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

Material Name: Diflucan® (fluconazole) tablets

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pfizer Pharmaceuticals Group</td>
</tr>
<tr>
<td></td>
<td>235 East 42nd Street</td>
</tr>
<tr>
<td></td>
<td>New York, New York 10017</td>
</tr>
<tr>
<td></td>
<td>1-212-573-2222</td>
</tr>
</tbody>
</table>

| Chemical Family: | Synthetic class of compounds known as bis-triazoles  |
| Intended Use:    | Pharmaceutical product used as antifungal agent    |

2. HAZARDS IDENTIFICATION

| Appearance       | Pink tablets                                     |
| Signal Word:     | WARNING                                          |
| Statement of Hazard: | Harmful if swallowed.   |
|                  | Suspected of damaging the unborn child.          |
|                  | May cause harm to breastfed babies.             |

| Long Term:       | Repeat-dose studies in animals have shown a potential to cause adverse effects on liver. |
| Known Clinical Effects: | Adverse effects most commonly reported in clinical use include skin rash, headache, nausea, and abdominal pain. Rare cases of serious liver damage and allergic reactions have been reported. 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. Fluconazole is found in human breast milk at concentrations similar to plasma. Therefore, nursing mothers should limit exposure. |

| EU Indication of danger: | Harmful |
| EU Hazard Symbols:       | T       |

| EU Risk Phrases:         | 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. |
2. HAZARDS IDENTIFICATION


Note: 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>Hazardous 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>45.5</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>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Calcium phosphate dibasic, anhydrous</td>
<td>7757-93-9</td>
<td>231-826-1</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>FD &amp; C Red No. 40, aluminum lake</td>
<td>68583-95-9</td>
<td>271-524-7</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
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: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8).

Storage Conditions: 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

**Microcrystalline cellulose**

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA Listed
Estonia OEL - TWA Listed
France OEL - TWA Listed
Ireland OEL - TWA = 10 mg/m³ TWA
Latvia OEL - TWA Listed
OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
Portugal OEL - TWA Listed
Romania OEL - TWA Listed
Spain OEL - TWA Listed

**Calcium phosphate dibasic, anhydrous**

Latvia OEL - TWA Listed

**Magnesium stearate**

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA Listed
Ireland OEL - TWAs = 10 mg/m³ TWA except lead stearate
Lithuania OEL - TWA Listed
Portugal OEL - TWA Listed
Spain OEL - TWA Listed
Sweden OEL - TWAs = 5 mg/m³ LLV

The exposure limit(s) listed for solid components are only relevant if dust may be generated.


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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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:

Physical State: Tablet
Odor: Odorless
Molecular Weight: Mixture
Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.
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)

Povidone
Rat Oral LD50 100 g/kg

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000mg/kg

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000mg/m³

Fluconazole
Rat (F) Oral LD50 1575 mg/kg
Rat (M) Oral LD50 1325mg/kg
Mouse Oral LD50 1410mg/kg
Mouse (M) Oral LD50 1520mg/kg
Dog Intravenous LD50 > 100mg/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)

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

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

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 & Developmental Toxicity: (Study Type, 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
11. TOXICOLOGICAL INFORMATION

In Vivo Cytogenetics
Mouse Bone Marrow  Negative

In Vitro Cytogenetics
Human Lymphocytes  Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

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.

Povidone
IARC:  Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:  The environmental characteristics of this mixture have not been fully evaluated.  Harmful effects to aquatic organisms could occur.  Releases to the environment should be avoided.

Bioaccumulation and Toxicity:  See aquatic toxicity data, below.

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

Aquatic Toxicity Comments:  A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility.  Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.
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. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

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

EU Symbol: T
EU Indication of danger: Harmful
Toxic to reproduction, Category 2

EU Risk Phrases:
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.

EU Safety Phrases:
S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.
S57 - Use appropriate containment to avoid environmental contamination.

OSHA Label:
WARNING
Harmful if swallowed.
Suspected of damaging the unborn child.
May cause harm to breastfed babies.

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

Microcrystalline cellulose
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present
EU EINECS/ELINCS List 232-674-9

Calcium phosphate dibasic, anhydrous
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 231-826-1

Povidone
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present
15. REGULATORY INFORMATION

Crocarmellose sodium
  Australia (AICS): Present

FD & C Red No. 40, aluminum lake
  Inventory - United States TSCA - Sect. 8(b): Present
  Australia (AICS): Present
  EU EINECS/ELINCS List: 271-524-7

Magnesium stearate
  Inventory - United States TSCA - Sect. 8(b): Present
  Australia (AICS): Present
  EU EINECS/ELINCS List: 209-150-3

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. Safety data sheets for individual ingredients.

Reasons for Revision:
Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard Identification. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting 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.

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet