

Material Safety Data Sheet



Preparation Date: 07/10/2001

SECTION 1: Chemical Product and Company Identification

Product Name: PENLAC NAIL LACQUER

CAS Number (for drug active): 29342-05-0

Synonyms: 6-Cyclohexyl-1-hydroxy-4-methyl-2-(1H)-pyridinone

Manufacturer's Name:

Dermik Laboratories, Inc.
1050 Westlakes Drive
Berwyn, PA 19312-2421
Information: 800-207-8049

Emergency Phone: (800) 424-9300 in US
(703) 527-3887 outside US

SECTION 2: Composition/Information on Ingredients

Material:	%:	CAS #:	TLV:
Ciclopirox Acid*	8%	29342-05-0	None
Isopropyl Alcohol*	>30%	67-63-0	TWA = 400 ppm STEL = 500 ppm
Gantrez ES-435*	>30%	25119-68-0	None
Ethyl Acetate*	>30%	141-78-6	TWA = 400 ppm

* OSHA hazardous according to 29 CFR 1910.1200

Nature of Hazard: Penlac Nail Lacquer is hazardous per the OSHA Hazard Communication Standard. This product is flammable and contains ingredients that can be hazardous if inhaled at high concentrations.

SECTION 3: Hazards Identification

EMERGENCY OVERVIEW:

In the healthcare environment, dispensing Penlac Nail Lacquer presents no occupational exposure hazards.

In the industrial environment, handling large quantities of Penlac Nail Lacquer can present flammability hazards. Overexposure to product vapors may induce central nervous system depression, characterized by headache, dizziness and nausea.

POTENTIAL HEALTH EFFECTS

ROUTES OF EXPOSURE:

Skin and inhalation.

SIGNS AND SYMPTOMS OF EXPOSURE:

Exposure to eyes can cause irritation. Inhalation may cause irritation of nose and throat. Exposure to high concentrations of vapor has a narcotic effect, producing symptoms of drowsiness and headache.

IMMEDIATE EFFECTS

SKIN:

Causes skin and mucous membrane irritation.

EYES:

Irritating to eyes.

INHALATION:

Overexposure to vapors may include central nervous system depression characterized by headache, dizziness, and nausea.

DEALYED/LONG TERM EFFECTS

CARCINOGENIC EFFECTS:

NTP, IARC or OSHA does not list this product as a carcinogen.

A carcinogenicity study in female mice dosed cutaneously with ciclopirox, a related molecule, twice per week for fifty weeks followed by a six-month drug-free observation period prior to necropsy revealed no evidence of tumors at the application site.

MUTAGENIC:

In two in vitro genotoxicity tests, Penlac Nail Lacquer was negative in one (Ames Test) and positive in another (cell transformation).

In a battery of in vitro genotoxicity tests with the active ingredient, ciclopirox, one assay was positive; however, in vivo testing did not substantiate the positive findings.

TERATOGENIC:

Reproduction studies have been performed in the mouse, rat, rabbit and monkey (via various routes of administration) at doses ten times or more the topical human dose and have revealed no significant evidence of impaired fertility or harm to the fetus due to ciclopirox olamine, a related compound.

TARGET ORGAN EFFECTS:

Isopropyl Alcohol: central nervous system

Ethyl Acetate: liver or kidneys

Gantrez ES-435: central nervous system

Penlac Nail Lacquer: eyes

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:

Existing hypersensitivity to ciclopirox acid, the active ingredient in Penlac Nail Lacquer.

SECTION 4: First Aid Measures

Inhalation: Remove to fresh air.

Eyes: Flush thoroughly with water for 15 minutes. Seek medical attention.

Skin: Remove contaminated clothing, wash affected area thoroughly with soap and water.

Ingestion: If material is ingested, seek medical attention.

SECTION 5: Fire Fighting Measures

This product is flammable. Wear full bunker gear, including SCBA, when responding to fires involving facilities where pharmaceutical products are stored. Water, foam, or CO₂ may be used to fight fires.

SECTION 6: Accidental Release Measures

Eliminate all sources of ignition. Absorb spilled Penlac Nail Lacquer with inert material and dispose of waste according to local, state and federal regulations.

SECTION 7: Handling and Storage

Avoid contact with skin, eyes, or clothing.

Do not breathe vapor.

Keep container closed tightly.

No other storage information available.

SECTION 8: Exposure Controls/Personal Protection

Aventis Pharmaceutical Occupational Exposure Standard: 3.5 mg/m³ (for active ingredient)

Ventilation: Penlac Nail Lacquer should be applied to nails in a ventilated room. The bottle should be capped when not in use.

In the industrial environment where Penlac Nail Lacquer is manufactured, provide general and local exhaust ventilation to meet TLV requirements for product ingredients. Ventilation fans and other electrical service must be non-sparking and have explosion-proof design. For emergency incidents, or where TLV's may be exceeded, use an appropriate NIOSH-approved respirator. Safety glasses or splash goggles should be worn. Impervious gloves or other protective clothing and equipment should be available and worn as necessary to prevent contact with skin eyes and clothing.

SECTION 9: Physical and Chemical Properties

Appearance: Penlac Nail Lacquer is supplied as a clear solution

Odor: ethyl acetate imparts a fruity odor

Flashpoint: 31 degrees F

This material is flammable.

SECTION 10: Stability and Reactivity

Chemical stability: chemically stable

Conditions to avoid: heat and open flame

Hazardous decomposition products: none

Hazardous polymerization: none

SECTION 11: Toxicological Information

Acute Toxicity

Oral LD₅₀ (rat): >10 ml/kg. Also, 0.1 ml of Penlac Nail Lacquer applied to rabbit eyes caused irritation, so Penlac Nail Lacquer would be considered an eye irritant

SubChronic Toxicity

A related molecule, ciclopirdox olamine, has the following toxicity:

SPECIES	ADMINISTRATION	LD ₅₀ (mg/kg)
Rat	intravenous	72
Rat	oral	3290

Mouse	oral	1742
Mouse	intraperitoneal	83
Mouse	subcutaneous	1730
Mouse	intravenous	71

SECTION 12: Ecological Information

Penlac Nail Lacquer administered to patients presents negligible impact on the environment.

SECTION 13: Disposal Considerations

This product should be incinerated as a RCRA hazardous waste (D001), in accordance with local, state and federal regulations.

SECTION 14: Transport Information

Transportation of Hazardous Material Description Ship according to DOT and/or IATA Regulations. Ship via surface transportation, no markings required. Hazardous via air transportation: ship via air according to IATA regulations, Declaration of Dangerous Goods required.

Proper Shipping Name: Consumer Commodity
Hazard Class: 9
UN/NA #: ID 8000
Packaging Group: Not applicable

SECTION 15: Regulatory Information

Penlac Nail Lacquer is regulated under the Food, Drug and Cosmetic Act.

HAZARD CATEGORIES FOR SARA 311/312 REPORTING:

XX Acute
Chronic
XX Fire
Pressure
Reactivity

STATE REGULATIONS:

The following chemicals associated with the product are subject to the right-to-know regulations in these states:

Isopropyl alcohol (67-63-0): CT, FL, IL, LA, MA, NJ, PA, RI

Ethyl acetate (141-78-6): CT, FL, IL, LA, MA, NJ, PA, RI

U.S.FEDERAL REGULATIONS:

TSCA Inventory status: These components are not listed:

Ciclopirox 8% (29342-05-0)

TSCA 12B: The following are listed:

Isopropyl alcohol (67-63-0)

Ethyl acetate (141-78-6)

ENVIRONMENTAL:

CERCLA: Ethyl acetate (141-78-6)

SARA 304: Ethyl acetate (141-78-6)

SECTION 16: Other Information

The information provided in this Material Safety Data Sheet has been compiled from our experience and the data presented in various technical publications. It is the users responsibility to determine the suitability of this information for the adoption of safety precautions as may be necessary. Aventis Pharmaceuticals reserves the right to revise the Material Safety Data Sheets from time to time as new information becomes available. It is recommended that the user contact the company to make sure that the sheet is the latest one issued.

Reference Document: HMR MSDS 01034, original version 06/08/1998
First revision, 07/10/2001.