

SAFETY DATA SHEET

Product Name: Bleomycin for Injection, USP

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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 - 61-290372994; UK - 44-870-8200418	
Hospira, Inc., Non-Emergency	224 212-2000	
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(S) IDENTIFICATION

Emergency Overview Bleomycin for Injection, USP is a lyophilized powder containing 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. In the workplace, this material should be considered cytotoxic, a potential occupational reproductive hazard, and a possible human carcinogen. Based on clinical use, possible target organs may include the lungs, liver, kidney, skin, and cardiovascular system.

U.S. OSHA GHS Classification

Physical Hazards	Hazard Class	Hazard Category
	Not Classified	Not Classified

Health Hazards	Hazard Class	Hazard Category
	Skin Corrosion/Irritation	2
	Eye damage/Irritation	2
	Germ Cell Mutagenicity	2
	Toxic to Reproduction	2
	STOT - RE	2

Label Element(s)

Pictogram



Signal Word

Warning

Hazard Statement(s)

Causes skin irritation
Causes serious eye irritation
Suspected of causing genetic defects
Suspected of damaging fertility or the unborn child
May cause damage to organs through prolonged or repeated exposure

2. HAZARD(S) IDENTIFICATION: continued

U.S. OSHA GHS Classification: continued

Precautionary Statement(s)

Prevention

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves/protective clothing/eye protection/face protection.
Do not breathe dust/fume/vapors/spray.
Wash hands thoroughly after handling.

Response

If exposed or concerned: Get medical advice/attention. Get medical attention if you feel unwell.

IF ON SKIN: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Bleomycin Sulfate
Chemical Formula Mixture of A2 (C₅₅H₈₄N₁₇O₂₁S₃), B2 (C₅₅H₈₄N₂₀O₂₁S₂)

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

Sulfuric acid or sodium hydroxide may be used to adjust the pH.

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 elevated 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 such as carbon dioxide, dry chemical extinguishing powder or foam.

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 Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Collect powder using techniques that minimize the creation of airborne dust. If spill occurs after reconstitution, absorb any 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 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 open containers of this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure Limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Bleomycin Sulfate	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
 AIHA WEEL: Workplace Environmental Exposure Level
 EEL: Employee Exposure Limit.
 TWA: 8-hour Time Weighted Average.

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/Freezing Point	158-160°F
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	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
Viscosity	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:

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.

11. TOXICOLOGICAL INFORMATION: continued

Occupational Exposure Potential	There are scientific studies which 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	None anticipated from normal handling of this material. 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.		
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	None anticipated from normal handling of this material. 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 hydroureter. 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. FDA Pregnancy Category D.		
Mutagenicity	Bleomycin has been shown to be mutagenic in a battery of <i>in vitro</i> and <i>in vivo</i> 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.		
Carcinogen Lists	IARC: Bleomycin has been classified by IARC as possibly carcinogenic to humans (group 2B)	NTP: Not listed	OSHA: Not listed
Specific Target Organ Toxicity – Single Exposure	NA		
Specific Target Organ Toxicity – Repeat Exposure	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, and cardiovascular system.		

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.

Notes:

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
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

US TSCA Status	Exempt.
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US 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

15. REGULATORY INFORMATION: continued

GHS/CLP 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	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. Do not breathe dust/fume/vapors/spray. Wash hands thoroughly after handling.			
Response	If exposed or concerned: Get medical advice/attention. Get medical attention if you feel unwell. IF ON SKIN: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it 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.			

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

Classification(s)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	NA
Safety Phrases	S23: Do not breathe vapor/spray S24: Avoid contact with the 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
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
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

16. OTHER INFORMATION: continued

MSDS Coordinator: Hospira GEHS
Date Prepared: October 17, 2012
Date Revised: June 02, 2014

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