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► **B**

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2183

of 18 October 2023

granting a Union authorisation for the biocidal product family ‘Evonik’s Hydrogen Peroxide Product Family’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

(OJ L 2183, 19.10.2023, p. 1)

Amended by:

		Official Journal		
		No	page	date
► <u>M1</u>	Commission Implementing Regulation (EU) 2026/749 of 31 March 2026	L 749	1	1.4.2026

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/2183****of 18 October 2023****granting a Union authorisation for the biocidal product family
'Evonik's Hydrogen Peroxide Product Family' in accordance with
Regulation (EU) No 528/2012 of the European Parliament and of
the Council****(Text with EEA relevance)***Article 1*

A Union authorisation with authorisation number EU-0028964-0000 is granted to Evonik Operations GmbH for the making available on the market and use of the biocidal product family 'Evonik's Hydrogen Peroxide Product Family' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 8 November 2023 until 31 October 2033.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

▼ **M1***ANNEX***Summary of product characteristics for a biocidal product family**

Evonik's Hydrogen Peroxide Product Family

Product type(s)

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

PT04: Food and feed area

Authorisation number EU-0028964-0000**R4BP asset number** EU-0028964-0000

PART I

FIRST INFORMATION LEVEL**1. ADMINISTRATIVE INFORMATION****1.1. Family name**

Name	Evonik's Hydrogen Peroxide Product Family
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1.2. Product type(s)

Product type(s)	PT02: Disinfectants and algacides not intended for direct application to humans or animals PT04: Food and feed area
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1.3. Authorisation holder

Name and address of the authorisation holder	Name	Evonik Operations GmbH
	Address	Rellinghauser Straße 1 - 11 45128 Essen DE
Authorisation number	EU-0028964-0000	
<i>R4BP asset number</i>	EU-0028964-0000	
Date of the authorisation	8.11.2023	
Expiry date of the authorisation	31.10.2033	

1.4. Manufacturer(s) of the product

Name of manufacturer	Evonik Antwerpen NV
Address of manufacturer	Tijdsmanstunnel West 2040 Antwerpen Belgium
Location of manufacturing sites	Evonik Antwerpen NV - Site 1 Tijdsmanstunnel 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 - Site 1 Untere Kanalstr. 3 79618 Rheinfelden Germany

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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	Hettenheuvelweg 37 /39 1101 BM Amsterdam Netherlands (the)
Location of manufacturing sites	Evonik Peroxide Netherlands BV - Site 1 Oosterhorn 14 9936 HD Farmsum Netherlands (the)
Name of manufacturer	Brenntag Schweizerhall AG
Address of manufacturer	Elsässerstrasse 231 4013 Basel Switzerland
Location of manufacturing sites	Brenntag Schweizerhall AG Site 1 Route Industrielle 10 1580 Avenches Switzerland Brenntag Schweizerhall AG Site 2 C/O Infrapark , Baselland, Rothausstrasse 61 4132 Muttens Switzerland
Name of manufacturer	Brenntag GmbH
Address of manufacturer	Messeallee 11 45131 Essen Germany
Location of manufacturing sites	Brenntag GmbH Site 1 Am Röhrenwerk 46 47259 Duisburg Germany Brenntag GmbH Site 2 Boschstraße 3 08371 Glauchau Germany Brenntag GmbH Site 3 Hannoversche Str. 40 21079 Hamburg Germany Brenntag GmbH Site 4 Dieselstraße 5 74076 Heilbronn Germany Brenntag GmbH Site 5 Merkurstraße 47 67663 Kaiserslautern Germany Brenntag GmbH Site 6 Am Fieseler Werk 9 34253 Lohfelden Germany
Name of manufacturer	Brenntag CEE GmbH
Address of manufacturer	Linke Wienzeile 152 1060 Wien Austria
Location of manufacturing sites	Brenntag CEE GmbH Site 1 Bahnstraße 13 2353 Guntramsdorf Austria Brenntag CEE GmbH Site 2 Fabrikstraße 4-6 8111 Judendorf Austria Brenntag CEE GmbH Site 3 Rubensstraße 48 4050 Traun Austria
Name of manufacturer	Brenntag Slovakia s. r. o.
Address of manufacturer	Glejovka 902 03 Pezinok Slovakia
Location of manufacturing sites	Brenntag Slovakia s. r. o. Site 1 Glejovka 15 902 03 Pezinok Slovakia Brenntag Slovakia s. r. o. Site 2 Priboj 558 976 13 Slovenská Ľupča Slovakia Brenntag Slovakia s. r. o. Site 3 Južná Trieda 72 042 85 Košice Slovakia

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Name of manufacturer	Brenntag S.p.A.
Address of manufacturer	Via Cusago, 150/4 20153 Milano Italy
Location of manufacturing sites	Brenntag S.p.A. Site 1 Via San Carlo Borromeo 24040 Levate Italy Brenntag S.p.A. Site 2 Via Galliera 6/2 40010 Bentivoglio Italy Brenntag S.p.A. Site 3 Via del Cimitero 6 80030 Castello di Cisterna Italy Brenntag S.p.A. Site 4 Strada Provinciale di Bonifica 34-36 65010 Villanova di Cepagatti Italy Brenntag S.p.A. Site 5 Via Provinciale per Bitetto 70027 Palo del Colle Italy Brenntag S.p.A. Site 6 Via Paduni 03012 Anagni Italy

Name of manufacturer	Brenntag Polska Sp. z o.o.
Address of manufacturer	Józefa Bema 21 47-224 Kędzierzyn-Koźle Poland
Location of manufacturing sites	Brenntag Polska Sp. z o.o. Site 1 Józefa Bema 21 47-224 Kędzierzyn-Koźle Poland Brenntag Polska Sp. z o.o. Site 2 Kwasowa 5 95-100 Zgierz Poland Brenntag Polska Sp. z o.o. Site 3 Przemysłowa 2 62-080 Jankowice Poland Brenntag Polska Sp. z o.o. Site 4 Towarowa 9 05-530 Góra Kalwaria Poland

Name of manufacturer	Brenntag Lietuva UAB
Address of manufacturer	Palemono g. 171D 52107 Kaunas Lithuania
Location of manufacturing sites	Brenntag Lietuva UAB Site 1 Palemono g. 171D 52107 Kaunas Lithuania

Name of manufacturer	Brenntag Hungária Kft.
Address of manufacturer	Bányalég u. 45 1225 Budapest Hungary
Location of manufacturing sites	Brenntag Hungária Kft. Site 1 Banyalég u. 45 1225 Budapest Hungary

Name of manufacturer	S.C. Brenntag S.R.L.
Address of manufacturer	Garii Street 1 077040 Chiajna Romania
Location of manufacturing sites	S.C. Brenntag S.R.L. Site 1 Garii Street 1 077040 Chiajna Romania

Name of manufacturer	Brenntag Hrvatska d.o.o.
Address of manufacturer	Radnička cesta 173p 10000 Zagreb Croatia
Location of manufacturing sites	Brenntag Hrvatska d.o.o. Site 1 Radnička cesta 173p 10000 Zagreb Croatia

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Name of manufacturer	Brenntag Bulgaria EOOD
Address of manufacturer	j.k. Drujba 2, ul. Obikolna 21, et. 1 1582 Sofia Bulgaria
Location of manufacturing sites	Brenntag Bulgaria EOOD Site 1 j.k. Drujba 2, ul. Obikolna 21, et. 1 1582 Sofia Bulgaria

Name of manufacturer	OQEMA S.P.A.
Address of manufacturer	Via Roggia Bartolomea 7 20090 Assago Italy
Location of manufacturing sites	OQEMA S.P.A. Site 1 VIA TORTONA 73 27055 Rivanazzano Italy

Name of manufacturer	Breustedt Chemie BV
Address of manufacturer	IJsseldijk 28 7325 WZ Apeldoorn Netherlands (the)
Location of manufacturing sites	Breustedt Chemie BV Site 1 IJsseldijk 28 7325 WZ Apeldoorn Netherlands (the)

Name of manufacturer	BEAUSEIGNEUR SAS
Address of manufacturer	6, Rue André Viellard 90140 Froidefontaine France
Location of manufacturing sites	BEAUSEIGNEUR SAS Site 1 6, Rue André Viellard 90140 Froidefontaine France

Name of manufacturer	Staub & Co. - Silbermann GmbH
Address of manufacturer	Ostendstraße 124 90482 Nürnberg Germany
Location of manufacturing sites	Staub & Co. - Silbermann GmbH Site 1 Industriestraße 3 6456 Gablingen Germany

Name of manufacturer	Möller GmbH & Co. KG
Address of manufacturer	Bürgerkamp 1 48565 Steinfurt Germany
Location of manufacturing sites	Möller GmbH & Co. KG Site 1 Bürgerkamp 1 48565 48565 Germany

Name of manufacturer	Häffner GmbH & Co. KG
Address of manufacturer	Friedrichstraße 3 71679 Asperg Germany
Location of manufacturing sites	Häffner GmbH & Co. KG Site 1 Friedrichstraße 3 71679 Asperg Germany

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Name of manufacturer	Gaches Chimie
Address of manufacturer	17 avenue de la Gare 31750 Escalquens France
Location of manufacturing sites	Gaches Chimie Site 1 17 avenue de la Gare 31750 Escalquens France Gaches Chimie Site 2 2 Chemin de la Scierie 64150 Os-Marsillon France

Name of manufacturer	Evonik España y Portugal SA
Address of manufacturer	Afuera s/n 50784 La Zaida Spain
Location of manufacturing sites	Evonik España y Portugal SA C/ Afueras s/n. 50784 La Zaida Spain

Name of manufacturer	Amira Srl
Address of manufacturer	Via Vecchia Milanese 12 20844 Triuggio (MB) Italy
Location of manufacturing sites	Amira Srl Site 1 Via Vecchia Milanese 12 20844 Triuggio (MB) Italy

Name of manufacturer	ASiRAL Industriereiniger GmbH
Address of manufacturer	Hermann-Wehrle-Str. 15 67433 Neustadt/Weinstraße Germany
Location of manufacturing sites	ASiRAL Industriereiniger GmbH Site 1 Hermann-Wehrle-Str. 15 67433 Neustadt/Weinstraße Germany

Name of manufacturer	abcr GmbH
Address of manufacturer	Im Schleht 10 76187 Karlsruhe Germany
Location of manufacturing sites	abcr GmbH Site 1 Im Schleht 10 76187 Karlsruhe Germany

Name of manufacturer	Antec International Limited
Address of manufacturer	Windham Road, Chilton Industrial Estate CO1 Sudbury United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Antec International Limited Site 1 Windham Road, Chilton Industrial Estate CO1 Sudbury United Kingdom of Great Britain and Northern Ireland (the)

Name of manufacturer	OQEMA GmbH
Address of manufacturer	Aachener Straße 258 41061 Mönchengladbach Germany
Location of manufacturing sites	OQEMA GmbH Site 1 Gutberletstraße 17 04316 Leipzig Germany

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Name of manufacturer	Brenntag Nordic AB
Address of manufacturer	Hyllie Boulevard 34 18 TR SE-215 32 Malmö Sweden
Location of manufacturing sites	Brenntag Nordic AB Site 1 Vevgatan 2 504 64 Borås Sweden

Name of manufacturer	ECSCA Chemicals SA
Address of manufacturer	Burgauerstrasse 17 9230 Flawil Switzerland
Location of manufacturing sites	ECSCA Chemicals SA Site 1 Via Luigi Favre 16 6828 Balerna Switzerland

Name of manufacturer	TENSID-CHEMIE GMBH
Address of manufacturer	Heinkelstraße 32 76461 Muggensturm Germany
Location of manufacturing sites	TENSID-CHEMIE GMBH Site 1 Heinkelstraße 32 76461 Muggensturm Germany

Name of manufacturer	Carl Roth GmbH + Co. KG
Address of manufacturer	Schoemperlenstraße 3-5 76185 Karlsruhe Germany
Location of manufacturing sites	Carl Roth GmbH + Co. KG Site 1 Schoemperlenstraße 3-5 76185 Karlsruhe Germany

Name of manufacturer	Hollu Systemhygiene GmbH
Address of manufacturer	Hollu Campus 1 6170 Zirl Austria
Location of manufacturing sites	Hollu Systemhygiene GmbH Site 1 Hollu Campus 1 6170 Zirl Austria

1.5. **Manufacturer(s) of the active substance(s)**

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

▼M1

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	Hettenheuvelweg 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 España y Portugal SA
Address of manufacturer	Afueras s/n 50784 La Zaida Spain
Location of manufacturing sites	Evonik España y Portugal SA C/ Afueras s/n. 50784 La Zaida Spain

2. PRODUCT FAMILY COMPOSITION AND FORMULATION**2.1. Qualitative and quantitative information on the composition of the family**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	35 - 49,9 % (w/w)

2.2. Type(s) of formulation

Formulation type(s)	SL Soluble concentrate
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PART II**SECOND INFORMATION LEVEL META SPC(S)****1. META SPC 1 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 1 identifier**

Identifier	Meta SPC: OXTERIL® Group 1
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1.2. Suffix to the authorisation number

Number	1-1
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▼M1**1.3. Product type(s)**

Product type(s)	PT02: Disinfectants and algacides not intended for direct application to humans or animals PT04: Food and feed area
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2. META SPC 1 COMPOSITION**2.1. Qualitative and quantitative information on the composition of the meta SPC 1**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	35 - 49,9 % (w/w)

2.2. Type(s) of formulation of the meta SPC 1

Formulation type(s)	SL Soluble concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects. H272: May intensify fire; oxidiser.
Precautionary statements	P261: Avoid breathing vapours. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P271: Use only outdoors or in a well-ventilated area. P273: Avoid release to the environment. P280: Wear protective gloves / eye protection / face protection.. P301+P312: IF SWALLOWED: Call a POISON CENTER / doctor / physician if you feel unwell. P330: Rinse mouth. P302+P352: IF ON SKIN: Wash with plenty of water/ soap. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER/ doctor/physician if you feel unwell. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER / doctor. P332+P313: If skin irritation occurs: Get medical advice. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents / in accordance with local requirements.

▼ **M1**

	P501: Dispose of container / in accordance with local requirements. 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.
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4. **AUTHORISED USE(S) OF THE META SPC**4.1. **Use description**

Table 1

Surface disinfection by vaporised hydrogen peroxide (VHP) process

Product type	PT02: Disinfectants and algacides 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 m³. Product concentration: 3 120 mg/m³. 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 1 092 mg/m³ (780 ppm) by the VHP generator. 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 1 000 litres HDPE ISO tank 20 m³

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.

▼ M1

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 1 092 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.

▼ **M1**

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: 3 120 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 1 092 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 1 000 litres HDPE ISO tank 20 m ³

▼ M1**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 1 092 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 .

▼ **M1**

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 For disinfection of bacteria, yeasts and bacterial spores the product should be diluted to 35 % (w/w) hydrogen 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. Number and timing of application: Automated chemo-thermal disinfectant processes. Temperature: ≥ 100 °C Contact time: at least 5,5 seconds

▼ **M1**

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 1 000 litres HDPE ISO tank 20 m ³

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: ≥ 100 °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.

▼ M1

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. 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 1 000 litres HDPE ISO tank 20 m ³

▼ M1

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	-

▼ **M1**

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. 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: add 200 ml product to 738 ml water. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Contact time: 60 minutes 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 1 000 litres HDPE ISO tank 20 m 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.

▼ M1

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).

▼ **M1**

Application rate(s) and frequency	Application Rate: 4,7 % (w/w) hydrogen peroxide. 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 1 000 litres HDPE ISO tank 20 m³

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.

▼ M1**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 USE OF THE META SPC 1**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.

▼ M1

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

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).

▼ M1**7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1****7.1. Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)		OXTERIL® 350 SPRAY		Market area: EU	
		BIS OKSAN		Market area: EU	
		Halades DI		Market area: EU	
		DEPTIL 350 SPRAY		Market area: EU	
		Amira Hydrogen Peroxide		Market area: EU	
		Asiral Des O		Market area: EU	
		OXTERIL® 350 VHP		Market area: EU	
		PERSYNT® 350 VHP		Market area: EU	
Authorisation number		EU-0028964-0001 1-1			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	35 % (w/w)

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)		OXTERIL® 350 SPRAY S		Market area: EU	
		DES O HR		Market area: EU	
Authorisation number		EU-0028964-0002 1-1			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	35 % (w/w)

1. META SPC 2 ADMINISTRATIVE INFORMATION**1.1. Meta SPC 2 identifier**

Identifier	Meta SPC: OXTERIL® Group 2
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1.2. Suffix to the authorisation number

Number	1-2
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▼M1**1.3. Product type(s)**

Product type(s)	PT04: Food and feed area
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2. META SPC 2 COMPOSITION**2.1. Qualitative and quantitative information on the composition of the meta SPC 2**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	35 - 49,9 % (w/w)

2.2. Type(s) of formulation of the meta SPC 2

Formulation type(s)	SL Soluble concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects. H272: May intensify fire; oxidiser.
Precautionary statements	P261: Avoid breathing vapours. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P271: Use only outdoors or in a well-ventilated area. P273: Avoid release to the environment. P280: Wear protective gloves / eye protection / face protection. P301+P312: IF SWALLOWED: Call a POISON CENTER / doctor / physician if you feel unwell. P330: Rinse mouth. P302+P352: IF ON SKIN: Wash with plenty of water/ soap. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER/doctor/physician if you feel unwell. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P332+P313: If skin irritation occurs: Get medical advice. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents / in accordance with local requirements.

▼ **M1**

	P501: Dispose of container / in accordance with local requirements. 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.
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4. **AUTHORISED USE(S) OF THE META SPC**4.1. **Use description**

Table 1

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 and feed packaging material in closed aseptic packaging systems by dipping, spraying or nebulising
Application method(s)	Method: Dipping, nebulising and spraying Detailed description: Automated dipping in closed systems. Automated nebulising and spraying in closed systems.
Application rate(s) and frequency	Application Rate: In-use concentration: 35% (w/w) hydrogen peroxide. For disinfection of bacteria, yeasts and bacterial spores, the product should be diluted to 35 % (w/w) hydrogen 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. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Automated chemo-thermal disinfection processes. In-use concentration: 35% (w/w) hydrogen peroxide Spraying or nebulizing: Temperature: $\geq 100^{\circ}\text{C}$ Contact time: at least 5,5 seconds Dipping: Temperature: $\geq 80^{\circ}\text{C}$ Contact time: at least 2,5 seconds
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 1 000 litres HDPE ISO tank 20 m³

▼ M1**4.1.1. 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. The packaging material in the form of (sheet) reels passes through a deep bath filled with 35 % (w/w) hydrogen peroxide by dipping. The pre-formed packs, tubs and bottles are sprayed or fogged with 35 % (w/w) hydrogen peroxide stepwise 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 nebulized gradually via a nozzle.

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

Contact time: at least 5,5 seconds

The packaging material in the form of (sheet) reels passes through a deep bath filled with 35 % (w/w) hydrogen peroxide by dipping.

Temperature: $\geq 80\text{ }^{\circ}\text{C}$

Contact time: at least 2,5 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.

4.1.2. 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 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.

▼ M1

The instructions for use of the re-filling station specify that the loading operations must take place in a cool and ventilated place. 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

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 Cleaning and 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 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 1 000 litres HDPE ISO tank 20 m ³

▼ M1**4.2.1. Use-specific instructions for use**

CIP (Cleaning in place): Clean prior to disinfection. 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.

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

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

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: -

▼ **M1**

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. 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: add 200 ml product to 738 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 60 min 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 1 000 litres HDPE ISO tank 20 m ³

4.3.1. *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 at least 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.

4.3.2. *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 and application. 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.

▼ M1

No access of other worker to the room is permitted during disinfection without wearing adequate PPE and RPE as described above.

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

Dipping bath has to be placed in a separate 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.

4.3.3. *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 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. 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.

▼ **M1**

	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 1 000 litres HDPE ISO tank 20 m ³

4.4.1. *Use-specific instructions for use*

Clean prior to disinfection. 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.

4.4.2. *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. 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.

4.4.3. *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.

▼ M1**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.

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 2**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 (e.g. made of plastic) using appropriate equipment (e.g. 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 (e.g. 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 of unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer depending on local requirements.

▼ M1**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

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).

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2**7.1. Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)			OXTERIL® 350 BATH		Market area: EU	
			DES-H2O2 35		Market area: EU	
Authorisation number			EU-0028964-0003 1-2			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	35 % (w/w)	

▼ M1**7.2. Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)			OXTERIL® 350 COMBI		Market area: EU	
			SPECIJAL PT		Market area: EU	
			Brennspec HP 35 aseptic		Market area: EU	
			Climax HPO Aseptisk		Market area: EU	
			OXTERIL® 350 LRD		Market area: EU	
Authorisation number			EU-0028964-0004 1-2			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	35 % (w/w)	

1. META SPC 3 ADMINISTRATIVE INFORMATION**1.1. Meta SPC 3 identifier**

Identifier	Meta SPC: CLARMARIN® Group 1
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1.2. Suffix to the authorisation number

Number	1-3
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1.3. Product type(s)

Product type(s)	PT02: Disinfectants and algacides not intended for direct application to humans or animals PT04: Food and feed area
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2. META SPC 3 COMPOSITION**2.1. Qualitative and quantitative information on the composition of the meta SPC 3**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	35 - 49,9 % (w/w)

2.2. Type(s) of formulation of the meta SPC 3

Formulation type(s)	SL Soluble concentrate
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▼ **M1**3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3**

Hazard statements	H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects. H272: May intensify fire; oxidiser.
Precautionary statements	P261: Avoid breathing vapours. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P271: Use only outdoors or in a well-ventilated area. P273: Avoid release to the environment. P280: Wear protective clothing / eye protection / face protection. P301+P312: IF SWALLOWED: Call a POISON CENTER / doctor / physician if you feel unwell. P330: Rinse mouth. P302+P352: IF ON SKIN: Wash with plenty of water/ soap. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER/doctor/physician if you feel unwell. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER / doctor. P332+P313: If skin irritation occurs: Get medical advice. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents / in accordance with local requirements. P501: Dispose of container / in accordance with local requirements. 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) OF THE META SPC**4.1. **Use description**

Table 1

Laundry disinfection in closed washing machines by dosing

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-

▼ **M1**

Target organism(s) (including development stage)	Common name: bacteria Development stage: - Common name: yeasts Development stage: - Common name: viruses Development stage: - Common name: fungi Development stage: -
Field(s) of use	indoor use Laundry disinfection in washing machines.
Application method(s)	Method: Loading (dosing) Detailed description: The product is automatically dosed into the closed washing machine during the washing process (main wash).
Application rate(s) and frequency	Application Rate: 0,019 - 0,029 % (w/w) hydrogen peroxide. The biocidal products are diluted accordingly in order to achieve an in-use concentration in the range of 0,019 - 0,029 % (w/w). For example, in the case of 35 % (w/w) hydrogen peroxide product: 0,5 ml or 0,75 ml concentrate add water up to 1 litre to achieve 0,019 % (w/w) or 0,029 % (w/w). For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Frequency: Daily / if required Bacteria, yeasts, fungi: In use concentration 0,019 % (w/w) hydrogen peroxide in the wash solution. Alkaline buffering agent: 0,6 ml/l BEIPUR ANP. Contact time: 10 minutes Temperature: 70 °C Viruses: In use concentration 0,029 % (w/w) hydrogen peroxide in the wash solution. Alkaline buffering agent: 0,6 ml/l BEIPUR ANP Contact time: 10 minutes Temperature: 80 °C Cloth: liquid ratio = 1:4
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 1 000 litres HDPE ISO tank 20 m ³

4.1.1. *Use-specific instructions for use*

The product and alkaline buffering agent (BEIPUR ANP) are automatically dosed into the closed washing machine during the washing process. The dosing of both components, i.e. the biocidal product and the alkaline buffering agent BEIPUR ANP, is realised via two separate pipes and dosing stations. Biocidal product and alkaline buffering agent should not be mixed prior the dosing into the washing machine. Treatment Interval - daily / if required (0,5 hours / day).

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 product, chemical resistant gloves classified under the European Standard EN 374 or equivalent, face shield and RPE (APF = 10) during mixing and loading. Glove 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.

▼ M1

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.

4.1.3. *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

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) in closed systems Detailed description: Disinfecting the interior surfaces of closed systems by CIP
Application rate(s) and frequency	Application Rate: 4,7 % (w/w) hydrogen peroxide For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7 % (w/w) hydrogen peroxide. For example, in the case of 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. Number and timing of application: Contact time: at least 3 hours Frequency: Daily / if required Temperature: room temperature

▼ **M1**

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 1 000 litres HDPE ISO tank 20 m ³

4.2.1. *Use-specific instructions for use*

CIP (Cleaning in place): Clean prior to disinfection. 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.

4.2.2. *Use-specific risk mitigation measures*

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

Glove and coverall material to be specified by the authorisation holder within the product information.

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.

4.2.3. *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.

▼ **M1****4.3. Use description***Table 3***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. 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. Number and timing of application: Contact time: 60 minutes 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 1 000 litres HDPE ISO tank 20 m ³

4.3.1. 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 of the immersion/dipping bath should be replaced after each disinfection cycle.

▼ M1**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 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. Glove 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 room is permitted during disinfection without wearing adequate PPE and RPE as described above.

Technical RMM: Local exhaust ventilation (50 %) and good standard of general ventilation (3 ACH). Dipping bath has to be placed in a separate 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.

4.3.3. 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 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.

▼ **M1**

Application method(s)	Method: CIP in closed systems 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. 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. 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 1 000 litres HDPE ISO tank 20 m ³

4.4.1. *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.

4.4.2. *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. See section 6 for the full titles of the EN standards.

Glove and coverall material to be specified by the authorisation holder within the product information.

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.

▼ M1**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.

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 3**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.

▼ M1

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 of 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

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).

▼ **M1****7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3****7.1. Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	CLARMARIN® 350	Market area: EU
	Wapo 35 Biozid	Market area: EU
	Calgonit spor-exalin	Market area: EU
	Hollu LG DES 851	Market area: EU
	Wapo 35	Market area: EU
	WEICOLUB®-DES	Market area: EU
	WEICOPER®-O	Market area: EU
	WP 35	Market area: EU
	Brennspec HP 35	Market area: EU
	BEIBLEACH WP 35	Market area: EU
	SANITER LP	Market area: EU
	OXY 50	Market area: EU
	OXY 50 PLUS	Market area: EU
	STERIL 130	Market area: EU
	OXY 50 DM	Market area: EU
	PEROXISOL	Market area: EU
	DEWA-OX	Market area: EU
	PEROGENO 130	Market area: EU
	EUROXY 50 AG SUPER	Market area: EU
	EUROGENO	Market area: EU
	OXICLEAN 2510/A	Market area: EU
	OXICLEAN 3000/A	Market area: EU
	AGRISAN 40	Market area: EU
	OXICLEAN 10	Market area: EU
	ENERSAN 2510A	Market area: EU
	ANTIFERMEN-TATIVO K	Market area: EU
	ANTIFERMEN-TATIVO K 100	Market area: EU

▼ **M1**

	ACQUA	Market area: EU			
	SBIANCANTE K	Market area: EU			
	OSSIDANTE ATTIVO	Market area: EU			
	LAUNDRY 05	Market area: EU			
	SYSTEMIC PROFESSIONAL M4 DES	Market area: EU			
	LAUNDRY 05 D	Market area: EU			
	RAPIDES OXY	Market area: EU			
	DES-H 35	Market area: EU			
	SYSTEM PROTEX 4	Market area: EU			
	ECSO 8670	Market area: EU			
	Komponente 2	Market area: EU			
	SANOLIFE HO	Market area: EU			
	E-FLOW DETERGENTE SP01	Market area: EU			
	CANDOR STERIL B	Market area: EU			
	OXY 70 DM	Market area: EU			
	BLUOXIRAPID	Market area: EU			
	ALFA-O-DUE	Market area: EU			
	BAR-O-DUE	Market area: EU			
	OXY ONE	Market area: EU			
	OXI 50 DM	Market area: EU			
	Idroxan WT	Market area: EU			
	BÜFA-Oxy WS	Market area: EU			
	O 33	Market area: EU			
	WAPERSOL® 35	Market area: EU			
	GRS 7325 S	Market area: EU			
	TH 830D	Market area: EU			
	KORASIL 3500-KA	Market area: EU			
Authorisation number		EU-0028964-0005 1-3			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	35 % (w/w)

▼ **M1**7.2. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)			CLARMARIN® 500	Market area: EU		
			Wapo 50 Biozid	Market area: EU		
			Wapo 50	Market area: EU		
			INO PEROX 50	Market area: EU		
			Mirasan Perox	Market area: EU		
			Brennspec HP 50	Market area: EU		
			INTERCLEAN® TW	Market area: EU		
			DES-H 50	Market area: EU		
			Sanivet TM AQUA	Market area: EU		
			OXINEUTRO	Market area: EU		
			Vet-Ox	Market area: EU		
			WAPERSOL® 50	Market area: EU		
			KORASIL 5000-GS	Market area: EU		
Authorisation number			EU-0028964-0006 1-3			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	49,9 % (w/w)	