on the basis of REACH etc. (Amendment etc.) (EU Exit) Regulations 2019



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

1.1 Product identifier

Trade name : octenisan® wash lotion

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

Use of the Sub- : Cosmetics

stance/Mixture

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, 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

responsible for the SDS/Contact person

: Application Specialists +49 (0)40/ 521 00 666 AD@schuelke.com

(Schülke & Mayr UK Ltd.: +44-1142543500)

1.4 Emergency telephone number

Emergency telephone num-

ber

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 The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019)

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) as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019)

The product falls under the cosmetics directive and therefore does not need to be labelled.

Not a hazardous substance or mixture.

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 : Aqueous solution

Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		

Remarks : No dangerous ingredients according to Regulation (EC) No.

1907/2006

Substances with a workplace exposure limit :			
glycerol	56-81-5	>= 1 - < 10	
	200-289-5		

For explanation of abbreviations see section 16.

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 swallowed : Do NOT induce vomiting.

Obtain medical attention.

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4.2 Most important symptoms and effects, both acute and delayed

: Treat symptomatically. **Symptoms**

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 : Water spray jet

Foam

Carbon dioxide (CO2)

Dry powder

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.

ucts

Hazardous combustion prod- : No hazardous combustion products are known

5.3 Advice for firefighters

for firefighters

Special protective equipment : 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

Wipe up with absorbent material (e.g. cloth, fleece). Methods for cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel,

acid binder, universal binder, sawdust).

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.

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

Keep away from heat. Keep away from direct sunlight. Rec-

ommended storage temperature: 15 - 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

	Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
П	glycerol	56-81-5	TWA (Mist)	10 mg/m3	GB EH40

Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
Amides, C12-18- (even numbered),N- [3- (dimethyla- mino)propyl],N`oxides	Workers	Inhalation	Long-term systemic effects	3.52 mg/m3
	Workers	Skin contact	Long-term systemic effects	5 mg/kg bw/day
1-Propanaminium, 3- amino-N- (carboxymethyl)-N,N- dimethyl-, N-C8-18 acyl derivs., hydrox- ides, inner salts	Workers	Skin contact	Long-term systemic effects	12.5 mg/kg
	Workers	Inhalation	Long-term systemic effects	44 mg/kg

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
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Amides, C12-18-(even num- bered),N-[3- (dimethylamino)propyl],N`oxides	Fresh water	0.0303 mg/l
	Marine water	0.00303 mg/l
	Fresh water sediment	0.214 mg/kg
	Marine sediment	0.0214 mg/kg
	Soil	0.000025 mg/kg
	Intermittent use/release	0.0068 mg/kg
	Effects on waste water treatment plants	9.7 mg/l
1-Propanaminium, 3-amino-N- (carboxymethyl)-N,N-dimethyl-, N-C8-18 acyl derivs., hydroxides, inner salts	Fresh water	0.0135 mg/l
	Marine water	0.00135 mg/l
	Fresh water sediment	11.1 mg/kg
	Marine sediment	1.11 mg/kg
	Soil	0.85 mg/kg
	Effects on waste water treatment plants	3000 mg/l

8.2 Exposure controls

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally re-

quired.

Protective measures : Avoid contact with eyes.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : viscous

Colour : nearly colourless

Odour : characteristic

Odour Threshold : not determined

pH : ca. 5 (20 °C)

Concentration: 100 %

Melting point/freezing point : < -5 °C

Decomposition temperature Not applicable

Boiling point/boiling range : ca. 100 °C

Flash point : > 100 °C

Evaporation rate : No data available

Upper explosion limit / Upper

flammability limit

Not applicable

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Lower explosion limit / Lower

flammability limit

Not applicable

Vapour pressure : No data available

Relative vapour density : No data available

Density : ca. 1.015 g/cm3 (20 °C)

Solubility(ies)

Water solubility : completely soluble (20 °C)

Partition coefficient: n-

octanol/water

Not applicable

Auto-ignition temperature : No data available

Viscosity

Viscosity, dynamic : ca. 550 mPa*s

Flow time : 50 - 80 s

Method: DIN 53211

Explosive properties : No data available

Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids) : Does not sustain combustion.

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 : None reasonably foreseeable.

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10.6 Hazardous decomposition products

None reasonably foreseeable.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Components:

glycerol:

Acute oral toxicity : LD50 (Rat, female): 27,200 mg/kg

Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Guinea pig, male and female): 56,750 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

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Further information

Product:

Remarks none

SECTION 12: Ecological information

12.1 Toxicity

Components:

glycerol:

Toxicity to fish : LC50 (Oncorhynchus mykiss): 54,000 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l

Exposure time: 24 h

12.2 Persistence and degradability

Product:

Biodegradability Remarks: The methods for determining biodegradability are

not applicable to inorganic substances.

12.3 Bioaccumulative potential

Components:

glycerol:

: log Pow: -1.75 (25 °C) Partition coefficient: n-

Method: OECD Test Guideline 107 octanol/water

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

This substance/mixture contains no components considered Assessment

> 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 poten-

tial

The substance/mixture does not contain components considered to have endocrine disrupting properties according to

REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

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Additional ecological infor-

mation

No data is available on the product itself.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Can be incinerated or landfilled together with household waste

in compliance with the regulations, and after consultation with

the waste disposal services.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

SECTION 14: Transport information

14.1 UN number

IMDG : Not regulated as a dangerous good

IATA : 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.

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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 List of restrictions (Annex 17) Conditions of restriction for the fol-

lowing entries should be considered:

Number on list 3

UK REACH Candidate list of substances of very high

concern (SVHC) for Authorisation

Not applicable

Not applicable

The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Brit-

ain)

Regulation (EC) No 1005/2009 on substances that de-

plete the ozone layer

Not applicable

Not applicable

UK REACH List of substances subject to authorisation

(Annex XIV)

Directive 2010/75/EU of 24 November 2010 on industrial Volatile organic compounds

emissions (integrated pollution prevention and control)

Volatile organic compounds (VOC) content: 4 %

The components of this product are reported in the following inventories:

TCSI Not in compliance with the inventory

TSCA For Cosmetic Use Only

AIIC Not in compliance with the inventory

DSL This product contains the following components that are not

on the Canadian DSL nor NDSL.

Amides, C12-18-(even numbered), N-[3-

(dimethylamino)propyl],N'oxides

1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-,

N-C8-18 acyl derivs., hydroxides, inner salts N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4ylidene)bis(octylammonium) dichloride

ENCS Not in compliance with the inventory

ISHL Not in compliance with the inventory

KECI Not in compliance with the inventory

PICCS Not in compliance with the inventory

IECSC Not in compliance with the inventory

NZIoC Not in compliance with the inventory

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TECI: Not in compliance with the inventory

15.2 Chemical safety assessment

Exempt

SECTION 16: Other information

Full text of other abbreviations

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 - 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; 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; 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.

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