

Summary of product characteristics for a biocidal product

Product name: Product 8-16 - Orapi

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

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

PT04 - Food and feed area (Disinfectants)

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

Authorisation number: FR-2023-0070

R4BP 3 asset reference number: FR-0021507-0091

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Administrative information

1.1. Trade names of the product

Product 8-16 - 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 1-8

R4BP 3 asset reference number

FR-0021507-0091

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	6,28
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

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements

Causes severe skin burns and eye damage.
Corrosive to the respiratory tract.

Precautionary statements

If medical advice is needed, have product container or label at hand.
Keep out of reach of children.
Read carefully and follow all instructions.
Do not breathe vapours.
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.
Avoid release to the environment.
Dispose of to .

4. Authorised use(s)

4.1 Use description

Use 1 - Disinfection of hard surfaces (small surfaces) and equipment by manual liquid spraying using a trigger sprayer – Professionals - PT2 – RTU product (Use 18)

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:

Field(s) of use

Indoor

Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals).

Application method(s)

Method: Manual surface spraying with a trigger sprayer
Detailed description:
Manual surface spraying with a trigger sprayer (liquid/foam spraying).

Application rate(s) and frequencies

Application Rate: -
Dilution (%): 0
Number and timing of application:
Ready to use product.

60 minutes, 20°C

Category(ies) of users

Professional

Pack sizes and packaging material

500mL to 1L HDPE/PET Prefilled trigger spray

5 to 30L HDPE Jerrican

60-220L HDPE Drum

1000L HDPE Bulk container (IBC)

4.1.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

4.1.2 Use-specific risk mitigation measures

For professional user :

-wear gloves, protective overall and chemical goggles (material to be specified by the authorisation holder within the product information) during loading and rinsing

-wear gloves, protective overall chemical goggles and a respiratory protective equipment (material to be specified by the authorisation holder within the product information) during application.

For professional bystander:

-Do not be present in the treatment area during disinfection process by spraying. If it is necessary to be present, wear same PPE as the professional user.

-Do not touch the surface until it is completely dried

General public:

-Do not be present in the treatment area during disinfection process.

-Do not touch the surface until it is rinsed and completely dried

-Children should not be present during disinfection and until the surface is rinsed and dried.

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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4.2 Use description

Use 2 - Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT2 – RTU product (Use 19)

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	-
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 Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals).
Application method(s)	Method: Wiping / mopping / brushing / scrubbing Detailed description: Wiping/mopping/brushing/scrubbing without mechanical action.
Application rate(s) and frequencies	Application Rate: - Dilution (%): 0 Number and timing of application: Ready to use product. 60 minutes, 20°C.
Category(ies) of users	Professional
Pack sizes and packaging material	100mL to 2L HDPE/PET Bottle 500mL to 1L HDPE/PET Prefilled trigger spray 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC)

4.2.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

4.2.2 Use-specific risk mitigation measures

For professional user :

-wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during loading, application and rinsing

- Pour the solution direct on the surface and wipe with a cloth / brush

-A mop/brush with a handle has to be used to apply the solution

-Do not immerse hands in the solution

For professional bystander:

-Do not touch the surface until it is completely dried

General public:

-Do not touch the surface until it is rinsed and completely dried

-Children should not be present during disinfection and until the surface is rinsed and dried.

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

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

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

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4.3 Use description

Use 3 - Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding – Professionals - PT2 – RTU product (Use 20)

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	-
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>Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals).</p>
Application method(s)	<p>Method: Spreading / flooding Detailed description: Direct spreading/flooding.</p>
Application rate(s) and frequencies	<p>Application Rate: - Dilution (%): 0 Number and timing of application: Ready to use product.</p> <p>60 minutes, 20°C.</p>
Category(ies) of users	Professional
Pack sizes and packaging material	<p>100mL to 2L HDPE/PET Bottle 750mL HDPE Angled bottle 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC)</p>

4.3.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

4.3.2 Use-specific risk mitigation measures

For professional user :

-wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during application by pouring and brushing

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

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

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

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4.4 Use description

Use 4 - Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT4 – RTU product (Use 23)

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:

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: Wiping / mopping / brushing / scrubbing
Detailed description:
Wiping/mopping/brushing/scrubbing without mechanical action.

Application rate(s) and frequencies

Application Rate: -
Dilution (%): 0
Number and timing of application:
Ready to use product.

60 minutes, 20°C

Category(ies) of users

Professional

Pack sizes and packaging material

100mL to 2L HDPE/PET Bottle

500mL to 1L HDPE/PET Prefilled trigger spray

5 to 30L HDPE Jerrican

60-220L HDPE Drum

1000L HDPE Bulk container (IBC)

4.4.1 Use-specific instructions for use

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4.4.2 Use-specific risk mitigation measures

For professional user :
-wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during loading, application and rinsing
- Pour the solution direct on the surface and wipe with a cloth / brush
-A mop/brush with a handle has to be used to apply the solution
-Do not immerse hands in the solution

For professional bystander:
-Do not touch the surface until it is completely dried

General public:
-Do not touch the surface until it is rinsed and completely dried
-Children should not be present during disinfection and until the surface is rinsed and dried.

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

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

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

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4.5 Use description

Use 5 - Disinfection of toilets bowls and sanitary facilities by direct spreading/flooding – General public - PT2 – RTU product (Use 26)

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 Indoors disinfection in private areas, households.
Application method(s)	Method: Spreading / flooding Detailed description: Direct spreading/flooding
Application rate(s) and frequencies	Application Rate: - Dilution (%): 0 Number and timing of application: Ready to use product. 60 minutes, 20°C.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100mL to 2L HDPE/PET Bottle 750mL HDPE Angled bottle

4.5.1 Use-specific instructions for use

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4.5.2 Use-specific risk mitigation measures

For non professional user during pouring and brushing :

- Wash hands after use
- Avoid any contact with eyes and skin
- Avoid any splashes and spills

For general public :

- Do not touch the surface until it is rinsed and totally dried
- Children should not be present during disinfection and until the surface is rinsed and dry

4.5.3 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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4.5.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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

- Keep out of reach of children and non-target animals/pets.

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.

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.
- If medical advice is needed, have product container or label at hand.

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

- Don't 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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