

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended
by UK REACH Regulations SI 2019/758



esemtan® active gel

No Change Service!

Version
03.00

Revision Date:
08.07.2024

Date of last issue: 05.09.2022

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

1.1 Product identifier

Trade name : esemtan® active gel

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

Use of the Sub-
stance/Mixture : Cosmetics

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.
Cygnat 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 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 GB-CLP Regulation, UK
SI 2019/720, and UK SI 2020/1567)**

Flammable liquids, Category 2
Eye irritation, Category 2

H225: Highly flammable liquid and vapour.
H319: Causes serious eye irritation.

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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)

The product falls under the cosmetics directive and therefore does not need to be labelled., Although this product does not need to be labelled, we recommend to observe the safety instructions.

Hazard pictograms	:	 
Signal word	:	Danger
Hazard statements	:	H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation.
Precautionary statements	:	Prevention: P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Response: P337 + P313 If eye irritation persists: Get medical advice/attention.

Additional Labelling

EUH208 Contains cineole. May produce an allergic reaction.

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 : Solution of the following substances with harmless additives.

Hazardous components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
ethanol	64-17-5 200-578-6 603-002-00-5 01-2119457610-43-XXXX	Flam. Liq. 2; H225 Eye Irrit. 2; H319	>= 30 - < 50
cineole	470-82-6 207-431-5	Flam. Liq. 3; H226 Skin Sens. 1B;	>= 0.1 - < 1

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	01-2119967772-24-XXXX		

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : Take off all contaminated clothing immediately.

If inhaled : Move to fresh air.

|| In case of skin contact : No hazards which require special first aid measures.

In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed : Do NOT induce vomiting.
Clean mouth with water and drink afterwards plenty of water.
If swallowed, seek medical advice immediately and show this container or label.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Treat symptomatically.

Risks : Causes serious eye irritation.

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
Alcohol-resistant 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 : Cool closed containers exposed to fire with water spray.

Hazardous combustion products : No hazardous combustion products are known

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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 : Remove all sources of ignition.

6.2 Environmental precautions

Environmental precautions : No special environmental precautions required.

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 : Do not smoke.
Advice on protection against : The hot product gives off combustible vapours.
fire and explosion

Hygiene measures : Keep away from food and drink.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage : Store at room temperature in the original container. Keep at
areas and containers temperature not exceeding 25 °C.

Further information on stor- : Keep container tightly closed. Keep away from direct sunlight.
age conditions Recommended storage temperature: 5 - 25°C

Advice on common storage : Do not store together with oxidising agents.

7.3 Specific end use(s)

Specific use(s) : none

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

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Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
ethanol	64-17-5	TWA	1,000 ppm 1,920 mg/m ³	GB EH40

Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
ethanol	Workers	Inhalation	Acute local effects	1900 mg/m ³
	Workers	Skin contact	Long-term systemic effects	343 mg/kg
	Workers	Inhalation	Long-term systemic effects	950 mg/m ³

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
ethanol	Fresh water	0.96 mg/l
	Marine water	0.79 mg/l
	Fresh water sediment	3.6 mg/kg
	Soil	0.63 mg/kg
	Marine sediment	2.9 mg/kg
	Sewage treatment plant	580 mg/l

8.2 Exposure controls

Personal protective equipment

Eye/face protection : If splashes are likely to occur, wear:
Goggles

Hand protection

Remarks : No special protective equipment required.

Respiratory protection : No personal respiratory protective equipment normally required.

Protective measures : Avoid contact with eyes.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: liquid, structurally viscous
Colour	: colourless
Odour	: camphor like
Odour Threshold	: not determined
pH	: 5 - 6 (20 °C) Concentration: 100 %
Melting point/freezing point	: < -5 °C
Decomposition temperature	No data available
Boiling point/boiling range	: ca. 80 °C
Flash point	: 20 °C Method: DIN 53213, Part 1

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Evaporation rate	:	No data available
Upper explosion limit / Upper flammability limit	:	15 %(V) Raw material
Lower explosion limit / Lower flammability limit	:	3.1 %(V) Raw material
Relative vapour density	:	No data available
Density	:	ca. 0.92 g/cm ³ (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	:	1,600 - 2,400 mPa*s (20 °C) Method: DIN 53019
Viscosity, kinematic	:	not determined
Explosive properties	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids)	:	Highly flammable liquid and vapour.
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 : Protect from frost, heat and sunlight.

10.5 Incompatible materials

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Materials to avoid : Strong oxidizing agents

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.

Components:

ethanol:

Acute oral toxicity	: LD50 (Rat): 10,470 mg/kg Method: OECD Test Guideline 401
Acute inhalation toxicity	: LC50 (Rat, male and female): 124.7 mg/l Exposure time: 4 h Test atmosphere: vapour
Acute dermal toxicity	: LD50 (Rabbit): > 2,000 mg/kg Method: OECD Test Guideline 402

cineole:

Acute oral toxicity	: LD50: 4,500 mg/kg Method: OECD Test Guideline 401 Remarks: Based on data from similar materials
Acute dermal toxicity	: LD50 (Rat, male and female): > 2,000 mg/kg Method: OECD Test Guideline 402 GLP: yes

Skin corrosion/irritation

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

Product:

Species	: Rabbit
Result	: No skin irritation

Components:

ethanol:

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

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Product:

Species : Rabbit
Result : Mildly irritant - does not need to be labelled

Components:

ethanol:

Method : OECD Test Guideline 405
Result : Eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Product:

Remarks : May cause sensitisation of susceptible persons by skin contact.

Components:

ethanol:

Test Type : Maximisation Test
Species : Guinea pig
Method : OECD Test Guideline 406
Result : Did not cause sensitisation on laboratory animals.

cineole:

Result : The product is a skin sensitiser, sub-category 1B.

Germ cell mutagenicity

Not classified based on available information.

Components:

ethanol:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: Not mutagenic in Ames Test

Genotoxicity in vivo : Result: Non mutagenic

Germ cell mutagenicity- Assessment : Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

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Carcinogenicity

Not classified based on available information.

Components:

ethanol:

Carcinogenicity - Assessment : Did not show carcinogenic effects in animal experiments.

Reproductive toxicity

Not classified based on available information.

Components:

ethanol:

Effects on foetal development : Species: Rat
Application Route: Oral
General Toxicity Maternal: NOAEL: 5,200 mg/kg bw/day
Developmental Toxicity: NOAEL: 5,200 mg/kg bw/day

Reproductive toxicity - Assessment : Animal experiments showed mutagenic and teratogenic effects.

STOT - single exposure

Not classified based on available information.

Components:

ethanol:

Remarks : No data available

STOT - repeated exposure

Not classified based on available information.

Components:

ethanol:

Remarks : No data available

Repeated dose toxicity

Components:

ethanol:

Species : Rat
NOAEL : 1,730 mg/kg
LOAEL : 3,160 mg/kg
Application Route : Oral
Exposure time : 90 d

Aspiration toxicity

Not classified based on available information.

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Further information

Product:

Remarks : No human information is available.

SECTION 12: Ecological information

12.1 Toxicity

Components:

ethanol:

Toxicity to fish	: LC50 (Leuciscus idus (Golden orfe)): 8,140 mg/l Exposure time: 48 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 5,000 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: EC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

12.2 Persistence and degradability

Product:

Biodegradability : Result: Readily biodegradable.
Method: OECD 301D / EEC 84/449 C6

Components:

ethanol:

Biodegradability	: Test Type: aerobic Result: Readily biodegradable. Biodegradation: > 70 % Exposure time: 5 d Method: OECD 301D / EEC 84/449 C6
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12.3 Bioaccumulative potential

Components:

ethanol:

Bioaccumulation	: Remarks: Bioaccumulation is unlikely.
Partition coefficient: n-octanol/water	: log Pow: -0.14 Method: Calculated value

12.4 Mobility in soil

Components:

ethanol:

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Mobility : Remarks: 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 : 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.

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 : UN 1170

IMDG : UN 1170

IATA : UN 1170

14.2 UN proper shipping name

ADR : ETHANOL SOLUTION

IMDG : ETHANOL SOLUTION

IATA : Ethanol solution

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADR	: 3	
IMDG	: 3	

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IATA : 3

14.4 Packing group

ADR

Packing group : II
Classification Code : F1
Hazard Identification Number : 33
Labels : 3
Tunnel restriction code : (D/E)

IMDG

Packing group : II
Labels : 3
EmS Code : F-E, S-D

IATA (Cargo)

Packing instruction (cargo aircraft) : 364
Packing instruction (LQ) : Y341
Packing group : II
Labels : Flammable liquid

IATA (Passenger)

Packing instruction (passenger aircraft) : 353
Packing instruction (LQ) : Y341
Packing group : II
Labels : Flammable liquid

14.5 Environmental hazards

ADR

Environmentally hazardous : no

IMDG

Marine pollutant : no

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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 List of restrictions (Annex 17) : Conditions of restriction for the following entries should be considered:
Number on list 3

UK REACH Candidate list of substances of very high : Not applicable

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concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) : Not applicable

Regulation (EC) No 1005/2009 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 emissions (integrated pollution prevention and control)
Volatile organic compounds (VOC) content: 45.85 %

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

15.2 Chemical safety assessment

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

SECTION 16: Other information

Full text of H-Statements

H225 : Highly flammable liquid and vapour.
H226 : Flammable liquid and vapour.
H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.

Full text of other abbreviations

Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
Skin Sens. : Skin sensitisation
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

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- 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

Classification of the mixture:

Flam. Liq. 2

H225

Eye Irrit. 2

H319

Classification procedure:

Based on product data or assessment

Calculation method

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.