



SAFETY DATA SHEET

Revision date: 27-Jul-2018

Version: 1.0

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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

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:

CHEMTREC (24 hours): 1-800-424-9300

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

Emergency telephone number:

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified

Hazard Statements: Not classified in accordance with international standards for workplace safety.

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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

| Ingredient | CAS Number | EU EINECS/ELINCS List | GHS Classification | % |
|------------|------------|-----------------------------|--------------------|---|
|------------|------------|-----------------------------|--------------------|---|

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3. COMPOSITION / INFORMATION ON INGREDIENTS

| | | | | |
|-----------------------|----------|-----------|------------|-----|
| 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 Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

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 Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other 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.

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.

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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 Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

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: | Powder | Color: | White to off-white |
| Odor: | No data available. | Odor Threshold: | No data available. |
| Molecular Formula: | C ₂₅ H ₄₈ N ₆ O ₈ . CH ₄ O ₃ S | Molecular Weight: | 656.79 |
| Solvent Solubility: | Slightly soluble: Methanol | | |
| Water Solubility: | No data available | | |
| Solubility: | Soluble: 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): | No data available | | |
| Vapor Pressure (kPa): | No data available | | |
| Vapor Density (g/ml): | No data available | | |
| Relative Density: | No data available | | |
| Viscosity: | No data available | | |
| Flammability: | | | |
| Autoignition Temperature (Solid) (°C): | | No data available | |
| Flammability (Solids): | | No data available | |
| Flash Point (Liquid) (°C): | | No data available | |
| Upper Explosive Limits (Liquid) (% by Vol.): | | No data available | |
| Lower 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 Products: | |
| No data available | |

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

| | | | |
|-------|-----------------|------|-------------|
| Rat | Oral | LD50 | 17300 mg/kg |
| Rat | Para-periosteal | LD50 | 330mg/kg |
| Rat | Subcutaneous | LD50 | 5500mg/kg |
| 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 | Mouse | Oral | 180 mg/kg/day | LOAEL | Developmental toxicity |
| Embryo / Fetal Development | Rat | Oral | 180 mg/kg/day | NOAEL | No effects at maximum dose |
| 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.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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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 | Not Listed |
| California Proposition 65 | Not Listed |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 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: New data sheet.

Revision date: 27-Jul-2018

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material 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