



# SAFETY DATA SHEET

Revision date: 16-Sep-2014

Version: 2.1

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

### Product Identifier

**Material Name:** Tioconazole Cream

**Trade Name:** TROSYD; TRALEN

**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

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Pfizer Pharmaceuticals Group  
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**Emergency telephone number:**

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

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## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Skin Sensitization: Category 1

#### EU Classification:

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.

### Label Elements

**Signal Word:** Warning

**Hazard Statements:** H317 - May cause an allergic skin reaction

#### Precautionary Statements:

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray

P272 - Contaminated work clothing should not be allowed out of the workplace

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P302+ P352 - IF ON SKIN: Wash with plenty of soap and water

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

P321 - Specific treatment (see supplemental instructions on the administration of antidotes on this label)

P363 - Wash contaminated clothing before reuse

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**Other Hazards**  
**Australian Hazard Classification (NOHSC):**

No data available  
Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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	GHS Classification	%
Benzyl Alcohol	100-51-6	202-859-9	Xn; R20/22	Acute Tox. 4 (H302) Acute Tox. 4 (H332)	1
Tioconazole	65899-73-2	265-973-8	Xn;R22 Xi;R43 N;R50/53 Repr.Cat.3;R63	Acute Tox.4 (H302) Skin Sens.1 (H317) Repr.2 (H361d) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	1
Sorbitan monostearate	1338-41-6	215-664-9	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Cetyl Esters Wax	17661-50-6	241-640-2	Not Listed	Not Listed	*
Cetyl/Stearyl alcohol	67762-27-0	267-008-6	Not Listed	Not Listed	*
Octyldodecanol	5333-42-6	226-242-9	Not Listed	Not Listed	*
Polysorbate 60	9005-67-8	Not Listed	Not Listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	Not Listed	*

**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 R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16**

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### 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.
- 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:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

- Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.
- Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

#### Advice for Fire-Fighters

During all fire fighting 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 spill with absorbent material. Clean spill area thoroughly.
- 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

#### Precautions for Safe Handling

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### 7. HANDLING AND STORAGE

Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Wash hands and any exposed skin after removal of PPE. 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.

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

**Storage Conditions:** Store as directed by product packaging.  
**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.

#### Benzyl Alcohol

Bulgaria OEL - TWA	5.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	40 mg/m <sup>3</sup>
Finland OEL - TWA	10 ppm
	45 mg/m <sup>3</sup>
Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Poland OEL - TWA	240 mg/m <sup>3</sup>

#### Cetyl Esters Wax

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>

#### Tioconazole

Pfizer OEL TWA-8 Hr: 100µg/m<sup>3</sup>

#### Sorbitan monostearate

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>

#### Exposure Controls

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.  
**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**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>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

pH: No data available.  
Melting/Freezing Point (°C): No data available  
Boiling Point (°C): No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

**Tioconazole**

No data available

**Polysorbate 60**

No data available

**Sorbitan monostearate**

No data available

**Cetyl/Stearyl alcohol**

No data available

**Octyldodecanol**

No data available

**Cetyl Esters Wax**

No data available

**Water, purified**

No data available

**Benzyl Alcohol**

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

### 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: May cause eye irritation. May cause skin irritation. (based on components)

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### 11. TOXICOLOGICAL INFORMATION

**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.

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

##### **Tioconazole**

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

##### **Polysorbate 60**

Rat Oral LD50 64,000 mg/kg

##### **Benzyl Alcohol**

Rat Oral LD50 1230 mg/kg  
Rat Para-periosteal LD50 53mg/kg  
Rat Inhalation LC50 >4.178mg/L

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

##### **Tioconazole**

Eye Irritation Rabbit Non-irritating

##### **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.

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### 12. ECOLOGICAL INFORMATION

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

**Toxicity:**

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

##### **Tioconazole**

*Mysidopsis bahia* (Mysid Shrimp) LC50 48 Hours 0.5 mg/L  
*Cyprinodon variegatus* (Sheepshead Minnow) LC50 48 Hours 0.71 mg/L  
Red Algae IC50 0.22 mg/L

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**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**

#### **Canada - WHMIS: Classifications**

##### **WHMIS hazard class:**

Class D, Division 2, Subdivision B

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## 15. REGULATORY INFORMATION

**Benzyl Alcohol**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

**Cetyl Esters Wax**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	241-640-2

**Cetyl/Stearyl alcohol**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	267-008-6

**Octyldodecanol**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	226-242-9

**Tioconazole**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 3 Schedule 4
EU EINECS/ELINCS List	265-973-8

**Polysorbate 60**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

**Sorbitan monostearate**

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



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### 15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	215-664-9

#### Water, purified

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
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	231-791-2

### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction  
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled  
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child  
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

Xi - Irritant  
Xn - Harmful  
N - Dangerous for the environment  
Toxic to Reproduction: Category 3

R43 - May cause sensitization by skin contact.  
R22 - Harmful if swallowed.  
R63 - Possible risk of harm to the unborn child.  
R20/22 - Harmful by inhalation and if swallowed.  
R50/53 - Very toxic 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 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

**Revision date:** 16-Sep-2014  
Product Stewardship Hazard Communication

**Prepared by:** 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**