MATERIAL SAFETY DATA SHEET

Product Name: Ampicillin and Sulbactam for Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Sandoz GmbH
Biochemiestrasse 10
A-6250 Kundl / Tirol
Austria

Distributor
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois 60045
USA

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

Hospira, Inc., Non-Emergency Product Name
Ampicillin and Sulbactam for Injection, USP

Synonyms
Monosodium (2S, 5R, 6R)-6-[(R)-2-amino-2-phenylacetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate
Sodium penicillinate sulfone; sodium (2S, 5R)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate 4,4-dioxide

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Sulbactam Sodium
Ampicillin Sodium

Chemical Formula
Ampicillin Sodium: C_{16}H_{18}N_{3}NaO_{4}S
Sulbactam Sodium: C_{8}H_{10}NNaO_{5}S

<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>Sulbactam Sodium</td>
<td>33</td>
<td>69388-84-7</td>
<td>XH92200000</td>
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<tr>
<td>Ampicillin Sodium</td>
<td>67</td>
<td>69-52-3</td>
<td>XH84000000</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>
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<tbody>
<tr>
<td>Ampicillin Sodium</td>
<td>3</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Sulbactam Sodium</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Ampicillin and Sulbactam for Injection, USP is a powder containing ampicillin sodium, beta-lactam antibiotic, and sulbactam sodium, a penicillanic acid sulfone that inhibits beta-lactamase. Clinically, this product is used to treat susceptible infections. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract and a potential sensitizer which may induce an allergic response. Persons known to be allergic to penicillins or other cephalosporins should take precautions when handling open containers of
Product Name: Ampicillin and Sulbactam for Injection, USP

this material. Based on clinical use, potential target organs in include the gastrointestinal system, immune system, and skin.

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
In the workplace, this material should be considered potentially irritating and a potential sensitizer. In clinical use, adverse effects may include gastrointestinal upset (diarrhea, nausea, and vomiting) especially after oral use. Skin rashes may occur and are urticarial (typical of penicillin hypersensitivity) or maculopapular eruptions which are characteristic of ampicillin. Other effects have included itching, candidiasis, fatigue, malaise, headache, chest pain, flatulence, abdominal distension, glossitis, urine retention, dysuria, edema, facial swelling, erythema, chills, tightness in throat, substernal pain, epistaxis, and mucosal bleeding.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to penicillin or cephalosporin antibiotics; pre-existing gastrointestinal 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 generation of dusty environments.

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. Collect powder using methods that minimize the creation of dust. If the spill occurs after reconstitution, 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 under conditions of normal product use.

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. However, persons with known allergies to penicillins or 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>Ampicillin Sodium</td>
<td>Not Applicable</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>None Established</td>
</tr>
<tr>
<td>Sulbactam 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 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

Appearance/Physical State
Solid

Color
White to yellowish dry powder for reconstitution

Odor
NA

Odor Threshold:
NA

pH:
8 to 10 after reconstitution

Melting point/Freezing point:
NA

Initial Boiling Point/Boiling Point Range:
NA

Evaporation Rate:
NA

Flammability (solid, gas):
NA
Product Name: Ampicillin and Sulbactam for Injection, USP

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

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>Ampicillin Sodium</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>&gt;5314</td>
<td>mg/kg</td>
<td>Rat, Mouse</td>
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<tr>
<td>Sulbactam Sodium</td>
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<td>LD50</td>
<td>Intravenous</td>
<td>6500</td>
<td>mg/kg</td>
<td>Rat</td>
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<td></td>
<td></td>
<td>8.1</td>
<td>mg/kg</td>
<td>Mouse</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 this product.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product. As a class, penicillin antibiotics are sensitizers; allergic reactions occur in 5-10 percent of patients during clinical use of penicillin antibiotics.
Reproduction studies have been performed in mice, rats, and rabbits at doses up to ten (10) times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ampicillin and Sulbactam.

Mutagenicity

Long-term studies in animals to evaluate the mutagenic potential have not been performed.

Carcinogenicity

Long-term studies in animals to evaluate the carcinogenic potential have not been performed. Ampicillin sodium is listed by IARC as Group 3 - Not classifiable.

Target Organ Effects

Based on clinical use, potential target organs include the gastrointestinal system, immune system, 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 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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<tbody>
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<tr>
<td>Sulbactam Sodium</td>
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</table>
Product Name: Ampicillin and Sulbactam for Injection, USP

RCRA Status  Not Listed
U.S. OSHA Classification Possible Sensitizer
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 Sulbactam Sodium Ampicillin Sodium.

Classification(s): Not Applicable
Symbol: Not Applicable
Indication of Danger: Not Applicable
Risk Phrases: R00 - 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:

<table>
<thead>
<tr>
<th>Notes:</th>
<th>ACGIH TLV</th>
<th>American Conference of Governmental Industrial Hygienists – Threshold Limit Value</th>
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<tbody>
<tr>
<td></td>
<td>CAS</td>
<td>Chemical Abstracts Service Number</td>
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<tr>
<td></td>
<td>CERCLA</td>
<td>US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act</td>
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<td></td>
<td>DOT</td>
<td>US Department of Transportation Regulations</td>
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<td></td>
<td>EEL</td>
<td>Employee Exposure Limit</td>
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<td></td>
<td>IATA</td>
<td>International Air Transport Association</td>
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<tr>
<td></td>
<td>LD50</td>
<td>Dosage producing 50% mortality</td>
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<tr>
<td></td>
<td>NA</td>
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<tr>
<td></td>
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<td></td>
<td>NIOSH</td>
<td>National Institute for Occupational Safety and Health</td>
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<td></td>
<td>OSHA PEL</td>
<td>US Occupational Safety and Health Administration – Permissible Exposure Limit</td>
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<tr>
<td></td>
<td>Prop 65</td>
<td>California Proposition 65</td>
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<tr>
<td></td>
<td>RCRA</td>
<td>US EPA, Resource Conservation and Recovery Act</td>
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<tr>
<td></td>
<td>RTECS</td>
<td>Registry of Toxic Effects of Chemical Substances</td>
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<tr>
<td></td>
<td>SARA</td>
<td>Superfund Amendments and Reauthorization Act</td>
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<td></td>
<td>STEL</td>
<td>15-minute Short Term Exposure Limit</td>
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<td></td>
<td>TSCA</td>
<td>Toxic Substance Control Act</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>8-hour Time Weighted Average</td>
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</tbody>
</table>

MSDS Coordinator: Hospira GEHS
Date Prepared: 11/09/2011
Obsolete Date: 09/26/2006

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