


Section 1: Identification

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| Common Name/Trade Name | KETOCONAZOLE USP | |
| Supplier Information | Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693 | IN CASE OF EMERGENCY: Chemtrec 1 (800) 424-9300 (24 hours) NSW Poisons Information Centre: 131 126 (24 hours) |
| Distributor Name | Bella Corp Trading Pty Ltd 6/34 Dominions Road, Ashmore QLD 4214, Australia Telephone: 07 5597 4169 Email: bellacorp@bellacorp.com.au | |
| Product Synonym(s) | Piperazine, 1-acetyl-4-[4-[[2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy] phenyl]-, cis- | |
| Relevant Use(s) of Product | Manufacture or Compounding of Substances | |

Section 2: Hazards Identification

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| Classification of Substance or Mixture | Acute toxicity, Oral (Category 3), Reproductive toxicity (Category 1B), Specific target organ toxicity, repeated exposure (Category 2, adrenal gland, liver) | |
| Signal Word | Danger | |
| Hazard Statement(s) | H301 H360 H373 | Toxic if swallowed May damage fertility or the unborn child May cause damage to organs through prolonged or repeated exposure |
| Pictogram(s) |  | |
| Precautionary Statement(s) | P201 P202 P260 P264 P280 P301+P310 P308+P313 P330 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. Wear protective gloves/protective clothing/eye protection/face protection. IF SWALLOWED Immediately call a POISON CENTER or doctor/physician. IF exposed or concerned get medical advice/attention. Rinse mouth. Store locked up. Dispose of contents/container to an approved waste disposal plant. |
| Hazards Not Otherwise Classified | 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. | |
| Ingredient(s) with Unknown Toxicity | No data available | |

Section 3: Composition/Information on Ingredients

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

Section 4: First Aid Measures

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| General Advice | Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed healthcare 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. |
| If Inhaled | 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. |
| In Case of Skin Contact | Rinse skin with water/shower. Get medical attention if irritation develops and persists. |
| In Case of Eye Contact | Rinse with water. Get medical attention if irritation develops and persists. |
| If Swallowed | If swallowed: Immediately call a poison center or doctor/physician. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. |

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| Most Important Symptoms and Effects | Liver damage. 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. Treatment of imidazole antifungal overdose may include the following: Toxicity after ingestion is unlikely. Gastrointestinal decontamination is generally unnecessary. For severe diarrhea or vomiting, monitor and correct fluid status. |
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Section 5: Fire Fighting Measures

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| Suitable Extinguishing Media | Suitable extinguishing media: Water. Foam. Dry chemical or CO ₂ . Use fire-extinguishing media appropriate for surrounding materials. Unsuitable extinguishing media: None known. |
| Special Hazards Arising From the Substance/Mixture | 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 PPE and/or Precautions for Firefighters | Wear suitable protective equipment. Firefighting 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. |

Section 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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. For personal protection, see section 8 of the SDS |
| Methods and Materials Used for Containment | 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. Avoid discharge into drains, water courses or onto the ground. |
| Cleanup Procedures | 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. |

Section 7: Handling and Storage

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| Precautions for Safe Handling | As a general rule, when handling, 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 | Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity. |

Section 8: Exposure Controls/Personal Protection

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| Components with Workplace Control Parameters | TWA 0.2 mg/m ³ . 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. |
| PPE - 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. |
| PPE - 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. |
| PPE - Body 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. Thermal hazards Wear appropriate thermal protective clothing, when necessary. |
| PPE - 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. |

Section 9: Physical and Chemical Properties

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| Appearance | White. Off-White Powder. |
| Upper/Lower Flammability or Explosive Limits | Not available |
| Odor | Odorless |
| Vapor Pressure | < 0.0000001 kPa at 25°C |
| Odor Threshold | Not available. |
| Vapor Density | Not available. |
| pH | pH in aqueous solution 7.7 (at concentrations < 0.01 g/L) |
| Relative Density | Not available. |
| Melting Point/Freezing Point | 298.4 - 305.6°F (148 - 152°C) |
| Solubility | Practically insoluble in water. Solubility (other): Alcohol: Sparingly soluble. Dichloromethane: Freely soluble. Methyl alcohol: Soluble. |
| Initial Boiling Point and Boiling Range | Not available. |
| Flash Point | Not available. |
| Evaporation Rate | Not available. |
| Flammability (Solid, Gas) | Not available. |
| Partition Coefficient | 3.78, 4.34 |
| Auto-Ignition Temperature | 968°F (520°C) |
| Decomposition Temperature | Not available. |
| Viscosity | Not available. |

Section 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 | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Contact with incompatible materials. |
| Incompatible Materials | Acids. Strong bases. |
| Hazardous Decomposition Products | Cl-. NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. |

Section 11: Toxicological Information

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| Acute Toxicity - LD50 Oral | Oral (rat) LD50: 166 mg/kg |
| Acute Toxicity - Inhalation | No data available. Knowledge about health hazard is incomplete |
| Acute Toxicity - Dermal | No data available. Knowledge about health hazard is incomplete |
| Acute Toxicity - Eye | No data available. Knowledge about health hazard is incomplete |
| Skin Corrosion/Irritation | No data available. Knowledge about health hazard is incomplete |
| Serious Eye Damage/Irritation | No data available. Knowledge about health hazard is incomplete |
| Respiratory or Skin Sensitization | No data available. Knowledge about health hazard is incomplete |
| Germ Cell Mutagenicity | Based on available data, the classification criteria are not met. Mutagenicity Dominant lethal test in mice Result: Negative |
| Carcinogenicity IARC | Not listed. |
| Carcinogenicity ACGIH | No data available |
| Carcinogenicity NTP | Not listed. |
| Carcinogenicity OSHA | Not regulated. |
| Reproductive Toxicity | May damage fertility or the unborn child. Reproductivity 800 - 1200 mg/kg/day Reproductivity study Result: Therapeutic doses in men were reported to decrease testosterone levels. >= 80 mg/kg/day Reproductivity study Result: Embryoethality was produced but no increase in incidence of malformations. Species: Rabbit >= 80 mg/kg/day Reproductivity study Result: Maternal toxicity, embryotoxicity, and congenital abnormalities were seen. Species: Rat |
| Specific Target Organ Toxicity - Single Exposure | Knowledge about health hazard is incomplete. |
| Specific Target Organ Toxicity - Repeated Exposure | May cause damage to organs (adrenal gland, liver) through prolonged or repeated exposure. |
| Aspiration Hazard | Based on available data, the classification criteria are not met. |

Section 12: Ecological Information

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| Toxicity | The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. |
| Persistence and Degradability | No data is available on the degradability of this product. |
| Bio-accumulative Potential | Octanol/water partition coefficient log Kow 3.78 0.7 4.34 0.7 |
| 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. |

Section 13: Disposal Considerations

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| Waste Treatment Methods Product | 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. |
| Waste Treatment Methods Packaging | Dispose in accordance with all applicable regulations. The waste code should be assigned in discussion between the user, the producer and the waste disposal company. Hazardous waste code 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). Since emptied containers may retain product residue, follow label warnings even after container is emptied. |
| Special Precautions Landfill or Incinerations | No data available |
| Other Information | No data available |

Section 14: Transport Information

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| UN Number | 2811 |
| UN Proper Shipping Name | Toxic solids, organic n.o.s. (Ketoconazole) |
| Transport Hazard Class(es) | 6.1 |
| Packaging Group | III |
| Environmental Hazards | No data available |

Section 15: Regulatory Information

US federal regulations: CERCLA/SARA Hazardous Substances - Not applicable. One or more components are not listed on TSCA. This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. 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- 1052) Not regulated. SARA 302 Extremely hazardous substance Superfund Amendments and Reauthorization Act of 1986 (SARA) Not listed. SARA 311/312 Hazardous Yes chemical Combustible dust Acute toxicity (any route of exposure) Reproductive toxicity Specific target organ toxicity (single or repeated exposure) Classified hazard categories 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 Not regulated. (SDWA) US state regulations California Proposition 65 California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. International Inventories Country(s) or region Inventory name On inventory (yes/no)* Australia Australian Inventory of Chemical Substances (AICS) Yes Canada Domestic Substances List (DSL) Yes Canada Non-Domestic Substances List (NDSL) No China Inventory of Existing Chemical Substances in China (IECSC) No Europe European Inventory of Existing Commercial Chemical Yes Substances (EINECS) Europe European List of Notified Chemical Substances (ELINCS) No Japan Inventory of Existing and New Chemical Substances (ENCS) No Korea Existing Chemicals List (ECL) Yes New Zealand New Zealand Inventory Yes Philippines Philippine Inventory of Chemicals and Chemical Substances No (PICCS) 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).

Section 16: Other Information

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| Additional Information | Symptoms related to the physical, chemical, and toxicological characteristics: Imidazole antifungals: Gastrointestinal disturbances. Central nervous system effects. Back pain. Fever. Chills. Skin rash. Itching. Blistering. Burning. Skin redness. Flushing. Visual disturbances. Yellowed eyes or skin. Swelling in arms or legs. Difficulty breathing. Pharmacologically active material. Occupational exposure may cause physiological effects. 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. |
| Prepared By | Scarlotte Smith |
| Revision Date | 12/06/2024 11:59 |

Disclaimer

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