

Summary of product characteristics for a biocidal product

Product name: SOPUROXID 3.2

Product type(s): PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT03 - Veterinary hygiene (Disinfectants)

PT04 - Food and feed area (Disinfectants)

Authorisation number: EU_0026179-0000

R4BP 3 asset reference number: EU-0026179-0003

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Administrative information

1.1. Trade names of the product

SOPUROXID 3.2
HyPro Biocide 3.2-23

1.2. Authorisation holder

Name and address of the authorisation holder	Name	SOPURA
	Address	rue de Trazegnies 199 6180 COURCELLES Belgium
Authorisation number	EU_0026179-0000 1-2	

R4BP 3 asset reference number

EU-0026179-0003

Date of the authorisation

12/07/2022

Expiry date of the authorisation

30/06/2032

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	SOPURA N.V.
Address of the manufacturer	Rue de Trazegnies 199 6180 COURCELLES Belgium
Location of manufacturing sites	Rue de Trazegnies 199 6180 COURCELLES Belgium

Name of the manufacturer	SOPURA QUIMICA
Address of the manufacturer	Poligon "La Canaleta", Avinguda Júpiter 7 25300 TARREGA Spain
Location of manufacturing sites	Poligon "La Canaleta", Avinguda Júpiter 7 25300 TARREGA Spain

Name of the manufacturer	HYPRED SAS (KERSIA Group)
Address of the manufacturer	55, Boulevard Jules Verger (BP 10180) 35803 DINARD France
Location of manufacturing sites	55, Boulevard Jules Verger (BP 10180) 35803 DINARD France
	Niepruszewo, ul. Kasztanowa 64-320 Buk Poland

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

Active substance	1340 - Peracetic acid
Name of the manufacturer	SOPURA N.V.
Address of the manufacturer	Rue de Trazegnies 199 6180 COURCELLES Belgium
Location of manufacturing sites	Rue de Trazegnies 199 6180 COURCELLES Belgium

Active substance	1340 - Peracetic acid
Name of the manufacturer	SOPURA QUIMICA
Address of the manufacturer	Poligon "La Canaleta", Avinguda Júpiter 7 25300 TARREGA Spain
Location of manufacturing sites	Poligon "La Canaleta", Avinguda Júpiter 7 25300 TARREGA Spain

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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 (%)
Peracetic acid		Active Substance	79-21-0	201-186-8	3,2
Sulfuric acid		Non-active substance	7664-93-9	231-639-5	0,8
Hydrogen peroxide		Non-active substance	7722-84-1	231-765-0	23,5
Acetic acid		Non-active substance	64-19-7	200-580-7	6,45

2.2. Type of formulation

SL - Soluble concentrate

3. Hazard and precautionary statements

Hazard statements	<p>May intensify fire; oxidiser</p> <p>May be corrosive to metals.</p> <p>Causes severe skin burns and eye damage.</p> <p>Causes serious eye damage.</p> <p>May cause respiratory irritation.</p> <p>Very toxic to aquatic life with long lasting effects.</p> <p>Harmful if swallowed.Harmful in contact with skin.</p>
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Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. -
No smoking.

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 POISON CENTER/doctor.

Wear eye protection.

Wear protective gloves.

Take any precaution to avoid mixing with combustibles .

Avoid breathing vapours.

Wash hands thoroughly after handling.

Do no eat, drink or smoke when using this product.

Use only outdoors or in a well-ventilated area.

Specific treatment (see information on this label).

Rinse mouth.

Wash contaminated clothing before reuse.

IF SWALLOWED:Call a POISON CENTER/doctor if you feel unwell.

IF SWALLOWED:Rinse mouth.Do NOT induce vomiting.

IF ON SKIN:Wash with plenty of water.

IF INHALED:Remove person to fresh air and keep comfortable for breathing.

Take off contaminated clothing.And wash it before reuse.

Store locked up.

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

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

Wear protective clothing.

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

Keep cool.

Avoid release to the environment.

Collect spillage.

IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with shower.

Avoid breathing spray.

Do not breathe spray.

Do not breathe vapours.

4. Authorised use(s)

4.1 Use description

Use 1 - Room Disinfection by fogging - In industrial, public and non-medical healthcare areas. (pharmaceutical and cosmetic industry)

Product type

PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)

Where relevant, an exact description of the authorised use

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Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Yeasts
Development stage:

Scientific name:
Common name: Bacterial spores
Development stage:

Field(s) of use

Indoor

In industrial, public and non-medical healthcare areas. :
Disinfection of hard/non-porous surfaces by fogging.

Application method(s)

Method: Fogging
Detailed description:
By fogging with the diluted product

Application rate(s) and frequencies

Application Rate: -
Dilution (%): Active against bacteria (including bacterial spores) and yeasts : With 5,6 mL/m³ (Dilution of the product at 40% i.e. 40 L / 100 L i.e. 1,28% PAA) at Room Temperature in 2h contact time (after diffusion)
Number and timing of application:
/

Category(ies) of users

Industrial
Professional

Pack sizes and packaging material

HDPE with screw and venting caps (weight depends on density of product):
Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

4.1.1 Use-specific instructions for use

See general directions for use

4.1.2 Use-specific risk mitigation measures

Dermal protection :

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance.

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

Use 2 - Room Disinfection by fogging - In agriculture & horticulture areas (in absence of plants - for general hygiene purpose only)

Product type

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Where relevant, an exact description of the authorised use

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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 agriculture/horticulture areas : Disinfection of hard/non-porous surfaces by fogging with prior cleaning
Application method(s)	Method: Fogging Detailed description: By fogging with the diluted product
Application rate(s) and frequencies	Application Rate: - Dilution (%): Against bacteria and yeasts : With 5,6 mL/m3 (Dilution of the product at 40% i.e. 40 L / 100 L i.e. 1,28% PAA) at Room Temperature in 2h contact time (after diffusion) Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

4.2.1 Use-specific instructions for use

See general directions for use

4.2.2 Use-specific risk mitigation measures

Dermal protection :

Use appropriate safety glasses and/or face shield during the mixing & loading.

Respiratory protection: .

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance.

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

Use 3 - Room Disinfection by fogging – In animal housing

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

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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 animal housing :
Disinfection of hard/non-porous surfaces by fogging with prior cleaning

Application method(s)

Method: Fogging
Detailed description:

By fogging with the diluted product

Application rate(s) and frequencies

Application Rate: -
Dilution (%): Against bacteria and yeasts : With 5,6 mL/m3 (Dilution of the product at 40% i.e. 40 L / 100 L i.e. 1,28% PAA) at Room Temperature in 2h contact time (after diffusion)
Number and timing of application:
/

Category(ies) of users

Industrial
Professional

Pack sizes and packaging material

HDPE with screw and venting caps (weight depends on density of product):
Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

4.3.1 Use-specific instructions for use

See general directions for use

4.3.2 Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing & loading.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance.

Only treatment of empty animal housings. Re-entry of animals only after adequate ventilation and when surfaces are dried.

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

Use 4 - Room Disinfection by fogging – In storage rooms with special device in storage cellar or room

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> <p>Scientific name: Common name: Bacterial spores Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>In food/feed areas (storage rooms) : Disinfection of hard/non-porous surfaces by fogging.</p>
Application method(s)	<p>Method: Fogging Detailed description: By fogging with the diluted product</p>
Application rate(s) and frequencies	<p>Application Rate: - Dilution (%): Active against bacteria (including bacterial spores) and yeasts With 5,6 mL/m³ (Dilution of the product at 40% i.e. 40 L / 100 L i.e. 1,28% PAA) at Room Temperature in 2h contact time (after diffusion) Number and timing of application: /</p>
Category(ies) of users	<p>Industrial</p> <p>Professional</p>

Pack sizes and packaging material

HDPE with screw and venting caps (weight depends on density of product):
Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1000 to 1200 kg), 1 L bottles, bulk delivery.

4.4.1 Use-specific instructions for use

See general directions for use

4.4.2 Use-specific risk mitigation measures

Dermal protection :

Use appropriate safety glasses and/or face shield during the mixing & loading.

Respiratory protection: .

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance.

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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..

5. General directions for use

5.1. Instructions for use

1. All the surfaces to be disinfected must be cleaned before the disinfection procedure.
For exceptions, please refer to the description of application method related to each use.

2. Disinfection cycle :

- Products must be diluted in potable water before use.
- Dilution rate & contact time depends on the use considered. Please refer to the description of application method related to each use.
- 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. For exceptions, please refer to the description of application method related to each use.

Meta SPC2 : Disinfection procedures by fogging

The product SOPUROXID 3.2 is a liquid disinfectant to be applied (after dilution at 40%) by fogging for airborne surface disinfection and to be used indoor by professional users only.

Always check compatibility of the products with the hard/non-porous surfaces to be disinfected.

The product SOPUROXID 3.2 has been developed and demonstrated as efficacious (via efficacy studies performed according to the NF T 72 281 standard), using one device HYSpray, for rooms with a volume between 30 & 150 m³ (volume per application and per device) with a flow rate of 0.047 mL/min/m³ .

The use of other devices is possible. They must be designed to work with PAA-based products and to ensure a fog production able to stay suspended in the air and provided that these devices meet following characteristics :

- 1) Particle (medium droplet) size : between 1 and 15 µm
- 2) Flow rate : 0.047 mL/min/m³
- 3) Application rate : 5,6 mL/m³
- 4) Room volume between 30 and 150 m³ per application and per device (i.e. diffusion time between 5 and 30 min)

- Airborne disinfection should be done only after thorough cleaning and rinsing.

The surfaces to be disinfected should be dried before the disinfection procedure. Please pay attention to open the cupboard doors. Please check the temperature and the relative room humidity (to be set between 40 and 80%) to obtain an optimal level for the product efficiency.

- The room where the fogging activity takes place is tightly sealed during fogging, no user is present :

Before the start of the disinfection cycle by fogging, the treated room is sealed. All the safety tasks for the implementation of decontamination are entrusted to an user who has completed the necessary training. Among them, first step is shutting down the air handling units and closing the air intake and return, so the product is not spread in the other rooms. The door or doors to the outside of the area are then locked and, if the joints are not tight enough, they are taped to seal. An orange tape, or bright color, is preferably chosen to attract attention and a sign "Access ban, room disinfection in progress" is put on. Only for use in areas that are inaccessible to the general public and companion animals".

- The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable "standard room", if applicable) with the devices to be used, after which a protocol for disinfection of these rooms can be made and used thereafter. Each device or specific installation is systematically validated when it is set up.

5.2. Risk mitigation measures

Dermal protection :

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

+ Additional specific RMM for fogging applications :

Only for use in areas that are inaccessible to the general public and companion animals.

- After disinfection product's application by fogging & required contact time for optimal disinfection (2h), the room must be ventilated, preferably by mechanical ventilation at least for 60 min.

The duration of the ventilation period has to be established by measurement with suitable measurement equipment (specified by the authorisation holder within the product information).

- After ventilation, re-entry in the disinfected area is only permitted after the air concentrations of peracetic acid and hydrogen peroxide have been checked and seen as dropped below the respective reference values (AEC) :

- The air concentration of PAA must have dropped to 0.5 mg/m³.

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

Indirect effects

The two products are oxidising agents and reactive. In case of thermal decomposition steam and oxygen will be released as decomposition products. The release of oxygen may support combustion.

Also, contact with impurities, decomposition catalysts, metallic salts, alkalis, reducing agents may lead to self-accelerated, exothermic decomposition and the formation of oxygen.

In case of decomposition of the products in confined spaces and pipers, there is a risk of overpressure and burst.

First aid measures**Ø General advice**

Move out of dangerous area.

Take care of your own personal safety.

Take off immediately all contaminated clothing.

Ø Inhalation

Take affected persons out into the fresh air.

Possible discomfort: Irritates skin and mucous linings of the eyes and respiratory tract and cough.

If breathing difficulties occur (e.g. severe continual coughing): Keep patient half sitting with upper body raised; keep warm and in a quiet place; call a physician immediately.

Ø Skin contact

After contact with skin, wash immediately with plenty of water.

Consult a physician.

Take off immediately all contaminated clothing.

Immediately rinse contaminated or saturated clothing with water.

Ø Eye contact

With eye held open, thoroughly rinse immediately with plenty of water for at least 10 minutes.

Protect unharmed eye.

Continue rinsing process with eye rinsing solution.

Call ambulance (caustic burn of the eyes)

Immediate further treatment in ophthalmic hospital/ophthalmologist.

Continue rinsing eye until arrival at ophthalmic hospital.

Ø Ingestion

Do not induce vomiting.

Danger of penetration of the lungs (danger to breathing) when swallowed or vomited, due to gas evolution and foam formation.

Only when patient fully conscious: have the mouth rinsed with water; have the patient drink plenty of water in small sips; keep patient warm and at rest.

Notify ambulance immediately (key word: acid burn).

Ø Notes to physician

Therapy as for chemical burn.

Following inhalation:

Formation of a toxic lung oedema is possible if product continues to be inhaled despite acute irritative effect (e.g. if it is not possible to leave the danger area).

Prophylaxis of a toxic lung oedema with inhalative steroids (dosing spray, e.g. auxilosone).

If substance has been swallowed:

Aspiration hazard.

Risk of gaseous embolisms.

In case of excessive strain on the stomach due to gas evolution, insert siphon tube.

Early endoscopy in order to assess mucosa lesions in the oesophagus and stomach which may appear.

If necessary, suck away leftover substance.

Do not administer activated charcoal, since risk of release of large amounts of gas from hydrogen peroxide.

Emergency measures to protect the environment

Observe regulations on prevention of water pollution (collect, dam up, cover up).

Do not allow to run into water channels, surface water or into the ground.

Ø Methods for cleaning up

Clean contaminated surface thoroughly; recommended cleaning agent is water.

In case of small spills, dilute product with lots of water and rinse away or absorb product with liquid-binding material, e.g. chemisorption, diatomaceous earth, universal binder. Do not use textiles, saw dust, combustible substances. After binding, pick up mechanically and collect in suitable containers. Dispose of absorbed material in accordance with the regulations.

Ø Additional advice

Make safe or remove all sources of ignition.

Isolate defective containers immediately, if possible and safe to do.

Shut off leak, if possible and safe to do.

Place defective containers in waste receptacle (waste packaging receptacle) made of plastic (not metal).

Do not seal defective containers or waste receptacles airtight (danger of bursting due to product decomposition).

Product taken out should not be returned into container.

Never return spilled product into its original container for re-use (risk of decomposition).

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

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

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 shelf life of the biocidal product is 6 months.

The products must be stored at temperatures below +30°C.

6. Other information

Reference values of peracetic acid and hydrogen peroxide used for the risk assessment :

PAA : AECinhal = 0.5 mg/m³

HP : AECinhal = 1.25 mg/m³