

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

1.1. Product identifier

Product form : Substance
 Trade name : MANNOGEM® XL Mannitol
 Product Code(s) : 112-1284

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

Use of the substance/mixture : Pharmaceutical ingredient

1.3. Details of the supplier of the safety data sheet

SPI Pharma Inc.
 Rockwood Office Park
 503 Carr Road
 Wilmington, Delaware 19809
 (302) 360-7200

1.4. Emergency telephone number

Emergency number : Chemtrec (800) 424-9300; Chemtrec (Outside USA) +1 703-527-3887 (24 hours; 7 days/week)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified

2.1.2. Classification according to Directive 67/548/EEC or 1999/45/EC

Not classified

2.1.3. Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

No labelling applicable

2.2.2. Labelling according to Directive 67/548/EEC or 1999/45/EC

No labelling applicable

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substance

Name : MANNOGEM® XL Mannitol

Name	Product identifier	%	GHS classification
D-Mannitol	(CAS No) 69-65-8 (EC no) 200-711-8	100	Not classified

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.

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

D-mannitol (69-65-8)

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

MANNOGEMTM XL Mannitol (69-65-8)

Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

MANNOGEMTM XL Mannitol (69-65-8)

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

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

14.1 Land Transport DOT

DOT Proper Shipping Name: Not dangerous goods

DOT Hazard Class:

UN/NA Number:

14.1. Land Transport (European ADR/RID)

ADR/RID Shipping Name: Not dangerous goods

UN Number:

Hazard Class:

14.3. Air Transport (ICAO/IATA)

ICAO/IATA Shipping Name Not dangerous goods

Additional Transport

Transport in accordance with local, state and federal regulations

14.7. Transportation in Bulk according to Annex II MARPOL73/78 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 additional information available

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

15.3. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

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

No additional information available

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

No additional information available

15.2.2. National regulations

No additional information available

SECTION 16: Other information

Abbreviations and acronyms

: CAS: Chemical Abstracts Service (division of the American Chemical Society)
CLP: Classification, Labelling and Packaging.
PBT: Persistent, Bioaccumulative and Toxic
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals.
vPvB: very persistent and very bioaccumulative substance.

Other information

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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. However, we make no warranty of merchantability or any other warranty, expressed or implied, with respect to such information, and we assume no liability resulting from its use. Consumer/User should make their own investigation to determine the suitability of the information for their particular use.