Material Safety Data Sheet

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

SORBITOLUM LIQUIDUM NON CRISTALLISABILE

Publication: 09/11/2022
Revision: 03/07/2024
Version: 01

MAGIS PHARMA

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

1.1 Product identifier

Product name:	Sorbitol, liquid 70% (non-crystallising) Sorbitolum liquidum non cristallisabile Sorbitol, vloeibaar 70% (niet-kristalliserend) Sorbitol liquid 70% (non cristallisable) Sorbitol-Lösung 70% (nicht kristallisierend)
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:	Magis-Pharma NV Neerlandweg 24 2610 Wilrijk 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

The substance is not classified as PBT or vPvB.

Material Safety Data Sheet

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

SORBITOLUM LIQUIDUM NON CRISTALLISABILE

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Aqueous solution of a hydrogenated, partly hydrolysed starch.

Content:	– anhydrous substance: 68.0 per cent m/m to 72.0 per cent m/m, – D-glucitol (D-sorbitol, $C_6H_{14}O_6$): 72.0 per cent to 92.0 per cent (anhydrous substance).
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:	$C_6H_{14}O_6$

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 complaints.
After skin contact:	Generally, the product does not irritate the skin. Rinse with water. 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:	If symptoms persist consult doctor.

4.2 Most important symptoms and effects, both acute and delayed

Gastric or intestinal disorders.

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:	CO_2, powder or water spray. Fight larger fires with water spray. Use fire extinguishing methods suitable to surrounding conditions.
Unsuitable extinguishing media:	Water with full jet.

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires:	Not available.

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

None under normal conditions at a temperature below 45 °C (always wear heat-resistant gloves).

For emergency responders

None under normal conditions at a temperature below 45 °C (always wear heat-resistant gloves).

6.2 Environmental precautions

Dilute with plenty of water.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Risk of slipping. May be drained into the ordinary sewerage system with a large quantity of hot water.

6.4 Reference to other sections

No dangerous substances are released.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	It is preferable to use tools that are suitable for hot and/or viscous liquids (see also item 9).
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store only in the original receptacle. Avoid surface condensation to avoid microbiological growth.
Conditions for safe storage, including any incompatibilities:	Avoid surface condensation to avoid microbiological growth. Store in a closed storage tank/container at the recommended temperature. Maximum storage temperature: 35 °C Minimum storage temperature: Sorbitol LGK: min 5 °C Sorbitol LGK-M, LGK-LC: min 0 °C Storage class: 12
Storage – away from:	Protect from humidity and water.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not required!

DNELs

Oral	DNEL	200 mg/kg bw/d (general population)
Dermal	DNEL	2 000 mg/kg bw/d (general population)
		2 000 mg/kg bw/d (worker)
Inhalative	DNEL	0.89 mg/m^3 (general population)
		5 mg/m^3 (worker)

PNECs

PNEC - Aquatic	973 µg/l (freshwater)
	97.3 µg/l (marinewater)
PNEC - Sediment	363 µg/kg dw (marinewater)
PNEC - Sediment	3.63 mg/kg dw (freshwater)
PNEC - Soil	0.15 mg/kg dw (-)
PNEC - Sewage treatment plant	67 mg/l (-)

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.

Individual protection measures

Eye/face protection:	Safety glasses.
Skin protection:	Protective glove clothing.
Hand protection:	Protective gloves.
	Material of gloves: Nitrile rubber.
	Layer thickness: 0.10 mm
	Penetration time > 480 min (Level 6)
	For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable: Nitrile rubber (i.e. KCL 740 nitrile disposable gloves Dermatril®)
Respiratory protection:	Not required.
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:	Clear, colourless, syrupy liquid, miscible with water.

Odour:	Product specific.
Odour threshold:	Not determined.
pH:	5-7
Melting/freezing point:	Not applicable.
Initial boiling point:	> 100 °C
Boiling range:	Not applicable.
Flash point:	Not applicable.
Evaporation rate:	Not determined.
Flammability (solid/gas):	Not applicable.
Upper/lower flammability or explosive limits:	Not determined.
Vapour pressure:	20 hPa (20 °C)
Vapour density:	Not determined.
Relative density:	Not determined.
Solubility:	Not available.
Solubility in water:	Miscible with water. > 3000 g/l (20 °C)
Partition coefficient (n-octanol/water):	(log P): < -2
Auto-ignition temperature:	Not determined.
Decomposition temperature:	+/- 200 °C
Viscosity:	Dynamic at 20 °C: 139 – 239 mPas Kinematic: Not determined
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

The product is not subject to spontaneous decomposition, is 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

Strong acids and oxidising agents.

10.6 Hazardous decomposition products

CO and CO_2 can be produced during combustion.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD_{50} (rat):	> 24,370 mg/kg (OECD 423)	
	Dermal LD_{50} (rat):	> 2,000 mg/kg	
	Based on available data, the classification criteria are not met.		
Skin corrosion/irritation:	No irritant effect.		
Serious eye damage/irritation:	No irritant effect.		
Respiratory/skin sensitisation:	No sensitizing effects known.		
Germ cell mutagenicity:	Genotoxicity - AMES-Test	(*Salmonella Typhimurium*) (OECD 471) negative	
	Genotoxicity - Mammalian Cell Gene Mutation Assay	(Mouse lymphoma cells) (OECD 476) negative	
	Genotoxicity - Micronucleus assay	(mouse) (OECD 474) negative	
	Genotoxicity - Chromosome aberration assay	(Chinese Hamster Ovary Cells) (OECD 473) negative	
	Based on available data, the classification criteria are not met.		
Carcinogenicity:	Not carcinogenic.		
Reproductive toxicity:	Oral	developmental toxicity – NOAEL	7,000 mg/kg (rat) (OECD 414)
		reproductive toxicity – NOAEL	> 5,000 mg/kg (rat) (OECD 416)
	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:	<u>Subacute to chronic toxicity</u>		
	Oral	NOAEL	> 5,000 mg/kg (rat) (OECD 452)
	Additional toxicological information: Gastric or intestinal disorders		
	<u>Repeated dose toxicity</u>		
	Oral	NOAEL	> 4,500 mg/kg (rat) (OECD 409 / OECD 453)

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:

EC50	> 994 mg/l (algae) (OECD 201)
	> 973 mg/l (daphnia) (OECD 202)
LC50	> 1,000 mg/l (fish) (OECD 203)

12.2 Persistence and degradability

Easily biodegradable.

Method:	OECD 301B
Analysing method:	CO_2-Evolution
Degree of elimination:	73 - 81%
Classification:	Readily biodegradable

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

Additional ecological information: General notes: Generally not hazardous for water.

12.5 Results of PBT and vPvB assessment

The substance is not classified as PBT or vPvB.

12.6 Other adverse effects

No environmental hazard or adverse effect on human exposure is anticipated as a result of any release of this product.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation: Smaller quantities can be disposed of with household waste.

Uncleaned packaging:	Recommendation: Disposal must be made according to official regulations.
	Recommended cleansing agents: Water, if necessary together with cleansing agents.

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 dangerous according to the above specifications.

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 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 Bioaccumalative

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

Classified based on the main component.

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.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FRAVER NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FRAVER NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

16.8 Department issuing MSDS

Quality Department
FRAVER NV
info@magis-pharma.be