

SAFETY DATA SHEETS

This SDS packet was issued with item:

078944634

N/A

Safety Data Sheet

Terbinafine Tablets USP 250mg

SECTION 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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|---------------------|---|
| Product Name | Terbinafine Tablets USP 250 mg |
| Manufacturer | Orchid Healthcare (A Division of Orchid Pharma Ltd.) Plot No. B5(Part) and B6(Part), SIPCOT Industrial Park, Irungattukottai, Sriperumbudur, Kancheepuram District - 602 117, India |

SECTION 2 - HAZARDS IDENTIFICATION SUMMARY

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| Emergency overview | Light pink with mottled surface, round, biconvex tablets debossed with "501" on one side and plain on the other side. Odor: No data available WARNING! May be harmful if swallowed. Accidental ingestion of large amounts may be harmful. |
| Primary Route(s) of Entry | Ingestion |
| Potential Health Effects | Inhalation: Not expected to be an inhalation hazard in final pharmaceutical form. Eye contact: Not expected to be a hazard to the eye in final pharmaceutical form. Skin contact: Not expected to be a hazard to the skin. Can cause hypertension reactions resulting in rash, redness, itching and inflammation. Ingestion: May be harmful if ingested. Ingestion may cause liver damage, taste disturbances, gastrointestinal effects and other systemic effects. |
| Effects of overexposure | The potential for exposure is reduced in finished pharmaceutical form. Overexposure by ingestion may cause nausea, vomiting, abdominal pain, dizziness, rash, frequent urination and headache. |
| Target Organs | Gastrointestinal Tract, Liver |

SECTION 3 - INFORMATION ON INGREDIENTS

| Strength and Label Claim | | |
|--|--|-------------------------|
| Strength | Label claim | |
| 250 mg | Each uncoated tablet contains 281.29 mg of Terbinafine hydrochloride equivalent to 250 mg of Terbinafine | |
| Chemical Name and Composition | | |
| Ingredients | CAS # | Quantity (% w/w) |
| Terbinafine Hydrochloride (active ingredient) | 78628-80-5 | 281.29 mg |
| Non hazardous Ingredients | -- | 118.71 mg |
| Chemical Name of Terbinafine Hcl: (E)-N,6,6-trimethyl-N-(naphthalen-1-ylmethyl)hept-2-en-4-yn-1-amine;hydrochloride | | |

SECTION 4 - FIRST AID MEASURES

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| Ingestion | Get medical aid immediately. Wash out mouth with water. |
| Eye Contact | Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses if worn. Get medical attention if symptoms persist. |
| Skin Contact | Wash with soap and water. Get medical attention if symptoms occur. |
| Ingestion | Call a physician or poison control centre immediately. |
| Inhalation | Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Get medical attention immediately. |

SECTION 5 - FIRE FIGHTING MEASURES

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| Flammability | Lower: N/A Upper: N/A |
| Flash point | Not Applicable |
| Extinguishing Media | Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area. |
| Special Fire Fighting Procedures | Wear full protective clothing and self-contained breathing apparatus. |
| Unusual Fire/Explosion Hazards | Not Applicable |
| Hazardous Combustion Products | Carbon dioxide, carbon monoxide, oxides of nitrogen, hydrogen chloride. |

SECTION 6 - ACCIDENTAL RELEASE MEASURES

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| STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED | Use appropriate personal protective equipment (see Section 8). Sweep up and containerize spill material in a compatible container. Dispose according to applicable regulations. Incineration of the waste at an approved facility is recommended. |
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SECTION 7 - HANDLING AND STORAGE

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| Precautions Handling Significant Quantities of Product: | Observe good industrial hygiene practices. |
| Storage | Store at 20° to 25° C (68° to 77°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs. |

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

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| Exposure Limits | None |
| Engineering Controls | Not required when handling tablets or containers. Ventilation should be matched to conditions. |
| Respiratory Protection | Not required when handling tablets or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to condition. |
| Personal Protection | Not required when handling tablets. If containers are compromised or exposure is likely wear: Goggles, Lab Coat and Gloves. |
| Recommended Facilities | Eye wash, washing facilities |

SECTION 9- PHYSICAL AND CHEMICAL PROPERTIES

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|-------------------------|---|
| Appearance | White, round, biconvex tablets |
| Melting point | 195 – 198°C |
| Specific Gravity | No applicable information found |
| pH | No applicable information found |
| Evaporation Rate | No applicable information found |
| Solubility | Soluble in methanol, ethanol, methylene chloride, slightly soluble in water |
| Vapor Density | No applicable information found |
| Vapour Pressure | No applicable information found |

SECTION 10 - STABILITY AND REACTIVITY

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|---------------------------------|---|
| Stability | Stable |
| Incompatibility | None known |
| Hazardous Decomposition | Oxides of carbon, oxides of nitrogen, hydrogen chloride |
| Condition to Avoid | Excessive heat, light |
| Hazardous Polymerization | Will not occur |

SECTION 11 - TOXICOLOGICAL INFORMATION

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| Terbinafine Hydrochloride Rat | LD ₅₀ : >20000 mg/kg |
| Irritancy data | No applicable information found |
| Corrosivity | No applicable information found |
| Reproduction | No adverse effects on fertility or other reproduction parameters were observed in studies in rats or rabbits |
| Mutagenicity | A standard battery of in vitro genotoxicity tests revealed no evidence of mutagenic or clastogenic potential |
| Chronic Exposure | May cause damage to liver |
| Acute Exposure | May lead to eye, skin and gastrointestinal and /or respiratory tract infections |
| Target Organ Effects | Liver |

SECTION 12 - ECOLOGICAL INFORMATION

Possibly hazardous short-term degradation products are not likely. However, long term degradation products may arise.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

SECTION 14 - TRANSPORT INFORMATION

This product is not subject to the regulations for the safe transport of hazardous chemicals.

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|------|---------------|
| DOT | Not regulated |
| TDG | Not regulated |
| IATA | Not regulated |
| IMDG | Not regulated |

SECTION 15 - REGULATORY INFORMATION

DEA: Terbinafine Hydrochloride is not a controlled substance

FDA: Terbinafine Hydrochloride is an approved prescription medication

Inventory status: This method is not listed on the US TSCA inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.
This material is not listed on the DSL inventory but is exempt.

SECTION 16 - OTHER INFORMATION

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Orchid shall not be held liable for any damage resulting from handling or from contact with the above product. Orchid reserves the right to revise this SDS.