

Summary of product characteristics for a biocidal product

Product name: SOPURCLEAN BN

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

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Authorisation number: EU-0021157-0000

R4BP 3 asset reference number: IS-0024234-0004

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Administrative information

1.1. Trade names of the product

SOPURCLEAN BN

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 1-1

R4BP 3 asset reference number

IS-0024234-0004

Date of the authorisation

18/05/2020

Expiry date of the authorisation

30/04/2030

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

SOPURA

Address of the manufacturer

rue de Trazegnies 199 6180 COURCELLES Belgium

Location of manufacturing sites

PIB de Tyberchamps 14 7180 SENEFFE Belgium
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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	1,8
Decanoic acid		Active Substance	334-48-5	206-376-4	1,2

Sulfuric acid	7664-93-9	231-639-5	29,64
Propionic acid	79-09-4	201-176-3	0
Phosphoric acid	7664-38-2	231-633-2	0
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	0
Citric acid	77-92-9	201-069-1	3

2.2. Type of formulation

SL - Soluble concentrate

3. Hazard and precautionary statements

Hazard statements

Causes severe skin burns and eye damage.

May be corrosive to metals.

Precautionary statements

Do not breathe vapours.

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.

Wear eye protection.

Wear face protection.

Wear protective clothing.

Wear protective gloves.

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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.

Keep only in original packaging.

Store in a well-ventilated place. Keep container tightly closed.

Absorb spillage to prevent material damage.

Dispose of contents to 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 - <u>For disinfection of pipes, tanks, etc ...:</u> - 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 yeasts: Dilution rate: 1.5%v/v In case of outbreaks caused by <i>Pediococcus damnosus</i> , the products must be used at 2%. 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 (containers containing the product are connected to CIP via installed pipes; connections with dry coupling).

- Treated equipment (vessels) and dosing equipment has to be rinsed.

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 - 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 small hard non-porous 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: 1.5%v/v In case of outbreaks caused by *Pediococcus damnosus*, the products must be used at 2%. Contact time: minimum 15 minutes at +4°C (and above, up to 20-25°C). -
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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*
- Bulk delivery.

*Depending on BP specific weight.

4.2.1 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.

4.2.2 Use-specific risk mitigation measures

During the post application phase:

Equipment is rinsed.

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.

5. General directions for use

5.1. Instructions for use

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: 1.5%
*In case of outbreaks caused by *Pediococcus damnosus*, the products must be used at 2%.*
 - Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C).
- Final rinsing (with drinking water)

5.2. Risk mitigation measures

Use in well-ventilated places.

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.

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 container 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

In order to guarantee efficacy of future products in Meta SPC 1, any new product must contain sufficient amounts of acids to yield a pH ≤ 2 at the use dilution of 1.5%.

Hazard and precautionary statements in Icelandic

H314: Veldur alvarlegum bruna á húð og augnskaða.

H290: Getur verið ætandi fyrir málma.

P260: Andið ekki að ykkur gufu.

P305 + P351 + P338: BERIST EFNID Í AUGU: Skolið varlega með vatni í nokkrar mínútur. Fjarlægið snertilinsur ef það er auðvelt. Skolið áfram.

P310: Hringið umsvífalaust í EITRUNARMÍÐSTÖÐ.

P310: Hringið umsvífalaust 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.

P390: Sogið upp allt sem hellist niður til að afstýra eignatjóni.

P501: Fargið innihaldi/íláti í samræmi við landsbundnar reglur.