



Material Safety Data Sheet

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Phone Calls: 301-816-8129
8 a.m. to 5 p.m. EST Mon. - Fri.

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SORBITOL

Catalog Number: 1617000

Revision Date:

August 2, 2006

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Sorbitol

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

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Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

Adverse Effects: This material occurs naturally in many fruits and is a common sweetening additive in foods. Adverse effects from large oral doses may include abdominal cramps, flatulence, bloating, diarrhea, and vomiting. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: n/f

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, diabetes mellitus, and fructose intolerance

Cross Sensitivity: n/f

Target Organs: n/f

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Common Name: Sorbitol

Formula: C₆H₁₄O₆

Synonym: D-Sorbitol

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Chemical Name: D-Glucitol

CAS: 50-70-4

RTECS Number: LZ4290000

Chemical Family: Polyhydric alcohol

Therapeutic Category: Pharmaceutic aid (flavor; tablet excipient)

Composition: Pure Material

SECTION 4 - FIRST AID MEASURES

Inhalation: May cause irritation. Remove to fresh air.

Eye: May cause irritation. Flush with copious quantities of water.

Skin: May cause irritation. Flush with copious quantities of water.

Ingestion: May cause irritation and sweet taste. Flush out mouth with water. This material is poorly absorbed from the gastrointestinal tract.

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Note to Physicians

Overdose Treatment: Treatment of overdose should be symptomatic and supportive and may include the following:

1. The use of catharsis is questionable after ingestion of sorbitol.
2. Activated charcoal is NOT recommended.
3. Perform oral rehydration and electrolyte replacement. For severe intoxication, aggressive parenteral fluid/electrolyte replacement may be necessary.
4. Assess serum electrolytes and osmolality frequently.
5. Severe cases may mandate cardiovascular monitoring. [Meditext 2006]

SECTION 5 - FIREFIGHTING MEASURES

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

SECTION 7 - HANDLING AND STORAGE

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. Wash thoroughly after handling.

Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection: Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving

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air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

Eye Protection: Safety glasses or goggles

Protective Clothing: Protect exposed skin.

Exposure Limits: n/f

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: White powder, granules or flakes; odorless.

Odor Threshold: n/f

pH: 3.5 - 7 (10% CO₂-free aqueous solution)

Melting Range: 110 - 112° C

Boiling Point: 105° C; also reported as 295° C

Flash Point: n/f

Autoignition Temperature: 420° C

Evaporation Rate: n/f

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: < 0.1 mm Hg

Vapor Density: < 1

Specific Gravity: 1.489

Solubility in Water: Vey soluble

Fat Solubility: n/f

Other Solubility: Soluble in methanol, in isopropanol, in butanol, in cyclohexanol, in phenol, in acetone, in acetic acid, in DMF, in pyridine, and in acetamide solutions; sparingly soluble in alcohol; practically insoluble in ethyl ether and in most other organic solvents

Partition Coefficient: n-octanol/water: -2.2

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: C₆H₁₄O₆

Molecular Weight: 182.17

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SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: Avoid exposure to moisture.

Incompatibilities: Strong oxidizing agents.

Decomposition Products: When heated to decomposition material emits acrid smoke and irritating fumes. Emits toxic fumes under fire conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50: 15900 mg/kg

Oral Mouse: LD50: 17800 mg/kg

Other Toxicity Data: n/f

Irritancy Data: n/f

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by: **NTP:** No **IARC:** No **OSHA:** No

Other Carcinogenicity Data: No

Mutagenicity Data: Sorbitol was negative for mutagenicity in the Salmonella Ames assay, with and without activation.

Reproductive and Developmental Effects: No increases in birth defects were found among the offspring of pregnant rats given diets containing 2.5 - 10% sorbitol, pregnant mice given 16 - 1600 mg/kg/day of sorbitol, or pregnant hamsters given either sorbitol doses of 12 - 1200 mg/kg/day or a single dose of 4100 mg/kg.

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: This material biodegrades at a moderate rate.

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 14 - TRANSPORT INFORMATION

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: n/f

International Regulatory Information: EINECS # 200-061-5

SECTION 16 - OTHER INFORMATION

Revision: 02-Aug-06

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Previous Revision Date:

03-Jul-03