



MATERIAL SAFETY DATA SHEET

Product Name: Bleomycin for Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA	Hospira Australia Pty Ltd 1 Lexia Place Mulgrave VIC 3170 AUSTRALIA
Emergency Telephone #'s	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia (02) 8014 4880	
Hospira, Inc., Non-Emergency	224 212-2055	
Material Name	Bleomycin for Injection, USP	
Synonyms	Blenoxane; Bleomycin A2, N1-[3-(dimethylsulfonio)propyl]-bleomycinamide; Bleomycin B2, N1-[4-(aminoiminomethyl)amino]butyl]-bleomycinamide.	

2. HAZARD INFORMATION / CLASSIFICATION

Emergency Overview	Bleomycin for Injection, USP is a lyophilized powder that contains bleomycin sulfate, a mixture of cytotoxic glycopeptide antibiotics produced by <i>Streptomyces verticillus</i> . 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.		
Carcinogen Lists:	IARC: Category 2B	NTP: Not listed	OSHA: Not listed

3. COMPOSITION/INFORMATION ON INGREDIENTS

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)

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Bleomycin Sulfate	100	9041-93-4	EC5991990

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	Not applicable.
Fire & Explosion Hazard	None anticipated for this material.
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	<p>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.</p> <p>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.</p>
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7. HANDLING AND STORAGE

Handling	<p>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.</p> <p>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.</p>
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7. HANDLING AND STORAGE: continued

- 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 USP controlled room temperature 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.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure limits			
	OSHA-PEL	ACGIH-TLV	Hospira EEL	Other Limits
Bleomycin Sulfate	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: 0.05 mcg/m ³	NA

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
 EEL: Employee Exposure Limit.
 TWA: 8 hour Time Weighted Average.
 STEL: 15-minute Short Term Exposure Limit.

- 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.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	A cream-colored, lyophilized powder in a vial.
Odor	NA
Odor Threshold:	NA
pH:	A 0.5% solution in water has a pH of 4.5 to 6.0.
Melting Point	158-160°F
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 (Air =1)	NA
Evaporation Rate	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 (CO _x), nitrogen oxides (NO _x), and sulfur oxides (SO _x).
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Bleomycin	100	LD50	Oral	> 2000	mg/kg	Mouse
Bleomycin Sulfate	100	LD50	Intravenous	210	mg/kg	Mouse
Bleomycin	100	LD50	Intravenous	53	mg/kg	Mouse

LD50 is the dosage producing 50% mortality.

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

DOT STATUS:	Not Regulated
Proper Shipping Name:	NA
Hazard Class:	NA
UN Number:	NA
Packing Group:	NA
Reportable Quantity:	NA

ICAO/IATA STATUS	Not Regulated
Proper Shipping Name:	NA
Hazard Class:	NA
UN Number:	NA
Packing Group:	NA
Reportable Quantity:	NA

IMDG STATUS	Not Regulated
Proper Shipping Name:	NA
Hazard Class:	NA
UN Number:	NA
Packing Group:	NA
Reportable Quantity:	NA

Notes: DOT – US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status	Exempt
CERCLA Status	Not listed
SARA 302 Status	Not listed
SARA 313 Status	Not listed
RCRA Status	Not listed
PROP 65 (Calif.)	Not listed





Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

<u>U.S. OSHA Classification</u>	Possible Skin Irritant Possible Eye Irritant Reproductive Toxin Target Organ Toxin
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15. REGULATORY INFORMATION: continued

GHS Classification*

*Where medicinal products are not exempt, the recommended GHS workplace classification for this product is as follows:

Hazard Class	Acute Oral Toxicity	Eye Irritation	Skin Irritation	Toxic to Reproduction	Mutagenicity	Target Organ Toxicity
Hazard Category	5	2B	2	2	2	2
Symbol	NA	NA				
Signal Word	Warning	Warning	Warning	Warning	Warning	Warning
Hazard Statement	May be harmful if swallowed	Causes eye irritation	Causes skin irritation	Suspected of damaging fertility or the unborn child	Suspected of causing genetic defects if ingested.	May cause damage to the lungs, liver, kidney, skin, and the cardiovascular system through prolonged or repeated exposure.

GHS Precautionary Statements:

Prevention: Do not eat, drink or smoke when using this product.
 Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Use personal protective equipment as required.
 Avoid breathing dust or vapors.
 In case of inadequate ventilation wear respiratory protection.
 Wear protective gloves.
 Wash hands thoroughly after handling.
 Contaminated work clothing should not be allowed out of the workplace.

Response: IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.
 IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms call a POISON CENTER or a doctor.
 IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs, seek medical attention. Take off contaminated clothing and wash before reuse.
 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.
 If exposed or concerned, get medical attention.

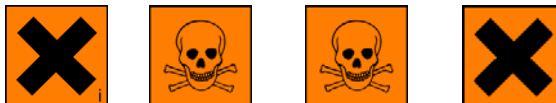
15. REGULATORY INFORMATION: continued

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): Irritant Mutagen Category 2 Toxic for Reproduction Category 2 Carcinogen Category 3

Symbol:



Indication of Danger: Xi T T Xn

Risk Phrases:

R36/37/38 - Irritating to eyes, respiratory system and skin
 R40 - Limited evidence of a carcinogenic effect
 R46 - May cause heritable genetic damage
 R48/25 - Danger of serious damage to health by prolonged exposure if swallowed
 R60 - May impair fertility
 R61 - May cause harm to the unborn child
 R64 - May cause harm to breastfed babies

Safety Phrases:

S22: Do not breathe dust
 S24: Avoid contact with the skin;
 S36/37/39 Wear suitable protective clothing, 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
LD ₅₀	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
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

16. OTHER INFORMATION: continued

MSDS Coordinator: Global Occupational Toxicology
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Disclaimer:

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