



MSDS: Erythromycin Ophthalmic Ointment, USP

Manufacturer: Akorn Inc
72-6 Veronica Avenue
Somerset, NJ 08873
Telephone: (732) 846-8066
Email: customer.service@akorn.com

Section 1 - IDENTIFICATION

TRADE NAME: Erythromycin Ophthalmic Ointment, 0.5%
NDC # 17478-070-35 Fill Size: 3.5 g
NDC # 17478-070-31 Fill Size: 1 g
Description: Colorless to light yellowish translucent mass.

Composition	CAS#	TLV (mg/m ³)	PEL (mg/m ³)	%Content
Erythromycin Base, Sterile	114-07-8	NE	NE	0.5
Petrolatum (Fonoline)	8009-03-8	NE	NE	< 90
Mineral Oil (Kaydol)	8042-47-5	NE	NE	< 20

Common name of active ingredients: Erythromycin

Chemical Formula: N/A

Section 2 – HAZARDOUS INGREDIENTS

Principal Hazardous Ingredients:

% Threshold Limit Value: NE

Carcinogenicity: NE

NTP- No

IARC- No

OSHA- No

NE= Not established

> = Greater Than

< = Less Than

Section 3 – PHYSICAL AND CHEMICAL CHARACTERISTICS

Physical State: Semi-Solid

Appearance: Colorless to light yellowish translucent mass

Odor: Odorless

Vapor Density (air = 1): NE

Viscosity: NE

Specific Gravity: NE

Evaporation Rate: NE

pH: NE

Boiling Point: NE

Vapor Pressure (mm Hg): NE

Solubility in Water: Immiscible

Volatile: NE

Reactivity in Water: NE

Melting Point: NE



MSDS: Erythromycin Ophthalmic Ointment, USP

Latex Free: Yes

NE=Not established

Section 4 – FIRE AND EXPLOSION HAZARD DATA

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Flammable Properties: Flash Point: NE Method: NE

Hazardous Products: When heated to decomposition, material emits toxic fumes of NO_x.

Fire Fighting Instructions: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Section 5 – REACTIVITY DATA

Stability: Stable

Incompatibility: Volatile organic solvents, acids, bases, alkali metals, alkali hydrides.

Hazardous Decomposition Products: When heated to decomposition, material emits toxic fumes of NO_x, Emits toxic fumes under fire conditions.

Hazardous Polymerization: No

Conditions to Avoid: Avoid exposure heat and moisture.

Section 6 – HEALTH HAZARDS

Adverse Effects: Adverse effects of Erythromycin may include skin rash, redness, or itching; liver toxicity (fever, nausea, or vomiting, skin rash, severe stomach pain, unusual tiredness or weakness, yellow eyes or skin, vomiting); abdominal or stomach cramping or discomfort; diarrhea; nausea; vomiting; sore mouth or tongue; white patches in mouth or on tongue; and genital itching or discharge. Possible allergic reaction to material, if inhaled, ingested, or comes in contact with skin.

Overdose Effects: Symptoms of overdose include ringing in ears, severe gastrointestinal discomfort, transient auditory impairment, and irregular heartbeat.

Acute: Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.

Chronic: Possible hypersensitization, hepatotoxicity, hearing loss and superinfections.

Chemical Listed as Carcinogen or Potential Carcinogen:

National Toxicology Program: No

I.A.R.C Monographs: No

OSHA: No

OSHA Permissible Exposure Limit: NE

ACGIH Threshold Limit Value: NE

NE= Not established



MSDS: Erythromycin Ophthalmic Ointment, USP

1. **Inhalation:** May cause irritation. Remove to fresh air.
2. **Eyes:** Causes mild irritation. Flush with copious quantities of water.
3. **Skin:** Causes irritation. Flush with copious quantities of soap and water.
4. **Ingestion:** May cause irritation and bitter taste. Flush out mouth with water. This material is variably absorbed from the gastrointestinal tract.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, impaired liver function, and a history of cardiovascular problems

Cross Sensitivity: Persons sensitive to other erythromycins or macrolide may be sensitive to this material also.

Pregnancy Comments: Adequate and well-controlled pregnancy studies have not been done in humans. Erythromycin showed no evidence of birth defects or any other adverse effects on reproduction in studies in female rats.

First Aid

General: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Section 7 – SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

Storage: Do not store near heat, light, oxidants and bases. Store at 20° – 25° C (68° – 77° F)

Handling: Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical and home environment.

Neutralizing Chemical Agent: Not relevant

Steps to be taken in case material is released or spilled: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.

Waste Disposal Methods: Dispose of waste in accordance with all applicable Federal, State and local laws.

Section 8 – PROTECTION INFORMATION

Engineering Controls: Provide exhaust ventilation or other engineering controls to keep the air born concentrations of vapors below their threshold limit value. Ensure that eyewash stations and safety showers are proximal to the work-station location.

Airborne Exposure Limits: NE

Ventilation: No special ventilation requirements

Skin Protection: Protect exposed skin and wear rubber gloves.



MSDS: Erythromycin Ophthalmic Ointment, USP

Eye Protection: Safety glasses or goggles

Respiratory Protection: When working with small quantities in a well-ventilated area, respiratory protection may not be required. The use of an approved dust mask is recommended.

Section 9 – TOXICOLOGY INFORMATION

LD 50 (Acute oral toxicity of):	Erythromycin
LD 50 rat, oral:	4600 mg/kg
LD50 mouse oral:	2580 mg/kg
LD 50 rat, intravenous =	NE
LD 50 rat, intramuscular =	NE
LD 50 mouse, intravenous =	NE

Section 10 – ECOLOGICAL INFORMATION

Ecotoxicity:	Not established
BOD₅ and COD:	Not available
Environmental fate information:	Not known
Other Precautions:	None

The information given herein is in good faith and to the best of our knowledge but no warranty expressed or implied is made.

Disclaimer: This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this MSDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this MSDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.