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 Substance/Mixture : Medical device

1.3 Details of the supplier of the safety data sheet

Producer :
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

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 responsible for the SDS/Contact person :
Application Specialists
+49 (0)40/ 521 00 666
AD@schuelke.com

1.4 Emergency telephone number

Emergency telephone number : Carechem 24 International:+44 1235 239670

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Not a hazardous substance or mixture according to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019.

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : viscous liquid

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

If inhaled : No hazards which require special first aid measures.

In case of skin contact : No hazards which require special 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 water jet.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting	:	No information available.
Hazardous combustion products	:	No hazardous combustion products are known

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	:	Store at room temperature in the original container.

areas and containers

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

Occupational Exposure Limits

none

8.2 Exposure controls

Personal protective equipment

Eye/face protection	:	No special protective equipment required.
Hand protection		
Remarks	:	No special protective equipment required.
Respiratory protection	:	No special protective equipment required.
Protective measures	:	No special precautions required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	viscous liquid
Colour	:	nearly colourless
Odour	:	odourless
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
Flammability	:	Does not sustain combustion.
Upper explosion limit / Upper flammability limit	:	Not applicable
Lower explosion limit / Lower	:	Not applicable

flammability limit		
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	:	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
Viscosity, kinematic	:	not determined
Explosive properties	:	Not applicable
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

Metal corrosion rate	:	None reasonably foreseeable.

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

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity
Based on available data, the classification criteria are not met.

Skin corrosion/irritation
Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation
Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation

Skin sensitisation
Based on available data, the classification criteria are not met.

Respiratory sensitisation
Based on available data, the classification criteria are not met.

Germ cell mutagenicity
Based on available data, the classification criteria are not met.

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

Reproductive toxicity
Based on available data, the classification criteria are not met.

STOT - single exposure
Based on available data, the classification criteria are not met.

STOT - repeated exposure
Based on available data, the classification criteria are not met.

Aspiration toxicity
Based on available data, the classification criteria are not met.

Further information

Product:

Remarks	:	none

SECTION 12: Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

Product:

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

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

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.

12.6 Other adverse effects

Product:

Endocrine disrupting potential	:	This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f) at levels of 0.1% or higher.
Additional ecological information	:	No data is available on the product itself.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Disposal together with normal waste is not allowed. Special disposal required according to local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: Transport information

14.1 UN number

ADR	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

14.2 UN proper shipping name

ADR	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADR	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

14.4 Packing group

ADR	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA (Cargo)	:	Not regulated as a dangerous good
IATA (Passenger)	:	Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

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

Relevant EU provisions transposed through retained EU law

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable
Regulation (EU) No 2024/590 on substances that deplete the ozone layer	:	Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable

Volatile organic compounds	:	Directive 2010/75/EU of 24 November 2010 on industrial and livestock rearing emissions (integrated pollution prevention and control) Not applicable

15.2 Chemical safety assessment

SECTION 16: Other information

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regula-

tion (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 Harmonised 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 Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; 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 - Organisation 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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

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.