



MATERIAL SAFETY DATA SHEET

Revision date: 13-Jul-2011

Version: 3.7

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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
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Material Name: Diflucan® (fluconazole) tablets

Trade Name: DIFLUCAN
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:
Known Clinical Effects: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver. 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
Toxic to reproduction, Category 2

EU Hazard Symbols:



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.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Fluconazole	86386-73-4	Not Listed	Xn;R22 Repr.Cat.2;R61 R64 R52/53	45.5
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*

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

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

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

Fire / Explosion Hazards: Not applicable

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). 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.

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

Calcium phosphate dibasic, anhydrous

Latvia OEL - TWA 10 mg/m³

Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³

Lithuania OEL - TWA 5 mg/m³

Sweden OEL - TWAs 5 mg/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m³

Australia TWA 10 mg/m³

Belgium OEL - TWA 10 mg/m³

Estonia OEL - TWA 10 mg/m³

France OEL - TWA 10 mg/m³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL - TWA	2 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³

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.
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	Color:	Pink
Odor:	Odorless	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Chemical 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

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11. TOXICOLOGICAL INFORMATION

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/m³

Fluconazole

Rat (F) Oral LD50 1575 mg/kg
Rat (M) Oral LD50 1325 mg/kg
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)

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
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

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11. TOXICOLOGICAL INFORMATION

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 (Water Flea) LC50 48 Hours 35 mg/L

Pimephales promelas (Fathead Minnow) LC50 > 50 mg/L

Cyprinodon variegatus (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

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

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

EU Risk Phrases:

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15. REGULATORY INFORMATION

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
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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

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)	Present
Australia (AICS):	Present

Croscarmellose sodium

Australia (AICS):	Present
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Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
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15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

Microcrystalline cellulose

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

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 7 - Handling and Storage.

Prepared by: Product Stewardship Hazard Communication
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