



# SAFETY DATA SHEET

## Erythromycin Ophthalmic Ointment, USP 0.5%

### 1. IDENTIFICATION

<b>Product Identifier:</b>	Erythromycin Ophthalmic Ointment, USP 0.5%
<b>Synonyms:</b>	((3R*, 4S*, 5S*, 6R*, 7R*, 9R*, 11R*, 12R*, 13S*, 14R*)-4-[(2,6-dideoxy-3-C-methyl-3-Omethyl- $\alpha$ -L- <i>ribo</i> -hexopyranosyl)-oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethyl-amino)- $\beta$ -D-xylo-hexopyranosyl]oxy]oxacy-clotetradecane-2,10-dione))
<b>National Drug Code (NDC):</b>	17478-070-31 17478-070-35
<b>Recommended Use:</b>	Erythromycin Ophthalmic Ointment, USP 0.5% is indicated for the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by organisms susceptible to Erythromycin.
<b>Company:</b>	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
<b>Contact Telephone:</b>	1-800-932-5676
<b>E mail:</b>	customer.service@akorn.com
<b>Emergency Phone Number:</b>	CHEMTREC 1-800-424-9300 (U.S. and Canada)

### 2. HAZARD(S) IDENTIFICATION

<b>Physical Hazards:</b>	Not classifiable.
<b>Health Hazards:</b>	Not classifiable.
<b>Symbol(s):</b>	None.
<b>Signal Word:</b>	None.
<b>Hazard Statement(s):</b>	None.
<b>Precautionary Statement(s):</b>	None.
<b>Hazards Not Otherwise Classified:</b>	None.
<b>Supplementary Information:</b>	While this material is not classifiable as hazardous under the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

## SAFETY DATA SHEET

### Erythromycin Ophthalmic Ointment, USP 0.5%

#### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Chemical Name	CAS Number	Chemical Formula	Molecular Weight	Percentage
Erythromycin	((3R*, 4S*, 5S*, 6R*, 7R*, 9R*, 11R*, 12R*, 13S*, 14R*)-4-[(2,6-dideoxy-3-C-methyl-3-Omethyl- $\alpha$ -L- <i>ribo</i> -hexopyranosyl)-oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9, 11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethyl-amino)- $\beta$ -D-xylo-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione))	114-07-8	C <sub>37</sub> H <sub>67</sub> NO <sub>13</sub>	733.94	0.5%

The formula also contains Mineral Oil and White Petrolatum.

#### 4. FIRST AID MEASURES

**Ingestion:**

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

**Eye Contact:**

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Skin Contact:**

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Inhalation:**

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Protection of First-Aiders:**

Use personal protective equipment (see section 8).

## SAFETY DATA SHEET

### Erythromycin Ophthalmic Ointment, USP 0.5%

<b>Signs and Symptoms:</b>	The most frequent reported adverse reactions are minor ocular irritations, redness, and hypersensitivity reactions.
<b>Medical Conditions Aggravated by Exposure:</b>	Hypersensitivity to any of the components of the product; impaired liver function; myasthenia gravis; porphyria; cardiovascular problems.
<b>Notes to Physician:</b>	Treat supportively and symptomatically.

#### 5. FIREFIGHTING MEASURES

<b>Suitable Extinguishing Media:</b>	Use water, carbon dioxide, dry chemical or alcohol-resistant foam as necessary.
<b>Unsuitable Extinguishing Media:</b>	Not determined.
<b><u>Specific Hazards Arising from the Chemical</u></b>	
<b>Hazardous Combustion Products:</b>	These products include carbon oxides, nitrogen oxides and toxic fumes.
<b>Other Specific Hazards:</b>	Closed containers may explode from the heat of fire.
<b>Special Protective Equipment and Precautions for Firefighters:</b>	Wear self-contained breathing apparatus and full and protective gear.

#### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions:</b>	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.
<b>Personal Protective Equipment:</b>	For personal protection see section 8.
<b>Methods for Cleaning Up:</b>	Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.
<b>Environmental Precautions:</b>	Contain material and prevent release to basements, confined spaces, waterways or soil.
<b>Reference to Other Sections:</b>	Refer to Sections 8, 12 and 13 for further information.

#### 7. HANDLING AND STORAGE

<b>Precautions for Safe Handling:</b>	Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.
---------------------------------------	--

## SAFETY DATA SHEET

### Erythromycin Ophthalmic Ointment, USP 0.5%

**Conditions for Safe Storage,  
Including Any Incompatibilities:**

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Avoid excessive heat. Protect from freezing.

**Specific End Use:**

Pharmaceutical drug product.

#### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Occupational Exposure Guidelines:**

Ingredient	Type	Value
Erythromycin	TWA	0.1 mg/m <sup>3</sup>
White Petrolatum	Not established	Not established
Mineral Oil	OSHA PEL	5 mg/m <sup>3</sup> (Mist)

*OSHA: Occupational Safety Health Administration; PEL: Permissible Exposure Limit;  
TWA: Time Weighted Average.*

**Engineering Controls:**

None required for the normal use of this product.

**Respiratory Protection:**

None required for the normal use of this product.

**Eyes Protection:**

None required for the normal use of this product.

**Hand Protection:**

None required for the normal use of this product.

**Skin Protection:**

None required for the normal use of this product.

**General Hygiene Considerations:**

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State/Color:**

Colorless to light yellowish translucent mass.

**Odor:**

No data available.

**Odor Threshold:**

No data available.

**pH:**

No data available.

**Melting Point:**

No data available.

**Freezing Point:**

No data available.

**Boiling Point:**

No data available.

**Flash Point:**

No data available.

**Evaporation Rate:**

No data available.

**Flammability (solid, gas):**

No data available.

**Flammability Limit - Lower:**

No data available.

**Flammability Limit - Upper:**

No data available.

**Vapor Pressure:**

No data available.

**Vapor Density:**

No data available.

**Relative Density:**

No data available.

**Solubility(ies):**

Immiscible in water.

## SAFETY DATA SHEET

### Erythromycin Ophthalmic Ointment, USP 0.5%

<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

#### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	No data available.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	Extreme heat or cold. Do not freeze.
<b>Incompatible Materials:</b>	Strong oxidizing agents.
<b>Hazardous Decomposition Products:</b>	No data available.

#### 11. TOXICOLOGICAL INFORMATION

##### Information on the Likely Routes of Exposure

<b>Inhalation:</b>	May cause irritation.
<b>Ingestion:</b>	May be harmful if swallowed.
<b>Skin Contact:</b>	May causes skin irritation.
<b>Eye Contact:</b>	May cause redness and minor ocular irritation.
<b>Symptoms Related to the Physical, Chemical and Toxicological Characteristics:</b>	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
<b>Delayed and Immediate Effects of Exposure:</b>	No data available.

##### Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Erythromycin	Rat	Oral	LD <sub>50</sub>	4,600 mg/kg
White Petrolatum	Rat	Oral	LD <sub>50</sub>	>5000 mg/kg
Mineral Oil	Rat	Oral	LD <sub>50</sub>	>5000 mg/kg

# SAFETY DATA SHEET

## Erythromycin Ophthalmic Ointment, USP 0.5%

### Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

### Repeated Dose Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available						

### Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
No data available						

### Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available

**Aspiration Hazard:** No data available.  
**Toxicokinetics/Metabolism:** No data available.  
**Target Organ Effects:** No data available.  
**Systemic Effects:** No data available.

**Reproductive Effects:** Pregnancy Category B. There are no adequate and well controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, the Erythromycins should be used during pregnancy only if clearly needed.

**Carcinogenicity:** No data available.

**National Toxicology Program (NTP):** Not considered to be a carcinogen.

**International Agency for Research on Cancer (IARC):** Not considered to be a carcinogen.

**Occupational Safety and Health Administration (OSHA):** Not considered to be a carcinogen.

## 12. ECOLOGICAL INFORMATION

### Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
Erythromycin	Whiteleg shrimp ( <i>Penaeus vannamei</i> )	EC <sub>50</sub>	0.0227 mg/l	48 hours
	Striped bass ( <i>Morone saxatilis</i> )	LC <sub>50</sub>	266 - 457 mg/l	96 hours
Mineral Oil	Bluegill ( <i>Lepomis macrochirus</i> )	LC <sub>50</sub>	> 10,000 mg/l	96 hours



# SAFETY DATA SHEET

## Erythromycin Ophthalmic Ointment, USP 0.5%

**Terrestrial Toxicity:** No data available.  
**Persistence and Degradability:** No data available.  
**Bioaccumulative Potential:** No data available.  
**Mobility in Soil:** No data available.  
**Mobility in Environment:** No data available.  
**Other Adverse Effects:** No data available.

### 13. DISPOSAL CONSIDERATIONS

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of all waste in accordance with Federal, State and Local regulations.

### 14. TRANSPORT INFORMATION

**Department of Transportation (DOT):** Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

**International Air Transport Association (IATA):** Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

**International Maritime Dangerous Good (IMDG):** Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

### 15. REGULATORY INFORMATION

#### US FEDERAL REGULATIONS

**Toxic Substance Control Act (TSCA):**

Ingredient	Inventory
Erythromycin	No
White Petrolatum	No
Mineral Oil	Yes

**CERCLA Hazardous Substance:**

Ingredient	Reportable Quantity
Not applicable	Not applicable

**EPCRA Extremely Hazardous Substances and Toxic Chemicals:**

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable



# SAFETY DATA SHEET

## Erythromycin Ophthalmic Ointment, USP 0.5%

### U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Erythromycin	Listed	Listed	Not listed
White Petrolatum	Listed	Listed	Not listed
Mineral Oil	Listed	Listed	Not listed

#### California Proposition 65:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

### 16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

**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 SDS 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 SDS 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.