

SAFETY DATA SHEET

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name 1% Clotrimazole Cream

Other means of identification

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended Use Antifungal - Topical, Non-Aerosol

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier Name Sheffield Pharmaceuticals
Supplier Address 170 Broad Street
New London
CT
06320
US
Supplier Phone Number Phone: 860-442-4451
Fax: 860-442-0356
Contact Phone: 860-442-4451
Supplier Email EHS@sheffield-pharmaceuticals.com
Emergency telephone number

2. HAZARDS IDENTIFICATION


Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2



GHS Label elements, including precautionary statements

Emergency Overview			
Signal word	Warning		
Hazard Statements Causes skin irritation Causes serious eye irritation			
			
Appearance	White	Physical State	Solid Gel Consistency Solid
		Odor	Odorless

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
 Wear protective gloves/protective clothing/eye protection/face protection
 Wear eye/face protection

Precautionary Statements - Response

Specific treatment (see supplemental first aid instructions on this label)

Eyes

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
 If eye irritation persists: Get medical advice/attention

Skin

IF ON SKIN: Wash with plenty of soap and water
 If skin irritation occurs: Get medical advice/attention
 Take off contaminated clothing and wash before reuse

Precautionary Statements - Storage

None

Precautionary Statements - Disposal

None

Hazards not otherwise classified (HNOC)

Not applicable

Unknown Toxicity

31.25% of the mixture consists of ingredient(s) of unknown toxicity

Other information

No information available

Interactions with Other Chemicals

No information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight-%	Trade Secret
Cetearyl alcohol	67762-27-0	10 - 30	*
Myristyl stearate	17661-50-6	5 - 10	*
Clotrimazole	23593-75-1	1 - 5	*
Benzyl alcohol	100-51-6	1 - 5	*

*The exact percentage (concentration) of composition has been withheld as a trade secret

4. FIRST AID MEASURES**First aid measures****General Advice**

Show this safety data sheet to the doctor in attendance.

Eye Contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. Do not rub affected area.

Skin Contact

Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

Inhalation

Remove to fresh air. Get medical attention immediately if symptoms occur.

Ingestion

Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a physician.

Self-protection of the first aider

Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Most Important Symptoms and Effects Burning sensation.

Indication of any immediate medical attention and special treatment needed**Notes to Physician**

Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

CAUTION: Use of water spray when fighting fire may be inefficient.

Specific Hazards Arising from the Chemical

No information available.

Hazardous Combustion Products

Carbon oxides.

Explosion Data

Sensitivity to Mechanical Impact No.

Sensitivity to Static Discharge No.

Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required.

Other Information Refer to protective measures listed in Sections 7 and 8.

Environmental Precautions

Environmental Precautions Refer to protective measures listed in Sections 7 and 8. Prevent further leakage or spillage if safe to do so.

Methods and material for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

Conditions for safe storage, including any incompatibilities

Storage Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatible Products Strong acids. Strong oxidizing agents. Strong bases.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Myristyl stearate 17661-50-6	TWA: 10 mg/m ³ except stearates of toxic metals	-	

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits Immediately Dangerous to Life or Health

Appropriate engineering controls

Engineering Measures Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection If splashes are likely to occur: Wear safety glasses with side shields (or goggles). None required for consumer use.

Skin and Body Protection Wear protective gloves and protective clothing.

Respiratory Protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical State	Solid Gel Consistency Solid	Odor	Odorless
Appearance	White		



Color	No information available	Odor Threshold	No information available
<u>Property</u>	<u>Values</u>	<u>Remarks</u>	<u>Method</u>
pH	4.0 – 6.0	None known	
Melting / freezing point	No data available	None known	
Boiling point / boiling range	No data available	None known	
Flash Point	No data available	None known	
Evaporation Rate	No data available	None known	
Flammability (solid, gas)	No data available	None known	
Flammability Limit in Air			
Upper flammability limit	No data available		
Lower flammability limit	No data available		
Vapor pressure	No data available	None known	
Vapor density	No data available	None known	
Specific Gravity	0.96 – 0.99	None known	
Water Solubility	Soluble in water	None known	
Solubility in other solvents	No data available	None known	
Partition coefficient: n-octanol/water	No data available	None known	
Autoignition temperature	No data available	None known	
Decomposition temperature	No data available	None known	
Kinematic viscosity	No data available	None known	
Dynamic viscosity	No data available	None known	
Explosive properties	No data available		
Oxidizing Properties	No data available		

Other Information

Softening Point	No data available
VOC Content (%)	No data available
Particle Size	No data available
Particle Size Distribution	

10. STABILITY AND REACTIVITY

Reactivity

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

None known based on information supplied.

Incompatible materials

Strong acids. Strong oxidizing agents. Strong bases.

Hazardous Decomposition Products

Carbon oxides.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.
Eye Contact	Specific test data for the substance or mixture is not available. Expected to be an irritant based on components. Irritating to eyes. May cause redness, itching, and pain. May cause temporary eye irritation.
Skin Contact	Specific test data for the substance or mixture is not available. Expected to be an irritant based on components. Irritating to skin. Prolonged contact may cause redness and irritation.
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause irritation to mucous membranes. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Cetearyl alcohol 67762-27-0	> 10000 mg/kg (Rat)	> 8000 mg/kg (Rabbit)	-
Clotrimazole 23593-75-1	= 708 mg/kg (Rat)	-	-
Benzyl alcohol 100-51-6	= 1230 mg/kg (Rat)	= 2 g/kg (Rabbit)	= 8.8 mg/L (Rat) 4 h

Information on toxicological effects

Symptoms Erythema (skin redness). May cause redness and tearing of the eyes.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Sensitization	No information available.
Mutagenic Effects	No information available.
Carcinogenicity	Contains no ingredient listed as a carcinogen.
Reproductive Toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Chronic Toxicity	No known effect based on information supplied.
Target Organ Effects	Respiratory system. Eyes. Skin.

Aspiration Hazard No information available.

Numerical measures of toxicity Product Information

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)

30,893.00 mg/kg

ATEmix (inhalation-dust/mist)

103.10 mg/l

ATEmix (inhalation-vapor)

756.00 ATEmix

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Cetearyl alcohol 67762-27-0				48h EC50: = 1666 mg/L
Benzyl alcohol 100-51-6	3h EC50: = 35 mg/L (Anabaena variabilis)	96h LC50: = 10 mg/L (Lepomis macrochirus) 96h LC50: = 460 mg/L (Pimephales promelas)	EC50 = 50 mg/L 5 min EC50 = 63.7 mg/L 15 min EC50 = 63.7 mg/L 5 min EC50 = 71.4 mg/L 30 min	48h EC50: = 23 mg/L

Persistence and Degradability

No information available.

Bioaccumulation

Chemical Name	Log Pow
Cetearyl alcohol 67762-27-0	6.65
Benzyl alcohol 100-51-6	1.1

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal methods

This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging

Dispose of contents/containers in accordance with local regulations.

California Hazardous Waste Codes 311

14. TRANSPORT INFORMATION

<u>DOT</u>	NOT REGULATED
Proper Shipping Name	NON REGULATED
Hazard Class	N/A

<u>TDG</u>	Not regulated
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<u>MEX</u>	Not regulated
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<u>ICAO</u>	Not regulated
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<u>IATA</u>	Not regulated
Proper Shipping Name	NON REGULATED
Hazard Class	N/A

<u>IMDG/IMO</u>	Not regulated
Hazard Class	N/A

<u>RID</u>	Not regulated
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<u>ADR</u>	Not regulated
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<u>ADN</u>	Not regulated
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15. REGULATORY INFORMATION

International Inventories

TSCA	Complies
DSL	All components are listed either on the DSL or NDSL.

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

US Federal Regulations



SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
Chronic Health Hazard	No
Fire Hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Benzyl alcohol 100-51-6		X	X		

International Regulations

Canada

WHMIS Hazard Class

Non-controlled

**16. OTHER INFORMATION**

NFPA	Health Hazards	1	Flammability	0	Instability	0	Physical and Chemical Hazards - Personal Protection X
HMIS	Health Hazards	2	Flammability	0	Physical Hazard	0	

Prepared By	Product Stewardship 23 British American Blvd. Latham, NY 12110 1-800-572-6501
Revision Date	16-Dec-2014
Revision Note	No information available

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 a 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

End of Safety Data Sheet