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

Manufacturer: Akorn
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Section 1 - IDENTIFICATION

Common/Trade Name: Bacitracin Zinc and Neomycin Sulfate and Polymyxin B Sulfate Ointment

Chemical Names: Bacitracin Zinc, Neomycin Sulfate, and Polymyxin B Sulfate

Chemical Formula: NA

Legal Category: Prescription Only

Section 2 – HAZARD(S) IDENTIFICATION

Routes of Entry: Eyes, skin, and digestive tract.

Carcinogenicity:

NTP: No

IARC: No

OSHA Regulated: No

Section 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS#	%w/w
Bacitracin Zinc	1405-89-6	400 units of Bacitracin
Neomycin Sulfate	1405-10-3	0.35% of Neomycin
Polymyxin B Sulfate	1405-20-5	10,000 Units of Polymyxin B
White Petrolatum	8009-03-8	Proprietary

Section 4 – FIRST AID MEASURES

Eyes: 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 (conjuctival 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 20 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

Skin: 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.

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.

Section 5 – FIRE FIGHTING MEASURES

Flash Point: NE

Auto ignition: NE

Lower Explosion Limit: NE

Upper Explosion Limit: NE

General Hazard: NA

Fire Fighting Instructions: Use extinguishing media appropriate for surrounding fire.

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.

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).

Section 6 – ACCIDENTAL RELEASE MEASURES

Clean-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.

Section 7 – HANDLING AND STORAGE

Precautions: NE

General Handing: 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.

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

Section 8 –EXPOSURE CONTROLS / PERSONAL PROTECTIVE

Engineering Controls: In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will maintain the dust and vapor levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Material Safety Data Sheets.

Personal Protective Equipment

Eye Protection:	(29 CFR 1910.133) Recommend goggles or chemical safety glasses.
Hand Protection:	Thick impermeable gloves.
Respiratory Protection:	(29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials.
	Warning: Do not use air purifying respirators in oxygen depleted environments. No respiratory protection is required in the clinical or home environment.
Skin Protection:	Protective clothing.
Ventilation:	Recommended.

Exposure Limits: NE

Section 9 – PHYSICAL/CHEMICAL CHARACTERISTICS

Physical Form/ Appearance:	pale yellow ointment
Boiling Point/Boiling Range:	NE
Melting Point/Melting Range:	NE
Freezing Point:	NE
Vapor Pressure:	NE
Relative Vapor Density:	NE
Percent Volatiles:	NE
pH:	NE
Molecular Weight:	NE
Solvent Solubility:	Immiscible in water
Latex Free:	Yes

Section 10 – STABILITY AND REACTIVITY

Reactivity:	NE
Chemical Stability:	Stable
Possibility of Hazardous Reactions:	NE
Conditions to Avoid:	This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.
Hazardous Polymerization:	Should not occur.
Hazardous Decomposition Products:	Emits SO_x, NO_x, and toxic fumes.

Section 11 – TOXICOLOGICAL INFORMATION

Signs & Symptoms of Exposure & Overexposure: NA

Chronic Effects: May cause irritation and hypersensitivity. As with other antibiotic preparations, prolonged use may result in the overgrowth of non-susceptible organisms, including fungi. Appropriate measures should be taken if this occurs.

Medical Conditions Aggravated by Accidental Exposure: Hypersensitivity to any of the components of the product. Ophthalmic ointments may retard corneal healing.

Acute Toxicity:

Compound	Type	Route	Species	Dosage
Bacitracin Zinc	LD_{50}	Oral	Mouse	>3750 mg/kg
Bacitracin Zinc	LD_{50}	Oral	Guinea Pig	2000 mg/kg
Bacitracin Zinc	LD_{50}	Oral	Quail	>316 mg/kg
Bacitracin Zinc	LD_{50}	Intraperitoneal	Rat	190 mg/kg
Bacitracin Zinc	LD_{50}	Intraperitoneal	Mouse	300 mg/kg
Bacitracin Zinc	LD_{50}	Subcutaneous	Mouse	1300 mg/kg
Bacitracin Zinc	LD_{50}	Intravenous	Mouse	360 mg/kg
Bacitracin Zinc	TCLo	Skin	Human	20 pph/48 hrs
Bacitracin Zinc	DNA Adduct	Bacteria	*E.Coli*	50 umol/L
Neomycin Sulfate	Standard Draize Test	Skin	Human	6mg/3 days
Neomycin Sulfate	TDLo	Oral	Woman	12,600mg/kg/7 days
Neomycin Sulfate	TCLo	Skin	Human	20 pph/48 hours
Neomycin Sulfate	LD_{50}	Oral	Mouse	8000 mg/kg
Neomycin Sulfate	LD_{50}	Subcutaneous	Rat	200mg/kg
Neomycin Sulfate	LD_{50}	Subcutaneous	Mouse	190 mg/kg

Neomycin Sulfate	LD_{50}	Intraperitoneal	Mouse	305 mg/kg
Neomycin Sulfate	LD_{50}	Intravenous	Mouse	17,400 ug/kg
Neomycin Sulfate	LD_{50}	Intramuscular	Mouse	142 mg/kg
Neomycin Sulfate	LD_{50}	Intramuscular	Guinea Pig	>250 mg/kg
Neomycin Sulfate	LD_{50}	Intracerebral	Mouse	32 mg/kg
Neomycin Sulfate	TDLo	Intracerebral	Rat	714.3 ug/kg
Neomycin Sulfate	TDLo	Subcutaneous	Rat	280 mg/kg/7 days
Neomycin Sulfate	TDLo	Subcutaneous	Mouse	560 mg/kg/7 days
Neomycin Sulfate	TDLo	Intramuscular	Monkey	500 mg/kg/ 5 days
Neomycin Sulfate	TDLo	Intramuscular	Cat	5050 mg/kg/14 weeks
Neomycin Sulfate	TDLo	Intramuscular	Guinea Pig	2000 mg/kg/8 days
Neomycin Sulfate	TDLo	Intraspinal	Rat	36.88 ug/kg
Polymyxin B Sulfate	LD_{50}	Oral	Mouse	790 mg/kg
Polymyxin B Sulfate	LD_{50}	Intraperitoneal	Mouse	20,500 ug/kg
Polymyxin B Sulfate	LD_{50}	Subcutaneous	Mouse	59,500 ug/kg
Polymyxin B Sulfate	LD_{50}	Subcutaneous	Guinea Pig	58 mg/kg
Polymyxin B Sulfate	LD_{50}	Intravenous	Mouse	5400 ug/kg
Polymyxin B Sulfate	LDLo	Intravenous	Dog	8 mg/kg
Polymyxin B Sulfate	LD_{50}	Intracerebral	Dog	320 ug/kg
Polymyxin B Sulfate	LDLo	Subcutaneous	Mouse	284 mg/kg/9 days
Polymyxin B Sulfate	DNA Adduct	Bacteria	*E.Coli*	50 mg/L

Section 12 – ECOLOGICAL INFORMATION

Ecotoxicity : NA

Biodegradable : NA

Section 13 – DISPOSAL INFORMATION

Disposal Procedure: Dispose of material according to Federal, State, and Local regulations. The method typically used is incineration.

Section 14 – TRANSPORT INFORMATION

UN/NA Nimber: NA

U.S. DOT Hazard Class: Not classified as hazardous by DOT regulations.

Proper Shipping Name: NA

Shipping Label: NA

Section 15 – REGULATORY INFORMATION

FDA (Food & Drug Administration):	Prescription only medication.
TSCA (Toxic Substance Control Act):	NA
HMIS (Hazardous Materials Information System (USA)):	NA
WHMIS (Workplace Hazardous Materials):	NA

Section 16 – OTHER INFORMATION

Date of preparation or last revision: 05-13

Key to Abbreviations:
NA = Not Available
NE = Not Established
< = Less Than
> = Greater Than