



# Erythromycin Ointment

Effective Date: 29-Jul-2004

**Eli Lilly and Company**  
**Material Safety Data Sheet**

## Section 1 - Chemical Product and Company

**Manufacturer:**  
 Eli Lilly and Company  
 Lilly Corporate Center  
 Indianapolis, IN 46285

**Manufacturer's Emergency Phone:**  
 1-317-276-2000  
**CHEMTREC:**  
 1-800-424-9300 (North America)  
 1-703-527-3887 (International)

**Common Name:** Erythromycin Ointment

**Chemical Name:** Erythromycin

**Synonym(s):** Erythromycin; Erythromycin ophthalmic ointment

**Trademarks(s):** Branerimicina; ITS; Ilocap; Iloticina; Ilotycin

**Lilly Item Code(s):** OO0052; UC5322; VF0152; VF0164

See attached glossary for abbreviations.

## Section 2 - Composition / Information on Ingredients

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration %</u>
Erythromycin	114-07-8	0.5 - 0.56
Oleaginous Base	NA	99

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

**Exposure Guidelines:**

Erythromycin - LEG 3 mg/m<sup>3</sup> TWA for 12 hours. WEEL 3 mg/m<sup>3</sup> TWA.

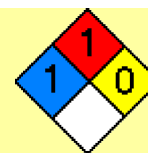
## Section 3 - Hazards Identification

**Appearance:** Translucent homogeneous ointment

**Physical State:** Solid

**Odor:** Odorless

## Emergency Overview



**Emergency Overview Effective Date:** 27-Oct-1999

**Lilly Laboratory Labeling Codes:**

**Health 1**

**Fire 1**

**Reactivity 0**

**Primary Physical and Health Hazards:** Suspect Allergen.

**Caution Statement:** Erythromycin Ointment may cause allergic reactions.

**Routes of Entry:** Skin contact.

**Effects of Overexposure:** Erythromycin Ointment is intended for human application under guidance of a physician. Ointments are not considered hazardous under normal handling conditions. Based on clinical data with erythromycin estolate, allergic reactions might be expected to occur in rare instances.

**Medical Conditions Aggravated by Exposure:**

Erythromycin - Hypersensitivity to erythromycin or macrolide antibiotics.

**Carcinogenicity:**

Erythromycin - Not listed by IARC, NTP, ACGIH, or OSHA. Two-year dietary studies with erythromycin stearate demonstrated no evidence of carcinogenicity in rats or mice.

Iron oxide - IARC Group 3 (not classifiable as to human carcinogenicity). ACGIH A4 (not classifiable as a human carcinogen). Not listed by NTP or OSHA.

## Section 4 - First Aid Measures

**Eyes:** Flush eyes with plenty of water. Get medical attention.

**Skin:** Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

**Inhalation:** Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

**Ingestion:** Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

## Section 5 - Fire Fighting Measures

**Flash Point:** No applicable information found

**UEL:** No applicable information found

**LEL:** No applicable information found

**Extinguishing Media:** Use water, carbon dioxide, dry chemical, foam, or Halon.

**Unusual Fire and Explosion Hazards:** None known.

**Hazardous Combustion Products:** May emit toxic fumes when exposed to heat or fire.

## Section 6 - Accidental Release Measures

**Spills:** Scoop or scrape up for disposal. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).

## Section 7 - Handling and Storage

**Storage Conditions:** Controlled Room Temperature: 15 to 30 C (59 to 86 F).

## Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting:

**Respiratory Protection:** Use an approved respirator.

**Eye Protection:** Safety glasses.

**Ventilation:** Laboratory fume hood or local exhaust ventilation.

**Other Protective Equipment:** Chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

## Section 9 - Physical and Chemical Properties

**Appearance:** Translucent homogeneous ointment

**Odor:** Odorless

**Boiling Point:** No applicable information found

**Melting Point:** No applicable information found

**Specific Gravity:** No applicable information found

**pH:** No applicable information found

**Evaporation Rate:** No applicable information found

**Water Solubility:** Insoluble

**Vapor Density:** No applicable information found

**Vapor Pressure:** No applicable information found

## Section 10 - Stability and Reactivity

**Stability:** Stable at normal temperatures and pressures.

**Incompatibility:** May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

**Hazardous Decomposition:** May emit toxic fumes when heated to decomposition.

**Hazardous Polymerization:** Will not occur.

## Section 11 - Toxicological Information

### Acute Exposure

The toxicity data for the material or related material(s) are presented.

**Oral:**

Erythromycin - Rat, median lethal dose 4600 mg/kg.

**Skin:** No applicable information found.

**Inhalation:** No applicable information found.

**Skin Contact:**

Erythromycin (5% solution) - Rabbit, slight irritant

**Eye Contact:**

Erythromycin ointment - Rabbit, slight irritant

### Chronic Exposure

The toxicity data for the material or related material(s) are presented.

**Target Organ Effects:** No applicable information found.

**Reproduction:**

Erythromycin - No effects identified in animal studies.

**Sensitization:**

Erythromycin - Guinea pig, not a contact sensitizer.

**Mutagenicity:**

Erythromycin - Negative in bacteria.

Erythromycin stearate - Negative in bacterial and mammalian cells.

## Section 12 - Ecological Information

The environmental data for the material or related material(s) are presented.

**Ecotoxicity Data:** No applicable information found.

**Environmental Fate:**

Erythromycin  
Log Kow: 3.06

**Environmental Summary:**

Erythromycin - Material is slightly soluble in water and not expected to leach significantly from the soil into groundwater. Material is not expected to bioaccumulate.

## Section 13 - Disposal Considerations

**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

## Section 14 - Transport Information

**Regulatory Organizations:**

**DOT:** Not Regulated

**ICAO/IATA:** Not Regulated

**IMO:** Not Regulated

## Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Eli Lilly and Company usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

### U.S. Regulations

Erythromycin and oleaginous base  
TSCA - No  
CERCLA - Not on this list  
SARA 302 - Not on this list  
SARA 313 - Not on this list  
OSHA Substance Specific - No

### EU Regulations

**EC Classification**

Not assigned an overall EC classification.

## Section 16 - Other Information

**MSDS Sections Revised:** Sections 1, 2, 3, 11, and 12.

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Eli Lilly and Company  
Hazard Communication  
317-277-6029

For additional copies contact:

Eli Lilly and Company  
1-800-LILLY-Rx (1-800-545-5979)

### GLOSSARY:

ACGIH = American Conference of Governmental Industrial Hygienists

AIHA = American Industrial Hygiene Association

BEI = Biological Exposure Index

CAS Number = Chemical Abstract Service Registry Number

CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)

CHAN = Chemical Hazard Alert Notice

CHEMTREC = Chemical Transportation Emergency Center

DOT = Department of Transportation

EC = European Community

EINECS = European Inventory of Existing Chemical Substances

ELINCS = European List of New Chemical Substances

EPA = Environmental Protection Agency

HEPA = High Efficiency Particulate Air (Filter)

IARC = International Agency for Research on Cancer

ICAO/IATA = International Civil Aviation Organization/International Air Transport Association

IEG = Lilly Interim Exposure Guideline

IMO = International Maritime Organization

Kow = Octanol/Water Partition Coefficient

LEG = Lilly Exposure Guideline

LEL = Lower Explosive Limit

MSDS = Material Safety Data Sheet

MSHA = Mine Safety and Health Administration

NA = Not Applicable, except in Section 14 where NA = North America

NADA = New Animal Drug Application

NAIF = No Applicable Information Found

NCI = National Cancer Institute

NIOSH = National Institute for Occupational Safety and Health  
NOS = Not Otherwise Specified  
NTP = National Toxicology Program  
OSHA = Occupational Safety and Health Administration  
PEL = Permissible Exposure Limit (OSHA)  
RCRA = Resource Conservation and Recovery Act  
RQ = Reportable Quantity  
RTECS = Registry of Toxic Effects of Chemical Substances  
SARA = Superfund Amendments and Reauthorization Act  
STEG = Lilly Short Term Exposure Guideline  
STEL = Short Term Exposure Limit  
TLV = Threshold Limit Value (ACGIH)  
TPQ = Threshold Planning Quantity  
TSCA = Toxic Substances Control Act  
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted  
UEL = Upper Explosive Limit  
UN = United Nations  
WEEL = Workplace Environmental Exposure Level (AIHA)