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
ADHI@schuelke.com (Schülke & Mayr UK Ltd.: +44-1142543500)

1.4 Emergency telephone number

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

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
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 firefighting: 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.
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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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Phenoxyethanol</td>
<td>122-99-6</td>
<td>Permissible exposure limit</td>
<td>20 ppm 110 mg/m3</td>
<td>TRGS 900</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td>Dermal absorption possible</td>
<td>Ceiling Limit Value 40 ppm 220 mg/m3</td>
<td>TRGS 900</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Phenoxyethanol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects, Long-term local effects</td>
<td>8,07 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>34,72 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term exposure, Short-term exposure, Local effects</td>
<td>2,5 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term local effects</td>
<td>20,83 mg/kg</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Consumers</th>
<th>Ingestion</th>
<th>Short-term exposure, Long-term exposure, Systemic effects</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>17.43 mg/kg</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Phenoxyethanol</td>
<td>Fresh water</td>
<td>0.943 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.0943 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>7.2366 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.7237 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>1.26 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>3.44 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>24.8 mg/l</td>
</tr>
</tbody>
</table>

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)
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 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-As: 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, 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 applica-
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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.

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

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
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).

Regulation (EC) No 850/2004 on persistent organic pollutants


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


15.2 Chemical safety assessment
Exempt

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!!!

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