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## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1. Product identifier

**Product Name** Deferoxamine Mesylate for Injection, USP (Hospira, Inc.)

Product Code(s) PZ03412

**Synonyms** Desferrioxamine Mesilate; Desferrioxamine Mesylate

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

**Chemical Family:** Not determined

## 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical active for the treatment of iron intoxication/overload

#### 1.3. 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

Pfizer Ireland Pharmaceuticals

**OSG Building** 

Ringaskiddy, Co. Cork.

Ireland

+353 21 4378701

pfizer-MSDS@pfizer.com E-mail address

## 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

#### **OSHA Classification**

Hazards not otherwise classified (HNOC)

Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

Not applicable

2.2. Label elements

Not classified Signal word

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

2.3. Other hazards

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

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PBT & vPvB The product does not contain any substance(s) classified as PBT or vPvB.

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors.

Note: This document has been prepared in accordance with standards for workplace safety, which

require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

## 3.1 Substances

Hazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Deferoxamine Mesylate (CAS #: 138-14-7)	100		205-314-3	[CLP] Not classified	Not classified	No data available	No data available

#### Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate No information available

Chemical name	Oral LD50 mg/kg	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapor - mg/L	hour - gas - ppm
Deferoxamine Mesylate 138-14-7	17300	No data available	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

## Additional information

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## **Section 4: FIRST AID MEASURES**

### 4.1. Description of first aid measures

Inhalation Remove to fresh air. Seek immediate medical attention/advice.

Eye contact If symptoms persist, call a physician.

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

medical attention.

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Never give anything by mouth to an unconscious person. Wash out mouth with water. Do Ingestion

not induce vomiting unless directed by medical personnel. Seek medical attention

immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects

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

Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

## Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

**Suitable Extinguishing Media** Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

Fine particles (such as dust and mists) may fuel fires/explosions.

**Hazardous combustion products** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and

other sulfur-containing compounds.

**Explosion data** 

Sensitivity to mechanical impact No information available. No information available. Sensitivity to static discharge

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Use personal protection equipment.

#### Section 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see

Section 8). Minimize exposure.

Use personal protection recommended in Section 8. For emergency responders

6.2. Environmental precautions

**Environmental precautions** Place waste in an appropriately labeled, sealed container for disposal. Care should be

taken to avoid environmental release.

#### 6.3. Methods and material for containment and cleaning up

**Methods for containment** 

Prevent further leakage or spillage if safe to do so.

Contain the source of the spill or leak. Collect spilled material by a method that controls dust Methods for cleaning up

generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean contaminated

surface thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

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Reference to other sections See section 8 for more information. See section 13 for more information.

## Section 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

Advice on safe handling

Minimize dust generation and accumulation. Avoid breathing

dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or 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.

**General hygiene considerations** 

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** 

Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s)

Pharmaceutical drug product.

#### Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

## **Pfizer Occupational Exposure Band**

(OEB) Statement:

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.

8.2. Exposure controls

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

> 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.

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

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

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Hand protection 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.).

Skin and body protection Wear impervious protective clothing to prevent skin contact. (Protective clothing must meet

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

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

> 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.).

Thermal hazards No information available.

**Environmental exposure controls** No information available.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

**Physical state** Powder

Color White to off-white Odor No information available. Odor threshold No information available

Values Property Melting point / freezing point 148-149

Boiling point or initial boiling point and boiling range No data available Flammability (solid, gas) No data available

Lower and upper explosion limit/flammability limit

Lower explosion limit No data available Upper explosion limit No data available Flash point No data available **Autoignition temperature** No data available

**Decomposition temperature** 

SADT (°C) No data available

3.7-5.5 рH No data available pH (as aqueous solution) No data available Kinematic viscosity No data available

**Dynamic viscosity** Solubility slightly soluble methanol Soluble Water

No data available Vapor pressure Density and/or relative density No data available **Bulk density** No data available **Liquid Density** No data available

Vapor density No data available **Particle characteristics** 

No information available **Particle Size Particle Size Distribution** No information available

9.2. Other information

Molecular formula C25H48N6O8 . CH4O3S

Molecular weight 656.79

#### 9.2.1. Information with regard to physical hazard classes

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No information available **Oxidizing properties** 

None

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#### 9.2.2. Other safety characteristics

No information available

## Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

**Reactivity** No information available.

10.2. Chemical stability

**Stability** Stable under normal conditions.

**Explosion data** 

**Sensitivity to mechanical impact** No information available. **Sensitivity to static discharge** No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

**Conditions to avoid** Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

**Incompatible materials**As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

### Section 11: TOXICOLOGICAL INFORMATION

#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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** Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Serious eye damage/eye irritation Skin corrosion/irritation Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Respiratory or skin sensitization STOT - single exposure Based on available data, the classification criteria are not met. STOT - repeated exposure Based on available data, the classification criteria are not met. Reproductive toxicity Based on available data, the classification criteria are not met. Germ cell mutagenicity Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Carcinogenicity Based on available data, the classification criteria are not met. **Aspiration hazard** 

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

**Deferoxamine Mesylate** 

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

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Deferoxamine Mesylate	= 17300 mg/kg (Rat)	-	-

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Reproduction & Development Toxicity: (Duration, 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

Not listed as a carcinogen by IARC, NTP or US OSHA. Carcinogenicity

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been thoroughly investigated. Releases to the

environment should be avoided.

12.1. Toxicity

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment Based on available data, the classification criteria are not met.

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#### 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

12.7. Other adverse effects

No information available. Other adverse effects

PMT or vPvM properties Based on available data, the classification criteria are not met.

### Section 13: DISPOSAL CONSIDERATIONS

#### 13.1. Waste treatment methods

#### Waste from residues/unused products

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 wastewater 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.

## Section 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.

**UN number:** Not applicable Not applicable UN proper shipping name: Not applicable Transport hazard class(es): Not applicable Packing group: **Environmental Hazard(s):** Not applicable

### Section 15: REGULATORY INFORMATION

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Deferoxamine Mesylate

CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed 205-314-3 **EINECS** 

National regulations

Germany

**Chemical Prohibition Ordinance (ChemVerbotsV)** 

Not applicable

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**TRGS 905** Not applicable

#### Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable Storage of Hazardous Material Not applicable Not applicable WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable Major Accidents Ordinance SR 814.012

#### **European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

#### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

#### **Persistent Organic Pollutants**

Not applicable

#### Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

#### **Explosives Precursors Marketing and Use (2019/1148)**

Not applicable

#### Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing Chemicals Inventory

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

**NZIoC** - New Zealand Inventory of Chemicals

TCSI - Taiwan Chemical Substance Inventory

#### 15.2. Chemical safety assessment

No information available **Chemical Safety Report** 

## Section 16: OTHER INFORMATION

#### Key or legend to abbreviations and acronyms used in the safety data sheet

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

raw material suppliers, or from the published literature.

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Updated Section 2 - Hazard Identification. Updated Section 11 - Toxicology Information. Reason for revision

Updated Section 12 - Ecological Information.

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**Prepared By** Pfizer Global Environment, Health, and Safety

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