

Summary of product characteristics for a biocidal product

Product name: Sure instant hand sanitizer

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

Authorisation number:

R4BP 3 asset reference number: BG-0023538-0000

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Administrative information

1.1. Trade names of the product

SURE Instant Hand Sanitizer

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Diversey Europe Operations B.V.
	Address	Regulatory team Maarssebroeksedijk 2 3542 DN Utrecht Netherlands
Authorisation number		
R4BP 3 asset reference number	BG-0023538-0000	
Date of the authorisation	25/11/2016	
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	Maarssebroeksedijk 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
Location of manufacturing sites	Via marconi 5 25030 Trenzano Italy

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	JUNGBUNGLAUER 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 use	Hygienic handrub. Ready-to-use disinfectant for hands with a bactericidal, yeasticidal and virudical (only against enveloped viruses) efficacy in medical, institutional and industrial area.
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage: Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage:
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) Pouches, Plastic: LDPE, LLDPE , 0.05-5L (professional) 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

Section 5.1. (Directions for use)

4.1.2 Use-specific risk mitigation measures

Section 5.2. (Directions for use)

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. (Directions for use)

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

Section 5.4. (Directions for use)

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. (Directions for use)

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.

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 to 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.

Conditions: Avoid cold, frost, heat, exposure to direct light .

6. Other information

Biocidal product is claimed as hygienic handrub with bactericidal, yeasticidal and virucidal activity only against enveloped viruses in medical (*), institutional and industrial area for professional and industrial users.
(*) Not surgical handrub