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>Emergency telephone number:</td>
<td>+00 44 (0)1304 616161</td>
</tr>
<tr>
<td>CHEMTREC (24 hours): 1-800-424-9300</td>
<td>Emergency telephone number:</td>
</tr>
<tr>
<td></td>
<td>ChemSafe (24 hours): +44 (0)208 762 8322</td>
</tr>
</tbody>
</table>

Contact E-Mail: pfizer-MSDS@pfizer.com

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:

EU Risk Phrases:
R11 - Highly flammable.
R36 - Irritating to eyes.
R43 - May cause sensitization by skin contact.
R67 - Vapors may cause drowsiness and dizziness.
2. HAZARDS IDENTIFICATION

R52/53 - Harmful 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>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tioconazole</td>
<td>65899-73-2</td>
<td>265-973-8</td>
<td>Xn;R22</td>
<td>1</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>
<tr>
<td>Isopropyl alcohol</td>
<td>67-63-0</td>
<td>200-661-7</td>
<td>F;R11</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>
</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.

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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Tioconazole
Pfizer OEL TWA-8 Hr: 100µg/m³

Isopropyl alcohol
ACGIH Threshold Limit Value (TWA) 200 ppm TWA
ACGIH Threshold Limit Value (STEL) 400 ppm STEL
Australia STEL 1230 mg/m³ 500 ppm
Australia TWA 400 ppm 983 mg/m³
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/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

Environmental Exposure Controls:
Refer to specific Member State legislation for requirements under Community environmental legislation.

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.
- 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
Molecular Formula: Mixture
Color: No data available.
Molecular Weight: Mixture

- Flash Point (Liquid) (°C): 12
  - Closed cup based on major component
  - Will not occur

10. STABILITY AND REACTIVITY

Chemical 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)

**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)  \textit{Salmonella}  Negative
Mammalian Cell Mutagenicity  HGPR\textit{T} Chinese Hamster Ovary (CHO) cells  Negative
\textit{In Vitro} Sister Chromatid Exchange  Negative

Tioconazole
\textit{In Vitro} Bacterial Mutagenicity (Ames)  \textit{Salmonella, E. coli}  Negative
\textit{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
\textit{Mysidopsis bahia} (Mysid Shrimp)  LC50  48 Hours  0.5 mg/L
\textit{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.

\textbf{UN proper shipping name:} Isopropanol Solution, 
\textbf{UN number:} UN 1219 
\textbf{Transport hazard class(es):} 3 
\textbf{Flash Point (°C):} 12 
\textbf{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.

\textbf{IATA / ICAO}
\textbf{IATA Proper shipping name:} Consumer Commodity 
\textbf{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
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

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