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

Product Identifier

Material Name: Deferoxamine Mesylate for Injection, USP (Hospira, Inc.)

Trade Name: Deferoxamine Mesylate for Injection, USP

Synonyms: Desferrioxamine Mesilate; Desferrioxamine Mesylate

Chemical Family: Not determined

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

Intended Use: Pharmaceutical active for the treatment of iron intoxication/overload

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company 275 North Field Drive Lake Forest, Illinois 60045

1-800-879-3477

Hospira UK Limited

Horizon Honey Lane Hurley

Maidenhead, SL6 6RJ United Kingdom

Emergency telephone number:

International CHEMTREC (24 hours): +1-703-527-3887

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Signal Word: Not Classified

Hazard Statements: May form combustible dust concentrations in air

Other Hazards An Occupational Exposure Value has been established for this substance (see Section 8).

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 upon the potential for exposure in your workplace.

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU	GHS Classification	%
		EINECS/ELINCS		
		List		
Deferoxamine Mesylate	138-14-7	205-314-3	Not Listed	100

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace

safety.

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get

medical attention.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek

medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not

induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of For information on potential signs and symptoms of exposure, See Section 2 - Hazards

Exposure: Identification and/or Section 11 - Toxicological Information.

Medical Conditions None known

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other

Products: sulfur-containing compounds.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

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.

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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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of

dry solids. Clean spill area thoroughly.

Additional Consideration for

Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Deferoxamine Mesylate

Pfizer Occupational Exposure OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Band (OEB):

Exposure Controls

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

room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne

contamination levels below the exposure limits listed above in this section.

Personal Protective

Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an

assessment of the workplace conditions, other chemicals used or present in the workplace and

specific operational processes.

Hands: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is

possible and for bulk processing operations. (Protective gloves must meet the standards in

accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety goggles if eye contact is possible. (Eye protection must meet the standards in

accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Wear impervious protective clothing to prevent skin contact. (Protective clothing must meet

the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is

exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:PowderColor:White to off-whiteOdor:No data available.Odor Threshold:No data available.

Molecular Formula: C25H48N6O8 . CH4O3S Molecular Weight: 656.79

Solvent Solubility: Slightly soluble: Methanol

Water Solubility:
Solubility:
No data available
Solubile: Water

pH: 3.7-5.5 (10% aqueous solution)

Melting/Freezing Point (°C): 148-149

Boiling Point (°C):

No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Deferoxamine Mesylate

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):

Vapor Pressure (kPa):

Vapor Density (g/ml):

Relative Density:

No data available

Flammablity:

Autoignition Temperature (Solid) (°C):No data availableFlammability (Solids):No data availableFlash Point (Liquid) (°C):No data availableUpper Explosive Limits (Liquid) (% by Vol.):No data availableLower 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: None

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions. **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition No data available

Products:

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

Short Term: Not acutely toxic (based on animal data).

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.

Known Clinical Effects: Adverse effects seen in clinical use include gastrointestinal discomfort, dizziness, and

headache. Effects on vision and hearing have been seen during clinical use.

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

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11. TOXICOLOGICAL INFORMATION

Deferoxamine Mesylate

Rat Oral LD50 17300 mg/kg 330mg/kg Rat Para-periosteal LD50 LD50 5500mg/kg Rat Subcutaneous Mouse Oral LD50 15200mg/kg Mouse Intravenous LD50 273mg/kg

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Deferoxamine Mesylate

Embryo / Fetal Development Rabbit Oral 180 mg/kg/day LOAEL Developmental toxicity Embryo / Fetal Development Oral 180 mg/kg/day LOAEL Developmental toxicity Mouse Embryo / Fetal Development Oral 180 mg/kg/day NOAEL No effects at maximum dose Rat

Embryo / Fetal Development Mouse Intraperitoneal 352 mg/kg/day LOAEL Maternal Toxicity, Fetotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Deferoxamine Mesylate

In Vitro Direct DNA Interaction Human Lymphocytes Positive

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

12. ECOLOGICAL INFORMATION

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

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.

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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

Deferoxamine Mesylate

CERCLA/SARA 313 Emission reporting

California Proposition 65

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Not Listed

Not Eisted

Not Listed

205-314-3

16. OTHER INFORMATION

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources,

raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

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Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc 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