

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

SURE Antimic Foam Hand Wash

Product type(s)

PT01: Human hygiene

Authorisation number: 2024-02-28-B01

R4BP asset number: MT-0032298-0000

1. ADMINISTRATIVE INFORMATION	3
1.1. Trade name(s) of the product	3
1.2. Authorisation holder	3
1.3. Manufacturer(s) of the product	3
1.4. Manufacturer(s) of the active substance(s)	4
2. PRODUCT COMPOSITION AND FORMULATION	6
2.1. Qualitative and quantitative information on the composition of the product	6
2.2. Type(s) of formulation	6
3. HAZARD AND PRECAUTIONARY STATEMENTS	7
4. AUTHORISED USE(S)	8
4.1. Use description	8
5. GENERAL DIRECTIONS FOR USE	10
5.1. Instructions for use	10
5.2. Risk mitigation measures	10
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	10
5.4. Instructions for safe disposal of the product and its packaging	10
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	10
6. OTHER INFORMATION	11

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	SURE Antimic Foam Hand Wash
---------------	-----------------------------

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Diversey Europe Operations B.V.
	Address	Regulatory team Maarssenbroeksedijk 2 3542 DN Utrecht Netherlands
Authorisation number	2024-02-28-B01	
<i>R4BP asset number</i>	MT-0032298-0000	
Date of the authorisation	28/02/2024	
Expiry date of the authorisation	05/12/2032	

1.3. Manufacturer(s) of the product

Name of manufacturer	SALVECO S.A.S
Address of manufacturer	Avenue Pierre Mendès-France, Z.I. Hellieule 4 F 88100 SAINT DIE DES VOSGES France
Location of manufacturing sites	Avenue Pierre Mendès-France, Z.I. Hellieule 4 F 88100 SAINT DIE DES VOSGES France

Name of manufacturer	Diversey Europe Operations B.V.
Address of manufacturer	Maarssenbroeksedijk 2 3542DN Utrecht Netherlands (the)
Location of manufacturing sites	Strada Statale 235 26010 Bagnolo Cremasco (CR) Italy Rembrandtlaan 414 7545 ZW Enschede Netherlands (the) Cotes Park Industrial Estate DE55 4PA Somercotes Alfreton United Kingdom of Great Britain and Northern Ireland (the) AvenidaConde Duque 5, 7 y 9 ; Poligono Industrial La Postura 28343 Valdemoro (Madrid) Spain Morschheimer Strasse 12 67292 Kirchheimbolanden Germany

Name of manufacturer	Multifill BV
Address of manufacturer	Constructieweg 25a 3640 AJ Mijdrecht Netherlands (the)
Location of manufacturing sites	

	Constructieweg 25a 3640 AJ Mijdrecht Netherlands (the)
--	--

Name of manufacturer	FOREVER PRODUCTS SA
Address of manufacturer	Rue de la Glacerie 122 6180 Courcelles, Belgium
Location of manufacturing sites	Rue de la Glacerie 122 6180 Courcelles, Belgium

Name of manufacturer	Vandeputte
Address of manufacturer	120 Boulevard Industriel 7700 Mouscron, Belgium
Location of manufacturing sites	120 Boulevard Industriel 7700 Mouscron, Belgium

Name of manufacturer	EMMEGI DETERGENTS SRL
Address of manufacturer	Via Merlo Carlo Giuseppe, 3 20122 Milano Italy
Location of manufacturing sites	Via marconi, 5 25030 Trezzano Italy

Name of manufacturer	GFL SA
Address of manufacturer	Via Sorengo 1 6900 Lugano Switzerland
Location of manufacturing sites	Via del Benessere, 4 27010 Siziano PV Italy

Name of manufacturer	BRUNEL - ALTAIR Group
Address of 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 manufacturer	Bio Armor
Address of 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 manufacturer	Cheport spol s.r.o.
Address of manufacturer	Lhotsko 93 76312 Vizovice Czechia
Location of manufacturing sites	Lhotsko 93 76312 Vizovice Czechia

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	Z.I Portuaire BP 32 67390 Marckolsheim France

Active substance	Lactic acid
------------------	-------------

Name of manufacturer	PURAC BIOQUIMICA
Address of 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 product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		active substance		200-018-0	1,98

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 - Disinfectant for hands

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: no data Scientific name: Yeast 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 Ready-to-use disinfectant for hands with bactericidal, yeasticidal efficacy and virucidal activity only against enveloped viruses in domestic, institutional, industrial and medical area.
Application method(s)	Method: Manual application, foam application 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 (%): - 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 (HDPE, LDPE, PET, PE, PP) : 0.05 - 2 litres Drum (HDPE) : 10 - 210 litres (professional and industrial users) Jerry can (HDPE, LDPE) : 1 - 60 litres (professional and industrial users) Jerry can (HDPE, LDPE) : 1 - 5 litres (non-professional users) Pouches (LDPE, LLDPE) : 0.05 - 5 litres Doypack (PE) : 1 - 2 litres PET – polyethylene terephthalate; PE – Polyethylene; HDPE – High density polyethylene; LDPE - Low density polyethylene; LLDPE - Linear low density polyethylene; PP – Polypropylene

4.1.1. Use-specific instructions for use

Section 5.1

4.1.2. Use-specific risk mitigation measures

Section 5.2

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

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

Section 5.4

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

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Comply with the instruction for use.

Wet hand and wrists with running 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. Apply once, repeat if renewed hand disinfection is needed.

5.2. Risk mitigation measures

Avoid contact with eyes.

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

IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.

IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

If medical advice is needed, have product container or label at hand.

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

Store in original container at room temperature. Protect from cold and frost. Keep out of reach of children and non-target animals / pets.

Shelf-life - 24 months at room temperature.

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

6. OTHER INFORMATION