

## MATERIAL SAFETY DATA SHEET

### SECTION 1: PRODUCT IDENTIFICATION

<b>PRODUCT NAME:</b>	<b>Terbinafine HCl Cream, 1%</b>	<b>PRODUCT No.:</b>	<b>51672-2080</b> <b>51672-2083</b> <b>51672-2084</b>
<b>CAS #:</b>	<b>78628-80-5</b>	<b>FORMULA:</b>	<b>C<sub>21</sub>H<sub>25</sub>N•HCl</b>
<b>SUBSTANCE CLASS:</b>	<b>Antifungal</b>	<b>M.W.:</b>	<b>327.90</b>

### SECTION 2: PHYSICAL/CHEMICAL DATA

<b>BOILING POINT:</b>	N/A
<b>APPEARANCE /PHYSICAL STATE:</b>	White cream
<b>SPECIFIC GRAVITY (H<sub>2</sub>O=1):</b>	N/A
<b>EVAPORATION RATE (Butyl Acetate=1):</b>	N/A
<b>SOLUBILITY:</b>	Slightly soluble in water
<b>ODOR DESCRIPTION:</b>	No discernible odor

### SECTION 3: FIRE AND EXPLOSION HAZARD DATA

This material is not flammable, however, it will burn in a fire. The dusts of this material at sufficient concentrations can form explosive mixtures with air creating an explosion hazard.

<b>FLASH POINT:</b>	N/A
<b>EXTINGUISHING MEDIA:</b>	Use water spray, carbon dioxide, dry chemical, or alcohol foam when fighting fires involving this material.
<b>SPECIAL FIRE FIGHTING PROCEDURES:</b>	As in any fire, wear a self-contained breathing apparatus pressure demand (MSHA/NIOSH approved or equivalent) and full protective gear.
<b>UNUSUAL FIRE AND EXPLOSION HAZARDS:</b>	Not known.
<b>HAZARDOUS COMBUSTION PRODUCTS:</b>	Not known.

### SECTION 4: STABILITY AND REACTIVITY DATA

<b>CHEMICAL STABILITY:</b>	Stable
<b>CONDITIONS TO AVOID:</b>	None
<b>INCOMPATIBILITY WITH OTHER MATERIALS:</b>	None
<b>HAZARDOUS DECOMPOSITION BY PRODUCTS:</b>	None
<b>HAZARDOUS POLYMERIZATION:</b>	Will not occur

## SECTION 5: HAZARDS IDENTIFICATION

**EMERGENCY OVERVIEW** White cream with no odor. Not expected to present an immediate concern for emergency response personnel. Not expected to present an immediate acute health, reactivity, or flammability hazard.

### POTENTIAL HEALTH EFFECTS

**Eye:** Exposure may cause eye irritation including pain, tearing and redness accompanied by a stinging sensation.

**Skin:** Generally not expected to be a skin irritant. However, exposure may cause irritation in individuals with heightened skin sensitivity. Irritation evidenced by rash and redness. Substance can be absorbed through the skin in small amounts.

**Ingestion:** Not expected to occur during normal industrial activities.

**Inhalation:** Inhalation is not expected to be a relevant route of exposure during normal industrial activities. However, exposure to large amounts may cause narcotic and central nervous system effects, as well as irritation to the lungs and throat.

**Chronic Effects/ Carcinogenicity:** No long-term chronic effects or carcinogenicity data are known or available on this product.

- NTP: *not listed*
- IARC: *not listed*
- OSHA: *not listed*

**Mutagenicity** No mutagenicity data are available on this product.

**Reproductive Effects** No reproductive effects data are available on this product.

**Teratogenicity (birth defects)** No teratogenicity data are available on this product.

**Medical Conditions Aggravated by Exposure** None known.

**Incompatibility** Non known

**Signs and Symptoms** Exposure to significant amounts of this product may cause irritation of the affected area.

*See Section 10 (Toxicological Information) for more information.*

## SECTION 6: HEALTH HAZARD DATA

**EMERGENCY OVERVIEW** This product is a non-prescription drug intended to provide temporary relief of athlete's foot, jock itch and ringworm. White cream with no odor. Not expected to present an immediate concern for emergency response personnel. Not expected to present an immediate acute health, reactivity, or flammability hazard.

### FIRST AID MEASURES

**Eye:** Flush eyes with water for several minutes. If irritation develops, seek medical attention.

**Skin:** Wash skin with soap and water. If irritation develops, seek medical attention.

**Ingestion:** In case of accidental overdose/ingestion, seek medical attention or contact a poison control center immediately.

**Inhalation:** If small amounts of the product are inhaled, no specific treatment is necessary since this product is not likely hazardous by inhalation. If exposed to excessive levels, remove to fresh air and get medical attention if cough or other symptoms develop.

## SECTION 7: SPILL OR LEAK PROCEDURES

### STEPS TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED:

Vacuum or sweep up material and place in a disposal container.  
Do not attempt to reuse recovered material.

### RCRA CLASSIFICATION:

If discarded in its manufactured form, this product is not expected to be either a listed or characteristic hazardous waste under RCRA. However, it is the responsibility of the user to determine at the time of disposal whether a material containing the product or derived from the product should be classified as a hazardous waste.

### WASTE DISPOSAL METHOD:

Soak up spills and leaks with standard absorbent materials. Dispose of these materials in a manner consistent with federal, state and local environmental regulations.

## SECTION 8: HANDLING AND STORAGE

**HANDLING:** Avoid contact with skin and eyes. Handle in well ventilated locations.  
**STORAGE:** Store in a cool dry area. Keep away from food and drinking water.

## SECTION 9: EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>ENGINEERING CONTROLS:</b>	Good general ventilation should be sufficient to control any airborne levels of the material.
<b>PERSONAL PROTECTION:</b>	
Respiratory:	Respiratory protection is not expected to be necessary unless significant quantities of the material become airborne. If so, the product should be treated as a nuisance dust.
Eye/Face:	Eye and face protection is not expected to be necessary unless significant quantities of the material become airborne.
Clothing:	Clothing protection is not expected to be necessary.
Gloves:	Glove protection is not expected to be necessary.
<b>WORK PRACTICES:</b>	There are no established exposure guidelines for this material.
Skin:	There are no established exposure guidelines for this material.

## SECTION 10: TOXICOLOGICAL INFORMATION

**Availability of Toxicological Information:** Limited toxicological data exist on this product.

**Acute Toxicological Data:** There are no acute (oral, skin, inhalation, eye) toxicological data on this product.

**Skin Sensitization:** This product is not expected to cause skin sensitization. There are no data on skin effects on this product.

**Subchronic Data:** There are no subchronic data on this product.

**Reproductive Toxicity:** There are no reproductive toxicity data on this product.

**Teratogenicity (birth defects):** There are no teratogenicity data on this product.

**Mutagenicity:** There are no mutagenicity data on this product.

**Chronic Effects/Carcinogenicity:** There are no chronic effects or carcinogenicity data on this product.

#### **SECTION 10: OTHER INFORMATION**

**Ecotoxicological Data:** No data are available. However, this product contains 1% terbinafine which was found to be very toxic to aquatic organisms.

#### **SECTION 11: TRANSPORTATION INFORMATION**

This product is not regulated as dangerous or hazardous goods under DOT, IMO, ICAO, IATA, or UN shipping regulations.

#### **SECTION 12: REGULATORY INFORMATION**

Taro Pharmaceuticals U.S.A., Inc.  
Attn: Regulatory Affairs Department  
3 Skyline Drive  
Hawthorne, NY 10532  
(914) 345-9001  
(914) 593-0078 fax

#### **DISCLAIMER**

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.

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