

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

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

1.1 Product identifier

Product name:	Hard fat Adeps solidus Vaste halfsynthetische glyceriden Glycérides hémi-synthétiques solides Hartfett
N° CAS:	67701-26-2
N° EC:	266-944-2

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:	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 N° 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

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The results of the substance evaluation show that the substance is not a PBT or vPvB substance.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Hard fat
IUPAC name:	Not available.
Synonyms:	Glycerides, C12-18 Witepsol
N° CAS:	67701-26-2
N° EC:	266-944-2
Molecular Formula:	Not available.
Content:	Mixture of triglycerides, diglycerides and monoglycerides, which may be obtained either by esterification of hydrogenated fatty acids of vegetable origin with glycerol or by interesterification of hydrogenated vegetable oils. Each type of hard fat is characterised by its melting point, its hydroxyl value and its saponification value. It does not contain additives.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	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:	Not relevant.
After skin contact:	Rinse/shower skin with water.
After eye contact:	Keep eyelids open and flush with clean, flowing water.
After ingestion:	Consult a physician if you feel unwell.

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

None.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

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

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5.2 Special hazards arising from the substance/mixture

Hazardous combustion products: No information available.

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 into the sewage system or water bodies. Collect contaminated extinguishing water separately. Extinguish from a reasonable distance using normal precautions.
Protection against fire:	Wear self-contained breathing apparatus.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Not required.

For emergency responders

Not required.

6.2 Environmental precautions

Not required.

6.3 Methods and material for containment and cleaning up

Advice on how to contain the spillage: Mechanical containment.

Advice on how to clean up the spillage: Pick up mechanically.

Other information related to spillage 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:	Dust deposits can accumulate on all surfaces in a commercial area. The product, in its delivered form, is not capable of causing a dust explosion, but the enrichment of fine dust leads to the danger of a dust explosion.
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Personal protection:	Not available.
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Technical protective measures:

Measures to prevent fire and aerosol or dust generation: Ground storage and collection tank.

Handling:

Wash hands after use. Do not eat, drink or smoke in work areas.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Not available.

Conditions for safe storage, including any incompatibilities:

Keep only in the original container.

Removal of dust deposits.

Store at a temperature at least 5 °C below the nominal melting point.

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

Human health values

Relevant DNEL and other threshold values :

Endpoint	Threshold	Protection target, route of exposure	Used in	Exposure time
DNEL	241.41 mg/m ³	human, by inhalation	(industrial) workers	chronic - systemic effects
DNEL	34.23 mg/kg bw/day	human, through the skin	(industrial) workers	chronic - systemic effects
DNEL	59.53 mg/m ³	human, by inhalation	consumers (private households)	chronic - systemic effects
DNEL	17.115 mg/kg bw/day	human, through the skin	consumers (private households)	chronic - systemic effects
DNEL	17.115 mg/kg bw/day	human, oral	consumers (private households)	chronic - systemic effects

8.2 Exposure controls

Appropriate engineering control

None.

Individual protection measures

Eye/face protection: Not required.

Skin protection: Not required.

Hand protection: Wear suitable gloves.

Material

Breakthrough time

Material thickness

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	NBR: acrylonitrile-butadiene rubber	> 480 minutes (permeation level: 6)	> 0.35 mm
	IIR: isobutene-isoprene (butyl) rubber	> 480 minutes (permeation level: 6)	> 0.5 mm
Respiratory protection:	(In case of insufficient ventilation) wear respiratory protection. Particle filter (EN 143). P1 (filters at least 80% of airborne particles, colour code: white).		
Thermal hazards:	Not determined.		
Environmental exposure control			
Not required.			

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, waxy, brittle mass. When heated to 50 °C it melts, giving a colourless or slightly yellowish liquid.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	Not applicable.
Melting/freezing point:	30 °C to 45 °C, and within 2 °C of the nominal value.
Initial boiling point:	Not determined.
Boiling range:	Not determined.
Flash point:	> 200 °C
Evaporation rate:	Not determined.
Flammability (solid/gas):	This material is flammable, but will not easily catch fire.
Upper/lower flammability or explosive limits:	Not determined.
Vapour pressure:	Not determined.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Slightly soluble in anhydrous ethanol. Slightly soluble in methylene chloride.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	> 8 (pH value: 6.2, 23 °C)
Auto-ignition temperature:	Not determined.
Decomposition temperature:	Not available.
Viscosity:	Not relevant (solid).
Explosive properties:	None.
Oxidising properties:	None.

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9.2 Other information

Density: 0.95 g/cm³

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

No specific conditions are known that must be avoided.

Indications on how to avoid fire and explosions: The product, in its delivered form, is not capable of causing a dust explosion, however, the enrichment of fine dust leads to the danger of a dust explosion.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Cannot be classified as acutely toxic.

Values for lethality

Acute toxicity:

Route of exposure	Endpoint	Value	Species
Oral	LD ₅₀	> 2,000 mg/kg	rat
Dermal	LD ₅₀	> 2,000 mg/kg	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 sensitiser.

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.

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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.

Aquatic toxicity (acute):

Endpoint	Value	Species	Exposure time
LC50	> 10,000 mg/l	Fish	96 h
EC50	> 100 mg/l	Aquatic invertebrates	48 h
ErC50	> 100 mg/l	Algae	72 h

Biodegradation: The substance is readily biodegradable.

12.2 Persistence and degradability

Process of degradability:

Process	Degradation rate	Time
Oxygen depletion	54 %	7 d

12.3 Bioaccumulative potential

The substance fulfils the criterion for strong bioaccumulation. n-octanol/water (log KOW): > 8 (pH value: 6.2, 23 °C)

12.4 Mobility in soil

No data are available.

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Henry's Law constant: 4.77 Pa m³/mol at 25 °C

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Classification according to GHS (1272/2008/EC, CLP): This substance does not meet the criteria for a classification according to Regulation No 1272/2008/EC.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Information on waste disposal: Recycling.

Information on waste water disposal: Do not empty into drains.

Waste treatment of containers/packaging: Completely emptied containers can be recycled.

Remarks: Please observe the relevant national or regional 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 subject to transport regulations.

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : None.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : No packing group assigned.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : None.

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

Information for each of the UN regulations

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

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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
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

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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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info@magis-pharma.be