MATERIAL SAFETY DATA SHEET

Product Name: Gentamicin Sulfate in 0.9% Sodium Chloride Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

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
Hospira, Inc., Non-Emergency 224 212-2055

Product Name
Gentamicin Sulfate in 0.9% Sodium Chloride Injection

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Gentamicin Sulfate, USP

Chemical Formula
NA

Component Approximate Percent by Weight CAS Number RTECS Number
Gentamicin Sulfate < 1 1405-41-0 LY2625000

Non-hazardous ingredients include water. Hazardous ingredients present at less than 1% include sodium chloride. Sulfuric acid and/or sodium hydroxide are added for pH adjustment.

3. HAZARD INFORMATION

Emergency Overview
Gentamicin Sulfate in 0.9% Sodium Chloride Injection contains 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 workplace exposure. In clinical use, adverse effects may include nausea, 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.

Carcinogen Lists: IARC: Not listed NTP: Not listed OSHA: Not listed
## 4. FIRST AID MEASURES

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Contact</td>
<td>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.</td>
</tr>
<tr>
<td>Skin Contact</td>
<td>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.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.</td>
</tr>
</tbody>
</table>

## 5. FIRE FIGHTING MEASURES

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability</td>
<td>None anticipated for this aqueous product.</td>
</tr>
<tr>
<td>Fire &amp; Explosion Hazard</td>
<td>None anticipated for this aqueous product.</td>
</tr>
<tr>
<td>Extinguishing Media</td>
<td>As with any fire, use extinguishing media appropriate for primary cause of fire.</td>
</tr>
<tr>
<td>Special Fire Fighting Procedures</td>
<td>No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.</td>
</tr>
</tbody>
</table>

## 6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spill Cleanup and Disposal</td>
<td>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.</td>
</tr>
</tbody>
</table>

## 7. HANDLING AND STORAGE

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handling</td>
<td>No special handling required under conditions of normal product use. Protect from light by retaining in carton until contents have been used.</td>
</tr>
<tr>
<td>Storage</td>
<td>No special storage required for hazard control. For product protection, follow USP controlled room temperature storage recommendations noted on the product case label, the primary container label, or the product insert.</td>
</tr>
<tr>
<td>Special Precautions</td>
<td>Protect from freezing, light, and extreme heat. Employees with known allergies to gentamicin sulfate or related antibiotics should consult a health and/or safety professional prior to working with open containers of this material.</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<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>Gentamicin Sulfate</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: 100 mcg/m3</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.
STEL: 15-minute Short Term Exposure Limit.

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>Appearance/Physical State</th>
<th>A sterile, nonpyrogenic solution of gentamicin (as sulfate) in 0.9% sodium chloride injection</th>
</tr>
</thead>
<tbody>
<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 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 (Air =1)</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility</td>
<td>Gentamicin Sulfate is a white to buff powder; it 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>
<tr>
<td>Decomposition temperature</td>
<td>NA</td>
</tr>
</tbody>
</table>
Product Name: Gentamicin Sulfate in 0.9% Sodium Chloride 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
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>
</tr>
</thead>
<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>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>245</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>430</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
</tbody>
</table>

LD 50: Dosage that produces 50% mortality.

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 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.

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.

Mutagenicity
No information available.

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.
Product Name:  Gentamicin Sulfate in 0.9% Sodium Chloride Injection

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:
1. LC50: Concentration in water that produces 50% mortality in fish.
2. EC50: Concentration in water that produces 50% inhibition of growth in algae.

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

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
# 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Status</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. TSCA Status</td>
<td>Exempt.</td>
</tr>
<tr>
<td>U.S. CERCLA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>U.S. SARA 302 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>U.S. SARA 313 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>U.S. RCRA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>U.S. PROP 65 (Calif.)</td>
<td>This product contains an aminoglycoside, a chemical known to the State of California to cause developmental reproductive toxicity.</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Classification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. OSHA Classification</td>
<td>Possible Irritant</td>
</tr>
<tr>
<td></td>
<td>Target Organ Toxin</td>
</tr>
</tbody>
</table>

**GHS Classification**

*Where medicinal products are not exempt, the recommended GHS workplace classification is as follows:

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Acute Oral Toxicity</th>
<th>Eye Irritation</th>
<th>Skin Sensitization</th>
<th>Toxic to Reproduction</th>
<th>Target Organ Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Category</td>
<td>Unclassified</td>
<td>2B</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symbol</th>
<th>NA</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Word</td>
<td>NA</td>
<td>Warning</td>
</tr>
</tbody>
</table>

| Hazard Statement | NA | Causes eye irritation | May cause an allergic skin reaction. | Suspected of damaging fertility or the unborn child | May cause damage to the kidneys, hearing, nervous system, gastrointestinal system, and eyes through prolonged or repeated exposure. |

**Prevention:**

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Use personal protective equipment as required.

Avoid breathing dust/vapors/spray.

In case of inadequate ventilation wear respiratory protection as specified by the manufacturer/supplier or the competent authority.

Wear protective gloves as specified by the manufacturer/supplier or the competent authority.

Contaminated work clothing should not be allowed out of the workplace.

**Response:**

IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms call a POISON CENTER or doctor/physician.

IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs, seek medical advice/attention. Wash contaminated clothing before reuse.

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. If skin irritation occurs, get medical advice/attention.

Get medical attention if you feel unwell.
15. REGULATORY INFORMATION: continued

**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):**
- Irritant
- Skin Sensitizer
- Toxic for Reproduction
- Category 2

**Symbol:**
- Xi
- Xi
- T

**Indication of Danger**
- R36/37 - Irritating to eyes and respiratory system
- R42/43 – May cause sensitization by inhalation and skin contact
- R61 – May cause harm to the unborn child

**Risk Phrases:**
- S23: Do not breathe vapor/spray
- S24: Avoid contact with the 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

**MSDS Coordinator:** Global Occupational Toxicology
**Date Prepared:** July 2, 2009

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