

Material Safety Data Sheet

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

MANNITOLUM

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:	Mannitol Mannitolum Mannitol Mannitol Mannitol
N° CAS:	69-65-8
N° EC:	200-711-8

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 pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

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.

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2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Mannitol
IUPAC name:	(2R,3R,4R,5R)-hexane-1,2,3,4,5,6-hexol
Synonyms:	D-mannitol Mannite
N° CAS:	69-65-8
N° EC:	200-711-8
Molecular Formula:	C ₆ H ₁₄ O ₆
Content:	97.0 per cent to 102.0 per cent (dried substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Not specifically necessary. Observance of good industrial hygiene is recommended.

4.2 Most important symptoms and effects, both acute and delayed

No episodes of damage to health ascribable to the product have been reported.

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:	The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.
Unsuitable extinguishing media:	None in particular.

5.2 Special hazards arising from the substance/mixture

Hazards caused by exposure in the event of fire: Do not breathe combustion products.

5.3 Advice for firefighters

Surrounding fires:	Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.
Protection against fire:	Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with

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self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

Hazardous combustion products:

Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Use breathing equipment if fumes or powders are released into the air.

For emergency responders

Use breathing equipment if fumes or powders are released into the air.

6.2 Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3 Methods and material for containment and cleaning up

Confine using earth or inert material. Collect as much material as possible and eliminate the rest using jets of water. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4 Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

Personal protection:

Not available.

Technical protective measures:

Not available.

Handling:

Before handling the product, consult all the other sections of this material safety data sheet.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Not available.

Conditions for safe storage, including any incompatibilities:

Keep the product in clearly labelled containers.

Storage – away from:

Keep containers away from any incompatible materials, see section 10 for details.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

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Appropriate engineering control

Comply with the safety measures usually applied when handling chemical substances.

Individual protection measures

Eye/face protection: None required.

Skin protection: None required.

Hand protection: None required.

Respiratory protection: None required, unless indicated otherwise in the chemical risk assessment.

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 almost white crystals or powder.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	165 °C to 170 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	990 °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:	Practically insoluble in ethanol (96 per cent).
Solubility in water:	Freely soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

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Molecular weight: 182.2 g/mol

Solid content: 100,00 %

VOC (Directive 1999/13/EC): 0

VOC (volatile carbon): 0

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2 Chemical stability

The product is stable in normal conditions of use and storage.

10.3 Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4 Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: LD₅₀ (ipr-mouse): 14 g/kg
Oral LD₅₀ (rat): 135 mg/kg

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: According to currently available data, this product has not yet produced health damages. However, it must be handled according to good industrial practices.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: Not available.

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Skin contact: Not available.

Inhalation: Not available.

Ingestion: Not available.

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

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6 Other adverse effects

Use this product according to good working practices.

Avoid littering.

Inform the competent authorities if the product enters waterways or sewers or contaminates soil or vegetation.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

Avoid littering. Do not contaminate soil, sewers and waterways.

Solid residues may be suitable for disposal in an authorised landfill site.

Contaminated packaging: Contaminated packaging must be recovered or disposed of in compliance with national waste management 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

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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

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

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

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

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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

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

FAC SECUNDUM ARTEM NV

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