

MATERIAL SAFETY DATA SHEET

Product Name: Fluconazole 0.2% in 0.9% Sodium Chloride Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name Hospira, Inc.

And Address 275 North Field Drive

Lake Forest, Illinois 60045

USA

Emergency Telephone CHEMTREC: 800 424-9300

Hospira, Inc. 224 212-2055

Product Name Fluconazole 0.2% in 0.9% Sodium Chloride Injection

Synonyms None

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Fluconazole **Chemical Formula** $C_{13}H_{12}F_2N_6O$

Component	Approximate Percent by Weight	CAS Number	RTECS Number	
Fluconazole	0.2	12125-02-9	P4550000	
Sodium Chloride	0.9	7647-14-5	VZ4725000	
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 Information on the absorption of this compound via ingestion,

Potential

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 Data suggest any preexisting ailments in the following organs: liver, central

Aggravated by Exposure 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

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

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.

7. HANDLING AND STORAGE

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

_	Exposure limits			
Component	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 Clear solution

State

Odor None

Boiling Point
Not Determined
Freezing Point
Not Determined
Vapor Pressure
Not Determined
Vapor Density (Air=1)
Not Applicable
Bulk Density
Not Applicable
Specific Gravity
Not Determined

Solubility Soluble in water, methanol, ethanol

pH 4.0 - 8.0

10. STABILITY AND REACTIVITY

Chemical Stability Stable under standard use and storage conditions.

Incompatibilities Oxidizing agents

Hazardous Oxides of nitrogen, carbon and fluorine.

Decomposition Products

Hazardous None

Polymerization

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 approximately 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 Dispose of container and unused contents in accordance with federal, state,

and Disposal and local regulations.

14. TRANSPORTATION INFORMATION

DOT Not Regulated

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status

CERCLA Status

Not Regulated
Not Regulated
Not Regulated
RCRA Status

Not Regulated
Not Regulated
Not Regulated
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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