

Summary of product characteristics for a biocidal product

Product name: PRODUCT 10-1 - Orapi

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

Authorisation number: FR-2023-0070

R4BP 3 asset reference number: FR-0021507-0113

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Administrative information

1.1. Trade names of the product

PRODUCT 10-1 - Orapi

1.2. Authorisation holder

Name and address of the authorisation holder

Name	ORAPI
Address	225 ALLEE DES CEDRES 01150 SAINT VULBAS France
Authorisation number	FR-2023-0070 1-10

R4BP 3 asset reference number

FR-0021507-0113

Date of the authorisation

19/12/2023

Expiry date of the authorisation

18/12/2033

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

ORAPI

Address of the manufacturer

25 Rue de l'Industrie 69200 VENISSIEUX France

Location of manufacturing sites

25 Rue de l'Industrie 69200 VENISSIEUX France

225 allées des cèdres - PI de la plaine de l'Ain 01150 SAINT VULBAS France
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1.4. Manufacturer(s) of the active substance(s)

Active substance	1322 - L-(+)-lactic acid
Name of the manufacturer	Corbion Purac Bioquimica sa
Address of the manufacturer	Gran Vial 19-25 08160 MONTMELÓ Spain
Location of manufacturing sites	Gran Vial 19-25 E-08160 MONTMELÓ Spain Arkelsedijk 46 NL-4200 GORINCHEM Netherlands
Active substance	1322 - L-(+)-lactic acid
Name of the manufacturer	Jungbunzlauer S.A
Address of the manufacturer	ZI Portuaire - BP 32 F-67390 Marcklosheim France
Location of manufacturing sites	Jungbunzlauer S.A - ZI Portuaire - BP 32 F-67390 Marcklosheim France

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 (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	30,16
Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6)	Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one	Non-active substance	55965-84-9	611-341-5	0,011

2.2. Type of formulation

SL - Soluble concentrate

3. Hazard and precautionary statements

Hazard statements

Causes severe skin burns and eye damage.

May cause an allergic skin reaction.

Corrosive to the respiratory tract.

Precautionary statements

Do not breathe spray.

Wash hands thoroughly after handling.

Wear protective gloves/ protective clothing/ eye protection.

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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

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

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 or doctor/physician.

Specific treatment (see on this label).

Wash contaminated clothing before reuse.

If skin irritation or rash occurs: Get medical .

IF ON SKIN: Wash with plenty of water.

Avoid release to the environment.

Dispose of to .

4. Authorised use(s)

4.1 Use description

Use 1 - Disinfection of hard surfaces and equipment by manual dipping/soaking– Professionals - PT4 – Soluble concentrate (Use 11)

Product type

PT04 - Food and feed area (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: Adults

Field(s) of use

Indoor
Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants).

Application method(s)

Method: Dipping, soaking
Detailed description:
Manual dipping/soaking.

Application rate(s) and frequencies

Application Rate: -
Dilution (%): -
Number and timing of application:
At a temperature of 40°C:

- Bacteria and yeasts: 20% v/v, 15 minutes.

Category(ies) of users

Professional

Pack sizes and packaging material

20mL PE+PET Pods
100mL to 2L HDPE/PET Bottle
1L LDPE Dosing bottle
1L HDPE Dosing bottle
1 to 5 L HDPE Pouch
5-10-20L LDPE/PET Bag in box (cubitainer)
5 to 30L HDPE Jerrican
60-220L HDPE Drum
1000L HDPE Bulk container (IBC)

4.1.1 Use-specific instructions for use

4.1.1 Use-specific instructions for use

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4.1.2 Use-specific risk mitigation measures

The professional user has to wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
-Do not immerse hands in the bath
-Let the equipment soak for the necessary time in the bath of cleaning/disinfectant solution, then empty the bath, and finish by rinsing without touching the equipment that has remained in the tank.

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

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

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

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5. General directions for use

5.1. Instructions for use

- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.
- Products have been tested against bacteria, including Enterobacter cloacae, Salmonella Typhimurium, Campylobacter jejuni and Listeria and Lactobacillus brevis at 40°C.
- During the product dilution, pour almost all water first, then the product, then the remaining of the water.

5.2. Risk mitigation measures

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

- IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid
- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.
- IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

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

- Protect from frost.
- Keep away from direct sunlight.
- Do not store above 40°C.
- Shelf-life = 2 years.

6. Other information

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