Official Journal
of the European Union

EN
L series

2026/277

6.2.2026

COMMISSION IMPLEMENTING REGULATION (EU) 2026/277

of 5 February 2026

granting a Union authorisation for the biocidal product family 'Hydrogen Peroxide Group' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 44(5), first subparagraph, thereof,

Whereas:

(1) On 10 January 2017, ARKEMA FRANCE submitted an application to the European Chemicals Agency ('the Agency') in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a biocidal product family named 'Hydrogen Peroxide Group' of product-types 2, 3 and 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under case number BC-PU028831-12 in the Register for Biocidal Products.

(2) 'Hydrogen Peroxide Group' contains hydrogen peroxide as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 2, 3 and 4.

(3) On 13 November 2024, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.

(4) On 5 June 2025, the Agency submitted to the Commission its opinion ([2]), the draft summary of the biocidal product characteristics ('SPC') of 'Hydrogen Peroxide Group' and the final assessment report on the biocidal product family, in accordance with Article 44(3) of Regulation (EU) No 528/2012.

(5) The opinion concludes that 'Hydrogen Peroxide Group' is a biocidal product family within the meaning of Article 3(1), point (s), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(6) of that Regulation.

(6) On 24 June 2025, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the biocidal product family 'Hydrogen Peroxide Group'.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) Opinion of 15 May 2025 on the Union authorisation of the biocidal product family 'Hydrogen Peroxide Group' (ECHA/BPC/478/2025), https://echa.europa.eu/opinions-on-union-authorisation.

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0035039-0000 is hereby granted to ARKEMA FRANCE for the making available on the market and use of the biocidal product family 'Hydrogen Peroxide Group' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 26 February 2026 until 31 January 2036.

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.

Done at Brussels, 5 February 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

Hydrogen Peroxide Group

Product type(s)

PT04: Food and feed area

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

PT03: Veterinary hygiene

Authorisation number: EU-0035039-0000

R4BP asset number: EU-0035039-0000

PART I

FIRST INFORMATION LEVEL

1. **ADMINISTRATIVE INFORMATION**

1.1. **Family name**

Name	Hydrogen Peroxide Group

1.2. **Product type(s)**

Product type(s)	PT04: Food and feed area PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT03: Veterinary hygiene

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	ARKEMA FRANCE
	Address	51, Esplanade du Général de Gaulle 92800 PUTEAUX - LA DEFENSE FR
Authorisation number	EU-0035039-0000	
R4BP asset number	EU-0035039-0000	
Date of the authorisation	26 February 2026	
Expiry date of the authorisation	31 January 2036	

1.4. **Manufacturer(s) of the product**

Name of manufacturer	ARKEMA FRANCE
Address of manufacturer	51, Esplanade du Général de Gaulle 92800 PUTEAUX - LA DEFENSE France
Location of manufacturing sites	ARKEMA FRANCE - USINE DE JARRIE Route National 85 BP 1 38560 JARRIE France

Name of manufacturer	Arkema Gmbh - KIRCHHEIMBOLANDEN
Address of manufacturer	Morschheimer Strasse 19 67292 KIRCHHEIMBOLANDEN Germany
Location of manufacturing sites	ARKEMA GMBH - KIRCHHEIMBOLANDEN Morschheimer Strasse 19 67292 KIRCHHEIMBOLANDEN Germany

Name of manufacturer	ARKEMA GMBH - NIEDERLASSUNG LEUNA
Address of manufacturer	Am Haupttor Bau 2410 06237 LEUNA Germany
Location of manufacturing sites	ARKEMA GMBH - NIEDERLASSUNG LEUNA Am Haupttor Bau 2410 06237 LEUNA Germany

Name of manufacturer	Quimidroga
Address of manufacturer	Tuset 26 08006 Barcelona Spain
Location of manufacturing sites	QUIMIDROGA QG11 Muelle de Inflambles-Delta 1, Port de Lagos, 2-8 Port de LAgos, 2-8 08039 Barcelona Spain

Name of manufacturer	QUIMITÉCNICA.COM – COMÉRCIO E IND. QUÍMICA, SA
Address of manufacturer	Lote 21 B PARQUE INDUSTRIAL DE MIDE 4815-169 LORDELO - GUIMARÃES Portugal
Location of manufacturing sites	Quimitecnica Estarreja Quinta da Indústria - Beduído 3860-680 Estarreja Portugal

Name of manufacturer	RAINOLDI S.p.A.
Address of manufacturer	VIA SAN CARLO BORROMEO snc 24040 LEVATE (BG) Italy
Location of manufacturing sites	Rainoldi SRL Viale dell'industria, 15 21052 Busto Arsizio (VA) Italy

Name of manufacturer	UNIVAR Spa
Address of manufacturer	Viale A. Volta, 49 20090 CUSAGO Italy
Location of manufacturing sites	UNIVAR Spa Viale A. Volta, 49 20090 CUSAGO (MI) Italy

Name of manufacturer	BRENNTAG -midi pyrenees
Address of manufacturer	1038 Avenue des Terres Noires 81370 SAINT SULPICE France
Location of manufacturing sites	BRENNTAG MIDI PYRENEES 1038 Avenue des Terres Noires 81370 SAINT SULPICE France

Name of manufacturer	BRENNTAG LORRAINE
Address of manufacturer	Pôle industriel Toul Europe Secteur A, 2890 Route de Villey St Etienne 2890 Route de Villey St Etienne 54200 TOUL France
Location of manufacturing sites	BRENNTAG LORRAINE Pôle industriel Toul Europe Secteur A, 2890 Route de Villey St Etienne 2890 Route de Villey St Etienne 54200 TOUL France

Name of manufacturer	BRENNTAG NORMANDIE
Address of manufacturer	12 Sente des Jumelles 76710 MONTVILLE France
Location of manufacturing sites	BRENNTAG NORMANDIE 12 Sente des Jumelles 76710 MONTVILLE France

Name of manufacturer	BRENNTAG PICARDIE
Address of manufacturer	ESPACE INDUSTRIEL NORD EIN, 121 Rue Endre Durouchez 121 rue Endre Durouchez 80081 AMIENS France
Location of manufacturing sites	BRENNTAG PICARDIE ESPACE INDUSTRIEL NORD EIN, 121 Rue Endre Durouchez 121 rue Endre Durouchez 80081 AMIENS France

Name of manufacturer	BRENNTAG VAL DE LOIRE
Address of manufacturer	816 rue de Gautray 45590 SAINT CYR EN VAL France
Location of manufacturing sites	BRENNTAG VAL DE LOIRE 816 rue de Gautray 45590 SAINT CYR EN VAL France

Name of manufacturer	BRENNTAG ARDENNES
Address of manufacturer	Route de Tournes CD N° 2 08090 CLIRON France
Location of manufacturing sites	BRENNTAG ARDENNES Route de Tournes CD N° 2 08090 CLIRON France

Name of manufacturer	BRENNTAG MEDITERRANEE
Address of manufacturer	21 Boulevard de l'Europe 13127 VITROLLES France
Location of manufacturing sites	BRENNTAG MEDITERRANEE 21 Boulevard de l'Europe 13127 VITROLLES France

Name of manufacturer	BRENNTAG LOIRE BRETAGNE
Address of manufacturer	14 route de Plessis Bouchet 44802 SAINT HERBLAIN France
Location of manufacturing sites	BRENNTAG LOIRE BRETAGNE 14 route de Plessis Bouchet 44802 SAINT HERBLAIN France

Name of manufacturer	BRENNTAG MAINE BRETAGNE
Address of manufacturer	ZI de la promenade 53290 GREZ EN BOUERE France
Location of manufacturing sites	BRENNTAG MAINE BRETAGNE ZI de la promenade 53290 GREZ EN BOUERE France

Name of manufacturer	BRENNTAG AQUITAINE
Address of manufacturer	20 rue Marcel Sembat 33100 BORDEAUX BASTIDE France
Location of manufacturing sites	BRENNTAG AQUITAINE 20 rue Marcel Sembat 33100 BORDEAUX BASTIDE France

Name of manufacturer	BRENNTAG CHASSIEU
Address of manufacturer	5 rue arago BP 19 69682 CHASSIEU cedex France
Location of manufacturing sites	BRENNTAG CHASSIEU 5 rue arago BP 19 69682 CHASSIEU cedex France

Name of manufacturer	BRENNTAG BOURGOGNE
Address of manufacturer	ZI de Torcy, Avenue des ferrancins Avenue des ferrancins 71210 TORCY France
Location of manufacturing sites	BRENNTAG BOURGOGNE ZI de Torcy, Avenue des ferrancins Avenue des ferrancins 71210 TORCY France

Name of manufacturer	BRENNTAG DAUPHINE
Address of manufacturer	Avenue Jean-Pierre Thimbaud BP306 38434 ECHIROLLES France
Location of manufacturing sites	BRENNTAG DAUPHINE Avenue Jean-Pierre Thimbaud BP306 38434 ECHIROLLES cedex France

Name of manufacturer	BRENNTAG ILE-DE-France
Address of manufacturer	ZAC du closeau Impasse Lavoisier 77220 TOURNAN EN BRIE France
Location of manufacturing sites	BRENNTAG ILE-DE-France ZAC du closeau Impasse Lavoisier 77220 TOURNAN EN BRIE France

Name of manufacturer	BRENNTAG NORD
Address of manufacturer	ZI de la Martinoire BP 40157 59391 WATTRELOOS France
Location of manufacturing sites	BRENNTAG NORD ZI de la Martinoire BP 40157 59391 WATTRELOOS cedex France

Name of manufacturer	BRENNTAG COTE D'AZUR
Address of manufacturer	293 CR n°4 La Roseyre, Zone d'activité économique Zone d'activité économique 06390 LA POINTE DE CONTES France
Location of manufacturing sites	BRENNTAG COTE D'AZUR 293 CR n°4 La Roseyre, Zone d'activité économique Zone d'activité économique 06390 LA POINTE DE CONTES France

Name of manufacturer	CG Chemikalien GmbH & Co. KG
Address of manufacturer	Ulmer Straße 1 30880 Laatzen Germany
Location of manufacturing sites	CG Chemikalien GmbH & Co. KG Ulmer Straße 1 30880 Laatzen Germany

Name of manufacturer	Reher & Ramsden Nachflg. GmbH & Co. KG
Address of manufacturer	Rubbertstraße 44 21109 Hamburg Germany
Location of manufacturing sites	Reher & Ramsden Nachflg. GmbH & Co. KG Rubbertstr. 44 21109 Hamburg Germany

Name of manufacturer	CSC JÄKLECHEMIE GmbH & Co. KG
Address of manufacturer	Matthiasstr. 10 - 12 90431 Nürnberg Germany
Location of manufacturing sites	CSC Jäklechemie GmbH & Co. KG Matthiasstr. 10-12 90257 Nürnberg Germany

Name of manufacturer	Hanke & Seidel Gmbh & Co KG
Address of manufacturer	Waldbadstr. 20-22 33803 Steinhagen Germany
Location of manufacturing sites	Hanke & Seidel GmbH & Co.KG Waldbadstr. 20-22 33803 Steinhagen Germany

Name of manufacturer	Brenntag Polska Sp zo.o
Address of manufacturer	ul. Przemyslowa 2, Jankowice k. Poznaniaul. 62-080 Tarnowo Podgórne Poland
Location of manufacturing sites	Brenntag Polska Sp zo.o Tarnowo Podgórne ul. Przemyslowa 2, Jankowice k. Poznaniaul. 62-080 Tarnowo Podgórne Poland

Name of manufacturer	Brenntag Polska Sp zo.o Góra Kalwaria
Address of manufacturer	ul. Towarowa 6 05-530 Góra Kalwaria Poland
Location of manufacturing sites	Brenntag Polska Sp zo.o Góra Kalwaria ul. Towarowa 6 05-530 Góra Kalwaria Poland

Name of manufacturer	Brenntag Polska Sp zo.o Zgierz
Address of manufacturer	ul. Kwasowa 5 95-100 Zgierz Poland
Location of manufacturing sites	Brenntag Polska Sp zo.o Zgierz ul. Kwasowa 5 95-100 Zgierz Poland

Name of manufacturer	Brenntag Polska Sp zo.o Kedzierzyn-Kozle
Address of manufacturer	ul. J.Bema 21 47-224 Kedzierzyn-Kozle Poland
Location of manufacturing sites	Brenntag Polska Sp zo.o Kedzierzyn-Kozle ul. J.Bema 21 47-224 Kedzierzyn-Kozle Poland

Name of manufacturer	ALLIANCE PRODUCTION
Address of manufacturer	ZA DES RAMASSIERS 4 BD DEODAT DE SEVERAC 31770 COLOMIERS France
Location of manufacturing sites	Groupe QUALLEO Environnement - Alliance Production ZAC des Ramassiers, 4 boulevard Deodat de Séverac 4 boulevard Deodat de Séverac 31770 Colomier France

Name of manufacturer	SAS Celtique Industrielle
Address of manufacturer	Rue brindejonc des moulinais 22190 PLERIN France
Location of manufacturing sites	SAS Celtique Industrielle Rue brindejonc des moulinais 22190 PLERIN France

Name of manufacturer	SOPRODIS
Address of manufacturer	RN133 11200 Lézignan Corbières France
Location of manufacturing sites	SOPRODIS RN133 11200 LEZIGNAN CORBIERES France

Name of manufacturer	RAI
Address of manufacturer	440 Rue de la cimenterie 39300 CHAMPAGNOLE France
Location of manufacturing sites	RAI 440 Rue de la cimenterie 39300 CHAMPAGNOLE France

Name of manufacturer	WIGOL W. Stache GmbH
Address of manufacturer	Textorstrasse 2 67547 WORMS Germany
Location of manufacturing sites	WIGOL W. Stache GmbH Textorstrasse 2 67547 WORMS Germany

Name of manufacturer	L.C.I. sarl
Address of manufacturer	2 ZAC Klengbousbierg 7795 BISSEN Luxembourg
Location of manufacturing sites	L.C.I. sarl 2 ZAC Klengbousbierg 7795 BISSEN Luxembourg

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

Active substance	hydrogen peroxide
Name of manufacturer	ARKEMA FRANCE
Address of manufacturer	51, Esplanade du Général de Gaulle 92800 PUTEAUX - LA DEFENSE France
Location of manufacturing sites	ARKEMA FRANCE - USINE DE JARRIE Route National 85 BP 1 38560 JARRIE France

Active substance	hydrogen peroxide
Name of manufacturer	ARKEMA GMBH - NIEDERLASSUNG LEUNA
Address of manufacturer	Am Haupttor Bau 2410 06237 LEUNA Germany
Location of manufacturing sites	ARKEMA GMBH - NIEDERLASSUNG LEUNA Am Haupttor Bau 2410 06237 LEUNA Germany

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	hydrogen peroxide	Active substance	7722-84-1	231-765-0	25 - 49,9 % (w/w)

2.2. **Type(s) of formulation**

Formulation type(s)	AL Any other liquid SL Soluble concentrate

PART II

SECOND INFORMATION LEVEL META SPC(S)

1. **META SPC 1 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 1 identifier**

Identifier	Meta SPC: 1a

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **Product type(s)**

Product type(s)	PT04: Food and feed area

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	hydrogen peroxide	Active substance	7722-84-1	231-765-0	35–35 % (w/w)

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

Formulation type(s)	AL Any other liquid

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1**

Hazard statements	H272: May intensify fire; oxidiser. 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.
Precautionary statements	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. 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 eye protection. P280: Wear face protection. P301+P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P330: Rinse mouth. P332+P313: If skin irritation occurs: Get medical advice. P332+P313: If skin irritation occurs: Get medical attention. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up.

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Use 1a.4a: Disinfection of food packaging by aseptic technology (bath and spray/vapour)

Product type	PT04: Food and feed area
Target organism(s) (including development stage)	Common name: bacteria Common name: Bacterial spores Common name: yeasts

Field(s) of use	indoor use Disinfection of cardboard or plastic packaging (e.g. bricks, bottles, cups, pouches …) before filling with sensitive food products to be stored at room temperature for a long period
Application method(s)	Method: closed system Detailed description: Surfaces must be cleaned before disinfection. Disinfection of food packaging is achieved by using two different techniques, usually called 'bath' and 'spray' technologies: 'bath' technology: the packaging material (cardboard or plastic rolls) is exposed to a 35 % hydrogen peroxide solution. Disinfection is achieved by heating hydrogen peroxide. The residual hydrogen peroxide on the packaging surface is removed by sterile compressed air. The sterile packaging is then folded, cut, filled with sterile food products and sealed. 'spray technology': the packaging material (preformed cardboard containers, plastic bottles and plastic preforms) is exposed to hydrogen peroxide vapor generated from a 35 % hydrogen peroxide solution which is sprayed and then vaporized, ensuring the complete sterilization of the inner surface of the packaging. Further hot sterile air removes hydrogen peroxide residual in the brick or bottle. The sterile packaging is then filled with sterile food products and sealed. The disinfection machines are closed systems with no access to professionals during operation. In case of maintenance, the machine is stopped, hydrogen peroxide is removed (vapour extraction).
Application rate(s) and frequency	Number and timing of application: Validated food processing systems that have control over the contaminant load on food packaging surfaces or food processing equipment prior to fill may vary concentration, temperature, and/or contact time to achieve the required level of disinfection. Container volume range (generally from 100 to 2 000 ml) may also influence operating parameters. Ready-to-use 35 % w/w hydrogen peroxide. Bath technology: Contact time: 2,5 seconds minimum Temperature : 80 °C minimum Spray technology: Application rate: 22,7–30 g H_2O_2/m^3 Contact time: 2 seconds Temperature: 115–250 °C
Category(ies) of users	professional
Pack sizes and packaging material	30 kilogram (kg) and 65 kg high-density polyethylene (HDPE) jerrycans 600 litre (L) and 1 000L HDPE intermediate bulk container (IBC)

4.1.1. *Use-specific instructions for use*

All surfaces must be cleaned before disinfection.

The user shall always carry out a microbiological validation of the disinfection process in the machine to be used with the devices to be used after which a protocol for disinfection of these machines can be made and used thereafter.

4.1.2. *Use-specific risk mitigation measures*

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 references to this act and the European Standards.

Mixing and loading (automated) or maintenance of the machine:

1. Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 4 is mandatory.
2. Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, polyvinyl chloride (PVC).
3. The use of eye protection (chemical goggles/face shield) (EN 166 or equivalent) during handling of the product is mandatory.
4. Wear coverall (EN 13034 or equivalent)

Mixing and loading (manual):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 10 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC.

— The use of eye protection (chemical goggles/face shield) (EN 166 or equivalent) during handling of the product is mandatory.

During use of the machine the following risk mitigation measures (RMMs) apply:

— All surfaces must be cleaned before disinfection.

— Machines to be operated in areas where local exhaust ventilation (LEV) or forced ventilation is operational.

— Wear coverall (EN 13034 or equivalent)

For other instructions, see General directions for use.

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*

See General directions for use.

4.1.4. *Where specific to the use, the 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*

See General directions for use.

4.2. **Use description**

Table 2

Use 1a.11: Disinfection of inner surfaces of aseptic filling machines

Product type	PT04: Food and feed area
Target organism(s) (including development stage)	Common name: bacteria Common name: Bacterial spores Common name: yeasts
Field(s) of use	indoor use Disinfection of inner non-porous surfaces of aseptic filling machines (generally named as 'aseptic zone').
Application method(s)	Method: closed system Detailed description: Disinfection of the inner surfaces of the filling machines ('spray' technologies for the container disinfection) is achieved by vaporizing hydrogen peroxide, ensuring the complete disinfection of the 'aseptic zone'. The aseptic filling machines are closed systems with no access to professionals during operation. In case of maintenance, the machine is stopped, hydrogen peroxide is removed (vapour extraction).
Application rate(s) and frequency	Number and timing of application: According to the packaging machine type (manufacturer and model), the biocidal products shall be used at a concentration of 35 % w/w hydrogen peroxide. Concentration active substance: 16,8 g calculated a.s. in gas phase /m^3 Generation temperature of vapour: minimum 250 °C Contact time: 24 minutes
Category(ies) of users	professional
Pack sizes and packaging material	600 litre (L) and 1 000L HDPE intermediate bulk container (IBC) 30 kilogram (kg) and 65 kg high-density polyethylene (HDPE) jerrycans

4.2.1. *Use-specific instructions for use*

Surfaces must be cleaned before disinfection.

Application rates may vary from one equipment to the other. It is possible to use the product with different decontamination devices or for machines with different volumes.

The user shall always carry out a microbiological validation of the disinfection process in the machine to be used with the devices to be used after which a protocol for disinfection of these machine can be made and used thereafter.

Rinse treated [surfaces/equipment/pipes/machinery] with drinking water after application.

4.2.2. *Use-specific risk mitigation measures*

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 references to this act and the European Standards.

Mixing and loading(automated) or maintenance of the machine:

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 4 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

Mixing and loading(manual):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 10 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166) during handling of the product is mandatory.

During use of the machine the following RMMs apply:

— All surfaces must be cleaned before disinfection.

— Machines to be operated in areas where LEV or forced ventilation is operational.

For other instructions, see General directions for use.

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*

See General directions for use.

4.2.4. *Where specific to the use, the 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*

See General directions for use.

5. **GENERAL DIRECTIONS FOR USE OF THE META SPC 1**

5.1. **Instructions for use**

Unless otherwise stated on the label, products must be diluted for use.

Follow the label instructions for use dilutions and application volumes according to the use required.

Surfaces shall be cleaned before disinfection.

See Use-specific instructions for use per use

5.2. **Risk mitigation measures**

— No access of third parties during application/treatment/maintenance, unless the required personal protective equipment as prescribed for the professional user is worn.

— Re-entry is only permitted once the air concentration for hydrogen peroxide has dropped below 0,9 ppm (1,25 mg/m³) or relevant lower national reference value

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

First-Aid measures

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.

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. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

Fire-fighting measures

Extinguishing media:

Suitable extinguishing media: In case of fire involving the product: Water spray Unsuitable extinguishing media: All other extinguishants.

Special hazards arising from the substance or mixture: Contact with combustible material may cause fire. Thermal decomposition gives: Oxygen, that can enhance sites of combustion. Hazards of over-pressurization in containers exposed to heat: explosion risk.

Precautions for fire-fighters: Specific methods: Keep upwind and operate from safe distance. In case of fire, remove exposed containers. Containers/tanks should be cooled with water spray.

Special protective actions for fire-fighters: Wear self-contained breathing apparatus and protective suit.

Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Evacuate non-essential staff and those not equipped with individual protection apparatus. Prohibit contact with eyes. Avoid contact with skin. Avoid inhalation of vapours. Prohibit all sources of sparks and ignition - Do not smoke. If safe to do so, plug or seal off leak. Remove all incompatible substances.

Environmental precautions: Dam up with sand or inert earth (do not use combustible materials). Dilute with large quantities of water before discharging into sewers or into the environment

Methods and materials for containment and cleaning up:

Recovery: Soak up with inert absorbent material. Never reintroduce the spilled product in another container. Risk of decomposition.

Neutralisation: Dilute with water.

Elimination: Dispose of rinse water as waste water.

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

Waste treatment

Disposal of product: Dilute with water.

Disposal of packaging: Clean container with water. Recycle or incinerate at an approved waste disposal site. In accordance with local and national regulations.

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

Shelf-life of 1 year.

The product should be stored in the original packaging.

Protect from light.

Store below 54 °C.

6. **OTHER INFORMATION**

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, p. 11).

Professionals (including industrial, professionals) mean trained professional if this is required by national legislation.

Please be aware of the European reference value of 1,25 mg/m³ for the active substance hydrogen peroxide (CAS No.: 7722-84-1) which was used for the risk assessment for the biocidal product (please be aware that relevant lower national limit values may apply).

The full titles of the EN standards referenced in the Risk mitigation measures are:

— EN 13832 – Footwear protecting against chemicals

— EN 374 – Protective gloves against dangerous chemicals and micro-organisms

— EN 405 – Respiratory protective devices

— EN 166 – Eye protection against chemicals

— EN 13034 – Protective coverall against liquid chemicals – type 6

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)	Peroxal 35 VHP	Market area: EU
	VALSTERANE 35 AL1	Market area: EU
	VALSTERANE 35 SB	Market area: EU
	VALSTERANE 35 AL3	Market area: EU
	VALSTERANE 35 AL4	Market area: EU
	VALSTERANE 35 B	Market area: EU
	VALSTERANE 35 S	Market area: EU

	VALSTERANE 35 SHP	Market area: EU
	PEROXAL 35 DW	Market area: EU
	PEROXAL 35ED	Market area: EU
	HYDROCYDE	Market area: EU
	ANTISEPT WT 35	Market area: EU
	ANTISEPT WS 35	Market area: EU
Authorisation number	EU-0035039-0001 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	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: 1b

1.2. **Suffix to the authorisation number**

Number	1-2

1.3. **Product type(s)**

Product type(s)	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area

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	hydrogen peroxide	Active substance	7722-84-1	231-765-0	49,9–49,9 % (w/w)

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

Formulation type(s)	SL Soluble concentrate

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2**

Hazard statements	H272: May intensify fire; oxidiser. 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.
Precautionary statements	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. 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 eye protection. P280: Wear face protection. P301+P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P330: Rinse mouth. P332+P313: If skin irritation occurs: Get medical advice. P332+P313: If skin irritation occurs: Get medical attention. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up.

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Use 1b.3: Disinfection of equipment by filling or immersion

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area
Target organism(s) (including development stage)	Common name: bacteria Common name: yeasts Common name: fungi

Field(s) of use	indoor use outdoor use Disinfection of equipments (e.g. pipes, tanks, fillers, mixers, boxes …) by filling with solution (disinfection of inner surfaces), or immersion in a solution (inner/outer disinfection) in industrial (e.g. cosmetics, chemical synthesis …), institutional, food and feed areas.
Application method(s)	Method: open system: immersion Detailed description: Filling or immersion. Equipment surfaces must be cleaned before disinfection.
Application rate(s) and frequency	Number and timing of application: The product shall be diluted to 10 % (active substance w/w) prior to use. The contact time is 5 minutes for bacteria, yeasts, and fungi. The diluted solution should be at room temperature. Frequency: once a day
Category(ies) of users	professional
Pack sizes and packaging material	600 litre (L) and 1 000L HDPE intermediate bulk container (IBC) 220 L HDPE Drum 30 kilogram (kg) and 65 kg high-density polyethylene (HDPE) jerrycans

4.1.1. *Use-specific instructions for use*

Thoroughly clean and rinse the surface. Remove excess water from the surface before disinfection.

The product is diluted manually or automatic to 10 % hydrogen peroxide by professionals for application.

Automatic dilution (IBC, drum): The product is pumped into an intermediate reservoir where it is mixed with water to the required dose. There is no manual dilution step.

Manual dilution (jerry can): Product dilution to the in-use concentration is achieved by an operator in a bucket or intermediate small reservoir.

The diluted solution is then either used in a bath (disinfection by immersion) or poured into the equipment to be disinfected (disinfection by filling).

Rinse treated [surfaces/equipment/pipes/machinery] with drinking water after application.

Solutions shall be disposed of after a single use

4.1.2. *Use-specific risk mitigation measures*

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 references to this act and the European Standards.

Mixing and loading (automated):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 4 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

— Wear coverall (EN 13034 or equivalent)

Mixing and loading (manual):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 10 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

— Wear coverall (EN 13034 or equivalent)

Disinfection of equipment by filling or immersion:

— Ensure that application is carried out in areas with a minimum ventilation of 4 air changes per hour.

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 20 is mandatory.

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

— The bath must be emptied directly after the contact time and removal of equipment.

— Leave the room directly after application.

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*

See General directions for use.

4.1.4. *Where specific to the use, the 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*

See General directions for use.

4.2. **Use description**

Table 2

Use 1b.4a: Disinfection of food packaging by aseptic technology (bath and spray/vapour)

Product type	PT04: Food and feed area
Target organism(s) (including development stage)	Common name: bacteria Common name: Bacterial spores Common name: yeasts
Field(s) of use	indoor use Disinfection of cardboard or plastic packaging (e.g. bricks, bottles, cups, pouches …) before filling with sensitive food products to be stored at room temperature for a long period

Application method(s)	Method: closed system Detailed description: Surfaces must be cleaned before disinfection. Disinfection of food packaging is achieved by using two different techniques, usually called 'bath' and 'spray' technologies: 'bath' technology: the packaging material (cardboard or plastic rolls) is exposed to a 35 % hydrogen peroxide solution. Disinfection is achieved by heating hydrogen peroxide. The residual hydrogen peroxide on the packaging surface is removed by sterile compressed air. The sterile packaging is then folded, cut, filled with sterile food products and sealed. 'spray technology': the packaging material (preformed cardboard containers, plastic bottles and plastic preforms) is exposed to hydrogen peroxide vapor generated from a 35 % hydrogen peroxide solution which is sprayed and then vaporized, ensuring the complete sterilization of the inner surface of the packaging. Further hot sterile air removes hydrogen peroxide residual in the brick or bottle. The sterile packaging is then filled with sterile food products and sealed. The disinfection machines are closed systems with no access to professionals during operation. In case of maintenance, the machine is stopped, hydrogen peroxide is removed (vapour extraction).
Application rate(s) and frequency	Number and timing of application: Validated food processing systems that have control over the contaminant load on food packaging surfaces or food processing equipment prior to fill may vary concentration, temperature, and/or contact time to achieve the required level of disinfection. Container volume range (generally from 100 to 2 000 ml) may also influence operating parameters. Dilute the product to 35 % w/w hydrogen peroxide before use. Bath technology: Contact time: 2,5 seconds minimum Temperature : 80 °C minimum Spray technology: Application rate: 22,7–30 g H_2O_2/m^3 Contact time: 2 seconds Temperature: 115–250 °C
Category(ies) of users	professional
Pack sizes and packaging material	600 litre (L) and 1 000L HDPE intermediate bulk container (IBC) 30 kilogram (kg) and 65 kg high-density polyethylene (HDPE) jerrycans

4.2.1. *Use-specific instructions for use*

All surfaces must be cleaned before disinfection.

The user shall always carry out a microbiological validation of the disinfection process in the machine to be used with the devices to be used after which a protocol for disinfection of these machine can be made and used thereafter.

4.2.2. *Use-specific risk mitigation measures*

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 references to this act and the European Standards.

Mixing and loading (automated) or maintenance of the machine:

1. Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 4 is mandatory.
2. Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, polyvinyl chloride (PVC).
3. The use of eye protection (chemical goggles/face shield) (EN 166 or equivalent) during handling of the product is mandatory.
4. Wear coverall (EN 13034 or equivalent)

Mixing and loading (manual):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 10 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC.

— The use of eye protection (chemical goggles/face shield) (EN 166 or equivalent) during handling of the product is mandatory.

During use of the machine the following risk mitigation measures (RMMs) apply:

— All surfaces must be cleaned before disinfection.

— Machines to be operated in areas where local exhaust ventilation (LEV) or forced ventilation is operational.

— Wear coverall (EN 13034 or equivalent)

For other instructions, see General directions for use.

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*

See General directions for use.

4.2.4. *Where specific to the use, the 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*

See General directions for use.

4.3. **Use description**

Table 3

Use 1b.5: Disinfection of inner surfaces of food and feed processing systems (including Cleaning-In-Place, CIP) and veterinary water systems

Product type	PT04: Food and feed area
Target organism(s) (including development stage)	Common name: Bacterial spores Common name: fungi Common name: bacteria Common name: yeasts

Field(s) of use	indoor use Disinfection of inner surfaces of pipes, pumps, valves, filters, tanks, fillers and other machines in contact with food or feed by filling or circulating a solution (including CIP Cleaning-In-Place) in food and feed processing systems. Disinfection of inner surfaces in veterinary drinking water systems (e.g. pipes, tanks, valves).
Application method(s)	Method: open system Detailed description: Equipment or system surfaces must be cleaned before disinfection. Automatic dilution (IBC, drum): The product is pumped into an intermediate reservoir where it is mixed with water to the required dose. Manual dilution (jerry can): Product dilution to the in-use concentration is achieved by an operator in a bucket or intermediate small reservoir. The diluted solution is then either automatically pumped into closed process systems or poured manually into the equipment/system to be disinfected. Disinfection is achieved either by filling without recirculation or with recirculation (Cleaning-In-Place CIP). Rinse treated [surfaces/ equipment/pipes/machinery] with drinking water after application.
Application rate(s) and frequency	Number and timing of application: For bacteria, yeasts and fungi: the product shall be diluted to 1,5 % (active substance w/w) prior to use. Temperature: 20 °C. The contact time is: — 5 minutes for bacteria and yeasts — 15 minutes for fungi Bacterial spores: the product shall be diluted to 8 % (active substance content w/w) prior to use. The contact time is 60 minutes. Frequency: once a day
Category(ies) of users	professional
Pack sizes and packaging material	220 L HDPE Drum 600 litre (L) and 1 000L HDPE intermediate bulk container (IBC) 30 kilogram (kg) and 65 kg high-density polyethylene (HDPE) jerrycans

4.3.1. *Use-specific instructions for use*

Thoroughly clean and rinse the surface. Remove excess water from the surface before disinfection

The drinking water system shall not be in use during disinfection. The product shall be diluted before use (automated or manual dilution in a bucket or reservoir) before pumping or pouring into the closed system. Disinfection is achieved either by filling without recirculation or with recirculation.

4.3.2. *Use-specific risk mitigation measures*

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 references to this act and the European Standards.

Mixing and loading(automated) or maintenance of the machine:

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 4 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

— Wear coverall (EN 13034 or equivalent)

Mixing and loading(manual):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 10 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

— Wear coverall (EN 13034 or equivalent)

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*

See General directions for use.

4.3.4. *Where specific to the use, the 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*

See General directions for use.

5. **GENERAL DIRECTIONS FOR USE OF THE META SPC 2**

5.1. **Instructions for use**

Unless otherwise stated on the label, products must be diluted for use.

Follow the label instructions for use dilutions and application volumes according to the use required.

Surfaces shall be cleaned before disinfection.

See Use-specific instructions for use per use

5.2. **Risk mitigation measures**

— No access of third parties during application/treatment/maintenance, unless the required personal protective equipment as prescribed for the professional user is worn.

— Re-entry is only permitted once the air concentration for hydrogen peroxide has dropped below 0,9 ppm (1,25 mg/m^3) or relevant lower national reference value

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

First-Aid measures

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.

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. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

Fire-fighting measures

Extinguishing media:

Suitable extinguishing media: In case of fire involving the product: Water spray Unsuitable extinguishing media: All other extinguishants.

Special hazards arising from the substance or mixture: Contact with combustible material may cause fire. Thermal decomposition gives: Oxygen, that can enhance sites of combustion. Hazards of over-pressurization in containers exposed to heat: explosion risk.

Precautions for fire-fighters: Specific methods: Keep upwind and operate from safe distance. In case of fire, remove exposed containers. Containers/tanks should be cooled with water spray.

Special protective actions for fire-fighters: Wear self-contained breathing apparatus and protective suit.

Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Evacuate non-essential staff and those not equipped with individual protection apparatus. Prohibit contact with eyes. Avoid contact with skin. Avoid inhalation of vapours. Prohibit all sources of sparks and ignition - Do not smoke. If safe to do so, plug or seal off leak. Remove all incompatible substances.

Environmental precautions: Dam up with sand or inert earth (do not use combustible materials). Dilute with large quantities of water before discharging into sewers or into the environment

Methods and materials for containment and cleaning up:

Recovery: Soak up with inert absorbent material. Never reintroduce the spilled product in another container. Risk of decomposition.

Neutralisation: Dilute with water.

Elimination: Dispose of rinse water as waste water.

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

Waste treatment

Disposal of product: Dilute with water.

Disposal of packaging: Clean container with water. Recycle or incinerate at an approved waste disposal site. In accordance with local and national regulations.

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

Shelf-life of 1 year.

The product should be stored in the original packaging.

Protect from light.

Store below 54 °C.

6. **OTHER INFORMATION**

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, p. 11).

Professionals (including industrial, professionals) mean trained professional if this is required by national legislation.

Please be aware of the European reference value of 1,25 mg/m³ for the active substance hydrogen peroxide (CAS No.: 7722-84-1) which was used for the risk assessment for the biocidal product (please be aware that relevant lower national limit values may apply).

The full titles of the EN standards referenced in the Risk mitigation measures are:

— EN 13832 – Footwear protecting against chemicals

— EN 374 – Protective gloves against dangerous chemicals and micro-organisms

— EN 405 – Respiratory protective devices

— EN 166 – Eye protection against chemicals

— EN 13034 – Protective coverall against liquid chemicals – type 6

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)			Antisept WS 50	Market area: EU	
			Antisept WT 50	Market area: EU	
Authorisation number			EU-0035039-0002 1-2		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	49,9 % (w/w)

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

Trade name(s)	VALSTERANE 50 AL4	Market area: EU
	VALSTERANE 50 B	Market area: EU
	PEROXAL 50 DW	Market area: EU
	PEROXAL 50 VHP	Market area: EU
	PEROXAL 50 ED	Market area: EU
Authorisation number	EU-0035039-0003 1-2	

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

1. **META SPC 3 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 3 identifier**

Identifier	Meta SPC: 2

1.2. **Suffix to the authorisation number**

Number	1-3

1.3. **Product type(s)**

Product type(s)	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area PT03: Veterinary hygiene

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	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

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3**

Hazard statements	H272: May intensify fire; oxidiser. 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.

Precautionary statements	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. 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 eye protection. P280: Wear face protection. P301+P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P330: Rinse mouth. P332+P313: If skin irritation occurs: Get medical advice. P332+P313: If skin irritation occurs: Get medical attention. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up.

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Use 2.2: Hard surface disinfection

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area
Target organism(s) (including development stage)	Common name: bacteria Common name: yeasts Common name: fungi
Field(s) of use	indoor use outdoor use Disinfection of non-porous hard surfaces (tables, floors, walls, hard furniture, equipment), by wiping, moping or using a hand held trigger spray in: — Hospitals, health care facilities, industries, institutions … (PT2) — Food and feed industry, kitchens, restaurants, abattoirs… (PT4)
Application method(s)	Method: manual application Detailed description: Wiping or mopping with a soaked cloth, or spraying with a trigger sprayer.

Application rate(s) and frequency	Number and timing of application: For bacteria, yeasts and fungi: the product shall be diluted to 1,5 % (expressed as active substance content in % w/w) prior to use. Application rate: 300 ml/m^2. The minimum contact time is: — 5 minutes for bacteria and yeasts — 15 minutes for fungi. Frequency: once a day Apply the product at room temperature.
Category(ies) of users	professional
Pack sizes and packaging material	30 kilogram (kg) and 65 kg high-density polyethylene (HDPE) jerrycans 1L and 5L HDPE bottle

4.1.1. *Use-specific instructions for use*

Thoroughly clean and rinse the surface. Remove excess water from the surface before disinfection, if appropriate.

Manual dilution (jerry can, bottle): Product dilution to the in-use concentration of 1,5 % hydrogen peroxide (w/w) is achieved by an operator in a bucket or small intermediate reservoir.

Wiping and mopping

Soak the wipe or mop with product until completely soaked and then wipe or mop the surface to be disinfected. Make sure to wet the surfaces completely.

Spraying

Fill a hand held sprayer with the diluted solution. Make sure to wet surfaces completely by spraying the product onto the surface to be disinfected.

Allow to take effect for at least the required contact time.

4.1.2. *Use-specific risk mitigation measures*

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 references to this act and the European Standards.

Mixing and loading (manual):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 10 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

Wiping and trigger spray application:

— Ensure that application is carried out in areas with a minimum ventilation of 4 air changes per hour.

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 4 is mandatory.

— Leave the room directly after application.

Mopping application:

— Ensure that application is carried out in areas with a minimum ventilation of 4 air changes per hour.

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 10 is mandatory.

— Leave the room directly after application.

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*

See General directions for use.

4.1.4. *Where specific to the use, the 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*

See General directions for use.

4.2. **Use description**

Table 2

Use 2.5: Disinfection of inner surfaces of food and feed processing systems (including Cleaning-In-Place, CIP) and veterinary water systems

Product type	PT04: Food and feed area
Target organism(s) (including development stage)	Common name: Bacterial spores Common name: fungi Common name: bacteria Common name: yeasts
Field(s) of use	indoor use Disinfection of inner surfaces of pipes, pumps, valves, filters, tanks, fillers and other machines in contact with food or feed by filling or circulating a solution (including CIP Cleaning-In-Place) in food and feed processing systems. Disinfection of inner surfaces in veterinary drinking water systems (e.g. pipes, tanks, valves).
Application method(s)	Method: open system Detailed description: Equipment or system surfaces must be cleaned before disinfection. Automatic dilution (IBC, drum): The product is pumped into an intermediate reservoir where it is mixed with water to the required dose. Manual dilution (jerry can): Product dilution to the in-use concentration is achieved by an operator in a bucket or intermediate small reservoir.The diluted solution is then either automatically pumped into closed process systems or poured manually into the equipment/system to be disinfected. Disinfection is achieved either by filling without recirculation or with recirculation (Cleaning-In-Place CIP).Rinse treated [surfaces/ equipment/pipes/machinery] with drinking water after application.

Application rate(s) and frequency	Number and timing of application: For bacteria, yeasts and fungi: the product shall be diluted to 1,5 % (active substance w/w) prior to use. Temperature: 20 °C. The contact time is: — 5 minutes for bacteria and yeasts — 15 minutes for fungi Bacterial spores: the product shall be diluted to 8 % (active substance content w/w) prior to use. The contact time is 60 minutes. Frequency: once a day
Category(ies) of users	professional
Pack sizes and packaging material	220 L HDPE Drum 600 litre (L) and 1 000L HDPE intermediate bulk container (IBC) 30 kilogram (kg) and 65 kg high-density polyethylene (HDPE) jerrycans

4.2.1. *Use-specific instructions for use*

Thoroughly clean and rinse the surface. Remove excess water from the surface before disinfection

The drinking water system shall not be in use during disinfection. The product shall be diluted before use (automated or manual dilution in a bucket or reservoir) before pumping or pouring into the closed system. Disinfection is achieved either by filling without recirculation or with recirculation.

4.2.2. *Use-specific risk mitigation measures*

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 references to this act and the European Standards.

Mixing and loading(automated) or maintenance of the machine:

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 4 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

— Wear coverall (EN 13034 or equivalent)

Mixing and loading(manual):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 10 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

— Wear coverall (EN 13034 or equivalent)

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*

See General directions for use.

4.2.4. *Where specific to the use, the 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*

See General directions for use.

4.3. **Use description**

Table 3

Use 2.6: Disinfection of hard surface by spraying for veterinary purpose

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: bacteria Common name: yeasts Common name: fungi Common name: viruses
Field(s) of use	indoor use outdoor use Porous and non-porous hard surfaces in animal husbandry (animal houses, pens), including tables, floors, walls, machinery, hard furniture and equipment, excluding outer surfaces of animal transportation.
Application method(s)	Method: open system: spray treatment Detailed description: Surfaces must be cleaned before disinfection. Disinfection of equipment by spraying (medium pressure); A portable spraying equipment (volume ~ 20 Litres, medium pressure, hand held) is filled with the product dilution and then used for disinfection. Manual dilution (jerry can): Product dilution to the in-use concentration is achieved by an operator in a bucket or spray reservoir. Surfaces must kept wet during disinfection.
Application rate(s) and frequency	Number and timing of application: Prior to use, the product shall be diluted to (all concentrations are expressed as active substance content % w/w): — 2 % for porous surfaces in animal husbandry — 1,5 % for non-porous surfaces in animal husbandry Application rate: 300 ml/m^2. The minimum contact time is: — 30 minutes for porous and non-porous surfaces in animal husbandry Frequency: once a week for porous and non-porous surfaces in animal husbandry.
Category(ies) of users	professional
Pack sizes and packaging material	30 kilogram (kg) and 65 kg high-density polyethylene (HDPE) jerrycans

4.3.1. *Use-specific instructions for use*

Clean surfaces before use.

Dose the concentrate in the reservoir of the pressure cleaner to obtain an in-use concentration of:

— 2 % for porous surfaces in animal husbandry

— 1,5 % for non-porous surfaces in animal husbandry

Use a pressure washer or other mechanical sprayer to apply the diluted solution at an application rate of 300 ml spray /m^2. The disinfection solution shall remain in contact with the surface to be disinfected for at least:

30 minutes for porous and non-porous surfaces in animal husbandry

4.3.2. *Use-specific risk mitigation measures*

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 references to this act and the European Standards.

Mixing and loading (automated):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 4 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

— Wear coverall (EN 13034 or equivalent)

Mixing and loading (manual):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 10 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

— Wear coverall (EN 13034 or equivalent)

Spraying, hard surfaces:

— Ensure that application is carried out in areas with a minimum ventilation of 4 air changes per hour.

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 20 is mandatory.

— Animals are not allowed to be present during treatment

— Do not allow re-entry of animals to the disinfected facilities before 15 minutes after disinfection.

— Leave the room directly after application.

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*

See General directions for use.

4.3.4. *Where specific to the use, the 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*

See General directions for use.

4.4. **Use description**

Table 4

Use 2.10: Disinfection of hard surfaces by medium pressure spraying

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area
Target organism(s) (including development stage)	Common name: bacteria Common name: yeasts Common name: fungi
Field(s) of use	indoor use outdoor use Non-porous hard surfaces (e.g. floors, walls, work surfaces including food contact surfaces) in industry, institutions and health care facilities.
Application method(s)	Method: open system: spray treatment Detailed description: Surfaces must be cleaned before disinfection. Disinfection of equipment by spraying (medium pressure); A portable spraying equipment (volume ~ 20 Liters, medium pressure, hand held) is filled with the product dilution and then used for disinfection.
Application rate(s) and frequency	Number and timing of application: For bacteria and yeasts and fungi, the product shall be diluted to 1,5 % (active substance % w/w) prior to use. The minimum contact time is: — 5 minutes for bacteria and yeasts — 15 minutes for fungi. Application rate: 300 ml/m^2 Apply the product at room temperature Frequency: once a day
Category(ies) of users	professional
Pack sizes and packaging material	220 L HDPE Drum 600 litre (L) and 1 000L HDPE intermediate bulk container (IBC) 30 kilogram (kg) and 65 kg high-density polyethylene (HDPE) jerrycans

4.4.1. *Use-specific instructions for use*

Thoroughly clean and rinse the surface. Remove excess water from the surface before disinfection.

Dose the concentrate in the reservoir of the pressure cleaner to obtain a suitable in-use concentration of the active substance (see application rate section).

Automatic dilution (IBC, drum): The product is pumped into the reservoir of the pressure cleaner where it is mixed with water to the required dose. There is no manual dilution step.

Manual dilution (jerry can): Product dilution to the in-use concentration is achieved by an operator in a bucket or spray reservoir.

Surfaces must kept wet during disinfection.

Use a pressure washer or other mechanical sprayer to apply the diluted solution at an application rate of 300 ml/m^2. The disinfection solution shall remain in contact with the surface to be disinfected 5 minutes for removal of bacteria and yeasts, and 15 minutes to remove fungi.

Premises shall be well-ventilated before re-entry

4.4.2. *Use-specific risk mitigation measures*

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 references to this act and the European Standards.

Mixing and loading (automated):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 4 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

Mixing and loading (manual):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 10 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

Spraying of hard surfaces:

— Ensure that application is carried out in areas with a minimum ventilation of 4 air changes per hour.

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 20 is mandatory.

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

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*

See General directions for use.

4.4.4. *Where specific to the use, the 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*

See General directions for use.

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

5.1. **Instructions for use**

Unless otherwise stated on the label, products must be diluted for use.

Follow the label instructions for use dilutions and application volumes according to the use required.

Surfaces shall be cleaned before disinfection.

See Use-specific instructions for use per use

5.2. **Risk mitigation measures**

— No access of third parties during application/treatment/maintenance, unless the required personal protective equipment as prescribed for the professional user is worn.

— Re-entry is only permitted once the air concentration for hydrogen peroxide has dropped below 0,9 ppm (1,25 mg/m^3) or relevant lower national reference value

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

First-Aid measures

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.

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. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

Fire-fighting measures

Extinguishing media:

Suitable extinguishing media: In case of fire involving the product: Water spray Unsuitable extinguishing media: All other extinguishants.

Special hazards arising from the substance or mixture: Contact with combustible material may cause fire. Thermal decomposition gives: Oxygen, that can enhance sites of combustion. Hazards of over-pressurization in containers exposed to heat: explosion risk.

Precautions for fire-fighters: Specific methods: Keep upwind and operate from safe distance. In case of fire, remove exposed containers. Containers/tanks should be cooled with water spray.

Special protective actions for fire-fighters: Wear self-contained breathing apparatus and protective suit.

Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Evacuate non-essential staff and those not equipped with individual protection apparatus. Prohibit contact with eyes. Avoid contact with skin. Avoid inhalation of vapours. Prohibit all sources of sparks and ignition - Do not smoke. If safe to do so, plug or seal off leak. Remove all incompatible substances.

Environmental precautions: Dam up with sand or inert earth (do not use combustible materials). Dilute with large quantities of water before discharging into sewers or into the environment

Methods and materials for containment and cleaning up:

Recovery: Soak up with inert absorbent material. Never reintroduce the spilled product in another container. Risk of decomposition.

Neutralisation: Dilute with water.

Elimination: Dispose of rinse water as waste water.

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

Waste treatment:

Disposal of product: Dilute with water.

Disposal of packaging: Clean container with water. Recycle or incinerate at an approved waste disposal site. In accordance with local and national regulations.

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

Shelf-life of 1 year.

The product should be stored in the original packaging.

Protect from light.

Store below 54 °C.

6. **OTHER INFORMATION**

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, p. 11).

Professionals (including industrial, professionals) mean trained professional if this is required by national legislation.

Please be aware of the European reference value of 1,25 mg/m^3 for the active substance hydrogen peroxide (CAS No.: 7722-84-1) which was used for the risk assessment for the biocidal product (please be aware that relevant lower national limit values may apply).

The full titles of the EN standards referenced in the Risk mitigation measures are:

— EN 13832 – Footwear protecting against chemicals

— EN 374 – Protective gloves against dangerous chemicals and micro-organisms

— EN 405 – Respiratory protective devices

— EN 166 – Eye protection against chemicals

— EN 13034 – Protective coverall against liquid chemicals – type 6

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)			OXMAVI	Market area: EU	
Authorisation number			EU-0035039-0004 1-3		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	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)			A CID HIS	Market area: EU	
Authorisation number			EU-0035039-0005 1-3		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	35 % (w/w)

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

Trade name(s)			HD 20 OXYGERMS	Market area: EU	
			HD 20S OXY GERMS SPRAY	Market area: EU	
			HD 22 AGRI GERMS	Market area: EU	
Authorisation number			EU-0035039-0006 1-3		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	35 % (w/w)

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

Trade name(s)			Hydrosan	Market area: EU	
Authorisation number			EU-0035039-0007 1-3		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	35 % (w/w)

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

Trade name(s)			162 Combitartre	Market area: EU	
Authorisation number			EU-0035039-0008 1-3		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	35 % (w/w)

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

Trade name(s)			Antisept WO 35	Market area: EU	
Authorisation number			EU-0035039-0009 1-3		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	35 % (w/w)

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

Trade name(s)			PEROXAL 35 AHS	Market area: EU	
			PEROXAL 35 DS	Market area: EU	
			PEROXAL 35 PG	Market area: EU	
			PEROXAL 35 HSD	Market area: EU	
			PEROXAL 35 SD	Market area: EU	
			ALBONE 35 S	Market area: EU	
			PEROXAL 35 CIP	Market area: EU	
Authorisation number			EU-0035039-0010 1-3		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	35 % (w/w)

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

Trade name(s)			Antisept WO 50		Market area: EU
Authorisation number			EU-0035039-0011 1-3		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	49,9 % (w/w)

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

Trade name(s)			PEROXAL 50 AHS		Market area: EU
			ALBONE 50		Market area: EU
			PEROXAL 50 HSD		Market area: EU
			PEROXAL 50 SD		Market area: EU
Authorisation number			EU-0035039-0012 1-3		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	49,9 % (w/w)

1. **META SPC 4 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 4 identifier**

Identifier	Meta SPC: 4

1.2. **Suffix to the authorisation number**

Number	1-4

1.3. **Product type(s)**

Product type(s)	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area PT03: Veterinary hygiene

2. **META SPC 4 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 4**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	>=30–<=30 % (w/w)

2.2. **Type(s) of formulation of the meta SPC 4**

Formulation type(s)	SL Soluble concentrate

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4**

Hazard statements	H272: May intensify fire; oxidiser. H302: Harmful if swallowed. H318: Causes serious eye damage. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	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. P261: Avoid breathing vapours. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P280: Wear eye protection. P280: Wear face protection. P301+P312: IF SWALLOWED: Call a POISON CENTER/doctor 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. P330: Rinse mouth.

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Use 4.2: Hard surface disinfection

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area
Target organism(s) (including development stage)	Common name: bacteria Common name: yeasts Common name: fungi

Field(s) of use	indoor use outdoor use Disinfection of non-porous hard surfaces (tables, floors, walls, hard furniture, equipment), by wiping, mopping or using a hand held trigger spray in: — Hospitals, health care facilities, industries, institutions … (PT2) — Food and feed industry, kitchens, restaurants, abattoirs… (PT4)
Application method(s)	Method: manual application Detailed description: Wiping or mopping with a soaked cloth, or spraying with a trigger sprayer.
Application rate(s) and frequency	Number and timing of application: For bacteria, yeasts and fungi: the product shall be diluted to 1,5 % (expressed as active substance content in % w/w) prior to use. Application rate: 300 ml/m^2. The minimum contact time is: — 5 minutes for bacteria and yeasts — 15 minutes for fungi. Frequency: once a day Apply the product at room temperature.
Category(ies) of users	professional
Pack sizes and packaging material	30 kilogram (kg) and 65 kg high-density polyethylene (HDPE) jerrycans 1 L and 5 L HDPE bottle

4.1.1. *Use-specific instructions for use*

Thoroughly clean and rinse the surface. Remove excess water from the surface before disinfection, if appropriate.

Manual dilution (jerry can, bottle): Product dilution to the in-use concentration of 1,5 % hydrogen peroxide (w/w) is achieved by an operator in a bucket or small intermediate reservoir.

Wiping and mopping

Soak the wipe or mop with product until completely soaked and then wipe or mop the surface to be disinfected. Make sure to wet the surfaces completely.

Spraying

Fill a hand held sprayer with the diluted solution. Make sure to wet surfaces completely by spraying the product onto the surface to be disinfected.

Allow to take effect for at least the required contact time.

4.1.2. *Use-specific risk mitigation measures*

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 references to this act and the European Standards.

Mixing and loading (manual):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 10 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

Wiping and trigger spray application:

— Ensure that application is carried out in areas with a minimum ventilation of 4 air changes per hour.

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 4 is mandatory.

— Leave the room directly after application.

Mopping application:

— Ensure that application is carried out in areas with a minimum ventilation of 4 air changes per hour.

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 10 is mandatory.

— Leave the room directly after application.

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*

See General directions for use.

4.1.4. *Where specific to the use, the 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*

See General directions for use.

4.2. **Use description**

Table 2

Use 4.3: Disinfection of equipment by filling or immersion

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area
Target organism(s) (including development stage)	Common name: bacteria Common name: yeasts Common name: fungi
Field(s) of use	indoor use outdoor use Disinfection of equipments (e.g. pipes, tanks, fillers, mixers, boxes …) by filling with solution (disinfection of inner surfaces), or immersion in a solution (inner/outer disinfection) in industrial (e.g. cosmetics, chemical synthesis …), institutional, food and feed areas.
Application method(s)	Method: open system: immersion Detailed description: Filling or Immersion. Equipment surfaces must be cleaned before disinfection.

Application rate(s) and frequency	Number and timing of application: The product shall be diluted to 10 % (active substance w/w) prior to use. The contact time is 5 minutes for bacteria, yeasts, and fungi. The diluted solution should be at room temperature. Frequency: once a day
Category(ies) of users	professional
Pack sizes and packaging material	600 litre (L) and 1 000L HDPE intermediate bulk container (IBC) 220 L HDPE Drum 30 kilogram (kg) and 65 kg high-density polyethylene (HDPE) jerrycans

4.2.1. *Use-specific instructions for use*

Thoroughly clean and rinse the surface. Remove excess water from the surface before disinfection.

The product is diluted manually or automatic to 10 % hydrogen peroxide by professionals for application.

Automatic dilution (IBC, drum): The product is pumped into an intermediate reservoir where it is mixed with water to the required dose. There is no manual dilution step.

Manual dilution (jerry can): Product dilution to the in-use concentration is achieved by an operator in a bucket or intermediate small reservoir.

The diluted solution is then either used in a bath (disinfection by immersion) or poured into the equipment to be disinfected (disinfection by filling).

Rinse treated [surfaces/equipment/pipes/machinery] with drinking water after application.

Solutions shall be disposed of after a single use

4.2.2. *Use-specific risk mitigation measures*

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 references to this act and the European Standards.

Mixing and loading (automated):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 4 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

— Wear coverall (EN 13034 or equivalent)

Mixing and loading (manual):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 10 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

— Wear coverall (EN 13034 or equivalent)

Disinfection of equipment by filling or immersion:

— Ensure that application is carried out in areas with a minimum ventilation of 4 air changes per hour.

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 20 is mandatory.

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

— The bath must be emptied directly after the contact time and removal of equipment.

— Leave the room directly after application.

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*

See General directions for use.

4.2.4. *Where specific to the use, the 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*

See General directions for use.

4.3. **Use description**

Table 3

Use 4.6: Disinfection of hard surface by spraying for veterinary purpose

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: bacteria Common name: yeasts Common name: fungi Common name: viruses
Field(s) of use	indoor use outdoor use Porous and non-porous hard surfaces in animal husbandry (animal houses, pens), including tables, floors, walls, machinery, hard furniture and equipment, excluding outer surfaces of animal transportation.
Application method(s)	Method: open system: spray treatment Detailed description: Surfaces must be cleaned before disinfection. Disinfection of equipment by spraying (medium pressure); A portable spraying equipment (volume ~ 20 Litres, medium pressure, hand held) is filled with the product dilution and then used for disinfection. Manual dilution (jerry can): Product dilution to the in-use concentration is achieved by an operator in a bucket or spray reservoir. Surfaces must kept wet during disinfection.

Application rate(s) and frequency	Number and timing of application: Prior to use, the product shall be diluted to (all concentrations are expressed as active substance content % w/w): — 2 % for porous surfaces in animal husbandry — 1,5 % for non-porous surfaces in animal husbandry Application rate: 300 ml/m². The minimum contact time is: — 30 minutes for porous and non-porous surfaces in animal husbandry Frequency: once a week for porous and non-porous surfaces in animal husbandry.
Category(ies) of users	professional
Pack sizes and packaging material	30 kilogram (kg) and 65 kg high-density polyethylene (HDPE) jerrycans

4.3.1. *Use-specific instructions for use*

Clean surfaces before use.

Dose the concentrate in the reservoir of the pressure cleaner to obtain an in-use concentration of:

— 2 % for porous surfaces in animal husbandry

— 1,5 % for non-porous surfaces in animal husbandry

Use a pressure washer or other mechanical sprayer to apply the diluted solution at an application rate of 300 ml spray /m². The disinfection solution shall remain in contact with the surface to be disinfected for at least:

30 minutes for porous and non-porous surfaces in animal husbandry

4.3.2. *Use-specific risk mitigation measures*

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 references to this act and the European Standards.

Mixing and loading (automated):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 4 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

— Wear coverall (EN 13034 or equivalent)

Mixing and loading (manual):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 10 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

— Wear coverall (EN 13034 or equivalent)

Spraying, hard surfaces:

— Ensure that application is carried out in areas with a minimum ventilation of 4 air changes per hour.

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 20 is mandatory.

— Animals are not allowed to be present during treatment

— Do not allow re-entry of animals to the disinfected facilities before 15 minutes after disinfection.

— Leave the room directly after application.

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*

See General directions for use.

4.3.4. *Where specific to the use, the 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*

See General directions for use.

4.4. **Use description**

Table 4

Use 4.10: Disinfection of hard surfaces by medium pressure spraying

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area
Target organism(s) (including development stage)	Common name: bacteria Common name: yeasts Common name: fungi
Field(s) of use	indoor use outdoor use Non-porous hard surfaces (e.g. floors, walls, work surfaces including food contact surfaces) in industry, institutions and health care facilities.
Application method(s)	Method: open system: spray treatment Detailed description: Surfaces must be cleaned before disinfection. Disinfection of equipment by spraying (medium pressure); A portable spraying equipment (volume ~ 20 Liters, medium pressure, hand held) is filled with the product dilution and then used for disinfection.
Application rate(s) and frequency	Number and timing of application: For bacteria and yeasts and fungi, the product shall be diluted to 1,5 % (active substance % w/w) prior to use. The minimum contact time is: — 5 minutes for bacteria and yeasts — 15 minutes for fungi. Application rate: 300 ml/m^2 Apply the product at room temperature Frequency: once a day

Category(ies) of users	professional
Pack sizes and packaging material	220 L HDPE Drum 600 litre (L) and 1 000L HDPE intermediate bulk container (IBC) 30 kilogram (kg) and 65 kg high-density polyethylene (HDPE) jerrycans

4.4.1. *Use-specific instructions for use*

Thoroughly clean and rinse the surface. Remove excess water from the surface before disinfection.

Dose the concentrate in the reservoir of the pressure cleaner to obtain a suitable in-use concentration of the active substance (see application rate section).

Automatic dilution (IBC, drum): The product is pumped into the reservoir of the pressure cleaner where it is mixed with water to the required dose. There is no manual dilution step.

Manual dilution (jerry can): Product dilution to the in-use concentration is achieved by an operator in a bucket or spray reservoir.

Surfaces must kept wet during disinfection.

Use a pressure washer or other mechanical sprayer to apply the diluted solution at an application rate of 300 ml/m^2. The disinfection solution shall remain in contact with the surface to be disinfected 5 minutes for removal of bacteria and yeasts, and 15 minutes to remove fungi.

Premises shall be well-ventilated before re-entry

4.4.2. *Use-specific risk mitigation measures*

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 references to this act and the European Standards.

Mixing and loading (automated):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 4 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

Mixing and loading (manual):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 10 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

Spraying of hard surfaces:

— Ensure that application is carried out in areas with a minimum ventilation of 4 air changes per hour.

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 20 is mandatory.

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

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*

See General directions for use.

4.4.4. *Where specific to the use, the 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*

See General directions for use.

5. **GENERAL DIRECTIONS FOR USE OF THE META SPC 4**

5.1. **Instructions for use**

Unless otherwise stated on the label, products must be diluted for use.

Follow the label instructions for use dilutions and application volumes according to the use required.

Surfaces shall be cleaned before disinfection.

See Use-specific instructions for use per use

5.2. **Risk mitigation measures**

— No access of third parties during application/treatment/maintenance, unless the required personal protective equipment as prescribed for the professional user is worn.

— Re-entry is only permitted once the air concentration for hydrogen peroxide has dropped below 0,9 ppm (1,25 mg/m^3) or relevant lower national reference value

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

First-Aid measures

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

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. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

Protection of first-aiders: In case of insufficient ventilation, wear suitable respiratory equipment. Protective suit

Fire-fighting measures

Extinguishing media:

Suitable extinguishing media: In case of fire involving the product: Water spray. Unsuitable extinguishing media: All other extinguishants

Special hazards arising from the substance or mixture: Contact with combustible material may cause fire. Thermal decomposition gives: Oxygen, that can enhance sites of combustion. Hazards of over-pressurization in containers exposed to heat: explosion risk.

Precautions for fire-fighters: Specific methods: Keep upwind and operate from safe distance. In case of fire, remove exposed containers. Containers/tanks should be cooled with water spray.

Special protective actions for fire-fighters: Wear self-contained breathing apparatus and protective suit.

Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Evacuate non-essential staff and those not equipped with individual protection apparatus. Prohibit contact with eyes. Avoid contact with skin. Avoid inhalation of vapours. Prohibit all sources of sparks and ignition - Do not smoke. If safe to do so, plug or seal off leak. Remove all incompatible substances.

Environmental precautions: Dam up with sand or inert earth (do not use combustible materials). Dilute with large quantities of water before discharging into sewers or into the environment

Methods and materials for containment and cleaning up:

Recovery: Soak up with inert absorbent material. Never reintroduce the spilled product in another container. Risk of decomposition.

Neutralisation: Dilute with water.

Elimination: Dispose of rinse water as waste water.

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

Waste treatment

Disposal of product: Dilute with water.

Disposal of packaging: Clean container with water. Recycle or incinerate at an approved waste disposal site. In accordance with local and national regulations.

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

Shelf-life of 1 year.

The product should be stored in the original packaging.

Protect from light.

Store below 54 °C.

6. **OTHER INFORMATION**

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, p. 11).

Professionals (including industrial, professionals) mean trained professional if this is required by national legislation.

Please be aware of the European reference value of 1,25 mg/m³ for the active substance hydrogen peroxide (CAS No.: 7722-84-1) which was used for the risk assessment for the biocidal product (please be aware that relevant lower national limit values may apply).

The full titles of the EN standards referenced in the Risk mitigation measures are:

— EN 13832 – Footwear protecting against chemicals

— EN 374 – Protective gloves against dangerous chemicals and micro-organisms

— EN 405 – Respiratory protective devices

— EN 166 – Eye protection against chemicals

— EN 13034 – Protective coverall against liquid chemicals – type 6

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4**

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

Trade name(s)			Antisept WO 30	Market area: EU	
Authorisation number			EU-0035039-0013 1-4		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	30 % (w/w)

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

Trade name(s)			PEROXAL 30 AHS	Market area: EU	
			ALBONE 30	Market area: EU	
			PEROXAL 30 HSD	Market area: EU	
			PEROXAL 30 SD	Market area: EU	
			PEROXAL 30 ED	Market area: EU	
Authorisation number			EU-0035039-0014 1-4		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	30 % (w/w)

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

Trade name(s)			ELIGERM PSA	Market area: EU	
			ELIGERM PEROX	Market area: EU	
Authorisation number			EU-0035039-0015 1-4		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	30 % (w/w)

1. **META SPC 5 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 5 identifier**

Identifier	Meta SPC: 6

1.2. **Suffix to the authorisation number**

Number	1-5

1.3. **Product type(s)**

Product type(s)	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area

2. **META SPC 5 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 5**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	>=25–<=25 % (w/w)

2.2. **Type(s) of formulation of the meta SPC 5**

Formulation type(s)	AL Any other liquid

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5**

Hazard statements	H272: May intensify fire; oxidiser. H302: Harmful if swallowed. H318: Causes serious eye damage. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	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. P261: Avoid breathing vapours. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P280: Wear eye protection. P280: Wear face protection. P301+P312: IF SWALLOWED: Call a POISON CENTER/doctor 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. P330: Rinse mouth.

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Use 6.1: Room disinfection with Nebulized Hydrogen Peroxide

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: bacteria Common name: yeasts Common name: fungi
Field(s) of use	indoor use Disinfection of dry surfaces in closed rooms and enclosed spaces by Nebulized hydrogen peroxide, e.g. laboratory equipment, hospital rooms, emergency vehicles, food and feed areas.
Application method(s)	Method: - Nebulization Detailed description: Nebulization to disinfect hard non-porous surfaces.
Application rate(s) and frequency	Number and timing of application: The product is a 25 % w/w hydrogen peroxide solution and is ready-to-use. Room volume: 30–150 m^3 Diffusion rate: Bacteria and yeast: 10 ml/m^3 product Fungi: 11,4 ml/m^3 product Diffusion time: Dependant upon the room volume. Temperature: room temperature Recommended relative humidity: 40 to 80 % Contact time: 3 hours Frequency: maximum 3 times per 24 hour period.
Category(ies) of users	professional
Pack sizes and packaging material	Sealed 1L HDPE cartridges.

4.1.1. *Use-specific instructions for use*

Thoroughly clean and rinse the surface. Remove excess water from the surface before disinfection, if appropriate install biological and chemical indicators to validate the disinfection cycle.

The nebulizer devices are fed by connecting a drum of hydrogen peroxide solution (automated transfer and dosing) or by inserting a sealed cartridge. Professionals seal the enclosed space or room and initiate the decontamination cycle.

During this step, exposure to hydrogen peroxide is not possible as access to the fog-treated area is denied. The decontamination process starts with a dehumidification phase in which the machine removes water from the atmosphere.

In the disinfection phase, the machine injects nebulized hydrogen peroxide, depending on the device, into the sealed area for decontamination to get the hydrogen peroxide concentration up to the effective levels.

The succeeding disinfection phase lasts 3 hours during which the hydrogen peroxide fog disinfects the surfaces inside the sealed space.

After finishing the decontamination phase, the aeration cycle starts. This step has variable durations since it is complete when sensors inform that the hydrogen peroxide level is below 1,25 mg/m³. Biological and chemical indicators can then be collected to confirm the efficacy of the decontamination cycle

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.

Access to the treated area is denied during the disinfection process.

4.1.2. *Use-specific risk mitigation measures*

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 references to this act and the European Standards.

All surfaces must be cleaned before disinfection

— Insert the sealed cartridge as delivered by the manufacturer into the machine. See equipment user's manual for proper equipment preparation and set-up

— The applicator must placard or post all entrances to the treatment enclosure with signs bearing:

— The signal word 'DANGER' in red. 'Area under treatment, DO NOT ENTER/NO ENTRY.'

— The statement 'This sign may only be removed 1 hour after the treatment enclosure has been aerated to hydrogen peroxide levels less than or equal to 1,25 mg/m³'.

— Identification of hydrogen peroxide as a hazard associated with the treatment process.

— Contact information for the applicator.

The following PPE are required if emergency re-entry is required before the air concentration has dropped below the AEC:

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

— Wear a protective coverall (at least type 6, EN 13034 or equivalent) (coverall material to be specified by the authorisation holder within the product information).

— Wear chemical resistant boots (EN 13832 or equivalent)

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 40 is mandatory.

— During exposure time, the treated room may only be entered wearing suitable personal protective equipment

For other instructions see General directions of use.

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*

See General directions for use.

4.1.4. *Where specific to the use, the 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*

See General directions for use.

4.2. **Use description**

Table 2

Use 6.4b: Disinfection of food packaging by aseptic technology (spray/vapour)

Product type	PT04: Food and feed area
Target organism(s) (including development stage)	Common name: bacteria Common name: Bacterial spores Common name: yeasts
Field(s) of use	indoor use Disinfection of cardboard or plastic packaging (e.g. bricks, bottles, cups, pouches …) before filling with sensitive food products to be stored at room temperature for a long period
Application method(s)	Method: closed system Detailed description: Surfaces must be cleaned before disinfection. 'spray technology': the packaging material (preformed cardboard containers, plastic bottles and plastic preforms) is exposed to hydrogen peroxide vapor generated from a 25 % hydrogen peroxide solution which is sprayed and then vaporized, ensuring the complete sterilization of the inner surface of the packaging. Further hot sterile air removes hydrogen peroxide residual in the brick or bottle. The sterile packaging is then filled with sterile food products and sealed. The disinfection machines are closed systems with no access to professionals during operation. In case of maintenance, the machine is stopped, hydrogen peroxide is removed (vapour extraction).
Application rate(s) and frequency	Number and timing of application: Validated food processing systems that have control over the contaminant load on food packaging surfaces or food processing equipment prior to fill may vary concentration, temperature, and/or contact time to achieve the required level of disinfection. Container volume range (generally from 100 to 2 000 ml) may also influence operating parameters. The biocidal product is 25 % w/w hydrogen peroxide solutions and is ready-to-use. Spray technology: Application rate: 20–30 g H_2O_2/m^3 Contact time: 12 seconds Temperature: 130 °C
Category(ies) of users	professional
Pack sizes and packaging material	600 litre (L) and 1 000L HDPE intermediate bulk container (IBC) 30 kilogram (kg) and 65 kg high-density polyethylene (HDPE) jerrycans

4.2.1. *Use-specific instructions for use*

All surfaces must be cleaned before disinfection.

The user shall always carry out a microbiological validation of the disinfection process in the machine to be used with the devices to be used after which a protocol for disinfection of these machine can be made and used thereafter.

4.2.2. *Use-specific risk mitigation measures*

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 references to this act and the European Standards.

Mixing and loading (automated) or maintenance of the machine:

1. Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 4 is mandatory.

2. Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, polyvinyl chloride (PVC).

3. The use of eye protection (chemical goggles/face shield) (EN 166 or equivalent) during handling of the product is mandatory.

4. Wear coverall (EN 13034 or equivalent)

Mixing and loading (manual):

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 10 is mandatory.

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC.

— The use of eye protection (chemical goggles/face shield) (EN 166 or equivalent) during handling of the product is mandatory.

During use of the machine the following risk mitigation measures (RMMs) apply:

— All surfaces must be cleaned before disinfection.

— Machines to be operated in areas where local exhaust ventilation (LEV) or forced ventilation is operational.

— Wear coverall (EN 13034 or equivalent)

For other instructions, see General directions for use.

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*

See General directions for use.

4.2.4. *Where specific to the use, the 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*

See General directions for use.

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

5.1. **Instructions for use**

Unless otherwise stated on the label, products must be diluted for use.

Follow the label instructions for use dilutions and application volumes according to the use required.

Surfaces shall be cleaned before disinfection.

See Use-specific instructions for use per use

5.2. **Risk mitigation measures**

— No access of third parties during application/treatment/maintenance, unless the required personal protective equipment as prescribed for the professional user is worn.

— Re-entry is only permitted once the air concentration for hydrogen peroxide has dropped below 0,9 ppm (1,25 mg/m^3) or relevant lower national reference value

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

First-Aid measures

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

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. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

Protection of first-aiders: In case of insufficient ventilation, wear suitable respiratory equipment. Protective suit

Fire-fighting measures

Extinguishing media:

Suitable extinguishing media: In case of fire involving the product: Water spray. Unsuitable extinguishing media: All other extinguishants

Special hazards arising from the substance or mixture: Contact with combustible material may cause fire. Thermal decomposition gives: Oxygen, that can enhance sites of combustion. Hazards of over-pressurization in containers exposed to heat: explosion risk.

Precautions for fire-fighters: Specific methods: Keep upwind and operate from safe distance. In case of fire, remove exposed containers. Containers/tanks should be cooled with water spray.

Special protective actions for fire-fighters: Wear self-contained breathing apparatus and protective suit.

Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Evacuate non-essential staff and those not equipped with individual protection apparatus. Prohibit contact with eyes. Avoid contact with skin. Avoid inhalation of vapours. Prohibit all sources of sparks and ignition - Do not smoke. If safe to do so, plug or seal off leak. Remove all incompatible substances.

Environmental precautions: Dam up with sand or inert earth (do not use combustible materials). Dilute with large quantities of water before discharging into sewers or into the environment

Methods and materials for containment and cleaning up:

Recovery: Soak up with inert absorbent material. Never reintroduce the spilled product in another container. Risk of decomposition.

Neutralisation: Dilute with water.

Elimination: Dispose of rinse water as waste water.

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

Waste treatment

Disposal of product: Dilute with water.

Disposal of packaging: Clean container with water. Recycle or incinerate at an approved waste disposal site. In accordance with local and national regulations.

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

Shelf-life of 1 year.

The product should be stored in the original packaging.

Protect from light.

Store below 54 °C.

6. **OTHER INFORMATION**

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, p. 11).

Professionals (including industrial, professionals) mean trained professional if this is required by national legislation.

Please be aware of the European reference value of 1,25 mg/m³ for the active substance hydrogen peroxide (CAS No.: 7722-84-1) which was used for the risk assessment for the biocidal product (please be aware that relevant lower national limit values may apply).

The full titles of the EN standards referenced in the Risk mitigation measures are:

— EN 13832 – Footwear protecting against chemicals

— EN 374 – Protective gloves against dangerous chemicals and micro-organisms

— EN 405 – Respiratory protective devices

— EN 166 – Eye protection against chemicals

— EN 13034 – Protective coverall against liquid chemicals – type 6

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5**

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

Trade name(s)	VALSTERANE 25 SHP	Market area: EU
Authorisation number	EU-0035039-0016 1-5	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	25 % (w/w)

1. **META SPC 6 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 6 identifier**

Identifier	Meta SPC: 7

1.2. **Suffix to the authorisation number**

Number	1-6

1.3. **Product type(s)**

Product type(s)	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area

2. **META SPC 6 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 6**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	>=25–<=25 % (w/w)

2.2. **Type(s) of formulation of the meta SPC 6**

Formulation type(s)	AL Any other liquid

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6**

Hazard statements	H272: May intensify fire; oxidiser. H302: Harmful if swallowed. H318: Causes serious eye damage. H412: Harmful to aquatic life with long lasting effects.

Precautionary statements	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. P261: Avoid breathing vapours. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P280: Wear eye protection. P280: Wear face protection. P301+P312: IF SWALLOWED: Call a POISON CENTER/doctor 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. P330: Rinse mouth.

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Use 7.1: Room disinfection with Nebulized Hydrogen Peroxide

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: bacteria Common name: yeasts Common name: fungi
Field(s) of use	indoor use Disinfection of dry surfaces in closed rooms and enclosed spaces by Nebulized hydrogen peroxide, e.g. laboratory equipment, hospital rooms, emergency vehicles, food and feed areas.
Application method(s)	Method: - Nebulization Detailed description: Nebulization to disinfect hard non-porous surfaces.
Application rate(s) and frequency	Number and timing of application: The product is a 25 % w/w hydrogen peroxide solution and is ready-to-use. Room volume: 30–150 m^3 Diffusion rate: Bacteria and yeast: 10 ml/m^3 product Fungi: 11,4 ml/m^3 product Diffusion time: Dependant upon the room volume. Temperature: room temperature Recommended relative humidity: 40 to 80 % Contact time: 3 hours Frequency: maximum 3 times per 24 hour period.
Category(ies) of users	professional
Pack sizes and packaging material	Sealed 1L HDPE cartridges.

4.1.1. *Use-specific instructions for use*

Thoroughly clean and rinse the surface. Remove excess water from the surface before disinfection, if appropriate install biological and chemical indicators to validate the disinfection cycle.

The nebulizer devices are fed by connecting a drum of hydrogen peroxide solution (automated transfer and dosing) or by inserting a sealed cartridge. Professionals seal the enclosed space or room and initiate the decontamination cycle.

During this step, exposure to hydrogen peroxide is not possible as access to the fog-treated area is denied. The decontamination process starts with a dehumidification phase in which the machine removes water from the atmosphere.

In the disinfection phase, the machine injects nebulized hydrogen peroxide, depending on the device, into the sealed area for decontamination to get the hydrogen peroxide concentration up to the effective levels.

The succeeding disinfection phase lasts 3 hours during which the hydrogen peroxide fog disinfects the surfaces inside the sealed space.

After finishing the decontamination phase, the aeration cycle starts. This step has variable durations since it is complete when sensors inform that the hydrogen peroxide level is below 1,25 mg/m^3. Biological and chemical indicators can then be collected to confirm the efficacy of the decontamination cycle

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.

Access to the treated area is denied during the disinfection process.

4.1.2. *Use-specific risk mitigation measures*

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 references to this act and the European Standards.

All surfaces must be cleaned before disinfection

— Insert the sealed cartridge as delivered by the manufacturer into the machine. See equipment user's manual for proper equipment preparation and set-up

— The applicator must placard or post all entrances to the treatment enclosure with signs bearing:

— The signal word 'DANGER' in red. 'Area under treatment, DO NOT ENTER/NO ENTRY.'

— The statement 'This sign may only be removed 1 hour after the treatment enclosure has been aerated to hydrogen peroxide levels less than or equal to 1,25 mg/m^3".

— Identification of hydrogen peroxide as a hazard associated with the treatment process.

— Contact information for the applicator.

The following PPE are required if emergency re-entry is required before the air concentration has dropped below the AEC:

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

— Wear a protective coverall (at least type 6, EN 13034 or equivalent) (coverall material to be specified by the authorisation holder within the product information).

— Wear chemical resistant boots (EN 13832 or equivalent)

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 40 is mandatory.

— During exposure time, the treated room may only be entered wearing suitable personal protective equipment

For other instructions see General directions of use.

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*

See General directions for use.

4.1.4. *Where specific to the use, the 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*

See General directions for use.

5. **GENERAL DIRECTIONS FOR USE OF THE META SPC 6**

5.1. **Instructions for use**

Unless otherwise stated on the label, products must be diluted for use.

Follow the label instructions for use dilutions and application volumes according to the use required.

Surfaces shall be cleaned before disinfection.

See Use-specific instructions for use per use

5.2. **Risk mitigation measures**

— No access of third parties during application/treatment/maintenance, unless the required personal protective equipment as prescribed for the professional user is worn.

— Re-entry is only permitted once the air concentration for hydrogen peroxide has dropped below 0,9 ppm (1,25 mg/m^3) or relevant lower national reference value

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

First-Aid measures

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

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. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

Protection of first-aiders: In case of insufficient ventilation, wear suitable respiratory equipment. Protective suit

Fire-fighting measures

Extinguishing media:

Suitable extinguishing media: In case of fire involving the product: Water spray Unsuitable extinguishing media: All other extinguishants

Special hazards arising from the substance or mixture: Contact with combustible material may cause fire. Thermal decomposition gives: Oxygen, that can enhance sites of combustion. Hazards of over-pressurization in containers exposed to heat: explosion risk.

Precautions for fire-fighters: Specific methods: Keep upwind and operate from safe distance. In case of fire, remove exposed containers. Containers/tanks should be cooled with water spray.

Special protective actions for fire-fighters: Wear self-contained breathing apparatus and protective suit.

Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Evacuate non-essential staff and those not equipped with individual protection apparatus. Prohibit contact with eyes. Avoid contact with skin. Avoid inhalation of vapours. Prohibit all sources of sparks and ignition - Do not smoke. If safe to do so, plug or seal off leak. Remove all incompatible substances.

Environmental precautions: Dam up with sand or inert earth (do not use combustible materials). Dilute with large quantities of water before discharging into sewers or into the environment

Methods and materials for containment and cleaning up:

Recovery: Soak up with inert absorbent material. Never reintroduce the spilled product in another container. Risk of decomposition.

Neutralisation: Dilute with water.

Elimination: Dispose of rinse water as waste water.

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

Waste treatment

Disposal of product: Dilute with water.

Disposal of packaging: Clean container with water. Recycle or incinerate at an approved waste disposal site. In accordance with local and national regulations.

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

Shelf-life of 1 year.

The product should be stored in the original packaging.

Protect from light.

Store below 54 °C.

6. **OTHER INFORMATION**

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, p. 11).

Professionals (including industrial, professionals) mean trained professional if this is required by national legislation.

Please be aware of the European reference value of 1,25 mg/m^3 for the active substance hydrogen peroxide (CAS No.: 7722-84-1) which was used for the risk assessment for the biocidal product (please be aware that relevant lower national limit values may apply).

The full titles of the EN standards referenced in the Risk mitigation measures are:

— EN 13832 – Footwear protecting against chemicals

— EN 374 – Protective gloves against dangerous chemicals and micro-organisms

— EN 405 – Respiratory protective devices

— EN 166 – Eye protection against chemicals

— EN 13034 – Protective coverall against liquid chemicals – type 6

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6**

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

Trade name(s)			PEROXAL 25 TNB		Market area: EU
Authorisation number			EU-0035039-0017 1-6		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	25 % (w/w)

1. **META SPC 7 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 7 identifier**

Identifier	Meta SPC: 8

1.2. **Suffix to the authorisation number**

Number	1-7

1.3. **Product type(s)**

Product type(s)	PT02: Disinfectants and algaecides not intended for direct application to humans or animals

2. **META SPC 7 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 7**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	>=35–<=35 % (w/w)

2.2. **Type(s) of formulation of the meta SPC 7**

Formulation type(s)	AL Any other liquid

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7**

Hazard statements	H272: May intensify fire; oxidiser. 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.
Precautionary statements	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. 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 eye protection. P280: Wear face protection. P301+P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P330: Rinse mouth. P332+P313: If skin irritation occurs: Get medical advice. P332+P313: If skin irritation occurs: Get medical attention. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up.

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Use 8.9: Disinfection of internal surfaces of pharmaceutical/medical isolators

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Target organism(s) (including development stage)	Common name: Bacterial spores Common name: fungi Common name: bacteria Common name: yeasts

Field(s) of use	indoor use Professional disinfection of inner surfaces of isolators (leak-proof enclosures where operators manipulate sterile products without direct contact) by vaporized hydrogen peroxide.
Application method(s)	Method: closed system Detailed description: Vaporisation of hydrogen peroxide
Application rate(s) and frequency	Number and timing of application: The product is a 35 % w/w hydrogen peroxide solution and is ready-to-use. Volume: 0,04–0,61 m^3 Application rate (recommended): 230–390 g product /m^3 Contact time: 8 to 60 minutes Temperature: 20 °C Recommended humidity: up to 50 % Aeration time: suitable to reach a 1 ppm residual H_2O_2 content in the enclosure Frequency: maximum 3 times per day
Category(ies) of users	professional
Pack sizes and packaging material	1L and 5L HDPE bottle

4.1.1. *Use-specific instructions for use*

Thoroughly clean and rinse the surface. Remove excess water from the surface before disinfection, if appropriate. Install biological and chemical indicators to validate the disinfection cycle.

The vaporiser unit is fed by connecting a 1l bottle of hydrogen peroxide solution.

The decontamination process starts with a dehumidification phase in which the machine removes water from the atmosphere.

In the disinfection phase, the machine injects vaporised hydrogen peroxide into the sealed area for decontamination to get the hydrogen peroxide concentration up to the effective level. During this phase, hydrogen peroxide vapour disinfects the surfaces inside the sealed space.

After finishing the decontamination phase, the aeration cycle starts. This step has variable durations since it is complete when sensors inform that the hydrogen peroxide level is below a defined value.

Biological and chemical indicators can then be collected to confirm the efficacy of the decontamination cycle. No one will actually enter the isolator after disinfection. No re-entry requirement is therefore necessary.

Application rates may vary from one equipment to the other. It is possible to use the product with different decontamination devices or for isolators with different volumes. The user shall always carry out a microbiological validation of the disinfection in the isolator to be disinfected with the devices to be used after which a protocol for disinfection of these isolators can be made and used thereafter.

4.1.2. *Use-specific risk mitigation measures*

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 references to this act and the European Standards.

Insert the sealed cartridge as delivered by the manufacturer into the VHP machine. See equipment user's manual for proper equipment preparation and set-up.

The applicator must placard or post all entrances to the treatment enclosure with signs bearing:

— The signal word 'DANGER' in red. 'Area under treatment, DO NOT ENTER/NO ENTRY.'

— The statement 'This sign may only be removed 1 hour after the treatment enclosure has been aerated to hydrogen peroxide levels less than or equal to 1,25 mg/m^3".

— Identification of hydrogen peroxide as a hazard associated with the treatment process.

— Contact information for the applicator.

The following PPE are required if emergency re-entry is required before the air concentration has dropped below the AEC:

— Wear protective chemical resistant gloves (EN 374 or equivalent) during product handling phase. Examples of preferred materials for insulating gloves: neoprene, PVC.

— The use of eye protection (chemical goggles/face shield) (EN166 or equivalent) during handling of the product is mandatory.

— Wear a protective coverall (at least type 6, EN 13034 or equivalent) (coverall material to be specified by the authorisation holder within the product information).

— Wear chemical resistant boots (EN 13832 or equivalent).

— Use of respiratory protective equipment (RPE) (EN 405 or equivalent) with APF 40 is mandatory.

— During exposure time, the treated room may only be entered wearing suitable personal protective equipment.

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*

See General directions for use.

4.1.4. *Where specific to the use, the 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*

See General directions for use.

5. **GENERAL DIRECTIONS FOR USE OF THE META SPC 7**

5.1. **Instructions for use**

Unless otherwise stated on the label, products must be diluted for use.

Follow the label instructions for use dilutions and application volumes according to the use required.

Surfaces shall be cleaned before disinfection.

See Use-specific instructions for use per use

5.2. **Risk mitigation measures**

— No access of third parties during application/treatment/maintenance, unless the required personal protective equipment as prescribed for the professional user is worn.

— Re-entry is only permitted once the air concentration for hydrogen peroxide has dropped below 0,9 ppm (1,25 mg/m^3) or relevant lower national reference value

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

First-Aid measures

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.

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. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

Fire-fighting measures

Extinguishing media:

Suitable extinguishing media: In case of fire involving the product: Water spray Unsuitable extinguishing media: All other extinguishants.

Special hazards arising from the substance or mixture: Contact with combustible material may cause fire. Thermal decomposition gives: Oxygen, that can enhance sites of combustion. Hazards of over-pressurization in containers exposed to heat: explosion risk.

Precautions for fire-fighters: Specific methods: Keep upwind and operate from safe distance. In case of fire, remove exposed containers. Containers/tanks should be cooled with water spray.

Special protective actions for fire-fighters: Wear self-contained breathing apparatus and protective suit.

Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Evacuate non-essential staff and those not equipped with individual protection apparatus. Prohibit contact with eyes. Avoid contact with skin. Avoid inhalation of vapours. Prohibit all sources of sparks and ignition - Do not smoke. If safe to do so, plug or seal off leak. Remove all incompatible substances.

Environmental precautions: Dam up with sand or inert earth (do not use combustible materials). Dilute with large quantities of water before discharging into sewers or into the environment

Methods and materials for containment and cleaning up:

Recovery: Soak up with inert absorbent material. Never reintroduce the spilled product in another container. Risk of decomposition.

Neutralisation: Dilute with water.

Elimination: Dispose of rinse water as waste water.

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

Waste treatment

Disposal of product: Dilute with water.

Disposal of packaging: Clean container with water. Recycle or incinerate at an approved waste disposal site. In accordance with local and national regulations.

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

Shelf-life of 1 year.

The product should be stored in the original packaging.

Protect from light.

Store below 54 °C.

6. **OTHER INFORMATION**

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, p. 11).

Professionals (including industrial, professionals) mean trained professional if this is required by national legislation.

Please be aware of the European reference value of 1,25 mg/m³ for the active substance hydrogen peroxide (CAS No.: 7722-84-1) which was used for the risk assessment for the biocidal product (please be aware that relevant lower national limit values may apply).

The full titles of the EN standards referenced in the Risk mitigation measures are:

— EN 13832 – Footwear protecting against chemicals

— EN 374 – Protective gloves against dangerous chemicals and micro-organisms

— EN 405 – Respiratory protective devices

— EN 166 – Eye protection against chemicals

— EN 13034 – Protective coverall against liquid chemicals – type 6

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 7**

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

Trade name(s)			HYDROCYDE	Market area: EU	
			RAIDOX	Market area: EU	
Authorisation number			EU-0035039-0018 1-7		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	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)			RAIDOX	Market area: EU	
Authorisation number			EU-0035039-0019 1-7		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
hydrogen peroxide	hydrogen peroxide	Active substance	7722-84-1	231-765-0	35 % (w/w)