SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

PRODUCT NAME: **Clotrimazole and Betamethasone Dipropionate Cream USP, 1%/0.05%** **PRODUCT No.:** **51672-4048**

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

Recommended Use: Clotrimazole and Betamethasone Dipropionate Cream is a combination of an azole antifungal and corticosteroid and is indicated for the topical treatment of symptomatic inflammatory tinea pedis, tinea cruris, and tinea corporis due to *Epidermophyton floccosum*, *Trichophyton mentagrophytes,* and *Trichophyton rubrum* in patients 17 years and older.

Restrictions on Use: None.

SUBSTANCE CLASS: Antifungal

FORMULA: $C_{22}H_{17}ClN_2$ & $C_{28}H_{37}FO_7$

M.W.: 344.84 & 504.59

SECTION 2: HAZARD(S) IDENTIFICATION

EMERGENCY OVERVIEW: White Lotion Odor unknown, May be absorbed through the skin. May be harmful if absorbed through skin or if swallowed. May cause dermal sensitization. May be irritating to skin. May be a reproductive toxicant. May cause developmental effects.

Causes effects to: skin, endocrine system

May cause effects to: muscoloskeletal system, immune system, liver, kidney, reproductive system, fetus

POTENTIAL HEALTH HAZARDS:

Eye: In animal studies, Clotrimazole caused slight eye ilTitation, tearing and salivation.

Skin: Clotrimazole I% application on skin included stinging, itching, redness, swelling, blisters, burning, peeling, itching eruptions (urticaria), and general irritation of the skin. Clotrimazole may cause sensitization of the skin in sensitive individuals. Reported occupational effects from betamethasone include allergic skin reactions such as dermatitis and rash. The most common side effects in studies with betamethasone-containing topical preparations were local, including erythema, steroid-induced rosacea (redness, acne-like reaction on face), mild burning, itching, skin dryness and irritation.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient: Clotrimazole and Betamethasone Dipropionate

CAS#: 23593-75-1 & 5593-20-4

Inactive Ingredients: Ceteareth-30, cetostearyl alcohol, mineral oil, phosphoric acid, propylene glycol, purified water, sodium phosphate monobasic, white petrolatum; benzyl alcohol as preservative

SECTION 4: FIRST-AID MEASURES

Inhalations: Remove to fresh air. If any trouble breathing, get immediate medical attention. Skin contact: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

Eye contact: In case of eye contact, immediately rinse eyes thoroughly with plenty water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

Ingestion: Rinse mouth and drink a glass of water. Do not induce vomiting. If symptoms persist, consult a physician.

Note to Physician: This product contains clotrimazole, a broad spectrum antifungal agent, and betamethasone dipropionate, a steroid hormone. This product is indicated for the topical treatment of dermal infections. Persons with prior history of asthma, treatment with systemic steroids, or pre-existing skin conditions, such as acne and dem1atitis, may be more susceptible to the adverse effects of exposure to this product. Serious health effects including death have occurred in asthmatic patients during transfer from systemic cmiicosteroid to topical corticosteroid clinical use.

SECTION 5: FIRE-FIGHTING MEASURES

Flash Point: >93.3° C (>200° F)

Extinguishing Media: Carbon dioxide (C02), extinguishing powder or water spray.

Special Fire Fighting Procedures: Wear full protective clothing and self-contained breathing apparatus (SCBA)

SECTION 6: ACCIDENTAL RELEASE MEASURES

All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

SECTION 7: HANDLING AND STORAGE

Handling: Ensure adequate ventilation. Handle in essentially closed systems, or in a laboratory fume hood. Cover containers during material transfer or transportation. Avoid contact with skin and clothing.

Storage: Store in a cool, dry, well ventilated area.
See section 8 for specific engineering controls and additional safe handling information.

Store Clotrimazole and Betamethasone Dipropionate Cream at room temperature between 68°F to 77°F (20° C to 25°C).

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: For laboratories and small-scale operations, no open handling. All operations must be performed in a properly functioning chemical fume hood, ventilated enclosure or glove box.
For manufacturing and large scale operations, no open handling. Totally enclosed processes and the use of containment technology are required. Recirculation of general room air or exhaust air is prohibited. Air locks with provisions for personnel and materials transfer into and out of the containment area are required.

Personal Protection:

Respiratory: In laboratories and small-scale operations, appropriate respiratory protection is required in situations where exposure may exceed any available recommended exposure limit. Consult your site safety staff for additional guidance.

In manufacturing and large-scale operations, only the use of powered air purifying respirators (PAPRs) or positive-pressure air supplied respirators with full-face coverage will be permitted. Consult your site safety staff for additional guidance.

Skin: In laboratories and small-scale operations, appropriate respiratory protection is required in situations where exposure may exceed any available recommended exposure limit. Consult your site safety staff for additional guidance.
In manufacturing and large-scale operations, only the use of powered air purifying respirators (PAPRs) or positive-pressure air supplied respirators with full-face coverage will be permitted. Consult your site safety staff for additional guidance.

Eye: Use of goggles or full face protection is recommended. Consult your site safety staff for additional guidance.

Body: In small-scale or laboratory operations, disposable Tyvek or other dust impermeable suit is required. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for additional guidance. In large-scale or manufacturing operations, disposable Tyvek of other dust impermeable suit is required. Use of additional PPE such as shoe

coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for additional guidance.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State (liquid/solid/gas):	Cream
Specific Gravity (H_2O=1):	Close to 1.00.
Solubility (water):	Not Determined.
Appearance:	Smooth white cream.
Odor Description:	Unknown

SECTION 10: STABILITY AND REACTIVITY

Stability/Reactivity:	Stable under normal conditions. None known.
Incompatibile Materials/ Conditions To Avoid:	None known.
Hazardous Decomposition Products/ Reactions:	No dangerous decomposition is expected if used according to manufacturer's specifications.

SECTION 11: TOXICOLOGICAL INFORMATION

Inhalation: Rats dosed with clotrimazole at 0.73 mg/L (maximum attainable level) for hours exhibited lacrimation, salivation, nasal discharge, ano-genital staining, stool changes, and dried black material on extremities. In an acute inhalation toxicity study in rats at 0.59 mg/1 betamethasone dipropionate (maximum attainable concentration), animals exhibited labored breathing, eye closure and decreased activity during exposure. Propylene glycol caused no adverse effects in monkeys or rats following exposure to saturated atmospheres for prolonged periods of time.

Skin: Clotrimazole was practically not irritating to rabbit skin. Betamethasone produced erythema, which was present five hours after dosing in a skin irritation study in rabbits but resolved by 96 hours after dosing. Propylene glycol: Dermal LD50: 20.8 g/kg (rabbit)
Eye: Clotrimazole and Betamethasone produced mild, reversible irritation in rabbits consisting of very slight conjunctival in-itation.

Oral: Clotrimazole: Oral LD50: 708 mg/kg (rat); 923 mg/kg (mouse) Betamethasone dipropionate: Oral LD50: >1000 mg/kg (dog);> 5000 mg/kg (rat);> 50 mg/kg (mice)

Sensitization: A betamethasone dipropionate (0.05%) ointment fonnulation was determined to be a potentially weak sensitizer in guinea pigs. Local irritation at the intradermal injection sites was observed during the induction phase.

SECTION 12: ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

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. This product may be harmful to contaminated terrestrial and aquatic plant and animal life, especially in large quantities.

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

Disposal Methods: It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Shipment of wastes must be done with appropriately permitted and registered transporters.

Disposal Containers: Waste materials must be placed in and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers be done to all applicable regulations.

Precautions To Be Followed During Waste Handling: Wear proper protective equipment when handling waste materials.

Preparing Wastes For Disposal: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of Canada. This product, if unaltered by handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

U.S. EPA Waste Number: Not applicable to wastes consisting only of this product.

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

Chemical Name:	TSCA
Propylene Glycol:	Listed
Petrolatum:	Listed
Mineral Oil:	Listed

Benzyl Alcohol: Listed

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: March 2016

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.