

Trade Name: 1% Tolnaftate Anti-Fungal Cream

1. Product and Company Identification

Product Name: Tolnaftate Anti-Fungal Cream

Recommended Use: Cures most Athlete's Foot, Jock Itch, and Ringworm

Synonyms: Athlete's Foot Cream

Manufacturer/Supplier

Natureplex, LLC

11085 Airport Road

Olive Branch, MS 38654-0221

662-874-1370 (Monday – Friday, 8:00 a.m. – 5:00 p.m. CST)

Emergency Telephone Number: 1-866-323-0107

CHEMTREC: 1-800-424-9300 (Transportation Spill Response 24 hours)

2. Hazard Identification

Classification of the Product

GHS Classification: Serious eye damage/eye irritation 2B

Pictogram:



Hazard Statements:

Causes eye irritation.

Precautionary Statements:

Hands: Wash thoroughly after handling.

Eyes: May be harmful to eyes.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Percent
Purified Water	7732-18-5	Trade Secret
Monosodium Phosphate*	7558-80-7	Trade Secret
Mineral Oil*	8012-95-1	Trade Secret
Propylene Glycol*	57-55-6	Trade Secret
Petrolatum*	8009-03-8	Trade Secret
Stearyl Alcohol*	112-92-5	Trade Secret
Ceteth-20*	9004-95-9	Trade Secret
Chlorocresol*	59-50-7	Trade Secret
Cetyl Alcohol*	36653-82-4	Trade Secret
Tolnaftate	2398-96-1	1.0



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*Specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First Aid Measures

Emergency and First Aid Procedures

Inhalation: Move victim to fresh air. If signs/symptoms continue, get medical attention.

Eye Contact: Do not rub eyes. Flush eyes thoroughly with water for 15 minutes. If condition worsens or irritation persists contact physician.

Skin Contact: Wash with plenty of soap and water. If skin irritation occurs get medical advice/attention.

Ingestion: Do not induce vomiting. Contact a physician or Poison Control Center.

5. Fire Fighting Measures

Extinguishing media

Suitable extinguishing agents: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide

Fire and/or Explosion Hazards:

Hazardous Combustion Products: Carbon oxides, nitrogen oxides, Hydrogen Chloride Gas

Special Fire Fighting Procedures: No special measures required.

6. Accidental Release Measures

Personal Precautions: Do not touch or walk through spilled material.

Environmental Precautions: **Large Spills:** Prevent entry into waterways, sewers, or confined areas.

Steps to Take in Case Product Is Released or Spilled: Sweep or vacuum up and place in an appropriate closed container. Clean up residual material by washing area with water and detergent. Collect washings for disposal.

7. Handling and Storage

Handling

- Avoid breathing fume/mist/vapors/spray.
- Avoid direct or prolonged contact with skin and eyes.

Storage

- Store in a cool, dry place.
- Keep container tightly closed.

Avoid freezing conditions.

8. Exposure Controls/Personal Protection

Personal Protective Equipment: No special measures required under normal usage.

Eye/Face: Wear safety glasses.

Skin/Body: Wear appropriate gloves.

Respiratory: For limited exposure use an N95 dust mask.

Engineering Measures/Controls: Adequate ventilation systems as needed to control concentrations airborne containments below applicable threshold limit values.

Environmental Exposure Controls: Follow best practice for site management and disposal of waste.

9. Physical and Chemical Properties

Appearance

Physical state: Smooth, White Cream

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Form: Cream Color: White Odor: None to slight wax scent Odor threshold: NDA pH: 4.5 – 6.5 Viscosity: >20,000 cps Specific Gravity: 0.90 to 1.03 Melting point/freezing point: NDA Initial boiling point and boiling range: NDA Flash point: NDA Evaporation rate: NDA Flammability (solid, gas): NDA Upper/lower flammability or explosive limits Flammability limit - lower (%): NDA Flammability limit - upper (%): NDA Explosive limit - lower (%): NDA Explosive limit - upper (%): NDA Vapor pressure: NDA Vapor density: NDA Relative density: NDA Solubility (water): Soluble Partition coefficient (n-octanol/water): NDA Auto-ignition temperature: NDA Decomposition temperature: NDA
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10. Stability and Reactivity

Reactivity: No dangerous reaction known under conditions of normal use.
Chemical Stability: Stable under recommended storage conditions.
Conditions to Avoid: Moisture.

Materials to Avoid: None Known

Hazardous Decomposition Products: Oxides of phosphorus. Oxides of sodium.

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

11. Toxicological Information

Acute Toxicity

Tolnaftate

In formation on toxicological effects Acute toxicity: LD50 Oral - rat - 500 mg/kg

Skin corrosion/irritation: no data available

Serious eye damage/eye irritation: no data available

Respiratory or skin sensitization: no data available

Germ cell mutagenicity: no data available

Carcinogenicity: This product is or contains a component that is not classifiable as to its carcinogenicity based on its IARC, ACGIH, NTP, or EPA classification.

IARC: No components of this product present at levels greater than or equal to 0.1% is identified as probable,



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possible or confirmed human carcinogen by IARC.

Reproductive toxicity: no data available

Specific target organ toxicity - single exposure: no data available

Specific target organ toxicity - repeated exposure: no data available

Aspiration hazard: no data available

Potential health effects: Inhalation may be harmful if inhaled. May cause respiratory tract irritation.

Ingestion harmful if swallowed.

Skin: May be harmful if absorbed through skin. May cause skin irritation.

Eyes: May cause eye irritation.

Signs and Symptoms or Exposure: To the best of our knowledge, the chemical, physical, toxicological properties have not been thoroughly investigated.

Stearyl Alcohol

Oral: Rat, LD50>2000 mg/kg

Dermal: Rat, LD50>2000 mg/kg

Inhalation: Rat, LD50> 0.003 mg/L

Skin corrosion/irritation Serious eye damage/irritation: None

Respiratory or skin sensitization: None

Mutagenicity: Negative

Carcinogenicity: Negative

Reproductive toxicity: Negative

STOT-single exposure: NDA

ST OT-repeated exposure: NDA

Aspiration Hazard: NDA

Chlorocresol

LD50 Oral -Rat -1,830 mg/kg

Inhalation: No data available

Skin corrosion/Irritation: No data available

Serious eye damage/eye irritation: No data available

Respiratory or skin sensitization: The preceding data, or interpretation of data, was determined using

Quantitative Structure Activity Relationship (QSAR) modeling.

Germ cell mutagenicity: No data available

Propylene Glycol

Not Available

Sodium Phosphate

Not Available

Cetyl Alcohol



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LD/LC50 Values relevant for classification:		
Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rabbit)
Inhalative	LC50	>0.375 mg/l Rat
	LD50	>0.014 ppm (rat)

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Dermal	LD50	>2000 mg/kg (rabbit)
Inhalative	LC50	>0.375 mg/l Rat
	LD50	>0.014 ppm (rat)

On the Skin: No irritating effect

On the eye: No irritating effect

Sensitization: No sensitizing effect known.

Petrolatum

Not Available

Mineral Oil

Acute oral toxicity: No Data Available

Acute inhalation toxicity: No Data Available

Acute dermal toxicity: No Data Available



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12. Ecological Information

Ecotoxicity effects: Avoid release to the environment

Aquatic toxicity effects: NDA

Bioaccumulative potential: NDA

13. Disposal Considerations

Waste Disposal Method: Dispose of in accordance with local and national regulations.

14. Transport Information

Transport Information This material is not classified as hazardous for transport.

U.S. Department of Transport (DOT) - Not regulated

Canadian Transport of Dangerous Goods (TDG) - Not regulated

International Civil Aviation Organization (ICAO) - Not regulated

International Air Transport Association (IATA) - Not regulated

International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO) - Not regulated

Transport of Dangerous Goods by Rail (RID) - Not regulated

Transport of Dangerous Goods by Road (ADR) - Not regulated

Transportation of Dangerous Goods via Inland Waterways (ADN) - Not regulated

15. Regulatory Information

OSHA Regulatory Status: This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazardous Categorization

Acute Health Hazard: No

Chronic Health Hazard: No

Fire Hazard: No

Sudden Release of Pressure Hazard: No

Reactive Hazard: No

This product does not contain any HAPs.

State Regulations

California Proposition 65 - This product does not contain any Proposition 65 chemicals.

Canada -Not classified

WHMIS Hazard Class - Non-controlled

European Union - In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

16. Other Information

Last Revision: August 15, 2017

Revised Date: 3 August 2022

See Patient Package Insert for more information



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Key to abbreviations: NDA = No Data Available

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