Schering-Plough Animal Health Corporation
556 Morris Avenue
Summit, NJ 07901

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 EC**

SYNONYM(S): Clinafarm Emulsifiable Concentrate

MSDS NUMBER: SP000953

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

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Liquid
Light yellow
Musty odor

Combustible.

Harmful by inhalation or if swallowed.
May be harmful if absorbed through skin.

May cause effects to:
eye
skin
respiratory system
liver
gastrointestinal tract
nervous system
reproductive system
fetus

SECTION 2. HAZARDS IDENTIFICATION

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

POTENTIAL HEALTH EFFECTS:

Clinafarm EC may cause skin and eye irritation and is harmful if inhaled or swallowed. It may also cause stomach and respiratory distress when taken orally or following inhalation exposure.

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.

Sodium dioctyl sulfosuccinate is a moderate skin and eye irritant. It is practically non-toxic by oral ingestion.

Castor oil polyethoxylate is slightly irritating to the skin. Prolonged contact to the eyes may cause redness and irritation. Oral ingestion may cause gastrointestinal irritation and laxative effects.

LISTED CARCINOGENS

CHEMICAL NAME	CAS NUMBER	OSHA	IARC	NTP	ACGIH
Ethyl Alcohol.	64-17-5				Group A4 Not classifiable as a human carcinogen.

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: 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 2.

CHEMICAL COMPOSITION

CHEMICAL NAME	CAS NUMBER	PERCENT
Imazalil Base.	35554-44-0	14
Dioctyl Sodium Sulfosuccinate / Ethyl Alcohol Solution:.		40-50
Dioctyl Sodium Sulfosuccinate.	577-11-7	
Castor Oil Polyethoxylated.	61791-12-6	30-40
Benzyl Alcohol.	100-51-6	< 10
Ethyl Alcohol.	64-17-5	< 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. 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.

SECTION 4. FIRST AID MEASURES

SKIN CONTACT: In case of skin contact, IMMEDIATELY flush exposed skin thoroughly with plenty of water. While wearing protective gloves, remove any contaminated clothing, including shoes and continue to wash skin thoroughly with soap and water for at least 15 minutes. Get IMMEDIATE medical attention. Treat symptomatically.

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: 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:	46 deg C (115 deg F)
Classification:	Combustible (US OSHA Criteria)

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

SUITABLE EXTINGUISHING MEDIA:
Water, carbon dioxide (CO_2), 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 skin and eye contact. 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:
Do not store near heat or open flame. Store at room temperature (ambient conditions).

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. 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 based on hazard, potential for contact, or level of exposure. 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)
Ethyl Alcohol.	64-17-5	1000 ppm	1900 mg/m^3 1000 ppm

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Liquid
COLOR: Light yellow
ODOR: Musty odor
pH: 9.5 (Saturated solution)
SPECIFIC GRAVITY: 1.094
SOLUBILITY:
Water: 300 mg/l (for 100% active substance)

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
Open flames and high temperatures. Oxidizers. Strong acids.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
Carbon oxides (COx). Nitrogen. Sulfur. Chlorine. Hydrogen chloride (HCl). Organic acids.

SECTION 11. TOXICOLOGICAL INFORMATION

There are no data available specifically for this formulation. The data shown below are from studies conducted using similar formulas containing the same active and/or hazardous ingredients found in this product, unless indicated otherwise. These data are based on a Clinafarm EC 15% formulation.

ACUTE TOXICITY DATA

PRODUCT / CHEMICAL NAME
Clinafarm EC (15%)

EXPOSURE ROUTE	STUDY DESCRIPTION	RESULT
Inhalation	LC50 (rat)	3.1 mg/L
Dermal	LD50 (rabbit)	> 900 mg/kg
Oral	LD50 (rat)	192 mg/kg (female) 309 mg/kg (male)
Skin	Skin Irritation (rabbit)	Slightly irritating
Skin	Skin Sensitization (guinea pig)	Not sensitizing
Eye	Eye Irritation (rabbit)	Moderately irritating

INHALATION:
In an acute inhalation study, rats (6 groups/5 rats/sex) were exposed for 4-hours, using the whole-body exposure method, to Clinafarm EC (15%) between 0.19 and 4.1 mg/L. Mortality was observed in all animals in the high dose group on the day of exposure. The LC50 for the 4-hour exposure and 14-day observation period was 3.1 mg/L. Clinical signs of toxicity included ataxia (only at the high dose), dyspnea, gasping or labored breathing, and a decrease in body weight gain. Pulmonary edema was noted in 12 animals at necropsy.

ORAL:
In an acute oral toxicity study with Clinafarm EC (15%) in rats at dose levels ranging from 0.125 to 1.00 ml per rat, exophthalmos, hypotonia, and diarrhea was observed at all dose levels tested. Other behavioral signs observed were sedation, ataxia, piloerection, hypothermia, palpebral ptosis or loss of righting reflex. These effects were also observed in the control groups at the higher doses tested.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
Rabbits administered 1 mg/kg doses of Clinafarm EC (15%) for 21 days (6 hr/day exposures) failed to exhibit signs of dermal 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)).

Benzyl alcohol caused dose-related effects in rats given oral dosages of 50 to 800 mg/kg/day for 13 weeks. Rats showed reductions in weight gain and also signs of staggering, lethargy, and respiratory difficulty, indicating neurotoxicity at the high dosage. Hemorrhages around the mouth and nose, and histological lesions in the brain, thymus, skeletal muscle, and kidney were also noted. Mice tested under similar conditions exhibited similar effects.

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.

Dioctyl sodium sulfosuccinate administered at doses of 0.5 and 1% was not maternally or developmentally toxic in rats.

Benzyl alcohol did not affect the gestation index, reproductive index, litter size, average litter weight, or postnatal weight gain or survival when given to rats by gavage during days 6 to15 of gestation.

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.

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

CARCINOGENICITY:
This material or product 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.

Benzyl alcohol was not carcinogenic in a 2 year oral gavage study in rats administered doses of up to 400 mg/kg/day for 5 days a week or in mice at doses up to 200 mg/kg/day for 5 days per week.

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

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

Benzyl alcohol: 96-hr LC50 (fathead minnow): 460 mg/L
Benzyl alcohol: 96-hr LC50 (bluegill): 10 mg/L
Benzyl alcohol: 48-hr EC50 (daphnid): 400 mg/L
Benzyl alcohol: 96-hr NOEL (E. coli): 1000 ppm

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.

Benzyl alcohol is expected to be readily biodegradable. Benzyl alcohol is characterized as a high risk air pollutant because it may emit toxic vapors when heated.

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:	Flammable liquids, toxic, n.o.s. (ethanol, imazalil)
Hazard Class:	3, 6.1
UN Number:	UN 1992
Packing Group:	III

IATA CLASSIFICATION:

Proper Shipping Name:	Flammable liquids, toxic, n.o.s. (ethanol, imazalil)
Hazard Class:	3, 6.1
UN Number:	UN 1992
Packing Group:	III

ADR CLASSIFICATION:

Proper Shipping Name:	Flammable liquids, toxic, n.o.s. (ethanol, imazalil)
Hazard Class:	3, 6.1
UN Number:	UN 1992
Packing Group:	III

IMDG CLASSIFICATION:

Proper Shipping Name:	Flammable liquids, toxic, n.o.s. (ethanol, imazalil)
Hazard Class:	3, 6.1
UN Number:	UN 1992
Packing Group:	III

SECTION 15. REGULATORY INFORMATION

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TSCA LISTING

CHEMICAL NAME	TSCA
Dioctyl Sodium Sulfosuccinate.	Listed.
Castor Oil Polyethoxylated.	Listed
Benzyl Alcohol.	Listed
Ethyl Alcohol.	Listed

U.S. STATE REGULATIONS

CHEMICAL NAME	California Proposition 65	CARTK	NJRTK	CTRTK	MARTK
Imazalil Base.			Substance no. 3343 Listed.		
Benzyl Alcohol.					Listed.
Ethyl Alcohol.		Listed.	Substance no. 0844 Listed.	Listed.	Listed.

CHEMICAL NAME	PARTK	MNRTK	MIRTK	ILRTK	LARTK	RIRTK
Benzyl Alcohol.	Listed.	Listed.				
Ethyl Alcohol.	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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