



SAFETY DATA SHEET

1. Identification

| | | |
|--|---|-----------------|
| Product identifier | Ciclopirox Olamine | |
| Other means of identification | | |
| Catalog number | 1134030 | |
| CAS number | 41621-49-2 | |
| Synonyms | Ciclopiroxolamine | |
| Chemical name | 6-Cyclohexyl-1-hydroxy-4-methyl-2(1H)-pyridone compound with 2-aminoethanol (1:1) | |
| Recommended use | For analytical laboratory use only. | |
| Recommended restrictions | Not for use as a drug. Not for administration to humans or animals. | |
| Manufacturer/Importer/Supplier/Distributor information | | |
| Manufacturer | | |
| Company name | U. S. Pharmacopeia | |
| Address | 12601 Twinbrook Parkway Rockville MD 20852-1790 United States | |
| Telephone | Technical Services | 301-816-8129 |
| Website | www.usp.org | |
| E-mail | RSTECH@usp.org | |
| Emergency phone number | CHEMTREC within US & Canada | 1-800-424-9300 |
| | CHEMTREC outside US & Canada | +1 703-527-3887 |

2. Hazard(s) identification

| | | |
|------------------------------|-----------------------------------|-------------|
| Physical hazards | Not classified. | |
| Health hazards | Serious eye damage/eye irritation | Category 2A |
| Environmental hazards | Not classified. | |
| OSHA defined hazards | Not classified. | |

Label elements



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|--|---|
| Signal word | Warning |
| Hazard statement | Causes serious eye irritation. |
| Precautionary statement | |
| Prevention | Wash thoroughly after handling. Wear eye protection/face protection. |
| Response | 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 advice/attention. |
| Storage | Not available. |
| Disposal | Not available. |
| Hazard(s) not otherwise classified (HNOC) | This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous. |
| Supplemental information | Pharmacologically active material. |

3. Composition/information on ingredients

Substance

| Chemical name | Common name and synonyms | CAS number | % |
|--------------------|--------------------------|------------|-----|
| Ciclopirox Olamine | Ciclopiroxolamine | 41621-49-2 | 100 |

4. First-aid measures

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| Inhalation | If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist. |
| Skin contact | Rinse skin with water/shower. Get medical attention if irritation develops and persists. |
| Eye contact | Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. |
| Ingestion | Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. |
| Most important symptoms/effects, acute and delayed | Pharmacologically active material. Occupational exposure may cause physiological effects. |
| Indication of immediate medical attention and special treatment needed | Provide general supportive measures and treat symptomatically. |
| General information | Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. |

5. Fire-fighting measures

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| Suitable extinguishing media | Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials. |
| Unsuitable extinguishing media | None known. |
| Specific hazards arising from the chemical | Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard. |
| Special protective equipment and precautions for firefighters | Wear suitable protective equipment. |
| Fire fighting equipment/instructions | Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. |
| Specific methods | Use standard firefighting procedures and consider the hazards of other involved materials. |
| General fire hazards | No unusual fire or explosion hazards noted. |

6. Accidental release measures

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| Personal precautions, protective equipment and emergency procedures | Keep unnecessary personnel away. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS. |
| Methods and materials for containment and cleaning up | Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS. |
| Environmental precautions | Avoid discharge into drains, water courses or onto the ground. |

7. Handling and storage

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| Precautions for safe handling | As a general rule, when handling USP materials, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. |
| Conditions for safe storage, including any incompatibilities | Store in tight container. This material should be handled and stored per label instructions to ensure product integrity. |

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

| Industrial Use Material | Type | Value |
|----------------------------|------|-------|
|----------------------------|------|-------|

| | | |
|--|-----|---------|
| Ciclopirox Olamine (CAS 41621-49-2) | TWA | 1 mg/m3 |
|--|-----|---------|

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of USP materials.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form

Powder.

Color

White.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

> 392 °F (> 200 °C) (decomposes)

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

Not available.

Vapor density

Not available.

| | |
|----------------------------------|---|
| Relative density | Not available. |
| Solubility(ies) | |
| Solubility (water) | Slightly soluble. |
| Solubility (other) | Methylene chloride: Very soluble. Dichloromethane: Very soluble. Ethyl acetate: Slightly soluble. Alcohol: Very soluble. |
| Auto-ignition temperature | > 392 °F (> 200 °C) |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |
| Other information | |
| Dust explosion properties | |
| St class | 2 |
| Molecular formula | C12H17NO2 . C2H7NO |
| Molecular weight | 268.35 |
| pH in aqueous solution | 8 - 9 (1% aqueous solution) |

10. Stability and reactivity

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|---|---|
| Reactivity | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| Chemical stability | Material is stable under normal conditions. |
| Possibility of hazardous reactions | No dangerous reaction known under conditions of normal use. |
| Conditions to avoid | Contact with incompatible materials. |
| Incompatible materials | Oxidizing agents. |
| Hazardous decomposition products | NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. |

11. Toxicological information

Information on likely routes of exposure

| | |
|---------------------|--|
| Inhalation | Knowledge about health hazard is incomplete. |
| Skin contact | Knowledge about health hazard is incomplete. |
| Eye contact | Causes serious eye irritation. |
| Ingestion | Knowledge about health hazard is incomplete. |

| | |
|---|-------------------------------------|
| Symptoms related to the physical, chemical and toxicological characteristics | Itching. Eye pain. Skin irritation. |
|---|-------------------------------------|

Information on toxicological effects

Acute toxicity

| Product | Species | Test Results |
|-------------------------------------|---------|--------------|
| Ciclopirox Olamine (CAS 41621-49-2) | | |
| Oral | | |
| LD50 | Mouse | 1740 mg/kg |
| | Rat | 2350 mg/kg |

| | |
|----------------------------------|---|
| Skin corrosion/irritation | Based on available data, the classification criteria are not met. |
|----------------------------------|---|

| | |
|--|---|
| Serious eye damage/eye irritation | Causes serious eye irritation. In animal tests, a related material caused eye irritation. |
|--|---|

Respiratory or skin sensitization

| | |
|----------------------------------|---|
| Respiratory sensitization | Knowledge about health hazard is incomplete. |
| Skin sensitization | Based on available data, the classification criteria are not met. |

Skin - 1% Draize sensitization assay
Result: Negative.
Species: Human

| | |
|-------------------------------|---|
| Germ cell mutagenicity | Based on available data, the classification criteria are not met. |
|-------------------------------|---|

Mutagenicity

In vitro Ames test (Salmonella)

Result: Negative.

In vitro mutagenicity assay (Saccharomyces cerevisiae)

Result: Negative.

In vivo mouse dominant lethal assay

Result: Negative.

In vivo mouse micronucleus assay

Result: Negative.

Carcinogenicity

Knowledge about carcinogenicity is incomplete.

Carcinogenicity: Dermal study of 1 - 5% cream, Female mice; limited study

Result: Negative.

Species: Mouse

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

Knowledge about health hazard is incomplete.

Reproductivity

100 mg/kg/day Dermal study

Result: No developmental effects

Species: Rabbit

30 mg/kg/day Oral study

Result: No maternal toxicity; no developmental effects.

Species: Rat

50 mg/kg/day Oral study

Result: No maternal toxicity; no developmental effects.

Species: Monkey

Specific target organ toxicity - single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure

Knowledge about health hazard is incomplete.

Aspiration hazard

Based on available data, the classification criteria are not met.

Further information

Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity

Very toxic to aquatic life with long lasting effects.

| Product | Species | | Test Results |
|-------------------------------------|---------|---------|----------------------------|
| Ciclopirox Olamine (CAS 41621-49-2) | | | |
| Aquatic | | | |
| Acute | | | |
| Crustacea | EC50 | Daphnia | 2.3 mg/l, 48 hours |
| Fish | LC50 | Fish | 0.32 - 0.52 mg/l, 96 hours |

Persistence and degradability

No data is available on the degradability of this substance.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products

Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

| | |
|-----------------------------------|---|
| UN number | UN3077 |
| UN proper shipping name | Environmentally hazardous substance, solid, n.o.s. (Ciclopirox Olamine) |
| Transport hazard class(es) | |
| Class | 9 |
| Subsidiary risk | - |
| Packing group | III |

IATA

| | |
|-----------------------------------|---|
| UN number | UN3077 |
| UN proper shipping name | Environmentally hazardous substance, solid, n.o.s. (Ciclopirox Olamine) |
| Transport hazard class(es) | |
| Class | 9 |
| Subsidiary risk | - |
| Packing group | III |

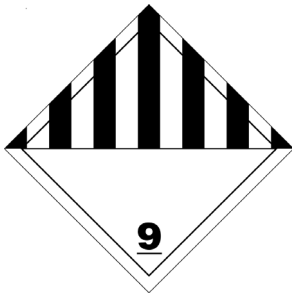
Other information

Passenger and cargo aircraft Allowed with restrictions.

Cargo aircraft only Allowed with restrictions.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

DOT; IATA



General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Classified hazard categories

Serious eye damage or eye irritation

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations**California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|-----------------------------|--|------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | No |
| Canada | Domestic Substances List (DSL) | No |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | No |
| Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | Yes |
| Europe | European List of Notified Chemical Substances (ELINCS) | No |
| Japan | Inventory of Existing and New Chemical Substances (ENCS) | No |
| Korea | Existing Chemicals List (ECL) | No |
| New Zealand | New Zealand Inventory | No |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No |
| Taiwan | Taiwan Chemical Substance Inventory (TCSI) | Yes |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No |

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision**Issue date** 12-17-2004**Revision date** 05-18-2021**Version #** 04**Further information** Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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