Merck & Co., Inc.
One Merck Dr.
Whitehouse Station, NJ 08889

MATERIAL SAFETY DATA SHEET

Merck urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

MSDS NAME: **Tolnaftate Solution 1%**

SYNONYM(S):
AFTATE Solution 1%
SPORILINE Lotion 1%
SPORILINE Solution 1%
TINACTIN Antifungal Solution 1%
TINACTIN Lotion 1%
TINACTIN Solucion 1%
TINACTIN Solution 1%
TINADERM Lozione 1%
TINADERM Solucao 1%
TINADERM Solucion 1%
TINADERM Solution 1%
TOLNOFTAL Losung 1%

MSDS NUMBER: SP001289

EMERGENCY NUMBER(S): Merck Security Control Center (908) 820-6921 (24 hours)

Safety/Environmental Affairs (901) 320-2384

Transportation Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

INFORMATION: Safety/Environmental Affairs (901) 320-2384

MERCK MSDS HELPLINE: (800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Solution
Clear, Colorless
Odor unknown

Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.

POTENTIAL HEALTH EFFECTS:

Although some ingredients used in the manufacture of this product are considered hazardous on an individual basis, the final formulation of this product is considered non-hazardous when used according to manufacturer's directions. The following summary is based upon available information about the individual ingredients of the mixture, or of the expected properties of the mixture.

Tolnaftate is a highly active synthetic fungicidal agent used in the treatment of superficial fungal infections of the skin. It is not readily absorbed; therefore, it does not cause systemic effects. Tolnaftate has been rarely reported to cause irritation, contact dermatitis, and hypersensitivity reactions in humans. Tolnaftate or formulated products containing tolnaftate may cause slight irritation of the skin or sensitization reactions in susceptible individuals.

Acute exposure to polyethelyene glycol may cause slight eye or skin irritation, abnormal taste, gas, nausea, vomiting, diarrhea, irregular heartbeat, low blood pressure, or fluid in the lungs. Repeated exposure of polyethylene glycol to damaged skin has been reported to cause kidney failure and necrosis. It may cause skin sensitization in sensitive individuals.

LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by OSHA, IARC, NTP or ACGIH are present in concentrations >0.1% in this mixture.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Consumer product

CHEMICAL FORMULA: Mixture.

The formulations for these products are proprietary information. These formulations have the same hazardous profile; however, the presence of hazardous ingredients may vary by formulation. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	PERCENT
Tolnaftate	2398-96-1	1
Polyethylene Glycol	25322-68-3	>90

ADDITIONAL INFORMATION: This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

SECTION 4. FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

SKIN CONTACT: In keeping with good hygienic practices, wash exposed areas thoroughly with soap and water.

EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

INGESTION: Rinse mouth with water. If symptoms develop, consult a physician.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

Flash Point: Not determined (liquids) or not applicable (solids).

SPECIAL FIRE FIGHTING PROCEDURES:
Wear full protective clothing and self-contained breathing apparatus (SCBA).

SUITABLE EXTINGUISHING MEDIA:
Carbon dioxide (CO2), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:
Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

SPILL RESPONSE / CLEANUP:
All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

HANDLING:
Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

STORAGE:
Store in a cool, dry, well ventilated area.

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

EXPOSURE CONTROLS
The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection:	None required for consumer use of this product. Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.
Skin Protection:	None required for consumer use of this product. Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.
Eye Protection:	None required for consumer use of this product. Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.

Body Protection: None required for consumer use of this product.

In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

EXPOSURE LIMIT VALUES

No exposure limits are available for the active ingredient(s) or any other hazardous ingredient in this formulation.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Solution
COLOR: Clear, Colorless
ODOR: Odor unknown
SOLUBILITY:
Water: Not determined

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
None known.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
No dangerous decomposition is expected if used according to manufacturer's specifications.

SECTION 11. TOXICOLOGICAL INFORMATION

There are no data available specifically for this formulation. The data shown below pertains to the following individual ingredients in the formulation, or are from studies conducted using similar formulas containing the same active and/or hazardous ingredients found in this product.

ACUTE TOXICITY DATA

INHALATION:
Polyethylene glycol: No mortalities were reported in animals (0/6) following a 4-hour exposure to polyethylene glycol vapors generated at 170 deg C; however, mortality was observed in all animals (6/6) following an 8-hour exposure to polyethylene glycol vapors generated at 170 deg C.

SKIN:
Tolnaftate has been rarely reported to cause irritation, contact dermatitis, and hypersensitivity reactions in humans.

Polyethylene glycols (200-9000 g/mol): Dermal LD50: >20 g/kg (unspecified species).
Polyethylene glycol was not irritating to the skin of rabbits and guinea pigs.
Polyethylene glycol was not irritating in a human patch test.

EYE:
Tolnaftate was slightly irritating to the eyes of rabbits.

Polyethylene glycols did not produce appreciable eye irritation in rabbits.

ORAL:
Tolnaftate: Practically not toxic

Polyetheylene Glycols (all molecular weights): Practically not toxic

DERMAL AND RESPIRATORY SENSITIZATION:
Polyethylene glycols did not produce skin sensitization in guinea pigs.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
A 3-week inhalation study was conducted in rats given a 1% tolnaftate powdered aerosol mixture. No mortality or other systemic effects were observed. No toxic effects were observed in mice, dogs or rabbits given 2500 mg tolnaftate/kg in 3-month oral studies.

Polyethylene glycol 400 produced no adverse effects in dogs and rats fed 2% in the diet for one or two years, respectively. Repeated dermal exposure to polyethylene glycol 300 for an eight-week period had no effect on mice. Repeated inhalation exposure to 1008 mg/m^3 of a higher molecular weight polyethylene glycol increased lung weight, and also produced reversible increases in neutrophil counts in male rats.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Pregnant mice and rats given tolnaftate at doses of 2000 and 500 mg/kg, respectively, had no significant effects on fetal development. No teratogenic effects were seen in rabbits given dermal doses of 1% and there were no developmental effects observed in guinea pig, rabbit, or dog studies.

Polyethylene glycol 200 was developmentally toxic in mice, causing malformations and other fetotoxicity, but elicited no similar response in rats at higher doses.

MUTAGENICITY / GENOTOXICITY:
Tolnaftate was negative in an in vitro chromosome aberration study and in a mutagenicity test with Neurospora crassa.

Polyethylene glycol was negative in a bacterial mutagenicity study (Ames), results were inconclusive in a bacterial DNA repair study.

CARCINOGENICITY:
This material or product has not been evaluated for carcinogenicity.

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

This product has not been tested for ecotoxicity.

ENVIRONMENTAL DATA

There are no environmental data available for these products or their components.

SECTION 13. DISPOSAL CONSIDERATIONS

MATERIAL WASTE:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

SECTION 15. REGULATORY INFORMATION

TSCA LISTING

INGREDIENT	TSCA
Tolnaftate	X
Polyethylene Glycol	X

U.S. STATE REGULATIONS

INGREDIENT	PARTK	MNRTK	MIRTK	RIRTK
Polyethylene Glycol		X		

Fields in the above tables that do not contain data indicate that those materials have not been listed by local regulations.

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

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