



# MATERIAL SAFETY DATA SHEET

Revision date: 16-Dec-2010

Version: 1.0

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

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### Material Name: Tioconazole Solution Spray

Trade Name:	TROSYD; TRALEN
Chemical Family:	Imidazole
Intended Use:	Pharmaceutical product used as antifungal agent

## 2. HAZARDS IDENTIFICATION

Appearance: Very pale yellow to yellow liquid  
Signal Word: DANGER

Statement of Hazard: Highly flammable liquid and vapor.  
May cause allergic reaction.  
Causes skin irritation.  
Harmful to aquatic life with long lasting effects.

Additional Hazard Information:  
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system, 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.

EU Classification  
EU Indication of danger: Highly flammable  
Dangerous for the Environment

EU Hazard Symbols:

F

Xi



EU Risk Phrases:

R11 - Highly flammable.  
R36 - Irritating to eyes.  
R43 - May cause sensitization by skin contact.  
R67 - Vapors may cause drowsiness and dizziness.

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## 2. HAZARDS IDENTIFICATION

**Australian Hazard Classification (NOHSC):** R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
Hazardous Substance. Dangerous Goods.

**Additional Information:** For a more detailed discussion of potential health hazards and toxicity see Section 11.  
**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	%
Tioconazole	65899-73-2	265-973-8	Xn;R22 Xi;R43 N;R50/53 Repr.Cat.3;R63	1
Isopropyl alcohol	67-63-0	200-661-7	F;R11 R67 Xi;R36	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Isopropyl myristate	110-27-0	203-751-4	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. For information on potential delayed effects, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**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, oxides of nitrogen, sulfur, hydrogen chloride and other chlorine- and sulfur-containing compounds

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

**Fire / Explosion Hazards:** Flammable liquid and vapor

### 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 the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

**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 vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

**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.

#### Tioconazole

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

#### Isopropyl alcohol

ACGIH Threshold Limit Value (TWA)	200 ppm TWA
ACGIH Threshold Limit Value (STEL)	400 ppm STEL
Australia STEL	1230 mg/m <sup>3</sup>
	500 ppm
Australia TWA	400 ppm
	983 mg/m <sup>3</sup>
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
Germany - TRGS 900 - TWAs	200 ppm
	500 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Germany (DFG) - MAK	200 ppm MAK 500 mg/m <sup>3</sup> MAK
Germany - Biological Exposure Limit:	Listed
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Japan - OELs - Ceilings	400 ppm 980 mg/m <sup>3</sup>
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELs - TWAs:	400 ppm 980 mg/m <sup>3</sup>
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Romania - Biological Exposure Limit:	Listed
Slovak Republic - Biological Exposure Limit:	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

<b>Analytical Method:</b>	Analytical method available for Tioconazole. Contact Pfizer Inc for further information.
<b>Engineering Controls:</b>	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.
<b>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	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>	Liquid	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Flash Point (Liquid) (°C):</b>	12 Closed cup based on major component
<b>Polymerization:</b>	Will not occur

### 10. STABILITY AND REACTIVITY

<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	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)

##### **Isopropyl alcohol**

Rat Oral LD50 > 2000 mg/kg  
Mouse Oral LD50 3600 mg/kg  
Rat Inhalation LC50-8h 16,000 ppm  
Rabbit Dermal LD50 12800 mg/kg  
Rat Inhalation LC50 30 mg/L

##### **Isopropyl myristate**

Mouse Oral LD50 49,700 mg/kg  
Rabbit Dermal LD50 5000 mg/kg

##### **Tioconazole**

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

##### **Isopropyl alcohol**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

##### **Tioconazole**

Eye Irritation Rabbit Non-irritating

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

##### **Isopropyl alcohol**

20 Week(s) Rat Inhalation 4000 ppm NOAEL Liver, Central nervous system  
104 Week(s) Rat Inhalation 5000 ppm Kidney

##### **Tioconazole**

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

#### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### **Isopropyl alcohol**

Prenatal & Postnatal Development Rat Inhalation 7,000 ppm LOAEL Maternal toxicity, Fetotoxicity, Embryotoxicity  
2 Generation Reproductive Toxicity Rat Oral 1000 mg/kg/day LOAEL Maternal Toxicity, Fetal mortality  
Prenatal & Postnatal Development Rat Oral 1200 mg/kg/day NOAEL No effects at maximum dose

##### **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

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### 11. TOXICOLOGICAL INFORMATION

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

##### Isopropyl alcohol

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
Mammalian Cell Mutagenicity HGPRT Chinese Hamster Ovary (CHO) cells Negative  
*In Vitro* Sister Chromatid Exchange Negative

##### 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.

##### Isopropyl alcohol

**IARC:** Group 3

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Harmful effects to aquatic organisms could occur. See aquatic toxicity data, below:  
**Bioaccumulation and Toxicity:** High acute toxicity to aquatic organisms is expected. Long-term adverse effects to aquatic organisms are possible.

#### 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

### 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

This material is regulated for transportation as a hazardous material/dangerous good.

**UN proper shipping name:** Isopropanol Solution,  
**UN number:** UN 1219  
**Transport hazard class(es):** 3  
**Flash Point (°C):** 12  
**Packing group:** II

For small quantities packed in combination packaging [limited to inner packaging < 1.0L (0.3 gal) and outer packaging < 30 kg (66 lb.) gross weight], the following will apply: If your commodity meets the definition of a limited quantity and is packaged for retail sale, it may be considered a consumer commodity and excepted from additional requirements as applicable.

#### IATA / ICAO

**IATA Proper shipping name:** Consumer Commodity  
**IATA UN / ID No:** ID 8000

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### 14. TRANSPORT INFORMATION

IATA Hazard Class: 9

#### IMDG

IMDG Proper shipping name: Isopropanol Solution, Ltd. Qty.  
IMDG UN / ID No: UN 1219  
IMDG Hazard Class: 3  
Flash Point (°C): 12  
IMDG Packing Group: II

#### ADR/RID

ADR/RID Proper shipping name: Isopropanol Solution, Ltd. Qty. ,  
ADR / RID UN / ID No: UN 1219  
ADR / RID Hazard Class: 3  
ADR / RID Packing Group: II  
ADR/RID Note: ADR Limited Quantity is <= 3.0 liters per inner packaging.

#### DOT

DOT Proper shipping name: Consumer Commodity  
DOT Hazard Class: ORM-D

### 15. REGULATORY INFORMATION

EU Symbol: F Xn N  
EU Indication of danger: Highly flammable  
Dangerous for the Environment

#### EU Risk Phrases:

R11 - Highly flammable.  
R36 - Irritating to eyes.  
R43 - May cause sensitization by skin contact.  
R67 - Vapors may cause drowsiness and dizziness.  
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

#### EU Safety Phrases:

S46 - If swallowed, seek medical advice immediately and show this container or label.  
S61 - Avoid release to the environment. Refer to special instructions/Safety data sheets.  
S36/37 - Wear suitable protective clothing and gloves.

#### OSHA Label:

DANGER  
Highly flammable liquid and vapor.  
May cause allergic reaction.  
Causes skin irritation.  
Harmful to aquatic life with long lasting effects.

#### Canada - WHMIS: Classifications

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## 15. REGULATORY INFORMATION

### WHMIS hazard class:

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B

Class B, Division 2



### Tioconazole

Standard for the Uniform Scheduling  
for Drugs and Poisons:

Schedule 2  
Schedule 3  
Schedule 4

EU EINECS/ELINCS List

265-973-8

### Isopropyl alcohol

CERCLA/SARA 313 Emission reporting

1.0% de minimis concentration only if manufactured by the strong  
acid process, no supplier notification

Inventory - United States TSCA - Sect. 8(b)

Listed

Australia (AICS):

Listed

EU EINECS/ELINCS List

200-661-7

### Isopropyl myristate

Inventory - United States TSCA - Sect. 8(b)

Listed

Australia (AICS):

Listed

EU EINECS/ELINCS List

203-751-4

## 16. OTHER INFORMATION

### Text of R phrases mentioned in Section 3

R11 - Highly flammable.

R67 - Vapors may cause drowsiness and dizziness.

R36 - Irritating to eyes.

R63 - Possible risk of harm to the unborn child.

R43 - May cause sensitization by skin contact.

R22 - Harmful if swallowed.

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

### Data Sources:

Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

### Prepared by:

Product Stewardship Hazard Communications  
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet