

MATERIAL SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME:	Ketoconazole Tablets USP, 200 mg	PRODUCT No.:	51672-4026
CAS #:	65277-42-1	FORMULA:	C ₂₅ H ₂₈ Cl ₂ N ₄ O ₄
SUBSTANCE CLASS:	An Imidazole	M.W.:	531.44

SECTION 2: PHYSICAL/CHEMICAL DATA

BOILING POINT:	Not found.
PHYSICAL STATE (liquid/solid/gas):	Solid.
SPECIFIC GRAVITY (H ₂ O=1):	Not found.
EVAPORATION RATE (Butyl Acetate=1):	Not found.
SOLUBILITY:	Practically insoluble in water.
APPEARANCE:	White to off-white.
ODOR DESCRIPTION:	Odorless.
MELTING POINT:	146°C

SECTION 3: FIRE AND EXPLOSION HAZARD DATA

FLASH POINT:	Not found, however, the auto-ignition temperature is 520°C.
EXTINGUISHING MEDIA:	Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.
SPECIAL FIRE FIGHTING PROCEDURES:	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
UNUSUAL FIRE AND EXPLOSION HAZARDS:	None found.
HAZARDOUS COMBUSTION PRODUCTS:	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.

SECTION 4: STABILITY AND REACTIVITY DATA

CHEMICAL STABILITY:	Stable.
CONDITIONS TO AVOID:	None found.
INCOMPATIBILITY WITH OTHER MATERIALS:	Acids, oxidants and strong bases.
HAZARDOUS DECOMPOSITION PRODUCTS:	When heated to decomposition material emits toxic fumes of Cl- and NOx. Emits toxic fumes under fire conditions.
HAZARDOUS POLYMERIZATION:	No.
CONDITIONS TO AVOID:	None found.
MATERIAL TO AVOID:	None found.

SECTION 5: HEALTH HAZARD DATA

EMERGENCY OVERVIEW	White to off-white round, flat tablets, scored on one side, engraved T57 on the side of the score, containing 200 mg of ketoconazole.
Usual Adult Dose:	The usual oral adult dose of ketoconazole is 200 to 400 mg once a day. The dose may need to be increased to a maximum of 400 mg per day (or more) in severe cases.
Adverse Effects:	Adverse effects include nausea and vomiting, abdominal pain, skin rash with redness or itching, headache, drowsiness, diarrhea and dizziness. Possible allergic reaction to material if inhaled, ingested or in contact with skin.
Overdose Effects:	Not found.

FIRST AID MEASURES

General:	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.
Overdose Treatment:	In the event of oral overdose, gastric lavage with sodium bicarbonate should be performed.

POTENTIAL HEALTH HAZARDS

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. Flush out mouth with water. This material is well-absorbed from the gastrointestinal tract.
Inhalation:	May cause irritation. Remove to fresh air.
Chronic Effects:	Possible hypersensitization and rarely, liver damage.
Acute:	Possible eye, skin, gastrointestinal and/or respiratory tract irritation.
Medical conditions aggravated by Exposure:	Hypersensitivity to material, active alcoholism and liver disease.
Cross Sensitivity:	Persons sensitive to miconazole or other imidazoles may be sensitive to this material also.
Pregnancy Comments:	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 is teratogenic, and therefore its therapeutic use by pregnant women should be avoided.
Pregnancy Category:	C

SECTION 6: SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED:

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

WASTE DISPOSAL METHOD:

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

SECTION 7: HANDLING AND STORAGE

HANDLING: As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust and/or vapors. 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 CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS: Not found.

PERSONAL PROTECTION:

Respiratory: 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. Ventilation is recommended.

Eye: Safety goggles.

Clothing: Protect exposed skin.

Gloves: Rubber.

WORK PRACTICES: Not found.

SECTION 9: TOXICOLOGICAL INFORMATION

Oral Rat:	LD ₅₀ :	166 mg/Kg	Target Organ(s):	Liver
Oral Mouse:	LD ₅₀ :	618 mg/Kg	Listed as Carcinogen?:	No

SECTION 10: OTHER INFORMATION

None specified.

SECTION 11: TRANSPORTATION INFORMATION

None specified.

SECTION 12: REGULATORY INFORMATION

None Specified.

DISCLAIMER

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the users responsibility to evaluate the information and use it in a prudent manner for its particular purpose. Taro Pharmaceuticals assumes no responsibility for the use of this information.