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Section 1 - Identification

- (a) **Product Identifier:** Polymyxin B for Injection, USP
- (b) **Product Code:** 70860-103
- Common/Trade Name:** Polymyxin B
- Chemical Name:** N-[4-amino-1-[[1-[[4-amino-1-oxo-1-[[6,9,18-tris(2-aminoethyl)-15-benzyl-3-(1-hydroxyethyl)-12-(2-methylpropyl)-2,5,8,11,14,17,20-hepta-oxo-1,4,7,10,13,16,19-heptazacyclotricos-21-yl]amino]butan-2-yl]amino]-3-hydroxy-1-oxobutan-2-yl]amino]-1-oxobutan-2-yl]-6-methyloctanamide; sulfuric acid.
- Chemical Family:** Antibiotic
- (c) **Product Use:** Pharmaceutical
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

Section 2 - Hazards Identification

- (a) **Classification:** **OSHA Classification:**...

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary	(c) Description of Hazards:
<u>Signal Word:</u>	Warning
	

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Hazard Statements

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.

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.

(d) Unknown Acute Toxicity N/A

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Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
N-[4-amino-1-[[[1-[[4-amino-1-oxo-1-[[[6,9,18-tris(2-aminoethyl)-15-benzyl-3-(1-hydroxyethyl)-12-(2-methylpropyl)-2,5,8,11,14,17,20-hepta-oxo-1,4,7,10,13,16,19-heptazacyclotricos-21-yl]amino]butan-2-yl]amino]-3-hydroxy-1-oxobutan-2-yl]amino]-1-oxobutan-2-yl]-6-methyloctanamide	Polymyxin B Sulfate, USP	500,000 units/vial	1405-20-5	N/A
Water	Water for Injection	q.s. to 3.0 mL	7732-18-5	N/A

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.
Eye Exposure:	Check for and remove any contacts lenses. Immediately flush eyes with plenty of water for at least 15 minutes. Seek medical attention immediately.
Skin Exposure:	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.
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.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

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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

- (a) **Extinguishing Media** **Small fire:** Use DRY chemical powder. **Large fire:** Use water spray, fog or foam. DO NOT use water jet.
- (b) **Hazardous Combustion Products:** Carbon oxides, nitrogen oxides, and sulfur oxides
- (c) **Special Protective Equipment / Precautions:** As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus and protective clothing.

Section 6 - Accidental Release Measures

Spill: **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

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General 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. May combust at high temperatures. Empty containers pose a fire risk, evaporate the residue under a fume hood. 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. 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 Conditions:

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.

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Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits **Not available**

(b) Engineering Controls

Ventilation: 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.

(c) Individual Protection Measures

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.
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.

Section 9 - Physical and Chemical Properties

(a)	Appearance	Solid powder
(b)	Color	White to buff-colored
(c)	Molecular Weight	1701.97
(d)	Taste	Not available
(e)	Odor	Odorless
(f)	Odor Threshold	Not available
(g)	pH	5 – 7.5 (0.5% aqueous solution)
(h)	Lower Flammable Limit	9 gm/ft ³
(i)	Upper Flammable Limit	10 gm/ft ³
(j)	Melting Point:	Not available
(k)	Boiling Point:	Not available
(l)	Freezing Point	Not available

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(m) Flash Point	Not available
(n) Evaporation Rate:	Not available
(o) Flammability	Not available
(p) Vapor Pressure:	Not available
(q) Vapor Density:	Not available
(r) Relative Density	Not available
(s) Solubility(ies)	Freely soluble.
(t) Partition Coefficient:	Not available
(u) Auto-ignition Temperature	805°C (1481°F)
(v) Decomposition Temperature	Not available
(w) Viscosity	Not available
(x) Dispersion Properties	Not available

Section 10 - Stability and Reactivity

(a) Reactivity	Stable
(b) Chemical Stability	Stable
(c) Possibility of Hazardous Reactions	Not available
(d) Conditions to Avoid	Avoid exposure to light, heat, and moisture.
(e) Incompatible Materials	Strong acids and alkalis. Strong oxidizing agents.
(f) Hazardous Decomposition Products	When heated to decomposition material emits toxic fumes of SO _x and NO _x . Emits toxic fumes under fire conditions.
(g) Corrosivity	Non-corrosive in presence of glass.
(h) Polymerization:	Will not occur.

Section 11 - Toxicological Information

(a) Routes of Exposure	Absorbed through skin, eye contact, inhalation and ingestion.
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(b)	Symptoms related to the physical, chemical and toxicological characteristics	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.
(c)	Reproductive Toxicity	Not available
(d)	FDA Pregnancy Category	C
(e)	Toxicity to animals:	Oral Dog: LDLO: 8mg/kg Oral Mouse: LD50: 790mg/kg
(f)	Measures of toxicity	Not available
(g)	Delayed and immediate effects and also chronic effects from short and long term exposure	Not Available
(h)	Acute Toxicity	Not Available
(i)	Hazardous Chemical Listings	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).		

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Section 12 - Ecological Information

(a)	Ecotoxicity	Not available
(b)	Bioaccumulation potential	Not Available
(c)	Products of biodegradation:	Not Available
(d)	Toxicity of the products of biodegradation:	Not Available
(e)	Persistence and degradability	Not Available
(f)	Mobility in soil	Not Available
(g)	Other Adverse Effects	Not Available

Section 13 - Disposal Considerations

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

IATA / ICAO – Non Hazardous - Not Regulated

IATA Proper shipping name: N/A
IATA UN / ID No: N/A
IATA Hazard Class: N/A
IATA Packing Group: N/A
IATA Label: N/A

IMDG – Non Hazardous - Not Regulated

IMDG Proper shipping name: N/A
IMDG UN / ID No: N/A
IMDG Hazard Class: N/A
IMDG Flash Point N/A
IMDG Label: N/A

DOT – Non Hazardous - Not Regulated

DOT Proper shipping name: N/A
DOT UN / ID No: N/A
DOT Hazard Class: N/A
DOT Flash Point N/A
DOT Packing Group: N/A
DOT Label: N/A

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Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division 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.

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

As of the date of effectiveness, 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 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.

For additional information contact:

Athenex Pharmaceutical Division
10 N. Martingale Road, Suite 230
Schaumburg, IL 60173
847-886-9515

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

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
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
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
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
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
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
SDS	Safety Data Sheet
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

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UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

Signature Manifest

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All dates and times are in Eastern Standard Time.

SDS007

Change Request

Name/Signature	Title	Date	Meaning/Reason
Michael Scribner (MSCRIBNER)	CORPORATE QA MANAGER	24 Jan 2017, 04:32:30 PM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
Tom Moutvic (TMOUTVIC)	VP of Regulatory Affairs	25 Jan 2017, 03:37:49 PM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	26 Jan 2017, 11:10:46 AM	Approved

Review: SDS007 01

Review

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	02 Jan 2018, 09:58:05 AM	Reviewed
Jeffery Gardell (JGARDELL)	Sr. RA Associate	09 Jan 2018, 01:23:30 PM	Reviewed

Review: SDS007 01 Polymyxin B for Injection, USP

Review

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	10 Dec 2018, 05:07:42 PM	Reviewed
Jeffery Gardell (JGARDELL)	Sr. RA Associate	11 Dec 2018, 12:43:37 PM	Reviewed

Review: SDS007 01 Polymyxin B for Injection, USP

Review

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)			No Action
Sheila Moran (SMORAN)	VP of Quality Assurance	14 Nov 2019, 01:56:49 PM	Reviewed - Under Revision