



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

PRODUCT: CLOTRIMAZOLE CREAM USP, 1%	SDS NO.	: SDSGHS.018.00
	EFFECTIVE DATE	:31/08/2015
	PAGE No.	:1 of 08

Section 1. Identification

1.1 Substance Name: Clotrimazole Cream USP, 1%

1.2 Relevant identified uses of the substance or mixture and uses advised against:

For the topical treatment of fungal skin infections including tinea, athlete's foot, ringworm and other candidal skin infections such as nappy rash.

1.3 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:

This product is not dangerous for the purposes of transport or storage. Repeated or prolonged use may cause localized irritation in sensitive individuals.



2.2 Label elements:

Signal word: Warning

2.3 Other hazards:

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

PRODUCT: CLOTRIMAZOLE CREAM USP, 1%

SDS NO. : SDSGHS.018.00

EFFECTIVE DATE :31/08/2015

PAGE No. :2 of 08

Precautionary statement(s)

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Section 3- Composition/Information on Ingredients

3.1 Substances

CHEMICAL NAME	CAS #	% w/w	EXPOSURE
Clotrimazole	23593-75-1	1	N/E
ingredients determined not to be hazardous [Mfr]	-	99	

Section 4. First aid Measures

4.1 Inhalation: Remove patient to fresh air. If breathing is difficult, give oxygen. Seek medical attention.

4.2 Skin: Wash affected area with soap and water. If hypersensitivity reaction occurs, seek medical advice.

4.3 Eyes: Flush the eyes with gently running water for at least 15 minutes. If redness or soreness occurs, seek medical advice.

4.4 Ingestion: Do not induce vomiting unless instructed to do so by medical personnel. If large quantities of this material are swallowed, seek medical attention. For advice contact a doctor or Poisons Information Centre.

4.5 Most important symptoms and effects, both acute and delayed

Treat Symptomatically



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

PRODUCT: CLOTRIMAZOLE CREAM USP, 1%

SDS NO. : SDSGHS.018.00

EFFECTIVE DATE :31/08/2015

PAGE No. :3 of 08

Section 5. Fire-fighting Measures

5.1 General Information: Fire-fighters should wear self-contained breathing apparatus as exposure to vapor or combustion products are likely.

5.2 Extinguishing Media: Small fire: dry chemical powder. Large fire: water spray, fog or foam.

5.3 Fire/Explosion Hazard: Oxides of carbon (CO, CO₂), nitrogen (NO, NO₂) and halogenated compounds.

5.4 NFPA Rating: Not Known

Section 6. Accidental Release Measures

6.1 General Information: Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Avoid breathing dust. For personal protection see section 8.

6.2 Minor/Major Spills: Collect and seal in properly labeled containers for disposal. Wash area down with excess water. Waste material may be incinerated under controlled conditions were permitted. Refer to local Waste Management Authority Regulations for other approved methods.

Section 7. Handling and Storage

7.1 Handling: Wash hands after use. Avoid contact with eyes.

7.2 Storage: Store below 25°C in a dry, well-ventilated area.

7.3 Storage incompatibility: Strong oxidizing agents



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

PRODUCT: CLOTRIMAZOLE CREAM USP, 1%

SDS NO. : SDSGHS.018.00

EFFECTIVE DATE :31/08/2015

PAGE No. :4 of 08

Section 8. Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits (OEL):

Components with workplace control parameters

Not Known

8.2 Exposure controls:

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal Protective Equipment

Eye/face protection

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

SAFETY DATA SHEET

PRODUCT: CLOTRIMAZOLE CREAM USP, 1%	SDS NO.	: SDSGHS.018.00
	EFFECTIVE DATE	:31/08/2015
	PAGE No.	:5 of 08

Section 9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	:	cream
Appearance	:	White opaque cream
Colour	:	White
pH Value	:	Not Known
Vapor Pressure	:	Not Known
Vapor 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	:	Not Known
Viscosity	:	Not Known
Water solubility	:	Not Known
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



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

PRODUCT: CLOTRIMAZOLE CREAM USP, 1%

SDS NO. : SDSGHS.018.00

EFFECTIVE DATE : 31/08/2015

PAGE No. : 6 of 08

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: Stable

10.2 Chemical stability: Product is stable.

10.3 Conditions to Avoid: Not Known

10.4 Incompatibilities with Other Materials: Strong oxidizing agents

10.5 Hazardous Decomposition Products: Not Known

10.6 Hazardous Polymerization: Will not occur

Section 11. Toxicological Information

11.1 Information on toxicological effects

Inhalation: May cause respiratory tract infection.

Ingestion: May be harmful and cause GI tract irritation with nausea, vomiting abdominal cramp or pain.



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

PRODUCT: CLOTRIMAZOLE CREAM USP, 1%

SDS NO. : SDSGHS.018.00

EFFECTIVE DATE :31/08/2015

PAGE No. :7 of 08

Skin: Redness, stinging, blistering, peeling swelling, itching and general irritation have been reported infrequently.

Eye: Eye irritation is possible.

Chronic Potential Health

Effects:

Allergic reactions are possible.

Clotrimazole (23593-75-1) Toxicity to Animals:

Acute oral toxicity (LD50): >2000mg/kg [Dog]

Acute oral toxicity (LD50): 923mg/kg [Mouse]

Acute oral toxicity (LD50): 708mg/kg [Rat]

Section 12. Ecological Information

12.1 Toxicity: Hazardous short term degradation products are not likely. However long term degradation products may be more toxic than the product itself.

12.2 Persistence and degradability: Not Known

12.3 Bioaccumulative potential: Not Known

12.4 Mobility in soil: Not Known

12.5 Other: Not Known

Section 13. Disposal Considerations

13.1 Waste treatment methods

Waste material may be incinerated under controlled conditions were permitted. Refer to local Waste Management Authority Regulations for other approved methods. Rinse containers in water.

**GLENMARK PHARMACEUTICALS LIMITED****SAFETY DATA SHEET****PRODUCT: CLOTRIMAZOLE CREAM USP, 1%****SDS NO. : SDSGHS.018.00****EFFECTIVE DATE :31/08/2015****PAGE No. :8 of 08****Section 14. Transport Information****14. 1 Special precautions for user:****ADR**

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

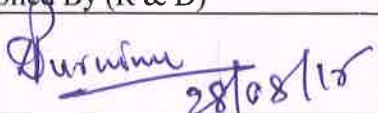
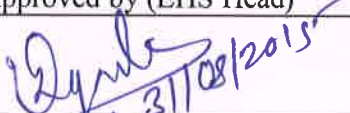
Not regulated as dangerous goods.

Section 15. Regulatory Information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:**

Scheduled using the criteria in the Standard Uniform Schedule for Drugs and Poisons as a Pharmacy Medicine (Schedule 2).

Section 16. 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)
 28/08/15	 31/08/2015
Signature /Date	Signature /Date