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

Product Identifier

Material Name: Tioconazole Powder
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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Emergency telephone number: ChemSafe (24 hours): +44 (0)208 762 8322
Contact E-Mail: pfizer-MSDS@pfizer.com

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
SAFETY DATA SHEET

Other Hazards
Australian Hazard Classification (NOHSC): No data available

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaolin</td>
<td>1332-58-7</td>
<td>310-194-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Silicon dioxide, colloidal NF</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Tioconazole</td>
<td>65899-73-2</td>
<td>265-973-8</td>
<td>Xn;R22 Xi;R43 N;R50/53 Repr.Cat.3;R63</td>
<td>Acute Tox.4 (H302) Skin Sens.1 (H317) Repr.2 (H361d) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium myristate</td>
<td>4086-70-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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

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 CO2, 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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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
Minimize dust generation and accumulation. Avoid breathing dust. 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

Conditions for Safe Storage, Including any Incompatibilities
SAFETY DATA SHEET

Material Name: Tioconazole Powder
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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.

Kaolin
ACGIH Threshold Limit Value (TWA) 2 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 2 mg/m³
Bulgaria OEL - TWA 3.0 mg/m³
          6.0 mg/m³
Denmark OEL - TWA 2 mg/m³
Finland OEL - TWA 2 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWA 2 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Poland OEL - TWA 10.0 mg/m³
Portugal OEL - TWA 2 mg/m³
Russia OEL - TWA 8 mg/m³
Slovakia OEL - TWA 2 mg/m³
          10 mg/m³
Spain OEL - TWA 2 mg/m³
Switzerland OEL - TWA 3 mg/m³

Silicon dioxide, colloidal NF
Australia TWA 2 mg/m³
Austria OEL - MAKs 4 mg/m³
          0.3 mg/m³
Czech Republic OEL - TWA 0.1 mg/m³
          4.0 mg/m³
Estonia OEL - TWA 2 mg/m³
Finland OEL - TWA 5 mg/m³
Germany - TRGS 900 - TWAs 4 mg/m³
Germany (DFG) - MAK 4 mg/m³
Ireland OEL - TWAs 6 mg/m³
          2.4 mg/m³
Latvia OEL - TWA 1 mg/m³
OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
          Listed
Slovakia OEL - TWA 4.0 mg/m³
Switzerland OEL - TWA 4 mg/m³
          0.3 mg/m³

Talc (non-asbestiform)
ACGIH Threshold Limit Value (TWA) 2 mg/m³
Australia TWA 2.5 mg/m³
Austria OEL - MAKs 2 mg/m³
Belgium OEL - TWA 2 mg/m³
Bulgaria OEL - TWA 1.0 fiber/cm³
          6.0 mg/m³
          3.0 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

- **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

- **Material Name**: Tioconazole Powder
- **Physical State**: Powder
- **Color**: White
- **Odor**: No data available.
- **Odor Threshold**: No data available.
- **Molecular Formula**: Mixture
- **Molecular Weight**: Mixture
- **Solvent Solubility**: No data available
- **Water Solubility**: No data available
- **pH**: No data available.
- **Melting/Freezing Point (°C)**: No data available
- **Boiling Point (°C)**: No data available.
- **Partition Coefficient**: (Method, pH, Endpoint, Value)
9. PHYSICAL AND CHEMICAL PROPERTIES

Tioconazole
No data available

Talc (non-asbestiform)
No data available

Silicon dioxide, colloidal NF
No data available

Magnesium myristate
No data available

Kaolin
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)

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

PZ02439
11. TOXICOLOGICAL INFORMATION

**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)

- **Talc (non-asbestiform)**
  - Rat  Oral  LD50  > 1600 mg/kg

**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, Fetal toxicity

**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.

**Talc (non-asbestiform)**

- IARC: Group 3 (Not Classifiable)

**Silicon dioxide, colloidal NF**

- IARC: Group 3 (Not Classifiable)

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**
  - *Mysisipedia bahia* (Mysid Shrimp)  LC50  48 Hours  0.5 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

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

Kaolin
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 310-194-1
15. REGULATORY INFORMATION

Magnesium myristate

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

Silicon dioxide, colloidal NF

- 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: 231-545-4

Talc (non-asbestiform)

- 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: 238-877-9

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

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
- 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
N - Dangerous for the environment
Xn - Harmful

R43 - May cause sensitization by skin contact.
R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Data Sources: Pfizer proprietary drug development information.

Revision date: 16-Sep-2014

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