

Trade name: Clotrimazole 1% Anti-fungal Cream

1 Product and Company Identification

Product Identifier: Clotrimazole 1% Anti-fungal Cream

Recommended Uses: External use medicinal product

Trade name: Clotrimazole 1% Anti-fungal 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: 866-323-0107

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

2 Hazard(s) Identification

Classified hazards

Skin corrosion/irritation: Category 2

Serious eye damage/eye irritation: Category 2

Pictogram:



Signal word: Warning

GHS Label elements including precautionary statements

Hazard Statements

Causes skin irritation

Causes serious eye irritation

Precautionary Statements – Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Use personal protective equipment as required

Avoid breathing dust/fume/gas/mist/vapors/spray

In case of inadequate ventilation wear respiratory protection

Contaminated work clothing should not be allowed out of the workplace

Wear protective gloves

Precautionary Statements - Response

- If exposed or concerned: Get medical advice/attention



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

Skin

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

Inhalation

- IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing
- If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician

Precautionary Statements - Storage

- none

Precautionary Statements - Disposal

- none

Hazard(s) not otherwise classified (HNOC)

- Not Applicable

Other information

- Repeated or prolonged skin contact may cause allergic reactions with susceptible persons

3 Composition/Information on Ingredients

<u>Chemical Name</u>	<u>CAS number</u>	<u>%</u>
Water*	7732-18-5	Proprietary
Carbomer*	9003-01-4	Proprietary
Stearic Acid*	57-11-4	Proprietary
Cetyl Alcohol*	36653-82-4	Proprietary
Glyceryl stearate*	123-94-4	Proprietary
Mineral oil*	8012-95-1	Proprietary
Methylparaben*	99-76-3	Proprietary
Propylparaben*	94-13-3	Proprietary
Clotrimazole	23593-75-1	1.0%
Isopropyl alcohol*	67-63-0	Proprietary
Polysorbate 20*	9005-64-5	Proprietary
Trisodium EDTA*	139-89-9	Proprietary
DMDM hydantoin*	6440-58-0	Proprietary
Triethanolamine*	102-71-6	Proprietary
Aloe barbadensis leaf juice*	85507-69-3	Proprietary



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

4 First Aid Measures

Inhalation: Move affected workers to fresh air. If necessary, administer CPR and oxygen. Call a physician if symptoms persist.

Eye contact: Remove contact lenses. Thoroughly flush eyes with water for at least 15 minutes. Keep eye(s) wide open while rinsing. Do not use an eye ointment as a first aid measure. Seek medical attention if irritation develops or persists.

Skin contact: Remove contaminated clothing and shoes. Wash skin with soap and water for at least 15 minutes. Get medical attention if irritation develops or persists.

Ingestion: Do not induce vomiting, unless directed to do so by medical personnel. Give nothing by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician and/or poison control immediately. Loosen tight clothing.

Most important symptoms/effects, acute and delayed: Burning sensation.

Indication of immediate medical attention and special treatment needed: Treat symptomatically.

General information: Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

5 Fire Fighting Measures

Extinguishing media

Suitable extinguishing agents: Use carbon dioxide, dry chemical, or alcohol resistant foam.

Unsuitable extinguishing agents: Use of water spray when fighting fire may be inefficient.

Fire and / or Explosion Hazards: No data available.

Special Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective gear.

6 Spill or Leak Procedures

Steps to Take in Case Product Is Released or Spilled

Small spill: use absorbent material to wipe up spill and place in a sealed container for disposal. Clean spill area thoroughly.

Large spill: contain the source of the spill or leak if it is safe to do so. Collect spill with a non-combustible absorbent material and transfer it to labeled container for disposal. Clean the spill area thoroughly.

7 Handling and Storage

Handling

No special technical protective measures required.

Storage

Store according to labeled instructions.



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No special restrictions on storage with other products.

8 Exposure Controls / Personal Protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels low. If user operations generate dust, fumes, or mist, ventilate to keep exposure to airborne contaminants low.

Individual protection measures, such as personal protective equipment

Eye/face protection

Avoid contact with eyes. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full-face protection may be required depending on the industrial exposure setting. None required for consumer use.

Skin protection

Wear a lab coat, rubber gloves, splash goggles, and a dust respirator. Use approved / certified respirator and equivalent gloves. Wash promptly with soap and water if skin becomes contaminated.

Respiratory protection

No protective equipment is needed under normal use conditions. If irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9 Physical and Chemical Properties

Appearance

Physical state: semi-solid liquid

Form: cream

Color: white to off white

Odor: slight wax scent

Odor threshold: Not Available

pH: 5.5-7.5

Melting point/freezing point: Not Available

Initial boiling point and boiling range: Not Available

Flash point: Not available



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Evaporation rate: Not available
Flammability (solid, gas): Not available
Upper/lower flammability or explosive limits
 Flammability limit - lower (%): Not available
 Flammability limit - upper (%): Not available
 Explosive limit - lower (%): Not available
 Explosive limit - upper (%): Not available
Vapor pressure: Not available
Vapor density: Not available
Relative density: Not available
Solubility
 Solubility (water): Not available
Partition coefficient (n-octanol/water): Not available
Auto-ignition temperature: Not available
Decomposition temperature: Not available
Viscosity: Not available

10 Stability and Reactivity

Product is stable under recommended storage conditions.

Instability information at different temperatures is unavailable. Conditions of instability may include excess heat and incompatible materials. For example, it reacts with oxidizing agents and strong acids and bases.

The product is incompatible with strong acids, strong bases, and strong oxidizing agents.

Polymerization will not occur.

11 Toxicological Information

Information on likely routes of exposure

Inhalation

May cause irritation of respiratory tract.

Skin contact

Expected to be an irritant based on components. Prolonged contact may cause redness and irritation.

Eye contact

Expected to be an irritant based on components. Direct contact with eyes may cause temporary irritation. May cause redness, itching, and pain.

Ingestion

Do not ingest. May cause irritation to mucous membranes, gastrointestinal irritation, nausea,



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vomiting, and diarrhea.

Symptoms related to the physical, chemical and toxicological characteristics

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

Information on toxicological effects

Acute toxicity

May be harmful if swallowed in large quantities. Oral median lethal dose 708 mg/kg (rat).

Skin corrosion/irritation

May cause irritation.

Serious eye damage/eye irritation

Direct contact with eyes may cause temporary irritation.

Respiratory sensitization

May cause irritation.

Skin sensitization

This product is not expected to cause skin sensitization.

Germ cell mutagenicity

No mutagenicity studies have been conducted.

Carcinogenicity

Long-term studies in animals have not been conducted to evaluate carcinogenic potential.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Specific target organ toxicity - single exposure

Not classified.

Specific target organ toxicity - repeated exposure

Respiratory system. Eyes. Skin.

Aspiration hazard

Not classified.

12 Ecological Information

Ecotoxicity effects: No data are available on the product itself.

Aquatic toxicity effects: No data are available on the product itself.

13 Disposal Considerations

Waste disposal must comply with relevant US, Federal, State, and international regulations.

14 Transport Information

The product is not classified as hazardous for transport.

The product is not regulated by USDOT, IATA, IMDG, or EUADR regulations.

15 Regulatory Information



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- **US federal regulations**

This material is not listed on the US TSCA 8(b) Inventory; therefore, it may only be used for TSCA exempt purposes such as R&D or drug use. Over-the-counter drugs in their solid final form (i.e. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

- **TSCA Section 12(b) Export Notification (40 CFR 707, Sub. D)** Not regulated.
- **OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)** Not listed.
- **CERCLA Hazardous Substance List (40 CFR 302.4)** Not listed.
- **Superfund Amendments and Reauthorization Act of 1986 (SARA)**
 - Immediate Hazard - YES
 - Delayed Hazard - No
 - Fire Hazard - No
 - Pressure Hazard - No
 - Reactivity Hazard - No
- **SARA 302 Extremely hazardous substance** Not listed.
- **SARA 311/312 Hazardous chemical** No
- **SARA 313 (TRI reporting)** Not regulated.
- **Other federal regulations**
 - **Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List** Not regulated.
 - **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)** Not regulated.
 - **Safe Drinking Water Act (SDWA)** Not regulated.
- **US state regulations**
 - **Massachusetts RTK - Substance List** Not regulated.
 - **New Jersey Worker and Community Right-to-Know Act** Not listed.
 - **Pennsylvania Worker and Community Right-to-Know Law** Not listed.
 - **Rhode Island RTK** Not regulated.
 - **California Proposition 65** Not Listed.
- **International Inventories**
 - **Canada - Domestic Substances List (DSL)**
Complies with inventory.
 - **United States and Puerto Rico - Toxic Substances Control Act (TSCA) Inventory**
Complies with inventory.

16 Additional Information

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Disclaimer

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