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***ANNEX***

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

SALVESAFE CO\_GPPRO

**Product type(s)**

PT01: Human hygiene

**Authorisation number:** EU-0016328-0000 1-5

**R4BP asset number:** EU-0016328-0034

## 1. ADMINISTRATIVE INFORMATION

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

Trade name(s)	SALVESAFE CO_GPPRO OSANIS - Mousse désinfectante mains BACTIDOSE GREEN Mousse Mains Mousse Désinfectante pour les Mains Pro - sans parfum Mousse Désinfectante pour les Mains Pro sans parfum by Biozeffi Mousse Désinfectante pour les Mains Pro sans parfum by Effibioz Milton - Antibacterial hand sanitiser - Mousse mains désinfectante OSANIS - Hand Disinfectant Foam OSANIS - Espuma desinfectante para as mãos OSANIS - Espuma desinfectante para manos OSANIS – Ontsmettend handschuim OSANIS - Schiuma disinfettante per le mani OSANIS - Hand-Desinfektionsschaum BÉABA – Mousse désinfectante mains BÉABA – Hand disinfecting foam BÉABA – Espuma desinfectante de manos BÉABA – Händedesinfektionsschaum BÉABA – Handdesinfecierend schuim BÉABA – Pianka do dezynfekcji rąk BÉABA – Sredstvo za dezinfekciju ruku BÉABA – Schiuma disinfettante mani Fragrance free pro hand disinfectant foam by effibioz Pro schiuma disinfettante per le mani senza profumo by effibioz Hand desinfektionsschaum ohne parfum by effibioz Ontsmettend handschuim zonder parfum by effibioz Espuma desinfectante para manos sin perfume by effibioz Espuma desinfectante para as mãos sem perfume by effibioz
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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 1-5	
<i>R4BP asset number</i>	EU-0016328-0034	
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
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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

Name of manufacturer	OTB COSMETICS
Address of manufacturer	37 Rue du Stiff - ZAE Saint-Eloi Leslouc'h 29800 PLOUEDERN France
Location of manufacturing sites	OTB COSMETICS site 1 37 Rue du Stiff - ZAE Saint- Eloi Leslouc'h 29800 PLOUEDERN France

Name of manufacturer	OTB COSMESOAP
Address of manufacturer	Boulevard Jean Mantelet 14700 FALAISE France
Location of manufacturing sites	OTB COSMESOAP site 1 Boulevard Jean Mantelet 14700 FALAISE 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

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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	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.

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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 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.

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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.