Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 1: Identification

Product Name	Ciclopirox Olamine USP
Commercial Name	Lorpox, Terit
Product Use	being a pharmacological active ingredient it is used only by manufacturers of pharmaceutical product
Restrictions On Use	Not available
Product Code	30-3069

Company

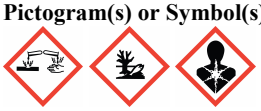
PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: CFR 1910.1200	Ox. So/. (Category 1)- H271 Eye Dam. (Category 1)-H318 Skrn Sens. (Category 1)-H317 Skin corr. (Category 1B)-H314 Aquatic Chronic (Category 1)-H410
Signal Word	DANGER
Hazard Statement(s)	It can cause a fire or an explosion; very combustious. Causes severe skin burns and eye damage. May cause an allergic skin reaction. Causes serious eye damage. Very toxic to aquatic life with long lasting effects

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

Prevention	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.No smoking. P22O Keep/Store away from clothi ng/. . ./combustible material s. P24O Ground/bond container and receiving equipment. P241 Use explosion-proof electrical/ventilating/lighting/.../equipment. P26 1 Avoid breath ng dust/fumes/gas/mist/vapours/spray. P273 Avoid release to the environment. p2BO Wear protective gloves/protective clothing/eye protection/face protection. P283 Wear fire/flame resistant/retardant clothing
Response	P302+P352 IF ON SKIN: Wash with plenty of soap and water. P3O3+361+353: IF ON SKIN (or hair): Take off immediately all contaminated clothing P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+ P351+ P338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing P306+360: IF ON CLOTHING: Rrnse immediately contaminated clothing and skin with plenty of water before removing clothes P310 Immediately call a POISON CENTER or doctor/physician P363 Wash contaminated clothing before reuse. P333+313: If skin irritation or rash occurs: Get medical advice/attention. P301+P330+331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P371+380+375: In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion. P391 Collect spillage
Storage	P404 Store in a closed container
Disposal	P501 Dispose of contents/container in a site approved for chemical and hazardous waste or burned in a specialised burning centre

Section 3: Composition/Information on Ingredients

Substance/Mixture	Substance
Components	Ciclopirox Olamine USP
% By Weight	100
CAS#	41621-49-2
Molecular Weight	268.40 g/mole
Chemical Formula	C12H17NO2 C2H7NO
Synonym(s)	6-Cyclohexyl-1-h ydroxy-4-methy l-2(h) -pyridone ethanolamine Salt

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Ciclopirox Olamine USP	41621-49-2	~100	Not available.	ORAL (LD50):Acute: 2350mg/kg [Rat].1740 mg/kg[Mouse]. 3065mg/kg [Rabbit].

Section 4: First-Aid Measures

Inhalation Allow the victim to rest in a well ventilated area. Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. In severe cases or if symptoms persists, seek medical attention

Skin Contact After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. If irritation persists, seek medical attention. Wash contaminated clothing before reusing

Eye Contact Immediately flush eyes with copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention

Ingestion Do not induce vomiting. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention

Symptoms/Effects

Acute Not available

Delayed Not available.

Immediate Medical Attention

Not available.

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media

In case of fire use water spray, foam, dry powder or CO2. Prevent run off of water from entering drains.

Unsuitable Extinguishing Media

Not available.

Products of Combustion

The substance evolves toxic fumes due to the presence of CO, CO2, NO

Firefighters Special Equipment and Precautions

Wear: -Gas masks scuba -Complete protective equipment composed by: helmet whit face shield and neck protection, fireproof jacket and trousers with straps around arms, legs and waist. As not expected at this point, refer to the personal protective equipment recommended in Section 8 of this sheet

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Keep away any ignition source. Wear protective equipment. Keep unprotected persons away. Use respiratory protective device against the effects of fumes. Ensure adequate ventilation. Methods and materials for containment and cleaning up: Absorb spillage in earth or sand. Sweep or shovel-up spillage and remove to a safe place. Damp down to avoid dust generation. Environmental precautions: Do not allow to penetrate the ground/soil. Prevent seepage into sewage system, workpits and cellars. Inform respective authorities in case of seepage into water course or sewage system.

Section 7: Handling and Storage

Handling: This product should be handled only by, or under the close supervision of, those properly qualified in the handling and use of potentially hazardous chemicals, who should take into account the fire, health and chemical hazard data given on this sheet. It should always be handled in an efficient fume hood or equivalent system and, if necessary, wear protective equipment. Care should be taken to prevent the chemical from coming into contact with the skin or eyes and from contaminating personal clothing. Conditions for safe storage, including any incompatibilities: Avoid contact with oxidising substances For safety purposes, the substance does not require any special storage conditions. As an indication, the information provided by official monographs are: USP: Preserve in tight containers, protected from light. Store between 5°C and 25°C. EP: Store protected from light. For storage of the substance for pharmaceutical use, or for registration purposes please refer to the stability data conducted in-house and reported in the document regulatory "Active Substance Master File" (ASMF or DMF). Specific end uses: Laboratory investigations, testing of pharmaceutical technology. Formulation in pharmaceutical preparations

Section 8: Exposure Controls/Personal Protection

Exposure Limits Contains no substances with occupational exposure limit value

Engineering Controls	Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Avoid contact with skin, eyes and clothing.
Personal Protection	Eye/face protection: Tightly fitting safety goggles. Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Hand protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.The selected protective gloves have tosatisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Skin and body protection: The type of protective equipment (es. Tyvek suit) must be selected according to the concentration and amount of the dangerous substance at the specific workplace. Complete suit protecting against chemicals, flame retardant antistatic protective clothing. Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N99 (US) or type P2 (EN 143) with cartridges P1 (inert substances) P2 (harmful substances) P3 (toxic substances). Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Section 9: Physical and Chemical Properties

Appearance	crystalline powder, white to pale yellow
Odor	odourless
Odor Threshold	Not available

Melting Point	135 -143 "C with decompos	**pH**	Not available.
Freezing Point	135 -143 "C with decompos	**Vapor Pressure**	0.00014 Pa at 20"C.
Boiling Point/Range	Not available.	**Vapor Density**	Not available.
Decomposition temperature	above 168'C	**Viscosity**	Not available.
Partition Coefficient: n-octanol/water	0.52	**Evaporation Rate**	Not available
Flash Point	Not available.	**Autoignition temperature**	400-425'C
Flammability	Not available.	**Flammability or Explosive Limits:**	
		Lower	Not available
		Upper	Not available

Solubility(ies)	Soluble in water: 31.3 mglml at 25"C.
Other	Oxidizing properties: Oxidizing

Section 10: Stability and Reactivity

Reactivity	Not available
Chemical Stability	The substances is stable at the normal conditions of temperature and pressure and if stored in closed containers iin a well ventitated and cool place
Hazardous Polymerization	The substance reacts with oxidizing and reducing agents, strong acids and bases.
Conditions to Avoid	Heat, flames and sparks
Incompatible Materials	Strong oxidising agents. Alkali metals, bases, strong acids, halogens
Hazardous Decomposition Products	The substance evolves toxic fumes due to the presence of CO, CO2, NOx.

Section 11: Toxicological Information

RTECS UU7785500

Acute Toxicity
Acute Oral LD 50 rat mg/kg 2350

Skin Corrosion/Irritation
Corrosive

Serious Eye Damage/Irritation
irritating potential to eyes

Respiratory or Skin Sensitization
May cause an allergic skin reaction

Germ Cell Mutagenicity
Ames test: negative

Carcinogenicity
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA

Reproductive Toxicity
No maternal toxicity; no developmental effects

Routes of Entry
Not available

Symptoms Related to Exposure
Not available.

Potential Health Effects
May be harmful if swallowed.

Target Organ(s) Not available

Section 12: Ecological Information

Ecotoxicity
EC50 (daphnia Magna 48h) 32.6 mg/l LC50 (daphnid 48h) 16.34 mg/l NOEC (Raphidocelis subcapitata 72h) 0.063 mg/l

Persistance and Degradability
Biodegradation: not readily biodegradabte

Bioaccumulative Potential
Not available

Mobility in Soil
Not available

Other Adverse Effects
Not available

Section 13: Disposal Considerations

Waste Disposal
Do not empty into drains. Use appropriate containment to avoid environmental contamination. Disposal should be in accordance with local, state or national regulation.

Disposal of Container
The containers and packing materials contaminated with dangerous substances or preparations, have the same treatment products.

Other Considerations
Not available

Section 14: Transport Information

DOT Classification
UN number ADR/RID: 3085 IMDG: 3085 IATA: 3085 14.2 UN proper shipping name ADR/RID Environment. Oxidizing solid, corrosive, n.o.s. (Ciclopirox Olamine) IMDG Environment. Oxidizing solid, corrosive, n.o.s. (Ciclopirox Olamine) IATA Environment. Oxidizing solid, corrosive, n.o.s. (Ciclopirox Olamine) 14.3 Transport hazard class(es) ADR/RID: 5.1(8) IMDG: 5.1(8) IATA: 5.1(8) 14.4 Packaging group ADR/RID: III IMDG: III IATA: III 14.5 Environmental hazards ADR/RID: yes IMDG: marine pollutant IATA: yes

Section 15: Regulatory Information

Regulations
Safety, health and environmental regulations/legislation specific for the substance: no data available REACH exempted as API (Active Pharmaceutical Ingredient) CLP notified with submission KG864885-20 02-2119453869-20-0000

Other
Not available

Section 16: Other Information

Not available.