

octenisept® gel **No Change Service!**

Version
01.08

Revision Date:
08.02.2017

Date of last issue: 05.12.2016
Date of first issue: 18.07.2005

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

1.1 Product identifier

Trade name : octenisept® gel

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

Use of the Sub-
stance/Mixture : Medical device

Recommended restrictions
on use : Restricted to professional users.

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 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.

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.

Contact with the eyes can cause irritation.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : viscous liquid

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Hazardous components

Remarks : No dangerous ingredients according to Regulation (EC) No. 1907/2006

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 eye irritation persists, consult a specialist.
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 : Treat symptomatically.,

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : For specialist advice physicians should contact the Poisons Information Service.

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 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).

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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.

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. Keep at temperature not exceeding 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

none

8.2 Exposure controls

Personal protective equipment

Protective measures : No special precautions required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : viscous
Colour : nearly colourless
Odour : odourless
Odour Threshold : not determined
pH : ca. 6,9, 20 °C
Melting point/freezing point : ca. 0 °C
Decomposition temperature : No data available
Boiling point/boiling range : ca. 90 °C
Flash point : > 61 °C, ISO 2719
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. 1,01 g/cm³, 20 °C
Solubility(ies)
Water solubility : in all proportions , 20 °C
Partition coefficient: n-octanol/water : Not applicable

Product information

on the basis of Regulation (EC) No. 1907/2006

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Auto-ignition temperature : ca. > 300 °C
Viscosity
 Viscosity, dynamic : ca. 5.050 mPa*s
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

Keep at temperature not exceeding 25 °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 : This information is not available.

Skin corrosion/irritation

Product:

No skin irritation

Serious eye damage/eye irritation

Product:

Contact with eyes may cause irritation.

Respiratory or skin sensitisation

Product:

Contains no substance or substances classified as sensitising. , May cause sensitisation of susceptible persons by skin contact.

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Germ cell mutagenicity

Product:

Germ cell mutagenicity- Assessment : Contains no ingredient listed as a mutagen

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

No data available

STOT - repeated exposure

No data available

Aspiration toxicity

No data available

SECTION 12: Ecological information

12.1 Toxicity

Product:

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

12.2 Persistence and degradability

Product:

Biodegradability

: The methods for determining biodegradability are not applicable to inorganic substances.

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

Product:

Mobility

: No data available

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

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) : 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

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- 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

SECTION 16: Other information

Full text of other abbreviations

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

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|| Changes compared with the previous edition!!!

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