



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

PRODUCT: FLUCONAZOLE TABLETS USP

SDS NO. : SDSGHS.030.00

EFFECTIVE DATE :02/11/2015

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Section 1. Identification

1.1 Substance Name: Fluconazole Tablets USP

1.2 Chemical Name: Not Known

1.3 Relevant identified uses of the substance or mixture and uses advised against:
Pharmaceutical product used as antifungal agent

1.4 Company Identification: Glenmark Pharmaceuticals Inc., USA
750 Corporate Drive
Mahwah, NJ 07430

1.6 Emergency Contact details: (201) 684-8000

Section 2. Hazard Identification

2.1 Classification of the substance or mixture

Classification according to Regulation GHS

Acute Oral Toxicity: Category 4

Reproductive Toxicity: Category 1B

Effects on or via lactation

Acute aquatic toxicity: Category 3

Chronic aquatic toxicity: Category 3

EU Classification:

EU Indication of danger: Harmful

Toxic to reproduction, Category 2

EU Risk Phrases:

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.

Signal Word: Danger

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2.2 Label elements:

2.3 Risk Phrase:

- H302 - Harmful if swallowed
- H360D - May damage the unborn child
- H362 - May cause harm to breast-fed children
- H402 - Harmful to aquatic life
- H412 - Harmful to aquatic life with long lasting effects

2.4 Safety Advice:

- P202 - Do not handle until all safety precautions have been read and understood
- P264 - Wash hands thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P273 - Avoid release to the environment
- P281 - Use personal protective equipment as required
- P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P330 - Rinse mouth
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations

2.5 Other hazards: Harmful if swallowed. Suspected of damaging the unborn child. May cause harm to breastfed babies.

Section 3- Composition/Information on Ingredients

3.1 Substances

COMPONENTS	CAS	CONCENTRATION (WT %)	EXPOSURE
Fluconazole	86386-73-4	45.455	N/E
ingredients determined not to be hazardous [Mfr]	-	Proprietary	N/E



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Section 4. First aid Measures

4.1 Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

4.2 Skin: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

4.3 Eyes: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

4.4 Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.5 Most important symptoms and effects, both acute and delayed

For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

Section 5. Fire-fighting Measures

5.1 General Information: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

5.2 Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

5.3 Fire/Explosion Hazard: Not Known

5.4 NFPA Rating: Not Known

Section 6. Accidental Release Measures

6.1 General Information: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean-up operations should only be undertaken by trained personnel. Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.



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6.2 Major/Minor Spills: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly. Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Section 7. Handling and Storage

7.1 Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

7.2 Storage: Store as directed by product packaging.

7.3 Storage Incompatibility: Not Known

Section 8. Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits (OEL):

Components	Type	Value
Fluconazole (CAS 86386-73-4) Pfizer OEL TWA-8 Hr	8 HR TWA	500 $\mu\text{g}/\text{m}^3$

8.2 Exposure controls:

Appropriate engineering controls



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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. Keep airborne contamination levels below the exposure limits listed above in this section.

Individual protection measures, such as personal protective equipment

General information: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Eye/face protection: Wear safety glasses or goggles if eye contact is possible.

Skin protection: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Hand protection: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: 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.

Section 9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	:	Tablet
Appearance	:	Tablet
Colour	:	Pink
pH Value	:	Not Known
Vapour Pressure	:	Not Known
Vapour Density	:	Not Known
Evaporation Rate	:	Not Known
<i>Other information</i>		
Flash point	:	Not Known



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Molecular Weight	:	Not Known
Melting point/range	:	Not Known
Boiling point/boiling range	:	Not Known
Density	:	Not Known
Viscosity	:	Not Known
Water solubility	:	Not Known
Solubility in other solvents	:	Not Known
Minimum ignition energy (MIE)	:	Not Known
Minimum ignition temperature (MIT)	:	Not Known
Layer ignition temperature (LIT)	:	Not Known
Flammability/explosivity	:	Not Known
Reactivity/exotherms	:	Not Known
Electrostatic nature	:	Not Known
Highly dusty material	:	Not Known
Any other properties which cause handling or processing difficulties	:	Not Known
Average PSD (particle size distribution (micron))	:	Not Known

9.2 Other Information: Not Known

Section 10. Stability and Reactivity

10.1 Reactivity: Not Known

10.2 Chemical stability: Stable under normal conditions of use.



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10.3 Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

10.4 Incompatibilities with Other Materials: As a precautionary measure, keep away from strong oxidizers

10.5 Hazardous Decomposition Products: Not Known

10.6 Hazardous Polymerization: Not Known

Section 11. Toxicological Information

11.1 Information on toxicological effects

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include skin rash, headache, nausea, and abdominal pain. 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.

Fluconazole (CAS 86386-73-4)

Rat (F) Oral LD50 1575 mg/kg

Rat (M) Oral LD50 1325mg/kg

Mouse Oral LD50 1410mg/kg

Mouse (M) Oral LD50 1520mg/kg

Dog Intravenous LD50 > 100mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.



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Section 12. Ecological Information

12.1 Toxicity:

Fluconazole

Daphnia magna (Water Flea) LC50 48 Hours 35 mg/L

Pimephales promelas (Fathead Minnow) LC50 > 50 mg/L

Cyprinodon variegatus (Sheepshead Minnow) LC50 > 50 mg/

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

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.

12.2 Persistence and degradability: Not Known

12.3 Bioaccumulative potential:

Fluconazole Predicted Log P 5.0

12.4 Mobility in soil: Not Known

12.5 Other: Not Known.

Section 13. Disposal Considerations

13.1 Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.



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Section 14. Transport Information

14. 1 Special precautions for user:

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Fluconazole

EU EINECS/ELINCS List 271-524-7

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

Standard for the Uniform Scheduling

Schedule 3

for Drugs and Poisons:

Schedule 4

EU EINECS/ELINCS List

Not Listed

REACH - Annex XVII - Restrictions on Certain Dangerous Substances:

Use restricted. See item 9[f]. powder

EU EINECS/ELINCS List 232-674-9



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Section 16. Additional Information

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Reproductive toxicity-Cat.1B; H360D - May damage the unborn child

Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children

Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life

Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

Toxic to Reproduction: Category 2

Xn - Harmful

R22 - Harmful if swallowed.

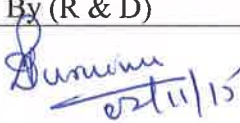
R61 - May cause harm to the unborn child.

R64 - May cause harm to breastfed babies.

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Disclaimer:

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Compiled By (R & D)	Approved by (EHS Head)
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Signature /Date	Signature /Date