

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Substance
 Trade name : MANNOGEM™ Mannitol USP/FCC (All Grades)
 Chemical name : D-mannitol
 EC no : 200-711-8
 CAS No : 69-65-8
 REACH Registration No. : Not applicable

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Industrial/Professional use spec : Industrial
 Use of the substance/mixture : Pharmaceutical ingredient

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

SPI Pharma SAS
 Chemin du Vallon du Maire
 13240 Septemes Les Vallons
 France
 T 33 4 91 96 36 00 - F 33 4 91 65 39 03
CBlasquez@spipharma.com

1.4. Emergency telephone number

Emergency number : +33 4 91 96 36 00 (Not 24 hours, business hours only)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substance

Name : MANNOGEM™ Mannitol USP/FCC (All Grades)
 CAS No : 69-65-8
 EC no : 200-711-8

Name	Product identifier	%	Classification according to Directive 67/548/EEC
D-Mannitol	(CAS No) 69-65-8 (EC no) 200-711-8	100	Not classified
Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
D-Mannitol	(CAS No) 69-65-8 (EC no) 200-711-8	100	Not classified

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according to Regulation (EC) No. 453/2010

Full text of R- and H-phrases: see section 16

3.2. Mixture

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Assure fresh air breathing. Allow the victim to rest. In all cases of doubt, or when symptoms persist, seek medical advice.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Seek medical attention if irritation develops.
First-aid measures after eye contact	: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. If a large quantity has been ingested : Obtain emergency medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries	: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/injuries after inhalation	: Overexposure to dusts may produce slight irritation of the respiratory system.
Symptoms/injuries after eye contact	: May cause slight irritation to eyes.
Symptoms/injuries after ingestion	: On ingestion in large quantities : may cause gastrointestinal disturbance.

4.3. Indication of any immediate medical attention and special treatment needed

None known.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Explosion hazard	: Accumulation of airborne dusts may present an explosion hazard in the presence of an ignition source.
Hazardous decomposition products in case of fire	: Thermal decomposition generates : Carbon dioxide. Carbon monoxide. Low molecular weight hydrocarbons.

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protective equipment for firefighters	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment	: Contain the discharged material using dust suppressant.
Methods for cleaning up	: On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Provide adequate ventilation. Avoid contact with eyes. Avoid generation of dust. Remove all sources of ignition. Use only non-sparking tools. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.
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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store at room temperature. Keep container tightly closed.
Incompatible products	: Strong bases. Strong acids. Strong oxidizing agents.
Incompatible materials	: Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls	: Provide local exhaust or general room ventilation to minimize exposure to dust. Exposures should be minimized in accordance with good industrial hygiene practices.
Personal protective equipment	: Avoid all unnecessary exposure. Protective goggles. Gloves.



Hand protection	: Wear protective gloves.
Eye protection	: Chemical goggles or safety glasses.
Respiratory protection	: In case of insufficient ventilation, wear suitable respiratory equipment.
Other information	: Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: White crystalline powder or granules.
Colour	: White.
Odour	: None.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: Not applicable
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: Not applicable
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1.52 (Specific Gravity)
Solubility	: Water: Soluble
Log Pow	: No data available
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: Not applicable
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable.

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10.2. Chemical stability

Stable.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures. Accumulation of airborne dusts.

10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizers.

10.6. Hazardous decomposition products

Fume. Carbon monoxide. Carbon dioxide. Low molecular weight hydrocarbons.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

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LD50 oral rat	13500 mg/kg
Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential Adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

MANNOGEM™ Mannitol USP/FCC (All Grades) (69-65-8)

Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

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Bioaccumulative potential	Not established.
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

: Avoid release to the environment

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

- Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Empty containers should be rinsed and discarded in a waste container or offered for recycling if possible. Do not re-use empty containers except for storage and shipment of original product.
- Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

- Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

- Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

- Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6. Special precautions for user

14.6.1. Overland transport

No additional information available

14.6.2. Transport by sea

No additional information available

14.6.3. Air transport

No additional information available

14.6.4. Inland waterway transport

Not subject to ADN : No

14.6.5. Rail transport

Carriage prohibited (RID) : No

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according to Regulation (EC) No. 453/2010

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Contains no substance on the REACH candidate list

Other information, restriction and prohibition regulations : Compliance with following regulations: Directive 1999/45/EC as amended. Regulation (EC) 1272/2008 as amended. Regulation (EC) 1907/2006 as amended.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Sources of Key data : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Abbreviations and acronyms : ATE - acute toxicity estimate. CAS - Chemical Abstracts Service. CLP - Classification, Labelling and Packaging. CSR - Chemical Safety Report. EEC - European Economic Community. GHS - Globally Harmonised System. PBT - Persistent, Bioaccumulative and Toxic substance. REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals. STEL- Short-Term Exposure Limit . TWA- Time Weighted Average. vPvB - Very Persistent and Very Bioaccumulative.

Other information : None.

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product