

SAFETY DATA SHEETS

This SDS packet was issued with item:

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N/A



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: Lotrimin AF Powder

SYNONYM(S): None

MSDS NUMBER: SP001226

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) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time) .

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Powder
White to off-white
Characteristic odor

May be irritating to eyes and respiratory tract.
May be harmful if swallowed.

POTENTIAL HEALTH EFFECTS:

This product is considered relatively not toxic when used according to manufacturer's specifications.

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. However, there are data to describe the toxicological properties of the individual ingredients. The following summary is based upon available information about the individual ingredients of the mixture(s), or of the expected properties of the mixture(s). Only information about the ingredients that are expected to contribute significantly to the potential health hazard profile of the formulation(s) are presented.

This product has been shown to be practically not irritating and not sensitizing to human skin.

Miconazole nitrate, the active ingredient in this product, is an imidazole antifungal agent used for the treatment of dermal infections. Miconazole nitrate is poorly absorbed through the skin or mucous membranes and miconazole is poorly absorbed through the gastrointestinal tract. Chronic oral exposure may cause nausea, vomiting, and diarrhea. Fetotoxicity was observed in animals administered miconazole; however, effects were seen at very high doses.

Corn starch is a mild skin irritant and may cause dermatitis with chronic skin exposure. Inhalation of corn starch may aggravate pre-existing lung conditions. Corn starch may cause mechanical irritation to the eye and respiratory tract.

Exposure to large amounts of zinc oxide is expected to cause mechanical irritation of the eye and respiratory tract. Inhalation of high levels may cause chest tightness, cough, dizziness, fever, chills, headache, nausea, and dry throat.

LISTED CARCINOGENS

CHEMICAL NAME	CAS NUMBER	OSHA	IARC	NTP	ACGIH
Starch.	9005-25-8				Not classifiable.
Kaolin.	1332-58-7				Not classifiable.

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

CHEMICAL NAME	CAS NUMBER	PERCENT
Starch.	9005-25-8	70-80
Zinc Oxide.	1314-13-2	
Kaolin.	1332-58-7	
Miconazole Nitrate.	22916-47-8	2

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 and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. If symptoms persist, consult a physician.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

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

SECTION 5. FIRE FIGHTING MEASURES

OTHER 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. 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 (CO₂), 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:

Ensure adequate ventilation. Keep containers tightly closed when not in use.

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:

For laboratories and small-scale operations, essentially no open handling. Open handling of small quantities may be performed if there is no potential for dust or aerosol generation. For larger quantities or materials that may become airborne, materials should be handled in a properly functioning chemical fume hood, ventilated enclosure or controlled by local exhaust ventilation.

For manufacturing and large-scale operations, essentially no open handling. Open handling is limited to small quantities in appropriately ventilated, enclosed environments. For larger quantities or materials that may become airborne, enclosed processes and the use of containment technology are preferred. Recirculation of general ventilation or local exhaust ventilation is not permitted unless appropriate scrubbing or filtration of incoming recirculated air is controlled.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection:

None required for consumer use of this product.

In laboratories and small-scale operations, respirators are not normally required; however, appropriate respiratory protection may be required in situations where exposure (e.g. spills, process upsets, or non-routine maintenance) may exceed any available recommended exposure limit. Consult your site safety staff for guidance.

In manufacturing and large-scale operations, powered air purifying respirators (PAPRs) or positive-pressure air supplied respirators with full-face coverage may be required dependent on the level of exposure. Appropriate respiratory protection is required in situations where exposure (e.g. spills, process upsets, or non-routine maintenance) may exceed any available recommended exposure limit. Consult your site safety staff for 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 other equivalent protective clothing is required. In large-scale or manufacturing operations, lab coats or other equivalent protective clothing is required.

EXPOSURE LIMIT VALUES

CHEMICAL NAME	CAS NUMBER	ACGIH TLV (TWA)	OSHA PEL (TWA)
Starch.	9005-25-8	10 mg/m ³	5 mg/m ³ Respirable fraction. 15 mg/m ³ Total dust.
Zinc Oxide.	1314-13-2	2 mg/m ³ Respirable fraction.	5 mg/m ³ Fume. 5 mg/m ³ Respirable fraction. 15 mg/m ³ Total dust.
Kaolin.	1332-58-7	2 mg/m ³ Respirable fraction. The value is for particulate matter containing no asbestos and <1% crystalline silica.	

CHEMICAL NAME	CAS NUMBER	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)	OSHA PEL (STEL / SKIN)	OSHA PEL (CEIL)
Zinc Oxide.	1314-13-2	10 mg/m ³ Respirable fraction.			

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

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 Irritation (human)	Practically not irritating
Skin	Skin Sensitization (Human RIPT)	Not sensitizing

EYE:

Zinc oxide was slightly irritating to animals.

ORAL:

Miconazole nitrate: Oral LD50: 578.1 to 640 mg/kg (animals)

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

Animals exposed to airborne concentrations of 5 mg/m³ of zinc oxide for 6 days showed signs of diffuse interstitial inflammatory response in the respiratory bronchioles and alveolar ducts. Systemic effects observed in animals receiving oral diets of 175 to 1000 mg of zinc oxide for periods of 3 to 35 weeks included glycosuria and fibrous degeneration of the pancreas.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:

Miconazole has been shown to be fetotoxic at high doses in animals.

Corn starch had no effect on reproduction in rats given 10% to 62% in the diet.

Zinc oxide given to pregnant rats at 4000 ppm in the diet caused an increase in resorption and fetal deaths; however, this may have been due to copper deficiency. In another study, 2 to 38 mg/day had no effect on reproduction in rats.

MUTAGENICITY / GENOTOXICITY:

Zinc oxide was positive in a mouse lymphoma assay and negative in a bacterial mutagenicity assay (Ames).

CARCINOGENICITY:

This material or product has not been evaluated for carcinogenicity.

SECTION 12. ECOLOGICAL INFORMATION**ECOTOXICITY DATA**

This material has not been tested for ecotoxicity.

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

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

SECTION 15. REGULATORY INFORMATION**TSCA LISTING**

CHEMICAL NAME	TSCA
Starch.	Listed
Zinc Oxide.	Listed
Kaolin.	Listed

U.S. STATE REGULATIONS

CHEMICAL NAME	California Proposition 65	CARTK	NJRTK	CTRKT	MARTK
Starch.					Listed.

CHEMICAL NAME	California Proposition 65	CARTK	NJRTK	CTRTK	MARTK
Zinc Oxide.			Substance no. 2037 Listed. Substance no. 2055 Listed.		Listed.

CHEMICAL NAME	PARTK	MNRTK	MIRTK	ILRTK	LARTK	RIRTK
Starch.	Listed.	Listed.		Listed.		Listed.
Zinc Oxide.	Listed.	Listed.		Listed.		Listed.
Kaolin.	Listed.	Listed.		Listed.		

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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