MATERIAL SAFETY DATA SHEET

Product Name: Pentamidine Isethionate for Injection, BP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

| Manufacturer Name And Address | Hospira Inc.  
| Address | 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 | Pentamidine Isethionate for Injection, BP  
| Synonyms | 4,4'- (pentamethylenedioxy)-dibenzamidine isethionate

2. COMPOSITION/INFORMATION ON INGREDIENTS

| Active Ingredient Name | Pentamidine Isethionate  
| Chemical Formula | C_{23}H_{36}N_{4}O_{10}S_{2}  

<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>Pentamidine Isethionate</td>
<td>100</td>
<td>140-64-7</td>
<td>CV6500000</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>Pentamidine Isethionate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview

Pentamidine Isethionate for Injection, BP is a lyophilized powder that contains pentamidine isethionate, an anti-parasitic aromatic diamidine. Clinically, it is indicated for the treatment of pneumonia due to Pneumocystis carinii. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the cardiovascular system, blood, kidneys, liver, respiratory system, skin and eyes.

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 work place exposures. In clinical use, fatalities due to severe hypotension, hypoglycemia and cardiac arrhythmias have been reported in patients treated with pentamidine isethionate. Profound and severe hypotension can occur after a single dose. More common adverse effects may include fainting, breathlessness, headache, nausea, vomiting, fever, dizziness, renal injury, cardiac irregularity, and hematologic changes. Following aerosol use, bronchospasm, rashes and air way irritation have been the predominant adverse effects found. Cough has occurred in up to 38% of patients following oral inhalation via nebulization. Bronchospasm has occurred in up to 15% of patients and may be associated with local histamine release in the bronchial mucosa (may be more likely in asthmatics). Ventricular
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tachycardia and ECG abnormalities may develop in patients receiving pentamidine isethionate. Leukopenia and thrombocytopenia, which can be severe, may occur occasionally in patients receiving pentamidine isethionate. Anemia occurs rarely. In a few cases, pentamidine therapy has been associated with neutropenia. Phlebitis can occur after intravenous injection.

Medical Conditions
Aggravated by Exposure
Pre-existing cardiovascular, hematological, liver, kidney, hepatic, skin or respiratory ailments; asthma.

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 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 techniques that minimize the creation of airborne dusts. If the spill occurs after reconstitution, absorb spill using an inert absorbent material. 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.

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.
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>Pentamidine Isethionate</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

NA

Odor

NA

Odor Threshold:

NA

pH:

4.5 to 7.5 after reconstitution

Melting point/Freezing point:

180ºC

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 and glycerin. Slightly soluble in alcohol. Insoluble in ether, acetone and chloroform.

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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</thead>
<tbody>
<tr>
<td>Pentamidine Isethionate</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>15.1, 28</td>
<td>mg/kg, mg/kg</td>
<td>Mouse, Mouse</td>
</tr>
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</table>

Aspiration Hazard  None anticipated from normal handling of this product. Inadvertent inhalation of product aerosol may produce respiratory irritation with coughing.

Dermal Irritation/Corrosion  None anticipated from normal handling of this product. Pentamidine isethionate was not irritating to the skin in a skin irritation test in rabbits.

Ocular Irritation/Corrosion  None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce severe irritation. In animals, pentamidine isethionate is a severe eye irritant; it produced maximal corneal opacity in an eye irritation test.

Dermal or Respiratory Sensitization  None anticipated from normal handling of this product. However, in clinical use, bronchospasm, irritation and coughing have been reported following the inhalation of nebulized product.

Reproductive Effects  Pentamidine isethionate was given to pregnant rats at dosages of 0, 4, and 20 mg/kg/day on days 6-11, 6-8, or 9-11 of gestation. A significant increase in embryotoxicity was noted following administration of 4 mg/kg/day during days 6-11 of gestation. Pentamidine Isethionate was assessed for fetotoxicity and teratogenic activity in mated female New Zealand white rabbits at dosage levels of 1, 2, 3 and 8 mg/kg intravenously once daily from gestation days 5 through 12. Maternal toxicity (severe central nervous system, somatomotor, respiratory and cardiovascular reactions) was evident at 8 mg/kg. A dose-related decrease in body weight and food consumption was also noted in the dams. Litter data parameters (viable fetuses, litter weight and fetal weight, sex ratio) remained largely unaffected by treatment except for a mild fetotoxic
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effect in all dosage groups as indicated by increased post-implantation loss and increased incidence of minor fetal skeletal anomalies which may have been linked to maternal toxicity.

Mutagenicity

Pentamidine isethionate was negative in the Ames Assay, with and without metabolic activation.

Carcinogenicity

The carcinogenic potential of pentamidine isethionate has not been evaluated.

Target Organ Effects

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

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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RCRA Status: Not Listed

U.S. OSHA Classification:

Target Organ Toxin

Irritant

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:

**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 Pentamidine Isethionate.*

**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
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: 11/01/2011
Obsolete Date: 07/14/2009

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