



MATERIAL SAFETY DATA SHEET

Product Name: Fluconazole 0.2% in 5.6% Dextrose Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address Hospira, Inc.
275 North Field Drive
Lake Forest, Illinois 60045
USA

Emergency Telephone Hospira, Inc. CHEMTREC: 800 424-9300
224 212-2055

Product Name Fluconazole 0.2% in 5.6% Dextrose Injection

Synonyms None

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Fluconazole
Chemical Formula C₁₃H₁₂F₂N₆O

| Component | Approximate Percent by Weight | CAS Number | RTECS Number |
|-------------|-------------------------------|------------|--------------|
| Fluconazole | 0.2 | 12125-02-9 | P4550000 |
| Dextrose | 5.6 | 50-99-7 | LZ660000 |
| Water | 94 | 7732-18-5 | ZC0110000 |

3. HAZARD INFORMATION

Emergency Overview In clinical use, this material is used to treat yeast infections. Target organs include the liver, hormonal system, nervous system, and the fetus.

Occupational Exposure Potential Information on the absorption of this compound via ingestion, inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact with solution.

Signs and Symptoms None known from occupational exposure. Clinical data suggests the following: abnormal liver function. Clinical overdose may result in hallucinations and/or psychiatric changes.

Medical Conditions Aggravated by Exposure Data suggest any preexisting ailments in the following organs: liver, central nervous system, and endocrine system. Pregnancy.

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5. FIRST AID MEASURES

| | |
|----------------------|---|
| Eye Contact: | Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. |
| Skin Contact: | Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. |
| Inhalation: | Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary. |
| Ingestion: | Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary. |

5. FIRE FIGHTING MEASURES

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| Flammability: | Non-flammable. |
| Fire & Explosion Hazard: | None |
| Extinguishing Media: | Use extinguishing media appropriate for the underlying cause of fire. |
| Special Fire Fighting Procedures | No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus. |

6. ACCIDENTAL RELEASE MEASURES

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| Spill Cleanup and Disposal | Absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations. |
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7. HANDLING AND STORAGE

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|----------------------------|---|
| Handling | No special handling required. |
| Storage | No special storage required for hazard control. For product protection store at controlled room temperature of 15-30°C (59-86°F). |
| Special Precautions | Protect from freezing and extreme heat. |

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

| Component | Exposure limits | | |
|-------------|---------------------------|--|----------------------|
| | OSHA-PEL | ACGIH-TLV | Hospira EEL |
| Fluconazole | 8 hr TWA: Not Established | 8 hr TWA: Not Established STEL: Not Established | 8 hr TWA: 200 mcg/m3 |

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
EEL: Employee Exposure Limit.
TWA: 8 hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.

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|-------------------------------|---|
| Respiratory Protection | Respiratory protection is not needed during normal product use. |
| Skin Protection | If solution contact with unprotected skin is likely, use of impervious gloves is a prudent practice. |
| Eye Protection | Eye protection is not required during expected product use conditions but may be warranted should a splash potential exist. |
| Engineering Controls | Engineering controls are not needed during normal product use conditions. |

9. PHYSICAL/CHEMICAL PROPERTIES

| | |
|----------------------------------|-------------------------------------|
| Appearance/Physical State | Clear solution |
| Odor | None |
| Boiling Point | Not Determined |
| Freezing Point | Not Determined |
| Vapor Pressure | Not Determined |
| Vapor Density (Air=1) | Not Applicable |
| Evaporation Rate | Not Applicable |
| Bulk Density | Not Applicable |
| Specific Gravity | Not Determined |
| Solubility | Soluble in water, methanol, ethanol |
| pH | 3.5 – 6.5 |

10. STABILITY AND REACTIVITY

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|---|---|
| Chemical Stability | Stable under standard use and storage conditions. |
| Incompatibilities | Oxidizing agents |
| Hazardous Decomposition Products | Oxides of nitrogen, carbon and fluorine. |
| Hazardous Polymerization | None |

11. TOXICOLOGICAL INFORMATION:

Toxicity

| Ingredient(s) | Percent | Test Type | Value | Units | Species |
|---------------|---------|-----------|----------------|-------|--------------|
| Fluconazole | 100 | LD50 | 1,271 1,408 | mg/kg | Rats Mice |

LD50 is the dosage producing 50% mortality.
Product contains less than 0.2% Fluconazole.

| | |
|-----------------------------|---|
| Mutagenicity | Negative in the Ames test. Negative in the mouse lymphoma assay. Negative in the micronucleus test. Negative in the chromosomal aberration assay. |
| Target Organ Effects | Target organs include the liver, hormonal system, nervous system, and the fetus. |

12. ECOLOGICAL INFORMATION:

| | |
|-------------------------|-----------------|
| Aquatic Toxicity | Not determined. |
|-------------------------|-----------------|

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13. DISPOSAL CONSIDERATIONS:

Waste Disposal Disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal Dispose of container and unused contents in accordance with federal, state, and local regulations.

14. TRANSPORTATION INFORMATION

DOT Not Regulated

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status Not Regulated

CERCLA Status Not Regulated

SARA Status Not Regulated

RCRA Status Not Regulated

PROP 65 (Calif.) Not Regulated

Notes: TSCA Toxic Substance Control Act
CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
SARA Superfund Amendments and Reauthorization Act
RCRA US EPA, Resource Conservation and Recovery Act
Prop 65, California Proposition 65

16. OTHER INFORMATION:

MSDS Coordinator Global Occupational Toxicology

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