Product Name: Cefazolin for 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 Cefazolin for Injection

Synonyms Cefazolin Sodium; 3-([(5-methyl-1,3,4-thiadiazol-2-yl)thio]-methyl)-8-oxo-7-[2-(1H-tetrazol-1-yl)acetamido]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, sodium salt.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Cefazolin Sodium

Chemical Formula C_{14}H_{13}N_{8}O_{4}S_{3} •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>Cefazolin Sodium</td>
<td>100</td>
<td>27164-46-1</td>
<td>XI0390000</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>Cefazolin Sodium</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Cefazolin for Injection is a powder for reconstitution containing cefazolin sodium, a cephalosporin antibacterial agent used to treat infections due to susceptible organisms. No adverse effects are anticipated from normal handling of the intact container. In the workplace, the powdered cefazolin sodium may produce skin, eye, or respiratory irritation and may induce an allergic response. The reconstituted product is not anticipated to be irritating. Persons known to be allergic to penicillins or other cephalosporins should take precautions when handling open containers of 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 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
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allergetic 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 cefazolin 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. During dispensing, avoid excessive aerosolization of the reconstituted product during dilution or transfers.

Storage
No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary
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can be found in the container label, or the product insert.

Special Precautions

None anticipated during the normal use of this product. Persons with known allergies to penicillins or other cephalosporins should consult a health or safety professional prior to handling this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mg/m³</td>
<td>ppm</td>
</tr>
<tr>
<td>Cefazolin Sodium</td>
<td>Not Applicable</td>
<td>N/A</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. Disposable gloves made from nitrile, neoprene, polyurethane or natural latex generally have low permeability to many chemical agents. Persons known to be allergic to latex rubber should select a non-latex glove. Gloves should be changed regularly, and removed immediately after known contamination.

**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**: White to off-white (yellowish) crystalline powder
**Odor**: Practically odorless
**Odor Threshold**: NA
**pH**: 4.6 - 6.0 for a 10% solution
**Melting point/Freezing point**: 198°C– 200°C
**Initial Boiling Point/Boiling Point Range**: NA
**Evaporation Rate**: NA
**Flammability (solid, gas)**: NA
**Upper/Lower Flammability or Explosive Limits**: NA
**Vapor Pressure**: NA
**Vapor Density**: NA
**Specific Gravity**: NA
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Solubility: Freely soluble in water, 0.9% sodium chloride, and glucose solution
Partition coefficient: n-octanol/water: NA
Auto-ignition temperature: NA
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. Cefazolin 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 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>Cefazolin Sodium</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>&gt; 11,000</td>
<td>mg/kg</td>
<td>Rat, Mouse</td>
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<tr>
<td>Cefazolin Sodium</td>
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<td>LD50</td>
<td>Intravenous</td>
<td>2760</td>
<td>mg/kg</td>
<td>Rat</td>
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<tr>
<td></td>
<td>100</td>
<td>LD50</td>
<td></td>
<td>3900</td>
<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td></td>
<td>100</td>
<td>LD50</td>
<td></td>
<td>2200</td>
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<td></td>
<td>100</td>
<td>LD50</td>
<td></td>
<td>2500</td>
<td>mg/kg</td>
<td>Rabbit</td>
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</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 non-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 of this product with eyes may produce irritation with redness and tearing.

Dermal or Respiratory Sensitization None anticipated from normal handling of intact containers. As a class, cephalosporin antibiotics are sensitizers in studies in animals. Allergic reactions have also been reported during the clinical use of this product.

Reproductive Effects Reproduction studies conducted in rats, mice, and rabbits at dosages up to 25 times the human dose have revealed no evidence of impaired fertility or harm
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to the fetus.

Mutagenicity The mutagenic potential of cefazolin sodium has not been evaluated.

Carcinogenicity The carcinogenic potential of cefazolin sodium has not been evaluated.

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

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 of all pharmaceuticals 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>
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<tr>
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<td>Not Listed</td>
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<td>Not Listed</td>
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</tr>
</tbody>
</table>

RCRA Status Not Listed

U.S. OSHA Possible Sensitizer

Classification Target Organ Toxin

GHS *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as
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**Classification**  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>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Category</td>
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</tr>
<tr>
<td>Signal Word</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Symbol</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

**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 Cefazolin Sodium.

<table>
<thead>
<tr>
<th>Classification(s):</th>
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<tbody>
<tr>
<td>Symbol:</td>
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<tr>
<td>Indication of Danger:</td>
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<tr>
<td>Risk Phrases:</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Safety Phrases:</td>
<td>S22: Do not breathe dust</td>
</tr>
<tr>
<td></td>
<td>S23 - Do not breathe vapor.</td>
</tr>
<tr>
<td></td>
<td>S24/25 - Avoid contact with skin and eyes.</td>
</tr>
<tr>
<td></td>
<td>S37/39 - Wear suitable gloves and eye/face protection.</td>
</tr>
</tbody>
</table>

**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
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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: 10/24/2011
Obsolete Date: 03/17/2009

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