



## MATERIAL SAFETY DATA SHEET

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### SECTION 1 - CHEMICAL PRODUCT & COMPANY IDENTIFICATION

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**Greenstone Limited**  
**100 Route 206 North**  
**Peapack, NJ 07977**

**Emergency telephone** 800-435-7095  
**Hours of operation** 24 hours

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<b>Product name</b>	<b>Fluconazole tablets</b>
<b>Chemical family</b>	Synthetic class of compounds known as bis-triazoles
<b>Therapeutic use</b>	Antifungal agent
<b>Description</b>	Pink trapezoidal tablets (50, 100, 200 mg); Pink oval tablets (150 mg)

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### SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

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**Hazardous ingredients**

<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Fluconazole*	86386-73-4	45.5%
Microcrystalline cellulose*	9004-34-6	Trade secret
Calcium phosphate dibasic, anhydrous	7757-93-9	Trade secret
Croscarmellose sodium*	74811-65-7	Trade secret
Povidone	9003-39-8	Trade secret
Magnesium stearate*	557-04-0	Trade secret
FD & C Red No. 40, aluminum lake	68583-95-9	Trade secret

\*Hazardous

Note: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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### SECTION 3 - HAZARDS IDENTIFICATION

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<b>Signal word</b>	<b>CAUTION!</b>
<b>Statements of hazard</b>	<b>MAY BE HARMFUL IF SWALLOWED</b> <b>CAN CAUSE LIVER DAMAGE</b> <b>POSSIBLE RISK OF HARM TO THE UNBORN CHILD</b> <b>DANGEROUS FOR THE ENVIRONMENT</b>

<b>Eye effects</b>	None known; however, direct contact with any foreign material may cause eye irritation.
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**SECTION 3 - HAZARDS IDENTIFICATION** ... continued

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<b>Skin effects</b>	No data available
<b>Inhalation effects</b>	An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8). See 'Statements of hazard', 'Known clinical effects', and/or 'Other potential health effects' in this section.
<b>Ingestion effects</b>	See 'Statements of hazard', 'Known clinical effects', and/or 'Other potential health effects' in this section.
<b>Known clinical effects</b>	Nausea, abdominal discomfort, headache, dizziness
<b>Other potential health effects</b>	Rare cases of serious liver damage and allergic reactions have been reported. There have been reports of multiple congenital abnormalities in infants whose mothers were being treated for 3 or more months with high dose (400-800mg/day) fluconazole. Fluconazole is found in human breast milk at concentrations similar to plasma. Therefore, nursing mothers should limit exposure.
<b>Additional data</b>	For a more detailed discussion of potential health hazards and toxicity see Section 11.
<b>NOTE:</b>	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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**SECTION 4 - FIRST AID MEASURES**

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<b>Eyes</b>	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
<b>Skin</b>	Remove contaminated clothing and shoes. Wash skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.
<b>Inhalation</b>	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.
<b>Ingestion</b>	Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

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## SECTION 5 - FIRE FIGHTING MEASURES

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<b>Fire fighting instructions</b>	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.
<b>Extinguishing media</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Flash point</b>	Not applicable
<b>Hazardous combustion products</b>	Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds

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## SECTION 6 - ACCIDENTAL RELEASE MEASURES

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<b>General</b>	Review Sections 3, 8 and 12 before proceeding with clean up.
<b>Small spill</b>	Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.
<b>Large spill</b>	Spills should be handled by vacuuming or wet mopping. Transfer all waste to a labeled container and move it to a secure holding area.

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## SECTION 7 - HANDLING AND STORAGE

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<b>General handling</b>	If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Minimize dust generation and accumulation. Use appropriate ventilation.
<b>Storage conditions</b>	Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature.
<b>Temperature range for storage</b>	<30°C (86°F)

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## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

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<b>Exposure limits</b>			
<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Microcrystalline cellulose	ACGIH	TWA-8 Hr	10 mg/m <sup>3</sup> (total dust)
	OSHA	TWA-8 Hr	5 mg/m <sup>3</sup> (respirable fraction)
	OSHA	TWA-8 Hr	15 mg/m <sup>3</sup> (total dust)
Croscarmellose sodium	OSHA	TWA-8 Hr	15 mg/m <sup>3</sup> (total dust)
	OSHA	TWA-8 Hr	5 mg/m <sup>3</sup> (respirable fraction)
Fluconazole	Manufacturer	TWA-8 Hr	0.5mg/m <sup>3</sup>
<b>Measurement method</b>	Fluconazole: STP D 58.7; CAM-JWT-93-05 (Contact Greenstone for additional details)		

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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION** ... continued

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<b>Ventilation</b>	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.
<b>Eye protection</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin protection</b>	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Hand protection</b>	None required under normal and foreseeable conditions of use. Wear impervious gloves if skin contact is possible.
<b>Respiratory protection</b>	None required under normal conditions of use. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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<b>Physical form</b>	Tablet
<b>Color</b>	Pink
<b>Odor</b>	Odorless
<b>Molecular weight</b>	Mixture
<b>Molecular formula</b>	Mixture
<b>pH</b>	No data available
<b>Melting point</b>	No data available
<b>Vapor pressure</b>	Not applicable
<b>Water solubility</b>	No data available
<b>Solvent solubility</b>	No data available

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**SECTION 10 - STABILITY AND REACTIVITY**

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<b>Reactivity</b>	Stable
<b>Conditions to avoid</b>	None known
<b>Incompatibilities</b>	Strong oxidizers
<b>Hazardous decomposition products</b>	None known
<b>Hazardous polymerization</b>	Will not occur

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## SECTION 11 - TOXICOLOGY INFORMATION

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**Toxicology summary** The information included in this section describes the potential hazards of the active ingredient.

**Acute toxicity**

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Result</u>
Fluconazole	LD <sub>50</sub>	Oral	Rat	1325 mg/kg
	LD <sub>50</sub>	Oral	Mouse	1410 mg/kg

**Eye** No data available. Dust may cause irritation if tablets are crushed or broken.

**Skin** No data available

**Inhalation** No data available

**Ingestion** See Acute toxicity table

**Mutagenicity** No evidence of mutagenic potential in *in vivo* or *in vitro* genetic toxicity studies.

**Sensitization** No data available

**Subchronic effects** Subchronic toxicity was evaluated in mice, rats and dogs orally for one, three or six months, respectively. Findings in all three species revealed increased liver weight and mild hepatic changes predominately at mid- and high-dose animals. However, these treatment-related effects were reversible in rats following cessation of the drug.

**Chronic toxicity** Chronic oral toxicity studies were conducted in rats at dose level of 10 mg/kg/day and in dogs at dose levels up to 15 mg/kg/day for 12 months. Mild liver changes and increased liver weights were seen in rats and dogs (mid- and high-dose).

**Chronic effects/  
carcinogenicity** Male rats treated with 5 or 10 mg/kg/day had an increased incidence of hepatocellular adenomas in a 24-month oral toxicity study. However, no carcinogenic potential was observed in female rats or among male and female mice at doses of 2.5, 5, or 10 mg/kg/day for 24 months. Taken together, these results are interpreted to indicate that fluconazole showed no evidence of carcinogenic potential in these rodent species.

**Carcinogen status** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

**Reproductive effects** At doses of 10 mg/kg/day in the rat, evidence of alterations in reproductive hormones and, secondarily, delayed parturition and delayed fetal development were observed. However, these hormonal alterations are not seen in humans and the resulting effects are not expected to occur.

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**SECTION 11 - TOXICOLOGY INFORMATION** ... continued

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<b>Teratogenicity</b>	<p>No evidence of embryotoxicity, fetotoxicity, or teratogenicity in rats or rabbits when fluconazole was administered at dose levels up to 20 mg/kg/day on days 6 to 15 or 7 to 18 of gestation, respectively. In another teratology study in rats, fluconazole administered at dose levels up to 125 mg/kg/day on days 7 to 17 of gestation, caused a placental weight increase in all dose levels. Also, three cases of missing paws were observed in separate litters in the high dose group, and there was an increased incidence of fetal anatomical variants at both the high- and mid-dose levels.</p> <p>At doses of 10 mg/kg/day and above, evidence of maternal toxicity in rabbits and changes in reproductive hormone levels in rats were observed. The hormonal alterations led to parturition difficulties, fetal anomalies and development delay, and early neonatal mortality. As explained above, these effects are not expected to occur in humans. However, at 80 mg/kg doses or above teratogenic craniofacial effects were observed, similar to those reported with other azole antifungals.</p>
<b>At increased risk from exposure</b>	Individuals with increased sensitivity to this drug and other drugs in the same class. Individuals with impaired kidney function.
<b>Additional information</b>	There have been reports of multiple congenital abnormalities in infants whose mothers were being treated for 3 or more months with high dose (400-800mg/day) fluconazole. Fluconazole is excreted in human milk at concentrations similar of plasma.

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**SECTION 12 - ECOLOGICAL INFORMATION**

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<b>Environmental overview</b>	The environmental characteristics of this mixture have not been fully evaluated. Harmful effects to aquatic organisms could occur. Releases to the environment should be avoided.
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**Aquatic toxicity**

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Result</u>
Fluconazole	LC50/48h	Daphnia magna	35 mg/l
	LC50	Fathead minnow	> 50 mg/L
	LC50	Sheepshead minnow	> 50 mg/L

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**SECTION 13 - DISPOSAL INFORMATION**

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<b>Disposal procedure</b>	Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.
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## SECTION 14 - TRANSPORTATION INFORMATION

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<b>General shipping instructions</b>	Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
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## SECTION 15 - REGULATORY INFORMATION

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<b>EU Classification</b>	Substance toxic to reproduction: Category 2; Dangerous for the Environment
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<b>EU Labelling</b>	T
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<b>EU Label Pictogram(s)</b>	
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<b>Risk phrases</b>	R22 - Harmful if swallowed. R61 - May cause harm to the unborn child. R64- May cause harm to breastfed babies. R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
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<b>Safety phrases</b>	S22 - Do not breathe dust. S53 - Avoid exposure - obtain special instructions before use. S57 - Use appropriate containment to avoid environmental contamination.
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<b>WHMIS Classification</b>	Class D, Division 2, Subdivision A
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## SECTION 16 - OTHER

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<b>Disclaimer</b>	<b>It is believed that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.</b>
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