

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

OXTERIL® 350 SPRAY S-EU-en

Product type(s)

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

PT04: Food and feed area

Authorisation number: 1-1

R4BP asset number: EU-0028964-0002

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1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	OXTERIL® 350 SPRAY S DES O HR
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Evonik Operations GmbH
	Address	Rellinghauser Straße 1-11 45128 Essen Germany
Authorisation number		1-1
<i>R4BP asset number</i>		EU-0028964-0002
Date of the authorisation		08/11/2023
Expiry date of the authorisation		31/10/2033

1.3. Manufacturer(s) of the product

Name of manufacturer	Evonik Antwerpen NV
Address of manufacturer	Tijsmanstunnel West 2040 Antwerpen Belgium
Location of manufacturing sites	Evonik Antwerpen NV Tijsmanstunnel West 2040 Antwerpen Belgium

Name of manufacturer	Evonik Operations GmbH
Address of manufacturer	Rellinghauser Straße 1-11 45128 Essen Germany
Location of manufacturing sites	Evonik Operations GmbH Untere Kanalstr. 3 79618 Rheinfelden Germany

Name of manufacturer	Evonik Peroxid GmbH
Address of manufacturer	Industriestraße 1 9721 Weißenstein Austria
Location of manufacturing sites	Evonik Peroxid GmbH Industriestraße 1 9721 Weißenstein Austria

Name of manufacturer	Evonik Peroxide Netherlands BV
Address of manufacturer	Hettenheuwelweg 37 /39 1101 BM Amsterdam Netherlands (the)
Location of manufacturing sites	Evonik Peroxide Netherlands BV Oosterhorn 14 9936 HD Farmsum Netherlands (the)

Name of manufacturer	Breustedt Chemie BV
Address of manufacturer	IJsseldijk 28 7325 WZ Apeldoorn Netherlands (the)
Location of manufacturing sites	Breustedt Chemie BV

	IJsseldijk 28 7325 WZ Apeldoorn Netherlands (the)
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Name of manufacturer	Evonik Peroxide Spain, S.L.U.
Address of manufacturer	C/ Afueras s/n. 50784 La Zaida Spain
Location of manufacturing sites	Evonik Peroxide Spain, S.L.U. C/ Afueras s/n. 50784 La Zaida Spain

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

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Antwerpen NV
Address of manufacturer	Tijsmanstunnel West 2040 Antwerpen Belgium
Location of manufacturing sites	Evonik Antwerpen NV Tijsmanstunnel West 2040 Antwerpen Belgium

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Operations GmbH
Address of manufacturer	Rellinghauser Straße 1-11 45128 Essen Germany
Location of manufacturing sites	Evonik Operations GmbH Untere Kanalstr. 3 79618 Rheinfeldern Germany

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Peroxid GmbH
Address of manufacturer	Industriestraße 1 9721 Weißenstein Austria
Location of manufacturing sites	Evonik Peroxid GmbH Industriestraße 1 9721 Weißenstein Austria

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Peroxide Netherlands BV
Address of manufacturer	Hettenheuwelweg 37 /39 1101 BM Amsterdam Netherlands (the)
Location of manufacturing sites	Evonik Peroxide Netherlands BV Oosterhorn 14 9936 HD Farmsum Netherlands (the)

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Peroxide Spain, S.L.U.
Address of manufacturer	C/ Afueras s/n. 50784 La Zaida Spain
Location of manufacturing sites	Evonik Peroxide Spain, S.L.U. C/ Afueras s/n. 50784 La Zaida Spain

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 (%)
Hydrogen peroxide		active substance	7722-84-1	231-765-0	35

2.2. Type(s) of formulation

SL Soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	<p>H302: Harmful if swallowed.</p> <p>H315: Causes skin irritation.</p> <p>H318: Causes serious eye damage.</p> <p>H335: May cause respiratory irritation.</p> <p>H412: Harmful to aquatic life with long lasting effects.</p> <p>H272: May intensify fire; oxidiser.</p>
Precautionary statements	<p>P261: Avoid breathing vapours.</p> <p>P264: Wash hands thoroughly after handling.</p> <p>P270: Do not eat, drink or smoke when using this product.</p> <p>P271: Use only outdoors or in a well-ventilated area.</p> <p>P273: Avoid release to the environment.</p> <p>P280: Wear protective gloves / eye protection / face protection..</p> <p>P301+P312: IF SWALLOWED: Call a POISON CENTER / doctor / physician if you feel unwell.</p> <p>P330: Rinse mouth.</p> <p>P302+P352: IF ON SKIN: Wash with plenty of water/ soap.</p> <p>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P312: Call a POISON CENTER/ doctor/physician if you feel unwell.</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>P310: Immediately call a POISON CENTER / doctor.</p> <p>P332+P313: If skin irritation occurs: Get medical advice.</p> <p>P403+P233: Store in a well-ventilated place. Keep container tightly closed.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents to / in accordance with local requirements.</p> <p>P501: Dispose of container to / in accordance with local requirements.</p>

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P220: Keep away from clothing or other combustible materials.

P370+P378: In case of fire: Use water to extinguish.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Surface disinfection by vaporised hydrogen peroxide (VHP) process

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: bacteria Development stage: - Common name: yeasts Development stage: -
Field(s) of use	indoor use Disinfection of dry surfaces and equipment in hospital rooms, laboratories and other enclosed spaces, which do not come in contact with food and feed.
Application method(s)	Method: Vaporisation Detailed description: Automated disinfection with Vaporised Hydrogen Peroxide, generated with the aid of a VHP generator. Main specifications of a VHP generator: Diffusion principle: vaporisation, disinfection with gaseous hydrogen peroxide. Room Volume: 30 - 150 m ³ . Product concentration: 3120 mg/m ³ . Relative humidity: 40 - 80%. Temperature: room temperature.
Application rate(s) and frequency	Application Rate: The ready to use product should be applied in a hydrogen peroxide concentration of 1092 mg/m ³ (780 ppm) by the VHP generator. Dilution (%): not applicable Number and timing of application: Contact time: at least 4 hours Frequency: daily /if required Maximum 3 times per day
Category(ies) of users	professional
Pack sizes and packaging material	High density polyethylene (HDPE) bottle 1, 5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1000 litres HDPE ISO tank 20m ³

4.1.1. Use-specific instructions for use

The area to disinfect is prepared for decontamination by removing standing liquid and by wiping down any visible dirt. Clean the area before disinfection. Cupboard doors should be opened, surfaces should be dried and wet areas (such as sinks) should be disinfected with suitable alternative products.

Specially trained professionals replace the cap of the sealed packaging with a special cap that has a degassing valve and a fast connector. The fast connector is connected to a pipe that connects to the VHP generator. Seal the enclosed space or room and make sure that access to the vapour-treated area is denied during the whole procedure.

Room volume ranging from 30 m³ to 150 m³.

Diffusion speed can vary from 1,5 to 20 g product /minute.

Starting temperature of 20°C, ± 2°C.

Relative humidity between 40 and 80 %.

During the disinfection cycle the VHP generator adjusts the hydrogen peroxide concentration up to the effective levels of 1092 mg/m³ (780 ppm) and keeps it at this level for at least 4 hours. Concentration of hydrogen peroxide is monitored during the disinfection. After disinfection the aeration of the sealed area is required to reduce the concentration of hydrogen peroxide below 1,25 mg/m³ or a lower relevant national reference value before entering the area. This step can be quick but can also last several hours resulting in a total decontamination cycle of 5 - 8 hours.

The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable 'standard room', if applicable) with the devices to be used, after which a protocol for disinfection of these rooms can be made and used thereafter. In the event that there are methods available for chemically monitoring the active substance in the air or on surfaces, chemical validation should be performed besides biological validation, for example with test strips or with a device that measures ppm hydrogen peroxide in the air.

When it concerns a 'standard room' for which a protocol is available, the validation may be limited to only a chemical validation.

4.1.2. Use-specific risk mitigation measures

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal products, chemical resistant gloves classified under European Standard EN 374 or equivalent, face shield and Respiratory Protective Equipment (RPE) (Assigned Protection Factor (APF) = 10) during mixing and loading. Gloves and coverall material to be specified by the authorisation holder within the product information. See section 6 for the full titles of the EN standards.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC .

No access to the treated area is permitted during treatment. During aeration and before permitting re-entry to the treated area it should be checked that the concentration of hydrogen peroxide is below 1,25 mg/m³ or a lower relevant national reference value, using for example test strips. During the operation of the VHP generator or in the event of malfunctions, entry to the room is only possible if wearing chemical protective suits and RPE (APF=10), when the concentration of hydrogen peroxide is at or below 12,5 mg/m³. Observe label instructions.

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

No use specific first aid instructions and emergency measures to protect the environment. See General directions for use.

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

No use specific instructions for safe disposal of the product and its packaging. See General directions for use.

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

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See General directions for use.

4.2. Use description

Table 2. Surface disinfection by vaporised hydrogen peroxide (VHP) process

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: bacteria Development stage: - Common name: yeasts

	Development stage: -
Field(s) of use	indoor use Disinfection of dry surfaces in food and feed areas and other enclosed spaces.
Application method(s)	Method: Vaporisation Detailed description: Automated disinfection with Vaporised Hydrogen Peroxide, generated with the aid of a VHP generator. Main specifications of a VHP generator: Diffusion principle: vaporisation, disinfection with gaseous hydrogen peroxide. Room Volume 30 - 150 m ³ . Product concentration: 3120 mg/m ³ . Relative humidity: 40 - 80%. Temperature: room temperature.
Application rate(s) and frequency	Application Rate: The ready to use product should be applied in a hydrogen peroxide concentration of 1092 mg/m ³ (780 ppm) by the VHP generator Number and timing of application: Contact time: at least 4 hours Frequency: daily /if required Maximum 3 times per day
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1, 5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1000 litres HDPE ISO tank 20m ³

4.2.1. Use-specific instructions for use

The area to disinfect is prepared for decontamination by removing standing liquid and by wiping down any visible dirt. Clean the area before disinfection. Cupboard doors should be opened, surfaces should be dried and wet areas (such as sinks) should be disinfected with suitable alternative products.

Specially trained professionals replace the cap of the sealed packaging with a special cap that has a degassing valve and a fast connector. The fast connector is connected to a pipe that connects to the VHP generator. Seal the enclosed space or room and make sure that access to the vapour-treated area is denied during the whole procedure.

Room volume ranging from 30 m³ to 150 m³.

Diffusion speed can vary from 1,5 to 20 g product /minute.

Starting temperature of 20°C, ± 2°C.

Relative humidity between 40 and 80 %.

During the disinfection cycle the VHP generator adjusts the hydrogen peroxide concentration up to the effective levels of 1092 mg/m³ (780 ppm) and keeps it at this level for at least 4 hours. Concentration of hydrogen peroxide is monitored during the disinfection. After disinfection the aeration of the sealed area is required to reduce the concentration of hydrogen peroxide below 1,25 mg/m³ or a lower relevant national reference value before entering the area. This step can be quick but can also last several hours resulting in a total decontamination cycle of 5 - 8 hours.

The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable 'standard room', if applicable) with the devices to be used, after which a protocol for disinfection of these rooms can be made and used thereafter. In the event that there are methods available for chemically monitoring the active substance in the air or on surfaces, chemical validation should be performed besides biological validation, for example with test strips or with a device that measures ppm hydrogen peroxide in the air.

When it concerns a 'standard room' for which a protocol is available, the validation may be limited to only a chemical validation.

4.2.2. Use-specific risk mitigation measures

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal products, chemical resistant gloves classified under European Standard EN 374 or equivalent, face shield and RPE (APF = 10) during mixing and loading. Gloves and coverall material to be specified by the authorisation holder within the product information. See section 6 for the full titles of the EN standards.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC .

No access to the treated area is permitted during treatment. During aeration and before permitting re-entry to the treated area it should be checked that the concentration of hydrogen peroxide is below 1,25 mg/m³ or a lower relevant national reference value, using for example test strips. During the operation of the VHP generator or in the event of malfunctions entry to the room is only possible by wearing chemical protective suits and RPE (APF=10), when the concentration of hydrogen peroxide is at or below 12,5 mg/m³. Observe label instructions.

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

No use specific first aid instructions and emergency measures to protect the environment. See general directions for use.

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

No use specific instructions for safe disposal of the product and its packaging. See general directions for use.

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

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See general directions for use.

4.3. Use description

Table 3. Aseptic packaging in food and feed industries

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: bacteria Development stage: - Common name: yeasts Development stage: - Common name: Bacterial spores Development stage: Bacterial spores
Field(s) of use	indoor use Disinfection of food packaging material in closed aseptic packaging systems by sprayed or nebulised product.
Application method(s)	Method: Nebulising Detailed description: Automated spraying or nebulising in closed systems.
Application rate(s) and frequency	Application Rate: In-use concentration: 35% (w/w) hydrogen peroxide. Product concentration in hot air: 10,83 g/kg Dilution (%): For disinfection of bacteria, yeasts and bacterial spores the product should be diluted to 35% (w/w) hydrogen

	<p>peroxide. For example, for a product containing 49,9% (w/w) hydrogen peroxide: add 700 ml product to 357 ml water to achieve a dilution of 35% (w/w) hydrogen peroxide.</p> <p>Number and timing of application: Automated chemo-thermal disinfectant processes. Temperature: $\geq 100^{\circ}\text{C}$ Contact time: at least 5,5 seconds</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>HDPE bottle 1, 5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1000 litres HDPE ISO tank 20m³</p>

4.3.1. Use-specific instructions for use

The aseptic filling systems are based on the principle of aseptically forming a tube from a sterilised sheet of package material, which is continuously filled with commercially sterile liquid food product and subsequently transversally sealed to form pouches, which in turn are folded into the final package shape. The packaging material are delivered to the aseptic filling machine either in the form of (sheet) reels or in the form of pre-formed packs, tubs and bottles. Then, 35% (w/w) hydrogen peroxide is sprayed or nebulised to the packaging material gradually via a nozzle. After that, several stages follow to evaporate any excess hydrogen peroxide with sterile hot air.

Depending on the size of the receptacle, an amount of 0,1 - 1 mL of 35 % (w/w) hydrogen peroxide is sprayed or nebulised gradually via a nozzle.

Temperature: $\geq 100^{\circ}\text{C}$

Contact time: at least 5,5 seconds.

For example, for a product containing 49,9% (w/w) hydrogen peroxide: add 700 ml product to 357 ml water to achieve a dilution of 35% (w/w) hydrogen peroxide.

The user shall always carry out a microbiological validation of the disinfection, after which a protocol for disinfection of this packaging / system can be made and used thereafter.

4.3.2. Use-specific risk mitigation measures

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal products, chemical resistant gloves classified under European Standard EN 374 or equivalent, face shield and RPE (APF = 10) when handling concentrated solutions during mixing and loading; chemical resistant gloves classified under European Standard EN 374 or equivalent, protective clothing chemically resistant to the biocidal products, and chemical resistant goggles consistent with European Standard EN 16321 or equivalent face shield during application. During maintenance work, wear chemical resistant gloves classified under EN 374 or equivalent, protective clothing chemically resistant to the biocidal products, chemical resistant goggles consistent with EN 16321 or equivalent face shield and RPE (APF=4) and spray water for approximately 10 seconds before opening the machine. The instructions for use of the re-filling station specify that the loading operations must take place in a cool and ventilated place. Gloves and coverall material to be specified by the authorisation holder within the product information. Observe label instructions. See section 6 for the full titles of the EN standards.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC .

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

No use specific first aid instructions and emergency measures to protect the environment. See general directions for use.

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

No use specific instructions for safe disposal of the product and its packaging. See general directions for use.

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

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See general directions for use.

4.4. Use description

Table 4. Disinfection of distribution system for drinking water by cleaning in place (CIP)

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: bacteria Development stage: - Common name: yeasts Development stage: - Common name: fungi Development stage: -
Field(s) of use	indoor use Disinfection of distributing and storing installations for drinking water
Application method(s)	Method: CIP (Cleaning in place) Detailed description: Disinfecting the interior surfaces of closed systems by CIP
Application rate(s) and frequency	Application Rate: 4,7% (w/w) hydrogen peroxide. Dilution (%): For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide. For example, in case of a 35%(w/w) hydrogen peroxide product: add 114 ml product to 819 ml water. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Contact time: at least 3 hours Frequency: Daily / if required Temperature: room temperature
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1, 5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1000 litres HDPE ISO tank 20m ³

4.4.1. Use-specific instructions for use

CIP (Cleaning in place): Clean before disinfection (Remove all deposits and dirt by a pre-flush or pre-scrape, and when necessary, a pre-soak treatment). Circulate the diluted product through the system under conditions of increased turbulence and flow velocity. After 3 hours contact time, pipelines and tanks are rinsed with water before refilled with drinking water. For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide. For example, for a product containing 35% (w/w) hydrogen peroxide: add

114 ml product to 819 ml water to achieve a dilution of 4,7% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.

4.4.2. Use-specific risk mitigation measures

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent/face shield, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN 374 or equivalent. and RPE (APF = 10) during mixing and loading. Gloves and coverall material to be specified by the authorisation holder within the product information. See section 6 for the full titles of the EN standards.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC .

Technical RMM: Local exhaust ventilation (50 %) and good standard of general ventilation (3 air changes per hour (ACH)). Observe label instructions.

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

No use specific first aid instructions and emergency measures to protect the environment. See general directions for use.

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

No use specific instructions for safe disposal of the product and its packaging. See general directions for use.

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

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See general directions for use.

4.5. Use description

Table 5. Disinfection of non-porous hard surfaces and equipment by immersion

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: bacteria Development stage: - Common name: yeasts Development stage: - Common name: fungi Development stage: -
Field(s) of use	indoor use Equipment in both food and drink industries, large scale catering kitchens and large scale canteens.
Application method(s)	Method: open system: immersion Detailed description: Manual immersion of equipment in closed baths. Automated immersion of equipment in closed baths.
Application rate(s) and frequency	Application Rate: 8,1% (w/w) hydrogen peroxide. Dilution (%): For disinfection of bacteria, yeasts and fungi the product should be diluted to 8,1% (w/w) hydrogen peroxide. For example, in case of a 35%(w/w) hydrogen peroxide product:

	<p>add 200 ml product to 738 ml water. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.</p> <p>Number and timing of application: Contact time: 60 minutes Frequency: Daily / if required Temperature: room temperature</p>
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1, 5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1000 litres HDPE ISO tank 20m ³

4.5.1. Use-specific instructions for use

For disinfection of bacteria yeasts and fungi the product should be diluted to 8,1% (w/w) hydrogen peroxide. For example, for a product containing 35% (w/w) hydrogen peroxide: add 200 ml product to 738 ml water to achieve a dilution of 8,1% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.

Immersion: Equipment in the food and feed industry is disinfected by immersion. Pre-clean the equipment. The disinfection solution should be diluted into vats (i.e. pouring or pumping the product into vats). The equipment to be disinfected is manually or automatically placed into these vats (closed baths) and taken out after a contact time of not less than 60 minutes. After the disinfection procedure is completed, equipment is rinsed with water. The disinfection solution in the immersion/dipping bath should be replaced after each disinfection cycle.

4.5.2. Use-specific risk mitigation measures

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN 374 or equivalent, face shield and RPE (APF = 10) during mixing and loading and application. Gloves and coverall material to be specified by the authorisation holder within the product information. No access of other worker to the room is permitted during disinfection without wearing adequate PPE and RPE as described above. See section 6 for the full titles of the EN standards.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC.

Technical RMM: Local exhaust ventilation (50 %) and good standard of general ventilation (3 ACH). Dipping bath has to be placed in a separated room. For use only in areas inaccessible to the general public. Professional users without PPE and RPE (APF=10) are not allowed to enter the disinfection room. Keep the bath closed during disinfection, only open to load and discharge.

Observe label instructions.

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

No use specific first aid instructions and emergency measures to protect the environment. See general directions for use.

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

No use specific instructions for safe disposal of the product and its packaging. See general directions for use.

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

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See general directions for use.

4.6. Use description

Table 6. Disinfection of surfaces by cleaning in place (CIP)

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: bacteria Development stage: - Common name: yeasts Development stage: - Common name: fungi Development stage: -
Field(s) of use	indoor use Disinfection of food contact inner surfaces of pipe work and tank systems in food and feed industry
Application method(s)	Method: Cleaning in Place (CIP) Detailed description: Disinfecting the interior surfaces of closed systems by Cleaning In Place (CIP).
Application rate(s) and frequency	Application Rate: 4,7% (w/w) hydrogen peroxide. Dilution (%): For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide. For example, in case of a 35%(w/w) hydrogen peroxide product: add 114 ml product to 819 ml water. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Contact time: at least 3 hours Frequency: Daily / if required Temperature: room temperature
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1, 5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1000 litres HDPE ISO tank 20m ³

4.6.1. Use-specific instructions for use

Clean prior to disinfection. The inner surfaces of pipe work and tank systems are disinfected by CIP process. For disinfection of bacteria yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide. For example, for a product containing 35% (w/w) hydrogen peroxide; add 114 ml product to 819 ml water to achieve a dilution of 4,7% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.

The process is carried out by circulating the disinfection solution through the system under conditions of increased turbulence and flow velocity. The application is automated and a closed process. After 3 hours contact time, pipelines and tanks are rinsed with water under closed system conditions as well.

4.6.2. Use-specific risk mitigation measures

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent/face shield, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN 374 or equivalent and RPE (APF = 10) during mixing and loading. Gloves and coverall

material to be specified by the authorisation holder within the product information. See section 6 for the full titles of the EN standards.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC.

Technical RMM: Local exhaust ventilation (50 %) and good standard of general ventilation (3 ACH). Observe label instructions.

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

No use specific first aid instructions and emergency measures to protect the environment. See general directions for use.

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

No use specific instructions for safe disposal of the product and its packaging. See general directions for use.

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

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See general directions for use.

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

See use specific instructions for each use.

5.2. Risk mitigation measures

See use specific risk mitigation measures for each use.

Observe label instructions.

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

First aid instructions

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance. Information to Healthcare personnel/ doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.

If symptoms: Call 112/ambulance for medical assistance.

If no symptoms: Call a POISON CENTRE or a doctor.

Accidental release measures

Large spillage: Collect product in suitable containers (for example made of plastic) using appropriate equipment (for example liquid pump) for disposal. Never return spills in original containers for re-use. Keep away from flammable and incompatible substances. Rinse away any residue with plenty of water. Dispose of absorbed material in accordance with the applicable environmental regulations.

Small spillage: Dilute product with lots of water and rinse away or absorb with liquid-binding material (for example diatomaceous earth or universal binder). Pick up mechanically and collect in suitable containers. Clean contaminated surface thoroughly. Pack and label wastes like the product. Do not detach label from the delivery containers prior to disposal.

5.4. Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer depending on local requirements.

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

Advice on protection against fire and explosion:

Store away from direct sunlight and heat sources.

Store away from sources of ignition - No smoking.

Store away from flammable substances.

Store away from incompatible substances.

Storage:

Temperature requirement- during storage maximum 40 °C and protect from frost.

Store in clean, dry and well-ventilated places.

Transport and store container in upright position only.

Always close container tightly after removal of product.

Avoid leakage and residues of the product on the containers.

Advice on common storage:

Do not store together with alkalis, reductants, metallic salts (risk of decomposition).

Do not store together with organic solvents (risk of explosion).

Shelf-life:

24 months

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

6. OTHER INFORMATION

The full titles of the EN standards referenced in the “Use-specific mitigation measures” sections are:

EN 16321 - Eye and face protection for occupational users

EN 374 – Protective gloves against chemicals and micro-organisms

The Council Directive referenced in the “Use-specific mitigation measures” sections is: Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998[RMJ1] , p.11).