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

<table>
<thead>
<tr>
<th>Pfizer Inc</th>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Pharmaceuticals Group</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>235 East 42nd Street</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>New York, New York 10017</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>1-212-573-2222</td>
<td>United Kingdom</td>
</tr>
<tr>
<td></td>
<td>+00 44 (0)1304 616161</td>
</tr>
</tbody>
</table>

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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

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: F Xn N

EU Risk Phrases:
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.

Australian Hazard Classification (NOHSC):
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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl acetate</td>
<td>141-78-6</td>
<td>205-500-4</td>
<td>F;R11</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R66</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R67</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Xi;R36</td>
<td></td>
</tr>
<tr>
<td>Undecylenic acid</td>
<td>112-38-9</td>
<td>203-965-8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tioconazole</td>
<td>65899-73-2</td>
<td>265-973-8</td>
<td>Xn;R22</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Xi;R43</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N;R50/53</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr.Cat.3;R63</td>
<td></td>
</tr>
</tbody>
</table>

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.
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.
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/m³ STEL

= 400 ppm STEL

Australia TWA  
= 200 ppm TWA

= 720 mg/m³ 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/m³ TWA

= 400 ppm TWA

Germany (DFG) - MAK  
= 1500 mg/m³ MAK

= 400 ppm MAK

Greece OEL - TWA  
Listed

Hungary OEL - TWA  
Listed

Ireland OEL - TWAs  
= 1400 mg/m³ TWA

= 400 ppm TWA

Latvia OEL - TWA  
Listed

Lithuania OEL - TWA  
Listed

Netherlands OEL - TWA  
Listed

OSHA - Final PELS - TWAs:  
= 1400 mg/m³ 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/m³ LLV

Tioconazole

Pfizer OEL TWA-8 Hr:  
100µg/m³

**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.
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:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Liquid</th>
<th>Color:</th>
<th>Very pale yellow to yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>Odorless</td>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Flash Point (Liquid) (°C): -4
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.
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 1870 mg/kg

Ethyl acetate
Rat Oral LD50 5620 mg/kg
Rat Inhalation LC50 200g/m³
Rat Inhalation LC50/4h 4000 ppm
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.
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
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
### 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**
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