# SAFETY DATA SHEETS

## This SDS packet was issued with item:

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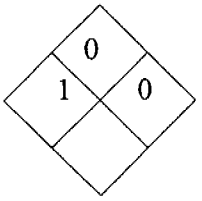
NOVARTIS




# MATERIAL SAFETY DATA SHEET

**NOVARTIS PHARMACEUTICALS CORPORATION**
One Health Plaza
East Hanover, NJ 07936

**24-Hour Emergency Telephone Number:** 1-862-778-7000
**Customer Interaction Center (MSDS requests):** 1-888-669-6682
**For Technical Information:** 1-862-778-3680 (9:00 AM – 5:00 PM E.S.T.)

## SECTION 1. PRODUCT IDENTIFICATION

| | |
|---|---|
| PRODUCT NAME: | **LAMISIL® Cream, 1%** |
| PRODUCT CODE(S): | NDC 0078-0170-40; NDC 0078-0170-46 |
| SYNONYMS: | Not available |
| THERAPEUTIC CATEGORY: | Antifungal; treatment of athlete's foot, jock itch, and ringworm. |
| GENERIC NAME: | Terbinafine hydrochloride cream |
| CHEMICAL NAME: | (E)-N-(6,6-dimethyl-2-hepten-4-ynyl)-N-methyl-1-naphthalenemethanamine hydrochloride |
| CHEMICAL FORMULA: | $C_{21}H_{26}ClN$ |
| MOLECULAR WEIGHT: | 327.90 |

## SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

| COMPOSITION | CAS# | CONCENTRATION |
|---|---|---|
| Terbinafine hydrochloride, USP | 91161-71-6 | 1% by wt. |
| Benzyl alcohol, NF | 100-51-6 | Not available |
| Cetyl alcohol, NF | 36653-82-4 | Not available |

## SECTION 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

**********

**FINISHED PHARMACEUTICAL PRODUCT**
**REFER TO PHYSICIANS' DESK REFERENCE**
**MAY CAUSE SKIN IRRITATION**

**********

| | |
|---|---|
| PRIMARY ROUTE(S) OF ENTRY: | Dermal |
| EFFECTS OF OVEREXPOSURE: | Finished pharmaceutical product. Potential for exposure is reduced in this form. |
| Skin: | Direct contact may cause skin irritation. |
| Eye: | Direct contact may cause eye irritation. |
| Inhalation: | No hazard is expected from normal clinical use. |
| Ingestion: | No hazard is expected from normal clinical use. |
| THERAPEUTIC SIDE EFFECTS: | Local irritation, itching, dryness, rash, and burning sensation. |
| TARGET ORGAN EFFECTS: | None reported. |
| REPRODUCTIVE HAZARDS: | There are no adequate and well-controlled studies in pregnant women. Terbinafine hydrochloride was not found to be teratogenic in experimental animals. Nursing mothers should avoid application of Lamisil® to the breast. |
| CARCINOGENICITY: | There are no adequate and well-controlled studies in humans. |
| MUTAGENICITY: | No evidence of mutagenic or clastogenic potential in five test systems (see Section 11). |

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Hypersensitivity to terbinafine hydrochloride or other components of the cream.

## SECTION 4. EMERGENCY AND FIRST AID MEASURES

| | |
|---|---|
| **Skin Contact:** | Wash contaminated area with soap and water. Overdosage through skin unlikely due to limited absorption of topically applied drug. |
| **Eye Contact:** | Flush with running water for 15 minutes holding eyelids open. |
| **Inhalation:** | No specific treatment is necessary since this product is not likely to be hazardous by inhalation. |
| **Ingestion:** | Get medical attention immediately. |

## SECTION 5. FIRE FIGHTING MEASURES

**Flash Point:** not available **Method Used:** not available

**Flammable Limits (% in air)**
Lower: not available Upper: not available

**Autoignition Temperature:** Not available

**Extinguishing Media:** Use media suitable for fire in surrounding area.

**Special Fire Fighting Procedures and Precautions:** Evacuate area and fight fire from safe distance.

**Fire and Explosion Hazards:** Not available

| | |
|---|---|
| **Fire-Fighting Equipment:** | Wear full protective clothing and positive pressure self-contained breathing apparatus. |
| **Decomposition Products:** | Thermal decomposition may result in the emission of carbon monoxide, carbon dioxide, nitrogen oxides and chlorine. |

NFPA Ratings: Health = 1 Flammability = 0 Reactivity = 0 Special Hazard = None
Hazard Rating Scales: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe U = Unknown

## SECTION 6. ACCIDENTAL RELEASE MEASURES

**Steps to be taken if Material is Released or Spilled:** Using appropriate protective equipment, sweep up and containerize spilled material.

## SECTION 7. HANDLING AND STORAGE

| | |
|---|---|
| **Storage Temperature (Min/Max):** | 41°F/ 86°F (5°C/30°C) |
| **Shelf Life:** | Not available |
| **Special Sensitivity:** | Protect from extreme heat or freezing. |
| **Handling and Storage Precautions:** | None |

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

| | |
|---|---|
| **Eye Protection:** | Not required under normal conditions of therapeutic administration and use. |
| **Skin Protection:** | Not required under normal conditions of therapeutic administration and use. |
| **Respiratory Protection:** | Not required under normal conditions of therapeutic administration and use. |
| **Ventilation Requirements:** | Not required under normal conditions of therapeutic administration and use. |
| **Additional Measures:** | None |

**Exposure Limits (Definition of terms):**

| | |
|---|---|
| ACGIH: | American Conference of Governmental Industrial Hygienists |
| Ceiling: | Ceiling Value |
| DTEL: | Derived Target Exposure Limit |
| MAK: | Federal Republic of Germany Maximum Concentration Values in the Workplace |
| NIOSH: | National Institute for Occupational Safety and Health |
| NPIEL: | Novartis Pharma Internal Exposure Limit |
| OSHA: | Occupational Safety and Health Administration [USA] |
| PEL: | Permissible Exposure Limit |
| REL: | Recommended Exposure Limit |
| Skin (notation): | Absorbed through skin |
| STEL: | Short Term Exposure Limit |
| TLV: | Threshold Limit Values |
| TWA: | Time-Weighted Average |

| Component | Exposure Limit |
|---|---|
| Terbinafine hydrochloride | NPIEL = 2 mg/m$^3$ (8 hr. TWA) |
| Benzyl alcohol, NF | Not available |
| Cetyl Alcohol, NF | Not available |

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|---|---|---|---|
| **Appearance :** | Cream | **Odor Threshold:** | Not available |
| **Color:** | White | **Odor Characteristics:** | Not available |
| **pH:** | Not available | **Vapor Pressure (mm Hg):** | Not applicable |
| **Boiling Point:** | Not applicable | **Vapor Density:** | Not applicable |
| **Melting/Freezing Pt.:** | Not available | **Specific Gravity:** | Not available |
| **Soluble In:** | Water (slt.); methanol | **Viscosity:** | Not available |

## SECTION 10. STABILITY AND REACTIVITY

| | |
|---|---|
| **Stable (yes/no):** | Yes |
| **Hazardous Polymerization:** | Will not occur. |
| **Conditions and Materials to Avoid:** | Protect from temperatures below 41°F (5°C) and above 86°F (30°C). |
| **Incompatibility:** | Not available |
| **Hazardous Decomposition Products:** | Thermal decomposition may result in the emission of carbon monoxide, carbon dioxide, nitrogen oxides, and chlorine. |

## SECTION 11. TOXICOLOGICAL INFORMATION

| | |
|---|---|
| **Eye Irritation:** | No data available. |
| **Skin Irritation/Sensitization:** | Erythema, edema and scale formation was observed following topical administration of doses in excess of 1.5 g/kg.. |
| **Oral Toxicity:** | $LD_{50}$ (mice) > 250 mg/kg; no drug-related toxicities noted. $LD_{50}$ (rats) > 250 mg/kg; no drug-related toxicities noted.<br>*The majority of deaths in animals occurred following oral administration of doses exceeding 3 g/kg. Overdosage in rats and mice by the oral route has produced sedation, drowsiness, ataxia, dyspnea, exophthalmus, and piloerection. |
| **Dermal Toxicity:** | No data available. |
| **Parenteral:** | Overdosage in rats and mice by the intravenous route has produced sedation, drowsiness, ataxia, dyspnea, exophthalmus, and piloerection. |
| **Inhalation Toxicity:** | No data available. |
| **Subchronic:** | No data available. |

**Chronic/Carcinogenicity:** In a carcinogenicity study in rats at the highest dose level, 69 mg/kg/day (equivalent to at least 173 times the maximum potential exposure at the recommended human topical dose), a 6% incidence of both liver tumors and skin lipomas were observed in males.
*The comparison of the oral animal dose and the human topical dose is based upon the application of 0.1 mg of terbinafine/$cm^2$ of human skin, the assumption of 100 $cm^2$ cutaneous exposure, and the *theoretical* worst case scenario of 100% human cutaneous absorption.

**Mutagenicity:** Lamisil® has not been found mutagenic or clastogenic in the following assays: Ames Test; mutagenicity evaluation in Chinese hamster ovarian cells; chromosome aberration test; Sister Chromatid Exchange; mouse micronucleus test.

**Reproductive Effects:** **FDA Use-in-Pregnancy Category B: No evidence of risk in humans**
Oral doses (up to 300 mg/kg/day), subcutaneous doses (up to 100 mg/kg/day) and percutaneous doses (up to 150 mg/kg/day) of terbinafine hydrochloride did not reveal any teratogenic potential.

## SECTION 12. ECOLOGICAL INFORMATION

No data available.

## SECTION 13. DISPOSAL CONSIDERATIONS

**Waste Disposal Method:** All wastes must be disposed of in accordance with local, state and federal laws and regulations. (Contact local or state environmental agency for specific rules).

**EPA Hazardous Waste Number:** None

## SECTION 14. TRANSPORTATION INFORMATION

**GROUND/RAIL/VESSEL REGULATIONS**

**DOT Proper Shipping Name:** Consumer Commodity
**DOT Hazard Class:** ORM-D
**DOT Identification Number:** None
**Packing Group:** None
**Hazard Label:** None
**Package Weight Limits:** None
**Special Requirements:** None
**Exceptions:** CFR 49 Sections 173.144, 172.101, 172.200, 173.156
**Non-Bulk Requirements:** None
**Bulk Requirements:** None
**Reportable Quantity (lbs.):** None
**Stowage:** A
**Other Requirements:** None

**AIR REGULATIONS**

| | |
|---|---|
| **IATA Proper Shipping Name:** | Cosumer Comodity |
| **IATA Hazard Class:** | 9 |
| **IATA Identification Number:** | ID 8000 |
| **Packing Group:** | III |
| **Hazard Label:** | Miscellaneous Dangerous Goods |
| **Special Requirements:** | None |
| **Max.wgt/pkg Passgr. Aircraft:** | 25 kg (55lb.) |
| **Max. wgt/pkg Cargo Only Air:** | 25 kg (55lb.) |

## SECTION 15. REGULATORY INFORMATION

**OSHA (Occupational Safety & Health Administration):** This Material Safety Data Sheet contains the information required by the Federal OSHA Hazard Communication Standard (29 CFR 1910.1200).

**OSHA PSM (Process Safety Management):** Not listed (29 CFR 1910.119, Appendix A)

**NJ TCPA (Toxic Catastrophe Prevention Act):** This product contains NONE of the substances subject to the reporting requirements of Section N.J.A.C. 7:31 of this act.

**TSCA (Toxic Substance Control Act):** Not applicable

**CERCLA (Comprehensive Response Compensation & Liability Act):** Not listed

**SARA Title III (Superfund Amendments & Reauthorization Act):**

| | |
|---|---|
| Section 302 Extremely Hazardous Substances: | Not listed |
| Section 311/312 Hazard Categories: | None |
| Section 313 Reportable Ingredients: | Not listed |

**RCRA (Resource Conservation & Recovery Act):** Not listed

**Other State Regulatory Information:**

**New Jersey:** NJ RTK Threshold Planning Quantity = 10,000 lbs.

**Other USA Regulations:** None

**California Proposition 65:** The following statement is made in order to comply with the California Safe Drinking Water and Toxic Enforcement Act of 1986. *This product contains no ingredients known to the State of California to cause cancer or reproductive toxicity.*

**Canada:**

WHMIS Ingredient Disclosure List

Not listed

**EEC Classification (European Economic Community):**

Warning Symbol: not available
Risk Phrases: not available
Safety Phrases: not available

## SECTION 16. OTHER INFORMATION

**Reason for Issue:** Revision #2 – Changes to Company address; changes to Company and Emergency telephone numbers; Section 2 – added CAS number; Section 8 – addition of NPIEL.

| | | | |
|---|---|---|---|
| **Supersedes Date:** | 14 Nov 97 | | |
| **Written By:** | C. Perino | **Date:** | 22 Nov 02 |
| **Approved By:** | J. Affuso | **Date:** | 22 Nov 02 |

**To the best of our knowledge, the information contained herein is accurate. However, Novartis Pharmaceuticals Corporation does not assume any liability whatsoever for the accuracy or completeness of the information contained herein except for the product's administration/use as intended. Final determination of the suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards which exist.**