

Summary of product characteristics for a biocidal product

Product name: Product 9-14 - Orapi

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)

PT04 - Food and feed area (Disinfectants)

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)

PT04 - Food and feed area (Disinfectants)

Authorisation number: FR-2023-0070

R4BP 3 asset reference number: FR-0021507-0110

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Administrative information

1.1. Trade names of the product

| |
|----------------------|
| Product 9-14 - 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 1-9 |

R4BP 3 asset reference number

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|-----------------|
| FR-0021507-0110 |
|-----------------|

Date of the authorisation

| |
|------------|
| 19/12/2023 |
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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 |
|--|

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 | 3,04 |
| 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 skin irritation.
Causes serious eye damage.

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.
Wash hands thoroughly after handling.
Wear protective gloves/protective clothing/eye protection.
IF ON SKIN:Wash with plenty of soap and 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 or doctor/physician.
Specific treatment (see on this label).
If skin irritation occurs:Get medical .
Take off contaminated clothing.And wash it before reuse.
Avoid release to the environment.
Dispose of to .

4. Authorised use(s)

4.1 Use description

Use 1 - 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: 60mL/m ² 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 1L HDPE Bottle with handle 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 coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander :

-Do not touch the surface until it is completely dried

For 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.

4.1.3 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

-

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

-

4.2 Use description

Use 2 - Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding – Professionals - PT2 – RTU product (Use 20)

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

-

Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Yeasts
Development stage:

Field(s) of use

| | |
|--|--|
| Application method(s) | <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> <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 | <p>Professional</p> |
| Pack sizes and packaging material | <p>100mL to 2L HDPE/PET Bottle</p> <p>750mL HDPE Angled bottle</p> <p>1L HDPE Bottle with handle</p> <p>5 to 30L HDPE Jerrican</p> <p>60-220L HDPE Drum</p> <p>1000L HDPE Bulk container (IBC)</p> |

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 pouring and brushing.

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

-

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

-

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

-

4.3 Use description

Use 3 - 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) |

4.3.1 Use-specific instructions for use

-

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 mixing and loading, application and rinsing.

For professional bystander :

- Do not touch the surface until it is completely dried

For 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.

4.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

-

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

-

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

-

4.4 Use description

Use 4 - Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – General public - PT2 – RTU product (Use 25)

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 areas, households.

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

General public (non-professional)

Pack sizes and packaging material

100mL to 2L HDPE/PET Bottle

500mL to 1L HDPE/PET Prefilled trigger spray

4.4.1 Use-specific instructions for use

-

4.4.2 Use-specific risk mitigation measures

For non professional user during application and rinsing :

- Wash hands after use
- Avoid contact with eyes and skin
- Avoid splashes and spills
- The packaging must be adapted with a child proof closure

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.

4.4.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

-

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

-

4.4.5 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.

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 | - |
| 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 1L HDPE Bottle with handle |

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 application and rinsing :

- Wash hands after use
- Avoid contact with eyes and skin
- Avoid splashes and spills
- The packaging must be adapted with a child proof closure

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

-

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.

4.6 Use description

Use 6 - Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – General public - PT4 – RTU product (Use 28)

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 private areas, domestic kitchens.

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

Pack sizes and packaging material

General public (non-professional)

100mL to 2L HDPE/PET Bottle

500mL to 1L HDPE/PET Prefilled trigger spray

1L HDPE Bottle with handle

4.6.1 Use-specific instructions for use

-

4.6.2 Use-specific risk mitigation measures

For non professional user during application and rinsing :

- Wash hands after use
- Avoid contact with eyes and skin
- Avoid splashes and spills
- The packaging must be adapted with a child proof closure

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.

4.6.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

-

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

-

4.6.5 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: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.
- 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: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a poison centre or a doctor
- IF INHALED: If symptoms occur 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

- 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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