

SAFETY DATA SHEET

1. **Identification**

**Product Identifier:** Clindamycin Phosphate Topical Solution USP, 1% (Pledgets)

**Synonyms:** Clindamycin 2-dihydrogen phosphate

**National Drug Code (NDC):** 61748-201-60 (60 Pledgets in a jar)

**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:** Flammable liquid Category 3

**Health Hazards:** Serious Eye Damage/Eye Irritation Category 2A

Skin Sensitization Category 1

Specific target organ systemic toxicity (single exposure) Category



**Symbol(s):**

**Signal Word:**

Warning.

**Hazard Statement(s):**

H226 Flammable liquid and vapor.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H336 May cause drowsiness and dizziness.

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### Precautionary Statement(s):

- 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.

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P333 If skin irritation or rash occurs: Get medical advice/attention.  
+  
P313

P321 Specific treatment (see supplemental instructions on the administration of antidotes on this label).

P363 Wash contaminated clothing before reuse.

**Hazards Not Otherwise Classified:** No data available.  
**Supplementary Information:** None.

### 3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Clindamycin Phosphate	24729-96-2	Clindamycin 2-dihydrogen phosphate	C <sub>18</sub> H <sub>34</sub> ClN <sub>2</sub> O <sub>8</sub> PS	504.96	1%

\*The formula also contains Isopropyl Alcohol 50% v/v, Propylene Glycol, Sodium Hydroxide (to adjust the pH to between 4.0 – 7.0) and Purified Water.

### 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.

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<b>Inhalation:</b>	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.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.
<b>Medical Conditions Aggravated by Exposure:</b>	None known.
<b>Notes to Physician:</b>	None.

### 5. Firefighting Measures

<b>Suitable Extinguishing Media:</b>	Extinguish fires with CO <sub>2</sub> , extinguishing powder, foam, or water.
<b>Unsuitable Extinguishing Media:</b>	Not determined.

#### Specific Hazards Arising from the Chemical:

<b>Hazardous Combustion Products:</b>	Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.
<b>Other Specific Hazards:</b>	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.
<b>Special Protective Equipment/Precautions for Firefighters:</b>	Wear self-contained breathing apparatus and full and protective gear.

### 6. Accidental Release Measures

<b>Personal Precautions:</b>	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
<b>Personal Protective Equipment:</b>	For personal protection see section 8.
<b>Methods for Cleaning Up:</b>	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.
<b>Environmental Precautions:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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

**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. Release 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. 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
Isopropyl Alcohol	ACGIH Threshold Limit Value (TWA) 200 ppm ACGIH Threshold Limit Value (STEL) 400 ppm ACGIH - Biological Exposure Limit: 40 mg/L OSHA - Final PELs - TWAs: 400 ppm; 980 mg/m <sup>3</sup>
Clindamycin Phosphate	Pfizer OEL: 100µg/m <sup>3</sup> , 8 Hour TWA

**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.

**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.

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**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.

### 9. Physical and Chemical Properties

**Physical State/Color:** Clear, colorless liquid.  
**Odor:** Characteristic alcohol odor.  
**Odor Threshold:** No data available.  
**pH:** 4.0 – 7.0.  
**Melting Point:** No data available.  
**Freezing Point:** No data available.  
**Boiling Point:** Refluxes at 55°C (131°F).  
**Flash Point:** 24°C (73.4°F).  
**Evaporation Rate:** 0.26.  
**Flammability (solid, gas):** No data available.  
**Flammability Limit - Lower:** 2.  
**Flammability Limit - Upper:** 12.7.  
**Vapor Pressure:** No data available.  
**Vapor Density:** No data available.  
**Relative Density:** No data available.  
**Solubility(ies):** Soluble 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):** 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:** Oxidizing agents, Acids, Bases.

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**Hazardous Decomposition Products:**

If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides, phosphorus oxides, sulfur oxides, and hydrogen chloride).

**11. Toxicological Information**

**Information on the Likely Routes of Exposure:**

**Inhalation:** 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.

**Ingestion:** May be harmful if swallowed.

**Skin Contact:** May cause skin irritation.

**Eye Contact:** Vapors irritating to eyes and respiratory tract.

**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.

**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	Route	Test Type	Dose
Clindamycin Phosphate	Rat	Oral	LD <sub>50</sub>	1,832 mg/kg
Clindamycin Phosphate	Rat	Para-periosteal	LD <sub>50</sub>	321 mg/kg
Clindamycin Phosphate	Rat	Intraperitoneal	LD <sub>50</sub>	745 mg/kg
Clindamycin Phosphate	Mouse	Oral	LD <sub>50</sub>	2,359 mg/kg
Clindamycin Phosphate	Mouse	Intravenous	LD <sub>50</sub>	820 mg/kg
Isopropyl Alcohol	Rat	Oral	LD <sub>50</sub>	>2,000 mg/kg
Isopropyl Alcohol	Mouse	Oral	LD <sub>50</sub>	3,600 mg/kg
Isopropyl Alcohol	Rat	Inhalation	LC <sub>50</sub> -8h	16,000 ppm
Isopropyl Alcohol	Rabbit	Dermal	LD <sub>50</sub>	12,800 mg/kg
Isopropyl Alcohol	Rat	Inhalation	LC <sub>50</sub>	30 mg/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.

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**Irritation/Sensitization:**

Compound	Species	Study Type	Severity
Clindamycin Phosphate	Rabbit	Eye irritation	Moderate
Clindamycin Phosphate	Rabbit	Skin irritation	Mild
Isopropyl Alcohol	Rabbit	Eye irritation	Severe
Isopropyl Alcohol	Rabbit	Skin irritation	Mild
Propylene Glycol	Rabbit	Eye irritation	Mild
Propylene Glycol	Rabbit	Skin irritation	Mild

**Repeated Dose Toxicity:**

Compound	Species	Route	End Point	Dose	Duration	Target Organ
Clindamycin Phosphate	Rat	Oral	NOAEL	600 mg/kg/d	6 Month(s)	No effects at maximum dose
Clindamycin Phosphate	Dog	Oral	NOAEL	600 mg/kg/d	6 Month(s)	Gastrointestinal system
Isopropyl Alcohol	Rat	Inhalation	NOAEL	4,000 ppm	20 Week(s)	Liver, Central nervous system
Isopropyl Alcohol	Rat	Inhalation	NOAEL	5,000 ppm	104 Week(s)	Kidney

**Reproduction & Development Toxicity:**

Compound	Study Type	Species	Route	End Point	Dose	Effect(s)
Clindamycin Phosphate	Prenatal & Postnatal Development	Rat	Subcutaneous	NOAEL	250 mg/kg	Not Teratogenic
Clindamycin Phosphate	Prenatal & Postnatal Development	Rat	Oral	NOAEL	300 mg/kg/d	Not Teratogenic
Clindamycin Phosphate	Parental & Postnatal Development	Mouse	Oral	NOAEL	600 mg/kg/d	Not Teratogenic
Clindamycin Phosphate	Parental & Postnatal Development	Rabbit	Subcutaneous	NOAEL	5 mg/kg/d	Not Teratogenic, Maternal Toxicity
Clindamycin Phosphate	Reproductive & Fertility	Rat	Oral	NOAEL	300 mg/kg/d	No effects at maximum dose
Isopropyl Alcohol	Parental & Postnatal Development	Rat	Inhalation	LOAEL	7,000 ppm	Maternal Toxicity, Fetotoxicity, Embryotoxicity
Isopropyl Alcohol	Parental & Postnatal Development	Rat	Oral	LOAEL	1,200 mg/kg/d	No effects at maximum dose
Isopropyl Alcohol	2 Generation Reproductive Toxicity	Rat	Oral	LOAEL	1,000 mg/kg/d	Maternal Toxicity, Fetal mortality



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**Genetic Toxicity:**

<b>Compound</b>	<b>Study Type</b>	<b>Cell Type/Organism</b>	<b>Results</b>
Clindamycin Phosphate	Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Clindamycin Phosphate	<i>In Vitro</i> Micronucleus	Rat	Negative
Isopropyl Alcohol	Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Isopropyl Alcohol	Mammalian Cell Mutagenicity	HGPRT Chinese Hamster Ovary (CHO) cells	Negative
Isopropyl Alcohol	<i>In Vitro</i> Sister Chromatid Exchange	N/A	Negative

**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:** No data available.  
**Toxicokinetics/Metabolism:** No data available.  
**Target Organ Effects:** No data available.  
**Reproductive Effects:** No data available.  
**Carcinogenicity:** None.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Group 3. Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

**Mutagenicity:** No data available.

**Aspiration Hazard:** Based on available data, the classification criteria are not met.

**12. Ecological Information**

**Ecotoxicity**

**Aquatic:** Clindamycin phosphate is freely soluble in water (1 g in 2.5-mL water). Based on its solubility data, clindamycin phosphate is expected to be relatively mobile and migrate toward the aquatic compartment.

**Terrestrial:** No data available.

**Persistence and Degradability:** No data available.

**Bioaccumulative Potential:** The octanol/water partition coefficient of Clindamycin Phosphate is not known. However, based on its water solubility, it would be expected to be less than 3 and thus, would have a low potential to bioaccumulate in aquatic organisms.

**Mobility in Soil:** No data available.

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**Mobility in Environment:** Clindamycin phosphate melts with decomposition at approximately 142°C. It has no measurable vapor pressure; therefore it is not expected to enter the air.

**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:** UN 1993

**UN Proper Shipping Name:** Flammable liquid, n.o.s. (contains isopropanol)

**Transport Hazard Class(es):** 3

**Packing Group:** III

**Flash Point (°C):** 24

**Exceptions:** For small quantities packed in combination packaging, exceptions, may apply. Please refer to the applicable dangerous goods regulations for additional information.

**Department of Transportation:** Regulated as a hazardous material.

**International Air Transport Association (IATA):** Regulated as a dangerous good.

**International Maritime Dangerous Good (IMDG):** Regulated as a dangerous good.

### 15. Regulatory Information

#### US Federal Regulations:

**Toxic Substance Control Act (TSCA):** Isopropyl Alcohol: Listed.

**CERCLA Hazardous Substance and Reportable Quantity:** Isopropyl Alcohol: 1%.

**SARA 313:** Isopropyl Alcohol: Listed.  
**SARA 302:** Not listed.

**WHMIS - Canada:** Class B, Division 2  
Class D, Division 2, Subdivision B

#### State Regulations

**California Proposition 65:** Not listed.



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### 16. Other Information

**Revision Date:** 04/29/2015

**Revision Number:** 1

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