

**octenilin® wound irrigation solution**      **No Change Service!**

Version                      Revision Date:                      Date of last issue: 08.02.2017  
02.00                      07.09.2018                      Date of first issue: 06.03.2006

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

**1.1 Product identifier**

Trade name                      : octenilin® wound irrigation solution

**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

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**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.

**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.

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

Chemical nature : Aqueous solution

**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 (CO<sub>2</sub>)

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.

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**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

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**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.

**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. Do not store at temperatures above 30°C.

Advice on common storage : No materials to be especially mentioned.

**7.3 Specific end use(s)**

Specific use(s) : none

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**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	: liquid
Colour	: colourless
Odour	: nearly odourless
Odour Threshold	: not determined
pH	: ca. 5,4 (20 °C)
Melting point/freezing point	: ca. 0 °C
Decomposition temperature	No data available
Boiling point/boiling range	: ca. 100 °C
Flash point	: Not applicable
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapour pressure	: ca. 25 hPa (20 °C) similar to water
Vapour density	: No data available
Relative density	: ca. 1,0 g/cm <sup>3</sup> (20 °C)
Solubility(ies)	
Water solubility	: in all proportions (20 °C)
Partition coefficient: n-octanol/water	: Not applicable
Auto-ignition temperature	: No data available

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Viscosity		
Viscosity, dynamic	:	No data available
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**

Hazardous reactions                   : None reasonably foreseeable.

**10.4 Conditions to avoid**

Conditions to avoid                    : Do not store at temperatures above 30°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**
**Product:**

Acute oral toxicity                     : This information is not available.

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

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

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**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.

**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**

**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:**  
||| Rat, NOAEL: 32 mg/kg, Oral, OECD Test Guideline, 408

**Aspiration toxicity**

No data available

**Further information**

**Product:**

No data is available on the product itself.

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**SECTION 12: Ecological information**
**12.1 Toxicity**
**Product:**
**Ecotoxicology Assessment**

Short-term (acute) aquatic hazard : This product has no known ecotoxicological effects.

**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

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**12.2 Persistence and degradability**
**Product:**

Biodegradability : Remarks: Not applicable

**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:**

Bioaccumulation	:	Remarks: No bioaccumulation is to be expected (log Pow <= 4).
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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**
**Product:**

Mobility : Remarks: No data available

**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 (Euro-
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pean 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**

**IMDG** : -

**IATA** : -

**14.2 UN proper shipping name**

**IMDG** : -

**IATA** : -

**14.3 Transport hazard class(es)**

**IMDG** : -

**IATA** : -

**14.4 Packing group**

**IMDG**  
Packing group : -

**IATA (Cargo)**  
Packing group : -

**IATA (Passenger)**  
||Packing group : -

**14.5 Environmental hazards**

**IMDG**  
Marine pollutant : no

**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

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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.

## 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

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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**

Changes compared with the previous edition!!!

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.

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