# MATERIAL SAFETY DATA SHEET

## 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

| Manufacturer Name And Address | Hospira Inc.  
|                              | 275 North Field Drive  
|                              | Lake Forest, Illinois USA  
|                              | 60045  
|                              | Hospira Australia Pty Ltd  
|                              | 1 Lexia Place  
|                              | Mulgrave, VIC 3170  
|                              | Australia  
| Emergency Telephone           | CHEMTREC: North America: 800-424-9300;  
|                              | International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418  
| Hospira, Inc., Non-Emergency  | 224-212-2000  
| Product Name                  | Bleomycin for Injection, USP  
| Synonyms                      | Blenoxane; Bleomycin A2, N1-[3-(dimethylsulfonio)propyl]-bleomycinamide;  
|                               | Bleomycin B2, N1-[4-(aminoiminomethyl)amino]butyl]-bleomycinamide.

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

| Active Ingredient Name | Bleomycin Sulfate  
| Chemical Formula       | Mixture of A2 (C_{55}H_{84}N_{17}O_{21}S_{3}), B2 (C_{55}H_{84}N_{20}O_{21}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>Bleomycin Sulfate</td>
<td>100</td>
<td>9041-93-4</td>
<td>EC5991990</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>Bleomycin Sulfate</td>
<td>2B</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

### Emergency Overview

Bleomycin for Injection, USP is a lyophilized powder that contains bleomycin sulfate, a mixture of cytotoxic glycopeptide antibiotics produced by *Streptomyces verticillus*. Clinically, bleomycin sulfate is an antineoplastic antibiotic to treat certain types of cancers. It is a cytotoxic agent, and should be considered a potential occupational reproductive hazard, harmful to the fetus, and a potential human carcinogen. Following an accidental over-exposure, possible target organs may include the lungs, liver, kidney, skin, cardiovascular system, and the fetus.

### Occupational Exposure Potential

There are scientific studies that suggest that personnel (e.g. nurses, pharmacists, etc.) who prepare and administer parenteral antineoplastics (e.g. in hospitals) may be at some risk due to potential mutagenicity, teratogenicity, and/or carcinogenicity of these agents if workplace exposures are not properly controlled. The actual risk in the workplace is not known.

### Signs and Symptoms

In the workplace, this product should be considered irritating to the skin, eyes, and respiratory
tract. In clinical use, the most serious adverse effect is a delayed pulmonary toxicity. Interstitial pneumonitis occurs in about 10% of patients, and progresses to fibrosis and death in about 1% of patients. Other adverse effects may include rash, erythema, pruritus, vesiculation, hyperkeratosis, nail changes, alopecia, and hyperpigmentation. Fever is also a common occurrence. Acute anaphylactoid-like reactions with hyperpyrexia and cardiorespiratory distress/collapse have occurred in about 1% of patients.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to bleomycin-like antibiotics. Pre-existing pulmonary, kidney, liver, skin, or cardiovascular ailments, or pregnancy.

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 material. 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
Firefighters should wear self-contained breathing apparatus. Protective equipment and clothing should be worn to minimize contact with the respiratory tract, skin and eyes.

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. 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
Bleomycin sulfate is a cytotoxic agent. Appropriate procedures should be implemented during the handling and disposal of cytotoxic antineoplastics.
agents to minimize potential exposures. Several guidelines on handling cytotoxic antineoplastic agents have been published. Consult your hygienist or safety professional for your site requirements. Avoid ingestion, inhalation, skin contact, and eye contact. When handling the powder, precautions may include the use of a containment cabinet during the weighing, reconstitution and/or solubilization of this antineoplastic agent. The use of disposable gloves and respiratory protection is recommended. Proper disposal of contaminated vials, syringes, or other materials is required when working with this material.

**Storage**

No special storage is required for hazard control. However, employees should be trained on the proper storage procedures for antineoplastic agents. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

**Special Precautions**

Persons with known allergies to bleomycin-like compounds, women who are pregnant, or women who want to become pregnant, should consult a health and/or safety professional prior to handling this material.

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### 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>Bleomycin Sulfate</td>
<td>Hospira EEL</td>
<td>N/A</td>
<td>N/A</td>
<td>0.05</td>
<td>8hr TWA</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 (N99 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**

When handling this material, disposable gloves should be worn at all times. Further, the use of double gloves is recommended. Disposable gloves made from nitrile, neoprene, polyurethane or natural latex generally have low permeability to this material. 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. Care should be taken to minimize inadvertent contamination when removing and/or disposing of gloves.

**Eye protection**

As a minimum, the use of chemical safety goggles is recommended when handling this material.

**Engineering Controls**

When handling the dry powder, local exhaust ventilation is recommended to minimize employee exposure. The use of an enclosure, such as an approved ventilated cabinet designed to minimize airborne exposures, is recommended.

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### 9. PHYSICAL/CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Appearance/Physical State</th>
<th>Solid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>cream colored, lyophilized powder</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
</tbody>
</table>
Product Name: Bleomycin for Injection, USP

pH: 0.5% solution in water 4.5 - 6.0
Melting point/Freezing point: 158-160oF
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 or saline; slightly soluble in dehydrated alcohol; practically insoluble in acetone.
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>
</tr>
</thead>
<tbody>
<tr>
<td>Bleomycin</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>&gt; 2000</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Bleomycin Sulfate</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>210</td>
<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td>Bleomycin</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>53</td>
<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td>Bleomycin Sulfate</td>
<td>100</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>240</td>
<td>mg/kg</td>
<td>Rat</td>
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<tr>
<td>Bleomycin Sulfate</td>
<td>100</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>210</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Bleomycin</td>
<td>100</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>168</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td>Bleomycin</td>
<td>100</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>35</td>
<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td>Bleomycin Sulfate</td>
<td>100</td>
<td>LD50</td>
<td>Subcutaneous</td>
<td>86</td>
<td>mg/kg</td>
<td>Rat</td>
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</table>
Product Name: Bleomycin for Injection, USP

<table>
<thead>
<tr>
<th></th>
<th>LD50</th>
<th>Route</th>
<th>Species</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleomycin Sulfate</td>
<td>100</td>
<td>Subcutaneous</td>
<td>Mouse</td>
<td>103 mg/kg</td>
</tr>
<tr>
<td>Bleomycin</td>
<td>100</td>
<td>Subcutaneous</td>
<td>Rat</td>
<td>168 mg/kg</td>
</tr>
<tr>
<td>Bleomycin</td>
<td>100</td>
<td>Subcutaneous</td>
<td>Mouse</td>
<td>188 mg/kg</td>
</tr>
</tbody>
</table>

**Aspiration Hazard**
None anticipated from normal handling of this material.

**Dermal Irritation/Corrosion**
None anticipated from normal handling of this material. However, inadvertent contact of this product with skin may produce irritation.

**Ocular Irritation/Corrosion**
None anticipated from normal handling of this material. 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 material. In clinical use, acute anaphylactoid-like reactions with hyperpyrexia and cardiorespiratory distress/collapse have occurred in about 1% of patients at clinical doses.

**Reproductive Effects**
The effects of bleomycin on fertility have not been fully evaluated. Bleomycin has been shown to be teratogenic in rats. Intraperitoneal administration to rats at a dosage of 1.5 mg/kg/day on days 6-15 of gestation caused skeletal malformations, and shortened innominate artery and hydrourerter. Bleomycin is an abortifacient, but not teratogenic, in rabbits at an intravenous dosage of 1.2 mg/kg/day when given on gestation days 6–18.

**Mutagenicity**
Bleomycin has been shown to be mutagenic in a battery of in vitro and in vivo assays.

**Carcinogenicity**
In a study where bleomycin was administered to rats by subcutaneous injection at a dosage of 0.35 mg/kg weekly, a dose-related increase in injection site fibrosarcomas, as well as various renal tumors, was noted.

**Target Organ Effects**
This material should be considered irritating to the skin, eyes, and respiratory tract. Following an accidental over-exposure, possible target organs may include the lungs, liver, kidney, skin, cardiovascular system, and the fetus.

### 12. ECOLOGICAL INFORMATION

**Aquatic Toxicity**
Not determined.

**Persistence/Biodegradability**
Not determined.

**Bioaccumulation**
Not determined.

**Mobility in Soil**
Not determined.

### 13. DISPOSAL CONSIDERATIONS

**Waste Disposal**
Disposal should be performed in accordance with the federal, state or local regulatory requirements.

**Container Handling and Disposal**
Dispose of containers 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>
</tr>
</thead>
<tbody>
<tr>
<td>Bleomycin Sulfate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

RCRA Status: Not Listed
U.S. OSHA Classification:
- Possible Skin Irritant
- Possible Eye Irritant
- Reproductive Toxin
- 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 Bleomycin Sulfate.

Classification(s): Not Applicable
Symbol: Not Applicable
Product Name: Bleomycin for Injection, USP

**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:**

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH TLV</td>
<td>American Conference of Governmental Industrial Hygienists – Threshold Limit Value</td>
</tr>
<tr>
<td>CAS</td>
<td>Chemical Abstracts Service Number</td>
</tr>
<tr>
<td>CERCLA</td>
<td>US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act</td>
</tr>
<tr>
<td>DOT</td>
<td>US Department of Transportation Regulations</td>
</tr>
<tr>
<td>EEL</td>
<td>Employee Exposure Limit</td>
</tr>
<tr>
<td>IATA</td>
<td>International Air Transport Association</td>
</tr>
<tr>
<td>LD50</td>
<td>Dosage producing 50% mortality</td>
</tr>
<tr>
<td>NA</td>
<td>Not applicable/Not available</td>
</tr>
<tr>
<td>NE</td>
<td>Not established</td>
</tr>
<tr>
<td>NIOSH</td>
<td>National Institute for Occupational Safety and Health</td>
</tr>
<tr>
<td>OSHA PEL</td>
<td>US Occupational Safety and Health Administration – Permissible Exposure Limit</td>
</tr>
<tr>
<td>Prop 65</td>
<td>California Proposition 65</td>
</tr>
<tr>
<td>RCRA</td>
<td>US EPA, Resource Conservation and Recovery Act</td>
</tr>
<tr>
<td>RTECS</td>
<td>Registry of Toxic Effects of Chemical Substances</td>
</tr>
<tr>
<td>SARA</td>
<td>Superfund Amendments and Reauthorization Act</td>
</tr>
<tr>
<td>STEL</td>
<td>15-minute Short Term Exposure Limit</td>
</tr>
<tr>
<td>TSCA</td>
<td>Toxic Substance Control Act</td>
</tr>
<tr>
<td>TWA</td>
<td>8-hour Time Weighted Average</td>
</tr>
</tbody>
</table>

MSDS Coordinator: Hospira GEHS

Date Prepared: 10/17/2012

Obsolete Date: 09/21/2011

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