# Saniswiss Sanitizer Instruments E

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CONFIDENTIAL

# **Presentation document**

- Main group and product type

Medical Device

# - Field (e.g. surface disinfection) and area (e.g. medical, veterinary) of use

Instruments disinfection in the medical area

#### - Chemical composition

<u>Components</u>	<u>Functions</u>	Concentration (% mass)
ethoxylated fatty alcohol	Surfactant	10≤x<25
Enzymes	Enzymes	<5
Sequestrant	Quelating agent	<2
Poly(oxy-1,2-ethanediyl) alpha-[2- (didecylmethylammonio)ethyl]-omega- hydroxy-propanoate (1:1) (salt) N° CAS 94667-33-1	Biocide	2,5≤x<10
Didecyldimethylammonium chloride N° CAS 7173-51-5	Biocide	2,5≤x<10
N-(2-carboxyethyl)-N-(2-ethylhexyl)- alaninate of sodium	Surfactant	2,5≤x<10
Colorants	Colorant	<1
Water	Solvent	QSP
Total		100

- **Type of product (concentrate, liquid, powder, etc.) and form of packaging** Concentrate liquid: 1L and 5L

# - Indications for use, concentration and contact time for each use (as applicable);

Exclusive use by professionals for the pre-disinfection of invasive and non-invasive medical devices, such as surgical instrument, equipment of operating room, scopes, the ophtalmological and contactology equipment. Concentration: 1 dose/5L (0.5%). Contact time 10 minutes, temperature 20°C.

#### - Storage, storage and final disposal conditions

Store at a temperature between 5°C and 35°C. Do not throw the residues into drains and watercourses.

#### - Dangerousness and first aid measures

Hazard statements:

H314 Causes severe skin burns and eye damage.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements - Prevention:

P264 Wash your hands thoroughly after handling.

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statements - Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

P321 Specific treatment (see on this label)

# 10. Toxicological data of the product

May cause irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following exposure between three minutes and one hour.

Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discolouration due to blanching of the skin, complete areas of alopecia, and scars.

Acute toxicity: SUBTILISIN (CAS: 9014-01-1) Oral route: LD50 = 1800 mg/kg OECD Guideline 401 (Acute Oral Toxicity) ETHYL ALCOHOL (CAS: 64-17-5) Oral route: LD50 = 10470 mg/kg Species: Rat OECD Guideline 401 (Acute Oral Toxicity) Dermal route: LD50 > 2000 mg/kg Species : Rabbit Inhalation route (Dusts/mist): LC50 > 51 mg/l Species : Rat OECD Guideline 403 (Acute Inhalation Toxicity) DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5) Oral route 1D50 - 411 mg/kg

Oral route:	LD50 = 411  mg/kg
Dermal route:	LD50 > 2000 mg/kg

POLY(OXY-1,2-ETHANEDIYL) ALPHA-[2-(DIDECYLMETHYLAMMONIO)ETHYL]-OMEGA-HYDROXY-PROPANOATE (1:1)

(SALT) (CAS: 94667-33-1)

Oral route:	DL50 = 1157/ mg/kg
	Species: Rat

ALCOHOLS, C12-15-LINEAR AND BRANCHED, ETHOXYLATED, PROPOXYLATED (CAS: 120313-48-6)

Oral route:	LD50 = 200 mg/kg
PROPANE-1,2-DIOL (CAS: 57-55-6)	
Oral route:	LD50 = 22000 mg/kg
	Species : Rat
Dermal route:	LD50 > 2000 mg/kg
	Species : Rabbit

Inhalation route (Dusts/mist):

LC50 = 41 mg/l

Species : Rat

Duration of exposure : 4 h

Skin corrosion/skin irritation :

POLY(OXY-1,2-ETHANEDIYL) ALPHA-[2-(DIDECYLMETHYLAMMONIO)ETHYL]-OMEGA-HYDROXY-PROPANOATE (1:1) (SALT) (CAS: 94667-33-1)

Corrosivity:

Causes severe skin burns.

Species : Rabbit

Germ cell mutagenicity :

PROPANE-1,2-DIOL (CAS: 57-55-6)

No mutagenic effect.

OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test)

Ames test (in vitro) :

Negative.