

# **MATERIAL SAFETY DATA SHEET**

**PRODUCT NAME:**  
**Ketoconazole Tablets**

**AS SOLD BY PHOENIX PHARMACEUTICAL**

A Service of



# MATERIAL SAFETY DATA SHEET

Effective: January 13, 2000  
Superseded: July 17, 1996

NE = Not Established NA = Not Applicable

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<b>IDENTITY (As Used on Label and List)</b> <b>KETOCONAZOLE</b> Piperazine, 1-acetyl-4-[[2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]-, cis- CAS No. 65277-42-1
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<b>SECTION I</b>	
<b>MANUFACTURER:</b> Wyckoff, Inc. 1421 Kalamazoo Street South Haven, MI 49090	<b>EMERGENCY TELEPHONE # Mon- Fri: 8:00 AM - 5:00 PM</b> 616-637-8474 <b>EMERGENCY TELEPHONE # Mon-Fri.:5:00 PM - 8:00 AM:</b> 616-639-0199 <b>EMERGENCY TELEPHONE # Sat-Sun: ALL DAY</b> 616-639-0199 <hr/> <b>TELEPHONE NUMBER FOR INFO. - 616-637-8474</b> <b>SIGNATURE OF PREPARER (OPTIONAL) A. Zeiler</b>

<b>SECTION II - Hazardous Ingredients/Identity Information</b>				
Hazardous Components (Common Names(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (Optional)
Ketoconazole	NA	NA	NA	100
Toxicity Data:				
LD 50: 166 mg/kg oral rat				
LDLow: 45 mg/kg/17 day--intermittent oral man				

<b>SECTION III - Physical/Chemical Characteristics</b>					
Boiling Point	NA	Vapor Pressure (mm Hg)	NA	Vapor Density (AIR=1)	NA
Specific Gravity (H20=1)	NA	Melting Point	146°C	Evaporation Rate (Butyl Acetate=1)	NA
Solubility in Water					
Practically insoluble					
Appearance and Odor					
White to off-white powder; odorless					

<b>SECTION IV - Fire and Explosion Hazard Data</b>				
Flash Point (Methods Used)	Flammable Limits		LEL	UEL
NA			NA	NA
Extinguishing Media				
Water spray, dry chemical, carbon dioxide or foam is appropriate for surrounding fire and material				
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				
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 build-up of static electricity.				

<b>SECTION V - Reactivity Data</b>			
Stability	Unstable		Conditions to Avoid
	Stable	X	Material is stable from the safety point of view.
Incompatibility (Materials to Avoid)			
Acids, oxidants and strong bases			
Hazardous Decomposition or by-Products			
Emits toxic fumes under fire conditions			
Hazardous Polymerization	May Occur		Conditions to Avoid
	Will Not Occur	X	NA

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<b>SECTION VI - Health Hazard Data</b>					
<b>Route (s) of Entry:</b>					
Inhalation?	Yes	Skin?	Limited	Ingestion?	Yes
<b>Health Hazards (Acute and Chronic)</b> Repeated administration may cause nausea, headache, dizziness, constipation or diarrhea, abdominal pain, somnolence, nervousness, fatigue, hypertension, malaise, anorexia and pruritus.					
<b>Carcinogenicity:</b>					
NTP?	No	IARC Monographs?	No	OSHA Regulated?	No
<b>Signs and Symptoms of Exposure</b> Eye, skin and/or respiratory tract irritation.					
<b>Medical Conditions Generally Aggravated by Exposure</b> Hypersensitivity to material, active alcoholism and liver disease					
<b>Emergency and First Aid Procedures</b> Remove from exposure. Persons developing serious hypersensitivity reactions must receive immediate medical attention. Upon eye or skin contact, flush area with copious quantities of water.					

<b>SECTION VII - Precautions for Safe Handling and Use</b>					
<b>Steps to Be Taken in Case Material is Released or Spilled</b> Sweep up material and package for disposal, wear a dust mask and protective clothing.					
<b>Waste Disposal Method</b> Dispose of waste in accordance with all applicable Federal, State and Local laws.					
<b>Precautions to Be Taken in Handling and Storing</b> None					
<b>Other Precautions</b> Avoid contact with eyes, skin, or clothing. Avoid breathing dust. Use with adequate dust control.					

<b>SECTION VIII - Control Measures</b>					
<b>Respiratory Protection (Specify Type)</b> NIOSH Approved Respirator					
<b>Ventilation</b>	<b>Local Exhaust</b>	Yes	Special	No	
Adequate	Mechanical(General)	Yes	Other	No	
<b>Protective Gloves</b>	Rubber	<b>Eye Protection</b>		Safety goggles	
<b>Other Protective Clothing or Equipment</b> None					
<b>Work/Hygienic/Maintenance Practices</b> Avoid breathing dust.					

**NOTE:** The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide.