Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

RISK ASSESSMENT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS

SoftOx Disinfectants Family

Product type(s) PT 1, 2 and 4

Active substance: Active chlorine released from sodium hypochlorite - Case Number in R4BP: BC-GE070579-37

Evaluating Competent Authority:
Swedish Chemicals Agency (Sweden)

Date: 2022-10-18

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1 CONCLUSION

The SoftOx Disinfectants Family (PT 1, 2 and 4) includes products for hand (PT1) and hard surfaces disinfection (PT2) for non-professional and professional use, including health care, and professional disinfection in areas were food and feed is handled (PT4).

The active substance in the product family is **active chlorine released from sodium hypochlorite**. At the pH of the product family (4.1-5.0) almost 100 % of the active chlorine is present in the products as hypochlorous acid. Therefore, analysis reports/certificates are reporting the content of active chlorine as hypochlorous acid. Throughout the report, when the word acid is used in conjunction with a ppm content of active substance, this refers to the acid used for pH regulation. The identity of this acid can be found in the confidential annex.

The evaluation of the Swedish Chemicals Agency shows that the biocidal product family is effective for the uses included in the summary of the product's characteristics (and section 2.1.4 of this PAR).

The human health risk assessment shows that the products can be used without risk for all claimed uses if the following risk mitigation measures (RMM) are added. For the PT1 hand disinfection products "*The product should not be used for hand disinfection of infants and toddlers (children below the age of 2 years)*", and for the PT2 surface disinfection products "*Do not apply on objects or surfaces that infants and toddlers (children below 2 years of age) can put in their mouth or lick on*".

Due to the highly reactive nature of the active substance, active chlorine released from sodium hypochlorite, it is not foreseen that the use of SoftOx disinfectants will pose a risk to the environment. The byproducts of active chlorine formed in the environment have not been assessed due to the current lack of guidance. This is in accordance with the agreement for disinfectants-by-products in the BPC Working Group for Environment (WG-I-2020).

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	Country (if relevant)
SoftOx Disinfectants Family	Sweden

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	SoftOx Solutions AS
	Address	Martin Linges vei 25, 1364 Fornebu, Norway
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer of the products of the family

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

2.1.1.4 Manufacturer of the active substance

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

2.1.2 Product (family) composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No X

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Active chlorine released from sodium hypochlorite
IUPAC or EC name	Sodium hypochlorite
EC number	231-668-3
CAS number	7681-52-9
Index number in Annex VI of CLP	017-011-00-1
Minimum purity / content	Minimum purity of the releaser sodium hypochlorite: aqueous solution with an active chlorine concentration ≤ 180 g/kg (i.e. ≤ 18 % w/w).
Structural formula	

2.1.2.2 Candidate(s) for substitution

The active substance is not considered a candidate for substitution.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Active chlorine released from sodium hypochlorite	Sodium Hypochlorite	Active substance	7681-52-9	231-668-3	0.02	0.02

The full composition of the biocidal product family is given in the Confidential Annex.

2.1.2.4 Information on technical equivalence

The active substance releaser Sodium hypochlorite is provided by Borregaard, Hjalmar Wessels vei 6, 1721 Sarpsborg, Norway, who is member of the Euro Chlor consortium that has applied for approval of the active substance, i.e., the active substance of the products is equivalent to the active substance listed in the Union list of approved active substances under Regulation No. 528/2012.

2.1.2.5 Information on the substance(s) of concern

The biocidal product family does not include any substance(s) of concern

2.1.2.6 Type of formulation

AL: Any other liquid

2.1.3 Hazard and precautionary statements[1]

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	No
Hazard statement	No
Labelling	
Signal words	No
Hazard statements	H290 May be corrosive to metals
Precautionary statements	P234 Keep only in original packaging.
Note	

2.1.4 Authorised uses

2.1.4.1 Table 1. Use # 1 – (0.02%) – PT1 Hand disinfection - Professionals

Product Type	1
Where relevant, an exact description of the authorised use	Hygienic handrub for professionals, including health care professionals.
Target organism (including development stage)	Bacteria, yeast, fungal spores and enveloped viruses.
Field of use	Hygienic Handrub
Application method(s)	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 frequency	3 ml, as often as necessary for health care and other professional users.
Category(ies) of users	Professional users, including health care professionals.
Pack sizes and packaging material	50ml, 100ml, 250ml, 500ml, 600ml, 1 liter and 5 liter bottles of PET / HD-PE

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 nails. Rub your hands together for 60 seconds to allow them to absorb the product and dry completely.

Use-specific risk mitigation measures

The product should not be used for hand disinfection of infants and toddlers (children below the age of 2 years).

2.1.4.2 Table 2. Use # 2 (0.02%) – PT1 Hand disinfection - Non-professionals

Product Type(s)	1
Where relevant, an exact description of the authorised use	Hygienic handrub for consumers
Target organism (including development stage)	Bacteria, yeast, fungal spores and enveloped viruses.
Field of use	Hygienic handrub for consumers
Application method(s)	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 frequency	3ml, as often as necessary
Category(ies) of user(s)	Non-professionals, consumers.
Pack sizes and packaging material	50 ml, 100 ml, 250 ml, 500 ml, 600 ml, 1 liter and 5 liter bottles of PET / HD-PE

Use-specific instructions for use

Read carefully and follow all instructions 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 nails. Rub your hands together for 60 seconds to allow them to absorb the product and dry completely.

Use-specific risk mitigation measures

The product should not be used for hand disinfection of infants and toddlers (children below the age of 2 years).

2.1.4.3 Table 3. Use # 3 – PT 2 (0.02%) Hard surface disinfection - Professionals including health care professionals

Product Type(s)	2
Where relevant, an exact description of the authorised use	Disinfection of hard surfaces. For professional use including health care.
Target organism (including development stage)	Bacteria, yeast, Tuberculosis bacilli and enveloped viruses.
Field of use	Disinfection of hard surfaces in for example: nursing homes, patient rooms, bathrooms, operation rooms, laboratories, dental centers, institutions, offices, public transportation. Suitable for all surfaces tolerant to water. For surfaces that do not come into contact with food and feed.

Application method(s)	Mopping, wiping, pouring. Apply disinfectant by mopping, wiping or pouring on clean and dry surfaces free of organic material. Make sure that the surface is kept moist for 5 minutes.
Application rate(s) and frequency	Daily disinfection after cleaning. 50 ml /m². Maximum usage time per day: 330 min
Category(ies) of user(s)	Professionals including health care professionals.
Pack sizes and packaging material	250 ml, 500 ml, 600 ml, and 1000 ml bottle PET / HD-PE and 5 liter containers PET / HD-PE

Use-specific instructions for use

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

Use-specific risk mitigation measures

Do not apply on objects or surfaces that infants and toddlers (children below 2 years of age) can put in their mouth or lick on.

2.1.4.4 Table 4. Use # 4 – PT 2 (0.02%) Hard surface disinfection - Non-professionals

Product Type(s)	2
Where relevant, an exact description of the authorised use	Disinfection of hard surfaces in private homes for consumers.
Target organism (including development stage)	Bacteria, yeast, Tuberculosis bacilli, bacterial spores and viruses.
Field of use	Disinfection of hard surfaces in private homes, in for example bathrooms and toilets. For surfaces that do not come into contact with food and feed.
Application method(s)	Mopping, wiping, pouring. Apply disinfectant on clean and dry surfaces free of organic material. Make sure that the surface is kept moist for 5 -10 minutes.
Application rate(s) and frequency	Daily disinfection after cleaning.
Category(ies) of user(s)	Non-Professionals, consumers.
Pack sizes and packaging material	250 ml, 500 ml, 600 ml, and 1000 ml bottle and 5 liter containers PET / HD-PE

Use-specific instructions for use

Read carefully and follow all instructions

Apply 50 ml / m² on clean and dry surfaces free of organic matter. Apply disinfectant on clean and dry surfaces free of organic material. Make sure that the surface is kept moist for 10 minutes for full bacterial sporicidal effect (5 minutes for effect on bacteria, yeast, mycobacteria and viruses). Air dry. Rinse not required.

Use-specific risk mitigation measures

Do not apply on objects or surfaces that infants and toddlers (children below 2 years of age) can put in their mouth or lick on.

2.1.4.5 Table 5. Use # 5 – PT 4 (0.02%) Disinfection of large surfaces that come into contact with food and feed - Professional

Product Type(s)	4
Where relevant, an exact description of the authorised use	Disinfection of hard surfaces.
Target organism (including development stage)	Bacteria, yeast, bacterial spores and viruses.
Field of use	Disinfectant to prevent and reduce risk of transferring microbes to food from food contact areas in restaurants and food and feed industry, like floors, benches, tables, cutting boards, freezers and cutting machines.
Application method(s)	Manual application. Apply disinfectant (mopping, wiping and pouring) on clean and dry surfaces free of organic material. Make sure that the surface is kept moist for 5-10 minutes.
Application rate(s) and frequency	Daily disinfection after cleaning. 50 ml /m²
Category(ies) of user(s)	Professionals
Pack sizes and packaging material	250 ml, 500 ml, 600 ml, and 1 liter and 5 liter bottle PET / HD-PE

Use-specific instructions for use

Disinfect critical surfaces after cleaning and drying, by mopping, wiping or pouring disinfection onto the surface to keep it wet for 5-10 minutes Efficiently kills or inactivates bacteria, yeast, viruses after 5 minutes of working time. Ensure that the surface is kept moist for 10 minutes for full effect against bacterial spores. Dosage: Apply 50 ml / m² on clean and dry surfaces free of organic matter. Rinse with water before next use. Suitable for all surfaces which tolerate water.

Risk mitigation measures

Non identified.

2.1.5 General directions for use

Instructions for use

See use specific instructions

Risk mitigation measures

See use specific instructions

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:
PT1 use: If irritation occurs wash with water and seek medical advice. In cases of unintentional skin exposure: wash with water.
PT2 and PT4 use: 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 material for containment and cleaning up.
Absorb large spills with a suitable binder and place in a container before forwarding for disposal. Clean the area with water.
Smaller spills - wipe up with a wet cloth.

Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local regulations. Dispose of wastes in an approved waste disposal facility

Not emptied containers are treated as the unused product, the content to be disposed of in accordance with local regulations. Empty containers should be taken 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.

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 (non-professional use)

The formulations in meta-SPC 1 – 3 have 9 months shelf-life in unopened bottle stored at room temperature (5-25°C). The product must not be exposed to elevated temperatures or direct sunlight. Protect from frost. Keep only in the original packaging.

2.1.6 Other information

Non identified

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	50 ml, 100 ml, 200 ml, 250 ml, 500 ml, 600 ml, 1 liter, 5 liter	PET, HD-PE	PET/PP	Professional and non-professional	Yes
Container	1 liter, 5 liter	PET/HD-PE	PET/PP	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

See Reference list (Annex 3.1)

2.1.8.2 Access to documentation

The applicant holds a letter of access (LoA) from Borregaard AS, which is a member of the Sodium Hypochlorite Biocides Registration Group, owners of data of the approved active substance: active chlorine released from sodium hypochlorite, for use in biocidal products of product-types 1-5, 11 and 12. The LoA authorises the use and reference to the Studies in support of the application for registration of the biocidal product family "SoftOx Disinfectants Family".

2.2 Assessment of the biocidal product family

2.2.1 Intended use(s) as applied for by the applicant

Table 1. Intended use # 1 & 2– PT01 Hygienic handrub

Product Type(s)	1
Where relevant, an exact description of the authorised use	This hand disinfectant is a virucidal hygienic handrub for use by professionals including professional health care workers to prevent and reduce risk of infection in hospitals. Also, for consumers to prevent / reduce the risk of getting sick in diseases caused by bacteria, viruses and yeast fungus.
Target organism (including development stage)	Bacteria, yeast, fungal spores and enveloped viruses.
Field of use	Hygienic Handrub
Application method(s)	Rubbing
Application rate(s) and frequency	3 ml, as often as necessary, by professional health care workers. 3 ml, as often as necessary for non-professional users.
Category(ies) of user(s)	Private and Professional use
Pack sizes and packaging material	50 ml, 100 ml, 250 ml, 500 ml, 600 ml, 1 liter and 5 liter bottles of PET / HD-PE

Table 2. Intended use # 3– PT 02 surface disinfection Professionals including health care professionals

Product Type(s)	2
Where relevant, an exact description of the authorised use	This disinfectant is ideal for prevention and reducing the risk of infection in health care settings like patient rooms, bathrooms, operation rooms, laboratories, dental centres, isolation rooms, nursing homes, institutions, offices, public transportation on all surfaces tolerant to water.
Target organism (including development stage)	Bacteria, yeast, Tuberculosis bacilli, and enveloped viruses
Field of use	Hard surface disinfection
Application method(s)	Mopping, scrubbing, flooding
Application rate(s) and frequency	Daily disinfection after cleaning
Category(ies) of user(s)	Professionals
Pack sizes and packaging material	250 ml, 500 ml, 600 ml, and 1000 ml bottle PET / HD-PE and 5 liter containers

Table 3. Intended use # 4 – PT 02 surface disinfection for Non-professionals

Product Type(s)	2
Where relevant, an exact description of the authorised use	Disinfection of hard surfaces in private homes, in for example: bathrooms and toilets.
Target organism (including development stage)	Bacteria, yeast, Tuberculosis bacilli, bacterial spores and viruses.
Field of use	Hard surface disinfection
Application method(s)	Mopping, scrubbing, flooding
Application rate(s) and frequency	Daily disinfection after cleaning
Category(ies) of user(s)	Non-professionals, consumers
Pack sizes and packaging material	250 ml, 500 ml, 600 ml, and 1000 ml bottle PET / HD-PE and 5 liter containers

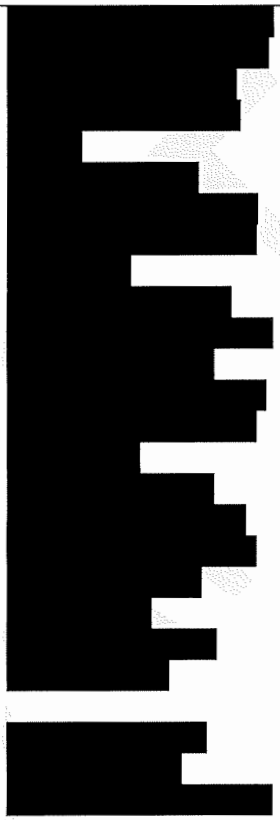
Table 4. Intended use # 5 – PT 04 surface disinfection for food and feed industry

Product Type(s)	4
Where relevant, an exact description of the authorised use	Effective disinfectant for preventing and reduing risk of transferring microbes to food from food contact areas in food and feed industry, like cutting boards, food benches, freezers, cutting machines etc.
Target organism (including development stage)	Bacteria, yeast, bacterial spores and viruses.
Field of use	Hard surface disinfection
Application method(s)	Mopping, scrubbing, flooding
Application rate(s) and frequency	Daily disinfection after cleaning
Category(ies) of user(s)	Professionals
Pack sizes and packaging material	250 ml, 500 ml, 600 ml, and 1 liter and 5 liter bottle PET / HD-PE

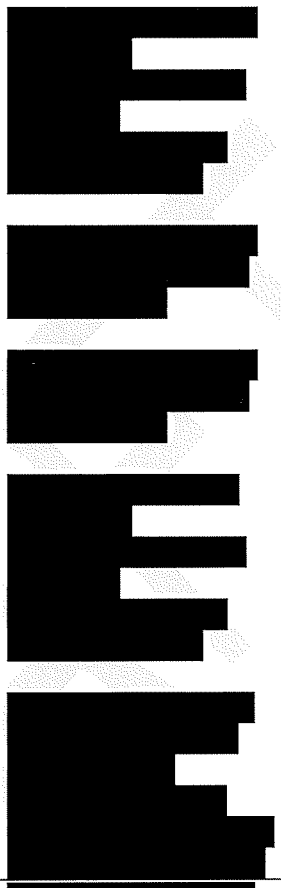
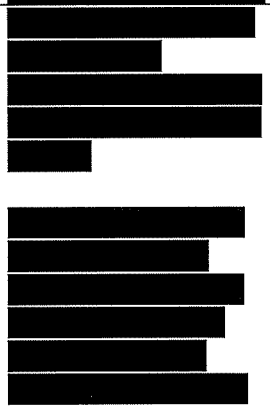
2.2.2 Physical, chemical and technical properties

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
Physical state at 20 °C and 101.3 kPa		200 ppm active chlorine released from NaClO	Liquid	(14) Apperance SOF-160-0,25 & SOF-450-1_7 mnd testpoint,Certificate of analysis 2019-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		(measured as HClO): pH 4,3. 0.25 % (w/w) acid.		08-01, Internal number D002743-01, Batch SOF0001779, Christensen C, 2019
Colour at 20 °C and 101.3 kPa		200 ppm active chlorine released from NaClO (measured as HClO): pH 4,3. 0.25 % (w/w) acid.	Clear	(14) Apperance SOF-160-0,25 & SOF-450-1_7 mnd testpoint, Internal number D002743-01, Batch SOF0001779, Christensen C, 2019
Odour at 20 °C and 101.3 kPa		200 ppm active chlorine released from NaClO (measured as HClO): pH 4,3. 0.25 % (w/w) acid.	Slight smell of acid and hypochlorous acid	N.A. Test of odour is no longer performed by commercial labs due to HSE-reasons
Acidity / alkalinity	Ph.Eur. 07/2016:20203, current edition. Concentrations reflect active chlorine released from NaClO, measured as hypochlorous acid.	For reference 81; 210 ppm active chlorine released from NaClO (measured as HClO): 4,3. 0.25 % (w/w) acid.	pH at 4.3 210 ppm active chlorine: 0.25 % (w/w) acid.	(81) File name; 81 PD 21-037 Report from long term stability testing of batch SOF001_03181 Report from the long term stability testing of Batch SOF001/031 at ambient temperature (reflects a starting concentration of 210 ppm active chlorine released from HOCl)".
Relative density / bulk density	ALS Scandinavia Internal gravimetric method having a	200 ppm active chlorine released from NaClO (measured as HClO): pH 4,3.	0,999-1,000 g/cm^3	(4) Density_report_Signed_21012019 GUT Report N1821808, ALS Scandinavia 2019-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	LOQ of 0.010 g/ml.	0.25 % (w/w) acid.		01-08, Fredriksen C Myrvoll R, 2018
Storage stability test – **long term storage in cold temperature (5 °C)**	Test accd. to ICH HARMONISED TRIPARTITE GUIDELINE STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS Q1A(R2), Step 4 version, dated 6 February 2003. Active chlorine released from NaClO, measured as hypochlorous acid spectrophotometrically at 236 nm. pH measured continuously throughout the test period.	160 ppm Active chlorine released from NaClO (measured as HClO) 0.25 % acid, pH 4.3).		(16) File name ;16 Stability study DBlab 318009_318011_318019 24 mth_5 and 25 degr (1), "Certificate of analysis – Stability study at 25 and 5 °C Batch 318009 Tryggedsson S, 2019.
Storage stability test – **accelerated storage at 54 °C.**	Test accd. to guideline CIPAC MT 46.3 (see Manual on the development and use of FAO and WHO	201 ppm active chlorine (released from NaClO (measured as HClO), 0,25% acid)		(30) PD 20-050 Report from stability testing Title "*Report from stability testing of batch SOF003_83 Short term storage at accelerated temperature (54 degrees)*". Utigard G, 2020.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	specifications for Pesticides, second ed., 2010). Active chlorine released from NaClO measured as hypochlorous acid spectrophotometrically at 236 nm. pH measured continuously throughout the test period.		[redacted]	
Storage stability test – **long term storage at ambient temperature (25 °C)**	Test accd. to guideline ICH HARMONISED TRIPARTITE GUIDELINE STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS Q1A(R2), Step 4 version, dated 6 February 2003.Active chlorine released from NaClO measured as hypochlorous acid	213 ppm active chlorine released from NaClO (measured as HClO), 0.25 % acid. **SOF004/077**	[redacted]	File name; 84_SOF 22-023 Long term storage stability study at ambient temperature of batch SOF004_077 (84) Langseth-Manrique K ," Long term storage stability study at ambient temperature of batch SOF004/077"

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	measured spectrophotometrically at 236 nm. pH measured continuously throughout the test period.			
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	ICH 279/95 guideline. 36 hours exposure at 25 °C. Hypochlorus acid measured spectrophotometrically at 236 nm. pH measured continuously throughout the test.	135 ppm active chlorine released from NaClO (measured as HClO), 0.225 % (w/w) acid).		(1) Certificate for Light Treatment of Samples_DB Lab_31082015Report title; *"Certificate of light treatment samples"*, Wamberg M. 2015

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			See results accelerated stability studies. Humidity not needed for water solution.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Observations from stability testing in PET-bottles as well as from one year of production.	160 active chlorine released from NaClO (measured as HClO), 0.25% (w/w) acid).	The long term stability study was performed in containers made from PET (Polyethylene terephthalate) Stability studies has been performed at 5, 25 and 54 degrees. Negative effects on the packaging materials, for example reactions, leakage or deformation has not been observed in any of the studies. SoftOx have had commercially available products in PET and HDPE containers on the market since fall 2018. So far there has not been any indications of incompatibility between the containers and formulations.	(5) Statement compatibility of biocidalproduct and packaging Utigard, 2021
Wettability	N/A			
Suspensibility, spontaneity and dispersion stability	N/A			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Wet sieve analysis and dry sieve test	N/A			
Emulsifiability, re-emulsifiability and emulsion stability	N/A			
Disintegration time	N/A			
Particle size distribution, content of dust/fines, attrition, friability	N/A			
Persistent foaming	N/A			
Flowability/Pourability/Dustability	N/A			
Burning rate — smoke generators	N/A			
Burning completeness — smoke generators	N/A			
Composition of smoke — smoke generators	N/A			
Physical compatibility	N/A		The product shall not be mixed with other products. Since the product is classified as corrosive towards metals, the product should be kept in its original packaging.	
Chemical compatibility	N/A		The product shall not be mixed with other products.	
Degree of dissolution and	N/A			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
dilution stability				
Surface tension	OECD 115, SS-EN ISO304/NF T 73-060	160 ppm active chlorine released from NaClO (measured as HClO), 0.25% acid, pH 4.3	[redacted]	(2) Surface-tension_report_signed 19122018 GUT, SINTEF report no 2018:01408; "Surface tension measurements of SoftOx Solutions", Haslene-Hox H Hatletveit A, Glomm W, 2018
Viscosity	OECD 114, SS-EN ISO3104	160 ppm active chlorine released from NaClO (measured as HClO), 0.25% acid, pH 4.3	[redacted]	(12) Viscosity report signed SafeDes_Effect-vet_19022019RISE-report, 2019-02-19, report nr 9P004625, Andersson L, 2019.

Conclusion on the physical, chemical and technical properties of the product

The products in the family are water based ready-to-use formulations. The tested representative products have a pH of typically 4.3. Accelerated stability studies are available for products containing 200 ppm active chlorine showing that the product is temperature sensitive. Effects on content of the active substance when exposed to light show a reduction of active substance content of 86%.
The products must be stored between 5-25 °C and should be kept away from direct sunlight.

A 9 months ambient temperature storage stability study, supporting products containing 200 ppm active chlorine are reported above. The products shelf-life has been set to 9 months based on claims, efficacy data and acceptable chlorate content.

The products should always be kept in its original packaging.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	N/A		Testing waived. Neither NaClO (CAS 7681-52-9) nor HClO (CAS 7790-92-3) are classified as explosive. Maximal concentration of active chlorine released from NaClO (measured as HClO) in the biocidal product family is 200 ppm. None of the other components of the biocidal product family are classified a explosive. The water contents of the biocidal product family is 99.6 % (w/w)	
Flammable gases	N/A			
Flammable aerosols	N/A			
Oxidising gases	N/A			
Gases under pressure	N/A			
Flammable liquids	EN ISO 2719	Formulation tested: 200 ppm active chlorine released from NaClO (measured as HOCl) with 0.25 % acid, with 1.0 % acid (Saybolt Sweden-report)	Flash point:> 99 °C. Due to the fact that the products contain 99.6 and 98.4 % (w/w) of water, respectively, it is not technically feasible to establish a flash point > 200 °C.	(9) Analysis report 11601/00060434.2/L/21, Saybolt Sweden, Andersson S, 2021-02-19

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Flammable solids	N/A			
Self-reactive substances and mixtures	N/A		Testing wavied. Neither NaClO (CAS 7681-52-9) nor HClO (CAS 7790-92-3) is classified as self-reactive substances. Maximal concentration of active chlorine released from NaClO (measured as HClO in the biocidal product family) is 200 ppm. The water contents of the biocidal product family is 99.6 %.	
Pyrophoric liquids	N/A		The products contain >99.5% water)	
Pyrophoric solids	N/A		Not applicable for liquids.	
Self-heating substances and mixtures	N/A		Not applicable for liquids.	
Substances and mixtures which in contact with water emit flammable gases	N/A		The products contain >99.5% water	
Oxidising liquids	See provided justification why testing not is needed.	The biocidal product does not contain any substances classified as oxidizing. The products contain >99.5% water		(11) Evaluation of oxidising capacity of the SoftOx biocide product family
Oxidising solids	N/A			
Organic peroxides	N/A			
Auto-ignition temperatures of products	N/A		It is not technically feasible to determine a flash point > 200 °C for an aqueous	(9) Analysis report 11601/00060434.2/L/21, Saybolt Sweden,

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
(liquids and gases)			solution. Only a verification of a flash point > 100 °C is technically feasible.	Andersson S, 2021-02-19
Corrosive to metals	UN Test C.1	200 ppm active chlorine released from NaClO (measured as HOCl), 0,25% acid	[redacted]	13 KIWA korrosjonstest 033230 Rev. A (1), KIWA 2020, report 3000-20-033230 Rev. A, "Test of liquids for corrosion to metals", 2020-12-01. Kirksaether M & Aksel J, 2020
Relative self-ignition temperature for solids	N/A			
Dust explosion hazard	N/A			

Table. Corrosive to metals test

AntiVir (200 ppm active chlorine, 0.25% acid) 168 hours	Steel sample dipped into solution Aluminum sample in gas face	Mass loss: 14,6 % Intrusion depth: 150 µm Above criteria

Conclusion on the physical hazards and respective characteristics of the product
Products are classified as H290 - May be corrosive to metal

2.2.4 Methods for detection and identification

[Description of analytical methods used for the analysis of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product]

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
HOCl, hyperchlorous acid	Spectrophotometric method, 236 nm	50-473 ppm of HOCl, 12 samples tested; 3 samples at 50 ppm, 3 samples at 106 ppm, 3 samples at 224 ppm and 3 samples at 473 ppm. Background concentration of acid of 0,5 %. Method validated for concentration of acid up to 5 % (w/w).	R^2>>0,999 for all variants of compoition of the biocicdal product	Nominally 100 %	[redacted]	[redacted]	[redacted]	11 ppm at 236 nm and Extinction coefficients measured were in good agreement with data reported in scientific literature (Feng et al., 2007)	(15) Report_P1682_validation of analytical method_final Anderson et al., 2017-06-01, Report P1682, CR Competence AB. Feng et al., Journal of Environmental Engineering and Science 6(3):277-284. (15) Report_P1682_validation of analytical method_final, report: "*Technical validation of a spectrophotometric assay method for HOCl and OCl-*", (report P1682, 2017), as well as 39 Memo HOCl assay_20120 ("*Memo HOCl method-Statement regarding HOCl spectroscopic assay method developed in project P1682*"), CR LAB 2020-12-02.

									38 Erratum regarding the reported concentrations of hypochlorite anion in biocidal product family stability studies, Intersolia 2020-12-03
ClO_3^-, Chlorate	Ion chromatographic analysis (IC) ALS method W-OCY-IC, SOP CZ_SOP_D06_02_098. The ALS Global ion chromatography method.		0.9996	100 % (specific retention time and no peak overlap)				Method LOQ is 0.01 mg/l for ALS validation (drinking water samples), however for samples with up to 450 ppm of HOCl, the LOQ has been adjusted to 0.2 mg/l	(92) 92 PR20C3144_attachment 1 v2 BILAGA 1A "Attachment no. 1 to the certificate of analysis for work order PR20B8879", 2020-12-09 and (93) 93 Calibration curves validation of ion chromatographic method for chlorate in typical SoftOx Solutions193524 2713843, ALS Scandinavia additional internal and external standard calibration curve.

RMS comment on Analytical methods:

The analytical methods for HOCl and ClO_3^- are considered acceptable for quantification in the product. All data on hypochlorite anion in this study and in reports/certificates using this method should be disregarded since the method is not applicable for hypochlorite anion quantification at the pH of the product family.

Analytical methods for soil

Not required due to instantaneous degradation of active substance.

Analytical methods for air

Not required.

Analytical methods for water
Analytical methods for water are available in the CAR.

Analytical methods for animal and human body fluids and tissues
Not required due to instantaneous degradation of active substance in contact with skin.

Analytical methods for monitoring of active substances and residues in food and feeding stuff
Other relevant methods are available in the CAR.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

SoftOx Disinfectants Family consists of PT1, PT2, and PT4 products, intended to control microbiological organisms.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

Use # 1 PT 1 Hygienic handrub for professional, including health care professionals
Organisms to be controlled: Bacteria, yeast, fungal spores and enveloped viruses.

Use # 2 PT 1 Hygienic handrub for consumers
Organisms to be controlled: Bacteria, yeast, fungal spores and enveloped viruses.

Use # 3 PT 2 - Hard surface disinfection - Professionals including health care professionals
Organisms to be controlled: Bacteria, yeast tuberculosis bacilli, and enveloped viruses.

Use # 4 PT 2 - Hard surface disinfection - Non-professionals
Organisms to be controlled: Bacteria, yeast, tuberculosis bacilli, bacterial spores and viruses.

Use # 5 PT4 - Disinfection of large surfaces that come into contact with food and feed - Professionals
Organisms to be controlled: Bacteria, yeast, bacterial spores and viruses.

2.2.5.3 Effects on target organisms, including unacceptable suffering

For short summaries including results of all efficacy studies see Annex 3.5 Summaries of the efficacy studies. Unacceptable suffering not relevant since the target organisms are bacteria, viruses, yeast and spores.

2.2.5.4 Mode of action, including time delay

The active substance in the SoftOx Disinfectants Family is active chlorine released from sodium hypochlorite. At the pH of the product family (4.1-5.0) [redacted] is present in the products as hypochlorous acid (HOCl). HOCl is a powerful oxidative agent, which is effective against a broad range of microorganisms and it has proven to have bactericidal, fungicidal, yeasticidal, sporicidal and virucidal activity. It reacts with many biological molecules, especially thiol and amino groups of proteins, lipids and carbohydrates. The microbicidal effects are induced through by non-specific oxidizing mode of action. The resistance of pathogens to active chlorine released from sodium hypochlorite is not very probable (see for instance studies presented in Ch. 2.2.5.6.) Resistance of pathogens to active chlorine is not higher than that of other active substances with a general mode of action (oxidation). Thus, there is no need for specific resistance management strategies for active chlorine-based disinfectants.
Due to the high reactivity of HOCl and its oxidizing properties, there are no results for systemic mode of action, only a local mode of action.

The products are effective within [redacted] seconds against bacteria, yeast, viruses and within [redacted] minutes against spores (see efficacy testing below).

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Virucidal	*PT2, PT4*	*SoftOx-Hand disinfectant* HOCl 160 ppm, acid 0.25%	[redacted]	EN 14476 - Suspention test, virucidal	[redacted]	[redacted]	61 SoftOx SafeDes Hand disinfection L20-0038A-1 Adeno Screening EN 14476 14.02.2020
Virucidal	*PT2, PT4*	*SoftOx-hand disinfectant* HOCl 160	[redacted]	EN 14476:2013+A2:2019	[redacted]	[redacted]	60 SoftOx SafeDes Hand disinfection L20-0038A-

		ppm, acid 0.25%					2 Adeno test report EN 14476 clean 03.04.2020
Virucidal	*PT2*	*SoftOx-hand disinfectant* HOCl 160 ppm , Acid 0.25%		EN 14476 - Suspention test, virucidal			*69 SoftOx SafeDes Virus Protection L20-0105Po-1 Polio Screening EN 14476 17.02.2020*
Virucidal	*PT2*	*SoftOx-hand disinfectant* HOCl 160 ppm, Acid 0.25%		EN 14476:2013+A2:2019			*68 SoftOx SafeDes Hand disinfection L20-0038Po-3 Polio test report EN 14476 clean 24.03.2020*
Virucidal	*PT2, PT4*	*SoftOx-hand disinfectant* HOCl 160 ppm, Acid 0.25%		EN 14476 - Suspention test, virucidal			*66 SoftOx SafeDes Virus Protection L20-0105M-1 MNV Screening EN 14476 17.02.2020*
Virucidal	*PT2, PT4*	*SoftOx-hand disinfectant* HOCl 160 ppm, Acid 0.25%		EN 14476:2013+A2:2019			*62 SoftOx SafeDes Hand disinfection L20-0038M.3M-3 MNV Test report EN 14476 24.03.2020*
Virucidal	*PT1, PT2*	*SoftOx-hand disinfectant* HOCl 160 ppm, Acid 0.25%		EN 14476 - Suspention test, virucidal			*65 SoftOx SafeDes Hand disinfection L20-0038MV-2 MVA expert opinion EN 14476 clean 09.04.2020*
Virucidal	*PT1, PT2*	*SoftOx-hand disinfectant* HOCl 160 ppm, Acid 0.25%		EN 14476:2013+A2:2019			*63 SoftOx SafeDes Hand disinfection L20-0038MV-2*

							[redacted]	*MVA test report EN 14476 clean 09.04.2020*
Bactericidal	*PT2, PT4*	SoftOx HOCl 160 ppm, Acid 0.13%.	[redacted]	EN 1276	[redacted]	[redacted]	*42 Soft Ox 0-en 1276-dz-16-07-15*
Bactericidal	*PT2, PT4*	SoftOx HOCl 160 ppm, Acid 0.13%.	[redacted]	EN 1276	[redacted]	[redacted]	*42 Soft Ox 0-en 1276-dz-16-07-15*
Bactericidal	*PT2, PT4*	SoftOx HOCl 160 ppm, Acid 0.13%.	[redacted]	EN 1276	[redacted]	[redacted]	*42 Soft Ox 0-en 1276-dz-16-07-15*
Bactericidal	*PT2, PT4*	SoftOx HOCl 160 ppm, Acid 0.13%.	[redacted]	EN 1276	[redacted]	[redacted]	*42 Soft Ox 0-en 1276-dz-16-07-15*
Bactericidal	*PT1*	SoftOx HOCl 160 ppm, Acid 0.25%.	[redacted]	EN 1500	[redacted]	[redacted]	*43 safedes hand-EN 1500-dz-77-04-20 (1)*
Bactericidal	*PT1, PT2*	SoftOx HOCl 160 ppm, Acid 0.25%	[redacted]	EN 13727	[redacted]	[redacted]	*57 EN13727-DZ-20-01-20*
Bactericidal	*PT1, PT2*	SoftOx0 HOCl 160 ppm, Acid 0.25%	[redacted]	EN 13727	[redacted]	[redacted]	*57 EN13727-DZ-20-01-20*
Bactericidal	*PT1, PT2*	SoftOx0 HOCl 160 ppm, Acid 0.25%	[redacted]	EN 13727	[redacted]	[redacted]	*57 EN13727-DZ-20-01-20*

Bactericidal	*PT1, PT2,*	SoftOx0 HOCl 160 ppm, Acid 0.25%		EN 13727			*57 EN13727-DZ-20-01-20*
Yeasticidal	*PT1, PT2,*	SoftOx HOCl 160 ppm, Acid 0.25%		EN13624			*51 EN13624-DZ-21-01-20*
Sporicidal (fungus)	*PT1*	SoftOx HOCl 160 ppm, Acid 0.25%		EN13624			*51 EN13624-DZ-21-01-20*
Sporicidal (bacteria)	*PT2, PT4*	SoftOx0 HOCl 160 ppm, Acid 0.25%		EN 13704			56 Soft Ox - en 13704 - dz-78-05-20 (2)
Sporicidal (bacteria)	*PT2, PT4*	SoftOx0 HOCl 160 ppm, Acid 0.25%		EN 13704			56 Soft Ox - en 13704 - dz-78-05-20 (2)
Sporicidal (bacteria)	*PT2, PT4*	SoftOx0 HOCl 160 ppm, Acid 0.25%		EN 17126			73 Soft Ox - en 17126 - dz-79-05-20 (1)
Sporicidal (bacteria)	*PT2, PT4*	SoftOx0 HOCl 160 ppm, Acid 0.25%		EN 17126			73 Soft Ox - en 17126 - dz-79-05-20 (1)

					[redacted]	[redacted]	
Sporicidal (bacteria)	*PT2, PT4*	SoftOx0 HOCl 160 ppm, Acid 0.25%	[redacted]	EN 17126	[redacted]	[redacted]	73 Soft Ox - en 17126 - dz-79-05-20 (1)
Bactericidal	*PT2, PT4*	SOF003111 1-01 HOCl 160 ppm, Acid 0.25%	[redacted]	EN 16615	[redacted]	[redacted]	72 EN 16615 safedes hand-surface HOCl 0,2g-kg -70-04-20 (1)
Bactericidal	*PT2, PT4*	SOF003111 1-01 HOCl 160 ppm, Acid 0.25%	[redacted]	EN 16615	[redacted]	[redacted]	72 EN 16615 safedes hand-surface HOCl 0,2g-kg -70-04-20 (1)
Bactericidal	*PT2, PT4*	SOF003111 1-01 HOCl 160 ppm, Acid 0.25%	[redacted]	EN 16615	[redacted]	[redacted]	72 EN 16615 safedes hand-surface HOCl 0,2g-kg -70-04-20 (1)
Yeastcidal	*PT2, PT4*	SOF003111 1-01 HOCl 160 ppm, Acid 0.25%	[redacted]	EN 16615	[redacted]	[redacted]	72 EN 16615 safedes hand-surface HOCl 0,2g-kg -70-04-20 (1)
Bactericidal	*PT2, PT4*	SoftOx HOCl 200 ppm; Acid 0.25%	[redacted]	EN13697	[redacted]	[redacted]	*53 soft ox antivir EN 13697 dz-66-10-20*
Bactericidal	*PT2, PT4*	SoftOx HOCl 200 ppm; Acid 0.25%	[redacted]	EN13697	[redacted]	[redacted]	*54 soft ox - en 13697-dz-38-04-20*

					[redacted]		
Bactericidal	*PT2, PT4*	SoftOx HOCl 200 ppm; Acid 0.25%	[redacted]	EN13697	[redacted]	[redacted]	*54 soft ox - en 13697-dz-38-04-20*
Bactericidal	*PT2, PT4*	SoftOx HOCl 200 ppm; Acid 0.25%	[redacted]	EN13697	[redacted]	[redacted]	*54 soft ox - en 13697-dz-38-04-20*
Bactericidal	*PT2, PT4*	SoftOx HOCl 200 ppm; Acid 0.25%	[redacted]	EN13697	[redacted]	[redacted]	*54 soft ox - en 13697-dz-38-04-20*
Bactericidal	*PT2, PT4*	SoftOx HOCl 200 ppm; Acid 0.25%	[redacted]	EN13697	[redacted]	[redacted]	*54 soft ox - en 13697-dz-38-04-20*
Bactericidal	*PT2, PT4*	SoftOx HOCl 200 ppm; Acid 0.25%	[redacted]	EN13697	[redacted]	[redacted]	*54 soft ox - en 13697-dz-38-04-20*
Bactericidal	*PT2, PT4*	SoftOx HOCl 200 ppm; Acid 0.25%	[redacted]	EN13697	[redacted]	[redacted]	*54 soft ox - en 13697-dz-38-04-20*
Bactericidal	*PT2, PT4*	SoftOx HOCl 200 ppm; Acid 0.25%	[redacted]	EN13697	[redacted]	[redacted]	*54 soft ox - en 13697-dz-38-04-20*
Yeasticidal	*PT2, PT4*	SoftOx HOCl 200 ppm; Acid 0.25%	[redacted]	EN13697	[redacted]	[redacted]	*54 soft ox - en 13697-dz-38-04-20*

Yeasticidal	*PT2, PT4*	SoftOx HOCl 200 ppm; Acid 0.25%	[redacted]	EN13697	[redacted]	[redacted]	*54 soft ox - en 13697-dz-38-04-20*
Mycobatericidal	*PT2*	AntiVir HOCl 160 ppm; Acid 0.25%	[redacted]	EN 14348:2005	[redacted]	[redacted]	*67 soft ox AntiVir Myco EN-14348-2005-L20-1403-2 3 engl V01 (1)*

Conclusion on the efficacy of the product

The efficacy against target organisms for the product family, as specified for each specific use in the Summary of Product Characteristics and section 2.1.4 of this report, has been demonstrated with the above mentioned studies performed in agreement with ECHA Guidance on the BPR Vol II Efficacy (2018). See also Annex 3.5 for list of studies.

2.2.5.6 Occurrence of resistance and resistance management

According to the assessment report of active chlorine released from calcium hypochlorite (published in January 2017, eCA Italy), although different species vary in their sensitivity to active chlorine, development of acquired resistance is not expected since its multiple molecular sites of attack on the surface and within the microbial cells. Active chlorine is in fact regarded by experts [see IFH (International Scientific Forum on Home Hygiene) review October 2003 and Submission to SCENIHR, February 2008)] as one of the biocides where acquired resistance is least likely to develop. For the same reasons cross-resistance is not to be expected, nor has it been observed. Despite its use for almost a century in purifying drinking water, where very low (sub ppm) concentrations are continuously maintained, the development of acquired resistance has not been observed. Adaptation of organisms to hypochlorite can be determined by comparison of the Minimum Inhibitory Concentration (MIC) but this is not relevant in practice as the actual use concentrations are much higher and thus a sufficient margin of safety is provided.

No management strategies are necessary as acquired resistance to active chlorine has not developed nor will develop due to its reactive nature and unspecific mode of action.

The SE eCA accepts that there is no significant risk of development of resistance for the active substance and the products, however, if the applicant becomes aware of any reports of resistance of the active substance and/or the products these should be reported to appropriate bodies (e.g. the Efficacy Working Group and/or concerned Member States) so that it can be determined if further action is needed.

2.2.5.7 Known limitations

No known limitations

2.2.5.8 Evaluation of the label claims

Use 1 (PT1) is claimed to be an effective hand disinfectant, for use by professionals including professional healthcare workers to prevent and reduce risk of infection in hospitals. The products have bactericidal, yeasticidal, fungal sporicidal and effect in [redacted] on enveloped viruses which is confirmed by the results of test 1-4 (PT1) in the summary of tests (Annex 3.5).

Use 2 (PT1) is claimed to be an effective hand disinfectant, for use by non-professional consumers to prevent and reduce risk of infection in private settings. The products have bactericidal, yeasticidal, fungal sporicidal and effect in [redacted] on enveloped viruses which is confirmed by the results of test 1-4 (PT1) in the summary of tests (Annex 3.5).

Use 3 (PT2) is claimed to be an effective hard surface disinfection, in health care settings like patient rooms, bathrooms, operation rooms, laboratories, dental centers, isolation rooms on all surfaces tolerant to water. For professional use, kept moist for [redacted] minutes for full effect on bacteria, yeast, Tuberculosis bacilli and enveloped viruses, which is confirmed by the results of test 1-10 (PT2) in the summary of tests (Annex 3.5).

Use 4 (PT2) is claimed to be an effective hard surface disinfection, in private homes for consumers on all surfaces tolerant to water. Kept moist for [redacted] minutes for full bacterial sporicidal effect and 5 minutes for effect on bacteria, Tuberculosis bacilli, viruses, and yeast. Confirmed by the results of test 1-13 (PT2) in the summary of tests (Annex 3.5).

Use 5 (PT4) is claimed to be an effective hard surface disinfection, to prevent and reduce the risk of transferring microbes to food from food contact areas in food and feed industry. Efficiently kills and inactivates bacteria, yeast, viruses after [redacted] minutes of working time. The product is also bacterial sporicidal after [redacted] minutes of contact time. Confirmed by the results of test 1-8 (PT4) in the summary of tests (Annex 3.5).

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The products in the product family will not be used with other biocidal products. However, it is very important that the hard surface, that should be treated, is cleaned thoroughly with a cleansing product and that hands are cleaned thoroughly before treatment with the products. Dirt causes degradation of the active substance.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Since the SoftOx Disinfectants Family contains only the active substance "Active chlorine released from sodium hypochlorite", water and two pH-regulators, the data from the Assessment Reports for "Active chlorine released from sodium hypochlorite" is relevant for the products. Since the toxicological profile of active chlorine (as an equilibrium of

chlorine, hypochlorous acid and sodium hypochlorite) is linked to that of sodium hypochlorite, hypochlorous acid and chlorine gas (BPC Opinion on the application for approval of the active substance: Active chlorine released from hypochlorous acid Product type: 1-4 ECHA/BPC/256/2020), also toxicity data for hypochlorous acid and chlorine gas are relevant to use in the risk assessment below.

In addition to data from the Assessment reports of the active substance also some new testing of the products has been performed, which are presented in the tables and also summarised in section 3.8.

The primary mode of action of active chlorine released from NaOCl is characterised by local irritation/corrosion and oxidation at the site of first contact triggered by direct chemical reactivity without prior metabolism. Active chlorine released from NaOCl does not become systemically available upon dermal contact, ingestion or inhalation. Any systemic effects seen in animal studies (at high doses) are considered to be secondary to local irritation/ corrosion.

The co-formulants are pH-regulators and are not considered to affect the toxicity or irritating properties of the product.

Skin corrosion and irritation

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Not GLP*	Rabbits & guinea pigs	sodium hypochlorite*	With sodium hypochlorite solutions ≥5% active chlorine (*at physiological pH, the HOCl/OCl:ratio is ca 50:50*), skin irritating properties were shown. Sodium hypochlorite is classified as Skin Corr. 1B, H314, according to Annex VI, Regulation (EC) 1272/2008 (harmonised classification)	The mean score obtained from intact skin (sum of mean erythema and edema scores at 4, 24 and 48 hours) was 1.0 for rabbits and 0.3 for guinea pigs. All findings were reversible.	The CAR (Nixon GA Tyson CA Wertz WC, Interspecies comparisons of skin irritancy Source: Toxicology and Applied Pharmacology 31, (1975) pp. 481-490)

**From the CAR (The applicant holds a letter of access (LoA) to the complete dossier for the active substance approval.)*

Summary table of human data on skin corrosion irritation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
Not GLP*	5-5.25% available chlorine (pH 10.7)	4 h exposure under occluded patch conditions.	A hypochlorite solution at 5-5.25% available chlorine (pH 10.7) was found to be severely irritating to intact human skin.	The assessment report (Nixon GA Tyson CA Wertz WC, Interspecies comparisons of skin irritancy Source: Toxicology and Applied Pharmacology 31, (1975) pp. 481-490)
Not GLP*	2% and 1% NaOCl	48 h exposure under patch conditions not specified, reported as "covered contact".	Weak to moderate irritation was observed in 15 of 69 dermatitis patients with 2% NaOCl. No irritation was observed in 20 persons from the same group after additional patch testing (48 h "covered contact") with 1% NaOCl *at physiological pH, the HOCl/OCl:ratio is ca 50:50*).	The assessment report (Habets JMW et al. Sensitization to sodium hypochlorite causing hand dermatitis Contact Dermatitis 15, Vol. 1986, pp. 140-142)
Clinical investigation GLP (Reliability score 1)	SWIS (160 ppm HOCl, 0.25% acid) Full composition can be found in the Conf. annex.	12 subjects diagnosed with chronic, non-healing, leg ulcers. The split skin wound, i.e. donor site, was irrigated with SWIS at 6 different occasions; day 0 (post-transplantation), days 2-5, and day 7. 14, and day 21. After day 21, the subjects had completed the study.	SoftOx Wound Irrigation Solution (SWIS) is a safe and well tolerated wound irrigation solution for acute skin trauma and not associated with any major risks. Performance outcomes demonstrate antimicrobial properties with excellent wound healing (epithelialization) observations Summary can be found in Section 3.8 of this report. The result is not fully relevant since the concentration of the active substance is lower than in the product applied for. But the study can be considered as supportive information.	79 Clinical Investigation Report SWIS-01

Clinical investigation GLP (Reliability score 2)	160 ppm (+/-24 ppm) HOCl, 0.25% acid Full composition can be found in the Conf. annex.	[redacted] applications. The skin barrier function was assessed (by TEWL-, electrical conductance-, pH-, and erythema - measurements) prior to the application procedure on day 1 and day 2, and again on day 3.	For TEWL, electrical conductance and erythema, no significant differences were found for the SoftOx product in the three application sites compared to baseline on day 3. For all application areas, the pH values [redacted] Summary can be found in Section 3.8 of this report. The result is not fully relevant since the concentration of the active substance is lower than in the product applied for. But the study can be considered as supportive information.	77 Report – Study 2a irritant properties of SoftOx disinfection solution on healthy skin

**From the CAR (The applicant holds a letter of access (LoA) to the complete dossier for the active substance approval.)*

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The Soft-Ox disinfectants are not skin corrosive or skin irritating
Justification for the value/conclusion	Results from the LLNA testing of SoftOx rinse solution (0.02% of active chlorine released from Hypochlorous acid and 0.25% Acid) showed no local irritation at the application sites throughout the study in any of the treated animals tested. Furthermore, based on the animal studies and the human data on the active ingredient and Sodium hypochlorite, presented in the tables above, it was concluded that Sodium hypochlorite causes skin irritation at concentration ≥ 5 % - < 10%. At a concentration of ≥ 5 % Sodium hypochlorite is classified as Skin Corr. 1B, H314, according to Annex VI, Regulation (EC) 1272/2008 (harmonised Active chlorine released classification). The concentration of Sodium hypochlorite in the SoftOx products are 100 times lower than the concentration of Sodium hypochlorite that gave skin irritation.
Classification of the product according to CLP and DSD	Not classified in accordance with methods enforced in the CLP regulation (EC nr 1272/2008).

Eye irritation

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
Not GLP*	Rabbits and monkeys	Sodium hypochlorite*	Two eye irritation studies in rabbits and monkeys		The CAR (Carter RO

			are available indicating eye irritating properties for concentrations of 5.25 and 5.5% active chlorine respectively.		Griffin JF. Experimental bases for the realistic assessment of safety of tropical agents.Toxicology and Applied Pharmacology, 7, (1965), pp. 60-73, Pashley EL et al. Cytotoxic effects of naoci on vital tissue efecto citotoxico del naoci en el tejido vital, Journal of Endodontists Vol. 11, No. 12, December 1985, pp. 525-528)

**From the CAR (The applicant holds a letter of access (LoA) to the complete dossier for the active substance approval.)*

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The SoftOx disinfectants are not eye irritating.
Justification for the value/conclusion	Eye irritation testing has not been performed on the products. The products within the product family consist of aqueous solutions containing 0.02 % (w/w) active chlorine. Based on the animal studies on Sodium hypochlorite, in the table above, it was concluded that Sodium hypochlorite, causes eye irritation at concentration ≥ 5 %. At a concentration of ≥ 5 % Sodium hypochlorite is classified as Eye Dam. 1, H318, according to Annex VI, Regulation (EC) 1272/2008 (harmonised Active chlorine released classification). The concentration of Sodium hypochlorite in the SoftOx products are 100 times lower than the concentration of Sodium hypochlorite that gave eye irritation.
Classification of the product according to CLP and DSD	Not classified in accordance with methods enforced in the CLP regulation (EC nr 1272/2008).

Respiratory tract irritation

Summary table of human data on respiratory tract irritation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
Lung function parameters, Not GLP*	Chlorine gas*	A group of 8 volunteers were exposed on a single occasion to either 0.5 or 1.0 ppm (1.5 or 3.0 mg/m3) chlorine gas for either 4 or 8 hours.	Sensory irritation and a transient impairment in lung function were seen in those exposed to 1 ppm (3 mg/m3), resolving within 1 day. Exposure to 0.5 ppm (1.5 mg/m3) chlorine gas resulted in only trivial changes of lung function parameters, therefore the NOAEC was derived at 0.5 ppm (1.5 mg/m3).	The CAR (Rotman HH et al. Effects of low concentrations of chlorine on pulmonary function in humans American Physiological Society, (1983), pp. 1120-1124)
Lung function parameters, Not GLP*	Chlorine gas*	A group of 8 male volunteers were exposed to 0, 0.1, 0.3 or 0.5 ppm (0, 0.3. 0.9 or 1.5 mg/m3) chlorine gas for 6 h/d on 3 consecutive days. Each individual was exposed to each of the four exposure scenarios in a double-blind fashion. A range of respiratory function parameters was measured and, in addition, nasal lavage fluid was analysed for a number of indicators of inflammatory cell damage.	No significant effects were seen in parameters measured, and a NOAEC of 0.5 ppm (1.5 mg/m3) was derived in the study.	The CAR (Schins RPF et al. Nasal inflammatory and respiratory parameters in human volunteers during and after repeated exposure to chlorine ERS Journal 16, (2000), pp. 626-632)

**From the CAR (The applicant holds a letter of access (LoA) to the complete dossier for the active substance approval)*

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	The SoftOx disinfectants are not respiratory tract irritating

Justification for the conclusion	Respiratory tract irritation tests on the products and on sodium hypochlorite has not been performed. However, sodium hypochlorite can be expected to be an irritant to the respiratory tract due to the corrosive character of the substance. From human volunteer repeated dose studies on chlorine gas, a NOAEC of 0.5 ppm (1.5 mg/m^3) has been derived. Several reports on accidental human exposure to chlorine are available. In the SoftOx products the pH is 4.3 and the active chlorine is present mainly as HOCl and evaporation of both HOCl and gaseous chlorine has to be considered. However, the concentration of active chlorine in the product (0.02%) is 100 times lower than the concentration triggering classification for skin or eye irritation and is therefore not considered to be of any concern.
Classification of the product according to CLP and DSD	Not classified in accordance with methods enforced in the CLP regulation (EC nr 1272/2008).

Skin sensitization

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance , Vehicle, Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
Buehler tests*	Guinea pig	Sodium hypochlorite*	The three studies showed no sensitising effects.		The CAR **See the references below the table.

**From the CAR (The applicant holds a letter of access (LoA) to the complete dossier for the active substance approval)*

** 1)Delayed contact dermal sensitization test - buehler method Source: MB Research Laboratories, Inc. PA Report No.: MB 99-7944.06 1160 GLP; (unpublished) Doc. No.: 567-004
2) Guinea pig sensitisation testing by ritz, h.l. and buchler, E.V. on E-2707.01 Source: IBR Forschungs GmbH,

Hannover, Germany Report No.: 2-5-326-85 Not GLP; (unpublished) Doc. No.: 567-003
3)Guinea pig sensitisation testing by ritz, h.l. and buchler, E.V. on E-2707.01 Source: IBR Forschungs GmbH, Hannover, Germany Report No.: 2-5-325-85 Not GLP; (unpublished) Doc. No.: 567-002

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	The SoftOx disinfectants do not have any skin sensitization potential
Justification for the value/conclusion	Based on the results from the LLNA test of Soft-Ox Wound Rinse solution (0.02% active chlorine released from sodium hypochlorite and 0.25% Acid) and based on available animal data showing that sodium hypochlorite solutions do not pose a skin sensitization hazard, it is concluded that the SoftOx products do not have any skin sensitising effects.
Classification of the product according to CLP and DSD	Not classified in accordance with methods enforced in the CLP regulation (EC nr 1272/2008).

Respiratory sensitization (ADS)

Data waiving	
Information requirement	ADS
Justification	Since neither the product (0.02% active chlorine released from hypochlorous acid, and 0.25% Acid) nor sodium hypochlorite had any skin sensitization potential the products are not expected to have any respiratory sensitisation potential.

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels Type of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
Not GLP*	Rat	Sodium hypochlorite*	Signs of toxicity were evident in the oral study characterised by hypoactivity, muscular weakness, haemorrhagic rhinitis and emaciation and in the dermal study by moderate to severe erythema.	>2000 mg active chlorine/kg bw		The CAR (BioFax, sodium hypochlorite Source: Industrial Bio-Test Laboratories Inc.- confidential)

**From the CAR (The applicant holds a letter of access (LoA) to the complete dossier for the active substance approval)*

Summary table of in vitro studies on cytotoxicity						
Method Guideline GLP status, Reliability	**Celltype**	**Test substance Dose levels Type of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LC50**	**Remarks** *(e.g. major deviations)*	**Reference**
ISO-10993-5, Good cell culture practices (Reliability score 1)	L929	SoftOx Wound Irrigation Solution, SOF 003/53 ([redacted]) and SOF 003/51 ([redacted]) Full composition can be found in the Conf. annex.	None of the SoftOx formulations caused a cytotoxic effect in the NCTC clone 929 (L-929) cells at the two shortest exposure [redacted] For more details se summary in section 3.8 of this report	Not presented		78 SoftOx_cytotox_report_SINTEF_02_2020, In vitro cytotoxicity assessment of SoftOx formulations, SINTF, Report no 2020:00222

Value used in the Risk Assessment – Acute oral toxicity	
Value	For Sodium hypochlorite the rat LD50 oral was >2000 mg active chlorine/kg bw
Justification for the selected value	The products have not been tested. However, sodium hypochlorite has been demonstrated to have low toxicity in acute oral studies in rats (see the table above). These data on NaOCl are supported by many data found in the literature, as described in the EU-RAR on sodium hypochlorite (2007). Furthermore, from accidental human data, reported for ingestion, it can be concluded that the effects of accidental ingestion of domestic sodium hypochlorite are not expected to lead to any permanent health consequences. Based on the data from sodium hypochlorite (*at physiological pH, the HOCl/OCl:ratio is ca 50:50*) it can be concluded that the products within the product family containing products with 0.02% active chlorine will have a low acute toxicity.
Classification of the product	Not classified in accordance with methods enforced in the CLP regulation (EC nr 1272/2008).

according to CLP and DSD	

Acute toxicity by inhalation

Summary table of animal studies on acute inhalation toxicity

Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD) Actual and nominal concentration, Type of administration** *(nose only / whole body/ head only)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LC50**	**Remarks** *(e.g. major deviations)*	**Reference**
Not GLP*	Rat	Sodium hypochlorite*	Inactivity and lacrimation were evident at the dose of 10.5 mg active chlorine/L (1 h exposure). No deaths occurred (LC0 >10.5 mg active chlorine/L).	The LC50 was determined to be > 10.5 mg active chlorine/L.		The CAR (BioFax, sodium hypochlorite Source: Industrial Bio-Test Laboratories Inc.- confidential)

**From the CAR (The applicant holds a letter of access (LoA) to the complete dossier for the active substance approval)*

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	For Sodium hypochlorite the rat LC50 inhalation was >10.5 mg active chlorine/L. This data is considered of limited interest since inhalation exposure of sodium hypochlorite is only possible if aerosols are formed (EU-RAR for Sodium hypochlorite).
Justification for the selected value	The products have not been tested. The available data on acute inhalation toxicity of sodium hypochlorite is not relevant since inhalation exposure of Hypochlorous acid/sodium hypochlorite is only possible if aerosols are formed. The Sodium hypochlorite is not

	classified with respect to acute inhalation toxicity. The products of the family contain 0.02 % (w/w) active chlorine, released from sodium hypochlorite. At a pH value of about 4.3, hypochlorous acid (HClO) is the predominant species and exposure to HClO vapour can be considered relevant. But due to the very low concentration of sodium hypochlorite in the products a low concentration of HClO vapour can be expected and it can be concluded that the products have low acute inhalation toxicity.
Classification of the product according to CLP and DSD	Not classified in accordance with methods enforced in the CLP regulation (EC nr 1272/2008).

Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
Detailed observation of wound, including planimetric measurements, macroscopic evaluation (scored for inflammation of wound edges and skin surrounding the wounds, haemorrhage, exudation, presence of necrotic tissue, granulation and presence of hyper-granulation) and histopathologi	Minipig (3 adult females)	SoftOx wound irrigation solutions ([redacted]. Full composition can be found in the Conf. annex.	No treatment related clinical signs or effects on body weight were recorded during the study. for more details of the study se Section 3.8 of this report. The results are not fully relevant since the study design is not for evaluation of acute toxicity, but could be considered as supportive information.		The test was performed according to requirements in the EU legislation for medical device Class III. [redacted]	76, 78197Final Report 22 day wound healing study in minipig, SoftOx Wound Irrigation Solution A 22-Day Wound Healing Study in Minipigs, citoxlab, study report 78197, 2018

cal examination. GLP (Reliability score 1)					[redacted]	
Not GLP*	Rat	Sodium hypochlorite	Signs of toxicity were evident in the oral study characterised by hypoactivity, muscular weakness, haemorrhagic rhinitis and emaciation and in the dermal study by moderate to severe erythema.	>2000 mg active chlorine/kg bw		The CAR (BioFax, sodium hypochlorite Source: Industrial Bio-Test Laboratories Inc.- confidential)

**From the CAR (The applicant holds a letter of access (LoA) to the complete dossier for the active substance approval)*

Value used in the Risk Assessment – Acute dermal toxicity	
Value	The data available indicates very low acute dermal toxicity of sodium hypochlorite.
Justification for the selected value	The SoftOx wound irrigation solutions with a similar formulation ([redacted]) as the products of this application have been tested in a 22-Day Wound Healing Study in Minipigs. No treatment related clinical signs or effects on body weight were recorded during the study. Furthermore, on undamaged skin dermal absorption resulting in systemic toxicity is not likely to occur because of the reactivity of hypochlorous acid and the hypochlorite ion. The data available indicates very low acute dermal toxicity of sodium hypochlorite., as described in the EU-RAR on sodium hypochlorite (2007). Based on the data from sodium hypochlorite and supported by the data from the Wound Healing Study it can be concluded that the products within the product family containing 0.02 % (w/w) active chlorine released from Sodium hypochlorite will have a low acute dermal toxicity.
Classification of the product according to CLP and DSD	Not classified in accordance with methods enforced in the CLP regulation (EC nr 1272/2008).

Information on dermal absorption

Data waiving	
Information requirement	CDS
Justification	No data on ADME are available for dermal exposure for the active chlorine releaser Sodium hypochlorite. Regarding dermal exposure, the potential of hypochlorite solutions to penetrate the skin is low given its reactivity to proteinaceous material at the site of first contact. BPC TOX-WGIII-2016 agreed that human health effects are primarily due to the local mode of action of chlorine gas (and related chlorine species) and potential systemic effects are secondary to its direct irritating reactivity. Moreover, chorine is a gas, and thus not available for dermal absorption. Consequently, dermal absorption of chlorine is not relevant (from list of end point in the Assessment report of the active substance).

Information on endocrine disrupting properties

The active substance, active chlorine released from sodium hypochlorite, is not considered to have ED properties. According to the assessment report of Active chlorine released from Sodium hypochlorite PT1, 2, and 4 (2017): "Based on the available experimental results, there is no indication that active chlorine released from sodium hypochlorite affects the endocrine system. Structural characteristics and SAR do not hint to possible effects of active chlorine released from sodium hypochlorite as endocrine disruptor".

An assessment of the ED properties of the co-formulants have been done and is reported in the confidential annex. There are no reasons to assume ED properties in any of the co-formulants.

Based on the current knowledge it can therefore be concluded that none of the components of the products have ED properties.

Available toxicological data relating to non-active substance(s) (i.e. substance(s) of concern)

The biocidal product family does not contain any co-formulants considered as substances of concern. For information on co-formulants, see Confidential annex.

Other

Sodium chlorate
Chlorate is a relevant impurity for active chlorine released from sodium hypochlorite. It has been proven that chlorate is formed during degradation of chlorine species. Chlorate is

identified in the SoftOx Disinfection Family products in a concentration of maximum [redacted]

However, no guideline is available on how to perform a risk assessment for chlorate formed during degradation of chlorine species. During 2021 at WGI-TOX risk assessment for chlorate was discussed and the conclusion was that it was not considered possible to perform the risk assessment of chlorate formation during storage at this stage due to the lack of reference values and other parameters. Due to this and the lack of guidance no risk assessment has been done for the formed chlorate except for a dietary risk assessment for the PT4 use.

2.2.6.2 Exposure assessment

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	Primary (direct) exposure			Secondary (indirect) exposure			
	Industrial use	Professional use	Non-professional use	Industrial use	Professional use	General public	Via food
Inhalation	n.r.	Yes (only local irritation and oxidation)	Yes (only local irritation and oxidation)	n.r.	Yes (only local irritation and oxidation)	Yes (only local irritation and oxidation)	n.r.
Dermal	n.r.	Yes (only local irritation and oxidation)	Yes (only local irritation and oxidation)	n.r.	Yes (only local irritation and oxidation)	Yes (only local irritation and oxidation)	n.r.
Oral	n.r.	n.r.	n.r.	n.r.	n.r.	Yes	Yes

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.1.	Application	PT1 - Primary – Inhalation exposure, Hand disinfectant health care 25 applications/ day -Tier 1	Professionals
1.2.	Application	PT1 - Primary – Inhalation exposure, Hand disinfectant health care 40 applications/ day -Tier 1	Professionals
1.3.	Application	PT1 - Primary – Dermal exposure, Hand disinfectant 25 & 40 applications/ day -Tier 1	Professionals
1.4	Application	PT1 – Secondary - Inhalation exposure, Hand disinfectant 25 & 40 applications/ day -Tier 1	Bystanders
1.5	Post-application	PT1 - Primary – Post-application (handling empty bottles)	Professionals
1.6	Application	PT1 - Primary – Inhalation exposure, Hand disinfectant	Non-professionals
1.7	Application	PT1 - Primary – Dermal exposure, Hand disinfectant	Non-professionals
1.8	Application	PT1 – Secondary - Inhalation exposure, Hand disinfectant	Bystanders
1.9	Post-application	PT1 - Primary – Post-application (handling empty bottles)	Non-professionals
2.1	Application	PT2 – Primary –Mopping/Wiping large room - Inhalation exposure -Tier 1	Professionals
2.2	Application	PT2 – Primary – Pouring large room - Inhalation exposure-Tier 1	Professionals
2.3	Application	PT2 – Primary –Mopping/wiping Bathroom – Inhalation exposure-Their 1	Non-professionals
2.4	Application	PT2 – Primary –Wiping small room– Inhalation exposure-Their 1	Non-professionals
2.5	Application	PT2 – Primary –Mopping/wiping/pouring – Dermal exposure-Tier 1	Professionals and Non-professionals
2.6	Application	PT2 – Secondary - Inhalation exposure -Tier 1	Bystanders
2.7	Post-application	PT2 - Primary – Post-application (disposal of treatment solution)	Professionals and Non-professionals
2.8	Post-application	PT2 - Primary – Post-application (handling empty bottles)	Professionals and Non-professionals

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
4.1	Application	PT4 – Primary –Mopping/wiping/pouring large room– Inhalation exposure-Tier 1	Professional users
4.2	Application	PT4 – Primary –Mopping/wiping very large room– Inhalation exposure-Tier 1	Professional users
4.3	Application	PT2 – Primary – Dermal exposure-Tier 1	Professional use
4.4	Application	PT4 – Secondary - Inhalation exposure -Tier 1	Bystanders
4.5	Post-application	PT4 - Primary – Post-application (disposal of treatment solution)	Professional users
4.6	Post-application	PT4 - Primary – Post-application (handling empty bottles)	Professional user

Industrial exposure

Not applicable, no industrial exposure is foreseen.

Professional and Non-professional exposure

General for all exposure scenarios

The primary mode of action of active chlorine released from NaOCl is characterised by local irritation/corrosion and oxidation at the site of first contact triggered by direct chemical reactivity without prior metabolism. Active chlorine released from NaOCl does not become systemically available upon dermal contact, ingestion or inhalation. Any systemic effects seen in animal studies (at high doses) are considered to be secondary to local irritation/ corrosion. Consequently, only a local exposure and risk assessment was performed for all relevant routes of exposure (i.e. dermal, inhalation) which is considered to also cover the risk resulting from potential systemic effects (Assessment reports of the active substance).

The products are ready-to-use (RTU) and are in most cases used directly from the bottle. If so, no exposure calculations for mixing and loading are needed (Biocides Human Health Exposure Methodology, ECHA). The products are sold in containers of up to 5 L and decanting to a smaller container can in some cases be considered necessary before use. However, since the concentration of the product (0.02 % active chlorine) is well below the NOAELdermal of 1 % no further assessment is required. The inhalation exposure during decanting, is in all cases considered to be lower than the exposure during use of the product and is therefore covered by the different inhalation scenarios presented in the report.

PT 1 Hand disinfection

Use #1 PT1 Hand disinfection - Professionals

Exposure scenario 1:1 - 1:5: Hand disinfection in hospitals

Application:
A standard rub-in technique in accordance with EN 1500 is followed to ensure an effective disinfection is followed. The disinfectant is applied onto dry palms and rub-in up to the wrists for 60 seconds in a technique of 6 steps to ensure that the whole surface of both hands is treated.

Step 1: Apply about 5 ml of disinfectant and rub into palm of hand. Rub palm to palm to spread disinfectant over entire hands and fingers.

Step 2: Rub the back of your left hand with the palm of the right hand. Reverse and repeat action.

Step 3: Open fingers and rub the finger webs. Reverse and repeat action.

Step 4: Rub palm to palm with fingers interlocked (5 times).

Step 5: Rub thumb of each hand using a rotating movement.

Step 6: Rub the tips of the fingers against the opposite palm using circular movement. Rub wrist with both hands. Allow hands to dry completely.

Exposure scenario 1:1 Inhalation exposure – Hand disinfection 25 applications/ day

It is assumed that a health care worker in a hospital performs 25 hand rubs per shift. In a Tier 1 approach describing the worst case it is considered that all disinfectant is applied in one room successive without break. Calculation of the inhalation exposure is based on the model ConsExpo Web "Exposure to vapour: Instantaneous release". The room size is assumed to be 80 m^3 and the assumed ventilation rate is 1.5/h. The assumption of the room size is for a two bed room (According to Recommendation no 9 of the Ad hoc *Working Group on Human Exposure, Hand disinfection in hospitals*, https://echa.europa.eu/documents/10162/21664016/rec_9_disinfection_in_hospitals_en.pdf/81f9a6d6-f9b5-42e9-97c1-62a5eb897c11). For other input parameters see table below.

All other types of professional use of hand disinfection are considered covered by scenario 1:1 and 1:2, professional use of hand disinfection in hospitals.

Input parameters for ConsExpo (Exposure to vapour: Instantaneous release) Default with 25 hand rubs per shift

Parameter	Input values	
Tier 1	Exposure model: Exposure to vapour - Instantaneous release	ConsExpo Worst case scenario
Concentration of a.s.	0.02% active chlorine	Information from manufacturer

Molecular weight matrix	18 g/mol	According to ConsExpo for products that mainly consist of water.
Applied amount	25 x 5 g = 125 g	Default value 25 applications (HEAdHoc Rec no. 9) and as worst case scenario 5 ml of the product is use/application
Room size	80 m^3	Default value (HEAdHoc Rec no. 9)
Ventilation rate	1.5/h	Default value (HEAdHoc Rec no. 9)
Exposure duration	25 x 1 min	Default value (HEAdHoc Rec no. 9)
Inhalation rate	1.25 m^3/h	Light exercise from HEAdHoc Rec No 14.
Body weight	60 kg	HEAdHoc Rec No 14.
Vapour pressure	2500 Pa	From Assessment report of hypchlorous acid.
Temperature	20° C	Room temperature
Molecular weight	52.46 g/mol	For Hypochlorous acid (the main component at pH 4.3)

Report from ConsExpo
Inhalation

Mean event concentration:
2.3×10^{-1} mg/m^3
Average air concentration on exposure event. Note: depends strongly on chosen exposure duration.

Peak concentration (TWA 15 min):
2.6×10^{-1} mg/m^3
Peak concentration (TWA 15 min) is the 15-minute time weighted average of the air concentration. In case the exposure duration is less than 15 minutes, the mean event air concentration is given instead.

External event dose:
2.0×10^{-3} mg/kg bw
The amount that can potentially be absorbed per kg body weight during one event.

Conclusion: Hand disinfection in hospitals by professionals, 25 hand rubs per shift, is acceptable. No further refinement is required.

Exposure scenario 1:2 Inhalation exposure – Hand disinfection 40 applications/ day

As a worst-case scenario health care workers in a hospital may perform 40 hand rubs per shift according to the instructions on the label. The other parameters are the same as in scenario 1.

Input parameters for ConsExpo (Exposure to vapour: Instantaneous release) Worst case scenario with 40 hand rubs per shift

Parameter	Input values	
Tier 1	Exposure model: Exposure to vapour - Instantaneous release	ConsExpo Worst case scenario
Concentration of a.s.	0.02% HOCl (0.02% active chlorine)	Information from manufacturer
Molecular weight matrix	18 g/mol	According to ConsExpo for products that mainly consist of water.
Applied amount	40 x 5 g = 200 g	Worst case scenario 40 applications/day and 5 ml of the product is use/application
Room size	80 m^3	Default value (HEAdHoc Rec no. 9)
Ventilation rate	1.5/h	Default value (HEAdHoc Rec no. 9)
Exposure duration	40 x 1 min	For 40 applications/day
Inhalation rate	1.25 m^3/h	Light exercise from HEAdHoc Rec No 14.
Body weight	60 kg	HEAdHoc Rec No 14.
Vapour pressure	2500 Pa	From Assessment report of hypchlorous acid.
Temperature	20° C	Room temperature
Molecular weight	52.46 g/mol	For Hypochlorous acid (the main component at pH 4.3)

Report from ConsExpo

Inhalation

Exposure model
Exposure to vapour - Instantaneous release

Mean event concentration:
3.2×10^{-1} mg/m^3
Average air concentration on exposure event. Note: depends strongly on chosen exposure duration.

Peak concentration (TWA 15 min):
4.2×10^{-1} mg/m^3

Peak concentration (TWA 15 min) is the 15-minute time weighted average of the air concentration. In case the exposure duration is less than 15 minutes, the mean event air concentration is given instead.

External event dose:
4.4×10^{-3} mg/kg bw
The amount that can potentially be absorbed per kg body weight during one event.

Conclusion: Hand disinfection in hospitals by professionals, 40 hand rubs per shift, is acceptable. No further refinement is required.

Exposure scenario 1:3: Dermal exposure – Professional users
The conditions are the same as in exposure scenario 1:1 and 1:2.
Only local effects are considered relevant for NaOCl (active chlorine), i.e. systemic toxicity has not been included in this risk assessment.

The concentration of active chlorine in the hand disinfectant is 0.02%. This can be compared with the NOAECdermal of 1% active chlorine from the assessment report of the active substance.

Exposure scenario 1:4: Inhalation exposure – Bystanders
Only inhalation is relevant for secondary exposure of bystanders and the inhalation exposure of bystanders is considered covered by the inhalation assessment for the professional user (Assessment report active substances PT1).

Exposure scenario 1:5: Post-application (handling empty bottles) – Professional users
After application, empty containers are handled and disposed of. As only minor amounts remain in the containers, exposure to active chlorine from empty containers is negligible, and thus considered not relevant.

Use #2 PT1 Hand disinfection – Non-professionals

Exposure scenario 1:6 – 1:9: Inhalation exposure - Hand disinfection – Non-professionals

Non-professional users are expected to apply hand disinfection products less frequently than professional users (10 times/day) in smaller rooms with worse ventilation.

Exposure scenario 1:6: Inhalation exposure - Hand disinfection – Non-professional users

Input parameters for ConsExpo (Exposure to vapour: Instantaneous release) Worst case scenario with 10 hand rubs per day

Parameter	Input values	
Tier 1	Exposure model: Exposure to vapour - Instantaneous release	ConsExpo Worst case scenario
Concentration of a.s.	0.02% active chlorine	Information from manufacturer

Molecular weight matrix	18 g/mol	According to ConsExpo for products that mainly consist of water.
Application rate	10 times/day	
Applied amount	5 x 10 =50 g	5 ml of the product is use/application
Room size	20 m^3	ConsExpo default for a non-specified room
Ventilation rate	0.6/h	ConsExpo default for a non-specified room
Exposure duration	10 min	Total exposure 10 applications
Inhalation rate	1.25 m^3/h	Light exercise from HEAdHoc Rec No 14.
Body weight	60 kg	HEAdHoc Rec No 14.
Vapour pressure	2500 Pa	From Assessment report of hypchlorous acid.
Temperature	20° C	Room temperature
Molecular weight	52.46 g/mol	For Hypochlorous acid (the main component at pH 4.3)

Result from ConsExpo
Inhalation

Exposure model
Exposure to vapour - Instantaneous release

Mean event concentration:
4.8×10^{-2} mg/m^3
Average air concentration on exposure event. Note: depends strongly on chosen exposure duration.

Peak concentration (TWA 15 min):
4.8×10^{-2} mg/m^3
Peak concentration (TWA 15 min) is the 15-minute time weighted average of the air concentration. In case the exposure duration is less than 15 minutes, the mean event air concentration is given instead.

Mean concentration on day of exposure:
3.3×10^{-4} mg/m^3
Average air concentration over the day (accounts for the number of events on one day).

Year average concentration:
3.3×10^{-4} mg/m^3
Mean daily air concentration averaged over a year.

External event dose:
1.7×10^{-5} mg/kg bw
The amount that can potentially be absorbed per kg body weight during one event.

External dose on day of exposure:
1.7×10^{-4} mg/kg bw

Conclusion: Hand disinfection by non-professionals, 10 hand rubs per day, is acceptable. No further refinement is required.

Exposure scenario 1:7: Dermal exposure –Non-professional users
Only local effects are considered relevant for active chlorine, i.e. systemic toxicity has not been included in this risk assessment.

The concentration of active chlorine in the hand disinfectant is 0.02%. This can be compared with the NOAECdermal of 1% active chlorine from the assessment report of the active substance.

Exposure scenario 1:8: Inhalation exposure – Bystanders
Only inhalation is relevant for secondary exposure of bystanders and the inhalation exposure of bystanders is considered covered by the inhalation assessment for the non-professional user (Assessment report active substances PT1).

Exposure scenario 1:9: Post-application (handling empty bottles) – Non-professional users
After application, empty containers are handled and disposed of. As only minor amounts remain in the containers, exposure to active chlorine from empty containers is negligible, and thus considered not relevant.

Inhalation exposure infants and toddlers
An inhalation scenario for infants and toddlers is not required since the limit value (AECinhal = 0.5 mg/m^3 available chlorine) is based on the air concentration, and only local effects are relevant for the evaluation. The exposure scenario for an adult, instantaneous release of the amount of product used for 10 hand disinfections, is considered as worst-case air concentration also for infants and toddlers.

Oral exposure
An oral exposure scenario is not relevant for the active substance. Oral exposure can be relevant for the stable degradation product chlorate, but since there is no guidance in how to perform the risk assessment no exposure assessment is performed.

PT2 Hard surface Disinfection

Use #3 Hard surface disinfection (0.02% active chlorine) –Professionals including health care professionals

Exposure scenarios 2:1-2:2 Hard surface disinfection – Health care and Non-health care areas – Professional use

The product with 0.02% active chlorine is used for disinfection of hard surfaces in health care areas like patient rooms, operation rooms, laboratories, dental centers, isolation rooms, and also in non-health care areas like nursing homes, institutions, hotels,

restaurants, cafés, offices and public transportation, but with the exception for surfaces **used for direct contact with food or feeding stuffs.** The product is applied by pouring, mopping, or wiping.

2:1. Input parameters for ConsExpo (Exposure to vapour: Evaporation) Mopping/Wiping – large room - 0.02% active chlorine

As a worst-case scenario it is estimated that an area of 35 m^2 is disinfected by mopping and wiping. An amount of 50 ml/ m^2 is applied, i.e. a total of 1750 ml of the product is used. Calculation of the inhalation exposure is based on the model ConsExpo Web "Exposure to vapour: Evaporation". The room size is assumed to be 80 m^3 and the assumed ventilation rate is 1.5/h (HEAdHoc rec. no. 9 for hospitals) and the time used for mopping and wiping is assumed to be 330 min (22 rooms x 15 min) (HEAdHoc rec. no 2. For professional use of public/industrial areas such as hospitals). For other input parameters see table below.

Parameter	**Input values**	
Exposure model	Exposure to vapour - Evaporation – Increasing release	ConsExpo Worst case scenario
Concentration of a.s.	0.02% active chlorine	Information from manufacturer – worst case
Molecular weight matrix	18 g/mol	According to ConsExpo for products that mainly consist of water.
Application times	22	Value from HEAdHoc Rec no 2.
Application duration	15 min	For mopping and wiping professional use of public/industrial areas such as hospitals (HEAdHoc Rec no 2.)
Applied amount	1750 g	50 ml/m^2 is applied on 35 m^2 (worst-case scenario)
Room size	80 m^3	Value from HEAdHoc Rec no. 9 (hospitals)
Ventilation rate	1.5/h	Value from HEAdHoc Rec no. 9 (hospitals)
Emission duration	15 min	Biocides Human Health Exposure Methodology, ECHA
Inhalation rate	1.25 m^3/h	Light exercise from HEAdHoc Rec No 14.
Vapour pressure	2500 Pa	From Assessment report of hypchlorous acid.
Temperature	20° C	Room temperature
Molecular weight	52.46 g/mol	For Hypochlorous acid (the main component at pH 4.3)
Mass transfer coefficient	10 m/h	Biocides Human Health Exposure Methodology, ECHA

Release area	35 m^2	See applied amount - Floor 32 m^2 + 3 m^2 other surface

Report from ConsExpo
Inhalation

Exposure model
Exposure to vapour - Evaporation

Mean event concentration:
4.3×10^{-1} mg/m^3
Average air concentration on exposure event. Note: depends strongly on chosen exposure duration.

Peak concentration (TWA 15 min):
4.3×10^{-1} mg/m^3
Peak concentration (TWA 15 min) is the 15-minute time weighted average of the air concentration. In case the exposure duration is less than 15 minutes, the mean event air concentration is given instead.

Mean concentration on day of exposure:
9.9×10^{-2} mg/m^3
Average air concentration over the day (accounts for the number of events on one day).

Year average concentration:
9.9×10^{-2} mg/m^3
Mean daily air concentration averaged over a year.

External event dose:
2.3×10^{-3} mg/kg bw
The amount that can potentially be absorbed per kg body weight during one event.

External dose on day of exposure:
5.0×10^{-2} mg/kg bw

Conclusion: Disinfection of hard surfaces by mopping and wiping, performed by professionals including health care professionals, with the product containing 0.02% active chlorine is acceptable. No further refinement is required.

2:2. Input parameters for ConsExpo (Exposure to vapour: Evaporation) Pouring – large room - 0.02% active chlorine

The product is applied on hard surface tolerant to water by pouring. Since the amount of the product used for pouring is the same as for mopping and wiping (50 ml/ m^2), the inhalation exposure scenarios will be exactly the same as for the application by mopping and wiping (large rooms), except that the exposure time is shorter (5 min) and the product is only applied on the floor (32 m^2), and Exposure to vapour - Evaporation – Constant release model is used.

Parameter	**Input values**	
Exposure model	Exposure to vapour - Evaporation – Constant release	ConsExpo Worst case scenario
Concentration of a.s.	0.02% active chlorine	Information from manufacturer – worst case
Molecular weight matrix	18 g/mol	According to ConsExpo for products that mainly consist of water.
Application times	22	For same as for mopping professional use of public/industrial areas such as hospitals (HEAdHoc Rec no 2.)
Application duration	5 min	For pouring product on 32 m^2 (expert judgement)
Applied amount	1600 g	50 ml/m^2 is applied on 32 m^2 (worst-case scenario)
Room size	80 m^3	Value from HEAdHoc Rec no. 9 (hospitals)
Ventilation rate	1.5/h	Value from HEAdHoc Rec no. 9 (hospitals)
Emission duration	60 min	Biocides Human Health Exposure Methodology, ECHA
Inhalation rate	1.25 m^3/h	Light exercise from HEAdHoc Rec No 14.
Vapour pressure	2500 Pa	From Assessment report of hypchlorous acid.
Temperature	20° C	Room temperature
Molecular weight	52.46 g/mol	For Hypochlorous acid (the main component at pH 4.3)
Mass transfer coefficient	10 m/h	Biocides Human Health Exposure Methodology, ECHA
Release area	32 m^2	See applied amount - Floor 32 m^2

Results from ConsExpo
Inhalation

Exposure model
Exposure to vapour - Evaporation

Mean event concentration:
4.8×10^{-1} mg/m³
Average air concentration on exposure event. Note: depends strongly on chosen exposure duration.

Peak concentration (TWA 15 min):
4.8×10^{-1} mg/m³
Peak concentration (TWA 15 min) is the 15-minute time weighted average of the air concentration. In case the exposure duration is less than 15 minutes, the mean event air concentration is given instead.

Mean concentration on day of exposure:
3.7×10^{-2} mg/m³
Average air concentration over the day (accounts for the number of events on one day).

Year average concentration:
3.7×10^{-2} mg/m³
Mean daily air concentration averaged over a year.

External event dose:
8.4×10^{-4} mg/kg bw
The amount that can potentially be absorbed per kg body weight during one event.

External dose on day of exposure:
1.8×10^{-2} mg/kg bw

Conclusion: Disinfection of hard surfaces by pouring the product, performed by professionals including health care professionals, is acceptable. No further refinement is required.

Use #4 Hard surface disinfection (0.02% active chlorine) – Non-professionals

Exposure scenario 2:3 - 2:4 Hard surface disinfection – Non-Professional use

The product with 0.02% active chlorine is used for prevention and reducing the risk of infection in private settings like bathrooms and toilets, on all surfaces tolerant to water. The product is applied on hard surfaces by mopping/wiping.

2:3. Input parameters for ConsExpo (Exposure to vapour: Evaporation) Mopping/Wiping Bathroom – Non-professional

A worst-case non-professional scenario for a domestic bathroom is estimated to be an area of 5.71 m^2 disinfected by mopping and wiping once a day. An amount of 50 ml/ m^2 is applied, i.e. 285.5 ml of the product is used. Calculation of the inhalation exposure is based on the model ConsExpo Web "Exposure to vapour: Evaporation, Increasing release". The room size is assumed to be 10 m^3 and the assumed ventilation rate is 2/h (ConsExpo

general fact sheet) and the time used for mopping and wiping is assumed to be 5 min. For other input parameters see table below.

Parameter	**Input values**	
Exposure model	Exposure to vapour - Evaporation – Increasing release	ConsExpo Worst case scenario
Concentration of a.s.	0.02% active chlorine	Information from manufacturer – worst case
Molecular weight matrix	18 g/mol	According to ConsExpo for products that mainly consist of water.
Application times	365 times/year (1 time/day)	Worst case
Application duration	5 min	For mopping and wiping, non-professional use in bathroom 5.71 m^2(expert judgement).
Applied amount	285.5 g	50 ml/m^2 is applied on 5.71 m^2 (worst-case scenario)
Room size	10 m^3	ConsExpo default spraying scenario disinfectants
Ventilation rate	2/h	ConsExpo default bathroom 2/h general fact sheet
Emission duration	5 min	For mopping and wiping, non-professional use of in bathroom 5.71 m^2.
Inhalation rate	1.25 m^3/h	Light exercise from HEAdHoc Rec No 14.
Vapour pressure	2500 Pa	From Assessment report of hypchlorous acid.
Temperature	20° C	Room temperature
Molecular weight	52.46 g/mol	For Hypochlorous acid (the main component at pH 4.3)
Mass transfer coefficient	10 m/h	Biocides Human Health Exposure Methodology, ECHA
Release area	5.71 m^2	See applied amount - Floor 4 m^2 + 1.71 m^2 other surface

Results ConsExpo
Inhalation
Exposure model
Exposure to vapour - Evaporation

Mean event concentration:
2.5×10^{-1} mg/m^3
Average air concentration on exposure event. Note: depends strongly on chosen exposure duration.

Peak concentration (TWA 15 min):
2.5×10^{-1} mg/m³
Peak concentration (TWA 15 min) is the 15-minute time weighted average of the air concentration. In case the exposure duration is less than 15 minutes, the mean event air concentration is given instead.
Mean concentration on day of exposure:
8.5×10^{-4} mg/m³
Average air concentration over the day (accounts for the number of events on one day)
Year average concentration:
8.5×10^{-4} mg/m³
Mean daily air concentration averaged over a year
External event dose:
4.3×10^{-4} mg/kg bw
The amount that can potentially be absorbed per kg body weight during one event
External dose on day of exposure:
4.3×10^{-4} mg/kg bw

Conclusion: Non-professional cleaning and disinfection of hard surfaces in bathrooms by mopping/wiping is acceptable. No further refinement is required.

2:4 Input parameters for ConsExpo (Exposure to vapour: Evaporation) Wiping – small room – Non-professional

A worst-case non-professional scenario for a non-specified small room in the domestic area (e.g. a toilet) is estimated to be an area of 3 m^2 that is disinfected by wiping once a day. An amount of 50 ml/ m^2 is applied, i.e. 150 ml of the product is used. Calculation of the inhalation exposure is based on the model ConsExpo Web "Exposure to vapour: Evaporation, Constant release". The room size is assumed to be 20 m^3 and the assumed ventilation rate is 0.6/h (ConsExpo general fact sheet) and the time used for wiping is assumed to be 3 min. For other input parameters see table below.

Input values in ConsExpo

Parameter	**Input values**	
Exposure model	Exposure to vapour - Evaporation – Constant release	ConsExpo Worst case scenario
Concentration of a.s.	0.02% active chlorine	Information from manufacturer – worst case
Molecular weight matrix	18 g/mol	According to ConsExpo for products that mainly consist of water.
Application times	365 times/year (1 time/day)	ConsExpo default
Application duration	3 min	ConsExpo default
Applied amount	150 g	50 ml/m^2 is applied on 3 m^2 (worst-case scenario)
Room size	20 m^3	ConsExpo default for a non-specified room
Ventilation rate	0.6/h	ConsExpo default for a non-specified room

Emission duration	60 min	Biocides Human Health Exposure Methodology, ECHA
Inhalation rate	1.25 m^3/h	Light exercise from HEAdHoc Rec No 14.
Vapour pressure	2500 Pa	From Assessment report of hypchlorous acid.
Temperature	20° C	Room temperature
Molecular weight	52.46 g/mol	For Hypochlorous acid (the main component at pH 4.3)
Mass transfer coefficient	10 m/h	Biocides Human Health Exposure Methodology, ECHA
Release area	3 m^2	Worst case (Default ConsExpo is 1.71 m^2)

Results from ConsExpo
Inhalation

Mean event concentration:
1.3×10^{-1} mg/m³
Average air concentration on exposure event. Note: depends strongly on chosen exposure duration.

Peak concentration (TWA 15 min):
1.3×10^{-1} mg/m³
Peak concentration (TWA 15 min) is the 15-minute time weighted average of the air concentration. In case the exposure duration is less than 15 minutes, the mean event air concentration is given instead.

Mean concentration on day of exposure:
2.6×10^{-4} mg/m³
Average air concentration over the day (accounts for the number of events on one day).

Year average concentration:
2.6×10^{-4} mg/m³
Mean daily air concentration averaged over a year.

External event dose:
1.3×10^{-4} mg/kg bw
The amount that can potentially be absorbed per kg body weight during one event.

External dose on day of exposure:
1.3×10^{-4} mg/kg bw

Conclusion: Non-professional cleaning and disinfection of hard surfaces in small rooms, e.g. toilets, by wiping is acceptable. No further refinement is required.

Scenarios common to all PT2 Uses, Use #3, #4

Exposure scenario 2:5 Dermal exposure
Only local effects are considered relevant for active chlorine, i.e. systemic toxicity has not been included in this risk assessment. The concentration of active chlorine in the product is 0.02%. This can be compared with the NOAECdermal of 1% active chlorine from the assessment report of the active substance.

Exposure scenario 2:6 Inhalation exposure – Bystanders
Only inhalation is relevant for secondary exposure of bystanders and the inhalation exposure of bystanders (adults and children) is considered covered by the inhalation assessment for the non-professional user.

Exposure scenario 2:7 Post-application (disposal of treatment solution) –
Since the product is ready-to-use and the product should be left on the surface to dry the need for disposal of treatment solution is very limited, i.e. the exposure is considered negligible.

Exposure scenario 2:8 Post-application (handling empty bottles) –
After application, empty containers are handled and disposed of. As only minor amounts remain in the containers, exposure to active chlorine from empty containers is negligible, and thus considered not relevant.

Inhalation exposure infants and toddlers
An inhalation scenario for infants and toddlers is not required since the limit value (AECinhal = 0.5 mg/m^3 available chlorine) is based on the air concentration, and only local effects are relevant for the evaluation. The exposure scenarios for adults are considered as worst case air concentration also for infants and toddlers.

Oral exposure
An oral exposure scenario is not relevant for the active ingredient. Oral exposure can be relevant for the stabile degradation product chlorate, but since there is no guidance in how to perform the risk assessment no exposure assessment is performed.

Use #5 Disinfection of large surfaces that come into contact with food and feed- Professionals

Exposure scenario 4.1 Large surface disinfection – Professional use

The product (0.02% active chlorine) is applied on hard surfaces such as floor and bench surfaces by mopping, wiping and pouring. Inhalation exposure and dermal exposure are considered.

Exposure scenario 4:1: Inhalation exposure – Mopping/wiping Large surface– Professional users
As a worst-case scenario it is estimated that an area of 50 m^2 is disinfected by wiping or mopping 2 times/day in for example restaurant kitchens. An amount of 50 ml/ m^2 is applied, i.e. a total of 2500 ml of the product (0.02% active chlorine) is used. Calculation of the inhalation exposure is based on the model ConsExpo Web "Exposure to vapour:

Evaporation". The room size is assumed to be 80 m^3 and the assumed ventilation rate is 5/h and the time used for mopping and wiping is assumed to be 15 min.

This scenario is considered to also cover the scenario for application of the product by pouring. The only difference is that the product is poured onto the floor and thereafter mopping, and wiping is performed, the surface area and the amount of product used are the same. Since, only local risk assessment is performed, and the concentration of the product is below NOAEC the application method is irrelevant for dermal exposure.

Input parameters for ConsExpo (Exposure to vapour: Evaporation) Mopping/Wiping – large room

Parameter	Input values	
Exposure model	Exposure to vapour - Evaporation – Increasing release	ConsExpo Worst case scenario
Concentration of a.s.	0.02% active chlorine	Information from manufacturer – worst case
Molecular weight matrix	18 g/mol	According to ConsExpo for products that mainly consist of water.
Application times	2 times/day	Before and after working day
Application duration	15 min	Biocides Human Health Exposure Methodology, ECHA
Applied amount	2500 g	50 ml/m^2 is applied on 50 m^2 (worst-case scenario)
Room size	80 m^3	Value from HEAdHoc Rec no. 9 (hospitals)
Ventilation rate	5/h	Data for kitchens in private house have been used. From ConsExpo General Fact sheet
Exposure duration	15 min	Biocides Human Health Exposure Methodology, ECHA
Inhalation rate	1.25 m^3/h	HEAdHoc Rec No 14
Vapour pressure	2500 Pa	From Assessment report of hypchlorous acid.
Temperature	20° C	Room temperature
Molecular weight	52.46 g/mol	For Hypochlorous acid (the main component at pH 4.3)
Mass transfer coefficient	10 m/h	Biocides Human Health Exposure Methodology, ECHA

Release area	50 m^2	See applied amount - Floor 32 m^2 + 18 m^2 other surface

Results from ConsExpo
Inhalation
Exposure model
Exposure to vapour - Evaporation
Mean event concentration:
4.9×10^{-1} mg/m^3
Average air concentration on exposure event. Note: depends strongly on chosen exposure duration
Peak concentration (TWA 15 min):
4.9×10^{-1} mg/m^3
Peak concentration (TWA 15 min) is the 15-minute time weighted average of the air concentration. In case the exposure duration is less than 15 minutes, the mean event air concentration is given instead.

Mean concentration on day of exposure:
1.0×10^{-2} mg/m^3
Average air concentration over the day (accounts for the number of events on one day).

Year average concentration:
1.0×10^{-2} mg/m^3
Mean daily air concentration averaged over a year.

External event dose:
2.6×10^{-3} mg/kg bw
The amount that can potentially be absorbed per kg body weight during one event.

External dose on day of exposure:
5.1×10^{-3} mg/kg bw
The amount that can potentially be absorbed per kg body weight during one day.

Conclusion: Professional cleaning and disinfection of food contact areas, such as floor and bench surfaces in restaurant kitchens, by mopping, wiping and pouring is acceptable. No further refinement is required.

Exposure scenario 4:2: Inhalation exposure – Very large rooms
As a worst-case scenario it is estimated that an area of 60 m^2 is disinfected by wiping or mopping in Food and Feed industry and large restaurant kitchens. An amount of 50 ml/ m^2 is applied, i.e. a total of 3000 ml of the product (0.02% active chlorine) is used.
Calculation of the inhalation exposure is based on the model ConsExpo Web "Exposure to vapour: Evaporation". The room size is assumed to be 188 m^3 and the assumed ventilation rate is 1.5/h (HEAdHoc Recommendation no. 9) and the time used for mopping and wiping is assumed to be 330 min (HEAdHoc recommendation no 2).

This scenario is considered to also cover the scenario for application of the product by pouring.

Input parameters for ConsExpo (Exposure to vapour: Evaporation)

Parameter	**Input values**	

Exposure model	Exposure to vapour – Evaporation – Increased release	ConsExpo Worst case scenario
Concentration of a.s.	0.02% active chlorine	Information from manufacturer – worst case
Molecular weight matrix	18 g/mol	According to ConsExpo for products that mainly consist of water.
Application times	2 times/day	Biocides Human Health Exposure Methodology, ECHA
Application duration	25 min	Calculated from exposure scenario 4.1
Applied amount	3000 g	50 ml/m^2 is applied on 60 m^2 (worst-case scenario)
Room size	188 m^3	
Ventilation rate	5/h	Data for kitchens in private house have been used. From ConsExpo General Fact sheet
Exposure duration	25 min	Calculated from exposure scenario 4.1
Inhalation rate	1.25 m^3/h	HEAdHoc Rec No 14
Vapour pressure	2500 Pa	From Assessment report of hypchlorous acid.
Temperature	20° C	Room temperature
Molecular weight	52.46 g/mol	For Hypochlorous acid (the main component at pH 4.3)
Mass transfer coefficient	10 m/h	Biocides Human Health Exposure Methodology, ECHA
Release area	60 m^2	Floor and other surfaces

Report from ConsExpo
Inhalation

Mean event concentration:

3.2×10^{-1} mg/m^3

Average air concentration on exposure event. Note: depends strongly on chosen exposure duration.

Peak concentration (TWA 15 min):

4.8×10^{-1} mg/m^3

Peak concentration (TWA 15 min) is the 15-minute time weighted average of the air concentration. In case the exposure duration is less than 15 minutes, the mean event air concentration is given instead.

Mean concentration on day of exposure:
1.1×10^{-2} mg/m³
Average air concentration over the day (accounts for the number of events on one day).
Year average concentration:
1.1×10^{-2} mg/m³
Mean daily air concentration averaged over a year.
External event dose:
2.8×10^{-3} mg/kg bw
The amount that can potentially be absorbed per kg body weight during one event.
External dose on day of exposure:
5.6×10^{-3} mg/kg bw

Conclusion: Professional cleaning and disinfection of food contact areas, such as floor and bench surfaces in food and feed industry and large restaurant kitchens, by mopping, wiping and pouring is acceptable. No further refinement is required

Exposure scenario 4:3: Dermal exposure
The conditions are the same as in exposure scenario 4:1
Only local effects are considered relevant for active chlorine, i.e. systemic toxicity has not been included in this risk assessment. The concentration of active chlorine in the disinfectant is 0.02%. This can be compared with the NOAECdermal of 1% active chlorine from the assessment report of the active substance.

Exposure scenario 4:4: Inhalation exposure – Bystanders
Only inhalation is relevant for secondary exposure of bystanders and the inhalation exposure of bystanders is considered covered by the inhalation assessment for the professional user (Assessment report active substances PT4).

Exposure scenario 4:5: Post-application (disposal of treatment solution) – Professional users
Since the product is ready-to-use and the product should be left on the surface to dry the need for disposal of treatment solution is very limited, i.e. the exposure is considered negligible.

Exposure scenario 4:6: Post-application (handling empty bottles) – Professional users
After application, empty containers are handled and disposed of. As only minor amounts remain in the containers, exposure to active chlorine from empty containers is negligible, and thus considered not relevant.

2.2.6.3 Results of exposure

Exposure of the professional users

Summary table: systemic exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
1:1-4.6		n.r.	n.r.	n.r.	n.r.

Systemic exposure is not considered relevant since the primary mode of action of active chlorine is characterised by local irritation/corrosion and oxidation at the site of first contact triggered by direct chemical reactivity without prior metabolism. Active chlorine does not become systemically available upon dermal contact, ingestion or inhalation. Consequently, only a local exposure and risk assessment was performed for all relevant routes of exposure (i.e. dermal, inhalation) which is considered to also cover the risk resulting from potential systemic effects.

Combined scenarios

Combined exposure is not relevant based on the absence of systemic effects after exposure towards active chlorine. The primary mode of action of active chlorine is characterised by local irritation/corrosion and oxidation at the site of first contact; thus, effects triggered by active chlorine are rather concentration than time-dependent.

Exposure of the general public

See exposure scenario 1.6-1.9 for non-professional hand disinfection and scenario 2.3-2.4 for non-professional use in bathroom and small rooms i.e. toilets.

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
1.6-1.9, and 2.3-2.4		n.r.	n.r.	n.r.	n.r.

Systemic exposure is not considered relevant since the primary mode of action of active chlorine is characterised by local irritation/corrosion and oxidation at the site of first contact triggered by direct chemical reactivity without prior metabolism. active chlorine does not become systemically available upon dermal contact, ingestion, or inhalation. Consequently, only a local exposure and risk assessment was performed for all relevant routes of exposure (i.e. dermal, inhalation) which is considered to also cover the risk resulting from potential systemic effects.

Combined scenarios

Combined exposure is not relevant based on the absence of systemic effects after exposure towards active chlorine. The primary mode of action of active chlorine is

characterised by local irritation/corrosion and oxidation at the site of first contact; thus, effects triggered by active chlorine are rather concentration than time-dependent.

Dietary exposure

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use**	**Description of scenario**	**Subject of exposure**
4.1-4.3	PT4 Professional use	Hard surfaces and cutting machines and other machines used for food are wiped, mopped or soaked with 50 ml disinfectant/m^2 for up to 5 minutes, rinsed with water and let dry.	Meat and other food stuff

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Scenario

With regards to professional intended PT 4 use, dietary exposure to available chlorine and chlorate in food was assessed and considered acceptable in the CAR. This refers to the EFSA Scientific Opinion of the EFSA CONTAM Panel on "*Risks for public health related to the presence of chlorate in food*" (EFSA Journal 2015;13(6):4135) which includes a comprehensive dietary exposure and risk assessment for chlorate residues in food and drinking water based on occurrence data. The conclusion of this assessment remains valid for intended professional PT 4 uses:

"Potential chlorate residues from the application of chlorine and hypochlorite in PTs 4 and 5 are considered to be included in the measured chlorate residue values, and the conclusions drawn by the EFSA CONTAM Panel on chlorate residues cover thus also the dietary risk arising from PT4 and PT5 uses of chlorine and hypochlorite. Since the EFSA Scientific Opinion on chlorate residues provides actual measured data for chlorate residues in food and an exhaustive exposure and risk assessment based on consumption data, the conclusions drawn in the EFSA Scientific Opinion are superior to any dietary risk assessment based on exposure models."

Conclusion
No further dietary risk assessment is deemed necessary for the intended PT4 professional uses.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

This scenario is not considered relevant since only hand disinfectants (PT1) and surface disinfectants (PT2) are used by non-professionals and the transfer of the active substances to food is considered negligible.

Exposure associated with production, formulation and disposal of the biocidal product

Scenarios
Exposure during production and formulation is not considered relevant for the product. See scenarios 1.5, 1.9, 2.7, 2.8, 4.5, 4.6; disposal of treatment solution or handling empty bottles (above).

Summary table: systemic exposure associated with production, formulation, and disposal					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
1.5, 1.9, 2.7, 2.8, 4.5, 4.6 (disposal of treatment solution and handling empty bottles)		n.r.	n.r.	n.r.	n.r.

Not relevant since the primary mode of action of active chlorine is characterised by local irritation/corrosion and oxidation at the site of first contact triggered by direct chemical reactivity without prior metabolism. Active chlorine does not become systemically available upon dermal contact, ingestion or inhalation. Consequently, only a local exposure and risk assessment was performed for all relevant routes of exposure (i.e. dermal, inhalation) which is considered to also cover the risk resulting from potential systemic effects.

Combined scenarios

Combined exposure is not relevant based on the absence of systemic effects after exposure towards active chlorine. The primary mode of action of active chlorine is

characterised by local irritation/corrosion and oxidation at the site of first contact; thus, effects triggered by active chlorine are rather concentration than time-dependent.

Aggregated exposure

Aggregated exposure can be considered not relevant based on the absence of systemic effects after exposure towards active chlorine. The primary mode of action of active chlorine is characterised by local irritation/corrosion and oxidation at the site of first contact; thus effects triggered by active chlorine are rather concentration than time-dependent.

However, for the stable by-products chlorate an aggregated exposure assessment can be considered relevant. This is, however, difficult due to lack of data. EFSA has found that current levels of chlorate in drinking water and in food are too high especially among infants and children but data on the possible origin of reported chlorate residues is often missing.

The US EPA has performed aggregate assessments of chlorate, by combining food, drinking water, and any residential or other non-occupational exposures. Short term aggregate risks, assessed for adults only using highest exposure scenario, are all below the levels of concern (LOC). Chronic aggregate risks, however, are above the LOC for both infants and children ages 1 to 2, when calculated using the estimated highest annual average drinking water concentration (0.69 mg/L). When the 90th percentile and median annual average water concentrations are used (0.24 or 0.11 mg/L, respectively), all population subgroups are below the LOC. The EPA believes that sodium chlorate does not constitute a risk of concern to the general population or any population subgroups, since the LOC exceedances are associated with a small number of water treatment facilities and inappropriate treatment practices (USEPA/Office of Pesticide Programs; Reregistration Eligibility Decision Document for Inorganic Chlorates p.8 EPA 738-R-06-014 (July 2006)).

The EFSA reported that assessment of the chronic risk indicated that the health of European consumer groups is not adversely affected by the reported chlorate residues in foods. In the absence of data available on the possible origin of the reported chlorate residues, the BfR estimated short-term intake in accordance with its recommendations for perchlorate. On the basis of this worst-case approach, the BfR estimation of short-term intake for certain product groups led to an exceedance of the ADI proposed for the acute risk assessment of chlorate. The BfR noted that refinement of both the toxicological assessment and the residue assessment would be possible with a better database (Scientific Opinion on risks for public health related to the presence of chlorate in food. EFSA Journal 2015; 13(6) :4 135).

In its scientific opinion "Risks for public health related to the presence of chlorate in food", EFSA found that current levels of chlorate in drinking water and in food were too high and could negatively impact iodine uptake especially among infants and children. Chlorate originates from chlorine disinfectants widely used in water treatment and food processing, drinking water being by far the main contributor.

2.2.6.4 Risk characterisation for human health

The BPC Working Group members supported that an assessment for systemic effects should not be performed and only a local risk assessment should be included. In addition, the WG agreed that AEL values should not be derived (Assessment reports from active substance).

Reference values to be used in the Risk Characterisation for local effects

Substance	Exposure route	Safety factor	Study	Reference value
active chlorine	Oral		rat 90-d subchronic repeated dose oral (drinking water) study rat 104-wks chronic repeated dose oral (drinking water) study	NOAECoral =0.1 % available chlorine
active chlorine	Dermal		human (dermatitis patients) 48 h-patch test study	NOAECdermal = 1 % available chlorine
active chlorine	Inhalation		No repeated dose inhalation toxicity study on NaOCl is available. In the absence of data, the BPC TOX-WGIII-2016 agreed to derive an AEC-inhalation based on chlorine data	AECinhal = 0.5 mg/m^3 available chlorine
Chlorate	Oral	-	Based on human 12-wks repeated dose oral (drinking water) clinical study according to EFSA CONTAM Panel (EFSAJournal 2015;13(6):4135	ARfD = 36 µg chlorate/ kg bw
Chlorate	Oral	-	Based on the TDI for perchlorate (derived from human observations) according to EFSA CONTAM Panel (EFSA Journal 2015;13(6):4135	ADI = 3 µg chlorate/ kg bw

Maximum residue limits or equivalent

Not relevant for substances such as NaOCl (active chlorine) which act by a local mode of action only. MRL for chlorate in certain products have recently been updated according to COMMISSION REGULATION (EU) 2020/749 of 4 June 2020, amending Annex III to

Regulation (EC) No 396/2005. For cow milk MRL is 0.1 mg/kg and for cow meat MRL is set to 0.05 mg/kg (see the EU Pesticide database at https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=1103).
Specific reference value for groundwater
According to BPR Annex VI, point 68: 0.1 µg/L (Assessment report for active substance).

Risk for industrial users
Industrial exposure is not relevant for the product.

Risk for professional users

Systemic effects

The primary mode of action of active chlorine is characterised by local irritation/ corrosion and oxidation at the site of first contact triggered by direct chemical reactivity without prior metabolism. active chlorine does not become systemically available upon dermal contact, ingestion or inhalation (i.e. estimate uptake in table below is not relevant). Consequently, only a local exposure and risk assessment was performed for all relevant routes of exposure (i.e. dermal, inhalation) which is considered to also cover the risk resulting from potential systemic effects.

Summary table: systemic exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
All scenarios PT1-4		n.r.	n.r.	n.r.	n.r.

Local effects

PT1: Hand disinfection

Results of exposure assessment and risk characterisation of the primary exposure

Intended use	**Task**	**Oral Exposure (active chlorine)**	**Oral Exposure as % of NOAEC oral**	**Dermal Exposure (active chlorine)[1]**	**Dermal Exposure as % of NOAEC dermal**	**Inhalation Exposure (mg active chlorine/ m³)**	**Inhalation Exposure as % of NOAEC inhal**	**Acceptable**

Scenario 1.1, 1.2 PT1: Skin disinfectant in health care - professionals	Application	n.r.	n.r.	0.02%	2%	0.26(25 appl/day) 0.42 (40 appl/day)	52% (25 appl/day) 84% (40 appl/day)	Yes
Scenario 1.5 PT1: Skin disinfectant in health care - professionals	Post-application (handling empty bottles)	n.r.	n.r.	negligible	n.r.	negligible	n.r.	Yes

[1] Scenario 1.3 Dermal exposure – Professional users

There are no separate exposure scenarios calculated for secondary exposure of bystanders. The secondary exposure of bystanders is considered covered by the primary exposure scenarios for professionals. Scenarios acceptable for professional users will also be acceptable for bystanders.

Conclusion (PT1)
Based on the results obtained from the quantitative exposure (application and post-application) of professional users and the risk assessment, exposure of professional users in the intended uses (PT1 hand disinfection) results in no unacceptable risk. Same conclusion is drawn for secondary exposure of professional bystanders.

PT2 Hard surface

Results of exposure assessment and risk characterisation of the primary exposure

Intended use	Task	Oral Exposure (active chlorine)	Oral Exposure as % of NOAEC oral	Dermal Exposure (active chlorine)[1]	Dermal Exposure as % of NOAEC dermal	Inhalation Exposure (mg active chlorine/ m^3)	Inhalation Exposure as % of NOAEC inhal	Acceptable
Scenario 2.1 Hard surface disinfection	Application	n.r.	n.r.	0.02%	2%	0.43	86%	Yes

mopping /wiping –large room -								
Scenario 2.2 Hard surface disinfection pouring – large room	Application	n.r.	n.r.	0.02%	2%	0.48	96%	Yes
Scenario 2.8Hard surface Professional use	Post-application (disposal of treatment solution)	n.r.	n.r.	negligible	negligible	negligible	negligible	Yes
Scenario 2.9 Hard surface Professional use	Post-application (handling empty bottles)	n.r.	n.r.	negligible	negligible	negligible	negligible	Yes

[1] See Scenario 2:5 Dermal exposure

There are no separate scenarios calculated for secondary exposure of bystanders. The exposure of bystanders is considered covered by the primary exposure scenarios. Scenarios acceptable for primary exposure will also be acceptable for secondary exposure of bystanders.

Conclusion (PT2)
Based on the results obtained from the quantitative exposure (application and post-application) of professional users and the risk assessment, exposure of professional users in the intended uses (PT2 hard surface disinfection) results in no unacceptable risk for mopping/wiping and pouring of large rooms.

PT4 Disinfection of hard surfaces that come into contact with food and feed

Results of exposure assessment and risk characterisation of the primary exposure

Intended use	**Task**	**Oral Exposure (active chlorine)**	**Oral Exposure as % ofNOAEC oral**	**Dermal Exposure (active chlorine)** [1]	**Dermal Exposure as % of NOAEC dermal**	**Inhalation Exposure (mg active chlorine / m³)**	**Inhalation Exposure as % of AEC inhal**	**Acceptable**
Scenario 4.1 Hard surface – Mopping / Wiping **large room**	Application	n.r.	n.r.	0.02%	2%	0.49	98%	Yes
Scenario 4.2 Hard surface – Mopping /Wiping /pouring **very large room**	Application	n.r.	n.r.	0.02%	2%	0.32	64%	Yes
Scenario 4.5 Hard surface PT4	Post-application (handling empty bottles)	n.r.	n.r.	negligible	negligible	negligible	negligible	Yes
Scenario 4.6 Hard surfacePT4	Post-application (disposal of treatment solution)	n.r.	n.r.	negligible	negligible	negligible	negligible	Yes

[1] See Scenario 4.3 Dermal exposure – professionals

There are no separate scenarios calculated for secondary exposure of bystanders. The exposure of bystanders is considered covered by the primary exposure scenarios. Scenarios acceptable for primary exposure will also be acceptable for secondary exposure of bystanders.

Conclusion (PT4)
Based on the results obtained from the quantitative exposure (application and post-application) of professional users and the risk assessment, exposure of professional users in the intended uses (PT4 hard surface disinfection) results in no unacceptable risk when a product with 0.02% active chlorine is used.

Risk for non-professional users

The primary mode of action of active chlorine is characterised by local irritation/ corrosion and oxidation at the site of first contact triggered by direct chemical reactivity without prior metabolism. Active chlorine does not become systemically available upon dermal contact, ingestion or inhalation (i.e. estimated uptake in table below is not relevant). Consequently, only a local exposure and risk assessment was performed for all relevant routes of exposure (i.e. dermal, inhalation) which is considered to also cover the risk resulting from potential systemic effects.

Systemic effects

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
All scenarios PT1 and PT2		n.r.	n.r.	n.r.	n.r.

Local effects

Intended use	**Task**	**Oral Exposure (active chlorine)**	**Oral Exposure as % ofNOAEC oral**	**Dermal Exposure (active chlorine) [1]**	**Dermal Exposure as % ofNOAEC dermal**	**Inhalation Exposure (mg active chlorine / m³)**	**Inhalation Exposure as % of AECinhal**	**Acceptable**
Scenario 1.6 Hand disinfectant – non-professionals	Application	n.r.	n.r.	0.02%	2%	0.048 (10 appl/day)	10% (10 appl/day)	Yes
Scenario 2.3 Mopping /Wiping	Application	n.r.	n.r.	0.02%	2%	0.25	50%	Yes

– **Bathroom**								
Scenario 2.4 Wiping – **small room**	Application	n.r.	n.r.	0.02%	2%	0.13	26%	Yes
Scenario 2.7 PT2 - Hard surface disinfection	Post-application (disposal of treatment solution)	n.r.	n.r.	negligible	negligible	negligible	negligible	Yes
Scenario 1.9, PT1 – Hand rub Scenario 2.8 PT2 – Hard surface disinfection	Post-application (handling empty bottles)	n.r.	n.r.	negligible	negligible	negligible	negligible	Yes

[1] See Scenario 1.7 and 2.9 Dermal exposure

Conclusion
Based on the results obtained from the quantitative exposure (application and post-application) of non-professional users and the risk assessment, exposure of non-professional users in the intended uses results in no unacceptable risk.

Risk for the general public

The risk of the general public is considered to be covered by the risk assessment performed for the non-professional user of the product.

Risk for consumers via residues in food

Since active chlorine does not become systemically available upon dermal contact, ingestion or inhalation, residue formation is assumed to be negligible for aqueous solutions of NaOCl. The BPC TOX-WGII-2016 concluded that only chlorate is relevant for the dietary risk assessment. Chlorate exposure for both professionals and non-professionals was therefore considered for the scenarios below.

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use[1]**	**Description of scenario**	**Subject of exposure[2]**
4.1-4.2	PT4 Mopping, Wiping, soaking	Hard surfaces and cutting machines and other machines used for food are wiped, mopped or soaked in 50 ml disinfectant/m^2 for 5 -10 minutes, rinsed with water and let dry	Meat and other food stuff

Risk for exposure to chlorate

Since the products contains chlorate as a degradation product, exposure to chlorate can be expected when the general public come into contact with the product or surfaces that have been treated with the product.

For hand disinfectants (PT1) the only relevant risk is for infants and toddlers that tend to put their hands into the mouth or lick on them. The risk of exceeding the ADI is considered low, but since it cannot be excluded, a risk mitigation measure *"The product should not be used for hand disinfection of infants and toddlers (children below the age of 2 years)"*, should be added to the label of hand disinfection products.

For surface disinfection products (PT2) it can be concluded that the contribution from the use of the product to the total intake of chlorate from different sources probably is negligible or a least very low for adults. It is also unlikely that infants and toddlers will be exposed to amounts exceeding the ADI, but since it cannot be excluded a risk mitigation measure "Do not apply on objects or surfaces that infants and toddlers (children below 2 years of age) can put in their mouth or lick on." should be added to the label on all PT2-products for surface disinfection.

For the products intended for PT4 uses no systemic exposure to chlorate of the professional users is expected. The exposure of the general public is covered by the risk assessment made by EFSA on chlorate residues in food, and no further risk assessment is required. However, since the user instructions includes a recommendation to rinse the surface after disinfection and to let the surface dry before use, the amount of chlorate residues can be considered negligible.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

In water sodium hypochlorite (NaClO) hydrolyses to hypochlorous acid (HClO). Hypochlorous acid participates in the following equilibrium with chlorine. The ratio of Cl2/HClO/ClO– is pH and temperature dependent. Since the pH in SoftOx disinfection solution is 4.3, literally all added sodium hypochlorite will be present as hypochlorous acid (se figure below). Acid and sodium hydroxide are only used to regulate and adjust the pH to 4.3. They will react and form sodium acetate, i.e. no risk characterisation from combined exposure is needed.

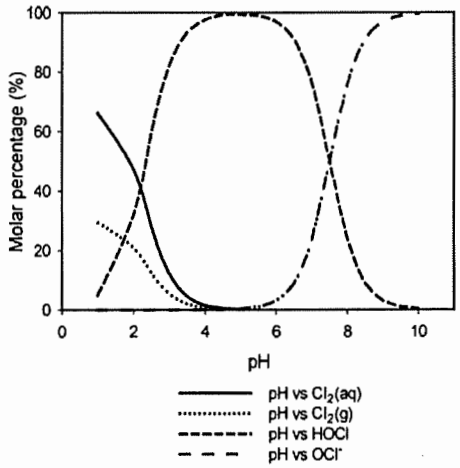


Figure 1. The chlorine species (Cl2, HOCl, Ocl-) as a function of pH

2.2.7 Risk assessment for animal health

No risk to animal health is expected, due to the use of the product, hand disinfection (PT1) hard surface disinfection (PT2) and disinfection of large surfaces that come into contact with food and feed, like restaurants and food and feed industry (PT4).

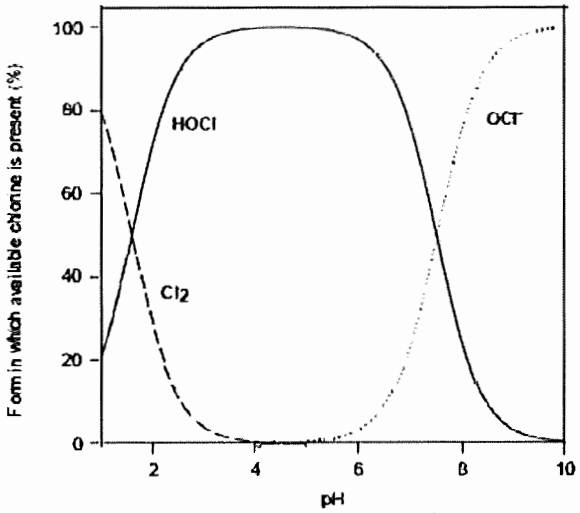
2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

No new studies have been submitted for this product authorisation.
The product contains the active substance at a maximum concentration of 0.02% at pH 4.3 as compared to the concentrations of the two theoretical products in the Euro Chlor active substance authorisation (CAR) of 5% respectively 14% at pH 4 to 5.

As the concentrations of the active substance is approximately more than two orders of magnitude lower (700 times lower) compared to the theoretical products and has a pH within the same range as for the theoretical products it is suggested that the ecotoxicological data from the active substance authorisation applies to the submitted product. Ecotoxicological data is therefore summarized from the CAR in the text below.

According to the CAR, the active substance released from hypochlorous acid in water is active chlorine. The hypochlorous acid (HClO) is in equilibrium with hypochlorite anion (ClO^-) and chlorine. The equilibrium depends on the pH value: chlorine is available below pH 4, in the neutral pH range hypochlorous acid is the predominant species, and at pH values higher than 10, the only species present is the hypochlorite ion.



The sum of these species (hypochlorite ion + hypochlorous acid + chlorine) is defined as active chlorine or available chlorine. For the chemical reactivity in aqueous solution with the same active chlorine concentrations and the same pH conditions, it is irrelevant whether active chlorine is generated from either chlorine gas, calcium hypochlorite or hypochlorous acid. Therefore, all studies investigating hypochlorite aqueous solutions can be used for evaluation and assessment of active chlorine released from any of the three substances.

The intended uses of the SoftOx products are all indoors and thus the only route for the products to reach the environment is basically via sewage treatment plants.

Active chlorine is highly reactive in contact with organic material and the substance therefore has a short half-life in the environment. In the CAR, the estimated half-lives (DT50) of hypochlorite were used in the exposure assessment to consider its degradation in relevant compartments. The DT50 values were transferred to an environmental temperature of 12°C using the Arrhenius equation:

$$DT_{50}\ (X°C) = DT_{50}\ (t)\ e^{(0.08\ (T-X))}$$

Table1. Estimated half-lives of hypochlorite in the environment according to the CAR

	Sewer system Due to similar high content of organic substance, also transferable to the aeration tank of the STP	*Surface water/ Sediment*	*Soil*	*Air*
DT_{50} of hypochlorite measured in tests	20 sec (*)	20 min (*)	20 sec (*)	114.6 days
DT_{50} of hypochlorite transferred to an environmental temperature of 12°C (by Arrhenius)	56 sec	56 min'	56 sec	-

Reference	Vandepitte and Schowanek (1997), Doc. No. 989-003 Doc. IIIA, Section A7.1.2	Worst case assumption, based on the kinetic model of Vandepitte and Schowanek (1997), Doc. IIIA, Sec. A7.1.2, assuming slower degradat ion due to lower content of Corg in surface water and sediment when compared to raw sewer.	Worst case assumption, based on the kinetic model of Vandepitte and Schowanek { 1997), Doc. IIIA, Sec. A7.1.2, assuming slower degradation due to lower content of Corg in soil when compared to raw sewer.	Garg, J, Glockner, T (2007), Sec. A7.3.1

* No temperature was indicated; a temperature of 25°C was assumed as worst case

According to the CAR, the photolysis half-life of aqueous chlorine in clear sky, summer noon sunlit (47°N) water of pH 8 is 12 min when measured at the surface. It increases with decreasing pH due to the decreasing ratio of ClO^-/HClO to 37 min at pH 7 and to 60 min at pH 5.

Not considered in the CAR-report, a more in-depth study of the hypochlorous acid oxidation reaction with organic compounds with different functional moieties (e.g., phenols[2], amino acids[3], halides[4], thiocyanates[5], and amines[6]) as well as with inorganic compounds such as NO_2, H_2S, SO_3^{2-}, Fe(II), Mn (II) etc., have shown that the reactions may proceed slightly differently depending on substrate (either via direct oxidation or via formation of different radical species such as ClO•), but all these oxidation reactions are extremely fast and in a majority of cases following first order or pseudo- second order kinetics[7].

Furthermore, hypochlorous acid is a strong oxidation agent with a redox potential of 1.49 Volts compared to ozone that has a redox potential of ca 2.07 Volts[8] . Hypochlorous acid oxidation proceeds very fast for most substrates. For example, the oxidation of thiols with hypochlorous acid to mercaptocarbonylic compounds, proceeds via a radical–radical coupling reaction with an overall kinetic constant of > 10^7 $M^{-1}*s^{-1}$ (Folkes et al., 1995).

Also the oxidation and thus cleavage of proteins with hypochlorous acid is very fast albeit

2 Gallard H and von Gunten U, *Chlorination of Phenols: Kinetics and Formation of Chloroform* Environ. Sci. Technol. 2002, 36, 5, 884–890

3 Folkes, L K, Candeias, L P, Wardman, P. *Kinetics and mechanisms of hypochlorous acid reactions.* Arch. Biochem. Biophys. Vol.,323:120–126; 1995

4 Kumar K and Margerum D, *Kinetics and mechanism of general-acid assisted oxidation of bromide by hypochlorite and hypochlorous acid*, 1987, Inorganic Chemistry, Vol. 26 (16), 2707-2711.

5 Ashby M T, Carlson A C, Scott J M, *Redox Buffering of Hypochlorous Acid by Thiocyanate in Physiologic Fluids*, 2004, J Am Chem Soc., Vol. 26(49):15976-15977.

6 Abia L, Armesto X L, Canle M L, García M V, Santaballa J A, *Oxidation of aliphatic amines by aqueous chlorine*, 1998, Tetrahedron, Vol. 54, Issues 3–4, 15, 521-530.

7 Villamena F A, in *Reactive Species Detection in Biology. From Fluorescence to Electron Paramagnetic Resonance Spectroscopy*, ISBN 978-0-12-420017-3, 2015

8 WHO, 2000, Disinfectants and Disinfectant by-products. ISBN 92 4 157216 7.

the fact that different amino acid moieties are oxidized according to varying kinetics[9]. With cysteine and methionine amino acid residues, the oxidation reactions proceed very fast with measured kinetic constants of $3.0 \cdot 10^7$-$3.8 \cdot 10^7$ $M^{-1}s^{-1}$ while the oxidation reactions with histidine- and lysine amino acid residues proceed with kinetic constants varying between $1 \cdot 10^5$ – $5 \cdot 10^3$ $M^{-1}s^{-1}$.

Predicted No-Effect Concentrations (PNECs)

No new studies have been submitted for the product assessment. In the CAR report, NOEC values were established for fish, invertebrates (molluscs) and algae. From available NOEC dataset in the CAR report, the lowest endpoint was derived from algae with a NOEC = 2.1 µg FAC/L, which was selected as reference value for the risk assessment.

Aquatic compartment

According to the CAR, an Assessment Factor (AF) of 50 has been used for the deduction of the aquatic PNEC. The use of an AF of 50 is justified according to the TGD, when two long-term NOECs from fresh- or saltwater species representing two trophic levels and one long-term NOEC from an additional marine taxonomic group (molluscs) are available.

$PNEC_{aquatic}$ = 2,1 µg FAC/L : 50 = **0,042 µg FAC/L**

Sediment
In the CAR, the **$PNEC_{sediment}$** was calculated to be **0.045 µg FAC/kg ww** on the basis of the PNECaquatic, using the equilibrium partitioning method according to the TGD.

Microbial activity in STP
The lowest available EC50 and NOEC value for micro-organisms in the activated sludge is 77.1 mg available chlorine/L and 41.1 mg available chlorine/L, respectively. The WGII2016 agreed that the $PNEC_{STP}$ should be derived after the application of an AF 10 to the NOEC (or EC10).

This results in a **$PNEC_{STP}$ of 4.11 mg available chlorine/L.** The fate of HClO and ClO^- in the environment, in the sewer and during sewage treatment is modelled by Vandepitte and Schowanek and is estimated to drop down to "zero" within a few minutes after release into the sewer, according to the CAR.

Atmosphere
The CAR indicates that at environmental pH values (6.5-8.5) half of the active chlorine is in the un-dissociated form of hypochlorous acid and half is dissociated to the hypochlorite anion. Only the hypochlorous acid fraction is volatile. The measured Henry's Law constant for hypochlorous acid of 0.11 Pa m³ mol-1 indicates that concentration in air is very low.

9 Pattison D I and Davies M J, *Absolute Rate Constants for the Reaction of Hypochlorous Acid with Protein Side Chains and Peptide Bonds*, 2001, Chem. Res. Toxicol. Vol. 14(10), 1453–1464.

Furthermore, the CAR also indicates that as the concentration of chlorine gas in water is low at environmentally relevant pH, thus the amount of chlorine that could volatilise from water into air compartment is expected to be very low. Consequently, air is not considered an environmental compartment of concern and hence further elaboration on the air compartment is waived.

Terrestrial compartment

The use pattern of the product emphasises that soil is only being exposed to the active substance in the product via the STP pathway by the application of sewage sludge. According to the CAR the active chlorine is highly reactive and reacts rapidly with organic matter in the sewer systems, in the STP. The fast chemical transformations of active chlorine in these systems results in PEC_{soil} values which are very low indicating that the emission to soil can be regarded to be negligible.

A $PNEC_{soil}$ was presented in the CAR using the equilibrium partitioning method based on the $PNEC_{aquatic}$ according to the TGD. The **$PNEC_{soil}$** was calculated to **0.015 µg FAC/kg ww.**

Overview of PNECs in relevant environmental compartements

Due to the instability and highly reactive nature of hypochlorite it will disappear very rapidly in the first receiving compartment, and further distribution of the active substance in the environment will be negligible.

PNEC	CAR PT1-5 (2017)	Unit
Surface water	4,2E-05	mg FAC/L
Sediment (surface water)	4,5E-05	mg FAC/ kg ww
STP micro-organism	4,1E+00	mg available chlorine/L
Soil (terrestrial)	1,5E-05	mg FAC/kg ww

Further Ecotoxicological studies

Not needed

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

Not needed

Supervised trials to assess risks to non-target organisms under field conditions

N/A

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

N/A

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Not relevant

Foreseeable routes of entry into the environment on the basis of the use envisaged

See section Fate and distribution in exposed environmental compartments.

Further studies on fate and behaviour in the environment (ADS)

Not needed

Leaching behaviour (ADS)

Not relevant

Testing for distribution and dissipation in soil (ADS)

Data waiving	
Information requirement	Not relevant
Justification	Distribution in the soil compartment is not considered relevant due to the rapid chemical reactions of the active substance with organic matter and the vast abundance of available organic carbon in the soil compartment. Since the dissipation rate (DT_{50}) of hypochlorous acid in soil, according to the CAR, has been calculated to be approx. 56 seconds at 12 °C, further elaboration on distribution and dissipation in the soil matrix is waived.

Testing for distribution and dissipation in water and sediment (ADS)

Data waiving

Information requirement	Not relevant
Justification	Distribution in both freshwater and marine water compartments is not considered relevant due to the rapid chemical transformations of the active substance in the first receiving compartment, STP. Distribution of hypochlorite/hypochloric acid to the sediment compartment is highly unlikely and can be waived. According to the CAR, no distribution in the sediments is expected.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	Not relevant
Justification	According to the CAR, half of the active chlorine is in the un-dissociated form of hypochlorous acid and half is dissociated to the hypochlorite anion at environmental pH values (6.5-8.5). Only the hypochlorous acid fraction is volatile. The measured Henry's Law constant for hypochlorous acid of 0.11 $Pa \cdot m^3 mol^{-1}$ indicates that concentration in air is very low. Consequently, air is not an environmental compartment of concern. However, hypochlorite may release chlorine (Cl_2) when accidentally mixed with strong acids, at pH 1-2, which is not considered relevant for this emission assessment.

If the biocidal product is to be sprayed near to surface waters, then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not relevant

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given, then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not relevant

2.2.8.2 Exposure assessment

General information

With regard to the different SoftOx product types where hypochlorous acid (active chlorine) is used as active substance, an overall waiver regarding the environmental exposure assessment has been compiled. According to the BPC ENV WG-I-2020 on the relevance of performing a quantitative risk assessment - for active chlorine released from hypochlorous acid; it was agreed that for releases via STP and direct release to soil a qualitative assessment for the active substance is sufficient due to the high reactivity with organic matter. Uses resulting in a direct release to surface water however should be assessed quantitatively.

Active chlore is highly reactive and a range of byproducts may be formed when released to the environment. However, according to the BPC ENV WG-I-2020 on the Disinfectant-by-product assessment it was agreed that for the time being the information provided by the applicants in their dossiers on DBPs of all ongoing authorisation applications should be only summarized and no conclusion should be drawn referring to the current lack of guidance.

Emission estimation

Given the conclusion of the BPC ENV WG-I-2020 mentioned above, no emission estimations were determined for the SoftOx products.

The following overview describes the foreseeable first environmental receiving compartments related to the intended uses of the SoftOx products.

Overview of intended uses of SoftOx and first environmental receiving compartment

PT	Intended use description	Indoor/ outdoor use	First receiving compartment
1	Hand disinfection	indoor	STP
2	Hard surface disinfection	indoor	STP
4	Hard surface disinfection when contact with food or feed – professional use	indoor	STP

PT 1 products

For the PT 1 products, the first environmental compartment to receive superfluous biocidal product will be the municipal STP. Huge surplus of organic carbon in the piping and the STP sewer system, will reduce the concentrations of hypochlorite/hypochloric acid

instantaneously. This is in line with the agreement in the BPC ENV WG-I-2020 that considered active chlorine released from sodium/calcium hypochlorite as highly reactive and posing no environmental risk because of a negligible release to the environment when released via STPs.

PT 2 and PT 4 products

For PT 2 and PT 4 products, the first environmental compartment to receive superfluous biocidal product will be the municipal STP. As above, a negligible release to the environment is assumed when released via STP.

Fate and distribution in exposed environmental compartments

The fate and distribution of the active substance in the environment is concisely described in the CAR indicating that active chlorine acts as a highly reactive oxidizing agent that reacts rapidly with organic matter in the sewer, STP, surface water and soil with most (≈ 99%) of the active chlorine converted to inorganic chloride.

The CAR indicates that according to the kinetic model of Vandepitte and Schowanek (1997), hypochlorite is eliminated during transport in the sewer within the first minutes. The same model is also applicable to the soil. According to the CAR, the ultimate fate of hypochlorite in soil is a reduction to chloride via a quick (order of seconds) reduction of HClO due to the high content of organic matter in soil.

Estimated half-lives of hypochlorite in the environment

The DT_{50} values were transferred to an environmental temperature of 12°C using the Arrhenius equation:

$$\mathbf{DT_{50}\ (X°C) = DT_{50}\ (t) \cdot e^{(0.08 \cdot (T-X))}}$$

Compartment	DT50 of hypochlorite measured in tests	DT50 of hypochlorite transferred to an environmental temperature of 12°C (using the Arrhenius equation)	Reference
Sewer system Due to similar high content of organic substance, also transferable to the STP	20 sec (*)	54 sec	Vandepitte and Schowanek (1997), Doc. No. 989-003 Doc. IIIA, Section A7.1.2
Soil	20 min (*)	54 min	Worst case assumption, based on the kinetic model of Vandepitte and Schowanek (1997), Doc. No. 989-003 Doc. IIIA, Section A7.1.2, assuming

Compartment	DT50 of hypochlorite measured in tests	DT50 of hypochlorite transferred to an environmental temperature of 12°C (using the Arrhenius equation)	Reference
			slower degradation due to lower content of Corg in soil when compared to raw sewer

According to the ESD on the general exposure pathways for the PT1, PT2 and PT4 the relevant receiving compartments can be described as identified in the table below. The first receiving compartment being the STP. Due to the rapid reactions of the active substance in the first receiving compartment further distribution to the environment is considered to be negligible.

Identification of relevant receiving compartments based on the exposure pathway

	Fresh-water	Fresh-water sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water
PT1								
Use 1: Hand disinfection - professionals	Negligible	Negligible	No	No	Yes	No	Negligible	Negligible
Use 2: Hand disinfection - non-professionals	Negligible	Negligible	No	No	Yes	No	Negligible	Negligible
PT2								
Use 3: Hard surface disinfection for professionals including health care professionals (0,02 %)	Negligible	Negligible	No	No	Yes	No	Negligible	Negligible
Use 4: Hard surface disinfection - non-professionals	Negligible	Negligible	No	No	Yes	No	Negligible	Negligible
Use 5: Disinfection of large surfaces that come into contact with food and feed - Professional	Negligible	Negligible	No	No	Yes	No	Negligible	Negligible

Primary and secondary poisoning

The active substance, according to the CAR, reacts rapidly with organic matter in the sewer, STP, soil and surface water. For this reason, primary poisoning is not considered relevant.

According to the CAR, active chlorine does not bioaccumulate or bioconcentrate due to its high water solubility and high reactivity. The low accumulation potential is supported by low BCF for fish and earthworms determined by EUSES 2.1.2. The bioconcentration factor for fish is 1.41 l/kg. The bioconcentration factor for earthworms is 0.841 l/kg. No further assessment of secondary exposure via the food chain is therefore considered necessary.

2.2.8.3 Risk characterisation

Atmosphere

Conclusion:

As mentioned before, air is not considered an environmental compartment of concern.

The CAR indicates that at environmental pH values (6.5-8.5) half of the active chlorine is in the un-dissociated form of hypochlorous acid and half is dissociated to the hypochlorite anion. Only the hypochlorous acid fraction is volatile. The measured Henry's Law constant for hypochlorous acid of 0.11 Pa m^3 mol^{-1} indicates that concentration in air is very low.

Furthermore, the CAR also indicates that as the concentration of chlorine gas in water is low at environmentally relevant pH, thus the amount of chlorine that could volatilise from water into air compartment is expected to be very low.

Aquatic compartment

Conclusion:

At the BPC ENV WG-I-2020 meeting, it was agreed that for releases via STP and direct release to soil a qualitative assessment for the active substance is sufficient due to the high reactivity with organic matter. Uses resulting in a direct release to surface water however should be assessed quantitatively.

There are no direct releases to surface water. The uses of the SoftOx products result in releases to STP, where the active substance will react rapidly with organic matter and almost completely be converted to inorganic chloride within the first minutes. Distribution to the terrestrial environment due to the application of sewage sludge to agricultural soil is considered to be negligible. Environmental transport of the active substance from soil to the aquatic compartment is therefore not likely.

Terrestrial compartment

Conclusion:

At the BPC ENV WG-I-2020 meeting, it was agreed that for releases via STP and direct release to soil a qualitative assessment for the active substance is sufficient due to the high reactivity with organic matter.

The uses of the SoftOx products result in releases to STP, where the active substance will react rapidly with organic matter and almost completely be converted to inorganic chloride within the first minutes. Further distribution to the terrestrial environment due to the application of sewage sludge to agricultural soil is therefore considered to be negligible.

Groundwater

Conclusion:

There are no direct releases to groundwater, and the distribution to ground water via soil due to the application of sewage sludge to agricultural soil is considered to be negligible. For this reason, environmental transport to the groundwater compartment is waived from further investigation.

Primary and secondary poisoning

Conclusion:

The active substance, according to the CAR, reacts rapidly with organic matter in the sewer, STP, soil and surface water. For this reason, primary poisoning is not considered relevant. Due to low bioaccumulation potential secondary exposure is not expected.

Mixture toxicity

No mixture toxicity is expected.

Aggregated exposure (combined for relevant emmission sources)

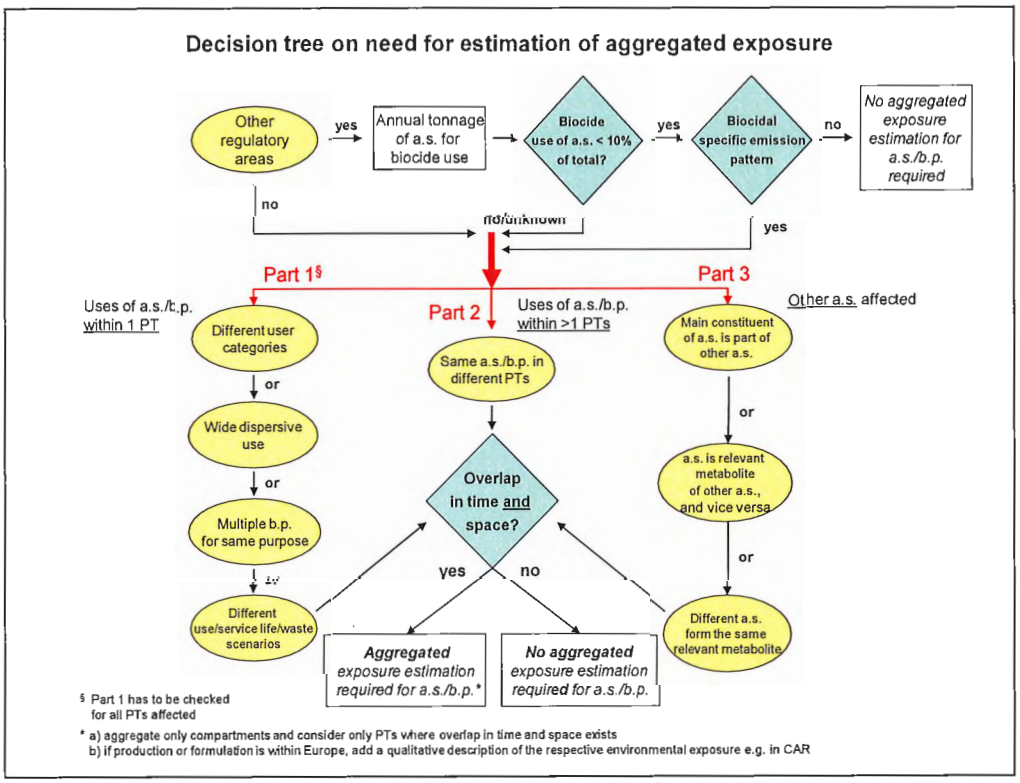


Figure 1: Decision tree on the need for estimation of aggregated exposure

Conclusion:

No aggregated exposure posing risk to the environment is expected.

Overall conclusion on the risk assessment for the environment of the product

Due to the highly reactive nature of the active substance, active chlorine, it is not foreseen that the use of SoftOx disinfectants will pose a risk to the environment.

Active chlorine is highly reactive and oxidative and will degrade rapidly during the transport to all predicted recipients due to the high content of organic matter in the waste water. The release of the active substance to secondary compartments is therefore considered to be negligible.

Active chlore is highly reactive and a range of byproducts may be formed when released to the environment. But the byproducts of active chlorine formed in the environment have not been assessed due to the current lack of guidance. This is in accordance with the agreement for disinfectants by products in the BPC Working Group for Environment meeting held in January this year (WG-I-2020).

2.2.9 Measures to protect man, animals and the environment

None required

3 ANNEXES

3.1 List of studies for the biocidal product family

90	Author (s)	Year	File name, Title. Source (where differnt from 'company), Company, Report no. GLP (where relevant)/ (un)published	Data protection claimed (Y/N)	Report number	Owner
2.2.2	Michael Wamberg	2015	1 Certificate for Light Treatment of Samples_DB Lab_31082015, DBLab, Report no 21275,01	Y	1	SoftOx Solutions AS
2.2.2	Hanne Haslene-Hox Anne Hatletveit, Wilhelm Glomm	2018	2 Surface-tension_report_signed 19122018 GUT, Surface tension measurements of SoftOx Solutions, SINTEF, report no 2018:01408	Y	2	SoftOx Solutions AS
2.2.2	Camilla Fredriksen Ragnhild Myrvoll	2019	4 Density_report_Signed_21012019 GUT, Density SOFTOX disinfection, ALS Scandinavia, report no N1821808	Y	4	SoftOx Solutions AS
2.2.2	Geir Utigard	2021	5 Statement compatibility of biocidalproduct and packaging, Statement regarding the compatibility of biocide formulations SOF-200-0,25 and SOF-450-1,0 with packaging material, SoftOx Solutions ASDate: 20210215	Y	5	SoftOx Solutions AS
2.2.2	Stefan Andersson	2021	Analysis report 11601/00060434.2/L/21, Saybolt Sweden, Andersson S, 2021-02-19, Flashpoint analysis softox 1 and 2	Y	9	SoftOx Solutions AS
2.2.3	Anne Aasprong	2018	10 PD 18-028 Verification and Validation Plan and Report v02, Verification and Validation Plan and Report SoftOx Solutions AS, Document no PD 18-028	Y	10	SoftOx Solutions AS
2.2.3		2018	11 Evaluation of oxidising capacity of the SoftOx biocide product family	Y	11	SoftOx Solutions AS
2.2.2	Leena Andersson	2019	Viscosity_report_signed_SafeDes_Effect-vet_19022019, Bestämning av viskositet, RISE, report nr 9P004625	Y	12	SoftOx Solutions AS
2.2.3	Mona Kirksaether, Jan Aksel	2020	13 KIWA korrosjonstest 033230 Rev. A (1), Test of liquids for corrosion to metals, Kiwa Teknologisk Institutt as, Report no 3000-20-033230 Rev. A	Y	13	SoftOx Solutions AS
2.2.2	Cecilie Christensen	2019	14 Apperance SOF-160-0,25 & SOF-450-1_7 mnd testpoint, Certificate of analysis 2019-08-01, Internal number D002743-01, DB lab, Batch SOF0001779	Y	14	SoftOx Solutions AS

2.2.3	Ingemo Andersson, Louise Persson and Stefan Ulvenlund	2017	15 Report_P1682_validation of analytical method_final, Technical validation of a spectrophotometric assay method for HOCl and OCl-, CR Competence AB, Report no P1682	Y	15	SoftOx Solutions AS
2.2.2	Stine Tryggedsson	2018	16 Stability study DBlab 318009_318011_318019 24 mth_5 and 25 degr (1) "Certificate of analysis – Stability study at 25 oC and 60 % RH, as well as at 5 °C, report batch 318009, DB-lab, int. Reg. No 26648,04"	Y	16	SoftOx Solutions AS
2.2.2	Geir Utigard	2021	25 Routine for incoming control NaOCl raw material_signed GUT, Procedure for incoming control of 15 % sodium hypochloite raw material. Date; 22.04.2021	Y	25	SoftOx Solutions AS
2.2.2	Geir Utigard	2020	27 PD20-048 Report from long term stability testing of batch SOF001031 at ambient temperature (25 degrees), Report from long term stability testing of batch SOF001031 Long term storage at ambient temperature (25 degrees), batch SOF001031, SoftOx Solutions AS, Doc. No. PD20-048	Y	27	SoftOx Solutions AS
2.2.2	Geir Utigard	2020	30 PD 20-050 Report from stability testing. Report from stability testing of batch SOF003_83 Short term storage at accelerated temperature (54 degrees), batch SOF003_69, SoftOx Solutions AS, Doc id. PD 20-050	Y	30	SoftOx Solutions AS
2.2.2	Anna Nordborg Cathrine Løvmo, Trude Guldberg, Charlotte Wedø, Hanne Haslene Hox	2020	31 SINTEF No 2020-00300 Stability Study - Analysis of SoftOx Samples, "Stability study of SoftOx solutions of varied composition (acetic acid and hypochloric acid concentration) and pH Stability of solutions stored in refrigerator, at room temperature, and at elevated temperature assessed by UV-measurements, pH determinations and ion chromatography (IC) analysis"., SINTEF, Report no: 2020: 00300, project no 102018130	Y	31	SoftOx Solutions AS
2.2.3	Andreas Woldegiorgis	2020	38 Erratum regarding the reported concentrations of hypochlorite anion in biocidal product family stability studies, Intersolia Sweden AB	Y	38	SoftOx Solutions AS

2.2.3	Louise Persson, Martin Lindsjö, Anna Stenstam	2020	39 Memo HOCl assay_20120, Statement regarding HOCl spectroscopic assay method, developed in project P1682, CR Competence AB	Y	39	SoftOx Solutions AS
2.2.5.6	Rie Jønsson Lasse Kvich	2018	41 Softox 180518 Minimum inhibitory concentration and resistance development, Biofilm Test Facility, University of Copenhagen	Y	41	SoftOx Solutions AS
2.2.5.5	Piotr Grudzinski	2014	42 Soft Ox 0-en 1276-dz-16-07-15, Evaluation of activity in suspension test according to PN-EN 1276:2010+AC:2010, LAB-TEST LABORATORIUM, Report no DZ/16/07/15	Y	42	SoftOx Solutions AS
2.2.5.5	Piotr Grudzinski	2020	43 Safedes hand-EN 1500-dz-77-04-20 (1), Evaluation of activity in suspension test according to PN-EN 1500:2013-07 'Hygienic handrub', LAB-TEST LABORATORIUM, Report no. DZ/77/04/20	Y	43	SoftOx Solutions AS
2.2.5.5	Piotr Grudzinski	2020	51 EN13624- DZ-21-01-20, Evaluation of activity according to PN-EN 13624:2013-12, LAB-TEST LABORATORIUM, Report no. DZ/21/01/20	Y	51	SoftOx Solutions AS
2.2.5.5	Piotr Grudzinski	2020	53 soft ox antivir -en 13697-dz-66-10-20, Evaluation of activity in the nonporous surfaces test according to PN-EN 13697+A1:2019-08, LAB-TEST LABORATORIUM, Report no. DZ/66/10/20	Y	53	SoftOx Solutions AS
2.2.5.5	Piotr Grudzinski	2020	54 soft ox -en 13697-dz-38-04-20, Evaluation of activity in the nonporous surfaces test according to PN-EN 13697+A1:2019-08, LAB-TEST LABORATORIUM, Report no. DZ/38/04/20	Y	54	SoftOx Solutions AS
2.2.5.5	Piotr Grudzinski	2020	56 Soft Ox -en 13704 -dz-78-05-20 (2), Evaluation of activity in suspension test according to PN-EN 13704:2018-09 (modified), LAB-TEST LABORATORIUM, Report no. DZ/78/05/20	Y	56	SoftOx Solutions AS
2.2.5.5	Piotr Grudzinski	2020	57 EN13727 DZ-20-01-20, Evaluation of activity according to 13727+A12:2015-12, LAB-TEST LABORATORIUM, Report no. DZ/20/01/20	Y	57	SoftOx Solutions AS
2.2.5.5		2020	60 SoftOx SafeDes Hand disinfection L20-0038A-2 Adeno test report EN 14476 clean 03.04.2020, Evaluation of the effectiveness of SafeDes Hand disinfection, Dr. Brill+Dr. Steinmann, Test report L20/0038A.2	Y	60	SoftOx Solutions AS
2.2.5.5		2020	61 SoftOx SafeDes Hand disinfection L20-0038A-1 Adeno Screening EN 14476 14.02.2020, Dr. Brill+Dr. Steinmann	Y	61	SoftOx Solutions AS
2.2.5.5		2020	62 SoftOx SafeDes Hand disinfection L20-0038M-3 MNV test report EN 14476 clean 24.03.2020, Evaluation of the effectiveness	Y	62	SoftOx Solutions AS

			of SafeDes Hand disinfection, Dr. Brill+Dr. Steinmann, Test report L20/0038M.3			
2.2.5.5		2020	63 SoftOx SafeDes Hand disinfection L20-0038MV-2 MVA test report EN 14476 clean 09.04.2020, Evaluation of the effectiveness of SafeDes Hand disinfection, Dr. Brill+Dr. Steinmann, Test report L20/0038MV.2	Y	63	SoftOx Solutions AS
2.2.5.5		2020	65 SoftOx SafeDes Hand disinfection L20-0038MV-2 MVA expert opinion EN 14476 clean 09.04.2020. Expert opinion, Dr. Brill+Dr. Steinmann	Y	65	SoftOx Solutions AS
2.2.5.5		2020	66 SoftOx SafeDes Virus Protection L20-0105M-1 MNV Screening EN 14476 17.02.2020, Dr. Brill+Dr. Steinmann	Y	66	SoftOx Solutions AS
2.2.5.5		2021	67 SoftOx Antivir Myco EN-14348-2005-L20-1403-2 engl, V01 (1), Expert opinion, Dr. Brill+Dr. Steinmann	Y	67	SoftOx Solutions AS
2.2.5.5		2020	68 SoftOx SafeDes Hand disinfection L20-0038Po-3 Polio test report EN 14476 clean 24.03.2020, Evaluation of the effectiveness of SafeDes Hand disinfection, Dr. Brill+Dr. Steinmann, L20/0038Po.3	Y	68	SoftOx Solutions AS
2.2.5.5		2020	69 SoftOx SafeDes Virus Protection L20-0105Po-1 Polio Screening EN 14476 17.02.2020, Dr. Brill+Dr. Steinmann	Y	69	SoftOx Solutions AS
2.2.5.5	Piotr Grudzinski	2020	72 EN 16615 safedes hand-surface HOCl 0,2g-kg -70-04-20 (1), Evaluation of activity according to PN-EN 16615:2015-06, LAB-TEST LABORATORIUM, Report no. DZ/70/04/20	Y	72	SoftOx Solutions AS
2.2.5.5	Piotr Grudzinski	2020	73 Soft Ox -en 17126 -dz-79-05-20 (1), Evaluation of activity in suspension test according to PN-EN 17126:2019-01, LAB-TEST LABORATORIUM, Report no. DZ/79/05/20	Y	73	SoftOx Solutions AS
2.2.6.1, Summary table of animal studies on skin sensitisation, Summary table of animal studies on skin corrosion /irritation	Morten Bendix	2018	75 Local Lymph Node Assay, SoftOx Wound Rinse Solution (SOF 0001/07-01) Local Lymph Node Assay in Mice, citoxlab, Study no 78203, GLP	Y	75	SoftOx Solutions AS
2.2.6.1, Summary table of animal studies on acute dermal toxicity	Susi Søgaard	2018	76 78197 Final Report 22 day wound healing study in minipigs, SoftOx Wound Irrigation Solution, A 22-Day Wound Healing Study in Minipigs, citoxlab, Study no 78197, GLP	Y	76	SoftOx Solutions AS

2.2.6.1, Summary table of human data on skin corrosion irritation	Yasemin Topal Yüksel, Tove Agner		77 Report - Study 2a- Irritant properties of SoftOx disinfection solution on healthy skin, Report assessing the irritant properties of SoftOx disinfection solution, Depart. of Dermatology, Bispebjerg Hospital, University of Copenhagen,	Y	77	SoftOx Solutions AS
2.2.6.1, Summary table of in vitro studies on cytotoxicity,	Ane Marit Wågbø Geir Klinkenberg Hanne Haslene-Hox	2020	78 SoftOx_cytotox_report_SINTEF_02_2020, In vitro cytotoxicity assessment of SoftOx formulations, SINTF, Report no 2020:00222	Y	78	SoftOx Solutions AS
Tox, Summary table of human data on skin corrosion irritation	Glenn Gundersen, Elin Ibstedt, Ewa Anna Burian	2019	79 PD 19-042_CIR_SWIS-01_v01_15 Nov 2019, Clinical Investigation Report (CIR) SWIS-01, SoftOx Solutions AS, Doc id. PD 19-042	Y	79	SoftOx Solutions AS
Table 2.2.2 Phys-Chem properties	Norlab SINTEF	2021	80 98940_report Norlab SINTEF (SOF001_079), analysis report from Norlab SINTEF	Y	80	SoftOx Solutions AS
Table 2.2.2 Phys-Chem properties	Pham A K	2021	81 Report from the long-term stability testing of batch SOF001/031", 2021-06-15.	Y	81	SoftOx Solutions AS
Table 2.2.2 Phys-Chem properties	ALS Global	2021	82 Attachment no. 01_PR2126394 (SOF001_079), analysis report ALS Global	Y	81	SoftOx Solutions AS
Table 2.2.2 Phys-Chem properties	Langseth Manrique K	2022	84_SOF 22-023 Long term storage stability study at ambient temperature of batch SOF004_077 " Long term storage stability study at ambient temperature of batch SOF004/077"	Y	84	SoftOx Solutions AS
Table 2.2.2 Phys-Chem properties	Østrem E, Nenseter B,	2021	85 102452_report, Norlab SINTEF-rapport. " Accelerated stability study - on products and raw material", 2021-06-30	Y	85	SoftOx Solutions AS
Table 2.2.2 Phys-Chem properties	Stine Tryggedsson	2019	DB-lab report "Certificate of analysis – Stability study at 40 °C and 75 % RH" 2018-11-07 (last page)	Y	86	SoftOx Solutions AS
Table 2.2.2 Phys-Chem properties	N/A		87 A20OVER-Chemical-Compatibility-for-Polyethylene-Items		87	

Table 2.2.2 Phys-Chem properties	N/A		88 ineos-hdpe-chemical-resistance-guide see page 4 suitable also for concentrated NaClO at 60 degC		88	
Table 2.2.2 Phys-Chem properties	N/A		89 orion-aw-chem_resistance see page 55		89	
Table 2.2.2 Phys-Chem properties	N/A		90 PET_ChemicalCompatibility see page 6		90	
Table 2.2.2 Phys-Chem properties	N/A		91 Polyethylene_Chemical_Resistance_Chart see page 5		91	
Table 2.2.4	ALS Global		92 PR20C3144_attachment 1 v2 BILAGA 1A		92	
Table 2.2.4	ALS Global		93 Calibration curves validation of ion chromatographic method for chlorate in typical SoftOx Solutions1935242713843		93	

3.2 Output tables from exposure assessment tools

The relevant information is included in Section 2.6

3.3 New information on the active substance

Not relevant

3.4 Residue behaviour

See information in *Methods för detection and identification*

3.5 Summaries of the efficacy studies

Product type 1

Use 1 Hand disinfection – Professionals (Composition: HOCl 0.02%; acid 0.25%)

Test 1: Bacteria (phase 2, step 1) - Required

The efficacy against the following bacterial strains have been tested in EN13727:2015-12 (Report: *EN13727- DZ-20-01-20):* Pseudomonas aeruginosa ATCC 15442, Staphylococcus aureus ATCC 6538, Enterococcus hirae ATCC 10541 and Escherichia coli K12 NCTC 10538
Test solution: Safe Des / Antibac Hand Disinfectant, containing HOCl 160 ppm, acid 0.25%.
Result: The product, batch: SOF003/045, tested according to EN 13727+A2:2015-12, at clean conditions (0.3 g/l bovine albumin), contact time [redacted] s, test temperature 20.0°C ± 0.6°C, diluted in distilled water is active (reduction [redacted]) against the four above mention bacteria at 76% v/v dilution. This EN efficacy test is passed with a formulation at lower concentration of HOCl and at lower concentration of acid than the biocidal product. The EN efficacy test therefore represent a worst case scenario compared to the biocidal product.

Test 2: Bacteria (phase 2, step 2) - Required

The efficacy against Escherichia coli K12 NCTC 10538 has been tested in the EN 1500:2013-07 (Report: safedes hand-EN 1500-dz-77-04-20)
Test solution: SOF0031111-01 disinfectant containing HOCl 160 ppm, acid 0.25%.
Result: The product, 3 ml applied on dry hands, [redacted] handrub, repeated, display bactericidal action (reduction [redacted]), is not significantly worse than the reference procedure with the level of significance at least 0.025.

Test 3: Yeast/ Fungal spores (phase 2, step 1) – Required/ Optional

The efficacy against Candida albicans ATCC 10231 and Aspergillus brasiliensis ATCC 16404 has been tested in EN 13624:2013-12 (Report: EN13624- DZ-21-01-20).
Test solution: Soft-Ox 0 disinfectant containing HOCl 160 ppm; acid 0.25%
Result: The product Soft-Ox 0, batch: SOF003/045, tested according to EN 13624:2013-12, at clean conditions (0.3 g/l bovine albumin), test temperature 20.0°C ± 1.0°C, diluted in distilled water is active (reduction [redacted]) against Candida albicans ATCC 10231 at 76 % v/v dilution, contact time [redacted] s and Aspergillus brasiliensis ATCC 16404 at 90% v/v dilution, contact time [redacted] and at 76% v/v dilution, contact time [redacted].

Test 4: Viruses (phase 2, step 1) – Optional

The efficacy against modified vaccinia virus Ankara (MVA) (Report: SoftOx SafeDes Hand disinfection L20-0038MV-2 MVA expert opinion EN 14476 clean Version 02 22.06.2020 (09.04.2020) and SoftOx SafeDes Hand disinfection L20-0038MV-2 MVA test report EN 14476 clean 09.04.2020.
Test solution: Batch SOF003/045, HOCl 160 ppm, acid 0.25%
Result: Based on EN 14476, the product SafeDes Hand desinfaction, when diluted at 80% (v/v), possesses viricidal activity (reduction [redacted]) in [redacted] at 20°C under clean conditions against modified vaccinia virus Ankara (MVA).

Use 2 Hand disinfection - Non-professionals (Composition: HOCl 0.02%; acid 0.25%)

Test 1: Bacteria (phase 2, step 1) - Required

The efficacy against the following bacterial strains have been tested in EN13727:2015-12 (Report: *EN13727- DZ-20-01-20):* Pseudomonas aeruginosa ATCC 15442, Staphylococcus aureus ATCC 6538, Enterococcus hirae ATCC 10541 and Escherichia coli K12 NCTC 10538
Test solution: Safe Des / Antibac Hand Disinfectant, containing HOCl 160 ppm, acid 0.25%.
Result: The product, batch: SOF003/045, tested according to EN 13727+A2:2015-12, at clean conditions (0.3 g/l bovine albumin), contact time [redacted] and [redacted] s, test temperature 20.0°C ± 0.6°C, diluted in distilled water is active (reduction 5 log) against the four above mention bacteria at 76% v/v dilution. This EN efficacy test is passed with a formulation at lower concentration of HOCl and at lower concentration of acid than the biocidal product. The EN efficacy test therefore represent a worst case scenario compared to the biocidal product.

Test 2: Bacteria (phase 2, step 2) - Required

The efficacy against Escherichia coli K12 NCTC 10538 has been tested in the EN 1500:2013-07 (Report: safedes hand-EN 1500-dz-77-04-20)
Test solution: SOF0031111-01 disinfectant containing HOCl 160 ppm, acid 0.25%.
Result: The product, 3 ml applied on dry hands, [redacted] s handrub, repeated, display bactericidal action (reduction >[redacted] log), is not significantly worse than the reference procedure with the level of significance at least 0.025.

Test 3: Yeast/ Fungal spores (phase 2, step 1) – Required/ Optional

The efficacy against Candida albicans ATCC 10231 and Aspergillus brasiliensis ATCC 16404 has been tested in EN 13624:2013-12 (Report: EN13624- DZ-21-01-20).
Test solution: Soft-Ox 0 disinfectant containing HOCl 160 ppm; acid 0.25%
Result: The product Soft-Ox 0, batch: SOF003/045, tested according to EN 13624:2013-12, at clean conditions (0.3 g/l bovine albumin), test temperature 20.0°C ± 1.0°C, diluted in distilled water is active (reduction [redacted] log) against Candida albicans ATCC 10231 at 76 % v/v dilution, contact time 30 s and 60 s and Aspergillus brasiliensis ATCC 16404 at 90% v/v dilution, contact time [redacted] and at 76% v/v dilution, contact time [redacted]

Test4: Viruses (phase 2, step 1) – Optional

The efficacy against modified vaccinia virus Ankara (MVA) (Report: SoftOx SafeDes Hand disinfection L20-0038MV-2 MVA expert opinion EN 14476 clean Version 02 22.06.2020 (09.04.2020) and SoftOx SafeDes Hand disinfection L20-0038MV-2 MVA test report EN 14476 clean 09.04.2020.
Test solution: Batch SOF003/045, HOCl 160 ppm, acid 0.25%
Result: Based on EN 14476, the product SafeDes Hand desinfaction, when diluted at 80% (v/v), possesses viricidal activity (reduction [redacted] log) in [redacted] sec at 20°C under clean conditions against modified vaccinia virus Ankara (MVA).

Product type 2

Use 3 Hard surface disinfection - Professionals including health care professionals
(Composition: HOCl 0.02%; 0.25%)

Test 1: Bacteria (phase 2, step 1) - Required

The efficacy against the following bacterial strains have been tested in EN13727:2015-12 (Report: *EN13727- DZ-20-01-20):* Pseudomonas aeruginosa ATCC 15442, Staphylococcus aureus ATCC 6538, Enterococcus hirae ATCC 10541 and Escherichia coli K12 NCTC 10538
Test solution: Safe Des / Antibac Hand Disinfectant, containing HOCl 160 ppm, acid 0.25%.
Result: The product, batch: SOF003/045, tested according to EN 13727+A2:2015-12, at clean conditions (0.3 g/l bovine albumin), contact time [redacted] s, test temperature 20.0°C ± 0.6°C, diluted in distilled water is active (reduction [redacted] log) against the four above mention bacteria at 76% v/v dilution. This EN efficacy test is passed with a formulation at lower concentration of HOCl and at lower concentration of acid than the biocidal product. The EN efficacy test therefore represent a worst-case scenario compared to the biocidal product.

Test 2: Bacteria (phase 2, step 1) - Required
The efficacy against the following bacterial strains have been tested in EN 1276:2010+AC:2010 (Report: Soft Ox 0-en 1276-dz-16-07-15): Pseudomonas aeruginosa ATCC 15442, Staphylococcus aureus ATCC 6538 Enterococcus hirae ATCC 10541, and Escherichia coli ATCC 10536
Test solution: Soft-Ox 0 disinfectant containing HOCl 160ppm, acid 0.13 %, batch 2014.10.70
Result: The product Soft-Ox 0 tested according to PN-EN 1276:2010+AC:2010 at clean conditions (0.3 g/l bovine albumin), contact time [redacted] min., test temperature 20.0°C ± 0.6°C, diluted in distilled water is active (reduction [redacted] log) against all the four above mention bacteria at 50%, 62.5 % and at 80% v/v dilutions.

Test 3: Yeast (phase 2, step 1) – Required
The efficacy against Candida albicans ATCC 10231 and Aspergillus brasiliensis ATCC 16404 has been tested in EN 13624:2013-12 (Report: EN13624- DZ-21-01-20).
Test solution: Soft-Ox 0 disinfectant containing HOCl 160 ppm; acid 0.25%.
Result: The product Soft-Ox 0, batch: SOF003/045, tested according to EN 13624:2013-12, at clean conditions (0.3 g/l bovine albumin), test temperature 20.0°C ± 1.0°C, diluted in distilled water is active (reduction [redacted] log) against Candida albicans ATCC 10231 at 76 % v/v dilution, contact time [redacted] s and Aspergillus brasiliensis ATCC 16404 at 90% v/v dilution, contact time [redacted] s and at 76% v/v dilution, contact time [redacted].

Test 4: Yeast (phase 2, step 2) – Required
The efficacy against Yeast Candica albicans have been tested in EN 13697: (Report: *soft ox -en 13697-dz-38-04-20):* Candida albicans ATCC 10231
Test solution: Safe Des hand-/Surface Disinfectant HOCl 200 ppm, acid 0.25%.
Result: The product, batch: SOF0031111-01, tested according to EN 13697, at clean conditions (0.3 g/l bovine albumin), contact time 5 mins, test temperature 20.0°C ± 1°C,

diluted in distilled water is active (reduction [redacted] log) against the above mentioned yeast at 100% and 80% v/v dilution.

Test 5: Viruses (phase 2, step 1) – Optional

The efficacy against modified vaccinia virus Ankara (MVA) (Report: SoftOx SafeDes Hand disinfection L20-0038MV-2 MVA expert opinion EN 14476 clean Version 02 22.06.2020 (09.04.2020)) and SoftOx SafeDes Hand disinfection L20-0038MV-2 MVA test report EN 14476 clean 09.04.2020.
Test solution: Batch SOF003/045, HOCl 160 ppm, acid 0.25%
Result: Based on EN 14476, the product SafeDes Hand desinfaction, when diluted at 80% (v/v), possesses viricidal activity (reduction [redacted] log) in [redacted] sec at 20°C under clean conditions against modified vaccinia virus Ankara (MVA).

Test 6: Bacteria (phase 2, step 2) – Required

The efficacy against the following bacterial strains have been tested in PN-EN 16615:2015-06 (Report: *safe des hand-surface -en 16615-dz-70-04-20):* Pseudomonas aeruginosa ATCC 15442, Staphylococcus aureus ATCC 6538, and Enterococcus hirae ATCC 10541

Test solution: Safe Des hand-/Surface Disinfectant HOCl 160 ppm, acid 0.25%.
Result: The product, batch: SOF0031111-01, tested according to PN-EN 16615:2015-06, at clean conditions (0.3 g/l bovine albumin), contact time [redacted] and [redacted] mins, test temperature 20.0°C ± 1°C, diluted in distilled water is active (reduction [redacted]og) against the three above mention bacteria at 100% and 80% v/v dilution.

Test 7: Yeast (phase 2, step 2) – Required

The efficacy against Candida albicans ATCC 10231 has been tested in PN-EN 16615:2015-06 (Report: *safe des hand-surface -en 16615-dz-70-04-20).*
Test solution: Safe Des hand-/Surface Disinfectant HOCl 160 ppm, acid 0.25%.
Result: The product, batch: SOF0031111-01, tested according to PN-EN 16615:2015-06, at clean conditions (0.3 g/l bovine albumin), contact time [redacted] mins, test temperature 20.0°C ± 1°C, diluted in distilled water is active (reduction [redacted] log) against Candida albicans ATCC 10231 at 100% and 80% v/v dilution.

Test 8: Bacteria (phase 2, step 2) – Required

The efficacy against the following bacterial strains have been tested in EN 13697: (Report: *soft ox -en 13697-dz-38-04-20):* Pseudomonas aeruginosa ATCC 15442, Staphylococcus aureus ATCC 6538, Enterococcus hirae ATCC 10541, Escherichia coli ATCC 10536
Test solution: Safe Des hand-/Surface Disinfectant HOCl 200 ppm, acid 0.25%.
Result: The product, batch: SOF0031111-01, tested according to EN 13697, at clean conditions (0.3 g/l bovine albumin), contact time [redacted] mins, test temperature 20.0°C ± 1°C, diluted in distilled water is active (reduction [redacted] log) against the above mention bacteria at 100% and 80% v/v dilution.

Test 9: Bacteria (phase 2, step 2) – Required

The efficacy against the following bacterial strains have been tested in EN 13697: (Report: *soft ox antivir -en 13697-dz-66-10-20):* Escherichia coli K12 NCTC10538
Test solution: Safe Des hand-/Surface Disinfectant HOCl 160 ppm, acid 0.25%.
Result: The product, batch: SOF0031111-01, tested according to EN 13697, at clean conditions (0.3 g/l bovine albumin), contact time [redacted] mins, test temperature 20.0°C ± 1°C, diluted in distilled water is active (reduction [redacted] log) against the above mention bacteria at 100% and 80% v/v dilution.

Test 10: Mycobacteria (phase 2, step 1) – Optional

The efficacy against the following mycobacterial strains have been tested in EN 14348:2005: (Report: *Soft ox Antivir -en Myco EN-14348-2005-L20-1403-2 3 engl, V01 (1):* Mycobacterium terrae ATCC 15755 and Mycobacterium avium ATCC 15769
Test solution: AntiVir HOCl 160 ppm, 0.25% acid.
Result: The product, batch: A20060901, tested according to PN-EN EN 14348:2005, at clean conditions (0.3 g/l bovine albumin), contact time [redacted] mins, test temperature 20.0°C ± 1°C, diluted in distilled water is active after 5 min (reduction [redacted] log) against the above mention mycobacteria at 80% v/v dilution.

Use 4 Hard surface disinfection - Non-professionals (Composition: HOCl 0.02%; 0.25%)

Test 1: Bacteria (phase 2, step 1) - Required

The efficacy against the following bacterial strains have been tested in EN13727:2015-12 (Report: *EN13727- DZ-20-01-20):* Pseudomonas aeruginosa ATCC 15442, Staphylococcus aureus ATCC 6538, Enterococcus hirae ATCC 10541 and Escherichia coli K12 NCTC 10538
Test solution: Safe Des / Antibac Hand Disinfectant, containing HOCl 160 ppm, acid 0.25%.
Result: The product, batch: SOF003/045, tested according to EN 13727+A2:2015-12, at clean conditions (0.3 g/l bovine albumin), contact time [redacted] s, test temperature 20.0°C ± 0.6°C, diluted in distilled water is active (reduction [redacted] log) against the four above mention bacteria at 76% v/v dilution. This EN efficacy test is passed with a formulation at lower concentration of HOCl and at lower concentration of acid than the biocidal product. The EN efficacy test therefore represent a worst case scenario compared to the biocidal product.

Test 2: Bacteria (phase 2, step 1) - Required

The efficacy against the following bacterial strains have been tested in EN 1276:2010+AC:2010 (Report: Soft Ox 0-en 1276-dz-16-07-15): Pseudomonas aeruginosa ATCC 15442, Staphylococcus aureus ATCC 6538 Enterococcus hirae ATCC 10541, and Escherichia coli ATCC 10536
Test solution: Soft-Ox 0 disinfectant containing HOCl 160 ppm, acid 0.13 %, batch 2014.10.70
Result: The product Soft-Ox 0 tested according to PN-EN 1276:2010+AC:2010 at clean conditions (0.3 g/l bovine albumin), contact time [redacted] min., test temperature 20.0°C ± 0.6°C, diluted in distilled water is active (reduction [redacted] log) against all the four above mention bacteria at 50%, 62.5 % and at 80% v/v dilutions.

Test 3: Yeast (phase 2, step 1) – Required

The efficacy against Candida albicans ATCC 10231 and Aspergillus brasiliensis ATCC 16404 has been tested in EN 13624:2013-12 (Report: EN13624- DZ-21-01-20).
Test solution: Soft-Ox 0 disinfectant containing HOCl 160 ppm; acid 0.25%.
Result: The product Soft-Ox 0, batch: SOF003/045, tested according to EN 13624:2013-12, at clean conditions (0.3 g/l bovine albumin), test temperature 20.0°C ± 1.0°C, diluted in distilled water is active (reduction [redacted] log) against Candida albicans ATCC 10231 at 76 % v/v dilution, contact time [redacted] s and Aspergillus brasiliensis ATCC 16404 at 90% v/v dilution, contact time [redacted] and at 76% v/v dilution, contact time [redacted] s.

Test 4: Viruses (phase 2, step 1) – Optional

The efficacy against Adenovirus Type 5 ATCC VR-5 (Report: SoftOx SafeDes Hand disinfection L20-0038A-2 Adeno test report EN 14476 clean 03.04.2020) and SoftOx SafeDes Hand disinfection L20-0038A-1 Adeno Screening EN 14476 14.02.2020.
Test solution: Batch SOF003/045, HOCl 160 ppm, acid 0.25%
Result: Based on EN 14476, the product SafeDes Hand desinfaction, when diluted at 80% (v/v), possesses viricidal activity (reduction [redacted] log) in [redacted] min at 20°C under clean conditions against Adenovirus Type 5 ATCC VR-5.

Test 5: Viruses (phase 2, step 1) – Optional

The efficacy against Poliovirus Type 1 LSc-2ab (Report: SoftOx SafeDes Hand disinfection L20-0038Po-3 Polio test report EN 14476 clean 24.03.2020) and SoftOx SafeDes Virus Protection L20-0105Po-1 Polio Screening EN 14476 17.02.2020.
Test solution: Batch SOF003/045, HOCl 160 ppm, acid 0.25%
Result: Based on EN 14476, the product SafeDes Hand desinfaction, when diluted at 97% (v/v), possesses viricidal activity (reduction [redacted] log) in [redacted] and [redacted] min at 20°C under clean conditions against Poliovirus Type 1 LSc-2ab.

Test 6: Viruses (phase 2, step 1) – Optional

The efficacy against Murine Norovirus (MNV Strain S99) RVB-651 (Report: SoftOx SafeDes Hand disinfection L20-0038M-3 MNV test report EN 14476 clean 24.03.2020) and SoftOx SafeDes Virus Protection L20-0105M-1 MNV Screening EN 14476 17.02.2020.
Test solution: Batch SOF003/045, HOCl 160 ppm, acid 0.25%
Result: Based on EN 14476, the product SafeDes Hand desinfaction, when diluted at 97% (v/v), possesses viricidal activity (reduction [redacted] log) in [redacted] min and (reduction [redacted] log) in [redacted] min at 20°C under clean conditions against Murine Norovirus (MNV Strain [redacted]).

Test 7: Yeast (phase 2, step 2) – Required

The efficacy against Yeast Candica albicans have been tested in EN 13697: (Report: *soft ox -en 13697-dz-38-04-20):* Candida albicans ATCC 10231
Test solution: Safe Des hand-/Surface Disinfectant HOCl 200 ppm, acid 0.25%.
Result: The product, batch: SOF0031111-01, tested according to EN 13697, at clean conditions (0.3 g/l bovine albumin), contact time [redacted] mins, test temperature 20.0°C ± 1°C, diluted in distilled water is active (reduction [redacted] log) against the above mentioned yeast at 100% and 80% v/v dilution.

Test 8: Bacterial spores (phase 2, step 1) – Optional

The efficacy against Bacillus subtilis ATCC 6633 and Clostridium sporogenes ATCC 19404 spores have been tested according to PN-EN 13704:2018-09 (modified) (Report: Soft Ox - en 13704 -dz-78-05-20)
Test solution: Softox-0, HOCl 160 ppm, acid 0.25%
Result: Based on EN 13704, the SafeDes Hand Disinfection products when diluted at 97 and 80% (v/v), possesses sporocidal activity (reduction [redacted] log) in [redacted] min at 20°C under clear conditions for Bacillus subtilis ATCC 6633 and Clostridium sporogenes ATCC 19404.

Test 9: Bacterial spores (phase 2, step 1) – Optional

The efficacy against Bacillus subtilis ATCC 6633, Bacillus cereus DSM 106266 and Clostridium difficile DSM 27147 spores have been tested according to EN 17126 (Report: Soft Ox -en 17126-dz-79-05-20)
Test solution: Softox-0, HOCl 160 ppm, acid 0.25%
Result: Based on EN 17126, the SafeDes Hand Disinfection products when diluted at 97 and 80% (v/v), possesses sporocidal activity (reduction [redacted] log) in [redacted] min at 20°C under clear conditions for Bacillus subtilis ATCC 6633 and Bacillus cereus DSM 106266, when

diluted at 97% (v/v), possesses sporocidal activity (reduction [redacted] log) and when diluted at 80% (v/v) possesses sporocidal activity (reduction [redacted]) in [redacted] min at 20°C under clear conditions for Clostridium sporogenes ATCC 19404.

Test 10: Bacteria (phase 2, step 2) – Required

The efficacy against the following bacterial strains have been tested in PN-EN 16615:2015-06 (Report: *safe des hand-surface -en 16615-dz-70-04-20):* Pseudomonas aeruginosa ATCC 15442, Staphylococcus aureus ATCC 6538, and Enterococcus hirae ATCC 10541
Test solution: Safe Des hand-/Surface Disinfectant HOCl 160 ppm, acid 0.25%.
Result: The product, batch: SOF0031111-01, tested according to PN-EN 16615:2015-06, at clean conditions (0.3 g/l bovine albumin), contact time [redacted] mins, test temperature 20.0°C ± 1°C, diluted in distilled water is active (reduction [redacted]) against the three above mention bacteria at 100% and 80% v/v dilution.

Test 11: Yeast (phase 2, step 2) – Required

The efficacy against Candida albicans ATCC 10231 has been tested in PN-EN 16615:2015-06 (Report: *safe des hand-surface -en 16615-dz-70-04-20).*
Test solution: Safe Des hand-/Surface Disinfectant HOCl 160 ppm, acid 0.25%.
Result: The product, batch: SOF0031111-01, tested according to PN-EN 16615:2015-06, at clean conditions (0.3 g/l bovine albumin), contact time [redacted] mins, test temperature 20.0°C ± 1°C, diluted in distilled water is active (reduction [redacted] log) against Candida albicans ATCC 10231 at 100% and 80% v/v dilution.

Test 12: Bacteria (phase 2, step 2) – Required

The efficacy against the following bacterial strains have been tested in EN 13697: (Report: *soft ox -en 13697-dz-38-04-20):* Pseudomonas aeruginosa ATCC 15442, Staphylococcus aureus ATCC 6538, Enterococcus hirae ATCC 10541, Escherichia coli ATCC 10536
Test solution: Safe Des hand-/Surface Disinfectant HOCl 200 ppm, acid 0.25%.
Result: The product, batch: SOF0031111-01, tested according to EN 13697, at clean conditions (0.3 g/l bovine albumin), contact time [redacted] mins, test temperature 20.0°C ± 1°C, diluted in distilled water is active (reduction [redacted] log) against the above mention bacteria at 100% and 80% v/v dilution.

Test 13: Mycobacteria (phase 2, step 1) – Optional

The efficacy against the following mycobacterial strains have been tested in EN 14348:2005: (Report: *Soft ox Antivir -en Myco EN-14348-2005-L20-1403-2 3 engl, V01 (1):* Mycobacterium terrae ATCC 15755 and Mycobacterium avium ATCC 15769
Test solution: AntiVir HOCl 160 ppm, 0.25% acid.
Result: The product, batch: A20060901, tested according to PN-EN EN 14348:2005, at clean conditions (0.3 g/l bovine albumin), contact time [redacted] mins, test temperature 20.0°C ± 1°C, diluted in distilled water is active after [redacted] min (reduction [redacted] log) against the above mention mycobacteria at 80% v/v dilution.

Tests not performed

NF T 72-281 has not be performed since the product will not be offered as an airborne surface disinfection product (flogging).

Product type 4: Hard surfaces

Use 5 Disinfection of equipment and small surfaces that come into contact with food and feed - Professional (Composition: HOCl 0.02%; 0.25%)

Test 1: Bacteria (phase 2, step 1) - Required

The efficacy against the following bacterial strains have been tested in EN 1276:2010+AC:2010 (Report: Soft Ox 0-en 1276-dz-16-07-15): Pseudomonas aeruginosa ATCC 15442, Staphylococcus aureus ATCC 6538 Enterococcus hirae ATCC 10541, and Escherichia coli ATCC 10536
Test solution: Soft-Ox 0 disinfectant containing HOCl 160 ppm, acid 0.13%.
Result: The product Soft-Ox 0 tested according to PN-EN 1276:2010+AC:2010 at clean conditions (0.3 g/l bovine albumin), contact time [redacted] min., test temperature 20.0°C ± 0.6°C, diluted in distilled water is active (reduction [redacted] log) against all the four above mention bacteria at 50%, 62.5 % and at 80% v/v dilutions.

Test 2: Viruses (phase 2, step 1) – Optional

The efficacy against Adenovirus Type 5 ATCC VR-5 (Report: SoftOx SafeDes Hand disinfection L20-0038A-2 Adeno test report EN 14476 clean 03.04.2020) and and SoftOx SafeDes Hand disinfection L20-0038A-1 Adeno Screening EN 14476 14.02.2020.
Test solution: Batch SOF003/045, HOCl 160 ppm, acid 0.25%
Result: Based on EN 14476, the product SafeDes Hand desinfaction, when diluted at 80% (v/v), possesses viricidal activity (reduction [redacted] log) in [redacted] min at 20°C under clean conditions against Adenovirus Type 5 ATCC VR-5.

Test 3: Viruses (phase 2, step 1) – Optional

The efficacy against Murine Norovirus (MNV Strain S99) RVB-651 (Report: SoftOx SafeDes Hand disinfection L20-0038M-3 MNV test report EN 14476 clean 24.03.2020) and SoftOx SafeDes Virus Protection L20-0105M-1 MNV Screening EN 14476 17.02.2020.
Test solution: Batch SOF003/045, HOCl 160 ppm, acid 0.25%
Result: Based on EN 14476, the product SafeDes Hand desinfaction, when diluted at 97% (v/v), possesses viricidal activity (reduction [redacted] log) in [redacted] min and (reduction [redacted] log) in [redacted] min at 20°C under clean conditions against Murine Norovirus (MNV Strain S99).

Test 4: Bacterial spores (phase 2, step 1) – Optional

The efficacy against Bacillus subtilis ATCC 6633 and Clostridium sporogenes ATCC 19404 spores have been tested according to PN-EN 13704:2018-09 (modified) (Report: Soft Ox - en 13704 -dz-78-05-20)
Test solution: Softox-0, HOCl 160 ppm, acid 0.25%
Result: Based on EN 13704, the SafeDes Hand Disinfection products when diluted at 97 and 80% (v/v), possesses sporocidal activity (reduction [redacted] log) in [redacted] min at 20°C under clear conditions for Bacillus subtilis ATCC 6633 and Clostridium sporogenes ATCC 19404.

Test 5: Bacterial spores (phase 2, step 1) – Optional

The efficacy against Bacillus subtilis ATCC 6633, Bacillus cereus DSM 106266 and Clostridium difficile DSM 27147 spores have been tested according to EN 17126 (Report: Soft Ox -en 17126-dz-79-05-20)
Test solution: Softox-0, HOCl 160 ppm, acid 0.25%
Result: Based on EN 17126, the SafeDes Hand Disinfection products when diluted at 97 and 80% (v/v), possesses sporocidal activity (reduction [redacted]) in [redacted] min at 20°C under clear conditions for Bacillus subtilis ATCC 6633 and Bacillus cereus DSM 106266, when diluted at 97% (v/v), possesses sporocidal activity (reduction [redacted] log) and when diluted at 80% (v/v) possesses sporocidal activity (reduction [redacted] log) in [redacted] min at 20°C under clear conditions for Clostridium sporogenes ATCC 19404.

Test 6: Bacteria (phase 2, step 2) – Required

The efficacy against the following bacterial strains have been tested in EN 13697: (Report: *soft ox -en 13697-dz-38-04-20):* Pseudomonas aeruginosa ATCC 15442, Staphylococcus aureus ATCC 6538, Enterococcus hirae ATCC 10541, Escherichia coli ATCC 10536
Test solution: Safe Des hand-/Surface Disinfectant HOCl 200 ppm, acid 0.25%.
Result: The product, batch: SOF0031111-01, tested according to PN-EN EN 13697, at clean conditions (0.3 g/l bovine albumin), contact time [redacted] mins, test temperature 20.0°C ± 1°C, diluted in distilled water is active (reduction [redacted]) against the above mention bacteria at 100% and 80% v/v dilution.

Test 7: Yeast (phase 2, step 2) – Required

The efficacy against Yeast Candica albicans have been tested in EN 13697: (Report: *soft ox -en 13697-dz-38-04-20):* Candida albicans ATCC 10231
Test solution: Safe Des hand-/Surface Disinfectant HOCl 200 ppm, acid 0.25%.
Result: The product, batch: SOF0031111-01, tested according to EN 13697, at clean conditions (0.3 g/l bovine albumin), contact time [redacted] mins, test temperature 20.0°C ± 1°C, diluted in distilled water is active (reduction [redacted] log) against the above mentioned yeast at 100% and 80% v/v dilution.

Test 8: Bacteria (phase 2, step 2) – Required

The efficacy against the following bacterial strains have been tested in EN 13697: (Report: *soft ox antivir -en 13697-dz-66-10-20):* Escherichia coli K12 NCTC10538
Test solution: Safe Des hand-/Surface Disinfectant HOCl 160 ppm, acid 0.25%.
Result: The product, batch: SOF0031111-01, tested according to PN-EN EN 13697:2015-06, at clean conditions (0.3 g/l bovine albumin), contact time [redacted] mins, test temperature 20.0°C ± 1°C, diluted in distilled water is active ([redacted]) against the above mention bacteria at 100% and 80% v/v dilution.

3.6 Confidential annex

See separate annex

3.7 Other references

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BPC TOX-WGII-2016

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COMMISSION REGULATION (EU) 2020/749 of 4 June 2020, amending Annex III to Regulation (EC) No 396/2005

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ConsExpo Fact Sheet - Genreal Fact Sheet

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Guidance on the Biocidal Products Regulation Volume I-IV

Guidance on the Biocidal Products Regulation Volume V, Guidance on Disinfection By-Products

HEAdHoc Recommendation no 2 - Mopping and wiping time PT2

HEAdHoc Recommendation no 9 - Professional hand disinfection in hospitals

HEAdHoc Recommendation no 13 - Teat Disinfection Products for Veterinary Hygiene (PT3)

HEAdHoc Rec No 14 - Default human factor values for use in exposure assessments for biocidal products

HEEG opinion 3 - Use of ConsExpo for the Exposure Assessment for Professional Users

3.8 Summary of studies in support of the health risk assessment

[redacted]

[redacted]

Clinical study
(79 Clinical Investigation Report SWIS-01)

[redacted]

[redacted]

Report assessing the irritant properties of SoftOx disinfection solution
(77 Report – Study 2a irritant properties of SoftOx disinfection solution on healthy skin

[redacted]

[redacted]