

Material Safety Data Sheet (MSDS)

Product Name: Terbinafine Hydrochloride IP Grade

MSDS Generate Date: 20-05-2017

Revision Date: 30-12-2024

Supplier:

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1. Identification of the Substance/Preparation and Company

Product identifier: Terbinafine Hydrochloride

Other names / Synonyms: (for labeling: terbinafine HCl)

Recommended use: Active pharmaceutical intermediate / API for antifungal formulations;
research & development; industrial use.

Restrictions on use: Not for direct human administration in bulk form; follow regulatory controls
for APIs.

2. Hazard(s) identification

GHS Classification:

- This product is **not classified** as a physical or health hazard under most GHS criteria when supplied as a solid crystalline powder. (Treat as potentially irritating — see below.)

Label elements: No mandatory GHS hazard pictograms required based on classification. Use precautionary labeling for handling (see Section 7 & 8).

Hazard statements (precautionary):

- May cause eye and skin irritation.
- Avoid inhalation of dust.
- May cause respiratory tract irritation if inhaled in large quantities.
- **Other hazards:** Dust may present a minor nuisance inhalation hazard. Handle to avoid dust generation.

3. Composition / information on ingredients

Substance: Terbinafine Hydrochloride (IP Grade).

Typical purity: $\geq 98.0\%$ (product specification dependent).

Impurities / stabilizers: As per batch COA.

(Note: provide CAS / EC numbers on company letterhead if required by regulation.)

4. First-aid measures

Inhalation: Move person to fresh air. If breathing is difficult or cough persists, seek medical attention. Give oxygen if breathing is difficult and qualified personnel are available.

Skin contact: Remove contaminated clothing. Wash skin thoroughly with soap and water. Seek medical attention if irritation develops or persists.

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do — continue rinsing. If irritation persists, obtain medical attention.

Ingestion: Rinse mouth. Do NOT induce vomiting unless directed by medical personnel. Obtain medical advice if large amount ingested or symptoms develop.

Notes to physician: Treat symptomatically. No specific antidote known.

5. Firefighting measures

Suitable extinguishing media: Use water spray, foam, dry chemical or CO₂ extinguishers appropriate for surrounding fire.

Unsuitable extinguishing media: Do not use full water jet on burning product.

Specific hazards: Combustion may produce irritating and/or toxic fumes (e.g., nitrogen oxides,

hydrogen chloride, carbon oxides) depending on conditions.

Special protective equipment: Firefighters should wear self-contained breathing apparatus (SCBA) and full turnout gear. Avoid inhalation of combustion products.

Special procedures: Prevent run-off from fire control from entering waterways or drains.

6. Accidental release measures

Personal precautions: Avoid dust formation. Use appropriate PPE (see Section 8). Keep unprotected persons away. Avoid breathing dust.

Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not allow product to enter drains or watercourses. Notify authorities if release to environment could occur.

Methods for containment & cleanup: Sweep/shovel into suitable containers for disposal. For small spills, vacuum with HEPA-filtered equipment or wet mop to avoid dust. Use non-sparking tools. Label and dispose of per local regulations (Section 13). Clean area with water after solids removed.

Reference to other sections: For disposal, see Section 13. For PPE, see Section 8.

7. Handling and storage

Handling:

- Avoid breathing dust. Use local exhaust ventilation where dust may be generated.
- Avoid contact with skin and eyes. Use good industrial hygiene practices.
- Keep containers tightly closed when not in use. Minimize generation of dust.

Storage:

- Store in a cool, dry, well-ventilated area away from incompatible materials (strong oxidizers, strong acids).
 - Keep containers properly labeled and closed. Protect from moisture and direct sunlight.
Recommended storage conditions: 15–25 °C, dry.
Incompatible materials: Strong oxidizing agents; strong acids and bases.
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8. Exposure controls / personal protection

Occupational exposure limits: No specific internationally harmonized OEL available for terbinafine hydrochloride. If workplace limits exist locally, follow those. Otherwise, control exposure to “as low as reasonably achievable” (ALARA).

Engineering controls: Use local exhaust ventilation or dust collection to maintain airborne dust concentrations below any applicable limits.

Personal protective equipment (PPE):

- **Respiratory protection:** If dusty conditions occur and engineering controls are insufficient, use NIOSH-approved respirator for particulates (P2/P3 or equivalent).
- **Hand protection:** Impervious gloves (nitrile or equivalent) for prolonged contact.
- **Eye protection:** Safety goggles or face shield.
- **Skin/body protection:** Lab coat or protective clothing to prevent skin contact.
Hygiene measures: Wash thoroughly after handling. Do not eat, drink or smoke in work areas.

9. Physical and chemical properties

Appearance: Off-white to white crystalline powder.

Odor: Slight or negligible.

pH: Not applicable (solid).

Melting point / range: Typical data available on technical datasheet.

Boiling point: Not applicable (decomposes on heating).

Flash point: Not applicable (solid).

Flammability (solid): Not highly flammable as supplied, but combustible under fire conditions.

Solubility: Soluble in organic solvents (e.g., alcohols) — refer to technical data. Slightly soluble in water (depending on form).

Vapor pressure / density / other data: Refer to technical specifications or certificate of analysis.

10. Stability and reactivity

Reactivity: Stable under recommended storage and handling conditions.

Chemical stability: Stable under normal temperatures and pressures.

Possibility of hazardous reactions: None known under normal handling and storage.

Conditions to avoid: Avoid strong heating, ignition sources, moisture and prolonged exposure

to air.

Incompatible materials: Strong oxidizing agents, strong acids, and strong bases.

Hazardous decomposition products: On thermal decomposition: hydrogen chloride, nitrogen oxides, carbon oxides, and other potentially irritating/toxic fumes.

11. Toxicological information

Acute toxicity: Limited acute toxicity by oral, dermal or inhalation routes in published data for active pharmaceutical intermediate forms; treat substance as potentially harmful if ingested or inhaled as dust.

Skin corrosion / irritation: May cause mild skin irritation in sensitive individuals.

Serious eye damage / irritation: May cause eye irritation.

Respiratory or skin sensitization: No reliable human data indicating sensitization; however, avoid repeated/prolonged exposure.

Chronic toxicity / Carcinogenicity / Reproductive toxicity: No clear evidence of carcinogenicity or reproductive toxicity in standard references for the technical grade; consult regulatory dossiers for pharmaceutical-grade risk assessments.

Toxicological note: Provide product-specific toxicology reports / safety studies where required for regulatory filings.

12. Ecological information

Ecotoxicity: No specific data included. Assume potentially harmful to aquatic organisms at high concentrations. Prevent releases to waterways.

Persistence and degradability: Not readily available — consult environment fate data for the API if needed.

Bioaccumulative potential: Data not available; treat conservatively.

Mobility in soil: Data not available.

Other adverse effects: Avoid release to surface water, groundwater, and sewer systems.

13. Disposal considerations

Waste treatment methods: Dispose of material in accordance with local, regional, national and international regulations. Incineration at licensed facilities is recommended for large quantities (subject to local regulation). Small amounts may be landfilled in accordance with local law if

permitted.

Contaminated packaging: Empty containers may retain residue—dispose as hazardous/non-hazardous waste per local rules after triple-rinsing (if applicable) and label removal.

Regulatory note: Consult local waste authority for classification of API-containing wastes and for permitted disposal routes.

14. Transport information — (DETAILED)

General statement: Terbinafine Hydrochloride (solid) **is generally not classified as a dangerous/goods hazardous substance for transport** under many national/international transport regulations when shipped as a dry solid in non-hazardous concentration and when not subject to other regulatory restrictions. **However, transport classification may vary by jurisdiction, packaging, quantity, and local regulations.** Always confirm with the applicable transport authority and carrier prior to shipment.

Below are practical transport details and guidance to include on shipping documents and to follow when packaging and transporting:

UN Number: Not assigned / Not applicable (unless an impurity or formulation creates a regulated hazardous material).

Proper Shipping Name: Not regulated for transport / Not classified as Dangerous Goods under ADR / IMDG / IATA (as a bulk solid, typical technical grade). If classification changes (e.g., due to formulation or impurities), use the assigned Proper Shipping Name.

Transport hazard class(es): Not applicable (no transport hazard class assigned).

Packing group: Not applicable.

Marine pollutant: Not listed as a regulated marine pollutant. Nonetheless, avoid marine release; treat as potentially harmful to aquatic environment if spilled.

Special precautions for user / carrier:

- Prevent dust release and avoid packaging damage. Use sealed, secure inner liners (e.g., polyethylene bags) inside robust outer packaging (fibre drum, cardboard box with inner lining, or as required by the carrier).
- Label packages with product name and “Handle with care — avoid dust” (or company-specific handling labels).
- Secure packages to prevent shifting during transport. Protect from moisture.

- Check for any country-specific restrictions on shipping APIs (pharmaceutical active materials may be subject to additional documentation).

Limited quantity / Excepted quantity provisions:

- Where applicable, shipments in small retail or small pack sizes may qualify for “limited quantity” exemptions under ADR, IMDG, and IATA Dangerous Goods regulations. Verify dimensions/quantities against the applicable regulation and the carrier’s acceptance policy.

Air transport (IATA / ICAO):

- Typically **not regulated** as dangerous goods for air transport when supplied as a stable solid and packed to prevent dust release. However, air carriers may require documentation; always confirm with the airline and IATA Dangerous Goods regulations before shipment. For bulk shipments, consult airline/forwarder.

Sea transport (IMDG):

- Typically **not regulated** under IMDG for solids in appropriate packages. Avoid release to sea; follow MARPOL and local port requirements for accidental release.

Road transport (ADR / national):

- Typically **not classified** under ADR for transport by road. Check for special local regulations for transport of active pharmaceutical ingredients.

Rail transport (RID):

- As ADR—typically not regulated but check local rail operator requirements.

Emergency response:

- For transport incidents, follow Section 4 (first aid) and Section 5 (firefighting). In the event of release to environment during transport notify relevant local emergency response authorities and the supplier. Provide SDS to emergency personnel.

Documentation to accompany shipment:

- A copy of this MSDS.
- Commercial invoice, packing list, and any export/import permits if required.
- Any applicable local / national declarations for APIs.

Note / disclaimer: This transport information is guidance only. Classification and regulatory status may differ depending on country, regulatory updates, impurities or formulation changes, or when shipped in combination with other materials. **Before shipping, confirm transport classification and documentation requirements with:** carrier, freight forwarder, and local transport and customs authorities.

15. Regulatory information

Regulatory status: Terbinafine Hydrochloride is an active pharmaceutical ingredient; regulatory listing and controls vary by jurisdiction. Follow local pharmaceutical regulations for manufacture, storage, transport, and sale.

Relevant regulations: Manufacturers and distributors must ensure compliance with applicable chemical, pharmaceutical, environmental, and occupational safety regulations (e.g., local implementations of GHS, pharmaceutical GMP, waste management rules).

Labeling: Use appropriate chemical and handling labels. Provide product batch and COA information as required.

16. Other information

Disclaimer: The information in this MSDS is believed to be accurate as of the revision date above but is provided without warranty. Users must verify suitability for their purpose and comply with all applicable laws and regulations. This document does not constitute a guarantee of product properties.

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- MSDS are based on the manufacturer's provided information.