

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: **Ephedrine Sulfate Injection, USP**
Manufacturer Name: Fresenius Kabi USA, LLC
Address: Three Corporate Drive
 Lake Zurich, Illinois 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
Distributor Name: Fresenius Kabi USA, LLC
Address: Three Corporate Drive
 Lake Zurich, Illinois 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
SDS Creation Date: November 01, 2022
SDS Revision Date: May 08, 2023

SECTION 2 : HAZARD(S) IDENTIFICATION

Signal Word: Caution
GHS Class: Not applicable.
Hazard Statements: Not applicable.
Precautionary Statements: Not applicable.
Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.
Route of Exposure: Inhalation, Ingestion, Eye contact, Skin Absorption, Injection.
Skin: Contact may cause irritation with symptoms of redness, rash and itching.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Ephedrine sulfate	134-72-5	50 mg/ mL by weight	
Water for Injection	7732-18-5	Quantity Sufficient by weight	
Sodium hydroxide	1310-73-2	For pH Adjustment only by weight	
Glacial Acetic acid	64-19-7	For pH Adjustment only by weight	

SECTION 4 : FIRST AID MEASURES

Eye Contact: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact: Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid: First aid providers should avoid contact with this chemical. Wear appropriate protective equipment. For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter into solution. Capture remaining liquid onto spill absorbents.
Methods for cleanup:	Place spill materials into a leak-proof container for disposal in accordance with applicable waste disposal regulations (see section 13). Decontaminate the area twice.

SECTION 7 : HANDLING and STORAGE

Handling:	Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid breathing dust. Wash thoroughly after handling.
Storage:	Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Store in carton until time of use.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling dust.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/ or enclosure at dust-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling of powders. High-energy operations such as milling, particle sizing, spraying or fluidizing should be done within an approved emission control or containment system.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist. . An emergency eye wash station should be available.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine powder handling tasks, an approved and properly fitted air-purifying respirator with HEPA filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with HEPA filters or combination filters or a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where a lower level of respiratory protection may not provide adequate protection.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid.
Color:	Colorless.
Odor:	No Data

Boiling Point:	260 °C
Melting Point:	38.1 °C
Specific Gravity:	Not determined.
Solubility:	Soluble in water.
Vapor Density:	Not determined.
Vapor Pressure:	Not determined.
Percent Volatile:	Not determined.
Evaporation Rate:	Not determined.
pH:	4.5 - 7
Viscosity:	Not determined.
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
VOC Content:	Not determined.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Avoid contact with extreme heat. Protect from light.
Incompatible Materials:	Strong oxidizers, Acids.
Special Decomposition Products:	Thermal decomposition can lead to release irritant fumes and toxic gases.

SECTION 11 : TOXICOLOGICAL INFORMATION

Ingestion:	Oral - Rat - LD50: 600 mg/kg
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SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.
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SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.
DOT Hazard Class:	Not Regulated.
DOT Packing Group:	Not Regulated.

SECTION 15 : REGULATORY INFORMATION

TSCA Inventory Status:	Exempt.
Canada WHMIS:	Not classified.

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 2
HMIS Fire Hazard: 0
HMIS Reactivity: 0
HMIS Personal Protection: X

SDS Creation Date: November 01, 2022

SDS Revision Date: May 08, 2023

SDS Revision Notes: Corrected the product name in Section 1 (from Ephedrine Sulfate for Injection, USP, which was incorrect [the product is not a lyophilized powder] to Ephedrine Sulfate Injection, USP [the product is a liquid], which is the correct product name). Corrected the physical status of the product in Section 9 (from Powder [which was incorrect] to Liquid [which is correct]).

Disclaimer:

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