



Safety Data Sheet

Polymyxin B for Injection, USP

Section 1: Chemical Product and Company Identification

Product Name: Polymyxin B for Injection, USP

Chemical Name(s): Polymyxin B, sulfate

Synonym: Polymyxin

CAS Number: 1405-20-5

RTECS #: TR1150000

Trade Name: Not available

Chemical Formula: $C_{43}H_{82}N_{16}O_{12} \cdot xH_2SO_4$



Health	2
Fire	1
Reactivity	0
Personal Protection	E

Contact Information:

X-GEN Pharmaceuticals, Inc.

PO Box 445, Big Flats, NY 14814

Technical Assistance: 607-562-2700

Online Assistance: www.x-gen.us

Emergency phone number:

National Poison Control

1-800-222-1222

**For information regarding recommended uses and restrictions on usage refer to the product package insert.

Section 2: Hazard Identification

Hazard pictograms (GHS-US):



Potential Acute Health Effects: Hazardous in case of eye, skin contact (irritant), or inhalation.

Potential Chronic Health Effects: Hazardous in case of skin contact (irritant), or inhalation.
Gastrointestinal and/or respiratory tract irritation. Possible hyper sensitization and kidney damage.

Carcinogenic Effects: Not available

Mutagenic Effects:

E.coli DNA adduct test results: Positive.

S. cerevisiae yeast mutagenicity test results: Positive.

Teratogenic Effects: Not available

Developmental Toxicity: Not available

Adverse effects: Adverse effects following ingestion may include dizziness, inability to coordinate muscular movements, visual disturbance, confusion, drowsiness, temporary absence of breathing, rash, fever, skin lesions and sensory disturbance of the face and extremities. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Section 3: Composition and Information on Ingredients

Principle Components:

<u>Name</u>	<u>CAS #</u>	<u>% by Weight</u>
Polymyxin B	1405-20-5	100

Section 4: First Aid Measures

General: Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposure. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Obtain medical attention.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Skin contact: In case of contact, immediately wash skin with plenty of water. Remove contaminated clothing and shoes. Wash clothes and thoroughly clean shoes before reuse. Seek medical attention immediately.

Eye contact: Check for and remove any contacts lenses. Immediately flush eyes with plenty of water for at least 15 minutes. Seek medical attention immediately.

Ingestion: DO NOT induce vomiting unless directed to do so by a medical professional. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call physician immediately. Loosen tight clothing such as tie, collar and/or belt. Seek medical attention immediately.

Notes to physician: Seek product package insert for complete information.

Overdose Treatment: Neostigmine or calcium salts are of little value in reversing neuromuscular blockade and artificial ventilation may be required if it develops. Neither hemodialysis nor peritoneal dialysis is effective in eliminating the drug. [Martindale 32nd ed. 1999; Mylers 14th ed. 2000]

Section 5: Fire Fighting Measures

Flammability of the product: May combust at high temperatures.

Combustion Products: Carbon oxides, nitrogen oxides, and sulfur oxides

Unusual Fire and Explosion Hazards: This product is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Extinguishing Media and Instruction:

Small fire: Use DRY chemical powder. **Large fire:** Use water spray, fog or foam. DO NOT use water jet.

Protective equipment & precautions for firefighters: As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus and protective clothing.

Special remarks on fire hazard: Not available

Special remarks on explosion hazard: Not available

Section 6: Accidental Release Measures

Release to land:

Small spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local, state, and federal regulations.

Large spill: Use a shovel to put the material into a convenient waste disposal container. Sweep up or vacuum with caution to avoid generation of dust during clean-up. Finish cleaning by spreading water on the contaminated surface and clean surface thoroughly to remove residual contamination. Avoid generation of dust during clean-up. Collect in suitable container for disposal. For proper waste disposal, see section 13 of the SDS.

Release to air: If dust is generated, reduce exposure by ventilating area. Be sure to wear protective equipment and clean up immediately.

Release to water: Refer to water authority. Drain disposal is not recommended. Refer to Federal, State and Local guidelines.

Protective equipment: Keep unnecessary personnel away. Wear chemically compatible gloves and safety glasses. Wear approved respiratory protection (N95) if dusting occurs. For larger spills, additional protective clothing such as protective coveralls, shoe covers for spills or boots and double gloves must be worn.

Section 7: Handling and Storage

Handling: As a general rule, when handling Polymyxin B for Injection, USP, avoid all contact and inhalation of dust, mist, and/or vapor associated with the material.

Keep locked up. Keep away from heat, sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. DO NOT breathe dust. Avoid contact with skin. Wear suitable protective clothing. If you feel unwell, seek medical attention and show label when possible. Use only in accordance with directions.

Storage: Store in tight container as defined in the USP-NF. Keep container in a cool, dry, well ventilated area (see USP CRT storage conditions). Store vials at 15°-30° C (59°-86° F). Refer to label instructions to ensure product integrity.

Incompatibilities: Strong acids and alkalis. Strong oxidizing agents.

Section 8: Exposure Controls / Personal Protection

Engineering controls: No special ventilation requirements. May use process enclosure, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generates dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protection: Safety glasses. Lab coat. Gloves. Dust respirator. Be sure to use an approved/certified respirator or equivalent. **In case of large spill:** Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Respiratory protection: Under normal use, respirators are not required. If dusts are generated, use a disposable mask (N95). Personnel wearing respirators should be fit tested and approved for respirator use, under OSHA Respiratory Protection Standard 29 CFR 1910.134.

Exposure limit: Not available

Section 9: Physical and Chemical Properties

Physical appearance: Solid powder
Color: white to buff-colored
Molecular Weight: 1701.97
Taste: Not available
Odor: Odorless
Odor Threshold: Not available
pH: 5 – 7.5 (0.5% aqueous solution)

Melting Point: Not available
Freezing Point: Not available
Boiling Point: Not available
Flash Point: Not available
Evaporation rate: Not available
Flammability: Not available
Upper Flammable Limit: 10 gm/ft³

Lower Flammable Limit: 9 gm/ft³
Vapor Pressure: Not available
Vapor Density: Not available
Relative density: Not available
Partition Coefficient: Not available

Auto-Ignition Temperature: 805°C (1481°F)
Decomposition Temperature: Not available
Viscosity: Not available
Dispersion Properties: Not available
Solubility: Freely soluble.

Section 10: Stability and Reactivity

Reactivity: Stable.

Chemical stability: Stable.

Possibility of hazardous reaction: Not available

Conditions to avoid: Avoid exposure to light, heat, and moisture.

Incompatible materials: Strong acids and alkalis. Strong oxidizing agents.

Hazardous decomposition products: When heated to decomposition material emits toxic fumes of SO_x and NO_x. Emits toxic fumes under fire conditions.

Corrosivity: Non-corrosive in presence of glass.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of exposure: Absorbed through skin, eye contact, inhalation and ingestion.

Symptoms:

Short term: Harmful if swallowed. May cause skin irritation. Possible dizziness, incoordination, convulsions, headaches, visual disturbance, drowsiness, confusion, decreased urination, rash and/or fever. Temporary absence or cessation of breathing. Numbness of the face and extremities.

Superinfections. **Long term:** Impaired kidney function. Chronic pulmonary disease. Myasthenia gravis. Neuromuscular disorders. May cause damage to the following organs: Kidneys.

Reproductive toxicity: Not available

FDA Pregnancy Category: C

Toxicity to animals:

Oral Dog: LDLO: 8mg/kg

Oral Mouse: LD50: 790mg/kg

Measures of toxicity: Not available

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

Section 12: Ecological Information

Ecotoxicity: Not available

Bioaccumulation potential: Not available

Products of biodegradation: Not available

Toxicity of the products of biodegradation: Not available

Section 13: Disposal Information

Waste classification: Not available

Waste from residues/unused products: Dispose of waste in accordance with all applicable federal, state and local laws.

Waste Disposal: Dispose of waste in accordance with all applicable federal, state and local laws.

Section 14: Transport Information

DOT Classification: Not a DOT controlled Material (United States).

UN Number: Not available

UN Shipping name: Not available

Transport hazard class: Not available

Packing Group: Not available

Environmental hazard: Not available

Transport in bulk: Not available

Special precautions needed with transport: Not available

Section 15: Regulatory Information

Federal and State Regulations: Xn (harmful)

Other Regulations: Not available

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC): R21 – Harmful with skin contact. R36/37/38 – Irritating to eyes, respiratory system, and skin. S24/25 – Avoid contact with skin and eyes. S36 – Wear suitable protective clothing.

HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 1

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 1

Reactivity: 0

Protective Equipment: Gloves, lab coat, safety glasses and dust respirator. Be sure to use an approved/certified respirator or equivalent.

Section 16: Other Information

References: Not available

Created: 2/25/2015

Last Updated: 3/25/2015

Prepared & Approved by: X-GEN Pharmaceuticals, Inc., Safety Committee

The above information is believed to be accurate and represents the best information currently available to us. The use of this product should be through or under the direction of a physician. This SDS does not address therapeutic use of this material. X-GEN Pharmaceuticals, Inc. makes no warranties, express or implied with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information. In no event should X-GEN Pharmaceuticals be liable for any claim, loss, or damage of any third party, even if X-GEN Pharmaceuticals has been advised of the possibility of such damages to occur.