MATERIAL SAFETY DATA SHEET

Product Name: Sodium Ferric Gluconate Complex in Sucrose Injection

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
Sodium Ferric Gluconate Complex in Sucrose Injection

Synonyms
NA

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Sodium Ferric Gluconate
Sucrose

Chemical Formula
\([\text{NaFe}_2\text{O}_3(\text{C}_6\text{H}_{11}\text{O}_7)(\text{C}_{12}\text{H}_{22}\text{O}_{11})_3]_{n=200}\)

Preparation
Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% includes benzyl alcohol.

<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>Sodium Ferric Gluconate</td>
<td>1.25</td>
<td>34089-81-1</td>
<td>NA</td>
</tr>
<tr>
<td>Sucrose</td>
<td>1.95</td>
<td>57-50-1</td>
<td>WN6500000</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>Sodium Ferric Gluconate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Sucrose</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Sodium Ferric Gluconate Complex in Sucrose Injection is a sterile, colloidal solution of ferric hydroxide in complex with sucrose in Water for Injection. Each milliliter of formulation contains 12.5 mg of elemental iron and 195 mg of 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 hypotension, cramps/leg cramps, nausea, headache, vomiting, and diarrhea. Infrequently, mild
Product Name: Sodium Ferric Gluconate Complex in Sucrose Injection

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 from this aqueous product.

Fire & Explosion Hazard
None anticipated from 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 fire fighting 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 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.

Special Precautions
No special precautions required for hazard control.
Product Name: Sodium Ferric Gluconate Complex in Sucrose Injection

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m³</th>
<th>ppm</th>
<th>µg/m³</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose</td>
<td>US OSHA 8 Hr PEL</td>
<td>N/A</td>
<td>N/A</td>
<td>15000</td>
<td>As total dust</td>
</tr>
<tr>
<td>Sucrose</td>
<td>US OSHA 8 Hr PEL</td>
<td>N/A</td>
<td>N/A</td>
<td>5000</td>
<td>As respirable dust</td>
</tr>
<tr>
<td>Sucrose</td>
<td>ACGIH 8 Hr TLV</td>
<td>N/A</td>
<td>N/A</td>
<td>10000</td>
<td>8hr TWA</td>
</tr>
<tr>
<td>Sodium Ferric Gluconate</td>
<td>ACGIH 8 Hr TLV</td>
<td>N/A</td>
<td>N/A</td>
<td>1000</td>
<td>as Fe</td>
</tr>
</tbody>
</table>

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. 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>Deep red</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH:</td>
<td>7.7 to 9.7</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point</td>
<td>NA</td>
</tr>
<tr>
<td>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: Sodium Ferric Gluconate Complex in Sucrose Injection

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 (COx) and iron oxides (FeOx).

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>Sodium Ferric Gluconate</td>
<td>100</td>
<td>LDLo</td>
<td>Intravenous</td>
<td>125</td>
<td>mg/kg</td>
<td>Mice</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>78.8</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>62.5</td>
<td>mg/kg</td>
<td>Rabbit</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>250</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
<tr>
<td>Sucrose</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>29,700</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td>Sucrose</td>
<td>100</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>14,000</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. However, 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
Studies to assess the effects of sodium ferric gluconate complex in sucrose injection on fertility have not been conducted. Sodium ferric gluconate complex in sucrose injection was not teratogenic at doses of elemental iron up to 100 mg/kg/day in mice and 20 mg/kg/day in rats.

Mutagenicity
Sodium ferric gluconate complex in sucrose injection was not mutagenic in the Ames test and the rat micronucleus test. It produced a clastogenic effect in an in vitro chromosomal aberration assay in Chinese hamster ovary cells.
Product Name: Sodium Ferric Gluconate Complex in Sucrose Injection

Carcinogenicity

The carcinogenic potential of sodium ferric gluconate in sucrose has not been evaluated in long-term studies in animals.

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>
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<tbody>
<tr>
<td>Sodium Ferric Gluconate</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
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<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

RCRA Status: Not Listed

U.S. OSHA Classification: Target Organ Toxin

Classification: Possible Irritant

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: Sodium Ferric Gluconate Complex in Sucrose Injection

Hazard Class: Not Applicable
Hazard Category: Not Applicable
Signal Word: Not Applicable
Symbol: Not Applicable
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 Sodium Ferric Gluconate Sucrose.

Classification(s): Not Applicable
Symbol: Not Applicable
Indication of Danger: Not Applicable
Risk Phrases: Not Applicable
Safety Phrases: S23 - Do not breathe vapor.
S24/25 - Avoid contact with skin and 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: Sodium Ferric Gluconate Complex in Sucrose Injection

MSDS Coordinator: Hospira GEHS
Date Prepared: 11/03/2011
Obsolete Date: 08/26/2008

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