

Material Safety Data Sheet

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

GLUCOSUM MONOHYDRICUM

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:	Glucose monohydrate Glucosum monohydricum Glucose monohydraat Glucose monohydraté Glucose-Monohydrat
N° CAS:	77938-63-7
N° EC:	616-580-9

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 has not been classified as dangerous according to the legislation in force: CLP Regulation (EC) No 1272/2008.

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.

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Additional applicable label elements:

Not applicable.

2.3 Other hazards

Dust may form an explosive mixture in the atmosphere.
Not fulfilling PBT (persistent/bioaccumulative/toxic) criteria.
Not fulfilling vPvB (very persistent/very bioaccumulative) criteria.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Glucose monohydrate
IUPAC name: (2R,3S,4R,5R)-2,3,4,5,6-pentahydroxyhexanal;hydrate
Synonyms: Dextrose monohydrate
D-Glucose monohydrate
N° CAS: 77938-63-7
N° EC: 616-580-9
Molecular Formula: $C_6H_{12}O_6 \cdot H_2O$
Content: 97.5 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

After inhalation: Move the exposed person to fresh air at once. Get medical attention if any discomfort continues.
After skin contact: Wash with soap and water.
After eye contact: Flush thoroughly with water for at least 15 minutes. Get medical assistance.
After ingestion: Product not hazardous when ingested.

4.2 Most important symptoms and effects, both acute and delayed

Dust may irritate the eyes and the respiratory system.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray.
Unsuitable extinguishing media: Dry chemicals or foams.

5.2 Special hazards arising from the substance/mixture

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Fire or excessive heat may produce hazardous decomposition products.

Dust may form an explosive mixture in the atmosphere.

See section 10.

5.3 Advice for firefighters

Surrounding fires:

Prevent dust clouds.

Protection against fire:

Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.

Hazardous combustion products:

Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

See section 8 for personal protective equipment.

For emergency responders

Not available.

6.2 Environmental precautions

Not regarded as dangerous for the environment.

6.3 Methods and material for containment and cleaning up

Remove material, as much as possible, using mechanical equipment.

Prevent dust clouds.

Collect and dispose of spillage as indicated in section 13.

6.4 Reference to other sections

For waste disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Not available.

Personal protection:

See section 8.

Technical protective measures:

Not available.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Not available.

Conditions for safe storage, including any incompatibilities:

Avoid contact with oxidising agents.

Store in a dry place.

Store at room temperature.

Storage – away from:

Avoid contact with oxidising agents.

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7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

This product does not contain any component with occupational exposure limits.

8.2 Exposure controls

Appropriate engineering control

Provide adequate ventilation. Observe Occupational Exposure Limits and minimise the risk of inhalation of dust. Handle the product in accordance with the good hygiene practices and safety instructions.

Individual protection measures

Eye/face protection: Wear dust-resistant safety goggles where there is danger of eye contact.

Skin protection: Wear suitable protective clothing.

Hand protection: No specific precautions.

Respiratory protection: In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter (type P1).

Thermal hazards: Not determined.

Environmental exposure control

Not regarded as dangerous for the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White or almost white, crystalline powder.

Odour: Odourless.

Odour threshold: Not available.

pH: ~ 4.7 at 50 %

Melting/freezing point: ~ 83 °C

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

Upper/lower flammability or explosive limits: Not available.

Vapour pressure: Not available.

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Vapour density:	Not available.
Relative density:	~ 0.62
Solubility:	Very slightly soluble in ethanol (96 per cent).
Solubility in water:	Freely soluble in water: ~ 1 000 g/l at 20 °C.
Partition coefficient (n-octanol/water):	-3.24 - Literature Reference -
Auto-ignition temperature:	~ 380 °C (Godbert-Greenwald) Cloud. ~ 330 °C product in deposit.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	- INERIS -Data from similar product. MIE (Minimum ignition energy): ~ 360 mJ (EN 13821 (Without Inductance)) Sensitive to ignition by an electrostatic phenomenon. MRP (Maximum Rate of Pressure): ~ 235 bar/s (EN 14034-2) MaxP (Maximum Pressure) ±10%: ~ 5.5 bar (EN 14034-1) Kst (Dust Explosion Description Number) ±20%: ~ 63 barm/s (EN 14034-2) Explosion Class: st 1 (VDI 3673) Volume resistivity: > 10 ⁹ Ω.m (CEI 1241-2-2) Moisture: ~ 8.5 % (ISO 589) Particle Size: ~ 69 µm (NFX 11-666) Other Data: Combustion index: 2 (VDI 2263-1)
Oxidising properties:	Not available.

9.2 Other information

Conductivity: ~ 10 µS/cm (at 50%)

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Strong oxidizing agents.

10.2 Chemical stability

Material is stable under normal conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions under ordinary conditions of use and storage.

10.4 Conditions to avoid

Prevent dust clouds. Dust clouds may be explosive under certain conditions.

10.5 Incompatible materials

Strong oxidizing substances.

10.6 Hazardous decomposition products

Carbon monoxide. Carbon dioxide.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	OECD 423 (similar substance): Oral LD50 (mouse): > 2 000 mg/kg, non toxic (literature reference)
Skin corrosion/irritation:	OECD 431 (similar substance): In vitro (human) (1h): Not irritating (literature reference)
Serious eye damage/irritation:	OECD 437 (similar substance): Not irritating (bovine cornea) (4h) (literature reference) OECD 405 (similar substance): Not irritating (rabbit) (72h) (literature reference)
Respiratory/skin sensitisation:	OECD 429 (similar substance): In vivo (mouse): not-sensitising (literature reference)
Germ cell mutagenicity:	OECD 473 (similar substance): In vitro (hamster): Negative OECD 471 (Ames) (similar substance): In vitro (S. typhimurium): Negative OECD 474 (similar substance): In vivo (mouse): Negative
Carcinogenicity:	OECD 453 (similar substance): Oral (rat) (2 years): No treatment related effects. (literature reference)
Reproductive toxicity:	OECD 416 (similar substance): Oral (rat) (12 weeks): No treatment related effects. OECD 414 (similar substance): Oral (hamster) (14 days): No treatment related effects. NOAEL: 1 200 mg/kg (literature reference)
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	OECD 453 (similar substance): No treatment related effects (rat) (52 weeks) (literature reference)
Aspiration Hazard:	Not available.
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

OECD 203 (similar substance): LC50 (Common Carp): > 100 mg/l, non toxic (96h) (literature reference)
OECD 202 (similar substance): LC50 (<i>Daphnia magna</i>): > 100 mg/l, non toxic (48h) (literature reference)
OECD 201 (similar substance): LC50 (<i>Pseudokirchneriella subcapitata</i>): > 100 mg/l, non toxic (72h) (literature reference)

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12.2 Persistence and degradability

OECD 301b (similar substance): 73 – 81 % / 28d, the product is readily biodegradable (literature reference)

12.3 Bioaccumulative potential

Substance: Glucose

Log Pow: -3.24

Bioconcentration Factor (BCF)/Bioaccumulation: Not determined.

Remarks: Potential to bioaccumulate is low.

12.4 Mobility in soil

This material is readily biodegraded and is not likely to bioconcentrate.

12.5 Results of PBT and vPvB assessment

Not fulfilling PBT (persistent/bioaccumulative/toxic) and vPvB (very persistent/very bioaccumulative) criteria.

12.6 Other adverse effects

None known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Dispose of waste in an appropriate authorised treatment facility in accordance with regulations in force and product characteristics at time of disposal.

Packaging material: Single use packaging. Collect for salvage or disposal.

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

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

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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

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
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.

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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

FAC SECUNDUM ARTEM NV

info@magis-pharma.be