

**MATERIAL SAFETY DATA SHEET**

Issued: 09/07/94	Prepared by: Gary Wong
Revised: 05/13/04	Manager EHS
Revision: 03	Core No. 034

**1. PRODUCT AND COMPANY INFORMATION**

**Product Name:** Neomycin and Polymyxin B Sulfates and Gramicidin Ophthalmic Solution USP

**Generic Name:** Same

**NDC No.** 24208-790-62 (10 ml)

**Legal Category:** Prescription only medicine, filled inside a plastic bottle suitable for dispensing, and overpacked inside a cardboard carton.

**Drug Composition:** Antibiotic combination

BAUSCH & LOMB INCORPORATED  
 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 <sup>3</sup> )		PEL (mg/m <sup>3</sup> )	% Content
Gramicidin	1405-97-6	NE	NE	NE	<1
Neomycin Sulfate	1405-10-3	NE	NE	NE	<1
Polymyxin B Sulfate	1405-20-5	NE	NE	NE	<1
Thimerosal	54-64-8	0.1	0.1 C	0.1 C	0.001

Ingredients <1% - Sodium Chloride, Alcohol, Polaxamer 188, Propylene Glycol

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### 3. HAZARDS IDENTIFICATION

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#### EMERGENCY OVERVIEW

Plastic bottle inside a cardboard box. Clear solution with a medicinal odor. Contains thimerosal. Decomposition products are toxic fumes and mercury vapor. Toxic by ingestion. For eyes only.

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#### POTENTIAL HEALTH HAZARDS

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

**Eye:** Can cause redness, swelling, itching and localized hypersensitivity of the eye and eyelids. This condition may be manifested as a failure to heal. This preparation is for the eyes only.

**Skin:** Neomycin sulfate may cause sensitization of the skin. May cause irritation, rash and hypersensitization.

**Ingestion:** May cause irritation and hypersensitization (anaphylactic). Large doses may induce dizziness, sensory disturbances, thirst, vomiting, nausea, diarrhea and skin rash.

**Inhalation:** Not likely with a liquid preparation. May cause irritation and hypersensitization.

**Chronic Effects:** Possible hypersensitization to antibiotics, including cross-reactions to kanamycin, paromomycin, streptomycin and possibly gentamicin.

**Target Organs:** Kidney, skin and brain.

**Medical Conditions Aggravated by Long Term Exposure:** Hypersensitivity to Neomycin Sulfate, Polymyxin B Sulfate or any of the components of the product. Anaphylactic cross-reactions may occur for antibiotics including kanamycin, paromomycin, streptomycin and possibly gentamicin. As with other anti-microbial preparations, prolonged use may result in overgrowth of nonsusceptible organisms including fungi. Appropriate measures should be taken if this occurs. Patients with chronic otitis medius may develop ototoxicity due to Neomycin.

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### 4. FIRST AID MEASURES

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**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:** Neomycin sulfate may cause sensitization of the skin. Can cause localized hypersensitivity of the eye, eyelids and conjunctival erythema. This condition may be manifested as a failure to heal. During long-term use of neomycin containing products, periodic examination for such signs is advisable and the patient should be told to discontinue using the product if the symptoms are confirmed. These symptoms subside quickly on withdrawing the medication. Neomycin containing applications should be avoided for the patient thereafter. Additional details are available on the package insert or in the Physicians Desk Reference.

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## 5. FIRE FIGHTING MEASURES

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**Flammable Properties:** Flash point: NE Method: NE

**Hazardous Products:** When heated to decomposition, product emits Sulfur Oxides (SO<sub>x</sub>), Nitrogen Oxides (NO<sub>x</sub>), Mercury Vapor (Hg), Sodium Oxides (Na<sub>2</sub>O).

**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.

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## 6. ACCIDENTAL RELEASE MEASURES

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**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.

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## 7. HANDLING AND STORAGE

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**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<sup>0</sup>-30<sup>0</sup> C (59<sup>0</sup>- 86<sup>0</sup> F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

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## 8. EXPOSURE CONTROL/PERSONAL PROTECTION

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**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 contaminated equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

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## 9. CHEMICAL & PHYSICAL PROPERTIES

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Appearance & Odor:	Clear solution with a medicinal odor.		
Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	1.0	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Miscible	Percent Volatile by Volume:	<1

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## 10. STABILITY AND REACTIVITY

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**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:** When heated to decomposition, product emits Mercury Vapor (Hg), Sulfur Oxides (SO<sub>x</sub>), Nitrogen Oxides (NO<sub>x</sub>), Sodium Oxides (Na<sub>2</sub>O).

**Hazardous Polymerization:** Should not occur.

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## 11. TOXICOLOGY

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**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 #

1405-97-6                    **Gramicidin**

May cause irritation of the skin, mucous membranes and respiratory tract. Prolonged and repeated exposure can produce hypersensitivity (anaphylactic) in some individuals. This material is not absorbed through the gut and presents no toxic hazard except when in a diseased or perforated state. Parenteral- mouse 15 micrograms/kg; IV-mouse LD<sub>50</sub> 1500 micrograms/kg.

1405-10-3                    **Neomycin Sulfate**

Prolonged or repeated contact can cause hypersensitivity (anaphylactic) in some individuals. Individuals sensitive to one aminoglycoside antibiotic may also be sensitive to neomycin sulfate. High level exposures may be toxic to kidneys (nephrotoxicity) and may cause hearing difficulties (ototoxicity) and diminished balance. Oral- rat LD<sub>50</sub> 2750 mg/kg.

1405-20-5                    **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 muscularcoordination, kidney damage (nephrotoxicity), and sensory disturbances. This material is not readily absorbed into the gut and so does not present a toxicological hazard. IV- mouse LD<sub>50</sub> 5.4 mg/kg, IP- mouse 20.5 mg/kg, Oral- mouse 790 mg/kg, SC- mouse LD<sub>50</sub> 59.5 mg/kg.

54-64-8                    **Thimerosal**

May cause irritation to mucous membranes of lungs and eyes. Sensitization dermatitis may occur in individuals previously exposed. Chemical burns can occur.

May cause conjunctivitis in cases of chronic exposure. Contains mercury. Toxic by ingestion and possibly inhalation. Oral-rat LD<sub>50</sub> 75 mg/kg.

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## 12. ECOLOGICAL INFORMATION

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

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## 13. DISPOAL INFORMATION

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**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

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## 14. TRANSPORTATION INFORMATION

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**Transportation Data:** Not classified as hazardous by DOT regulations.

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## 15. REGULATORY INFORMATION

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**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.  
24208-790-62 (10 ml)

**OSHA Designations:** 29 CFR 1910.1000, Table Z  
Mercury compounds listed

**SARA TITLE III (Superfund Amendments and Reauthorization Act):**

**SECTION 302:** Extremely Hazardous Substances: No Components Listed

**SECTION 311, 312:** Hazard Categories: NA

**SECTION 313:** Toxic Chemicals CAS# 54-64-8: Mercury compounds are subject to the reporting requirements of Section 313 of SARA Title III.

**CALIFORNIA PROPOSITION 65:** This product contains chemical(s) known to the State of California to cause reproductive / developmental toxicity: CAS# 54-64-8, listed as mercury and mercury compounds.

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**16. OTHER INFORMATION**

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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