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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Material Name: Fluconazole Powder for Oral Suspension

Trade Name: DIFLUCAN
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antifungal agent

2. HAZARDS IDENTIFICATION

Appearance: White powder
Signal Word: WARNING

Statement of Hazard:
Suspected of damaging the unborn child.
May cause harm to breastfed babies.

Additional Hazard Information:
Short Term: Active ingredient may be harmful if swallowed. May cause eye irritation (based on components).
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: Toxic to reproduction, Category 2

EU Hazard Symbols:

EU Risk Phrases:
R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.

Australian Hazard Classification (NOHSC):
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>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 Repr.Cat.2;R61 R64 R52/53</td>
<td>6.6</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Citric acid, anhydrous</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4 EEC No. 418-260-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium citrate, dihydrate</td>
<td>6132-04-3</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>532-32-1</td>
<td>208-534-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Xanthan gum</td>
<td>11138-66-2</td>
<td>234-394-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Natural orange flavor</td>
<td>NOT ASSIGNED</td>
<td>Not listed</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.
### MATERIAL SAFETY DATA SHEET

**Material Name:** Fluconazole Powder for Oral Suspension  
**Revision date:** 16-Sep-2008  
**Version:** 3.5

<table>
<thead>
<tr>
<th><strong>6. ACCIDENTAL RELEASE MEASURES</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hazardous Combustion Products:</strong> Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds</td>
</tr>
<tr>
<td><strong>Fire Fighting Procedures:</strong> During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.</td>
</tr>
<tr>
<td><strong>Fire / Explosion Hazards:</strong> Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
<tr>
<td><strong>Health and Safety Precautions:</strong> Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.</td>
</tr>
<tr>
<td><strong>Measures for Cleaning / Collecting:</strong> 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.</td>
</tr>
<tr>
<td><strong>Measures for Environmental Protections:</strong> Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.</td>
</tr>
<tr>
<td><strong>Additional Consideration for Large Spills:</strong> Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>7. HANDLING AND STORAGE</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Handling:</strong> Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Wash hands and any exposed skin after removal of PPE.</td>
</tr>
<tr>
<td><strong>Storage Conditions:</strong> Store out of direct sunlight in a well ventilated area at room temperature. Store as directed by product packaging.</td>
</tr>
</tbody>
</table>
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

Sucrose

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

Titanium dioxide

ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA
Australia TWA 10 mg/m³
Austria OEL - MAKs Listed
Belgium OEL - TWA Listed
Bulgaria OEL - TWA Listed
Denmark OEL - TWA Listed
Estonia OEL - TWA Listed
France OEL - TWA Listed
Germany (DFG) - MAK 1.5 mg/m³ MAK
Greece OEL - TWA Listed
Ireland OEL - TWAs Listed
Latvia OEL - TWA Listed
Lithuania OEL - TWA Listed
Netherlands OEL - TWA Listed
OSHA - Final PELS - TWAs: 15 mg/m³ total
Poland OEL - TWA Listed
Portugal OEL - TWA Listed
Romania OEL - TWA Listed
Spain OEL - TWA Listed
Sweden OEL - TWAs Listed

Colloidal silicon dioxide

Australia TWA = 2 mg/m³ TWA
Austria OEL - MAKs Listed
Czech Republic OEL - TWA Listed
Estonia OEL - TWA Listed
Germany - TRGS 900 - TWAs = 4 mg/m³ TWA
Germany (DFG) - MAK = 4 mg/m³ MAK
Ireland OEL - TWAs = 2.4 mg/m³ TWA
= 6 mg/m³ TWA
Latvia OEL - TWA Listed
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

OSHA - Final PELs - Table Z-3 Mineral D: 
(80)/(% SiO2) mg/m³ TWA = 20 mppcf TWA
Slovenia OEL - TWA: Listed

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: Powder
Odor: Oranges (natural flavoring added)
Molecular Weight: Mixture
Color: White
Molecular Formula: 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)

**Sodium benzoate**
- Rat Oral LD50 4,070 mg/kg
- Mouse Oral LD50 1600mg/kg

**Sucrose**
- Rat Oral LD50 29.7 g/kg

**Xanthan gum**
- Rat Oral LD50 > 5000 mg/kg

**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

**Citric acid, anhydrous**
- Rat Oral LD50 3000 mg/kg

**Titanium dioxide**
- Rat Oral LD50 > 7500 mg/kg
- Rat Subcutaneous LD 50 50mg/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)

**Citric acid, anhydrous**
- Eye Irritation Rabbit Severe
- Skin Irritation Rabbit Mild
- No data available No data available

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

**Sodium benzoate**
- 10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood
- 10 Day(s) Mouse Oral 45 g/kg LOAEL Liver Kidney Blood 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 NOAEL 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))
11. TOXICOLOGICAL INFORMATION

Sodium benzoate
Embryo / Fetal Development  Rat  Oral 44 g/kg  LOEL  Developmental toxicity

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))

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:  See below

Colloidal silicon dioxide
IARC:  Group 3 (Not Classifiable)

Titanium dioxide
IARC:  Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION
12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Harmful effects to aquatic organisms could occur. See Aquatic toxicity data of the active ingredient, below:

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluconazole</td>
<td></td>
<td>LC50</td>
<td>48 Hours</td>
<td>35 mg/L</td>
</tr>
<tr>
<td>Daphnia Magna</td>
<td></td>
<td>LC50</td>
<td>48 Hours</td>
<td>35 mg/L</td>
</tr>
<tr>
<td>Fathead minnow</td>
<td></td>
<td>LC50</td>
<td>&gt; 50</td>
<td>mg/L</td>
</tr>
<tr>
<td>Sheepshead Minnow</td>
<td></td>
<td>LC50</td>
<td>&gt; 50</td>
<td>mg/L</td>
</tr>
</tbody>
</table>

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: Toxic to reproduction, Category 2
EU Risk Phrases: R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.
EU Safety Phrases: S22 - Do not breathe dust.
S36 - Wear suitable protective clothing.
S53 - Avoid exposure - obtain special instructions before use.
### 15. REGULATORY INFORMATION

OSHA Label:
15. REGULATORY INFORMATION

WARNING
15. REGULATORY INFORMATION

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

<table>
<thead>
<tr>
<th>Standard for the Uniform Scheduling</th>
<th>Schedule 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>for Drugs and Poisons:</td>
<td>Schedule 4</td>
</tr>
</tbody>
</table>

Sucrose

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Present</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
<td>Present</td>
</tr>
</tbody>
</table>

| EU EINECS/ELINCS List                     | 200-334-9 |

Sodium citrate, dihydrate

| Australia (AICS):                         | Present |
| Standard for the Uniform Scheduling       | Schedule 5 |
| for Drugs and Poisons:                    | Schedule 6 |

Citric acid, anhydrous

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
<td>Listed</td>
</tr>
</tbody>
</table>

| EU EINECS/ELINCS List                      | 201-069-1 |

Sodium benzoate

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Present</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
</tbody>
</table>

| EU EINECS/ELINCS List                      | 208-534-8 |

Titanium dioxide

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
<td>Listed</td>
</tr>
</tbody>
</table>

| EU EINECS/ELINCS List                      | 236-675-5 |

Colloidal silicon dioxide

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Present</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
</tbody>
</table>

| EU EINECS/ELINCS List                      | 231-545-4 |
| EEC No. 418-260-2                          |         |

Xanthan gum

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>XU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
</tbody>
</table>

| EU EINECS/ELINCS List                      | 234-394-2 |
15. REGULATORY INFORMATION

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.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. 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 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological 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