

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

Version Revision Date: Date of last issue: 10.07.2018
02.01 14.08.2020 Date of first issue: 22.08.2007

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

Supplier : 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.com

E-mail address of person : Application Department
responsible for the +49 (0)40/ 521 00 666
SDS/Contact person AD@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

Classification (REGULATION (EC) No 1272/2008)

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

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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.

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

Chemical nature : viscous liquid

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; M = 100 Aquatic Chronic 1; H410; M = 10	>= 0.025 - < 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.

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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 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 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.

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 : Keep away from direct sunlight. Recommended storage tem-

Product information

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

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Colour	:	nearly colourless
Odour	:	odourless
Odour Threshold	:	not determined
pH	:	6.9 (20 °C) Concentration: 100 %
Melting point/freezing point	:	ca. 0 °C
Decomposition temperature	:	No data available
Boiling point/boiling range	:	ca. 90 °C
Flash point	:	> 100 °C
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. 1.01 g/cm ³ (20 °C)
Solubility(ies) Water solubility	:	completely soluble (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
Oxidizing properties	:	No data available

9.2 Other information

No data available

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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 Method: OECD Test Guideline 401 Remarks: Harmful if swallowed.
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Acute inhalation toxicity	:	Remarks: No data available
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Acute dermal toxicity	:	Remarks: No data available
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Skin corrosion/irritation**Product:**

Remarks	:	No skin irritation
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Components:**N,N'-(decane-1,10-diyl-di-1(4H)-pyridyl-4-ylidene)bis(octylammonium) dichloride:**

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	Skin irritation

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Remarks : Contact with eyes may cause irritation.

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

Species	: Rabbit
Method	: Read-across (Analogy)
Result	: Eye irritation

Respiratory or skin sensitisation**Components:****N,N'-(decane-1,10-diyl-di-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**Components:****N,N'-(decane-1,10-diyl-di-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**Components:****N,N'-(decane-1,10-diyl-di-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.
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Reproductive toxicity**Components:****N,N'-(decane-1,10-diyl-di-1(4H)-pyridyl-4-ylidene)bis(octylammonium) dichloride:**

Effects on foetal development	: Species: Rat Application Route: Oral
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Method: OECD Test Guideline 414

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

Reproductive toxicity - Assessment : No toxicity to reproduction
Did not show teratogenic effects in animal experiments.

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

Remarks : No data available

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

Remarks : No data available

Repeated dose toxicity**Components:****N,N'-(decane-1,10-diyl-di-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

Further information**Product:**

Remarks : 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

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Toxicity to algae/aquatic plants	:	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.

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

12.3 Bioaccumulative potential**Components:****N,N'-(decane-1,10-diyl-di-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

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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.

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 : No data is available on the product itself.

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

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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 - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3

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

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : 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 : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Not applicable

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

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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
GB EH40	:	UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA	:	Long-term exposure limit (8-hour TWA reference period)

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


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

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