

Material Safety Data Sheet

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

LACTOSUM MONOHYDRICUM

EN

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

1.1 Product identifier

Product name:	Lactose monohydrate Lactosum monohydricum Lactose monohydraat Lactose monohydraté Lactosemonohydrat
N° CAS:	10039-26-6
N° EC:	200-559-2

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

The substance is not classified 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

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

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Lactose monohydrate
IUPAC name:	(2R,3R,4S,5R,6S)-2-(hydroxymethyl)-6-[(2R,3S,4R,5R)-4,5,6-trihydroxy-2-(hydroxymethyl)oxan-3-yl]oxyoxane-3,4,5-triol;hydrate
Synonyms:	Lactose D-Lactose monohydrate
N° CAS:	10039-26-6
N° EC:	200-559-2
Molecular Formula:	$C_{12}H_{22}O_{11}$, H_2O
Content:	100%

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Remove contaminated clothing immediately.
After inhalation:	Supply fresh air; consult doctor in case of complaints.
After skin contact:	Wash immediately with soap and water and rinse thoroughly. If skin irritation persists, consult a doctor.
After eye contact:	Rinse eyes under running water for several minutes while keeping eyelids open. If symptoms persist, consult a doctor.
After ingestion:	If the symptoms persist, consult a doctor

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:	Water, extinguishing powder, foam, CO_2 .
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

In case of heating or fire, toxic gases may be formed.

5.3 Advice for firefighters

Surrounding fires:	Not available.
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Protection against fire:

Wear respiratory protection equipment that is not dependent on the ambient air.

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. Keep unprotected persons away. Avoid formation of dust.

For emergency responders

Wear protective clothing. Keep unprotected persons away. Avoid formation of dust.

6.2 Environmental precautions

Do not allow to enter sewers/surface water/groundwater.

6.3 Methods and material for containment and cleaning up

Pick up mechanically.

Dispose of contaminated material such as waste according to section 13.

6.4 Reference to other sections

See section 7 for information on safe use.

See section 8 for information on personal protective equipment.

See section 13 for information on storage.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Keep tanks impermeably sealed.

Avoid formation of dust.

Personal protection:

Not available.

Technical protective measures:

Ensure good ventilation/exhaustion at the workplace.

Information regarding fire and explosion hazards: Keep ignition sources away - no smoking. Take precautionary measures against static discharges.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Keep in original, unopened packing.

Conditions for safe storage, including any incompatibilities:

Keep containers tightly sealed.

Store in cool and dry conditions.

Store tank in a well-ventilated place.

Storage – away from:

Keep away from strongly odorous materials.

Protect from heat and direct sunlight.

7.3 Specific end use(s)

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

The usual precautions when handling chemicals should be observed.

Wash hands before breaks and at the end of work.

Individual protection measures

Eye/face protection: Tight-fitting safety goggles. EN166.

Skin protection: Wear suitable protective work clothing.

Hand protection: Protective gloves.

The glove material must be impermeable and resistant to the product/substance/preparation. No recommendation for the glove material for the product/the preparation/the chemical mixture can be made on the basis of failed tests. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves: EN374.

The selection of a suitable glove is not only dependent on the material, but also on other quality characteristics and varies from manufacturer to manufacturer.

Penetration time of glove material: The exact penetration time has to be found out by the manufacturer of the glove and has to be observed.

Respiratory protection: Respiratory protection in case of insufficient ventilation.

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, crystalline powder.

Odour: Characteristic.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: Not available.

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not applicable.

Evaporation rate: Not available.

Flammability (solid/gas): The substance is not flammable.

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Upper/lower flammability or explosive limits:	Lower: 30 - 125 g/m ³ Upper: Not determined.
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 applicable.
Explosive properties:	Dust explosion hazard. Class: ST1
Oxidising properties:	Not available.

9.2 Other information

Molecular mass: 360.3 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not determined.

No further relevant information available.

10.2 Chemical stability

Thermal degradation/conditions to be avoided: No degradation if used as directed.

10.3 Possibility of hazardous reactions

Dust explosion hazard.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

No dangerous decomposition products known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Based on available data, the classification criteria are not met.
Skin corrosion/irritation:	Based on available data, the classification criteria are not met.
Serious eye damage/irritation:	Based on available data, the classification criteria are not met.
Respiratory/skin sensitisation:	Based on available data, the classification criteria are not met.

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Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
Carcinogenicity:	Based on available data, the classification criteria are not met.
Reproductive toxicity:	Based on available data, the classification criteria are not met.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Based on available data, the classification criteria are not met.
STOT-repeated exposure:	Based on available data, the classification criteria are not met.
Aspiration Hazard:	Based on available data, the classification criteria are not met.
Other:	No toxic effects are to be expected when the product is handled appropriately.

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

No ecological problems are to be expected when the product is handled and used with due care and attention.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

General information:
Water hazard class 1 (D) (Self-assessment): slightly hazardous for water.
Do not allow to enter ground water, surface water or sewage system.

12.5 Results of PBT and vPvB assessment

Not applicable.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation: Must not be disposed of together with household rubbish.
Contaminated packaging: Recommendation: Dispose of in accordance with official regulations. Recommended cleansing agent: Water, with cleansing agents added if required.

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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 applicable.

14.6 Special precautions for user

Not applicable.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not applicable.

14.8 Additional transport information

Not subject to transport 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

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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

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

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