

**SECTION 1: IDENTIFICATION**

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**Product Identifier**

**Product Name:** Clindamycin Phosphate Topical Solution USP  
**Other Name:** Clindamycin Phosphate 1% w/v  
**Chemical Family:** Mixture

**Product Use:** Pharmaceutical (Topical, used as antibiotic agent)

**Supplier:** **Teligent Canada Inc.**  
 5995 Avebury Road, Suite 804  
 Mississauga, Ontario L5R 3P9  
 1-800-656-0793

**Manufacturer:** **Teligent OÜ**  
 Akadeemia tee 21/5, Tallinn, Estonia

**Emergency Phone Number:**  
**Chemical Emergency Response Unit (Canada):** 1-613-946-5690  
**Poison Control Center (US):** 1-800-222-1222

**SECTION 2: HAZARD IDENTIFICATION**

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This pharmaceutical product is for human use under prescribed dosage form. Under normal handling and use, and in a manner consistent with the labeled instructions, this product is not chemically hazardous.

**Classification of the Substance or Mixture**

**GHS Classification**

Flammable Liquids	Category 2
Acute Toxicity	Category 4
Eye Irritation	Category 2A
Sensitization, Skin	Category 1
Specific target organ toxicity - single exposure	Category 3

**GHS Label Elements, Including Hazard and Precautionary Statements**

**Pictogram:**



**Signal Word:** Danger

**Hazard Statements:**

H302 Harmful if swallowed.  
 H317 May cause an allergic skin reaction.

H319	Causes serious eye irritation.
H225	Highly Flammable liquid and vapor.
H336	May cause drowsiness or dizziness.
H410	Very toxic to aquatic life with long lasting effects

**Precautionary statements:** Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.  
 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
 Do not eat, drink or smoke when using this product.  
 Wash thoroughly after handling.  
 Wear protective gloves/protective clothing/eye protection/face protection.  
 IF ON SKIN: Wash with plenty of soap and water.  
 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  
 If skin irritation or rash occurs: Get medical advice/attention.  
 Take off contaminated clothing and wash before reuse.  
 Dispose of contents/container in accordance with all local and national regulations.

### SECTION 3: COMPOSITION/ INFORMATION OF INGREDIENTS

Ingredients	CAS Number	Quantity	Acute toxicity, LD50, Rat
Clindamycin Phosphate	24729-96-2	10 mg/mL	1832 mg/kg (Oral)
Propylene glycol	57-55-6	50 mg/mL	20000 mg/kg (Oral)
Isopropyl alcohol	67-63-0	393 mg/mL	> 2000 mg/kg (Oral)
Sodium Hydroxide	1310-73-2	For pH adjustment	No data available
Purified Water	7732-18-5	-	Not applicable

### SECTION 4: FIRST AID MEASURES

**After Eye Contact:** Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

**After Skin Contact:** Remove clothing and wash affected skin with plenty of soap and water. If irritation occurs or persists, get medical attention.

**After Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

**After Ingestion:** Never give anything by mouth to an unconscious person. Rinse mouth with water. Get medical attention.

### SECTION 5: FIRE FIGHTING MEASURES

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

**Hazardous Combustion**

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

**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.

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

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

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**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:** 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.

**SECTION 7: HANDLING AND STORAGE**

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**Precautions for Safe Handling**

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Use with adequate ventilation. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided.

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

**Storage Conditions:** Store at controlled room temperature (15° - 30 °C). Protect from exposure to heat and light. The bottle must be stored upright. Do not freeze.

**SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION**

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**Control parameters****Clindamycin Phosphate**

No data available

**Propylene Glycol**

Ontario, OHS OEL- TWAs:

155 mg/m<sup>3</sup>

**Isopropyl Alcohol**

<b>USA, ACGIH Threshold Limit Values (TLV):</b>	492 mg/m <sup>3</sup>
<b>Québec, OHS PELs- TWAs:</b>	983 mg/m <sup>3</sup>
<b>Alberta, OEL TWAs:</b>	492 mg/m <sup>3</sup>
<b>British Columbia, OEL TWAs:</b>	492 mg/m <sup>3</sup>
<b>Ontario OEL TWAs:</b>	492 mg/m <sup>3</sup>

**Sodium Hydroxide**

<b>OSHA - Final PELs - TWAs:</b>	2 mg/m <sup>3</sup>
<b>USA, ACGIH Threshold Limit Values (TLV):</b>	2 mg/m <sup>3</sup>
<b>Québec, OHS PELs- TWAs:</b>	2 mg/m <sup>3</sup>
<b>Alberta, OEL TWAs:</b>	2 mg/m <sup>3</sup>
<b>British Columbia, OEL TWAs:</b>	2 mg/m <sup>3</sup>

**Personal Protection Equipment**

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

**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.

**Eye Protection:** Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

**Skin Protection:** Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly with water after handling this product.

**Hand Protection:** Protective gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

**Respiratory Protection:** Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, wear an appropriate respirator with a protection factor sufficient to control exposures.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

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<b>Physical State:</b>	Liquid
<b>Colour:</b>	Colourless
<b>Odour:</b>	Characteristic alcohol odor
<b>Odour threshold:</b>	No data available
<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	Mixture
<b>Specific Gravity:</b>	0.92 g/mL

<b>pH:</b>	4 - 7
<b>Boiling Point:</b>	Mixture
<b>Freezing Point:</b>	Mixture
<b>Solubility in Water:</b>	Miscible in water
<b>Flash Point:</b>	24 °C
<b>Vapor Density:</b>	No data available
<b>Vapor Pressure:</b>	No data available
<b>Evaporation Rate:</b>	No data available
<b>Partition Coefficient:</b>	No data available
<b>Flammability:</b>	No data available
<b>Auto-ignition Temperature:</b>	No data available
<b>Decomposition Temperature:</b>	No data available
<b>Viscosity:</b>	No data available

**SECTION 10: STABILITY AND REACTIVITY**

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<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions:</b>	No data available
<b>Conditions to Avoid:</b>	Direct sunlight, conditions that might generate heat, and sources of ignition.
<b>Incompatibility:</b>	Strong bases, acids and oxidizing agents.
<b>Hazardous Decomposition Products:</b>	Hazardous decomposition products formed under fire conditions: Carbon oxides, nitrogen oxides (NOx), Sulphur oxides.

**SECTION 11: TOXIOLOGICAL INFORMATION**

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**Acute toxicity (Species, Root, Endpoint, Dose)**

**Clindamycin Phosphate**

Rat	Oral	LD50	1832 mg/kg
Rat	Intravenous	LD50	321 mg/kg
Mouse	Oral	LD50	2359 mg/kg
Mouse	Intravenous	LD50	820 mg/kg

**Propylene Glycol**

Mouse	Oral	LD50	22000 mg/kg
Rat	Oral	LD50	20000 mg/kg
Rabbit	Dermal	LD50	820 mg/kg

**Isopropyl Alcohol**

Rat	Oral	LD50	5045 mg/kg
Rat	Inhalation	LC50	37.5 mg/l
Rabbit	Dermal	LD50	12800 mg/kg

**Repeated dose toxicity**

No effects evident in rats, pigs and dogs at maximum dose for 21 days.

**Other information on acute toxicity**

No data available

**Skin corrosion/irritation**

No data available

**Serious eye damage/eye irritation**

No effects evident in rats at normal dose.

**Respiratory or skin sensitization**

No data available

**Germ cell mutagenicity**

No effects evident

**Carcinogenicity**

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

**Reproductive toxicity**

No effects evident at non-maternally toxic dose.

**Teratogenicity**

No data available

**SECTION 12: ECOLOGICAL INFORMATION**

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**Toxicity**

**Clindamycin Phosphate**

No data available

**Propylene Glycol**

Pimephales promelas (fathead minnow)	NOEC	52930 mg/l - 96 h
Daphnia (water flea)	NOEC	13020 mg/l - 48 h

**Isopropyl Alcohol**

Pimephales promelas (fathead minnow)	LC50	9640 mg/l - 96 h
Daphnia (water flea)	EC50	13299 mg/l - 48 h

**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available

**Other adverse effects**

No data available

**SECTION 13: DISPOSAL CONSIDERATIONS**

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**Waste Disposal:** Dispose of in accordance with all applicable federal, state and local regulations. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural 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.

**Packaging:** Dispose of in accordance with all applicable federal, state and local regulations. Handle packaging in the same way as the product itself. If not officially specified differently, packaging may be treated like household waste or recycled.

**SECTION 14: TRANSPORTATION INFORMATION**

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

**UN number:** UN1993  
**UN proper shipping name:** Flammable liquid, n.o.s. (contains isopropanol)  
**Transport hazard class:** 3  
**Packing group:** III  
**Flash Point (°C):** 24

For small quantities packed in combination packaging, the following may be applicable. Please refer to the applicable dangerous goods regulations for additional information.

**IATA**

**IATA Proper shipping name:** Consumer Commodity  
**IATA UN / ID No:** ID8000  
**IATA Hazard Class:** 9  
**IATA Packing Group:** Not applicable

**IMDG**

**IMDG Proper shipping name:** Flammable Liquid, n.o.s. (contains isopropanol), Ltd Qty  
**IMDG UN / ID No:** UN1993  
**IMDG Hazard Class:** 3  
**IMDG Packing Group:** III

**US DOT**

**DOT Proper shipping name:** Consumer Commodity  
**DOT Hazard Class:** ORM-D

**SECTION 15: REGULATORY INFORMATION**

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The product described in this SDS is regulated under the Federal Food, Drug and Cosmetics Act and is safe to use as per directions on container, box or accompanying literature (where applicable).

**SECTION 16: OTHER INFORMATION**

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The information contained in this Safety Data Sheet has been compiled from information believed to be accurate. While we believe that the data presented here is factual, Teligent Canada Inc. and its affiliates make no warranty or representation, nor assumes any responsibility in conjunction with the use of this information.

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