

## SAFETY DATA SHEET

### SECTION 1 : IDENTIFICATION

**Product Name:** **Bleomycin for Injection, USP**  
**Product Use/Restriction:** Antineoplastic.  
**Manufacturer Name:** Fresenius Kabi USA, LLC  
**Address:** Three Corporate Drive  
 Lake Zurich, Illinois 60047  
**General Phone Number:** (847) 550-2300  
**Customer Service Phone Number:** (888) 386-1300  
**Health Issues Information:** (800) 551-7176  
**SDS Creation Date:** June 01, 2015  
**SDS Revision Date:** February 13, 2024

### SECTION 2 : HAZARD(S) IDENTIFICATION

**GHS Pictograms:**



**Signal Word:** DANGER.

**GHS Class:** Respiratory sensitisation. category 1.  
 Carcinogenicity. Category 1A.  
 Germ cell mutagenicity. Category 2.  
 Reproductive toxicity. Category 2.  
 Skin Irritation. Category 2.  
 Skin Sensitization. category 1.  
 Reproductive toxicity. Effects on or via lactation.

**Hazard Statements:** May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
 May cause cancer.  
 Suspected of causing genetic defects.  
 Suspected of damaging fertility or the unborn child.  
 Causes skin irritation.  
 May cause an allergic skin reaction.  
 May cause harm to breast-fed children.

**Precautionary Statements:** Obtain special instructions before use.  
 Do not handle until all safety precautions have been read and understood.  
 Do not breathe dust/fume/gas/mist/vapours/spray.  
 Avoid breathing dust/fume/gas/mist/vapours/spray.  
 Avoid contact during pregnancy and while nursing.  
 Wash hands thoroughly after handling.  
 Do not eat, drink or smoke when using this product.  
 Contaminated work clothing should not be allowed out of the workplace.  
 Wear protective gloves/protective clothing/eye protection/face protection.  
 In case of inadequate ventilation wear respiratory protection.  
 IF ON SKIN: Wash with plenty of water.  
 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  
 IF exposed or concerned: Get medical advice/attention.  
 Specific treatment (see ... on this label).  
 If skin irritation occurs: Get medical advice/attention.  
 If skin irritation or rash occurs: Get medical advice/attention.  
 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.  
 Take off contaminated clothing and wash it before reuse.  
 Store locked up.  
 Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

**Emergency Overview:** This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

**Route of Exposure:** Inhalation, Ingestion, Eye contact, Skin Absorption., Injection.

**Potential Health Effects:** There is limited but increasing evidence that personnel involved in the preparation and administration of parenteral antineoplastics may be at some risk due to potential mutagenicity, teratogenicity, and/or carcinogenicity of these agents. The actual risk is not known..Occupational exposure has not been fully investigated.

**Eye:** Contact with eyes may cause irritation.

**Skin:** May cause skin irritation.

**Inhalation:** May cause irritation of respiratory tract.

**Ingestion:** May cause irritation.

**Signs/Symptoms:** Adverse reactions from therapeutic doses include: hypotension, mental confusion, fever, chills, wheezing, rales, dyspnea, erythema, rash, striae, vesiculation, hyperpigmentation, skin tenderness, hyperkeratosis, nail changes, alopecia, puritis, and stomatitis. Occupational exposure has not been fully investigated.

**Aggravation of Pre-Existing Conditions:** Individuals with hypersensitivity or previous idiosyncratic reaction to bleomycin. Individuals with impaired renal function or compromised pulmonary function.

## SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Bleomycin Sulfate	9041-93-4	100 %	
<b>Chemical Name:</b>	N'-[3-(dimethylsulphonio)propyl]bleomycin-amide (bleomycin A2) and N'-[4-(guaniodobutyl)]bleomycin-amide (bleomycin B2)		

## SECTION 4 : FIRST AID MEASURES

<b>Eye Contact:</b>	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
<b>Skin Contact:</b>	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
<b>Inhalation:</b>	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
<b>Ingestion:</b>	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
<b>Other First Aid:</b>	For Adverse Event Information, please call Vigilance: (905) 770-3711.

## SECTION 5 : FIRE FIGHTING MEASURES

<b>Flash Point:</b>	Not established.
<b>Flash Point Method:</b>	Not established.
<b>Auto Ignition Temperature:</b>	Not established.
<b>Lower Flammable/Explosive Limit:</b>	Not established.
<b>Upper Flammable/Explosive Limit:</b>	Not established.
<b>Fire Fighting Instructions:</b>	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
<b>Extinguishing Media:</b>	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Protective Equipment:</b>	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
<b>Hazardous Combustion Byproducts:</b>	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

## SECTION 6 : ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions:</b>	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing dust. Use proper personal protective equipment as listed in Section 8.
<b>Environmental Precautions:</b>	Avoid runoff into storm sewers, ditches, and waterways.
<b>Methods for containment:</b>	This material will settle out of the air.
<b>Methods for cleanup:</b>	Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

## SECTION 7 : HANDLING and STORAGE

<b>Handling:</b>	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions. The US Pharmacopeia advisory panels recommends the cautious handling in both preparation and disposal of antineoplastic agents. Precautions that have been suggested include: use of a biological containment cabinet during reconstitution and dilution of parenteral medications, use of disposable surgical gloves and masks, use of proper technique to prevent contamination of medication onto the work area and operator, and proper disposal of needles, syringes, vials, and ampules.
<b>Storage:</b>	Store at refrigerated temperatures 2 to 8°C (36 to 46°F). Avoid contact with incompatible materials.
<b>Work Practices:</b>	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
<b>Hygiene Practices:</b>	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling dust, vapor or mist.

## SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

<b>Engineering Controls:</b>	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
<b>Eye/Face Protection:</b>	Chemical splash goggles. Wear a face shield also when splash hazard exist.
<b>Skin Protection Description:</b>	Protective laboratory coat, apron, or disposable garment recommended.
<b>Hand Protection Description:</b>	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
<b>Respiratory Protection:</b>	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site ( <a href="http://www.cdc.gov/niosh/npptl/topics/respirators/">http://www.cdc.gov/niosh/npptl/topics/respirators/</a> ) for a list of respirator types and approved suppliers.
<b>Other Protective:</b>	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

### EXPOSURE GUIDELINES

#### **Bleomycin Sulfate:**

<b>Guideline ACGIH:</b>	Not established.
<b>Guideline OSHA:</b>	Not established.

## SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

<b>Physical State:</b>	Lyophilized powder.
<b>Color:</b>	Clear to yellow.
<b>Boiling Point:</b>	Not established.
<b>Melting Point:</b>	71 deg C (160 deg F)
<b>Solubility:</b>	Freely soluble in water.
<b>Vapor Density:</b>	Not established.
<b>Vapor Pressure:</b>	Not established.
<b>Percent Volatile:</b>	Not established.
<b>pH:</b>	4.5-6 (1% solution)
<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	1416.6
<b>Flash Point:</b>	Not established.
<b>Flash Point Method:</b>	Not established.
<b>Auto Ignition Temperature:</b>	Not established.

## SECTION 10 : STABILITY and REACTIVITY

<b>Chemical Stability:</b>	Stable under normal temperatures and pressures.
<b>Hazardous Polymerization:</b>	Not reported.
<b>Conditions to Avoid:</b>	Protect from freezing.

## SECTION 11 : TOXICOLOGICAL INFORMATION

#### **Bleomycin Sulfate:**

<b>RTECS Number:</b>	EC5988000
<b>Ingestion:</b>	Oral - Mouse LD50: >2 gm/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)
<b>Chronic Effects:</b>	Toxicity including pulmonary fibrosis, renal, and hepatic toxicities.
<b>Carcinogenicity:</b>	IARC: Group 2B: Possibly carcinogenic to humans. Not listed
<b>Teratogenicity:</b>	Bleomycin can cause fetal harm and should not be given during pregnancy. Women of childbearing age should be advised to avoid becoming pregnant during therapy with bleomycin.

**Other Toxicological Information:** Subcutaneous - Mouse LD50: 188 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Subcutaneous - Rat LD50: 168 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Intraperitoneal. - Rat LD50: 168 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Intraperitoneal. - Mouse LD50: 35 mg/kg [Tumorigenic - Active as anti-cancer agent]  
Intramuscular - Mouse LD50: 270 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Intravenous. - Mouse LD50: 53 mg/kg [Details of toxic effects not reported other than lethal dose value](RTECS)

## SECTION 12 : ECOLOGICAL INFORMATION

**Ecotoxicity:** No ecotoxicity data was found for the product.  
**Environmental Stability:** No environmental information found for this product.

## SECTION 13 : DISPOSAL CONSIDERATIONS

**Waste Disposal:** Dispose of in accordance with Local, State, Federal and Provincial regulations.

## SECTION 14 : TRANSPORT INFORMATION

**DOT Shipping Name:** Not Regulated.  
**DOT UN Number:** Not Regulated.

## SECTION 15 : REGULATORY INFORMATION

### **Bleomycin Sulfate :**

**TSCA Inventory Status:** Listed  
**Canada DSL:** Listed

## SECTION 16 : ADDITIONAL INFORMATION

### HMIS Ratings:

**HMIS Health Hazard:** 3\*  
**HMIS Fire Hazard:** 0  
**HMIS Reactivity:** 0  
**HMIS Personal Protection:** C

**SDS Creation Date:** June 01, 2015  
**SDS Revision Date:** February 13, 2024  
**SDS Revision Notes:** Overall SDS review - no changes to formulation. Updated the HMIS rating for Personal Protective Equipment (PPE) only.

**Disclaimer:** The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

Copyright© 1996-2018 Enviance. All Rights Reserved.