

Material Name: Clindamycin Phosphate Topical Solution USP, 1%

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MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND THE COMPANY / UNDERTAKING

**Product Identifier**

**Product Name:** Clindamycin Phosphate Topical Solution USP, 1%

**Chemical Family:** --

**Relevant Identified Uses of the Substance or Mixture and Uses Advised against Intended Use:** Pharmaceutical product used as antibiotic agent

**Company Name:**

**Encube Ethicals Pvt. Ltd**  
Plot No.C-1, Madkaim Industrial Estate,  
Madkaim, Post- Mardol, Ponda  
Goa – 403 404  
India  
Tel. No.: +91-0832-6618600

2. HAZARDS IDENTIFICATION

**Classification of the Substance or Mixture**

**GHS – Classification**

Serious Eye Damage/Eye Irritation: Category 2A

Skin Sensitization: Category 1

Specific target organ systemic toxicity (single exposure): Category 3  
Flammable liquids- Category 3

**EU Classification:**

EU Indication of danger: Irritant

EU Risk Phrases:

R10 - Flammable.

R36 - Irritating to eyes.

R43 - May cause sensitization by skin contact.

R67 - Vapors may cause drowsiness and dizziness.

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## Label Elements



G  
Flammable liquid and vapor  
Causes serious eye irritation  
May cause an allergic skin reaction  
H336 - May cause drowsiness and dizziness

## Precautionary Statements:

P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking  
P233 - Keep container tightly closed  
P240 - Ground/Bond container and receiving equipment  
P241 - Use explosion-proof electrical/ventilating/lighting/equipment  
P242 - Use only non-sparking tools  
P243 - Take precautionary measures against static discharge  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing.  
Rinse skin with water/shower  
P403 + P235 - Store in a well-ventilated place. Keep cool  
P501 - Dispose of contents/container in accordance with all local and national regulations  
P264 - Wash hands thoroughly after handling  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove Contact lenses, if present and easy to do. Continue rinsing  
P337 + P313 - If eye irritation persists: Get medical advice/attention  
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P272 - Contaminated work clothing should not be allowed out of the workplace  
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water  
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention  
P321 - Specific treatment (see supplemental instructions on the administration of antidotes on this label)  
P363 - Wash contaminated clothing before reuse

## Other Hazards

No data available

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**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 INGREDIENTS

#### Hazardous

Ingredient	CAS Number	%
Clindamycin Phosphate	24729-96-2	1
Isopropyl Alcohol	67-63-0	50
Propylene glycol	57-55-6	*
Sodium Hydroxide	1310732	-
Purified Water	7732-18-5	*

**Additional Information:**

\* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

**For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 15**

#### 4. FIRST AID MEASURES

##### Description of First Aid Measures

###### Eye Contact:

Flush with water while holding eyelids open for at least 15 minutes. If irritation occurs or persists, get medical attention.

###### Skin Contact:

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

###### Ingestion:

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.

###### Inhalation:

Remove to fresh air and keep patient at rest. Seek medical attention immediately.

##### Most Important Symptoms and Effects, Both Acute and Delayed Symptoms and Effects of Exposure:

For information on potential signs and symptoms of exposure, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

##### Medical Conditions Aggravated by Exposure:

None known

##### Indication of the Immediate Medical Attention and Special Treatment Needed

###### Notes to Physician:

None

#### 5. FIRE FIGHTING MEASURES

##### Extinguishing Media:

Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

##### Special Hazards Arising from the Substance or Mixture

###### Hazardous Combustion Products:

Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

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**Fire / Explosion Hazards:**

Flammable liquid. Vapors will form flammable or explosive mixtures with air at room temperature. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

**Advice for Fire-Fighters**

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**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 Material for Containment and Cleaning Up**

**Measures for Cleaning / Collecting:**

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity). Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Additional Consideration for Large Spills:**

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

**7. HANDLING AND STORAGE**

**Precautions for Safe Handling**

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

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**Conditions for Safe Storage, Including any Incompatibilities**

**Storage Conditions:** Store as directed by product packaging.  
**Incompatible Materials:** Oxidising agents, Acids, Bases.  
**Specific end use(s):** Pharmaceutical drug product

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

**Control Parameters**

Refer to available public information for specific member state Occupational Exposure Limits.

**Analytical Method:**

**Exposure Controls**

Analytical method available for clindamycin. Contact Encube Ethicals Private Limited for further information.

**Engineering Controls:**

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**Personal Protective Equipment:**

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

**Hands:**

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:**

Wear safety glasses or goggles if eye contact is possible.

**Skin:**

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**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.

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**9. PHYSICAL AND CHEMICAL PROPERTIES**

<b>Physical State:</b>	Solution
<b>Odor:</b>	Characteristic alcohol odor
<b>Molecular Formula:</b>	Mixture
<b>Color:</b>	Colorless
<b>Odor Threshold:</b>	No data available.
<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	No data available.
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>	
<b>Clindamycin Phosphate:</b>	
No data available	

**Isopropyl alcohol**  
No data available

**Propylene glycol**  
No data available

**Sodium Hydroxide**  
No data available

**Water, purified**  
No data available

<b>Decomposition Temperature (°C):</b>	No data available.
<b>Evaporation Rate (Gram/s):</b>	No data available
<b>Vapor Pressure (kPa):</b>	No data available
<b>Vapor Density (g/ml):</b>	No data available
<b>Relative Density:</b>	No data available
<b>Viscosity:</b>	No data available

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## Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	24 - Closed cup
Upper Explosive Limits (Liquid) (% by Vol.):	12.7
Lower Explosive Limits (Liquid) (% by Vol.):	2

## 10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	

Keep away from heat, spark, flames and all other sources of ignition. Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials:	Oxidising agents, Acids, Bases.
Hazardous Decomposition Products:	No data available

## 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:

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 sensitive to this material or other materials in its chemical class may develop allergic reactions. Clinical use of this drug has caused sore throat, fever, gastrointestinal disturbances, abnormal liver function tests, kidney dysfunction. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur.

### Acute Toxicity: (Species, Route, End Point, Dose)

#### Clindamycin Phosphate

Rat	Oral	LD 50	1832 mg/kg
Rat	Para-periosteal	LD 50	321mg/kg



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Rat Intraperitoneal LD 50 745mg/kg  
Mouse Oral LD 50 2359mg/kg  
Mouse Intravenous LD 50 820mg/kg

### **Isopropyl alcohol**

Rat Oral LD50 > 2000 mg/kg  
Mouse Oral LD50 3600 mg/kg Rat Inhalation LC50-8h 16,000 ppm  
Rabbit Dermal LD50 12800 mg/kg Rat Inhalation LC50 30mg/L

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

### **Irritation / Sensitization: (Study Type, Species, Severity)**

#### **Clindamycin Phosphate**

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

#### **Isopropyl alcohol**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

#### **Propylene glycol**

Skin Irritation Rabbit Mild  
Eye 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

#### **Isopropyl alcohol**

20 Week(s) Rat Inhalation 4000 ppm NOAEL Liver, Central nervous system  
104 Week(s) Rat Inhalation 5000 ppm Kidney

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

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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

## Isopropyl alcohol

Prenatal & Postnatal Development    Rat    Inhalation    7000 ppm    LOAEL  
Maternal toxicity, Fetotoxicity, Embryotoxicity  
2 Generation Reproductive Toxicity    Rat    Oral 1000 mg/kg/day    LOAEL    Maternal Toxicity, Fetal mortality Prenatal & Postnatal Development    Rat    Oral **1200 mg/kg/day**  
NOAEL    No effects at maximum dose

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

### Clindamycin Phosphate

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Micronucleus	Rat	Negative

### Isopropyl alcohol

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Mammalian Cell Mutagenicity	HGPRT Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i>	Sister Chromatid Exchange	Negative

## Carcinogen Status:

### Isopropyl alcohol

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.  
See below

### IARC:

Group 3 (Not Classifiable)

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## 12. ECOLOGICAL INFORMATION

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

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

## 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 categories of classifications unless specified below.

<b>UN number:</b>	UN 1993
<b>UN proper shipping name:</b>	Flammable liquid, n.o.s. (contains isopropanol)
<b>Transport hazard class(es):</b>	3
<b>Packing group:</b>	III
<b>Flash Point (°C):</b>	24

**Exceptions:** For small quantities packed in combination packaging, exceptions may apply.

<b>Flash Point (°C):</b>	24
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**15. OTHER INFORMATION**

**Text of R phrases and GHS Classification abbreviations mentioned in Section 3**

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

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

Xn - Harmful

Xi - Irritant

F - Highly flammable

R11 - Highly flammable.

R22 - Harmful if swallowed.

R36 - Irritating to eyes.

R43 - May cause sensitization by skin contact.

R67 - Vapors may cause drowsiness and dizziness.

**Data Sources:** Publicly available toxicity information. Encube Ethicals Private Limited proprietary drug development information. Safety data sheets for individual ingredients.

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### Product Stewardship Hazard Communication

**Prepared by: Encube Ethicals Private Limited**

Encube Ethicals Private Limited believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**

**Authorized Signatory**

A handwritten signature in black ink that reads "Chirag Mistri".

**Mr. Chirag Mistri**

Sr. Manager – Regulatory Affairs

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