



## MATERIAL SAFETY DATA SHEET

**Product Name: Deferoxamine Mesylate for Injection, USP**

### 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

<b>Manufacturer Name And Address</b>	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA	Hospira Australia Pty Ltd 1 Lexia Place Mulgrave VIC 3170 AUSTRALIA
<b>Emergency Telephone #'s</b>	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia (02) 8014 4880	
<b>Hospira, Inc., Non-Emergency</b>	224 212-2055	
<b>Product Name</b>	Deferoxamine Mesylate for Injection, USP Desferrioxamine Mesilate for Injection	
<b>Synonyms</b>	Desferioxamine mesylate; <i>N</i> -[5-[3-[(5-Aminopentyl)hydroxycarbamoyl]propionamido] pentyl]-3-[[5-(Nhydroxyacetamido)pentyl]carbamoyl]propionohydroxamic acid monomethanesulfonate (salt).	

### 2. HAZARD INFORMATION

<b>Emergency Overview</b>	Deferoxamine Mesylate for Injection, USP is a powder that contains deferoxamine mesylate powder, an iron chelating agent. Clinically, deferoxamine mesylate is used for the treatment of acute iron intoxication and of chronic iron overload. In the workplace, this product should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs may include the eyes, respiratory and gastrointestinal systems, and auditory system (hearing).		
<b>Occupational Exposure Potential</b>	Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.		
<b>Signs and Symptoms</b>	None known from work place exposures. Clinical use has been associated with eye and hearing changes, rash, allergic reactions (urticaria), gastrointestinal upset, diarrhea, flushing, increased heart rate and lowered blood pressure. Ocular and auditory disturbances have been reported when deferoxamine mesylate was given over prolonged periods of time at high doses. The ocular disturbances include blurred of vision; cataracts (after prolonged administration in chronic iron overload), decreased visual acuity (including visual loss, visual defects, scotoma, impaired peripheral, color, and night vision), optic neuritis, corneal opacities, and retinal pigmentary abnormalities. The auditory abnormalities reported include tinnitus and hearing loss (including high frequency sensorineural hearing loss).		
<b>Medical Conditions Aggravated by Exposure</b>	Pre-existing hypersensitivity to this material; pre-existing ocular, gastrointestinal, or auditory (hearing) ailments.		
<b>Carcinogen Lists:</b>	<b>IARC:</b> Not listed	<b>NTP:</b> Not listed	<b>OSHA:</b> Not listed

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<b>Active Ingredient Name</b>	Deferoxamine Mesylate (Desferrioxamine Mesilate)
<b>Chemical Formula</b>	$C_{25}H_{48}N_6O_8 \cdot CH_4O_3S$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Deferoxamine Mesylate	100	138-14-7	UG5310000

#### **4. FIRST AID MEASURES**

<b>Eye Contact</b>	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Skin Contact</b>	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Inhalation</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Ingestion</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

#### **5. FIRE FIGHTING MEASURES**

<b>Flammability</b>	None anticipated for this product.
<b>Fire &amp; Explosion Hazard</b>	None anticipated for this product.
<b>Extinguishing Media</b>	As with any fire, use extinguishing media appropriate for primary cause of fire.
<b>Special Fire Fighting Procedures</b>	No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

#### **6. ACCIDENTAL RELEASE MEASURES**

<b>Spill Cleanup and Disposal</b>	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Collect powder using methods that minimize the creation of airborne dusts. If the spill occurs after reconstitution, absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.
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#### **7. HANDLING AND STORAGE**

<b>Handling</b>	No special handling required under conditions of normal product use. Protect from light by retaining in carton until contents have been used.
<b>Storage</b>	No special storage required for hazard control. For product protection, follow USP controlled room temperature storage recommendations noted on the product case label, the primary container label, or the product insert.
<b>Special Precautions</b>	Protect from freezing, light, and extreme heat.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Exposure Guidelines

Component	Exposure limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Deferoxamine Mesylate	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: 2000 mcg/m <sup>3</sup>

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit  
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.  
 AIHA WEEL : Workplace Environmental Exposure Level  
 EEL: Employee Exposure Limit.  
 TWA: 8-hour Time Weighted Average.  
 STEL: 15-minute Short Term Exposure Limit.

**Respiratory Protection**      Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. Since protection provided by air purifying respirators is limited, a powered air purifying respirator or supplied air should be considered during an uncontrolled release event, if exposure levels are not known, or during events where air-purifying respirators may not provide adequate protection. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin Protection**      If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

**Eye Protection**      Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

**Engineering Controls**      Engineering controls are normally not needed during the normal use of this product.

## 9. PHYSICAL/CHEMICAL PROPERTIES

<b>Appearance/Physical State</b>	Sterile white to off-white powder.
<b>Odor</b>	NA
<b>Odor Threshold:</b>	NA
<b>pH:</b>	Ranges from 3.7 to 5.5 for a 10% w/v solution
<b>Melting point/Freezing point:</b>	NA
<b>Initial Boiling Point/Boiling Point Range</b>	NA
<b>Evaporation Rate:</b>	NA
<b>Flammability (solid, gas):</b>	NA
<b>Upper/Lower Flammability or Explosive Limits:</b>	NA
<b>Vapor Pressure</b>	NA
<b>Vapor Density (Air =1)</b>	NA
<b>Evaporation Rate</b>	NA
<b>Specific Gravity</b>	NA
<b>Solubility</b>	It is freely soluble in water and slightly soluble in methanol.
<b>Partition coefficient: n-octanol/water:</b>	NA
<b>Auto-ignition temperature</b>	NA
<b>Decomposition temperature</b>	NA

## 10. STABILITY AND REACTIVITY

<b>Reactivity</b>	Not determined.
<b>Chemical Stability</b>	Stable under standard use and storage conditions.
<b>Hazardous Reactions</b>	Not determined
<b>Conditions to avoid</b>	Not determined
<b>Incompatibilities</b>	Not determined
<b>Hazardous Decomposition Products</b>	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO <sub>x</sub> ), nitrogen oxides (NO <sub>x</sub> ), and sulfur oxides (SO <sub>x</sub> ).
<b>Hazardous Polymerization</b>	Not anticipated to occur with this product.

## 11. TOXICOLOGICAL INFORMATION

### Acute Toxicity

Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Deferoxamine Mesylate	100	LD50	Intravenous	330	mg/kg	Rat
				273	mg/kg	Mouse
Deferoxamine Mesylate	100	LD50	Oral	17,300	mg/kg	Rat
				15,200	mg/kg	Mouse
Deferoxamine Mesylate	100	LD50	Intraperitoneal	1240	mg/kg	Mouse

LD 50: Dosage that produces 50% mortality.

<b>Aspiration Hazard</b>	None anticipated from normal handling of this product.
<b>Dermal Irritation/Corrosion</b>	None anticipated from normal handling of this product.
<b>Ocular Irritation/Corrosion</b>	None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce irritation and redness.
<b>Dermal or Respiratory Sensitization</b>	None anticipated from normal handling of this product. In clinical use, generalized rash, urticaria, anaphylactic reaction with or without shock, and angioedema have been reported in patients.
<b>Reproductive Effects</b>	Delayed ossification in mice and skeletal anomalies in rabbits were reported after deferoxamine mesylate was administered in daily doses up to 4.5 times the maximum daily human dose. No adverse effects were noted in similar studies in rats.
<b>Mutagenicity</b>	Cytotoxicity may occur since deferoxamine mesylate has been shown to inhibit DNA synthesis <i>in vitro</i> .
<b>Carcinogenicity</b>	Long-term carcinogenicity studies in animals have not been performed with deferoxamine mesylate.
<b>Target Organ Effects</b>	Work place exposure to this product may produce ocular and respiratory irritation. Based on clinical use, possible target organs may include the eyes, respiratory system, gastrointestinal system, and auditory system (hearing).

## 12. ECOLOGICAL INFORMATION

<b>Aquatic Toxicity</b>	Not determined for product
<b>Persistence/Biodegradability</b>	Not determined for product.
<b>Bioaccumulation</b>	Not determined for product.
<b>Mobility in Soil</b>	Not determined for product.

Notes:

1. LC50: Concentration in water that produces 50% mortality in fish.
2. EC50: Concentration in water that produces 50% inhibition of growth in algae.

## 13. DISPOSAL CONSIDERATIONS

<b>Waste Disposal</b>	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
<b>Container Handling and Disposal</b>	Dispose of container and unused contents in accordance with federal, state and local regulations.

## 14. TRANSPORTATION INFORMATION

<b>DOT STATUS:</b>	Not regulated
<b>Proper Shipping Name:</b>	NA
<b>Hazard Class:</b>	NA
<b>UN Number:</b>	NA
<b>Packing Group:</b>	NA
<b>Reportable Quantity:</b>	NA

<b>ICAO/IATA STATUS</b>	Not regulated
<b>Proper Shipping Name:</b>	NA
<b>Hazard Class:</b>	NA
<b>UN Number:</b>	NA
<b>Packing Group:</b>	NA
<b>Reportable Quantity:</b>	NA

<b>IMDG STATUS</b>	Not regulated
<b>Proper Shipping Name:</b>	NA
<b>Hazard Class:</b>	NA
<b>UN Number:</b>	NA
<b>Packing Group:</b>	NA
<b>Reportable Quantity:</b>	NA

Notes: DOT - US Department of Transportation Regulations


**15. REGULATORY INFORMATION**

<b>U.S. TSCA Status</b>	Exempt.
<b>U.S. CERCLA Status</b>	Not listed
<b>U.S. SARA 302 Status</b>	Not listed
<b>U.S. SARA 313 Status</b>	Not listed
<b>U.S. RCRA Status</b>	Not listed
<b>U.S. PROP 65 (Calif.)</b>	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

**U.S. OSHA Classification** Possible Irritant  
Target Organ Toxin

**GHS Classification** \*Where medicinal products are not exempt, the recommended GHS workplace classification is as follows:

<b>Hazard Class</b>	Acute Oral Toxicity	Eye Irritation	Target Organ Toxicity
<b>Hazard Category</b>	Not Classified	2B	2
<b>Symbol</b>	NA	NA	
<b>Signal Word</b>	NA	Warning	Warning
<b>Hazard Statement</b>	NA	Causes eye irritation	May cause damage to the eyes, respiratory system, gastrointestinal system, and auditory system (hearing) through prolonged or repeated exposure.

**Prevention:** Do not breathe dust, mist or spray.

**Response:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

**15. REGULATORY INFORMATION: continued**

**EU Classification\***

\*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance deferoxamine mesylate.

**Classification(s):** Irritant

**Symbol:**



**Indication of Danger** Xi

**Risk Phrases:** R36/37 - Irritating to eyes and respiratory system

**Safety Phrases:** S22 – Do not breathe dust  
S23: Do not breathe vapor/spray  
S24: Avoid contact with the skin  
S25: Avoid contact with eyes  
S37/39 Wear suitable gloves and eye/face protection.

**16. OTHER INFORMATION**

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD <sub>50</sub>	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Global Occupational Toxicology  
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