Material Safety Data Sheet

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

ALCOHOL CETYLICUS ET STEARYLICUS

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MAGIS PHARMA

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

1.1 Product identifier

Product name:	Cetostearyl alcohol Alcohol cetylicus et stearylicus Cetostearyl alcohol Cétostéarylique (alcool) Cetostearylalkohol
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.

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

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

This substance/mixture does not meet the PBT and vPvB criteria of REACH regulation, annex XIII.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Product name:	Tetradecanol
IUPAC name:	Tetradecan-1-ol
Synonyms:	Myristyl alcohol
	Alfol 14
N° CAS:	112-72-1
N° EC:	204-000-3
Molecular Formula:	$C_{14}H_{30}O$
Content:	≤ 1 per cent

Product name:	Octadecan-1-ol
IUPAC name:	Octadecan-1-ol
Synonyms:	Stearyl alcohol
	Alfol 18
N° CAS:	112-92-5
N° EC:	204-017-6
Molecular Formula:	$C_{18}H_{38}O$
Content:	Minimum 40.0 per cent

Product name:	Hexadecan-1-ol
IUPAC name:	Hexadecan-1-ol
Synonyms:	Cetyl alcohol
	Alfol 16
N° CAS:	36653-82-4
N° EC:	253-149-0
Molecular Formula:	$C_{16}H_{34}O$
Content:	Not available.

Sum of the contents of stearyl alcohol and cetyl alcohol: minimum 90.0 per cent.

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. If necessary, seek medical advice.
After eye contact:	Irrigate copiously with clean, fresh water for at least 15 minutes, holding the eyelids apart. Obtain emergency medical attention.
After ingestion:	Do not induce vomiting. Rinse mouth. May result in aspiration into the lungs, causing chemical pneumonia. 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

Treat symptomatically.

Material Safety Data Sheet

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ALCOHOL CETYLICUS ET STEARYLICUS

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Carbon dioxide (CO_2), dry chemical powder, foam.
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 CO_2).

Reactivity: Reacts with oxidising compounds and reducing agents.

5.3 Advice for firefighters

Surrounding fires:	Prevent fire fighting water from entering the 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

No naked flames, sparks, and do not smoke.

Protective equipment: Wear suitable protective clothing.

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

For emergency responders

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, surface water 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:	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.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.

Conditions for safe storage, including any incompatibilities:	Store tightly closed in a dry and cool place. Exclude sources of heat, sparks and open flame. Avoid dust formation. Prevent build-up of electrostatic charges (e.g, by grounding). Earth the equipment. Use spark-/explosion-proof appliances and lighting system.
Storage – away from:	Exclude sources of heat, sparks and open flame.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Octadecan-1-ol (112-92-5)

Germany	TRGS 900 Occupational exposure limit value (mg/m^3)	224 mg/m^3
Germany	TRGS 900 Occupational exposure limit value (ppm)	20 ppm

Hexadecan-1-ol (36653-82-4)

Germany	TRGS 900 Occupational exposure limit value (mg/m^3)	20 mg/m^3
Germany	TRGS 900 Occupational exposure limit value (ppm)	200 ppm

Tetradecanol (112-72-1)

Germany	TRGS 900 Occupational exposure limit value (mg/m^3)	20 mg/m^3
Germany	TRGS 900 Occupational exposure limit value (ppm)	178 ppm

Hexadecan-1-ol (36653-82-4)

DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	125 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	220 mg/m^3
DNEL/DMEL (General population)	
Long-term - systemic effects, oral	75 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	65 mg/m^3
Long-term - systemic effects, dermal	75 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.00156 mg/l
PNEC aqua (marine water)	0.000156 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	4.8 mg/kg dwt
PNEC sediment (marine water)	0.48 mg/kg dwt
PNEC (Soil)	
PNEC soil	4 mg/kg dwt

Hexadecan-1-ol (36653-82-4)

PNEC (STP)	
PNEC sewage treatment plant	0.00013 mg/l

Tetradecanol (112-72-1)

DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	89 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	313 mg/m^3

Long-term - local effects, inhalation	178 mg/m^3
DNEL/DMEL (General population)	
Long-term - systemic effects, oral	44.4 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	77 mg/m^3
Long-term - systemic effects, dermal	44.4 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.00126 mg/l
PNEC aqua (marine water)	0.000126 mg/l
PNEC aqua (intermittent, freshwater)	1.6 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	4,3 mg/kg dwt
PNEC sediment (marine water)	0.43 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.86 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	10 mg/l

8.2 Exposure controls

Appropriate engineering control

Provide appropriate exhaust ventilation at places of dust forming.

Individual protection measures

Eye/face protection:	In case of risky circumstances: safety glasses or face shield.
Skin protection:	Wear suitable protective clothing.
Hand protection:	Wear suitable gloves. Nitrile rubber gloves. Protective gloves made of latex.
Respiratory protection:	Where exposure through inhalation may occur from use, approved respiratory protection equipment is recommended. Respiratory protective device with particle filter. Gas/vapour filter, type A: organic vapours (EN141).
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, wax-like mass, plates, flakes or granules.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	48 °C to 52 °C
Initial boiling point:	249 °C (760 mm Hg)
Boiling range:	Not available.
Flash point:	174 °C
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.

Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	< 0.01 hPa (20°C)
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	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:	Practically insoluble in water. < 0.811 g/L
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	230 °C (1013 hPa)
Decomposition temperature:	Not available.
Viscosity:	Kinematic: No data available. Dynamic: 7 mPa.s (70 °C)
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Density: 0.81 g/cm^3 (60 °C)

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Reacts with: oxidising compounds and reducing agents.

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

No naked flames, sparks, and do not smoke.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

On burning: release of carbon monoxide - carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Not classified (Based on available data, the classification criteria are not met).

Cetostearyl alcohol

LD_{50} oral rat	> 2000 mg/kg

Octadecan-1-ol (112-92-5)

LD_{50} oral rat	> 2000 mg/kg (OECD 401)
LD_{50} dermal rabbit	8000 mg/kg (Read across 112-72-1)

Hexadecan-1-ol (36653-82-4)

	LD_{50} oral rat	> 2000 mg/kg (OECD 401)
	LD_{50} dermal rabbit	2000 mg/kg (Read across 112-72-1)
	LD_{50} inhalation rat (ppm)	> 0.14 ppm (Read across 112-72-1)
	Tetradecanol (112-72-1)	
	LD_{50} oral rat	> 2000 mg/kg (OECD 401)
	LD_{50} dermal rabbit	8000 mg/kg
	LD_{50} inhalation rat (mg/L)	> 1.5 mg/L
Skin corrosion/irritation:	Not classified (Based on available data, the classification criteria are not met)	
Serious eye damage/irritation:	Not classified (Based on available data, the classification criteria are not met)	
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)	
	Octadecan-1-ol (112-92-5)	
	NOAEL (subacute, oral, animal/male, 28 days)	1000 mg/kg bodyweight (OECD 407)
	Hexadecan-1-ol (36653-82-4)	
	NOAEL (oral, rat, 90 days)	> 4275 mg/kg bodyweight/day
	Tetradecanol (112-72-1)	
	LOAEL (oral, rat, 90 days)	3548 mg/kg bodyweight/day (OECD 408)
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

Octadecan-1-ol (112-92-5)

LC_{50} fish 1	> 0.4 mg/L (96 h, *Oncorhynchus mykiss*)
LC_{50} other aquatic organisms 1	> 10 mg/L *Desmodesmus subspicatus* (96h)
EC_{50} Daphnia 1	> 1700 mg/L *Daphnia Magna* (48h)

Hexadecan-1-ol (36653-82-4)

LC_{50} fish 1	> 0.4 mg/L (96 h, *Oncorhynchus mykiss*) (OECD 203)
LC_{50} other aquatic organisms 1	> 0.01 mg/L *Desmodesmus subspicatus* (96h) (OECD 201)
EC_{50} Daphnia 1	> 0.01 mg/L *Daphnia Magna* (48h)

Tetradecanol (112-72-1)

LC_{50} fish 1	> 1 mg/L (96 h, *Oncorhynchus mykiss*)
LC_{50} other aquatic organisms 1	> 10 mg/l *Desmodesmus subspicatus* (96h) (OECD 201)
EC_{50} Daphnia 1	3.2 mg/L *Daphnia Magna* (48h)
EC_{50} other aquatic organisms 1	> 1000 mg/L (*Heterocypris incongruens*) (EPA OPPTS 850.1735)
EC_{50} other aquatic organisms 2	> 1000 mg/L (*Caenorhabditis elegans*) (OECD 207)
NOEC (chronic)	0.0016 mg/L *Daphnia* (21 days) (OECD 211)

12.2 Persistence and degradability

Cetostearyl alcohol

Persistence and degradability	Readily biodegradable.

Octadecan-1-ol (112-92-5)

Persistence and degradability	Readily biodegradable. > 90% Bismuth-active substance (OECD 301B).

Hexadecan-1-ol (36653-82-4)

Persistence and degradability	Readily biodegradable. > 80% (28d) OECD 301 B.

12.3 Bioaccumulative potential

Cetostearyl alcohol

Bioaccumulative potential	Not potentially bioaccumulable.

Octadecan-1-ol (112-92-5)

BCF fish 2	390 - 590 l/kg

Hexadecan-1-ol (36653-82-4)

Log Pow	6.65

Tetradecanol (112-72-1)

Log Pow	6.03

12.4 Mobility in soil

Octadecan-1-ol (112-92-5)

Log Koc	5.67

Hexadecan-1-ol (36653-82-4)

Log Koc	5.15
Ecology - soil	Low mobility (soil).

Tetradecanol (112-72-1)

Log Koc	6.03

12.5 Results of PBT and vPvB assessment

Cetostearyl alcohol:

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

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 regulated for transport.

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Other information: No supplementary information available.

14.6 Special precautions for user

Not available.

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

Not available.

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

For the following substances of this mixture a chemical safety assessment has been carried out: Cetyl alcohol.

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
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 Bioaccumalative

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

info@magis-pharma.be