

SAFETY DATA SHEETS

This SDS packet was issued with item:

078941322

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078941323

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MASTER COPY		AUROBINDO PHARMA LIMITED, UNIT - VIII		Page 1 of 7
AUROBINDO		MATERIAL SAFETY DATA SHEET		
Product	FLUCONAZOLE		Version No.	03
MSDS No.	MSDS/FC/FP020		Effective Date	28/01/2011

1 Identification of the substance/preparation and of the company/undertaking

Common Name : FLUCONAZOLE
Supplier : M/s. AUROBINDO PHARMA LIMITED
Regd. Office : PLOT NO: 2, MAITHRIVIHAR COMPLEX,
AMEERPET, HYDERABAD - 500 038.
PHONE : ++91 40 6672 5000, FAX : ++91 40 2374 6833
Manufacturing Site : SURVEY NO: 10 & 13, GADDAPOTHARAM (Village),
JINNARAM (Mandal), MEDAK (District),
ANDHRAPRADESH - 502319, INDIA.
PHONE : ++91 8458 277 115/277 000,
FAX : ++91 8458 277 000

2 Composition / information on ingredients

Common Name : Fluconazole
Formula : $C_{13}H_{12}F_2N_6O$
Synonym : n/f
Chemical name : 2,4-Difluoro-1',1'-bis (1H-1,2,4-triazol-1-yl methyl)benzyl
alcohol
CAS No. : 86386-73-4
RTECS Number : XZ4810000
Chemical Family : Triazole derivative
Therapeutic Category : Antifungal
Composition : Pure Material

3 Hazards identification

EMERGENCY OVERVIEW : Irritant.
Adverse Effects : Adverse effects may include fever and chills, skin rash or
itching, dizziness, constipation, loss of appetite, taste perversion,
nausea, headache, vomiting, acid or sour stomach, menstrual
disorders, swelling of face, bloating, diarrhea, flatulence,
abdominal pain, and fatigue. Possible allergic reaction to
material if inhaled, ingested, or in contact with skin.
Overdose Effects : n/f

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Acute	:	Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.
Chronic	:	Possible hypersensitization, liver damage, and hair loss.
Medical Conditions Aggravated by Exposure	:	Hypersensitivity to material, alcoholism, congestive heart failure, ventricular dysfunction, hypochlorhydria or achlorhydria, impaired liver or kidney function, AIDS, or malignancy.
Cross Sensitivity	:	Persons sensitive to imidazoles, azoles, or amphotericin B may be sensitive to this material also.
Target Organs	:	n/f

4 First-aid measures

Inhalation	:	May cause irritation. Avoid inhalation. Remove to fresh air.
Eye	:	May cause irritation. Avoid contact. Flush with copious quantities of water.
Skin	:	Causes irritation. Avoid contact. Flush with copious quantities of soap and water.
Ingestion	:	May cause irritation. 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	:	Treatment of overdose should be symptomatic and supportive, including gastric lavage if clinically indicated. Monitor platelet count and liver function. (Meditext 2006)
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5 Fire-fighting 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.
Fire fighting Procedures	:	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

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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 labeled container for disposal. Wash spill site.

7 Handling and storage

Handling : Handle with care, wear hand gloves and nose mask during sampling.

Storage : Preserve in tight containers and store below 30°C

8 Exposure controls/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

Eye Protection : Safety glasses or goggles


Protective Clothing : Protect exposed skin

Exposure Limits : n/f

Protective Clothing
(Pictograms)




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Physical and chemical properties

Appearance and Odor	:	White or almost white crystalline powder; odorless or almost odorless.
Odor Threshold	:	n/f
pH	:	5.5 - 7.0 (in a 0.2 grams/liter aqueous solution)
Melting Range	:	138 - 142 ° C
Boiling Point	:	n/f
Flash Point	:	n/f
Autoignition Temperature	:	450° 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	:	Slightly soluble
Fat Solubility	:	n/f
Other Solubility	:	Freely soluble in methanol; soluble in alcohol and in acetone; sparingly soluble in isopropanol and in chloroform; slightly soluble in toluene.
Partition Coefficient: n-octanol/water	:	n/f
Percent Volatile	:	n/f
Reactivity in Water	:	n/f
Explosive Properties	:	n/f
Oxidizing Properties	:	n/f
Formula	:	C ₁₃ H ₁₂ F ₂ N ₆ O
Molecular Weight	:	306.27

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10 Stability and reactivity

Conditions to Avoid	:	Avoid exposure to heat.
Incompatibilities	:	Acids and strong oxidizers.
Decomposition Products	:	When heated to decomposition, material emits toxic fumes of NOx and HF. Emits toxic fumes under fire conditions.
Stable?	:	Yes
Hazardous Polymerization ?	:	No

11 Toxicological information

Oral Rat	:	LD50: 1271 mg/kg
Oral Mouse	:	LD50: 1408 mg/kg
Other Toxicity Data	:	Oral Dog LD50: > 300 mg/kg
Rabbit dermal (Micro crystalline cellulose)	:	LD 50: > 2000 mg/kg
Irritancy Data	:	RTECS - Human/skin: moderate
Corrosivity	:	n/f
Sensitization Data	:	n/f
Listed as a Carcinogen by:NTP	:	No
IARC	:	No
OSHA	:	No
Other Carcinogenicity Data	:	Rats treated with 5 to 10 mg/kg/day had an increased incidence of hepatocellular adenomas.
Mutagenicity Data	:	Tests for fluconazole (with and without metabolic activation) in four strains of S. typhimurium and in the mouse lymphoma L5178Y system were negative. Cytogenetic studies in vivo and in vitro showed no evidence of chromosomal mutations.
Reproductive and Developmental Effects	:	In animal studies, fluconazole has caused maternal toxicity at doses above 5 mg/kg/day and miscarriage at 75 mg/kg/day in rabbits, and impaired maternal weight gain, increase in stillbirths, decrease in newborn survival, and fetal abnormalities and death in rats at doses of 25 or 80 mg/kg/day. There was no

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evidence of maternal toxicity or embryotoxicity in rats at 5 or 10 mg/kg/day. Effects in rats may be the result of lowered estrogen, an effect not seen in humans treated with fluconazole. There have been reports of congenital abnormalities in some infants born to mothers who were treated with high doses (400 or 800 mg/day) of fluconazole for three months or more; the relationship between the fluconazole and pregnancy outcomes is unclear.

12 Ecological information

Ecological Information : n/f

13 Disposal considerations

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

14 Transport Information

Shipping Name : n/f

Class : n/f

UN Number : n/f

Packing Group : n/f


Additional Transport Information : n/f

15 Regulatory information

U.S. Regulatory Information : n/f

International Regulatory Information : Hazard code: Xn
Risk phrases: R22, R36/37/38
Safety phrases: S53, S22, S36/37/39, S26

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16 Other InformationNotice to Reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.