

Section 1. Product and Company Identification

Product Name Ketoconazole
CAS Number 65277-42-1

Parchem - fine & specialty chemicals
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New Rochelle, NY 10801
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EMERGENCY RESPONSE NUMBER
CHEMTEL
Toll Free US & Canada: 1 (800) 255-3924
All other Origins: 1 (813) 248-0585
Collect Calls Accepted

Section 2. Hazards Identification

Classification of the substance or mixture

Acute toxicity, Oral (Category 3)
Reproductive toxicity (Category 1B)
Specific target organ toxicity - repeated exposure (Category 2)
Acute aquatic toxicity (Category 1)
Chronic aquatic toxicity (Category 1)

GHS Label Elements

Pictograms:



Signal word: Danger

Hazard and precautionary statements

Hazard Statement(s)

H301 Toxic if swallowed.

H360 May damage fertility or the unborn child.

H373 May cause damage to organs through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statement(s)

P201 Obtain special instructions before use.

P273 Avoid release to the environment.

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician.

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

P501 Dispose of contents/ container to an approved waste disposal plant.



Emergency Overview

OSHA Hazards: Target Organ Effect, Toxic by ingestion, Reproductive hazard

Target Organs: Liver, Male reproductive system

HMIS Classification

Health hazard: 2

Chronic Health Hazard: *

Flammability: 0

Physical hazards: 0

NFPA Rating

Health hazard: 2

Fire: 0

Reactivity Hazard: 0

Potential Health Effects

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Skin: May be harmful if absorbed through skin. May cause skin irritation.

Eyes: May cause eye irritation.

Ingestion: Toxic if swallowed.

Section 3. Composition / Information on Ingredients

Common Name	Ketoconazole
Synonym(s)	(±)-cis-1-Acetyl-4-(4-[(2-[2,4-dichlorophenyl]-2-[1H-imidazol-1-yl)methyl]-1,3-dioxolan-4-yl)-methoxy]phenyl)piperazine
Formula	$C_{26}H_{28}Cl_2N_4O_4$
CAS Number	65277-42-1

Section 4. First Aid Measures

General Advice: Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If Inhaled: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In Case of Skin Contact: Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

In Case of Eye Contact: Flush eyes with water as a precaution.

If Swallowed: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.



Section 5. Firefighting Measures

Conditions of Flammability: Not flammable or combustible.

Suitable Extinguishing Media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special Protective Equipment for Firefighters: Wear self-contained breathing apparatus for firefighting if necessary.

Hazardous Combustion Products: Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NO_x), Hydrogen

Section 6. Accidental Release Measures

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

Environmental Precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

Methods and Materials for Containment and Cleaning Up: Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Section 7. Handling and Storage

Precautions for Safe Handling: Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

Conditions for Safe Storage: Keep container tightly closed in a dry and well-ventilated place.

Recommended Storage Temperature: 2 - 8°C

Section 8. Exposure Controls / Personal Protection

Contains no substances with occupational exposure limit values.

Personal Protective Equipment

Respiratory Protection: Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (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.

Eye Protection: Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and Body Protection: Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.



Hygiene Measures: Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Section 9. Physical and Chemical Properties

Appearance

Form: solid

Color: white

Safety Data

pH: No data available.

Melting Point/Freezing Point: 147 °C (297 °F)

Boiling Point: No data available.

Flash Point: No data available.

Ignition Temperature: No data available.

Autoignition Temperature: No data available.

Lower Explosion Limit: No data available.

Upper Explosion Limit: No data available.

Vapor Pressure: No data available.

Density: No data available.

Water Solubility: No data available.

Partition Coefficient (n-Octanol/Water): log Pow: 3.507

Relative Vapor Density: No data available.

Odor: No data available.

Odor Threshold: No data available.

Evaporation Rate: No data available.

Section 10. Stability and Reactivity

Chemical Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: No data available.

Conditions to Avoid: No data available.

Materials to Avoid: Strong oxidizing agents.

Hazardous Decomposition Products

Hazardous Decomposition Products Formed under Fire Conditions: Carbon oxides, nitrogen oxides (NO_x), Hydrogen chloride gas.

Other Decomposition Products: No data available.

Section 11. Toxicological Information

Acute Toxicity

Oral LD50

LD50 Oral - rat - 166 mg/kg

LD50 Oral - rat - 166 mg/kg

Inhalation LC50: No data available.

Dermal LD50: No data available.

Other Information on Acute Toxicity: No data available.

Skin Corrosion/Irritation: No data available.

Serious Eye Damage/Eye Irritation: No data available.

Respiratory or Skin Sensitization: No data available.

Germ Cell Mutagenicity: Genotoxicity in vitro - Human - lymphocyte
DNA inhibition

Carcinogenicity

IARC: No component of this product present at levels $\geq 0.1\%$ is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels $\geq 0.1\%$ is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels $\geq 0.1\%$ is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels $\geq 0.1\%$ is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive Toxicity: Presumed human reproductive toxicant.

Teratogenicity: No data available.

Specific Target Organ Toxicity - Single Exposure (Globally Harmonized System): No data available.

Specific Target Organ Toxicity - Repeated Exposure (Globally Harmonized System):
May cause damage to organs through prolonged or repeated exposure.

Aspiration Hazard: No data available.

Potential Health Effects

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion: Toxic if swallowed.

Skin: May be harmful if absorbed through skin. May cause skin irritation.

Eyes: May cause eye irritation.

Synergistic Effects: No data available.

Additional Information: RTECS: TK7912300



Section 12. Ecological Information

Toxicity: No data available.

Persistence and Degradability: No data available.

Bioaccumulative Potential: No data available.

Mobility in Soil: No data available.

PBT and vPvB Assessment: No data available.

Other Adverse Effects: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Very toxic to aquatic life with long lasting effects.

Section 13. Disposal Considerations

Waste Treatment Methods: Dispose of product and contaminated packaging in accordance with all local, state, and federal environmental control regulations.

Section 14. Transport Information

DOT (US)

UN Number: 2811

Class: 6.1

Packing Group: III

Proper Shipping Name: Toxic solids, organic, n.o.s. (Ketoconazole)

Marine Pollutant: No

Poison Inhalation Hazard: No

IMDG

UN Number: 2811

Class: 6.1

Packing Group: III

EMS-No: F-A, S-A

Proper Shipping Name: TOXIC SOLID, ORGANIC, N.O.S. (Ketoconazole)

Marine Pollutant: No

IATA

UN Number: 2811

Class: 6.1

Packing Group: III

Proper Shipping Name: Toxic solid, organic, n.o.s. (Ketoconazole)



Section 15. Regulatory Information

OSHA Hazards: Target Organ Effect, Toxic by ingestion, Reproductive hazard

SARA 302 Components: SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components: SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards: Acute Health Hazard, Chronic Health Hazard

Massachusetts Right to Know Components: No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right to Know Components: Ketoconazole, CAS-No. 65277-42-1, Revision Date 2009-07-17

New Jersey Right To Know Components: Ketoconazole , CAS-No. 65277-42-1, Revision Date 2009-07-17

California Prop. 65 Components: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

Section 16. Other Information

Disclaimer: 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.

REVISION DATE: 6/16/2015

