

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

Product Name: Miconazole Nitrate Cream USP, 2% **Product No.:** 51672-2001

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

Recommended Use: Effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis), for effective relief of itching, scaling, burning and discomfort that can accompany these conditions.

Restrictions on Use: Do not use on children less than 2 years of age unless directed by a doctor. When using this product avoid contact with eyes. Stop use and ask a doctor if irritation occurs, condition persists, there is no improvement of athlete's foot or ringworm within 4 weeks or jock itch within 2 weeks.

Substance Class: Antifungal

Formula: $C_{18}H_{14}Cl_4N_2O.HNO_3$

M.W.: 479.15

SECTION 2: HAZARD(S) IDENTIFICATION

Note: This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.

Physical Hazards: Not classified.

Health Hazards: Acute toxicity, oral Category 4
Sensitization, skin Category 1

OSHA Hazard(s): Not classified.

Label Elements

Signal Word: Warning

Hazard Statement: Harmful if swallowed. May cause an allergic skin reaction.

Precautionary Statement

Prevention: Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves.

Response: If swallowed: Call a poison center/doctor/medical professional/ if you feel unwell. Rinse mouth. If on skin: Wash with plenty of water/soap. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

Disposal: Dispose of contents/container to an approved disposal site.

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

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient:	Miconazole Nitrate	CAS#: 22832-87-7
Inactive Ingredients:	Apricot kernel oil, benzoic acid, BHT, glycol stearate, mineral oil, PEG-6, PEG-6-32 stearate, purified water	

SECTION 4: FIRST-AID MEASURES

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

Skin Contact: Wash off with soap and plenty of water. For minor skin contact, avoid spreading material on unaffected skin. If skin irritation or rash occurs: Get medical advice/attention.

Eye Contact: Rinse with water. Get medical attention if irritation develops and persists.

Ingestion: Rinse mouth. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

Most Important Symptoms/Effects, Acute and Delayed: May cause allergic skin reaction.

Indication of Immediate Medical Attention and Special Treatment Needed: Treatment of imidazole antifungal overdose should be symptomatic and supportive and may include the following: Toxicity after ingestion is unlikely. Gastrointestinal decontamination is generally unnecessary. For severe diarrhea or vomiting, monitor and correct fluid status. (Poisindex) For mild/moderate allergic reactions, administer antihistamines with or without inhaled beta agonists, corticosteroids, or epinephrine. For severe allergic reaction, administer oxygen, antihistamines, epinephrine, or corticosteroids. (Poisindex)

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: Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Unsuitable Extinguishing Media: None known.

Specific Hazards Arising From the Chemical: Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

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: Cool containers exposed to flames with water until well after the fire is out.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. 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. Wash spill site.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling: Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. 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. Use of a designated area is recommended for handling of potent materials.

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 at 20° - 25°C (68° - 77°F).

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limit Values

Industrial Use

<u>Material</u>	<u>Type</u>	<u>Value</u>
Miconazole Nitrate (CAS 22832-87-7)	TWA	0.75 mg/l

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

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: Wash hands after handling and before eating. Keep away from food and drink. Handle in accordance with good industrial hygiene and safety practice.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point: N/A

Physical State (liquid/solid/gas): Solid

Specific Gravity (H₂O = 1): N/A

Evaporation Rate (Butyl Acetate = 1): N/A

Solubility: Miscible in water

Appearance: White cream

Odor Description: No characteristic odor

SECTION 10: STABILITY AND REACTIVITY

Reactivity: No reactivity hazards known.

Chemical Stability: Stable at normal conditions.

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

Conditions to Avoid: None known.

Incompatible Materials: Oxidizing agents. Strong bases.

Hazardous Decomposition Products: NO_x, Cl⁻, irritating and/or toxic fumes or gases, emits toxic fumes under fire conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Likely Routes of Exposure

Ingestion: Harmful if swallowed.

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

Skin Contact: May cause an allergic skin reaction.

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

Symptoms Related to the Physical, Chemical, and Toxicological Characteristics: For imidazole antifungals: nausea, vomiting, diarrhea, abdominal pain, headache, back pain, fever, chills, drowsiness, fatigue, dizziness, skin rash, itching, blistering, burning, skin redness, flushing, constipation, loss of appetite, visual disturbances, yellowed eyes or skin, swelling in arms or legs, difficulty breathing, confusion, depression, sedation, trembling, convulsions.

Cross Sensitivity: Persons sensitive to one azole may be sensitive to this material also.

Medical Conditions Aggravated by Exposure: Porphyria, liver impairment.

Acute Toxicity: Harmful if swallowed.

<u>Product</u>	<u>Species</u>	<u>Test Results</u>
Miconazole Nitrate (CAS 22832-87-7)		
<i>Oral</i>		
LD50	Dog	> 160 mg/kg
	Guinea pig	275.9 mg/kg
	Mouse	578 mg/kg
	Rat	920 mg/kg

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

Serious Eye Damage/Eye Irritation: Due to lack of data the classification is not possible.

Respiratory Sensitization: Due to lack of data the classification is not possible. Rare occurrences of anaphylactic reactions following therapeutic use of this material have been reported.

Skin Sensitization: May cause an allergic skin reaction. Allergic skin reactions have been reported in literature.

Germ Cell Mutagenicity: Based on available data, the classification criteria are not met.

Mutagenicity:

In vitro bacterial reverse mutation (Ames) assay

Result: Negative.

In vivo mouse bone marrow micronucleus test

Result: Negative.

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

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: Very toxic to aquatic life with long lasting effects.

Product	Species	Test Results
Miconazole Nitrate (CAS 22832-87-7) Fish LC50	Fish	0.11 mg/l, 96 hours

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 of contents/container in accordance with local/regional/national/international regulations.

Local Disposal Regulations: Not available.

Hazardous Waste Code: Not regulated.

Waste from Residues / Unused Products: 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

UN Number: UN3077

UN Proper Shipping Name: Environmentally hazardous substance, solid, n.o.s. (Miconazole Nitrate)

Transport Hazard Class(es): 9

Subsidiary Class(es): Not available.

Packing group: III

IATA

UN Number: UN3077

UN Proper Shipping Name: Environmentally hazardous substance, solid, n.o.s. (Miconazole Nitrate)

Transport Hazard Class(es): 9

Subsidiary Class(es): -

Packaging Group: III

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. One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard Categories:

Immediate Hazard - Yes

Delayed Hazard - No

Fire Hazard - Yes

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
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