

2024/2587

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2587

of 2 October 2024

granting a Union authorisation for the biocidal product family 'Divosan PAA products' 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 21 December 2023, Diversey Europe Operations B.V. submitted to the European Chemicals Agency ('the Agency') an application 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 'Divosan PAA products', of product-types 2, 3 and 4, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-CB091187-53 in the Register for Biocidal Products ('the Register'). The application also indicated the authorisation number of the related reference biocidal product family 'Airedale PAA product family', authorised by Commission Implementing Regulation (EU) 2023/1200 (³) with the authorisation number EU-0028970-0000.
- (2) The same biocidal product family 'Divosan PAA products' contains peracetic acid 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 14 March 2024, the Agency submitted to the Commission its opinion (4) and the draft summary of the biocidal product characteristics ('SPC') of 'Divosan PAA products' in accordance with Article 6 of Implementing Regulation (EU) No 414/2013.
- (4) In its opinion, the Agency concludes that the proposed differences between 'Divosan PAA products' and the related reference biocidal product family 'Airedale PAA product family' are limited to information which can be the subject of an administrative change in accordance with Article 11 of Commission Implementing Regulation (EU) No 354/2013 (³), and that based on the assessment of the related reference biocidal product family 'Airedale PAA product family' and subject to compliance with the draft SPC, 'Divosan PAA products' meets the conditions laid down in Article 19(1) and (6) of Regulation (EU) No 528/2012.

^{(&}lt;sup>1</sup>) 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) 2023/1200 of 21 June 2023 granting a Union authorisation for the biocidal product family 'Airedale PAA product family' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 159, 22.6.2023, p. 3, ELI: http://data.europa.eu/eli/reg_impl/2023/1200/oj)

^{(&}lt;sup>4</sup>) ECHA opinion of 14.3.2024 on the Union authorisation of the same biocidal product family 'Divosan PAA products', Opinion number UBS-C-1719835-03-00/F, 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 21 March 2024, the Agency transmitted to the Commission the draft SPC of 'Divosan PAA products' in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012 and based on the SPC of the related reference biocidal product family 'Airedale PAA product family'.
- (6) 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 'Divosan PAA products'.
- (7) The expiry date of this authorisation should be aligned with the expiry date of the authorisation of the related reference biocidal product family 'Airedale PAA product family'.
- (8) 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-0032463-0000 is hereby granted to Diversey Europe Operations B.V. for the making available on the market and use of the same biocidal product family 'Divosan PAA products' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 23 October 2024 until 30 June 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, 2 October 2024.

For the Commission The President Ursula VON DER LEYEN ANNEX

Summary of product characteristics for a biocidal product family

Divosan PAA products

Product type(s)

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

PT03: Veterinary hygiene

PT04: Food and feed area

Authorisation number EU-0032463-0000

R4BP asset number EU-0032463-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

| Name | Divosan PAA products |
|------|----------------------|
| | |

1.2. Product type(s)

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

1.3. Authorisation holder

| | Name | Diversey Europe Operations B.V. |
|--|-----------------|---|
| Name and address of the authorisation holder | Address | Regulatory team Maarssenbroeksedijk 2 3542 DN Utrecht NL |
| Authorisation number | EU-0032463-0000 | |
| R4BP asset number | EU-0032463-0000 | |
| Date of the authorisation | 23 October 2024 | |
| Expiry date of the authorisation | 30 June 2033 | |

1.4. Manufacturer(s) of the product

| Name of manufacturer | Airedale Chemical Company Ltd |
|-------------------------|--|
| Address of manufacturer | Airedale Mills, Skipton Road, Cross Hills BD20 7BX Keighley United Kingdom of Great Britain and Northern Ireland (the) |

| Name of manufacturer | Diversey Europe Operations B.V. |
|---------------------------------|--|
| Address of manufacturer | Maarssenbroeksedijk 2 3542DN Utrecht Netherlands (the) |
| Location of manufacturing sites | Diversey Europe Operations B.V. site 1 Strada Statale 235 26010 Bagnolo Cremasco (CR) Italy |
| | Diversey Europe Operations B.V. site 2 Rembrandtlaan 414 7545 ZW Enschede Netherlands (the) |
| | Diversey Europe Operations B.V. site 3 Cotes Park Industrial Estate DE55 4PA Somercotes Alfreton United Kingdom of Great Britain and Northern Ireland (the) |
| | Diversey Europe Operations B.V. site 4 AvenidaConde Duque 5, 7 y 9 ; Poligono Industrial La Postura 28343 Valdemoro (Madrid) Spain |
| | Diversey Europe Operations B.V. site 5 Morschheimer Strasse 12 67292 Kirchheimbolanden Germany |

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

| Active substance | Peracetic acid |
|---------------------------------|--|
| Name of manufacturer | Airedale Chemical Company Ltd |
| Address of manufacturer | Airedale Mills, Skipton Road, Cross Hills BD20 7BX Keighley United Kingdom of Great Britain and Northern Ireland (the) |
| Location of manufacturing sites | Airedale Chemical Company Ltd site 1 Airedale Mills, Skipton Road, Cross Hills BD20 7BX Keighley United Kingdom of Great Britain and Northern Ireland (the) |

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 (%) |
|------------------------|------------------------|---------------------------|------------|-----------|--------------------------|
| Peracetic acid | | active substance | 79-21-0 | 201-186-8 | 4,5 - 15,9 % (w/w) |
| Hydrogen perox- ide | Hydrogen Per- oxide | Non-Active sub- stance | 7722-84-1 | 231-765-0 | 21,62 - 25,97 % (w/w) |

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|-------------|----------------|---------------------------|------------|-----------|-------------------------|
| Acetic Acid | Acetic Acid | Non-Active sub- stance | 64-19-7 | 200-580-7 | 7,7 - 15,9 % (w/w) |
| HEDP | etidronic acid | Non-Active sub- stance | 2809-21-4 | 220-552-8 | 0,99 - 0,99 % (w/ w) |

2.2. Type(s) of formulation

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

PART II

SECOND INFORMATION LEVEL - META SPC(S)

META SPC 1 ADMINISTRATIVE INFORMATION 1.

1.1. Meta SPC 1 identifier

| Identifier | Meta SPC: Peracetic Acid 5% |
|------------|-----------------------------|
|------------|-----------------------------|

1.2. Suffix to the authorisation number

| | Number 1-1 | |
|--|------------|--|
|--|------------|--|

1.3. Product type(s)

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

META SPC 1 COMPOSITION 2.

2.1. Qualitative and quantitative information on the composition of the meta SPC 1

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|------------------------|------------------------|---------------------------|------------|-----------|--------------------------|
| Peracetic acid | | active substance | 79-21-0 | 201-186-8 | 4,5 - 5,5 % (w/w) |
| Hydrogen perox- ide | Hydrogen Per- oxide | Non-Active sub- stance | 7722-84-1 | 231-765-0 | 21,62 - 24,38 % (w/w) |
| Acetic Acid | Acetic Acid | Non-Active sub- stance | 64-19-7 | 200-580-7 | 7,7 - 9,4 % (w/w) |
| HEDP | etidronic acid | Non-Active sub- stance | 2809-21-4 | 220-552-8 | 0,99 - 0,99 % (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 | H242: Heating may cause a fire. |
|--------------------------|---|
| | H290: May be corrosive to metals. |
| | H302+H312+H332: Harmful if swallowed, in contact with skin or if inhaled. |
| | H314: Causes severe skin burns and eye damage. |
| | H410: Very toxic to aquatic life with long lasting effect |
| | EUH071: Corrosive to the respiratory tract. |
| Precautionary statements | P210: Keep away from heat, hot surfaces, sparks, oper flames and other ignition sources. No smoking. |
| | P234: Keep only in original packaging. |
| | P260: Do not breathe vapours. |
| | P260: Do not breathe spray. |
| | P264: Wash exposed skin thoroughly after handling. |
| | P271: Use only outdoors or in a well-ventilated area. |
| | P273: Avoid release to the environment. |
| | P280: Wear protective gloves. |
| | P280: Wear protective clothing. |
| | P280: Wear eye protection. |
| | P280: Wear face protection. |
| | P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting. |
| | P303+P361+P353: IF ON SKIN (or hair): Take off imm diately all contaminated clothing. Rinse skin with wate [or shower]. |
| | P303+P361+P353: IF ON SKIN (or hair): Take off imm diately all contaminated clothing. Rinse skin with wate [or shower]. |
| | P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if pasent and easy to do. Continue rinsing. |
| | P310: Immediately call a POISON CENTER. |
| | P310: Immediately call a doctor. |
| | P363: Wash contaminated clothing before reuse. |
| | P391: Collect spillage. |
| | P403+P233: Store in a well-ventilated place. Keep container tightly closed. |

| |
|---|
| P411: Store at temperatures not exceeding 30°C/86°F. P501: Dispose of contents to a licensed hazardous-waste collection point. |
| P501: Dispose of container to a licensed hazardous-waste collection point. |

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

CIP including in pharmaceutical and cosmetic industry

| Product type | PT02: Disinfectants and algaecides not intended for direct applica- tion to humans or animals |
|--|---|
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Scientific name: - Common name: Bacteria Development stage: - |
| | Scientific name: - Common name: Yeasts Development stage: - |
| | Scientific name: - Common name: fungi Development stage: - |
| | Scientific name: - Common name: Viruses Development stage: - |
| Field(s) of use | indoor use |
| | General (including pharmaceutical and cosmetic industry) Disinfection of hard and non-porous surfaces by CIP procedures (with circulation) |
| Application method(s) | Method: CIP - Manual or automated dosing |
| | Detailed description: The diluted product shall be transferred to equipment by manual dosing or automated dosing. Final rinsing (with potable water) is mandatory: after the disinfection procedure, treated surfaces must be rinsed with water and the water must be drained into the sewer system. |
| Application rate(s) and frequency | Application rate: at room temperature, for 15 minutes contact time • Active against bacteria and yeasts 0,02 % PAA (e.g. 0,4 % product with 5 % PAA, that is 4 ml product/litre) • Active against bacteria, yeasts and fungi : 0,1 % PAA (e.g. 2% product with 5 % PAA, that is 20 ml product/ litre) • Active against bacteria, yeasts, fungi and viruses: 0,15 % PAA (e.g. 3 % product with 5 % PAA, that is 30 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. |

| | Dilution (%): 0,4-3 % |
|-----------------------------------|--|
| | Number and timing of application: 1-2 applications per day |
| Category(ies) of users | industrial ; professional |
| Pack sizes and packaging material | HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres HDPE drum with PP bung: 200 litres HDPE IBC with HDPE screw cap: 1 000 litres |

4.1.1. Use-specific instructions

See general directions for use

4.1.2. Use-specific risk mitigation measures

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

Surface disinfection by spraying or pouring (followed by wiping for a homogenous distribution) including in pharmaceutical and cosmetic industries

| Product type | PT02: Disinfectants and algaecides not intended for direct applica- tion to humans or animals |
|--|--|
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Scientific name: - Common name: Bacteria Development stage: - |
| | Scientific name: - Common name: Yeasts Development stage: - |
| | Scientific name: - Common name: fungi Development stage: - |
| | Scientific name: - Common name: Viruses Development stage: - |

| Field(s) of use | indoor use General (including pharmaceutical and cosmetic industry) Disinfection of hard and non-porous surfaces by spraying or pour- ing |
|-----------------------------------|---|
| Application method(s) | Method: Spraying or pouring (followed by wiping for a homoge- nous distribution) Detailed description: The diluted product shall be placed in and sprayed with a trigger spray bottle or poured onto the equipment or surface to be disin- fected (followed by wiping for a homogenous distribution). |
| Application rate(s) and frequency | Application rate: at room temperature, for 15 minutes contact time • Active against bacteria, yeasts, fungi and viruses: 0,15 % PAA (e.g. 3 % product with 5 % PAA, that is 30 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. |
| | Dilution (%): 3 % Number and timing of application: 1-2 applications per day |
| Category(ies) of users | industrial ; professional |
| Pack sizes and packaging material | HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres HDPE drum with PP bung: 200 litres HDPE IBC with HDPE screw cap: 1 000 litres |

4.2.1. Use-specific instructions

See general directions for use

4.2.2. Use-specific risk mitigation measures

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

Surface disinfection by spraying or pouring (followed by wiping for a homogenous distribution) for veterinary hygiene

| Product type | PT03: Veterinary hygiene |
|--|---|
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Viruses Development stage: - |
| Field(s) of use | indoor use WITH prior cleaning By spraying: On hard and non-porous and porous surfaces By pouring: ONLY on hard/non-porous surfaces |
| Application method(s) | Method: Spraying or pouring (followed by wiping for homogenous distribution) Detailed description: The diluted product shall be placed in and sprayed with a trigger spray bottle or poured onto the equipment or surface to be disin-fected (followed by wiping for homogenous distribution).Cleaning of the surface prior to disinfection is mandatory. Do not use equipment and surfaces, or allow animals/poultry to enter the treated area until product is completely absorbed to the surface or air dried. |
| Application rate(s) and frequency | Application rate: at +10 °C for 5 minutes contact time • Active against bacteria, yeasts and viruses: 0,2 % PAA (e.g. 4 % product with 5 % PAA, that is 40 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 4 % Number and timing of application: Disinfection of animal housing takes place once animals have been moved out and the building has been cleaned and cleared of objects not to be disinfected, maximum 1-2 times per day. |
| Category(ies) of users | industrial ; professional |
| Pack sizes and packaging material | HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres HDPE drum with PP bung: 200 litres HDPE IBC with HDPE screw cap: 1 000 litres |

4.3.1. Use-specific instructions

See general directions for use

4.3.2. Use-specific risk mitigation measures

See general directions for use

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

| Disinfection by dipping for veterinary hygiene |
|--|
|--|

| Product type | PT03: Veterinary hygiene |
|--|--|
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Scientific name: - Common name: Bacteria Development stage: - |
| | Scientific name: - Common name: Yeasts Development stage: - |
| | Scientific name: - Common name: Viruses Development stage: - |
| Field(s) of use | indoor use |
| | Disinfection of equipment (hard and non-porous and porous sur- faces by dipping), WITH prior cleaning |
| Application method(s) | Method: Dipping |
| | Detailed description: The equipment to be disinfected must be placed in a dipping bath. Cleaning prior to use is mandatory. |
| Application rate(s) and frequency | Application rate: at +10 °C for 5 min contact time • Active against bacteria, yeasts and viruses: 0,2 % PAA (e.g. 4 % product with 5 % PAA, that is 40 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. |
| | Dilution (%): 4 % |

| | Number and timing of application: 1-2 applications per day maximum | |
|-----------------------------------|--|--|
| Category(ies) of users | industrial ; professional | |
| Pack sizes and packaging material | HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres HDPE drum with PP bung: 200 litres HDPE IBC with HDPE screw cap: 1 000 litres | |

4.4.1. Use-specific instructions

See general directions for use

4.4.2. Use-specific risk mitigation measures

See general directions for use

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

4.5. Use description

Table 5

Disinfection of inner surfaces (tanks, pipes, vessels, filling machines, ...) by CIP in food and feed industry

| Product type | PT04: Food and feed area | | |
|--|---|--|--|
| Where relevant, an exact description of the authorised use | - | | |
| Target organism(s) (including development stage) | Scientific name: - Common name: Bacteria Development stage: - | | |
| | Scientific name: - Common name: Yeasts Development stage: - | | |
| | Scientific name: - Common name: fungi Development stage: - | | |
| | Scientific name: - Common name: Viruses Development stage: - | | |
| Field(s) of use | indoor use | | |
| | In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood) | | |

| | Disinfection of hard and non-porous surfaces by CIP procedures (with circulation) |
|-----------------------------------|--|
| Application method(s) | Method: Manual or automated dosing Detailed description: The diluted product shall be transferred to equipment by manual dosing or automated dosing. For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. For all industries, final rinsing (with potable water) is mandatory: after the disinfection procedure, treated surfaces must be rinsed with water and the water must be drained into the sewer system. |
| Application rate(s) and frequency | Application rate: at room temperature, for 15 minutes contact time • Active against bacteria and yeasts: 0,02 % PAA (e.g. 0,4 % product with 5 % PAA, that is 4 mLml product/litre) • Active against bacteria, yeasts and fungi: 0,1 % PAA (e.g. 2 % product with 5 % PAA, that is 20 ml product/litre) • Active against bacteria, yeasts, fungi and viruses: 0,15 % PAA (e.g. 3 % product with 5 % PAA, that is 30 ml product/ litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. |
| | Dilution (%): 0,4-3 % |
| | Number and timing of application: 1-2 applications per day |
| Category(ies) of users | industrial ; professional |
| Pack sizes and packaging material | HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres HDPE drum with PP bung: 200 litres HDPE IBC with HDPE screw cap: 1 000 litres |

4.5.1. Use-specific instructions

See general directions for use

4.5.2. Use-specific risk mitigation measures

See general directions for use

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

See general directions for use

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

See general directions for use

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

See general directions for use

EN

4.6. Use description

Table 6

Surface disinfection by spraying or pouring (followed by wiping for a homogenous distribution) in food and feed industry

| Product type | PT04: Food and feed area | | |
|--|--|--|--|
| Where relevant, an exact description of the authorised use | - | | |
| Target organism(s) (including development stage) | Scientific name: - Common name: Bacteria Development stage: - | | |
| | Scientific name: - Common name: Yeasts Development stage: - | | |
| | Scientific name: - Common name: fungi Development stage: - | | |
| | Scientific name: - Common name: Viruses Development stage: - | | |
| Field(s) of use | indoor use | | |
| | In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood) Disinfection of hard and non-porous surfaces by spraying or pour- ing | | |
| Application method(s) | Method: Spraying or pouring (followed by wiping for a homoge- nous distribution) | | |
| | Detailed description: The diluted product shall be placed in and sprayed with a trigger spray bottle or poured onto the equipment or surface to be disin- fected (followed by wiping for a homogenous distribution). For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. | | |
| Application rate(s) and frequency | Application rate: at room temperature, for 15 minutes contact time • Active against bacteria, yeasts, fungi and viruses: 0,15 % PAA (e.g. 3 % product with 5 % PAA, that is 30 ml product/litre). The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. | | |
| | Dilution (%): 3 % | | |
| | Number and timing of application: 1-2 applications per day | | |
| Category(ies) of users | industrial ; professional | | |
| Pack sizes and packaging material | HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres HDPE drum with PP bung: 200 litres HDPE IBC with HDPE screw cap: 1 000 litres | | |

4.6.1. Use-specific instructions

See general directions for use

4.6.2. Use-specific risk mitigation measures

See general directions for use

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

See general directions for use

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

See general directions for use

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

See general directions for use

4.7. Use description

Table 7

Disinfection by dipping in food and feed industry

| Product type | PT04: Food and feed area - | | |
|--|---|--|--|
| Where relevant, an exact description of the authorised use | | | |
| Target organism(s) (including development stage) | Scientific name: - Common name: Bacteria Development stage: - | | |
| | Scientific name: - Common name: Yeasts Development stage: - | | |
| | Scientific name: - Common name: fungi Development stage: - | | |
| | Scientific name: - Common name: Viruses Development stage: - | | |
| Field(s) of use | indoor use | | |
| | In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood) Disinfection of equipment (hard and non-porous surfaces) by dip- ping | | |
| Application method(s) | Method: Dipping | | |
| | Detailed description: The equipment to be disinfected shall be placed in a dipping bath. For uses in dairy industries, cleaning prior to the disinfection pro- cedure is mandatory. | | |

| Application rate(s) and frequency | Application rate: at room temperature, for 15 minutes contact time • Active against bacteria, yeasts, fungi and viruses: 0,15 % PAA (e.g. 3 % product with 5 % PAA, that is 30 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): | | |
|-----------------------------------|--|--|--|
| | 3 % Number and timing of application: 1-2 applications per day | | |
| Category(ies) of users | industrial ; professional | | |
| Pack sizes and packaging material | HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres HDPE drum with PP bung: 200 litres HDPE IBC with HDPE screw cap: 1 000 litres | | |

4.7.1. Use-specific instructions

See general directions for use

4.7.2. Use-specific risk mitigation measures

See general directions for use

4.7.3. 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

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

See general directions for use

4.7.5. 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

Disinfection cycle (for surface disinfection ONLY):

- the surfaces to be disinfected must be cleaned before the disinfection procedure, and the user must thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected;
- products must be diluted in potable water before use.

Dilution rate and contact time depends on the use considered. Please refer to the description of application method related to each use.

- Disinfection procedures by CIP:
 - final rinsing step (with potable water).

After the disinfection procedure, CIP vessels (pipework and tanks) are drained and rinsed with water under closed system conditions

- Disinfection procedures by dipping:
 - the solution shall not be re-used.

Use only once a day after production and replace it with a fresh solution daily.

- Disinfection procedures by spraying:
 - wet the surface completely

(application rate > 20 ml/m² but maximum 100ml/m²) in order to keep the surface wet during the required contact time.

— do not use equipment until product is completely absorbed to the surface or air dried.

For PT3 uses:

- do not use equipment and surfaces or allow animals/poultry to enter the treated area until product is completely absorbed to the surface or air dried.
- the products shall not be used for the disinfection of animal transport vehicles.

5.2. Risk mitigation measures

- Wear chemical goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal product, and chemical resistant gloves classified under European Standard EN 374 or equivalent. Goggles, protective clothing and glove material (preferably butyl rubber) 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 titles of the EN standards and legislation.
- Use with adequate ventilation: Use engineering controls to maintain airborne level below exposure limit requirements or guidelines. Atmospheric levels shall be maintained below the exposure guideline. For all wiping and spraying application, a ventilation rate of at least 10 air changes/hour is required in the rooms where the application takes place.
- When respiratory protection is required (that is when the concentration of PAA and/or hydrogen peroxide are above their respective Acute Exposure Concentration (AEC)inhalation (0,5 mg/m3 and 1,25 mg/m3 respectively), use an approved air-purifying or positive-pressure supplied-air respirator depending on the potential airborne concentration.
- Do not use equipment and surfaces or allow animals/poultry to enter the treated area until product is completely absorbed to the surface or air dried.
- Keep out of reach of children and non-target animals and pets.
- Re-entrance into treated area is only allowed once the levels of peracetic acid and hydrogen peroxide in the air are below the AEC inhalation (respectively 0,5 mg/m3 for PAA & 1,25 mg/m3 for hydrogen peroxide)
- No bystanders are allowed in treated area during the application phase.
- Animals shall be removed before treatment takes place.

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

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.

- IF ON SKIN: Immediately wash skin with plenty of water. Take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. After washing the skin: Call 112/ambulance for medical assistance.
- Information to healthcare personnel/doctor: Initiate life support measures, thereafter call a POISON CENTRE
- 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.
- IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Immediately call 112/ ambulance for medical assistance.
- Information to healthcare personnel/doctor: Immediately initiate life support measures, thereafter call a POISON CENTRE.
- If symptoms: Call 112/ambulance for medical assistance.
- If no symptoms: Call a POISON CENTRE or a doctor.
- Information to healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

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

- This biocidal product, when being disposed of in its unused and uncontaminated state, should be treated as a hazardous waste in accordance with Directive 2008/98/EC. Any disposal practices must be in compliance with all national and provincial laws and any municipal or local by-laws governing hazardous waste. Do not dump into any sewers, on the ground, or into any body of water. Avoid release to the environment. High-temperature incineration is an acceptable practice.
- Containers are non-refillable. Do not reuse or refill the containers. Containers should be triple or pressure rinsed with water promptly after they are emptied. They can then be offered for recycling or reconditioning for biocidal products, or they can be punctured and disposed of in a sanitary landfill or by other procedures approved by national and local authorities. Send waste liquid from rinsing of used containers to an approved waste handling facility.

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

- Store between 0 °C and 30 °C
- Store in dark conditions
- Keep in a well-ventilated place. Keep this product in the original container when not in use. Container must be stored and transported in an upright position to prevent spilling the contents through the vent, where fitted.
- Do not store in and avoid contact with aluminium, carbon steel, copper, mild steel, iron.
- Avoid contact with amines, ammonia, strong acids, strong bases, strong oxidizers.
- Shelf-life: Meta-SPC 2 (5 % PAA): 6 months

6. **OTHER INFORMATION**

With respect to the 'Category (ies) of users' note:

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

Full titles of EN standards and legislation referred to in section 5.2:

EN 16321- Eye and face protection for occupational users - Part 1: general requirements.

EN 374 – Protective gloves against dangerous chemicals and micro-organisms. Part 1: terminology and performance requirements for chemical risks.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, (OJ L 312, 22.11.2008, p. 3).

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).

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 Noble VT100 | | Market area: EU | | |
|------------------------|------------------------|-------------------------|---------------------------|---------------------|-----------------|-----------|----------------|
| Authorisation number | | | EU-00 | EU-0032463-0001 1-1 | | | |
| Common name | IUPAC name | Function | | CAS | S number | EC number | Content (%) |
| Peracetic acid | | active substance | | 79-21 | -0 | 201-186-8 | 5 % (w/w) |
| Hydrogen perox- ide | Hydrogen Per- oxide | Non-Active substance | | 7722 | -84-1 | 231-765-0 | 23,513 % (w/w) |
| Acetic Acid | Acetic Acid | Non-Active substance | | 64-19 |)-7 | 200-580-7 | 8,453 % (w/w) |
| HEDP | etidronic acid | Non-Active substance | | 2809 | -21-4 | 220-552-8 | 0,99 % (w/w) |

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

| Identifier | Meta SPC: Peracetic Acid 15 % |
|------------|-------------------------------|
|------------|-------------------------------|

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 PT03: Veterinary hygiene 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 | Function CAS number | | Content (%) | |
|------------------------|------------------------|---------------------------|---------------------|-----------|-------------------------|--|
| Peracetic acid | | active substance | 79-21-0 | 201-186-8 | 14,1 - 15,9 % (w/ w) | |
| Hydrogen perox- ide | Hydrogen Per- oxide | Non-Active sub- stance | 7722-84-1 | 231-765-0 | 23 - 25,97 % (w/ w) | |
| Acetic Acid | Acetic Acid | Non-Active sub- stance | 64-19-7 | 200-580-7 | 14,1 - 15,9 % (w/ w) | |
| HEDP | etidronic acid | Non-Active sub- stance | 2809-21-4 | 220-552-8 | 0,99 - 0,99 % (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 | H242: Heating may cause a fire. |
|--------------------------|--|
| | H290: May be corrosive to metals. |
| | H302: Harmful if swallowed. |
| | H311: Toxic in contact with skin. |
| | H331: Toxic if inhaled. |
| | H314: Causes severe skin burns and eye damage. |
| | H410: Very toxic to aquatic life with long lasting effects. |
| | EUH071: Corrosive to the respiratory tract. |
| Precautionary statements | P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. |
| | P234: Keep only in original packaging. |
| | P260: Do not breathe vapours. |
| | P260: Do not breathe spray. |
| | P264: Wash exposed skin thoroughly after handling. |

| P271: Use only outdoors or in a well-ventilated area. |
|--|
| P273: Avoid release to the environment. |
| P280: Wear protective gloves. |
| P280: Wear protective clothing. |
| P280: Wear eye protection. |
| P280: Wear face protection. |
| P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting. |
| P303+P361+P353: IF ON SKIN (or hair): Take off imme diately all contaminated clothing. Rinse skin with water [or shower]. |
| 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 an 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. |
| P361+P364: Take off immediately all contaminated clothing and wash it before reuse. |
| P310: Immediately call a doctor. |
| P310: Immediately call a POISON CENTER. |
| P391: Collect spillage. |
| P403+P233: Store in a well-ventilated place. Keep con- tainer tightly closed. |
| P411: Store at temperatures not exceeding 30 °C/86 °F. |
| P501: Dispose of contents to a licensed hazardous-wast collection point. |
| P501: Dispose of container to a licensed hazardous-wast collection point. |

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

CIP, including in pharmaceutical and cosmetic industry

| Product type | PT02: Disinfectants and algaecides not intended for direct applica- tion to humans or animals |
|--|--|
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Scientific name: - Common name: Bacteria Development stage: - |

| | Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: fungi Development stage: - Scientific name: - Common name: Viruses |
|-----------------------------------|---|
| | Development stage: - |
| Field(s) of use | indoor use General (including pharmaceutical and cosmetic industry) Disinfection of hard and non-porous surfaces by CIP procedures (with circulation) |
| Application method(s) | Method: CIP - Manual or automated dosing Detailed description: The diluted product shall be transferred to equipment by manual dosing or automated dosing.Final rinsing (with potable water) is mandatory: after the disinfection procedure, treated surfaces must be rinsed with water and the water must be drained into the sewer system. |
| Application rate(s) and frequency | Application rate: at room temperature, for 15 minutes contact time • Active against bacteria and yeasts: 0,02 % PAA (e.g. 0,135 % product with 15 % PAA, that is 1,35 ml product/litre) • Active against bacteria, yeasts and fungi: 0,1 % PAA (e.g. 0,675 % product with 15 % PAA, that is 6,75 ml product/litre) • Active against bacteria, yeasts, fungi and viruses: 0,15 % PAA (e.g. 1 % product with 15 % PAA, that is 10 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. |
| | Dilution (%): 0,135-1 % |
| | Number and timing of application: 1-2 applications per day |
| Category(ies) of users | industrial ; professional |
| Pack sizes and packaging material | HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres HDPE drum with PP bung: 200 litres HDPE IBC with HDPE screw cap: 1 000 litres |

4.1.1. Use-specific instructions

See general directions for use

4.1.2. Use-specific risk mitigation measures

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

Surface disinfection by spraying or pouring (followed by wiping for a homogenous distribution), including in pharmaceutical and cosmetic industries

| Product type | PT02: Disinfectants and algaecides not intended for direct applica- tion to humans or animals |
|--|--|
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Scientific name: - Common name: Bacteria Development stage: - |
| | Scientific name: - Common name: fungi Development stage: - |
| | Scientific name: - Common name: Yeasts Development stage: - |
| | Scientific name: - Common name: Viruses Development stage: - |
| Field(s) of use | indoor use General (including pharmaceutical and cosmetic industry) Disinfection of hard and non-porous surfaces by spraying or pour- ing |
| Application method(s) | Method: Spraying or pouring (followed by wiping for a homogenous distribution) |
| | Detailed description: The diluted product shall be placed in and sprayed with a trigger spray bottle or poured onto the equipment or surface to be disin- fected (followed by wiping for a homogenous distribution). |
| Application rate(s) and frequency | Application rate: at room temperature, for 15 minutes contact time • Active against bacteria, yeasts, fungi and viruses: 0,15 % PAA (e.g. 1 % product with 15 % PAA, that is 10 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. |
| | Dilution (%): 1 % |
| | Number and timing of application: 1-2 applications per day |

| Category(ies) of users | industrial ; professional |
|-----------------------------------|--|
| Pack sizes and packaging material | HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres HDPE drum with PP bung: 200 litres HDPE IBC with HDPE screw cap: 1 000 litres |

4.2.1. Use-specific instructions

See general directions for use

4.2.2. Use-specific risk mitigation measures

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

Surface disinfection by spraying or pouring (followed by wiping for a homogenous distribution) for veterinary hygiene

| Product type | PT03: Veterinary hygiene |
|--|---|
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Scientific name: - Common name: Bacteria Development stage: - |
| | Scientific name: - Common name: Yeasts Development stage: - |
| | Scientific name: - Common name: Viruses Development stage: - |
| Field(s) of use | indoor use Disinfection of hard and non-porous and porous surfaces by spraying or pouring WITH prior cleaning |
| Application method(s) | Method: Spraying or pouring (followed by wiping for homogenous distribution) |
| | Detailed description: The diluted product shall be placed in and sprayed with a trigger spray bottle or poured onto the equipment or surface to be disin- fected (followed by wiping for homogenous distribution).Cleaning prior to use is mandatory. |

| Application rate(s) and frequency | Application rate: at +10 °C for 5 minutes contact time • Active against bacteria, yeasts and viruses: 0,2 % PAA (e.g. approximately 1,33 % product with 15 % PAA, that is 13,3 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 1,33 % Number and timing of application: Disinfection of animal housing takes place once animals have been |
|-----------------------------------|--|
| | moved out and the building has been cleaned and cleared of objects not to be disinfected, maximum 1-2 times per day. |
| Category(ies) of users | industrial ; professional |
| Pack sizes and packaging material | HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres HDPE drum with PP bung: 200 litres HDPE IBC with HDPE screw cap: 1 000 litres |

4.3.1. Use-specific instructions

See general directions for use

4.3.2. Use-specific risk mitigation measures

See general directions for use

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

Disinfection by dipping for veterinary hygiene

| Product type | PT03: Veterinary hygiene |
|--|--|
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - |

| | Scientific name: - Common name: Viruses Development stage: - |
|-----------------------------------|---|
| Field(s) of use | indoor use |
| | Disinfection of equipment (hard and non-porous and porous sur- faces) by dipping, WITH prior cleaning |
| Application method(s) | Method: Dipping |
| | Detailed description: The equipment to be disinfected must be placed in a dipping bath.Cleaning prior to use is mandatory. |
| Application rate(s) and frequency | Application rate: at +10 °C in 5 minutes contact time: • Active against bacteria, yeasts and viruses: 0,2 % PAA (e.g. approximately 1,33 % product with 15 % PAA, that is 13,3 mLml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. |
| | Dilution (%): 1,33 % |
| | Number and timing of application: 1-2 applications per day |
| Category(ies) of users | industrial ; professional |
| Pack sizes and packaging material | HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres HDPE drum with PP bung: 200 litres HDPE IBC with HDPE screw cap: 1 000 litres |

4.4.1. Use-specific instructions

See general directions for use

4.4.2. Use-specific risk mitigation measures

See general directions for use

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

Table 5

Disinfection of inner surfaces (e.g. tanks, pipes, vessels, filling machines) by CIP in food and feed industry

| Product type | PT04: Food and feed area |
|--|---|
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Scientific name: - Common name: Bacteria Development stage: - |
| | Scientific name: - Common name: Yeasts Development stage: - |
| | Scientific name: - Common name: fungi Development stage: - |
| | Scientific name: - Common name: Viruses Development stage: - |
| Field(s) of use | indoor use In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood). Disinfection of hard and non-porous surfaces by CIP procedures (with circulation). |
| Application method(s) | Method: CIP - Manual or automated dosing Detailed description: The diluted product must be transferred to equipment by manual dosing or automated dosing. For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. For all industries, final rinsing (with potable water) is mandatory: after the disinfection procedure, treated surfaces are rinsed with water and the water is drained into the sewer system. |
| Application rate(s) and frequency | Application rate: at room temperature, for 15 minutes contact time • Active against bacteria and yeasts: 0,02 % PAA (e.g. 0,135 % product with 15 % PAA, that is 1,35 ml product/litre) • Active against bacteria, yeasts and fungi: 0,1 % PAA (e.g. 0,675 % product with 15 % PAA, that is 6,75 ml product/litre) • Active against bacteria, yeasts, fungi and viruses: 0,15 % PAA (e.g. 1 % product with 15 % PAA, that is 10 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. |
| | Dilution (%): 0,135-1 % Number and timing of application: 1-2 applications per day |

| Category(ies) of users | industrial ; professional |
|-----------------------------------|--|
| Pack sizes and packaging material | HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres HDPE drum with PP bung: 200 litres HDPE IBC with HDPE screw cap: 1 000 litres |

4.5.1. Use-specific instructions

See general directions for use

4.5.2. Use-specific risk mitigation measures

See general directions for use

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

See general directions for use

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

See general directions for use

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

See general directions for use

4.6. Use description

Table 6

Surface disinfection by spraying or pouring (followed by wiping for a homogenous distribution) in food and feed industry

| Product type | PT04: Food and feed area | | | |
|--|---|--|--|--|
| Where relevant, an exact description of the authorised use | - | | | |
| Target organism(s) (including development stage) | Scientific name: - Common name: Bacteria Development stage: - | | | |
| | Scientific name: - Common name: Yeasts Development stage: - | | | |
| | Scientific name: - Common name: fungi Development stage: - | | | |
| | Scientific name: - Common name: Viruses Development stage: - | | | |
| Field(s) of use | indoor use | | | |
| | In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood). Disinfection of hard and non-porous surfaces by spraying or pour- ing. | | | |

| Application method(s) | Method: Spraying or pouring (followed by wiping for a homogenous distribution) | | | |
|-----------------------------------|--|--|--|--|
| | Detailed description: The diluted product shall be placed in and sprayed with a trigger spray bottle or poured onto the equipment or surface to be disin- fected (followed by wiping for a homogenous distribution). For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. | | | |
| Application rate(s) and frequency | Application rate: at room temperature, for 15 minutes contact time • Active against bacteria, yeasts, fungi and viruses: 0,15 % PAA (e.g. 1 % product with 15 % PAA, that is 10 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. | | | |
| | Dilution (%): 1 % | | | |
| | Number and timing of application: 1-2 applications per day | | | |
| Category(ies) of users | industrial ; professional | | | |
| Pack sizes and packaging material | HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres HDPE drum with PP bung: 200 litres HDPE IBC with HDPE screw cap: 1 000 litres | | | |

4.6.1. Use-specific instructions

See general directions for use

4.6.2. Use-specific risk mitigation measures

See general directions for use

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

See general directions for use

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

See general directions for use

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

See general directions for use

4.7. Use description

Table 7

Disinfection by dipping in food and feed industry

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

| Target organism(s) (including development stage) | Scientific name: - Common name: Bacteria Development stage: - | | | |
|--|--|--|--|--|
| | Scientific name: - Common name: Yeasts Development stage: - | | | |
| | Scientific name: - Common name: fungi Development stage: - | | | |
| | Scientific name: - Common name: Viruses Development stage: - | | | |
| Field(s) of use | indoor use | | | |
| | In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood). Disinfection of equipment (hard and non-porous surfaces) by dip- ping. | | | |
| Application method(s) | Method: Dipping | | | |
| | Detailed description: The equipment to be disinfected must be placed in a dipping bath.For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. | | | |
| Application rate(s) and frequency | Application rate: at room temperature, for 15 minutes contact time • Active against bacteria, yeasts, fungi and viruses: 0,15 % PAA (e.g. 1 % product with 15 % PAA, that is 10 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. | | | |
| | Dilution (%): 1 % | | | |
| | Number and timing of application: 1-2 applications per day | | | |
| Category(ies) of users | industrial ; professional | | | |
| Pack sizes and packaging material | HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litre HDPE drum with PP bung: 200 litres HDPE IBC with HDPE screw cap: 1 000 litres | | | |

4.7.1. Use-specific instructions

See general directions for use

4.7.2. Use-specific risk mitigation measures

See general directions for use

4.7.3. 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

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

See general directions for use

4.7.5. 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

Disinfection cycle (for surface disinfection ONLY):

- the surfaces to be disinfected must be cleaned before the disinfection procedure, and the user must thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected;
- products must be diluted in potable water before use.

Dilution rate and contact time depends on the use considered. Please refer to the description of application method related to each use.

- Disinfection procedures by CIP:
 - final rinsing step (with potable water).

After the disinfection procedure, CIP vessels (pipework and tanks) are drained and rinsed with water under closed system conditions

- Disinfection procedures by dipping:
 - the solution shall not be re-used.

Use only once a day after production and replace it with a fresh solution daily.

- Disinfection procedures by spraying:
 - wet the surface completely (application rate > 20 ml/m² but maximum 100ml/m²) in order to keep the surface wet during the required contact time.
 - do not use equipment until product is completely absorbed to the surface or air dried.

For PT3 uses:

- do not use equipment and surfaces or allow animals/poultry to enter the treated area until product is completely absorbed to the surface or air dried.
- the products shall not be used for the disinfection of animal transport vehicles.

5.2. Risk mitigation measures

- Wear chemical goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal product, and chemical resistant gloves classified under European Standard EN 374 or equivalent. Goggles, protective clothing and glove material (preferably butyl rubber) 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 titles of the EN standards and legislation.
- Use with adequate ventilation: Use engineering controls to maintain airborne level below exposure limit requirements or guidelines. Atmospheric levels shall be maintained below the exposure guideline. For all wiping and spraying application, a ventilation rate of at least 10 air changes/hour is required in the rooms where the application takes place.

- When respiratory protection is required (that is when the concentration of PAA and/or hydrogen peroxide are above their respective Acute Exposure Concentration (AEC)inhalation (0,5 mg/m3 and 1,25 mg/m3 respectively), use an approved air-purifying or positive-pressure supplied-air respirator depending on the potential airborne concentration.
- Do not use equipment and surfaces or allow animals/poultry to enter the treated area until product is completely absorbed to the surface or air dried.
- Keep out of reach of children and non-target animals and pets.
- Re-entrance into treated area is only allowed once the levels of peracetic acid and hydrogen peroxide in the air are below the AEC inhalation (respectively 0,5 mg/m3 for PAA & 1,25 mg/m3 for hydrogen peroxide)
- No bystanders are allowed in treated area during the application phase.
- Animals shall be removed before treatment takes place.

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

- 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.
- IF ON SKIN: Immediately wash skin with plenty of water. Take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. After washing the skin: Call 112/ambulance for medical assistance.
- Information to healthcare personnel/doctor: Initiate life support measures, thereafter call a POISON CENTRE
- 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.
- IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Immediately call 112/ ambulance for medical assistance.
- Information to healthcare personnel/doctor: Immediately initiate life support measures, thereafter call a POISON CENTRE.
- If symptoms: Call 112/ambulance for medical assistance.
- If no symptoms: Call a POISON CENTRE or a doctor.
- Information to healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

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

- This biocidal product, when being disposed of in its unused and uncontaminated state, should be treated as a hazardous waste in accordance with Directive 2008/98/EC. Any disposal practices must be in compliance with all national and provincial laws and any municipal or local by-laws governing hazardous waste. Do not dump into any sewers, on the ground, or into any body of water. Avoid release to the environment. High-temperature incineration is an acceptable practice.
- Containers are non-refillable. Do not reuse or refill the containers. Containers should be triple or pressure rinsed with water promptly after they are emptied. They can then be offered for recycling or reconditioning for biocidal products, or they can be punctured and disposed of in a sanitary landfill or by other procedures approved by national and local authorities. Send waste liquid from rinsing of used containers to an approved waste handling facility.

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

- Store between 0 °C and 30 °C
- Store in dark conditions
- Keep in a well-ventilated place. Keep this product in the original container when not in use. Container must be stored and transported in an upright position to prevent spilling the contents through the vent, where fitted.
- Do not store in and avoid contact with aluminium, carbon steel, copper, mild steel, iron.
- Avoid contact with amines, ammonia, strong acids, strong bases, strong oxidizers.
- Shelf-life: Meta-SPC 3 (15 % PAA): 12 months

6. **OTHER INFORMATION**

With respect to the 'Category (ies) of users' note:

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

Full titles of EN standards and legislation referred to in section 5.2:

EN 16321 - Eye and face protection for occupational users - Part 1: general requirements.

EN 374 – Protective gloves against dangerous chemicals and micro-organisms. Part 1: terminology and performance requirements for chemical risks.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, (OJ L 312, 22.11.2008, p. 3).

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).

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) | | | Divosan Splendid VT99 | | Market area: EU | | |
|------------------------|------------------------|-------------------------|-----------------------------|---------|-----------------|-----------|----------------|
| Authorisation number | | | EU-0032463-0002 1-2 | | | | |
| Common name | IUPAC name | Function | | CAS | 5 number | EC number | Content (%) |
| Peracetic acid | | active substance | | 79-21-0 | | 201-186-8 | 15 % (w/w) |
| Hydrogen perox- ide | Hydrogen Per- oxide | Non-Active substance | | 7722 | -84-1 | 231-765-0 | 25,109 % (w/w) |
| Acetic Acid | Acetic Acid | Non-Active substance | | 64-19 | 9-7 | 200-580-7 | 15,07 % (w/w) |
| HEDP | etidronic acid | Non-Active substance | | 2809 | -21-4 | 220-552-8 | 0,99 % (w/w) |