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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

SALVESAFE A44M

Product type(s)

PT01: Human hygiene

Authorisation number: EU-0006622-0000 1-4

R4BP asset number: EU-0006622-0017

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1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	SALVESAFE A44M SalveSafe Soap X MG HYGIOS Savon mains désinfectant
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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-0006622-0000 1-4
<i>R4BP asset number</i>		EU-0006622-0017
Date of the authorisation		02/11/2014
Expiry date of the authorisation		02/11/2024

1.3. Manufacturer(s) of the product

Name of manufacturer	SALVECO S.A.S.
Address of manufacturer	Avenue Pierre Mendes-France F-88100 SAINT DIE DES VOSGES France
Location of manufacturing sites	SALVECO S.A.S. site 1 Avenue Pierre Mendes-France F-88100 SAINT DIE DES VOSGES France

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

Active substance	Lactic acid
Name of manufacturer	PURAC BIOQUIMICA
Address of manufacturer	Gran Vial 19-25 08160 Montmelo Spain
Location of manufacturing sites	PURAC BIOQUIMICA site 1 Gran Vial 19-25 08160 Montmelo Spain

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	
Precautionary statements	

4. AUTHORISED USE(S)

4.1. Use description

Table 1. PT1 - disinfectants for hands

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	Ready-to-use disinfectant for hands with a bactericidal, yeasticidal and virucidal efficacy against only Influenza virus A/H1N1 in domestic, 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: Influenza virus A/N1H1 Common name: Viruses Development stage: no data
Field(s) of use	indoor use outdoor use
Application method(s)	Method: manual application, spreading, foam application, brush treatment. Detailed description: Wet hand and wrists with water. Place 3 ml of product in the hollow of the hand. Rub hands and wrists for at least 30 seconds. Rinse thoroughly with clean water.
Application rate(s) and frequency	Application Rate: 3 mL Dilution (%): 0 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	Bag /Sack, Plastic: HDPE, LDPE, PET, PE, PP , 0.01-5L Bottle, Plastic: HDPE, LDPE, PET, PE, PP , 0.01-2L Can /Tin, Plastic: HDPE, LDPE, PET, PE, PP , 0.1-1L Drum, Plastic: HDPE, LDPE, PET, PE, PP , 10-210L Airspray, Plastic: HDPE, LDPE, PET, PE, PP , 0.15-1L Jerry can, Plastic: HDPE, LDPE, PET, PE, PP , 1-80L pouches, Plastic: HDPE, LDPE, PET, PE, PP , 0.05-5L 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 for use

Wet hand and wrists with water. Place 3 ml of product in the hollow of the hand. Rub hands and wrists for at least 30 seconds. Rinse thoroughly with clean water.

4.1.2. Use-specific risk mitigation measures

Section 5.2. (Risk mitigation measures)

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

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

Section 5.4. (Instructions for safe disposal of the products and its packaging)

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

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

PT1: Wet hands and wrists with water. Place 3mL of product in the hollow of the hand. Rub hands and wrists for at least 30 seconds. Rinse thoroughly with clean water.

5.2. Risk mitigation measures

Additional statements:

For general users: If medical advice is needed, have product container or label at hand. Keep out of reach of children.

For professional users only: Safety data sheet available on request.

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 content/container according to national regulation.

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

Shelf-life: Products can be stored at room temperature up to 24 months.

Conditions: Avoid cold, frost 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