Product Name: Fluconazole Injection Solution

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

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

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency
224-212-2000

Product Name
Fluconazole Injection Solution

Synonyms
2,4-difluoro-α,α1-bis(1H-1,2,4-triazol-1-ylmethyl) benzyl alcohol

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Fluconazole

Chemical Formula
C\textsubscript{13}H\textsubscript{12}F\textsubscript{2}N\textsubscript{6}O

Preparation
Non-hazardous ingredients include Water for Injection and may include dextrose.
Hazardous ingredients present at

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluconazole</td>
<td>0.2</td>
<td>86386-73-4</td>
<td>XZ4810000</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluconazole</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Fluconazole Injection Solution is a solution containing fluconazole, a triazole antifungal agent. Clinically, it is used for superficial mucosal candidiasis and/or for skin or systemic fungal infections. In the workplace, fluconazole injection solution should be considered potentially irritating to the skin, eyes and respiratory tract. Based on clinical use, possible target organs include the central nervous system, gastrointestinal system, liver and skin.

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
In the workplace, this product should be considered potentially irritating to the skin, eyes, and respiratory tract. In clinical use, adverse effects include nausea, headache, dizziness, skin rash, vomiting, abdominal pain, and diarrhea. Elevated hepatic enzyme levels may occur. There have been rare cases of serious hepatic reactions during treatment with fluconazole. Anaphylaxis and angioedema have also been reported rarely.
Product Name: Fluconazole Injection Solution

Medical Conditions

Aggravated by Exposure

Hypersensitivity to fluconazole or to other ingredients in this product. Pre-existing central nervous system, gastrointestinal, liver, or skin ailments.

4. 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

None anticipated for this aqueous product.

Fire & Explosion Hazard

None anticipated for this aqueous product.

Extinguishing media

As with any fire, use extinguishing media appropriate for primary 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

Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling

No special handling required under conditions of normal product use.

Storage

No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions

No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mg/m3</td>
<td>ppm</td>
</tr>
<tr>
<td>Fluconazole</td>
<td>Not Applicable</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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Product Name: Fluconazole Injection Solution

Respiratory protection
Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection
If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection
Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls
Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State
Liquid, Fluconazole injection is an iso-osmotic, sterile, nonpyrogenic solution of fluconazole in a sodium chloride or dextrose diluents.

Color
NA

Odor
NA

Odor Threshold:
NA

pH:
The pH ranges from 4.0 to 8.0 in the sodium chloride diluents and from 3.5 to 6.5 in the dextrose diluent

Melting point/Freezing point:
NA

Initial Boiling Point/Boiling Point Range:
NA

Evaporation Rate:
NA

Flammability (solid, gas):
NA

Upper/Lower Flammability or Explosive Limits:
NA

Vapor Pressure:
NA

Vapor Density:
NA

Specific Gravity:
NA

Solubility:
Fluconazole is a white crystalline solid which is slightly soluble in water and saline.

Partition coefficient: n-octanol/water:
NA

Auto-ignition temperature:
NA

Decomposition temperature:
NA

10. STABILITY AND REACTIVITY

Reactivity
Not determined

Chemical Stability
Stable under standard use and storage conditions

Hazardous Reactions
Not determined
**Product Name: Fluconazole Injection Solution**

**Conditions to avoid**
Not determined

**Incompatibilities**
Not determined

**Hazardous decomposition products**
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen fluoride.

**Hazardous Polymerization**
Not anticipated to occur with this product.

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**11. TOXICOLOGICAL INFORMATION**

**Acute Toxicity**
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
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<tbody>
<tr>
<td>Fluconazole</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>1271</td>
<td>mg/kg;</td>
<td>Rat</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1408</td>
<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;300</td>
<td>mg/kg</td>
<td>Dog</td>
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<tr>
<td>Fluconazole</td>
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<td>LD50</td>
<td>Intravenous</td>
<td>&gt;200</td>
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<td>Rat</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;100</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
</tbody>
</table>

**Aspiration Hazard**
None anticipated from normal handling of this product.

**Dermal Irritation/Corrosion**
None anticipated from normal handling of this product. Inadvertent contact of this product with the skin may produce skin irritation.

**Ocular Irritation/Corrosion**
None anticipated from normal handling of this product. Inadvertent contact of this product with the eyes may produce eye irritation.

**Dermal or Respiratory Sensitization**
None anticipated from normal handling of this product. Rarely, hypersensitivity reactions, including anaphylaxis, have been reported during the clinical use of this product.

**Reproductive Effects**
Fluconazole did not affect the fertility of male or female rats treated orally with daily dosages of 5, 10 or 20 mg/kg or with parenteral dosages of 5, 25 or 75 mg/kg, although the onset of parturition was slightly delayed after an oral dosage of 20 mg/kg. In an intravenous perinatal study in rats at dosages of 5, 20 and 40 mg/kg, dystocia and prolongation of parturition were observed in a few dams at 20 mg/kg and 40 mg/kg, but not at 5 mg/kg. A slight increase in the number of still-born pups and decrease of neonatal survival were also noted at these dosages. These effects on parturition are consistent with the estrogen-lowering effect produced by high doses of fluconazole. A similar hormone change has not been noted in women treated with fluconazole. In two studies, fluconazole was given orally to pregnant rabbits during organogenesis at dosages of 5, 10 and 20 mg/kg or at 5, 25 and 75 mg/kg, respectively. Maternal weight gain was impaired at all dose levels, and abortions occurred at 75 mg/kg; no adverse fetal effects were detected. In several studies in which pregnant rats were treated orally with fluconazole during organogenesis at various dosages, maternal weight gain was impaired and placental weights were increased at 25 mg/kg. There were no fetal effects at 5 or 10 mg/kg; increases in fetal anatomical variants (super-numerary ribs, renal pelvis dilation) and delays in ossification were observed at 25 and 50 mg/kg and higher doses. At dosages ranging from 80 mg/kg to 320 mg/kg.
embryolethality in rats was increased and fetal abnormalities included wavy ribs, cleft palate and abnormal cranio-facial ossification. These effects are consistent with the inhibition of estrogen synthesis in rats and may be a result of known effects of lowered estrogen on pregnancy, organogenesis and parturition.

**Mutagenicity**

Fluconazole, with or without metabolic activation, was negative in tests for mutagenicity in 4 strains of S. typhimurium, and in the mouse lymphoma L5178Y system. Cytogenetic studies in vivo (murine bone marrow cells, following oral administration of fluconazole) and in vitro (human lymphocytes exposed to fluconazole at 1000 mcg/mL) showed no evidence of chromosomal mutations.

**Carcinogenicity**

Fluconazole showed no evidence of carcinogenic potential in mice and rats treated orally for 24 months at dosages of 2.5, 5 or 10 mg/kg/day. Male rats treated with 5 and 10 mg/kg/day had an increased incidence of hepatocellular adenomas.

**Target Organ Effects**

This material should be considered potentially irritating to the skin, eyes and respiratory tract. Based on clinical use, possible target organs include the central nervous system, gastrointestinal system, liver and skin.

### 12. ECOLOGICAL INFORMATION

**Aquatic Toxicity**

Not determined for product

**Persistence/Biodegradability**

Not determined for product

**Bioaccumulation**

Not determined for product

**Mobility in Soil**

Not determined for product

### 13. DISPOSAL CONSIDERATIONS

**Waste Disposal**

All waste materials must be properly characterized. Further, 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 STATUS**

Not regulated

**ICAO/IATA STATUS:**

Not regulated

**IMDG STATUS:**

Not regulated

### 15. REGULATORY INFORMATION

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Product Name: Fluconazole Injection Solution

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluconazole</td>
<td>Exempt</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**RCRA Status**
Not Listed

**GHS Classification**
*Where medicinal products are not exempt, the recommended GHS workplace classification is as follows:

**U.S. OSHA Classification**
- Target Organ Toxin
- Possible Irritant

**Hazard Class**
Not Applicable

**Hazard Category**
Not Applicable

**Signal Word**
Not Applicable

**Symbol**
Not Applicable

**Prevention**
P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

**Hazard Statement**
Not Applicable

**Response:**
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

**EU Classification***
*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Fluconazole.

**Classification(s):**
Not Applicable

**Symbol:**
Not Applicable

**Indication of Danger:**
Not Applicable

**Risk Phrases:**
Not Applicable

**Safety Phrases:**
- S23 - Do not breathe vapor.
- S24 - Avoid contact with skin.
- S25 - Avoid contact with eyes.
- S37/39 - Wear suitable gloves and eye/face protection.
### 16. OTHER INFORMATION:

<table>
<thead>
<tr>
<th>Notes:</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>ACGIH TLV</td>
<td>American Conference of Governmental Industrial Hygienists – Threshold Limit Value</td>
</tr>
<tr>
<td>CAS</td>
<td>Chemical Abstracts Service Number</td>
</tr>
<tr>
<td>CERCLA</td>
<td>US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act</td>
</tr>
<tr>
<td>DOT</td>
<td>US Department of Transportation Regulations</td>
</tr>
<tr>
<td>EEL</td>
<td>Employee Exposure Limit</td>
</tr>
<tr>
<td>IATA</td>
<td>International Air Transport Association</td>
</tr>
<tr>
<td>LD50</td>
<td>Dosage producing 50% mortality</td>
</tr>
<tr>
<td>NA</td>
<td>Not applicable/Not available</td>
</tr>
<tr>
<td>NE</td>
<td>Not established</td>
</tr>
<tr>
<td>NIOSH</td>
<td>National Institute for Occupational Safety and Health</td>
</tr>
<tr>
<td>OSHA PEL</td>
<td>US Occupational Safety and Health Administration – Permissible Exposure Limit</td>
</tr>
<tr>
<td>Prop 65</td>
<td>California Proposition 65</td>
</tr>
<tr>
<td>RCRA</td>
<td>US EPA, Resource Conservation and Recovery Act</td>
</tr>
<tr>
<td>RTECS</td>
<td>Registry of Toxic Effects of Chemical Substances</td>
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<tr>
<td>SARA</td>
<td>Superfund Amendments and Reauthorization Act</td>
</tr>
<tr>
<td>STEL</td>
<td>15-minute Short Term Exposure Limit</td>
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<tr>
<td>TSCA</td>
<td>Toxic Substance Control Act</td>
</tr>
<tr>
<td>TWA</td>
<td>8-hour Time Weighted Average</td>
</tr>
</tbody>
</table>

**MSDS Coordinator:** Hospira GEHS  
**Date Prepared:** Fri. 05/19/2011  
**Obsolete Date:**

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