

Summary of product characteristics for a biocidal product

Product name: SOPURCLEAN NR

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

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Authorisation number: EU-0021157-0000

R4BP 3 asset reference number: IS-0024234-0006

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Administrative information

1.1. Trade names of the product

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|---------------|
| SOPURCLEAN NR |
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1.2. Authorisation holder

Name and address of the authorisation holder

| | |
|----------------------|---|
| Name | SOPURA |
| Address | rue de Trazegnies 199 6180 COURCELLES Belgium |
| Authorisation number | EU-0021157-0000 1-2 |

R4BP 3 asset reference number

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|-----------------|
| IS-0024234-0006 |
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Date of the authorisation

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|------------|
| 18/05/2020 |
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Expiry date of the authorisation

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|------------|
| 30/04/2030 |
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1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

| |
|--------|
| SOPURA |
|--------|

Address of the manufacturer

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|---|
| rue de Trazegnies 199 6180 COURCELLES Belgium |
|---|

Location of manufacturing sites

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|--|
| PIB de Tyberchamps 14 7180 SENEFFE Belgium |
|--|

| |
|---|
| Rue de Trazegnies 199 6180 COURCELLES Belgium |
|---|

| | |
|--|---|
| Name of the manufacturer | SOPURA QUIMICA |
| Address of the manufacturer | Poligon "La Canaleta", Avinguda Júpiter 9 25300 TARREGA Spain |
| Location of manufacturing sites | Poligon "La Canaleta", Avinguda Júpiter 9 25300 TARREGA Spain |

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

| | |
|--|---|
| Active substance | 1336 - Octanoic acid |
| Name of the manufacturer | Emery Oleochemicals (M) Sdn Bhd (63112-D) |
| Address of the manufacturer | Lot 4, Jalan Perak, Kawasan Perusahaan, Telok Panglima Garang 42500 Selangor Malaysia |
| Location of manufacturing sites | Lot 4, Jalan Perak, Kawasan Perusahaan, Telok Panglima Garang 42500 Selangor Malaysia |

| | |
|--|---|
| Active substance | 1287 - Decanoic acid |
| Name of the manufacturer | Emery Oleochemicals (M) Sdn Bhd (63112-D) |
| Address of the manufacturer | Lot 4, Jalan Perak, Kawasan Perusahaan, Telok Panglima Garang 42500 Selangor Malaysia |
| Location of manufacturing sites | Lot 4, Jalan Perak, Kawasan Perusahaan, Telok Panglima Garang 42500 Selangor Malaysia |

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---------------|------------|------------------|------------|-----------|-------------|
| Octanoic acid | | Active Substance | 124-07-2 | 204-677-5 | 2,7 |
| Decanoic acid | | Active Substance | 334-48-5 | 206-376-4 | 0,3 |

| | | | |
|-----------------------|-----------|-----------|------|
| Sulfuric acid | 7664-93-9 | 231-639-5 | 0 |
| Propionic acid | 79-09-4 | 201-176-3 | 19,5 |
| Phosphoric acid | 7664-38-2 | 231-633-2 | 3,8 |
| Nitric acid | 7697-37-2 | 231-714-2 | 0 |
| Methane sulfonic acid | 75-75-2 | 200-898-6 | 0 |
| Glycolic acid | 79-14-1 | 201-180-5 | 0 |
| Lactic acid | 79-33-4 | 201-196-2 | 35,2 |
| Citric acid | 77-92-9 | 201-069-1 | 0 |

2.2. Type of formulation

SL - Soluble concentrate

3. Hazard and precautionary statements

Hazard statements

May be corrosive to metals.
 Causes severe skin burns and eye damage.
 May cause respiratory irritation.

Precautionary statements

Do not breathe vapours.
 Wear protective gloves.
 Wear protective clothing.
 Wear eye protection.
 Wear face protection.
 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with shower.
 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.
 Immediately call a doctor.
 Keep only in original packaging.
 Store in a well-ventilated place. Keep container tightly closed.

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

Dispose of contents in accordance with local/regional/national/international regulations..

4. Authorised use(s)

4.1 Use description

Use 1 - Cleaning in place (CIP with circulation).

| | |
|---|--|
| Product type | PT04 - Food and feed area (Disinfectants) |
| 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: |
| Field(s) of use | Indoor In food & feed areas |
| Application method(s) | Closed system - For disinfection of pipes, tanks, etc ...: - Biocidal product (semi-)automatically dosed in the CIP vessel (either by volume or conductivity measurements) - Circulation in a closed CIP system |
| Application rate(s) and frequencies | -- For an effect on bacteria and on yeasts: Dilution rate: 1 %v/v In case of outbreaks caused by <i>Pediococcus damnosus</i> , the products must be used at 1.5%. Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C) - - |
| Category(ies) of users | Industrial Trained professional |
| Pack sizes and packaging material | <ul style="list-style-type: none">• Jerrycan (PE-HD), containing: 10 to 12,5 kg*.• Jerrycan (PE-HD), containing: 20 to 25 kg*.• Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*• IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* |

*Depending on BP specific weight.

- Bulk delivery.

4.1.1 Use-specific instructions for use

In case of re-use of the disinfectant solution for CIP procedures, the active substance concentration must be measured and restored to its intended level before re-use.

4.1.2 Use-specific risk mitigation measures

During the mixing and loading & application phase:

- Transfer in closed systems and industrial RMM excluding risk for skin and eye exposure (IBC containers containing the product are connected to CIP via installed pipes; connections with dry coupling)

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

No use specific instructions.

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

No use specific instructions.

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

No use specific instructions.

4.2 Use description

Use 2 - Spraying

Product type

PT04 - Food and feed area (Disinfectants)

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: |
| Field(s) of use | Indoor In food & feed areas |
| Application method(s) | Spraying - For disinfection of hard non-porous surfaces in contact with food processing: - Diluted biocidal product sprayed via a low pressure spraying device |
| Application rate(s) and frequencies | Maximum application rate : 100 mL/m ² - For an effect on bacteria and on yeasts: Dilution rate: 1%v/v In case of outbreaks caused by <i>Pediococcus damnosus</i> , the products must be used at 1.5%. Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C) - - |
| Category(ies) of users | Industrial Trained professional |
| Pack sizes and packaging material | Jerrycan (PE-HD), containing: 10 to 12,5 kg*. <ul style="list-style-type: none"> • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. <ul style="list-style-type: none"> • Containers (PE-HD) containing 600 to 750 kg.* • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* *Depending on BP specific weight. <ul style="list-style-type: none"> • Bulk delivery. |

4.2.1 Use-specific instructions for use

See general direction for use

4.2.2 Use-specific risk mitigation measures

Fully automated process where workers are not present during spraying.
 Workers only re-enter in the work area when spraying solution has been drained.

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

No use specific instructions.

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

No use specific instructions

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

No use specific instructions.

4.3 Use description

Use 3 - Manual disinfection

Product type

PT04 - Food and feed area (Disinfectants)

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: Yeast
Development stage:

Field(s) of use

Indoor

In food & feed areas

Application method(s)

Manual application -
For disinfection of hard non-porous small parts and surfaces used along the food manufacturing process:
- Diluted biocidal product sprayed via a low pressure spraying device
- After the optimal disinfection contact time, the small parts will be wiped/mopped/brushed.

Application rate(s) and frequencies

Maximum application rate : 100 mL/m² - For an effect on bacteria and on yeasts:
Dilution rate: 1%v/v In case of outbreaks caused by *Pediococcus damnosus*, the products must be used at 1.5%. Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C) -

| | |
|--|--|
| | - |
| Category(ies) of users | Industrial Trained professional |
| Pack sizes and packaging material | Jerrycan (PE-HD), containing: 10 to 12,5 kg*. <ul style="list-style-type: none"> • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*. • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* *Depending on BP specific weight. <ul style="list-style-type: none"> • Bulk delivery. |

4.3.1 Use-specific instructions for use

See general direction for use

4.3.2 Use-specific risk mitigation measures

No use specific instructions.

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

No use specific instructions.

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

No use specific instructions.

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

No use specific instructions.

4.4 Use description

Use 4 - Dipping / soaking

| | |
|---|---|
| Product type | PT04 - Food and feed area (Disinfectants) |
| 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: |
| Field(s) of use | Indoor In food & feed areas |
| Application method(s) | Open system: immersion - For disinfection of hard non-porous small parts (spare parts, tools, valves, hoses,...) used along the food manufacturing process: - Concentrated product pumped in the bath and tap water added to reach the required use concentration - Immersion |
| Application rate(s) and frequencies | - - For an effect on bacteria and on yeasts: Dilution rate: 1%v/v In case of outbreaks caused by <i>Pediococcus damnosus</i> , the products must be used at 1.5%. Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C. - - |
| Category(ies) of users | Industrial Trained professional |
| Pack sizes and packaging material | Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. Containers (PE-HD) containing 600 to 750 kg*. • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* *Depending on BP specific weight. |

- Bulk delivery.

4.4.1 Use-specific instructions for use

The dipping solution must be replaced by a fresh solution when it becomes visually polluted, and in all cases daily.

4.4.2 Use-specific risk mitigation measures

No use specific instructions.

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

No use specific instructions.

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

No use specific instructions.

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

No use specific instructions.

5. General directions for use

5.1. Instructions for use

Main steps:**For an effect on bacteria and on yeasts**

- Rinsing & cleaning before disinfection: Not mandatory (even if a pre-rinsing is always recommended and usually performed by the users).

For disinfection procedures in slaughterhouses, a cleaning step (with a cold alkaline solution) before disinfection is always mandatory.

- Disinfecting cycle:
 - Dilution of the concentrated product in tap water before use : 1.0%*In case of outbreaks caused by *Pediococcus damnosus*, the products must be used at 1.5%.*
 - Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C).
 - Disinfection via spraying/ manual disinfection : Make sure to wet surfaces completely.
- Final rinsing : may be skipped

5.2. Risk mitigation measures

During the mixing& loading and application phases : A protective coverall shall be worn. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). The use of eye protection during handling of the product is mandatory. Wear face protection.

Use in well ventilated places.

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

Particulars of likely direct or indirect adverse effects:

- Severe chemical burns and/or corrosion of the eyes, mucosae, respiratory and digestive tract with the risk of perforation and intense pain. (The absence of visual oral burns does not exclude esophageal burns).
- If aspiration and/or ingestion occurs this may induce chemical pneumonia and metabolic acidosis.

First aid instructions:

- Relocate the individual from the exposure source and remove any contaminated/spattered clothing articles.
- In case of inhalation : Remove to fresh air. Allow the affected person to rest. Not expected to require first aid measures.
- In case of eye exposure : Seek medical attention immediately. ALWAYS check for and remove contact lenses. Rinse immediately with plenty of water during 15 minutes and keep the eyelids open. (Keep a bottle of water at hand).
- In case of skin contact : Obtain medical attention. Remove contaminated clothing and shoes. Wash affected area with plenty of water. NO scrubbing.
- In case of mouth contact or ingestion : Do NOT induce vomiting, if the individual is conscious, able to swallow saliva without coughing and ingestion occurred in less than one hour proceed to mouth wash with plenty of water. Take to hospital.
- 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.
- Keep the individual calm and at rest, conserve body temperature and control breathing. If necessary check for pulse and initiate artificial respiration.
- If symptoms persist or worsen bring individual to a healthcare center, bring packaging or label whenever possible.
- NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

Advice for medical and healthcare personnel:

- In case of ingestion assess realizing an endoscopic procedure.
- The use of ipecac syrup, neutralization and activated charcoal is not advised.
- Symptomatic and supportive treatment.
- WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER

Emergency measures to protect the environment:

- Prevent entry into sewers and public waters.
- Clean up any spills as soon as possible, using an absorbent material (earth, sand, ...) to collect the spill. Use suitable disposal containers.

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

Keep only in the original packaging tightly closed in a cool and well-ventilated place
Keep products away from direct sunlight, source of heat and ignition.
The biocidal product must be stored at temperatures below +30°C.
Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains
Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

Storage conditions:

- Store in a clean area allowing recuperation of leaks and effusion.
 - Protect from freezing. Provide local exhaust or general room ventilation to minimize dust and/or vapour concentrations. Keep packaging closed when not in use.
 - Handle in accordance with good industrial hygiene and safety procedures.
- Packaging material: Use approved materials suitable for corrosive liquids.

Shelf-life : 12 months in its original packaging.

6. Other information

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Hazard and precautionary statements in Icelandic

H314: Veldur alvarlegum bruna á húð og augnskaða.
H290: Getur verið ætandi fyrir málma.
H335: Getur valdið ertingu í öndunarfærum.

P260: Andið ekki að ykkur gufu.
P305 + P351 + P338: BERIST EFNID Í AUGU: Skolið varlega með vatni í nokkrar mínútur. Fjarlægjið snertilinsur ef það er auðvelt. Skolið áfram.
P310: Hringið umsvífaust í EITRUNARMÍÐSTÖÐ.
P310: Hringið umsvífaust í lækni.
P280: Notið hlífðarhanska.
P280: Notið hlífðarfatnað.
P280: Notið augnhlífur.
P280: Notið andlitshlífur.
P301 + P330 + P331: EFTIR INNTÖKU: Skolið munninn. EKKI framkalla uppköst.
P303 + P361 + P353: BERIST EFNID Á HÚÐ (eða í hár): Farið strax úr fötum sem óhreinkast af efninu. Skolið húðina með vatni eða farið í sturtu
P234: Má aðeins geyma í upprunalegum umbúðum.
P403 + P233: Geymist á vel loftræstum stað. Ílát skal vera vel lukt.
P501: Fargið innihaldi/íláti í samræmi við landsbundnar reglur.