



MATERIAL SAFETY DATA SHEET

Revision date: 16-Sep-2008

Version: 3.5

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

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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): Hazardous Substance. Non-Dangerous Goods.

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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	Classification	%
Fluconazole	86386-73-4	Not listed	Xn;R22 Repr.Cat.2;R61 R64 R52/53	6.6
Sucrose	57-50-1	200-334-9	Not Listed	*
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Colloidal silicon dioxide	7631-86-9	231-545-4 EEC No. 418-260-2	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Sodium citrate, dihydrate	6132-04-3	Not listed	Not Listed	*
Sodium benzoate	532-32-1	208-534-8	Not Listed	*
Xanthan gum	11138-66-2	234-394-2	Not Listed	*
Natural orange flavor	NOT ASSIGNED	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.

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Hazardous Combustion Products: Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds

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

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

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: 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.

Storage Conditions: Store out of direct sunlight in a well ventilated area at room temperature. Store as directed by product packaging.

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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/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Ireland OEL - TWAs	= 10 mg/m ³ TWA
Lithuania OEL - TWA	Listed
OSHA - Final PELS - TWAs:	= 15 mg/m ³ TWA total = 5 mg/m ³ TWA
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
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/m ³ 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/m ³ 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/m ³ TWA
Austria OEL - MAKs	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Germany - TRGS 900 - TWAs	= 4 mg/m ³ TWA
Germany (DFG) - MAK	= 4 mg/m ³ MAK
Ireland OEL - TWAs	= 2.4 mg/m ³ TWA = 6 mg/m ³ TWA
Latvia OEL - TWA	Listed

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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

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

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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 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))

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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

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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)

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:

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.

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15. REGULATORY INFORMATION

OSHA Label:

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15. REGULATORY INFORMATION

WARNING

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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

Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 3
Schedule 4

Sucrose

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List 200-334-9

Sodium citrate, dihydrate

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

Citric acid, anhydrous

Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 201-069-1

Sodium benzoate

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 208-534-8

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 236-675-5

Colloidal silicon dioxide

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 231-545-4
EEC No. 418-260-2

Xanthan gum

Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present
EU EINECS/ELINCS List 234-394-2

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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