

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

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ALCOHOL CETYLICUS ET STEARYLICUS EMULSIFICANS A

Publication: 23/02/2022

Revision: 23/02/2022

Version: 00



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

1.1 Product identifier

Product name:	Cetostearyl alcohol (type A), emulsifying Alcohol cetylicus et stearylicus emulsificans A Emulgerende cetylstearylalcohol type A Cétostéarylique (alcool) émulsifiant (type A) Cetylstearylalkohol, emulgierender (Typ A)
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.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

The product is not subject to classification according to GHS criteria.

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.

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2.3 Other hazards

Dust formed by abrasion can form flammable mixtures with air.

The product does not contain substances meeting the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Chemical character

Mixture based on: alcohols, C16-18, Sulfuric acid, C12-18 (even numbered) alkyl esters, sodium salts

Ph. Eur.: Cetostearylalcohol (Type A), Emulsifying

A suitable buffer may be added.

Hazardous components (GHS)

According to Regulation (EC) No. 1272/2008

Product name: Sulfuric acid, mono-C16-18-alkyl esters, sodium salts

IUPAC name: Sodium;heptadecyl sulfate

Synonyms: Sodium heptadecyl sulfate

Heptadecyl sulfate, sodium salt

N° CAS: 68955-20-4

N° EC: 273-258-7

Molecular Formula: $C_{37}H_{76}Na_2O_6S_2$

Content: $\geq 5\% - \leq 15\%$

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Avoid contact with skin, eyes and clothing. If you feel unwell: Seek medical advice.

After inhalation: Fresh air.

After skin contact: In case of contact with skin, wash immediately with plenty of soap and water. Seek medical advice in case of irritation.

After eye contact: Rinse thoroughly under running water for 15 minutes while holding eyelids open. Do not rub the eyes dry, to avoid damage to the cornea due to mechanical rubbing. Consult a doctor in case of irritation.

After ingestion: Rinse mouth and drink 200-300 ml of water.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms: The most important symptoms and known effects are described on the label (see section 2) and/or in section 11.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Symptomatic treatment (decontamination, vital functions).

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

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Suitable extinguishing media: Carbon dioxide, foam, extinguishing powder, water mist.
Unsuitable extinguishing media: Unknown.

5.2 Special hazards arising from the substance/mixture

Combustion causes unpleasant and toxic fumes.

5.3 Advice for firefighters

Surrounding fires: Cool endangered containers with water.
Fire residues and contaminated extinguishing water must be disposed of in accordance with local regulations.
Protection against fire: Use self-contained breathing apparatus.
Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Avoid airborne dust (i.e. remove dust from surfaces with compressed air). Avoid formation and deposit of dust - danger of dust explosion.

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear eye/face protection.
Use respiratory protection if vapours/dusts/aerosols are generated.
Wear chemical resistant protective gloves.

For emergency responders

Wear eye/face protection.
Use respiratory protection if vapours/dusts/aerosols are generated.
Wear chemical resistant protective gloves.

6.2 Environmental precautions

Do not discharge into drains, surface or ground water.

6.3 Methods and material for containment and cleaning up

Small quantities: Use mechanical handling equipment.
Large quantities: Use mechanical handling equipment.
Dispose of collected material in accordance with relevant regulations.

6.4 Reference to other sections

Information on exposure control/personal protection and disposal considerations are given in Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Avoid excessive dust formation - danger of explosion. The usual precautionary measures for handling chemicals should be observed.
Personal protection: Use suitable gloves and eye/face protection.
Technical protective measures: Fire and explosion protection: Accumulation of fine dust may pose a risk of explosion in the presence of air. Avoid accumulation of electrostatic charges. Avoid all sources of ignition: heat, sparks, open flames.
Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

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Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Appropriate materials: High-density polyethylene (HDPE). Keep container tightly closed. Storage temperature: $\leq 30^{\circ}\text{C}$
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

Components with limit values to be observed at the workplace: No occupational exposure limit is known.

8.2 Exposure controls

Appropriate engineering control

General protection and hygiene measures: Avoid contact with skin, eyes and clothing. The usual precautionary measures for handling chemicals should be observed. Wash hands and face before breaks and at the end of work.

Individual protection measures

Eye/face protection:	Safety glasses with side protection (cage glasses) (e.g. EN 166).
Skin protection:	Choose suitable protective equipment according to the activity and exposure, e.g. apron, boots, suitable clothing (according to EN 14605 in case of splashes or EN 13982 in case of dust).
Hand protection:	Protective gloves are recommended in accordance with the following specification. The recommendation applies to laboratory use; workplace conditions must be considered separately. Suitable materials for direct and prolonged contact (Recommendation: protection factor 6, corresponding to > 480 minutes permeation time according to EN 374): nitrile rubber (NBR) - 0.2 mm thickness.
Respiratory protection:	Respiratory protection in case of development of respirable aerosols and dusts.
Thermal hazards:	Not determined.

Environmental exposure control

For information on environmental exposure controls, see section 6.

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:	Odourless.
Odour threshold:	Not applicable as odour is imperceptible.
pH:	6.5 – 8.0 (water, 20 °C)
Melting/freezing point:	Melting range: 50.0 - 54.0 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	177 °C
Evaporation rate:	The product is not volatile.
Flammability (solid/gas):	Not readily flammable.

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Upper/lower flammability or explosive limits:	Not relevant for classification and labelling of solids.
Vapour pressure:	Negligible.
Vapour density:	0.81 - 0.83 g/cm ³ (60 °C)
Relative density:	The product is not volatile. (20 °C)
Solubility:	Slightly soluble in ethanol (96 per cent) and in light petroleum. When melted, it is miscible with fatty oils, with liquid paraffin and with melted wool fat.
Solubility in water:	Soluble in hot water giving an opalescent solution, practically insoluble in cold water.
Partition coefficient (n-octanol/water):	Not applicable to mixtures.
Auto-ignition temperature:	Not available.
Decomposition temperature:	No decomposition if stored and handled as prescribed/indicated.
Viscosity:	Dynamic viscosity (20 °C): Not applicable, the product is a solid.
Explosive properties:	Explosion hazard: non-explosive.
Oxidising properties:	Fire behaviour characteristics: non-oxidising.

9.2 Other information

Self-combustion capacity: The substance does not spontaneously combust.

Apparent density: approx. 850 kg/m³ (20 °C)

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No hazardous reaction if storage and handling regulations/indications are followed.

Corrosion of metals: A corrosive effect on metal is not to be expected.

10.2 Chemical stability

The product is stable if the requirements/indications for handling and storage are followed.

10.3 Possibility of hazardous reactions

None are known under normal conditions of use.

10.4 Conditions to avoid

See SDS Section 7 - Handling and Storage.

10.5 Incompatible materials

Substances to avoid: No known substances to avoid.

10.6 Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Practically non-toxic for a single ingestion. Experimental/calculated data: LD ₅₀ (oral): > 5,000 mg/kg
Skin corrosion/irritation:	Slightly irritating in contact with skin.
Serious eye damage/irritation:	May cause slight eye irritation.
Respiratory/skin sensitisation:	There is no evidence of a potential sensitising effect on the skin.
Germ cell mutagenicity:	The substance was not found to be mutagenic on bacteria. Experimental/calculated data: Ames test, negative (OECD - guideline 471)

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Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Based on available data, the criteria for classification are not met.
STOT-repeated exposure:	Based on available data, the criteria for classification are not met.
Aspiration Hazard:	No risk of aspiration is expected.
Other:	The product has not been tested. Toxicological data have been deduced from the properties of the individual components.

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

Aquatic toxicity assessment: The product has not been tested. The indication is derived from the properties of the individual components.

Ichthyotoxicity: $LC_{50} > 10 - 100$ mg/L, *Brachydanio rerio* (DIN EN ISO 7346-2)

Microorganisms/Effects on activated sludge: $EC_0 > 100$ mg/L, *Pseudomonas putida* (OECD - guideline 209)

Chronic toxicity to aquatic invertebrates: NOEC $> 1 - 10$ mg/L

12.2 Persistence and degradability

Readily biodegradable (according to OECD criteria).

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Transport assessment between environmental departments: Volatility: not applicable.

12.5 Results of PBT and vPvB assessment

According to Annex XIII of Regulation (EC) No.1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH): The product does not contain substances meeting the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria.

12.6 Other adverse effects

The product does not contain substances listed in Regulation 1005/2009/EC on substances that deplete the ozone layer.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

In accordance with local regulations it must be sent to a controlled landfill or a suitable thermal destruction plant.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

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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) : Not applicable.

14.6 Special precautions for user

None known.

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

Regulation: Not evaluated.

Shipment approved: Not evaluated.

Pollution name: Not evaluated.

Pollution category: Not evaluated.

Ship Type: Not evaluated.

14.8 Additional transport information

Not classified as a dangerous good under transport regulations.

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

The product is not classified as dangerous.

SECTION 16: OTHER INFORMATION

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

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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

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