MATERIAL SAFETY DATA SHEET

Product Name: Meropenem 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
Meropenem for Injection

Synonyms
(4R,5S,6S)-3-[[3S,5S]-5-(Dimethylcarbamoyl)-3-pyrrolidinyl]thio]-6-[(1R)-1-hydroxyethyl]-4-methyl-7-oxo-1-azabicyclo[3.2.0]hept-2-ene-2-carboxylic acid trihydrate

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Meropenem Trihydrate

Chemical Formula
C_{17}H_{25}N_{3}O_{5}S•3H_{2}O

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
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<td>119478-56-7</td>
<td>CL5446507</td>
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<td>8</td>
<td>497-19-8</td>
<td>VZ4050000</td>
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3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
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<tr>
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<tr>
<td>Sodium Carbonate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</table>

Emergency Overview
Meropenem for Injection is a powder containing meropenem, a carbapenem beta-lactam antibacterial with actions and uses similar to those of imipenem. Clinically, it is used to treat infections caused by susceptible Gram-positive and Gram-negative bacteria. In the workplace, this material should be considered potentially irritating to the skin, eyes and respiratory tract, and a potential sensitizer which may induce allergic reactions in persons known to be sensitized to penicillins and cephalosporins. Based on clinical use, possible target organs include the gastrointestinal system, central nervous system, skin, hematopoietic system, and liver.

Occupational Exposure Potential
Information on the absorption of this product via inhalation or skin contact is not available. Avoid dust or liquid aerosol generation and skin contact.

Signs and Symptoms
None known from occupational exposure. In clinical use, the most common adverse effects of meropenem include headache, nausea, diarrhea, vomiting, rash, seizures, pruritus, urticaria, thrombocytosis, abdominal pain, and elevated liver enzymes. Some patients with a history of penicillin hypersensitivity have experienced severe hypersensitivity reactions when treated with meropenem.
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another beta-lactam antibiotic.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to meropenem; penicillins, cephalosporins or other lactam-like antibiotics; pre-existing gastrointestinal, skin, hematopoietic, or liver 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. However, many organic powders will combust at high temperatures.

Fire & Explosion Hazard
None anticipated. 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 provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal
For spilled powder, 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. Absorb any liquid with an inert absorbent material (e.g. absorbent pad). 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 handling required 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 are required for hazard controls. Employees with known allergies to penicillin and cephalosporin antibiotics should consult a
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health and/or safety professional prior to working with 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>
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<td>Sodium Carbonate</td>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>None Established</td>
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<td>Meropenem Trihydrate</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 pale yellow crystalline powder.

**Odor**

NA

**Odor Threshold:**

NA

**pH:**

7.3 - 8.3 for freshly constituted aqueous solutions

**Melting point/Freezing point:**

NA

**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

**Solubility:**

Soluble in water

**Partition coefficient: n-octanol/water:**

NA

**Auto-ignition temperature:**

NA

**Decomposition temperature:**

NA
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10. STABILITY AND REACTIVITY

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions.

Hazardous Reactions
Not determined.

Conditions to avoid
Strong oxidizers and strong bases.

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), or 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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<tr>
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<td>LD50</td>
<td>Oral</td>
<td>NA</td>
<td>NA</td>
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<td>LD50</td>
<td>Oral</td>
<td>&gt;5000</td>
<td>mg/kg</td>
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<tr>
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<td>mg/kg</td>
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<td>mg/kg</td>
<td>Mouse</td>
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</table>

Aspiration Hazard
None anticipated from normal handling of the intact product.

Dermal Irritation/Corrosion
None anticipated from normal handling of the intact product. However, inadvertent contact with this product formulation may be irritating to mucous membranes and the respiratory system.

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

Dermal or Respiratory Sensitization
None anticipated from normal handling of the intact product. The active ingredient in this product is a potential sensitizer and may induce allergic reactions in persons known to be sensitized to penicillins and cephalosporins. If known to be allergic to penicillins or cephalosporins, consult a health or safety professional prior to handling open containers of this product.

Reproductive Effects
Reproductive studies conducted with meropenem in rats at dosages up to 750 mg/kg/day, and cynomolgus monkeys at dosages of up to 360 mg/kg/day. These studies revealed no evidence of impaired fertility or harm to the fetus due to meropenem, although there were slight changes in fetal body weight at dosages of 250 mg/kg/day. There was increased evidence of abortions at 500 mg/kg in a preliminary study in monkeys.
Mutagenicity

Genetic toxicity studies were performed with meropenem using the bacterial reverse mutation test, the Chinese hamster ovary HGPRT assay, cultured human lymphocytes cytogenetic assay, and the mouse micronucleus test. There was no evidence of mutagenic potential found in any of these tests.

Carcinogenicity

The carcinogenic potential of meropenem has not been evaluated.

Target Organ Effects

Based on clinical use, possible target organs include the gastrointestinal system, central nervous system, skin, hematopoietic system, and liver.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Not determined for product. Information for ingredients is as follows: LC50 = 320 mg/L; 96 Hr.; static Conditions, for Bluegill/Sunfish for sodium carbonate

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. Disposal should be performed in accordance with 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>
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<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
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RCRA Status

Not Listed

U.S. OSHA

Possible Sensitizer

Classification

Target Organ Toxin

Possible Irritant
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**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**

*Medical products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Meropenem Trihydrate.

**Classification(s):** Not Applicable

**Symbol:** Not Applicable

**Indication of Danger:** Not Applicable

**Risk Phrases:** R00 - 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
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
Product Name: Meropenem for Injection

TSCA          Toxic Substance Control Act
TWA           8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 10/18/2011
Obsolete Date: 05/18/2010

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