

# SAFETY DATA SHEET

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

### Product identifier

Product Name Tolnaftate 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 800-222-1087

## 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 1
Skin sensitization	Category 1



**GHS Label elements, including precautionary statements****Emergency Overview**

<b>Signal word</b>	<b>Danger</b>
<b>Hazard Statements</b> Causes skin irritation Causes serious eye damage May cause an allergic skin reaction	
	
<b>Appearance</b> White	<b>Physical State</b> Cream Liquid
	<b>Odor</b> Medicinal

**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling  
Wear protective gloves/protective clothing/eye protection/face protection  
Avoid breathing dust/fume/gas/mist/vapors/spray  
Contaminated work clothing should not be allowed out of the workplace

**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  
Immediately call a POISON CENTER or doctor/physician

**Skin**

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

**Precautionary Statements - Storage**

None

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**Hazards not otherwise classified (HNOC)**

Not applicable

**Unknown Toxicity**

31% of the mixture consists of ingredient(s) of unknown toxicity

**Other information**

Toxic to aquatic life  
Repeated or prolonged skin contact may cause allergic reactions with susceptible persons

**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	*
White mineral oil (petroleum)	8042-47-5	7 - 13	*
Ceteth-2	9004-95-9	1 - 5	*
Propylene Glycol	57-55-6	1 - 5	*
P-chloro-m-cresol	59-50-7	0.1 - 1	*

\*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. Immediate medical attention is required.

**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. Do not rub affected area. Seek immediate medical attention/advice.

**Skin Contact**

Wash off immediately with soap and plenty of water for at least 15 minutes. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.

**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. Itching. Rashes. Hives.

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

May cause sensitization of susceptible persons. 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

Product is or contains a sensitizer. May cause sensitization by skin contact.

Uniform Fire Code

Sensitizer: Liquid

### 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

Soak up with inert absorbent material. 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. Store locked up. Keep out of the reach of children.

**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
White mineral oil (petroleum) 8042-47-5	TWA: 5 mg/m <sup>3</sup> inhalable fraction excluding metal working fluids, highly & severely refined	TWA: 5 mg/m <sup>3</sup> (vacated) TWA: 5 mg/m <sup>3</sup>	IDLH: 2500 mg/m <sup>3</sup> TWA: 5 mg/m <sup>3</sup> STEL: 10 mg/m <sup>3</sup>

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

**Other Exposure Guidelines** See section 15 for national exposure control parameters

### Appropriate engineering controls

**Engineering Measures** Showers  
Eyewash stations  
Ventilation systems

### Individual protection measures, such as personal protective equipment

**Eye/Face Protection** Tight sealing safety goggles.

**Skin and Body Protection** Wear protective gloves and protective clothing. Long sleeved clothing. Impervious gloves.

**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. Take off contaminated clothing and wash before reuse. 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	Cream, Liquid	Odor	Medicinal
Appearance	White	Odor Threshold	No information available
Color	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	0.88 – 0.98	None known	
Water Solubility	Partially dispersible	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. Severely irritating to eyes. Causes serious eye damage. May cause burns. May cause irreversible damage to eyes.

##### 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 )	-
White mineral oil (petroleum) 8042-47-5	> 5000 mg/kg ( Rat )	-	-
Propylene Glycol 57-55-6	= 20000 mg/kg ( Rat )	= 20800 mg/kg ( Rabbit )	-

P-chloro-m-cresol 59-50-7	-	> 2000 mg/kg ( Rat )	> 0.583 mg/L ( Rat ) 4 h
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**Information on toxicological effects**

**Symptoms** Erythema (skin redness). May cause redness and tearing of the eyes. May cause blindness. Burning. Itching. Rashes. Hives.

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

**Sensitization** May cause sensitization of susceptible persons. May cause sensitization by skin contact.

**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)  
11,901.00 mg/kg  
ATEmix (dermal)  
1,435,200.00



## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

Toxic to aquatic organisms.

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
White mineral oil (petroleum) 8042-47-5		96h LC50: > 10000 mg/L (Lepomis macrochirus)		
Propylene Glycol 57-55-6	96h EC50: = 19000 mg/L (Pseudokirchneriella subcapitata)	96h LC50: = 51600 mg/L (Oncorhynchus mykiss) 96h LC50: 41 - 47 mL/L (Oncorhynchus mykiss) 96h LC50: = 51400 mg/L (Pimephales promelas) 96h LC50: = 710 mg/L (Pimephales promelas)	-	24h EC50: > 10000 mg/L 48h EC50: > 1000 mg/L
P-chloro-m-cresol 59-50-7	72h EC50: = 4.2 mg/L (Desmodesmus subspicatus) 96h EC50: > 10 mg/L (Desmodesmus subspicatus)	96h LC50: 3.11 - 5.27 mg/L (Pimephales promelas) 96h LC50: 1000 - 10000 µg/L (Pimephales promelas) 96h LC50: 5.81 - 7.76 mg/L (Poecilia reticulata) 96h LC50: = 917 µg/L (Oncorhynchus mykiss)	EC50 = 0.27 mg/L 5 min EC50 = 0.28 mg/L 15 min EC50 = 0.34 mg/L 30 min EC50 = 23 mg/L 60 h	48h EC50: = 2 mg/L 48h EC50: 1.13 - 1.94 mg/L

### Persistence and Degradability

No information available.

### Bioaccumulation

Chemical Name	Log Pow
Cetearyl alcohol 67762-27-0	6.65
White mineral oil (petroleum) 8042-47-5	6
P-chloro-m-cresol 59-50-7	3.02

### 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.

Chemical Name	RCRA	RCRA - Basis for Listing	RCRA - D Series Wastes	RCRA - U Series Wastes
P-chloro-m-cresol 59-50-7	U039	Included in waste streams: F039, K001		U039

Chemical Name	RCRA - Halogenated Organic Compounds	RCRA - P Series Wastes	RCRA - F Series Wastes	RCRA - K Series Wastes
P-chloro-m-cresol 59-50-7	Category II - Semi-volatiles			

California Hazardous Waste Codes 311

### 14. TRANSPORT INFORMATION

**DOT**  
 Proper Shipping Name NOT REGULATED  
 Hazard Class NON REGULATED  
 N/A

**TDG** Not regulated

**MEX** Not regulated

**ICAO** Not regulated

**IATA**  
 Proper Shipping Name Not regulated  
 Hazard Class NON REGULATED  
 N/A

**IMDG/IMO**  
 Hazard Class Not regulated  
 N/A

**RID** Not regulated

**ADR** Not regulated

**ADN** Not regulated

### 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 contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

Chemical Name	CAS No	Weight-%	SARA 313 - Threshold Values %
P-chloro-m-cresol - 59-50-7	59-50-7	0.1 - 1	0.1

**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 contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
P-chloro-m-cresol 59-50-7		X	X	

**CERCLA**

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

Chemical Name	Hazardous Substances RQs	Extremely Hazardous Substances RQs	RQ
P-chloro-m-cresol 59-50-7	5000 lb		RQ 5000 lb final RQ RQ 2270 kg final RQ

**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
Propylene Glycol 57-55-6	X		X		

**International Regulations****Mexico****National occupational exposure limits**

Component	Carcinogen Status	Exposure Limits
White mineral oil (petroleum) 8042-47-5 ( 7 - 13 )		Mexico: TWA 5 mg/m <sup>3</sup> Mexico: STEL 10 mg/m <sup>3</sup>

Mexico - Occupational Exposure Limits - Carcinogens



Canada  
WHMIS Hazard Class  
D2B - Toxic materials



## 16. OTHER INFORMATION

NFPA	Health Hazards 3	Flammability 0	Instability 0	Physical and Chemical Hazards -
HMIS	Health Hazards 3	Flammability 0	Physical Hazard 0	Personal Protection X

Prepared By	Product Stewardship 23 British American Blvd. Latham, NY 12110 1-800-572-6501
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### 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