

MATERIAL SAFETY DATA SHEET

DPT Laboratories
318 McCullough
San Antonio, TX, 78215

Product name: 1% Pimecrolimus Cream

DATE ISSUED: April 29, 2015

EMERGENCY TELEPHONE NUMBER (800) 424-9300

1. SUBSTANCE IDENTIFICATION

CHEMICAL NAME: 1% Pimecrolimus Cream

MOLECULAR WEIGHT: 810.47

MOLECULAR FORMULA: C₄₃H₆₈ClNO₁₁

CAS NUMBER: 137071-32-0 (Pimecrolimus)

TRADEMARK: Elidel®

SYNONYMS: (1R, 9S,12S, 13R, 14S, 17R, 18E, 21S,23S, 24R, 25S, 27R)-12[(1E)-2-[(1R,3R,4S)-4-chloro-3-methoxycyclohexyl]-1-methylvinyl]-17-ethyl-1,14-dihydroxy-23,25-dimethoxy-13,19,21,27-tetramethyl-11,28-dioxa-4-aza-tricyclo[22.3.1.0]octacos-18-ene-2,3,10,16-tetraone

CHEMICAL FAMILY: Calcineurin Inhibitor

PRODUCT USE: Atopic dermatitis cream

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW

CAUTION STATEMENT: WARNING - *This is prescription medication for the treatment of mild to moderate atopic dermatitis. This material must be used in the manner directed by the prescribing physician. A licensed pharmacist may have additional information. Should any adverse reaction occur, immediately contact the nearest emergency room and/or your physician.*



Precautionary Statements:

P264: Wash hands thoroughly after handling

P270: Do not eat, drink or smoke when handling this product

P302 + P352: If on skin: Wash with plenty of soap and water

P332 + P313: If skin irritation occurs, Get immediate medical advice/attention

P362: Take off contaminated clothes and wash before re-use

ROUTES OF ENTRY: Primary: Skin absorption, Secondary: Inhalation, ingestion, eye contact.

TARGET ORGANS: Skin

ACUTE EXPOSURE: Irritation, skin burning sensations, or pruritus

SIGNS AND SYMPTOMS OF EXPOSURE: Skin Irritation

CHRONIC EXPOSURE: Malignancy (e.g.: skin and lymphoma) although no causal relationships have been established. Continuous long-term use of topical calcineurin inhibitors should be avoided.

MEDICAL CONDITIONS POTENTIALLY AGGRAVATED BY EXPOSURE: Immunosuppressed Patients, Pimecrolimus 1% cream is not recommended for children less than 2 years of age. Patients with malignant or pre-malignant skin conditions

CARCINOGENICITY: Not listed/listed as carcinogen or potential carcinogen by NTP, IARC Monographs or OSHA.

3. COMPONENTS

MATERIAL	WEIGHT %	EXPOSURE LIMITS
Active Ingredient		
Pimecrolimus	1%	N/E
Incipient		
Purified Water	50 to 75	N/E
Caprylic/Capric Triglycerides	10 to 20	N/E
Benzyl Alcohol	1 to 10	N/E
Cetyl Alcohol	1 to 10	N/E
Oleyl Alcohol	1 to 10	N/E
Stearyl Alcohol	1 to 10	N/E
Citric Acid	<1 to 5	15 mg/M3 (PNOC)
Glyceryl Monostearate	<1 to 5	N/E
Propylene Glycol	<1 to 5	10 mg/M3 (AIHA)
Sodium Cetostearyl Sulphate	<1 to 5	N/E
Sodium Hydroxide	<1 to 5	2 mg/M3

N/E = Not Established

4. EMERGENCY FIRST AID PROCEDURES

GENERAL: In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person.

INHALATION: Remove from area to fresh air. Seek medical attention if respiratory irritation develops or if breathing becomes difficult. (Not expected to be an inhalation hazard.)

INGESTION: If swallowed, obtain immediate medical attention. Keep person at rest. **DO NOT** induce vomiting. (Not expected to be an ingestion hazard.) Ingestion may be harmful and cause nausea, vomiting, diarrhea, or other systemic effects.

SKIN CONTACT: Remove contaminated clothing. Wash affected areas with plenty of water, and soap if available, for several minutes. Seek medical attention if irritation or rash develops and persists. Causes skin irritation. Absorbed through the skin. May cause allergic reaction in some individuals. Exposure causes redness, itching and inflammation.

INJECTION: In case of accidental injection, wash and thoroughly disinfect, get medical attention.

EYE CONTACT: Flush eyes with large amounts of running water for 15 minutes. Get immediate medical attention. Contact with eyes causes irritation, redness and burning.

5. FIRE AND EXPLOSION HAZARD DATA

Flash Point	Flammable Limits	
	Upper	Lower
ND	ND	ND

FIRE EXTINGUISHING MEDIA: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

SPECIAL FIRE FIGHTING PROCEDURES: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use water spray to keep fire-exposed containers cool and protect against all exposures.

6. SPILL AND ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN THE EVENT OF A SPILL: Put on appropriate personal protective equipment. Wash contaminated clothing before re-use. Small Liquid Spill: Wipe up and place into approved container for disposal. Large Liquid Spill: Wipe up and place into approved container for disposal. Prevent runoff from entering drains, sewers, or streams. Wash down spill site and control wash water.

Environmental Precautions: Do not allow spill and/or runoff to enter drains or waterways. Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet.

7. PRECAUTIONS FOR SAFE HANDLING AND USE

HANDLING AND STORAGE PRECAUTIONS: Store in tight container and away from foodstuffs. This material should be handled and stored as per label and other instructions to ensure product integrity.

STEPS TO BE TAKEN IN CASE MATERIAL IS SPILLED OR RELEASED: Act in accordance with local procedures and SOPs. Small Liquid Spill: Wipe up and place into approved container for disposal. Large Liquid Spill: Wipe up and place into approved container for disposal. Prevent runoff from entering drains, sewers, or streams. Wash down spill site and control wash water.

OTHER PRECAUTIONS: Avoid contact with eyes, skin or clothing. Do not taste or swallow. Use with adequate ventilation. Wash hands thoroughly after handling. Wear fresh clothing daily.

8. CONTROL MEASURES

ENGINEERING CONTROLS: Good general ventilation (typically 10 air changes per hour) should be in place. Ventilation rates should match existing workplace conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain exposure limits below recommended exposure limits. If exposure limits have not been established, then maintain airborne levels to an acceptable level. Act in accordance with local procedures and SPOs.

RESPIRATORY PROTECTION: If engineering controls do not maintain airborne concentrations below recommended limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. A qualified person should determine the

need for the type of respiratory protection required. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection: Safety glasses with side shields or goggles
Hand Protection: Gloves
Protective Clothing: Laboratory coats
Other: Eye wash & safety shower

WORK/HYGIENIC PRACTICES: Use good personal hygiene practices. Wash hands before eating, drinking, smoking, or using the toilet. Promptly remove contaminated clothing and wash thoroughly before re-use.

9. PHYSICAL/CHEMICAL CHARACTERISTICS

APPEARANCE AND ODOR: White to Off-White semi-solid (cream)

Boiling Point: N/D	Specific Gravity: N/D
Vapor Pressure (mm Hg): N/D	Melting Point: N/D
Vapor Density: N/D	Evaporation Rate: N/D
Water Solubility: N/D	Volatiles, %: N/D

10. REACTIVITY DATA

STABILITY: Stable under normal storage conditions
CONDITIONS TO AVOID: Heat and Light
INCOMPATIBLE MATERIALS: Oxidizers
HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: When heated to decomposition or under fire conditions, material emits: Oxides of carbon and nitrogen.
HAZARDOUS POLYMERIZATION: N/D

11. TOXICOLOGICAL INFORMATION

TOXICITY: Prolonged systemic use of calcineurin inhibitors for sustained immunosuppression in animal studies and transplant patients following systemic administration has been associated with an increased risk of infections, lymphomas, and skin malignancies. Pimecrolimus Cream should not be used in patients with Netherton's Syndrome or other skin diseases where there is the potential for increased systemic absorption.

GENOTOXICITY: **Pregnancy Category C.** There are no adequate and well-controlled studies of topically administered Pimecrolimus in pregnant women. The experience with 1% pimecrolimus cream when used by pregnant women is too limited to permit assessment of the safety of its use during pregnancy.

In dermal embryofetal developmental studies, no maternal or fetal toxicity was observed up to the highest practicable doses tested, 10 mg/kg/day (1% pimecrolimus cream) in rats (0.14X MRHD based on body surface area) and 10 mg/kg/day (1% pimecrolimus cream) in rabbits (0.65X MRHD based on AUC comparisons). The 1% pimecrolimus cream was administered topically for 6 hours/day during the period of organogenesis in rats and rabbits (gestational days 6-21 in rats and gestational days 6-20 in rabbits).

12. ECOLOGICAL INFORMATION

Persistence and degradability: no data available

Toxicity: Bacterial toxicity: no data available

Bio accumulative potential: no data available
Mobility in soil: no data available
PBT and vPvB: assessment: no data available
Other adverse effects: no data available

Pimecrolimus - Active Ingredient

Persistence and degradability: Degradation (28 Days), subject to slight degradation OECD 301E

Toxicity: Bacterial toxicity: Pseudomonas putida, EC 10 (16 h) = 0.45 mg/l DEV, DIN 38412

Bio accumulative potential: no data available

Mobility in soil: no data available

PBT and vPvB: assessment: no data available

Other adverse effects: no data available

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL CONSIDERATIONS: Dispose of in accordance with local, state and federal regulations.

14. TRANSPORT INFORMATION

	DOT	IMO/IMDG	ICAO/IATA
14.1 UN Number	Not Applicable	Not Regulated	Not Regulated
14.2 UN Proper Shipping Name	Not Regulated	Not Regulated	Not Regulated
14.3 Transport Hazard Class(es)	Not Applicable	Not Applicable	Not Applicable
14.4 Packing Group	Not Applicable	Not Applicable	Not Applicable

15. REGULATORY INFORMATION

Regulatory Overview: The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.

Toxic Substance Control Act (TSCA): Not Applicable. Substances that are regulated under other federal regulations (i.e.: food additives, drug, cosmetics, etc.) are not subject to TSCA.

16. OTHER INFORMATION

ABBREVIATIONS:

N/E: Not Established

N/A: Not Applicable

N/D: Not Determined

Prepared by: Environmental Health and Safety Group

Date Prepared: April 29, 2015

Replaces: New

Sections Revised:

NOTICE:

The use of the information contained herein is intended for persons having technical skill and at their own discretion and risk. The information has been developed by from sources considered reliable but has not been independently verified by DPT Laboratories. (DPT). Therefore, DPT cannot guarantee the accuracy of the information in these sources nor should the *statements contained* herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein. It is the user's obligation to determine the conditions of safe use of this material. DPT urges the users of this product to study this MSDS and become aware of any hazards associated with this material. In the interests of safety, the information contained herein should be made available to your employees, agents and contractors who handle this material.

REFERENCES:

Elidel ® Package Insert

Pimecrolimus 1% Cream Manufacturing Batch Record

Pimecrolimus MSDS – BioVision

Pimecrolimus MSDS – BrightGene Bio-Medical Technology Company