MATERIAL SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

PRODUCT NAME: **Ketoconazole Cream 2.0%** **PRODUCT No.:** 51672-1298

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

Recommended Use: Ketoconazole cream, 2%is indicated for the topical treatment of tinea corporis, tinea cruris and tinea pedis caused by Trichophyton rubrum, T. mentagrophytes and Epidermophyton floccosum; in the treatment of tinea (pityriasis) versicolor caused by Malassezia furfur (Pityrosporum orbiculare); in the treatment of cutaneous candidiasis caused by Candida spp. and in the treatment of seborrheic dermatitis.

Restrictions on Use: Ketoconazole cream, 2% is contraindicated in persons who have shown hypersensitivity to the active or excipient ingredients of this formulation.

SUBSTANCE CLASS: Anti-fungi Agent

FORMULA: $C_{26}H_{28}Cl_2N_4O_4$

M.W.: 531.43

SECTION 2: HAZARD(S) IDENTIFICATION

Health Hazards: The primary health hazard associated with occupational exposure to this product is the potential for irritation of contaminated eyes and mild irritation of contaminated skin, especially if contamination is repeated.

Flammability Hazards: If heated to high temperatures for a prolonged period, the water in this product can evaporate off and the residue may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, and hydrogen chloride).

Reactivity Hazards: This product is not reactive.

Environmental Hazards: Large quantities released to the environment may have an adverse effect.

Emergency Considerations: Emergency responders should wear appropriate protection for situation to which they respond.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient:	Ketoconazole 2%	CAS#: 65277-42-1
Inactive Ingredients:	Butylated hydroxyanisole (BHA), cetyl alcohol, isopropyl myristate, polysorbate 60, polysorbate 80, propylene glycol, purified water, sorbitan monostearate and stearyl alcohol.	

SECTION 4: FIRST-AID MEASURES

Eye: Rinse with water for few minutes.

Skin: Wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Cover the irritated skin with emollient. If irritation persists, seek medical attention. Wash contaminated clothing before reusing.

Ingestion: Do not induce vomiting. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.

Inhalation: Allow the victim to rest in a well ventilated area. Seek immediate medical attention.

Eye: Rinse with water for few minutes.

SECTION 5: FIRE-FIGHTING MEASURES

Flash Point:	Not Available
Extinguishing Media:	Small fire: Use DRY chemical powder
	Large fire: Use water spray, fog or foam. Do not use water jet.
Special Fire Fighting Procedures:	Not Available
Hazardous Combustion Products:	Carbon oxides (CO, CO_2), Nitrogen oxides (NO, NO_2)

SECTION 6: ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED: Use appropriate tools to put the spill solid in a convenient waste disposal container.

SECTION 7: HANDLING AND STORAGE

HANDLING: Keep away from heat and source of ignition.

STORAGE: Keep container dry in cool place and tightly closed in well-ventilated place.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: Local exhaust ventilation or other engineering control to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limits.

PERSONAL PROTECTION:

Respiratory:	Dust respirator.
Eye:	Safety glasses.
Clothing:	Lab coat.
Gloves:	Appropriate gloves.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

BOILING POINT:	Not Available
PHYSICAL STATE (liquid/solid/gas):	Solid
SPECIFIC GRAVITY (H2O=1):	Not Available
EVAPORATION RATE (Butyl Acetate=1):	Not Available
SOLUBILITY:	Not Available
APPEARANCE:	Aqueous cream
ODOR DESCRIPTION:	Not Available

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability:	Stable
Conditions to Avoid:	Avoid flames and sparks.
Incompatibility with other Materials:	Not Available
Hazardous Decomposition Products:	Carbon oxides (CO, CO_2), Nitrogen oxides (NO, NO_2)
Hazardous Reactions:	Will not occur

SECTION 11: TOXICOLOGICAL INFORMATION

The substance can be absorbed through skin, eye contact and ingestion. Classified Reproductive system/toxin/female/male. The substance is toxic to liver and endocrine.

SECTION 12: ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: This product has not been tested for soil absorption or mobility. The following information is available for the components of this product:

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability. The following information is available for the components of this product: as identifiable molecular species will occur.

BIOACCUMULATION: This product has not been tested for bioconcentration. The following information is available for the components of this product:

SECTION 13: DISPOSAL CONSIDERATIONS

Assure conformity with applicable disposal regulations. Dispose of absorbed material at approved incineration or chemical landfill waste disposal site.

SECTION 14: TRANSPORT INFORMATION

Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labeling for air, maritime, US or European ground transport purposes

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for any component of this product.

U.S. CERCLA REPORTABLE QUANTITIES (RQ): Not applicable.

U.S. TSCA INVENTORY STATUS: This product is regulated by the Food and Drug Administration; it is not subject to requirements under TSCA.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): The components of this product are not on the California Proposition 65 lists.
OTHER U.S. FEDERAL REGULATIONS: Not applicable.

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: January 2015

D I S C L A I M E R

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user's responsibility to evaluate the information and use it in a prudent manner for its particular purpose. Taro Pharmaceuticals assumes no responsibility for the use of this information.