SAFETY DATA SHEETS

This SDS packet was issued with item:

078934103

N/A

Section 1. Identification

1.1 Substance Name: Clotrimazole and Betamethasone Dipropionate Cream USP,1%/0.05% (base)

1.2 Synonyms: D-Alpha-Tocopherol, Formulated Product, calcipotriol, BMS 181161,BMY 30434, MC 903

1.3 Chemical Name: 1-(o-Chloro-α,α-diphenylbenzyl)imidazole/9-fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-Dipropionate

1.4 Relevant identified uses of the substance or mixture and uses advised against: Topical treatment of symptomatic inflammatory tinea pedis, tinea cruris, and tinea

1.5 Company Identification: Glenmark Pharmaceuticals Inc., USA

750 Corporate Drive

Mahwah, NJ 07430

1.6 Emergency Contact details: (201) 684-8000

Section 2. Hazard Identification

2.1 Classification of the substance or mixture

Classification according to Regulation GHS

Emergency Overview:

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, Betamethasone Dipropionate, other imidazoles, or any of the other components may experience allergic reactions to this product. Repeated skin exposure to Betamethasone Dipropionate may cause adverse reproductive effects, based on animal data.

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, hydrogen fluoride, 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.

2.2 Other hazards: Not Known

Section 3- Composition/Information on Ingredients

3.1 Substances

Ingredient	CAS No.	% w/w
Betamethasone dipropionate	5593-20-4	0.0643
Clotrimazole	23593-75-1	1.0
Mineral oil	8012-95-1	Proprietary
White petrolatum	8009-03-8	Proprietary
Cetyl alcohol plus Stearyl alcohol (Stenol 1665)	67762-27-0	Proprietary
Ceteareth-30	68439-49-6	Proprietary
Sodium Phosphate monobasic monohydrate	10049-21-5	Proprietary
Propylene glycol	57-55-6	Proprietary
Phosphoric acid	7664-38-2	Proprietary

Benzyl alcohol	100-51-6	Proprietary
Sodium hydroxide	1310-73-2	QS to adjust pH
Purified water	7732-18-5	Proprietary

Molecular Formula: C22H17ClN2/C28H37FO7

Section 4. First aid Measures

4.1 Inhalation: If vapours of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air

4.2 Skin: If adverse skin effects occur, discontinue use. Seek medical attention.

4.3 Eyes:
If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

4.4 Ingestion: If this product is swallowed, call physician or poison control centre for most current information. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

4.5 Most important symptoms and effects, both acute and delayed
Pre-existing skin conditions may be aggravated by repeated overexposures to this product.

4.6 Indication of any immediate medical attention and special treatment needed
This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treat symptoms and eliminate exposure Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.

Section 5. Fire-fighting Measures

5.1 General Information: Incipient fire responders should wear eye protection. Structural fire-fighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Fire-fighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

5.2 Extinguishing Media: Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.

5.3 Fire/Explosion Hazard: 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 vapours and toxic compounds (including carbon oxides, nitrogen oxides, hydrogen fluoride, and hydrogen chloride).

5.4 NFPA Rating:
Health=1
Fire=0
Reactivity=0

Section 6. Accidental Release Measures

6.1 General Information: Proper protective equipment should be used. In the event of a spill, clear the area and protect people. The atmosphere must have levels of components lower than those listed in Section 8 (Exposure Controls-Personal Protection) if applicable, and have at least 19.5 percent oxygen before personnel can be allowed into the area without Self-Contained Breathing Apparatus (SCBA).

6.2 Minor Spills: Wear goggles and gloves while wiping up small spills of this product with polypad or sponge.

6.3 Major Spills: Trained personnel following pre-planned procedures should handle non-incidental releases. Access to the spill areas should be restricted. Protective apparel should be used with a respirator when there is any danger of mists or sprays being generated. Minimum

Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. The dispersal of mists or sprays into surrounding air and the possibility of inhalation is a serious matter and should be treated as such.

Section 7. Handling and Storage

7.1 Handling: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers that contain this product. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration.
Employees must be trained to properly use this product. Use of this product should be performed in a designated area for working with drugs.

7.2 Storage: Ensure product is properly labelled. Store this product away from incompatible materials. Store this product in original container.

7.3 Storage incompatibility: Avoid heat, light, and contact with incompatible chemicals

Section 8. Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits (OEL):

Chemical Name	CAS	Exposure Limits In Air							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	Other
		TWA mg/m3	STEL mg/m3	TWA mg/m3	STEL mg/m3	TWA mg/m3	STEL mg/m3	IDLH mg/m3	mg/m3
Benzyl Alcohol	100-51-6	NE	NE	NE	NE	NE	NE	NE	AIHA WEELs: TWA = 10 ppm

Betamethasone Dipropionate	5593-20-4	NE	NE	NE	NE	NE	NE	NE	NE
Ceteareth	68439-49-6	NE	NE	NE	NE	NE	NE	NE	NE
Cetostearyl Alcohol	67762-27-0	NE	NE	NE	NE	NE	NE	NE	NE
Clotrimazole	23593-75-1	NE	NE	NE	NE	NE	NE	NE	NE
Mineral Oil	8012-95-1	5 (inhalable fraction)	NE	NE	NE	NE	NE	NE	NE
Propylene Glycol	57-55-6	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established See Section 16 for Definitions of Terms Used.
The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132) or equivalent standards of Canada (including CSA Standard Z94.4-02 and CSA Standard Z94.3-07). Please reference applicable regulations and standards for relevant details.

8.2 Exposure controls:

Appropriate engineering controls

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS.

Personal protective equipment

Respiratory Protection: A respirator is not required for routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, or Canadian CSA Standard Z94.4-02. Oxygen levels below 19.5% are considered

IDLH by OSHA. In such atmospheres, use of a full-face piece pressure/demand SCBA or a full face piece, supplied air respirator with auxiliary self-contained air supply is required under OSHA's Respiratory Protection Standard (1910.134-1998).

Eye Protection: Not normally needed during normal use. If necessary, refer to U.S. OSHA 29 CFR 1910.133 or Canadian CSA Standard Z94.3-07.

Hand Protection: For situations, in which prolonged skin contact is anticipated, double glove, using latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff. If necessary, refer to U.S. OSHA 29 CFR 1910.138 or appropriate standards of Canada.

Body Protection: During patient administration, use of lightweight cotton gown or other medical attire is recommended. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee's feet may be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR 1910.136 and the Canadian CSA Standard Z195-02, Protective Footwear.

Section 9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	:	Ointment
Appearance	:	white to off-white cream with a slight waxy odour
Colour	:	white to off-white
pH Value	:	4.5–6.5
Vapour Pressure	:	Not Known
Vapour Density	:	Not Known
Evaporation Rate	:	Not Known
Other information		
Flash point	:	Not Known
Molecular Weight	:	Not Known

Melting point/range	:	Not Known
Boiling point/boiling range	:	Not Known
Density	:	0.84–1.02
Viscosity	:	Not Known
Water solubility	:	Partially soluble
Solubility in other solvents	:	Not Known
Minimum ignition energy (MIE)	:	Not Known
Minimum ignition temperature (MIT)	:	Not Known
Layer ignition temperature (LIT)	:	Not Known
Flammability/explosivity	:	Not Known
Reactivity/exotherms	:	Not Known
Electrostatic nature	:	Not Known
Highly dusty material	:	Not Known
Any other properties which cause handling or processing difficulties	:	Not Known
Average PSD (particle size distribution (micron)	:	Not Known

9.2 Other Information

No data available

Section 10. Stability and Reactivity

10.1 Reactivity: This product is stable

10.2 Chemical stability: This product is stable.

10.3 Conditions to Avoid: Avoid heat, light, and contact with incompatible chemicals

10.4 Incompatibilities with Other Materials: Acids, caustics, and other chemicals that could affect its performance should be avoided

10.5 Hazardous Decomposition Products: Decomposition: If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides, hydrogen fluoride, and hydrogen chloride). Hydrolysis: None known.

10.6 Hazardous Polymerization: Will not occur under normal transport or storage conditions

Section 11. Toxicological Information

11.1 Information on toxicological effects

Target organs:
Acute: Occupational Exposure: Skin, eyes. Therapeutic Doses: Skin.
Chronic: Occupational Exposure: Skin. Therapeutic Doses: Skin, endocrine system.

Toxicity Data: The toxicity data available for the active components of this product are presented in this MSDS.

Betamethasone dipropionate:
LD50 (Oral-rat) > 4000 mg/kg
LD50 (Oral-mouse) > 5000 mg/kg; Behavioral: antipsychotic; Skin and Appendages: hair
LD50 (Intraperitoneal-rat) > 4000 mg/kg
LD50 (Intraperitoneal-mouse) 103 mg/kg
LD50 (Subcutaneous-rat) > 4000 mg/kg
LD50 (Subcutaneous-mouse) 78100 µg/kg

Clotrimazole:
LD50 (Oral-Rat) 708 mg/kg
LD50 (Oral-Mouse) 761 mg/kg
LD50 (Oral-Dog) > 2000 mg/kg: Gastrointestinal: nausea or vomiting
LD50 (Oral-Cat) > 1000 mg/kg: Gastrointestinal: nausea or vomiting
LD50 (Oral-Rabbit) > 1000 mg/kg: Behavioral: somnolence (general depressed activity), convulsions or effect on seizure threshold, muscle weakness

LD50 (Oral-Mammal) 750 mg/kg
LD50 (Intraperitoneal-Rat) 445 mg/kg
LD50 (Intraperitoneal-Mouse) 108 mg/kg
LD50 (Intravenous-Mouse) 198 mg/kg

Carcinogenic Information: There have been no long-term studies performed in animals to evaluate the carcinogenic potential of Clotrimazole or topical corticosteroids. The incipient components of this product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

Mineral Oil: IARC-3 (Not Classifiable as to Carcinogenicity to Humans)
The remaining components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

Reproductive Toxicity Information: Listed below is information concerning the effects of this compound on animal or human reproductive systems.
Mutagenicity: Betamethasone was positive in the in vitro human lymphocyte chromosome aberration assay, and equivocal in the in vivo mouse bone marrow micronucleus assay. It was negative in the bacterial mutagenicity assay (Salmonella typhimurium and Escherichia coli), and in the mammalian cell mutagenicity assay (CHO/HGPRT).

Embryotoxicity: This product has not been tested for embryotoxic effects.

Teratogenicity: Betamethasone Dipropionate has been shown to be teratogenic in rabbits when given by the intramuscular route at doses of 0.05 mg/kg. This dose is approximately 0.2 fold the maximum human dose based on a mg/m2 comparison. The abnormalities observed included umbilical hernias, cephalocele, and cleft palates. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. No human data are available.

Reproductive Toxicity: Reproductive studies with Betamethasone Dipropionate carried out in rabbits at doses of 1.0 mg/kg by the intramuscular route and in mice up to 33 mg/kg by the intramuscular route indicated no impairment of fertility except for dose-related increases in fetal resorption rates in both species. These does are approximately 5 and 38 fold the human dose based on a mg/m2 comparison, respectively. No human data are available.

Acgih Biological Exposure Indices (BEIs): Currently, there are no ACGIH Biological Exposure Indices (BEIs) determined for components of this product.

Section 12. Ecological Information

12.1 Toxicity: 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.

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

Benzyl Alcohol:
An estimated BCF of 1 was calculated for Benzyl Alcohol, using a log Kow of 1.1 and a regression-derived equation. According to a classification scheme, this BCF suggests the potential for bioconcentration in aquatic organisms is low.

Propylene glycol:
An estimated BCF of 3 was calculated for Propylene Glycol, using a log Kow of -0.92 and a regression-derived equation. According to a classification scheme, this BCF suggests the potential for bioconcentration in aquatic organisms is low.

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

Benzyl Alcohol:
Experimental Koc values for Benzyl Alcohol are < 5 for three different soils; Apison (0.11% organic carbon), Fullerton (0.06% organic carbon), and Dormont (1.2% organic carbon). An experimental Koc of 15 was determined for Benzyl Alcohol on a red-brown Australian soil (1.09% organic carbon). According to a classification scheme, these Koc values suggest that Benzyl Alcohol is expected to have very high mobility in soil.

Propylene glycol:
The Koc of Propylene Glycol is estimated as 8, using a log Kow of -0.92 and a regression-derived equation. According to a classification scheme, this estimated Koc value suggests that Propylene Glycol is expected to have very high mobility in soil.

12.5 Other: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways. No component of this product is known to have ozone depletion potential.

Section 13. Disposal Considerations

13.1 Waste treatment methods

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

14. 1 Special precautions for user:

U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS:
This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS:
This product is not classified as Dangerous Goods, per regulations of Transport Canada

Section 15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

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. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

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.

CANADIAN regulations:

CANADIAN DSL/NDSL inventory status: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it is exempt from requirements of the DSL/NDSL Inventory.

CANADIAN environmental protection act (CEPA) priorities substances lists: The components of this product are not on the CEPA Priorities Substances Lists.

CANADIAN WHMIS classification and symbols: The WHMIS Requirements of the

Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

Section 16. Additional Information

Product Name:

ANSI Labelling (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): CAUTION! MAY CAUSE ALLERGIC REACTION. MAY CAUSE SKIN AND EYE IRRITATION. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs from allergic reaction, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting-seek immediate medical attention. IN CASE OF FIRE: Use water fog, dry chemical, CO2, or "alcohol" foam. IN CASE OF SPILL: Wipe up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Material Safety Data Sheet for additional information

Disclaimer:

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Compiled By (R & D)	Approved by (EHS Head)
18/06/15	19/06/2015
Signature /Date	Signature /Date