



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 2.2

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

Pfizer Inc
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CHEMTREC (24 hours): 1-800-424-9300

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ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: DIFLUCAN® (Fluconazole) capsules

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Fluconazole	86386-73-4	Not listed	42.5
Silica colloidal, Ph. Eur.	112945-52-5	Not listed	*
Corn Starch	9005-25-8	232-679-6	*
Magnesium stearate	557-04-0	209-150-3	*
Sodium lauryl sulfate	151-21-3	205-788-1	*

Ingredient	CAS Number	EU EINECS List	%
Lactose	63-42-3	200-559-2	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White capsules
Signal Word: WARNING

Statement of Hazard: May be harmful if swallowed.
Can cause liver damage.
Possible risk of harm to the unborn child.
Dangerous for the environment.

Additional Hazard Information:
Long Term:

Known Clinical Effects:

Repeat-dose studies in animals have shown a potential to cause adverse effects on : liver.
Rare cases of serious liver damage and allergic reactions have been reported .
Clinical use of this drug has caused Nausea, abdominal discomfort, headache, dizziness . Birth defects have occurred in infants of women taking this drug. This drug may decrease the quantity/quality of breast milk.

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EU Indication of danger: Toxic
Toxic to Reproduction: Category 2
Dangerous for the Environment

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.

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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

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

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

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.

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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:

If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

Storage Conditions:

Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature.

Storage Temperature:

< 30 °C (86°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Fluconazole

Pfizer OEL TWA-8 Hr:

0.5 mg/m³

Corn Starch

OSHA - Final PELs - TWAs:

= 15 mg/m³ TWA total

= 5 mg/m³ TWA

ACGIH Threshold Limit Value (TWA)

= 10 mg/m³ TWA

Australia TWA

= 10 mg/m³ TWA

Magnesium stearate

ACGIH Threshold Limit Value (TWA)

= 10 mg/m³ TWA

except stearates of toxic metals

Australia TWA

= 10 mg/m³ TWA

Sodium lauryl sulfate

Pfizer OEL TWA-8 Hr:

0.3 mg/m³

Pfizer STEL

0.75 mg/m³

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.

Personal Protective Equipment:

Hands:

Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Eyes:

Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin:

Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection:

Not required for the normal use of this product. 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:

Capsule

Color:

White

Molecular Formula:

Mixture

Molecular Weight:

Mixture

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10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: Humidity
Incompatible Materials: Strong oxidizers
Polymerization: Will not occur

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)

Lactose

Rat Oral LD50 > 10 g/kg

Sodium lauryl sulfate

Rat Oral LD50 1288 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)

Sodium lauryl sulfate

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

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

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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: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Silica colloidal, Ph. Eur.

IARC: Group 3

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.

Mobility, Persistence and Degradability: The environmental characteristics of this material have not been fully evaluated.

Bioaccumulation and Toxicity: Moderately toxic to aquatic organisms. See aquatic toxicity data, 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.

14. TRANSPORT INFORMATION

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

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15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic
Toxic to Reproduction: Category 2
Dangerous for the Environment

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.

EU Safety Phrases:
S22 - Do not breathe dust.
S36 - Wear suitable protective clothing.
S53 - Avoid exposure - obtain special instructions before use.
S57 - Use appropriate containment to avoid environmental contamination.

OSHA Label:
WARNING
May be harmful if swallowed.
Can cause liver damage.
Possible risk of harm to the unborn child.
Dangerous for the environment.

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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Silica colloidal, Ph. Eur.

Australia (AICS):	Present
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Corn Starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

Lactose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

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EU EINECS List	200-559-2
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Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3

Sodium lauryl sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-788-1

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet