



**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>CICLOPIROX OLAMINE, USP</b>
<b>PRODUCT CODE</b>	<b>0313</b>
<b>SUPPLIER</b>	<b>MEDISCA Inc.</b> Tel.: 1.800.932.1039   Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 <b>MEDISCA Pharmaceutique Inc.</b> Tel.: 1.800.665.6334   Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 <b>MEDISCA Australia PTY LTD</b> Tel.: 1.300.786.392   Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
<b>EMERGENCY PHONE</b>	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
<b>RECOMMENDED USES</b>	Pharmaceutical Manufacturing
<b>RESTRICTIONS ON USE</b>	Not applicable

**SECTION 2: HAZARDS IDENTIFICATION**

<b>GHS CLASSIFICATION</b>	Acute Toxicity - Oral (Category 5) Eye Irritation (Category 2A) Chronic Aquatic Toxicity (Category 1)
<b>PICTOGRAM</b>	
<b>SIGNAL WORD</b>	Warning
<b>HAZARD STATEMENT(S)</b>	May be harmful if swallowed. Causes serious eye irritation. Causes skin irritation. May cause allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Very toxic to aquatic life with long lasting effects.
<b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</b>	Not Applicable.

<b>PRECAUTIONARY STATEMENT(S)</b>	<b>Prevention</b>	Wash hands thoroughly after handling. Do not touch eyes. Wear protective gloves. Wear eye and face protection. Avoid breathing dust, fume, gas, mist, vapors, spray. In case of inadequate ventilation wear respiratory protection.  Avoid release to the environment.		
	<b>Response</b>	IF SWALLOWED: Get medical help. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical help. IF ON SKIN (HAIR): Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms call a poison center or medical professional. COLLECT SPILLAGE.		
	<b>Storage</b>	Not applicable		
	<b>Disposal</b>	Dispose of contents in accordance with local regulation.		
<b>HMS CLASSIFICATION</b>	<b>Health Hazard</b>	1	<b>Flammability</b>	1
	<b>Reactivity</b>	0	<b>Personal Protection</b>	G

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<b>CHEMICAL NAME</b>	2(1H)-Pyridinone, 6-cyclohexyl-1-hydroxy-4-methyl-, compound with 2-aminoethanol (1:1)
<b>BOTANICAL NAME</b>	Not applicable
<b>SYNONYM</b>	Ciclopiroxolamine
<b>CHEMICAL FORMULA</b>	C <sub>12</sub> H <sub>17</sub> NO <sub>2</sub> C <sub>2</sub> H <sub>7</sub> NO
<b>CHEMICAL FAMILY</b>	Hydroxypyridinone
<b>CAS NUMBER</b>	41621-49-2
<b>ALTERNATE CAS NUMBER</b>	Not applicable
<b>MOLECULAR WEIGHT</b>	268.3546

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
CICLOPIROX OLAMINE	41621-49-2	255-464-9	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

### SECTION 4: FIRST-AID MEASURES

<b>IN CASE OF EYE CONTACT</b>	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
<b>IN CASE OF SKIN CONTACT</b>	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
<b>IF SWALLOWED</b>	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
<b>IF INHALED</b>	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

**MEDICAL ATTENTION AND  
SPECIAL TREATMENT**

Get emergency medical help.

**SYMPTOMS CAUSED BY  
EXPOSURE**

Not expected to present a significant hazard under anticipated conditions of normal use.

**SECTION 5: FIREFIGHTING MEASURES****SPECIFIC HAZARDS ARISING  
FROM THE CHEMICAL**

Not applicable

**FLAMMABLE PROPERTIES**

May be combustible at high temperature

**HAZARDOUS COMBUSTION  
PRODUCTS**

Under fire conditions, hazardous fumes will be present.

**SUITABLE & UNSUITABLE  
EXTINGUISHING MEDIA**

**Small fire:** dry chemical, CO<sub>2</sub> or water spray. **Large fire:** dry chemical, CO<sub>2</sub>, alcohol resistant foam or water spray. Do not get water inside containers.

**PROTECTIVE EQUIPMENT AND  
PRECAUTIONS FOR  
FIREFIGHTERS**

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

**SECTION 6: ACCIDENTAL RELEASE MEASURES****PERSONAL PRECAUTIONS**

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

**METHODS & MATERIAL FOR  
CONTAINMENT**

On land, sweep or shovel into suitable containers. Minimize generation of dust.

**CLEANUP PROCEDURE**

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

**REFERENCE TO OTHER  
SECTIONS**

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

**SECTION 7: HANDLING AND STORAGE****PRECAUTIONS FOR SAFE  
HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**CONDITIONS FOR SAFE  
STORAGE**

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**STORAGE CONDITIONS**

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Store between 5° and 25 °C. Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

**SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION**

Chemical Name: CICLOPIROX OLAMINE CAS #: 41621-49-2

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

**EXPOSURE GUIDELINES**

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m<sup>3</sup>

**PERSONAL PROTECTIVE  
EQUIPMENT**

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

**SPECIFIC ENGINEERING  
CONTROLS**

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

**BIOLOGICAL MONITORING**

Not available

**CONTROL BANDING**

Not available

**NOTES**

OEB - 8h: 1.0 - 0.1 mg/m<sup>3</sup>

USP:ELV: industrial: TWA: 1 mg/m<sup>3</sup>

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**
**PHYSICAL  
STATE**

Solid

**DESCRIPTION**

White to slightly yellowish-white, crystalline powder.

**SOLUBILITY**

Very soluble in alcohol and in methylene chloride; slightly soluble in water; practically insoluble in cyclohexane.

**ODOR**

Odorless

<b>FLAMMABILITY</b>	May be combustible at high temperature				
<b>AUTO-IGNITION TEMPERATURE</b>	400-425 °C (752 - 797 °F)	<b>BOILING POINT</b>	Not available	<b>DECOMPOSITION TEMPERATURE</b>	> 168 °C (> 334.4 °F)
<b>EVAPORATION RATE</b>	Not available	<b>EXPLOSIVE LIMIT</b>	Not available	<b>FLASH POINT</b>	Not available
<b>log P (OCTANOL-WATER)</b>	2.73	<b>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available	<b>MELTING/FREEZING POINT</b>	138 -145 °C (280.4 - 293 °F)
<b>PARTICLE CHARACTERISTICS</b>	Not available	<b>OXIDIZING PROPERTY</b>	Not available	<b>pH</b>	8 - 9 (1%)
<b>RELATIVE DENSITY (WATER = 1)</b>	Not available	<b>SPECIFIC GRAVITY</b>	Not available	<b>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available
<b>VAPOR DENSITY (AIR = 1)</b>	Not available	<b>VAPOR PRESSURE</b>	<0.0000001 kPa (25 °C)	<b>VISCOSITY</b>	Not available

The physical data presented above are typical values and should not be construed as a specification.

## SECTION 10: STABILITY AND REACTIVITY

<b>REACTIVITY</b>	Not established
<b>CHEMICAL STABILITY</b>	Stable under recommended storage conditions
<b>INCOMPATIBLE MATERIALS</b>	Strong oxidants, Alkali metals, bases, strong acids, halogens
<b>HAZARDOUS DECOMPOSITION PRODUCTS</b>	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
<b>HAZARDOUS POLYMERIZATION</b>	Will not occur
<b>POSSIBILITY OF HAZARDOUS REACTION</b>	Not established
<b>CONDITIONS TO AVOID</b>	Moisture, sunlight and extreme temperatures

## SECTION 11: TOXICOLOGICAL INFORMATION

<b>ACUTE TOXICITY</b>	Oral: Rat: LD50: (mg/kg): 2350 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
<b>SKIN CORROSION/IRRITATION</b>	Based on available data, the classification criteria are not met. Human: Skin - 1% Draize, 21 day cumulative irritation study. Result: Negative. Rabbit: Skin irritation, Solution: 1%; Result: Positive.
<b>SERIOUS EYE DAMAGE/EYE IRRITATION</b>	Causes serious eye irritation: pH 8 - 9 (1%) Rabbit : Eye - 1% solution in polyethylene glycol 400. Result: Slight ocular irritation (Ciclopirox). Rabbit : Eye - 1% solution in sterile water. Result: Slight lacrimation and irritation (Ciclopirox). Rabbit : Eye - 100 mg powdered Ciclopirox. Result: Severe ocular irritation. Species: Rabbit

<b>RESPIRATORY SENSITIZATION</b>	Due to lack of data the classification is not possible.								
<b>SKIN SENSITIZATION</b>	Based on available data, the classification criteria are not met. Skin - 1% Draize sensitization assay. Result: Negative. Species: Human								
<b>GERM CELL MUTAGENICITY</b>	Based on available data, the classification criteria are not met. Pregnant or nursing workers exposure to this substance should be avoided. Ames test (Salmonella typhimurium); Result: Negative. Mutagenicity, In vitro BALB/c3T3 cell transformation assay; Result: Negative. Mutagenicity, In vitro chromosome aberration assay (V79 Chinese hamster lung fibroblasts); Result: Positive, with and without activation. Mutagenicity, In vitro gene mutation assay/HGPRT test (V79 Chinese hamster lung fibroblasts); Result: Negative. Mutagenicity, In vivo chromosome aberration assay (Chinese hamster bone marrow); Result: Negative.								
<b>CARCINOGENICITY</b>	<table border="0"> <tr> <td style="vertical-align: top;"><b>OSHA</b></td> <td>CICLOPIROX OLAMINE is not listed.</td> </tr> <tr> <td style="vertical-align: top;"><b>NTP</b></td> <td>CICLOPIROX OLAMINE is not listed.</td> </tr> <tr> <td style="vertical-align: top;"><b>IARC</b></td> <td>CICLOPIROX OLAMINE is not evaluated.</td> </tr> <tr> <td style="vertical-align: top;"><b>California Proposition</b></td> <td>This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.</td> </tr> </table>	<b>OSHA</b>	CICLOPIROX OLAMINE is not listed.	<b>NTP</b>	CICLOPIROX OLAMINE is not listed.	<b>IARC</b>	CICLOPIROX OLAMINE is not evaluated.	<b>California Proposition</b>	This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.
<b>OSHA</b>	CICLOPIROX OLAMINE is not listed.								
<b>NTP</b>	CICLOPIROX OLAMINE is not listed.								
<b>IARC</b>	CICLOPIROX OLAMINE is not evaluated.								
<b>California Proposition</b>	This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.								
<b>ADDITIONAL CARCINOGENICITY INFORMATION</b>	Based on available data, the classification criteria are not met. Mouse: Dermal study of 1 - 5% cream, Female mice; limited study. Result: No evidence of tumors.								
<b>REPRODUCTIVE TOXICITY</b>	Due to lack of data the classification is not possible. Rabbit: 100 mg/kg/day Dermal study. Result: No developmental effects. Rat: 30 mg/kg/day Oral study. Result: No maternal toxicity; no developmental effects. Monkey: 50 mg/kg/day Oral study. Result: No maternal toxicity; no developmental effects.  Pregnant or nursing workers exposure to this substance should be avoided.								
<b>SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE</b>	Due to lack of data the classification is not possible.								
<b>SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE</b>	Due to lack of data the classification is not possible.								
<b>ASPIRATION HAZARDS</b>	Due to lack of data the classification is not possible.								
<b>SIGNS AND SYMPTOMS OF EXPOSURE</b>	ROUTES OF EXPOSURE: Oral, Dermal, Inhalation, Eye contact EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Not available DELAYED HEALTH EFFECT FROM EXPOSURE: Not available  Symptoms related to the physical, chemical, and toxicological characteristics: Itching. Eye pain.								
<b>POTENTIAL HEALTH EFFECTS</b>	<table border="0"> <tr> <td style="vertical-align: top;"><b>Inhalation</b></td> <td>May be harmful if inhaled. May cause respiratory tract irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.</td> </tr> <tr> <td style="vertical-align: top;"><b>Ingestion</b></td> <td>May be harmful if swallowed.</td> </tr> <tr> <td style="vertical-align: top;"><b>Skin</b></td> <td>May be harmful if absorbed through skin. Causes skin irritation. May cause allergic skin reaction.</td> </tr> <tr> <td style="vertical-align: top;"><b>Eyes</b></td> <td>Causes serious eye irritation.</td> </tr> </table>	<b>Inhalation</b>	May be harmful if inhaled. May cause respiratory tract irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.	<b>Ingestion</b>	May be harmful if swallowed.	<b>Skin</b>	May be harmful if absorbed through skin. Causes skin irritation. May cause allergic skin reaction.	<b>Eyes</b>	Causes serious eye irritation.
<b>Inhalation</b>	May be harmful if inhaled. May cause respiratory tract irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.								
<b>Ingestion</b>	May be harmful if swallowed.								
<b>Skin</b>	May be harmful if absorbed through skin. Causes skin irritation. May cause allergic skin reaction.								
<b>Eyes</b>	Causes serious eye irritation.								

**SECTION 12: ECOLOGICAL INFORMATION**

<b>ECOTOXICITY</b>	EC50: 48 Hr: Crustacea: Daphnia Magna: (mg/L): 3.8 LC50: 96 Hr: Fish: (mg/L): 0.32 - 0.56 EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available
<b>PERSISTENCE AND DEGRADABILITY</b>	Under test conditions no biodegradation observed (100%)
<b>BIOACCUMULATIVE POTENTIAL</b>	LogPow: 2.73
<b>MOBILITY IN SOIL</b>	Slightly soluble in water
<b>OTHER ADVERSE EFFECTS</b>	Very toxic to aquatic organisms. This product is not intended to be released into the environment

## SECTION 13: DISPOSAL CONSIDERATIONS

<b>DISPOSAL METHODS</b>	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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## SECTION 14: TRANSPORT INFORMATION

<b>UN PROPER SHIPPING NAME</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
<b>UN NUMBER</b>	3077
<b>CLASS</b>	9
<b>PACKING GROUP</b>	III
<b>AUSTRALIA HAZCHEM</b>	2Z
<b>EU TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE</b>	Not Listed
<b>ENVIRONMENTAL HAZARDS</b>	Not applicable
<b>SPECIAL SHIPPING INFORMATION</b>	Not applicable

## SECTION 15: REGULATORY INFORMATION

### UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
CICLOPIROX OLAMINE 41621-49-2	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

### AUSTRALIAN REGULATIONS



**DISCLAIMER**

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

**SUPPLEMENTARY INFORMATION**

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.