MATERIAL SAFETY DATA SHEET

Product Name: Iron Sucrose Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency 224-212-2000

Product Name Iron Sucrose Injection, USP

Synonyms Iron Sucrose; Iron Complex

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Iron Sucrose

Chemical Formula \([\text{Na}_2\text{Fe}_5\text{O}_8\cdot\text{3(H}_2\text{O)}\cdot n\cdot m(\text{C}_{12}\text{H}_{22}\text{O}_{11})]\)

Preparation Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium hydroxide which is added to adjust the pH of the product. Approximate concentration of Iron Sucrose 20 mg/ml for elemental iron and ~300 mg/ml sucrose.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron Sucrose</td>
<td>20 mg/ml for elemental iron</td>
<td>8047-67-4</td>
<td>NA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Iron Sucrose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>20 mg/ml for elemental iron</td>
</tr>
<tr>
<td></td>
<td>~300 mg/ml sucrose</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron Sucrose</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview

Iron Sucrose Injection, USP, is a sterile, colloidal solution of ferric hydroxide in complex with sucrose in water for injection. Each milliliter of formulation contains 20 mg elemental iron and up to about 340 mg of sucrose as iron sucrose in water. Clinically, this product is used in the treatment of iron-deficiency anemia. In the workplace, this material should be considered potentially irritating to the eyes, mucus membranes, and the respiratory tract. Based on clinical use, potential target organs include the gastrointestinal tract and blood.

Occupational Exposure Potential

Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms

None known from occupational exposures. Inadvertent contact of this product with the eyes or mucus membranes may produce irritation. In clinical use, adverse events may include
Product Name: Iron Sucrose Injection, USP

hypotension, cramps/leg cramps, nausea, headache, vomiting, and diarrhea. Infrequently, mild
or moderate hypersensitivity reactions including wheezing, dyspnea, hypotension, rashes, or
pruritus have been reported. Very rarely, life-threatening reactions (anaphylactic shock, loss of
consciousness or collapse, bronchospasm with dyspnea, or convulsion) have also occurred.
Chronic or excess intake of iron may lead to accumulation of iron in storage sites resulting in
hemosiderosis.

Medical Conditions
Aggravated by Exposure
Pre-existing hypersensitivity to iron or iron compounds; pre-existing gastrointestinal or
hematological ailments.

4. FIRST AID MEASURES

Eye contact
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.

Skin contact
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.

Inhalation
Remove from source of exposure. If signs of toxicity occur, seek medical
attention. Provide symptomatic/supportive care as necessary.

Ingestion
Remove from source of exposure. If signs of toxicity occur, seek medical
attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability
None anticipated for this aqueous product.

Fire & Explosion Hazard
None anticipated for this aqueous product.

Extinguishing media
As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting
Procedures
No special provisions required beyond normal firefighting equipment such as
flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal
Isolate area around spill. Put on suitable protective clothing and equipment as
specified by site spill procedures. 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.

7. HANDLING AND STORAGE

Handling
No special handling required for hazard control under conditions of normal
product use.

Storage
No special storage required for hazard control. For product protection, follow
storage recommendations noted on the product case label, the primary
container label, or the product insert.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Exposure Guidelines**

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron</td>
<td>ACGIH 8hr TWA</td>
<td>1000 ppm As Fe</td>
</tr>
<tr>
<td>Sucrose</td>
<td>OSHA 8hr TWA</td>
<td>15,000 ppm As total dust</td>
</tr>
<tr>
<td>Sucrose</td>
<td>OSHA 8hr TWA</td>
<td>5,000 ppm As respirable dust</td>
</tr>
</tbody>
</table>

**Respiratory protection**

Respiratory protection is normally not needed during intended product use. However, if the generation of 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 aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Brown</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH:</td>
<td>10.5 to 11.1 at 20°</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range:</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density:</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity:</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility:</td>
<td>NA</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water:</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition temperature:</td>
<td>NA</td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td>NA</td>
</tr>
</tbody>
</table>
Product Name: Iron Sucrose Injection, USP

10. STABILITY AND REACTIVITY

Reactivity  Not determined

Chemical Stability  Stable under standard use and storage conditions.

Hazardous Reactions  Not determined

Conditions to avoid  Not determined

Incompatibilities  Strong oxidizers, acids

Hazardous decomposition products  Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides, sodium peroxide, and iron oxide.

Hazardous Polymerization  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:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron Sucrose</td>
<td>100%</td>
<td>LD50</td>
<td>Intravenous</td>
<td>100</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td>100%</td>
<td>LD50</td>
<td>Intravenous</td>
<td>150</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
</tbody>
</table>

Aspiration Hazard  None anticipated from normal handling of this product.

Dermal Irritation/Corrosion  None anticipated from normal handling of this product.

Ocular Irritation/Corrosion  None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce moderate to severe irritation with redness and discomfort.

Dermal or Respiratory Sensitization  None anticipated from normal handling of this product. Rarely, serious or life threatening reactions (anaphylactic shock, loss of consciousness or collapse, bronchospasm with dyspnea, or convulsion) have occurred during the clinical use of this product.

Reproductive Effects  Intravenous administration of iron sucrose at dosages up to 15 mg iron/kg/day was reported to have no effect on fertility and reproductive performance of male and female rats. Intravenous administration of iron sucrose to rats at dosages up to 13 mg iron/kg/day and to rabbits at dosages up to 13 mg iron/kg/day resulted in no evidence of impaired fertility or harm to the fetus.

Mutagenicity  Iron sucrose was not genotoxic in the Ames test, the mouse lymphoma cell (L5178Y/TK+/−) forward mutation test, the human lymphocyte chromosome aberration test, or the mouse micronucleus test.

Carcinogenicity  The carcinogenic potential of iron sucrose has not been evaluated in long-term studies in animals.
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Target Organ Effects
This product should be considered potentially irritating to the eyes, mucus membranes, and respiratory tract. Following an accidental over-exposure, possible target organ may include the gastrointestinal tract and blood.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity
Not determined for product

Persistence/Biodegradability
Not determined for product

Bioaccumulation
Not determined for product

Mobility in Soil
Not determined for product

13. DISPOSAL CONSIDERATIONS

Waste Disposal
All waste materials must be properly characterized by the waste generator. Further, disposal of all pharmaceuticals should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal
Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS:
Not regulated

IMDG STATUS:
Not regulated

ICAO/IATA STATUS:
Not regulated

Transport Comments:
None

15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron Sucrose</td>
<td>Not Listed</td>
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<td>Not Listed</td>
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RCRA Status
Not Listed

U.S. OSHA Classification
Possible Irritant
Target Organ Toxin

GHS Classification
*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.:*
Product Name: Iron Sucrose Injection, USP

Hazard Class    Not Applicable
Hazard Category Not Applicable
Signal Word    Not Applicable
Symbol    Not Applicable

Prevention  P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

Hazard Statement Not Applicable
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.

EU Classification*
*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Iron Sucrose.

Classification(s): Not Applicable
Symbol:    Not Applicable
Indication of Danger: Not Applicable
Risk Phrases: Not Applicable
Safety Phrases:  S23 - Do not breathe vapor.
S24 - Avoid contact with 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
LD50 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
Product Name: Iron Sucrose Injection, USP

MSDS Coordinator: Hospira GEHS
Date Prepared: 07/08/2011
Obsolete Date: 03/10/2008

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