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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

PRODUCT 2-2 - 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 1-2

R4BP asset number: FR-0021510-0005

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	PRODUCT 2-2 - Soprodís
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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 1-2	
<i>R4BP asset number</i>	FR-0021510-0005	
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 Bioquímica sa
Address of manufacturer	Gran Vial 19-25 08160 MONTMELÓ Spain
Location of manufacturing sites	Corbion Purac Bioquímica sa site 1 Gran Vial 19-25 E-08160 MONTMELÓ Spain Corbion Purac Bioquímica 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

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	25,13 % (w/w)
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 % (w/w)

2.2. Type(s) of formulation

SL Soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	<p>H290: May be corrosive to metals.</p> <p>H314: Causes severe skin burns and eye damage.</p> <p>H317: May cause an allergic skin reaction.</p> <p>H412: Harmful to aquatic life with long lasting effects.</p> <p>EUH071: Corrosive to the respiratory tract.</p>
Precautionary statements	<p>P234: Keep only in original packaging.</p> <p>P260: Do not breathe spray.</p> <p>P264: Wash hands thoroughly after handling.</p> <p>P280: Wear protective gloves/ protective clothing/ eye protection.</p> <p>P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.</p> <p>P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].</p> <p>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P310: Immediately call a POISON CENTER or doctor/physician.</p> <p>P321: Specific treatment (see ... on this label).</p> <p>P363: Wash contaminated clothing before reuse.</p> <p>P390: Absorb spillage to prevent material damage.</p> <p>P406: Store in a a corrosive resistant/... container with a resistant inner liner.</p> <p>P333+P313: If skin irritation or rash occurs: Get medical advice/attention.</p> <p>P273: Avoid release to the environment.</p> <p>P501: Dispose of {0:....:contents container} to {1:....}.</p>

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Disinfection of hard surfaces and equipment by manual liquid spraying – Professionals - PT2 – Soluble concentrate (Use 1)

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: spraying Detailed description: Manual surface spraying.
Application rate(s) and frequency	Application rate: - Dilution (%): - Number and timing of application: At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes.
Category(ies) of users	professional
Pack sizes and packaging material	100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 5L HDPE Jerrican with distributor pump

	5 to 30L HDPE Jerrican
	60-220L HDPE Drum
	1000L HDPE Bulk container (IBC)

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 mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- 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 manual spraying using mural cleaning station (liquid/foam spraying) – Professionals - PT2 – Soluble concentrate (Use 2)

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 spraying with a mural cleaning station Detailed description: Manual spraying with a mural cleaning station (liquid/foam spraying) with automated dilution.
Application rate(s) and frequency	Application rate: - Dilution (%): - Number and timing of application: At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes.
Category(ies) of users	professional
Pack sizes and packaging material	5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC)

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 mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- 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 hard surfaces of equipment by manual dipping/soaking– Professionals - PT2 – Soluble concentrate (Use 3)

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: Dipping/Soaking Detailed description: Manual dipping/soaking.
Application rate(s) and frequency	Application rate: - Dilution (%): - Number and timing of application: At a temperature of 20°C: - Bacteria and yeasts: 20% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes.
Category(ies) of users	professional
Pack sizes and packaging material	100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle

	1L HDPE Dosing bottle
	1 to 5 L HDPE Pouch
	5 to 30L HDPE Jerrican
	5-10-20L LDPE/PET Bag in box (cubitainer)
	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

- 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.

4.3.3. 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 - PT2 – Soluble concentrate (Use 4)

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 (%): - Number and timing of application: At a temperature of 20°C: - Bacteria and yeasts: 20% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes.
Category(ies) of users	professional

Pack sizes and packaging material	<p>100mL to 2L HDPE/PET Bottle</p> <p>1L LDPE Dosing bottle</p> <p>1L HDPE Dosing bottle</p> <p>1 to 5 L HDPE Pouch</p> <p>5 to 30L HDPE Jerrican</p> <p>5-10-20L LDPE/PET Bag in box (cubitainer)</p> <p>60-220L HDPE Drum</p> <p>1000L HDPE Bulk container (IBC)</p>
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4.4.1. Use-specific instructions

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

4.4.2. Use-specific risk mitigation measures

- For professional users: 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.
- Pour the solution direct on the surface and wipe with a cloth / brush for wiping activities
- A mop/brush with a handle has to be used to apply the in-use solution
- Do not immerse hands in the solution

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.

4.4.3. 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 hard surfaces and equipment by manual liquid spraying – Professionals - PT4 – Soluble concentrate (Use 9)

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: no data Common name: Bacteria Development stage: no data</p> <p>Scientific name: no data Common name: Yeasts Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants).</p>
Application method(s)	<p>Method: spraying</p> <p>Detailed description: Manual surface spraying.</p>

Application rate(s) and frequency	Application rate: - Dilution (%): - Number and timing of application: At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes.
Category(ies) of users	professional
Pack sizes and packaging material	5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC)

4.5.1. Use-specific instructions

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4.5.2. 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 be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

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

4.5.3. 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

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4.6. Use description

Table 6. Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) – Professionals - PT4 – Soluble concentrate (Use 10)

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: Manual spraying with a mural cleaning station Detailed description: Manual spraying with a mural cleaning station (liquid/foam spraying) with automated dilution.
Application rate(s) and frequency	Application rate: - Dilution (%): - Number and timing of application: At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes.
Category(ies) of users	professional
Pack sizes and packaging material	5 to 30L HDPE Jerrican

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

4.6.1. Use-specific instructions

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4.6.2. 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 be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

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

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

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

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

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4.7. Use description

Table 7. Disinfection of hard surfaces and equipment by manual dipping/soaking– Professionals - PT4 – Soluble concentrate (Use 11)

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: Dipping/Soaking Detailed description: Manual dipping/soaking.
Application rate(s) and frequency	Application rate: - Dilution (%): - Number and timing of application: At a temperature of 20°C: - Bacteria and yeasts: 20% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes.
Category(ies) of users	professional
Pack sizes and packaging material	100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch

	5 to 30L HDPE Jerrican
	5-10-20L LDPE/PET Bag in box (cubitainer)
	60-220L HDPE Drum
	1000L HDPE Bulk container (IBC)

4.7.1. Use-specific instructions

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4.7.2. 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.

4.7.3. 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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4.7.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

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

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4.8. Use description

Table 8. Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT4 – Soluble concentrate (Use 12)

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 without mechanical action. Detailed description: -
Application rate(s) and frequency	Application rate: - Dilution (%): - Number and timing of application: At a temperature of 20°C: - Bacteria and yeasts: 20% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes.
Category(ies) of users	professional
Pack sizes and packaging material	100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle

	1 to 5 L HDPE Pouch
	5 to 30L HDPE Jerrican
	5-10-20L LDPE/PET Bag in box (cubitainer)
	60-220L HDPE Drum
	1000L HDPE Bulk container (IBC)

4.8.1. Use-specific instructions

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4.8.2. Use-specific risk mitigation measures

- For professional users: 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.
- Pour the solution direct on the surface and wipe with a cloth / brush for wiping activities.
- A mop/brush with a handle has to be used to apply the in-use solution.
- Do not immerse hands in the solution.

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.

4.8.3. 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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4.8.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

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4.8.5. 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 USE¹

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 monocytogenes* at 20°C and 40°C 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.

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

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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