

BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

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1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Erythromycin Ophthalmic Ointment USP, 0.5%
Generic Name: Same
NDC No. 24208-910-55 (3.5 gm)

Legal Category: Prescription only medication, filled inside a 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
Erythromycin	114-07-8	NE	NE	<1
Mineral Oil	8042-47-5	5(mist)	5	≥1
White Petrolatum	8009-03-8	NE	NE	≥1

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Tube packed in a cardboard box. Translucent ointment.

POTENTIAL HEALTH HAZARDS

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

Eye: May infrequently cause irritation. May cause hypersensitivity (anaphylactic) in some individuals.

Skin: May cause irritation and hypersensitivity in some individuals. In some cases, repeated and prolonged contact can induce hypersensitivity (anaphylactic).

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

Inhalation: May cause irritation and hypersensitivity in some individuals.

Chronic Effects: May cause irritation and hypersensitivity. Prolonged application can induce changes in vision.

Target Organs: None

Medical Conditions Aggravated by Long Term Exposure: Hypersensitivity to any of the components of the product. The use of antimicrobial agents may be associated with the overgrowth of antibiotic-resistant organisms; in such a case antibiotic administration should be stopped and appropriate measures taken. There are no adequate and well controlled studies of erythromycin in pregnant women. Because animal reproduction studies are not always predictive of human response caution should be exercised in the administration of erythromycin to pregnant women.

4. FIRST AID MEASURES

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: Erythromycin is excreted in breast milk, so caution should be exercised when administered to nursing mothers.

5. FIRE FIGHTING MEASURES

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.

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

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 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: Toxic fumes, sulfur oxides (SO_x).

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#

114-07-8 **Erythromycin**

May cause irritation to skin, mucous membranes, digestive and respiratory tract. Prolonged and repeated contact can produce hypersensitivity (anaphylactic) in some individuals. Individuals hypersensitive to one erythromycin may be allergic to other types. Oral- rat LD₅₀- 9272 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/M³.

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. 24208-910-55 (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