Safety Data Sheet

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

Section 1: Identification

Product Name Ketoconazole USP
Commercial Name Not available.
Product Use Not available
Restrictions On Use Not available

Product Code 30-3194

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

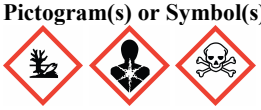
Section 2: Hazard(s) Identification

OSHA Haz Com: CFR 1910.1200 Acute Toxicity (Oral): Category 3

Signal Word DANGER

Hazard Statement(s) Toxic if swallowed. May damage fertility. May cause damage to organs through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid release to the environment. Use personal protective equipment as required.

Response IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. IF exposed or concerned: Get medical advice/ attention. Rinse mouth. Collect spillage.

Storage Not available

Disposal Not available.

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components Ketoconazole USP
% By Weight 100
CAS# 65277-42-1
Molecular Weight 531.48 g/mole
Chemical Formula C26-H28-CL2-N4-O4
Synonym(s) Piperazine, 1-acetyl-4-(4-((2-(2,4 dichlorophenyl)-2-(1H-imidazol-1- methyl)-1,3-dioxolan-4-yl)methoxy henyl) -,cis-

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Ketoconazole USP	65277-42-1	100		

Section 4: First-Aid Measures

Inhalation ? If fumes or combustion products are inhaled remove from contaminated area. ? Lay patient down. Keep warm and rested. ? Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. ? Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. ? Transport to hospital, or doctor.

Skin Contact If skin or hair contact occurs: ? Flush skin and hair with running water (and soap if available). ? Seek medical attention in event of irritation.

Eye Contact If this product comes in contact with the eyes: ? Immediately hold eyelids apart and flush the eye continuously with 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. ? Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. ? Transport to hospital or doctor without delay. ? Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

Ingestion ? IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. ? Urgent hospital treatment is likely to be needed. ? In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition. ? If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the MSDS should be provided. Further action will be the responsibility of the medical specialist. ? If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the MSDS. ? Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise: ? INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. NOTE: Wear a protective glove when inducing vomiting by mechanical means.

Symptoms/Effects

Acute Not available

Delayed Not available

Immediate Medical Attention

Not available

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media

? Water spray or fog. ? Foam. ? Dry chemical powder. ? BCF (where regulations permit). ? Carbon dioxide.

Unsuitable Extinguishing Media

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

Products of Combustion

These products are carbon oxides (CO, CO2), nitrogen oxides (NO, NO2...).

Firefighters Special Equipment and Precautions

? Alert Fire Brigade and tell them location and nature of hazard. ? Wear full body protective clothing with breathing apparatus. ? Prevent, by any means available, spillage from entering drains or water course. ? Use fire fighting procedures suitable for surrounding area. ? Do not approach containers suspected to be hot. ? Cool fire exposed containers with water spray from a protected location. ? If safe to do so, remove containers from path of fire. ? Equipment should be thoroughly decontaminated after use. ? Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions. ? 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.

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 ? Clear area of personnel and move upwind. ? Alert Fire Brigade and tell them location and nature of hazard. ? Wear full body protective clothing with breathing apparatus. ? Prevent, by any means available, spillage from entering drains or water course. ? Stop leak if safe to do so. ? Contain spill with sand, earth or vermiculite. ? Collect recoverable product into labelled containers for recycling. ? Neutralise/decontaminate residue. ? Collect solid residues and seal in labelled drums for disposal. ? Wash area and prevent runoff into drains. ? After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using. ? If contamination of drains or waterways occurs, advise emergency services.

Section 7: Handling and Storage

PROCEDURE FOR HANDLING ? Avoid all personal contact, including inhalation. ? Wear protective clothing when risk of exposure occurs. ? Use in a well-ventilated area. ? Prevent concentration in hollows and sumps. ? DO NOT enter confined spaces until atmosphere has been checked. ? DO NOT allow material to contact humans, exposed food or food utensils. ? Avoid contact with incompatible materials. ? When handlings, DO NOT eat, drink or smoke. ? Keep containers securely sealed when not in use. ? Avoid physical damage to containers. ? Always wash hands with soap and water after handling. ? Work clothes should be laundered separately. Launder contaminated clothing before re-use. ? Use good occupational work practice. ? Observe manufacturer's storing and handling recommendations. ? Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained. 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 authorization or permit. SUITABLE CONTAINER ? Glass container is suitable for laboratory quantities ? Lined metal can, lined metal pail/ can. ? Plastic pail. ? Polyliner drum. ? Packing as recommended by manufacturer. ? Check all containers are clearly labeled and free from leaks. STORAGE INCOMPATIBILITY ? Avoid reaction with oxidizing agents STORAGE REQUIREMENTS ? Store in original containers. ? Keep containers securely sealed. ? Store in a cool, dry, well-ventilated area. ? Store away from incompatible materials and foodstuff containers. ? Protect containers against physical damage and check regularly for leaks. ? Observe manufacturer's storing and handling recommendations.

Section 8: Exposure Controls/Personal Protection

Exposure Limits
Not available.

Engineering Controls
Powders Handling: ? To prevent contamination and overexposure, no open handling of powder should be allowed. ? Powder handling operations are to be done in powders weighing hood, a glove box, or other equivalent ventilated containment system. ? In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used. ? Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs. ? An air-purifying respirator should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.). ? Powder should be put into solution or a closed or covered container after handling. ? If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.

Personal Protection
EYE 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 HANDS/FEET 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.

Section 9: Physical and Chemical Properties

Appearance	Crystals; partly soluble in water.
Odor	Not available.
Odor Threshold	Not available

Melting Point	146C	**pH**	Not available
Freezing Point	Not available	**Vapor Pressure**	Not applicable.
Boiling Point/Range	Not available.	**Vapor Density**	Not available.
Decomposition temperature	Not available	**Viscosity**	Not available.
Partition Coefficient: n-octanol/water	Not available.	**Evaporation Rate**	Not available
Flash Point	Not available.	**Autoignition temperature**	Not available
Flammability	Not available	**Flammability or Explosive Limits:**	
		Lower	Not available
		Upper	Not available

Solubility(ies)	Miscible in water.
Other	Not available

Section 10: Stability and Reactivity

Reactivity	Not available
Chemical Stability	Product is considered stable.
Hazardous Polymerization	Hazardous polymerisation will not occur.
Conditions to Avoid	Presence of incompatible materials.
Incompatible Materials	Not available
Hazardous Decomposition Products	Not available.

Section 11: Toxicological Information

RTECS TK7912300

Acute Toxicity
Oral (rat) LD50: 166 mg/kg

Skin Corrosion/Irritation
Not available

Serious Eye Damage/Irritation
Not available

Respiratory or Skin Sensitization
Not available

Germ Cell Mutagenicity
Not available

Carcinogenicity
Not available

Reproductive Toxicity
Not available

Routes of Entry
Not available

Symptoms Related to Exposure
Not available

Potential Health Effects
Not available

Target Organ(s) Not available.

Section 12: Ecological Information

Ecotoxicity
? Toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment. ? Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters. Wastes resulting from use of the product must be disposed of on site or at approved waste sites. ? DO NOT discharge into sewer or waterways.

Persistance and Degradability
No data available

Bioaccumulative Potential
No data available

Mobility in Soil
No data available

Other Adverse Effects
No data available

Section 13: Disposal Considerations

Waste Disposal
? Containers may still present a chemical hazard/ danger when empty. ? Return to supplier for reuse/ recycling if possible. Otherwise: ? If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorized landfill. ? Where possible retain label warnings and MSDS and observe all notices pertaining to the product. 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)

Disposal of Container
Not available

Other Considerations
Not available

Section 14: Transport Information

DOT Classification
Labels Required: TOXIC HAZCHEM: 2X Land Transport UNDG: Class or division: 6.1
Subsidiary risk: None UN No.: 2811 UN packing group: III
Shipping name: Toxic solid, organic, n.o.s. (Ketoconazole) Air Transport IATA: ICAO/IATA Class: 6.1
ICAO/IATA Sub risk: None UN/ID Number: 2811 Packing Group: III
Shipping name: Toxic solid, organic, n.o.s. (Ketoconazole) Maritime Transport IMDG: IMDG Class: 6.1
IMDG Sub risk: None UN Number: 2811 Packing Group: III
Shipping name: Toxic solid, organic, n.o.s. (Ketoconazole)

Section 15: Regulatory Information

Regulations
Not available

Other
WHMIS (Canada) Class D-1B: Material causing immediate and serious toxic effects (TOXIC).;DSCL (EEC) R25- Toxic if swallowed. R40- Possible risks of irreversible effects. 62- Possible risk of impaired fertility.;Gloves.;Lab coat.;Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate.;Safety glasses.

Section 16: Other Information

Not available