



SDS: Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment, USP

SAFETY DATA SHEET

1. Identification

Product Identifier: Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment, USP

Synonyms: Bacitracins, zinc complex, Neomycin B Sulfates, Polymyxin B Sulfates.

National Drug Code (NDC): 17478-235-35

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.
Health Hazards: Not classifiable.
Symbol(s): None.
Signal Word: None.
Hazard Statement(s): None.
Precautionary Statement(s): None.
Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Neomycin Sulfate	1405-10-3	Neomycin B Sulfate	$C_{23}H_{46}N_6O_{13} \cdot 3H_2SO_4$	908.89	0.35%
Polymyxin B Sulfate	1405-20-5	Polymyxin B Sulfate	$C_{43}H_{82}N_{16}O_{12} \cdot xH_2O_4S$	1701.97	10,000 Units of Polymyxin B

* The formula also contains Bacitracin Zinc equal to 400 units of Bacitracin units, and White Petrolatum.



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4. First Aid Measures

Ingestion:

May cause irritation and hypersensitivity in some individuals. Ingestion of large quantities may induce gastric disturbances. If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

Eye Contact:

When used topically, Bacitracin Zinc and Polymyxin B Sulfate are rarely irritating. May cause hypersensitivity (anaphylactic) in some individuals. The most frequent adverse reactions are localized hypersensitivity with itching, swelling, and diffused redness of the eye (conjunctival erythema). If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 15 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

Skin Contact:

When used topically, Bacitracin Zinc and Polymyxin B Sulfate are rarely irritating, and absorption from the intact skin or mucous membrane is insignificant. May cause hypersensitivity in some individuals. If adverse skin effects occur, discontinue use. Seek medical attention.

Inhalation:

May cause irritation and hypersensitivity in some individuals. Inhalation is not likely with an ointment preparation. If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.

Protection of First-Aiders:

Use personal protective equipment (see section 8).

Signs and Symptoms:

No data available. See package insert for more information.

**Medical Conditions Aggravated
by Exposure:**

Hypersensitivity to any of the components of the product. Ophthalmic ointments may retard corneal healing.

Notes to Physician:

Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:

Use extinguishing media for type of surrounding fire.

Unsuitable Extinguishing Media:

Not determined.

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Fire Fighting Equipment: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: This product is combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, and sulfur oxides).

Other Specific Hazards: Not determined.

**Special Protective Equipment/
Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State, and Local regulations.

Environmental Precautions: No data available.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment. Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage,
Including Any Incompatibilities:** Store product upright in original containers with the cap tightly closed at a controlled room temperature 15°C – 30°C (59°F – 86°F). KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Specific End Use: Pharmaceuticals.

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8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Neomycin Sulfate	100 mg/m ³ TWA
Polymyxin B Sulfate	Not established.
Bacitracin Zinc	Not established.

Engineering Controls:

Engineering controls should be used as the primary means to control exposures.

Respiratory Protection:

Warning: Do not use air purifying respirators in oxygen depleted environments. No respiratory protection is required in the clinical or home environment. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection:

Not required for the normal use of this product. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection:

Not required for the normal use of this product. Wear chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection:

Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:

Pale yellow ointment.

Odor:

No data available.

Odor Threshold:

No data available.

pH:

No data available.

Melting Point:

No data available.

Freezing Point:

No data available.

Boiling Point:

No data available.

Flash Point:

No data available.

Evaporation Rate:

No data available.

Flammability (solid, gas):

No data available.

Flammability Limit - Lower:

No data available.

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Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Immiscible in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.
Incompatible Materials:	No data available.
Hazardous Decomposition Products:	Emits SO _x , NO _x , and toxic fumes.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	May cause irritation and hypersensitivity in some individuals. Inhalation is not likely with an ointment preparation. If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.
Ingestion:	May cause irritation and hypersensitivity in some individuals. Ingestion of large quantities may induce gastric disturbances. If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION.
Skin Contact:	When used topically, Bacitracin Zinc and Polymyxin B Sulfate are rarely irritating, and absorption from the intact skin or mucous membrane is insignificant. May cause hypersensitivity in some individuals. If adverse skin effects occur, discontinue use. Seek medical attention.

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Eye Contact:

When used topically, Bacitracin Zinc and Polymyxin B Sulfate are rarely irritating. May cause hypersensitivity (anaphylactic) in some individuals. The most frequent adverse reactions are localized hypersensitivity with itching, swelling, and diffused redness of the eye (conjunctival erythema).

Symptoms Related to the Physical, Chemical and Toxicological Characteristics:

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure:

No data available.

Acute Toxicity:

Compound	Species	Route	Type	Dose
Neomycin Sulfate	Woman	Oral	LD _{Lo}	12,600 mg/kg/7 days
Neomycin Sulfate	Mouse	Oral	LD ₅₀	8,000 mg/kg
Neomycin Sulfate	Human	Skin	TC _{Lo}	20 pph/48 hours
Neomycin Sulfate	Human	Skin	Standard Draize Test	6 mg/3 days
Neomycin Sulfate	Mouse	Intraperitoneal	LD ₅₀	305 mg/kg
Neomycin Sulfate	Rat	Subcutaneous	LD ₅₀	200 mg/kg
Neomycin Sulfate	Rat	Subcutaneous	TD _{Lo}	280 mg/kg/7 days
Neomycin Sulfate	Mouse	Subcutaneous	LD ₅₀	190 mg/kg
Neomycin Sulfate	Mouse	Subcutaneous	TD _{Lo}	560 mg/kg/7 days
Neomycin Sulfate	Mouse	Intravenous	LD ₅₀	17,400 mg/kg
Neomycin Sulfate	Mouse	Intramuscular	LD ₅₀	142 mg/kg
Neomycin Sulfate	Guinea Pig	Intramuscular	LD ₅₀	>250 mg/kg
Neomycin Sulfate	Guinea Pig	Intramuscular	TD _{Lo}	2,000 mg/kg/8 days
Neomycin Sulfate	Monkey	Intramuscular	TD _{Lo}	500 mg/kg/5 days
Neomycin Sulfate	Cat	Intramuscular	TD _{Lo}	5,050 mg/kg/14 weeks
Neomycin Sulfate	Mouse	Intracerebral	LD ₅₀	32 mg/kg
Neomycin Sulfate	Rat	Intracerebral	TD _{Lo}	714.3 mg/kg
Neomycin Sulfate	Rat	Intraspinal	TD _{Lo}	36.88 ug/kg
Bacitracin Zinc	Mouse	Oral	LD ₅₀	>3,750 mg/kg
Bacitracin Zinc	Guinea Pig	Oral	LD ₅₀	2,000 mg/kg
Bacitracin Zinc	Quail	Oral	LD ₅₀	>316 mg/kg
Bacitracin Zinc	Rat	Intraperitoneal	LD ₅₀	190 mg/kg
Bacitracin Zinc	Mouse	Intraperitoneal	LD ₅₀	300 mg/kg
Bacitracin Zinc	Mouse	Subcutaneous	LD ₅₀	1300 mg/kg
Bacitracin Zinc	Mouse	Intravenous	LD ₅₀	360 mg/kg
Bacitracin Zinc	<i>E. Coli</i>	Bacteria	DNA Adduct	50 umol/L
Bacitracin Zinc	Human	Skin	TC _{Lo}	20 pph/48 hours
Polymyxin B Sulfate	Mouse	Oral	LD ₅₀	790 mg/kg
Polymyxin B Sulfate	Mouse	Intraperitoneal	LD ₅₀	20,500 ug/kg
Polymyxin B Sulfate	Mouse	Subcutaneous	LD ₅₀	59,500 ug/kg
Polymyxin B Sulfate	Mouse	Subcutaneous	LD _{Lo}	284 mg/kg/9 days
Polymyxin B Sulfate	Guinea Pig	Subcutaneous	LD ₅₀	58 mg/kg
Polymyxin B Sulfate	Mouse	Intravenous	LD ₅₀	5,400 ug/kg
Polymyxin B Sulfate	Dog	Intravenous	LD _{Lo}	8 mg/kg
Polymyxin B Sulfate	Dog	Intracerebral	LD ₅₀	320 ug/kg
Polymyxin B Sulfate	<i>E. Coli</i>	Bacteria	DNA Adduct	50 mg/L

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Acute Toxicity – Dermal:	No data available.
Acute Toxicity – Inhalation:	No data available.
Corrosivity:	No data available.
Dermal Irritation:	No data available.
Eye Irritation:	No data available.
Sensitization:	No data available.
Toxicokinetics/Metabolism:	No data available.
Target Organ Effects:	No data available.
Reproductive Effects:	No data available.
Carcinogenicity:	No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity: No data available.

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

12. Ecological Information

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.

Department of Transportation: Not regulated as a hazardous material.

International Air Transport Association (IATA): Not regulated as a dangerous good.

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.



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15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act
(TSCA): Not listed.

CERCLA Hazardous Substance
and Reportable Quantity: Not listed.

SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

California Proposition 65: Not listed.

16. Other Information

Not made with natural rubber latex.

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