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octenisept®gelNo ChVersionRevision Date:01.0808.02.2017	nange Service! Date of last issue: 05.12.2016 Date of first issue: 22.08.2007
SECTION 1: Identification of t	he substance/mixture and of the company/undertaking
1.1 Product identifier	
Trade name	: octenisept® gel
1.2 Relevant identified uses of th	e 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
Supplier	<ul> <li>Schülke &amp; Mayr UK Ltd.</li> <li>Cygnet House</li> <li>Jenkin Road, Meadowhall</li> </ul>
	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 Department +49 (0)40/ 521 00 8800 ADHI@schuelke.com (Schülke & Mayr UK Ltd.: +44-1142543500)
1.4 Emergency telephone numbe	r

Emergency telephone num-	: UK Poisons Emergency number: 0870 600 6266
ber Emergency telephone num-	: +49 (0)40/ 52100-0
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.

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### 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

#### 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	<ul> <li>Do NOT induce vomiting. Drink water as a precaution. Consult a physician if necessary.</li> </ul>

#### 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- : No information available. fighting

#### 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.

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#### 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	: No special protective measures against fire required.
fire and explosion	

#### 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 stor- age conditions Advice on common storage	<ul> <li>Keep away from direct sunlight. Keep at temperature not exceeding 25 °C.</li> <li>No materials to be especially mentioned.</li> </ul>
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
рН	: 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

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Upper explos	ion limit	:	Not applicable
Lower explos	ion limit	:	Not applicable
Vapour press	sure	:	ca. 25 hPa, 20 °C, similar to water
Relative vapo	our density	:	No data available
Density		:	ca. 1.01 g/cm3, 20 °C
Solubility(ies)	1		
Water solu		:	in all proportions , 20 °C
Partition coef	ficient: n-		Not applicable
octanol/water	•		
Auto-ignition	temperatur	e :	ca. > 300 °C
Viscosity			
Viscosity, o	dynamic		ca. 5,050 mPa*s
v 100001ty, C	ay non no	•	

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:

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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- As-	: Contains no ingredient listed as a mutagen
sessment	

#### Carcinogenicity

# Product:

Carcinogenicity - Assess-	:	Contains no ingredient listed as a carcinogen
ment		

#### **Reproductive toxicity**

#### Product:

Reproductive toxicity - As-	: Contains no ingredient listed as toxic to reproduction
sessment	

# 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 applica-
	ble 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:



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Assessm	ent	: 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 ad	lverse effects	
Product: Additiona	l ecological infor-	: none

# **SECTION 13: Disposal considerations**

#### **13.1 Waste treatment methods**

Product	
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mation

Product	: Dispose of the product according to the defined EWC (Euro- 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, deter- gents, 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 pol- lutants	: Not applicable
Seveso III: Directive : Not applicable	

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2012/18/EU Parliament on the cont accident ha dangerous	J of the European and of the Council rol of major- azards involving substances.	
Volatile org	anic compounds	: none, Directive 2010/75/EC on the limitation of emissions of volatile organic compounds
Other regul	ations	: 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

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#### Further information

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) No. 1272/2008

: Calculation method

Changes compared with the previous edition!!!

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