SAFETY DATA SHEET

Product Name: Heparin Sodium Injection, USP

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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

Emergency Telephone  CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
Hospira, Inc., Non-Emergency 224 212-2000

Product Name  Heparin Sodium Injection, USP
Synonyms  None

2. HAZARD(S) IDENTIFICATION

Emergency Overview  Heparin Sodium Injection, USP, is a solution containing heparin sodium, a heterogeneous group of straight-chain anionic mucopolysaccharides, called glycosaminoglycans, having anticoagulant properties. This product is used clinically as an anti-coagulant. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the blood and liver.

U.S. OSHA GHS Classification

Physical Hazards  Hazard Class  Hazard Category
Not Classified  Not Classified

Health Hazards  Hazard Class  Hazard Category
STOT – RE  2

Label Element(s)

Pictogram

Signal Word  Warning

Hazard Statement(s)  May cause damage to organs through prolonged or repeated exposure.

Precautionary Statement(s)

Prevention  Do not breathe vapor or spray.
Wash hands thoroughly after handling.

Response  Get medical attention if you feel unwell.
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.
Product Name: Heparin Sodium Injection, USP

3. COMPOSITION/INFORMATION ON INGREDIENTS

<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>Heparin Sodium</td>
<td>&lt; 7.0%</td>
<td>9041-08-1</td>
<td>M10850000</td>
</tr>
</tbody>
</table>

Non-hazardous ingredients include Water for Injection and may include dextrose. Hazardous ingredients present at less than 1% may include sodium chloride, citric acid monohydrate, and dibasic sodium phosphate heptahydrate; for preparations containing dextrose, sodium metabisulfite may be added as an antioxidant. Sodium hydroxide and/or hydrochloric acid may be used to adjust the pH.

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 such as carbon dioxide, dry chemical extinguishing powder or foam.

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 control 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.

Special Precautions
No special precautions required for hazard control.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA-PEL</th>
<th>ACGIH-TLV</th>
<th>AIHA WEEL</th>
<th>Hospira EEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heparin Sodium</td>
<td>8-hr TWA: Not Established</td>
<td>8-hr TWA: Not Established</td>
<td>8-hr TWA: Not Established</td>
<td>8-hr TWA: Not Established</td>
</tr>
</tbody>
</table>

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.

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

- **Appearance/Physical State**: Clear, colorless to practically colorless solution
- **Odor**: NA
- **Odor Threshold**: NA
- **pH**: 5.0-7.5
- **Melting point/Freezing Point**: NA
- **Initial Boiling Point/Boiling Point Range**: NA
- **Flash Point**: NA
- **Evaporation Rate**: NA
- **Flammability (solid, gas)**: NA
- **Upper/Lower Flammability or Explosive Limits**: NA
- **Vapor Pressure**: NA
- **Vapor Density (Air =1)**: NA
- **Relative Density**: 1.01-1.039 at 25°C
- **Solubility**: NA
- **Partition Coefficient: n-octanol/water**: NA
- **Auto-ignition Temperature**: NA
- **Decomposition Temperature**: NA
- **Viscosity**: NA
Product Name: Heparin Sodium 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
Not determined

Hazardous Decomposition
Not determined. During thermal decomposition, it may be possible to generate
irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx),
sodium oxides (NaOx), and oxides of sulfur.

Hazardous Polymerization
Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Not determined for the product formulation. Information for the active ingredient 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>Heparin Sodium</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>&gt;5770 mg/kg</td>
<td>&gt;5000 mg/kg</td>
<td>Rat Mouse</td>
</tr>
<tr>
<td>Heparin Sodium</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>2902 mg/kg</td>
<td>2800 mg/kg</td>
<td>Rat Mouse</td>
</tr>
<tr>
<td>Heparin Sodium</td>
<td>100</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>&gt;2500 mg/kg</td>
<td>Mouse</td>
<td></td>
</tr>
</tbody>
</table>

LD50: Dosage that produces 50% mortality.

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 anticipated from normal handling of this product. Based on clinical use, adverse effects may include hemorrhage, prolongation of coagulation test times, increased susceptibility to bruising, bleeding, decreases in thrombocytes, and elevation in liver function parameters. Significant elevations of liver enzyme levels have occurred in a high percentage of patients (and healthy subjects) who have received heparin. Less frequently, allergic hypersensitivity reactions to heparin have occurred. Local irritation, erythema, mild pain, hematoma, or ulceration can occur after deep subcutaneous injection or intramuscular injection.

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 redness and discomfort.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product. In clinical use, allergic hypersensitivity reactions to heparin have occurred. In addition, this product contains sodium metabisulfite which may cause an allergic-type reaction in people sensitive to sulfites.
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11. TOXICOLOGICAL INFORMATION: continued

Reproductive Effects
None anticipated from normal handling of this product. Studies to evaluate the effects of heparin on fertility or fetal development have not been conducted in animals.

Mutagenicity
Studies to evaluate the genotoxic potential of heparin have not been conducted.

Carcinogenicity
Studies to evaluate the effects of heparin on fertility or fetal development have not been conducted in animals.

Carcinogen Lists
IARC: Not listed  NTP: Not listed  OSHA: Not listed

Specific Target Organ Toxicity – Single Exposure
NA

Specific Target Organ Toxicity – Repeat Exposure
Based on clinical use, possible target organs include the blood and liver.

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.

Notes:

13. DISPOSAL CONSIDERATIONS

Waste Disposal
All waste materials must be properly characterized. Further, disposal 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

Proper Shipping Name
NA

Hazard Class
NA

UN Number
NA

Packing Group
NA

Reportable Quantity
NA

ICAO/IATA STATUS
Not regulated

Proper Shipping Name
NA

Hazard Class
NA

UN Number
NA

Packing Group
NA

Reportable Quantity
NA

IMDG STATUS
Not regulated

Proper Shipping Name
NA

Hazard Class
NA

UN Number
NA

Packing Group
NA

Reportable Quantity
NA

Notes: DOT - US Department of Transportation Regulations
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### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Status/Classification</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>US TSCA Status</td>
<td>Exempt.</td>
</tr>
<tr>
<td>US CERCLA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US SARA 302 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US SARA 313 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US RCRA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US PROP 65 (Calif.)</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

**Notes:** TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

#### GHS/CLP 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.

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
<th>Pictogram</th>
<th>Signal Word</th>
<th>Hazard Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Prevention**

Do not breathe vapor or spray. Wash hands thoroughly after handling.

**Response**

Get medical attention if you feel unwell.

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.

#### EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

<table>
<thead>
<tr>
<th>Classification(s)</th>
<th>Symbol</th>
<th>Indication of Danger</th>
<th>Risk Phrases</th>
<th>Safety Phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>S23: Do not breathe vapor/spray</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>S24: Avoid contact with the skin</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>S25: Avoid contact with eyes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>S37/39 Wear suitable gloves and eye/face protection.</td>
</tr>
</tbody>
</table>
Product Name: Heparin Sodium Injection, USP

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
LD<sub>50</sub> 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
STOT - SE Specific Target Organ Toxicity – Single Exposure
STOT - RE Specific Target Organ Toxicity – Repeated Exposure
TSCA    Toxic Substance Control Act
TWA     8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: October 18, 2012
Date Revised: June 02, 2014

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