BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

Issued:	09/07/94	Prepared by:	Gary Wong
Revised:	01/25/02		Manager EHS
Revision:	02	Core No. 035	

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Neomycin & Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment USP

Generic Name: Same

NDC No. 24208-780-55 (3.5 gm)

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

Drug Composition: Antibiotics

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	$\geq$1
Neomycin Sulfate	1405-10-3	NE	NE	<1
Polymyxin B Sulfate	1405-20-5	NE	NE	<1
Mineral Oil	8042-47-5	5(mist)	5	$\geq$1
White Petrolatum	8009-03-8	NE	NE	$\geq$1

3. HAZARDS IDENTIFICATION

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EMERGENCY OVERVIEW

Tube packed in a cardboard box. Smooth, unctuous, cloudy white 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 and absorption from the intact skin or mucous membrane is insignificant. Neomycin sulfate causes cutaneous sensitization. A precise incidence of allergic reactions (primarily skin rash) due to topical neomycin is not known. Can also cause local irritation on installation and hypersensitivity (anaphylactic) in some individuals. The most frequent adverse reactions are localized hypersensitivity with itching, swelling of the conjunctiva and eyelid, and diffused redness of the eye (conjunctival erythema). It may be manifest as a failure to heal.

Skin: Neomycin sulfate causes cutaneous sensitization. A precise incidence of allergic reactions (primarily skin rash) due to topical neomycin is not known. Can cause hypersensitivity in some individuals. The most frequent adverse reactions are localized hypersensitivity with itching, swelling and diffused redness of the skin (erythema).

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

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

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.

Target Organs: Eyes, skin and digestive tract.

Medical Conditions Aggravated by Long Term Exposure: Hypersensitivity to antibiotics or any of the components of the product. Allergic cross-reactions may occur which could prevent the use of any or all of the following antibiotics for the treatment of future infections: kanamycin, paromomycin, streptomycin, and possibly gentamicin. 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: Wash out mouth and drink plenty of water and bland fluids. The use of an emetic drug and/or gastric lavage is advisable. Do not give anything to an unconscious person. Contact physician.

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

Note to Physicians: Additional details are available on the package insert or in the Physicians Desk Reference.

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Hazardous Products: Emits SO_x, NO_x and toxic fumes.

Extinguishing Media: Dry chemical, carbon dioxide, halon, water spray or fog, and foam on surrounding materials.

Fire Fighting Instructions: Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool.

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:	Smooth, unctuous cloudy		
Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	NE	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Immisicble	Percent Volatile by Volume:	<1

10. STABILITY AND REACTIVITY

Chemical Stability: Stable

Conditions to avoid: Extreme heat or cold.

Incompatibility: This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

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 raw materials 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 may 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.

1404-04-2 **Neomycin Sulfate**

Prolonged or repeated contact may cause hypersensitivity (anaphylactic) in some individuals. People sensitive to one aminoglycoside antibiotic may also be sensitive neomycin sulfate. High level overdosage is toxic to kidneys (nephrotoxicity) and may cause hearing difficulties (ototoxicity) and diminished balance. Oral-rat LD_{50} 2750 mg/kg.

1404-26-8 **Polymyxin B Sulfate**

May cause irritation to skin, mucous membranes and respiratory tract. Prolonged and repeated contact can 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.

8042-47-5.1 **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 TLV5 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. 24208-780-55 (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