



2024/2432

17.9.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2432

of 16 September 2024

granting a Union authorisation for the biocidal product family 'Diversey Hydrogen Peroxide Product Family' 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 31 January 2017, Diversey Europe Operations B.V. ('the applicant') submitted an application to the European Chemicals Agency ('the Agency') in accordance with Article 43(1) of Regulation (EU) No 528/2012 and Article 4 of Commission Implementing Regulation (EU) No 414/2013 ⁽²⁾ for Union authorisation of the same biocidal product family, as referred to in Article 1 of Implementing Regulation (EU) No 414/2013, named 'Diversey Hydrogen Peroxide Product Family', of product-type 4, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-WV029790-00 in the Register for Biocidal Products. The application also indicated the case number of the related reference biocidal product family 'Evonik's Hydrogen Peroxide Product Family' later authorised by Commission Implementing Regulation (EU) 2023/2183 ⁽³⁾, recorded in that register under case number BC-UE029056-42.
- (2) The biocidal product family 'Diversey Hydrogen Peroxide Product Family' 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-type 4.
- (3) On 9 September 2022, the Agency submitted to the Commission its opinion ⁽⁴⁾ and the draft summary of the biocidal product characteristics ('SPC') of 'Diversey Hydrogen Peroxide Product Family' in accordance with Article 6 of Implementing Regulation (EU) No 414/2013.
- (4) In its opinion, the Agency concludes that the proposed differences between the biocidal product family 'Diversey Hydrogen Peroxide Product Family' and the related reference biocidal product family 'Evonik's Hydrogen Peroxide Product Family' are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 ⁽⁵⁾, and that based on the assessment of the related reference biocidal product family 'Evonik's Hydrogen Peroxide Product Family' and subject to compliance with the draft SPC, the same biocidal product family 'Diversey Hydrogen Peroxide Product Family' meets the conditions laid down in Article 19(6) of Regulation (EU) No 528/2012.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>.

⁽²⁾ Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 125, 7.5.2013, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2013/414/oj).

⁽³⁾ Commission Implementing Regulation (EU) 2023/2183 of 18 October 2023 granting a Union authorisation for the biocidal product family Evonik's Hydrogen Peroxide Product Family in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L, 2023/2183, 19.10.2023, ELI: http://data.europa.eu/eli/reg_impl/2023/2183/oj).

⁽⁴⁾ European Chemicals Agency opinion of 9 September 2022 on the Union authorisation of the same biocidal product family 'Diversey Hydrogen Peroxide Product Family', <https://echa.europa.eu/opinions-on-union-authorisation>

⁽⁵⁾ Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2013/354/oj).

- (5) On 15 May 2024, the Agency transmitted to the Commission the revised draft SPCs of 'Diversey Hydrogen Peroxide Product Family' in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (6) On 13 June 2024, the Agency informed the Commission that, due to an error, the Agency's opinion and the draft SPC submitted to the Commission include a reference to product-types 2 and 4, while the applicant had restricted the application to uses of product-type 4.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the same biocidal product family 'Diversey Hydrogen Peroxide Product Family' for product-type 4.
- (8) The expiry date of the authorisation should be aligned with the expiry date of the authorisation of the related reference biocidal product family 'Evonik's Hydrogen Peroxide Product Family'.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0029435-0000 is hereby granted to Diversey Europe Operations B.V for the making available on the market and use of the same biocidal product family 'Diversey Hydrogen Peroxide Product Family' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 7 October 2024 until 31 October 2033.

Article 2

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

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

Done at Brussels, 16 September 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

Diversey Hydrogen Peroxide Product Family

Product type(s)

PT04: Food and feed area

Authorisation number EU-0029435-0000

R4BP asset number EU-0029435-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	Diversey Hydrogen Peroxide Product Family
------	---

1.2. Product type(s)

Product type(s)	PT04: Food and feed area
-----------------	--------------------------

1.3. Authorisation holder

Name and address of the authorisation holder	Name	Diversey Europe Operations B.V.
	Address	Regulatory team Maarssenbroeksedijk 2 3542 DN Utrecht NL
Authorisation number	EU-0029435-0000	
R4BP asset number	EU-0029435-0000	
Date of the authorisation	7 October 2024	
Expiry date of the authorisation	31 October 2033	

1.4. Manufacturer(s) of the product

Name of manufacturer	Diversey Europe Operations B.V.
Address of manufacturer	Maarssenbroeksedijk 2 3542DN Utrecht Netherlands (the)
Location of manufacturing sites	Strada Statale 235 26010 Bagnolo Cremasco (CR) Italy Rembrandtlaan 414 7545 ZW Enschede Netherlands (the) Cotes Park Industrial Estate DE55 4PA Somercotes Alfreton United Kingdom of Great Britain and Northern Ireland (the) Avenida Conde Duque 5, 7 y 9 ; Poligono Industrial La Postura 28343 Valdemoro (Madrid) Spain

	Morschheimer Strasse 12 67292 Kirchheimbolanden Germany
Name of manufacturer	Evonik Antwerpen NV
Address of manufacturer	Tijsmanstunnel West 2040 Antwerpen Belgium
Location of manufacturing sites	Tijsmanstunnel West 2040 Antwerpen Belgium
Name of manufacturer	Evonik Operations GmbH
Address of manufacturer	Rellinghauser Straße 1-11 45128 Essen Germany
Location of manufacturing sites	Untere Kanalstr. 3 79618 Rheinfelden Germany
Name of manufacturer	Evonik Peroxid GmbH
Address of manufacturer	Industriestraße 1 9721 Weißenstein Austria
Location of manufacturing sites	Industriestraße 1 9721 Weißenstein Austria
Name of manufacturer	Evonik Peroxide Netherlands BV
Address of manufacturer	Hettenheuvelweg 37 /39 1101 BM Amsterdam Netherlands (the)
Location of manufacturing sites	Oosterhorn 14 9936 HD Farmsum Netherlands (the)
Name of manufacturer	Evonik Peroxide Spain, S.L.U.
Address of manufacturer	C/ Afueras s/n. 50784 La Zaida Spain
Location of manufacturing sites	C/ Afueras s/n. 50784 La Zaida Spain
Name of manufacturer	ELETTROCHIMICA VALLE STAFFORA SPA
Address of manufacturer	VIA TORTONA 73 27055 Rivanazzano Italy
Location of manufacturing sites	VIA TORTONA 73 27055 Rivanazzano Italy
Name of manufacturer	Brenntag SA
Address of manufacturer	Zone d'Activités les Sauzets 07340 Andance France
Location of manufacturing sites	Zone d'Activités les Sauzets 07340 Andance France 12 sente des Jumelles 76710 Montville France

Name of manufacturer	CHEPORT, spol. s r.o.
Address of manufacturer	Lhotsko 93 763 12 Vizovice Czechia
Location of manufacturing sites	Lhotsko 93 763 12 Vizovice Czechia

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

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

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

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

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

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

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

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

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

2.2. Type(s) of formulation

Formulation type(s)	SL Soluble concentrate
---------------------	------------------------

PART II

SECOND INFORMATION LEVEL - META SPC(S)**1. META SPC 1 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 1 identifier**

Identifier	Meta SPC: META Divosan Spray
------------	------------------------------

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		active substance	7722-84-1	231-765-0	35-49,9 % (w/w)

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

Formulation type(s)	SL Soluble concentrate
---------------------	------------------------

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	<p>H302: Harmful if swallowed.</p> <p>H315: Causes skin irritation.</p> <p>H318: Causes serious eye damage.</p> <p>H335: May cause respiratory irritation.</p> <p>H412: Harmful to aquatic life with long lasting effects.</p> <p>H272: May intensify fire; oxidiser.</p>
Precautionary statements	<p>P261: Avoid breathing vapours.</p> <p>P264: Wash hands thoroughly after handling.</p> <p>P270: Do not eat, drink or smoke when using this product.</p> <p>P271: Use only outdoors or in a well-ventilated area.</p> <p>P273: Avoid release to the environment.</p> <p>P280: Wear protective gloves/eye protection/face protection..</p> <p>P301 + P312: IF SWALLOWED: Call a POISON CENTER/doctor/physician if you feel unwell.</p> <p>P330: Rinse mouth.</p> <p>P302 + P352: IF ON SKIN: Wash with plenty of water/soap.</p> <p>P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P312: Call a POISON CENTER/doctor/physician if you feel unwell.</p> <p>P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P310: Immediately call a POISON CENTER/doctor.</p> <p>P332 + P313: If skin irritation occurs: Get medical advice.</p> <p>P403 + P233: Store in a well-ventilated place. Keep container tightly closed.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents to/in accordance with local requirements.</p> <p>P501: Dispose of container to/in accordance with local requirements.</p> <p>P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</p> <p>P220: Keep away from clothing or other combustible materials.</p> <p>P370 + P378: In case of fire: Use water to extinguish.</p>

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Aseptic packaging in food and feed industries

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: Bacterial spores Development stage: Bacterial spores
Field(s) of use	indoor use Disinfection of food packaging material in closed aseptic packaging systems by sprayed or nebulised product.
Application method(s)	Method: Nebulising Detailed description: Automated spraying or nebulising in closed systems.
Application rate(s) and frequency	Application rate: In-use concentration: 35 % (w/w) hydrogen peroxide. Product concentration in hot air: 10,83 g/kg Dilution (%): For disinfection of bacteria, yeasts and bacterial spores the product should be diluted to 35 % (w/w) hydrogen peroxide. For example, for a product containing 49,9 % (w/w) hydrogen peroxide: add 700 ml product to 357 ml water to achieve a dilution of 35 % (w/w) hydrogen peroxide. Number and timing of application: Automated chemo-thermal disinfectant processes. Temperature: ≥ 100 °C Contact time: at least 5,5 seconds
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1, 5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20 m³

4.1.1. Use-specific instructions

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

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

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

Contact time: at least 5,5 seconds.

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

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

4.1.2. *Use-specific risk mitigation measures*

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

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

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

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

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

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

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

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

4.2. **Use description**

Table 2

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

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-

Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: fungi Development stage: no data
Field(s) of use	indoor use Disinfection of distributing and storing installations for drinking water
Application method(s)	Method: CIP (Cleaning in place) Detailed description: Disinfecting the interior surfaces of closed systems by CIP
Application rate(s) and frequency	Application rate: 4,7 % (w/w) hydrogen peroxide. Dilution (%): For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7 % (w/w) hydrogen peroxide. For example, in case of a 35 % (w/w) hydrogen peroxide product: add 114 ml product to 819 ml water. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Contact time: at least 3 hours Frequency: Daily/if required Temperature: room temperature
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1, 5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20 m ³

4.2.1. Use-specific instructions

CIP (Cleaning in place): Clean before disinfection (Remove all deposits and dirt by a pre-flush or pre-scrape, and when necessary, a pre-soak treatment). Circulate the diluted product through the system under conditions of increased turbulence and flow velocity. After 3 hours contact time, pipelines and tanks are rinsed with water before refilled with drinking water. For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7 % (w/w) hydrogen peroxide. For example, for a product containing 35 % (w/w) hydrogen peroxide: add 114 ml product to 819 ml water to achieve a dilution of 4,7 % (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.

4.2.2. Use-specific risk mitigation measures

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

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

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

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

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

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

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

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

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

4.3. **Use description**

Table 3

Disinfection of non-porous hard surfaces and equipment by immersion

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: no data Common name: Bacteria Development stage: no data</p> <p>Scientific name: no data Common name: Yeasts Development stage: no data</p> <p>Scientific name: no data Common name: fungi Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>Equipment in both food and drink industries, large scale catering kitchens and large scale canteens.</p>
Application method(s)	<p>Method: open system: immersion</p> <p>Detailed description: Manual immersion of equipment in closed baths. Automated immersion of equipment in closed</p>
Application rate(s) and frequency	<p>Application rate: 8,1 % (w/w) hydrogen peroxide.</p> <p>Dilution (%): For disinfection of bacteria, yeasts and fungi the product should be diluted to 8,1 % (w/w) hydrogen peroxide. For example, in case of a 35 % (w/w) hydrogen peroxide product: add 200 ml product to 738 ml water. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.</p> <p>Number and timing of application: Contact time: 60 minutes Frequency: Daily/if required Temperature: room temperature</p>

Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1, 5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20 m³

4.3.1. Use-specific instructions

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

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

4.3.2. Use-specific risk mitigation measures

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

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

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

Observe label instructions.

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

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

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

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

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

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

4.4. Use description

Table 4

Disinfection of surfaces by cleaning in place (CIP)

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: no data Common name: Bacteria Development stage: no data</p> <p>Scientific name: no data Common name: Yeasts Development stage: no data</p> <p>Scientific name: no data Common name: fungi Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>Disinfection of food contact inner surfaces of pipe work and tank systems in food and feed industry</p>
Application method(s)	<p>Method: Cleaning in Place (CIP)</p> <p>Detailed description: Disinfecting the interior surfaces of closed systems by Cleaning In Place (CIP).</p>
Application rate(s) and frequency	<p>Application rate: 4,7 % (w/w) hydrogen peroxide.</p> <p>Dilution (%): For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7 % (w/w) hydrogen peroxide. For example, in case of a 35 % (w/w) hydrogen peroxide product: add 114 ml product to 819 ml water. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.</p> <p>Number and timing of application: Contact time: at least 3 hours Frequency: Daily/if required Temperature: room temperature</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>HDPE bottle 1, 5 litres</p> <p>HDPE jerry can 10, 20, 30, 60 litres</p> <p>HDPE drum 200 litres</p> <p>HDPE container 1 000 litres</p> <p>HDPE ISO tank 20 m³</p>

4.4.1. Use-specific instructions

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

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

4.4.2. *Use-specific risk mitigation measures*

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

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

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

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

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

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

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

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

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

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

5.1. **Instructions for use**

See use specific instructions for each use.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures for each use.

Observe label instructions.

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

First aid instructions

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

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

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

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

If symptoms: Call 112/ambulance for medical assistance.

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

Accidental release measures

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

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

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

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

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

Advice on protection against fire and explosion:

Store away from direct sunlight and heat sources.

Store away from sources of ignition - No smoking.

Store away from flammable substances.

Store away from incompatible substances.

Storage:

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

Store in clean, dry and well-ventilated places.

Transport and store container in upright position only.

Always close container tightly after removal of product.

Avoid leakage and residues of the product on the containers.

Advice on common storage:

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

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

Shelf-life:

24 months

6. OTHER INFORMATION

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

EN 16321 - Eye and face protection for occupational users

EN 374 – Protective gloves against chemicals and micro-organisms

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

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)			Divosan HS 35 VT68	Market area: EU		
			Divosan HS 35	Market area: EU		
Authorisation number			EU-0029435-0001 1-1			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
Hydrogen peroxide		active substance	7722-84-1	231-765-0	35 % (w/w)	

1. **META SPC 2 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 2 identifier**

Identifier	Meta SPC: META Divosan Bath
------------	-----------------------------

1.2. **Suffix to the authorisation number**

Number	1-2
--------	-----

1.3. **Product type(s)**

Product type(s)	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		active substance	7722-84-1	231-765-0	35-49,9 % (w/w)

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

Formulation type(s)	SL Soluble concentrate
---------------------	------------------------

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	<p>H302: Harmful if swallowed.</p> <p>H315: Causes skin irritation.</p> <p>H318: Causes serious eye damage.</p> <p>H335: May cause respiratory irritation.</p> <p>H412: Harmful to aquatic life with long lasting effects.</p> <p>H272: May intensify fire; oxidiser.</p>
Precautionary statements	<p>P261: Avoid breathing vapours.</p> <p>P264: Wash hands thoroughly after handling.</p> <p>P270: Do not eat, drink or smoke when using this product.</p> <p>P271: Use only outdoors or in a well-ventilated area.</p> <p>P273: Avoid release to the environment.</p> <p>P280: Wear protective gloves/eye protection/face protection..</p> <p>P301 + P312: IF SWALLOWED: Call a POISON CENTER/doctor/physician if you feel unwell.</p> <p>P330: Rinse mouth.</p> <p>P302 + P352: IF ON SKIN: Wash with plenty of water/soap.</p> <p>P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P312: Call a POISON CENTER/doctor/physician if you feel unwell.</p> <p>P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P310: Immediately call a POISON CENTER/doctor.</p> <p>P332 + P313: If skin irritation occurs: Get medical advice.</p> <p>P403 + P233: Store in a well-ventilated place. Keep container tightly closed.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents to/in accordance with local requirements.</p> <p>P501: Dispose of container to/in accordance with local requirements.</p> <p>P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</p> <p>P220: Keep away from clothing or other combustible materials.</p> <p>P370 + P378: In case of fire: Use water to extinguish.</p>

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Aseptic packaging in food and feed industries

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: no data Common name: Bacteria Development stage: no data</p> <p>Scientific name: no data Common name: Yeasts Development stage: no data</p> <p>Scientific name: no data Common name: Bacterial spores Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>Disinfection of food and feed packaging material in closed aseptic packaging systems by dipping, spraying or nebulising</p>
Application method(s)	<p>Method: Dipping, nebulising and spraying</p> <p>Detailed description: Automated dipping in closed systems Automated nebulising and spraying in closed systems</p>
Application rate(s) and frequency	<p>Application rate: In-use concentration: 35 % (w/w) hydrogen peroxide.</p> <p>Dilution (%): For disinfection of bacteria, yeasts and bacterial spores, the product should be diluted to 35 % (w/w) hydrogen peroxide. For example, for a product containing 49,9 % (w/w) hydrogen peroxide; add 700 ml product to 357 ml water to achieve a dilution of 35 % (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.</p> <p>Number and timing of application: automated chemo-thermal disinfection processes. In-use concentration: 35 % (w/w) hydrogen peroxide</p> <p>Spraying or nebulizing: Temperature: $\geq 100^{\circ}\text{C}$ Contact time: at least 5,5 seconds</p> <p>Dipping: Temperature: $\geq 80^{\circ}\text{C}$ Contact time: at least 2,5 seconds</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>HDPE bottle 1, 5 litres</p> <p>HDPE jerry can 10, 20, 30, 60 litres</p> <p>HDPE drum 200 litres</p> <p>HDPE container 1 000 litres</p> <p>HDPE ISO tank 20m³</p>

4.1.1. *Use-specific instructions*

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

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

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

Contact time: at least 5,5 seconds

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

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

Contact time: at least 2,5 seconds

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

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

4.1.2. *Use-specific risk mitigation measures*

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

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

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

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

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

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

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

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

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

4.2. **Use description**

Table 2

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

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: no data Common name: Bacteria Development stage: no data</p> <p>Scientific name: no data Common name: Yeasts Development stage: no data</p> <p>Scientific name: no data Common name: fungi Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>Cleaning and disinfection of distributing and storing installations for drinking water</p>
Application method(s)	<p>Method: CIP (Cleaning in place)</p> <p>Detailed description: Disinfecting the interior surfaces of closed systems by CIP</p>
Application rate(s) and frequency	<p>Application rate: 4,7 % (w/w) hydrogen peroxide</p> <p>Dilution (%): For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7 % (w/w) hydrogen peroxide. For example, in case of a 35 % (w/w) hydrogen peroxide product: add 114 ml product to 819 ml water. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.</p> <p>Number and timing of application: Contact time: at least 3 hours Frequency: Daily/if required Temperature: room temperature</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>HDPE bottle 1, 5 litres</p> <p>HDPE jerry can 10, 20, 30, 60 litres</p> <p>HDPE drum 200 litres</p> <p>HDPE container 1 000 litres</p> <p>HDPE ISO tank 20 m³</p>

4.2.1. Use-specific instructions

CIP (Cleaning in place): Clean prior to disinfection. Circulate the diluted product through the system under conditions of increased turbulence and flow velocity. After 3 hours contact time, pipelines and tanks are rinsed with water before refilled with drinking water. For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7 % (w/w) hydrogen peroxide. For example, for a product containing 35 % (w/w) hydrogen peroxide: add 114 ml product to 819 ml water to achieve a dilution of 4,7 % (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.

4.2.2. Use-specific risk mitigation measures

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent/face shield, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN 374 or equivalent and RPE (APF = 10) during mixing and loading. Technical RMM: Local exhaust ventilation (50 %) and good standard of general ventilation (3 ACH). Observe label instructions. Gloves and coverall material to be specified by the authorisation holder within the product information. See section 6 for the full titles of the EN standards.

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

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

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

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

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

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

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

4.3. Use description

Table 3

Disinfection of non-porous hard surfaces and equipment by immersion

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: fungi Development stage: no data

Field(s) of use	indoor use Equipment in both food and drink industries, large scale catering kitchens and large scale canteens.
Application method(s)	Method: open system: immersion Detailed description: Manual immersion of equipment in closed baths. Automated immersion of equipment in closed baths.
Application rate(s) and frequency	Application rate: 8,1 % (w/w) hydrogen peroxide. Dilution (%): For disinfection of bacteria, yeasts and fungi the product should be diluted to 8,1 % (w/w) hydrogen peroxide. For example, in case of a 35 % (w/w) hydrogen peroxide product: add 200 ml product to 738 ml water. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Contact time: at least 60 mininutes Frequency: Daily/if required Temperature: room temperature
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1, 5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20 m ³

4.3.1. Use-specific instructions

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

Immersion:

Equipment in the food and feed industry is disinfected by immersion. Pre-clean the equipment. The disinfection solution should be diluted into vats (i.e. pouring or pumping the product into vats). The equipment to be disinfected is manually or automatically placed into these vats (closed baths) and taken out after a contact time of at least 60 minutes. After the disinfection procedure is completed, equipment is rinsed with water. The disinfection solution in the immersion/dipping bath should be replaced after each disinfection cycle.

4.3.2. Use-specific risk mitigation measures

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

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

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

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

Dipping bath has to be placed in a separate room. For use only in areas inaccessible to the general public. Professional users without PPE and RPE (APF=10) are not allowed to enter the disinfection room. Keep the bath closed during disinfection, only open to load and discharge.

Observe label instructions.

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

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

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

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

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

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

4.4. **Use description**

Table 4.

Disinfection of surfaces by cleaning in place (CIP)

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: fungi Development stage: no data
Field(s) of use	indoor use Disinfection of food contact inner surfaces of pipe work and tank systems in food and feed industry
Application method(s)	Method: Cleaning in Place (CIP) Detailed description: Disinfecting the interior surfaces of closed systems by Cleaning In Place (CIP).
Application rate(s) and frequency	Application rate: 4,7 % (w/w) hydrogen peroxide. Dilution (%): For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7 % (w/w) hydrogen peroxide. For example, in case of a 35 %(w/w) hydrogen peroxide product: add 114 ml product to 819 ml water. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.

	Number and timing of application: Contact time: at least 3 hours Frequency: Daily/if required Temperature: room temperature
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1, 5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20 m ³

4.4.1. Use-specific instructions

Clean prior to disinfection. For disinfection of bacteria yeasts and fungi the product should be diluted to 4,7 % (w/w) hydrogen peroxide. For example, for a product containing 35 % (w/w) hydrogen peroxide; add 114 ml product to 819 ml water to achieve a dilution of 4,7 % (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.

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

4.4.2. Use-specific risk mitigation measures

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

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

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

Observe label instructions.

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

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

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

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

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

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

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 2

5.1. Instructions for use

See use specific instructions for each use.

5.2. Risk mitigation measures

See use specific risk mitigation measures for each use.

Observe label instructions.

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

First aid instructions

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

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

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

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

If symptoms: Call 112/ambulance for medical assistance.

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

Accidental release measures

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

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

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

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

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

Advice on protection against fire and explosion:

Store away from direct sunlight and heat sources.

Store away from sources of ignition - No smoking.

Store away from flammable substances.

Store away from incompatible substances.

Storage:

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

Store in clean, dry and well-ventilated places.

Transport and store container in upright position only.

Always close container tightly after removal of product.

Avoid leakage and residues of the product on the containers.

Advice on common storage:

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

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

Shelf-life:

24 months

6. OTHER INFORMATION

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

EN 16321 - Eye and face protection for occupational users

EN 374 – Protective gloves against chemicals and micro-organisms

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

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

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

Trade name(s)	Divozon 35 VT66	Market area: EU			
	Divozon 35	Market area: EU			
	Divosan BA 35 VT66	Market area: EU			
	Divosan BA 35	Market area: EU			
	Divozon 350	Market area: EU			
	Divozon 350 Bath	Market area: EU			
Authorisation number		EU-0029435-0002 1-2			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		active substance	7722-84-1	231-765-0	35 % (w/w)

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	Meta SPC: META Divosan D
------------	--------------------------

1.2. Suffix to the authorisation number

Number	1-3
--------	-----

1.3. Product type(s)

Product type(s)	PT04: Food and feed area
-----------------	--------------------------

2. META SPC 3 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 3

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

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

Formulation type(s)	SL Soluble concentrate
---------------------	------------------------

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects. H272: May intensify fire; oxidiser.
Precautionary statements	P261: Avoid breathing vapours. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P271: Use only outdoors or in a well-ventilated area. P273: Avoid release to the environment. P280: Wear protective clothing / eye protection / face protection. P301+P312: IF SWALLOWED: Call a POISON CENTER/ doctor/physician if you feel unwell. P330: Rinse mouth.

	<p>P302+P352: IF ON SKIN: Wash with plenty of water/ soap.</p> <p>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P312: Call a POISON CENTER/doctor/physician if you feel unwell.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P310: Immediately call a POISON CENTER / doctor.</p> <p>P332+P313: If skin irritation occurs: Get medical advice.</p> <p>P403+P233: Store in a well-ventilated place. Keep container tightly closed.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents to / in accordance with local requirements.</p> <p>P501: Dispose of container to / in accordance with local requirements.</p> <p>P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</p> <p>P220: Keep away from clothing or other combustible materials.</p> <p>P370+P378: In case of fire: Use water to extinguish.</p>
--	--

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

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

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: no data Common name: Bacteria Development stage: no data</p> <p>Scientific name: no data Common name: Yeasts Development stage: no data</p> <p>Scientific name: no data Common name: fungi Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>Disinfection of distributing and storing installations for drinking water.</p>

Application method(s)	Method: CIP (Cleaning in place) in closed systems Detailed description: Disinfecting the interior surfaces of closed systems by CIP
Application rate(s) and frequency	Application rate: 4,7 % (w/w) hydrogen peroxide Dilution (%): For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide. For example, in the case of a product containing 35% (w/w) hydrogen peroxide: add 114 ml product to 819 ml water to achieve a dilution of 4,7% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Contact time: at least 3 hours Frequency: Daily / if required Temperature: room temperature
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1, 5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20m ³

4.1.1. Use-specific instructions

CIP (Cleaning in place): Clean prior to disinfection. Circulate the diluted product through the system under conditions of increased turbulence and flow velocity. After 3 hours contact time, pipelines and tanks are rinsed with water before refilled with drinking water. For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide.

For example, for a product containing 35% (w/w) hydrogen peroxide: add 114 ml product to 819 ml water to achieve a dilution of 4,7% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.

4.1.2. Use-specific risk mitigation measures

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

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

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

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

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

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

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

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

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

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

4.2. **Use description**

Table 2

Disinfection of non-porous hard surfaces and equipment by immersion

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: no data Common name: Bacteria Development stage: no data</p> <p>Scientific name: no data Common name: Yeasts Development stage: no data</p> <p>Scientific name: no data Common name: fungi Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>Equipment in both food and drink industries, large scale catering kitchens and large scale canteens.</p>
Application method(s)	<p>Method: Open system: immersion</p> <p>Detailed description: Manual immersion of equipment in closed baths. Automated immersion of equipment in closed baths.</p>
Application rate(s) and frequency	<p>Application rate: 8,1% (w/w) hydrogen peroxide.</p> <p>Dilution (%): For disinfection of bacteria, yeasts and fungi the product should be diluted to 8,1% (w/w) hydrogen peroxide. For example, for a product containing 35% (w/w) hydrogen peroxide: add 200 ml product to 738 ml water to achieve a dilution of 8,1% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.</p> <p>Number and timing of application: Contact time: 60 minutes Frequency: Daily / if required Temperature: room temperature</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>HDPE bottle 1, 5 litres</p> <p>HDPE jerry can 10, 20, 30, 60 litres</p> <p>HDPE drum 200 litres</p> <p>HDPE container 1 000 litres</p> <p>HDPE ISO tank 20m³</p>

4.2.1. Use-specific instructions

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

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

4.2.2. Use-specific risk mitigation measures

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

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC. No access to the room is permitted during disinfection without wearing adequate PPE and RPE as described above.

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

Observe label instructions.

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

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

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

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

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

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

4.3. Use description

Table 3

Disinfection of surfaces by cleaning in place (CIP)

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-

Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: fungi Development stage: no data
Field(s) of use	indoor use Disinfection of food contact inner surfaces of pipe work and tank systems in food and feed industry.
Application method(s)	Method: CIP in closed systems Detailed description: Disinfecting the interior surfaces of closed systems by Cleaning In Place (CIP).
Application rate(s) and frequency	Application rate: 4,7% (w/w) hydrogen peroxide. Dilution (%): For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide. For example, for a product containing 35% (w/w) hydrogen peroxide: add 114 ml product to 819 ml water to achieve a dilution of 4,7% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Contact time: at least 3 hours Frequency: Daily / if required Temperature: room temperature
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1, 5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20m ³

4.3.1. Use-specific instructions

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

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

4.3.2. Use-specific risk mitigation measures

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

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

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

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

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

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

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

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

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

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

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

5.1. **Instructions for use**

See use specific instructions for each use.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures for each use.

Observe label instructions.

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

First aid instructions

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

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

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

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

If symptoms: Call 112/ambulance for medical assistance.

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

Accidental release measures

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

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

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

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

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage**Advice on protection against fire and explosion**

Store away from direct sunlight and heat sources.

Store away from sources of ignition - No smoking.

Store away from flammable substances.

Store away from incompatible substances.

Storage

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

Store in clean, dry and well- ventilated places.

Transport and store container in upright position only.

Always close container tightly after removal of product.

Avoid leakage and residues of the product on the containers.

Advice on common storage

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

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

Shelf-life:

24 months

6. OTHER INFORMATION

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

EN 16321 - Eye and face protection for occupational users

EN 374 – Protective gloves against chemicals and micro-organisms

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

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)			Divosan D30	Market area: EU		
			Divosan D30 VT91	Market area: EU		
Authorisation number			EU-0029435-0003 1-3			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
Hydrogen peroxide		active substance	7722-84-1	231-765-0	35 % (w/w)	