

# BAUSCH & LOMB

Pharmaceutical Division

## MATERIAL SAFETY DATA SHEET

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Core No. 100

### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Solution USP

**Generic Name:** Same  
**NDC No.** 24208-631-10 (10 ml)

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

**Drug Composition:** Antibiotic/Corticosteroid

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 <sup>3</sup> )	PEL(mg/m <sup>3</sup> )	% Content
Hydrocortisone	50-23-7	NE	NE	≥1
Neomycin Sulfate	1405-10-3	NE	NE	<1
Polymyxin B Sulfate	1405-20-5	NE	NE	<1
Glycerin	56-81-5	10 (mist)	15 (Total mist) 5 (Respirable Fraction)	≥1
Propylene Glycol	57-55-6	NE	NE	≥1
Ingredients <1% - Potassium Metabisulfite, Hydrochloric Acid				

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### 3. HAZARDS IDENTIFICATION

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#### EMERGENCY OVERVIEW

Glass bottle packed in a cardboard box. Clear, colorless, slightly viscous solution. For use in ears only. Toxic by ingestion.

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#### POTENTIAL HEALTH HAZARDS

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

**Ear:** May cause irritation and hypersensitivity (anaphylactic) in some individuals. It has been shown, though not in humans, that through large doses or prolonged topical administration, adrenocorticosteroids may be systemically adsorbed by pregnant mothers and produce fetal abnormalities.

**Eye:** Redness, swelling and itching of the eye. May cause hypersensitivity (anaphylactic) in some individuals. Not an ophthalmic suspension.

**Skin:** May cause rash, swelling and itching due to hypersensitivity.

**Ingestion:** May cause allergic reaction (hyper-sensitivity) and could result in gastrointestinal irritation. Large doses may induce kidney injury, blood disorders, adrenal gland suppression, Cushing's syndrome, hyper-glycemia, and possibly birth defects in pregnant mothers.

**Inhalation:** May cause irritation; however, at controlled room temperatures, vapors should not reach high concentrations. Repeated or prolonged inhalation, at high concentration, may induce central nervous system depression indicated by dizziness, headaches, and drowsiness.

**Chronic Effects:** Hypersensitization is possible in some individuals. Long term use may cause ototoxicity.

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

**Medical Conditions Aggravated by Long Term Exposure:** Hypersensitivity to Neomycin Sulfate, Polymyxin B Sulfate, Hydrocortisone or any of the components of the product. Anaphylactic cross-reactions may occur for corticosteroids and antibiotics including kanamycin, paromomycin, streptomycin and possibly gentamicin. This medication is contraindicated for patients with herpes simplex, vaccinia and varicella infections. 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 media may develop ototoxicity due to Neomycin.

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#### 4. FIRST AID MEASURES

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**Eyes:** If not prescribed this medication, 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 give plenty of water and bland fluids. Seek professional assistance.

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

**Note to Physicians:** Hydrocortisone appears in the milk of nursing mothers when orally administered, so caution should be exercised when prescribing Neomycin Sulfate, Polymyxin B Sulfate, Hydrocortisone Otic Solution, USP, (Sterile).

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#### 5. FIRE FIGHTING MEASURES

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

**Hazardous Products:** 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. Do not spray water into the burning material.

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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 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, colorless, slightly viscous solution.		
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 no incompatibilities except those of water e.g. strong acids, bases, alkali metals, alkali hydrides.

**Hazardous Decomposition Products:** Sulfur oxides (SO<sub>x</sub>), nitrogen oxides (NO<sub>x</sub>), sodium oxides (NaO<sub>x</sub>) and emits toxic fumes.

**Hazardous Polymerization:** Should not occur.

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## 11. TOXICOLOGY INFORMATION

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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#

50-23-7

### **Hydrocortisone**

May cause irritation to eyes, skin and respiratory tract. Prolonged or repeated contact can cause hypersensitivity (anaphylactic) in some individuals. May cause allergic reaction if inhaled, ingested or on contact with the skin. Adverse reactions include suppression of adrenal gland secretion, Cushing's syndrome, water retention, electrolyte imbalance, and hyper-glycemia. Studies in animals indicate that topical adrenocorticoids, when use in large amounts, can be systemically absorbed and may cause fetal abnormalities. Human pregnancy studies have not been done. IP-rat LD<sub>50</sub> 150 mg/kg, SC-rat LD<sub>50</sub> 449 mg/kg.

1404-04-2

### **Neomycin Sulfate**

Prolonged or repeated contact can cause hypersensitivity (anaphylactic) in some individuals. People sensitive to one aminoglycoside antibiotic may also be sensitive to neomycin sulfate. High level overdosage is toxic to kidneys (nephrotoxicity) and also may cause hearing difficulties (ototoxicity) and diminished balance. Oral-rat LD<sub>50</sub> 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 muscularcoordination, kidney damage (nephrotoxicity) and sensory disturbances.

This material is not readily adsorbed into the gut and 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.

56-81-5                      **Glycerin**

May cause irritation to eyes and skin. Repeated or prolonged exposure can cause dermatitis or eye conjunctivitis. Inhalation is not likely due to low evaporation rate, but fumes may cause irritation and defatting of the tissues. Ingestion can cause headache, restlessness, insomnia, dizziness, vomiting, diarrhea and fever. Large doses can cause hemolysis, hemoglobinuria, hyperglycemia, glycosuria, renal failure, convulsions, narcosis and paralysis. Oral-rat LD<sub>50</sub> 12,600 mg/kg. Decomposition releases corrosive fumes of acrolein. Avoid open flame and extreme heat. Incompatibilities include strong acids, strong oxidizers, metal oxides and metal hydrides.

57-55-6                      **Propylene Glycol**

May cause irritation to respiratory and digestive tract, eyes and skin. Prolonged or repeated contact can produce hypersensitivity (anaphylactic) in some individuals causing headache, nausea, dullness, abdominal spasms, vomiting and unconsciousness. Repeated exposure can also cause nystagmus and lymphocytosis. High vapor concentration exposure may cause central nervous system depression with headaches, dizziness, and drowsiness. This material is adsorbed by inhalation, ingestion and through the skin. Kidney injury and blood disorders may occur. Combustible liquid. Oral- rat LD<sub>50</sub>- 20 g/kg, Skin-rabbit LD<sub>50</sub>- 20800 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. DISPOSAL 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.  
NDC No. 24208-631-10 (10 ml)
- 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

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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