Summary of product characteristics for a biocidal product

Product name: Product 9-2 - Rochex

Product type(s):

 $\mbox{\sc PTO2}$ - 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)

 $\mbox{\sc PTO2}$ - 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-2023-0072

R4BP 3 asset reference number: FR-0021509-0098

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Administrative information

1.1. Trade names of the product

Product 9-2 - Rochex		

1.2. Authorisation holder

Name and address of the authorisation holder

Name	LABORATOIRES ROCHEX
Address	BP 263 288 rue Georges Charpak 74106 Annemasse Cedex France

Authorisation number

FR-2023-0072 1-9

R4BP 3 asset reference number

FR-0021509-0098

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

LABORATOIRES ROCHEX

Address of the manufacturer

TECHNOSITE ALTEA 288 Rue Georges Charpak 74100 JUVIGNY France

Location of manufacturing sites

TECHNOSITE ALTEA 288 Rue Georges Charpak 74100 JUVIGNY 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

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)

 $\label{thm:policy} \mbox{Method: Wiping/mopping/brushing/scrubbing without mechanical action} \\ \mbox{Detailed description:} \\$

-

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

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 googles (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 di	sinfection and until the surface is rinsed and dried	
<u>=</u> '	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment	
-		
4.1.4 Where specific to the uspackaging	se, the instructions for safe disposal of the product and its	
-		
	se, the conditions of storage and shelf-life of the product	
under normal conditions of s	torage	
-		
4.2 Use description		
Use 2 - Disinfection of toilet boo Professionals - PT2 – RTU prod	vls and sanitary facilities by direct spreading/flooding – uct (Use20)	
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:	
	Indoor	
Field(s) of 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 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

750mL HDPE Angled bottle

1L HDPE Bottle with handle

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 googles (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 us under normal conditions of s	se, the conditions of storage and shelf-life of the product storage			
-				
4.3 Use description				
Use 3 - Disinfection of hard sur PT4 – RTU product (Use 23)	faces by wiping / mopping / brushing / scrubbing – Professionals -			
Product type	PT04 - Food and feed area (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:			
	Indoor			
Field(s) of 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 without mechanical action Detailed description:			
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 instruction	ns for use		
-			
4.3.2 Use-specific risk mitiga	ation measures		
within the product information) during mix For professional bystander :			
-Do not touch the surface until it is compl For general public:	letely dried		
-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 u packaging	se, the instructions for safe disposal of the product and its		
-			

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		
-	faces by wiping / mopping / brushing / scrubbing – General public -	
PT2 – RTU product (Use 25)	laces by wiping / mopping / brushing / scrubbing – General public -	
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:	
	Loden	
Field(s) of use	Indoor	
	Indoors disinfection in private areas, households	
Application method(s)	Method: Wiping/mopping/brushing/scrubbing without mechanical action Detailed description:	
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
-
1.4.5 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:
	Ladan
Field(s) of use	Indoor
	Indoors disinfection in private areas, households
Application method(s)	Method: Spreading / flooding Detailed description:
P.P. 133. 13. (17)	Direct spreading/flooding
Application rate(s) and	Application Rate: - Dilution (%): 0
frequencies	Number and timing of application: Ready to use product.
	60 minutes, 20°C
Category(ies) of users	General public (non-professional)
Category(les) of users	
Pack sizes and packaging	100mL to 2L HDPE/PET Bottle
material	750ml LIDDE Angled home
	750mL HDPE Angled bottle
	1L HDPE Bottle with handle

4.5.1 Use-specific instructions for use		
-		
4.5.2 Use-specific risk mitiga	ation measures	
For non professional user during application -Wash hands after use -Avoid contact with eyes and skin -Avoid splashes and spills -The packaging must be adapted with a contact with a spill of the packaging must be adapted.		
For general public : -Do not touch the surface until it is rinsec -Children should not be present during d	d and totally dried is infection and until the surface is rinsed and dry	
	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment	
-		
4.5.4 Where specific to the u packaging	se, the instructions for safe disposal of the product and its	
-		
4.5.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product storage	
- Keep out of reach of children and non-t	arget animals/pets	
4.6 Use description		
Use 6 - Disinfection of hard sur PT4 – RTU product (Use 28)	faces by wiping / mopping / brushing / scrubbing – General public -	
Product type	PT04 - Food and feed area (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:	
	Indoor	
Field(s) of use		
	Indoors disinfection in private areas, domestic kitchens.	
Application method(s)	Method: Wiping/mopping/brushing/scrubbing without mechanical action Detailed description:	
	-	
Application rate(s) and	Application Rate: - Dilution (%): 0	
frequencies	Number and timing of application:	
	Ready to use product.	
	60 minutes, 20°C	
Catagory/ica) of wasys	General public (non-professional)	
Category(ies) of users		
Dook since and neeks since	100mL to 2L HDPE/PET Bottle	
Pack sizes and packaging material	Tooline to ZETIDI E/I E/I Botac	
	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		
wash hands and 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
1.6.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid nstructions and emergency measures to protect the environment
-
1.6.4 Where specific to the use, the instructions for safe disposal of the product and its backaging
-
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 posion 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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