Schering-Plough Animal Health Corporation
1095 Morris Ave
Union, NJ 07083

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: **Clinafarm Smoke Generator**

SYNONYM(S): Clinafarm (Enilconazole) Smoke Generator

MSDS NUMBER: SP000830

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

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

Rocky Mountain Poison Center (For Human Exposure):
(303) 595-4869

Animal Health Technical Services:
For Animal Adverse Events: Small Animals and Horses: (800) 224-5318
For Animal Adverse Events: Livestock: (800) 211-3573
For Animal Adverse Events: Poultry: (800) 219-9286

INFORMATION: Animal Health Technical Services:
For Small Animals and Horses: (800) 224-5318
For Livestock: (800) 211-3573
For Poultry: (800) 219-9286

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. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Veterinary 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. For additional information about carcinogenic ingredients see Section 3.

CHEMICAL COMPOSITION

CHEMICAL NAME	CAS NUMBER	PERCENT
Imazalil Base	35554-44-0	15
Potassium Chlorate	3811-04-9	10-20
Lactose	63-42-3	10-20
Talc (non-asbestos form)	14807-96-6	50-60

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 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

White, Gray, Brown
Powder
Odor unknown

Harmful by inhalation.
May be harmful if swallowed.
May be severely irritating or corrosive to eyes, or mucous membranes.
May be irritating to skin.
May be irritating to respiratory system.

May cause effects to:
- eye
- skin
- respiratory system
- liver
- reproductive system
- fetus

Very toxic to aquatic organisms.
May cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS:

Exposure to smoke from the Clinafarm Smoke Generator may cause eye and skin irritation. However, the unignited content of the Clinafarm Smoke Generator canister is corrosive and may cause irreversible eye damage. This product is practically non-toxic by inhalation and dermal contact.

Imazalil, the active ingredient, is a systemic imidazole fungicide. The United States Environmental Protection Agency (EPA) has not reported any significant adverse effects following exposure to imazalil containing products. However, several cases of skin rash were reported following direct contact with imazalil.

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.

Lactose is not expected to produce significant toxicity with workplace exposure. Lactose may cause irritation to the eyes, skin, and mucous membranes from mechanical action. Lactose may cause abdominal pain, bloating and diarrhea if ingested in large amounts or in lactose-intolerant individuals. Lactose may cause allergic reactions in sensitive individuals.

Inhalation exposure to potassium chlorate causes irritation of the throat and lungs and may cause coughing and shortness of breath. The ingestion of potassium chlorate may cause nausea, vomiting, diarrhea, abdominal pain, changes in the blood (hemolysis and methemoglobinemia), convulsions and coma.

LISTED CARCINOGENS

CHEMICAL NAME	CAS NUMBER	OSHA	IARC	NTP	ACGIH
Talc (non-asbestos form)	14807-96-6	Not classifiable.	Not classifiable.	Not classifiable.	Not classifiable.

Talc listed in the carcinogen table above is for talc containing asbestos fibers and does not apply to this product.

SECTION 4. FIRST AID MEASURES

INHALATION: Remove to fresh air. Administer artificial respiration if breathing has ceased. Get IMMEDIATE medical attention.

SKIN CONTACT: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

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. Get IMMEDIATE medical attention.

INGESTION: DO NOT induce vomiting. Do not attempt to give anything by mouth to a seizing, drowsy or unconscious person. If alert, rinse mouth, drink a glass of water and IMMEDIATELY consult a physician.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

FLASH POINT: < 22 deg C (< 72 deg F)

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. 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:
Water, carbon dioxide (CO2), foam, or dry chemical.

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

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 contact with skin, eyes, and mucosa. Avoid breathing dust. 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:
Store in a cool, dry, well ventilated area.

SPECIAL PRECAUTIONS:
Storage temperture should not exceed 37 deg C (100 deg F).

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

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

The following guidance applies to the handling of the active ingredient(s) in this formulation.

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:	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:	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:	Safety glasses with side shields. Use of goggles or full face protection may be required if there is potential for contact with this material. Consult your site safety staff for guidance.
Body Protection:	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)
Talc (non-asbestos form)	14807-96-6	2 mg/m^3 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)	

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Powder
COLOR: White, Gray, Brown
ODOR: Odor unknown
SOLUBILITY:
Water: Not determined

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable up to 125 dec C.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
Oxidizers. Organic materials. Keep away from heat, sparks, open flame, and direct sunlight.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
May emit carbon oxides (COx), nitrogen, potassium magnesium silicate, chlorine, and organic vapors when heated to decomposition.

SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the formulated product unless indicated otherwise.

ACUTE TOXICITY DATA

PRODUCT / CHEMICAL NAME	EXPOSURE ROUTE	STUDY DESCRIPTION	RESULT
Clinafarm Smoke Generator	Inhalation	LC50 (rat)	> 2 - 10.73 g/m^3
	Oral	LD50 (rat)	2100 - 2280 mg/kg
	Dermal	LD50 (rat)	> 2000 mg/kg
		LD50 (rabbit)	> 0.6 ml/kg
	Skin	Skin Irritation (rabbit)	Slightly to moderately irritating
	Skin	Skin Sensitization (guinea pig)	Not sensitizing
	Eye	Eye Irritation (rabbit)	Moderately irritating

INHALATION:
Inhalation exposure to rats at a maximum attainable concentration 10.73 g/m^3 (10.73 mg/L), did not result in toxic signs or mortality.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
Imazalil was evaluated in repeat dose toxicity studies by oral administration in the mouse, rat and dog over a dose range of 1.25 to 80 mg/kg day over 3 to 24 months duration. A slight decreased appetite and a decreased body weight gain were observed in rats and dogs. The liver was the primary target organ. Liver changes included centri-lobular swelling, fatty surcharge and numerous vacuoles at 20 and 80 mg/kg (NOEL: 5 mg/kg (rat); 2.5 mg/kg (dog)).

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Imazalil was evaluated in several multigeneration studies in rats and in several developmental toxicity studies in rabbits. Maternal effects were limited to an increase in the duration of gestation. Fetal effects were limited to a decrease in the number of live pups and an increase in stillborn pups at 80 mg/kg. No developmental toxicity was observed.

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

MUTAGENICITY / GENOTOXICITY:
Imazalil was negative in a battery of mutagenicity tests including Ames, a DNA repair assay in E. coli, an unscheduled DNA synthesis, a chromosome aberration test, a point mutation assay, a micronucleus rat and mouse, and a dominant lethal testing in mice.

CARCINOGENICITY:
This material has not been evaluated for carcinogenicity.

During oral carcinogenicity studies of Imazalil in mice (2.5-130 mg/kg) and rats (1-40 mg/kg) there was a significant increased incidence of hepatocellular adenomas in male mice at 33 to 100 mg/kg and in female mice at 130 mg/kg. Liver tumors were not observed in rats.

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

INGREDIENT ECOTOXICITY

Imazalil: 48-hr (static) EC50 (daphnia): 3.54 ug/L
Imazalil: 48-hr (renewal) EC50 (daphnia) 3.16 ug/L
Imazalil: 96-hr (renewal) LC50 (rainbow trout): 2.0 ug/L

ENVIRONMENTAL DATA

There are no environmental data available for this material.

OTHER INGREDIENT ENVIRONMENTAL DATA:

Imazalil is very toxic to aquatic organisms. It may cause long-term adverse effects in the aquatic environment.

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.

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: Oxidizing solid, toxic, n.o.s. (potassium chlorate, imazalil)
Hazard Class: 5.1, 6.1
UN Number: UN 3087
Packing Group: II

IATA CLASSIFICATION:

Proper Shipping Name: Oxidizing solid, toxic, n.o.s. (potassium chlorate, imazalil)
Hazard Class: 5.1, 6.1
UN Number: UN 3087
Packing Group: II

ADR CLASSIFICATION:

Proper Shipping Name: Oxidizing solid, toxic, n.o.s. (potassium chlorate, imazalil)
Hazard Class: 5.1, 6.1
UN Number: UN 3087
Packing Group: II

IMDG CLASSIFICATION:

Proper Shipping Name: Oxidizing solid, toxic, n.o.s. (potassium chlorate, imazalil)
Hazard Class: 5.1, 6.1
UN Number: UN 3087
Packing Group: II

SECTION 15. REGULATORY INFORMATION

TSCA LISTING

CHEMICAL NAME	TSCA
Potassium Chlorate	Listed
Lactose	Listed
Talc (non-asbestos form)	Listed

U.S. STATE REGULATIONS

CHEMICAL NAME	California Proposition 65	CARTK	NJRTK	CTRTK	MARTK
Imazalil Base			Substance no. 3343 Listed.		
Potassium Chlorate			Substance no. 1560 Listed.	Listed.	Listed.
Talc (non-asbestos form)	Not applicable.	Listed.	Substance no. 1773 Listed.		Listed.

CHEMICAL NAME	PARTK	MNRTK	MIRTK	ILRTK	LARTK	RIRTK
Potassium Chlorate	Listed.					Listed.
Talc (non-asbestos form)	Listed.	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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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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