

# Ciclopirox Olamine

sc-204688

Material Safety Data Sheet



The Power is Question

Hazard Alert Code Key:

EXTREME

HIGH

MODERATE

LOW

## Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

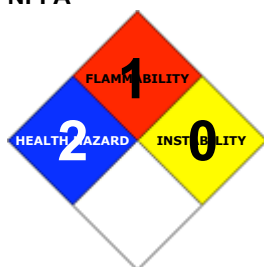
### PRODUCT NAME

Ciclopirox Olamine

### STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

### NFPA



### SUPPLIER

Santa Cruz Biotechnology, Inc.  
2145 Delaware Avenue  
Santa Cruz, California 95060  
800.457.3801 or 831.457.3800

### EMERGENCY:

ChemWatch  
Within the US & Canada: 877-715-9305  
Outside the US & Canada: +800 2436 2255  
(1-800-CHEMCALL) or call +613 9573 3112

### SYNONYMS

C12-H17-N-O2, "2-aminoethanol compd. with 6-cyclohexyl-1-hydroxy-4-methyl-2(1H)-", "pyridinone (1:1)", "ciclopirox ethanolamine salt (1:1)", ciclopiroxolamine, "6-cyclohexyl-1-hydroxy-4-methyl-2(1H)-pyridinone compd. with 2-", "aminoethanol (1:1)", "6-cyclohexyl-1-hydroxy-4-methyl-2(1H)-pyridinon, 2-aminoethanol-salz", "6-cyclohexyl-1-hydroxy-4-methyl-2(1H)-pyridone ethanolamine salt", Batrafen, Brumixol, Ciclochem, Dafnegin, Fungowas, Hoe-296, Loprox, LorpoX, Miclast, Micomicen, Micoxolamina, MycoSter, Terit, "antifungal agent"

## Section 2 - HAZARDS IDENTIFICATION

### CHEMWATCH HAZARD RATINGS

		Min	Max
Flammability:	1		
Toxicity:	2		
Body Contact:	2		
Reactivity:	1		
Chronic:	2		

Min/Nil=0  
Low=1  
Moderate=2  
High=3  
Extreme=4



### CANADIAN WHMIS SYMBOLS



## EMERGENCY OVERVIEW

### RISK

Irritating to eyes, respiratory system and skin.

### POTENTIAL HEALTH EFFECTS

#### ACUTE HEALTH EFFECTS

#### SWALLOWED

- Accidental ingestion of the material may be damaging to the health of the individual.

#### EYE

- This material can cause eye irritation and damage in some persons.

#### SKIN

- This material can cause inflammation of the skin on contact in some persons.
- The material may accentuate any pre-existing dermatitis condition.
- Skin contact is not thought to have harmful health effects, however the material may still produce health damage following entry through wounds, lesions or abrasions.
- Open cuts, abraded or irritated skin should not be exposed to this material.
- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

#### INHALED

- The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.
- Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

#### CHRONIC HEALTH EFFECTS

■ Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

There is limited evidence that, skin contact with this product is more likely to cause a sensitization reaction in some persons compared to the general population.

Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.

## Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
ciclopiproxy olamine	41621-49-2	>98

## Section 4 - FIRST AID MEASURES

#### SWALLOWED

· If swallowed do NOT induce vomiting. · If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

#### EYE

■ If this product comes in contact with the eyes: · Wash out immediately with fresh running water. · Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

#### SKIN

■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

#### INHALED

· If fumes or combustion products are inhaled remove from contaminated area. · Lay patient down. Keep warm and rested.

#### NOTES TO PHYSICIAN

- Treat symptomatically.

## Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible
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Upper Explosive Limit (%):	Not available.
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available

## EXTINGUISHING MEDIA

- Water spray or fog.
- Foam.

## FIRE FIGHTING

- Alert Emergency Responders and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.

## GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

- Combustible solid which burns but propagates flame with difficulty.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>), nitrogen oxides (NO<sub>x</sub>), other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

May emit corrosive fumes.

## FIRE INCOMPATIBILITY

- Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

## PERSONAL PROTECTION

Glasses:

Chemical goggles.

Gloves:

Respirator:

Particulate

## Section 6 - ACCIDENTAL RELEASE MEASURES

### MINOR SPILLS

- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.
- Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- Dampen with water to prevent dusting before sweeping.
- Place in suitable containers for disposal.

### MAJOR SPILLS

- Moderate hazard.
- CAUTION: Advise personnel in area.
- Alert Emergency Responders and tell them location and nature of hazard.

## Section 7 - HANDLING AND STORAGE

### PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
  - Wear protective clothing when risk of exposure occurs.
- Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.
- Do NOT cut, drill, grind or weld such containers.
  - In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

### RECOMMENDED STORAGE METHODS

- Glass container.
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

### STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.

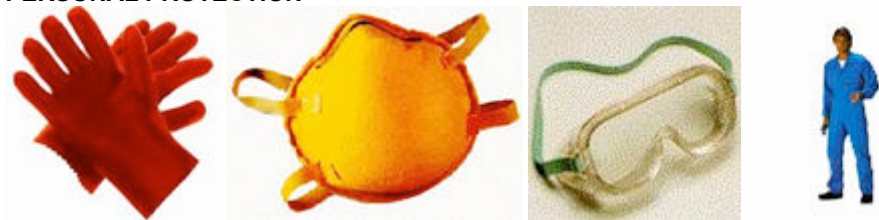
## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

### EXPOSURE CONTROLS

Source	Material	TWA mg/m <sup>3</sup>	Notes
US - Oregon Permissible Exposure Limits (Z-3)	ciclopiroxy olamine (Inert or Nuisance Dust: Total dust)	10	(d)
US OSHA Permissible Exposure Levels (PELs) - Table Z3	ciclopiroxy olamine (Inert or Nuisance Dust: (d) Respirable fraction)	5	
US OSHA Permissible Exposure Levels (PELs) - Table Z3	ciclopiroxy olamine (Inert or Nuisance Dust: (d) Total dust)	15	
US - Hawaii Air Contaminant Limits	ciclopiroxy olamine (Particulates not other wise regulated - Total dust)	10	
US - Hawaii Air Contaminant Limits	ciclopiroxy olamine (Particulates not other wise regulated - Respirable fraction)	5	
US - Oregon Permissible Exposure Limits (Z-3)	ciclopiroxy olamine (Inert or Nuisance Dust: Respirable fraction)	5	(d)
US ACGIH Threshold Limit Values (TLV)	ciclopiroxy olamine (Particles (Insoluble or Poorly Soluble) [NOS] Inhalable particles)	10	See Appendix B current TLV/BEI Book
US - California Permissible Exposure Limits for Chemical Contaminants	ciclopiroxy olamine (Particulates not otherwise regulated Respirable fraction)	5	(n)
US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants	ciclopiroxy olamine (Particulates not otherwise regulated Respirable fraction)	5	
US - Michigan Exposure Limits for Air Contaminants	ciclopiroxy olamine (Particulates not otherwise regulated, Respirable dust)	5	
Canada - Prince Edward Island Occupational Exposure Limits	ciclopiroxy olamine (Particles (Insoluble or Poorly Soluble) [NOS] Inhalable particles)	10	See Appendix B current TLV/BEI Book
US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants	ciclopiroxy olamine (Particulates not otherwise regulated (PNOR)(f)-Respirable fraction)	5	

ENDOELTABLE

## PERSONAL PROTECTION



### RESPIRATOR

Particulate

Consult your EHS staff for recommendations

### EYE

■ When handling very small quantities of the material eye protection may not be required.

For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- Chemical goggles
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

### HANDS/FEET

■ NOTE: The material may produce skin sensitization in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

· When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.

- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
  - Contaminated gloves should be replaced.
- Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.
- Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
  - Double gloving should be considered.
  - PVC gloves.
  - Protective shoe covers.
  - Head covering.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- polychloroprene
- nitrile rubber
- butyl rubber
- fluorocautchouc
- polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

#### OTHER

- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- Eye wash unit.
- Ensure there is ready access to an emergency shower.
- For Emergencies: Vinyl suit.

#### ENGINEERING CONTROLS

- Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.
- HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

## Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

### PHYSICAL PROPERTIES

Solid.

Mixes with water.

State	Divided solid	Molecular Weight	268.4
Melting Range (°F)	289.4	Viscosity	Not available
Boiling Range (°F)	Not available	Solubility in water (g/L)	Miscible
Flash Point (°F)	>230	pH (1% solution)	Not available
Decomposition Temp (°F)	Not available	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available.	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	>1
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

### APPEARANCE

Solid; mixes with water, ethanol.

## Section 10 - CHEMICAL STABILITY

### CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.

### STORAGE INCOMPATIBILITY

- Avoid reaction with oxidizing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

## Section 11 - TOXICOLOGICAL INFORMATION

CICLOPIROXY OLAMINE

### TOXICITY AND IRRITATION

#### CICLOPIROXY OLAMINE:

■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY	IRRITATION
Oral (rat) LD50: 2350 mg/kg	Nil Reported
Intraperitoneal (rat) LD50: 146 mg/kg	
Subcutaneous (rat) LD50: 9800 mg/kg	
Intravenous (rat) LD50: 72 mg/kg	
Oral (mouse) LD50: 1740 mg/kg	
Intraperitoneal (mouse) LD50: 83 mg/kg	
Subcutaneous (mouse) LD50: 1730 mg/kg	
Intravenous (mouse) LD50: 71 mg/kg	
Oral (rabbit) LD50: >3065 mg/kg	

■ Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.

Change in motor activity, dyspnea, body temperature decrease recorded.

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A carcinogenicity study of ciclopirox (1% and 5% solutions in polyethylene glycol 400) in female mice dosed cutaneously twice per week for 50 weeks followed by a 6-month drug-free observation period prior to necropsy revealed no evidence of tumors at the application site.

The following battery of in vitro genotoxicity tests was conducted with ciclopirox: evaluation of gene mutation in the Ames Salmonella and E. coli assays (negative); chromosome aberration assays in V79 Chinese hamster cells, with and without metabolic activation (positive); gene mutation assays in the HGPRT-test with V79 Chinese hamster cells (negative); and a primary DNA damage assay (i.e., unscheduled DNA synthesis assay in A549 human cells) (negative). An in vitro cell transformation assay in BALB/c 3T3 cells was negative for cell transformation. In an in vivo Chinese hamster bone marrow cytogenetic assay, ciclopirox was negative for chromosome aberrations at 5000 mg/kg.

Reproductive toxicity: Reproduction studies of ciclopirox revealed no significant evidence of impaired fertility in rats exposed orally up to 5 mg/kg body weight (approximately 5 times the maximum recommended topical human dose based on surface area). No foetotoxicity was shown due to ciclopirox in the mouse, rat, rabbit, and monkey at oral doses up to 100, 30, 30, and 50 mg/kg body weight, respectively (approximately 37.5, 30, 44, and 77 times the maximum recommended topical human dose based on surface area). By the dermal route of administration, no foetotoxicity was shown due to ciclopirox in the rat and rabbit at doses up to 120 and 100 mg/kg body weight, respectively (approximately 121 and 147 times, respectively, the maximum recommended topical human dose based on surface area).

## Section 12 - ECOLOGICAL INFORMATION

No data

## Section 13 - DISPOSAL CONSIDERATIONS

### Disposal Instructions

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

! Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

## Section 14 - TRANSPORTATION INFORMATION

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

## Section 15 - REGULATORY INFORMATION

**ciclopiroxy olamine (CAS: 41621-49-2) is found on the following regulatory lists;**

"US - Hawaii Air Contaminant Limits", "US - Oregon Permissible Exposure Limits (Z-3)", "US OSHA Permissible Exposure Levels (PELs) - Table Z3"

## Section 16 - OTHER INFORMATION

### LIMITED EVIDENCE

- Ingestion may produce health damage\*.
- Cumulative effects may result following exposure\*.
- Possible skin sensitiser\*.

\* (limited evidence).

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- Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

A list of reference resources used to assist the committee may be found at:

[www.chemwatch.net/references](http://www.chemwatch.net/references).

- The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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Issue Date: Feb-15-2010

Print Date: Nov-10-2010