SAFETY DATA SHEET

1. Identification

Product Identifier:	Erythromycin Ophthalmic Ointment, USP, 0.5%
Synonyms:	Erythromycin Base; (3R*, 4S*, 5S*, 6R*, 7R*, 9R*, 11R*, 12R*, 13S*, 14R*)-4-[(2,6-dideoxy-3-C-methyl-3-Omethyl-α-L-ribo-hexopyranosyl)-oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethyl-amino)-D-xylo-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione.
National Drug Code (NDC):	17478-070-35
Recommended Use:	Pharmaceutical.
Company:	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
Contact Telephone:	1-800-932-5676
E mail:	customer.service@akorn.com
Emergency Phone Number:	CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards:	Not classifiable.
Health Hazards:	Not classifiable.
Symbol(s):	None.
Signal Word:	None.
Hazard Statement(s):	None.
Precautionary Statement(s):	None.
Hazards Not Otherwise Classified:	Not classifiable.
Supplementary Information:	While this material is not classifiable as hazardous under the OSHA standard, 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.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Petrolatum (Fonoline)	8009-03-8	White Petrolatum; Petroleum Jelly; Mineral Grease	Not applicable	Not applicable	85
Mineral Oil (Kaydol)	8042-47-5	Mineral oil	Not applicable	Not applicable	10
(3R*, 4S*, 5S*, 6R*, 7R*, 9R*, 11R*, 12R*, 13S*, 14R*)-4-[(2,6-dideoxy-3-C-methyl-3-Omethyl-α-L-ribo-hexopyranosyl)-oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethyl-amino)-D-xylo-hexopyranosyl]oxy]oxacyclotetradec-ane-2,10-dione	114-07-8	Erythromycin; Erythromycin Base	$C_{37}H_{67}NO_{13}$	733.94	5

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. Keep victim warm and quiet. Loosen tight clothing such as a collar, tie, belt or waistband. 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. Effects of exposure (ingestion) to substance may be delayed.

Eye Contact: Remove from source of exposure. Move individual(s) to fresh air. Check for and remove any contact lenses. Flush with copious amounts of water for at least 20 minutes. Effects of exposure may be delayed. 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. 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).
Signs and Symptoms:	Individuals sensitive to erythromycin or other materials in its chemical class may develop allergic reactions. Serious allergic reactions, including anaphylaxis, have been reported. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted; liver effects, effects on hearing, skin rash; gastrointestinal disturbances (vomiting, abdominal pain, diarrhea, anorexia, nausea); unusual tiredness or weakness; yellow eyes or skin; sore mouth or tongue; white patches in mouth or on tongue; irregular heartbeat.
Medical Conditions Aggravated by Exposure:	Hypersensitivity to any of the components of the product; impaired liver function; myasthenia gravis; porphyria; cardiovascular problems.
Notes to Physician:	Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:	Use extinguishing media for type of surrounding fire.
Unsuitable Extinguishing Media:	Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:	These products include carbon oxides, nitrogen oxides and toxic fumes.
Other Specific Hazards:	Closed containers may explode from the heat of fire.
Special Protective Equipment Precautions for Firefighters:	Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions:	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.
Personal Protective Equipment:	For personal protection see section 8.
Methods for Cleaning Up:	Dike ahead of liquid spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.
Environmental Precautions:	Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

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

Conditions for Safe Storage, Including Any Incompatibilities: Store according to label and/or product insert information. Store away from oxidizing agents and acids.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
White petrolatum, USP	Not established.
Mineral Oil	OSHA PEL: 5 mg/m^3 (Mist)
Erythromycin Base	OEL*: 0.1 mg/m^3, 8 Hour TWA; OEL*: 3 mg/m^3, 8 Hour TWA; OEL*: 3 mg/m^3, 12 Hour TWA; AIHA WEEL: 3 mg/m^3, 8 Hour TWA.

* Occupational Exposure Levels (OELs) have been established by private industry.

Engineering Controls: Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand: Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize

	direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Skin:	Protective laboratory coat, apron, or disposable garment.

9. Physical and Chemical Properties

Physical State/Color:	Semi-solid/Colorless to light yellowish translucent.
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.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.
Incompatible Materials:	Oxidizing agents, acids and bases.
Hazardous Decomposition Products:	No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	May be harmful if swallowed.
Skin Contact:	May be harmful if absorbed through skin. May cause skin irritation.
Eye Contact:	May cause eye irritation.
Symptoms Related to the Physical, Chemical and Toxicological Characteristics:	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: No data available.

Acute Toxicity – Oral: LD50, Rat: >5000 mg/kg (Petrolatum)
LD50, Rat: >5000 mg/kg (Mineral Oil)
LD50 Rat: 4600 mg/kg (Erythromycin)

Acute Toxicity – Dermal: No data available.
Acute Toxicity – Inhalation: No data available.
Corrosivity: No data available.
Dermal Irritation: No data available.
Eye Irritation: No data available.

Sensitization: Prolonged or repeated exposure (via ingestion, inhalation or skin contact) may cause allergic skin and/or respiratory reactions in certain sensitive individuals.

Toxicokinetics/Metabolism: No data available.
Target Organ Effects: Due to lack of data, the classification is not possible.
Reproductive Effects: Due to lack of data, the classification is not possible.

Carcinogenicity:
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.

Mutagenicity: Due to lack of data, the classification is not possible.
Aspiration Hazard: Based on available data, the classification criteria are not met.

12. Ecological Information

Ecotoxicity
Aquatic: No data available.
Terrestrial: No data available.

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

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and local regulations.

14. Transport Information

UN Number: Not applicable.

UN Proper Shipping Name: Not applicable.

Transport Hazard Class(es): Not applicable.

Packing Group: Not applicable.

DOT: Not regulated as a hazardous material.

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

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

15. Regulatory Information

US Federal Regulations:

TSCA Inventory This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.
SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

Massachusetts: Not listed.
New Jersey: Erythromycin.
Pennsylvania: Erythromycin.
California Proposition 65: Not listed.

16. Other Information

Not made with natural rubber latex.

NFPA Rating: (Erythromycin)		**HMIS Classification: (Erythromycin)**	
Health:	1	Health:	0
Flammability:	0	Flammability:	0
Reactivity:	0	Physical Hazard:	0

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