

Clotrimazole And
Retamethasone Dispropionate
Cream USP 1.0%

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

PRODUCT NAME: Clotrimazole Cream USP, 1.0% **PRODUCT No.:** 51672-1275

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

Recommended Use: Clotrimazole cream USP is indicated for the topical treatment of candidiasis due to *Candida albicans* and tinea versicolor due to *Malassezia furfur*.

Restrictions on Use: Clotrimazole cream USP is contraindicated in individuals sensitive to its components.

SUBSTANCE CLASS: Antifungal agent

FORMULA: $C_{22}H_{17}ClN_2$

M.W.: 344.84

SECTION 2: HAZARD(S) IDENTIFICATION

EMERGENCY OVERVIEW

Product Description: This product is a white to off-white cream with a slight waxy odor.

Health Hazards: The chief health hazard associated with exposure during normal use and handling is the potential for irritation of contaminated skin. Individuals who have had allergic reactions to products containing the active ingredients, Clotrimazole, other imidazoles, or any of the other components may experience allergic reactions to this product.

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: This product has not been tested for environmental effects.

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

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient: Clotrimazole CAS#: 23593-75-1

Inactive Ingredients: Cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate 60, purified water, sorbitan monostearate, and benzyl alcohol (1%) as preservative.

SECTION 4: FIRST-AID MEASURES

- Eye:** Immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. WARM water MUST be used. Get medical attention.
- Skin:** Wash immediately with plenty of water. Cover the irritated skin with an emollient. In case of serious skin contact, wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Wash contaminated clothing and shoes before reusing. Get medical attention.
- Ingestion:** Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.
- Inhalation:** If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

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, CO₂), Nitrogen oxides (NO, NO₂), halogenated compounds.

SECTION 6: ACCIDENTAL RELEASE MEASURES

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.

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:	Splash goggles
Clothing:	Lab coat
Gloves:	Appropriate gloves

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
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BOILING POINT:	Not Available
PHYSICAL STATE (liquid/solid/gas):	Solid
SPECIFIC GRAVITY (H₂O=1):	Not Available
EVAPORATION RATE (Butyl Acetate=1):	Not Available
SOLUBILITY:	Very slightly soluble in cold water, diethyl ether. Soluble in acetone.
APPEARANCE:	Smooth, white cream, free of lumps.
ODOR DESCRIPTION:	Odorless

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability:	Stable
Conditions to Avoid:	Avoid heat and dust
Incompatibility with other Materials:	Not Available
Hazardous Decomposition Products:	Carbon oxides (CO, CO ₂), Nitrogen oxides (NO, NO ₂), halogenated compounds.
Hazardous Polymerization:	Will not occur

SECTION 11: TOXICOLOGICAL INFORMATION
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The substance can be absorbed through inhalation and ingestion. Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation. May cause adverse reproductive effects. Topical or oral overdose with this material is not expected to be life threatening. Possible allergic reaction to material if inhaled, ingested or in contact with skin. Although it is poorly absorbed from the gastrointestinal tract, chronic ingestion may also affect liver, urinary tract and blood.

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.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability.

BIOACCUMULATION: This product has not been tested for bioconcentration.

ECOTOXICITY: No specific information is currently available on the effect of this product on plants or animals in the environment.

ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

OTHER ADVERSE EFFECTS: No component of this product is known to have ozone depletion potential.

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. 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: May 2015

DISCLAIMER

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