

COMMISSION IMPLEMENTING REGULATION (EU) 2020/579**of 27 April 2020****granting a Union authorisation for the biocidal product family 'HYPRED's octanoic acid based products'****(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 the first subparagraph of Article 44(5) thereof,

Whereas:

- (1) On 25 August 2015, HYPRED SAS, submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'HYPRED's octanoic acid based products' of product-type 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under the case number BC-LR019297-17 in the Register for Biocidal Products.
- (2) 'HYPRED's octanoic acid based products' contains octanoic acid, as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012.
- (3) On 19 December 2017, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency').
- (4) On 11 July 2019, the Agency submitted to the Commission an opinion (²), including the draft summary of the biocidal product characteristics ('SPC') of 'HYPRED's octanoic acid based products' and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that 'HYPRED's octanoic acid based products' is a 'biocidal product family' within the meaning of Article 3(1)(s) of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (6) On 25 July 2019, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'HYPRED's octanoic acid based products'.
- (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-0021020-0000 is granted to HYPRED SAS for the making available on the market and use of the biocidal product family 'HYPRED's octanoic acid based products' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 18 May 2020 until 30 April 2030.

(¹) OJ L 167, 27.6.2012, p. 1.

(²) ECHA opinion of 26 June 2019 on the Union authorisation of 'HYPRED's octanoic acid based products' (ECHA/BPC/226/2019), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>.

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, 27 April 2020.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

HYPRED's octanoic acid based products

Product type 4 – Food and feed area (Disinfectants)

Authorisation number: EU-0021020-0000

R4BP asset number: EU-0021020-0000

PART I

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

| | |
|------|---------------------------------------|
| Name | HYPRED's octanoic acid based products |
|------|---------------------------------------|

1.2. Product type(s)

| | |
|-----------------|---|
| Product type(s) | PT04 – Food and feed area (Disinfectants) |
|-----------------|---|

1.3. Authorisation holder

| | |
|--|--|
| Name and address of the authorisation holder | Name HYPRED SAS Address 55 boulevard Jules Verger, 35803 DINARD, France |
| Authorisation number | EU-0021020-0000 |
| R4BP asset number | EU-0021020-0000 |
| Date of the authorisation | 18 May 2020 |
| Expiry date of the authorisation | 30 April 2030 |

1.4. Manufacturer(s) of the biocidal products

| | |
|---------------------------------|---|
| Name of manufacturer | HYPRED SAS |
| Address of manufacturer | 55 Boulevard Jules Verger, 35803 DINARD France |
| Location of manufacturing sites | HYPRED SAS – 55 Boulevard Jules Verger – BP 10180, 35803 DINARD France HYPRED POLSKA SP. Z O.O. NIEPRUSZEWO, KASZTANOWA 4, 64320 buk Poland HYPRED IBERICA S.L Pol. Ind. Arazuri-Orcoyen C/C n° 32, 31160 Orcoyen – NAVARRA Spain HYPRED GmbH Marie-Curie-Straße 23, 53332 Bornheim – Sechtem Germany HYPRED Italia s.r.l. Strada Montodine-Gombito Loc. Cà Nova, 26010 Ripalta Arpina CR Italy AG France S.A.S – Zone Industrielle Le Roineau, 72500 Vaas France Anti-Germ Austria GmbH – 'Pfongauer Straße 17, 5202 Neumarkt am Wallersee' Austria Anti-Germ Deutschland GmbH – Oberbrühlstraße 16-18, 87700 Memmingen Germany |

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

| | |
|---------------------------------|---|
| Active substance | Octanoic acid |
| Name of manufacturer | Emery Oleochemicals (M) |
| Address of manufacturer | Sdn Bhd (63112-D), Lot 4, Jalan Perak, Kawasan Perusahaan, 42500 Telok Panglima Garang, Selangor Malaysia |
| Location of manufacturing sites | Sdn Bhd (63112-D), Lot 4, Jalan Perak, Kawasan Perusahaan, 42500 Telok Panglima Garang, Selangor Malaysia |

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 (%) | |
|-----------------------------------|---------------------|----------------------|------------|-----------|-------------|------|
| | | | | | Min | Max |
| Octanoic acid | | Active Substance | 124-07-2 | 204-677-5 | 3,0 | 10,0 |
| Methanesulfonic acid | | Non-active substance | 75-75-2 | 200-898-6 | 0,0 | 21,0 |
| L-(+)-Lactic acid | | Non-active substance | 79-33-4 | 201-196-2 | 0,0 | 17,6 |
| N,N-dimethyl-1-Decanamine, N-oxid | | Non-active substance | 2605-79-0 | 220-020-5 | 2,25 | 6,0 |
| Ethoxylated alcohol | Ethoxylated alcohol | Non-active substance | 31726-34-8 | 500-077-5 | 0,0 | 15,0 |

2.2. Type(s) of formulation

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

PART II

SECOND INFORMATION LEVEL – META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

| | |
|------------|------------|
| Identifier | Meta SPC 1 |
|------------|------------|

1.2. Suffix to the authorisation number

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

1.3. Product type(s)

| | |
|-----------------|---|
| Product type(s) | PT04 – Food and feed area (Disinfectants) |
|-----------------|---|

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 (%) | |
|-----------------------------------|---------------------|----------------------|------------|-----------|-------------|------|
| | | | | | Min | Max |
| Octanoic acid | | Active Substance | 124-07-2 | 204-677-5 | 3,0 | 3,0 |
| Methanesulfonic acid | | Non-active substance | 75-75-2 | 200-898-6 | 21,0 | 21,0 |
| L-(+)-Lactic acid | | Non-active substance | 79-33-4 | 201-196-2 | 0,0 | 0,0 |
| N,N-dimethyl-1-Decanamine, N-oxid | | Non-active substance | 2605-79-0 | 220-020-5 | 2,25 | 2,25 |
| Ethoxylated alcohol | Ethoxylated alcohol | Non-active substance | 31726-34-8 | 500-077-5 | 5,0 | 5,0 |

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

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

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

| | |
|--------------------------|---|
| Hazard statements | May be corrosive to metals. Causes severe skin burns and eye damage. May cause respiratory irritation. Harmful to aquatic life with long lasting effects. |
| Precautionary statements | Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED:Rinse mouth.Do NOT induce vomiting. IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with water. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER. Dispose of contents according to local/regional/national/international regulation. Avoid release to the environment. |

4. AUTHORISED USE(S) OF THE META SPC 1

4.1. Use description

Table 1. Use # 1 – Circulation in dairy industry

| | |
|--|---|
| Product type | PT04 – Food and feed area (Disinfectants) |
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Bacteria Yeast |

| | |
|-----------------------------------|--|
| Field(s) of use | Indoor Cleaning – disinfection of circuits in dairy industry |
| Application method(s) | Closed system: Circulation Clean-in-place (CIP), circulation |
| Application rate(s) and frequency | - Use 1 % product solution for bactericidal activity and 1,5 % product solution for yeasticidal activity 1 to 3 cycles per day, 208 to 360 days per year |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | Opaque jerrycan High-density polyethylene (HDPE) 5L Opaque jerrycan HDPE 10L Opaque jerrycan HDPE 22L Opaque drum HDPE 60L Opaque drum HDPE 120L Opaque drum HDPE 220L Opaque container HDPE 640L Opaque container HDPE 1000L |

4.1.1. Use-specific instructions for use

Rinse the circuits with drinking water before disinfection.

Apply the product by circulation.

Product concentration and contact time:

— 1 % bactericidal in 5 minutes

— 1,5 % yeasticidal in 15 minutes

Temperature of the product solution: 40 – 85 °C

Rinse with drinking water.

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. Use # 2 – Circulation in farms

| | |
|--|---|
| Product type | PT04 – Food and feed area (Disinfectants) |
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Bacteria Yeasts |

| | |
|-----------------------------------|---|
| Field(s) of use | Indoor Cleaning – disinfection of milking equipment and milking robots in farms |
| Application method(s) | Closed system: Circulation |
| Application rate(s) and frequency | - Use 0,8 % product solution for bactericidal activity and 1,5 % product solution for yeasticidal activity. The milk installations cleaned and disinfected twice a day and the milk tank is cleaned and disinfected once every three days. |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | Opaque jerrycan HDPE 5L Opaque jerrycan HDPE 10L Opaque jerrycan HDPE 22L Opaque drum HDPE 60L Opaque drum HDPE 120L Opaque drum HDPE 220L Opaque container HDPE 640L Opaque container HDPE 1000L |

4.2.1. Use-specific instructions for use

Milk installations with or without a programmer.

- (1) After milking, rinse the equipment with warm drinking water.
- (2) Apply the solution by circulation at an initial recommended temperature of 60 °C minimum to achieve a final temperature of 40– 45 °C.

Product concentration and contact time:

0,8 % bactericidal in 10 minutes

1,5 % yeasticidal in 15 minutes

Do not use at temperature above 75 °C.

- 3) Rinse with cold drinking water.

Use the product twice a day or once a day when alternating with another product.

When alternating, use an alternative cleaner-disinfectant or a cleaning product 1 to 4 times per week depending on the temperature reached in the system.

Contact your supplier for choosing the alternative product and the frequency of use.

Do not mix the product with an alkaline or chlorinated alkaline product.

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

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 1

5.1. Instructions for use

See use specific instructions for use.

5.2. Risk mitigation measures

- Wear protective chemical resistant gloves, coverall and eye protection during product handling phase (protective material to be specified by the authorisation holder in the product information).
- Ensure adequate ventilation during the application.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID

- IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician.
- IF IN EYES: Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open. Remove contact lenses if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
- IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

See Safety Data Sheets. They contain an emergency phone number

When asking for medical advice keep packaging or label at hand and call a POISON CENTER or doctor/physician.

NEVER administer liquids/solids orally to an impaired or unconscious individual; place individual in left sideways position with the head lowered and the knees bent.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

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

Do not discharge the product directly to sewer or to the environment.

Dispose the product and its packaging in accordance with applicable local and national regulations.

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

Shelf-life: 2 years in HDPE

Conditions of storage: keep only in the original packaging. Keep container closed. Do not store at temperature above 40 °C.

6. OTHER INFORMATION

The cleaning properties of the product has not been assessed as they are not covered by Regulation (EU) No 528/2012.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.

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) | HYPRACID ONE DEPTACID BD prevides®MS | | | | |
|-----------------------------------|--|----------------------|------------|-----------|-------------|
| Authorisation number | EU-0021020-0001 1-1 | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| Octanoic acid | | Active Substance | 124-07-2 | 204-677-5 | 3,0 |
| Methanesulfonic acid | | Non-active substance | 75-75-2 | 200-898-6 | 21,0 |
| N,N-dimethyl-1-Decanamine, N-oxid | | Non-active substance | 2605-79-0 | 220-020-5 | 2,25 |
| Ethoxylated alcohol | Ethoxylated alcohol | Non-active substance | 31726-34-8 | 500-077-5 | 5,0 |

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

| | |
|------------|------------|
| Identifier | Meta SPC 2 |
|------------|------------|

1.2. Suffix to the authorisation number

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

1.3. Product type(s)

| | |
|-----------------|---|
| Product type(s) | PT04 – Food and feed area (Disinfectants) |
|-----------------|---|

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 (%) | |
|-----------------------------------|---------------------|----------------------|------------|-----------|-------------|------|
| | | | | | Min | Max |
| Octanoic acid | | Active Substance | 124-07-2 | 204-677-5 | 10,0 | 10,0 |
| Methanesulfonic acid | | Non-active substance | 75-75-2 | 200-898-6 | 14,0 | 14,0 |
| L-(+)-Lactic acid | | Non-active substance | 79-33-4 | 201-196-2 | 0,0 | 0,0 |
| N,N-dimethyl-1-Decanamine, N-oxid | | Non-active substance | 2605-79-0 | 220-020-5 | 4,5 | 4,5 |
| Ethoxylated alcohol | Ethoxylated alcohol | Non-active substance | 31726-34-8 | 500-077-5 | 15,0 | 15,0 |

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

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

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

| | |
|--------------------------|---|
| Hazard statements | May be corrosive to metals. Harmful if swallowed. Causes severe skin burns and eye damage. Harmful to aquatic life with long lasting effects. |
| Precautionary statements | Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER. Dispose of contents according to local/regional/national/international regulation. Avoid release to the environment. |

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. Use description

Table 3. Use # 1 – Circulation

| | |
|--|--|
| Product type | PT04 – Food and feed area (Disinfectants) |
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Bacteria Yeast |
| Field(s) of use | Indoor Disinfection of circuits in breweries, dairy and beverage industries |
| Application method(s) | Closed system: Circulation CIP, circulation |
| Application rate(s) and frequency | - Use 0,4 % product solution for bactericidal activity and 0,6 % product solution for yeasticidal activity. 1 to 3 cycles per day, 208 to 360 days per year |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | Opaque jerrycan HDPE 5L Opaque jerrycan HDPE 10L Opaque jerrycan HDPE 22L Opaque drum HDPE 60L Opaque drum HDPE 120L Opaque drum HDPE 220L Opaque container HDPE 640L Opaque container HDPE 1000L |

4.1.1. Use-specific instructions for use

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

5. GENERAL DIRECTIONS FOR USE ⁽²⁾OF THE META SPC 2**5.1. Instructions for use**

Prior to the application of the product, clean with a detergent and rinse with drinking water.

Apply the product by circulation.

Product concentration and contact time:

- 0,4 % bactericidal in 5 minutes
- 0,6 % yeasticidal in 15 minutes

Temperature of the product solution: 20 – 85 °C

Rinse with drinking water.

5.2. Risk mitigation measures

- Wear protective chemical resistant gloves, coverall and eye protection during product handling phase (protective material to be specified by the authorisation holder in the product information).
- Ensure adequate ventilation during the application.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID

- IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician.
- IF IN EYES: Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open. Remove contact lenses if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
- IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

See Safety Data Sheets. They contain an emergency phone number.

When asking for medical advice keep packaging or label at hand and call a POISON CENTER or doctor/physician.

⁽²⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

NEVER administer liquids/solids orally to an impaired or unconscious individual; place individual in left sideways position with the head lowered and the knees bent.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

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

Do not discharge the product directly to sewer or to the environment.

Dispose the product and its packaging in accordance with applicable local and national regulations.

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

Shelf-life: 2 years in HDPE

Conditions of storage: keep only in the original packaging. Keep container closed. Keep in a cool place. Do not store at temperature above 40 °C.

6. OTHER INFORMATION

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) | DEPTACID CCB | | | | |
|-----------------------------------|---------------------|----------------------|------------|-----------|-------------|
| Authorisation number | EU-0021020-0002 1-2 | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| Octanoic acid | | Active Substance | 124-07-2 | 204-677-5 | 10,0 |
| Methanesulfonic acid | | Non-active substance | 75-75-2 | 200-898-6 | 14,0 |
| N,N-dimethyl-1-Decanamine, N-oxid | | Non-active substance | 2605-79-0 | 220-020-5 | 4,5 |
| Ethoxylated alcohol | Ethoxylated alcohol | Non-active substance | 31726-34-8 | 500-077-5 | 15,0 |

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

| | |
|------------|------------|
| Identifier | Meta SPC 3 |
|------------|------------|

1.2. Suffix to the authorisation number

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

1.3. Product type(s)

| | |
|-----------------|---|
| Product type(s) | PT04 – Food and feed area (Disinfectants) |
|-----------------|---|

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 (%) | |
|-----------------------------------|---------------------|----------------------|------------|-----------|-------------|------|
| | | | | | Min | Max |
| Octanoic acid | | Active Substance | 124-07-2 | 204-677-5 | 10,0 | 10,0 |
| Methanesulfonic acid | | Non-active substance | 75-75-2 | 200-898-6 | 0,0 | 0,0 |
| L-(+)-Lactic acid | | Non-active substance | 79-33-4 | 201-196-2 | 17,6 | 17,6 |
| N,N-dimethyl-1-Decanamine, N-oxid | | Non-active substance | 2605-79-0 | 220-020-5 | 6,0 | 6,0 |
| Ethoxylated alcohol | Ethoxylated alcohol | Non-active substance | 31726-34-8 | 500-077-5 | 0,0 | 0,0 |

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

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

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

| | |
|--------------------------|---|
| Hazard statements | May be corrosive to metals. Causes severe skin burns and eye damage. Harmful to aquatic life with long lasting effects. |
| Precautionary statements | Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED:Rinse mouth.Do NOT induce vomiting. IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with water. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER. Dispose of contents according to local/regional/national/international regulation. Avoid release to the environment. |

4. AUTHORISED USE(S) OF THE META SPC 3

4.1. Use description

Table 4. Use # 1 – Circulation

| | |
|--|---|
| Product type | PT04 – Food and feed area (Disinfectants) |
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Bacteria Yeast |

| | |
|-----------------------------------|--|
| Field(s) of use | Indoor Disinfection of circuits in breweries, dairy and beverage industries |
| Application method(s) | Closed system: Circulation CIP, circulation |
| Application rate(s) and frequency | - Use 0,4 % product solution 1 to 3 cycles per day, 208 to 360 days per year |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | Opaque jerrycan HDPE 5L Opaque jerrycan HDPE 10L Opaque jerrycan HDPE 22L Opaque drum HDPE 60L Opaque drum HDPE 120L Opaque drum HDPE 220L Opaque container HDPE 640L Opaque container HDPE 1000L |

4.1.1. Use-specific instructions for use

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

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

5.1. Instructions for use

Prior to the application of the product, clean with a detergent and rinse with drinking water.

Apply the product by circulation.

Product concentration: 0,4 %

Contact time:

— 5 minutes for bactericidal activity

— 15 minutes for yeasticidal activity

Temperature of the product solution: 20 – 85 °C

Rinse with drinking water.

5.2. Risk mitigation measures

- Wear protective chemical resistant gloves, coverall and eye protection during product handling phase (protective material to be specified by the authorisation holder in the product information).
- Ensure adequate ventilation during the application.

^(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 3.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID

- IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician.
- IF IN EYES: Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open. Remove contact lenses if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
- IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

See Safety Data Sheets. They contain an emergency phone number.

When asking for medical advice keep packaging or label at hand and call a POISON CENTER or doctor/physician.

NEVER administer liquids/solids orally to an impaired or unconscious individual; place individual in left sideways position with the head lowered and the knees bent.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

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

Do not discharge the product directly to sewer or to the environment.

Dispose the product and its packaging in accordance with applicable local and national regulations.

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

Shelf-life: 2 years in HDPE

Conditions of storage: keep only in the original packaging. Keep container closed. Do not store at temperature above 40 °C.

6. OTHER INFORMATION

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) | DEPTACID CB | | | | |
|-----------------------------------|---------------------|----------------------|------------|-----------|-------------|
| Authorisation number | EU-0021020-0003 1-3 | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| Octanoic acid | | Active Substance | 124-07-2 | 204-677-5 | 10,0 |
| L-(+)-Lactic acid | | Non-active substance | 79-33-4 | 201-196-2 | 17,6 |
| N,N-dimethyl-1-Decanamine, N-oxid | | Non-active substance | 2605-79-0 | 220-020-5 | 6,0 |

META SPC 4

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 4 identifier

| | |
|------------|------------|
| Identifier | Meta SPC 4 |
|------------|------------|

1.2. **Suffix to the authorisation number**

| | |
|--------|-----|
| Number | 1-4 |
|--------|-----|

1.3. **Product type(s)**

| | |
|-----------------|---|
| Product type(s) | PT04 – Food and feed area (Disinfectants) |
|-----------------|---|

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

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|-----------------------------------|---------------------|----------------------|------------|-----------|-------------|------|
| | | | | | Min | Max |
| Octanoic acid | | Active Substance | 124-07-2 | 204-677-5 | 3,0 | 3,0 |
| Methanesulfonic acid | | Non-active substance | 75-75-2 | 200-898-6 | 21,0 | 21,0 |
| L-(+)-Lactic acid | | Non-active substance | 79-33-4 | 201-196-2 | 0,0 | 0,0 |
| N,N-dimethyl-1-Decanamine, N-oxid | | Non-active substance | 2605-79-0 | 220-020-5 | 3,0 | 3,0 |
| Ethoxylated alcohol | Ethoxylated alcohol | Non-active substance | 31726-34-8 | 500-077-5 | 5,0 | 5,0 |

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

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

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

| | |
|--------------------------|---|
| Hazard statements | May be corrosive to metals. Causes severe skin burns and eye damage. May cause respiratory irritation. Harmful to aquatic life with long lasting effects. |
| Precautionary statements | Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER. Dispose of contents according to local/regional/national/international regulation. Avoid release to the environment. |

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

4.1. Use description

Table 5. Use # 1 – Separative membranes circulation

| | |
|--|--|
| Product type | PT04 – Food and feed area (Disinfectants) |
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Bacteria Yeast |
| Field(s) of use | Indoor Disinfectant or cleaner-disinfectant for membranes used in reverse osmosis and nanofiltration in dairy and beverage industries. |
| Application method(s) | Closed system: Circulation |
| Application rate(s) and frequency | — Use 0,75 % product solution if cleaning is applied prior to the disinfection — Use 1 % product solution if no cleaning is applied prior to the disinfection 1 to 3 cycles per day, 104 to 312 days per year |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | Opaque jerrycan HDPE 5L Opaque jerrycan HDPE 10L Opaque jerrycan HDPE 22L Opaque drum HDPE 60L Opaque drum HDPE 120L Opaque drum HDPE 220L Opaque container HDPE 640L Opaque container HDPE 1000L |

4.1.1. Use-specific instructions for use

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

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

5.1. Instructions for use

Rinse the membranes with drinking water or clean and rinse with drinking water before disinfection.

(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 4.

Apply the product by circulation

Product concentration if no cleaning is applied prior to the disinfection: 1 %

Product concentration if cleaning is applied prior to the disinfection: 0,75 %

Contact time:

— 5 minutes for bactericidal activity

— 15 minutes for yeasticidal activity

Temperature of the product solution: 40 – 85 °C

Rinse with drinking water.

5.2. Risk mitigation measures

- Wear protective chemical resistant gloves, coverall and eye protection during product handling phase (protective material to be specified by the authorisation holder in the product information).
- Ensure adequate ventilation during the application.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID

- IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician.
- IF IN EYES: Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open. Remove contact lenses if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
- IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

See Safety Data Sheets. They contain an emergency phone number

When asking for medical advice keep packaging or label at hand and call a POISON CENTER or doctor/physician.

NEVER administer liquids/solids orally to an impaired or unconscious individual; place individual in left sideways position with the head lowered and the knees bent.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

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

Do not discharge the product directly to sewer or to the environment.

Dispose the product and its packaging in accordance with applicable local and national regulations.

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

Shelf life: 2 years in HDPE

Conditions of storage: keep only in the original packaging. Keep container closed. Do not store at temperature above 40 °C.

6. OTHER INFORMATION

The cleaning properties of the product has not been assessed as they are not covered by Regulation (EU) No 528/2012.

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

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

| Trade name(s) | DEPTACID WCM | | | | |
|-----------------------------------|---------------------|----------------------|------------|-----------|-------------|
| Authorisation number | EU-0021020-0004 1-4 | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| Octanoic acid | | Active Substance | 124-07-2 | 204-677-5 | 3,0 |
| Methanesulfonic acid | | Non-active substance | 75-75-2 | 200-898-6 | 21,0 |
| N,N-dimethyl-1-Decanamine, N-oxid | | Non-active substance | 2605-79-0 | 220-020-5 | 3,0 |
| Ethoxylated alcohol | Ethoxylated alcohol | Non-active substance | 31726-34-8 | 500-077-5 | 5,0 |