

Revision date 16-Jun-2025 Version 3 Page 1/13

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

1.1. Product identifier

Product NameBleomycin 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

Ringaskiddy, Co. Cork.

Ireland

OSG Building

Pfizer Ireland Pharmaceuticals

+353 21 4378701

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 mutagenicityCategory 1BCarcinogenicityCategory 2Reproductive toxicityCategory 1B

OSHA Classification

Hazards not otherwise classified (HNOC)

Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

Not applicable

2.2. Label elements



Product Name Bleomycin for Injection, USP (Hospira Inc.)

Page 2/13 Revision date 16-Jun-2025 Version 3

Signal word Danger

Hazard statements H340 - May cause genetic defects

H351 - Suspected of causing cancer H360D - May damage the unborn child

Precautionary Statements - EU (§28, P201 - Obtain special instructions before use

1272/2008)

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 advice/attention

P405 - Store locked up

P501 - Dispose of contents/container in accordance with local, regional, national, and

international regulations as applicable

2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for one or more of the ingredients

(see Section 8).

PBT & vPvB The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

This document has been prepared in accordance with standards for workplace safety, which Note:

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 (EU Index 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 classified	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5 (011-002-00-6)	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	**		231-639-5	Skin Corr. 1A	Eye Irrit. 2 ::	No data	No data

Product Name Bleomycin for Injection, USP (Hospira Inc.) Page 3/13 Revision date 16-Jun-2025 Version 3

%	(016-020-00)-8) (H314)	5%<=C<15%	available	available
(CAS #: 7664-93-9)			Skin Corr. 1A ::		
1			C>=15%		
			Skin Irrit. 2 ::		
			5%<=C<15%		

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

Acute Toxicity Estimate No information available

Chemical name	Oral LD50 mg/kg	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapor - mg/L	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

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

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.

Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Eye contact

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

For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

PZ03076

effects

Page 4/13

Product Name Bleomycin for Injection, USP (Hospira Inc.)

Revision date 16-Jun-2025 Version 3

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

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

chemical

Hazardous combustion products Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and

other sulfur-containing compounds.

Explosion data

Sensitivity to mechanical impact No information available. No information available. Sensitivity to static discharge

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Personal precautions

Section 8). Minimize exposure.

Use personal protection recommended in Section 8. For emergency responders

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.

Contain the source of the spill or leak. Collect spilled material by a method that controls dust Methods for cleaning up

generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean contaminated

surface thoroughly.

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/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or 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.

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

7.2. Conditions for safe storage, including any incompatibilities

Store as directed by product packaging. **Storage Conditions**

Product Name Bleomycin for Injection, USP (Hospira Inc.)

Revision date 16-Jun-2025

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/m³ **ACGIH TLV** Ceiling: 2 mg/m³

Austria TWA-TMW: 2 mg/m³; inhalable fraction

STEL-KZGW: 4 mg/m³ (8 X 5 min); inhalable fraction

TWA: 2.0 mg/m³; alkaline aerosols Bulgaria

Czech Republic 1 mg/m^3

Ceiling: 2 mg/m³ Ceiling: 2 mg/m³; Denmark Estonia TWA: 1 mg/m³; STEL: 2 mg/m3;

Finland Ceiling: 2 mg/m3;

France 2 mg/m³

TWA-AK: 1 mg/m³; Hungary STEL-CK: 2 mg/m3;

Ireland STEL: 2 mg/m³; Ceiling Limit Value 2 ma/m3 Latvia TWA: 0.5 mg/m³;

Poland TWA-NDS: 0.5 mg/m³; STEL-NDSCh: 1 mg/m3;

TWA: 1 mg/m³; STEL: 3 mg/m³;

Slovakia TWA: 2 mg/m³; Spain STEL (VLA-EC): 2 mg/m3;

Switzerland

TWA-MAK: 2 mg/m3; inhalable dust STEL-KZGW: 2 mg/m3; inhalable dust

OSHA PEL TWA: 2 mg/m³

(vacated) Ceiling: 2 mg/m³

United Kingdom STEL: 2 mg/m3;

+ SULPHURIC ACID ... %

Romania

ACGIH TLV TWA: 0.2 mg/m³ thoracic particulate matter TWA-TMW: 0.1 mg/m³; inhalable fraction Austria STEL-KZGW: 0.2 mg/m3 (); inhalable fraction

TWA: 0.05 mg/m³; respirable aerosol Bulgaria

1 mg/m³ Czech Republic

0.05 mg/m³ Ceiling: 2 mg/m³

Denmark TWA: 0.05 mg/m³; mist STEL: 0.1 mg/m3; mist

TWA: 0.05 mg/m³; particles that reach the upper respiratory tract Estonia

European Union TWA: 0.05 mg/m³; mist (thoracic fraction) Finland TWA: 0.05 mg/m3; thoracic fraction

STEL: 0.1 mg/m3; thoracic fraction

France 0.05 mg/m³

Germany DFG TWA-MAK: 0.1 mg/m³; I(1);inhalable fraction

Product Name Bleomycin for Injection, USP (Hospira Inc.)

Page 6/13 Revision date 16-Jun-2025 Version 3

Peak: 0.1 mg/m³; inhalable fraction

Germany TRGS TWA-AGW; 0.1 mg/m³ (exposure factor 1); inhalable fraction

Hungary TWA-AK: 0.05 mg/m³; Ireland TWA: 0.05 ppm;

STEL: 0.15 ppm (calculated); Italy MDLPS

TWA: 0.05 mg/m3; thoracic fraction, mist

Ceiling Limit Value 1 mg/m^3

Latvia TWA: 0.05 mg/m³; fog, which is defined as the thoracic fraction Netherlands TWA: 0.05 mg/m³; mist, thoracic fraction Poland TWA-NDS: 0.05 mg/m³; thoracic fraction Romania TWA: 0.05 mg/m³; thoracic fraction

Russia MAC: 1 mg/m³

Skin

Slovakia TWA: 0.05 mg/m³;

Spain TWA-(VLA-ED): 0.05 mg/m3; mist Switzerland TWA-MAK: 0.1 mg/m³; inhalable dust STEL-KZGW: 0.2 mg/m3; inhalable dust

OSHA PEL TWA: 1 mg/m³

(vacated) TWA: 1 mg/m³ United Kingdom TWA: 0.05 mg/m³; mist STEL: 0.15 mg/m³; mist

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

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

Skin and body protection

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.

Contact your safety and health professional or safety equipment supplier for assistance in Personal protective equipment

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.).

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.).

Page 7/13

Product Name Bleomycin for Injection, USP (Hospira Inc.)

Revision date 16-Jun-2025 Version 3

Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is Respiratory protection

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.).

Thermal hazards No information available.

Environmental exposure controls No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance in vial, Lyophilized powder Physical state Liquid Powder Color Cream

Odorless. Odor

Odor threshold No information available

Property Values

Melting point / freezing point 70-71

Boiling point or initial boiling point and boiling range No data available Flammability (solid, gas) No data available

Lower and upper explosion limit/flammability limit

Lower explosion limit No data available No data available **Upper explosion limit** Flash point No data available

Autoignition temperature No data available **Decomposition temperature**

No data available SADT (°C)

4.5-6.0

pH (as aqueous solution) No data available Kinematic viscosity No data available No data available

Dynamic viscosity Solubility No data available Soluble

No data available Vapor pressure No data available Density and/or relative density

No data available **Bulk density Liquid Density** No data available Vapor density No data available Particle characteristics

Particle Size No information available

Particle Size Distribution No information available

9.2. Other information

C55 H84 N17 O21 S3 Molecular formula

1415.56 Molecular weight

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

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Product Name Bleomycin for Injection, USP (Hospira Inc.)

Revision date 16-Jun-2025

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

No information available. Reactivity

10.2. Chemical stability

Stable under normal conditions. Stability

Explosion data

Sensitivity to mechanical impact No information available. Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions

No information available. Possibility of hazardous reactions

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

Effects of ingestion are not known. Avoid swallowing this material. Short term

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.

Adverse effects associated with therapeutic use include pulmonary toxicity, beginning with **Known Clinical Effects:**

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. Based on available data, the classification criteria are not met. Serious eye damage/eye irritation Skin corrosion/irritation Based on available data, the classification criteria are not met. 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 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 ma/ka

g,g			
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

Product Name Bleomycin for Injection, USP (Hospira Inc.)

Page 9/13 Revision date 16-Jun-2025 Version 3

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

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

Group 2B IARC

+ SULPHURIC ACID ... %

Group 1 IARC NTP Known

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

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

11.2.2. Other information

No information available. Other adverse effects

Section 12: ECOLOGICAL INFORMATION

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

be avoided.

12.1. Toxicity

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Page 10 / 13 Version 3

Product Name Bleomycin for Injection, USP (Hospira Inc.)

Revision date 16-Jun-2025

No information available. **Bioaccumulation**

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

Based on available data, the classification criteria are not met. PBT and vPvB assessment

Chemical name	PBT and vPvB assessment	
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply	
+ SULPHURIC ACID %	Not PBT/vPvB PBT assessment does not apply	

12.6. Endocrine disrupting properties

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

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

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.

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.

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

Product Name Bleomycin for Injection, USP (Hospira Inc.) Revision date 16-Jun-2025

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 Schedule 4

Poisons (SUSMP)

Sodium hydroxide

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

+ SULPHURIC ACID ... %

CERCLA/SARA Section 313 de minimus % 1.0 % Hazardous Substances RQs 1000 lb California Proposition 65 Carcinogen TSCA Present EINECS 231-639-5 AICS Present Standard for Uniform Scheduling of Medicines and Schedule 6

Poisons (SUSMP)

National regulations

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905 Not applicable

Chemical name	Netherlands - List of Carcinogens	Netherlands - List of Mutagens	Netherlands - List of Reproductive Toxins
+ SULPHURIC ACID % 7664-93-9	Present	-	-

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018

Storage of Hazardous Material

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20

Major Accidents Ordinance SR 814.012

Not applicable

Not applicable

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.

Product Name Bleomycin for Injection, USP (Hospira Inc.) Revision date 16-Jun-2025

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	Substance subject to authorization per	
		Annex XVII	REACH Annex XIV	
	Sodium hydroxide	75	-	
	1310-73-2			
	+ SULPHURIC ACID %	75	-	
	7664-93-9			

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Chemical name	Limit value	Upper limit value for the purpose of licensing under article 5(3)	Reportable explosives precursors
+ SULPHURIC ACID % 7664-93-9	15 %w/w	40 %w/w	-

Legend:

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

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

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

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing Chemicals Inventory

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

TCSI - Taiwan Chemical Substance Inventory

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 any hazard and/or precautionary statements referred to under Sections 2-15

H314 - Causes severe skin burns and eye damage H340 - May cause genetic defects H351 - Suspected of causing cancer H360D - May damage the unborn child

Product Name Bleomycin for Injection, USP (Hospira Inc.) Revision date 16-Jun-2025 Page 13 / 13 Version 3

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.

Revision date 16-Jun-2025

Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this 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.