

Summary of product characteristics for a biocidal product family

Family name: SALVESAFE B

Product type(s): PT01 - Human hygiene (Disinfectants)

Authorisation number: EU-0014276-0000

R4BP 3 asset reference number: EU-0014276-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

SALVESAFE B

1.2. Product type(s)

PT01 - Human hygiene (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder

Name	SALVECO S.A.S.
Address	Avenue Pierre Mendès-France Z.A. Hellieule 4 F 88100 SAINT DIE DES VOSGES France

Authorisation number

EU-0014276-0000

R4BP 3 asset reference number

EU-0014276-0000

Date of the authorisation

25/11/2016

Expiry date of the authorisation

25/11/2026

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer

SALVECO S.A.S.

Address of the manufacturer

Avenue Pierre Mendes-France F-88100 SAINT DIE DES VOSGES France

Location of manufacturing sites

Avenue Pierre Mendes-France F-88100 SAINT DIE DES VOSGES France

1.5. Manufacturer(s) of the active substance(s)

Active substance	1421 - Lactic acid
Name of the manufacturer	JUNGBUNGLAUER S.A
Address of the manufacturer	Z.I Portuaire BP 32 67390 Marckolsheim France
Location of manufacturing sites	Z.I Portuaire BP 32 67390 Marckolsheim France

2. Product family composition and formulation

2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	1,75 - 1,75

2.2. Type(s) of formulation

AL - Any other liquid

Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

PT01 - Human hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	1,75 - 1,75

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Safety data sheet available on request.

Precautionary statements

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - PT01A

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Hygienic handrub. Ready-to-use disinfectant for hands with a bactericidal, yeasticidal and virudical (only against enveloped viruses) efficacy in medical, institutional and industrial area.
Target organism(s) (including development stage)	<p>Scientific name: bacteria Common name: Bacteria Development stage:</p> <p>Scientific name: Yeasts Common name: Yeasts Development stage:</p> <p>Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Outdoor</p>
Application method(s)	<p>Method: manual application: spreading and foam application Detailed description: Place 3ml on clean hands and wrists. Rub for at least 30 seconds. Do not rinse.</p>
Application rate(s) and frequencies	<p>Application Rate: 3 mL Dilution (%): 0 Number and timing of application: Apply once, repeat if renewed hand disinfectant is needed.</p>
Category(ies) of users	<p>Industrial</p> <p>Professional</p>
Pack sizes and packaging material	<p>Bottle, Plastic: PET, PE, PP , 0.05-5L (professional users)</p> <p>Drum, Plastic: HDPE , 10-210L (professional and industrial users)</p> <p>Pouches, Plastic: LDPE, LLDPE , 0.05-5L (professional)</p> <p>IBC (intermediate bulk container), Plastic: HDPE , 1000L (industrial) *</p> <p>* Authorisation holder supplies to customer with agreement on repackaging (according to above mentioned packagings) for making available on the market.</p> <p>Description (not mentioned on the label): All the used packaging are secure, closed, tight, strong and durable. Packaging can be refilled only with product foreseen for that purpose.</p>

4.1.1 Use-specific instructions for use

Section 5.1. (Directions for use)

4.1.2 Use-specific risk mitigation measures

Section 5.2. (Directions for use)

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

Section 5.3. (Directions for use)

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

Section 5.4. (Directions for use)

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

Section 5.5. (Directions for use)

5. General directions for use of the meta SPC

5.1. Instructions for use

Place 3 ml on clean hands and wrists. Rub for at least 30 seconds. Do not rinse.

5.2. Risk mitigation measures

Not applicable

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

No direct or indirect adverse effects are known.

First aid instructions:

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
If swallowed: immediately call a POISON CENTER or doctor/physician.

In case of contact with eyes, remove contact lenses if present and rinse the eye slowly and gently with clean water.

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

Dispose of contents/container to in accordance with national regulation.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Products can be stored at room temperature up to 24 months.

Conditions: Avoid cold, frost, heat, exposure to direct light .

6. Other information

Biocidal product family SALVESAFE B is claimed as hygienic handrub with bactericidal, yeasticidal and virucidal activity only against enveloped viruses in medical (*), institutional and industrial area for professional and industrial users.

(*) Not surgical handrub

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7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE B2	Market area: EU
	SalveSafe Rub	Market area: EU
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small>	EU-0014276-0001 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	1,75

Trade name(s)	SALVESAFE B1	Market area: EU
	SalveSafe Rub Icy	Market area: EU
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small>	EU-0014276-0002 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	1,75
