MATERIAL SAFETY DATA SHEET

Product Name: Gentamicin Sulfate 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
Gentamicin Sulfate Injection

Synonyms
Gentamicin Sulfate, USP; 0-3-Deoxy-4-C-methyl-3(methylamino)-β-L-arabinopyranosyl-(1->6-0-[2,6-diamino-2,3,4,6-tetradecoxy-α-D-erythro-hexopyranosyl-(l->4)]-2-deoxy-D-streptamine.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Gentamicin Sulfate

Chemical Formula
NA

Preparation
Non-hazardous ingredients include Water for Injection. Hazardous ingredients which may be present at less than 1% include sodium metabisulfite, edetate disodium anhydrous, methylparaben, and propylparaben. May contain sulfuric acid and/or sodium hydroxide for pH adjustment.

<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>Gentamicin Sulfate</td>
<td>4</td>
<td>1405-41-0</td>
<td>LY2625000</td>
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</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>Gentamicin Sulfate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Gentamicin Sulfate Injection is a solution containing gentamicin sulfate, a complex aminoglycoside antibiotic substance with three components, sulfates of gentamicin C1, gentamicin C2 and gentamicin C1A. Clinically, gentamicin sulfate is used to treat severe systemic infections due to sensitive Gram-negative and other organisms. In the workplace, this material should be considered potentially irritating to the eyes and respiratory system, a potential sensitizer, and a potential reproductive hazard. Based on clinical use, possible target organs include the kidneys, hearing, nervous system, gastrointestinal system, eyes and fetus.

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 work place exposure. In clinical use, adverse effects may include nausea,
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Vomiting, diarrhea, headache, depression, dizziness, impaired balance and eye irritation, skin rashes, respiratory depression, possible kidney injury and hearing loss. Nephrotoxicity manifested by an elevated BUN or serum creatinine level or a decrease in the creatinine clearance has been reported with gentamicin. Gentamicin has produced vestibular and auditory toxicity in man and in experimental animals. Neurotoxicity manifested by ototoxicity, both vestibular and auditory, can occur in patients treated with gentamicin sulfate. Gentamicin-induced ototoxicity is usually irreversible. Allergic reactions have also been reported.

Medical Conditions Aggravated by Exposure

Pre-existing hypersensitivity to gentamicin sulfate or related products; pre-existing ocular, renal, auditory or gastrointestinal ailments; pregnancy.

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 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 for hazard control.

**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. Employees with known allergies to gentamicin sulfate or related antibiotics should consult a health and/or safety professional prior to handling open containers of this material.

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>Gentamicin Sulfate</td>
<td>Not Applicable</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>None Established</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. Since protection provided by air purifying respirators is limited, a powered air purifying respirator or supplied air should be considered during an uncontrolled release event, if exposure levels are not known, or during events where air-purifying respirators may not provide adequate protection. 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>Clear, colorless</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>NA</td>
</tr>
<tr>
<td>pH</td>
<td>3.8 (3.0 to 5.5)</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>Gentamicin Sulfate is soluble in water, moderately soluble in methanol, ethanol, acetone and practically insoluble in benzene.</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water:</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition temperature:</td>
<td>NA</td>
</tr>
</tbody>
</table>
Product Name: Gentamicin Sulfate Injection

Decomposition temperature: NA

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

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>
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<tbody>
<tr>
<td>Gentamicin Sulfate</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>&gt; 5000</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt; 11,269</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt; 9050</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Gentamicin Sulfate</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>96</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>47</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>75</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Gentamicin Sulfate</td>
<td>100</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>630</td>
<td>mg/kg</td>
<td>Rat</td>
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<td>245</td>
<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>430</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 irritation. Gentamicin sulfate produced significant conjunctival irritation in an irritation study in animals.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product. Allergic reactions have been reported during the clinical use of this product in patients. This product contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.
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Reproductive Effects  Animal reproduction studies conducted on rats and rabbits did not reveal evidence of impaired fertility or harm to the fetus due to gentamicin sulfate. Aminoglycoside antibiotics cross the placenta, and there have been several reports of total irreversible bilateral congenital deafness in children whose mothers received streptomycin or tobramycin during pregnancy. Also, aminoglycosides may be nephrotoxic in the human fetus. FDA Pregnancy Category D.

Mutagenicity  The mutagenic potential of gentamicin sulfate has not been evaluated.

Carcinogenicity  The carcinogenic potential of gentamicin sulfate has not been evaluated.

Target Organ Effects  Gentamicin has produced vestibular and auditory toxicity in patients and experimental animals. Based on clinical use, possible target organs include the kidneys, hearing, nervous system, gastrointestinal system, eyes and fetus.

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. 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

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>Gentamicin Sulfate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Listed</td>
</tr>
</tbody>
</table>

**RCRA Status** Not Listed  
**U.S. OSHA Classification**  
- Target Organ Toxin  
- Possible Reproductive Toxin  
- 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:*

**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 Gentamicin Sulfate.***  

**Classification(s):** Not Applicable  
**Symbol:** Not Applicable  
**Indication of Danger:** Not Applicable  
**Risk Phrases:** Not Applicable  
**Safety Phrases:** $23 - Do not breathe vapor. $24/25 - Avoid contact with skin and eyes. $37/39 - 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

MSDS Coordinator: Hospira GEHS
Date Prepared: 09/26/2011
Obsolete Date: N/A

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