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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: **Tinactin Powder Sprays**

SYNONYM(S): Tinactin Aerosol Powder
Tinactin Deodorant Powder Spray
Tinactin Jock Itch Powder Spray
Tinactin Athlete's Foot Powder Spray
Tinactin poudres en aerosol
Tinactin poudre deodorante en aerosol
Tinactin poudre en aerosol contre demangeaisons de l'aine
Tinactin poudre en aerosol pour le pied d'athlete

MSDS NUMBER: SP001371

EMERGENCY NUMBER(S): Schering-Plough 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

SCHERING-PLOUGH MSDS HELPLINE: (800) 770-8878 (US and Canada)
(908) 629-3657 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

White
Powder aerosol
Characteristic odor
Highly Flammable.
Harmful by inhalation.
May be irritating to respiratory system.

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:

The toxicological properties of this material have not been fully characterized in humans. Therefore, laboratory or process control systems and appropriate work practices should be in place to minimize the potential for inhalation exposure, skin contact, eye contact, or ingestion when working with this material. Only information about the ingredients that are expected to contribute significantly to the potential health hazard profile of the formulation(s) is presented.

These products have been shown to be not irritating and not sensitizing to human skin. Eye contact may cause slight eye irritation with temporary stinging, redness, tearing, and increased blinking.

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.

Isobutane, the propellant component of this product, is a non-toxic gas. However, it is an asphyxiant and exposure to high concentrations may cause dizziness, fatigue, decreased vision, mood disturbances, numbness of extremities, headache, confusion, incoordination, cyanosis, nausea, vomiting, coughing, pulmonary irritation, or anesthesia. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal. Direct contact with liquefied isobutane causes frostbite and/or burns.

Ethanol (ethyl alcohol) is an eye, nose, and mucous membrane irritant. It may cause skin irritation or sensitization after prolonged exposure. Acute effects of ethanol may include headache, dizziness, nausea, sensations of warmth and cold, numbness, fatigue, breathing difficulty, cough, tearing, vision impairment, incoordination, decreased reaction time, alteration of mood and personality, slurred speech, coma and respiratory depression. Chronic effects may include concentration difficulty, sleepiness, kidney and liver damage, and cardiac effects. Chronic ingestion of ethanol may cause cancer of the oral cavity, pharynx, larynx, esophagus, and liver. Oral ingestion of alcohol during pregnancy may cause Fetal Alcohol Syndrome (FAS) including joint, limb, and cardiac abnormalities and behavioral and learning impairment. There have been no reports of FAS as a result of occupational handling of ethanol.

LISTED CARCINOGENS

CHEMICAL NAME	CAS NUMBER	OSHA	IARC	NTP	ACGIH
Ethyl Alcohol	64-17-5		Listed.		Group A4 Not classifiable as a human carcinogen.
Talc (non-asbestos form)	14807-96-6	Not classifiable.	Not classifiable.	Not classifiable.	Not classifiable.

Ethanol (ethyl alcohol): IARC (International Agency for Research on Cancer) has classified Alcoholic Beverages as Group 1 (indicating in their evaluation that the agent is carcinogenic to humans). However, occupational handling or manufacturer's specified use of this product is not expected to result in relevant exposures.

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

CHEMICAL NAME	CAS NUMBER	PERCENT
Tolnaftate	2398-96-1	0.09
Isobutane	75-28-5	70-80
Ethyl Alcohol	64-17-5	10-20
Talc (non-asbestos form)	14807-96-6	<10

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. Administer artificial respiration if breathing has ceased. IMMEDIATELY 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 and drink a glass of water. Do not induce vomiting. If symptoms persist, consult a physician.

SECTION 5. FIRE FIGHTING MEASURES**FLAMMABILITY DATA:**

Flash Point:	-84.4 deg C (-120 deg F) (Isobutane)
Classification:	Flammable (US OSHA Criteria) Flammable (Canada WHMIS Criteria) Highly Flammable (EU Criteria)
UEL:	8.4 vol % (Isobutane)
LEL:	1.8 vol % (Isobutane)

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.

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:

Keep away from heat, sparks, open flames, and direct sunlight. 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. However, PPE should not be used as a method of permanent or long-term exposure control. 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

CHEMICAL NAME	CAS NUMBER	ACGIH TLV (TWA)	OSHA PEL (TWA)
Ethyl Alcohol	64-17-5	1000 ppm	1900 mg/m ³ 1000 ppm
Talc (non-asbestos form)	14807-96-6	2 mg/m ³ Respirable fraction. The value is for particulate matter containing no asbestos and <1% crystalline silica.	20 mppcf (containing <1% quartz)

CHEMICAL NAME	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 aerosol
COLOR: White
ODOR: Characteristic odor
VAPOR PRESSURE: 35 to 50 psi @ 25 deg C
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:
Oxidizers.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:

Carbon oxides (COx).

SECTION 11. TOXICOLOGICAL INFORMATION

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. The information presented below pertains to the formulated product unless indicated otherwise.

ACUTE TOXICITY DATA

EXPOSURE ROUTE	STUDY DESCRIPTION	RESULT
Inhalation	LC50	Practically not toxic
Skin	Skin Sensitization (Human RIPT)	Not sensitizing
Skin	Skin Irritation	Not irritating
Eye	Eye Irritation	Slightly irritating

INHALATION:

Isobutane caused CNS depression, rapid and shallow respiration, and apnea in mice exposed to high concentrations. In dogs, 45% isobutane caused anesthetic effects.

Ethanol, at high concentrations, caused dose dependent effects following inhalation exposure in rats on the central nervous system including drowsiness, incoordination, narcosis and excitation.

REPEAT DOSE TOXICITY DATA**SUBCHRONIC / CHRONIC TOXICITY:**

Ethanol: Repeated oral and inhalation exposure to high concentrations has caused kidney and liver damage in animals.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:

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

Ethanol: Exposure to large doses during gestation is reported to cause effects on reproduction, including fetotoxicity and growth retardation in mice, rats, and rabbits. However, no teratogenic effects were reported.

MUTAGENICITY / GENOTOXICITY:

Tolnaftate was negative in an in vitro chromosome aberration study.

Isobutane was negative in a bacterial mutagenicity study (Ames).

Ethanol was positive in a bacterial mutagenicity study (Ames) and negative in a mammalian mutagenicity study (mouse lymphoma).

CARCINOGENICITY:

This material or product has not been evaluated for carcinogenicity.

Rats and mice were exposed to aerosols containing 6 or 18 mg/m³ 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.

Rats given 25 to 50% ethanol by oral gavage or in the drinking water for one to two years did not show a significant increase in tumors compared to the control groups. Mice given 43% ethanol in drinking water for three years showed an increase in papillomas of the forestomach, malignant lymphomas and lung adenomas. Ethanol was an effective promotor of liver tumors in rats given a single intraperitoneal dose of diethylnitrosamine followed by treatment of ethanol in the drinking water for 12 to 18 months.

SECTION 12. ECOLOGICAL INFORMATION

There are no data for the final product or its formulation(s). The information presented below pertains to the following ingredient(s).

ECOTOXICITY DATA**INGREDIENT ECOTOXICITY**

Ethanol: 96-hr (static) LC50 (rainbow trout): 13 g/L
 Ethanol: 96-hr (flow-through) LC50 (fathead minnow): 12.9-15.3 g/L
 Ethanol: Toxicity threshold-cell multiplication inhibition test (green algae): 5000 mg/L

ENVIRONMENTAL DATA

There are no environmental data available for this material.

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

Refer to site-specific procedures and requirements for additional guidance.

DOT CLASSIFICATION:

Proper Shipping Name: Aerosols
 Hazard Class: 2.1
 UN Number: UN 1950
 Packing Group: None

IATA CLASSIFICATION:

Proper Shipping Name: Aerosols, flammable
 Hazard Class: 2.1
 UN Number: UN 1950
 Packing Group: None

ADR CLASSIFICATION:

Proper Shipping Name: Aerosols
 Hazard Class: 2.1
 UN Number: UN 1950
 Packing Group: None

IMDG CLASSIFICATION:

Proper Shipping Name: Aerosols
 Hazard Class: 2
 UN Number: UN 1950
 Packing Group: None

SECTION 15. REGULATORY INFORMATION

TSCA LISTING

CHEMICAL NAME	TSCA
Tolnaftate	Listed
Isobutane	Listed
Ethyl Alcohol	Listed
Talc (non-asbestos form)	Listed

U.S. STATE REGULATIONS

CHEMICAL NAME	California Proposition 65	CARTK	NJRTK	CTRCK	MARTK
Isobutane			Substance no. 1040 Listed.		Listed.
Ethyl Alcohol		Listed.	Substance no. 0844 Listed.	Listed.	Listed.
Talc (non-asbestos form)	Not applicable.	Listed.	Substance no. 1773 Listed.		Listed.

CHEMICAL NAME	PARTK	MNRTK	MIRTK	ILRTK	LARTK	RIRTK
Isobutane	Listed.					
Ethyl Alcohol	Listed.	Listed.		Listed.		Listed.
Talc (non-asbestos form)	Listed.	Listed.		Listed.		Listed.

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).

DEPARTMENT ISSUING MSDS:

Global Safety and Environmental Affairs
Occupational and Environmental Toxicology
Schering-Plough Corporation
1095 Morris Avenue
Union, NJ 07083 USA

SCHERING-PLOUGH MSDS HELPLINE:

(800) 770-8878 (US and Canada)
(908) 629-3657 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

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