

Material Safety Data Sheet

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

EN

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TRIGLYCERIDA MEDIA



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

1.1 Product identifier

Product name:	Triglycerides, medium-chain Triglycerida media Triglyceride met middelmatige ketenlengte Triglycérides à chaîne moyenne Triglyceride, mittelkettig
N° CAS:	73398-61-5
N° EC:	277-452-2

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:	FRAVER NV Keizershoek 336 2550 Kontich 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 substance is not classified according to the CLP regulation.

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

PBT: Substance characteristics do not meet screening criteria.
vPvB: Substance characteristics do not meet screening criteria.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Triglycerides, medium-chain
IUPAC name:	11-(2,3-dihydroxypropoxycarbonyl)heptadecanoate
Synonyms:	Glycerides, mixed decanoyl and octanoyl
N° CAS:	73398-61-5
N° EC:	277-452-2
Molecular Formula:	Not applicable.
Content:	Minimum 95.0 per cent of saturated fatty acids with 8 and 10 carbon atoms.

3.2 Mixtures

Mixture of triglycerides of saturated fatty acids, mainly of caprylic (octanoic) acid and of capric (decanoic) acid. The fatty acids are obtained from the oil extracted from the hard, dried fraction of the endosperm of *Cocos nucifera* L. or from the dried endosperm of *Elaeis guineensis* Jacq.

Content: minimum 95.0 per cent of saturated fatty acids with 8 and 10 carbon atoms.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	If symptoms persist or in case of doubt, seek medical advice.
After inhalation:	Supply fresh air; consult a doctor in case of pain.
After skin contact:	Wash with water and soap.
After eye contact:	Rinse opened eye for several minutes under running water.
After ingestion:	Rinse mouth with water. Drink plenty of water, but never give anything to an unconscious person. If symptoms persist, consult doctor.

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

Symptomatic treatment

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Foam. Fire-extinguishing powder. Carbon dioxide (CO ₂) Use fire fighting measures that suit the environment.
Unsuitable extinguishing media:	Water.

5.2 Special hazards arising from the substance/mixture

In case of fire, the following can be released: Noxious gases/vapours.

5.3 Advice for firefighters

Surrounding fires:	Do not inhale combustion vapours.
Protection against fire:	Wear self-contained respiratory protective device.

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Hazardous combustion products:

Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear protective clothing. Product forms slippery surface when combined with water.

For emergency responders

Wear protective clothing. Product forms slippery surface when combined with water.

6.2 Environmental precautions

Do not allow product to reach sewage system or any water course.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Make sure to recycle or dispose of in suitable receptacles

6.4 Reference to other sections

See section 8 for information on personal protection equipment.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Keep away from heat and direct sunlight.

Information about protection against explosions and fires: Observe the general rules of industrial fire protection.

Personal protection:

Not available.

Technical protective measures:

Ensure good ventilation/exhaustion at the workplace.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

In a well-filled container.

Conditions for safe storage, including any incompatibilities:

Store at ambient temperature. Keep receptacle tightly sealed.

Storage class: 10 Combustible liquids

Storage – away from:

Store protected from light. Store away from foodstuffs. Store away from feed. Store away from oxidising agents.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

DNELs

Abbreviations:

In = Industrial

Prof = Professional

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Cons = Consumer

LLE = Long term, local effects

LSE = Long term, systemic effects

SLE = Short term, local effects

SSE = Short term, systemic effects

Oral DNEL/Cons/LSE 12.61 mg/kg bw/day (human)

Dermal DNEL/Cons/LSE 12.61 mg/kg bw/day (human)

DNEL/In/LSE 25.21 mg/kg bw/day (human)

Inhalative DNEL/Cons/LSE 43.84 mg/m³ (human)

DNEL/In/LSE 177.79 mg/m³ (human)

PNECs

Since the substance has no potential for bioaccumulation, no PNEC oral was derived. No long term toxicity to aquatic organisms expected. Therefore, no derivation of PNEC.

Additional Information: The lists that were valid during the creation were used as basis.

8.2 Exposure controls

Appropriate engineering control

General protective and hygienic measures: The usual precautionary measures should be adhered to when handling chemicals. Wash hands before breaks and at the end of work. Use skin protection cream for skin protection.

Individual protection measures

Eye/face protection: Safety glasses.

Skin protection: Protective work clothing.

Hand protection: Chemical resistant gloves (EN 374)

Material of gloves: The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material: The exact penetration time has to be found out by the manufacturer of the protective gloves and has to be observed.

Respiratory protection: Under normal conditions of use not required.

At formation of aerosols and mist: Short term filter device: Filter A (colour code: brown). Filter A-P2. Full mask with filter: ABEK-P2

Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust.

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: Colourless or slightly yellowish, oily liquid.

Odour: Odourless.

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Odour threshold:	Not applicable.
pH:	~ 6 (23 °C)
Melting/freezing point:	< 0 °C
Initial boiling point:	Not determined.
Boiling range:	Not determined.
Flash point:	~ 220 °C (DIN ISO 2592)
Evaporation rate:	Not available.
Flammability (solid/gas):	Not applicable.
Upper/lower flammability or explosive limits:	Not applicable.
Vapour pressure:	Not determined.
Vapour density:	Not determined.
Relative density:	0.93 – 0.96 (20 °C)
Solubility:	Miscible with ethanol (96 per cent), with methylene chloride, with light petroleum and with fatty oils.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	> 8 (23 °C) pH 6,2; OECD 117
Auto-ignition temperature:	Product is not self-igniting.
Decomposition temperature:	Not determined.
Viscosity:	Dynamic at 20 °C: 25 mPa·s to 33 mPa·s Kinematic: Not determined.
Explosive properties:	Product does not present an explosion hazard.
Oxidising properties:	None.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Thermal decomposition/conditions to be avoided: No decomposition if used and stored according to specifications. To avoid thermal decomposition, do not overheat.

10.3 Possibility of hazardous reactions

No dangerous reactions known

10.4 Conditions to avoid

Strong heating. Dirt. Chemical contamination. Sunlight, UV or ionizing radiation

10.5 Incompatible materials

Strong oxidants.

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10.6 Hazardous decomposition products

No hazardous decomposition products if instructions for storage and handling are followed

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral	LD50	> 2000 mg/kg (mouse)
	Dermal	LD50	> 2000 mg/kg (rat) RA from 91845-19-1
	Inhalative	LC50/6h	> 1.86 mg/l (rat) max. attainable conc.
Skin corrosion/irritation:	Skin irritation test (rabbit): no irritation EPA OPP 81-5		
Serious eye damage/irritation:	Skin irritation test (rabbit): no irritation EPA OPP 81-4		
Respiratory/skin sensitisation:	No sensitisation species: guinea pig OECD 406 (Buehler Test) In analogy to similar products		
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.		
Carcinogenicity:	Based on available data, the classification criteria are not met.		
Reproductive toxicity:	Oral	NOAEL (P)	1000 mg/kg bw/day (rat) (OECD 422)
		NOAEL (developmental)	1000 mg/kg bw/day (rat) (OECD 422) RA from 91052-13-0
	Based on available data, the classification criteria are not met.		
Summary of evaluation of the CMR properties:	Not available.		
STOT-single exposure:	Based on available data, the classification criteria are not met.		
STOT-repeated exposure:	Oral	NOAEL	1000 mg/kg/day (rat) (OECD 422)
			5000 mg/kg bw/d (rat) (OECD 408)
			90d RA from 8001-79-4
	Based on available data, the classification criteria are not met.		
Aspiration Hazard:	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.

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SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity: The product is insoluble in water; therefore it is not dangerous to water organisms if applied appropriately.

12.2 Persistence and degradability

Readily biodegradable.

Henry's Law constant H (atm m³/mol): 0.000034 Pa m³/mol at 25 °C (QSAR)

Other information: Biological degradation: > 60% after 28 days, BODIS-Test; ISO 10708

12.3 Bioaccumulative potential

log P (o/w) > 3 - Considerable bioaccumulation is to be expected.

12.4 Mobility in soil

Strong adsorption to soil.

Adsorption coefficient K_{oc}: (calculated) > 5000

Additional ecological information: General notes: Not hazardous to water according to VwVwS (German regulation) appendix 1 dated 17.05.1999

12.5 Results of PBT and vPvB assessment

PBT: Substance characteristics do not meet screening criteria.

vPvB: Substance characteristics do not meet screening criteria.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation: Must be recycled or disposed of according to the regulations. Waste has to be classified according to the European Waste Catalogue based on the identification of the waste generating source. Disposal according to instructions of local authorities

Uncleaned packagings: Recommendation: Disposal must be made according to official regulations.

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 classified.

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.

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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) : Not classified.

14.6 Special precautions for user

Not applicable.

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

A chemical safety assessment has not been carried out.

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 Bioaccumulative

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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

[Insert relevant information] [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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