SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : octenisept®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/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.com

E-mail address of person responsible for the SDS/Contact person : Application Department
+49 (0)40/ 521 00 8800
ApplicationDepartment.SM@schuelke.com
(Schülke & Mayr UK Ltd.: +44-1142543500)

1.4 Emergency telephone number

Emergency telephone number : UK Poisons Emergency number: 0870 600 6266

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

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.

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

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
2-phenoxyethanol	122-99-6 204-589-7 603-098-00-9 01-2119488943-21-XXXX	Acute Tox. 4; H302 Eye Irrit. 2; H319	2
N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride	70775-75-6 274-861-8 - - - 01-2120750372-60-0000	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Aquatic Acute 1; H400; M = 100 Aquatic Chronic 1; H410; M = 10	0,1

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 (CO_2)

Unsuitable extinguishing media : Do not use a solid water stream as it may scatter and spread fire.

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 for firefighters : In the event of fire, wear self-contained breathing apparatus.

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 : Do not freeze. 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

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 effects, Long-term local effects	8,07 mg/m3
	Workers	Skin contact	Long-term systemic effects	34,72 mg/kg
	Consumers	Inhalation	Long-term exposure, Short-term exposure, Local effects	2,5 mg/m3
	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)

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 / Upper flammability limit	:	Not applicable
Lower explosion limit / Lower flammability limit	:	Not applicable
Vapour pressure	:	ca. 25 hPa (20 °C) similar to water
Vapour density	:	No data available
Relative density	:	ca. 1,005 g/cm3 (20 °C)
Solubility(ies)		
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 Method: 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

Hazardous reactions	:	None reasonably foreseeable.

10.4 Conditions to avoid

Conditions to avoid : Do not store at temperatures above 30°C.

10.5 Incompatible materials

Materials to avoid : 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 oral toxicity : LD50 (Rat): 1.850 mg/kg
Assessment: Harmful if swallowed.

Acute inhalation toxicity : (Rat): Exposure time: 8 h
Remarks: 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
Remarks: Based on available data, the classification criteria are not met.

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Acute oral toxicity : LD50 (Rat): > 800 mg/kg
Method: OECD Test Guideline 401
Remarks: Harmful if swallowed.

Acute inhalation toxicity : LC50 (Rat): > 4,0 mg/l
Exposure time: 4 h
Method: OECD Test Guideline 403
Test substance: 0,1 % solution

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 intravenous (Rat): 10 mg/kg
Method: OECD Test Guideline 401

Skin corrosion/irritation

Product:

Result : No skin irritation

Components:

2-phenoxyethanol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Irritating to skin.

Serious eye damage/eye irritation

Product:

Result : Assessment of eye tolerance in rabbits - slightly irritating.
Remarks : According to the classification criteria of the European Union, the product is not considered as being an eye irritant.

Components:

2-phenoxyethanol:

Species : Rabbit
Assessment : Causes serious eye irritation.
Method : OECD Test Guideline 405

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Species : Rabbit
Method : Read-across (Analogy)
Result : Irritating to eyes.

Respiratory or skin sensitisation

Product:

Result : Does not cause skin sensitisation.

Components:

2-phenoxyethanol:

Test Type : Maximisation Test
Species : Guinea pig
Method : OECD Test Guideline 406
Result : Did not cause sensitisation on laboratory animals.

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Test Type	:	Maximisation Test
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity

Product:

Germ cell mutagenicity- Assessment	:	Not mutagenic in Ames Test

Components:

2-phenoxyethanol:

Germ cell mutagenicity- Assessment	:	Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Genotoxicity in vitro	:	Test Type: Ames test Method: OECD Test Guideline 471 Result: Non mutagenic
Germ cell mutagenicity- Assessment	:	Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

Carcinogenicity

Product:

Carcinogenicity - Assessment	:	Contains no ingredient listed as a carcinogen

Components:

2-phenoxyethanol:

Carcinogenicity - Assessment	:	No data available

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Species	:	Mouse
Application Route	:	Dermal exposure
Method	:	OECD Test Guideline 451
Remarks	:	Based on available data, the classification criteria are not met.
Carcinogenicity - Assessment	:	Animal testing did not show any carcinogenic effects.

Reproductive toxicity

Product:

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

Components:

2-phenoxyethanol:

Reproductive toxicity - Assessment : Animal testing did not show any effects on fertility.

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Effects on foetal development : Species: Rat
Application Route: Oral
Method: OECD Test Guideline 414
Remarks: Based on available data, the classification criteria are not met.

Reproductive toxicity - Assessment : No toxicity to reproduction

STOT - single exposure

Components:

2-phenoxyethanol:

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

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Remarks : No data available

STOT - repeated exposure

Components:

2-phenoxyethanol:

Remarks : No data available

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Remarks : No data available

Repeated dose toxicity

Components:

2-phenoxyethanol:

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

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Species	:	Rat
NOAEL	:	32 mg/kg
Application Route	:	Oral
Method	:	OECD Test Guideline, 408

Aspiration toxicity

No data available

SECTION 12: Ecological information

12.1 Toxicity

Product:

Toxicity to microorganisms	:	EC50 : > 3.200 mg/l Method: OECD 209

Components:

2-phenoxyethanol:

Toxicity to fish	:	LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 : > 500 mg/l Exposure time: 48 h
Toxicity to algae	:	EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l Exposure time: 72 h
Toxicity to fish (Chronic toxicity)	:	NOEC: 23 mg/l Exposure time: 34 d Species: Pimephales promelas (fathead minnow)
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 9,43 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Toxicity to fish	:	LC50 (Brachydanio rerio (zebrafish)): 0,17 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 0,007 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae	:	EC50 (Desmodesmus subspicatus (green algae)): 0,034 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	100

Toxicity to microorganisms	:	EC50 (activated sludge): 2,77 mg/l Exposure time: 3 h Method: OECD Test Guideline 209
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 0,0056 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	10
Toxicity to soil dwelling organisms	:	LC50: > 1.000 mg/kg Species: Eisenia fetida (earthworms) Method: OECD Test Guideline 207
Plant toxicity	:	LC50: > 1.000 mg/kg Species: Lactuca sativa (lettuce) Method: OECD Test Guideline 208
Toxicity to terrestrial organisms	:	EC50: > 1.000 mg/kg Method: OECD Test Guideline 216

12.2 Persistence and degradability

Product:

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

Components:

2-phenoxyethanol:

Biodegradability	:	Biodegradation: 90 - 100 % Exposure time: 15 d Method: OECD Test Guideline 301A Remarks: According to the results of tests of biodegradability this product is considered as being readily biodegradable.

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Biodegradability	:	Result: Not biodegradable Method: OECD 301D / EEC 84/449 C6

12.3 Bioaccumulative potential

Components:

2-phenoxyethanol:

Bioaccumulation	:	Bioconcentration factor (BCF): 0,35 Remarks: No bioaccumulation is to be expected (log Pow <=

4).

Partition coefficient: n-octanol/water : log Pow: 1,16

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: 1,5 (23 °C)
Method: OECD Test Guideline 123

12.4 Mobility in soil

Components:

2-phenoxyethanol:

Mobility : Remarks: Mobile in soils

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Mobility : Remarks: Adsorbs on soil.

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..

12.6 Other adverse effects

Product:

Additional ecological information : none

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.

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

Not applicable
For personal protection see section 8.

14.7 Transport in bulk according to Annex II of Marpol 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	:	Volatile organic compounds (VOC) content: < 3 % 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

SECTION 16: Other information

Full text of H-Statements

H302	:	Harmful if swallowed.
H315	:	Causes skin irritation.
H319	:	Causes serious eye irritation.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Irrit.	:	Eye irritation
Skin Irrit.	:	Skin 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; SVHC - Substance of Very High Concern; 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

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

II

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 guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.