SAFETY DATA SHEET

1. Identification

Product identifier: Mannitol

Other means of identification:
- Catalog number: 1375105
- Chemical name: D-Mannitol
- Synonym(s): 1,2,3,4,5,6-Hexanohexol * Mannite

Recommended use: Specified quality tests and assay use only.

Recommended restrictions: Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway
  Rockville
  MD
  20852-1790
  US
- Telephone: RS Technical Services 301-816-8129
- Website: www.usp.org
- E-mail: RSTECH@usp.org
- Emergency phone number: CHEMTREC within US & Canada 1-800-424-9300
  CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards: Not classified.

OSHA hazard(s): Not classified.

Label elements

- Hazard symbol: No symbol.
- Signal word: Not available.
- Hazard statement: Not available.

Precautionary statement

- Prevention: Not available.
- Response: Not available.
- Storage: Not available.
- Disposal: Not available.

Hazard(s) not otherwise classified (HNOC): Not classified.

3. Composition/information on ingredients

Non-hazardous components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mannitol</td>
<td>1,2,3,4,5,6-Hexanohexol</td>
<td>69-65-8</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>Mannite</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. First-aid measures

Inhalation: Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact: Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact: Rinse with water. Get medical attention if irritation develops and persists.

Ingestion: Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed
Not available.

Indication of immediate medical attention and special treatment needed
Provide general supportive measures and treat symptomatically.

General information
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures
Suitable extinguishing media
Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters
Wear suitable protective equipment.

Fire-fighting equipment/instructions
As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods
Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures
Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and storage
Precautions for safe handling
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.

Conditions for safe storage, including any incompatibilities
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection
Biological limit values
No biological exposure limits noted for the ingredient(s).

Exposure guidelines
No exposure standards allocated.

Appropriate engineering controls
Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Individual protection measures, such as personal protective equipment
Eye/face protection
Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Hand protection
Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other
For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory protection
Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards: Not available.

General hygiene considerations: Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance: White or almost white crystalline powder or free-flowing granules.

Physical state: Solid.

Form: Powder.

Odor: Odorless.

Odor threshold: Not available.

pH: 5 - 6.5 (in solution) at 25 °C

Melting point/freezing point: 330.8 - 338 °F (166 - 170 °C)

Initial boiling point and boiling range: 554 - 563 °F (290 - 295 °C) 0.466628 kPa

Flash point: > 300.00 °F (> 148.89 °C) (method not specified)

Evaporation rate: Not available.

Flammability (solid, gas): Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%): Not available.

Flammability limit - upper (%): Not available.

Explosive limit - lower (%): Not available.

Explosive limit - upper (%): Not available.

Vapor pressure: < 0.0000001 kPa at 25 °C

Vapor density: 6.3

Relative density: Not available.

Solubility in water: Freely soluble.

Partition coefficient (n-octanol/water): -3.1

Auto-ignition temperature: 860 °F (460 °C)

Viscosity: Not available.

Other information

Chemical family: Polyalcohol derivative.

Molecular formula: C6H14O6

Molecular weight: 182.2

Percent volatile: Negligible

Solubility (other): Soluble in alkaline solutions and aniline; slightly soluble in pyridine; very slightly soluble in alcohol; insoluble in ether.

Specific gravity: 1.52 at 20 °C

10. Stability and reactivity

Reactivity: No reactivity hazards known.

Chemical stability: Stable at normal conditions.

Possibility of hazardous reactions: No dangerous reaction known under conditions of normal use.

Conditions to avoid: None known.

Incompatible materials: Strong oxidizers.

Hazardous decomposition products: Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion: Based on available data, the classification criteria are not met.

Inhalation: Due to lack of data the classification is not possible.

Skin contact: Due to lack of data the classification is not possible.
Eye contact: Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics:
- Sweet taste
- Nausea
- Vomiting
- Diarrhea
- Skin rash
- Hives
- Dry mouth
- Headache
- Blurred vision
- Muscle pain
- Numbness, pain, tingling, or weakness in hands or feet
- Increased urination
- Dizziness
- Tiredness
- Weakness
- Weakness or numbness of arm or leg
- Confusion
- Trembling
- Seizures

Delayed and immediate effects of exposure:
- Gastrointestinal disturbances
- Laxative effect
- Fluid and electrolyte imbalance
- Irregular heartbeat

Chronic effects:
- Intracranial hemorrhage
- Congestive heart failure
- Death

Medical conditions aggravated by exposure:
- Kidney impairment
- Kidney disease
- Dehydration
- Heart problems

Acute toxicity:
- Based on available data, the classification criteria are not met.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mannitol (CAS 69-65-8)</td>
<td>Mouse</td>
<td>22 g/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>13500 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation:
- Due to lack of data the classification is not possible.

Serious eye damage/eye irritation:
- Due to lack of data the classification is not possible.

Respiratory sensitization:
- Due to lack of data the classification is not possible.

Skin sensitization:
- Due to lack of data the classification is not possible.

Germ cell mutagenicity:
- Based on available data, the classification criteria are not met.
  - In vivo and in vitro mutagenicity studies were negative.

Carcinogenicity:
- Based on available data, the classification criteria are not met.
  - This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

  - 50000 ppm Carcinogenicity study, dietary doses
  - Result: No evidence of carcinogenicity.
  - Species: Mouse
  - Test Duration: 103 weeks

  - 50000 ppm Carcinogenicity study, dietary doses
  - Result: No evidence of carcinogenicity.
  - Species: Rat
  - Test Duration: 103 weeks

Reproductive toxicity:
- Based on available data, the classification criteria are not met.
  - This material has not caused birth defects in animal studies.
  - Adverse fetal effects were not seen in animal studies.

Specific target organ toxicity - single exposure:
- Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure:
- Based on available data, the classification criteria are not met.

Aspiration hazard:
- Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity:
- No ecotoxicity data noted for the ingredient(s).

Persistence and degradability:
- No data is available on the degradability of this product.

Bioaccumulative potential:
- Not available.

Mobility in soil:
- Not available.

Other adverse effects:
- Not available.

13. Disposal considerations

Disposal instructions:
- This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose of waste in accordance with all applicable Federal, State, and local laws.

Local disposal regulations:
- Not available.

Hazardous waste code:
- Not regulated.

Waste from residues / unused products:
- Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging
Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT
Not regulated as a hazardous material by DOT.

IATA
Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
No information available.

15. Regulatory information

US federal regulations
CERCLA/SARA Hazardous Substances - Not applicable.
All components are on the U.S. EPA TSCA Inventory List.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
Hazard categories
Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No
SARA 302 Extremely hazardous substance
No
SARA 311/312 Hazardous chemical
No

Other federal regulations
Safe Drinking Water Act (SDWA)
Not regulated.
Food and Drug Administration (FDA)
Total food additive

US state regulations
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
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<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>Yes</td>
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<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
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<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>Yes</td>
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<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>Yes</td>
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<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>Yes</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*A “Yes” indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date 09-02-2005
Revision date 05-23-2013
Version # 02
Further information Not available.
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Revision Information

This document has undergone significant changes and should be reviewed in its entirety.