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*ANNEX*

**SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT**

Product 8-3 - Soprodin

**Product type(s)**

PT02: Disinfectants and algicides not intended for direct application to humans or animals

PT04: Food and feed area

**Authorisation number:** FR-2023-0071 1-8

**R4BP asset number:** FR-0021510-0078

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## 1. ADMINISTRATIVE INFORMATION

### 1.1. Trade name(s) of the product

Trade name(s)	Product 8-3 - Soprodis
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### 1.2. Authorisation holder

Name and address of the authorisation holder	Name	SOPRODIS
	Address	44 RUE DU LANGUEDOC 11200 LEZIGNAN CORBIERES France
Authorisation number	FR-2023-0071 1-8	
<i>R4BP asset number</i>	FR-0021510-0078	
Date of the authorisation	19/12/2023	
Expiry date of the authorisation	18/12/2033	

### 1.3. Manufacturer(s) of the product

Name of manufacturer	SOPRODIS
Address of manufacturer	44 Rue du LANGUEDOC 11200 LEZIGNAN CORB IERES France
Location of manufacturing sites	SOPRODIS site 1 44 Rue du LANGUEDOC 11200 LEZIGNAN CORBIERES France

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

Active substance	L-(+)-lactic acid
Name of manufacturer	Corbion Purac Bioquimica sa
Address of manufacturer	Gran Vial 19-25 08160 MONTMELÓ Spain
Location of manufacturing sites	Corbion Purac Bioquimica sa site 1 Gran Vial 19-25 E-08160 MONTMELÓ Spain  Corbion Purac Bioquimica sa site 2 Arkelsedijk 46 NL-4200 GORINCHEM Netherlands (the)

Active substance	L-(+)-lactic acid
Name of manufacturer	Jungbunzlauer S.A
Address of manufacturer	ZI Portuaire - BP 32 F-67390 Marcklosheim France
Location of manufacturing sites	Jungbunzlauer S.A site 1 Jungbunzlauer S.A - ZI Portuaire - BP 32 F-67390 Marcklosheim France

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## 2. PRODUCT COMPOSITION AND FORMULATION

### 2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		active substance	79-33-4	201-196-2	6,28 % (w/w)

### 2.2. Type(s) of formulation

AL Any other liquid

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### 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H314: Causes severe skin burns and eye damage. EUH071: Corrosive to the respiratory tract.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read carefully and follow all instructions. P260: Do not breathe spray. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/ protective clothing/ eye protection. P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physician. P321: Specific treatment (see ... on this label). P363: Wash contaminated clothing before reuse. P273: Avoid release to the environment. P501: Dispose of {0:...:contents container} to {1:...:}.

## 4. AUTHORISED USE(S)

### 4.1. Use description

**Table 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 algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data  Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	indoor use  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 frequency	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)

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#### **4.1.1. Use-specific instructions**

- 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 loading and rinsing

-wear gloves, protective coverall 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**

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

Product type	PT02: Disinfectants and algacides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data  Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	indoor use  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 frequency	Application rate: -  Dilution (%): 0  Number and timing of application: Ready to use product.  60 minutes, 20°C
Category(ies) of users	professional

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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)
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#### **4.2.1. Use-specific instructions**

- 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**

**Table 3. 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
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data  Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	indoor use  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: Spreading / flooding  Detailed description: Direct spreading/flooding.
Application rate(s) and frequency	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  750mL HDPE Angled bottle  5 to 30L HDPE Jerrican  60-220L HDPE Drum  1000L HDPE Bulk container (IBC)

#### **4.3.1. Use-specific instructions**

- 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**

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

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data  Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	indoor use  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 frequency	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

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	60-220L HDPE Drum
	1000L HDPE Bulk container (IBC)

#### **4.4.1. Use-specific instructions**

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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**

**Table 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
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data  Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	indoor use  Indoors disinfection in private areas, households.
Application method(s)	Method: Spreading / flooding  Detailed description: Direct spreading/flooding.
Application rate(s) and frequency	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**

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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

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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.

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## **5. GENERAL DIRECTIONS FOR USE<sup>1</sup>**

### **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.

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<sup>1</sup>Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

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### **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.



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## **6. OTHER INFORMATION**

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