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**ANNEX**

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

SALVESAFE C16\_C

**Product type(s)**

PT01: Human hygiene

**Authorisation number:** EU-0016328-0000 1-2

**R4BP asset number:** EU-0016328-0033

## 1. ADMINISTRATIVE INFORMATION

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

Trade name(s)	SALVESAFE C16_C Evercleanhand-rub OSANIS - Mousse Désinfectante mains parfum Feuilles de Menthe OSANIS – Ontsmettend handschuim, geparfumeerd met munt OSANIS - Schiuma disinfettante per le mani alla menta OSANIS - Hand-Desinfektionsschaum Minzblattduft OSANIS - Espuma desinfectante para manos hoja de menta OSANIS - Espuma desinfectante para as mãos folhas de menta OSANIS - Hand Disinfectant Foam Icy
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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. Hellieule 4 F 88100 SAINT DIE DES VOSGES France
Authorisation number		EU-0016328-0000 1-2
<i>R4BP asset number</i>		EU-0016328-0033
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. Hellieule 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 HEROUVILLE SAINT CLAIR France
Location of manufacturing sites	Laboratoires Gilbert site 1 AVENUE DU GENERAL DE GAULLE 14200 HEROUVILLE SAINT CLAIR France

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#### 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

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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 (%)
Lactic acid		active substance		200-018-0	1,75

### 2.2. Type(s) of formulation

AL Any other liquid

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### 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	
Precautionary statements	P102: Keep out of reach of children.  P101: If medical advice is needed, have product container or label at hand.

## 4. AUTHORISED USE(S)

### 4.1. Use description

**Table 1. Hygienic handrub for non-professional users – 24 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 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: 3 mL  Dilution (%): Ready-to-use  Number and timing of application: Apply once. Repeat if renewed hand disinfection is needed.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Bottle, Plastic: PET, PE, PP , 0.01 -5L (consumers)  Pouches, Plastic: LDPE, LLDPE , 0.01-5L (consumers)  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.

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**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)

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

### **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 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 24 months.

Protect from cold and heat.

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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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## **6. OTHER INFORMATION**

(\* ) Not surgical handrub.