

BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

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Core No. 421

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Erythromycin Topical Solution USP, 2%
Generic Name: Same
NDC No. 24208-421-60 (60 ml)

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

Drug Composition: Anti-bacterial, 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	2
Ethyl Alcohol	64-17-5	1880	1900	66
Propylene Glycol	57-55-6	NE	NE	≥1

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Plastic container packed in a cardboard box. Clear, colorless solution. Flammable mixture that emits toxic fumes when burned. May flashback from point of ignition. May cause eye irritation.

POTENTIAL HEALTH HAZARDS

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

Eye: May cause irritation.

Skin: May cause irritation, possibly with a cumulative effect. Repeated and prolonged contact can induce hypersensitivity (anaphylactic) in some individuals.

Ingestion: May cause irritation, nausea and vomiting. Ingestion of sufficient quantities can induce central nervous system depression indicated by headache, drowsiness, fatigue and narcosis.

Inhalation: May cause irritation. Inhalation of high vapor concentrations can induce central nervous system depression.

Chronic Effects: Repeated and prolonged contact may produce effects similar to acute effects. Hypersensitivity can occur in some individuals.

Target Organs: Skin, eyes, mucous membranes and liver (ethyl alcohol).

Medical Conditions Aggravated by Long Term Exposure: Hypersensitivity to Erythromycin or any of the components of the product. Individuals susceptible to dermatitis.

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: 72⁰ F Method: Closed Cup

Hazardous Products: Carbon monoxide (CO), carbon dioxide (CO₂), nitrogen oxides (NO_x), oxygen and toxic fumes

Extinguishing Media: Water spray, dry chemical, alcohol foam, CO₂.

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 concentrations exceed those stated in section 2.

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: Clear colorless 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:	66

10. STABILITY AND REACTIVITY

Chemical Stability: Stable

Conditions to avoid: Extreme heat or cold.

Incompatibility: Oxidizing materials.

Hazardous Decomposition Products: Ethanol vapors, carbon monoxide, carbon dioxide 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 #

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.

64-17-5

Ethyl Alcohol

May cause irritation to eyes, upper respiratory tract, skin and mucous membranes. Prolonged contact can produce headache, drowsiness, fatigue and narcosis. The IARC monograph on ethyl alcohol concluded that ingestion may cause reproductive effects and is carcinogenic. Flammable liquid. This material is adsorbed readily in the gut and lungs and is toxic. Oral- rat LD₅₀- 6.2- 17.8 mg/kg Inhalation- rat LC₅₀- 16,000 ppm/8 hrs.

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 can also cause involuntary movement of the eyeball (nystagmus) and lymphocytosis. High vapor concentration exposure can cause central nervous system depression with headaches, dizziness and drowsiness. This material is absorbed 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.

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL INFORMATION

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 sole responsibility of the waste generator.

14. TRANSPORTATION INFORMATION

Transportation Data:

Shipping Name: Consumer Commodity
Hazard Class: ORM-D
UN Number: N/A

Packing Group: N/A

Limited quantities no placard required, no labels required unless transported by aircraft.

15. REGULATORY INFORMATION

DOT Designations: Consumer Commodity
ORM-D

FDA Designations: Prescription only medication.
NDC No. 24208-421-60 (60 ml)

OSHA Designations: (29 CFR 1910.1000, Table Z-1) Ethanol Listed

SARA Title III: Ethanol is not a SARA reportable substance.

CALIFORNIA PROPOSITION 65:

This product contains no listed substances known to the State of California to cause cancer, birth defects or other reproductive harm, at levels which would require a warning under the statute.

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