MATERIAL SAFETY DATA SHEET

Product Name: Amikacin 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 Amikacin Sulfate Injection

Synonyms
0-3-amino-3-deoxy-α-D-glucopyranosyl(1 — 6)-0-[6-amino-6-deoxy-α-D-
glucopyranosyl(1 — 4)]-N1-(4-amino-2-hydroxy-1-oxobutyl)-2-deoxy-, (S)-, sulfate
(1:2) (salt).

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Amikacin Sulfate

Chemical Formula C_{22}H_{43}N_{5}O_{13} • 2H_{2}SO_{4}

Preparation
Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include sodium metabisulfite. Sulfuric acid is added 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>Amikacin Sulfate</td>
<td>5 ~ 25</td>
<td>39831-55-5</td>
<td>WK1961200</td>
</tr>
<tr>
<td>Sodium Citrate Dihydrate</td>
<td>≤3</td>
<td>6132-04-3</td>
<td>NA</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>Amikacin Sulfate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Sodium Citrate Dihydrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview

Amikacin Sulfate Injection is a solution that contains amikacin sulfate, a semisynthetic aminoglycoside antibiotic (similar to gentamicin) used clinically to treat severe infections. In the workplace, this material may be irritating to the eyes and respiratory tract, and should be considered a potential occupational reproductive hazard. Based on clinical use, possible target organs include the central nervous system, kidneys, and possibly the 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 occupational exposures. In clinical use, as a class, aminoglycosides can
Product Name: Amikacin Sulfate Injection

produce irreversible, cumulative ototoxicity (hearing loss). Reversible nephrotoxicity may also occur and acute renal failure has been reported. Aminoglycosides have a neuromuscular-blocking action and respiratory depression and muscular paralysis have been reported. Hypersensitivity reactions have occurred, especially after local use, and cross-sensitivity between aminoglycosides may occur. Infrequent effects reported for other aminoglycosides include blood dyscrasias, purpura, nausea and vomiting, stomatitis, and signs of liver dysfunction such as increased serum-aminotransferase values and increased serum-bilirubin concentrations. Aminoglycosides can cause fetal harm when administered to a pregnant woman. Aminoglycosides may cross the placenta.

Medical Conditions Aggravated by Exposure

- Hypersensitivity to amikacin sulfate or related aminoglycoside antibiotics; pre-existing kidney, hearing/ears/auditory system 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 under conditions of normal product use. Protect from light by retaining in carton until contents have been used.

**Storage**

No special storage required for hazard control. For product protection, follow
Product Name: Amikacin Sulfate Injection

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

<table>
<thead>
<tr>
<th>Exposure Guidelines</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component</td>
<td>Type</td>
</tr>
<tr>
<td>Amikacin Sulfate</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Sodium Citrate Dihydrate</td>
<td>Not Applicable</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>Physical Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Colorless to light straw</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH:</td>
<td>4.5 (3.5 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>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>
</tbody>
</table>
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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</thead>
<tbody>
<tr>
<td>Amikacin Sulfate</td>
<td>100%</td>
<td>LD50</td>
<td>Oral</td>
<td>&gt;4000</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;10,679</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>&gt;3000</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td>Amikacin Sulfate</td>
<td>100%</td>
<td>LD50</td>
<td>Intravenous</td>
<td>234</td>
<td>mg/kg</td>
<td>Rat</td>
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<tr>
<td></td>
<td></td>
<td></td>
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<td>181</td>
<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td>248</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
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<td></td>
<td></td>
<td>383</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
<tr>
<td>Sodium Citrate Dihydrate</td>
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<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
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</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.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product. In clinical use, hypersensitivity reactions have occurred, especially after local use, and cross-sensitivity between aminoglycosides may occur.

Reproductive Effects
Amikacin sulfate administered subcutaneously to rats at doses up to 4 times the human daily dose did not impair male or female fertility. Reproduction studies of amikacin have been performed in rats and mice and revealed no evidence of impaired fertility or harm to the fetus due to amikacin. Aminoglycosides can cause fetal harm when administered to a pregnant woman. Aminoglycoside
Product Name: Amikacin Sulfate Injection

Antibiotics may cross the placenta. FDA Pregnancy Category D.

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

Carcinogenicity
Long term studies in animals to evaluate carcinogenic potential have not been performed.

Target Organ Effects
Based on clinical use, possible target organs include the central nervous system, kidneys, and possibly the 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>Amikacin Sulfate</td>
<td>Not Listed</td>
<td>Not Listed</td>
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<td>Not Listed</td>
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Product Name: Amikacin Sulfate Injection

**RCRA Status**  
Not Listed

**U.S. OSHA Classification**  
Possible Sensitizer
Target Organ 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 Amikacin Sulfate.

**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
Product Name: Amikacin Sulfate Injection

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: 08/31/2011
Obsolete Date: 10/21/2008

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