

EFGERA MATERIAL SAFETY DATA SHEET

HC #16
p.1

Manufacturer's Name: ALTANA INC. - BYK PHARMACEUTICAL GROUP
 Divisions: E. FOUGERA & COMPANY DIVISION
 PHARMADERM DIVISION
 SAVAGE LABORATORIES DIVISION
 Street Address: 60 BAYLIS ROAD
 City, State, Zip Code: MELVILLE, NEW YORK 11747
 Emergency Telephone No.: (516) 454-7577

SECTION 1: IDENTITY

Product Name: Bacitracin Zinc and Polymyxin B Ophthalmic Ointment
 Synonyms: Not Applicable
 CAS #: Not Applicable
 Chemical Family: Antibiotic
 Formula: Bacitracin Zinc, Polymyxin B Sulfate, Mineral Oil, white Petrolatum

SECTION 2: SAFETY AND HAZARD RATINGS

Health (Acute-Chronic): 1-0
 Flammability: 1
 Reactivity: 0
 Environment (Air-Water-Soil): 0-0-1
 Special Hazards: None
 Protective Equipment: (None required under standard usage)

RATINGS

Minimal	0
Slight	1
Moderate	2
Severe	3
Extreme	4

SECTION 3: EMERGENCY AND FIRST AID PROCEDURES

EYES: Flush with plenty of water for at least 15 minutes.
 SKIN: Flush with plenty of soap and water.
 INGESTION: Give plenty of water to drink and induce vomiting.
 INHALATION: Not Applicable for ointment

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 Applicable	
Polymyxin B Sulfate	1405-20-5		No	No	No	Not Applicable	
White Petrolatum	8009-03-8		No	No	No	Not Applicable	
Mineral Oil	8042-47-5		No	No	No	Not Applicable	

I-328784 C-#0168-0021-09
 I-246411 C-#0168-0021-35
 I-180060 C-#0168-0021-31

Product Name: Bacitracin Zinc and Polymyxin Ophthalmic Ointment

SECTION 5: FIRE AND EXPLOSION HAZARD DATA

Flash Point: Not Indicated
Auto-Ignition Temperature °F: Not Indicated
Flammable Limits in Air by Volume LEL: Not Indicated
UEL: Not Indicated

Extinguishing Media: Foam, Dry Chemical, Carbon Dioxide

Special Fire Fighting Procedures: Use self-contained breathing apparatus when firefighting

Unusual Fire and Explosion Hazards: May emit toxic fumes when burning.

SECTION 6: REACTIVITY DATA (PHYSICAL HAZARDS)

Stability: ☒ Stable ☐ Unstable

Conditions and Chemicals to Avoid: Heat, light, oxidants, bases

Hazardous Combustion or Decomposition Products: Carbon Monoxide and Carbon Dioxide

Hazardous Polymerization: ☐ May Occur ☒ Will Not Occur

SECTION 7: HEALTH HAZARDS

Primary Route(s) of Entry: Ingestion, dermal

Signs and Symptoms of Exposure

a. Overexposure Effects: Possible allergic reaction.

b. Chronic Effects: Possible hypersensitization

1. Inhalation: Not expected under normal condition of use

2. Eyes: May cause irritation

3. Skin: May cause irritation

4. Ingestion: May cause irritation

5. Medical Conditions Potentially Aggravated By: Hypersensitivity to any of the ingredients

SECTION 8: SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

Hygienic Practices: Use proper personal hygiene

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. Report major leaks and spills to the appropriate local, state and/or federal governmental agency.

Waste Disposal Methods: Assure conformity with applicable disposal regulations. Dispose of absorbed material at approved incineration or chemical landfill waste disposal site.

Product Name: Bectracin Zinc and Polymyxin Ophthalmic Ointment

SECTION 9: SPECIAL PROTECTION INFORMATION

Respiratory Protection:	Adequate ventilation
Skin Protection:	Normal Hygiene
Eye Protection:	Normal Hygiene
Other Protective Clothing or Equipment:	Care to avoid slippery conditions

SECTION 10: CONTAINERS AND LABELING

Special Precautions:	Keep container closed. Keep away from heat, light, flame, oxidants and bases.
Recommended Container:	As supplied (not sold in bulk quantity)
Protect The Container By:	Avoiding physical damage and heat
Container Should Be Handled In An Area With:	Adequate general ventilation
The Empty Container Is:	Not reusable
Precautionary Label:	Federal law prohibits dispensing without a prescription
Warning Placard:	Keep out of reach of children (See Package Insert)
IMO Hazard Class #:	Not Applicable
Hazard Classification:	Not Applicable
DOT Name:	Not Applicable
Shipping Instructions:	Keep away from oxidants, alkalies, heat, flame and light

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:	Not Applicable
DOT Regulations:	Not Applicable
EPA Regulations:	Not Applicable
Other:	FDA:

Product Name: Bacitracin Zinc and Polymyxin Ophthalmic Ointment

SECTION 13: PHYSICAL DATA

Appearance and Odor:	A white to off-white odorless ointment
Molecular Weight:	Not Applicable
pH:	Not Determined
Refractive Index @ 20°C:	Not Determined
Viscosity:	20-80cSt
Freezing/Melting Point:	Melts at about 46°C
Boiling Point:	Decomposition begins at about 220°C
Congelling Point:	Not Determined
Vapor Pressure (mm Hg @ 20°C):	Not Determined
Vapor Density (Air=1):	Not Determined
Solubility in Water:	Insoluble
Solubility in Alcohol:	Insoluble
Solubility in Oil:	Miscible
Specific Gravity (H ₂ O = 1):	0.87 @ 60°C
% Volatile by Volume:	Not Applicable
Evaporation Rate(Ether = 1):	0.0

Date of Preparation/Change: November 24, 1998 Revision 0 Replaces ---

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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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