



# MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.2

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

**Emergency telephone number:**  
**ChemSafe (24 hours): +44 (0)208 762 8322**

**Material Name: Tioconazole Cream**

**Trade Name:** Trosyd®  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as antifungal agent

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Tioconazole	65899-73-2	265-973-8	1
Cetyl Esters Wax	17661-50-6	241-640-2	*
Sorbitan monostearate	1338-41-6	215-664-9	*
Benzyl Alcohol	100-51-6	202-859-9	*

Ingredient	CAS Number	EU EINECS List	%
Stearyl Alcohol	112-92-5	204-017-6	*
Water, purified	7732-18-5	231-791-2	*
Polysorbate 60	9005-67-8	Not listed	*
Octyldodecanol	5333-42-6	226-242-9	*

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

## 3. HAZARDS IDENTIFICATION

**Appearance:** White cream  
**Signal Word:** WARNING

**Statement of Hazard:** May cause allergic skin reaction.

### Additional Hazard Information:

**Short Term:** May cause eye irritation. May cause skin irritation. (based on components)  
**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system and the developing fetus. Adverse reproductive effects seen in repeat-dose animal studies are consistent with the pharmacologic action of this drug and are expected to be relevant to humans.

**Known Clinical Effects:** Adverse clinical reactions include the development of hypersensitivity and/or irritation leading to rashes, itching, and burning.

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EU Indication of danger: Irritant

EU Hazard Symbols:



EU Risk Phrases:

R43 - May cause sensitization by skin contact.  
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 active substance or its intermediates 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:** 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.

## 5. FIRE FIGHTING MEASURES

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

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**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 spill with absorbent material. 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.

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### 7. HANDLING AND STORAGE

**General Handling:** Use appropriate ventilation. Avoid contact with eyes, skin and clothing.

**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Tioconazole

Pfizer OEL TWA-8 Hr: 0.1mg/m<sup>3</sup>

#### Cetyl Esters Wax

ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA except stearates of toxic metals  
Australia TWA = 10 mg/m<sup>3</sup> TWA

#### Sorbitan monostearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA except stearates of toxic metals  
Australia TWA = 10 mg/m<sup>3</sup> TWA

**Analytical Method:** Analytical method available for Tioconazole. 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:** 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:** 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>	Cream	<b>Color:</b>	White
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** None known

**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)**

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### Tioconazole

Rat Oral LD50 770 mg/kg  
Mouse Oral LD50 1870 mg/kg

### Polysorbate 60

Rat Oral LD50 64,000 mg/kg

### Benzyl Alcohol

Rat Oral LD50 1.23 g/kg  
Rat Intravenous LD50 53 mg/kg

### Irritation / Sensitization: (Study Type, Species, Severity)

#### Tioconazole

Eye Irritation Rabbit Non-irritating

#### Stearyl Alcohol

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

#### Benzyl Alcohol

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Moderate  
Skin Irritation Guinea Pig Moderate

### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

#### Tioconazole

26 Week(s) Rat Subcutaneous 1820 mg/kg/day Liver, Skin

### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### Tioconazole

Embryo / Fetal Development Rat Oral 165 mg/kg/day Not teratogenic  
Embryo / Fetal Development Rabbit Oral 165 mg/kg/day Not Teratogenic  
Prenatal & Postnatal Development Rat No route specified 55 mg/kg/day LOAEL Developmental toxicity  
Fertility and Embryonic Development Rat Subcutaneous 30 mg/kg/day LOAEL Reproductive toxicity, Fetotoxicity

### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

#### Tioconazole

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
*In Vivo* Cytogenetics Mouse Negative

### Carcinogen Status:

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

## 12. ECOLOGICAL INFORMATION

### Environmental Overview:

The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

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

#### Tioconazole

Mysid Shrimp LC50 48 Hours 0.5 mg/L  
Sheepshead Minnow LC50 48 Hours 0.71 mg/L  
Red Algae IC50 0.22 mg/L

### 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.

### 15. REGULATORY INFORMATION

**EU Symbol:** Xi  
**EU Indication of danger:** Irritant

**EU Risk Phrases:**

R43 - May cause sensitization by skin contact.  
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**EU Safety Phrases:**

S24 - Avoid contact with skin.  
S57 - Use appropriate containment to avoid environmental contamination.

**OSHA Label:**  
WARNING  
May cause allergic skin reaction.

#### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
Class D, Division 2, Subdivision B



Tioconazole

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<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 2 Schedule 3 Schedule 4
<b>EU EINECS List</b>	265-973-8
<b>Cetyl Esters Wax</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	241-640-2
<b>Stearyl Alcohol</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-017-6
<b>Water, purified</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2
<b>Polysorbate 60</b>	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
<b>Sorbitan monostearate</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	215-664-9
<b>Benzyl Alcohol</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-859-9
<b>Octyldodecanol</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	226-242-9

## 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

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

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End of Safety Data Sheet