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Section 1 - Chemical Product and Company

Distributor:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

Emergency Telephone: 866-625-1618

Product Identifier: Polymyxin B for Injection, USP (500,000 units/vial)
Product Code: NDC 25021-117-10
Common/Trade Name: Polymyxin B Sulfate
Chemical Name: C₅₅H₉₆N₁₆O₁₃·2H₂SO₄
Chemical Family: Antibiotic
Product Use: Pharmaceutical
Product Type: Regulated Prescription Drug
Container Information: Vial

Section 2 - Composition / Information on Ingredients

Ingredient	Weight %	OSHA PEL	ACGGIH TLV	Other Limits Recommended	CAS No.
Polymyxin B Sulfate	100	None	None	None	1405-20-5


Section 3 - Hazards Identification

Primary Physical and Health Hazards: Polymyxin B is an antibiotic used to treat urinary, meninges and bloodstream infections. Product affects the skin, respiratory system and possibly the kidneys.

Routes of Entry: Inhalation, ingestion, injection and skin contact.

Signs & Symptoms of Exposure: Nausea, vomiting, dizziness, inability to coordinate muscular movements and sensory disturbances of the face and extremities. Irritation to eyes, skin and respiratory tract may occur.

Chemical Listed as Carcinogen: NTP: No IARC: No OSHA: No

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Medical Conditions Generally Aggravated by Exposure: May cause kidney damage. Parenteral administration may cause neurotoxic reactions including dizziness, ataxia (muscle weakness), and sensory disturbances of the face and extremities. Reversible respiratory paralysis has occurred, especially in patients with impaired renal function. Overgrowth of fungus or nonsusceptible organisms. Impaired renal function.

Section 4 - First Aid Measures

Eye Exposure: Flush eyes with large volumes of water for 15 minutes.

Skin Exposure: Wash skin with cool, soapy water.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately. If person is conscious, induce vomiting. Never induce vomiting with an unconscious person.

Injection: No information available.

Inhalation: If difficulty breathing, administer oxygen. Seek attention of a physician immediately. If necessary, provide artificial respiration.

Notes to Physician: See patient package insert in shipping carton for complete information.

Section 5 - Fire Fighting Measures

Flash Point Not established


Autoignition Temperature: Not established

Flammable Limits in Air Lower Explosion Limit: 9g/ft³
Upper Explosion Limit: 10g/ft³

Flammable Limits: Not established

Extinguishing Media Use water or multi-purpose ABC extinguisher

Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters must wear SCBA (self-contained breathing apparatus) to avoid inhalation.

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Unusual Fire/Explosion Hazards: None

Section 6 - Accidental Release Measures

Spill: Wet polymyxin with water and absorb with absorbent wipes or pads and dispose of according to local, state, and federal guidelines. Wash spill area with soap and water.

Release to Air: If dust is generated, reduce exposures by ventilating area; clean up immediately and wear protective equipment.

Release to Water: Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 - Handling and Storage

General Handling: When handling pharmaceutical products, avoid all contact with skin, eyes, nostrils, and mouth. Avoid inhalation of dust, fumes, mist, and/or vapors.

Waste Disposal Method: Incineration at an approved/permitted facility is recommended. Refer to local, state, and federal guidelines.


Storage Conditions: Protect from light and store at controlled room temperature 20°-25°C (68°-77°F). Follow instructions provided in packaging.

Section 8 - Exposure Controls / Personal Protection

Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting.

Respiratory Protection: Under normal use, respirators are not required. If dusts of product are generated, a half-mask respirator with HEPA filters is recommended. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard, 29 CFR 1910.134.

Eye Protection: Safety glasses or goggles are recommended.

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Ventilation: Handle in a well-ventilated area.

Skin Protection: Disposable garments if direct skin contact is anticipated. For larger spills, additional protective clothing such as boots, coveralls, and double gloves must be worn.

Other Protective Equipment: Appropriate laboratory apparel.

Additional Exposure Precautions: Wash hands following use. No eating, drinking, or smoking while handling this product.

Exposure Limits

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Polymyxin B Sulfate	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

Section 9 - Physical and Chemical Properties

Physical State:	Powder	Specific Gravity:	Approx. 1
Appearance and Odor:	White to light tan, odorless	Evaporation Rate:	Approx to water
Boiling Point:	Approx to water	Solubility in Water:	Soluble
Vapor Pressure:	Approx to water	pH:	5.0-7.5
Vapor Density:	0.6	Molecular Weight:	1385.61


Section 10 - Stability and Reactivity

Stability: Stable

Incompatibility (Materials to avoid): Oxidizers

Hazardous Decomposition: Decomposition products of this compound may include potentially hazardous byproducts of nitrogen oxides, carbon monoxide, and carbon dioxide.

Hazardous Polymerization: Will not occur.

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Conditions to Avoid: None.


Section 11 - Toxicological Information

Signs & Symptoms of Exposure & Overexposure: 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. Adverse reactions from therapeutic doses include: fever, urticarial rash, pain (severe) at intramuscular injection sites, and thrombophlebitis at intravenous injection site.

Medical Conditions Aggravated by Accidental Exposure: Individuals with a prior history of hypersensitivity reactions to polymyxins, impaired renal function, and concurrent use of other nephrotoxic drugs particularly bacitracin, streptomycin, neomycin, kanamycin, gentamicin, tobramycin, amikacin, cephaloridine, paromomycin, viomycin, and colistin.

Acute Toxicity

Component	Type	Route	Species	Dosage
Polymyxin B Sulfate	LD ₅₀	Oral	Mouse	790 mg/kg
Polymyxin B Sulfate	LD ₅₀	Intraperitoneal	Mouse	20,500 mg/kg
Polymyxin B Sulfate	LD ₅₀	Subcutaneous	Mouse	59,500 mg/kg
Polymyxin B Sulfate	LD ₅₀	Intravenous	Mouse	5,400 mg/kg
Polymyxin B Sulfate	LDL ₀	Intravenous	Dog	8 mg/kg
Polymyxin B Sulfate	LDL ₀	Intercerebral	Dog	320 mg/kg
Polymyxin B Sulfate	LD ₅₀	Subcutaneous	Rat	50 mg/kg
Polymyxin B Sulfate	LD ₅₀	Intramuscular	Rat	13.3 mg/kg

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Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

Section 12 - Ecological Information

No applicable ecological information found.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.


U.S. Regulations

CERCLA - *Not on this list*


SARA 313 - *Not on this list*

Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

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Glossary: This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)