Summary of product characteristics for a biocidal product

Product name: Sure instant hand sanitizer

Product type(s): PT01 - Human hygiene (Disinfectants)

Authorisation number: it/2018/00482/AUT

R4BP 3 asset reference number: IT-0016940-0000

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Administrative information

1.1. Trade names of the product

| Sure instant hand sanitizer | | |
|-----------------------------|--|--|
| | | |

1.2. Authorisation holder

| 1.2. Addionisation notice | | |
|----------------------------------|-------------------|--|
| Name and address of the | Name | Diversey Europe Operations B.V. |
| authorisation holder | Address | Regulatory team Maarssenbroeksedijk 2 3542 DN Utrecht Netherlands |
| Authorisation number | it/2018/00482/AUT | |
| R4BP 3 asset reference number | IT-0016940-0000 | |
| Date of the authorisation | 14/03/2018 | |
| Expiry date of the authorisation | 20/04/2027 | |

1.3. Manufacturer(s) of the biocidal products

| Name of the manufacturer | SALVECO S.A.S. |
|---------------------------------|---|
| Address of the manufacturer | Avenue Pierre Mendes-France F-88100 SAINT DIE DES VOSGES France |
| Location of manufacturing sites | Avenue Pierre Mendes-France F-88100 SAINT DIE DES VOSGES France |
| | |
| Name of the manufacturer | Multifill BV |
| Address of the manufacturer | Constructieweg 25a 3640 AJ Mijdrecht Netherlands |
| Location of manufacturing sites | Constructieweg 25a 3640 AJ Mijdrecht Netherlands |

| Name of the manufacturer | Bio Armor |
|---------------------------------|--|
| Address of the manufacturer | Zone de la gare, 10/12 route du Pré Chevalier 22940 Plaintel France |
| Location of manufacturing sites | Zone de la gare, 10/12 route du Pré Chevalier 22940 Plaintel France |
| | |
| Name of the manufacturer | BRUNEL - ALTAÏR Group |
| Address of the manufacturer | ZI A - 132 Rue du Mont de Templemars 59139 NOYELLES LES SECLIN France |
| Location of manufacturing sites | ZI A - 132 Rue du Mont de Templemars 59139 NOYELLES LES SECLIN France |
| | |
| Name of the manufacturer | Cheport spol s.r.o |
| Address of the manufacturer | Lhotsko 93 76312 Vizovice Czech Republic |
| Location of manufacturing sites | Lhotsko 93 76312 Vizovice, Czech Republic |
| | |
| Name of the manufacturer | Diversey Europe Operations B.V. |
| Address of the manufacturer | Maarssenbroeksedijk 2 3542DN Utrecht Netherlands |
| Location of manufacturing sites | Strada Statale 235 26010 Bagnolo Cremasco (CR) Italy |
| | Rembrandtlaan 414 7545 ZW Enschede Netherlands |
| | Cotes Park Industrial Estate DE55 4PA Somercotes Alfreton United Kingdom |
| | AvenidaConde Duque 5, 7 y 9 ; Poligono Industrial La Postura 28343 Valdemoro (Madrid) Spain |
| | Morschheimer Strasse 12 67292 Kirchheimbolanden Germany |
| | |
| Name of the manufacturer | Emmegi Detergents SRL |
| Address of the manufacturer | Via Merlo Carlo Giuseppe 3 20122 Milano Italy |

Via marconi 5 25030 Trenzano Italy

Location of manufacturing sites

| Name of the manufacturer | FOREVER PRODUCTS SA |
|---------------------------------|---|
| Address of the manufacturer | Rue de la Glacerie 122 6180 Courcelles, Belgium |
| Location of manufacturing sites | Rue de la Glacerie 122 6180 Courcelles, Belgium |
| | |
| Name of the manufacturer | GFL SA |
| Address of the manufacturer | Via Sorengo 1 6900 Lugano Switzerland |
| Location of manufacturing sites | Via del Benessere 4 27010 Siziano Italy |
| | |
| Name of the manufacturer | Vandeputte |
| Address of the manufacturer | 120 Boulevard Industriel 7700 Mouscron, Belgium |
| Location of manufacturing sites | 120 Boulevard Industriel 7700 Mouscron, Belgium |

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

| Active substance | 1421 - Lactic acid |
|---------------------------------|---|
| Name of the manufacturer | JUNGBUNGZLAUER S.A |
| Address of the manufacturer | Z.I Portuaire BP 32 67390 Marckolsheim France |
| Location of manufacturing sites | Z.I Portuaire BP 32 67390 Marckolsheim France |

| Active substance | 1421 - Lactic acid |
|---------------------------------|--------------------------------------|
| Name of the manufacturer | PURAC BIOQUIMICA |
| Address of the manufacturer | Gran Vial 19-25 08160 Montmelo Spain |
| Location of manufacturing sites | Gran Vial 19-25 08160 Montmelo Spain |

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|-------------|------------|------------------|------------|-----------|-------------|
| Lactic acid | | Active Substance | | 200-018-0 | 1,75 |

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements

Safety data sheet available on request.

Precautionary statements

4. Authorised use(s)

4.1 Use description

Use 1 - PT01A

Product type

PT01 - Human hygiene (Disinfectants)

Where relevant, an exact description of the authorised Hygienic handrub. Ready-to-use disinfectant for hands with a bactericidal, yeasticidal and virudical (only against enveloped viruses) efficacy in medical, institutional and industrial

Target organism(s) (including development stage)

Scientific name: Pseudomonas aeruginosa Common name: Bacteria, aerobic Gram-negative Development stage: NC

Scientific name: Staphylococcus aureus Common name: Bacteria, aerobic Gram-positive Development stage: NC

Scientific name: Escherichia coli Common name: Bacteria, aerobic Gram-negative Development stage: NC

Scientific name: Enterococcus hirae Common name: Bacteria, aerobic Gram-positive Development stage: NC

Scientific name: Candida albicans Common name: Fungi/yeasts Development stage: NC

Scientific name: Modified Vaccinia Virus Ankara Common name: Enveloped viruses Development stage: NC

Field(s) of use

Indoor

Outdoor

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 frequencies

Application Rate: 3 mL

Dilution (%): 0

Number and timing of application:

Apply once, repeat if renewed hand disinfectant is needed.

Category(ies) of users

Industrial

Professional

Pack sizes and packaging material

Bottle, Plastic: PET, PE, PP, 0.05-5L (professional users)

Drum, Plastic: HDPE, 10-210L (professional and industrial 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 instructio | ons for use |
| Section 5.1. (Directions for use) | |
| 4.1.2 Use-specific risk mitig | ation measures |
| Section 5.2. (Directions for use) | |
| - | use, the particulars of likely direct or indirect effects, first aid measures to protect the environment |
| Section 5.3. (Directions for use) | |
| 4.1.4 Where specific to the ι packaging | use, the instructions for safe disposal of the product and its |
| Section 5.4. (Directions for use) | |
| 4.1.5 Where specific to the u | ise, the conditions of storage and shelf-life of the product |
| Section 5.5. (Directions for use) | Storage |
| | |
| | |

Pouches, Plastic: LDPE, LLDPE , 0.05-5L (professional)

5. General directions for use

5.1. Instructions for use

| Place 3 ml on clean hands and wrists. Rub for at least 30 seconds. Do not rinse. |
|---|
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| |
| |
| 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. |
| , , |
| |
| The product is 100% biodegradable, therefore, there are not specific emergency measures to take to protect the environment in case of accident. |
| of accident. |
| |
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| 5.4. Instructions for safe disposal of the product and its packaging |
| |
| Dispose of contents/container to in accordance with national regulation. |
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| 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. |
| |
| Conditions: Avoid cold, frost, heat, exposure to direct light . |
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