

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

ARVO XY PE

Product type(s)

PT02: Disinfectants and algaecides not intended for direct application to humans or animals

PT04: Food and feed area

Authorisation number: FR-2019-0071

R4BP asset number: FR-0016875-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	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 EQO PEROXY EQO XY DES SPRAY EQO XY DESINF EQO XY SURFACE H2O2-DESINF H2O2-DSVA H2O2-PAE H2O2-SPRAY H2O2-SURFACE PEROXY DVA PEROXY SPRAY PEROXY SURFACE SANITOXOXY SURFACE WPB-7
---------------	--

1.2. Authorisation holder

Name and address of the authorisation holder	Name	STOCKMEIER FRANCE SAS
	Address	3 rue de la Buhotière 35091 RENNES France
Authorisation number	FR-2019-0071	
<i>R4BP asset number</i>	FR-0016875-0000	
Date of the authorisation	26/07/2024	
Expiry date of the authorisation	05/06/2029	

1.3. Manufacturer(s) of the product

Name of manufacturer	STOCKMEIER FRANCE SAS
Address of manufacturer	3 rue de la Buhotière - Saint-Jacques de la Lande BP 8 9152 35091 Rennes CEDEX 9 France
Location of manufacturing sites	STOCKMEIER FRANCE SAS site 1 3 rue de la Buhotière - Saint-Jacques de la Lande BP 89152 35136 RENNES France STOCKMEIER FRANCE SAS site 2 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	STOCKMEIER CHEMIE EILENBURG site 1 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	STOCKMEIER CHEMIE GMBH & CO. KG site 1 AM STADTHOLZ 37 33609 BIELEFELD Germany

1.4. Manufacturer(s) of the active substance(s)

Active substance	Peroxyde d'hydrogène
Name of manufacturer	SOLVAY CHEMICALS INTERNATIONAL SA
Address of manufacturer	Rue de Ransbeek 310 1120 Bruxelles Belgium
Location of manufacturing sites	<p>SOLVAY CHEMICALS INTERNATIONAL SA site 1 Solvay Interox Limited, Baronet Road, Solvay House WA4 6HA Warrington, Cheshire United Kingdom of Great Britain and Northern Ireland (the)</p> <p>SOLVAY CHEMICALS INTERNATIONAL SA site 2 Solvay Chemicals Finland Oy, YRJONOJANTIE 2 45910 VOIKKAA Finland</p> <p>SOLVAY CHEMICALS INTERNATIONAL SA site 3 Solvay Chemicals GmbH Germany, KOETHENSCHER STRASSE 13, 06406 BERNBURG Germany</p> <p>SOLVAY CHEMICALS INTERNATIONAL SA site 5 Solvay Chimica Italia SpA Italy, VIA PIAVE, 6 57013 ROSIGNANO SOLVAY LI Italy</p> <p>SOLVAY CHEMICALS INTERNATIONAL SA site 6 Solvay Chemie SA Belgium, RUE SOLVAY, 39 5190 Jemeppe-sur-Sambre Belgium</p> <p>SOLVAY CHEMICALS INTERNATIONAL SA site 7 Solvay Chemie SA Belgium, SCHELDELAAN 600, HAVEN 725 2040 ANTWERPEN Belgium</p> <p>SOLVAY CHEMICALS INTERNATIONAL SA site 8 Solvay Interox Produtos Peroxidados SA, RUA ENG. CLEMENT DUMOULIN 2625106 POVOA DE SANTA IRIA Portugal</p>

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Peroxyde d'hydrogène		active substance	7722-84-1	231-765-0	7,44 % (w/w)

2.2. Type(s) of formulation

AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H319: Causes serious eye irritation.
Precautionary statements	<p>P264: Wash hands thoroughly after handling.</p> <p>P280: Wear protective gloves/protective clothing/eye protection/face protection.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P337+P313: If eye irritation persists: Get medical advice.</p> <p>P337+P313: If eye irritation persists: Get medical attention.</p> <p>P501: Dispose of contents to be in accordance with local/regional/national/international regulations.</p> <p>P501: Dispose of container to be in accordance with local/regional/national/international regulations.</p>

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Spray disinfectant, PT2

Product type	PT02: 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 sanitariums, bathrooms, etc.								
Target organism(s) (including development stage)	<p>Scientific name: Bacteria Common name: Bacteria Development stage: no data</p> <p>Scientific name: Bacterial spores Common name: Bacterial spores Development stage: no data</p> <p>Scientific name: Yeasts Common name: Yeasts Development stage: no data</p> <p>Scientific name: Fungi Common name: Fungi Development stage: no data</p> <p>Scientific name: Tuberculosis bacilli Common name: Tuberculosis bacilli Development stage: no data</p> <p>Scientific name: Virus Common name: Virus Development stage: no data</p>								
Field(s) of use	<p>indoor use</p> <p>Medical sector and institutions (no food contact)</p>								
Application method(s)	<p>Method: spraying</p> <p>Detailed description: Surface spraying</p>								
Application rate(s) and frequency	<p>Application rate: % (v/v)</p> <p>Dilution (%): 0 Dilution (%): Ready for use</p> <p>Number and timing of application: Ready for use (100 % v/v)</p> <p>Hard surfaces:</p> <table border="1" data-bbox="678 1899 1388 2040"> <thead> <tr> <th>Target organism(s)</th> <th>Healthcare area</th> <th>Institutions area</th> </tr> </thead> <tbody> <tr> <td>Bacteria, yeast</td> <td>Clean conditions, 15 min contact time</td> <td>Dirty conditions, 15 min contact time</td> </tr> </tbody> </table>			Target organism(s)	Healthcare area	Institutions area	Bacteria, yeast	Clean conditions, 15 min contact time	Dirty conditions, 15 min contact time
Target organism(s)	Healthcare area	Institutions area							
Bacteria, yeast	Clean conditions, 15 min contact time	Dirty conditions, 15 min contact time							

	Fungi	Clean conditions, 15 min contact time	Dirty conditions, 15 min contact time
	Bacterial spores, tuberculosis bacilli, virus	Clean conditions, 60 min contact time	Clean conditions, 60 min contact time
	Soft surfaces		
	Target organism(s)	Healthcare area	Institutions area
	Bacteria, yeast	Clean conditions, 15 min contact time	Clean conditions, 15 min contact time
	Room temperature Application rate: max 50 ml/m ²		
Category(ies) of users	professional		
Pack sizes and packaging material	<ul style="list-style-type: none"> • 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 • 5L PE pouch (smart bag) • 220L barrels and 1000L IBC HDPE with filling kit 		

4.1.1. Use-specific instructions

- 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 rinsing 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 rinsing 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.

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 $1.25 \text{ mg} / \text{m}^3$ 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 $1.25 \text{ mg} / \text{m}^3$ by using an H_2O_2 detector before allowing re-entry in the room.

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

-

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

-

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

-

4.2. Use description

Table 2. Spray disinfectant, PT4

Product type	PT04: 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(s) (including development stage)	<p>Scientific name: Bacteria Common name: Bacteria Development stage: no data</p> <p>Scientific name: Bacterial spores Common name: Bacterial spores Development stage: no data</p> <p>Scientific name: Yeasts Common name: Yeasts Development stage: no data</p> <p>Scientific name: Fungi Common name: Fungi Development stage: no data</p> <p>Scientific name: virus Common name: Virus Development stage: no data</p>														
Field(s) of use	<p>indoor use</p> <p>Professional use in agro-food industry and collective central kitchens (food contact)</p>														
Application method(s)	<p>Method: spraying</p> <p>Detailed description: Surface spraying</p>														
Application rate(s) and frequency	<p>Application rate: max 50 ml/m²</p> <p>Dilution (%): 0 Dilution (%): Ready to use</p> <p>Number and timing of application: Ready for use (100 % v/v)</p> <table border="1" data-bbox="678 1646 1388 2038"> <thead> <tr> <th>Target organism(s)</th> <th>Hard surfaces</th> <th>Soft surfaces</th> </tr> </thead> <tbody> <tr> <td>Bacteria, yeast</td> <td>Dirty conditions, 15 min contact time</td> <td>Clean conditions, 15 min contact time</td> </tr> <tr> <td>Fungi</td> <td>Dirty conditions, 15 min contact time</td> <td>/</td> </tr> <tr> <td>Bacterial spores, virus</td> <td>Clean conditions, 60 min contact time</td> <td>/</td> </tr> </tbody> </table>			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 spores, virus	Clean conditions, 60 min contact time	/
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 spores, virus	Clean conditions, 60 min contact time	/													

	Room temperature Application rate: max 50 ml/m ²
Category(ies) of users	professional
Pack sizes and packaging material	<ul style="list-style-type: none"> • 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 • 5L PE pouch (smart bag) • 220L barrels and 1000L IBC HDPE with filling kit

4.2.1. Use-specific instructions

- 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.

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/ m³ by using an H₂O₂ 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/ m³ by using an H₂O₂ 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/ m³ by using an H₂O₂ detector before allowing re-entry in the room.

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

-

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

-

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

-

4.3. Use description

Table 3. Fogger disinfectant, PT2

Product type	PT02: Disinfectants and algacides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Airborne diffusion
Target organism(s) (including development stage)	<p>Scientific name: Bacteria Common name: Bacteria Development stage: no data</p> <p>Scientific name: Bacterial spores Common name: Bacterial spores Development stage: no data</p> <p>Scientific name: Yeasts Common name: Yeasts Development stage: no data</p> <p>Scientific name: Fungi Common name: Fungi Development stage: no data</p>

	<p>Scientific name: Mycobacteria Common name: Mycobacteria Development stage: no data</p> <p>Scientific name: Virus Common name: Virus Development stage: no data</p>															
Field(s) of use	<p>indoor use</p> <p>Healthcare and institutions areas</p>															
Application method(s)	<p>Method: fogging - Airborne diffusion</p> <p>Detailed description:</p>															
Application rate(s) and frequency	<p>Application rate: 12 mL/m³</p> <p>Dilution (%): 0</p> <p>Number and timing of application:</p> <p>• 12 mL of product /m³ in combination with a fogger equipment with the following characteristics:</p> <p>Cold nebulisation Range of median droplet diameters: 5-10 µm Room volume between 30 and 150 m³</p> <table border="1"> <thead> <tr> <th>Target organism(s)</th> <th>Healthcare area</th> <th>Institutions area</th> </tr> </thead> <tbody> <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> </tbody> </table> <p>Room temperature Humidity: 50-75%</p> <p>• 6.5 mL of product /m³ in combination with a fogger equipment with the following characteristics:</p> <p>Cold nebulisation Range of median droplet diameters: 5-10 µm Room volume between 4 and 150 m³ Contact time: 3H for bacteria, bacterial spores, yeasts, fungi, mycobacteria and virus Room temperature</p>	Target organism(s)	Healthcare area	Institutions area	Bacteria, yeasts	Clean conditions Contact time 2H	Dirty conditions Contact time 2H	Fungi	Clean conditions Contact time 2H	Dirty conditions Contact time 2H	Bacterial spores, virus	Clean conditions Contact time 3H	Dirty conditions Contact time 3H	Mycobacteria, virus	Clean conditions Contact time 4H	Clean conditions Contact time 4H
Target organism(s)	Healthcare area	Institutions area														
Bacteria, yeasts	Clean conditions Contact time 2H	Dirty conditions Contact time 2H														
Fungi	Clean conditions Contact time 2H	Dirty conditions Contact time 2H														
Bacterial spores, virus	Clean conditions Contact time 3H	Dirty conditions Contact time 3H														
Mycobacteria, virus	Clean conditions Contact time 4H	Clean conditions Contact time 4H														

	Humidity: 50-75 % Clean conditions
Category(ies) of users	professional
Pack sizes and packaging material	<ul style="list-style-type: none"> • 1L Opaque bottle with nebulization equipment • 2L, 5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment • 5L PE pouch (smart bag) • 220L barrels and 1000L IBC HDPE with filling kit

4.3.1. Use-specific instructions

- 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 rinsing step with drinking water before application of the product in this area.
- For the application rate of 6.5 ml/m³, clean carefully the surfaces before application of the product followed by a rinsing 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/m³ (contact time 3H; clean conditions), the product has been tested against additional virucidal strain Human Coronavirus.
- At the application rate of 12 ml/m³ (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/m³ (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/m³ (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/m³ 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.

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.

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

-

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

-

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

-

4.4. Use description

Table 4. Fogger disinfectant, PT4

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	Room disinfection
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: no data Scientific name: Bacterial spores Common name: Bacterial spores Development stage: no data Scientific name: Yeasts Common name: Yeasts Development stage: no data Scientific name: Fungi Common name: Fungi Development stage: no data Scientific name: Mycobacteria Common name: Mycobacteria Development stage: no data Scientific name: Virus

	Common name: Virus Development stage: no data										
Field(s) of use	indoor use Professional use in agro-food industry and collective central kitchens (food contact)										
Application method(s)	Method: fogging Detailed description: Airbone diffusion										
Application rate(s) and frequency	<p>Application rate: 12 ml/m³</p> <p>Dilution (%): 0</p> <p>Number and timing of application:</p> <p>• 12 ml of product /m³ in combination with a fogger equipment with the following characteristics:</p> <p>Cold nebulisation Range median droplet size: 5-10 µm Room volume between 30 and 150 m³</p> <table border="1"> <thead> <tr> <th>Target organism(s)</th> <th>Conditions of use</th> </tr> </thead> <tbody> <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> </tbody> </table> <p>Room temperature Humidity: 50-75%</p> <p>• 6.5 mL of product /m³ in combination with a fogger equipment with the following characteristics:</p> <p>Cold nebulisation Range of median droplet size: 5-10 µm Room volume between 4 and 150 m³ Contact time: 3h for bacteria, bacterial spores, yeasts, fungi, mycobacteria and virus Room temperature Humidity: 50-75% Clean conditions</p>	Target organism(s)	Conditions of use	Bacteria, yeasts	Dirty conditions Contact time 2H	Fungi	Dirty conditions Contact time 2H	Bacterial spores, virus	Dirty conditions Contact time 3H	Mycobacteria and virus	Clean conditions Contact time 4H
Target organism(s)	Conditions of use										
Bacteria, yeasts	Dirty conditions Contact time 2H										
Fungi	Dirty conditions Contact time 2H										
Bacterial spores, virus	Dirty conditions Contact time 3H										
Mycobacteria and virus	Clean conditions Contact time 4H										

Category(ies) of users	professional
Pack sizes and packaging material	<ul style="list-style-type: none"> • 1L Opaque bottle with nebulization equipment • 2L, 5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment • 5L PE pouch (smart bag) • 220L barrels and 1000L IBC HDPE with filling kit

4.4.1. Use-specific instructions

- For the application rate of 6.5 ml/m³, clean carefully the surfaces before application of the product followed by a rinsing 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/m³ (contact time 3H;clean conditions), the product has been tested against against additional virucidal strain Human Coronavirus.
- At the application rate of 12 ml/m³ (contact time 3H;dirty conditions), the product has been tested against against additional virucidal strain ECBO.
- At the application rate of 12 ml/m³ (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/m³ (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/m³ 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.

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.

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

-

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

-

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

-

5. GENERAL DIRECTIONS FOR USE¹

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.

5.2. Risk mitigation measures

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.

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.

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.

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

6. OTHER INFORMATION

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