

## Section 1: Identification

<b>Common Name/Trade Name</b>	KETOCONAZOLE USP	
<b>Supplier Information</b>	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	<b>IN CASE OF EMERGENCY:</b> Chemtrec 1 (800) 424-9300 (24 hours)
<b>Product Synonym(s)</b>	(±)-cis-1-Acetyl-4-(4-[(2-[2,4-dichlorophenyl]-2-[1H-imidazol-1-ylmethyl]-1,3-dioxolan-4-yl)-methoxy]phenyl)piperazine	
<b>Relevant Use(s) of Product</b>	Manufacture or Compounding of Substances	

## Section 2: Hazards Identification

<b>Classification of Substance or Mixture</b>	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)	
<b>Signal Word</b>	Danger	
<b>Hazard Statement(s)</b>	H301 H360 H373 H410	Toxic if swallowed May damage fertility or the unborn child May cause damage to organs through prolonged or repeated exposure Very toxic to aquatic life with long lasting effects
<b>Pictogram(s)</b>		
<b>Precautionary Statement(s)</b>	P201 P202 P260 P264 P270 P273 P281 P301+P310 P308+P313 P330 P391 P405 P501	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapours/spray. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid release to the environment. Use personal protective equipment as required. IF SWALLOWED Immediately call a POISON CENTER or doctor/physician. IF exposed or concerned Get medical advice/attention. Rinse mouth. Collect spillage. Store locked up. Dispose of contents/container to an approved waste disposal plant.
<b>Hazards Not Otherwise Classified</b>	No data available	
<b>Ingredient(s) with Unknown Toxicity</b>	No data available	

## Section 3: Composition/Information on Ingredients

<b>Chemical Name</b>	(±)-cis-1-Acetyl-4-(4-[(2-[2,4-dichlorophenyl]-2-[1H-imidazol-1-ylmethyl]-1,3-dioxolan-4-yl)-methoxy]phenyl)piperazine
<b>Common Name</b>	Ketoconazole
<b>CAS Number</b>	65277-42-1
<b>Impurities and/or Stabilizing Additives</b>	No data available

## Section 4: First Aid Measures

<b>General Advice</b>	Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.
<b>If Inhaled</b>	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
<b>In Case of Skin Contact</b>	Wash off with soap and plenty of water. Take victim immediately to the hospital. Consult a physician.
<b>In Case of Eye Contact</b>	Flush eyes with water as a precaution.
<b>If Swallowed</b>	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
<b>Most Important Symptoms and Effects</b>	The most important known symptoms and effects are described in the labeling (see section 2.2) and/or in section 11.

## Section 5: Fire Fighting Measures

<b>Suitable Extinguishing Media</b>	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
<b>Special Hazards Arising From the Substance/Mixture</b>	Carbon oxides, nitrogen oxides (NOx), Hydrogen chloride gas.
<b>Special PPE and/or Precautions for Firefighters</b>	Wear self contained breathing apparatus for fire fighting if necessary.

## Section 6: Accidental Release Measures

<b>Personal Precautions, Protective Equipment and Emergency Procedures</b>	Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist, or gas.. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
<b>Methods and Materials Used for Containment</b>	Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.
<b>Cleanup Procedures</b>	Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal. Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

## Section 7: Handling and Storage

<b>Precautions for Safe Handling</b>	Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.
<b>Conditions for Safe Storage</b>	Keep container tightly closed in a dry and well-ventilated place.

## Section 8: Exposure Controls/Personal Protection

<b>Components with Workplace Control Parameters</b>	Contains no substances with occupational exposure limit values.
<b>Appropriate Engineering Controls</b>	Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.
<b>PPE - Eye/Face Protection</b>	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).
<b>PPE - Skin Protection</b>	Handle with gloves. Glove 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.
<b>PPE - Body Protection</b>	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. Handle with gloves. Glove 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.
<b>PPE - Respiratory Protection</b>	Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN143) respirator cartridges as a backup to engineering controls. If 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).

## Section 9: Physical and Chemical Properties

<b>Appearance</b>	Form: Solid Colour: White, Light Brown
<b>Upper/Lower Flammability or Explosive Limits</b>	No data available
<b>Odor</b>	No data available
<b>Vapor Pressure</b>	No data available
<b>Odor Threshold</b>	No data available
<b>Vapor Density</b>	No data available
<b>pH</b>	No data available
<b>Relative Density</b>	No data available
<b>Melting Point/Freezing Point</b>	147 °C (297 °F)
<b>Solubility</b>	No data available
<b>Initial Boiling Point and Boiling Range</b>	No data available
<b>Flash Point</b>	No data available
<b>Evaporation Rate</b>	No data available
<b>Flammability (Solid, Gas)</b>	No data available
<b>Partition Coefficient</b>	log Pow: 3.507
<b>Auto-Ignition Temperature</b>	No data available
<b>Decomposition Temperature</b>	No data available
<b>Viscosity</b>	No data available

## Section 10: Stability and Reactivity

<b>Reactivity</b>	No data available
<b>Chemical Stability</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions</b>	No data available
<b>Conditions to Avoid</b>	No data available
<b>Incompatible Materials</b>	Strong oxidizing agents
<b>Hazardous Decomposition Products</b>	Other decomposition products-No data available

## Section 11: Toxicological Information

<b>Acute Toxicity - LD50 Oral</b>	LD50 Oral - rat - 166 mg/kg
<b>Acute Toxicity - Inhalation</b>	No data available
<b>Acute Toxicity - Dermal</b>	No data available
<b>Acute Toxicity - Eye</b>	No data available
<b>Skin Corrosion/Irritation</b>	No data available
<b>Serious Eye Damage/Irritation</b>	No data available
<b>Respiratory or Skin Sensitization</b>	No data available
<b>Germ Cell Mutagenicity</b>	Human lymphocyte DNA inhibition
<b>Carcinogenicity IARC</b>	No component of this product present at levels greater than or equal 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
<b>Carcinogenicity ACGIH</b>	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
<b>Carcinogenicity NTP</b>	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by NTP.
<b>Carcinogenicity OSHA</b>	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
<b>Reproductive Toxicity</b>	Presumed human reproductive toxicant.
<b>Specific Target Organ Toxicity - Single Exposure</b>	No data available
<b>Specific Target Organ Toxicity - Repeated Exposure</b>	May cause damage to organs through prolonged or repeated exposure.
<b>Aspiration Hazard</b>	No data available

## Section 12: Ecological Information

<b>Toxicity</b>	No data available
<b>Persistence and Degradability</b>	No data available
<b>Bio-accumulative Potential</b>	No data available
<b>Mobility in Soil</b>	No data available
<b>Other Adverse Effects</b>	An environment hazard cannot be excluded in the event of unprofessional handling and disposal. Very toxic to aquatic life with long lasting effects.

## Section 13: Disposal Considerations

<b>Waste Treatment Methods Product</b>	Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material . Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.
<b>Waste Treatment Methods Packaging</b>	Dispose of as unused product.
<b>Special Precautions Landfill or Incinerations</b>	No data available
<b>Other Information</b>	No data available

## Section 14: Transport Information

<b>UN Number</b>	2811
<b>UN Proper Shipping Name</b>	Toxic solids, organic n.o.s. (Ketoconazole)
<b>Transport Hazard Class(es)</b>	6.1
<b>Packaging Group</b>	III
<b>Environmental Hazards</b>	Marine Pollutant: No Poison Inhalation Hazard: No

## Section 15: Regulatory Information

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 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 not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

## Section 16: Other Information

<b>Additional Information</b>	
<b>Prepared By</b>	Lisa Russell
<b>Revision Date</b>	01/11/2019 12:37

### Disclaimer

Letco Medical, LLC believes that the above information is 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. If the product is used as a component in another product, this information may not be applicable. NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IS MADE CONCERNING THE INFORMATION PROVIDED ABOVE. Letco Medical shall not be held liable for any loss or damage resulting from handling, storage, use or from contact with the above product.