

MATERIAL SAFETY DATA SHEET

Manufacturer's Name: ALTANA INC.
Divisions: E. FOUGERA & COMPANY DIVISION
 PHARMADERM DIVISION
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SECTION 1: IDENTITY

Product Name:	Neomycin and Polymyxin B Sulfates, Bacitracin Zinc and Hydrocortisone Acetate Ophthalmic Ointment USP
Synonyms:	Bacitracin-Neomycin-Polymyxin with Hydrocortisone Acetate Ophthalmic Ointment.
CAS #:	Not applicable.
Chemical Family:	Pharmaceutical ointment primarily composed of alkanes.
Formula:	Bacitracin Zinc, Polymyxin B Sulfate, Neomycin Sulfate, Hydrocortisone Acetate, White Petrolatum and Mineral Oil.

SECTION 2: SAFETY and HAZARD RATINGS

Health (Acute-Chronic):	1-1	RATINGS Minimal 0 Slight 1 Moderate 2 Severe 3 Extreme 4
Flammability:	1	
Reactivity:	0	
Environment (Air-Water-Soil):	0-0-1	
Special Hazards:	None.	
Protective Equipment:	General ventilation, eye and hand wash.	

SECTION 3: EMERGENCY and FIRST AID PROCEDURES

Eyes:	Flush eyes with plenty of water for at least 15 minutes.
Skin:	Wash thoroughly with soap and water.
Ingestion:	Give two glasses of water and induce vomiting, if directed by medical personnel. Never give anything by mouth to an unconscious person.
Inhalation:	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
Bacitracin Zinc	1405-89-6		no	no	no	not established	
Polymyxin B Sulfate	1405-20-5		no	no	no	not established	
Neomycin Sulfate	1405-10-3		no	no	no	not established	
Hydrocortisone Acetate	50-03-3		no	no	no	not established	
White Petrolatum	8009-03-8		no	no	no	not established	
Mineral Oil	8042-47-5		no	no	no	not established	

SECTION 5: FIRE and EXPLOSION HAZARD DATA

Flash Point:	Not determined.
Auto-ignition Temperature °F:	Not determined.
Flammable Limits in Air by Volume LEL:	Not determined.
UEL:	Not determined.
Extinguishing Media:	Alcohol foam, Dry chemical, Carbon dioxide.
Special Fire Fighting Procedures:	Wear full protective clothing and self-contained breathing apparatus.
Unusual Fire and Explosion Hazards:	May emit toxic fumes, Carbon oxides (CO, CO ₂) in a fire.

SECTION 6: REACTIVITY DATA (PHYSICAL HAZARDS)

Stability:	<input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable
Conditions and Chemicals to Avoid:	Avoid strong oxidizers, strong acids, bases and sources of heat.
Hazardous Combustion or Decomposition Products:	May emit toxic fumes when burned.
Hazardous Polymerization:	<input type="checkbox"/> May Occur <input checked="" type="checkbox"/> Will Not Occur

SECTION 7: HEALTH HAZARDS**Primary Route(s) of Entry:**
Signs and Symptoms of Exposure

- a. Overexposure Effects:
b. Chronic Effects:

1. Inhalation:
2. Eyes:
3. Skin:
4. Ingestion:
5. Medical Conditions Potentially Aggravated:

Dermal, Ingestion.

- a. May cause skin irritation.
- b. Prolonged use may result in intraocular pressure, glaucoma, optic nerve damage, posterior subcapsular cataract formation, and allergic reactions in sensitive individuals. Secondary infections may occur through the combined use of steroids and antimicrobials. Carcinogenicity studies on highly refined mineral oils (IARC Monographs Suppl. 7, 252, 1987) have been reviewed by IARC who found that they "do not permit an evaluation of its carcinogenicity."
 1. Not likely due to the physical state of the product.
 2. None expected under normal conditions of use. Prolonged use may result in intraocular pressure, glaucoma, optic nerve damage and posterior subcapsular cataract formation.
 3. May cause irritation.
 4. May cause indigestion, nausea and vomiting.
 5. May cause allergic reaction and skin irritation to individuals sensitive to any cortisone drug or the antibiotic components.

SECTION 8: SPECIAL PRECAUTIONS and SPILL/LEAK PROCEDURES

Precautions to be Taken in Handling/Storage:	Keep container closed when not in use. Do not handle or store near strong oxidizers, strong acids, bases and sources of heat. Store at controlled room temperature 15°-30°C (59°-86°F).
Hygienic Practices:	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.
When Material is Released or Spilled:	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.
Waste Disposal Methods:	Assure conformity with applicable disposal regulations. Dispose of absorbed material at approved incineration or chemical landfill waste disposal site.

SECTION 9: SPECIAL PROTECTION INFORMATION

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

SECTION 10: CONTAINERS and LABELING

Special Precautions:	Keep container closed when not in use. Avoid strong oxidizers, strong acids, bases and sources of heat. Store at controlled room temperature 15°-30°C (59°-86°F).
Recommended Container:	As supplied (not sold in bulk quantity).
Protect the Container by:	Avoid physical damage and heat.
Container Should be Handled in an Area with:	Cool, dry conditions.
The Empty Container is:	Not reusable.
Precautionary Label:	Federal law prohibits dispensing without a prescription. Use as directed. For external use only. (See package insert.)
Warning Placard:	Keep out of reach of children.
IMO Hazard Class #:	Not applicable.
UN/NA #:	Not applicable.
Hazard Classification:	Not applicable.
DOT Name:	No applicable.
Shipping Instructions:	Keep away from strong oxidizers, strong acids, bases and sources of heat.

SECTION 11: ENVIRONMENTAL RISKS

Aquatic Toxicity:	Not indicated.
Biodegradability:	Not indicated.
Partition Coefficient:	Not indicated.

SECTION 12: REGULATORY INFORMATION

Refer to the following references:	OSHA Regulations:	If respirator used, 29 CFR 1910.134
	DOT Regulations:	Not applicable.
	EPA Regulations:	Not applicable.
	Other:	FDA: 21 CFR 448.313b NDC: 0168-0029-38

SECTION 13: PHYSICAL DATA

Appearance and Odor:	A pale yellow ointment with no discernible odor.
Molecular Weight:	Not applicable.
pH:	Not determined.
Refractive Index @ 20°C:	Not determined.
Viscosity @ 25°C:	Not determined.
Boiling Point:	Approximately 149°C (300°F)
Freezing/Melting Point:	57°C (134.6°F)
Congealing Point:	Not determined.
Vapor Pressure (mm Hg @ 20°C):	Not determined.
Vapor Density (Air=1):	Not determined.
Solubility in Water:	Insoluble.
Solubility in Alcohol:	Mainly insoluble.
Solubility in Oil:	Mainly soluble.
Solubility in Other:	Not determined.
Specific Gravity (H₂O=1):	0.86 @ 20°C
% Volatile by Volume:	0
Evaporation Rate (Ether=1):	0

Date of Preparation/Change:
October 25, 2004

Revision # 2

Replaces
March 25, 1992

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:

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