



Material Safety Data Sheet

Bleomycin Sulfate for Injection, USP

1. PRODUCT IDENTIFICATION

Product Name	Bleomycin Sulfate for Injection, USP
Product Use	Medical treatment of squamous cell carcinomas, lymphomas, testicular carcinomas
Manufacturer	Teva Sicor Pharmaceuticals, Inc.
Address	11 Hughes Irvine, CA 92618-1902
Chemtrec Emergency No.	1-800-424-9300 (United States) 1-202-483-7617 (International Collect)
Business Phone	1-800-729-9991
Website Address	http://www.newsicor.com
Common Names	Bleomycin, Blenoxane
Chemical Name	Bleomycin A ₂ - N ₁ -[3-(dimethylsulfonic) propyl]-bleomycinamide Bleomycin B ₂ - N ₁ -[4(aminoiminomethyl)amino] butyl]-bleomycinamid
Chemical Formula	Bleomycin A ₂ - C ₅₅ H ₈₄ N ₁₇ O ₂₁ S ₃ Bleomycin B ₂ - C ₅₅ H ₈₄ N ₂₀ O ₂₁ S ₂
Chemical Family	Glycopeptide antibiotic
How Supplied	15 units of compound/vial
Date of Preparation:	December 2, 2005

2. COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	Wt%	EXPOSURE LIMITS IN AIR				
			ACGIH		OSHA		Other
			TLV	STEL	PEL	STEL	
Bleomycin Sulfate, USP	9041-93-4	100	NE	NE	NE	NE	NE

NE - Not Established C - Ceiling Limit

NOTE: All WHMIS required information is included. It is located in appropriate sections based on the ANSI Z400.1 format

CHEMTREC NUMBER: Use only in the event of a chemical emergency involving a spill, leak, fire, exposure or accident involving this drug.

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: Material is a colorless to yellow powder. It is a cytotoxic agent and possible cancer hazard. May cause damage to lungs. May cause allergic skin and/or respiratory reactions. Harmful to the fetus. Fine powders are considered combustible. Avoid contact with eyes, skin and clothing. Avoid exposure during pregnancy and while breastfeeding. Do not taste or swallow. Wash thoroughly after handling.

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3. HAZARD IDENTIFICATION cont...

Symptoms of Overexposure by Route of Exposure: This material is intended for injection under the supervision of physicians.

Inhalation: Inhalation of significant amounts of the product is not anticipated to occur because of the small size of individual containers.

Contact with Skin or Eyes: Contact may cause mild irritation. Effects may include stinging, watering, and redness of the eyes and redness, itching, and a burning sensation on the skin. May cause an allergic skin reaction. .

Ingestion: Ingestion is not an anticipated route of occupational exposure. However, it is considered slightly toxic based on animal data. Symptoms similar to those identified under injection may occur.

Injection: Local redness and pain are the primary symptoms of accidental injection in an occupational setting. Medical personnel are not anticipated to experience over-exposures to the therapeutic doses of this product. However, effects including coughing, sneezing, breathing difficulties, nausea, vomiting, skin rash, hyperpigmentation, weight loss, fever, chills, mental confusion, nail changes, alopecia, pneumonitis (inflammation of the lungs) and pulmonary fibrosis may occur. See package insert for other adverse reactions associated with therapeutic doses of this product.

Health Effects or Risks From Exposure (An explanation in lay terms):

Acute: The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, effects such as coughing, sneezing, breathing difficulties, nausea, vomiting, skin rash, hyperpigmentation, weight loss, fever, chills, mental confusion, nail changes, hair loss, pneumonitis (inflammation of the lungs) and pulmonary fibrosis may occur.

Cancer: Probable cancer hazard (see Section 11). .

Chronic: Potential hazard to the fetus (see Section 11). .

Target Organs: Potential hazard to the lungs (see Section 11). .

Pre-Existing Medical Conditions: Conditions aggravated by exposure may include skin and respiratory (asthma-like) disorders.

4. FIRST-AID MEASURES

Skin Exposure: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.

Eye Exposure: If irritation or redness develops, move victim away from exposure and into fresh air. Flush eyes with clean water and seek medical attention.



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6. ACCIDENTAL RELEASE MEASURES

Spill and Leak Response:

For small releases of this product, wear latex or nitrile gloves and safety glasses. Absorb spilled liquid and rinse area thoroughly with soap and water.

For large or uncontrolled releases, stay away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

7. HANDLING and STORAGE

BLEOMYCIN SULFATE IS A CYTOTOXIC AGENT. ALL WORK PRACTICES MUST BE DESIGNED TO REDUCE HUMAN EXPOSURE TO THE LOWEST LEVEL.

Work and Hygiene Practices: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities:

- Withdrawal of needles from drug vials.
- Drug transfers using syringes and needles or filter straws.
- Expulsion of air from drug-filled syringes.

Storage and Handling Practices: Employees must be trained to properly use the product. Ensure vials are properly labeled. Store only in approved containers. Protect from light. Keep away from any incompatible materials or conditions (see Section 10). Store at 2-8°C (36-46°F).

Protective Practices During Maintenance of Contaminated Equipment: When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly.



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8. EXPOSURE CONTROLS - PERSONAL PROTECTION

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures.

Respiratory Protection: Not normally required for routine, medical administration of this product. A NIOSH certified air-purifying respirator with a type 100 filter may be used under conditions where airborne concentrations are expected to be excessive. Protection provided by air purifying respirators is limited (see manufacturer's respirator selection guide). Use a positive pressure air supplied respirator if there is potential for uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions warrant a respirator's use.

Eye Protection: Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended. Depending on conditions of use, a face shield may be necessary.

Hand Protection: Use latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before and after using gloves.

Body Protection: A full body gown which is closed at the front and has long sleeves is recommended.

Product Preparation Instructions for Medical Personnel: Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

9. PHYSICAL and CHEMICAL PROPERTIES

Relative Vapor Density (air = 1):	Not applicable	Evaporation Rate (n-BuAc=1):	Not applicable
Specific Gravity (water = 1):	Not determined	Melting/Freezing Point:	71°C (160°F)
Solubility in Water:	14 mg/mL	Boiling Point:	Not determined
Vapor Pressure, mm Hg @ 25°C.	Not applicable	pH: (sol. reconst. for injection)	4.5-6
Odor Threshold: Odorless			
Appearance and Color: Colorless to yellowish powder			

ND = No Data

10. STABILITY and REACTIVITY

Stability: Stable under normal conditions of storage and handling.

Materials With Which Substance is Incompatible: This product is generally compatible with other common materials in a medical facility. Keep away from acids and caustics.

Hazardous Polymerization: Will not occur.

Hazardous Combustion Products: Heat may cause product to decompose, destroying the product or producing toxic fumes.



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11. TOXICOLOGICAL INFORMATION

Toxicity Data: The following information is for Bleomycin Sulfate the active ingredient

Oral LD50(rat) >2 g/kg	Subcutaneous LD50(rat) = 86 mg/kg
IV LD50 (mouse) = 210 mg/kg	Subcutaneous LD50(mouse) = 103 mg/kg
IP LD50((rat) = 240 mg/kg	IP LD50 (mouse) = 210 mg/kg

Suspected Cancer Agent: At doses of 0.35 mg/kg weekly in the rat, there was a dose-related increase in injection site fibrosarcomas and renal (kidney) tumors. It is listed as carcinogenic by OSHA and IARC.

Irritancy of Product: This product is expected to be mildly irritating to eyes and skin.

Sensitization to the Product: Allergic skin response from repeated clinical use.

Reproductive Toxicity Information: Listed below is information concerning the effects of Bleomycin Sulfate on human and animal reproductive systems. This material is classified as a Pregnancy Category D (Positive evidence of risk).

Mutagenicity: Bleomycin is mutagenic in a battery of in-vitro and in-vivo studies.

Embryotoxicity/Teratogenicity/Reproductive Toxicity: No data available on reproductive toxicity. Bleomycin was teratogenic in rats at a dose of 1.5 mg/kg/day during gestation. Bleomycin is an abortifacient, but not teratogenic in rabbits at doses of 1.2 mg/kg/day.

ACGIH Biological Exposure Indices: Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

12. ECOLOGICAL INFORMATION

All work practices must be aimed at eliminating environmental contamination.

Environmental Stability: This product will be relatively stable under ambient environmental conditions.

Effect of Materials on Plants or Animals: No specific information is available on the effect of Bleomycin Sulfate on plants or animals in the environment.

Effect of Chemicals on Aquatic Life: No specific information is available on the effect of Bleomycin Sulfate on plants or animals in the aquatic environment.

13. DISPOSAL CONSIDERATIONS

Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

U.S. EPA Waste Number: None



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14. TRANSPORTATION INFORMATION

This Materials is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation

Proper Shipping Name: Not applicable

Hazard Class Number and Description: Not applicable

UN Identification Number: Not applicable

Packing Group: Not applicable

DOT Label(s) Required: Not applicable

North American Emergency Response Guidebook Number (1996): Not applicable.

MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)

Transport Canada Transportation of Dangerous Goods Regulations: Not applicable.

15. REGULATORY INFORMATION

U.S. REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304 and 313 of Title II of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity: Not applicable

U.S. CERCLA Reportable Quantities (RQ): Not applicable

U.S. TSCA Inventory Status: Bleomycin Sulfate is a "drug" as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product does NOT contain chemicals known to the State of California to cause cancer or reproductive effects.

Other U.S. Federal Regulations: Based on this product's use, the requirements of the OSHA Bloodborne pathogen Standard (29 CFR 1910.1030) are applicable.

CANADIAN REGULATIONS:

Canadian DSL/NDSL Status: Bleomycin Sulfate is regulated by the Food and Drug Administration of Health Canada and is therefore exempt from the requirements of CEPA.

ANSI Labeling (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): DANGER! Cytotoxic agent and possible cancer hazard. May cause damage to lungs. May cause allergic skin and respiratory reactions. Harmful to the fetus. Fine powders are considered combustible. Avoid contact with eyes, skin and clothing. Avoid exposure during pregnancy and while breastfeeding. Do not taste or swallow. Wash thoroughly after handling. Avoid accidental injection. Do not eat, drink or smoke when handling. Clean up spills promptly.



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16. OTHER INFORMATION

Issue Date: 12/03/05

Previous Issue Date: 3/20/98

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