

SAFETY DATA SHEETS

This SDS packet was issued with item:

078948564

N/A



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

**PRODUCT: CICLOPIROX OLAMINE CREAM
USP, 0.77%**

SDS NO. : SDSGHS.017.00

EFFECTIVE DATE :24/08/2015

PAGE No. :1 of 9

Section 1. Identification

1.1 Substance Name: Ciclopirox Olamine Cream USP, 0.77%

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

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:

Primary Route(s) of Entry: Dermal, Ingestion.

Signs and Symptoms of Exposure

a. Overexposure Effects: May cause skin irritation and allergic reaction in sensitive individuals.

b. Chronic Effects:

1. Inhalation: None expected under normal condition of use.

2. Eyes: Topical forms will cause moderate irritation. Not for ophthalmic use.

3. Skin: No effects expected under normal conditions of use.



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

**PRODUCT: CICLOPIROX OLAMINE CREAM
USP, 0.77%**

SDS NO. : SDSGHS.017.00

EFFECTIVE DATE :24/08/2015

PAGE No. :2 of 9

4. Ingestion: May induce low toxicity.

5. Medical Conditions: Skin conditions. Systemic effects may be produced.

2.2 Label elements: Not Known

2.3 Other hazards: Not Known

Section 3- Composition/Information on Ingredients

3.1 Substances

CHEMICAL NAME	CAS #	% w/w	EXPOSURE
Ciclopirox (as Ciclopirox Olamine)	41621-49-2	0.77	N/E
ingredients determined not to be hazardous [Mfr]	-	99.23	

Section 4. First aid Measures

4.1 Inhalation: Remove to fresh air. If breathing is difficult, give oxygen. If breathing has stopped, give artificial respiration..

4.2 Skin: Wash thoroughly with soap and water.

4.3 Eyes: Flush eyes with plenty of water for at least 15 minutes.

4.4 Ingestion: Give two glasses of water and induce vomiting if directed by medical personnel. Never give anything by mouth to an unconscious person.

4.5 Most important symptoms and effects, both acute and delayed
Treat Symptomatically



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

PRODUCT: CICLOPIROX OLAMINE CREAM
USP, 0.77%

SDS NO. : SDSGHS.017.00

EFFECTIVE DATE :24/08/2015

PAGE No. :3 of 9

Section 5. Fire-fighting Measures

5.1 General Information: Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. Chemical resistant clothing may be necessary. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects. Move containers from fire area if it can be done without risk to personnel. Water spray can be used to cool fire-exposed containers. Water fog or spray can also be used by trained firefighters to disperse this product's vapors and to protect personnel. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

5.2 Extinguishing Media: Foam, Dry chemical, Carbon dioxide.

5.3 Fire/Explosion Hazard: May emit toxic fumes.

5.4 NFPA Rating: Health= 1, Flammability= 0 and Instability= 0

Section 6. Accidental Release Measures

6.1 General Information: Wash thoroughly after handling. Use normal hygiene to protect hands, eyes and skin. Use general ventilation to protect your lungs. Do not wear contaminated clothing until thoroughly laundered.

6.2 Minor/Major Spills: Assure slippery conditions are nullified. Add sand or dirt. Scoop up and remove. Wash area with soap and water. Dispose of in accordance with federal, state and local regulations.

**GLENMARK PHARMACEUTICALS LIMITED****SAFETY DATA SHEET****PRODUCT: CICLOPIROX OLAMINE CREAM
USP, 0.77%****SDS NO. : SDSGHS.017.00****EFFECTIVE DATE : 24/08/2015****PAGE No. : 4 of 9****Section 7. Handling and Storage****7.1 Handling:** Keep container closed when not in use.**7.2 Storage:** Store at controlled room temperature 15^o-30^oC (59^o-86^oF).**7.3 Storage incompatibility:** Avoid heat, light, oxidants and bases**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**

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-facepiece pressure/demand SCBA or a full facepiece, 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



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

PRODUCT: CICLOPIROX OLAMINE CREAM USP, 0.77%	SDS NO. : SDSGHS.017.00
	EFFECTIVE DATE : 24/08/2015
	PAGE No. : 5 of 9

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	:	cream
Appearance	:	Smooth and homogeneous cream
Colour	:	white to off-white,
pH Value	:	5 - 8
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	:	45,000 - 200,000 cps



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

**PRODUCT: CICLOPIROX OLAMINE CREAM
USP, 0.77%**

SDS NO. : SDSGHS.017.00

EFFECTIVE DATE :24/08/2015

PAGE No. :6 of 9

Water solubility	:	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: Stable

10.2 Chemical stability: Stable

10.3 Conditions to Avoid: Avoid heat, light, oxidants and bases

10.4 Incompatibilities with Other Materials: Heat, light, oxidants and bases

10.5 Hazardous Decomposition Products: Carbon dioxide, Carbon monoxide

10.6 Hazardous Polymerization: Will not occur



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

PRODUCT: CICLOPIROX OLAMINE CREAM
USP, 0.77%

SDS NO. : SDSGHS.017.00

EFFECTIVE DATE :24/08/2015

PAGE No. :7 of 9

Section 11. Toxicological Information

11.1 Information on toxicological effects

Toxicity:

LD50 oral Rat 2350 mg/ kg

LD50 oral Mouse 1740 - 3200 mg/ kg

LD50 oral Rabbit >3065 mg/ kg

Section 12. Ecological Information

12.1 Toxicity: Not Known.

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

Assure conformity with applicable disposal regulations. Dispose of absorbed material at approved incineration or chemical landfill waste disposal site.



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

**PRODUCT: CICLOPIROX OLAMINE CREAM
USP, 0.77%**

SDS NO. : SDSGHS.017.00

EFFECTIVE DATE :24/08/2015

PAGE No. :8 of 9

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:

Refer to the following references:

OSHA Regulations: If respirator used, 29 CFR 1910.134

DOT Regulations: Not applicable.

EPA Regulations: Not applicable.



GLENMARK PHARMACEUTICALS LIMITED

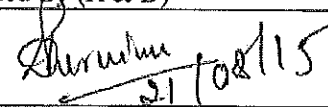
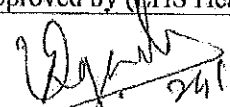
SAFETY DATA SHEET

PRODUCT: CICLOPIROX OLAMINE CREAM USP, 0.77%	SDS NO. : SDSGHS.017.00
	EFFECTIVE DATE : 24/08/2015
	PAGE No. : 9 of 9

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)
 21/08/15	 24/08/2015
Signature /Date	Signature /Date