

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

Product Name: Deferoxamine Injection, USP Manufacturer Name: Fresenius Kabi USA, LLC Address: Three Corporate Drive Lake Zurich, Illinois 60047

General Phone Number: Customer Service Phone (847) 550-2300

Number:

(888) 386-1300

Health Issues Information: SDS Creation Date: SDS Revision Date:

(800) 551-7176 November 14, 2012 November 14, 2012

SECTION 2: HAZARD(S) IDENTIFICATION

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Calcium Chloride, Dihydrate	10035-04-8	- %	
Water for Injection	7732-18-5	- %	

SECTION 4: FIRST AID MEASURES

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. Eve Contact:

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.

If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained Inhalation:

personnel. Seek immediate medical attention

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 Ingestion:

anything by mouth to an unconscious person.

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

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.

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, Fire Fighting Instructions:

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

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

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.

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

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. Methods for cleanup:

SECTION 7: HANDLING and STORAGE

When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Handling:

Use with adequate ventilation. Use only in accordance with directions.

Do not store above 77 °F (25 °C). Protect from light. Storage:

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

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

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

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.

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.

EXPOSURE GUIDELINES

SECTION 9: PHYSICAL and CHEMICAL PROPERTIES

Liquid solution. Physical State:

Color: Colorless.

Boiling Point: Not established. Melting Point: Not established. Solubility: Soluble. in water. Not established. Vapor Density: Vapor Pressure: Not established. Percent Volatile: Not established.

5.5 - 7.5 Molecular Formula: Mixture Molecular Weight: 111.0

Flash Point: Not established. Flash Point Method: Not established. Auto Ignition Temperature: Not established.

SECTION 10: STABILITY and REACTIVITY

Chemical Stability: Stable under normal temperatures and pressures.

Hazardous Polymerization: Not reported.

Conditions to Avoid: Protect from freezing.

SECTION 11: TOXICOLOGICAL INFORMATION

<u>Calcium Chloride</u>, <u>Dihydrate</u>:

Acute LD50 IP Mouse: 20500 mg/kg Acute Toxicity:

<u>Calcium Chloride</u>, <u>Dihydrate</u>:

RTECS Number: EV9810000

Acute LD50 Dermal Rabbit: > 5000 mg/kg Skin:

Ingestion: Acute LD50 Oral Rat: 1000-1940 mg/kg

Acute LD50 Oral Rabbit: 1000-1940 mg/kg Acute LD50 Oral Mice: 1000-1940 mg/kg

Reproductive Toxicity:

Pregnancy Category C: Deferoxamine Mesylate caused delayed ossification in mice and skeletal anomalies in rabbits when administered in daily doses up to 4.5 times the maximum daily human dose. There are no adequate and well-controlled studies in pregnant women. Deferoxamine Mesylate should be used during pregnancy only if the potential benefit justifies the risk to the fetus.

Other Toxicological Information: $Intraperitoneal. - Mouse \ LD50: 20500 \ mg/kg \ [Details of toxic effects not reported other than lethal]{Mouse LD50: 20500 \ mg/kg} is a simple of the contraction of the contractio$

dose value]

SECTION 12: ECOLOGICAL INFORMATION

SECTION 13: DISPOSAL CONSIDERATIONS

SECTION 14: TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated. DOT UN Number: Not Regulated.

SECTION 15: REGULATORY INFORMATION

SECTION 16: ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Personal Protection:

SDS Creation Date: November 14, 2012 SDS Revision Date: November 14, 2012

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party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data

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