

Material Safety Data Sheet

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

EN

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CERA CETOMACROGOLIS EMULSIFICANS

Publication: 11/09/2022

Revision: 23/08/2024

Version: 01



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

1.1 Product identifier

Product name: Cetomacrogol emulsifying wax
Cera cetomacrogolis emulsificans
Cetomacrogol emulgerende was
Cire émulsifiante au cétomacrogol
Cetomacrogolwachs, emulgierender

N° CAS: 97069-99-0

N° EC: Not available.

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: Magis-Pharma NV
Neerlandweg 24
2610 Wilrijk
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

Eye Irritation 2 H319

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H319 Causes serious eye irritation.

Precautionary statements:

P264 Wash hands, forearms and face thoroughly after handling.

P280 Wear protective clothing/eye protection/face protection.

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P305+P351+P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313

If eye irritation persists: Get medical advice/attention.

Additional applicable label elements:

Not applicable.

2.3 Other hazards

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

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Product name: Alcohols, C16-18

IUPAC name: Hexadecan-1-ol; octadecan-1-ol

Synonyms: Cetearyl alcohol
Cetyl-stearyl alcohol

N° CAS: 67762-27-0

N° EC: 267-008-6

Molecular Formula: $(CH_2)_{15,17}CH_4O$

Content: $\geq 50\%$ w/w

Product name: Alcohols, C16-18, ethoxylated ($\geq 15 \leq 25$ EO)

IUPAC name: Alcohols, C16-18 ethoxylated

Synonyms: C16-18 fatty alcs., ethoxylated

N° CAS: 68439-49-6

N° EC: Polymer

Molecular Formula: Not available.

Content: 10 – 25 % w/w

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.

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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 (CO₂), 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 CO₂).

Explosion hazard: Its 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

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

For non-emergency personnel

Wear suitable protective clothing. Mark out the contaminated area with signs and prevent access to unauthorized personnel. Spill area may be slippery.

For emergency responders

Not available.

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: Smoking, eating and drinking should be prohibited in areas of storage and use. Handle in accordance with good industrial hygiene and safety practice.

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Personal protection:	Not available.
Technical protective measures:	Avoid dust formation. Prevent build-up of electrostatic charges (e.g. by grounding). Earth the equipment. Use spark-/explosionproof appliances and lighting system.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	In a well-closed container. Packaging materials: Stainless steel. Polyethylene. Paper.
Conditions for safe storage, including any incompatibilities:	Store tightly closed in a dry and cool place. Storage temperature: < 70 °C
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

Alcohols, C16-18 (67762-27-0)

DNEL/DMEL (Workers)

Acute - systemic effects, dermal	400 mg/kg bodyweight/day
Acute - systemic effects, inhalation	237.76 mg/m ³
Acute - local effects, dermal	1.124 mg/cm ²
Acute - local effects, inhalation	6.52 mg/m ³
Long-term - systemic effects, dermal	200 mg/kg bodyweight/day
Long-term - local effects, dermal	1.124 mg/cm ²
Long-term - systemic effects, inhalation	237.76 mg/m ³
Long-term - local effects, inhalation	6.52 mg/m ³

DNEL/DMEL (General population)

Acute - systemic effects, dermal	200 mg/kg bodyweight/day
Acute - systemic effects, inhalation	118,9 mg/m ³
Acute - systemic effects, oral	75 mg/kg bodyweight/day
Acute - local effects, dermal	0.562 mg/cm ²
Acute - local effects, inhalation	0.652 mg/m ³
Long-term - systemic effects, oral	75 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	118.88 mg/m ³
Long-term - systemic effects, dermal	100 mg/kg bodyweight/day
Long-term - local effects, dermal	0.562 mg/cm ²
Long-term - local effects, inhalation	0.652 mg/m ³

PNEC (Water)

PNEC aqua (freshwater)	0.13 mg/l
PNEC aqua (marine water)	0.12 mg/l

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PNEC aqua (intermittent, freshwater)	1 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	13.61 mg/kg dwt
PNEC sediment (marine water)	1.361 mg/kg dwt
PNEC (Soil)	
PNEC soil	100 mg/kg dwt
PNEC (Oral)	
PNEC oral (secondary poisoning)	86.7 mg/kg food
PNEC (STP)	
PNEC sewage treatment plant	1000 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. Protective gloves made of PVC. Standard: EN ISO 374.
Respiratory protection:	Where exposure through inhalation may occur from use, approved respiratory protection equipment is recommended.
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 flakes.
Odour:	Characteristic.
Odour threshold:	Not available.
pH:	6 – 8 (1% sol.)
Melting/freezing point:	48 to 53 °C
Initial boiling point:	> 250 °C
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.

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Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Moderately soluble in ethanol (96%) and partly soluble in ether.
Solubility in water:	Practically insoluble in water, forming an emulsion.
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

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

Strong oxidisers.

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:	Acute toxicity (oral):	Not classified.
	Acute toxicity (dermal):	Not classified.
	Acute toxicity (inhalation):	Not classified.
	WAX B1	
	LD ₅₀ oral rat	> 200 mg/kg Source: CESIO
Skin corrosion/irritation:	Alcohols, C16-18, ethoxylated (≥ 15 ≤ 25 EO) (68439-49-6)	
	LD ₅₀ oral rat	> 2000 mg/kg
	Not classified (Based on available data, the classification criteria are not met).	
	pH: 6 – 8 (1% sol.)	

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	Additional information: Non-irritant (rabbit), source: CESIO
Serious eye damage/irritation:	Causes serious eye irritation. pH: 6 – 8 (1% sol.) Additional information: Irritant (rabbit eye), source: CESIO
Respiratory/skin sensitisation:	Not classified (Based on available data, the classification criteria are not met). Additional information: Non-sensitizing (Guinea pig), source: CESIO
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). Alcohols, C16-18 (67762-27-0) NOAEL (chronic, oral, animal/female, 2 years) 133 mg/kg bodyweight Animal: mouse, Animal sex: female, Effect type: carcinogenicity (migrated information)
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). Alcohols, C16-18 (67762-27-0) NOAEL (dermal, rat/rabbit, 90 days) 1000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 411 (Subchronic Dermal Toxicity: 90-Day Study) NOAEC (inhalation, rat, gas, 90 days) 120 ppm Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study) NOAEL (subchronic, oral, animal/male, 90 days) ≥ 1175 mg/kg bodyweight Animal: dog, Animal sex: male NOAEL (subchronic, oral, animal/female, 90 days) > 1054 mg/kg bodyweight Animal: dog, Animal sex: female
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.

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WAX B1

LC₅₀ - Fish [1] > 100 mg/l *Carassius auratus* (96h)

EC₅₀ - Crustacea [1] > 100 mg/l *Daphnia magna* (48h)

Alcohols, C16-18, ethoxylated (≥ 15 ≤ 25 EO) (68439-49-6)

LC₅₀ - Fish [1] > 100 mg/l *Carassius auratus* (96h) CESIO

EC₅₀ - Crustacea [1] > 100 mg/l (48h) CESIO

Alcohols, C16-18 (67762-27-0)

EC₅₀ - Other aquatic organisms [1] 140 mg/l

Test organisms (species): other: Daphnid species

EC₅₀ 72h - Algae [1] 79.7 mg/l

Test organisms (species): *Pseudokirchneriella subcapitata* (previous names: *Raphidocelis subcapitata*, *Selenastrum capricornutum*)

EC₅₀ 72h - Algae [2] 20.5 mg/l

Test organisms (species): *Pseudokirchneriella subcapitata* (previous names: *Raphidocelis subcapitata*, *Selenastrum capricornutum*)

12.2 Persistence and degradability

WAX B1

Readily biodegradable.

Alcohols, C16-18, ethoxylated (≥ 15 ≤ 25 EO) (68439-49-6)

Readily biodegradable.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

WAX B1

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

Alcohols, C16-18, ethoxylated (≥ 15 ≤ 25 EO EO) (68439-49-6)

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 Readily biodegradable.

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.

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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:



Risk phrases:

R36 Irritating to eyes.

Safety phrases:

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

15.2 Chemical safety assessment

Not available.

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

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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.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

info@magis-pharma.be