

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

Product Name: Tolnaftate Cream 1% **Product No.:** 51672-2020

Distributor: Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive, Hawthorne, New York 10532
Telephone: 1-888-TARO-USA

Recommended Use:

- Proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- Helps prevent most athlete's foot with daily use
- For effective relief of itching, burning and cracking

Restrictions on Use: **For external use only**

When using this product avoid contact with eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks

Do not use on children under 2 years of age except under the advice and supervision of a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Substance Class: Antifungal

Formula: C₁₉H₁₇NOS

M.W.: 307.41

SECTION 2: HAZARD(S) IDENTIFICATION

Physical Hazards: Not classified.

Health Hazards: Serious eye damage/eye irritation Category 2B

OSHA Hazard(s): Not classified.

Label Elements

Hazard Symbol: No symbol.

Signal Word: Warning

Hazard Statement: Causes eye irritation.

Precautionary Statement

Prevention: Wash thoroughly after handling.

Response: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Disposal: Not available.

Hazard(s) Not Otherwise Classified (HNOC): Not classified.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient: Tolnaftate 1% CAS#: 2398-96-1
Inactive Ingredients: BHT, PEG-400, PEG-3350, titanium dioxide, white petrolatum

SECTION 4: FIRST-AID MEASURES

Inhalation: Move to fresh air. Call a physician if symptoms develop or persist.

Skin Contact: Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye Contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion: Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most Important Symptoms/Effects, Acute and Delayed: Irritation of eyes and mucous membranes.

Indication of Immediate Medical Attention and Special Treatment Needed: Provide general supportive measures and treat symptomatically.

General Information: Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

SECTION 5: FIRE-FIGHTING MEASURES

Suitable Extinguishing Media: Use fire-extinguishing media appropriate for surrounding materials. Water, foam, dry chemical or CO₂.

Unsuitable Extinguishing Media: None known.

Specific Hazards Arising From the Chemical: No unusual fire or explosion hazards noted.

Special Protective Equipment and Precautions for Firefighters: Wear suitable protective equipment.

Fire-Fighting Equipment/Instructions: Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific Methods: Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate

protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Methods and Materials for Containment and Cleaning Up: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling: As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Conditions for Safe Storage, Including Any Incompatibilities: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Store between 20° to 25°C (68° to 77°F).

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Biological Limit Values: No biological exposure limits noted for the ingredient(s).

Exposure Guidelines: No exposure standards allocated.

Appropriate Engineering Controls: Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Individual Protection Measures, Such As Personal Protective Equipment

Eye/Face Protection: Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin Protection

Hand Protection: Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other: For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal Hazards: Not available.

General Hygiene Considerations: Handle in accordance with good industrial hygiene and safety practice.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point:	No data available at this time.
Melting Point:	110°-112°C
Physical State (Liquid/Solid/Gas):	Solid.
Evaporation Rate:	No Data Available.
Solubility In Water:	Insoluble.
Appearance And Odor:	Smooth cream with characteristic odor.

SECTION 10: STABILITY AND REACTIVITY

Reactivity: No reactivity hazards known.

Chemical Stability: Material is stable under normal conditions.

Possibility of Hazardous Reactions: No dangerous reaction known under conditions of normal use.

Conditions to Avoid: None known.

Incompatible Materials: Peroxides, oxidizing agents, strong acids, bases.

Hazardous Decomposition Products: Irritating and/or toxic fumes or gases, emits toxic fumes under fire conditions, NO_x, SO_x.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Likely Routes of Exposure

Ingestion: Based on available data, the classification criteria are not met.

Inhalation: Due to lack of data the classification is not possible.

Skin Contact: Due to lack of data the classification is not possible.

Eye Contact: Causes eye irritation.

Symptoms Related to the Physical, Chemical, and Toxicological Characteristics: Irritation of eyes and mucous membranes.

Acute Toxicity

<u>Product</u>	<u>Species</u>	<u>Test Results</u>
Tolnaftate (CAS 2398-96-1)		
<i>Oral</i>		
LD50	Mouse	10 g/kg
	Rat	> 6 g/kg

Skin Corrosion/Irritation: Due to lack of data the classification is not possible.

Serious Eye Damage/Eye Irritation: Causes eye irritation.

Respiratory Sensitization: Due to lack of data the classification is not possible.

Skin Sensitization: Due to lack of data the classification is not possible.

Sensitization: Contact dermatitis has been reported rarely following therapeutic use of tolnaftate.

Germ Cell Mutagenicity: Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

Mutagenicity:

Chromosomal aberrations and mutagenicity (neurospora crassa)

Result: Negative.

Carcinogenicity: Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data noted for the ingredient(s).

Persistence and Degradability: No data is available on the degradability of this product.

Bioaccumulative Potential: Not available.

Mobility in Soil: Not available.

Other Adverse Effects: Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal Instructions: Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local Disposal Regulations: Not available.

Hazardous Waste Code: Not available.

Waste from Residues / Unused Products: Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated Packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

SECTION 14: TRANSPORT INFORMATION

DOT: Not regulated as a hazardous material by DOT.

IATA: Not regulated as a dangerous good.

Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: No information available.

SECTION 15: REGULATORY INFORMATION

U.S. Federal Regulations: CERCLA/SARA Hazardous Substances - Not applicable. All components are on the U.S. EPA TSCA Inventory List.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard Categories:

Immediate Hazard - Yes

Delayed Hazard - No

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

SARA 302 Extremely Hazardous Substance: No

SARA 311/312 Hazardous Chemical: No

Other Federal Regulations

Safe Drinking Water Act (SDWA): Not regulated.

Food and Drug Administration (FDA): Not regulated.

U.S. State Regulations: California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

SECTION 16: OTHER INFORMATION

Contact: Taro Pharmaceuticals U.S.A., Inc., Regulatory Affairs Department
3 Skyline Drive, Hawthorne, NY 10532

Preparation and/or Revision Date: February 2016

DISCLAIMER

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