

Summary of product characteristics for a biocidal product

Product name: SOPURCLEAN OP-N

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

Authorisation number: EU-0021157-0000

R4BP 3 asset reference number: IS-0024234-0007

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Administrative information

1.1. Trade names of the product

SOPURCLEAN OP-N

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 1-3

R4BP 3 asset reference number

IS-0024234-0007

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 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

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
	Rue de Trazegnies 199 6180 COURCELLES Belgium

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Decanoic acid		Active Substance	334-48-5	206-376-4	1,2
Sulfuric acid			7664-93-9	231-639-5	0
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	18
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	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.
 Harmful if inhaled.

Precautionary statements

Do not breathe vapours.
 Wear protective clothing.
 Wear eye protection.
 Wear protective gloves.
 Wear face protection.
 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 doctor.
 Immediately call a POISON CENTER.
 Keep only in original packaging.

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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

Absorb spillage to prevent material damage.

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)	<p>Scientific name: Common name: Bacteria Development stage:</p> <p>Scientific name: Common name: Yeasts Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>In food & feed areas</p>
Application method(s)	<p>Closed system - For disinfection of pipes, tanks, etc ...</p> <ul style="list-style-type: none"> - 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	<p>- - For an effect on bacteria and on 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). -</p> <p>-</p>
Category(ies) of users	<p>Industrial</p> <p>Trained professional</p>

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.

4.1.1 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& loading and application phases :
- 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)
During the mixing& loading phase :
- Wear respiratory Mask.

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.

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 overall 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

Only the concentrated biocidal product is expected to have undesirable affect because of its corrosive nature, once diluted sufficiently harmful effects will be limited.

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.
H332: Hættulegt við innöndun.

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 umsvifalaust í EITRUNARMÍÐSTÖÐ.
P310: Hringið umsvifalaust 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.
P390: Sogið upp allt sem hellist niður til að afstýra eignatjóni.