## 1. PRODUCT IDENTIFICATION

<table>
<thead>
<tr>
<th>Common/Trade Name:</th>
<th>Fluconazole Injection USP</th>
</tr>
</thead>
<tbody>
<tr>
<td>How Supplied:</td>
<td>Strength: 2 mg/mL</td>
</tr>
<tr>
<td>Chemical Class</td>
<td>Synthetic Triazole antifungal agent</td>
</tr>
<tr>
<td>Chemical Name</td>
<td>2,4-difluoro-α,α1 -bis (1H-1,2,4-triazol-1-ylmethyl)benzyl alcohol</td>
</tr>
<tr>
<td>Formula</td>
<td>C_{13}H_{12}F_{2}N_{5}O</td>
</tr>
<tr>
<td>Product Type</td>
<td>Prescription Drug</td>
</tr>
<tr>
<td>Product Use</td>
<td>Pharmaceutical, Injectable</td>
</tr>
<tr>
<td>Distributor Name</td>
<td>CLARIS LIFESCIENCES INC.</td>
</tr>
<tr>
<td>Distributor Address</td>
<td>CHACARWADI-VASANA, AHMEDABAD - 382 213, INDIA.</td>
</tr>
<tr>
<td>Manufacturer's Name</td>
<td>CLARIS INJECTABLES LIMITED</td>
</tr>
<tr>
<td>Address</td>
<td>CHACARWADI-VASANA, AHMEDABAD - 382 213, INDIA.</td>
</tr>
<tr>
<td>Date Prepared</td>
<td>04th February 2015</td>
</tr>
</tbody>
</table>
2. COMPOSITION INFORMATION

<table>
<thead>
<tr>
<th>Component</th>
<th>Content mg/ml</th>
<th>Content mg/ml</th>
<th>CAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluconazole</td>
<td>2.0</td>
<td>2.0</td>
<td>[86386-73-4]</td>
</tr>
<tr>
<td>Dextrose Monohydrate</td>
<td>----</td>
<td>56.0</td>
<td>[14431-43-7]</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>9.0</td>
<td>----</td>
<td>[7647-14-5]</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>q.s.to 1.0 mL</td>
<td>q.s.to 1.0 mL</td>
<td>[7732-18-5]</td>
</tr>
</tbody>
</table>

3. HAZARDOUS IDENTIFICATION

Emergency Overview
Fluconazole Injection 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.

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 firefighting 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 for hazard control 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 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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION INFORMATION

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m³</th>
<th>ppm</th>
<th>µg/m³</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluconazole</td>
<td>Not Applicable</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>None</td>
</tr>
</tbody>
</table>

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.
9.0 PHYSICAL AND CHEMICAL DATA

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Clear and colorless</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>NA</td>
</tr>
<tr>
<td>pH</td>
<td>4.0-8.0 with NS, 3.5-6.5 with Dextrose</td>
</tr>
<tr>
<td>Melting point/Freezing point</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility</td>
<td>Slightly soluble in water and saline</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>NA</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>NA</td>
</tr>
</tbody>
</table>

9.0 STABILITY AND REACTIVITY

Reactivity: Not determined.
Chemical Stability: Stable under standard use and storage conditions.
Hazardous Reactions: Not determined.
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 sulfur oxides (SOx).
Hazardous Polymerization: Not anticipated to occur with this product.

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>
</tr>
</thead>
<tbody>
<tr>
<td>Fluconazole</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>1271</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1408</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;300</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
<tr>
<td>Fluconazole</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>&gt;200</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;200</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;100</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
</tbody>
</table>
FLUCONAZOLE INJECTION USP

Aspiration Hazard : None anticipated from normal handling of this product.
Dermal Irritation/Corrosion : None anticipated from normal handling of this product. However, inadvertent contact of this product with the skin may produce skin irritation.
Ocular Irritation/Corrosion : None anticipated from normal handling of this product. However, 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 (supernumerary 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. TRANSPORT INFORMATION

ADR/ADG/ DOT STATUS : Not regulated
IMDG STATUS : Not regulated
ICAO/IATA STATUS : Not regulated
Transport Comments : None

15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCRA Status</td>
<td>Not Listed</td>
</tr>
<tr>
<td>U.S. OSHA Classification</td>
<td>Target Organ Toxin Possible Reproductive Toxin Possible Irritant</td>
</tr>
<tr>
<td>GHS Classification</td>
<td>*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:</td>
</tr>
<tr>
<td>Hazard Class</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Hazard Category</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Signal Word</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Symbol</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Prevention</td>
<td>P260 - Do not breathe dust/fume/gas/mist/vapors/spray.</td>
</tr>
<tr>
<td>Hazard Statement</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Response:</td>
<td>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.</td>
</tr>
</tbody>
</table>

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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

<table>
<thead>
<tr>
<th>Classification(s):</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symbol:</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Indication of Danger:</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Risk Phrases:</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Safety Phrases:</td>
<td>S23 - Do not breathe vapor.</td>
</tr>
<tr>
<td></td>
<td>S24 - Avoid contact with skin.</td>
</tr>
<tr>
<td></td>
<td>S25 - Avoid contact with eyes.</td>
</tr>
<tr>
<td></td>
<td>S37/39 - Wear suitable gloves and eye/face protection.</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

<table>
<thead>
<tr>
<th>ACGIH TLV</th>
<th>American Conference of Governmental Industrial Hygienists – Threshold Limit Value</th>
</tr>
</thead>
<tbody>
<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>RCRRA</td>
<td>US EPA, Resource Conservation and Recovery Act</td>
</tr>
<tr>
<td>RTECS</td>
<td>Registry of Toxic Effects of Chemical Substances</td>
</tr>
<tr>
<td>SARA</td>
<td>Superfund Amendments and Reauthorization Act</td>
</tr>
<tr>
<td>STEL</td>
<td>15-minute Short Term Exposure Limit</td>
</tr>
<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>

The above information is believed to be correct based on our present knowledge but does not purport to be complete. The product is for research use only and for trained personnel. The burden of safe use of this material rests entirely with the user.