

octenisept® wound disinfection**No Change Service!**Version
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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name : octenisept® wound disinfection

1.2 Relevant identified uses of the substance or mixture and uses advised againstUse of the Sub-
stance/Mixture : Medicinal products, Disinfectants**1.3 Details of the supplier of the safety data sheet**Manufacturer/ Supplier : Schülke & Mayr GmbH
Robert-Koch-Str. 2

22851 Norderstedt
Germany
Telephone: +49 (0)40/ 52100-0
Telefax: +49 (0)40/ 52100318
mail@schuelke.com
www.schuelke.comSupplier : Schülke & Mayr UK Ltd.
Cygnet House
1, Jenkin Road, Meadowhall

Sheffield S9 1AT
United Kingdom
Telephone: +44 114 254 35 00
Telefax: +44 114 254 35 01
mail.uk@schulke.comE-mail address of person
responsible for the
SDS/Contact person : Application Department
+49 (0)40/ 521 00 8800
ADHI@schuelke.com
(Schülke & Mayr UK Ltd.: +44-1142543500)**1.4 Emergency telephone number**Emergency telephone num-
ber : UK Poisons Emergency number: 0870 600 6266
Emergency telephone num-
ber : +49 (0)40/ 52100-0**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

octenisept® wound disinfection**No Change Service!**Version
02.03Revision Date:
07.02.2017Date of last issue: 09.01.2017
Date of first issue: 07.09.2007**2.3 Other hazards**

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

No special risks known.

SECTION 3: Composition/information on ingredients**3.2 Mixtures**

Chemical nature : Aqueous solution

Hazardous components

Chemical name	Index-Number CAS-No. EC-No. Registration number	Classification	Concentration (% w/w)
2-Phenoxyethanol	603-098-00-9 122-99-6 204-589-7 01-2119488943-21-XXXX	Acute Tox. 4; H302 Eye Irrit. 2; H319	2

For explanation of abbreviations see section 16.

SECTION 4: First aid measures**4.1 Description of first aid measures**

In case of eye contact : Flush eyes with water as a precaution.
If swallowed : Do NOT induce vomiting. Drink water as a precaution. Consult a physician if necessary.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Gastrointestinal discomfort,

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media : Dry powder, Foam, Water spray jet, Carbon dioxide (CO₂)

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : No information available.

5.3 Advice for firefighters

Special protective equipment : In the event of fire, wear self-contained breathing apparatus.

octenisept® wound disinfection**No Change Service!**Version
02.03Revision Date:
07.02.2017Date of last issue: 09.01.2017
Date of first issue: 07.09.2007

for firefighters

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : No special precautions required.

6.2 Environmental precautions

Environmental precautions : Avoid subsoil penetration.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).

6.4 Reference to other sections

See chapter 13

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Advice on safe handling : not required under normal use

Advice on protection against fire and explosion : No special protective measures against fire required.

Hygiene measures : Keep away from food and drink. Keep away from children.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Store at room temperature in the original container.

Further information on storage conditions : Keep away from direct sunlight. Recommended storage temperature: 15 - 25°C

Advice on common storage : No materials to be especially mentioned.

7.3 Specific end use(s)

Specific use(s) : none

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
2-Phenoxyethanol	122-99-6	Permissible exposure limit	20 ppm 110 mg/m ³	TRGS 900
Further information	Dermal absorption possible			
		Ceiling Limit Value	40 ppm 220 mg/m ³	TRGS 900

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
2-Phenoxyethanol	Workers	Inhalation	Long-term systemic	8.07 mg/m ³

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

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octenisept® wound disinfection

No Change Service!

Version
02.03

Revision Date:
07.02.2017

Date of last issue: 09.01.2017
Date of first issue: 07.09.2007

			effects, Long-term local effects	
	Workers	Skin contact	Long-term systemic effects	34.72 mg/kg
	Consumers	Inhalation	Long-term exposure, Short-term exposure, Local effects	2.5 mg/m ³
	Consumers	Skin contact	Long-term local effects	20.83 mg/kg
	Consumers	Ingestion	Short-term exposure, Long-term exposure, Systemic effects	17.43 mg/kg

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
2-Phenoxyethanol	Fresh water	0.943 mg/l
	Marine water	0.0943 mg/l
	Fresh water sediment	7.2366 mg/kg
	Marine sediment	0.7237 mg/kg
	Soil	1.26 mg/kg
	Intermittent use/release	3.44 mg/l
	Sewage treatment plant	24.8 mg/l

8.2 Exposure controls

Personal protective equipment

Protective measures : Avoid contact with eyes.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : liquid
Colour : colourless
Odour : nearly odourless
Odour Threshold : not determined
pH : ca. 6, 20 °C, concentrate
Melting point/freezing point : ca. 0 °C
Decomposition temperature : Not applicable
Boiling point/boiling range : ca. 100 °C
Flash point : Not applicable
Evaporation rate : No data available
Flammability (solid, gas) : Not applicable
Upper explosion limit : Not applicable
Lower explosion limit : Not applicable
Vapour pressure : ca. 25 hPa, 20 °C, similar to water
Relative vapour density : No data available
Density : ca. 1.005 g/cm³, 20 °C
Solubility(ies)

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

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octenisept® wound disinfection

No Change Service!

Version
02.03

Revision Date:
07.02.2017

Date of last issue: 09.01.2017
Date of first issue: 07.09.2007

Water solubility	:	in all proportions , 20 °C
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Flow time	:	< 15 s at 20 °C, DIN 53211
Explosive properties	:	No data available
Oxidizing properties	:	No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

The product is chemically stable.

10.3 Possibility of hazardous reactions

None reasonably foreseeable.

10.4 Conditions to avoid

Do not store at temperatures above 30°C.

10.5 Incompatible materials

Do not mix with other products.,

10.6 Hazardous decomposition products

None reasonably foreseeable.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product:

Acute oral toxicity : LD50 (Rat): > 45,000 mg/kg

Components:

2-Phenoxyethanol:

Acute inhalation toxicity : (Rat): 8 h, An LC50/ inhalation could not be determined because no mortality of rats was observed at the maximum achievable concentration.

Acute dermal toxicity : LD50: > 2,000 mg/kg, Based on available data, the classification criteria are not met.

Skin corrosion/irritation

Product:

No skin irritation

Serious eye damage/eye irritation

Product:

Assessment of eye tolerance in rabbits - slightly irritating., According to the classification criteria

octenisept® wound disinfection**No Change Service!**Version
02.03Revision Date:
07.02.2017Date of last issue: 09.01.2017
Date of first issue: 07.09.2007

of the European Union, the product is not considered as being an eye irritant.

Respiratory or skin sensitisation**Product:**

Does not cause skin sensitisation.

Germ cell mutagenicity**Product:**

Germ cell mutagenicity- Assessment : Not mutagenic in Ames Test

Carcinogenicity**Product:**

Carcinogenicity - Assessment : Contains no ingredient listed as a carcinogen

Reproductive toxicity**Product:**

Reproductive toxicity - Assessment : Contains no ingredient listed as toxic to reproduction

STOT - single exposure**Components:****|| 2-Phenoxyethanol:**

|| Based on available data, the classification criteria are not met.

STOT - repeated exposure**Components:****|| 2-Phenoxyethanol:**

|| No data available

Repeated dose toxicity**Components:****|| 2-Phenoxyethanol:**

|| Rat, NOAEL: 400 mg/kg, Oral, Based on available data, the classification criteria are not met.

Aspiration toxicity

No data available

SECTION 12: Ecological information**12.1 Toxicity****Product:**

Toxicity to bacteria : EC50 : > 3,200 mg/l , OECD 209

Components:**|| 2-Phenoxyethanol:**

|| Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l, 96 h

|| Toxicity to daphnia and other aquatic invertebrates : EC50 : > 500 mg/l, 48 h

|| Toxicity to algae : EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l,

octenisept® wound disinfection**No Change Service!**Version
02.03Revision Date:
07.02.2017Date of last issue: 09.01.2017
Date of first issue: 07.09.2007

72 h	
Toxicity to fish (Chronic toxicity)	: NOEC: 23 mg/l , 34 d, Pimephales promelas (fathead minnow)
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC: 9.43 mg/l , 21 d, Daphnia magna (Water flea)

12.2 Persistence and degradability**Product:**

Biodegradability	: The methods for determining biodegradability are not applicable to inorganic substances.
Chemical Oxygen Demand (COD)	: 594 mg/l , 1 % solution

Components:**2-Phenoxyethanol:**

Biodegradability	: Biodegradation: 90 - 100 %, Exposure time: 15 d, OECD Test Guideline 301A, According to the results of tests of biodegradability this product is considered as being readily biodegradable.
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12.3 Bioaccumulative potential**Components:****2-Phenoxyethanol:**

Bioaccumulation	: Bioconcentration factor (BCF): 0.35, No bioaccumulation is to be expected (log Pow <= 4).
Partition coefficient: n-octanol/water	: log Pow: 1.16

12.4 Mobility in soil**Components:****2-Phenoxyethanol:**

Mobility	: Mobile in soils
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12.5 Results of PBT and vPvB assessment**Product:**

Assessment	: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
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12.6 Other adverse effects**Product:**

Additional ecological information	: none
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SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product	: Dispose of the product according to the defined EWC (European Waste Code) No.
Contaminated packaging	: Take empty packaging to the recycling plant.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

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octenisept® wound disinfection

No Change Service!

Version
02.03

Revision Date:
07.02.2017

Date of last issue: 09.01.2017
Date of first issue: 07.09.2007

Waste key for the unused product : European waste catalog (EWC) 070601
Waste key for the unused product(Group) : Waste material of HZVA from fats, lubricants, soaps, detergents, disinfectants and personal protection products.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

For personal protection see section 8.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. : Not applicable

Volatile organic compounds : none, Directive 2010/75/EC on the limitation of emissions of volatile organic compounds

Other regulations : Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. Take note of Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values.

15.2 Chemical safety assessment

Exempt

octenisept® wound disinfection**No Change Service!**Version
02.03Revision Date:
07.02.2017Date of last issue: 09.01.2017
Date of first issue: 07.09.2007**SECTION 16: Other information****Full text of H-Statements**

H302 : Harmful if swallowed.
 H319 : Causes serious eye irritation.

Full text of other abbreviations

Acute Tox. : Acute toxicity
 Eye Irrit. : Eye irritation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) No. 1272/2008

, : Calculation method

Changes compared with the previous edition!!!

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guid-

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



octenisept® wound disinfection

No Change Service!

Version
02.03

Revision Date:
07.02.2017

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