

Summary of product characteristics for a biocidal product family

Family name: SoftOx Disinfectants

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

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

Authorisation number: 5833

R4BP 3 asset reference number: SE-0028008-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

SoftOx Disinfectants

1.2. Product type(s)

PT01 - Human hygiene (Disinfectants)

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder

Name

SOFTOX SOLUTIONS AS

Address

Martin Linges vei 25 1364 Fornebu Norway

Authorisation number

5833

R4BP 3 asset reference number

SE-0028008-0000

Date of the authorisation

18/10/2022

Expiry date of the authorisation

17/10/2032

1.4. 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

1.5. 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 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 (%)
Active chlorine released from sodium hypochlorite		Active Substance			0,02 - 0,02

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

Meta 1: PT1 Hand disinfection

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

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

May be corrosive to metals.

Precautionary statements

Keep only in original packaging.

4. Authorised use(s) of the meta SPC

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 of the meta SPC

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

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)

SafeDes	Market area: SE
AntiVir	Market area: SE
Softox	Market area: SE
Assist	Market area: SE
Aeris	Market area: SE
SafeDes Hand Disinfection	Market area: SE
Authorisation number (R4BP 3 asset reference number - National Authorisation) SE-0028008-0001 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Active chlorine released from sodium hypochlorite		Active Substance			0,02

1. Meta SPC administrative information**1.1. Meta SPC identifier**

Meta 2: PT2 Hard surface disinfection for professional and non-professional use
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1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (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 (%)
Active chlorine released from sodium hypochlorite		Active Substance			0,02 - 0,02

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

May be corrosive to metals.

Precautionary statements

Keep only in original packaging.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Use 3: PT2- Hard surface disinfection - Professionals including health care

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Disinfection of hard surfaces. For professional use including healthcare.
Target organism(s) (including development stage)	<p>Scientific name: Bacteria Common name: Bacteria Development stage:</p> <p>Scientific name: Yeast Common name: Yeast Development stage:</p> <p>Scientific name: Tuberculosis bacilli Common name: Tuberculosis bacilli Development stage:</p> <p>Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Disinfection of hard surfaces in, for example, nursing homes, patient rooms, bathrooms, operating rooms, laboratories, dental clinics, institutions, offices, public transport. Suitable for all surfaces tolerant to water. Not for surfaces that come into contact with food and animal feed.</p>
Application method(s)	<p>Method: Mopping, wiping, pouring Detailed description: Apply disinfectant by mopping, wiping or pouring on clean, dry surfaces free of organic matter. Make sure the surface is kept moist for 5 minutes.</p>
Application rate(s) and frequencies	<p>Application Rate: 50 ml / m² Dilution (%): 0 Number and timing of application: Daily disinfection after cleaning. Maximum usage time per day: 330 min</p>
Category(ies) of users	Professional
Pack sizes and packaging material	250 ml, 500 ml, 600 ml, and 1000 ml bottles PET / HD-PE and 5 liter cans PET / HD-PE

4.1.1 Use-specific instructions for use

4.1.1 Use-specific instructions for use

Apply 50 ml / m² by mopping, wiping or pouring on clean and dry surfaces free of organic matter.
Make sure the surface is kept moist for 5 minutes to get the full effect on bacteria, yeast, mycobacteria and enveloped viruses.
Air dry. Rinse not required.

4.1.2 Use-specific risk mitigation measures

Do not apply to objects or surfaces that infants and toddlers (children under 2 years of age) may put in their mouths or lick on.

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: Wash skin with water. 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.

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 4: PT2- Hard surface disinfection - Non-professionals

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Disinfection of hard surfaces in private homes 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: Tuberculosis bacilli Common name: Tuberculosis bacilli Development stage: Scientific name: Virus Common name: Viruses Development stage:
Field(s) of use	Indoor Disinfection of hard surfaces in private homes, for example in bathrooms and toilets. Not for use in kitchens or on surfaces that come into contact with food or animal feed
Application method(s)	Method: Mopping, wiping and pouring Detailed description: Apply disinfectant by mopping, wiping or pouring onto clean, dry surfaces free of organic material. Make sure the surface is kept moist for 5-10 minutes.
Application rate(s) and frequencies	Application Rate: 50 ml/m ² Dilution (%): 0 Number and timing of application: Daily disinfection after cleaning.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	250 ml, 500 ml, 600 ml, and 1000 ml bottles PET / HD-PE

4.2.1 Use-specific instructions for use

Read carefully and follow all instructions.
Apply 50 ml / m² on clean and dry surfaces free of organic material.
Make sure the surface is kept moist for 10 minutes for full bacterial sporicidal effect (5 minutes for full effect on bacteria, mycobacteria, viruses and yeast).
Air dry. Rin sing is not required.

4.2.2 Use-specific risk mitigation measures

Do not apply to objects or surfaces that infants and toddlers (children under 2 years of age) may put in their mouths or lick on.

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: Wash skin with water. 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.

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 non-target 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 of the meta SPC

5.1. Instructions for use

See Use specific instructions for use.

5.2. Risk mitigation measures

See Use specific instructions for use.

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

See Use specific instructions for use.

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

See Use specific instructions for use.

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

See Use specific instructions for use.

6. Other information

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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)	EffectDes	Market area: SE
	SoftOx	Market area: SE
	EffectDes Surface Disinfection	Market area: SE
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small>	SE-0028008-0002 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Active chlorine released from sodium hypochlorite		Active Substance			0,02

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta 3: PT4 Disinfection of surfaces that come into contact with food and feed

1.2. Suffix to the authorisation number

1-3

1.3 Product type(s)

PT04 - Food and feed area (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 (%)
Active chlorine released from sodium hypochlorite		Active Substance			0,02 - 0,02

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

May be corrosive to metals.

Precautionary statements

Keep only in original packaging.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Use 5: PT4 - Disinfection of large surfaces that come into contact with food and feed - Professional

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Disinfection of hard surfaces.
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeast Common name: Yeast Development stage: Scientific name: Bacterial spores Common name: Bacterial spores Development stage: Bacterial spores Scientific name: Virus Common name: Virus Development stage:
Field(s) of use	Indoor Disinfectants to prevent and reduce the risk of transferring microbes to food from food contact areas in restaurants and food and feed industry, such as floors, benches, tables, cutting boards, freezers and cutting machines.
Application method(s)	Method: Manual application Detailed description: Apply disinfectant by mopping, wiping or pouring onto clean and dry surfaces free of organic material. Make sure the surface is kept moist for 5-10 minutes.
Application rate(s) and frequencies	Application Rate: 50 ml/m ² Dilution (%): 0 Number and timing of application: Daily disinfection after cleaning.
Category(ies) of users	Professional
Pack sizes and packaging material	250 ml, 500 ml, 600 ml, 1 liter and 5 liter bottles PET / HD-PE

4.1.1 Use-specific instructions for use

4.1.1 Use-specific instructions for use

Disinfect critical surfaces after cleaning and drying, by mopping, wiping or pouring disinfectant onto the surfaces and keep it wet for 5-10 minutes.
Efficiently kills or inactivates bacteria, yeast, and viruses after 5 minutes. Make sure the surface is kept wet for 10 minutes for full effect against bacterial spores.
Dosage: Apply 50 ml / m² on clean and dry surfaces without organic material. Air dry. Rinse with water before next use.
Suitable for all surfaces which tolerate water.

4.1.2 Use-specific risk mitigation measures

Non identified.

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: Wash skin with water. 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.

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

5. General directions for use of the meta SPC

5.1. Instructions for use

See Use-specific instructions for use

5.2. Risk mitigation measures

None identified.

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

See Use-specific instructions for use

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

See Use-specific instructions for use

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

See Use-specific instructions for use

6. Other information

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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)	SoftOx	Market area: SE
	EffectDes	Market area: SE
	EffectDes Surface Disinfection	Market area: SE
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small>	SE-0028008-0003 1-3	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Active chlorine released from sodium hypochlorite		Active Substance			0,02
