

MATERIAL SAFETY DATA SHEET

SECTION 1. PRODUCT IDENTIFICATION

Product Name: Fluconazole
Chemical Formula: C13-H12-F2-N6-O
Synonym: Fluconazole; Diflucan
Company Identification: Lasa Supergenerics Limited
C-105, MIDC, Mahad (Dist. - Raigad).
Telephone No. - 022-49701092

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

CAS#	Chemical Name	Percent
86386-73-4	Fluconazole	100

Toxicological Data on Ingredients: Fluconazole: ORAL (LD50): Acute: 1271 mg/kg [Rat]. 1408 mg/kg [Mouse].

SECTION 3. HAZARD IDENTIFICATION

Potential Acute Health Effects: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Potential Chronic Health Effects:

CARCINOGENIC EFFECTS: Not available

MUTAGENIC EFFECTS: Not available.

TERATOGENIC EFFECTS: Classified Possible for human.

DEVELOPMENTAL TOXICITY: Not available. Repeated or prolonged exposure is not known to aggravate medical condition.

SECTION 4. FIRST AID

Eye Contact: Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.

Skin Contact: Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops.

Serious Skin Contact: Not available.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

Serious Ingestion: Not available.

SECTION 5. FIRE AND EXPLOSION

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: Not available.

Flammable Limits: Not available.

Products of Combustion: These products are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂...), halogenated compounds.

Fire Hazards in Presence of Various Substances:

Slightly flammable to flammable in presence of heat. Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:

Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available.

Fire Fighting Media and Instructions:

SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: Not available.

Special Remarks on Explosion Hazards: Not available.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Small Spill:

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:

Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

SECTION 7. HANDLING AND STORAGE

Precautions:

Keep locked up. Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area. Do not store above 25°C (77°F).

SECTION 8. PERSONAL PROTECTION/EXPOSURE CONTROLS

Engineering Controls:

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state and appearance: Solid. (Crystalline solid.)

Odor: Not available.

Taste: Not available.

Molecular Weight: 306.3 g/mole

Color: White.

pH (1% soln/water): Not available.

Boiling Point: Not available. **Melting**

Point: Not available. **Critical**

Temperature: Not available. **Specific**

Gravity: Not available. **Vapor**

Pressure: Not applicable. **Vapor**

Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: Not available.

Solubility: Not available.

SECTION 10. REACTIVITY/STABILITY

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat

Incompatibility with various substances: Not available.

Corrosivity: Not available.

Special Remarks on Reactivity: Not available.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

SECTION 11. TOXICOLOGICAL INFORMATION

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): 1271 mg/kg [Rat].

Chronic Effects on Humans: TERATOGENIC EFFECTS: Classified POSSIBLE for human.

Other Toxic Effects on Humans: Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans:

May cause birth defects (teratogenic). There are no adequate and well controlled studies of pregnant women. There have

been reports of multiple congenital abnormalities in infants whose mothers were being treated for 3 or more months with high

doses (400-800 mg/day). Excreted in maternal milk in human.

Special Remarks on other Toxic Effects on Humans:

Acute Potential Health Effects: Skin: Eyes: May cause eye irritation. Inhalation: May cause respiratory tract irritation. Ingestion: May cause gastrointestinal tract irritation with nausea, vomiting, abdominal pain, diarrhea, dyspepsia, and taste perversion.

May also affect behavior/central nervous system (headache, dizziness, seizures), metabolism (Hypercholesterolemia, Hypertriglyceridemia, Hypokalemia), liver, blood (leukopenia, neutropenia, agranulocytosis, thrombocytopenia), and cardiovascular system. Other symptoms may include skin rashes, exfoliative skin disorders such as Stevens-Johnson

syndrome and toxic epidermal necrolysis and alopecia. Anaphylaxis in rare cases has been reported. Clinically or potentially significant drug interactions between Fluconazole and the following agents/classes have been observed: Oral hypoglycemics, Coumarin-type anticoagulants, Phenytoin, Cyclosporine, Rifampin, Theophylline, Terfenadine, Cisapride, Astemizole, Rifabutin, Tacrolimus.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The products of degradation are as toxic as the product itself.

Special Remarks on the Products of Biodegradation: Not available.

SECTION 13. DISPOSAL

Waste Disposal:

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

SECTION 14. TRANSPORTATION

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable

SECTION 15. REGULATORY INFORMATION

Federal and State Regulations: TSCA 8(b) inventory: No products were found.

Other Regulations: Not available.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC):

R22- Harmful if swallowed. R63- Possible risk of harm to the unborn child. S2- Keep out of the reach of children. S46- If swallowed, seek medical advice immediately and show this container or label.

HMIS (U.S.A.):

Health Hazard: 1

Fire Hazard: 1

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health

Flammability: 1

Reactivity: 0

Specific hazard:

Protective Equipment:

Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Safety glasses

SECTION 16 - ADDITIONAL INFORMATION

This document is intended only as a guide to the appropriate precautionary handling of material by a person trained in chemical handling. The user is responsible for determine the precautions & dangers of this chemical for his or her particular application depending on usage. Adequate protective clothing, including eye / face guards, approved respirators must be used to avoid contact with the material or breathing chemical vapors / fumes. Exposure to this product may cause adverse health effects.



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This chemical may interact with other substances. Since the potential uses are so varied, M/s. **Lasa Supergenerics Limited.** cannot warn of all of the potential dangers of use or interaction with chemicals of materials. M/s. **Lasa Supergenerics Limited.** warrants that, the chemical meets the specifications set forth on the test report.

M/s. **Lasa Supergenerics Limited.** Disclaims any other warranties expressed or implied with regard to the product supplied hereunder its merchantability or its fitness for a particular purpose. The user should recognize that, this product can cause severe injury, especially if improperly handled or the known dangers of use are not heeded.

READ ALL PRECAUTIONARY INFORMATIONS.