

Material Safety Data Sheet

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

EN

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ADEPS SOLIDUS CUM ADDITAMENTIS

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

1.1 Product identifier

Product name:	Hard fat with additives Adeps solidus cum additamentis Vaste halfsynthetische glyceriden met additieven Glycérides hémisynthétiques solides avec additifs Hartfett mit Additiven
N° CAS:	N/A
N° EC:	N/A

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

The product is not classified as hazardous to health or environment 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

Results of PBT and vPvB assessment: PBT: Not applicable. vPvB: Not applicable.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

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Not applicable.

3.2 Mixtures

Dangerous components: Mixture: consisting of the following components. This section describes all components of the mixture. When no classification is mentioned below, the identification of the substance, the substance shall be considered not classified according to Regulation EC 1272/2008 and Directive 67/548/EEC.

Product name: Glycerides, C10-18

IUPAC name: Not available.

Synonyms: C10-18 triglycerides

N° CAS: 856665-33-4

N° EC: 288-123-8

Molecular Formula: Not available.

Content: 75.0 < A1 < 100 %

Product name: Polysorbate 65

IUPAC name: Polyethylene (20) sorbitan tristearate

Synonyms: Tween 65

N° CAS: 9005-71-4

N° EC: Not applicable.

Molecular Formula: Not available.

Content: 5.0 < D < 10.0

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: No special measures required.

After inhalation: Supply fresh air; consult doctor in case of complaint.

After skin contact: Wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.

After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After ingestion: Seek immediate medical advice.

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: CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Not available.

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5.3 Advice for firefighters

Surrounding fires:	No special measures required.
Protection against fire:	No special measures required.
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. Particular danger of slipping on leaked/spilled product.

For emergency responders

Wear protective clothing. Particular danger of slipping on leaked/spilled product.

6.2 Environmental precautions

- Do not allow product to reach sewage system or any water course.
- Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

- Pick up mechanically.
- Ensure adequate ventilation.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Keep ignition sources away - Do not smoke.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	No special requirements.
Conditions for safe storage, including any incompatibilities:	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

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

Appropriate engineering control

General protective and hygienic measures: The usual precautionary measures are to be adhered to when handling chemicals.

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Individual protection measures

Eye/face protection: Safety glasses.

Skin protection: Protective work clothing.

Hand protection: Protective gloves.

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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Respiratory protection: Not necessary if room is well-ventilated.

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 or pale yellow, waxy, brittle mass. When heated to 50 °C it melts, giving a colourless or slightly yellowish liquid.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	Not available.
Initial boiling point:	250.0 °C
Boiling range:	Not available.
Flash point:	200.0 °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:	Slightly soluble in anhydrous ethanol and in methylene chloride.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	> 300.00 °C
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Danger of explosion: Product does not present an explosion hazard.
Oxidising properties:	Not available.

9.2 Other information

Not available.

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SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Stable.

10.2 Chemical stability

Stable.

Thermal decomposition/conditions to be avoided: No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Carbon monoxide and carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Oral, LD₅₀: > 2001 mg/kg (rat)

Skin corrosion/irritation: No irritating effect.

Not classified (Dangerous Preparations Directive DPD 88/379/EEC).

Serious eye damage/irritation: No irritating effect.

Not classified (Dangerous Preparations Directive DPD 88/379/EEC).

Respiratory/skin sensitisation: No sensitizing effects known.

Not classified (Dangerous Preparations Directive DPD 88/379/EEC).

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: Subacute to chronic toxicity: Not classified (Dangerous Preparations Directive DPD 88/379/EEC). No data available.

Additional toxicological information: The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

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

85665-33-4 Glycerides, C10-18

Fish, LC₀: (96H) > 10000 mg/L

Fish, LC₅₀: (96H) > 10000 mg/L

Alga, EC₅₀: (72H) > 100 mg/L

Daphnia, EC₅₀ (S): (48H) > 100 mg/L

Daphnia, NOEC: (21DAY) > 0.01 mg/L

/, Biodegradability: (28DAY) 84 %

/, log P oct/wat: > 8 (MEASURED) /

12.2 Persistence and degradability

Biodegradable. Not classified (Dangerous Preparations Directive DPD 88/379/EEC).

12.3 Bioaccumulative potential

A worth-mentioning accumulation in organisms is not expected.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not classified PBT and vPvB (Annex VI Regulation (EC) No 1272/2008).

12.6 Other adverse effects

Indications about product: No ecotoxicity study has been done on the product. The ecotoxicity assessment of our product is based on a read-across approach (structurally related substances). Environment effect and environmental fate of our product are predicted from data on similar substances.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation: Must be disposed of an incinerator.

Recommendation about packaging: Disposal must be made according to official regulations. Packaging may be reused or recycled after cleaning.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

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

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

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

Not available.

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

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.

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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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