

MATERIAL SAFETY DATA SHEET

Ciclopirox Gel

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SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: Ciclopirox Gel
COMMON NAME: Ciclopirox Acid
CHEMICAL NAME: 6-cyclohexyl-1-hydroxy-4-methyl-2(1H)-pyridinone
CHEMICAL FORMULA: C₁₂H₁₇NO₂
CHEMICAL FAMILY: Hydroxypyridone antifungal agent

SECTION 2: ACTIVE INGREDIENT

CHEMICAL NAME	CAS#	% w/w	OSHA PEL	ACGIH TLV	IDLH
Ciclopirox USP	29342-05-0	0.77	NE	NE	NE

NE = Not Established, Specific amounts are considered proprietary information.

SECTION 3: HAZARDOUS INGREDIENTS

CHEMICAL NAME	CAS#	% w/w	OSHA PEL	ACGIH TLV	IDLH
Isopropyl Alcohol USP	67-63-0	20	NE	NE	NE

NE = Not Established, Specific amounts are considered proprietary information.

SECTION 4: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: Ciclopirox Gel is a homogenous white gel.

Symptoms of Overexposure by Route of Exposure: Overexposure by dermal contact does not cause skin or mucous membrane irritation.

Inhalation: Inhalation is not likely to occur.

Contact with Skin or Eyes: Contact with eyes causes severe eye irritation due to alcohol content. Additionally, a related molecule, Ciclopirox Olamine, when applied as a pure powder to laboratory animals, was shown to be a severe eye irritant. However, a 1% solution of Ciclopirox Olamine in sterile water was not irritating to the eyes of

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rabbits.

Ingestion: Effects of accidental ingestion is not known.

Health Effects or Risks From Exposure (An explanation in lay terms):

Acute/Chronic: Not Known/Not Known

Medical Conditions Aggravated by Over Exposure: Ciclopirox gel should not be used by any individuals who have shown hypersensitivity to any of its components.

Pre-Existing Medical Conditions: Not Known

SECTION 5: FIRST AID MEASURES

Skin Exposure: Thoroughly wash with mild soap and water if irritation develops.

Eye Exposure: Flush eyes with water for at least 15 minutes. Contact a physician.

Inhalation: Is not expected to occur, however if inhalation occurs and patient is not breathing begin artificial respiration and seek medical attention immediately.

Ingestion: If conscious, give water to drink and induce vomiting. Never give anything by mouth to an unconscious person. Seek medical attention immediately.

SECTION 6: FIRE / EXPLOSION HAZARDS & FIRE-FIGHTING MEASURES

Flash Point: 33°C (91°F)

Autoignition Temperature: NE

Flammable Limits (in air by volume, %): Lower: NE Upper: NE

Fire Extinguishing Equipment: Use extinguishing agent suitable for type of surrounding fire.

Water Spray: OK Carbon Dioxide: OK Halon: OK
Foam: OK Dry Chemical: OK Other: Any "ABC" Class

Unusual Fire and Explosion Hazards: No unusual fire or explosion hazards are expected.

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

Special Fire Fighting Procedures: For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by the DOT *Emergency Response Guidebook*, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.

SECTION 7: SPILL AND LEAK PROCEDURES

Spill and Leak Response:

Clean up material and place in an appropriate disposal container. Avoid runoff into storm sewers and ditches which lead to waterways. Consult local authorities regarding notification requirements.

SECTION 8: HANDLING AND STORAGE

Work and Hygiene Practices: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Storage and Handling Practices: Store at controlled room temperature 15°C to 30°C (59°F to 86°F). Wash hands before eating or drinking. Avoid contact with eyes.

Protective Practices During Maintenance of Contaminated Equipment: ND

SECTION 9: EXPOSURE CONTROLS / PERSONAL PROTECTION

Ventilation and Engineering Controls: No special ventilation required under normal condition of use.

Respiratory Protection: No special requirements under normal conditions, avoid breathing excessive dust.

Eye Protection: Although the risk from eye exposure is minimal, prudence recommends the use of safety glasses.

Hand Protection: No special requirements under normal condition of use.

Body Protection: No special requirements under normal conditions of use.

Product Preparation Instructions for Medical Personnel: Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

SECTION 10: PHYSICAL / CHEMICAL PROPERTIES

Boiling Point:	ND	Vapor Pressure:	ND
Melting/Freezing Point:	ND	pH:	5.5 – 7.5
Water Solubility:	ND	Water Reactive:	No
Specific Gravity (Water =1):	ND	Evaporation Rate (Butyl acetate = 1):	ND
Appearance/Odor:	Ciclopirox Gel is a white to off-white gel.		

ND = No Data

SECTION 11: STABILITY AND REACTIVITY

Stability: Stable under labeled storage conditions.

Incompatible Materials: None Known

Hazardous Polymerization: Will not occur.

Conditions to Avoid: Avoid heat and open flame.

SECTION 12: TOXICOLOGICAL INFORMATION

Toxicity Data: Ciclopirox gel is not considered toxic.

Suspected Cancer Agent: This product has **NOT** been identified as a carcinogen by NTP, IARC or OSHA.

Irritancy of Product: During normal use of product no eye contact should occur.

Sensitization to the Product: Not Known.

Reproductive Toxicity Information: This material is classified as a Pregnancy Category B (Risk to Fetus Cannot be Ruled-Out).

Mutagenicity: ND

Embryotoxicity/Teratogenicity/Reproductive Toxicity: ND

ACGIH Biological Exposure Indices: Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

SECTION 13: ECOLOGICAL INFORMATION

All work practices must be aimed at eliminating environmental contamination.

Environmental Stability: This product will be relatively stable under ambient environmental conditions.

Effect of Materials on Plants or Animals: Ecological tests have not been performed for Ciclopirox gel.

Effect of Chemicals on Aquatic Life: No specific information is available on the effects of Ciclopirox gel on aquatic life.

SECTION 14: WASTE DISPOSAL

Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

U.S. EPA Waste Number: None

SECTION 15: TRANSPORTATION INFORMATION

Due to the isopropyl alcohol content, the hazardous class definitions of 49 CFR 173 are applicable to this product.

Hazard Class Number and Description: ORM-D

UN Identification Number: Not applicable.

Packing Group: Not applicable.

DOT Label(s) Required: ORM-D

North American Emergency Response Guidebook Number (1996): Not applicable.

MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)

SECTION 16: REGULATORY INFORMATION

U.S. REGULATIONS:

U.S. SARA Reporting Requirements: 311/312 Hazard Categories: Immediate Health, 313 Reportable Ingredients: None

U.S. SARA Threshold Planning Quantity: Not applicable

U.S. CERCLA Reportable Quantities (RQ): Not applicable

U.S. TSCA Inventory Status: Ciclopirox gel is a “drug” as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product does NOT contain a chemical known to the State of California to cause developmental and reproductive effects.

Other U.S. Federal Regulations: Based on this product's use, the requirements of the OSHA Bloodborne pathogen Standard (29 CFR 1910.1030) are applicable.

ANSI Labeling (Based on 129.1. Provided to Summarize Occupational Exposure Hazards):

WARNING! Ciclopirox gel should be administered under the supervision of a qualified physician.

SECTION 17: OTHER INFORMATION

DEFINITIONS OF ABBREVIATIONS USED:

ACGIH:	American Conference of Governmental Industry Hygienists
CAS:	Chemical Abstract Service
IARC:	International Agency for Research on Cancer
IDLH:	Immediately Dangerous to Life or Health Level
LC ₅₀ :	Medial Lethal Concentration
LD ₅₀ :	Medial Lethal Dose
MSHA:	Mine Safety and Health Administration
N/A:	Not Available
NIOSH:	National Institute for Occupational Safety and Health
NTP:	National Toxicology Program
OSHA:	Occupational Safety and Health Administration
PEL:	Permissible Exposure Limit
STEL:	Short Term Exposure Limit
TLV:	Threshold Limit Value
TWA:	Time Weighted Average