

MATERIAL SAFETY DATA SHEET

MSDS Identifier: Clindamycin Phosphate and Benzoyl Peroxide Gel, 1.2%/5%



SDS No.

Version :

SECTION 1: IDENTIFICATION

Product Name: Clindamycin Phosphate and Benzoyl Peroxide Gel, 1%/5% **Product No.:** 21922-022

Distributor: Encube Ethicals Inc.
200 Meredith Avenue, Suite 101A Durham, NC 27713
United States (USA).

Recommended Use: Clindamycin and Benzoyl Peroxide Gel, 1%/5% is indicated for the topical treatment of acne vulgaris.

Restrictions on Use: Clindamycin and Benzoyl Peroxide Gel, 1%/5% is contraindicated in those individuals who have shown hypersensitivity to any of its components or to lincomycin. It is also contraindicated in those having a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis.

Formula: Clindamycin Phosphate: $C_{18}H_{34}ClN_2O_8PS$
Benzoyl Peroxide: $C_{14}H_{10}O_4$

M.W.: Clindamycin Phosphate: 504.97
Benzoyl Peroxide: 242.23

SECTION 2: HAZARD(S) IDENTIFICATION

United States (US)

According to: OSHA 29 CFR 1910.1200 HCS

Classification of the Substance or Mixture

OSHA HCS 2012: Skin Irritation 2
Eye Irritation 2A
Skin Sensitization 1

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Label Elements

OSHA HCS 2012:

WARNING



Hazard Statement: Causes skin irritation
May cause an allergic skin reaction
Causes serious eye irritation

Precautionary Statement

Prevention: Avoid breathing dust, fume, gas, mist, vapours and/or spray.
Wash thoroughly after handling.
Wear eye/face protection.
Wear protective gloves.
Contaminated work clothing should not be allowed out of the workplace.

Response: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
If on skin: Wash with plenty of water.
If skin irritation occurs: Get medical advice/attention.
Take off contaminated clothing and wash before reuse.

Storage/Disposal: Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other Hazard(s)

OSHA HCS 2012: No data available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient: Clindamycin Phosphate and Benzoyl Peroxide **CAS#:** Clindamycin Phosphate: 24729-96-2
Benzoyl Peroxide: 94-36-0

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Inactive Ingredients: Carbomer homopolymer type C, potassium hydroxide, propylene glycol, and purified water

SECTION 4: FIRST-AID MEASURES

- Inhalation:** No adverse effects anticipated by breathing small amounts. If large amounts are inhaled, remove to fresh air.
- Skin Contact:** IF ON SKIN (and not prescribed): Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.
- Eye Contact:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
- Ingestion:** If swallowed, get medical help or contact a Poison Control Center immediately.

Most Important Symptoms/Effects, Acute and Delayed: No data available.

Indication of Immediate Medical Attention and Special Treatment Needed: No data available.

SECTION 5: FIRE-FIGHTING MEASURES

- Suitable Extinguishing Media:** Carbon dioxide, dry chemical powder, appropriate foam or water fog.
- Unsuitable Extinguishing Media:** No data available.
- Firefighting Procedures:** As in any fire, wear self-contained breathing apparatus and full protective gear.

Specific Hazards Arising From the Substance or Mixture

- Unusual Fire and Explosion Hazards:** No data available.
- Hazardous Combustion Products:** No data available.
- Advice for Firefighters:** No data available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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Personal Precautions: No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures: Ventilate area. Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Minimize contact of spilled material with soils to prevent runoff to surface waterways. Dispose of in accordance with Section 13.

Environmental Precautions: Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and Materials for Containment and Cleaning

Up Containment/Clean-up Measures: No data available

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Handling: Avoid contact with eyes. Avoid prolonged or repeated exposure to skin or mucous membranes, and breathing mists/vapors. Use in a well ventilated area, away from all sources of ignition. Keep container closed. Wash thoroughly with soap and water after handling.

Conditions for Safe Storage, Including Any Incompatibilities

Storage: Prior to Dispensing: Store in a cold place, preferably in a refrigerator, between 2°C and 8°C (36°F and 46°F). Do not freeze.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

Exposure Limits/Guidelines					
	Result	ACGIH	Canada Quebec	NIOSH	OSHA
Benzoyl peroxide (94-36-0)	TWAs	5 mg/m ³ TWA	5 mg/m ³ TWAEV	5 mg/m ³ TWA	5 mg/m ³ TWA

Exposure Limits/Guidelines: Refer to the occupational exposure limits / guidelines for the

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individual product components.

Exposure Control Notations

ACGIH: Benzoyl Peroxide (94-36-0): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen)

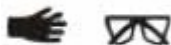
Exposure Limits Supplemental

ACGIH: Benzoyl Peroxide (94-36-0): **TLV Basis - Critical Effects:** (skin and upper respiratory tractirritation)

EXPOSURE CONTROLS

Engineering Measures/Controls: No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment



Pictograms

Respiratory: In the event of a bulk spill, and where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face: Wear eye/face protection.

Hands: Wear protective gloves.

Skin/Body: No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

General Industrial Hygiene Considerations: Handle in accordance with good industrial hygiene and safety practice.

Environmental Exposure Controls: No data available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Gel

Odor: None

Initial Boiling Point and Boiling Range: No data available.

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Flash Point: Not relevant
Evaporation Rate: No data available.
Solubility in water: Readily soluble in water.
Appearance: White to off-white, opaque gel.

SECTION 10: STABILITY AND REACTIVITY

Reactivity: Stable under normal temperatures and pressures.
Chemical Stability: Stable when stored at room temperature below 25°C (77°F). Use before expiration date marked on carton and/or container.
Possibility of Hazardous Reactions: No data available.
Conditions to Avoid: Do not freeze.
Incompatible Materials: Light, strong oxidizers, alkalis.
Hazardous Decomposition Products: No data available.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

Components		
Clindamycin (1%)	24729-96-2	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 2539 mg/kg; Ingestion/Oral-Rat LD50 • 1832 mg/kg; <i>Behavioral: Somnolence (general depressed activity)</i>
Benzoyl peroxide (5%)	94-36-0	Acute Toxicity: Ingestion/Oral-Rat LD50 • 6400 mg/kg

GHS Properties	Classification
Acute toxicity	OSHA HCS 2012 • Classification criteria not met
Skin corrosion/Irritation	OSHA HCS 2012 • Skin Irritation 2
Serious eye damage/Irritation	OSHA HCS 2012 • Eye Irritation 2A
Skin sensitization	OSHA HCS 2012 • Skin Sensitizer 1
Respiratory sensitization	OSHA HCS 2012 • Classification criteria not met
Aspiration Hazard	OSHA HCS 2012 • Classification criteria not met
Carcinogenicity	OSHA HCS 2012 • Classification criteria not met
Germ Cell Mutagenicity	OSHA HCS 2012 • Classification criteria not met

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Toxicity for Reproduction	OSHA HCS 2012 • Classification criteria not met
STOT-SE	OSHA HCS 2012 • Classification criteria not met
STOT-RE	OSHA HCS 2012 • Classification criteria not met

POTENTIAL HEALTH EFFECTS

Inhalation

Acute (Immediate): Under normal conditions of use, no health effects are expected.

Chronic (Delayed): No data available

Skin: **Acute (Immediate):** Causes irritation of the skin including dryness, peeling, itching, burningsensation, erythema, inflammation.

Chronic (Delayed): Repeated and prolonged exposure may cause sensitization.

Eye: **Acute (Immediate):** Causes serious eye irritation.

Chronic (Delayed): Repeated and prolonged exposure may be harmful.

Ingestion: **Acute (Immediate):** May be harmful.

Chronic (Delayed): No data available

Carcinogenic Effects: Data from a study using mice known to be highly susceptible to cancer suggests thatbenzoyl peroxide acts as a tumor promoter. The clinical significance of this is unknown. No animal studies have been performed to evaluate the carcinogenic and mutagenic potential or effects on fertility of topical erythromycin. However, long-term (2 -year) oral studies in rats with erythromycin ethylsuccinate and erythromycin base did not provide evidence of tumorigenicity.

Carcinogenic Effects		
	CAS	IARC
Carbomer	9003-01-4	Group 3-Not Classifiable
Benzoyl peroxide	94-36-0	Group 3-Not Classifiable

Other Information: Systemic absorption of clindamycin has been demonstrated following

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topical use of clindamycin. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: This material has not been tested for environmental effects.

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

WASTE TREATMENT METHODS

Product Waste: Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging Waste: Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

SECTION 14: TRANSPORT INFORMATION

	UN Number	UN Proper Shipping Name	Transport Hazard Class(es)	Packing Group	Environmental Hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

Special Precautions for User: No data available

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Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: No data available

SECTION 15: REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture SARA Hazard Classifications: No data available

United States

Labor

U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals

Benzoyl peroxide	94-36-0	7500 lb TQ
Clindamycin	24729-96-2	Not Listed

Environment

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

Benzoyl peroxide	94-36-0	Not Listed
Clindamycin	24729-96-2	Not Listed

U.S. - CERCLA/SARA - Section 313 - Emission Reporting

Benzoyl peroxide	94-36-0	1.0 % de minimis concentration
Clindamycin	24729-96-2	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

Benzoyl peroxide	94-36-0	Not Listed
Clindamycin	24729-96-2	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

Benzoyl peroxide	94-36-0	Not Listed
Clindamycin	24729-96-2	Not Listed

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U.S. - California - Proposition 65 - Reproductive Toxicity - Female

Benzoyl peroxide	94-36-0	Not Listed
Clindamycin	24729-96-2	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

Benzoyl peroxide	94-36-0	Not Listed
Clindamycin	24729-96-2	Not Listed

SECTION 16: OTHER INFORMATION

Contact: Encube Ethicals Inc., 200 Meredith Avenue, Suite 101A Durham,
NC 27713 United States (USA).

Preparation and/or Revision Date: April 2021

DISCLAIMER

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user's responsibility to evaluate the information and use it in a prudent manner for its particular purpose. Taro Pharmaceuticals assumes no responsibility for the use of this information.

Authorized Signatory

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