BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

Issued:	09/07/94	Prepared by:	Gary Wong
Revised:	01/28/02		Manager EHS
Revision:	02	Core No. 075	

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Bacitracin Zinc & Polymyxin B Sulfate Ophthalmic Ointment USP
Generic Name: Same
NDC No. 24208-555-55 (3.5 gm)

Legal Category: Prescription only medication, filled inside tube suitable for dispensing, and overpacked inside a cardboard carton.

Drug Composition: Antibiotic

BAUSCH & LOMB PHARMACEUTICALS, INC.
8500 Hidden River Parkway
Tampa, FL 33637
Information: (800) 323-0000 (M-F) 8am-5pm EST
Emergency: (800) 227-1427 24 hrs

2. COMPOSITION/INFORMATION ON INGREDIENTS

Description	CAS #	TLV (mg/m^3)	PEL(mg/m^3)	% Content
Bacitracin Zinc	1405-89-6	NE	NE	≥1
Polymyxin B Sulfate	1404-26-8	NE	NE	<1
Mineral Oil	8042-47-5	5(mist)	5	≥1
White Petrolatum	8009-03-8	NE	NE	≥1

3. HAZARDS IDENTIFICATION

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EMERGENCY OVERVIEW

Tube packed in a cardboard box. Translucent, off-white to yellowish, soft-bodied ointment.

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POTENTIAL HEALTH HAZARDS

Carcinogenicity: **(NTP)** No **(IARC)** No **(OSHA)** No

Eye: 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).

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.

Ingestion: May cause irritation and hypersensitivity in some individuals. Ingestion of large quantities may induce gastric disturbances.

Inhalation: May cause irritation and hypersensitivity in some individuals. Inhalation is not likely with an ointment preparation.

Chronic Effects: May cause irritation and hyper-sensitivity. 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.

Target Organs: Eyes and digestive tract.

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

4. FIRST AID MEASURES

Eyes: Rinse immediately with copious amounts of water for at least 20 minutes. Contact a physician.

Skin: Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician if skin becomes irritated.

Ingestion: Immediately administer slurry of activated charcoal. The use of an emetic drug and/or gastric lavage is advisable. Wash out mouth and give plenty of water and bland fluids. Do not give anything to an unconscious person. Seek professional assistance.

Inhalation: Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician immediately.

Note to Physicians: None.

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Hazardous Products: Emits toxic fumes.

Extinguishing Media: Dry chemical, carbon dioxide, halon, water fog and foam for surrounding materials. Water spray will froth if sprayed into the burning material.

Fire Fighting Instructions: Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material.

6. ACCIDENTAL RELEASE MEASURES

Large/Small Spills: 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.

7. HANDLING AND STORAGE

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.

Storage: Store product upright in original containers with the cap tightly closed at a controlled room temperature 15^0-30^0 C (59^0- 86^0 F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

8. EXPOSURE CONTROL/PERSONAL PROTECTION

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.

Eye Protection: (29 CFR 1910.133) Recommend goggles or chemical safety glasses.

Skin Protection: Thick impermeable gloves and protective clothing.

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.

Other: None

Ventilation: Recommended

Contaminated Equipment: Wash contaminated clothing separately. Wash equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

9. CHEMICAL & PHYSICAL PROPERTIES

Appearance & Odor: Translucent, off-white to yellowish, soft-bodied ointment.

Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	NE	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Immiscible	Percent Volatile by Volume:	<1

10. STABILITY AND REACTIVITY

Chemical Stability: Stable

Conditions to avoid: Extreme heat or cold.

Incompatibility: This product has no incompatibilities except those of water e.g. strong acids, bases, alkali metals, alkali hydrides.

Hazardous Decomposition Products: Emits SO_x, NO_x and toxic fumes.

Hazardous Polymerization: Should not occur.

11. TOXICOLOGY INFORMATION

Summary of Risks: Toxicological information refers to the raw materials of the product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on chemical material.

CAS#

1405-89-6 **Bacitracin Zinc**
May cause irritation to skin or mucous membranes. Prolonged or repeated exposure can cause hypersensitivity in some individuals. Prolonged high level exposure is toxic to kidneys (nephrotoxic). This material is not readily adsorbed in the digestive tract so accidental ingestion presents little toxic hazard. Oral-guinea pig LD_{50} 2000 mg/kg.

1404-26-8 **Polymyxin B Sulfate**
May cause irritation to skin, mucous membranes and respiratory tract. Prolonged and repeated contact may produce hypersensitivity (anaphylactic) in some individuals. Overexposure may produce dizziness, diminished muscular coordination, kidney damage (nephrotoxicity), and sensory disturbances. This material is not readily absorbed into the gut and does not present a toxicological hazard. IV- mouse LD_{50} 5.4 mg/kg, IP- mouse 20.5 mg/kg, Oral- mouse 790 mg/kg, SC-mouse LD_{50} 59.5 mg/kg.

8042-47-5 **Mineral Oil**
May cause mild irritation to the eyes or skin.Can cause irritation if mist is inhaled and act as a laxative if ingested in large quantities causing abdominal cramps and diarrhea. Inhalation control for oil mists 5 mg/M^3.

8009-03-8 **White Petrolatum**
May cause irritation to the eyes and inhalation can also cause irritation. Mist levels regulated as an oil mist at TLV 5 mg/M3.

12. ECOLOGICAL INFORMATION

Chemical Fate Information: Product administered to patients presents a negligible impact on the environment.

13. DISPOSAL INFORMATION

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

EPA Designations: RCRA Hazardous Waste: Not Listed

SARA Title III: Not Listed

14. TRANSPORTATION INFORMATION

Transportation Data: Not classified as hazardous by DOT regulations.

15. REGULATORY INFORMATION

DOT Designations: Not classified as hazardous by DOT regulations.

EPA Designations: RCRA Hazardous Waste
(40 CFR 261.33) Not Listed

FDA Designations: Prescription only medication.
NDC No. 24208-555-55 (3.5 gm)

OSHA Designations: (29 CFR 1910.1000, Table Z)
Not Listed

SARA Title III: Not listed under Section 313 of Toxic Release Reporting.

CALIFORNIA PROPOSITION 65: Not Listed

16. OTHER INFORMATION

None

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

NE- Not Established
< - Less Than
> - Greater Than