MATERIAL SAFETY DATA SHEET

Product Name: Cefuroxime for Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

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

Hospira, IKKT
Factory Plot Nos. B3-B6 & B11-B14
Sipcot Industrial Park
Irungattukottai, India 602105

Emergency Telephone
CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency Product Name
Cefuroxime for Injection, USP

Synonyms
Sodium salt of (6R, 7R)-3-carbamoyloxymethyl-7-[Z-2-methoxyimino-2-(fur-2-yl)acetamido]ceph-3-em-4-carboxylate; Cefuroxime sodium.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Cefuroxime Sodium

Chemical Formula
C_{16}H_{15}N_{4}O_{8}S • Na

<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>Cefuroxime Sodium</td>
<td>100</td>
<td>56238-63-2</td>
<td>XI0330000</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>Cefuroxime Sodium</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Cefuroxime for Injection, USP is a powder containing cefuroxime sodium, a semisynthetic, broad-spectrum, cephalosporin antibiotic for parenteral administration. No adverse effects are anticipated from normal handling of the intact container. Following an accidental exposure, the powdered cefuroxime sodium may produce skin, eye, or respiratory irritation. The reconstituted product is not anticipated to be irritating. In the workplace, this material should be considered a potential sensitizer. Persons known to be allergic to penicillins or other cephalosporins should take precautions when handling this material. Following an accidental over-exposure, possible target organs may include the gastrointestinal system, liver, kidneys, blood, and skin.

Occupational Exposure Potential
Minimal occupational exposure is anticipated from normal handling of the intact container. Avoid dust and liquid aerosol generation and inadvertent skin contact.

Signs and Symptoms
No signs or symptoms of exposure are anticipated from normal handling of the intact container. Based on clinical use of this product in patients, following an accidental occupational exposure,
possible adverse effects may include gastrointestinal upset (nausea, vomiting, stomach cramps, loss of appetite), headache, dizziness, elevated liver enzymes, elevated kidney enzyme levels, and altered hematological parameters (anemia, neutropenia, thrombocytopenia). Persons allergic to penicillins or other cephalosporin antibiotics may experience allergic reactions including fever, rash, itching, difficulty breathing, or anaphylaxis.

Medical Conditions Aggravated by Exposure: Pre-existing allergy to cefuroxime sodium, penicillins, or other cephalosporin antibiotics. Pre-existing gastrointestinal system, liver, kidney, skin, 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 for this product. However, many organic powders will combust at high temperatures. |
| Fire & Explosion Hazard | None anticipated for this product. Avoid the creation of dusty environments. |
| Extinguishing media | As with any fire, use extinguishing media appropriate for primary cause of fire. |
| Special Fire Fighting Procedures | No special requirements are needed for single units or packages. For larger amounts, self-contained breathing apparatus and protective equipment and clothing are recommended to minimize contact with respiratory tract, skin and eyes. |

6. ACCIDENTAL RELEASE MEASURES

| Spill Cleanup and Disposal | If a container breaks, isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Collect the spilled powder using techniques that minimize powder migration. Clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations. If a spill occurs after reconstitution, absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations. |
7. HANDLING AND STORAGE

Handling  
No special control measures are required during the normal use of this product.

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. Persons with known allergies to penicillins or other cephalosporins should consult a health 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>Cefuroxime Sodium</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 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 contact with unprotected skin is possible, the use of gloves is recommended. Persons with known allergies to penicillins or other cephalosporins should consult their site health or safety professional regarding appropriate selection of gloves prior to handling this material.

Eye protection  
Eye protection is not required during expected product use conditions but may be warranted if eye contact is likely. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls  
Engineering controls are not needed during normal product use conditions.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State  
Solid

Color  
Powder white to off-white. Solution light yellow to amber

Odor  
NA

Odor Threshold:  
NA

pH:  
6 to 8.5 for constituted solution

Melting point/Freezing point:  
NA

Initial Boiling Point/Boiling Point Range:  
NA

Evaporation Rate:  
NA

Flammability (solid, gas):  
NA
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Upper/Lower Flammability or Explosive Limits: NA
Vapor Pressure: NA
Vapor Density: NA
Specific Gravity: NA
Solubility: NA
Partition coefficient: n-octanol/water: NA
Auto-ignition temperature: NA
Decomposition temperature: NA

10. STABILITY AND REACTIVITY

Chemical Stability
Stable under recommended storage conditions and use.

Incompatibilities
Not determined. Cefuroxime sodium is reported to be clinically incompatible with aminoglycosides.

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), sodium oxides (Na2O), and sulfur oxides (SOx).

Hazardous Polymerization
Not determined. Not anticipated to occur with this material.

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>Cefuroxime Sodium</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>&gt; 10,000</td>
<td>mg/kg</td>
<td>Rat, Mouse</td>
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<tr>
<td>Cefuroxime Sodium</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>4000</td>
<td>mg/kg</td>
<td>Rat</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10,400</td>
<td>mg/kg</td>
<td>Mouse</td>
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<td></td>
<td></td>
<td></td>
<td>&gt; 1500</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt; 1500</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
<tr>
<td>Cefuroxime Sodium</td>
<td>100</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>10,000</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;10,000</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 intact containers. This material is reported to be slightly irritating in a skin irritation study in rabbits.

Ocular Irritation/Corrosion
None anticipated from normal handling of intact containers. This material is reported to be slightly irritating in an eye irritation study in rabbits. Inadvertent contact with eyes may produce redness and discomfort.

Dermal or Respiratory Sensitization
None anticipated from normal handling of intact containers. Allergic reactions have been reported in patients during the clinical use of this product.

Reproductive Effects
Reproduction studies in mice at dosages up to 3,200 mg/kg/day have revealed no impairment of fertility. Reproduction studies conducted in mice at dosages up to 6,400 mg/kg/day and rabbits at dosage up to 400 mg/kg/day have
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revealed no evidence of impaired fertility or harm to the fetus due to cefuroxime.

Mutagenicity

No mutagenic activity was found for cefuroxime in the mouse lymphoma assay and a battery of bacterial mutation tests. Positive results were obtained in an in vitro chromosome aberration assay, however, negative results were found in an in vivo micronucleus test at doses up to 10 g/kg.

Carcinogenicity

Lifetime studies in animals have not been performed to evaluate carcinogenic potential.

Target Organ Effects

Based on clinical use, possible target organs include the gastrointestinal system, liver, kidneys, blood, and skin.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Cefuroxime sodium is not toxic to activated sludge microorganisms. The IC50: > 87.6 mg/l, 3 Hours, activated sludge. Cefuroxime is toxic to several other microorganisms: MIC=, 0.18 mg/l, Azotobacter beijerinckii 0.18 mg/l, Nostoc commune > 0.88 mg/l, Pseudomonas aeruginosa > 0.88 mg/l, Trichoderma harzianum > 0.88 mg/l, Aspergillus niger Cefuroxime sodium is not toxic to algae. The IC50: > 91 mg/l, 72 Hours, in Selenastrum capricornutum (green algae); Static test. The NOEC: 91 mg/l. Cefuroxime sodium is not toxic to daphnids. The EC50: > 876 mg/l, 48 Hours, Daphnia magna, Static Test. The NOEC: > 876 mg/l, 48 Hours, Daphnia magna, Static Test. Cefuroxime sodium is not toxic to fish. In juvenile Oncorhyncus mykiss, rainbow trout, the EC50: > 105 mg/l, 96 Hours, Static test. The NOEC: 105 mg/l. *GlaxoSmithKline MSDS for Zinacef (Cefuroxime for Injection); SDS Number 127337.

Persistence/Biodegradability

Hydrolysis Cefuroxime sodium is chemically unstable in water. Hydrolysis is anticipated to be a significant depletion mechanism. Neutral: 30.2 Hours Half-Life, Acidic: 299 Hours Half-Life, Basic: 1.05 Hours space Photolysis Cefuroxime sodium is anticipated to undergo photodegradation. Absorption in the UV/Visible spectrum occurs at 290 nm. Biodegradation Cefuroxime sodium is not readily biodegradable. However, it is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not anticipated to persist in the environment. Aerobic – Ready - Percent Degradation: 42 %, 64 days, Modified Sturm test. space Aerobic – Ready - Percent Degradation: 28 %, 28 days, Modified Sturm test. space Aerobic – Inherent Percent Degradation: 74 %, < 1 day, Modified Zahn-Wellens, primary biodegradation, loss of parent., activated sludge space Aerobic – Soil - Percent Degradation: 42.8 to 80 %, 64 days. space

*GlaxoSmithKline MSDS for Zinacef (Cefuroxime for Injection); SDS Number 127337.

Bioaccumulation

Cefuroxime sodium is not anticipated to bioaccumulate in the food chain. The octanol/water partition coefficient data for cefuroxime sodium suggests that for environmental fate predictions, the active pharmaceutical ingredient will not have the tendency to distribute into fats.

*GlaxoSmithKline MSDS for Zinacef (Cefuroxime for Injection); SDS Number 127337.

Mobility in Soil

Cefuroxime sodium is not anticipated to adsorb to, or persist in, soil or
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sediment if released directly to the environment. The Soil Sediment Sorption (log Koc): 1.09 to 1.19.

*GlaxoSmithKline MSDS for Zinacef (Cefuroxime for Injection); SDS Number 127337.

13. DISPOSAL CONSIDERATIONS

Waste Disposal
All waste materials must be properly characterized by the waste generator. Disposal of all pharmaceuticals wastes 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>
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</tr>
</tbody>
</table>

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 Not Applicable
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**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 Cefuroxime Sodium.*

**Classification(s):** Not Applicable

**Symbol:** Not Applicable

**Indication of Danger:** Not Applicable

**Risk Phrases:** Not Applicable

**Safety Phrases:**

- S22 - Do not breathe dust.
- 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

**MSDS Coordinator:** Hospira GEHS

Date Prepared: 09/21/2011

Obsolescent Date: 04/22/2009
Product Name: Cefuroxime for Injection, USP

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