



MATERIAL SAFETY DATA SHEET

Revision date: 17-Jul-2008

Version: 1.1

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

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Material Name: Tioconazole Nail Solution

Trade Name:	Trosyd® Nail Solution
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.
Harmful if swallowed.
May cause allergic skin reaction.
Causes skin irritation.
Suspected of damaging fertility or the unborn child.
Very toxic 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 Indication of danger: Highly flammable
Harmful
Dangerous for the Environment

EU Hazard Symbols:



EU Risk Phrases:

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2. HAZARDS IDENTIFICATION

R11 - Highly flammable.
R22 - Harmful if swallowed.
R36 - Irritating to eyes.
R43 - May cause sensitization by skin contact.
R63 - Possible risk of harm to the unborn child.
R66 - Repeated exposure may cause skin dryness or cracking.
R67 - Vapors may cause drowsiness and dizziness.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Hazardous Substance. Dangerous Goods.

Australian Hazard Classification (NOHSC):

Additional Information: Note:

For a more detailed discussion of potential health hazards and toxicity see Section 11. 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	%
Ethyl acetate	141-78-6	205-500-4	F;R11 R66 R67 Xi;R36	*
Tioconazole	65899-73-2	265-973-8	Xn;R22 Xi;R43 N;R50/53 Repr.Cat.3;R63	28
Undecylenic acid	112-38-9	203-965-8	Xi;R36	*

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.

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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.
- 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.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Ethyl acetate

ACGIH Threshold Limit Value (TWA)	= 400 ppm TWA
Australia STEL	= 1440 mg/m ³ STEL
	= 400 ppm STEL
Australia TWA	= 200 ppm TWA
	= 720 mg/m ³ TWA
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
France OEL - TWA	Listed
Germany - TRGS 900 - TWAs	= 1500 mg/m ³ TWA
	= 400 ppm TWA
Germany (DFG) - MAK	= 1500 mg/m ³ MAK
	= 400 ppm MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	= 1400 mg/m ³ TWA
	= 400 ppm TWA
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELs - TWAs:	= 1400 mg/m ³ TWA
	= 400 ppm TWA
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	= 150 ppm LLV
	= 500 mg/m ³ LLV

Tioconazole

Pfizer OEL TWA-8 Hr:	100µg/m ³
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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. 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.

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.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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:	Liquid	Color:	Very pale yellow to yellow
Odor:	Odorless	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

Flash Point (Liquid) (°C):	-4 Closed cup based on major component
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)

Tioconazole

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

Ethyl acetate

Rat Oral LD50 5620 mg/kg
Rat Inhalation LC50 200g/m³
Rat Inhalation LC50/4h 4000ppm
Rabbit Dermal LD50 > 20ml/kg

Undecylenic acid

Rat Oral LD50 2500 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)

Tioconazole

Eye Irritation Rabbit Non-irritating

Ethyl acetate

Skin Irritation Rabbit Non-irritating

Undecylenic acid

Skin Irritation Rabbit Severe

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

Tioconazole

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

Reproduction & Development Toxicity: (Duration, 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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11. TOXICOLOGICAL INFORMATION

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

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: Observe all local and national regulations when disposing of this material. This product may qualify as a RCRA Hazardous Waste. Status should be confirmed by testing for RCRA hazardous characteristics (i.e. corrosivity, toxicity, reactivity, or ignitability).

Ethyl acetate

RCRA - U Series Wastes

waste number U112 (Ignitable waste)

14. TRANSPORT INFORMATION

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

Proper shipping name: Tinctures, medicinal
UN / ID No: UN 1293

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Hazard class: 3
Flash Point (°C): -4
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
IATA Hazard Class: 9

IMDG

IMDG Proper shipping name: Tinctures, medicinal, Ltd. Qty.
IMDG UN / ID No: UN 1293
IMDG Hazard Class: 3
Flash Point (°C): -4
IMDG Packing Group: II

ADR/RID

ADR/RID Proper shipping name: Tinctures, medicinal, Ltd. Qty.
ADR / RID UN / ID No: UN 1293
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

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15. REGULATORY INFORMATION

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

EU Risk Phrases:

- R11 - Highly flammable.
- R22 - Harmful if swallowed.
- R36 - Irritating to eyes.
- R43 - May cause sensitization by skin contact.
- R63 - Possible risk of harm to the unborn child.
- R66 - Repeated exposure may cause skin dryness or cracking.
- R67 - Vapors may cause drowsiness and dizziness.
- R50/53 - Very toxic 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.
Harmful if swallowed.
May cause allergic skin reaction.
Causes skin irritation.
Suspected of damaging fertility or the unborn child.
Very toxic to aquatic life with long lasting effects.

Canada - WHMIS: Classifications

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



Ethyl acetate

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ = 5000 lb final RQ
Inventory - United States TSCA - Sect. 8(b)	T
Australia (AICS):	Present
EU EINECS/ELINCS List	205-500-4

Tioconazole

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Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 3 Schedule 4
EU EINECS/ELINCS List	265-973-8

Undecylenic acid

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	203-965-8

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R11 - Highly flammable.
R66 - Repeated exposure may cause skin dryness or cracking.
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.

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 13 - Disposal Considerations. Updated Section 14 - Transport Information. 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