

Material Safety Data Sheet

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

SORBITOLUM

EN

FORM-06-14-01 (V00)

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Version: 00



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

1.1 Product identifier

Product name: Sorbitol
Sorbitolum
Sorbitol
Sorbitol
Sorbitol
N° CAS: 50-70-4
N° EC: 200-061-5

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

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 substance is not classified according to Regulation (EC) 1272/2008 (CLP).

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

None.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Sorbitol
IUPAC name:	(2R,3R,4R,5S)-hexane-1,2,3,4,5,6-hexol
Synonyms:	D-Glucitol D-Sorbitol
N° CAS:	50-70-4
N° EC:	200-061-5
Molecular Formula:	C ₆ H ₁₄ O ₆
Content:	97.0 per cent to 102.0 per cent (anhydrous substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: It is not specifically required. In any case, compliance with good industrial hygiene is recommended.

4.2 Most important symptoms and effects, both acute and delayed

There are no known relevant acute or delayed effects from exposure to the product.

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:	Foam, dry powder, carbon dioxide, sand, water mist. Neighbouring fires (containers exposed to fire): Water spray or fog.
Unsuitable extinguishing media:	Direct water jet.

5.2 Special hazards arising from the substance/mixture

Avoid breathing products derived from combustion.

5.3 Advice for firefighters

Surrounding fires:	Cool containers with water to prevent decomposition of product and development of potential health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues in accordance with current regulations.
Protection against fire:	Helmet with visor, flame retardant clothing (jacket and trousers with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137).

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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

In case of vapours or dust dispersed in air, wear respiratory protection.

For emergency responders

In case of vapours or dust dispersed in air, wear respiratory protection.

6.2 Environmental precautions

Do not allow product to enter sewage system.

6.3 Methods and material for containment and cleaning up

Collect and prepare for disposal without causing dust. Clean and shovel. Store in suitable closed containers for disposal.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Avoid contact with eyes and skin. Avoid formation of dust and aerosols.

Personal protection: Not available.

Technical protective measures: Adequate extraction should be provided where dust is formed.

Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Not available.

Conditions for safe storage, including any incompatibilities: Store in a cool place. Keep container tightly closed in a dry and well-ventilated place.

Storage – away from: Not available.

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

Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask

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your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a viscoelastic tray.

Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

Individual protection measures

Eye/face protection: Protective face shields and safety goggles according to EN166.

Skin protection: No protection is required for this product.

Hand protection: Handle with gloves. The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard.

Respiratory protection: Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).

Thermal hazards: Not determined.

Environmental exposure control

Contains no substances with occupational exposure limit values.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	5 – 7
Melting/freezing point:	95 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	> 100 °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:	Very soluble in water. 2 350 g/l (20 °C)
Partition coefficient (n-octanol/water):	LogPow -2.2
Auto-ignition temperature:	380 °C

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Decomposition temperature: Not available.

Viscosity: Not available.

Explosive properties: Not available.

Oxidising properties: Not available.

9.2 Other information

Molecular weight: 182.17 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The product is stable if used properly.

No special conditions.

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Protect from moisture and water.

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: Oral LD₅₀ (rat): 15 900 mg/kg

Dermal LD₅₀ (rat): > 2 000 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:

STOT-single exposure: Not available.

STOT-repeated exposure: Not available.

Aspiration Hazard: Not available.

Other: Not available.

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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

Aquatic toxicity (OECD 201, algae): > 994 mg/l
Aquatic toxicity (OECD 202, daphnia): > 973 mg/l
Aquatic toxicity (OECD 203, fish): > 1 000 mg/l

12.2 Persistence and degradability

Readily biodegradable.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment is not available as chemical safety assessment is not required/not performed.

12.6 Other adverse effects

Use in accordance with good working practices, avoiding dispersal of the product into the environment. Notify the competent authorities if the product reaches watercourses, sewers, soil or vegetation.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.
Contaminated container: Dispose of as unused product.

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) : It is not dangerous in transport.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : It is not dangerous in transport.

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14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : It is not dangerous in transport.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : It is not dangerous in transport.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : It is not dangerous in transport.

14.6 Special precautions for user

It is not dangerous in transport.

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 to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (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 of the product 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

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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

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