MATERIAL SAFETY DATA SHEET

Product Name: Foscarnet Sodium 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
Foscarnet Sodium Injection

Synonyms
Phosphonoformic acid, trisodium salt

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Foscarnet Sodium

Chemical Formula
Na₃CO₅P•6 H₂O

Preparation
Non-hazardous ingredients include Water for Injection. Hydrochloric acid and/or sodium hydroxide may be added to adjust the pH.

<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>Foscarnet Sodium</td>
<td>2.4</td>
<td>34156-56-4</td>
<td>SY8300000</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>Foscarnet Sodium</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Foscarnet Sodium Injection is a solution containing foscarnet sodium, a non-nucleoside pyrophosphate analogue active against herpes viruses. Clinically, it is used as the trisodium salt mainly for the treatment of CMV retinitis in AIDS patients. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, potential target organs include the skin, eyes, respiratory tract, blood, bone, liver and kidneys.

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 occupational exposure. In clinical use, the major toxicity of foscarnet sodium is renal impairment. Foscarnet sodium has also been associated with changes in serum electrolytes including hypocalcemia, hypophosphatemia and hyperphosphatemia, hypomagnesemia, and hypokalemia. Foscarnet sodium treatment was associated with seizures. Anemia may be common and granulocytopenia and thrombocytopenia have been reported. Other adverse effects reported include nausea, vomiting, diarrhea, malaise, fatigue, fever,
Product Name: Foscarnet Sodium Injection

headache, dizziness, paraesthesia, tremor, mood disturbances, rash, abnormal liver function tests, blood pressure and ECG changes, and isolated reports of pancreatitis. Intravenous injection may cause phlebitis at the site of injection.

Medical Conditions
Aggravated by Exposure
Pre-existing hypersensitivity to this material; pre-existing blood, liver, or kidney 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 aqueous product.

Fire & Explosion Hazard
None anticipated for this aqueous product.

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. 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 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>Foscarnet Sodium</td>
<td>Not Applicable</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Not Established</td>
</tr>
</tbody>
</table>

**Respiratory protection**

Respiratory protection is normally not needed during intended product use. However, if the generation of 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 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**

Liquid

**Color**

Clear, Colorless

**Odor**

NA

**Odor Threshold:**

NA

**pH:**

7.4

**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:**

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), sodium oxides (NaOx) and phosphorus oxides (POx).

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>Foscarnet Sodium</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>500</td>
<td>mg/kg</td>
<td>Rat</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>510</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. However, inadvertent contact of this product with skin may produce mild irritation.

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.

Reproductive Effects Daily subcutaneous doses up to 75 mg/kg administered to female rats prior to and during mating, during gestation, and 21 days postpartum caused a slight increase (< 5%) in the number of skeletal anomalies compared with the control group. Daily subcutaneous doses up to 75 mg/kg administered to rabbits and 150 mg/kg administered to rats during gestation caused an increase in the frequency of skeletal anomalies/variations. On the basis of estimated drug exposure (as measured by AUC), the 150 mg/kg dose in rats and 75 mg/kg dose in rabbits were approximately one-eighth (rat) and one-third (rabbit) the estimated maximal daily human exposure.

Mutagenicity Foscarnet sodium showed genotoxic effects in the BALB/3T3 in vitro transformation assay at concentrations greater than 0.5 mcg/mL and an increased frequency of chromosome aberrations in the sister chromatid exchange assay at 1000 mcg/mL. A high dose of foscarnet (350 mg/kg) caused
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an increase in micronucleated polychromatic erythrocytes in vivo in mice at doses that produced exposures (area under curve) comparable to that anticipated clinically.

Carcinogenicity
Carcinogenicity studies were conducted in rats and mice at oral doses of 500 mg/kg/day and 250 mg/kg/day. Oral bioavailability in unfasted rodents is < 20%. No evidence of oncogenicity was reported at plasma drug levels equal to 1/3 and 1/5, respectively, of those in humans (at the maximum recommended human daily dose) as measured by the area-under-the-time/concentration curve (AUC).

Target Organ Effects
Based on clinical use, potential target organs include the skin, eyes, respiratory tract, blood, bone, liver and kidneys.

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
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
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 Foscarnet Sodium.

Classification(s): Not Applicable
Symbol: Not Applicable
Indication of Danger: Not Applicable
Risk Phrases: Not Applicable
Safety Phrases: S23 - Do not breathe vapor.
S24 - Avoid contact with skin.
S25 - Avoid contact with 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
**Product Name: Foscarnet Sodium Injection**

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: 09/23/2011
Obsolete Date: 10/21/2008

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