Tier 2a/RPE factor 4	1.25	3.92	314	No

	Tier 2b/RPE factor 10	1.25	1.57	126	No
	Tier 2c/RPE factor 40	1.25	0.39	31	Yes
Scenario [2] – Fogger application	Tier 1/No RPE	1.25	0.196	15.7	Yes

PT4 Small kitchens:

Scenarios combined	**Tier**	**AEL mg/m³**	**Estimated exposure mg/m³**	**Estimated exposure / AEL (%)**	**Acceptable (yes/no)**
Scenario [1] – Spray application/ wiping of surfaces	Tier 1/No RPE	1.25	6.98	559	No
	Tier 2a/RPE factor 4	1.25	1.75	140	No
	Tier 2b/RPE factor 10	1.25	0.70	56	Yes
	Tier 2c/RPE factor 40	1.25	0.17	14	Yes
Scenario [2] – Fogger application	Tier 1/No RPE	1.25	0.16	12.8	Yes

PT4 Canteens:

Scenarios combined	**Tier**	**AEL mg/m³**	**Estimated exposure mg/m³**	**Estimated exposure / AEL (%)**	**Acceptable (yes/no)**
Scenario [1] – Spray application/ wiping of surfaces	Tier 1/No RPE	1.25	10.18	815	No
	Tier 2a/RPE factor 4	1.25	2.55	204	No
	Tier 2b/RPE factor 10	1.25	1.02	81	Yes
	Tier 2c/RPE factor 40	1.25	0.25	20	Yes
Scenario [2] – Fogger application	Tier 1/No RPE	1.25	0.16	12.8	Yes

PT4 Food processing industry:

Scenarios combined	Tier	AEL mg/m³	Estimated exposure mg/m³	Estimated exposure / AEL (%)	Acceptable (yes/no)
Scenario [1] – Spray application wiping of surfaces	Tier 1/No RPE	1.25	3.42	274	No
	Tier 2a/RPE factor 4	1.25	0.86	68	Yes
	Tier 2b/RPE factor 10	1.25	0.34	27	Yes
	Tier 2c/RPE factor 40	1.25	0.09	7	Yes
Scenario [2] – Application by fogger	Tier 1/No RPE	1.25	0.086	6.9	Yes

Spraying:

For PT2 Hospitals, PT2 Medical practices and PT2 Food Processing Industry, the risk is acceptable during spraying provided a RPE APF 4 is worn.

For PT4 Small kitchens and PT4 Canteens, the risk is acceptable during spraying provided a RPE APF 10 is worn.

For PT2 Hotels and nurseries, the risk is acceptable during spraying provided a RPE APF 40 is worn.

Fogger:

For all claimed uses (PT2 and PT4), the risk is acceptable for professionals considering fogging application via an automatic device.

After fogging application the concentration of active substance in the air must not exceed the AEC (1.25 mg/ m^3) for the re-entry of professional users in the treated room. Therefore, a re-entry period has to be calculated.

Data of scenario [2e] are used.

Tier 1 – Ventilation not activated

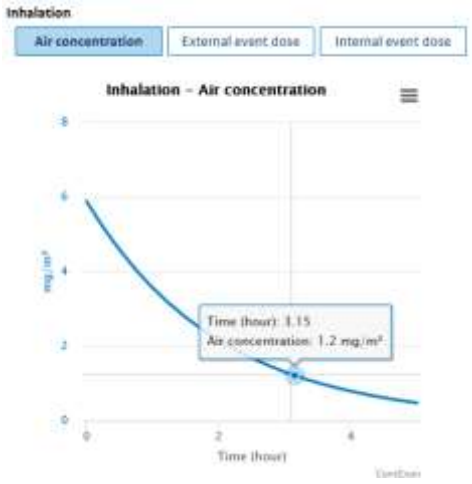


Figure 3: re-entry delay after the product contact time for PT2 and PT4 "kitchens and canteens"

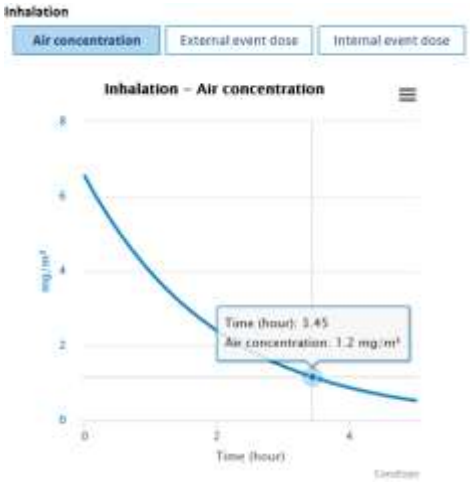


Figure 4: re-entry delay after the product contact time for PT4 "food processing industry"

The concentration of the a.s in the air is below the AEC after around 3.15 hours (equivalent to 3h09) for PT2 and PT4 "kitchens and canteens" and approximately 3.45 hours (equivalent to 3h27) for PT4 "food processing industry" (after the product contact time), leading to an acceptable risk.

Tier 2 – Ventilation re-activated

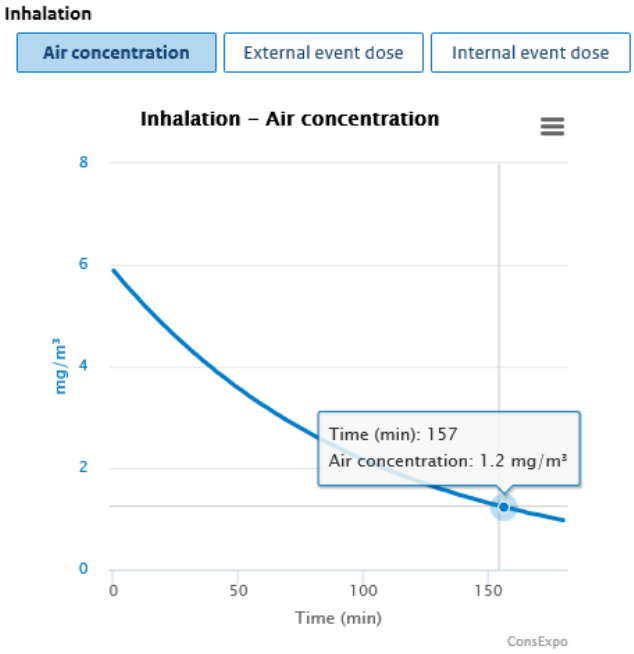


Figure 5: re-entry delay after the product contact time for PT2

Figure 6: re-entry delay after the product contact time for PT4 "kitchens and canteens"

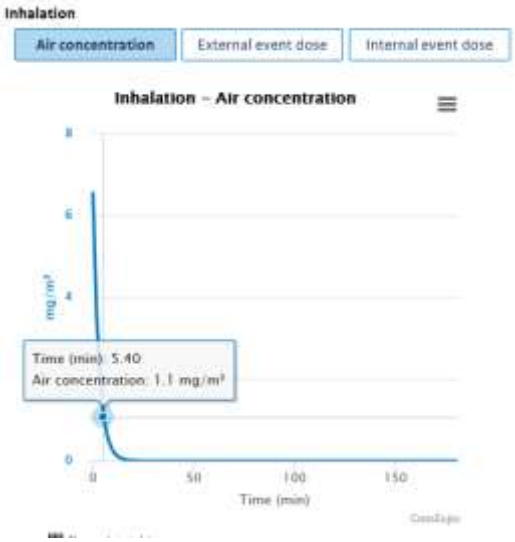


Figure 7: re-entry delay after the product contact time for PT4 "food processing industry"

The concentration of the a.s in the air is below the AEC after around 157 min (2 hours and 37 min) for PT2, 20 min for PT4 "kitchens and canteens" and approximately 6 min for PT4 "food processing industry" (after the product contact time), leading to an acceptable risk provided that the ventilation system can be re-activated without entering the treated room.

Therefore, for fogger application, it is recommended for professionals to enter the room after:

- a minimum of 3h09 for PT2 and PT4 "kitchens and canteens" and 3h30 for PT4 "food processing industry" (after the product contact time) if the ventilation system cannot

be re-activated without entering the treated room;
- a minimum of 2h37 for PT2, 20 min for PT4 "kitchens and canteens" and 6 min for PT4 "food processing industry" (after the product contact time) if the ventilation system can be re-activated without entering the treated room.

Local effects – dermal exposure

As the product is irritant for eyes (Eye Irrit 2 – H319), a local risk assessment according to the guidance on the BPR: Volume III HH part B is performed.

Hazard			Exposure							Risk
Hazard Category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk
Low	Eye Irrit 2	-	2-4	Professional	Spraying downward on surfaces in area without controlled atmosphere	ocular	More than few minutes per day but equal to or less than few hours per day	Low	**RMM Technics:** - Minimisation of splashes and spills (during the loading of the product); - Avoidance of contact with contaminated tools and objects **RMM Organisation:** - Management/supervision in place to check that the RMMs in place are being used correctly	The spray application should be downward in order to avoid any facial exposure. Considering that these recommendations can be followed during these tasks, the risk is acceptable according to RMMs and PPE.

									and OCs followed; - Training for staff on good practice; - Good standard of personal hygiene **PPE** - Eye protection (chemical goggles)	
Low	Eye Irrit 2	-	2 - 4	Professional	Loading of the fogger device for fogger application with an automatic device	ocular	More than few minutes per day but equal to or less than few hours per day	Low	**RMM Technics:** - Minimisation of splashes and spills; - Avoidance of contact with contaminated tools and objects **RMM Organisation:** - Management/supervision in place to check that the RMMs in place	The loading of the fogger device (bottle) must be done slowly in order to avoid any splashes and spills. Considering that these recommendations can be followed during these tasks, the risk is acceptable.

									are being used correctly and OCs followed; - Training for staff on good practice; - Good standard of personal hygiene **PPE** - Eye protection (chemical goggles)	

Conclusion for professional users

For PT2 Hospitals, PT2 Medical practices and PT4 Food Processing Industry, the risk is considered acceptable for professional users during the application of the product by spraying (and during rinsing if this step is required), considering the wear of a respiratory equipment with an APF of 4.

For PT4 Small kitchens and PT4 Canteens, the risk is considered acceptable for professional users during the application of the product by spraying (and during rinsing if this step is required), considering the wear of a respiratory equipment with an APF of 10.

For PT2 Hotels and nurseries, the risk is considered acceptable for professional users during the application of the product by spraying (and during rinsing if this step is required), considering the wear of a respiratory equipment with an APF of 40.

For the fogger application, the risk is considered acceptable for professional considering an automatic device (the operator is not present in the room during the treatment) and a re-entry period of:

- a minimum of 3h09 for PT2 and PT4 "kitchens and canteens" and 3h30 for PT4 "food processing industry" (after the product contact time) if the ventilation system cannot be re-activated without entering the treated room;
- a minimum of 2h37 for PT2, 20 min for PT4 "kitchens and canteens" and 6 min for PT4 "food processing industry" (after the product contact time) if the ventilation system can be re-activated without entering the treated room.

Due to the classification of product, facial exposure to generated aerosols has to be limited by the use of PPE (goggles) and application of technical and organisational RMMs for both application.

Risk for non-professional users

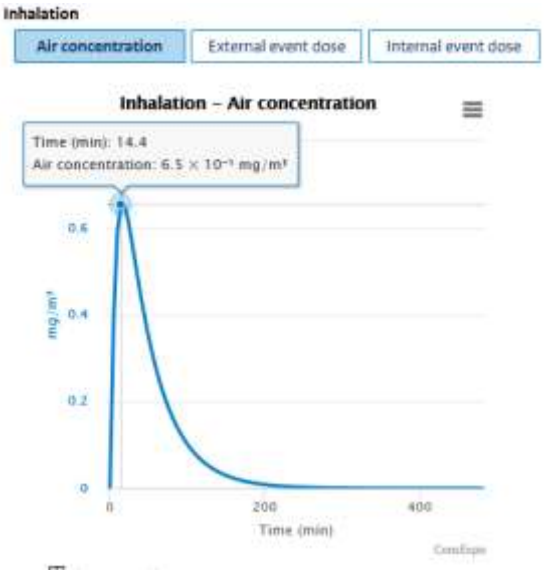
The product is intended for professional uses only.

Risk for the general public

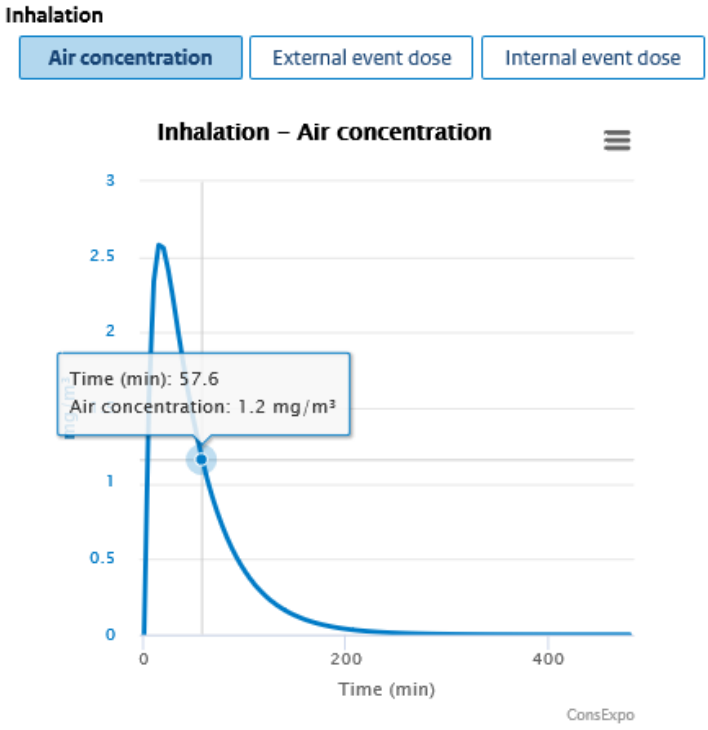
<u>Risk regarding exposure to volatilized residues after spraying application</u>

Considering the data of scenario [3] and graphs presented below (from ConsExpo) representing the evaporation kinetic of the product, it is assumed that, after 58 min for PT2 Medical practices, 125 min for PT2 Hotels and nurseries, 29 min for PT4 Small kitchens, 39 min for PT4 Canteens and 15 min for PT4 Food Processing Industry, after the end of the rinsing step, bystanders can re-entry into the treated rooms. For PT2 Hospitals, because the AEC is never reached, no re-entry period is foreseen.

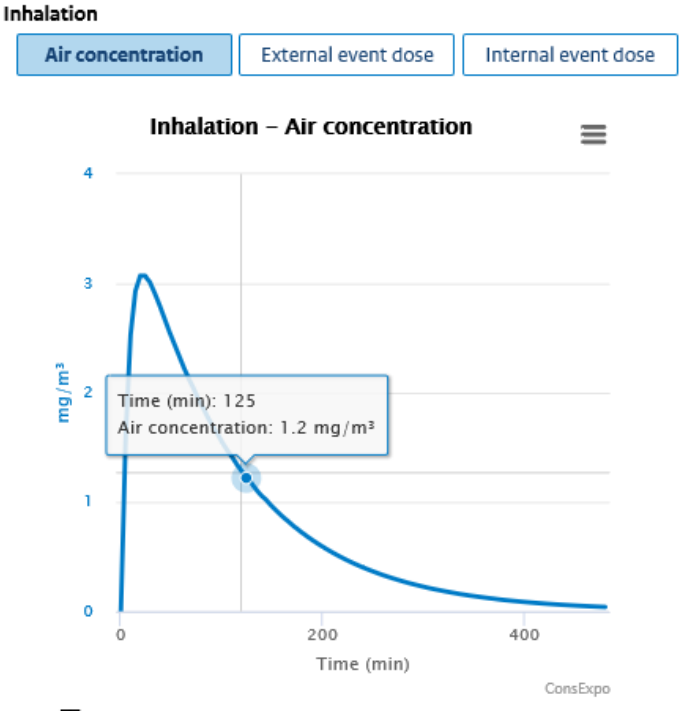
PT2 Hospitals



PT2 Medical practices



PT2 Hotels and nurseries



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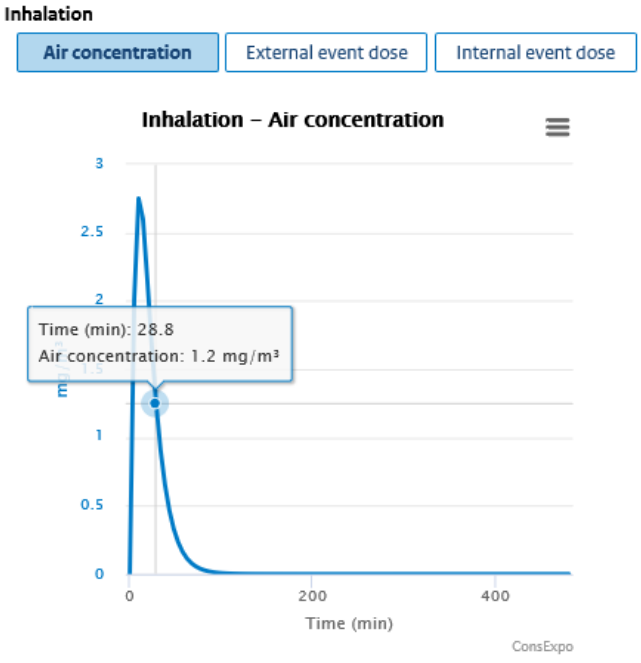
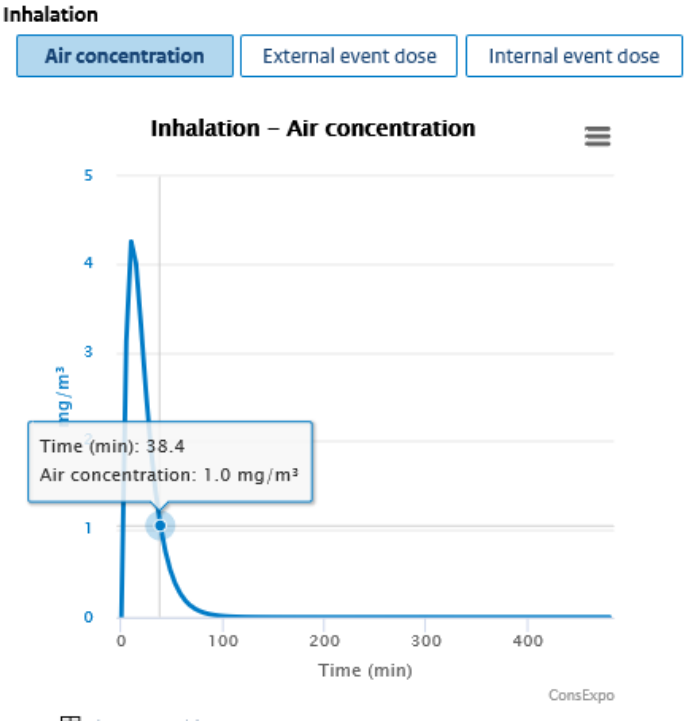
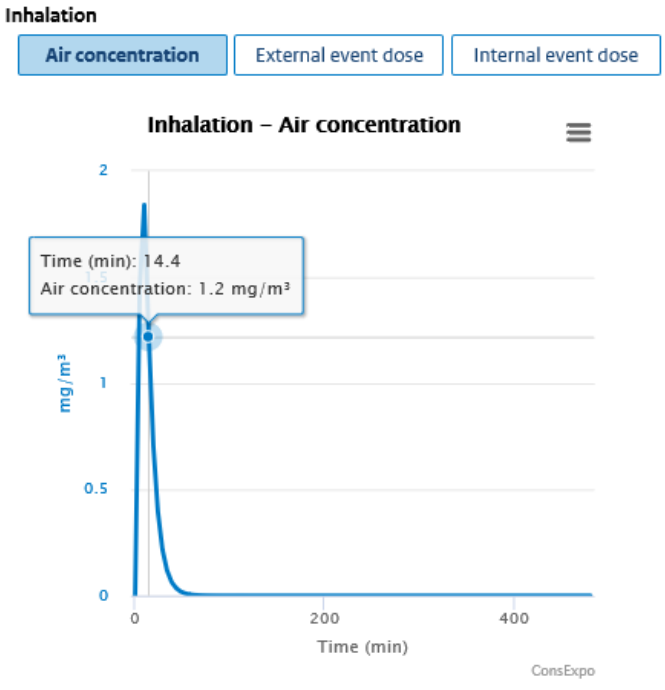
PT4 Small kitchens



PT4 Canteens



PT4 Food Processing Industry



Risk regarding volatilized residues after fogging application

As for professional users, in order not to exceed AEC (1.25 mg/m^3), it is recommended for a bystander to not enter the room after:

- a minimum of 3h09 for PT2 and PT4 "kitchens and canteens" and 3h30 for PT4 "food processing industry" (after the product contact time) if the ventilation system cannot be re-activated without entering the treated room;
- a minimum of 2h37 for PT2, 20 min for PT4 "kitchens and canteens" and 6 min for PT4 "food processing industry" (after the product contact time) if the ventilation system can be re-activated without entering the treated room.

Risk regarding exposure to treated surfaces

Local effects - dermal exposure

Because of the high volatility of the a.s containing in the product, dermal exposure to H_2O_2 applied in the product is considered negligible.

However, H_2O_2 is a highly reactive active substance that will react with organic matter present on the surfaces to be treated leading to the formation of Disinfectant By-Product (DBP).
The number of DBP formed is very high and no identification neither quantification is possible.

The submitted study by the applicant demonstrates that post application methods are efficient and allow to lower hydroxyl residues exposure on treated surfaces.

However, although hydroxyl residues are good markers of DBP synthesis, DBP in this study are not directly measured. Moreover, in absence of validated methodoly to identify, measure and evaluate DBP, they are not taken into account in the risk assessment.

Conclusion for the general public

For fogger application, the risk is considered acceptable for bystanders entering a room with freshly treated surfaces (fogging), provided the re-entry period is respected.

For spray application, the risk is considered acceptable for bystanders entering a room with freshly treated surfaces, provided that the re-entry period after rinsing or wiping is respected.

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

Not applicable

2.2.7 Risk assessment for animal health

Not applicable

2.2.8 Risk assessment for the environment

Infobox 1 – FR CA

Please notice that the risk assessment for the environment (section 2.2.8) is reported as provided by the applicant. The FR CA position is presented in **green evaluation boxes**.

The "PEROXYDE D'HYDROGÈNE SOLUTION 7,4% PRÊTE À L'EMPLOI" is a PT2 and PT4 disinfectant. It is used for the disinfection of surfaces (sanitary, surfaces, equipment, and furniture) in the food industry, medical sector, and institutional buildings (hotels, sport halls). The product is applied either with a trigger spray, or via airbone diffusion (fogging).

The specific uses and applications of "PEROXYDE D'HYDROGÈNE SOLUTION 7,4% PRÊTE À L'EMPLOI" are not covered by the hydrogen peroxide assessment report. A complete risk assessment for the environment was therefore carried out for the product.

- **Major change 2023**

The risk assessment is covered by the first evaluation. Indeed, the changes do not impact the classification nor the previous risk assessment.

2.2.8.1 Effects assessment on the environment

"PEROXYDE D'HYDROGÈNE SOLUTION 7,4% PRÊTE À L'EMPLOI" does not contain any environmental SOCs that would need to be addressed in a risk evaluation for the environment and no relevant metabolites are formed in the environment.

No new environmental studies have been carried out with the product "PEROXYDE D'HYDROGÈNE SOLUTION 7,4% PRÊTE À L'EMPLOI". All data pertaining to the active substance is therefore derived from the hydrogen peroxide assessment report.

Ecotoxicological studies on the active substance were carried out for aquatic organisms and activated sewage sludge. The measured endpoints are summarized in the following table.

Summary table of ecotoxicological studies from the hydrogen peroxide assessment report			
Species	**Time-scale**	**Endpoint**	**Toxicity**
Fish			
Pimephales promelas	96 h, semi-static	Mortality, LC50	*16.4 mg a.s./L*
Invertebrates			
Daphnia pulex (crustaceans)	48 h, semi-static	Immobility, EC50	*2.34 mg a.s./L*
Daphnia magna (crustaceans)	21 d, flow-through	Reproduction, NOEC	*0.63 mg a.s./L*
Algae			
Skeletonema costatum	72 h, static	Growth rate, NOEC	*1.69 mg a.s./L*

(marine diatom)			
Microorganisms			
Activated sewage sludge from sewage treatment plant	0.5 hours and 3 hours, static	Respiration inhibition, EC50	466 mg a.s./l

Corresponding PNEC values for each environmental compartment were calculated with EUSES 2.1.2. and are indicated in the table hereunder. These PNEC values are identical to values presented in assessment report.

Summary table on PNEC values							
PNECSTP	**PNECwater**	**PNECsed**	**PNECseawater**	**PNECseased**	**PNECsoil**	**Trigger value GW**	**PNECair**
[mg/l]	[mg/l]	[mg/kgwwt]	[mg/l]	[mg/kgwwt]	[mg/kgwwt]	[µg/l]	[mg/m^3]
4.66	0.0126	0.0101	0.00126	0.00101	0.0017	0.1	-

Infobox 2 – FR CA

The PNEC values are correct. However, for the PNEC freshwater sediment, no value is set in the CAR of hydrogen peroxide (March, 2015). The following explanation is provided: "*Considering the low n-octanol/water partition coefficient of hydrogen peroxide (log K_{ow} – 1.57), the expected low adsorption to organic matter (QSAR based log K_{OC} 0.2036) and its generally rapid abiotic and biotic degradation in surface waters […], hydrogen peroxide is not expected to partition into the sediment. Because of the lack of exposure, a proposal for a PNEC for sediment-dwelling organisms is not considered necessary. Furthermore, any potential risk to sediment dwelling organisms is considered to be adequately covered by using the PNEC for the water phase.*" Therefore, no risk assessment for the sediment has to be carried out.

Moreover, concerning the marine compartment, it is considered covered by the assessment of the freshwater compartment.

Concerning the PNEC soil, a slightly different value is indicated in the CAR and will be used for the risk assessment (1.84E-3 mg/kg wwt).

For the STP and aquatic compartments, PNEC values were derived from the ecotoxicological endpoints reported in the hydrogen peroxide assessment report.

No ecotoxicological data was generated for sediment dwelling and soil organisms as the physicochemical properties of hydrogen peroxide do not point towards a risk for their corresponding environmental compartments. PNEC values for both these compartments were therefore derived through equilibrium partitioning.

The 0.1 µg/L trigger value for pesticides was applied for the groundwater compartment, as indicated in the Guidance on the BPR. Vol. IV Part B Risk Assessment (2015).

No PNEC value can be derived for the air compartment. However, a typical natural background value for air is available and indicated in the hydrogen peroxide assessment report. Natural background values are also available for surface water and groundwater. This data is useful for a more qualitative assessment of the risk for these compartments.

No data is derived for primary poisoning as product use is not expected to lead to direct exposure of birds and mammals. No secondary poisoning is expected for hydrogen peroxide either. The log Kow is -1.57, indicating that hydrogen peroxide has a negligible potential for bioconcentration in biota. The BCFs for fish and earthworms are 1.4 and 0.84 respectively, indicating that the risk of secondary poisoning for aquatic and terrestrial predators will be negligible. No accumulation of hydrogen peroxide in the food chain is therefore expected.

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

Infobox 3 - FR CA

Classification of the Active Substance Hydrogen peroxide	
Value/conclusion	**Active substance –** Hydrogen peroxide is not classified according to the harmonised classification. Nevertheless, this active substance should be **classified H 412 according to the available data of the CAR.**
Justification for the value/conclusion	**Daphnia was the most sensitive aquatic organism with the lowest lowest chronic ecotoxicity endpoint (21d): NOEC= 0.63 mg/L and the substance is considered as rapidly degradable.**

Classification of the Product PEROXYDE D'HYDROGENE SOLUTION 7.4% PRÊTE A L'EMPLOI	
Value/conclusion	**The product is not classified.**

Further Ecotoxicological studies

Infobox 4 – FR CA

No data is available.

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

Infobox 5 – FR CA

No data is available.

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

Infobox 6 – FR CA

No data is available.

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

Infobox 7 – FR CA

No data is available.

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

Infobox 8 – FR CA

No data is available.

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

Infobox 9 – FR CA

See the foreseeable routes of entry into the environment in the Infobox 11.

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

Infobox 1 – FR CA

No data is available.

Leaching behaviour (ADS)

Infobox 2 – FR CA

No data is available.

Testing for distribution and dissipation in soil (ADS)

Infobox 3 – FR CA

No data is available.

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

Infobox 4 – FR CA

No data is available.

Testing for distribution and dissipation in air (ADS)

Infobox 5 – FR CA

No data is available.

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

Infobox 6 – FR CA

No data is available.

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)

Infobox 7 – FR CA

No data is available.

2.2.8.2 Exposure assessment

The "PEROXYDE D'HYDROGÈNE SOLUTION 7,4% PRÊTE À L'EMPLOI" is a PT 2 and 4 used for the disinfection of surfaces (sanitary, surfaces, equipment, and furniture) in the food industry, medical sector, and institutional buildings (hotels, sport halls).

The product can be applied in two different manners:

- Spray application: Application of the pure product (without dilution) to surfaces. The product is applied as a spray at 30 to 50 ml/m². After application, the product can either be left on the surface (natural drying without rinsing) or removed after required contact time (wiping with single use paper or rinsing with potable water). The spray must be applied at an adequate frequency based on the hygiene plan in place.

- Airborne diffusion (fogger): Application of the pure product (without dilution) to surfaces. The product is diffused with a suitable device, at a rate of 12 ml/m³, in a hermetically closed room (no ventilation) and in the absence of personnel, animals or unwrapped food products. After a product contact time of minimum 2 hours and before re-entry of persons, ventilate the room. Before reuse of the surfaces, the product can either be left (natural drying without rinsing) or removed after required contact time (wiping with single use paper or rinsing with potable water). The product must be applied at an adequate frequency based on the hygiene plan in place.

Four different scenarios were selected to cover the various product uses. The two first scenarios were obtained from the Emission Scenario Document for Product Type 2 (Private and public health area disinfectants and other biocidal products, 2001 and 2011). The third scenario is detailed in the ESD PT4 (Disinfectants used in food and feed areas, 2011). The fouth is an adaptation of the ESD PT4 (Disinfectants used in food and feed areas, 2011) with indications from the TAB 2017.

- Scenario 1 "Medical sector: Disinfection of rooms, furniture and objects" (ESD PT2, 2001, p.17): Disinfectants applied by spraying in the medical sector are assessed via the scenario "Medical sector: Disinfection of rooms, furniture and objects" (ESD PT2, 2001, p.17). This model includes a tonnage-based and an average use based scenario. Worst-case must be selected based on breakeven tonnage. The average use model includes disinfection for general sanitary purposes and disinfection of brushes by dipping. This second application was not considered here as it is not

representative of the actual use.

- Scenario 2 "Disinfection in institutional areas" (ESD PT2, 2011, p.12): Disinfectant application by spraying on general surfaces and on lavatory and bathroom equipment in the institutional buildings (hotels, sport halls) was assessed via the scenario "Disinfection in institutional areas" (ESD PT2, 2011, p.12). This model includes a tonnage-based and an average use scenario. Worstcase must be selected based on break-even tonnage. The average use model includes disinfection of surfaces and lavatory equipment, both applications were included in the assessment.

- Scenario 3 "Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries" (ESD PT4, 2011, p.17): Disinfectant application by spraying in the agro-food industry was assessed via the scenario "Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries" (ESD PT4, 2011, p.17). This average-use based model includes disinfection of "slaughterhouses" and "large scale catering kitchens". Only the last model was used as it corresponds to the small-scale application of the product. However, the model "large scale catering kitchens" is, in itself, an overestimation of the potential use of the product as it considers 2000m² treated per day. This scale of application is unlikely considering the product is an RTU spray. Based on comments in TAB (Technical Agreements for Biocides, p18, question ENV 36), the product is considered a small-scale kitchen application limited to max 200 m² treated per day.

- Scenario 4 "Room disinfection via fogging" (ESD PT4, 2011, p.17 adapted with recommendations from the TAB 2017): Product application with the airborne diffuser takes place in the medical sector, in collectivities, in the agri-food industry and in collective central kitchens. Disinfection in the medical sector is already covered by scenario 1, which considers product consumption per hospital bed. For the three remaining sectors, the volume of rooms disinfected by fogging is based on the data referenced in the TAB 2017:
    - ENV 44: Default volume for industrial premises in PT2 when applying the biocidal product by e.g. vaporizing or fogging : 4000 m³.
    - ENV 54: Default volume for PT4 large kitchens disinfected by fogging: 6000 m³.

  Based on these indications, it can be assumed that a worst case room volume of 6000 m³ will cover disinfection events taking place in collectivities, the agri-food industry and collective central kitchens. Emissions to the environment were therefore estimated by adapting the scenario "Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries" (ESD PT4, 2011, p.17) and integrating a room volume of 6000 m³.

General information

Assessed PT	PT 2 and 4
Assessed scenarios	• Scenario 1 "Medical sector: Disinfection of rooms, furniture and objects" (ESD PT2, 2001, p.17) • Scenario 2 "Disinfection in institutional areas" (ESD PT2, 2011, p.12) • Scenario 3 "Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries" (ESD PT4, 2011, p.17 • Scenario 4 "Room disinfection via fogging" (ESD PT4,

	2011, p.17 adapted with recommendations from the TAB 2017)
ESD(s) used	ESD PT2: Private and public health area disinfectants and other biocidal products, 2001 and 2011 ESD PT4: Disinfectants used in food and feed areas, 2011
Approach	Scenario 1: Average consumption and tonnage based Scenario 2: Average consumption and tonnage based Scenario 3: Average consumption Scenario 4: Average consumption
Distribution in the environment	Estimated according to: • Guidance on the Biocidal Products Regulation, Vol. IV. Env., Part B Risk Assessment (active substances), April 2015. • Assessment report: Hydrogen peroxide, Product types 1-6, March 2015.
Groundwater simulation	No
Confidential Annexes	Tonnage data are confidential
Life cycle steps assessed	Scenario 1: product use Scenario 2: product use Scenario 3: product use Scenario 4: product use
Remarks	-

Infobox 8 – FR CA

We agree with the proposed scenarios.
Please note that no tonnage based scenario was proposed by the applicant. Only a comparison via the break-even point was presented.

Emission estimation

Scenario 1: "Medical sector: Disinfection of rooms, furniture and objects" (ESD PT2, 2001, p.17)

When used in the medial sector, the product is sprayed on surfaces. After contact time, the product is either left in place, wiped off or rinsed off. Ultimately the product will thus be emitted to waste water or solid waste. This last case is out of the scope of the biocide risk assessment. The main release pathway of the product is therefore to waste water, which will be emitted to the sewer system, the STP and ultimately surface water and soil (sludge).

The local emission of hydrogen peroxide to waste water was calculated using the scenario "Medical sector: Disinfection of rooms, furniture and objects" (ESD PT2, 2001, p.17). This model includes a tonnage-based and an average use-based scenario. Worst-case must be selected based on break-even tonnage. This is the value of sales tonnage at which both models give the same result. When the actual sales tonnage is below the break-even point the "use-based" model should be used. Above the break-even tonnage, "tonnage-based" scenario is used. The table here below provided input values for calculating local emission via model "Medical sector: Disinfection of rooms, furniture and objects" (ESD PT2, 2001, p.17)

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: "Medical sector: Disinfection of rooms, furniture and objects" (ESD PT2, 2001, p.17)			
Average use-based model inputs			
Concentration at which active substance is used [C_{san}]	0.074	kg/L	Product specific value
Fractions released to wastewater, sanitary purposes [Q_{water_san}]	0.55	-	Default value
Amount of water with active substance [$F_{san,water}$]	25	L	Default value
Tonnage-based model inputs			
Fraction for the region *[Freg]*	0.1	-	Default value
Fraction for the hospital *[$F_{hospital}$]*	0.007	-	Default value
Fractions released to wastewater *[F_{water}]*	0.75	-	Default value
Number of emission days per year *[$T_{emission}$]*	260	d/y	Default value

Calculations for Scenario 1

Break-even tonnage, with default values

Break-even EU tonnage a.s. = Qwater_san * Csan * Temission * Fsan,water / (10^3 * Fhospital * Fwater) = 50.4 T/year

Break-even EU tonnage product: Break-even EU tonnage a.s. * Csan*1000 = 3730 T/year

The sales tonnage of the product "Peroxyde d'hydrogène solution 7,4% prête à l'emploi" is below the break even tonnage. The use-based model should thus be used.

Local emission based on average use model

Elocal,water = Qwater_san * Csan * Fsan,water = 1.02 kg/day

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	1.02	

Infobox 18 – FR CA

The input parameters and calculations provided for the medical sector are relevant. It is worth noting that the density of the product is close to 1 kg/L (1.024 kg/L). Nevertheless, in order to be conservative enough, the disinfection of objects was also assessed as the intended uses for the medical sector (spray) cover the surfaces but the equipment and furniture as well. The concentration in active substance was adjusted to the technical value: 7.44%.

According to the ESD for PT 2 (2001) the emission rate to waste water ($Elocal_{water}$ in kg/d) may be estimated using:

$Elocal_{water} = Q_{water\_san} \times C_{san} \times Fsan_{water} + Q_{water\_obj} \times C_{obj} \times Fobj_{water}$

Where:

Input parameters for calculating the local emission for scenario 1 (Medical sector)

Input	Value	Unit	Remarks
Scenario 1: "Medical sector: Disinfection of rooms, furniture and objects" (ESD PT2, 2001, p.17)			
Average use-based model inputs			
Concentration at which active substance is used [C_{san}]	0.0744	[-]	Technical concentration and density
Fractions released to wastewater, sanitary purposes [F_{water_san}]	0.55	[-]	Default value
Fractions released to wastewater, brushes [F_{water_obj}]	0.95	[-]	Default value
Amount of water with active substance, sanitary purposes [Q_{water_san}]	25	$L.d^{-1}$	Default value
Amount of water with active substance, brushes [Q_{water_obj}]	25	$L.d^{-1}$	Default value
Local emission ($Elocal_{compartment}$)	2.79	$kg.d^{-1}$	Output

*Default values are taken from ESD for PT 2 (2001)

According to the CAR of hydrogen peroxide only a fraction of 0.024 of the discharged hydrogen peroxide reaches the STP after a residence time in the sewage system of 1 hour and considering a DT_{50} of 11.2 mins in this system according to the CAR. The revised local emission value is summarized in the table below:

Local emission before the release to the STP compartment for scenario 1 (Spray - Medical sector)

Compartment	Elocal [kg/d]
STP	6.70E-02

Scenario 2 "Disinfection in institutional areas" (ESD PT2, 2011, p.12)

When used in the disinfection in institutional areas (hotels, sport halls etc.), the product is sprayed on both surfaces and lavatory equipment; after contact time, the product is either left in place, wiped off or rinsed off. The main release pathway of the product is therefore to waste water as for use in the medical sector.

The local emission of hydrogen peroxide to waste water was calculated using the scenario "Disinfection in institutional areas" (ESD PT2, 2011, p.12). As for the medical sector application, the model includes a tonnage-based and an average use-based scenario. Worst-case must be selected based on break-even tonnage. As the product is used for both general purposes and lavatory, this is taken into account in the average use model. The table here below provided input values for calculating local emission via model "Disinfection in institutional areas" (ESD PT2, 2011, p.12)

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 2: "Disinfection in institutional areas" (ESD PT2, 2011, p.12)			
Average use-based model inputs			
Concentration at which active substance is used [C_{san}]	0.074	kg/L	Product specific value
Number of inhabitants feeding one STP [N_{local}]	10000	-	Default value
Fraction released to wastewater [F_{water}]	1	-	Default value
Consumption per capita, general purpose and lavatory [$Q_{product}$]	0.007	$L.cap^{-1}.d^{-1}$	Default value
Penetration factor of disinfectant [F_{penetr}]	0.5	-	Default value
Tonnage-based model inputs			
Fraction for the region *[Freg]*	0.1	-	Default value
Fraction for the main source (STP) *[$F_{main\ source}$]*	0.002	-	Default value
Fractions released to wastewater *[F_{water}]*	0.75	-	Default value
Number of emission days per year *[$T_{emission}$]*	260	d/y	Default value

Calculations for Scenario 2

Break-even tonnage, with default values
Break-even EU tonnage a.s. = Qwater_san * Csan * Temission * Fsan,water / (10^3 * Fhospital * Fwater) = 337 T/year

Break-even EU tonnage product : Break-even EU tonnage a.s. * Csan*1000 = 24938 T/year

The sales tonnage of the product "Peroxyde d'hydrogène solution 7,4% prête à l'emploi" is below the break-even tonnage. The use-based model should thus be used.

Local emission based on average-use model

Elocal,water = Qwater_san * Csan * Fsan,water = 2.59 kg/day

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	2.59	

Infobox 19 – FR CA

The technical concentration at which active substance is used is 0.0744 kg/L.
Moreover, according to the CAR of hydrogen peroxide only a fraction of 0.024 of the discharged hydrogen peroxide reaches the STP after a residence time in the sewage system of 1 hour and considering a DT_{50} of 11.2 mins in this system according to the CAR. The revised local emission value for the disinfection in institutional areas is summarized in the table below:

Local emission before the release to the STP compartment for scenario 2 (Spray - Institutional areas)	
Substance	**Elocal [kg/d]**
Hydrogen peroxide	6.25E-02

Scenario 3 "Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries" (ESD PT4, 2011, p.17)

When used in the disinfection in agro-food-industry, the product is sprayed on small surfaces potentially in contact with food. After contact time, the product is either left in place, wiped off or rinsed off. The main release pathway of the product is therefore to waste water as for the two other scenarios.

The local emission of hydrogen peroxide to waste water was calculated using the scenario "Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries" (ESD PT4, 2011, p.17). This model only includes an average use scenario. Based on the fact the product is an RTU spray and based on comments in TAB (p18, question ENV 36), the model considers a small-scale kitchen application limited to max 200 m² treated per day. The table here below provided input values for calculating local emission via model "Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries" (ESD PT4, 2011, p.17)

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 3 "Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries" (ESD PT4, 2011, p.17)			
Average use-based model inputs			
Concentration at which active substance is used [C_{san}]	7.4	%	Product specific value
Maximum application rate of product	50	ml/m²	Product specific value
Application rate of the active substance	3.7	g/m²	Intermediate calculation, product specific value
Small scale application in collective catering kitchens [$AREA_{surface}$]	200	m²	Default value
Number of application per day [Nappl]	1	d^{-1}	Default value
Fraction released to waste water [F_{water}]	1	-	Default value

Calculations for Scenario 3

Elocal,water = Qaiappl * AREAsurface * Nappl * Fwater /1000 = 0.74 kg/day

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	0.74	

Infobox 20 – FR CA

According to the ESD PT4, the default surface area of a large scale kitchen is 2000 m². However, this product is used as RTU solution with hand-held trigger spray and thus a treated daily surface area of 2000 m² is very unrealistic. In TAB (2017), ENV 55, a more realistic surface area of 50 m² is proposed for small scale applications.

Therefore:

Input parameters for calculating the local emission for scenario 3 (Large scale catering kitchen – RTU spray - small scale applications)			
Input	**Value**	**Unit**	**Remarks**
Scenario 3 "Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries" - RTU small scale applications			
Average use-based model inputs			
Concentration at which active substance is used [C_{san}]	0.0744	[-]	Technical concentration and density
Maximum application rate of product	50	ml/m²	Product specific value
Application rate of the active substance	3.72	g/m²	Intermediate calculation, product specific value
Small scale application in collective catering kitchens [$AREA_{surface}$]	50	m²	TAB 2017
Number of application per day [Nappl]	1	d^{-1}	Default value
Fraction released to waste water [F_{water}]	1	-	Default value
Local emission ($Elocal_{compartment}$)	1.86E-01	$kg.d^{-1}$	Output

According to the CAR of hydrogen peroxide only a fraction of 0.024 of the discharged hydrogen peroxide reaches the STP after a residence time in the sewage system of 1 hour and considering a DT_{50} of 11.2 mins in this system according to the CAR. The local emission value corresponding to the highest concentration of active substance used is summarized in the table below:

Local emission before the release to the STP compartment for scenario 3 (Large scale catering kitchen – RTU spray - small scale application)		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	4.46E-03	

Considering the claimed areas (collective central kitchen and food and feed production areas), as well as the fact that the product is RTU, the exposure assessment as small scale applications in a large scale kitchens is considered more relevant than in slaughterhouses and butcheries.

Scenario 4 "Room disinfection via fogging" (ESD PT4, 2011, p.17 adapted with recommendations from the TAB 2017)

When applied for the disinfection of rooms by fogging, the product is diffused with a suitable device in a hermetically closed room (no ventilation). After the defined contact time, the product is either left in place, wiped off or rinsed off. The main release pathway of the product is therefore to waste water as for the previous scenarios.

The local emission of hydrogen peroxide to waste water was calculated using the scenario "Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries" (ESD PT4, 2011, p.17) and applying a room volume of 6000 m³ as described in the TAB 2017 (ENV 54). This model only includes an average use scenario. The table here below provided input values for calculating local emission.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 4 "Room disinfection via fogging" (ESD PT4, 2011, p.17 adapted with recommendations from the TAB 2017)			
Average use-based model inputs			
Active ingredient concentration in the biocidal product [C_{ai}]	7.4	%	Product specific value
Application rate of the product [$Q_{product}$]	12	ml/m³	Product specific value
Application rate of the active substance [Qai_{appl}]	0.888	g/m³	Intermediate calculation, product specific value
Application in collective catering kitchens [VOLUME]	6000	m³	TAB 2017
Number of application per day [Nappl]	1	d^{-1}	Default value
Fraction released to waste water [F_{water}]	1	-	Default value

Calculations for Scenario 4

Elocal,water = Qaiappl * VOLUME * Nappl * Fwater /1000 = 5.32 kg/day

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	5.32	

Infobox 9 – FR CA

The calculations have been updated considering the technical concentration of the active substance of 0.0744 kg/L.

Input parameters for calculating the local emission for scenario 4 (Fogging in

large scale kitchen)			
Input	**Value**	**Unit**	**Remarks**
Scenario 4 "Room disinfection via fogging" (ESD PT4, 2011, p.17 adapted with recommendations from the TAB 2017)			
Average use-based model inputs			
Active ingredient concentration in the biocidal product [C_{ai}]	7.44	%	Product specific value – Technical value
Application rate of the product [$Q_{product}$]	12	ml/m^3	Product specific value
Application rate of the active substance [Qai_{appl}]	0.89	g/m^3	Intermediate calculation, product specific value
Application in collective catering kitchens [VOLUME]	6000	m^3	TAB 2017
Number of application per day [Nappl]	1	d^{-1}	Default value
Fraction released to waste water [F_{water}]	1	-	Default value
Local emission ($Elocal_{compartment}$)	5.36	kg.d^{-1}	Output

According to the CAR of hydrogen peroxide, only a fraction of 0.024 of the discharged hydrogen peroxide reaches the STP after a residence time in the sewage system of 1 hour and considering a DT_{50} of 11.2 mins in this system according to the CAR. The revised local emission value is summarized in the table below:

Local emission before the release to the STP compartment for scenario 4 (Fogging in large scale kitchen)		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	1.29E-01	

Considering the volume for large kitchens application by fogging, it is worth noting that the exposure scenario for TP4 cover the claimed use for TP2.

Fate and distribution in exposed environmental compartments

For all three local emission scenarios, the primary receiving compartment is the STP. It is thus possible to select a worst-case scenario for the assessment of fate and distribution in exposed environmental compartments. The worst-case local emission is observed for Scenario 4 "Room disinfection via fogging": 5.32 kg/d

After entering the STP, the active substance will distribute to the different environmental compartments. The fate and distribution of hydrogen peroxide in the exposed environmental compartments was calculated via EUSES 2.1.

Infobox 10 – FR CA

We agree with the proposal of the applicant to select the worst-case scenario corresponding to the scenario 4 "Room disinfection via fogging" for the risk assessment. However, an aggregate risk assessment considering all the intended uses is also proposed.

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	+	+	+	+	++	+	+	+	-
Scenario 2	+	+	+	+	++	+	+	+	-
Scenario 3	+	+	+	+	++	+	+	+	-

Infobox 11 – FR CA

Note that for the scenario 4, the relevant receiving compartments are the same :

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment*	Sea-water**	Seawater sediment**	STP	Air	Soil	Ground-water	Other
Scenario 4	+	+	+	+	++	+	+	+	-

* covered by the assessment of freshwater
** covered by the assessment of the freshwater compartment

Input parameters for calculating the fate and distribution of the active substance in the environment were selected from the hydrogen peroxide assessment report.

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	34.01	g/mol	
Melting point	-0.43	°C	
Boiling point	150.2	°C	
Vapour pressure (at 20°C)	299	Pa	
Water solubility	Miscible with water in all proportions	mg/l	EUSES set to maximum value : 10^5 mg/L
Log Octanol/water partition coefficient	-1.57	Log 10	EUSES set to minimum value : -1
Organic carbon/water partition coefficient (Koc)	0.2036	l/kg	EUSES set to minimum value : 1 l/kg
Henry's Law Constant (at 20°C)	7.5×10^{-4}	$Pa/m^3/mol$	
Biodegradability	Readily biodegradable		
BCF earthworm	0.84	l/kg	
BCF fish	1.4	l/kg	
DT_{50} for biodegradation in STP	2	minutes	

DT_{50} for biodegradation in surface water	5	d (at 12ºC)	
DT_{50} for degradation in soil	12	hr (at 12ºC)	
DT_{50} for photolysis in air	24	hr	
Use or bypass marine STP	Use marine STP		

Infobox 12 – FR CA

The input parameters are correct, however according to the CAR of hydrogen peroxide, the QSAR calculated the log Koc of 0.2036 ml/g and Koc of 1.598 ml/g.

Moreover, the DT50 value of 22.8 hours for degradation in soil at 12°C will be considered according to the CAR of the active substance.

Hydrogen peroxide shows high levels of degradation both in the sewer and in the STP. Data provided in the hydrogen peroxide active substance report Doc IIB indicates a 97.6% reduction in the sewer (based on the publication by Spain J. *et al*, 1989[5]) and a 99.3% removal in the STP by degradation (based on the study by Groenevel A. and de Groot W., 1999[6]).

In view of these high degradation values, it is considered that the marine STP is not bypassed for product use on industrial plants in coastal areas (scenario 3). Indeed, it is unlikely that waste water effluents in the agri food industry will not undergo treatment in an STP. This treatment will occur either in a communal STP or in an on-site STP. In the worst-case event that the STP is indeed bypassed following the release of waste water to the sewer system, hydrogen peroxide will undergo intense degradation in the sewer, as indicated in the study by Spain J. *et al*. When used in coastal areas, hydrogen peroxide will therefore degrade before reaching marine waters. To simplify this risk assessment, and considering the similarity of the degradation values in the STP and in the sewer, it is considered that the industrial effluents are all treated in an STP and the degradation values in the STP are applied accordingly.

In the case of product use in medical or institutional sector (scenarios 1 and 2), it is considered that all waste water is released to the sewer system and will undergo treatment in an STP.

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
Air	1.04×10^{-4}	
Water	0.685	
Sludge	9.03×10^{-3}	
Degraded in STP	99.3	

Infobox 25 – FR CA

According to the CAR of hydrogen peroxide, the distribution in the STP is slightly different for the air and sludge compartment. The values that should be used in the assessment

[5] Spain JC, Milligan JD, Downey DC and Slaughter JK (1989), Excessive bacterial decomposition of H2O2 during enhanced biodegradation. Groundwater 27, 163-167

[6] Groeneveld AHC and de Groot WA (1999), Activated sludge, respiration inhibition test with hydrogen peroxide. Solvay Pharmaceuticals. A.SOL.S.003

are presented in the table below:

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
Air	0.001	
Water	0.685	
Sludge	1.6×10^{-2}	
Degraded in STP	99.3	

Hydrogen peroxide shows rapid biodegradation in sewage sludge with a DT50 of 2 minutes (at 20°C). The main fraction of active substance is therefore degraded in the STP (99.3% degraded in STP). Because of hydrogen peroxide's physico-chemical properties, only negligible amounts of the active substance will evaporate to air or partition to solid phases. The 0.7% of active substance remaining in the STP after degradation will therefore mainly fraction to the water phase, and distribute in the aquatic compartments.

The PEC values resulting from the active substance distribution in the environment are indicated in the following table. PEC values related to primary and secondary poisoning are not reported as risk is negligible (please refer to section 1.3. Risk characterisation).

Calculated PEC values

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/m³]	[mg/l]	[mg/kg$_{wwt}$]	[mg/l]	[mg/kg$_{wwt}$]	[mg/m³]	[µg/l]	[mg/m³]
Scenario 4	0.0182	1.82×10^{-3}	1.47×10^{-3}	1.82×10^{-4}	1.47×10^{-4}	2.13×10^{-5}	2.63×10^{-2}	1.55×10^{-9}

Infobox 13 – FR CA

The revised PEC values are summarized in the following table:

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}***	**PEC_{soil}**	**PEC_{GW}**
	[mg/l]	[mg/l]	[mg/kg$_{wwt}$]	[mg/kg$_{wwt}$]	[µg/l]
Scenario 4	4.40E-04	4.40E-05	Not relevant	3.85E-05	1.93E-03

* covered by the assessment of freshwater

In order to cover the aggregate risk assessment, the emissions from all the intended uses were also summed up (0.26 kg/d) and the PEC values from this total emission were derived as follows:

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}***	**PEC_{soil}**	**PEC_{GW}**
	[mg/l]	[mg/l]	[mg/kg$_{wwt}$]	[mg/kg$_{wwt}$]	[µg/l]
Aggregate emissions	8.99E-04	8.99E-05	Not relevant	7.82E-05	3.93E-03

(scenario 1 to 4)					

Primary and secondary poisoning

Infobox 14 - FR CA

Hydrogen peroxide has a log Kow <3 (with a Log Kow= -1.57) and a BCF <100 (BCF fish=1.4; BCF earthworm = 0.84). Thus, these values indicate a negligible potential for bioconcentration in biota and no accumulation of substance in the food chain is expected. The secondary poisoning assessment is not relevant for this substance.

2.2.8.3 Risk characterisation

Summary table on calculated PEC/PNEC values						
	STP	**Water**	**Sediment**	**Seawater**	**Marine sediment**	**Soil**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]
Scenario 4	3.91 x 10^{-3}	0.145	0.145	0.145	0.145	0.0125

Infobox 15 – FR CA

The revised PEC/PNEC values are presented in the following table :

Summary table on calculated PEC/PNEC values				
	STP	**Water***	**Soil**	**PEC_{GW}**
Scenario 4	9.45E-05	3.49E-03	2.08E-02	1.93E-03
Aggregate emissions (scenario 1 to 4)	1.93E-05	7.13E-03	4.25E-02	3.93E-03

* covering the risk for freshwater sediment and the marine compartment

The risk assessment is acceptable for the worst case scenario (scenario 4: fogging application in large scale canteen) and for the aggregate emissions from all the scenarios (1 to 4) for all the compartments.

Atmosphere

The PEC for air was calculated to be 1.55 x 10^{-9} mg/m³ in worst case scenario. No PNEC value exists for the air compartment, however natural background concentrations are available for hydrogen peroxide.

The hydrogen peroxide assessment report indicates that typical natural background concentrations for air are 0.14-1.4 µg/m3 (0.1-1 ppb), maximum 10 µg/m3 (7 ppb). The PECair calculated for the product uses is negligible compared to these background values. No unacceptable risk for the air compartment is therefore expected following the use of the product.

Aquatic compartment and sewage treatment plant (STP)

For the aquatic compartments including STP, all PEC/PNEC ratios are below the trigger value of 1. No unacceptable risk is to be expected for these compartments.

Terrestrial compartment

For the terrestrial compartment, the PEC/PNEC ratio is below the trigger value of 1. No unacceptable risk is to be expected for this compartment.

Groundwater

No unacceptable risk is identified for the groundwater compartment as the calculated PEC_{GW} of 2.63 x 10^{-2} µg/L is below the EU trigger value of 0.1 µg/L. Furthermore, typical natural background concentrations of hydrogen peroxide in groundwater are 0.7 µg/L, maximum 2.3 µg/L.

Primary and secondary poisoning

Primary poisoning

Primary poisoning is not likely to occur as the product is intended for an indoor use. No direct exposure of birds or mammals is therefore expected.

Secondary poisoning

No secondary poisoning is expected for hydrogen peroxide. The log Kow is -1.57, indicating that hydrogen peroxide has a negligible potential for bioconcentration in biota. The BCFs for fish and earthworms are 1.4 and 0.84 respectively, indicating that the risk of secondary poisoning for aquatic and terrestrial predators will be negligible. No accumulation of hydrogen peroxide in the food chain is therefore expected.

Infobox 29– FR CA

We agree with the conclusion of the primary and secondary poisoning.

Aggregated exposure (combined for relevant emission sources)

As indicated in the hydrogen peroxide assessment report, an aggregated risk assessment is not relevant for this substance due to its high reactivity.

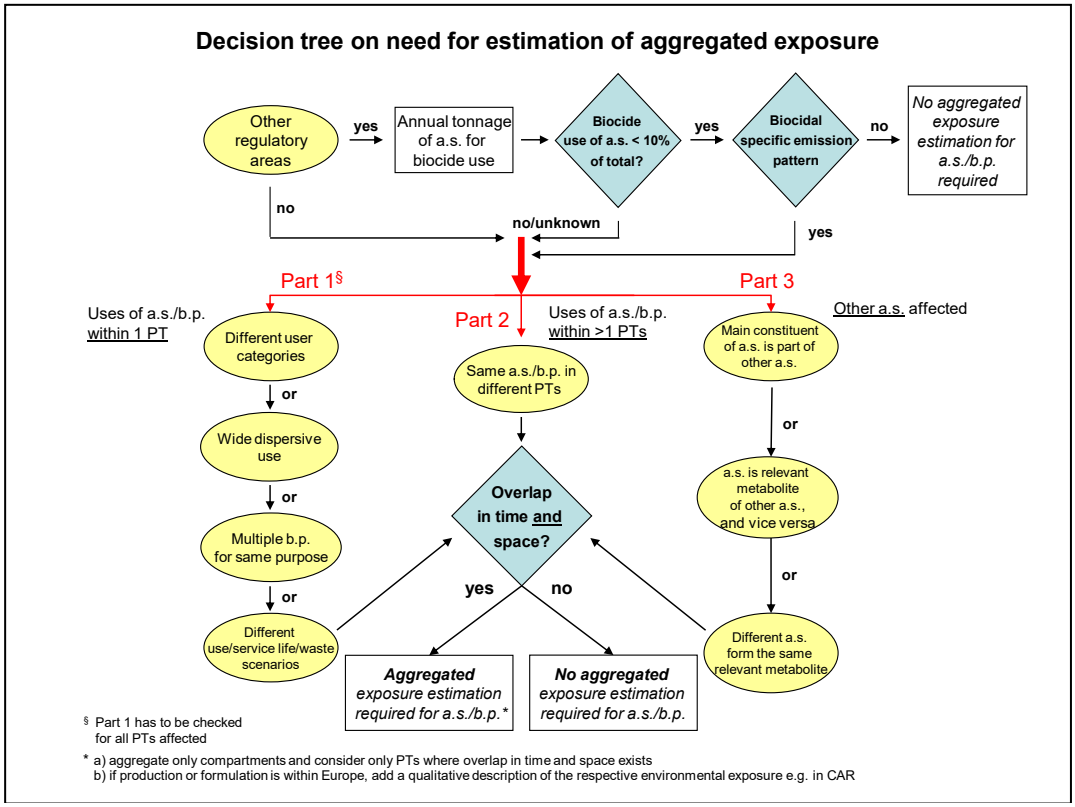


Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product
Based on this risk assessment and on available data, no unacceptable risk to the environment has been identified for the product "PEROXYDE D'HYDROGÈNE SOLUTION 7,4% PRÊT À L'EMPLOI", when applied according to the intended uses

Infobox 16 – FR CA

We agree with the overall conclusion on the risk assessment for the environment of the product.

2.2.9 Comparative assessment

Not relevant

3 ANNEXES

3.1 List of studies for the biocidal product

Section No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published	Data protection (Yes/No)	Owner
Sections 3, 4 and 5	[redacted]	[redacted]	FINAL REPORT Stability of "PEROXYDE D'HYDROGENE SOLUTION 7,4% PRÊTE A L'EMPLOI" over accelerated storage and shelf life determination Part 1: Physical-chemical properties upon receipt and after accelerated storage conditions. PHYTOSAFE s.a.r.l [redacted] GLP ; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 3	[redacted]	[redacted]	Discharge rate and spray pattern for 'Peroxyde d'hydrogene solution 7,4% PAE' as filled sprayers over a 24-month storage period at room temperature – Interim report. PHYTOSAFE s.a.r.l [redacted] GLP ; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 4	[redacted]	[redacted]	METAL CORROSION TEST FOR THE PRODUCT PEROXYDE D'HYDROGENE SOLUTION 7,4% PAE (CAS N° 7722-84-1) Merieux Nutrisciences [redacted] Non-GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 5	[redacted]	[redacted]	Validation of analytical methods for the determination of hydroxyl radicals formed from hydrogen peroxide in water, and peroxyl radicals formed from peroxoacids in water – Application to the determination of residues in water for hydrogen peroxide and/or peroxoacid containing biocidal products – Part 1: Determination of hydroxyl radicals formed from hydrogen peroxide in water. PHYTOSAFE s.a.r.l [redacted] GLP ; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Test d'efficacité bactéricide selon la norme NF EN 1276 (mars 2010) PEROXYDE D'HYDROGENE SOLUTION 7,4% PAE LMH Microbiology Expert [redacted]1 Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides

Section No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published	Data protection (Yes/No)	Owner
Section 6	[redacted]	[redacted]	Test d'efficacité bactéricide selon la norme NF EN 13697 LMH Microbiology Expert [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE - Evaluation of bactericidal activity on non-porous surfaces with mechanical action according to UNI EN16615:2015 [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE - Evaluation of bactericidal activity against Legionella according to UNI EN 13623:2010 [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Test d'efficacité fongicide selon la norme NF EN 1650 + A1 (juillet 2013), PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE LMH Microbiology Expert [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Test d'efficacité fongicide selon la norme NF EN 13697 (juin 2015) PEROXYDE D'HYDROGENE SOLUTION 7,4% PAE LMH Microbiology Expert [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE - Evaluation of yeaticidal activity on non-porous surfaces with mechanical action according to UNI EN 16615:2015 [redacted]0 Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE - Evaluation of fungicidal activity on non-porous surfaces with mechanical action [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides

Section No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published	Data protection (Yes/No)	Owner
Section 6	[redacted]	[redacted]	PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE - Evaluation of sporicidal activity according to UNI EN 13704:2005 [redacted]2 Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Test d'efficacité sporicide - Essai quantitatif de surface non poreuse - Protocole adapté aux spores de Bacillus subtilis, Bacillus cereus et Clostridium sporogenes [redacted]1 Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Test d'efficacité sporicide - Essai quantitatif de surface non poreuse - Protocole adapté aux spores de Bacillus cereus [redacted]1 Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE - Evaluation of tuberculocidal activity according to UNI EN 14348:2005 [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE - Evaluation of tuberculocidal activity for instrument disinfection according to UNI EN 14563:2009 [redacted]6 Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Test d'efficacité bactéricide sleon la norme NF EN 13697(juin2015) - PEROXYDE D'HYDROGEN [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Peroxyde d'hydrogène solution 7.4% PAE - Evaluation of bactericidal activity according to UNI EN 13697:2015 [redacted]2 Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE - Evaluation of fungicidal activity according to UNI EN 13697:2015 [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides

Section No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published	Data protection (Yes/No)	Owner
Section 6	[redacted]	[redacted]	Determination of virucidal, bactericidal, fungicidal and yeasticidal activity of airborne-based surface cleaning and disinfection process [redacted] / O2SAFE 7.4 [redacted]A) - according to NF T72-281 (2014) [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Validation of the bactericidal and sporicidal effectiveness of the commercially available biocide formula provided by Quaron (Peroxyde d'hydrogène solution 7.4% PAE) used for the airborne decontamination of surfaces. [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Evaluation de l'efficacité desodorisante du peroxyde d'hydrogène solution 7.4% PAE par analyses olfactometriques et sensorielles [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 8	[redacted]	[redacted]	Determination of hydroxyl residues of 'Peroxyde d'hydrogene solution 7,4% PAE Com18 after rinsing and/or wiping and/or drying and/or soaking PHYTOSAFE s.a.r.l [redacted] Non GLP ; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 8	[redacted]	[redacted]	Evaluation de l'efficacité d'un produit désinfectant et de sa cinétique de disparition ODOURNET [redacted] Non GLP ; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
	[redacted]	[redacted]	Determination of hydroxyl residues of 'Peroxyde d'hydrogene solution 7,4% PAE Com18 after rinsing and/or wiping and/or drying and/or soaking PHYTOSAFE s.a.r.l [redacted] Non GLP ; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides

- **Post-authorisation 2020**

Section 3	[redacted]	[redacted]	Final Report Discharge rate and spray pattern for 'Peroxyde d'hydrogene solution 7,4% PAE' as filled sprayers over a 24-month storage period at room temperature PHYTOSAFE s.a.r.l [redacted] GLP ; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 3	[redacted]	[redacted]	Final Report Stability of "Peroxyde d'hydrogene solution 7,4% PAE" over accelerated storage and shelf-life determination Part 2: Shelf-life determination PHYTOSAFE s.a.r.l [redacted] GLP ; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides

- **Major change application - 2023**

Section 4.16	[redacted]	[redacted]	Test methods for corrosion to metals on ARVO XY PE UN Method C.1 [redacted] Non GLP; Unpublished.	Yes	Stockmeier
Section 4.16	[redacted]	[redacted]	Test methods for corrosion to metals on ARVO XY PE UN Method C.1 [redacted] Non GLP; Unpublished.	Yes	Stockmeier
Section 6	[redacted]	[redacted]	Evaluation of the bactericidal activity according to an adaptation of NF EN 16437+A1 : 2019 standard. [redacted]3 Non GLP; Unpublished.	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Evaluation of the bactericidal activity according to the NF EN 13697 + A1 : 2019 standard (Legionella). [redacted]1 Non GLP; Unpublished.	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Evaluation of the bactericidal activity according to the NF EN 1276 : 2019 standard (Legionella). [redacted] Non GLP; Unpublished.	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Evaluation of the yeasticidal activity according to an adaptation of NF EN 16437+A1 : 2019 standard. [redacted]3 NON GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Evaluation of the virucidal efficacy according to EN 14476. [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides

Section 6	[redacted]	[redacted]	Evaluation of the virucidal efficacy according to EN 14476. [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Evaluation of the virucidal efficacy according to EN 14476. [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Evaluation of the virucidal efficacy according to EN 14476. [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Evaluation of the virucidal efficacy according to EN 14476. [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Evaluation of the virucidal efficacy according to EN 14476. [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Evaluation of the virucidal efficacy according to EN 14476. [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Test of virucidal activity of the product PEROXYDE D'HYDROGÈNE SOLUTION 7,4% PAE on Vaccinia virus Ankara with 10 minutes of contact time in clean conditions (0.3g/L of BSA) according to NF EN 14476 + A2 (2019) standard. [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Test of virucidal activity of the product PEROXYDE D’HYDROGENE SOLUTION 7,4% PAE against Human Coronavirus HCoV-229E with 15 minutes of contact time in clean condition (0.3g/L of BSA) according to NF EN 14476 + A2 (2019) standard. [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Evaluation of the virucidal efficacy according to EN 16777. N°RE-1284/0620. Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides

Section 6	[redacted]	2018	Determination of virucidal and mycobactericidal activity of airborne-based surface cleaning and disinfection process PHILEAS75 / O2SAFE 7.4 (DEVEA) _according to NF T72-281 (2014). N°R-DSVADEV003 Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	2018	Determination of virucidal, bactericidal, fungicidal and yeasticidal activity of airborne-based surface cleaning and disinfection process PHILEAS75 / O2SAFE 7.4 (DEVEA) _according to NF T72-281 (2014). N°R-DSVADEV002_3 Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	2021	Détermination des activités bactéricides, virucides, fongicide, levuricide, mycobactéricides et sporicide du processus automatisé de désinfection des surfaces par voie aérienne [redacted] INDAL OXY DVA selon le protocole de la norme NF EN 17272 (2020). R2112DSVADEP005-1 Non GLP; Unpublished	Yes	Quaron
Section 6	[redacted]	2023	Determination of virucidal activity of the airborne room disinfection automated process [redacted] / PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE according to the standard NF EN 17272 (2020). R2304GFB1053DSVA-01-V2 Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	2023	Determination of mycobactericidal activity of the airborne room disinfection automated process [redacted] / PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE according to the standard NF EN 17272 (2020). R2304GFB1053DSVA-02-V1 Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides

Section 6	[redacted]	[redacted]	Determination of virucidal activity of product PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE against Human Adenovirus Type 5 with a contact time of 60 minutes at 20°C with 0.3 g/L BSA according to the standard NF EN 14476+A2 (2019). [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Determination of virucidal activity of product PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE against Bovine Enterovirus Type 1 with a contact time of 60 minutes at 20°C in clean conditions with 0.3 g/L BSA according to the standard NF EN 16777 (2018). [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Determination of virucidal activity of product PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE against Human Influenza H1N1 with a contact time of 30 minutes at 20°C in clean conditions with 0.3 g/L BSA according to the standard NF EN 16777 (2018). [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Determination of virucidal activity of product PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE against Vaccinia Virus with a contact time of 30 minutes at 20°C in clean conditions with 0.3 g/L BSA according to the standard NF EN 16777 (2018). [redacted]1 Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]	Determination of virucidal activity of product PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE against Human Coronavirus 229E with a contact time of 30 minutes at 20°C in clean conditions with 0.3 g/L BSA according to the standard NF EN 16777 (2018). [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides

Section 6	[redacted]	[redacted]	Determination of virucidal activity of product PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE against Pseudorabies Virus with a contact time of 60 minutes at 20°C in clean conditions with 0.3 g/L BSA according to the standard NF EN 16777 (2018). [redacted] Non GLP; Unpublished	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides
Section 6	[redacted]	[redacted]3	DETERMINATION OF YEASTICIDAL ACTIVITY OF THE PEROXYDE D'HYDROGENE 7.4% PAE PRODUCT ACCORDING TO THE EN 13624 STANDARD [redacted]	Yes	Commission 18 du GIE Groupement des Formulateurs de Biocides

3.2 Output tables from exposure assessment tools

Spraying PT2 Hospitals.xlsx

Spraying PT2 Medical practices.xls

Spraying PT2 Hotels and nurseries.xlsx

Spraying PT4 Small kitchens.xlsx

Spraying PT4 Canteens.xlsx

Spraying PT4 Food Processing Industry.

Fogger PT 2.xlsx

Fogger PT4 Kitchens and Cantee

Fogger PT4 Food Processing Industry.

3.3 New information on the active substance

Not relevant

3.4 Residue behaviour

To demonstrate the efficacy of post application methods on remaining DBP residues on surfaces, the applicant provided the following study : *"Determination of hydroxyl residues of PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE Com18 after rinsing and/or wiping and/or drying and /or soaking*.". This study was aimed at the determination of residues for PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE COM18 after rinsing and/or wiping and/or drying and/or soaking.
In this study, the test item was sprayed at 50 mL/m^2 (representative of highest intended application rate) onto different materials representative of surfaces commonly present in food and feed industries: glass, aluminium and polypropylene.
Determination of hydroxyl residues was performed on treated surfaces after drying, wiping, rinsing and soaking surfaces.

1- <u>Protocol:</u>

Before application, small objects of known dimensions (inserts) were placed onto glass plates and were used for further determination of residual hydrogen peroxide. Three materials were selected as representative of the variability of the surfaces on which the

product ”PEROXYDE D’HYDROGEN SOLUTION 7.4% PAE” can be applied (glass for mineral surfaces, aluminium for metals (Al), polypropylene (PP) for plastic polymers). Aluminium was chosen in order to present results on a metallic surface, even if it is clear that aluminium is less inert than other surfaces usually used in agri-food industries (i.e. stainless steel). But due to material difficulties, it was not possible to use standardized stainless steel inserts in the laboratory. After placing inserts on plates, the test item was evenly sprayed onto 20x20 cm glass plates. Application rate of test item was of 50 mL/m^2, corresponding to 3700 mg H_2O_2/m^2. The aplication rate was predicted to be checked by weighing for the different tested post application method. Nevertheless, due to unknown technical reasons verification of the tretment application was only done for drying protocol.
Conditions of post application method performed in the study are detailed below:
- for drying: inserts were withdrawn after spraying and allowed to stand for 24 hours at room temperature (20±3°C) and hydrometry (50%±10%), without forced ventilation. At the end of drying period, inserts were analysed for residue determination.
- for wiping: inserts were withdrawn after spraying and immediatly wiped by sliding twice an absorbent paper onto the surface. The remaining residues were then collected each with 1.5mL of water and analysed;
- for rinsing: after spraying, inserts were kept in place and the glass plate was sprayed at 200 mL/m^2 with demineralised water. Inserts and the glass plate were dismantled and placed vertically for 10 min so as to allow draining of the deposit. At the end of the draining period, one insert were selected at random for hydroxyl residues analysis. For other rinsing, remaining inserts were placed back onto the glass and rinsed once again by spraying 200 mL/m^2 of deminelarised water. The same procedure was applied for draining and an other insert was selected for residues determination.
- for soaking, inserts were withdrawn after spraying and dipped into water for 10-15 seconds. Three distinct volumes of water were used: 10, 40 and 100 mL. After dipping, inserts were placed vertically to allow draining of the deposit. At the end of draining period, inserts were analysed for residue determination.

2- **Results:**

a- Drying protocol:

The verification of the treatment applications showed that 3700 mg H_2O_2/m^2 was achieved by spraying whatever the material and the replicate. Measured concentrations ranged between 87-119% of the nominal value.

Measured concentrations for hydrogen peroxide residue after drying are presented in table below.

Table: Measured hydrogen peroxide residue (mg/m²) directly after spraying and after drying and drying efficacy

Residue results - drying		Glass 1	Glass 2	Glass 3	Al 1	Al 2
After product application	Control 1 (mg H_2O_2/m^2)	3724	3659	3991	4111	4215
	Control 2 (mg H_2O_2/m^2)	3287	4157	4218	4352	4062
	Mean (mg H_2O_2/m^2**)**	**3506**	**3908**	**4105**	**4232**	**4139**
After drying	Insert 1(mg H_2O_2/m^2)	18.89	7.61	3.96	0.33	0.31
	Insert 2(mg H_2O_2/m^2)	12.88	3.57	3.92	0.36	0.24
	Insert 3(mg H_2O_2/m^2)	3.81	3.74	4.36	0.39	0.22
	Insert 4(mg H_2O_2/m^2)	20.78	5.09	2.69	0.37	0.35
	Mean insert (mg H_2O_2/m^2**)**	**14.09**	**5.00**	**3.73**	**0.36**	**0.28**
	Median insert (mg H_2O_2/m^2**)**	**15.89**	**4.42**	**3.94**	**0.37**	**0.28**
Drying efficacy on residues	**Mean efficacy**	**99.60**	**99.87**	**99.91**	**>99.99**	**>99.99**
	Median efficacy	**99.55**	**99.89**	**99.90**	**>99.99**	**>99.99**

b- Wiping protocol:

No verification of the treatment applications took place because of unknown technical reasons. Therefore, for calculation, residues of 3700 mg H_2O_2/m^2 after application was considered.

Measured concentrations for hydrogen peroxide residue after drying are presented in table below.

Table: Measured hydrogen peroxide residue (mg/m²) directly after wiping and wiping efficacy

Residue results - Wiping		Glass 1	Glass 2	Glass 3	Al 1	Al 2	Al 3	
After product application	**Mean (**mg H_2O_2/m^2**)**	No control - technical re						
After wiping	Insert 1(mg H_2O_2/m^2)	0.24	0.13	0.12	0.10	0.17	0.16	
	Insert 2(mg H_2O_2/m^2)	0.20	0.10	0.16	0.18	0.14	0.12	
	Insert 3(mg H_2O_2/m^2)	0.04	0.13	0.19	0.26	0.19	0.14	
	Insert 4(mg H_2O_2/m^2)	0.15	0.10	0.27	0.16	0.16	0.20	
	Mean insert (mg H_2O_2/m^2**)**	0.16	0.12	0.19	0.18	0.17	0.16	
	Median insert (mg H_2O_2/m^2**)**	0.18	0.12	0.18	0.17	0.17	0.15	
Wiping efficacy	**Mean efficacy**	**>99.99**	**>99.99**	**>99.99**	**>99.99**	**>99.99**	**>99.99**	

on residues	**Median efficacy**	**>99.99**	**>99.99**	**>99.99**	**>99.99**	**>99.99**	**>99.99**	

c- Rinsing protocol:

No verification of the treatment applications took place because of unknown technical reasons. Therefore, for calculation, residues of 3700 mg H_2O_2/m^2 after application was considered.

Measured concentrations for hydrogen peroxide residue after rinsing are presented in table below.

Table: Measured hydrogen peroxide residue (mg/m^2) on glass directly after rinsing and rinsing efficacy on glass

Residue results - Rinsing		**Glass 1**	**Glass 2**	**Glass 3**	**Mean glass rinsing**	**M**
After product application	**Means (mg H_2O_2/m^2)**	No control - technic				
After rinsing	**Rinsing 1 (mg H_2O_2/m^2)**	564.46	545.25	343.91	484.54	5
	Rinsing 2 (mg H_2O_2/m^2)	175.53	179.66	196.68	183.96	1
	Rinsing 3 (mg H_2O_2/m^2)	4.68	4.56	8.29	5.84	
	Rinsing 4 (mg H_2O_2/m^2)	2.84	3.40	4.47	3.57	

Table: Measured hydrogen peroxide residue (mg/m^2) on aluminium directly after rinsing and rinsing efficacy on aluminium

Residue results - Rinsing		**Aluminium 1**	**Aluminium 2**	**Aluminium 3**	**Mean glass rinsing**	**M**
After product application	**Means (mg H_2O_2/m^2)**	No control - technica				
After rinsing	**Rinsing 1 (mg H_2O_2/m^2)**	1098.60	2030.70	768.40	1299.20	10
	Rinsing 2 (mg H_2O_2/m^2)	182.50	697.48	749.88	543.30	6

	Rinsing 3 (mg H_2O_2/m^2)	478.30	165.10	507.74	383.70	4
	Rinsing 4 (mg H_2O_2/m^2)	232.19	156.32	87.06	158.50	1

Table: Measured hydrogen peroxide residue (mg/m^2) on polypropylene directly after rinsing and rinsing efficacy on polypropylene

Residue results - Rinsing		**Polypropylene 1**	**Polypropylen 2**	**Polypropylene 3**	**M gl rin**
After product application	**Means (mg H_2O_2/m^2)**	No control - technical reasons			
After rinsing	**Rinsing 1 (mg H_2O_2/m^2)**	66.43	60.80	55.64	6
	Rinsing 2 (mg H_2O_2/m^2)	7.88	8.29	6.99	7
	Rinsing 3 (mg H_2O_2/m^2)	5.52	5.26	4.25	5
	Rinsing 4 (mg H_2O_2/m^2)	5.35	2.17	0.60	2

d- Soaking protocol:

No verification of the treatment applications took place because of unknown technical reasons. Therefore, for calculation, residues of 3700 mg H_2O_2/m^2 after application was considered.
Measured concentrations for hydrogen peroxide residue after soaking are presented in table below.

Table: Measured hydrogen peroxide residue (mg/m^2) directly after soaking and soaking efficacy

Residue results - soaking		**Glass 1**	**Glass 2**	**Glass 3**	**Al 1**	**Al 2**	**Al 3**	
After product application	**Control 1 (mg H_2O_2/m^2)**	No control - technical r						
	Control 2 (mg H_2O_2/m^2)							
	Mean (mg H_2O_2/m^2)							
After soaking	**Insert 1(mg H_2O_2/m^2)**	6.03	1.24	0.40	10.35	4.09	4.25	
	Insert 2(mg H_2O_2/m^2)	2.19	1.94	0.49	6.42	8.49	3.91	
	Mean insert (mg H_2O_2/m^2)	4.11	1.59	0.45	8.39	6.29	4.08	
Soaking efficacy	**Mean efficacy**	**99.89**	**99.96**	**99.99**	**99.77**	**99.83**	**99.89**	

3- <u>Conclusion</u>

This study was aimed at demonstrating post application methods efficacy intended in the frame of this dossier. In this study, hydroxyl residues for PEROXYDE D'HYDROGENE SOLUTION 7.4% PAE COM18 after rinsing and/or wiping and/or drying and/or soaking were measured. Through hydroxyl residues determination, it can be estimated potential DBP quantity on treated surfaces.

Post application method efficacies were calculated:
- For drying: lowest efficacy was calculated for glass (99.60 %) and highest efficacy was found for aluminium and Polypropylene (> 99.99%);
- For wiping: efficacy was upper than 99.99% for all kind of tested surfaces;
- For rinsing: lowest efficacy was of 95.72% for aluminium and upper than 99.90% for glass and polypropylene;
- For soaking: lowest efficacy was calculated for aluminium (99.77 %) and highest efficacy was found for glass and Polypropylene (> 99.90%).

Wiping was the most universal and efficient procedure wich resulted in less than 0.01% of residual hydroxyl residues whatever the materials.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[7]

See IUCLID

3.6 Confidential annex

See confidential annex in an annex document.

3.7 Other

Not relevant

7 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.