

Material Safety Data Sheet

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

MYVACET 9/08

EN

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

1.1 Product identifier

Product name:	Diacetylated monoglycerides Myvacet 9/08 Gediacetyleerde monoglyceride Monoglycérde diacétilé Diacetyliertes Monoglycerid
N° CAS:	Not applicable.
N° EC:	Not applicable.

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

This substance/preparation is not classified as dangerous according to Directive 67/548/EEC or Directive 1999/45/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

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Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Diacetylated monoglycerides
IUPAC name:	Not applicable.
Synonyms:	Not applicable.
N° CAS:	Not applicable.
N° EC:	Not applicable.
Molecular Formula:	Not applicable.
Content:	Not applicable.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	Ventilate the premises. The patient is to be removed immediately from the premises contaminated and made to rest in a well-ventilated area. Should the patient feel unwell, consult a physician.
After skin contact:	Immediately take off all contaminated clothing. Areas of the body that have - or are only even suspected of having - come into contact with the product must be rinsed immediately with plenty of running water and possibly with soap and if necessary, seek medical attention. Ensure that safety showers are close to the workstation.
After eye contact:	Wash immediately with water for at least 10 minutes. Ensure that eye wash stations are close to the workstation.
After ingestion:	Rinse mouth thoroughly with water and drink plenty of water afterwards. SEEK A MEDICAL EXAMINATION IMMEDIATELY and present the safety data sheet.

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

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	CO ₂ , foam and dry chemical.
Unsuitable extinguishing media:	No specific hazard, according to the materials involved in the fire.

5.2 Special hazards arising from the substance/mixture

Risks arising from combustion: No specific hazard, avoid inhaling the fumes.

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5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Use protection for the airways.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Use appropriate personal protective equipment

For emergency responders

Use appropriate personal protective equipment

6.2 Environmental precautions

Limit spills or leaks with appropriate equipment. If the substance/preparation has escaped into a water course or an external drainage system or has contaminated ground or vegetation, notify the appropriate competent authority.

6.3 Methods and material for containment and cleaning up

Prevent the spills or leaks from entering external drainage systems and then use spillage containment procedures to undertake cleaning operation.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Avoid contact and inhalation of the vapours. See also section 8. Do not eat or drink while working. Incompatible materials: None in particular, or this is to be assessed by the site H&S and site Quality manager.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	In an airtight container. Preserve in tight, light-resistant containers.
Conditions for safe storage, including any incompatibilities:	We recommend that this product is stored in sound, clean warehousing. Exposure to excessive hot or cold temperatures (frost and direct sunlight) should be avoided.
Storage – away from:	Protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Adequate ventilation to the premises where substance/preparation is stored and/or handled.

Individual protection measures

Eye/face protection: Use appropriate safety goggles.

Skin protection: Use clothing that provides comprehensive protection to the skin.

Hand protection: Use appropriate protective gloves.

Respiratory protection: Not determined.

Thermal hazards: Not determined.

Environmental exposure control

Local authorities should be advised if significant spillages cannot be contained.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Liquid, straw yellow.

Odour: Not available.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: -12 °C (Typical)

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Ca. 200 °C

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

Upper/lower flammability or explosive limits: Not available.

Vapour pressure: Not available.

Vapour density: Not available.

Relative density: Not available.

Solubility: Not available.

Solubility in water: Not available.

Partition coefficient (n-octanol/water): Not available.

Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

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Viscosity: Not available.

Explosive properties: Not available.

Oxidising properties: Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

This product is stable under normal conditions of use.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

No hazardous conditions have been identified.

10.5 Incompatible materials

Strong oxidating agents.

10.6 Hazardous decomposition products

No specific products have been identified.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Not available.

Skin corrosion/irritation: Not available.

Serious eye damage/irritation: Not available.

Respiratory/skin sensitisation: Not available.

Germ cell mutagenicity: Not available.

Carcinogenicity: Not available.

Reproductive toxicity: Not available.

Summary of evaluation of the CMR properties: Not available.

STOT-single exposure: Not available.

STOT-repeated exposure: Not available.

Aspiration Hazard: Not available.

Other: Acetoglycerides are readily hydrolysed in the gastrointestinal tract and dealt within the body in a manner similar to other glycerides. Short and long-term feeding studies in rats showed no substance related adverse effects (WHO Food Additives Series, no.5, 1974, p 210).

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11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	May cause slight irritation (redness).
Skin contact:	Prolonged skin contact may cause slight skin irritation.
Inhalation:	Over-exposure by inhalation may cause allergic respiratory reaction (coughing).
Ingestion:	Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of in compliance with local, national and EU regulation currently in force.

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.

14.4 Packing group

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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

This product is not a dangerous good according to international regulations for transport. No special precautions required.

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

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
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

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

FRAVER NV

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