

octenisan® md nasal gel **No Change Service!**

Version Revision Date: Date of last issue: 08.02.2017
02.00 10.07.2018 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 : octenisan® md nasal gel

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

Use of the Sub- : Medical device
stance/Mixture

Recommended restrictions : Restricted to professional users.
on use

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

1.4 Emergency telephone number

Emergency telephone num- : UK Poisons Emergency number: 0870 600 6266
ber

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 eyes may cause irritation.

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SECTION 3: Composition/information on ingredients
3.2 Mixtures

Chemical nature : viscous liquid

Hazardous components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
N,N'-(decane-1,10-diyl-di-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 Aquatic Chronic 1; H410	< 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 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 : Do not use a solid water stream as it may scatter and spread fire.

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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.

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: -5 - 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

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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 Method: 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
Vapour density	: No data available
Relative density	: ca. 1,01 g/cm ³ (20 °C)
Solubility(ies)	
Water solubility	: in all proportions (20 °C)
Partition coefficient: n-octanol/water	: Not applicable
Auto-ignition temperature	: ca. > 300 °C
Viscosity	
Viscosity, dynamic	: ca. 5.050 mPa*s
Explosive properties	: No data available

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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 : Keep at temperature not exceeding 25 °C.

10.5 Incompatible materials

Materials to avoid : Never mix concentrates directly.

10.6 Hazardous decomposition products

None reasonably foreseeable.

SECTION 11: Toxicological information
11.1 Information on toxicological effects
Acute toxicity
Components:
N,N'-(decane-1,10-diyl-di-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Acute oral toxicity	: LD50 (Rat): > 800 mg/kg, OECD Test Guideline 401, Harmful if swallowed.
Acute inhalation toxicity	: LC50 (Rat): > 4,0 mg/l, 4 h, OECD Test Guideline 403, 0,1 % solution
Acute dermal toxicity	: No data available
Acute toxicity (other routes of administration)	: LD50 intravenous (Rat): 10 mg/kg , OECD Test Guideline 401

Skin corrosion/irritation
Product:

No skin irritation

Serious eye damage/eye irritation
Product:

Contact with eyes may cause irritation.

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Respiratory or skin sensitisation**Components:**

N,N'-(decane-1,10-diyl-di-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:
 Did not cause sensitisation on laboratory animals. Maximisation Test, Guinea pig, OECD Test Guideline 406

Germ cell mutagenicity**Components:**

N,N'-(decane-1,10-diyl-di-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:
 Genotoxicity in vitro : Ames test, OECD Test Guideline 471, Non mutagenic
 Germ cell mutagenicity- Assessment : Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

Carcinogenicity**Components:**

N,N'-(decane-1,10-diyl-di-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:
 Mouse, Dermal exposure, OECD Test Guideline 451, Based on available data, the classification criteria are not met.
 Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

Reproductive toxicity**Components:**

N,N'-(decane-1,10-diyl-di-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:
 Effects on fertility : Rat, Oral, Based on available data, the classification criteria are not met.
 Effects on foetal development : Rat, Oral, OECD Test Guideline 414, Based on available data, the classification criteria are not met.
 Reproductive toxicity - Assessment : No toxicity to reproduction

STOT - single exposure**Components:**

N,N'-(decane-1,10-diyl-di-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:
 No data available

STOT - repeated exposure**Components:**

N,N'-(decane-1,10-diyl-di-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:
 No data available

Repeated dose toxicity**Components:**

N,N'-(decane-1,10-diyl-di-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:
 Mouse, NOAEL: 32 mg/kg, Oral, OECD Test Guideline, 408

Aspiration toxicity

No data available

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Further information**Product:**

||none

SECTION 12: Ecological information**12.1 Toxicity****Components:****N,N'-(decane-1,10-diyl-di-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 (Short-term (acute) aquatic hazard)	:	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 (Long-term (chronic) aquatic hazard)	:	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

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not applicable to inorganic substances.

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

Biodegradability	:	Result: Not biodegradable Method: OECD 301D / EEC 84/449 C6
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12.3 Bioaccumulative potential
Components:
N,N'-(decane-1,10-diyl-di-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

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

Mobility	:	Remarks: Adsorbs on soil.
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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	:	No data is available on the product itself.
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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.

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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 : Remarks: 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.

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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

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Further information

|| Changes compared with the previous edition!!!

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