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Function: Regulatory Affairs	Effective Date: July 15, 2020	Version Number: 2.0

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form:** Substance

**Product Name:** Bleomycin for Injection, USP

**CAS-No.:** 9041-93-4

### 1.2. Intended Use of the Product

**Use of the Substance/Mixture:** Pharmaceutucial, use only as directed. Refer to product insert for product information and usage instructions. Antineoplastic, Antibacterial. For professional use only.

### 1.3. Name, Address, and Telephone of the Responsible Party

#### Company

Meitheal Pharmaceuticals, Inc.  
8700 W. Bryn Mawr, Suite 600S  
Chicago, IL 60631  
224-443-4617

[www.meithealpharma.com](http://www.meithealpharma.com)

### 1.4. Emergency Telephone Number

**Emergency Number** : 844-824-8426

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

Skin Irrit. 2	H315
Eye Irrit. 2	H319
Skin Sens. 1	H317
Muta. 1B	H340
Carc. 2	H351
Repr. 1B	H360
Lact.	H362
STOT RE 1	H372
Comb. Dust	

Full text of hazard classes and H-statements : see section 16

### 2.2. Label Elements

#### GHS-US Labeling

**Hazard Pictograms (GHS-US)**



**Signal Word (GHS-US)**

: Danger

**Hazard Statements (GHS-US)**

: May form combustible dust concentrations in air.  
H315 - Causes skin irritation.  
H317 - May cause an allergic skin reaction.  
H319 - Causes serious eye irritation.  
H340 - May cause genetic defects.



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**Precautionary Statements (GHS-US)**

- H351 - Suspected of causing cancer.
- H360 - May damage fertility or the unborn child.
- H362 - May cause harm to breast-fed children.
- H372 - Causes damage to organs through prolonged or repeated exposure.
- P201 - Obtain special instructions before use.
- P202 - Do not handle until all safety precautions have been read and understood.
- P260 - Do not breathe dust.
- P263 - Avoid contact during pregnancy/while nursing.
- P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
- P270 - Do not eat, drink or smoke when using this product.
- P272 - Contaminated work clothing must not be allowed out of the workplace.
- P280 - Wear protective gloves, protective clothing, and eye protection.
- P302+P352 - If on skin: Wash with plenty of water.
- P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P308+P313 - If exposed or concerned: Get medical advice/attention.
- P314 - Get medical advice/attention if you feel unwell.
- P321 - Specific treatment (see section 4 on this SDS).
- P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
- P337+P313 - If eye irritation persists: Get medical advice/attention.
- P362+P364 - Take off contaminated clothing and wash it before reuse.
- P405 - Store locked up.
- P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

**2.3. Other Hazards**

Exposure may aggravate pre-existing eye, skin, or respiratory conditions. Exposure may aggravate individuals with pre-existing skin, kidney, liver, and pulmonary disorders

**2.4. Unknown Acute Toxicity (GHS-US)**

No data available

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

**3.1. Substance**

Name : Bleomycin for Injection, USP  
 CAS-No. : 9041-93-4

Name	Product Identifier	%	GHS-US classification
Bleomycin, sulfate (salt)	(CAS-No.) 9041-93-4	100	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 Muta. 1B, H340 Carc. 2, H351 Lact., H362 Repr. 1B, H360 STOT RE 1, H372 Comb. Dust



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Full text of H-phrases: see section 16

### 3.2. Mixture

Not applicable

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of First-aid Measures

**First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

**First-aid Measures After Inhalation:** Using proper respiratory protection, move the exposed person to fresh air at once. Encourage exposed person to cough, spit out, and blow nose to remove dust. Immediately call a poison center, physician, or emergency medical service.

**First-aid Measures After Skin Contact:** Remove contaminated clothing. Immediately drench affected area with water for at least 15 minutes. If exposed or concerned: Get medical advice/attention.

**First-aid Measures After Eye Contact:** Immediately rinse with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

**First-aid Measures After Ingestion:** Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

### 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**Symptoms/Injuries:** Please refer to the package insert for more detailed information. Causes skin irritation. Causes serious eye irritation. Skin sensitization. Causes damage to organs through prolonged or repeated exposure. May cause genetic defects. Suspected of causing cancer. May damage fertility. May damage the unborn child. May cause harm to breast-fed children.

**Symptoms/Injuries After Inhalation:** Dust may be harmful or cause irritation.

**Symptoms/Injuries After Skin Contact:** May cause an allergic skin reaction. Redness, pain, swelling, itching, burning, dryness, and dermatitis.

**Symptoms/Injuries After Eye Contact:** Contact causes severe irritation with redness and swelling of the conjunctiva.

**Symptoms/Injuries After Ingestion:** Potent pharmaceutical- ingestion may be harmful or have adverse effects.

**Chronic Symptoms:** Causes damage to organs (lungs) through prolonged or repeated exposure. May cause genetic defects. Suspected of causing cancer. May damage fertility or the unborn child.

### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

In the event of accidental injection, immediately call a poison center or seek medical advice. If exposed or concerned, get medical advice and attention.

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Water spray, fog, carbon dioxide (CO<sub>2</sub>), alcohol-resistant foam, or dry chemical.

**Unsuitable Extinguishing Media:** Do not use a heavy water stream. Use of heavy stream of water may spread fire.

### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Combustible Dust.

**Explosion Hazard:** Dust explosion hazard in air.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers. Do not breathe fumes from fires or vapours from decomposition.



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**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** Carbon oxides (CO, CO<sub>2</sub>). Nitrogen oxides. Sulfur oxides. Sodium oxides.

**Other Information:** Risk of dust explosion.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Do not breathe dust. Do not get in eyes, on skin, or on clothing. Avoid generating dust. Remove ignition sources. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking.

#### 6.1.1. For Non-Emergency Personnel

**Protective Equipment:** Use appropriate personal protective equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Personnel

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and Materials for Containment and Cleaning Up

**For Containment:** Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams. Avoid generation of dust during clean-up of spills.

**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Use explosion proof vacuum during cleanup, with appropriate filter. Do not mix with other materials. Vacuum clean-up is preferred. If sweeping is required use a dust suppressant. Use only non-sparking tools. Contact competent authorities after a spill.

### 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Additional Hazards When Processed:** Accumulation and dispersion of dust with an ignition source can cause a combustible dust explosion. Keep dust levels to a minimum and follow applicable regulations.

**Precautions for Safe Handling:** Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not breathe dust. Do not get in eyes, on skin, or on clothing. Avoid contact during pregnancy/while nursing. Avoid creating or spreading dust. Keep away from heat, sparks, open flames, and hot surfaces. No smoking.

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations. Avoid creating or spreading dust. Use explosion-proof electrical, ventilating, lighting equipment. Proper grounding procedures to avoid static electricity should be followed.

**Storage Conditions:** Store in a dry, cool and well-ventilated place. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area. Protect from moisture.

**Incompatible Materials:** Strong acids, strong bases, strong oxidizers. Moisture.

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### 7.3. Specific End Use(s)

Pharmaceutical, use only as directed. Refer to product insert for product information and usage instructions. Antineoplastic, Antibacterial. For professional use only.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

### 8.2. Exposure Controls

#### Appropriate Engineering Controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment. Use local exhaust or general dilution ventilation or other suppression methods to maintain dust levels below exposure limits. Power equipment should be equipped with proper dust collection devices. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment. Ensure all national/local regulations are observed.

#### Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



#### Materials for Protective Clothing

##### Hand Protection

: Chemically resistant materials and fabrics.

##### Eye and Face Protection

: Wear protective gloves.

##### Skin and Body Protection

: Chemical safety goggles.

##### Respiratory Protection

: Wear suitable protective clothing.

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

#### Consumer Exposure Controls

: Avoid contact during pregnancy/while nursing.

#### Other Information

: When using, do not eat, drink or smoke.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

#### Physical State

: Solid

#### Appearance

: Lyophilized powder in vial. When reconstituted, a colorless to slightly yellow solution.



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<b>Odor</b>	: Odorless
<b>Odor Threshold</b>	: No data available
<b>pH</b>	: 4.5 - 6.0 (Reconstituted)
<b>Evaporation Rate</b>	: No data available
<b>Melting Point</b>	: 71 °C (159.8 °F)
<b>Freezing Point</b>	: No data available
<b>Boiling Point</b>	: No data available
<b>Flash Point</b>	: No data available
<b>Auto-ignition Temperature</b>	: No data available
<b>Decomposition Temperature</b>	: No data available
<b>Flammability (solid, gas)</b>	: No data available
<b>Vapor Pressure</b>	: No data available
<b>Relative Vapor Density at 20°C</b>	: No data available
<b>Relative Density</b>	: No data available
<b>Solubility</b>	: Water: Soluble
<b>Partition Coefficient: N-Octanol/Water</b>	: No data available
<b>Viscosity</b>	: No data available

**9.2. Other Information** No additional information available

## SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials. Sparks, heat, open flame and other sources of ignition. Dust accumulation (to minimize explosion hazard).
- 10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers. Moisture.
- 10.6. Hazardous Decomposition Products:** Thermal decomposition generates: Nitrogen oxides. Sulfur oxides. Carbon oxides (CO, CO<sub>2</sub>). Sodium oxides.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects

**Acute Toxicity:** Not classified

**Skin Corrosion/Irritation:** Causes skin irritation.

**pH:** 4.5 - 6.0 (Reconstituted)

**Serious Eye Damage/Irritation:** Causes serious eye irritation.

**pH:** 4.5 - 6.0 (Reconstituted)

**Respiratory or Skin Sensitization:** May cause an allergic skin reaction.

**Germ Cell Mutagenicity:** May cause genetic defects.

**Carcinogenicity:** Suspected of causing cancer.

**Bleomycin, sulfate (salt) (9041-93-4)**



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<b>IARC group</b>	2B
<b>OSHA Hazard Communication Carcinogen List</b>	In OSHA Hazard Communication Carcinogen list.

**Reproductive Toxicity:** May damage fertility or the unborn child. May cause harm to breast-fed children. (This material or its emissions may appear in breast milk of nursing mothers.)

**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Causes damage to organs through prolonged or repeated exposure.

**Aspiration Hazard:** Not classified

**Symptoms/Injuries After Inhalation:** Dust may be harmful or cause irritation.

**Symptoms/Injuries After Skin Contact:** May cause an allergic skin reaction. Redness, pain, swelling, itching, burning, dryness, and dermatitis.

**Symptoms/Injuries After Eye Contact:** Contact causes severe irritation with redness and swelling of the conjunctiva.

**Symptoms/Injuries After Ingestion:** Potent pharmaceutical- ingestion may be harmful or have adverse effects.

**Chronic Symptoms:** Causes damage to organs (lungs) through prolonged or repeated exposure. May cause genetic defects. Suspected of causing cancer. May damage fertility or the unborn child.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecology - General** : Not classified.

### 12.2. Persistence and Degradability

**Bleomycin for Injection, USP (9041-93-4)**

**Persistence and Degradability** : Not established.

### 12.3. Bioaccumulative Potential

**Bleomycin for Injection, USP (9041-93-4)**

**Bioaccumulative Potential** : Not established.

### 12.4. Mobility in Soil

No additional information available

### 12.5. Other Adverse Effects

**Other Information** : Avoid release to the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste Treatment Methods

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, and international regulations.

**Additional Information:** Container may remain hazardous when empty. Continue to observe all precautions.

**Ecology - Waste Materials:** Avoid release to the environment.

## SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.





Meitheal Pharmaceuticals, Inc.

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- 14.1. In Accordance with DOT** Not regulated for transport
- 14.2. In Accordance with IMDG** Not regulated for transport
- 14.3. In Accordance with IATA** Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

### 15.1. US Federal Regulations

<b>Bleomycin for Injection, USP (9041-93-4)</b>	
<b>SARA Section 311/312 Hazard Classes</b>	Health hazard - Specific target organ toxicity (single or repeated exposure) Health hazard - Respiratory or skin sensitization Health hazard - Skin corrosion or Irritation Health hazard - Serious eye damage or eye irritation Health hazard - Germ cell mutagenicity Health hazard - Carcinogenicity Health hazard - Reproductive toxicity Physical hazard - Combustible dust

**15.2. US State Regulations** Neither this product nor its chemical components appear on any US state lists, or its chemical components are not required to be disclosed.

## SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

**Date of Preparation or Latest Revision** : 07/15/2020  
**Other Information** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

### GHS Full Text Phrases:

Carc. 2	Carcinogenicity Category 2
Comb. Dust	Combustible Dust
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Lact.	Reproductive toxicity (Lact.)
Muta. 1B	Germ cell mutagenicity Category 1B
Repr. 1B	Reproductive toxicity Category 1B
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization, Category 1
STOT RE 1	Specific target organ toxicity (repeated exposure) Category 1
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H340	May cause genetic defects
H351	Suspected of causing cancer
H360	May damage fertility or the unborn child

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Meitheal Pharmaceuticals, Inc.

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H362	May cause harm to breast-fed children
H372	Causes damage to organs through prolonged or repeated exposure

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*