

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product identifier used on the label:

Product Name: Deferoxamine Mesylate for Injection, USP

Other means of identification:

Recommended use of the chemical and restrictions on use:

Chemical manufacturer address and telephone number:

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

SECTION 2 : HAZARD(S) IDENTIFICATION

Classification of the chemical in accordance with CFR 1910.1200(d)(f):

GHS Class: Not classified.

Hazards not otherwise classified that have been identified during the classification process:

OSHA Class: Not classified. In large quantities may form combustible dust concentrations if airborne (i.e. dust cloud).

Deferoxamine Mesylate

Physical Health Hazard: Not classified. May form combustible dust concentrations in air.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures:

Chemical Name	CAS#	Ingredient Percent	EC Num.
Deferoxamine Mesylate	138-14-7	100 %	

SECTION 4 : FIRST AID MEASURES

Description of necessary 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.

Most important symptoms/effects, acute and delayed:

Other First Aid: For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Suitable and unsuitable extinguishing media:

Suitable 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.

Specific hazards arising from the chemical:

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. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

Special protective equipment and precautions for fire-fighters:

Protective Equipment: As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

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.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

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:

Environmental Precautions: Avoid runoff into storm sewers, ditches, and waterways.

Methods and materials for containment and cleaning up:

Methods for containment: Contain spills with an inert absorbent material such as soil, sand or oil dry.

Methods for cleanup: Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Precautions for safe handling:

Handling: When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.

Hygiene Practices: Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

Conditions for safe storage, including any incompatibilities:

Storage: Store at: 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Specific end use(s):

Work Practices: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE GUIDELINES:

Appropriate engineering controls:

Engineering Controls: General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

Individual protection measures:

Eye/Face Protection: Chemical splash goggles. Wear a face shield also when splash hazard exist.

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:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.
General Hygiene Considerations:	Wash thoroughly after handling. Do not eat, drink, smoke or apply cosmetics while handling the product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Work should be performed in a designated area for working with hazardous drugs. Contaminated waste must be properly handled. Work areas must be regularly decontaminated.

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Lyophilized powder.
Color:	White to off-white powder.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Soluble in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile :	Not established.
pH:	Not established.
Molecular Weight:	656.79
Flash Point:	Not established.
Flash Point Method:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:

Chemical Stability:	Stable under normal temperatures and pressures.
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Possibility of hazardous reactions:

Hazardous Polymerization:	Not reported.
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Conditions To Avoid:

Conditions to Avoid:	None reported.
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SECTION 11 : TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:

Deferoxamine Mesylate :

Acute Toxicity:	Rat Oral LD50 17300 mg/kg; Rat Para-periosteal LD50 330 mg/kg; Rat Subcutaneous LD50 5500 mg/kg; Mouse Oral LD50 15200 mg/kg; Mouse Intravenous LD50 273 mg/kg.
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SECTION 12 : ECOLOGICAL INFORMATION

Notes :	Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided. Toxicity: No data available. Persistence and Degradability: No data available. Bio-accumulative Potential: No data available. Mobility in Soil: No data available.
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SECTION 13 : DISPOSAL CONSIDERATIONS

Description of waste:

Deferoxamine Mesylate :

Waste Disposal: Dispose of waste in accordance with all applicable laws and regulations. As a finished product in its final form, without being mixed with any other substance(s), it would be considered a Non-Hazardous (non-RCRA) waste for incineration.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.

DOT UN Number: Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Safety, health and environmental regulations specific for the product:

Deferoxamine Mesylate :

SARA: Not listed

CERCLA Section 302: Not listed

California PROP 65: Not listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 1

HMIS Fire Hazard: 0

HMIS Reactivity: 0

HMIS Personal Protection: C

Health Hazard	1
Fire Hazard	0
Reactivity	0
Personal Protection	C

SDS Creation Date: November 14, 2012

SDS Revision Date: September 08, 2022

SDS Revision Notes: Added information to Section 2. Corrected the formulation in Section 3. Updated storage information in Section 7. Physical state corrected from 'liquid solution' (erroneous physical state) to 'lyophilized powder' (correct physical state) in Section 9. Added color, corrected molecular weight, and removed erroneous pH from former version in Section 9. Removed erroneous conditions to avoid from former version in Section 10. Added Acute Toxicity Information to Section 11. Added information to Section 12. Added Waste Disposal information to Section 13. Added information to Section 15. Added HMIS Ratings to Section 16. Updated revision date in Section 16.

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