

MATERIAL SAFETY DATA SHEET

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1. PRODUCT AND COMPANY INFORMATION

Product Name: Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Suspension USP
Generic Name: Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Suspension USP
NDC No. 24208-635-62 (10 ml)
Legal Category: Prescription only medicine, filled inside plastic or glass bottle suitable for dispensing, and overpacked inside a cardboard carton.

Drug Composition: Antibiotic/Corticosteroid

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 ³)	PEL (mg/m ³)	% 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
Cetyl Alcohol	36653-82-4	NE	NE	≥1
Polyoxyl 40 Stearate	9004-99-3	NE	NE	≥1
Polysorbate 80	9005-65-6	NE	NE	1
Thimerosal	54-64-8	0.1	0.1(C)	0.01
Purified Water	7732-18-5	NE	NE	≥1

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Plastic or glass bottle packed in a cardboard box. White, to off-white, flowing suspension. Contains thimerosal. Decomposition product mercury vapor. For use in ears only. Toxic by ingestion.

POTENTIAL HEALTH HAZARDS

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

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

Skin: Rash, swelling and itching due to hyper-sensitivity. Not a topical preparation. It has been shown, though not in humans, that through large doses or prolonged topical administration adrenocorti-costeroids may be systemically adsorbed by pregnant mothers and produce fetal abnormalities.

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: Not likely for a liquid preparation because evaporation at controlled room temperature is minimal. May cause irritation, and repeated or prolonged inhalation of vapors at high concentration can 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 medius may develop ototoxicity due to Neomycin.

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: 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 Suspension Non-Buffered. Additional details are available on the package insert or in the Physicians Desk Reference.

Nursing Mothers: 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 Suspension Non-Buffered.

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Hazardous Products: Emits toxic fumes; Mercury Vapors (Hg), Sulfur Oxides (SO^x), Nitrogen Oxides (NO^x), Sodium Oxides (NaO^x).

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 15⁰-30⁰ C (59⁰- 86⁰ 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. Required if vapor concentration exceeds that in section 2. See Engineering controls.

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.

9. CHEMICAL & PHYSICAL PROPERTIES

Appearance & Odor:	White to off-white, flowing suspension.		
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

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:

Hazardous Polymerization: Should not occur.

11. TOXICOLOGY

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 #

36653-82-4 **Cetyl Alcohol** (Palmityl alcohol)

May cause irritation to eyes, skin, respiratory tract and gastrointestinal system. Repeated and prolonged exposure may cause hypersensitivity in some individuals. Chemical is a normal constituent of the human body and is considered non-toxic. Gastrointestinal system irritation symptoms are hypermotility and diarrhea. Irritation SKN-HMN 75mg/kg mild. Oral-rat LD₅₀ 5 gm/kg.

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 used in large amounts, can be systemically absorbed and may cause fetal abnormalities. Human pregnancy studies have not been done. IP-rat LD₅₀ 150 mg/kg, SC-rat LD₅₀ 449 mg/kg.

1404-04-2 **Neomycin Sulfate**

Prolonged or repeated contact can cause hyper-sensitivity (anaphylactic) in some individuals. People sensitive to one aminoglycoside antibiotic may also be sensitive to neomycin sulfate. High level overdosage may be toxic to kidneys (nephrotoxicity) and may cause hearing difficulties (ototoxicity) and diminished balance. Oral- rat LD₅₀ 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 adsorbed into the gut and does not present a toxicological hazard. IV- mouse LD₅₀ 5.4 mg/kg, IP- mouse 20.5 mg/kg, Oral- mouse 790 mg/kg, SC- mouse LD₅₀ 59.5 mg/kg.

9004-99-3 **Polyoxyl 40 Stearate**

Little health hazard. Practically nonirritating to eyes. Inhalation suggested control figure for good hygiene 10 mg/m³. Oral-rat LD₅₀ > 34.8 g/kg.

9005-65-6 **Polysorbate 80**

Limited toxicity data is available on this chemical. Screening tests indicate that it is not likely to irritate the eyes, skin, respiratory or digestive tract. Skin hypersensitization was not observed in 50 human subjects tested by patch test. The toxicity by ingestion is relatively mild. Oral-rat LD₅₀ >38.0 g/kg. No other symptoms of exposure were recorded.

57-55-6 **Propylene Glycol**

May cause irritation to respiratory tract, 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 may 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 LD₅₀- 20 g/kg, Skin-rabbit LD₅₀- 20800 mg/kg.

54-64-8 **Thimerosal**

May cause irritation to mucous membranes of lungs and eyes. Sensitization dermatitis may occur in persons previously exposed. Chemical burns can occur and may cause conjunctivitis in cases of chronic exposure. Contains mercury. Toxic by ingestion and possibly inhalation. Oral-rat LD₅₀ 75 mg/kg.

12. ECOLOGICAL INFORMATION

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

13. DISPOAL INFORMATION

Dispose of material according to Federal, State, and Local regulations. All disposal methods must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste

characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

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—635-62 (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.

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