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

Product Identifier

**Material Name:** Fluconazole Powder for Oral Suspension

**Trade Name:** DIFLUCAN; TRIFLUCAN; FUNGUSTATIN

**Chemical Family:** Mixture

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

**GHS - Classification**

- Reproductive Toxicity: Category 1B
- Effects on or via lactation

**US OSHA Specific - Classification**

- Combustible Dust

**Physical Hazard:**

**Signal Word:** Danger

**Hazard Statements:**

- H360D - May damage the unborn child
- H362 - May cause harm to breast-fed children
- May form combustible dust concentrations in air

**Precautionary Statements:**

- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P281 - Use personal protective equipment as required
- P260 - Do not breathe dust/fume/gas/mist/vapors/spray
- P263 - Avoid contact during pregnancy/while nursing
- P264 - Wash hands thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations
Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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

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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.

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.
**SAFETY DATA SHEET**

**Material Name:** Fluconazole Powder for Oral Suspension

**Revision date:** 16-Mar-2018

**Version:** 5.0

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

**Advice for Fire-Fighters**
During all firefighting 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. Cleanup operations should only be undertaken by trained personnel.

---

**7. HANDLING AND STORAGE**

**Precautions for Safe Handling**
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.

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

- **Storage Conditions:**
  Store as directed by product packaging.
**SAFETY DATA SHEET**

Material Name: Fluconazole Powder for Oral Suspension  
Revision date: 16-Mar-2018  
Revision version: 5.0

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/m³

### Titanium dioxide

- **ACGIH Threshold Limit Value (TWA)**: 10 mg/m³
- **Australia TWA**: 10 mg/m³
- **Austria OEL - MAKs**: 5 mg/m³
- **Belgium OEL - TWA**: 10 mg/m³
- **Bulgaria OEL - TWA**: 10.0 mg/m³
- **Denmark OEL - TWA**: 6 mg/m³
- **Estonia OEL - TWA**: 5 mg/m³
- **France OEL - TWA**: 10 mg/m³
- **Greece OEL - TWA**: 10 mg/m³
- **Ireland OEL - TWAs**: 10 mg/m³
- **Latvia OEL - TWA**: 10 mg/m³
- **Lithuania OEL - TWA**: 6 mg/m³
- **OSHA - Final PELS - TWAs**: 15 mg/m³
- **Poland OEL - TWA**: 10.0 mg/m³
- **Portugal OEL - TWA**: 10 mg/m³
- **Romania OEL - TWA**: 10 mg/m³
- **Russia OEL - TWA**: 10 mg/m³
- **Spain OEL - TWA**: 10 mg/m³
- **Sweden OEL - TWAs**: 5 mg/m³
- **Switzerland OEL - TWAs**: 3 mg/m³
- **Vietnam OEL - TWAs**: 6 mg/m³

### Sucrose

- **ACGIH Threshold Limit Value (TWA)**: 10 mg/m³
- **Australia TWA**: 10 mg/m³
- **Belgium OEL - TWA**: 10 mg/m³
- **Bulgaria OEL - TWA**: 10.0 mg/m³
- **Estonia OEL - TWA**: 10 mg/m³
- **France OEL - TWA**: 10 mg/m³
- **Ireland OEL - TWAs**: 10 mg/m³
- **Latvia OEL - TWA**: 5 mg/m³
- **Lithuania OEL - TWA**: 5 mg/m³
- **OSHA - Final PELS - TWAs**: 15 mg/m³
- **Portugal OEL - TWA**: 10 mg/m³
- **Slovakia OEL - TWA**: 6 mg/m³
- **Spain OEL - TWA**: 10 mg/m³

### Colloidal silicon dioxide

- **Australia TWA**: 2 mg/m³
- **Austria OEL - MAKs**: 4 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Powder
Odor: Oranges (natural flavoring added)
Color: White
Odor Threshold: No data available.
Molecular Formula: Mixture
Molecular Weight: 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: No data available
Natural orange flavor
No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

Fluconazole
Predicted Log P  5.0

Sucrose
No data available

Colloidal silicon dioxide
No data available

Titanium dioxide
No data available

Xanthan gum
No data available

Sodium citrate, dihydrate
No data available

Citric acid, anhydrous
No data available

Sodium benzoate
No data available

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

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions
  Oxidizing Properties: No data available
  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
  Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

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

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.
11. TOXICOLOGICAL INFORMATION

**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.

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

**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

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

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

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

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

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

**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

**Sodium benzoate**
11. TOXICOLOGICAL INFORMATION

11.1 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

**Sodium benzoate**
- Embryo / Fetal Development: Rat, Oral 44 g/kg, LOEL, 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

**Sucrose**
- Bacterial Mutagenicity (Ames): *Salmonella*, 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)
- NTP: Reasonably Anticipated To Be a Human Carcinogen

**Titanium dioxide**
- IARC: Group 2B (Possibly Carcinogenic to Humans)

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.

**Toxicity:**
- **Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**
SAFETY DATA SHEET

Material Name: Fluconazole Powder for Oral Suspension
Revision date: 16-Mar-2018

12. AQUATIC TOXICITY

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.

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

Citric acid, anhydrous
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present

298
### 15. REGULATORY INFORMATION

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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.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 16-Mar-2018


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