Safety Data Sheet
Clindamycin Phosphate Topical Solution USP, 1%
Strength: 1 % **Pack Size:** 30 mL 60 mL **NDC** 72578-084-02 72578-084-03 **Revision No.:** 00

Emergency Overview

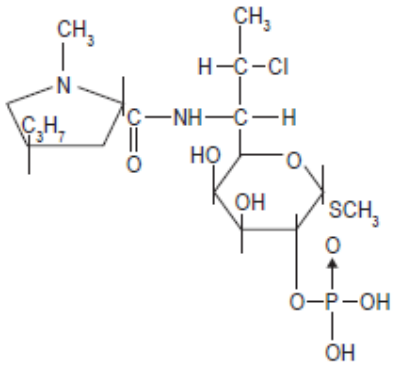
Clindamycin phosphate topical solution USP, 1% contains clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per milliliter.

Section 1 : Identification

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

Formula: $C_{18}H_{34}ClN_2O_8PS$

Chemical Name: 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).



Molecular Weight: 504.96 g/mol

Description: Clindamycin phosphate topical solution USP, 1% contains clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per milliliter. Clindamycin phosphate is a water soluble ester of the semi-synthetic antibiotic produced by a 7(S)-chloro-substitutiion of the 7(R)-hydroxyl group of the parent antibiotic lincomycin.

Dosage forms and strengths: Apply a thin film of Clindamycin phosphate topical solution, twice daily to affected area. Keep all liquid dosage forms in containers tightly closed.

Manufacturer / supplier identification

Company	Cadila Healthcare Ltd. Ahmedabad, India
Address	Cadila Healthcare, Ltd. Changodar (Topical Formulation facility) Plot No. 254, Opp. Laxmi Narayan Petrol Pump, N. H 8A, Ahmedabad -382210 India
Contact for information	Tel.:+91 2717-616430 Fax: +91 2717-616430
Emergency Telephone No	Tel.:+91 2717-616401

Recommended use / Therapeutic Category	Clindamycin phosphate topical solution USP, 1% is indicated in the treatment of acne vulgaris. The mechanism of action of Clindamycin in treating acne vulgaris is unknown. In view of the potential for diarrhea, bloody diarrhea and pseudomembranous colitis, the physician should consider whether other agents are more appropriate.
Restriction on Use / Contraindications	Clindamycin phosphate topical solution is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin, a history of regional enteritis or ulcerative colitis, or a history of antibiotic-associated colitis.

Section 2 : Hazard (s) Identification

Dose and Administration

Apply a thin film of Clindamycin phosphate topical solution, twice daily to affected area.
Keep all liquid dosage forms in containers tightly closed.

Adverse effects

In 18 clinical studies of various formulations of Clindamycin phosphate using placebo vehicle and/or active comparator drugs as controls, patients experienced a number of treatment emergent adverse dermatologic events.

Treatment Emergent Adverse Event	**Number of patients reporting events**		
	Solution n=553(%)	**Gel Gel n=148**	**Lotion N=160(%)**
Burning	62 (11)	15 (10)	17 (11)
Itching	36 (7)	15 (10)	17 (11)
Burning/Itching	60 (11)	# (-)	# (-)
Dryness	105 (19)	34 (23)	29 (18)
Erythema	86 (16)	10 (7)	22 (14)
Oiliness/Oily Skin	8 (1)	26 (18)	12* (10)
peeling	61 (11)	# (-)	11 (7)

not recorded
* of 126 subjects

Orally and parenterally administered clindamycin has been associated with severe colitis which may end fetally.
Cases of diarrhea, bloody diarrhea and colitis (including pseudomembranous colitis) have been reported as adverse reactions in patients treated with oral and parenteral formulation of clindamycin and rarely with topical clindamycin.
Abdominal pain, gastrointestinal disturbances, gram-negative folliculitis, eye pain and contact dermatitis have also been reported in association with the use of topical formulations of clindamycin.

Over Dose Effect

Topically applied clindamycin phosphate can be absorbed in sufficient amount to produce systemic effects.

Pregnancy Comments	**Teratogenic effects** In clinical trials with pregnant women, the systemic administration of clindamycin during the second and third trimesters has not been associated with an increased frequency of congenital abnormalities. There are no adequate studies in pregnant women during the first trimester of pregnancy. Clindamycin should be used during first trimester of pregnancy only if clearly needed.
Pharmacokinteics	Following multiple topical applications of clindamycin phosphate at a concentration equivalent to 10 mg clindamycin per mL in an isopropyl alcohol and water solution, very low levels of clindamycin are present in the serum (0–3 ng/mL) and less than 0.2% of the dose is recovered in urine as clindamycin. Although clindamycin phosphate is inactive in vitro, rapid in vivo hydrolysis converts this compound to the antibacterially active clindamycin.
Microbiology	Clindamycin inhibits bacterial protein synthesis by binding to the 23S RNA of the 50S subunit of the ribosome. Clindamycin is bacteriostatic.
Antimicrobial Activity	Clindamycin is active in vitro against most isolates of Propionibacterium acnes; however, the clinical significance is unknown.
Resistance	Resistance to clindamycin is most often caused by modification of specific bases of the 23S ribosomal RNA. Cross-resistance between clindamycin and lincomycin is complete. Because the binding sites for these antibacterial drugs overlap, cross resistance is sometimes observed among lincosamides, macrolides and streptogramin B. Macrolideinducible resistance to clindamycin occurs in some isolates of macrolide-resistant bacteria.

Section 3: Composition / information on ingredients

Contains: Active: Clindamycin phosphate, USP 10 mg/mL (1%)

Section 4: 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.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure.

Section 5: Fire -fighting measures

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

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

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self- contained breathing apparatus.

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.

Section 6: Accidental Release Measures

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
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.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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.

Section 7: Handling and Storage

General Handling:	Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment. 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.
Storage Conditions:	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Section 8: Exposure controls/personal protection

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
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.

Section 9: Physical and chemical properties

Physical State	Solution
Odor	Characteristic alcohol odor
Color	Colorless

Section 10: Stability and reactivity

Stability	Stable at normal conditions
Conditions to avoid	Keep away from heat, spark, flames and all other sources of Ignition.
Hazardous decomposition products	Oxidizing agents, acids, bases.

Section 11: Toxicological information

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Clindamycin Phosphate
Rat Oral LD 50 1832 mg/kg
Rat Intravenous LD 50 321mg/kg
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 3600mg/kg
Rat Inhalation LC50-8h 16,000ppm
Rabbit Dermal LD50 12800mg/kg
Rat Inhalation LC50 30mg/L

Propylene glycol
Mouse Oral LD50 22,000 mg/kg

Rat Oral LD50 20,000mg/kg Rabbit
Dermal LD50 20,800mg/kg
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)	Oral 600	No effects at maximum
6 Month(s)	Oral 600	Gastrointestinal system

Isopropyl alcohol

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

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

Isopropyl alcohol
IARC: Group 3
OSHA: Present

Section 12: Ecological information

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

Section 13: Disposal consideration

Disposal 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.

Section 14: Transport information

The following refers to all categories of classifications unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

Proper shipping name: Flammable liquid, n.o.s. (contains isopropanol)
UN / ID No: UN1993
Hazard class: 3
Packing group: III

Section 15: Regulatory information

Generic Medicine. NDC no- 72578-084-02 (30 mL) and 72578-084-03 (60 mL)

Section 16: Other information

None

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product

Date of issue: 29/10/20 **Supersedes edition:** N/A