

Material Safety Data Sheet

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

PROPYLENGLYCOLI DICAPRYLOCAPRAS

EN

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

1.1 Product identifier

Product name:	Propylene glycol dicaprylocaprate Propylenglycoli dicaprylocapras Propyleenglycol dicaprylocapraat Propylèneglycol (dicaprylocaprate de) Propylenglycoldicaprylocaprat
N° CAS:	68583-51-7
N° EC:	271-516-3

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

This substance does not meet the criteria for a classification according to Regulation No 1272/2008/EC.

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

Results of PBT and vPvB assessment: The results of the assessment of the substance indicate that this substance is not a PBT or vPvB substance.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Propylene glycol dicaprylocaprate
IUPAC name:	Decanoic acid;octanoic acid;propane-1,2-diol
Synonyms:	Miglyol® 840 Decanoic acid, mixed diesters with octanoic acid and propylene glycol
N° CAS:	68583-51-7
N° EC:	271-516-3
Molecular Formula:	C ₂₁ H ₄₄ O ₆
Content:	100 % Propylene glycol diesters of saturated fatty acids, mainly caprylic (octanoic) acid and capric (decanoic) acid, of vegetable origin.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Do not leave the victim unattended. Move the victim out of the danger zone. Keep casualty warm, quiet and covered. Remove contaminated clothing immediately. If in doubt or if symptoms persist, consult a doctor. If unconscious, place the victim in the stable side-position. Do not give anything by mouth.
After inhalation:	In case of respiratory irritation, consult a doctor. Provide fresh air.
After skin contact:	Wash with plenty of water and soap.
After eye contact:	Remove contact lenses, if possible. Continue rinsing. Rinse with clean, flowing water for at least 10 minutes while keeping eyelids open.
After ingestion:	Rinse mouth with water (only if the person is conscious). Do not induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

No symptoms or effects are known so far.

4.3 Indication of any immediate medical attention and special treatment needed

In any case, consult a doctor.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water, foam, alcohol resistant foam, dry extinguishing powder, BC powder, carbon dioxide (CO ₂).
Unsuitable extinguishing media:	Full water jet.

5.2 Special hazards arising from the substance/mixture

Hazardous combustion products: carbon monoxide (CO), carbon dioxide (CO₂).

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5.3 Advice for firefighters

Surrounding fires:	In case of fire and/or explosion, do not breathe fumes. Adapt fire-fighting measures to the surrounding area. Do not pour extinguishing water down sewers or into surface water. Collect contaminated extinguishing water separately. Extinguish from a reasonable distance using normal precautions.
Protection against fire:	Not available.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Bringing people to safety.

For emergency responders

Wear respiratory equipment when exposed to vapours/dust particles/aerosols/gases.

6.2 Environmental precautions

Avoid the product getting into drains, surface water or groundwater. Retain and dispose of contaminated wash water.

6.3 Methods and material for containment and cleaning up

Advice on how to contain the spillage: Covering drains.

Advice on how to clean up the spillage: Wipe with absorbent material (e.g. rag, fleece). Cleaning up leaks/spills: sand, sawdust, kieselguhr (diatomite), universal binder.

Appropriate containment methods: Use of absorbent materials.

Other information in connection with discharge or release: Transfer to suitable containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5.

Personal protective equipment: see section 8.

Incompatible materials: see section 10.

Disposal considerations: see section 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:	Measures to prevent fire and aerosol or dust generation: Use local and general ventilation. Use only in well-ventilated areas.
Handling:	Advice on general occupational hygiene: Wash hands after use. Do not eat, drink or smoke in work areas.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store only in the original packaging.
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Conditions for safe storage, including any incompatibilities: Not available.

Storage – away from: Store protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Relevant PNEC and other thresholds

End point	Threshold	Species	Environmental compartments	Exposure time
PNEC	0.264 mg/kg	terrestrial organisms	soil	short term (one-off)

8.2 Exposure controls

Appropriate engineering control

General ventilation.

Individual protection measures

Eye/face protection: Wear eye/face protection.

Skin protection: Include rest periods for skin regeneration. Preventive skin protection (skin protecting creams) is recommended. Wash hands thoroughly after use. Wear protective clothing against liquid chemicals.

Hand protection: Wear suitable gloves.
Suitable are gloves tested against chemicals according to EN 374. Determine leak-tightness/impermeability before use. When re-using gloves, clean them before taking them off and ventilate them well afterwards. In case of special applications, it is recommended to check the chemical resistance of the above mentioned protective gloves with the glove supplier.

Material: CR: chloroprene (chlorobutadiene) rubber

Breakthrough time: > 30 minutes (permeation level: 2)

Material thickness: > 0.2 mm

Respiratory protection: (In case of inadequate ventilation) wear respiratory protection.

Thermal hazards: Not determined.

Environmental exposure control

Take appropriate measures to prevent dispersal in the environment. Avoid discharge into drains, surface water or groundwater.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Almost colourless or light yellow, oily liquid.

Odour: Odourless.

Odour threshold: Not available.

pH: Not determined.

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Melting/freezing point:	< -40 °C
Initial boiling point:	342 °C
Boiling range:	Not available.
Flash point:	185 °C
Evaporation rate:	Not determined.
Flammability (solid/gas):	Not relevant (liquid).
Upper/lower flammability or explosive limits:	Not determined.
Vapour pressure:	< 0.001 Pa at 20 °C
Vapour density:	0.92 g /cm ³ at 20 °C
Relative density:	About 0.92
Solubility:	Soluble in fatty oils and in light petroleum, slightly soluble in anhydrous ethanol.
Solubility in water:	Practically insoluble in water (< 0.05 mg/l at 20 °C)
Partition coefficient (n-octanol/water):	5.21 (log KOW)
Auto-ignition temperature:	306 °C
Decomposition temperature:	Not available.
Viscosity:	Kinematic viscosity: 11.2 mm ² /s at 20 °C
Explosive properties:	None.
Oxidising properties:	None.

9.2 Other information

Temperature class (EU, according to ATEX): T2 (maximum permissible surface temperature of the equipment: 300 °C)
Partition coefficient (soil/water organic carbon (log KOC)): 3.79 – 4.83

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

For incompatible products, see "Conditions to avoid" and "Incompatible materials".

10.2 Chemical stability

The material is stable under normal atmospheric conditions and expected temperature and pressure during storage and handling.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

There are no specific conditions known to be avoided.

10.5 Incompatible materials

None.

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Cannot be classified as acutely toxic.

Lethality values

Acute toxicity

Route of exposure	End point	Value	Species
Oral	LD ₅₀	> 2000 mg/kg	rat
Inhalation: vapour	LC ₅₀	> 2.916 mg/l/1h	rat

Skin corrosion/irritation: Cannot be classified as corrosive/irritating to skin.

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

Serious eye damage/irritation: Cannot be classified as causing serious damage to eyes or irritating to eyes.

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

Respiratory/skin sensitisation: Does not classify as inhalation or skin allergy.

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

Germ cell mutagenicity: Cannot be classified as germ cell mutagen.

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

Carcinogenicity: Not classifiable as a carcinogen.

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

Reproductive toxicity: Not classifiable as toxic for reproduction.

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

Summary of evaluation of the CMR properties: Not available.

STOT-single exposure: Cannot be classified as toxic to specific target organs (single exposure).

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

STOT-repeated exposure: Cannot be classified as toxic to specific target organs (repeated exposure).

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

Aspiration Hazard: Not classifiable as hazardous by aspiration.

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

Cannot be classified as hazardous to the aquatic environment.

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Aquatic toxicity (acute)

End point	Value	Species	Time of exposure
EL ₅₀	> 2.4 mg/l	aquatic invertebrates	48 h

Biodegradation: The substance is readily biodegradable.

12.2 Persistence and degradability

Process of degradability

Process	Degradation rate	Time
Carbon dioxide development	82 %	28 d

12.3 Bioaccumulative potential

The substance fulfils the criterion for strong bioaccumulation.

n-octanol/water (log KOW): 5.21

12.4 Mobility in soil

No data are available.

Normalised adsorption coefficient for organic carbon: 3.79 – 4.83

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Endocrine disrupting capacity: Not stated.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Information for disposal: Dispose of contents/container to any approved waste disposal facility.

Information on waste water disposal: Do not empty into drains. Avoid release into the environment. Ask for special instructions/safety data sheet.

Waste treatment of containers/packaging: Completely emptied packages can be recycled. Contaminated packaging should be treated like the substance itself.

Remarks

Please observe the relevant national or regional regulations. Waste is separated into the categories that can be treated separately by the local or national waste management authorities.

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 subject to transport regulations.

14.2 UN proper shipping name

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

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14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

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

14.6 Special precautions for user

There is no further information.

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

The cargo is not intended to be transported in bulk.

14.8 Additional transport information

Information for each of the UN Regulations

Transport of dangerous goods by road, rail or inland waterways (ADR/RID/ADN): Not subject to the ADR, RID and ADN.

International Maritime Dangerous Goods Code (IMDG): Not subject to the IMDG.

International Civil Aviation Organisation (ICAO-IATA/DGR): Not subject to ICAO-IATA.

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

A chemical safety assessment has been carried out for this substance.

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

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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

Not applicable.

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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