# Summary of product characteristics for a biocidal product family

Family name: FAMILY SALVESAFE F

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

**Authorisation number:** EU-0019494-0000

**R4BP 3 asset reference number:** EU-0019494-0000

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#### Part I.- First information level

#### 1. Administrative information

#### 1.1. Family name

FAMILY SALVESAFE F
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#### 1.2. Product type(s)

PT01 - Human hygiene (Disinfectants)

#### 1.3. 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
	<u> </u>

**Authorisation number** 

EU-0019494-0000

R4BP 3 asset reference number

EU-0019494-0000

Date of the authorisation

11/01/2019

Expiry date of the authorisation

11/01/2029

#### 1.4. 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 BULKONTVANGST
Address of the manufacturer	Constructieweg 25A 3641 SB Mijdrecht Netherlands
Location of manufacturing sites	Constructieweg 25A 3641 SB Mijdrecht Netherlands
Name of the manufacturer	Diversey Netherlands Production BV
Address of the manufacturer	Rembrandtlaan 414 7545 ZW Enschede Netherlands
Location of manufacturing sites	Rembrandtlaan 414 7545 ZW Enschede Netherlands
Name of the manufacturer	Diversey UK Production Ltd
Address of the manufacturer	Cotes Park Industrial Estate, Somercotes DE55 4PA Alfreton United Kingdom
Location of manufacturing sites	Cotes Park Industrial Estate, Somercotes DE55 4PA Alfreton United Kingdom
Name of the manufacturer	Diversey Espana Production S.L.U
Address of the manufacturer	Avenida Conde Duque 5, 7 y 9, Poligono Industrial La Postura 28343 Valdemoro (Madrid) Spain
Location of manufacturing sites	Avenida Conde Duque 5, 7 y 9, Poligono Industrial La Postura 28343 Valdemoro (Madrid) Spain
Name of the manufacturer	Diversey Italy Production Srl
Address of the manufacturer	Strada Statale 235 26010 Bagnolo Cremasco Italy
Location of manufacturing sites	Strada Statale 235 26010 Bagnolo Cremasco Italy
Name of the manufacturer	Diversey Germany Production oHG
Address of the manufacturer	Morschheimer Strasse 12 67292 Kirchheimbolanden Germany

Morschheimer Strasse 12 67292 Kirchheimbolanden Germany

Location of manufacturing sites

#### 1.5. 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

### 2. Product family composition and formulation

### 2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	1,75 - 2,38

#### 2.2. Type(s) of formulation

AL - Any other liquid			

### Part II.- Second information level - meta SPC(s)

#### 1. Meta SPC administrative information

#### 1.1. Meta SPC identifier

SALVESAFE F\_GPRO (for Professional Users)

#### 1.2. Suffix to the authorisation number

1-1

#### 1.3 Product type(s)

PT01 - Human hygiene (Disinfectants)

#### 2. Meta SPC composition

#### 2.1.Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	1,75 - 2,38

#### 2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

#### 3. Hazard and precautionary statements of the meta SPC

**Hazard statements** 

Safety data sheet available on request.

**Precautionary statements** 

#### 4. Authorised use(s) of the meta SPC

#### 4.1 Use description

#### Use 1 - PT1 - Disinfectant for hands

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	u	uct	L y	pυ

PT01 - Human hygiene (Disinfectants)

Where relevant, an exact description of the authorised

Ready-to-use disinfectant for hands with a bactericidal and yeasticidal efficacy in institutional, industrial and medical area.

Target organism(s) (including development stage)

Scientific name: bacteria Common name: Bacteria Development stage:

Scientific name: yeasts Common name: Yeasts Development stage:

Field(s) of use

Indoor

Outdoor

Application method(s)

Method: Manual application, foam application

Detailed description:

Wet hand and wrists with water. Place 2 ml of product in the hallow of the hand. Rub hands and wrists for at least 30 seconds. Rinse thoroughly with clean water.

Application rate(s) and frequencies

Application Rate: 2 ml

Dilution (%): 0

Number and timing of application:

Apply once, repeat if renewed hand disinfection is needed.

Category(ies) of users

Industrial

Professional

Pack sizes and packaging material

Bottle, Plastic: HDPE, LDPE, PET, PE, PP, 0.01-2L

Drum, Plastic: HDPE, 10-210L Jerrycan, Plastic: HDPE, LDPE, 1-80L Pouches, Plastic: LDPE, LLDPE, 0.05-5L

IBC (intermediate bulk container), Plastic: HDPE, 1000L

#### 4.1.1 Use-specific instructions for use

Wet hand and wrists with water. Place 2 ml of product in the hallow 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 use of the meta SPC

#### 5.1. Instructions for use

**PT1** - Wet hands and wrists with water. Place 2ml 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

Not applicable

#### 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency

measures to protect the envi							
No direct or indirect adverse effects ar	e known.						
First aid instructions:							
If swallowed: immediately call a POISON CENTER or doctor/physician.							
In case of contact with eyes, remove contact	tact lenses if present and rinse the eye slowly ar	nd gently with clean water.					
5.4. Instructions for safe disp	oosal of the product and its pack	aging					
Dispose of content/container according to	national regulation.						
5.5. Conditions of storage and	d shelf-life of the product under i	normal conditions of storage					
Shelf-life: Products can be stored at roo	m temperature up to 24 months.						
Conditions: Avoid cold, frost and heat.							
6. Other information							
medical area - not surgical handwash							
medical area - not surgical nandwash							
7. Third information level:	individual products in the me	ta SPC					
7.1 Trade name(s) authorica	tion number and specific compo	sition of each individual					
product	non number and specific compos	sition of each marvidual					
•							
Trade name(s)	SALVESAFE F0dil_GPRO	Market area: EU					

SURE Antibac Foam Hand Wash Free H1

SURE Antibacterial Foam Hand Wash

**Authorisation number** 

Market area: EU

EU-0019494-0001 1-1

(R4BP 3 asset reference number - National Authorisation)

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

Trade name(s)

SALVESAFE F0\_GPRO

Market area: EU

**Authorisation number** 

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0002 1-1

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

Trade name(s)

SALVESAFE Fv0\_GPRO

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0003 1-1

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

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SALVESAFE F1\_GPRO

Market area: EU

#### **Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0004 1-1

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

Trade name(s)

SALVESAFE Fv1\_GPRO

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0005 1-1

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

SALVESAFE F3\_GPRO

Market area: EU

#### **Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0008 1-1

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

Trade name(s)

SALVESAFE Fv3\_GPRO

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0009 1-1

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

Trac	le	name	:(s)
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SALVESAFE F4\_GPRO

Market area: EU

#### **Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0010 1-1

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

Trade name(s)

SALVESAFE Fv4\_GPRO

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0011 1-1

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

Trac	le	name	:(s)
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SALVESAFE F7\_GPRO

Market area: EU

#### **Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0016 1-1

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

Trade name(s)

SALVESAFE Fv7\_GPRO

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0017 1-1

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

SALVESAFE F8\_GPRO

Market area: EU

#### **Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0018 1-1

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

Trade name(s)

SALVESAFE Fv8\_GPRO

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0019 1-1

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

#### 1. Meta SPC administrative information

#### 1.1. Meta SPC identifier

**SALVESAFE F\_GP (for General Public)** 

1.2. Suffix to the authorisation number

1-2

#### 1.3 Product type(s)

PT01 - Human hygiene (Disinfectants)

#### 2. Meta SPC composition

#### 2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	1,75 - 2,38

#### 2.2. Type(s) of formulation of the meta SPC

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AL - Any other liquid

### 3. Hazard and precautionary statements of the meta SPC

Hazard statements	
Precautionary statements	If medical advice is needed, have product container or label at hand.  Keep out of reach of children.

### 4. Authorised use(s) of the meta SPC

#### 4.1 Use description

#### Use 1 - PT1 - Disinfectant for hands

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Ready-to-use disinfectant for hands with a bactericidal and yeasticidal efficacy in domestic area.
Target organism(s) (including development stage)	Scientific name: bacteria Common name: Bacteria Development stage:
	Scientific name: yeasts Common name: Yeasts Development stage:
Field(s) of use	Indoor
•	Outdoor

### Application method(s)

Method: Manual application, foam application

Detailed description:

Wet hand and wrists with water. Place 2 ml of product in the hallow of the hand. Rub hands and wrists for at least 30 seconds. Rinse thoroughly with clean water.

# Application rate(s) and frequencies

Application Rate: 2 ml

Dilution (%): 0

Number and timing of application:

Apply once, repeat if renewed hand disinfection is needed.

#### Category(ies) of users

General public (non-professional)

## Pack sizes and packaging material

Bottle, Plastic: HDPE, LDPE, PET, PE, PP, 0.01-2L

Pouches, Plastic: LDPE, LLDPE, 0.05-5L

#### 4.1.1 Use-specific instructions for use

Wet hand and wrists with water. Place 2 ml of product in the hallow 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)  1.1.5 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 use of the meta SPC
PT1 - Wet hands and wrists with water. Place 2mL 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
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 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.
5. Other information

### 7. Third information level: individual products in the meta SPC

# 7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

SALVESAFE F0\_GP

Market area: EU

Authorisation number

EU-0019494-0020 1-2

(R4BP 3 asset reference number - National Authorisation)

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

Trade name(s)

SALVESAFE Fv0\_GP

Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

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

Trade name(s)

SALVESAFE F1\_GP

Market area: EU

**Authorisation number** 

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0022 1-2

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

Trade name(s)

SALVESAFE Fv1\_GP

Market area: EU

**Authorisation number** 

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0023 1-2

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

Trade name(s)

SALVESAFE F3\_GP

Market area: EU

**Authorisation number** 

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0026 1-2

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

Trade name(s)

SALVESAFE Fv3\_GP

Market area: EU

**Authorisation number** 

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0027 1-2

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

Trade name(s)

SALVESAFE F4\_GP

Market area: EU

**Authorisation number** 

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0028 1-2

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

Trade name(s)

SALVESAFE Fv4\_GP Market area: EU

Savon mains désinfectant - Fleur de cerisier

Market area: EU

**Authorisation number** 

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0029 1-2

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

Trade	name	(s)
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SALVESAFE F7_GP	Market area: EU
OSANIS - Savon mousse désinfectant pour les mains	Market area: EU

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0034 1-2

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

### Trade name(s)

SALVESAFE Fv7_GP	Market area: EU
Savon mains désinfectant - Pomme verte	Market area: EU
OSANIS - Savon Mains désinfectant	Market area: EU

OSANIS - Desinfizierende Handseife	Market area: EU
OSANIS - Desinfecterende handzeep	Market area: EU
OSANIS - Sapone disinfettante per le mani	Market area: EU
EU-0019494-0035 1-2	

(R4BP 3 asset reference number - National Authorisation)

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

Trac	le	na	me	(s)
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SALVESAFE F8\_GP

Market area: EU

#### **Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0036 1-2

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

SALVESAFE Fv8\_GP

Market area: EU

#### **Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0019494-0037 1-2

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