

MATERIAL SAFETY DATA SHEET



Product Name: Clindamycin Phosphate Topical Lotion, 1%

Revision Date: 07.04.2022

Version No.: 00

1. IDENTIFICATION

Product Name	Clindamycin Phosphate Topical Lotion, 1%
Manufacturer Name	Encube Ethicals Pvt. Ltd.
Address	Plot No.C-1, Madkaim Industrial Estate Madkaim, Post- Mardol, Ponda Goa – 403 404, India.
Chemical name	L-threo- α -D-galacto-Octopyranoside, methyl 7-chloro-6,7,8-trideoxy-6-[[1-methyl-4-propyl-2-pyrrolidinyl]carbonyl]amino]-1-thio-,2-(dihydrogen phosphate), (2S-trans)-; Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-trans-4-propyl-L-2-pyrrolidinecarboxamido)1-thio-L-threo- α -D-galacto- octopyranoside 2-(dihydrogen phosphate)
Recommended use	Pharmaceutical product used as antibiotic agent indicated in the treatment of acne vulgaris
Restrictions on use	Use only as directed by the physician.

2. HAZARD(S) IDENTIFICATION

Appearance	This product is a white to off-white creamy liquid with a slight odor
Signal Word	WARNING
Statement of Hazard	Employees administering the product should not experience adverse effects if handled properly. The chief health hazard associated with exposure during normal use and handling is the potential for irritation of contaminated skin
Additional Hazard Information	
Short Term	May be harmful if swallowed. May cause skin irritation. Vapors irritating to eyes and respiratory tract. Breathing high vapor concentrations may cause central nervous system (CNS) depression resulting in dizziness, light-headedness, headache, nausea, and loss of coordination. Continued inhalation may result in unconsciousness and death.
Known Clinical Effects	Individuals who have had allergic reactions to products containing the active ingredient, Clindamycin Phosphate (or any other components of this product) may experience allergic reactions to this product. Use of the topical formulation of Clindamycin results in absorption of the antibiotic from the skin surface. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use

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of topical and systemic Clindamycin. See Section 11 (Toxicological Information) for additional information on possible adverse effects..

EU Indication of danger

Irritant

EU Risk Phrases

Xi



Flammability Hazards:

If heated to high temperatures for a prolonged period, the water in this product can evaporate off and the residue may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic gases (e.g., carbon, nitrogen, phosphorus and sulfur oxides, acrolein, and hydrogen chloride).

Reactivity Hazards:

This product is not reactive.

Note

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENT

Common name / Chemical name	Clindamycin Phosphate
CAS No.	24729-96-2
Concentration	1%
Other Ingredients	Cetostearyl alcohol, Glycerin, Glyceryl Stearate SE, Isostearyl alcohol, Methyl paraben, Sodium Lauroyl Sarcosinate, Stearic acid, Purified water

4. FIRST-AID MEASURES

Inhalation Remove to fresh air and keep patient at rest. If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention immediately.

Skin contact Remove contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation occurs.

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Eye contact	If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.
Ingestion	If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Most important symptoms/effects, acute and delayed	For information on potential signs and symptoms of exposure, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE-FIGHTING MEASURES

Extinguishing media	Use carbon dioxide, dry chemical, or water spray.
Specific hazards arising from the chemical	If heated to high temperatures for a prolonged period, the water in this product can evaporate off and the residue may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic gases (e.g., carbon, nitrogen, phosphorus and sulfur oxides, acrolein, and hydrogen chloride).
Special protective equipment and precautions for fire-fighters	Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Methods and materials for containment and	The product should be gently covered with absorbent pads. Clean spill

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cleaning up with pad and dispose of properly. Decontaminate the spill area (three times) using a bleach and detergent solution and then rinse with clean water.

Additional Consideration for Large Spills Restrict access to the spill areas. For spills of amounts larger than 5 mL limit spread by gently covering with absorbent sheets, or spill-control pads or pillows. Be sure not to generate aerosols. The dispersion of aerosols into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Do not apply chemical in-activators as they may produce hazardous by-products. Thoroughly clean all contaminated surfaces three times using a bleach and detergent solution and then rinse with clean water.

7. HANDLING AND STORAGE

Precautions for safe handling All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this product. Appropriate personal protective equipment must be worn (see Section 8, Engineering Controls and Personal Protection). Avoid generation of aerosols.

Conditions for safe storage Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Recommended Storage Temperature: 20-25°C (68-77°F) [USP Controlled Room Temperature]. Protect from freezing. Store away from incompatible materials (see Section 10, Stability and Reactivity). Product should be stored in secondary containers. Keep containers tightly closed when not in use.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Clindamycin Phosphate 100 ug/m³ TWA

Analytical Method Analytical method available for clindamycin. Contact Encube Ethicals for further information.

Appropriate engineering controls Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS.

Individual protection measures Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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Respiratory protection	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.
Skin protection	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Eye protection	Wear safety glasses or goggles if eye contact is possible.
Hand	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	White to off-white lotion free from foreign particles
Odor threshold	Mild
Flash Point (Liquid) (°C)	Not applicable
Upper Explosive Limits (Liquid) (% by Vol.)	Not applicable
Lower Explosive Limits (Liquid) (% by Vol.)	Not applicable
pH	4.0 - 7.0
Viscosity	20-500 cp
Specific Gravity	0.90 -1.100

10. STABILITY AND REACTIVITY

Reactivity	No data available.
Chemical stability	Stable under normal conditions of use.
Possibility of hazardous reactions	Will not occur.
Incompatible materials	This product is generally compatible with other common materials in a medical facility. Acids, strong oxidizers, water reactive materials, and other chemicals that could affect its performance should be avoided.
Hazardous decomposition products	Combustion: If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon, nitrogen, phosphorus and sulfur oxides, acrolein, and hydrogen chloride). Hydrolysis: None known.

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11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects General Information	The information included in this section describes the potential hazards of the individual ingredients
Short Term	Use of the topical formulation of Clindamycin results in absorption of the antibiotic from the skin surface. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic Clindamycin.
Known Clinical Effects	Individuals who have had allergic reactions to products containing the active ingredient, Clindamycin Phosphate (or any other components of this product) may experience allergic reactions to this product. Use of the topical formulation of Clindamycin results in absorption of the antibiotic from the skin surface. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic Clindamycin.
Acute Toxicity: (Species, Route, End Point, Dose)	Clindamycin Phosphate Rat Oral LD ₅₀ 1832 mg/kg Rat Para-periosteal LD ₅₀ 321mg/kg Rat Intraperitoneal LD ₅₀ 745mg/kg Mouse Oral LD ₅₀ 2359mg/kg Mouse Intravenous LD ₅₀ 820mg/kg
Irritation / Sensitization: (Study Type, Species, Severity)	Clindamycin Phosphate Eye Irritation (Rabbit) Moderate Skin Irritation (Rabbit) Mild
Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)	Clindamycin Phosphate 6 Month(s) Rat Oral 600 mg/kg/day NOAEL No effects at maximum dose 6 Month(s) Dog Oral 600 mg/kg/day NOAEL Gastrointestinal system
Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))	Clindamycin Phosphate Prenatal & Postnatal Development Rat Subcutaneous 250 mg/kg NOAEL Not teratogenic Prenatal & Postnatal Development Rat Oral 300 mg/kg/day NOAEL

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Not Teratogenic

Prenatal & Postnatal Development Mouse Oral 600 mg/kg/day NOAEL
Not Teratogenic

Prenatal & Postnatal Development Rabbit Subcutaneous 5 mg/kg/day
NOAEL Not Teratogenic, Maternal Toxicity

Reproductive & Fertility Rat Oral 300 mg/kg/day NOAEL No effects at
maximum dose

Genetic Toxicity: (Study Type, Cell
Type/Organism, Result)

Clindamycin Phosphate

Bacterial Mutagenicity (Ames) Salmonella Negative

12. ECOLOGICAL INFORMATION

Environmental Overview

Environmental properties have not been thoroughly investigated.
Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health, And Environmental
Regulations/Legislation Text of R phrases
and GHS Classification abbreviations

Specific target organ toxicity, single exposure; Narcotic effects-Cat.3;
H336 - May cause drowsiness and dizziness

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mentioned in Section 3

Flammable liquids-Cat.3; H225 - Highly flammable liquid and vapor

Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Skin corrosion/irritation-Cat.3; H316 - Causes mild skin irritation

Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

Xi - Irritant

R10 - Flammable.

R36 - Irritating to eyes.

R43 - May cause sensitization by skin contact.

R67 - Vapors may cause drowsiness and dizziness.

OSHA Label:

WARNING

Flammable liquid and vapor.

Causes eye irritation.

Vapors may cause drowsiness and irritation of the eyes or respiratory tract

May cause allergic reaction.

16. OTHER INFORMATION

Contact Information

Encube Ethicals, Inc.
200 Meredith Avenue, Suite 101A, Durham,
NC27713, USA
<https://www.encubeethicals.com/>

Disclaimer: This material safety data sheet has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

End of Safety Data Sheet