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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

SALVESAFE C16_GPPRO

Product type(s)

PT01: Human hygiene

Authorisation number: EU-0016328-0000 1-5

R4BP asset number: EU-0016328-0039

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	SALVESAFE C16_GPPRO EverCleanHand-lotion OSANIS - Mousse désinfectante mains parfumée OSANIS – Hand Sanitiser Foam BACCIDE Mousse Mains Hand disinfectant foam Mint Schiuma disinfettante per le mani Menta Hand desinfektionsschaum Minze Ontsmettend handschuim Munt Espuma desinfectante para manos Menta Espuma desinfetante para as mãos Hortelã Mousse désinfectante pour les mains parfumée menthe
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	SALVECO S.A.S.
	Address	Avenue Pierre Mendès-France Z.A. Hellioule 4 F 88100 SAINT DIE DES VOSGES France
Authorisation number		EU-0016328-0000 1-5
<i>R4BP asset number</i>		EU-0016328-0039
Date of the authorisation		07/06/2017
Expiry date of the authorisation		07/06/2027

1.3. Manufacturer(s) of the product

Name of manufacturer	SALVECO S.A.S.
Address of manufacturer	Avenue Pierre Mendès-France Z.A. Hellioule 4 F 88100 SAINT DIE DES VOSGES France
Location of manufacturing sites	SALVECO S.A.S. Avenue Pierre Mendès-France F-88100 SAINT DIE DES VOSGES France

Name of manufacturer	GESTRA S.A.S.
Address of manufacturer	Allée Robert Schumann F 88110 RAON- L'ETAPE France
Location of manufacturing sites	GESTRA S.A.S site 1 Allée Robert Schumann 88110 RAON-L'ETAPE France

Name of manufacturer	Laboratoires Gilbert
Address of manufacturer	AVENUE DU GENERAL DE GAULLE 14200 HEROUILLE SAINT CLAIR France
Location of manufacturing sites	Laboratoires Gilbert site 1 AVENUE DU GENERAL DE GAULLE 14200 HEROUILLE SAINT CLAIR France

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

Active substance	Lactic acid
Name of manufacturer	JUNGBUNZLAUER S.A
Address of manufacturer	Z.I Portuaire BP 32 67390 Marckolsheim France
Location of manufacturing sites	JUNGBUNZLAUER S.A site 1 Z.I Portuaire BP 32 67390 Marckolsheim 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 (%)
Lactic acid		active substance		200-018-0	1,75

2.2. Type(s) of formulation

AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	EUH210: Safety data sheet available on request.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Hygienic handrub for professional and non-professional users – 30 months

Product type	PT01: Human hygiene
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 domestic, medical, institutional and industrial area.
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: no data Scientific name: Yeasts Common name: Yeasts Development stage: no data Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage: no data
Field(s) of use	indoor use outdoor use
Application method(s)	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.
Application rate(s) and frequency	Application rate: 3mL Dilution (%): Ready-to-use Number and timing of application: Apply once. Repeat if renewed hand disinfection is needed.
Category(ies) of users	industrial ; professional ; general public (non-professional)
Pack sizes and packaging material	Bottle, Plastic: PET, PE, PP , 0.01 -5L (consumers and professional users) Pouches, Plastic: LDPE, LLDPE , 0.01-5L (consumers and professional users) Drum, Plastic: HDPE , 10-210L (professional, industrial) 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.

4.1.1. Use-specific instructions

Section 5.1. (Directions for use)

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

Section 5.2. (Directions for use)

4.1.4. 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)

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

Section 5.4. (Directions for use)

4.1.6. 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 USE¹

5.1. Instructions for use

Place 3 ml on clean hands and wrists. Rub for at least 30 seconds. Do not rinse. Apply once, repeat if renewed hand disinfection is needed.

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:

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 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 30 months.

Protect from cold and heat.

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

6. OTHER INFORMATION

(*) Not surgical handrub.