SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Bleomycin for Injection, USP (Hospira Inc.)

Trade Name: Bleomycin for Injection, USP
Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as Antineoplastic Antibacterial

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Germ Cell Mutagenicity: Category 1B
Reproductive Toxicity: Category 1B
Carcinogenicity: Category 2

Label Elements

Signal Word: Danger
Hazard Statements:
H340 - May cause genetic defects
H351 - Suspected of causing cancer
H360D - May damage the unborn child

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards No data available
Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Bleomycin Sulfate	9041-93-4	232-925-2	Muta 1B (H340)2 (H351)1B (H360D)	100
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**
SULPHURIC ACID ... %	7664-93-9	231-639-5	Skin Corr. 1A (H314)	**

Additional Information: ** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Restrict access to work area. Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit:	2 mg/m^3
Australia PEAK	2 mg/m^3
Austria OEL - MAKs	2 mg/m^3
Bulgaria OEL - TWA	2.0 mg/m^3
Czech Republic OEL - TWA	1 mg/m^3
Estonia OEL - TWA	1 mg/m^3
France OEL - TWA	2 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Greece OEL - TWA	2 mg/m^3
Hungary OEL - TWA	2 mg/m^3
Japan - OELs - Ceilings	2 mg/m^3
Latvia OEL - TWA	0.5 mg/m^3
OSHA - Final PELS - TWAs:	2 mg/m^3
Poland OEL - TWA	0.5 mg/m^3
Slovakia OEL - TWA	2 mg/m^3
Slovenia OEL - TWA	2 mg/m^3
Sweden OEL - TWAs	1 mg/m^3
Switzerland OEL -TWAs	2 mg/m^3

SULPHURIC ACID ... %

ACGIH Threshold Limit Value (TWA)	0.2 mg/m^3
Australia STEL	3 mg/m^3
Australia TWA	1 mg/m^3
Austria OEL - MAKs	0.1 mg/m^3
Belgium OEL - TWA	0.2 mg/m^3
Bulgaria OEL - TWA	0.05 mg/m^3
Cyprus OEL - TWA	0.05 mg/m^3
Czech Republic OEL - TWA	1 mg/m^3 0.05 mg/m^3
Denmark OEL - TWA	0.05 mg/m^3
Estonia OEL - TWA	1 mg/m^3
Finland OEL - TWA	0.05 mg/m^3
France OEL - TWA	0.05 mg/m^3
Germany - TRGS 900 - TWAs	0.1 mg/m^3
Germany (DFG) - MAK	0.1 mg/m^3
Greece OEL - TWA	0.05 mg/m^3
Hungary OEL - TWA	0.05 mg/m^3
Ireland OEL - TWAs	0.05 ppm
Italy OEL - TWA	0.05 mg/m^3
Japan - OELs - Ceilings	1 mg/m^3
Latvia OEL - TWA	0.05 mg/m^3
Lithuania OEL - TWA	0.05 mg/m^3
Luxembourg OEL - TWA	0.05 mg/m^3
Malta OEL - TWA	0.05 mg/m^3
Netherlands OEL - TWA	0.05 mg/m^3
OSHA - Final PELS - TWAs:	1 mg/m^3
Poland OEL - TWA	0.05 mg/m^3
Portugal OEL - TWA	0.05 mg/m^3
Romania OEL - TWA	0.05 mg/m^3
Slovakia OEL - TWA	0.1 mg/m^3
Slovenia OEL - TWA	0.05 mg/m^3
Spain OEL - TWA	0.05 mg/m^3
Sweden OEL - TWAs	0.1 mg/m^3
Switzerland OEL -TWAs	0.1 mg/m^3
Vietnam OEL - TWAs	1 mg/m^3

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Bleomycin Sulfate

Pfizer Occupational Exposure Band (OEB): OEB 5 (control exposure to <1ug/m^3)

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section. It is recommended that all operations be fully enclosed and no air recirculated.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure. Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Lyophilized powder in vial	**Color:**	Cream
Odor:	Odorless	**Odor Threshold:**	No data available.
Molecular Formula:	C55 H84 N17 O21 S3	**Molecular Weight:**	1415.56

Solvent Solubility: No data available
Water Solubility: Soluble
pH: 4.5-6.0
Melting/Freezing Point (°C): 70-71
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Bleomycin Sulfate
No data available
SODIUM HYDROXIDE
No data available
SULPHURIC ACID ... %
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	None
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

Short Term:	Effects of ingestion are not known. Avoid swallowing this material.
Long Term:	Animal studies have shown a potential to cause adverse effects on the fetus.
Known Clinical Effects:	Adverse effects associated with therapeutic use include pulmonary toxicity, beginning with cough and progressing to pulmonary fibrosis. Effects on blood and blood-forming organs have also occurred.

Acute Toxicity: (Species, Route, End Point, Dose)

Bleomycin Sulfate

Rat Para-periosteal LD50 240 mg/kg
Rat Subcutaneous LC50 86mg/kg
Mouse Intravenous LD50 210mg/kg
Mouse Intraperitoneal LD50 210mg/kg
Mouse Oral LD50 > 2000mg/kg

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Bleomycin Sulfate

Embryo / Fetal Development Rat Intraperitoneal 1.5 mg/kg/day LOAEL Fetotoxicity, Teratogenic
Embryo / Fetal Development Rabbit Intravenous 15.6 mg/kg LOAEL Fetotoxicity
Reproductive & Fertility Rabbit Intravenous 1.2 mg/kg/day LOEL Not Teratogenic, Embryotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Bleomycin Sulfate

In Vivo Chromosome Aberration Mouse Positive
In Vivo Sister Chromatid Exchange Mouse Positive
In Vivo Micronucleus Mouse Positive
Bacterial Mutagenicity (Ames) Positive
In Vitro Chromosome Aberration Human Lymphocytes Positive
Genetic Toxicity Comments: Mutagenic effects were seen in humans taking this drug.

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Bleomycin Sulfate
Not specified Rat Subcutaneous 0.35 mg/kg/week LOEL Kidneys, Connective tissue

Carcinogen Status: See below

Bleomycin Sulfate
IARC: Group 2B (Possibly Carcinogenic to Humans)

SULPHURIC ACID ... %
IARC: Group 1 (Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Bleomycin Sulfate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	232-925-2

SODIUM HYDROXIDE

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

SULPHURIC ACID ... %

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	1000 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	1000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	231-639-5

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Germ cell mutagenicity-Cat.1B; H340 - May cause genetic defects
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Revision date: 25-Jul-2016

Product Stewardship Hazard Communication
Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet