Material Safety Data Sheet

Material Name: Clindagel® clindamycin phosphate topical gel equivalent to 1% clindamycin

* * * Section 1 - Chemical Product and Company Identification * * *

Manufacturer Information

PreCision Dermatology, Inc.
900 Highland Corporate Drive
Cumberland, RI 02864
Phone: Emergency Number: 1-888-713-8154

* * * Section 2 - Hazards Identification * * *

Emergency Overview

The product may cause allergic or sensitivity reaction for individuals sensitive to one or more of the components.

Potential Health Effects: Eyes

May cause irritation and stinging or burning.

Potential Health Effects: Skin

Allergic or sensitivity reactions are possible, causing irritation, rash, itching or redness.

Potential Health Effects: Ingestion

Not a likely route of entry. If swallowed may cause gastrointestinal discomfort.

Potential Health Effects: Inhalation

None anticipated under normal product handling conditions.

HMIS Ratings: Health: 1 **Fire:** 0 **HMIS Reactivity** 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

* * * Section 3 - Composition / Information on Ingredients * * *

CAS #	Component
57-55-6	1,2-Propylene glycol
25322-68-3	Polyethylene glycol
1310-73-2	Sodium hydroxide
7732-18-5	Water
24729-96-2	Methyl (2S-trans)-7-chloro-6,7,8-trideoxy-6-[[(1-methyl-4-propyl-2-pyrrolidinyl)carbonyl]amino]-1-thio-L-threo-α-D-galacto-octopyranoside, 2-(dihydrogen phosphate)
9003-01-4	Acrylic resin
99-76-3	Methyl p-hydroxybenzoate

* * * Section 4 - First Aid Measures * * *

First Aid: Eyes

Remove contact lenses. Immediately flush eyes with water for at least 15 minutes, while holding eyelids open. Seek medical attention at once.

First Aid: Skin

Should skin irritation, allergic reaction or rash occur, physically remove as much of the product as possible and thoroughly flush the area with water. If irritation persists, seek medical attention.

First Aid: Ingestion

Product is water soluble with low toxicity. Do not induce vomiting as aspiration of the product might occur. Drink large amounts of water. In cases where the ingestion of a large amount is suspected, gastric lavage may be performed by experienced medical personnel.

First Aid: Inhalation

None necessary.

* * * Section 5 - Fire Fighting Measures * * *

General Fire Hazards

See Section 9 for Flammability Properties.

None identified.

Hazardous Combustion Products

Oxides of carbon.

Extinguishing Media

Use ABC all-purpose extinguisher, water, CO2.

Fire Fighting Equipment/Instructions

Fire fighters should wear full-face, self-contained breathing apparatus and impervious protective clothing. Fire fighters should avoid inhaling any combustion products.

NFPA Ratings: Health: 1 **Fire:** 0 **Reactivity:** 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

* * * Section 6 - Accidental Release Measures * * *

Containment Procedures

Contain the discharged material.

Clean-Up Procedures

Collect in a suitable container or by use of an absorbent pad.

Evacuation Procedures

None necessary.

Special Procedures

Wear appropriate personal protective equipment.

* * * Section 7 - Handling and Storage * * *

Handling Procedures

Avoid eye contact. Keep out of reach of children. Wash thoroughly after handling.

Storage Procedures

Store in a dry area at room temperature. Avoid temperatures greater than 80°F (27°C) or storage near a heat source.

* * * Section 8 - Exposure Controls / Personal Protection * * *

A: Component Exposure Limits

Sodium hydroxide (1310-73-2)

ACGIH: 2 mg/m3 Ceiling
OSHA: 2 mg/m3 TWA
NIOSH: 2 mg/m3 Ceiling

Engineering Controls

Use general ventilation and use local exhaust, where possible, in confined or enclosed spaces.

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment: Eyes/Face

When handling large quantities, use approved eye protection to safeguard against potential eye contact.

Personal Protective Equipment: Skin

Wear chemical resistant gloves and other protective clothing (lab coat, apron, etc.) when cleaning a large spill.

Personal Protective Equipment: Respiratory

Respiratory protection; not normally required for ambient air concentrations not exceeding the Occupational Exposure Limit.

Personal Protective Equipment: General

None.

* * * Section 9 - Physical & Chemical Properties * * *

Appearance:	Colorless	**Odor:**	ND
Physical State:	Gel	**pH:**	ND
Vapor Pressure:	ND	**Vapor Density:**	ND
Boiling Point:	N/A	**Melting Point:**	N/A
Solubility (H2O):	ND	**Specific Gravity:**	ND
Evaporation Rate:	ND	**VOC:**	ND
Octanol/H2O Coeff.:	ND	**Flash Point:**	ND
Flash Point Method:	ND	**Upper Flammability Limit (UFL):**	ND
Lower Flammability Limit (LFL):	ND	**Burning Rate:**	ND
Auto Ignition:	ND		

* * * Section 10 - Chemical Stability & Reactivity Information * * *

Chemical Stability

Stable under normal conditions.

Chemical Stability: Conditions to Avoid

Excessive heat above 80°F for prolonged periods.

Incompatibility

None

Hazardous Decomposition

Oxides of carbon.

Possibility of Hazardous Reactions

None identified.

* * * Section 11 - Toxicological Information * * *

Acute Dose Effects

A: General Product Information

This product is considered safe for its intended use; however, as is the case with all topical products, a small number of individuals may experience sensitivity reactions such as redness, rash and/or itching. Use of this product should be discontinued any time a reaction occurs. Diarrhea, and less frequently, abdominal pain, bloody diarrhea and colitis may occur. A physician, emergency room or Poison Control Center should be called any time the product is ingested orally.

B: Component Analysis - LD50/LC50

1,2-Propylene glycol (57-55-6)

Oral LD50 Rat 20000 mg/kg; Dermal LD50 Rabbit 20800 mg/kg

Polyethylene glycol (25322-68-3)

Oral LD50 Rat 28 g/kg; Dermal LD50 Rabbit >20 g/kg

Sodium hydroxide (1310-73-2)

Dermal LD50 Rabbit 1350 mg/kg

Methyl (2S-trans)-7-chloro-6,7,8-trideoxy-6-[[(1-methyl-4-propyl-2-pyrrolidinyl)carbonyl]amino]-1-thio-L-threo-α-D-galacto-octopyranoside, 2-(dihydrogen phosphate) (24729-96-2)
Oral LD50 Rat 1832 mg/kg

Water (7732-18-5)
Oral LD50 Rat >90 mL/kg

Acrylic resin (9003-01-4)
Oral LD50 Rat 2500 mg/kg

Methyl p-hydroxybenzoate (99-76-3)
Oral LD50 Rat 2100 mg/kg

Carcinogenicity

Component Carcinogenicity

Acrylic resin (9003-01-4)

IARC: Supplement 7 [1987]; Monograph 19 [1979] (Group 3 (not classifiable))

* * * Section 12 - Ecological Information * * *

Ecotoxicity

A: General Product Information

No data available for this product.

B: Component Analysis - Ecotoxicity - Aquatic Toxicity

1,2-Propylene glycol (57-55-6)

Test & Species		Conditions
96 Hr LC50 Oncorhynchus mykiss	51600 mg/L [static]	
96 Hr LC50 Oncorhynchus mykiss	41 - 47 mL/L [static]	
96 Hr LC50 Pimephales promelas	51400 mg/L [static]	
96 Hr LC50 Pimephales promelas	710 mg/L	
96 Hr EC50 Pseudokirchneriella subcapitata	19000 mg/L	
24 Hr EC50 Daphnia magna	>10000 mg/L	
48 Hr EC50 Daphnia magna	>1000 mg/L [Static]	

Polyethylene glycol (25322-68-3)

Test & Species		Conditions
24 Hr LC50 Carassius auratus	>5000 mg/L	PEG 200, 400, 800

Sodium hydroxide (1310-73-2)

Test & Species		Conditions
96 Hr LC50 Oncorhynchus mykiss	45.4 mg/L [static]	

Acrylic resin (9003-01-4)

Test & Species		Conditions
96 Hr LC50 Lepomis macrochirus	580 mg/L	
96 Hr EC50 water flea	168 mg/L	

* * * Section 13 - Disposal Considerations * * *

US EPA Waste Number & Descriptions

A: General Product Information

No information available for the product.

B: Component Waste Numbers

No EPA Waste Numbers are applicable for this product's components.

Disposal Instructions

All wastes must be handled in accordance with local, state and federal regulations.

See Section 7 for Handling Procedures. See Section 8 for Personal Protective Equipment recommendations.

* * * Section 14 - Transportation Information * * *

US DOT Information

Shipping Name: Finished packaged product transported by ground (DOT): Consumer Commodity, ORM-D

* * * Section 15 - Regulatory Information * * *

US Federal Regulations

Component Analysis

This material contains one or more of the following chemicals required to be identified under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65) and/or CERCLA (40 CFR 302.4).

Sodium hydroxide (1310-73-2)

CERCLA: 1000 lb final RQ; 454 kg final RQ

State Regulations

Component Analysis - State

The following components appear on one or more of the following state hazardous substances lists:

Component	CAS	CA	MA	MN	NJ	PA	RI
1,2-Propylene glycol	57-55-6	No	No	Yes	Yes	Yes	No
Polyethylene glycol	25322-68-3	No	No	Yes	No	No	No
Sodium hydroxide	1310-73-2	Yes	Yes	Yes	Yes	Yes	No

Component Analysis - WHMIS IDL

The following components are identified under the Canadian Hazardous Products Act Ingredient Disclosure List:

Component	CAS #	Minimum Concentration
1,2-Propylene glycol	57-55-6	1 %
Sodium hydroxide	1310-73-2	1 %

Additional Regulatory Information

Component Analysis - Inventory

Component	CAS #	TSCA	CAN	EEC
1,2-Propylene glycol	57-55-6	Yes	DSL	EINECS
Polyethylene glycol	25322-68-3	Yes	DSL	No
Sodium hydroxide	1310-73-2	Yes	DSL	EINECS
Methyl (2S-trans)-7-chloro-6,7,8-trideoxy-6-[[(1-methyl-4-propyl-2-pyrrolidinyl)carbonyl]amino]-1-thio-L-threo-α-D-galacto-octopyranoside, 2-(dihydrogen phosphate)	24729-96-2	No	No	EINECS
Water	7732-18-5	Yes	DSL	EINECS
Acrylic resin	9003-01-4	Yes	DSL	No
Methyl p-hydroxybenzoate	99-76-3	Yes	DSL	EINECS

* * * Section 16 - Other Information * * *

Other Information

The information herein is presented in good faith and believed to be accurate as of the effective date given. However, no warranty, expressed or implied, is given. It is the buyer's responsibility to ensure that its activities comply with Federal, State or provincial, and local laws.

Key/Legend

EPA = Environmental Protection Agency; TSCA = Toxic Substance Control Act; ACGIH = American Conference of Governmental Industrial Hygienists; IARC = International Agency for Research on Cancer; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration., NJTSR = New Jersey Trade Secret Registry. CAN = Canada; EEC = European Economic Community.