



# SAFETY DATA SHEET

Revision date: 31-May-2016

Version: 4.1

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Diflucan (fluconazole) tablets

**Trade Name:** DIFLUCAN

**Chemical Family:** Synthetic class of compounds known as bis-triazoles

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product used as antifungal agent

### Details of the Supplier of the Safety Data Sheet

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-800-879-3477

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

**Emergency telephone number:**

**CHEMTREC (24 hours): 1-800-424-9300**

**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Emergency telephone number:**

**International CHEMTREC (24 hours): +1-703-527-3887**

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Acute Oral Toxicity: Category 4

Reproductive Toxicity: Category 1B

Effects on or via lactation

Acute aquatic toxicity: Category 3

Chronic aquatic toxicity: Category 3

### Label Elements

**Signal Word:** Danger

**Hazard Statements:**  
H302 - Harmful if swallowed  
H360D - May damage the unborn child  
H362 - May cause harm to breast-fed children  
H402 - Harmful to aquatic life  
H412 - Harmful to aquatic life with long lasting effects

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**Precautionary Statements:**

- P202 - Do not handle until all safety precautions have been read and understood
- P264 - Wash hands thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P273 - Avoid release to the environment
- P281 - Use personal protective equipment as required
- P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P330 - Rinse mouth
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations



**Other Hazards Note:**

No data available  
 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

**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Fluconazole	86386-73-4	Not Listed	Acute Tox. 4(H302) Repr. 1B (H360D) Lact. (H362) Aquatic Acute 3 (H402) Aquatic Chronic 3 (H412)	45.5
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
FD & C Red No. 40, aluminum lake	68583-95-9	271-524-7	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	*
Calcium phosphate dibasic, anhydrous	7757-93-9	231-826-1	Not Listed	*

**Additional Information:**

\* Proprietary  
 Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.  
 In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of 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.

#### Most Important Symptoms and Effects, Both Acute and Delayed

- 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.
- Medical Conditions Aggravated by Exposure:** None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

### 5. FIRE FIGHTING MEASURES

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

#### Special Hazards Arising from the Substance or Mixture

- Hazardous Combustion Products:** Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds
- Fire / Explosion Hazards:** Not applicable

#### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

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

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

- 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.
- 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.

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### 7. HANDLING AND STORAGE

#### Precautions for Safe 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). Wash thoroughly after handling. 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.  
**Specific end use(s):** Pharmaceutical drug product

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Fluconazole

Pfizer OEL TWA-8 Hr: 500µg/m<sup>3</sup>

#### Calcium phosphate dibasic, anhydrous

Latvia OEL - TWA 10 mg/m<sup>3</sup>

#### Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>

Australia TWA 10 mg/m<sup>3</sup>

Belgium OEL - TWA 10 mg/m<sup>3</sup>

Estonia OEL - TWA 10 mg/m<sup>3</sup>

France OEL - TWA 10 mg/m<sup>3</sup>

Ireland OEL - TWAs 10 mg/m<sup>3</sup>

4 mg/m<sup>3</sup>

Latvia OEL - TWA 2 mg/m<sup>3</sup>

OSHA - Final PELs - TWAs: 15 mg/m<sup>3</sup>

Portugal OEL - TWA 10 mg/m<sup>3</sup>

Romania OEL - TWA 10 mg/m<sup>3</sup>

Russia OEL - TWA 6 mg/m<sup>3</sup>

Spain OEL - TWA 10 mg/m<sup>3</sup>

Switzerland OEL - TWAs 3 mg/m<sup>3</sup>

Vietnam OEL - TWAs 10 mg/m<sup>3</sup>

5 mg/m<sup>3</sup>

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

Sweden OEL - TWAs 5 mg/m<sup>3</sup>

#### Analytical Method:

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

#### Exposure Controls

##### 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:

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

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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

<b>Physical State:</b>	Tablet	<b>Color:</b>	Pink
<b>Odor:</b>	Odorless	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

**Solvent Solubility:** No data available  
**Water Solubility:** No data available  
**pH:** No data available.  
**Melting/Freezing Point (°C):** No data available.  
**Boiling Point (°C):** No data available.

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Croscarmellose sodium**

No data available

**Calcium phosphate dibasic, anhydrous**

No data available

**Povidone**

No data available

**FD & C Red No. 40, aluminum lake**

No data available

**Microcrystalline cellulose**

No data available

**Magnesium stearate**

No data available

**Fluconazole**

Predicted Log P 5.0

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Viscosity:** No data available

**Flammability:**

**Autoignition Temperature (Solid) (°C):** No data available

**Flammability (Solids):** No data available

**Flash Point (Liquid) (°C):** No data available

**Upper Explosive Limits (Liquid) (% by Vol.):** No data available

**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

**Polymerization:** Will not occur

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### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products:</b>	No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients.
<b>Long Term:</b>	Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.
<b>Known Clinical Effects:</b>	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.

#### 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 > 2000 mg/kg

##### **Magnesium stearate**

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### **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)

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### 11. TOXICOLOGICAL INFORMATION

#### 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

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vivo</i> Cytogenetics	Mouse Bone Marrow	Negative
<i>In Vitro</i> 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.

#### Toxicity:

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

#### Fluconazole

<i>Daphnia magna</i> (Water Flea)	LC50	48 Hours	35 mg/L
<i>Pimephales promelas</i> (Fathead Minnow)	LC50	> 50 mg/L	
<i>Cyprinodon variegatus</i> (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.

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**Persistence and Degradability:** No data available

**Bio-accumulative Potential:**  
**Partition Coefficient: (Method, pH, Endpoint, Value)**  
**Fluconazole**

Predicted Log P 5.0

**Mobility in Soil:** No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** 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

The following refers to all modes of transportation unless specified below.

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

### 15. REGULATORY INFORMATION

**Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture**

**FD & C Red No. 40, aluminum lake**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	271-524-7

**Croscarmellose sodium**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed



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### 15. REGULATORY INFORMATION

#### Fluconazole

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3 Schedule 4
EU EINECS/ELINCS List	Not Listed

#### Povidone

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### Calcium phosphate dibasic, anhydrous

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-826-1

#### Microcrystalline cellulose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 9[f]. powder
EU EINECS/ELINCS List	232-674-9

#### Magnesium stearate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child  
Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children  
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

**Data Sources:** Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information.

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**Revision date:** 31-May-2016  
Product Stewardship Hazard Communication  
**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

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**