



# SAFETY DATA SHEET

Sorbitol Solution USP (70% w/w)

SDS DATE: 30-Sep-2015

## SECTION 1: IDENTIFICATION

**PRODUCT NAME:** Sorbitol Solution USP (70% w/w)

**SYNONYMS:** Glucitol

**NDC Number:** 46287-500-01 and 46287-500-30

**MANUFACTURER:** CMP Pharma, Inc.

**ADDRESS:** PO Box 147

8026 US Hwy. 264A

Farmville, NC 27828

**EMERGENCY PHONE:** 1-800-227-6637

**CHEMTREC PHONE:** 1-908-859-2151

**OTHER CALLS:** 1-252-753-7111

**CHEMICAL NAME (for active ingredient):** (2S,3R,4R,5R)-Hexane-1,2,3,4,5,6-hexol

**CHEMICAL FAMILY (for active ingredient):** Sugar Alcohol

**CHEMICAL FORMULA (for active ingredient):** C<sub>6</sub>H<sub>14</sub>O<sub>6</sub>

**PRODUCT USE:** Pharmaceutical sweetening agent.

## SECTION 2: HAZARD(S) IDENTIFICATION

**PHYSICAL HAZARDS:** None classified.

**HEALTH HAZARDS:** None classified.

**SIGNAL WORD:** None

**HAZARD STATEMENT:** May be cause gastrointestinal discomfort if ingested.

**HAZARD SYMBOLS:** None

**PRECAUTIONARY STATEMENTS:**

Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wash hands and face thoroughly after handling. Do not eat, drink, or smoke when using this product. Contaminated work clothing must not be allowed out of the workplace.

**HAZARDS NOT OTHERWISE CLASSIFIED:** None classified.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<u>INGREDIENT:</u>	<u>CAS NO.</u>	<u>Amount</u>
Sorbitol	50-70-4	≥ 70%

## SECTION 4: FIRST AID MEASURES

**EYE CONTACT:** Flush with copious amounts of water for at least 15 minutes. Hold eyelids away from eyeball to ensure thorough rinsing. Irrigate each eye continuously with normal saline during transport. Seek medical attention immediately.

**SKIN CONTACT:** Wash the affected area with plenty of warm water and soap. If irritation, redness, or rash persists, seek medical attention.

**INGESTION:** This product is not hazardous when ingested.

**INHALATION:** This product is not expected to be an inhalation hazard under normal use conditions.



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### MOST IMPORTANT SYMPTOMS/EFFECTS

#### ACUTE OR DELAYED:

May cause abdominal pain or diarrhea.

#### NOTES TO PHYSICIANS OR FIRST AID PROVIDERS:

This product should only be given to patients by medical professionals educated in the therapy intended for this product. Treat any symptoms and eliminate exposure.

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### SECTION 5: FIRE-FIGHTING MEASURES

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**SUITABLE EXTINGUISHING MEDIA:** Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

**UNSUITABLE EXTINGUISHING MEDIA:** None known.

**UNUSUAL FIRE AND EXPLOSION HAZARDS:** Hazardous decomposition products may be formed under fire conditions.

**SPECIAL FIRE FIGHTING PROCEDURES:** Evacuate personnel to a safe area. Wear self-contained breathing apparatus and personal protective equipment to prevent contact with skin and eyes.

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### SECTION 6: ACCIDENTAL RELEASE MEASURES

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**PERSONAL PRECAUTIONS:** Non-essential personnel should be evacuated from the affected area. Spills should be cleaned up in a manner that minimizes exposure to personnel. Personnel involved in the clean up of spills should wear the appropriate respiratory protection, gloves, eye protection, and protective coveralls. Contaminated surfaces may be slippery. Remove all sources of heat and ignition.

**METHODS/MATERIALS USED FOR CONTAINMENT & CLEANING:** Use an inert absorbent material to remove and collect spillage. Dampen remaining residue with water, then clean spill area thoroughly with soap and water. Collect wash with absorbent material and transfer all waste to a labeled container for disposal. Observe all applicable regulations when disposing of this substance.

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### SECTION 7: HANDLING AND STORAGE

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**HANDLING PRECAUTIONS:** Clean equipment and work surfaces with suitable detergent or solvent after use. Wash hands and exposed skin thoroughly with soap and water after use. Remove any contaminated clothing and clean before reuse. Destroy contaminated belts, shoes, and any other items that cannot be decontaminated.

**STORAGE PRECAUTIONS:** When not in use, store in a cool, dry, well-ventilated area, in tightly sealed containers that are labeled in accordance with OSHA's Hazard Communication Standard [29CFR 1910.1200]. Keep away from ignition sources including electrostatic charge, heat, sparks, open flame, and strong oxidizers. Maintain an appropriate temperature during storage to minimize crystallization issues.

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### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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#### EXPOSURE LIMITS/GUIDELINES:

Component Name	WEEL (TWA)	OSHA PEL (TWA)	ACGIH TLV (TWA)	HSE WEL (TWA)
Sorbitol Solution USP	N/A	N/A	N/A	N/A



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**ENGINEERING CONTROLS:** The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces.

### PERSONAL PROTECTIVE EQUIPMENT (PPE)

**EYE PROTECTION:** Wear appropriate chemical safety goggles, safety glasses, or face shield as described by OSHA's eye and face protection regulations in 29 CFR 1910.133. Have eyewash stations available where eye contact can occur.

**SKIN PROTECTION:** Wear gloves impervious to conditions of use. A safety shower should be located in the work area.

**RESPIRATORY PROTECTION:** No specific precautions.

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### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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**APPEARANCE/ODOR:** This product is a clear viscous liquid with no discernible aroma.

<b>FLASH POINT:</b>	Not established.	<b>% VOLATILE:</b>	Not established.
<b>AUTOIGNITION TEMP:</b>	Not established.	<b>VISCOSITY:</b>	Not established.
<b>BOILING POINT:</b>	> 100°C	<b>pH:</b>	Approx. 6.1
<b>MELTING POINT:</b>	Not established.	<b>Octanol/H<sub>2</sub>O PART. COEFFICIENT:</b>	-2.2
<b>VAPOR PRESSURE (mmHg):</b>	< 12.1 hPa @ 20°C	<b>POUR POINT:</b>	Not established.
<b>EVAPORATION RATE (H<sub>2</sub>O = 1):</b>	Not established.	<b>% SOLUBILITY IN WATER:</b>	100% at 20°C
<b>VAPOR DENSITY (AIR = 1):</b>	Approx. 0.7	<b>SPECIFIC GRAVITY (H<sub>2</sub>O = 1):</b>	Not established.
<b>LOWER FLAMMABILITY LIMIT:</b>	Not established.	<b>UPPER FLAMMABILITY LIMIT:</b>	Not established.

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### SECTION 10: STABILITY AND REACTIVITY

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**REACTIVITY:** Oxidizing agents.

**CHEMICAL STABILITY:** Material is stable under normal conditions.

**POSSIBILITY OF HAZARDOUS REACTIONS:** No dangerous reaction known under conditions of normal use.

**CONDITIONS TO AVOID:** Thickening and cloudiness may occur at depressed temperatures.

**INCOMPATIBLE MATERIALS:** Acids, caustics, and other chemicals that could affect its performance should be avoided.

**HAZARDOUS DECOMPOSITION PRODUCTS:** Under fire conditions, thermal decomposition may generate irritating and/or toxic fumes or gases (i.e. carbon oxides).

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### SECTION 11: TOXICOLOGICAL INFORMATION

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#### INFORMATION ON LIKELY ROUTES OF EXPOSURE:

**INGESTION:** In an occupational setting, ingestion of this product is unlikely. Ingestion may cause irritation.

**INHALATION:** Although unlikely due to product form, inhalation of vapors may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon exposure to fresh air.

**SKIN CONTACT:** Non irritating.

**EYE CONTACT:** Avoid contact with eyes. May cause irritation of the eyes.

**SIGNS AND SYMPTOMS OF OVEREXPOSURE:**  
Gastrointestinal discomfort or diarrhea may occur.



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### CHRONIC EFFECTS:

May include gastrointestinal discomfort or diarrhea.

### ACUTE TOXICITY VALUES:

LD 50 (oral, daphnia magna) = 1390 mg/L

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### SECTION 12: ECOLOGICAL INFORMATION

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#### ECOLOGICAL INFORMATION:

This product has not been tested for persistence, biodegradability, bioconcentration, soil absorption, or mobility.

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### SECTION 13: DISPOSAL CONSIDERATIONS

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#### WASTE DISPOSAL METHOD:

It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with all local, state, and federal regulations. Wear proper protective equipment when handling waste materials.

#### WASTE DISPOSAL CONTAINERS:

Waste materials must be placed in and shipped in appropriate poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers is done in accordance with all applicable regulations.

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### SECTION 14: TRANSPORT INFORMATION

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#### U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS:

This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

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### SECTION 15: REGULATORY INFORMATION

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This product is in conformance with the GHS Standard.

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### SECTION 16: OTHER INFORMATION

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#### NATIONAL FIRE PROTECTION ASSOCIATION (NFPA) RATINGS:

Health: 1      Flammability: 0      Reactivity: 0      Other: 0

#### CREATION DATE:

30Sep2015

#### REVISION DATE:

N/A

#### DISCLAIMER:

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The information contained herein is designated only as guidance for safe handling and storage of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment, should handle all chemicals. CMP Pharma, Inc. shall not be held liable for any loss, injury, or damage from contact with the product.