

# MATERIAL SAFETY DATA SHEET

**Manufacturer's Name:** ALTANA INC.  
**Divisions:** E. FOUGERA & COMPANY DIVISION  
 PHARMADERM DIVISION  
**Street Address:** 60 BAYLIS ROAD  
**City, State, Zip Code:** MELVILLE, NEW YORK 11747  
**Emergency Telephone No.:** (631) 454-7677

## SECTION 1: IDENTITY

<b>Product Name:</b>	Neomycin Sulfate, Polymyxin B Sulfates and Bacitracin Zinc Ointment and Ophthalmic Ointment USP
<b>Synonyms:</b>	"Triple" Antibiotic Ointment.
<b>CAS #:</b>	Not applicable.
<b>Chemical Family:</b>	Antibiotic Ointment
<b>Formula:</b>	Neomycin Sulfate Micronized USP Sterile, Polymyxin B Sulfate Micronized USP Sterile, Bacitracin Zinc Micronized USP Sterile, and White Petrolatum USP. Ophthalmic ointment also contains Mineral Oil USP.

## SECTION 2: SAFETY and HAZARD RATINGS

<b>Health (Acute-Chronic):</b>	1-1	<b>RATINGS</b>
<b>Flammability:</b>	1	
<b>Reactivity:</b>	0	
<b>Environment (Air-Water-Soil):</b>	0-0-3	
<b>Special Hazards:</b>	Not indicated.	
<b>Protective Equipment:</b>	General ventilation, eye and hand wash.	
		<b>Minimal</b> 0
		<b>Slight</b> 1
		<b>Moderate</b> 2
		<b>Severe</b> 3
		<b>Extreme</b> 4

## SECTION 3: EMERGENCY and FIRST AID PROCEDURES

<b>Eyes:</b>	Flush eyes with plenty of water for at least 15 minutes (non-ophthalmic form only).
<b>Skin:</b>	Wash thoroughly with soap and water.
<b>Ingestion:</b>	Give two glasses of water and induce vomiting if directed by medical personnel. Never give anything by mouth to an unconscious person.
<b>Inhalation:</b>	Remove to fresh air. If breathing is difficult, give oxygen. If breathing has stopped, give artificial respiration.

**CALL A PHYSICIAN**  
**CONTACT A POISON CONTROL CENTER**

## SECTION 4: INGREDIENTS

NAME	CAS#	%	CARCINOGEN			HAZARD DATA	
			IARC	NTP	OSHA	ACGIH TLV	OSHA PEL
Neomycin Sulfate	1405-10-3		no	no	no	not established	
Polymyxin B Sulfate	1405-20-5		no	no	no	not established	
Bacitracin Zinc	1405-89-6		no	no	no	not established	
White Petrolatum	8009-03-8		no	no	no	not established	
Mineral Oil	8012-95-1		no	no	no	5mg/m <sup>3</sup> *	5mg/m <sup>3</sup> *

\* as mist

**SECTION 5: FIRE and EXPLOSION HAZARD DATA**

<b>Flash Point:</b>	199°C (390°F) (closed cup) (97% Petrolatum Concentration)
<b>Auto-ignition Temperature °F:</b>	Not determined.
<b>Flammable Limits in Air by Volume LEL:</b>	Not determined.
<b>UEL:</b>	Not determined.
<b>Extinguishing Media:</b>	Alcohol Foam, Dry chemical, Carbon dioxide.
<b>Special Fire Fighting Procedures:</b>	Wear full protective clothing.
<b>Unusual Fire and Explosion Hazards:</b>	May emit toxic fumes.

**SECTION 6: REACTIVITY DATA (PHYSICAL HAZARDS)**

<b>Stability:</b>	<input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable
<b>Conditions and Chemicals to Avoid:</b>	Avoid extreme heat, sparks, open flame, oxidizers, strong acids and alkalies.
<b>Hazardous Combustion or Decomposition Products:</b>	Carbon dioxide, Carbon monoxide.
<b>Hazardous Polymerization:</b>	<input type="checkbox"/> May Occur <input checked="" type="checkbox"/> Will Not Occur

**SECTION 7: HEALTH HAZARDS**

<b>Primary Route(s) of Entry:</b>	Dermal, Ingestion.
<b>Signs and Symptoms of Exposure</b>	
<b>a. Overexposure Effects:</b>	<ol style="list-style-type: none"> <li>a. Allergy, kidney and liver impairment, dizziness, uncoordination, sensory loss, deafness, nausea, vomiting and diarrhea.</li> </ol>
<b>b. Chronic Effects:</b>	<ol style="list-style-type: none"> <li>b. May cause allergic reactions in susceptible individuals. <ol style="list-style-type: none"> <li>1. Not likely due to the physical state of the product.</li> <li>2. Use only specified ophthalmic ointment in eyes. topical ointment will cause eye irritation.</li> <li>3. Non-toxic under standard application.</li> <li>4. May cause kidney, liver and gastrointestinal impairment; may induce dizziness, uncoordination, sensory loss and deafness.</li> <li>5. Allergic reaction in sensitive individuals.</li> </ol> </li> </ol>
<ol style="list-style-type: none"> <li>1. Inhalation:</li> <li>2. Eyes:</li> <li>3. Skin:</li> <li>4. Ingestion:</li> <li>5. Medical Conditions</li> </ol> Potentially Aggravated:	

**SECTION 8: SPECIAL PRECAUTIONS and SPILL/LEAK PROCEDURES**

<b>Precautions to be Taken in Handling/Storage:</b>	Keep container closed when not in use. Store at controlled room temperature 15°-25°C (59°-77°F). Do not handle or store near heat, flame or oxidizers.
<b>Hygienic Practices:</b>	Wash thoroughly after handling. Use normal hygiene to protect hands, eyes and skin. Use general ventilation to protect your lungs., Do not wear contaminated clothing until thoroughly laundered.
<b>When Material is Released or Spilled:</b>	Assure slippery conditions are nullified. Add sand or dirt. Scoop up and remove. Wash area with soap and water. Dispose of in accordance with federal, state and local regulations.
<b>Waste Disposal Methods:</b>	Assure conformity with applicable disposal regulations. Dispose of absorbed material at approved incineration or chemical landfill waste disposal site.

**SECTION 9: SPECIAL PROTECTION INFORMATION**

<b>Respiratory Protection:</b>	General ventilation.
<b>Skin Protection:</b>	Normal hygiene.
<b>Eye Protection:</b>	Normal hygiene.
<b>Other Protective Clothing or Equipment:</b>	As needed to prevent repeated/prolonged contact.

**SECTION 10: CONTAINERS and LABELING**

<b>Special Precautions:</b>	Keep container closed when not in use. Store at controlled room temperature 15°-25°C (59°-77°F).
<b>Recommended Container:</b>	As supplied (not sold in bulk quantity).
<b>Protect the Container by:</b>	Avoid physical damage and heat.
<b>Container Should be Handled in an Area with:</b>	Cool, dry conditions.
<b>The Empty Container is:</b>	Not reusable.
<b>Precautionary Label:</b>	<b>Ophthalmic Ointment:</b> Federal law prohibits dispensing without a prescription. For ophthalmic use only. (See package insert.)
<b>Warning Placard:</b>	Keep out of reach of children.
<b>IMO Hazard Class #:</b>	Not applicable.
<b>UN/NA #:</b>	Not applicable.
<b>Hazard Classification:</b>	Not applicable.
<b>DOT Name:</b>	Not applicable.
<b>Shipping Instructions:</b>	Keep away from extreme heat, flame and oxidizers.

**SECTION 11: ENVIRONMENTAL RISKS**

<b>Aquatic Toxicity:</b>	Not indicated.
<b>Biodegradability:</b>	Not indicated.
<b>Partition Coefficient:</b>	Not indicated.

**SECTION 12: REGULATORY INFORMATION**

<b>Refer to the following references:</b>	<b>OSHA Regulations:</b>	If respirator used, 29 CFR 1910.134
	<b>DOT Regulations:</b>	Not applicable.
	<b>EPA Regulations:</b>	Not applicable.
	<b>Other:</b>	FDA: 21 CFR 300.5 21 CFR 369.21
		NDC: 0168-0012-09 Ointment 0168-0012-35 Ointment 0168-0012-31 Ointment 0168-0027-38 Ophthalmic Ointment

**SECTION 13: PHYSICAL DATA**

Appearance and Odor:	A pale yellow ointment. Odorless.
Molecular Weight:	Not applicable.
pH:	Not determined.
Refractive Index @ 20°C:	Not determined.
Viscosity:	Not determined.
Boiling Point:	200°C (392°F)
Freezing/Melting Point:	58°C (136°F)
Congearing Point:	Not determined.
Vapor Pressure (mm Hg @ 20°C):	<1mm
Vapor Density (Air=1):	Not determined.
Solubility in Water:	Insoluble.
Solubility in Alcohol:	Practically insoluble.
Solubility in Oil:	Soluble.
Solubility in Other:	Most polar solvents.
Specific Gravity (H <sub>2</sub> O=1):	0.85 @ 60°C
% Volatile by Volume:	0
Evaporation Rate (Ether=1):	0

Date of Preparation/Change:  
March 16, 2005

Revision # 2

Replaces  
November 29, 2001  
*previously known as* Bacitracin Zinc-Neomycin  
Sulfate-Polymyxin B Sulfate Ointment and  
Ophthalmic Ointment

The information presented herein relates to the specific material described and may not be valid for this material used in combination with any other materials or in any process. This information is, to the best of our knowledge, accurate and reliable on the date compiled. We make no representation, warranty or guarantee as to its accuracy, reliability or completeness.

It is the reader's responsibility to ascertain whether the information supplied is suitable and complete for that person's specific uses. This Material Safety Data Sheet was prepared for ALTANA INC. by:

COMPLIANCE INNOVATIONS, INC.  
706 Route 15 South, Suite 207  
Lake Hopatcong, New Jersey 07849  
973-663-1120 • fax 973-663-2378  
helpdesk@chemply.com