esemtan® skin lotion

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



Version 01.05	Revision Date: 06.08.2024		Date of last issue: 23.09.2022
SECTION 1:	Identification of t	he	substance/mixture and of the company/undertaking
1.1 Product id	dentifier		
Trade na	me	:	esemtan® skin lotion
1.2 Relevant	identified uses of th	ne s	substance or mixture and uses advised against
Use of the stance/M		:	Cosmetics
	the supplier of the		-
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
responsit	ldress of person ble for the tact person	:	Application Specialists +49 (0)40/ 521 00 666 AD@schuelke.com

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1.4 Emergency telephone number

Emergency telephone num- : Carechem 24 International:+44 1235 239670 ber

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.

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

esemtan® skin lotion

Version	Revision Date:	Date of last issue: 23.09.2022
01.05	06.08.2024	

No Change Service!

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)

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

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 : oil in water emulsion

Hazardous components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Substances with a workplace exposure	e 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

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. Rinse mouth with water. Obtain medical attention.

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.

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



esemtan® skin lotion

Version Re	vision Date:
01.05 06.	08.2024

No Change Service!

04.05	
01.05 06.08.2024	

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 prod- ucts	:	No hazardous combustion products are known

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 : Increased risk of slipping in the presence of leaked / spilled product.

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).
	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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling Advice on protection against fire and explosion	:	not required under normal use No special protective measures against fire required.
Hygiene measures	:	Keep away from food and drink.

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

esemtan® skin lotion

Version 01.05	Revision Date: 06.08.2024	Date of last issue: 23.09.2022

No Change Service!

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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: 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

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

Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
White mineral oil (pe- troleum)	Workers	Skin contact	Long-term systemic effects	217.1 mg/kg
	Workers	Inhalation	Long-term systemic effects	164.6 mg/m3
Fatty acids, C16-18	Workers	Skin contact	Long-term systemic effects	10 mg/kg bw/day
	Workers	Inhalation	Long-term systemic effects	17.63 mg/m3

8.2 Exposure controls

Personal protective equipment

Respiratory protection	: No personal respiratory protective equipment normally re- auired.
Protective measures	: Avoid contact with eyes.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: liquid, emulsion
Colour	: white
Odour	: odourized
Odour Threshold	: not determined
рН	: 5 (20 °C) Concentration: 100 %

esemtan® skin lotion

Version

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

Revision Date:



-	rsion Revision Date: .05 06.08.2024		Date of last issue: 23.09.2022
	Melting point/freezing point	:	not determined
	Decomposition temperature		Not applicable
	Boiling point/boiling range	:	not determined
	Flash point	:	Not applicable
	Evaporation rate	:	No data available
	Upper explosion limit / Upper flammability limit	:	Not applicable
	Lower explosion limit / Lower flammability limit	:	Not applicable
	Vapour pressure	:	No data available
	Relative vapour density	:	No data available
	Density	:	ca. 0.98 g/cm3 (20 °C)
	Solubility(ies) Water solubility Partition coefficient: n- octanol/water Auto-ignition temperature	::	immiscible Not applicable No data available
	Viscosity Viscosity, dynamic	:	ca. 700 mPa*s (20 °C) Method: DIN 53019
	Viscosity, kinematic	:	not determined
	Explosive properties	:	According to experience not expected
I	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

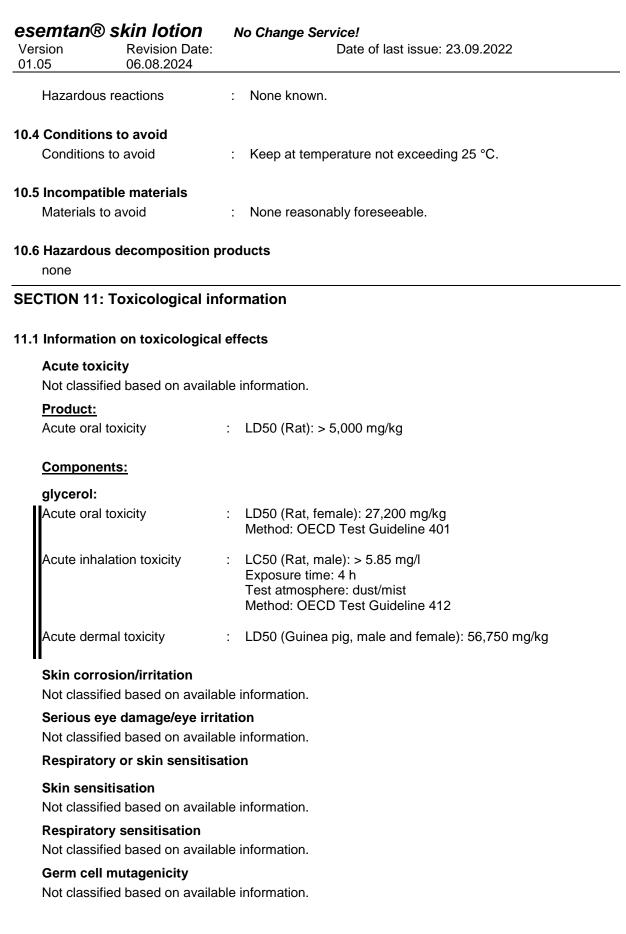
No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

The product is chemically stable.

10.3 Possibility of hazardous reactions

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



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



esemtan® skin lotion

Version	Revision Date:
01.05	06.08.2024

No Change Service!

Version	Revision Date:	Date of last issue: 23.09.2022
01.05	06.08.2024	

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.

2

Further information

Product:

Remarks

The product has not been tested. No data is available on the product itself.

SECTION 12: Ecological information

12.1 Toxicity

Product:

Ecotoxicology Assessment		
Acute aquatic toxicity	:	This product has no known ecotoxicological effects.

Components:

glycerol:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss): 54,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 10,000 mg/l Exposure time: 24 h

12.2 Persistence and degradability

Product:

: Remarks: No data available Biodegradability

12.3 Bioaccumulative potential

Product:		
Bioaccumulation	:	Remarks: No data available

Components:

glycerol:

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

esemtan® skin lotionVersionRevision Date:01.0506.08.2024	No Change Service! Date of last issue: 23.09.2022
Partition coefficient: n- octanol/water	: log Pow: -1.75 (25 °C) Method: OECD Test Guideline 107
12.4 Mobility in soil	
<u>Product:</u> Mobility	: Remarks: No data available
12.5 Results of PBT and vPvB as	ssessment
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 poten- tial	: The substance/mixture does not contain components consid- ered 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.
Additional ecological infor- mation	: No data is available on the product itself.
SECTION 13: Disposal consid	lorations

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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.
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SECTION 14: Transport information

14.1 UN number		
ADR	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	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

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



Version 01.05	Revision Date: 06.08.2024	No Change Service! Date of last issue: 23.09.2022
ΙΑΤΑ		: Not regulated as a dangerous good
4.3 Transpor	t hazard class(es)	
ADR		: Not regulated as a dangerous good
IMDG		: Not regulated as a dangerous good
ΙΑΤΑ		: Not regulated as a dangerous good
14.4 Packing g	group	
ADR		: Not regulated as a dangerous good
IMDG		: Not regulated as a dangerous good
IATA (Car	go)	: Not regulated as a dangerous good
IATA (Pas	ssenger)	: Not regulated as a dangerous good
	ental hazards ited as a dangerous	aood
		9000
14.6 Special p Not applic	recautions for user able	-
Not applic	able	to Annex II of Marpol and the IBC Code
Not applic 14.7 Transpor Not applic	able t in bulk according	to Annex II of Marpol and the IBC Code supplied.
Not applic 14.7 Transpor Not applic SECTION 15: 15.1 Safety, h mixture	able t in bulk according able for product as s : Regulatory infor ealth and environn	to Annex II of Marpol and the IBC Code supplied.
Not applic 14.7 Transpor Not applic SECTION 15: 15.1 Safety, h mixture Relevant EU pr	able t in bulk according able for product as s : Regulatory infor ealth and environm rovisions transposed	to Annex II of Marpol and the IBC Code supplied. mation nental regulations/legislation specific for the substance or
Not applic 14.7 Transpor Not applic SECTION 15: 15.1 Safety, h mixture Relevant EU pr UK REAC UK REAC	able t in bulk according able for product as s Regulatory infor ealth and environn rovisions transposed H List of restrictions H Candidate list of s	to Annex II of Marpol and the IBC Code supplied. mation mental regulations/legislation specific for the substance or I through retained EU law (Annex 17) : Not applicable ubstances of very high : Not applicable
Not applic 14.7 Transpor Not applic SECTION 15: 15.1 Safety, h mixture Relevant EU pr UK REAC UK REAC Concern (S The Persis Regulatior	able t in bulk according able for product as s Regulatory infor ealth and environn rovisions transposed H List of restrictions H Candidate list of s SVHC) for Authorisat stent Organic Polluta	to Annex II of Marpol and the IBC Code supplied. mation mental regulations/legislation specific for the substance or I through retained EU law (Annex 17) : Not applicable ubstances of very high : Not applicable
Not applic Not applic Not applic SECTION 15: 15.1 Safety, h mixture Relevant EU pr UK REAC UK REAC Concern (S The Persis Regulatior ain) Regulatior	able t in bulk according able for product as s Regulatory infor ealth and environm rovisions transposed H List of restrictions H Candidate list of s SVHC) for Authorisat stent Organic Polluta n (EU) 2019/1021 as	to Annex II of Marpol and the IBC Code supplied. mation mental regulations/legislation specific for the substance or I through retained EU law (Annex 17) : Not applicable ubstances of very high : Not applicable tion ants Regulations (retained : Not applicable
Not applic Not applic 14.7 Transpor Not applic SECTION 15: 15.1 Safety, h mixture Relevant EU pr UK REAC UK REAC UK REAC Concern (S The Persis Regulatior ain) Regulatior plete the c	able t in bulk according able for product as s Regulatory infor ealth and environm rovisions transposed H List of restrictions H Candidate list of s SVHC) for Authorisat stent Organic Polluta to (EC) No 1005/2009 poone layer H List of substances	to Annex II of Marpol and the IBC Code supplied. mation nental regulations/legislation specific for the substance or I through retained EU law (Annex 17) : Not applicable ubstances of very high : Not applicable ition ants Regulations (retained : Not applicable amended for Great Brit-

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		
Z40000056 ZSDB_P_GB EN	Page 9/11		

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

esemtan® s Version 01.05	kin lotion Revision Date: 06.08.2024	^	No Change Service! Date of last issue: 23.09.2022
			on the Canadian DSL nor NDSL.
			Hexanoic acid, 2-ethyl-, C16-18-alkyl esters Stearic acid, esters with methyl α-D-glucoside 1,2,3-Propanetriol, homopolymer,octadecanoate
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		:	On the inventory, or in compliance with the inventory
TECI		:	Not in compliance with the inventory

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15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this mixture.

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

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



esemtan® skin lotion

Version	Revision Date:	Date of last issue: 23.09.2022
01.05	06.08.2024	

No Change Service!

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.