

SAFETY DATA SHEET



Revision Date: 02.03.2020

Version 1.0

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1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND THE COMPANY / UNDERTAKING

Product Identifier

Material Name: Sorbitol - Mannitol Irrigation, USP

Trade Name: Not Established

Synonyms: None

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product

Details of the supplier of the Safety Data Sheet:

ICU Medical, Inc.
275 North Field Drive
Lake Forest, IL 60045
(844) 654-7780

Emergency Telephone Number:

Phone: 1-(800) 241-4002, Option 6
CHEMTREC (24 hours): 1-800-424-9300
email: MedInfo_US@icumed.onmicrosoft.com

2. HAZARD IDENTIFICATION

Classification of the Substance or Mixture

GHS – Classification Not classified as hazardous

Label Elements

Signal Word: Not classified

Hazard Statements: Not classified in accordance with international standards for workplace safety

Other Hazards: No data available

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS / ELINCS List	GHS Classification	%
Mannitol	69-65-8	200-711-8	Not Listed	0.1-1
Sorbitol	50-70-4	200-061-5	Not Listed	1-5
Water for injection	7732-18-5	231-791-2	Not Listed	*

Additional Information: * Proprietary

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: As a precaution, flush with water while holding eyelids open for at least 15 minutes. If irritation occurs or persists, obtain medical attention.

Skin Contact: If irritation occurs, wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance.

Ingestion: Never give anything by mouth to an unconscious person. Wash mouth out with water and obtain medical attention immediately. Do not induce vomiting unless directed by medical personnel.

Inhalation: Not an expected route of exposure.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: No data available

Medical Conditions Aggravated by Exposure: None Known

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, dry chemical, foam or water.

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Special Hazards Arising from the Substance or Mixture

Hazardous Combustion

Products: Formation of toxic gases is possible during heating or fire. May include oxides of carbon.

Fire / Explosion Hazards: Not applicable

Advice for Firefighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning /

Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for

Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

No special handling requirements for normal use of this material.

Conditions for safe storage, including any incompatibilities

Storage Conditions: Store as directed by product packaging

Incompatible Materials: None

Specific End Use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective

Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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Eye Protection: Wear safety glasses or goggles if eye contact is possible.

Skin Protection: Not required for the normal use of this product.

Respiratory protection: None required under normal conditions of use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Colorless
Odor:	None	Odor Threshold:	No data available
Molecular Formula:	Mixture	Molecular Weight:	Mixture

pH	4.0 – 7.0
Melting/Freezing Point (°C):	No data available

Decomposition Temperature (°C):	No data available
Evaporation Rate (gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	1.01 g/mL at 25 deg. C
Viscosity:	1.03 cps at 25 deg. C

Flammability:

Autoignition Temperature (Solid)(°C):	No data available
Flammability (solids):	No data available
Flash Point (Liquid)(°C):	No data available
Upper Explosive Limits (Liquid)(% by vol.)	No data available
Lower Explosive Limits (Liquid) (% by vol.)	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use
Possibility of Hazardous Reactions:	
Oxidizing Properties:	No data available
Conditions to Avoid:	None
Incompatible Materials:	None
Hazardous Decomposition:	No data available
Products:	

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Mannitol

Rat	Oral	LD50	13500 mg/kg
Mouse	Oral	LD50	22 g/kg

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Sorbitol

Rat	Oral	LD50	15900 mg/kg
Mouse	Oral	LD50	17800 mg/kg

Carcinogen Status: None of the components in this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. TOXICOLOGICAL INFORMATION

Environmental Overview:	Releases to the environment should be avoided. No acute toxicity to aquatic organisms is expected.
Toxicity:	No data available
Persistence and Degradability:	No data available
Bio-accumulative Potential:	No data available
Mobility in Soil:	No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

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Mannitol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS)	Present
EU EINECS/ELINCS List	200-711-8

Sorbitol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS)	Present
EU EINECS/ELINCS List	200-061-5

Water for injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	231-791-2

16. OTHER INFORMATION

Data Sources:	Publicly available toxicity information.
Reasons for Revision:	Company/Undertaking.
Development date:	January 31, 2020
Prepared by:	ICU Medical Environment, Health & Safety Department

ICU Medical believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

END OF SAFETY DATA SHEET