

EN

ANNEX

**SUMMARY OF PRODUCT CHARACTERISTICS
FOR A BIOCIDAL PRODUCT FAMILY**

SALVESAFE C

Product type(s)

PT01: Human hygiene

Authorisation number EU-0016328-0000

R4BP asset number EU-0016328-0000

Part I.
FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	SALVESAFE C
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1.2. Product type(s)

Product type(s)	PT01: Human hygiene
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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
Authorisation number	EU-0016328-0000	
<i>R4BP asset number</i>	EU-0016328-0000	
Date of the authorisation	07/06/2017	
Expiry date of the authorisation	07/06/2027	

1.4. 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

Name of manufacturer	OTB COSMETICS
Address of manufacturer	37 Rue du Stiff - ZAE Saint-Eloi Leslouc'h 29800 PLOUEDERN France
Location of manufacturing sites	OTB COSMETICS site 1 37 Rue du Stiff - ZAE Saint-Eloi Leslouc'h 29800 PLOUEDERN France

Name of manufacturer	OTB COSMESOAP
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Address of manufacturer	Boulevard Jean Mantelet 14700 FALAISE France
Location of manufacturing sites	OTB COSMESOAP site 1 Boulevard Jean Mantelet 14700 FALAISE France

1.5. 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 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 - 1,75 % (w/w)

2.2. Type(s) of formulation

Formulation type(s)	AL Any other liquid
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Part II.
SECOND INFORMATION LEVEL - META SPC(S)

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	Meta SPC: Hygienic handrub for non-professional users – 24 months
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. Product type(s)

Product type(s)	PT01: Human hygiene
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2. META SPC 1 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		active substance		200-018-0	1,75 - 1,75 % (w/w)

2.2. Type(s) of formulation of the meta SPC 1

Formulation type(s)	AL Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	
Precautionary statements	P102: Keep out of reach of children. P101: If medical advice is needed, have product container or label at hand.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1. Hygienic handrub for 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 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: 3 mL Dilution (%): Ready-to-use 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: PET, PE, PP , 0.01 -5L (consumers) Pouches, Plastic: LDPE, LLDPE , 0.01-5L (consumers) 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 USE OF THE META SPC 1

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 disinfection is needed.

5.2. Risk mitigation measures

5.3. Risk mitigation measures

Not applicable

5.4. 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.

5.5. Instructions for safe disposal of the product and its packaging

Dispose of contents/container in accordance with national regulation.

5.6. 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.

6. OTHER INFORMATION

(* Not surgical handrub.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

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

Trade name(s)	SALVESAFE C0_C	Market area: EU
	Mousse désinfectante mains	Market area: EU
	BACTIDOSE GREEN Mousse	Market area: EU
	La désinfection honnête - Mousse désinfectante mains	Market area: EU
	Milton Antibacterial hand sanitiser	Market area: EU
	Milton Mousse mains désinfectante	Market area: EU
	Mousse Désinfectante pour les Mains sans parfum	Market area: EU
	Mousse Désinfectante pour les Mains sans parfum by Biozeffi	Market area: EU
	Mousse Désinfectante pour les Mains sans parfum by Effibioz	Market area: EU
	Desinfizierend Handschaum, parfümfrei, by Effibioz	Market area: EU
	Hand Sanitising Foam Fragrance free by Effibioz	Market area: EU

	Mousse desinfectante para manos sin fragrancia by Effibioz	Market area: EU
	Mousse disinfettante mani Senza profumo by Effibioz	Market area: EU
	Mapa Mousse desinfectante para Manos sin fragrancia by Effibioz	Market area: EU
	Spontex Mousse desinfectante para Manos sin fragrancia by Effibioz	Market area: EU
Authorisation number	EU-0016328-0016 1-2	

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

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE C16_C	Market area: EU
	Evercleanhand rub	Market area: EU
	OSANIS - Mousse Désinfectante mains parfum Feuilles de Menthe	Market area: EU
	OSANIS – Ontsmettend handschuim, geparfumeerd met munt	Market area: EU
	OSANIS - Schiuma disinfettante per le mani alla menta	Market area: EU

	OSANIS - Hand- Desinfektions- Minzblattduft	Market area: EU
	OSANIS - Espuma desinfectante para manos hoja de menta	Market area: EU
	OSANIS - Espuma desinfectante para as mãos folhas de menta	Market area: EU
	OSANIS - Hand Disinfectant Foam Icy	Market area: EU
Authorisation number	EU-0016328-0033 1-2	

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

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	Meta SPC: Hygienic handrub for professional and non-professional users – 30 months
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1.2. Suffix to the authorisation number

Number	1-5
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1.3. Product type(s)

Product type(s)	PT01: Human hygiene
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2. META SPC 2 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		active substance		200-018-0	1,75 - 1,75 % (w/w)

2.2. Type(s) of formulation of the meta SPC 2

Formulation type(s)	AL Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

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) OF THE META SPC

4.1. Use description

Table 1. Hygienic handrub for professional and non-professional users – 30 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 (professional, industrial) 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

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 USE OF THE META SPC 2

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

5.3. Risk mitigation measures

Not applicable.

5.4. 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.

5.5. Instructions for safe disposal of the product and its packaging

Dispose of contents/container in accordance with national regulation.

5.6. Conditions of storage and shelf-life of the product under normal conditions of storage

Products can be stored at room temperature up to 30 months.

Protect from cold and heat.

6. OTHER INFORMATION

(* Not surgical handrub.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

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

Trade name(s)	SALVESAFE C0_GPPRO	Market area: EU
	OSANIS - Mousse désinfectante mains	Market area: EU
	BACTIDOSE GREEN Mousse Mains	Market area: EU
	Mousse Désinfectante pour les Mains Pro - sans parfum	Market area: EU
	Mousse Désinfectante pour les Mains Pro sans parfum by Biozeffi	Market area: EU
	Mousse Désinfectante pour les Mains Pro sans parfum by Effibioz	Market area: EU
	Milton - Antibacterial hand sanitiser - Mousse mains désinfectante	Market area: EU
	OSANIS - Hand Disinfectant Foam	Market area: EU
	OSANIS - Espuma desinfetante para as mãos	Market area: EU
	OSANIS - Espuma desinfectante para manos	Market area: EU
	OSANIS – Ontsmettend handschuim	Market area: EU

OSANIS - Schiuma disinfettante per le mani	Market area: EU
OSANIS - Hand- Desinfektionsschaum	Market area: EU
BÉABA – Mousse désinfectante mains	Market area: EU
BÉABA – Hand disinfecting foam	Market area: EU
BÉABA – Espúma desinfectante de manos	Market area: EU
BÉABA – Händedesinfektionsschaum	Market area: EU
BÉABA – Handdesinfec- terend schuim	Market area: EU
BÉABA – Pianka do dezynfekcji rąk	Market area: EU
BÉABA – Sredstvo za dezinfekciju ruku	Market area: EU
BÉABA – Schiuma disinfettante mani	Market area: EU
Fragrance free pro hand disinfectant foam by effibioz	Market area: EU
Pro schiuma disinfettante per le mani senza profumo by effibioz	Market area: EU
Hand desinfektionsschaum ohne parfüm by effibioz	Market area: EU

	Ontsmettend handschuim zonder parfum by effibioz	Market area: EU
	Espuma desinfectante para manos sin perfume by effibioz	Market area: EU
	Espuma desinfectante para as mãos sem perfume by effibioz	Market area: EU
Authorisation number	EU-0016328-0034 1-5	

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

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE C8_GPPRO	Market area: EU
	Mousse Désinfectante pour les Mains Parfumée Golden	Market area: EU
	Mousse Désinfectante pour les Mains Parfumée Golden by Biozeffi	Market area: EU
	Mousse Désinfectante pour les Mains Parfumée Golden by Effibioz	Market area: EU
	Mousse Désinfectante pour les Mains Pro - Parfumée Golden	Market area: EU
	Mousse Désinfectante pour les	Market area: EU

Mains Pro Parfumée Golden by Biozeffi	
Mousse Désinfectante pour les Mains Pro Parfumée Golden by Effibioz	Market area: EU
Dettol Foam Hand Sanitiser	Market area: EU
Dettol Anti- bacterial Hand Sanitiser	Market area: EU
Dettol Hand Hygiene Foam	Market area: EU
Sagrotan Desinfektion Handschaum	Market area: EU
Sagrotan Desinfektion Handhygiene- Schaum	Market area: EU
Sagrotan Desinfektion Handmousse	Market area: EU
Hand disinfectant foam Golden	Market area: EU
Schiuma disinfettante per le mani Golden	Market area: EU
Hand desinfektionsschaum Golden	Market area: EU
Ontsmettend handschuim Golden	Market area: EU
Espuma desinfectante para manos Golden	Market area: EU
Espuma desinfetante para as mãos Golden	Market area: EU

Authorisation number	EU-0016328-0036 1-5
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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		active substance		200-018-0	1,75

7.3. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE C9_GPPRO	Market area: EU
Authorisation number	EU-0016328-0037 1-5	

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

7.4. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE C12_GPPRO	Market area: EU
Authorisation number	EU-0016328-0038 1-5	

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

7.5. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE C16_GPPRO	Market area: EU
	EverCleanHand lotion	Market area: EU
	OSANIS - Mousse désinfectante mains parfumée	Market area: EU
	OSANIS – Hand Sanitiser Foam	Market area: EU
	BACCIDE Mousse Mains	Market area: EU
	Hand disinfectant foam Mint	Market area: EU
	Schiuma disinfettante per le mani Menta	Market area: EU

	Hand desinfektionsschaum Minze	Market area: EU
	Ontsmettend handschuim Munt	Market area: EU
	Espuma desinfectante para manos Menta	Market area: EU
	Espuma desinfetante para as mãos Hortelã	Market area: EU
	Mousse désinfectante pour les mains parfumée menthe	Market area: EU
Authorisation number	EU-0016328-0039 1-5	

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

7.6. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE C17_GPPRO	Market area: EU
	Mousse Désinfectante pour les Mains Parfumée Fleurs de printemps	Market area: EU
	Mousse Désinfectante pour les Mains Parfumée Fleurs de printemps by Biozeffi	Market area: EU
	Mousse Désinfectante pour les Mains Parfumée Fleurs de printemps by Effibioz	Market area: EU

	Mousse Désinfectante pour les Mains Pro - Parfumée Fleurs de printemps	Market area: EU
	Mousse Désinfectante pour les Mains Pro Parfumée Fleurs de printemps by Biozeffi	Market area: EU
	Mousse Désinfectante pour les Mains Pro Parfumée Fleurs de printemps by Effibioz	Market area: EU
Authorisation number	EU-0016328-0040 1-5	

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

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	Meta SPC: Hygienic handrub for professional and non-professional users – 24 months
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1.2. Suffix to the authorisation number

Number	1-6
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1.3. Product type(s)

Product type(s)	PT01: Human hygiene
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2. META SPC 3 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		active substance		200-018-0	1,75 - 1,75 % (w/w)

2.2. Type(s) of formulation of the meta SPC 3

Formulation type(s)	AL Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

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) OF THE META SPC

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)	<p>Scientific name: Bacteria Common name: Bacteria Development stage: no data</p> <p>Scientific name: Yeasts Common name: Yeasts Development stage: no data</p> <p>Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage: no data</p>
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	<p>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)</p> <p>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.</p>

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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 USE OF THE META SPC 3

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

5.3. Risk mitigation measures

Not applicable.

5.4. 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.

5.5. Instructions for safe disposal of the product and its packaging

Dispose of contents/container in accordance with national regulation.

5.6. 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.

6. OTHER INFORMATION

(* Not surgical handrub.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

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

Trade name(s)	SALVESAFE C18_GPPRO	Market area: EU
	Même - La mousse désinfectante mains sensibles	Market area: EU
Authorisation number	EU-0016328-0041 1-6	

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

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE C3_GPPRO	Market area: EU
Authorisation number	EU-0016328-0035 1-6	

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