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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

SALVESAFE C3_GPPRO

Product type(s)

PT01: Human hygiene

Authorisation number: EU-0016328-0000 1-6

R4BP asset number: EU-0016328-0035

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

| | |
|---------------|--------------------|
| Trade name(s) | SALVESAFE C3_GPPRO |
|---------------|--------------------|

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 1-6 | |
| <i>R4BP asset number</i> | EU-0016328-0035 | |
| 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 |

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 – 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, 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 (industrial, professional users) 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)

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 24 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.