Schering-Plough HealthCare Products, Inc.
3030 Jackson Avenue
Memphis, TN 38151

MATERIAL SAFETY DATA SHEET

Schering-Plough 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: **DR. SCHOLL'S Athlete's Foot Antifungal Powder**

SYNONYM(S): DR. SCHOLL'S Athlete's Foot Antifungal Powder
DR. SCHOLL'S Athlete's Foot Powder
TRITIN Antifungal Powder

MSDS NUMBER: SP001112

EMERGENCY NUMBER(S): (908) 423-6000 (24/7/365) English Only

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

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

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SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Powder
White to off-white
Characteristic odor
May be irritating to eyes, skin or respiratory tract.

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 information presented below pertains to the following individual ingredients, and not to the mixture(s).

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.

Prolonged exposure to talc may cause eye irritation. Acute aspiration of talc may cause vomiting, fluid in the lungs and irritation of the lungs including cough, sneezing, shortness of breath, and rapid breathing. Long-term inhalation exposure may cause permanent lung damage characterized by chest expansion, fibrosis and lesions. Ingestion of large amounts may cause stomach distress including irritation, nausea and diarrhea.

High concentrations of cellulose may produce respiratory tract irritation.

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 formulation for this product is proprietary information. 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
Talc (non-asbestos form)	14807-96-6	70 - 80
Cellulose	9004-34-6	20 - 30

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).

EXPLOSION HAZARDS:
Under normal conditions of use, this material does not present a significant fire or explosion hazard. However, like most organic compounds, this material may present a dust deflagration hazard if sufficient quantities are suspended in air. This hazard may exist where sufficient quantities of finely divided material are (or may become) suspended in air during typical process operations. An assessment of each operation should be conducted and suitable deflagration prevention and protection techniques employed. The sensitivity of this material to ignition by electrostatic discharges has not been determined. In the absence of testing data, all conductive plant items and operations personnel handling this material should be suitably grounded.

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

SUITABLE EXTINGUISHING MEDIA:
Carbon dioxide (CO_2), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:
Avoid generation of dust during clean-up. 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:
Avoid dust generation. 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

INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	OSHA PEL (TWA)
Talc (non-asbestos form)	14807-96-6	2 mg/m^3	20 mppcf (containing <1% quartz)
Cellulose	9004-34-6	10 mg/m^3	15 mg/m^3

INGREDIENT	CAS NUMBER	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)	OSHA PEL (STEL / SKIN)	OSHA PEL (CEIL)
Talc (non-asbestos form)	14807-96-6			20 mppcf (containing <1% quartz)	

Fields in the above table(s) that do not contain data indicate that exposure limits are not available for those endpoints.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Powder
COLOR: White to off-white
ODOR: Characteristic odor
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 POLYMERIZATION PRODUCTS / REACTIONS:
Does not occur.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
Carbon oxides (COx).

SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the following individual ingredients, and not to the mixture(s).

ACUTE TOXICITY DATA

INHALATION:
Cellulose: Inhalation LC50 (4hr): >5.8 mg/L (rat)

SKIN:
Tolnaftate has been rarely reported to cause irritation, contact dermatitis, and hypersensitivity reactions in humans. Tolnaftate was not irritating to the skin of rabbits.

Talc is not a primary skin irritant.

Cellulose: Dermal LD50: >2000 mg/kg (rabbit)
Cellulose is not irritating to the skin.

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

Talc: Prolonged exposure to the eye may cause irritation. Granulomas were observed in and around eyes exposed to talc used as a dusting powder for surgeon's gloves.

Cellulose is slightly irritating to the eyes.

ORAL:
Tolnaftate: Practically not toxic

Cellulose: Oral LD50: >5000 mg/kg (rat)

DERMAL AND RESPIRATORY SENSITIZATION:
Talc is not sensitizing.

ADDITIONAL INFORMATION:
In an ototoxicity study, guinea pigs were exposed to tolnaftate for one-week with no apparent effect.

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.

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.

Talc was not teratogenic when evaluated in animals following oral administration.

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

CARCINOGENICITY:
Rats and mice were exposed to aerosols containing 6 or 18 mg/m^3 talc (cosmetic grade, non-asbestiform) up to 122 weeks. An increased incidence of benign and malignant pheochromocytomas of the adrenal gland, alveolar/bronchiolar adenomas and carcinomas of the lung was observed in rats. The only effects observed in mice were chronic active inflammation and the accumulation of macrophages in the lung.

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

There are no ecototoxicity data available for this product or its components.

ENVIRONMENTAL DATA

There are no environmental data available for this product or its 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
Talc (non-asbestos form)	X
Cellulose	X

Substances not included in the table above are TSCA exempt or not regulated under TSCA.

U.S. STATE REGULATIONS

INGREDIENT	California Proposition 65	CARTK	NJRTK	CTRTK	MARTK
Talc (non-asbestos form)	Not applicable.	X	1773		X
Cellulose			3227		X

INGREDIENT	PARTK	MNRTK	MIRTK	RIRTK
Talc (non-asbestos form)	X	X		X
Cellulose	X	X		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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ACKLANDS GRAINGER®