MATERIAL SAFETY DATA SHEET

Erythromycin Ophthalmic Ointment, 0.5%

Section 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.

NDC Code: 72485-670-35 3.5 g
72485-670-31 1 g

Recommended Use: Pharmaceutical

Manufacturer: Ophtapharm AG
Riethofstrasse 1
CH-8442 Hettlingen
Switzerland

Telephone: +1855-473-6847

Email: quality@sentiss.ch

Section 2 – HAZARD(S) IDENTIFICATION

Physical Hazards: Not classifiable.
Health Hazards: Not classifiable.
Symbol(s): Not classifiable.
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.

Section 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	No data available.	No data available.	<86%
Mineral Oil (Kaydol)	8042-47-5	Mineral oil	No data available.	No data available.	<15%

Erythromycin	114-07-8	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.	$C_{37}H_{67}NO_{13}$	733.94	0.5 %

Section 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).

Signs and Symptoms: Individuals sensitive to erythromycin or other materials in its chemical class may develop allergic reactions. Serios 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.

Section 5 – FIREFIGTING 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

Section 6 – ACCIDENTIAL RELEASE MEASURES

Personal Precautions: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment a 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. Reco product and place in an appropriate container for disposal in accordance witl 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.

Section 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. Store at 20° to 25°C (68° to 77°F).

Specific End Use: Pharmaceutical.

Section 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 ; OEL*: 3 mg/m^3, 8 Hour A; 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: Engineering controls should be used as the primary means to control exposures.

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 Protection:	Not required for the normal use of this product. 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 Protection:	Not required for the normal use of this product. 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 Protection:	Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

Section 9 – PHYSICAL AND CHEMICAL PROPERTTIES

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.

Section 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.

Section 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:

Compound	Species	Test Type	Dose
Petrolatum	Rat	LD_{50}	>5,000 mg/kg
Mineral Oil	Rat	LD_{50}	>5,000 mg/kg
Erythromycin	Rat	LD_{50}	4,600 mg/kg

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

Section 12 – ECOLOGICAL INFORMATION

Ecotoxicity

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

Section 13 – DISPOSAL CONSIDERATIONS

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

Section 14 – TRANSPORT INFORMATION

Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	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.

Section 15 – REGULATORY INFORMATION

US Federal Regulations:

Toxic Substance Control Act (TSCA):	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

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

Section 16 – OTHER INFORMATION

Not made with natural rubber latex.

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

Revision Date: 11/16/2023

Revision Number: 0

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