

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

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ALCOHOL CETYLICUS ET STEARYLICUS EMULSIFICANS B

Publication: 18/03/2022

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name:	Cetostearyl alcohol (type B), emulsifying Alcohol cetylicus et stearylicus emulsificans B Emulgerende cetostearylalcohol type B Cétostéarylique (alcool) émulsifiant (type B) Cetostearylalkohol (Typ B), Emulgierender
N° CAS:	N/A
N° EC:	N/A

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreatipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Not classified.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):	Not applicable.
Signal word(s):	Not applicable.
Hazard statements:	Not applicable.
Precautionary statements:	Not applicable.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

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3.2 Mixtures

Product name:	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts
IUPAC name:	Not available.
Synonyms:	Sodium alkyl sulfate Sodium lauryl sulfate
N° CAS:	85586-07-8
N° EC:	287-809-4
Molecular Formula:	Not available.
Content:	7 – 12.5 %
A suitable buffer may be added.	

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Remove immediately contaminated clothing.
After inhalation:	Fresh air, rest. Never attempt to induce vomiting: risk of inhalation. Call a doctor.
After skin contact:	Wash skin with plenty of water and soap.
After eye contact:	Irrigate copiously with clean, fresh water for at least 15 minutes, holding the eyelids apart. Obtain emergency medical attention.
After ingestion:	Give nothing to drink. Do NOT induce vomiting. (Irritation of the stomach possible.) Ask for medical advice. Immediately consult a doctor/medical service.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Carbon dioxide (CO ₂), dry chemical powder, foam. Water spray.
Unsuitable extinguishing media:	Do not use a solid water stream as it may scatter and spread fire.

5.2 Special hazards arising from the substance/mixture

Fire hazard: In case of fire it can release carbon oxides (CO and CO₂).
Explosion hazard: It's dust is explosive with air.

5.3 Advice for firefighters

Surrounding fires:	Avoid (reject) fire-fighting water to enter environment.
Protection against fire:	Use a self-contained breathing apparatus and also a protective suit.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

General measures: No naked flames, sparks, and do not smoke.
Protective equipment: Wear suitable protective clothing.

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Emergency procedures: Mark out the contaminated area with signs and prevent access to unauthorized personnel. Spill area may be slippery.

For emergency responders

General measures: No naked flames, sparks, and do not smoke.

6.2 Environmental precautions

Use appropriate container to avoid environmental contamination.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Vacuum with an equipment that avoids ignition risk. Provide the tank with earthing.

Other information: Not in groundwater, surfacewater or sewerage. Notify authorities if product enters sewers or public waters.

6.4 Reference to other sections

Reference to other sections (8, 13).

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Not available.
Personal protection:	Not available.
Technical protective measures:	Keep away from sources of ignition - No smoking. Avoid raising dust. Do not eat, drink or smoke when using this product. Use only explosion-proof equipment.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Avoid dust formation. Prevent build-up of electrostatic charges (e.g. by grounding). Earth the equipment. Use spark-/explosionproof appliances and lighting system. Store tightly closed in a dry and cool place. Exclude sources of heat, sparks and open flame. Storage temperature: < 70 °C Packaging materials: Stainless steel. Polyethylene. Paper.
Storage – away from:	Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Sulfuric acid, mono-C12-14-alkyl esters, sodium salts (85586-07-8)

DNEL/DMEL (Workers)

Long-term - systemic effects, dermal	4060 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	285 mg/m ³

DNEL/DMEL (General population)

Long-term - systemic effects, oral	24 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	85 mg/m ³

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Long-term - systemic effects, dermal	2440 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.131 mg/L
PNEC aqua (marine water)	0.0131 mg/L
PNEC aqua (intermittent, freshwater)	0.036 mg/L
PNEC (Sediment)	
PNEC sediment (freshwater)	4.61 mg/kg dwt
PNEC sediment (marine water)	0.461 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.846 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	1.35 mg/L

8.2 Exposure controls

Appropriate engineering control

Provide appropriate exhaust ventilation at places of dust forming.

Individual protection measures

Eye/face protection: Face-shield.

Skin protection: Wear suitable protective clothing.

Hand protection: Wear suitable gloves. Protective gloves made of PVC. Neoprene protective gloves.

Material: Polyvinylchloride (PVC), Nitrile rubber (NBR), Latex

Permeation: 6 (> 480 minutes)

Standard: EN ISO 374

Respiratory protection: Breathing apparatus needed only when vapour or mist is formed. Wear anti dust mask (FFP3/NPF 50 type according to EN 149-2009).

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or pale yellow, waxy mass, plates, flakes or granules.
Odour:	Characteristic.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	≈ 50 °C
Initial boiling point:	> 250 °C
Boiling range:	Not available.
Flash point:	> 125 °C
Evaporation rate:	Not available.
Flammability (solid/gas):	> 125 °C
Upper/lower flammability or explosive limits:	Not available.

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Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Slightly soluble in ethanol (96 per cent).
Solubility in water:	Soluble in hot water giving an opalescent solution, practically insoluble in cold water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	> 200 °C
Viscosity:	Not available.
Explosive properties:	Not applicable.
Oxidising properties:	Not applicable.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Stable at normal conditions. See section 7.

10.2 Chemical stability

Stable under normal conditions of use.

10.3 Possibility of hazardous reactions

Finely dispersed particles form explosive mixtures in air.

10.4 Conditions to avoid

Stable at normal conditions. See section 7.

10.5 Incompatible materials

Strong oxidising compounds.

10.6 Hazardous decomposition products

It may generate irritant/toxic mists/gases.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Acute toxicity (oral):	Not classified (Based on available data, the classification criteria are not met)
	Acute toxicity (dermal):	Not classified.
	Acute toxicity (inhalation):	Not classified.
	WAX SX BP	
	LD ₅₀ oral rat	> 2000 mg/kg
	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts (85586-07-8)	
	LD ₅₀ oral rat	500 – 2000 mg/kg bodyweight, Animal: rat, Guideline: EU Method B.1 bis (Acute Oral Toxicity - Fixed Dose Procedure)

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LD₅₀ dermal rat > 2000 mg/kg bodyweight, Animal: rat, Guideline: OECD
Guideline 402 (Acute Dermal Toxicity)

Skin corrosion/irritation:	Causes skin irritation.
Serious eye damage/irritation:	Causes serious eye irritation. Additional information: Irritant (rabbit eye)
Respiratory/skin sensitisation:	Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity:	Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity:	Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity:	Not classified (Based on available data, the classification criteria are not met)
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure:	Not classified (Based on available data, the classification criteria are not met)
Aspiration Hazard:	Not classified (Based on available data, the classification criteria are not met)
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Hazardous to the aquatic environment, short-term (acute):	Not classified.
Hazardous to the aquatic environment, long-term (chronic):	Not classified

WAX SX BP

LC ₅₀ fish 1	> 10 mg/L <i>Carassius Auratus</i> (96h)
EC ₅₀ Daphnia 1	> 10 mg/L <i>Daphnia Magna</i> (48h)

Sulfuric acid, mono-C12-14-alkyl esters, sodium salts (85586-07-8)

LC ₅₀ fish 1	3.6 mg/L Test organisms (species): <i>Oncorhynchus mykiss</i> (previous name: <i>Salmo gairdneri</i>)
EC ₅₀ Daphnia 1	4.7 mg/L Test organisms (species): <i>Daphnia magna</i>
EC ₅₀ 72h algae (1)	> 20 mg/L Test organisms (species): <i>Desmodesmus subspicatus</i> (previous name: <i>Scenedesmus subspicatus</i>)
EC ₅₀ 72h algae (2)	12 mg/L Test organisms (species): <i>Desmodesmus subspicatus</i> (previous name: <i>Scenedesmus subspicatus</i>)
NOEC chronic fish	≥ 1.357 mg/L Test organisms (species): <i>Pimephales promelas</i> Duration: '42 d'

12.2 Persistence and degradability

WAX SX BP	Persistence and degradability: Readily biodegradable.
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12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

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12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Ecology - waste materials: Collect all waste in suitable and labelled containers and dispose according to local legislation.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not applicable.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not applicable.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not applicable.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not applicable.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Dangerous for the environment: No.
Marine pollutant: No.

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not applicable.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol: Not applicable.

Risk phrases: Not applicable.

Safety phrases: Not applicable.

15.2 Chemical safety assessment

Not available.

SECTION 16: OTHER INFORMATION

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16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Classification based on the main component.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available.

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

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