



SAFETY DATA SHEET

Revision date 22-Apr-2022

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Bleomycin for Injection, USP (Hospira Inc.)
Product Code(s) PZ03076
Trade Name: Bleomycin for Injection, USP
Chemical Family: Not determined

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product used as Antineoplastic Antibacterial

1.3. 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

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Germ cell mutagenicity Category 1B
Carcinogenicity Category 2
Reproductive toxicity Category 1B

2.2. 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

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2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Bleomycin Sulfate (CAS #: 9041-93-4)	100		232-925-2	Muta 1B (H340)2 (H351)1B (H360D)	Not Listed	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5	Skin Corr. 1A (H314)	Eye Irrit. 2 :: 0.5%≤C<2% Skin Corr. 1A :: C≥5% Skin Corr. 1B :: 2%≤C<5% Skin Irrit. 2 :: 0.5%≤C<2%	No data available	No data available
+ SULPHURIC ACID ... % (CAS #: 7664-93-9)	**		231-639-5	Skin Corr. 1A (H314)	Eye Irrit. 2 :: 5%≤C<15% Skin Corr. 1A :: C≥15% Skin Irrit. 2 :: 5%≤C<15%	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

No information available

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Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ SULPHURIC ACID ... % 7664-93-9	2140	No data available	0.375	No data available	No data available

Additional information

** to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
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.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.
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Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical, CO2, alcohol-resistant foam or water spray.
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5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Fine particles (such as dust and mists) may fuel fires/explosions.
Hazardous combustion products	Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

5.3. Advice for firefighters

Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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Section 6: ACCIDENTAL RELEASE MEASURES

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6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.
Methods for cleaning up Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.
Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on 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.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

Sodium hydroxide

ACGIH OEL (Ceiling)	2 mg/m ³
ACGIH TLV	Ceiling: 2 mg/m ³
Austria	2 mg/m ³
	STEL 4 mg/m ³
Bulgaria	2.0 mg/m ³
Czech Republic	1 mg/m ³
	Ceiling: 2 mg/m ³
Denmark	Ceiling: 2 mg/m ³
Estonia	1 mg/m ³

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Finland	STEL: 2 mg/m ³
France	Ceiling: 2 mg/m ³
Hungary	2 mg/m ³
	1 mg/m ³
Ireland	STEL: 2 mg/m ³
Ceiling Limit Value	STEL: 2 mg/m ³
Latvia	2 mg/m ³
Poland	0.5 mg/m ³
	STEL: 1 mg/m ³
	0.5 mg/m ³
Romania	1 mg/m ³
	STEL: 3 mg/m ³
Slovakia	2 mg/m ³
Spain	STEL: 2 mg/m ³
Switzerland	2 mg/m ³
	STEL: 2 mg/m ³
OSHA PEL	2 mg/m ³
United Kingdom	(vacated) Ceiling: 2 mg/m ³
+ SULPHURIC ACID ... %	STEL: 2 mg/m ³
ACGIH TLV	
Austria	0.2 mg/m ³
	0.1 mg/m ³
	STEL 0.2 mg/m ³
Bulgaria	0.05 mg/m ³
Czech Republic	1 mg/m ³
	0.05 mg/m ³
	Ceiling: 2 mg/m ³
Denmark	0.05 mg/m ³
Estonia	0.05 mg/m ³
European Union	TWA: 0.05 mg/m ³
Finland	0.05 mg/m ³
	STEL: 0.1 mg/m ³
France	0.05 mg/m ³
Germany	0.1 mg/m ³
	Ceiling / Peak: 0.1 mg/m ³
Germany	0.1 mg/m ³
Hungary	0.05 mg/m ³
Ireland	0.05 ppm
	STEL: 0.15 ppm
Italy	0.05 mg/m ³
Ceiling Limit Value	1 mg/m ³
Latvia	0.05 mg/m ³
Netherlands	0.05 mg/m ³
Poland	0.05 mg/m ³
Romania	0.05 mg/m ³
Russia	MAC: 1 mg/m ³
	Skin
Slovakia	0.05 mg/m ³
Spain	0.05 mg/m ³
Switzerland	0.1 mg/m ³
	STEL: 0.2 mg/m ³
OSHA PEL	1 mg/m ³
	(vacated) TWA: 1 mg/m ³
United Kingdom	TWA: 0.05 mg/m ³
	STEL: 0.15 mg/m ³

Pfizer Occupational Exposure Band (OEB) Statement:

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

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upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

8.2. 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.
Environmental exposure controls	No information available.
Personal protective equipment	Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Eye/face protection	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.).
Hand protection	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.).
Skin and body protection	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	Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (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.).

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Lyophilized powder in vial
Color	Cream
Odor	Odorless.
Odor threshold	No information available
Molecular formula	C55 H84 N17 O21 S3
Molecular weight	1415.56

Property	Values
pH	4.5-6.0
Melting point / freezing point	70-71
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available

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Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	Soluble
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

Oxidizing properties None

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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	Based on available data, the classification criteria are not met.

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Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

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

Bleomycin Sulfate

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

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
+ SULPHURIC ACID ... %	= 2140 mg/kg (Rat)	-	= 0.375 mg/L (Rat) 4 h

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Reproduction & Development Toxicity: (Duration, 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

Carcinogenicity See below

Bleomycin Sulfate

IARC Group 2B (Possibly Carcinogenic to Humans)

+ SULPHURIC ACID ... %

IARC Group 1 (Carcinogenic to Humans)
NTP Known Human Carcinogen

11.2. Information on other hazards

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11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

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

12.1. Toxicity

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical name	PBT and vPvB assessment
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
+ SULPHURIC ACID ... %	The substance is not PBT / vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. 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 wastewater 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.

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Section 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.

UN number: Not applicable
UN proper shipping name: Not applicable
Transport hazard class(es): Not applicable
Packing group: Not applicable
Environmental Hazard(s): Not applicable

Special precautions for user: Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Bleomycin Sulfate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	232-925-2
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4

Sodium hydroxide

CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	1000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	215-185-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5
	Schedule 6

+ SULPHURIC ACID ... %

CERCLA/SARA Section 313 de minimus %	1.0 %
Hazardous Substances RQs	1000 lb
California Proposition 65	carcinogen 3/14/2003
TSCA	Present
EINECS	231-639-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 6

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium hydroxide - 1310-73-2	Use restricted. See item 75.	
+ SULPHURIC ACID ... % - 7664-93-9	Use restricted. See item 75.	

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Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under 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.

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

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Prepared By Pfizer Global Environment, Health, and Safety

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