



MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Clindamycin Phosphate Foam, 1%

Product No.: 4T5

Synonyms: None

Manufacturer Name:

Perrigo Company

515 Eastern Avenue

Allegan, MI 49010, USA

Telephone Number: 269-673-8451

Emergency Telephone:

3E Emergency Response: 888-464-2986

Intended Use: Prescription antibiotic drug for the topical treatment of acne

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Foam

Color: White

Odor: Alcohol

WARNING!

Flammable aerosol – may cause flash fire.

Causes eye irritation.

May cause skin irritation.

May cause diarrhea, bloody diarrhea and colitis.

High vapor concentrations may cause central nervous system effects.

Consumers: Refer to the package insert for consumer-specific information about the directional use and effects of this product.

Potential Health Effects

Only information about the ingredients that are expected to contribute to the potential health effects of the product is mentioned.

Clindamycin phosphate is an antibiotic (against *Propionibacterium acnes*) for topical dermatologic use in the treatment of acne vulgaris. Use of the medication can cause skin irritation and burning; direct contact of foam with the eye may cause eye irritation. Adverse effects are rare for the topical usage. Adverse effects may include abdominal pain, gastrointestinal disturbances,

diarrhea, bloody diarrhea, colitis and gram-negative folliculitis. The severity of these effects may be dose related. Overexposure to clindamycin phosphate may cause worsened adverse effects.

Propane/iso-butane/n-butane mixture is used as a propellant in pharmaceutical topical foams. It can cause eye irritation. If high vapor concentrations are present, they can cause central nervous system effects which include drowsiness and dizziness.

Propylene glycol is used as a humectant in pharmaceutical topical foams. It may cause skin and eye irritation.

Cetyl alcohol is used as a foam stabilizer in pharmaceutical topical foams. It can cause skin and eye irritation.

Contraindications: Clindamycin phosphate 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.

Chronic Health Effects: Colitis

Target Organ(s): Eye, skin, colon.

Pregnancy Category: Clindamycin phosphate: Category B

Reproduction studies have been performed in rats and mice using subcutaneous and oral doses of clindamycin phosphate, clindamycin hydrochloride and clindamycin palmitate hydrochloride. These studies revealed no evidence of fetal harm. The highest dose used in the rat and mouse teratogenicity studies was equivalent to a clindamycin phosphate dose of 432 mg/kg. For a rat, this dose is 84 fold higher, and for a mouse 42 fold higher, than the anticipated human dose of clindamycin phosphate from Evoclin based on an mg/m² comparison. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

OSHA Regulatory Status: Hazardous

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| 3 | COMPOSITION / INFORMATION ON INGREDIENTS |
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| Chemical Name | CAS No. | wt% |
|--------------------------------------|-------------------------|-----|
| † Propane/Isobutane/n-Butane mixture | mixture; not applicable | < 5 |
| † Propylene glycol | 57-55-6 | < 3 |
| † Cetyl alcohol | 36653-82-4 | < 2 |
| Clindamycin phosphate | 24729-96-2 | 1 |

† This chemical is hazardous according to OSHA/WHMIS criteria
Components not listed are not hazardous or are below reportable limits.

Note: This MSDS is written to provide environmental, health and safety information for the individuals who will be handling the final product during research, manufacturing and distribution. For information on the individual ingredients, please refer to the appropriate MSDS for each ingredient separately. For consumers, refer to the package insert or product label for handling guidance.

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| 4 | FIRST AID MEASURES |
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Inhalation: If symptomatic, move to fresh air. Get medical attention if symptoms persist.

Eye Contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Skin Contact: Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing if required, then physically remove as much of the product as possible. Wash affected area with soap and water, and then thoroughly flush the area with water. If irritation persists, seek medical advice.

Ingestion: If symptomatic, seek medical advice.

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| 5 | FIRE-FIGHTING MEASURES |
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Extinguishing Media: Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

Unsuitable Extinguishing Media: Not applicable

Special Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool.

Unusual Fire & Explosion Hazards: Pressurized containers may explode. Vapors may cause a flash fire or ignite explosively. Vapors may travel considerable distance to a source of ignition and flash back. Prevent accumulation of vapors to explosive concentrations. Pressurized containers may rupture in a fire situation.

Hazardous Combustion Products: Carbon oxides, nitrogen oxides, sulfur oxides, phosphorous oxides, hydrogen chloride

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| 6 | ACCIDENTAL RELEASE MEASURES |
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Personal Precautions: Wear appropriate personal protective equipment (See Section 8).

Spill Cleanup Methods: Eliminate all ignition sources. Wipe up spilled material and place in a suitable container for disposal.

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| 7 | HANDLING AND STORAGE |
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Precautions Handling Significant Quantities of Product: Observe good industrial hygiene practices. Avoid breathing high vapor concentrations and contact with eyes.

Storage: Store at controlled room temperature 68°-77°F (20°-25°C). Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperature above 120°F (49°C).

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| 8 | EXPOSURE CONTROLS / PERSONAL PROTECTION |
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Industrial Exposure Limits:

| Chemical Name | Source | Type | Exposure Limits | Notes |
|---|--------|------|----------------------|---------------------------------------|
| Propylene glycol, aerosol only | AIHA | WEEL | 10 mg/m ³ | ---- |
| Aliphatic hydrocarbon gases: Alkane (C1-C4) | ACGIH | TWA | 1000 ppm | Cardiac sensitization, CNS impairment |
| Propane | OSHA | TWA | 1000 ppm | ---- |

Engineering Controls: The health hazard risks of handling this material are dependent on factors, such as physical form. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Respiratory Protection: None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.

Eye Protection: None required for consumer use. In laboratory and industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Hand Protection: None required for consumer use. In laboratory, medical or industrial settings, gloves are recommended when product contact is possible. Contact a health and safety professional for specific information.

Skin Protection: None required for consumer use. In laboratory, medical or industrial settings, lab coats are recommended. Disposable Tyvek or other dust impermeable suits should also be considered depending on the level of exposure. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

Hygiene Measures: Wash hands after handling. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

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| 9 | PHYSICAL AND CHEMICAL PROPERTIES |
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Color: White

Odor: Alcohol

Odor Threshold: No data available

Physical State: Foam

pH: No data available

Melting Point: No data available

Freezing Point: No data available

Boiling Point: No data available

Flash Point: -81°C (-115°F) (estimated for propane/isobutane/n-butane mixture)

Evaporation Rate: No data available

Vapor Pressure: No data available

Vapor Density (Air=1): No data available

Density: No data available

Viscosity: No data available

Solubility in Water: No data available

Partition Coefficient (n-Octanol/water): No data available

Auto-ignition Temperature: No data available

Decomposition Temperature: No data available

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| 10 | STABILITY AND REACTIVITY |
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Stability: Stable.

Conditions to Avoid: Elevated temperatures, heat, sparks, flame, ignition sources

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: Carbon oxides, nitrogen oxides, sulfur oxides, phosphorous oxides, hydrogen chloride

Possibility of Hazardous Reactions: Will not occur

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| 11 | TOXICOLOGICAL INFORMATION |
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The information in this section is for the individual ingredients that are expected to contribute to the potential health effects of this product.

Acute Toxicity Data

Skin:

Clindamycin phosphate, propylene glycol and cetyl alcohol may cause skin irritation.

Eye:

Clindamycin phosphate, propylene glycol and cetyl alcohol may cause eye irritation. Propane/isobutane/n-butane mixture causes moderate eye irritation.

Oral:

Propylene glycol: LD50 (rat, oral): 20,000 mg/kg

Cetyl alcohol: LD50 (rat, oral): 5,000 mg/kg

Clindamycin phosphate: LD50 (rat, oral): 1832 mg/kg; LD50 (mouse, oral): 2539 mg/kg

Sensitization: Not expected to cause sensitization.

Chronic Toxicity Data

Subchronic/Chronic: Long-term usage of clindamycin phosphate may cause colitis.

Reproductive/Developmental: Reproduction studies in rats using oral doses of clindamycin hydrochloride and clindamycin palmitate hydrochloride have revealed no evidence of impaired fertility.

Mutagenicity/Genotoxicity: Genotoxicity tests performed included a rat micronucleus test and an Ames Salmonella reversion test. Both tests were negative.

Carcinogenicity: The carcinogenicity of a 1% clindamycin phosphate gel similar to this product was evaluated by daily application to mice for two years. The daily doses used in this study were approximately 3 and 15 times higher than the human dose of clindamycin phosphate from 5 milliliters of product, assuming complete absorption and based on a body surface area comparison. No significant increase in tumors was noted in the treated animals.

A 1% clindamycin phosphate gel similar to this product caused a statistically significant shortening of the median time to tumor onset in a study in hairless mice in which tumors were induced by exposure to simulated sunlight.

Listed Carcinogens: None listed.

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| 12 | ECOLOGICAL INFORMATION |
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Ecotoxicity: This product's components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Mobility: No data available

Persistence and Degradability: No data available

Bioaccumulation Potential: No data available

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| 13 | DISPOSAL CONSIDERATIONS |
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General Information: Disposal must be in accordance with applicable federal, state/provincial and/or local regulations.

Disposal Methods: Do not incinerate.

Container: Since emptied containers retain product residue, follow label warnings even after container is emptied. Dispose empty containers according to applicable federal, state/provincial and/or local regulations.

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| 14 | TRANSPORT INFORMATION |
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DOT: ORM-D

Proper Shipping Name: Consumer Commodity

Packaging Requirements: Inner packagings not over 1 liter (61.0 cubic inches) net capacity each for aerosols, and packed in strong outer packagings not to exceed 30 kg (66 pounds) gross weight.

Packages over 1.0 Liter Capacity:

UN-Number: 1950

Proper Shipping Name: Aerosols, flammable, n.o.s. (propane/iso-butane/n-butane mixture)

Class: 2.1

Label Code(s): 2.1

TDG:

Limited Quantity

Inner packaging must not exceed 1 liter capacity. The gross mass of the package must not exceed 30 kilograms (66 pounds).

Packages over 1.0 Liter Capacity:

UN-Number: 1950

Proper Shipping Name: Aerosols, flammable, n.o.s. (propane/iso-butane/n-butane mixture)

Class: 2.1

Label: Flammable Gas

IATA:

For Limited Quantities of aerosols of UN 1950 Aerosols, Flammable; Class 2.1:

Passenger & Cargo Aircraft Packing Instructions: Y203

Passenger & Cargo Aircraft Limited Quantity Maximum Quantity Package: 30 kg G

Single packagings are not permitted. Gas cartridges must not exceed 1 liter capacity.

The gross mass of the package must not exceed 30 kilograms (66 pounds).

Packages over 1.0 Liter Capacity:

UN-Number: 1950

Proper Shipping Name: Aerosols, flammable, n.o.s. (propane/iso-butane/n-butane mixture)

Class: 2.1

Label: Flammable Gas

Passenger & Cargo Aircraft Pkg Instr: 203

Passenger & Cargo Aircraft Max Qty: 75 kg

Cargo Aircraft Only Pkg Instr: 203

Cargo Aircraft Only Max Qty: 150 kg

IMDG:

Limited Quantities Exception: Dangerous Goods in limited quantities of Class 2.

Limited quantity value is 1 L. The gross mass of the package must not exceed 30 kilograms (66 pounds).

Packages over 1.0 Liter Capacity:**UN-Number:** 1950**Proper Shipping Name:** Aerosols, flammable, n.o.s. (propane/iso-butane/n-butane mixture)**Class:** 2.1**Label:** Flammable Gas**EMS No:** F-D, S-U**15 REGULATORY INFORMATION**

Canadian Controlled Products Regulations: This product has been classified according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.

WHMIS Classification: A, B5, D2B

Inventory Status

One or more components of this product are not listed on the following inventories or are exempt: TSCA, DSL

Drug Enforcement Act: Not regulated.

TSCA: Not regulated

FDA: Clindamycin phosphate is an FDA approved prescription drug product for topical use.

State Regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): None listed.

Massachusetts Right-To-Know List: Isobutane; Propane; n-Butane

New Jersey Right-To-Know List: Alcohol, n.o.s.; Isobutane; Propane; n-Butane

16 OTHER INFORMATION**Hazard Ratings**

| | Health Hazard | Fire Hazard | Reactivity Hazard |
|------|---------------|-------------|-------------------|
| HMIS | 2 | 4 | 0 |

| | Health Hazard | Fire Hazard | Reactivity Hazard | Special Hazard |
|------|---------------|-------------|-------------------|----------------|
| NFPA | 2 | 4 | 0 | N/A |

* – Chronic health effect; 0 – Minimal; 1 – Slight; 2 – Moderate; 3 – Serious; 4 – Severe

Issue Date: October 26, 2009

Supersedes Date: New

SDS No.: 0000004

Disclaimer: This MSDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.

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