

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

#### 1.1. Product identifier

Product form : Substance  
Trade name : Granular Mannitol USP

#### 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

##### GHS-US classification

Not classified

#### 2.2. Label elements

##### GHS-US labelling

No labelling applicable

#### 2.3. Other hazards

No additional information available

#### 2.4. Unknown acute toxicity (GHS-US)

No data available

### SECTION 3: Composition/information on ingredients

#### 3.1. Substance

Name : Granular Mannitol USP

Name	Product identifier	%	GHS-US classification
D-Mannitol	(CAS No) 69-65-8	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.

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- 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.  
Reactivity : Stable.

### 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.

#### 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.

### 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.

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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) : No data available  
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  
Log Kow : 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.

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### 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  
(Based on available data, the classification criteria are not met)

D-mannitol (69-65-8)	
LD50 oral rat	13500 mg/kg
ATE US (oral)	13500.0000 mg/kg bodyweight

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.

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.

## SECTION 12: Ecological information

### 12.1. Toxicity

No additional information available

### 12.2. Persistence and degradability

Granular Mannitol USP	
Persistence and degradability	Not established.

### 12.3. Bioaccumulative potential

Granular Mannitol USP	
Bioaccumulative potential	Not established.

### 12.4. Mobility in soil

No additional information available

### 12.5. Other adverse effects

Effect on ozone layer : No additional information available

Effect on the global warming : No known ecological damage caused by this product.

Other information : 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 DOT

Not regulated for transport

#### Additional information

Other information : No supplementary information available.

#### ADR

Transport document description :

#### Transport by sea

No additional information available

#### Air transport

No additional information available

### SECTION 15: Regulatory information

#### 15.1. US Federal regulations

No additional information available

#### 15.2. 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

#### 15.3. US State regulations

No supplementary information available

### SECTION 16: Other information

Abbreviations and acronyms : ATE - acute toxicity estimate. CAS - Chemical Abstracts Service. HCS - Hazard Communication Standard. HMIS - Hazardous Materials Identification System. GHS - Globally Harmonised System. OSHA - Occupational Safety and Health Administration. SDS - Safety Data Sheet.

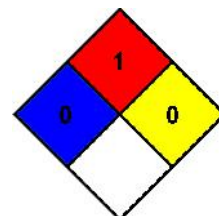
Date of SDS preparation : 05/01/2015

Other information : None.

NFPA health hazard : 0 - Exposure under fire conditions would offer no hazard beyond that of ordinary combustible materials.

NFPA fire hazard : 1 - Must be preheated before ignition can occur.

NFPA reactivity : 0 - Normally stable, even under fire exposure conditions, and are not reactive with water.



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### HMIS III Rating

Health	: 0 Minimal Hazard - No significant risk to health
Flammability	: 1 Slight Hazard
Physical	: 0 Minimal Hazard
Personal Protection	: Safety glasses with side shields

SDS US (GHS HazCom 2012)

*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*