



Material Safety Data Sheet

12601 Twinbrook Parkway,
Rockville, MD 20852 USA

Phone Calls: 301-881-0666
8 a.m. to 5 p.m. EST Mon. - Fri.

ATTENTION !

USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

KETOCONAZOLE

Catalog Number: 1356508

Revision Date:

March 18, 2005

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Ketoconazole

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

Mailing Address: 12601 Twinbrook Parkway, Rockville, MD 20852 USA

Phone: 301-816-8129

Hours: 8 a.m. to 5 p.m. EST Mon. - Fri.

Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

EMERGENCY OVERVIEW - Toxic.

Adverse Effects: Adverse effects may include nausea and vomiting, abdominal pain, constipation, loss of appetite, fever and chills, skin rash with redness or itching, headache, drowsiness, diarrhea, and dizziness. Concurrent ingestion of ketoconazole and alcohol may cause facial flushing, difficulty breathing, slight fever, and tightness in chest. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: n/f

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization and rarely, liver damage.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, history of congestive heart failure, ventricular dysfunction, alcoholism, and impaired liver or kidney function.

Cross Sensitivity: Persons sensitive to other imidazoles (fluconazole, itraconazole, miconazole) may be sensitive to this material also.

Target Organs: Liver.

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Common Name: Ketoconazole

Formula: C₂₆H₂₈Cl₂N₄O₄

KETOCONAZOLE

Catalog Number: 1356508

Revision Date:

March 18, 2005

Synonym: n/f

Chemical Name: Piperazine, 1-acetyl-4-[4-[[2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy] phenyl]-, cis-

CAS: 65277-42-1

RTECS Number: TK7912300

Chemical Family: Imidazole

Therapeutic Category: Antifungal

Composition: Pure Material

SECTION 4 - FIRST AID MEASURES

Inhalation: May cause irritation and systemic effects. Remove to fresh air.

Eye: May cause irritation. Flush with copious quantities of water.

Skin: May cause irritation, but is not systemically absorbed through the skin. Flush with copious quantities of water.

Ingestion: May cause irritation and toxicity. Avoid ingestion. Flush out mouth with water. This material is well absorbed from the gastrointestinal tract.

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Note to Physicians

Overdose Treatment: In the event of oral overdose, perform gastric lavage with sodium bicarbonate. [PDR 2005]

SECTION 5 - FIREFIGHTING MEASURES

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately-labelled container for disposal. Wash spill site.

SECTION 7 - HANDLING AND STORAGE

Handling: As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

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 CONTROL / PERSONAL PROTECTION

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection: Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

KETOCONAZOLE

Catalog Number: 1356508

Revision Date:

March 18, 2005

Eye Protection: Safety goggles

Protective Clothing: Protect exposed skin.

Exposure Limits: n/f

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: White to off-white powder; odorless.

Odor Threshold: n/f

pH: 7.7 (@ concentrations < 0.01 g/L)

Melting Range: 146 - 152° C

Boiling Point: n/f

Flash Point: n/f

Autoignition Temperature: 520° C

Evaporation Rate: n/f

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: n/f

Specific Gravity: n/f

Solubility in Water: Practically insoluble

Fat Solubility: n/f

Other Solubility: Sparingly soluble in alcohol; freely soluble in dichloromethane; soluble in methyl alcohol.

Partition Coefficient: n-octanol/water: log P = 3.78

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: C₂₆H₂₈Cl₂N₄O₄

Molecular Weight: 531.43

KETOCONAZOLE

Catalog Number: 1356508

Revision Date:

March 18, 2005

SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: n/f

Incompatibilities: Acids, oxidants and strong bases.

Decomposition Products: When heated to decomposition material emits toxic fumes of Cl- and NOx. Emits toxic fumes under fire conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50: 166 mg/kg

Oral Mouse: LD50: 618 mg/kg

Other Toxicity Data: Oral Guinea Pig: LD50: 178 mg/kg
Oral Dog: LD50: 178 mg/kg

Irritancy Data: n/f

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by: **NTP:** No **IARC:** No **OSHA:** No

Other Carcinogenicity Data: No

Mutagenicity Data: Dominant lethal mutation tests have not shown mutation in any stage of germ cell development in male and female mice given single, oral doses of ketoconazole as high as 80 mg/kg. In addition, the Ames/Salmonella microsomal activator tests have not shown evidence of mutagenicity.

Reproductive and Developmental Effects: Adequate and well-controlled pregnancy studies in humans have not been done. However, studies in rats given 10 times the maximum recommended human dose of ketoconazole have shown that it causes birth defects. In one study, the frequencies of fetal death and anomalies were increased among the offspring of rats treated with ketoconazole during pregnancy. Therapeutic use of ketoconazole has the potential to impair fertility in males and females, although effects are reversible when therapy is discontinued.

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: n/f

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 14 - TRANSPORT INFORMATION

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

Class: 6.1

UN Number: UN2811

Packing Group: III

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: n/f

KETOCONAZOLE

Catalog Number: 1356508

Revision Date:

March 18, 2005

International Regulatory Information: EINECS # 265-667-4
Hazard code: Xn
Risk phrases: R22
Safety phrases: S38

SECTION 16 - OTHER INFORMATION

Revision: 18-Mar-05

Previous Revision Date: 01-Oct-01