1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Material Name: Fluconazole Solution for Infusion, IV

| Trade Name: | DIFLUCAN®, FUNGUSTATIN; TRIFLUCAN; ZOLTEC |
| Chemical Family: | Synthetic class of compounds known as bis-triazoles |
| Intended Use: | Pharmaceutical product used as antifungal agent |

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless liquid packaged in glass or in Viaflex® Plus plastic containers

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

- **Short Term:** May cause irritation (based on components).
- **Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on liver and the developing fetus.

Known Clinical Effects: Clinical use of this drug has caused headache, skin rash, vomiting, abdominal pain, and diarrhea. Fluconazole is found in human breast milk at concentrations similar to plasma. Therefore, nursing mothers should limit exposure. 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. Rare cases of serious liver damage and allergic reactions have been reported.

EU Indication of danger: Not classified


3. COMPOSITION/INFORMATION ON INGREDIENTS

Note: For a more detailed discussion of potential health hazards and toxicity see Section 11. This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluconazole</td>
<td>86386-73-4</td>
<td>Not listed</td>
<td>Xn;R22</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr.Cat.2;R61</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R64</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R52/53</td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td></td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

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

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

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.

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

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

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:
Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling:
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8).

Storage Conditions:
Store in properly labeled containers. Protect from freezing.

Storage Temperature:
Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Fluconazole
Pfizer OEL TWA-8 Hr: 500µg/m³

Sodium chloride
Latvia OEL - TWA = 5 mg/m³ TWA
Lithuania OEL - TWA = 5 mg/m³ IPRV

Analytical Method:
Analytical method available for Fluconazole. Contact Pfizer Inc for further information.

Engineering Controls:
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.

Personal Protective Equipment:

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

Eyes:
Wear safety glasses or goggles if eye contact is possible.

Skin:
Impervious protective clothing is 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.

9. PHYSICAL AND CHEMICAL PROPERTIES:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>Odorless</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>pH:</td>
<td>4 - 8; 3.5 - 6.5 (sodium chloride solution); (dextrose solution)</td>
</tr>
</tbody>
</table>

Color: Colorless
Molecular Formula: Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: Protect from freezing

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Polymerization: Will not occur
11. TOXICOLOGICAL INFORMATION

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

Acute Toxicity: (Species, Route, End Point, Dose)

Sodium chloride
Mouse Oral LD50 4000 mg/kg

Fluconazole
Mouse Oral LD50 1410 mg/kg
Mouse (M) Oral LD50 1520 mg/kg
Dog Intravenous LD50 > 100 mg/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.

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium chloride
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Sodium chloride
10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

Fluconazole
3 Month(s) Rat Oral 5 mg/kg/day NOAEL Liver
6 Month(s) Dog Oral 7.5 mg/kg/day NOAEL Liver
12 Month(s) Rat Oral 10 mg/kg/day LOAEL Liver
12 Month(s) Dog Oral 2.5 mg/kg/day NOAEL Liver

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Fluconazole
Reproductive & Fertility Rat Oral 20 mg/kg/day NOAEL Negative
Embryo / Fetal Development Rabbit Oral 20 mg/kg/day NOAEL Maternal Toxicity, Not Teratogenic
Embryo / Fetal Development Rat Oral 5 mg/kg/day NOAEL Fetotoxicity, Maternal Toxicity
Embryo / Fetal Development Rat Oral 80 mg/kg/day LOAEL Maternal Toxicity, Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Fluconazole
In Vitro Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative
In Vivo Cytogenetics Mouse Bone Marrow Negative
In Vitro Cytogenetics Human Lymphocytes Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))
11. TOXICOLOGICAL INFORMATION

Fluconazole
24 Month(s) Rat Female Oral 10 mg/kg/day NOAEL Not carcinogenic
24 Month(s) Rat Female Oral 5 mg/kg/day LOEL Benign tumors, Liver
24 Month(s) Mouse Oral 10 mg/kg/day NOEL Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Based on the concentration of the active ingredient in the formulation, no harmful effects to aquatic organisms are expected.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Fluconazole
Daphnia Magna LC50 48 Hours 35 mg/L
Fathead minnow LC50 > 50 mg/L
Sheepshead Minnow LC50 > 50 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

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

EU Indication of danger: Not classified

OSHA Label: Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class: Class D, Division 2, Subdivision A

Fluconazole
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 3
- Schedule 4

Sodium chloride
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 231-598-3

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
- Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet