

Summary of product characteristics for a biocidal product

Product name: SafeDes Hand Disinfection

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

PT01 - Human hygiene (Disinfectants)

Authorisation number: 5833

R4BP 3 asset reference number: SE-0028008-0001

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Administrative information

1.1. Trade names of the product

SafeDes
AntiVir
Softox
Assist
Aeris
SafeDes Hand Disinfection

1.2. Authorisation holder

Name and address of the authorisation holder	Name	SOFTOX SOLUTIONS AS
	Address	Martin Linges vei 25 1364 Fornebu Norway
Authorisation number	5833 1-1	
R4BP 3 asset reference number	SE-0028008-0001	
Date of the authorisation	18/10/2022	
Expiry date of the authorisation	17/10/2032	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	SoftOx Solutions AS
Address of the manufacturer	Martin Linges vei 25 1364 Fornebu Norway
Location of manufacturing sites	Ose Water, Austad 84 4745 Bygland Norway

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

Active substance	1391 - Active chlorine released from sodium hypochlorite
Name of the manufacturer	Borregaard
Address of the manufacturer	Hjalmar Wessels vei 6 1721 Sarpsborg Norway
Location of manufacturing sites	Hjalmar Wessels vei 6 1721 Sarpsborg Norway

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 (%)
Active chlorine released from sodium hypochlorite		Active Substance			0,02

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements

May be corrosive to metals.

Precautionary statements

Keep only in original packaging.

4. Authorised use(s)

4.1 Use description

Use 1 - Use 1: PT1 -Hand disinfection - Professionals

Product type

PT01 - Human hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Hygienic handrub for professionals, including healthcare professionals.

Target organism(s) (including development stage)

Scientific name: Bacteria
Common name: Bacteria
Development stage:

Scientific name: Yeast
Common name: Yeast
Development stage:

Scientific name: Fungal spores
Common name: Fungal spores
Development stage: Spores and spore producing structures

Scientific name: Enveloped viruses
Common name: Enveloped viruses
Development stage:

Field(s) of use

Indoor

Hygienic handrub for professionals, including healthcare professionals.

Application method(s)

Method: Manual application
Detailed description:

Rub in 3 ml, spread over the entire hand so that the skin is covered for a minimum of 60 seconds.

Application rate(s) and frequencies

Application Rate: 3 ml
Dilution (%): 0

	Number and timing of application: As often as needed.
Category(ies) of users	Professional
Pack sizes and packaging material	50 ml, 100 ml, 250 ml, 500 ml, 600 ml, 1 liter and 5-liter bottles PET-/HD-PE

4.1.1 Use-specific instructions for use

Make sure that all organic material such as dirt and grease is removed from your hands. Apply 3 ml in the palm of your hand. Rub your hands together so that all surfaces on both hands are covered, including between the fingers and up around the fingertips and nail. Rub your hands together for 60 seconds to allow them to absorb the product and dry completely.

4.1.2 Use-specific risk mitigation measures

The product should not be used for hand disinfection on infants and toddlers (children under 2 years).

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

First aid instructions:

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

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

IF ON SKIN: If irritation occurs wash with water and seek medical advice. In cases of unintentional skin exposure: wash with water.

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.

Environmental precautions:

The product should not be allowed to enter ground water systems or contaminate surface water. Should not be released into the environment.

Methods and materials for containment and cleanup:

Collect larger spills with absorbent material and place in containers for forwarding to waste disposal.

Clean the area with water.

Less spillage - wipe up with a damp cloth.

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

After completion of treatment, discard unused product and the packaging in accordance with local regulations. Dispose of wastes in an approved waste disposal facility.

Unemptied containers are treated as the unused product. The contents must be disposed of in accordance with local regulations.

Bring empty containers to an approved waste handling site for recycling or disposal. Dispose of packaging only if completely empty and closed. Do not re-use empty containers. Dispose of in accordance with local regulations.

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Store at room temperature (5 to 25 °C) in the original package, tightly closed. The product must not be exposed to high temperatures or direct sunlight. Protect against frost.
Shelf life: 9 months

4.2 Use description

Use 2 - Use 2: PT1 -Hand disinfection - Non-professionals

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Hygienic handrub for consumers.
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeast Common name: Yeast Development stage: Scientific name: Fungal spores Common name: Fungal spores Development stage: Spores and spore producing structures Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage:
Field(s) of use	Indoor Hygienic handrub for consumers.
Application method(s)	Method: Manual application Detailed description: Rub in 3 ml, spread over the entire hand so that the skin is covered for a minimum of 60 seconds.
Application rate(s) and frequencies	Application Rate: 3 ml Dilution (%): 0 Number and timing of application: As often as needed.
Category(ies) of users	General public (non-professional)

Pack sizes and packaging material

50 ml, 100 ml, 250 ml, 500 ml, 600 ml, 1 liter and 5-liter bottles PET-/HD-PE

4.2.1 Use-specific instructions for use

Read carefully and follow all instructions.

Make sure all organic material such as dirt and grease is removed from the hands. Apply 3 ml in the palm of your hand. Rub your hands so that all surfaces of both hands are covered, including between the fingers and around fingertips and nails. Rub your hands for 60 seconds to allow them to absorb the product and dry completely.

4.2.2 Use-specific risk mitigation measures

The product should not be used for hand disinfection on infants and toddlers (children under 2 years).

4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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

First aid instructions:

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

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

IF ON SKIN: If irritation occurs wash with water and seek medical advice. In cases of unintentional skin exposure: wash with water.

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.

Environmental precautions:

The product should not be allowed to enter ground water systems or contaminate surface water. Should not be released into the environment.

Methods and materials for containment and cleanup:

Collect larger spills with absorbent material and place in containers for forwarding to waste disposal.

Clean the area with water.

Less spillage - wipe up with a damp cloth.

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

After completion of treatment, discard unused product and the packaging in accordance with local regulations. Dispose of wastes in an approved waste disposal facility.

Unemptied containers are treated as the unused product. The contents must be disposed of in accordance with local regulations.

Bring empty containers to an approved waste handling site for recycling or disposal. Dispose of packaging only if completely empty and closed. Do not re-use empty containers. Dispose of in accordance with local regulations.

4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Keep out of reach of children and animals/pets.

Store at room temperature (5 to 25 °C) in the original package, tightly closed. The product must not be exposed to high temperatures or direct sunlight. Protect against frost.

Shelf life: 9 months

5. General directions for use

5.1. Instructions for use

See Use-specific instructions.

5.2. Risk mitigation measures

See Use-specific instructions.

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

See Use-specific instructions.

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

See Use-specific instructions.

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

See Use-specific instructions.

6. Other information

