

773-55

3-27-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MAR 27 2003

Diane deBruin
Schering-Plough Animal Health Corporation
1095 Morris Avenue
P.O. Box 3182
Union, New Jersey 07083-1982

Subject: Clinafarm® EC Emulsifiable Concentrate
EPA Registration Number 773-55
Your label amendment application dated February 11,
2003

Dear Ms. deBruin,

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended is acceptable, provided that you comply with the following conditions.

1. Make the following changes to the label.

a. Near the top of the label correct the spelling of *fumigates* (the specific name of the fungus claimed to be controlled). This correction is required on both the bottle and the carton versions of the labels.

b. In the carton version of the label correct the chemical name of the active ingredient (a "-" is needed before "propenyloxy").

2. Submit one copy of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration may be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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If you have any questions about this letter, please contact John Bazuin at (703)305-7381.

Sincerely yours,

DS

Dennis McNeilly
Acting Product Manager (22)
Fungicide Branch
Registration Division (7505C)

Attachment: Label stamped "ACCEPTED with COMMENTS"

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BOTTLE LABEL Front Panel

Clinafarm® EC

Emulsifiable Concentrate

For control of *Aspergillus fumigatus* contamination in poultry hatchery equipment

ACTIVE INGREDIENT:

Imazalil (enilconazole):1-(2-(2,4-Dichlorophenyl)-	
2-(2-propenyloxy)ethyl)-1H-imidazole.....	13.8% w/w
INERT INGREDIENTS.....	86.2%
	100.0% w/w

<p>KEEP OUT OF REACH OF CHILDREN DANGER See back Panel for Additional Precautionary Statements</p>
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FIRST AID	
If in Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for further treatment advice.
If Swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person. • Promptly drink either large quantity of milk, egg white, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol.
If on Skin or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If Inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling the poison control center or doctor or going for treatment. You may also contact the Rocky Mountain Poison Center at 1-303-595-4869 for emergency medical treatment information.	

Net Contents: 750 mL (1.58 U.S. Pints)



Schering-Plough Animal Health

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Product of Jansen Research

EPA Reg. No. 773-55
EPA Est. No. 6125-LA-1

20724404 Rev. xxx
ACCEPTED
with COMMENTS
In EPA Letter Dated:
MAR 27 2003

BOTTLE LABEL Back Panel

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.**

773-55

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**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER**

Corrosive, causes irreversible eye damage. Harmful or fatal if swallowed. Harmful if absorbed through skin or inhaled. Avoid breathing spray mist and contact with skin. Do not get in eyes, wear goggles or face shield. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

TAKE TIME



OBSERVE

LABEL DIRECTIONS

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. For the control of *Aspergillus* organisms in cleaned poultry and turkey hatchery equipment prior to introduction of the eggs. Equipment would include empty hatcher cabinets, setters, coolers, storerooms, handling equipment, etc. CLINAFARM® EC will dramatically reduce the levels of infectious organisms and spores in treated areas. To make 1 gallon of 1:100 dilution, add 1.25 fl. oz. (36 mL) of CLINAFARM® EC to one gallon of clean water to provide an antifungal concentration of 0.15% active ingredient. Do not use product undiluted. To assure proper efficacy, the area or equipment to be treated should be clean and closed off from outside air currents before treatment. Ventilations ducts may be treated but fans must be shut off. Fog or spray area to be treated at the rate of ½ fl. oz. diluted product per 150 cu. ft. (1 mL per 10 cu. ft.). Fog or spray to ensure good contact with surface areas. Do not re-enter treatment areas for two hours. CLINAFARM® EC is compatible with other commonly used disinfectants such as quaternary ammonium compounds, glutaraldehyde, formaldehyde and phenolic compounds.

PHYSICAL/CHEMICAL HAZARDS: Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. **STORAGE:** Store at room temperature. **PESTICIDE DISPOSAL:** Do not contaminate water when disposing of equipment washwaters. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **CONTAINER DISPOSAL:** Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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CARTON LABEL Front Panel (left side)

Clinafarm® EC

Emulsifiable Concentrate

For control of *Aspergillus fumigates* contamination in poultry hatchery equipment

ACTIVE INGREDIENT:

Imazalil (enilconazole):1-(2-(2,4-Dichlorophenyl)-
2-(2propenyloxy)ethyl)-1H-imidazole.....13.8% w/w

INERT INGREDIENTS.....86.2%
100.0% w/w

KEEP OUT OF REACH OF CHILDREN
DANGER
See Side Panel for Additional Precautionary Statements.

FIRST AID	
If in Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for further treatment advice.
If Swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person. • Promptly drink either large quantity of milk, egg white, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol.
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HOT LINE NUMBER	
Have the product container or label with you when calling the poison control center or doctor or going for treatment. You may also contact the Rocky Mountain Poison Center at 1-303-595-4869 for emergency medical treatment information.	

Net Contents: 4 - 750 mL (1.58 U.S. Pints) Bottles A Product of Jansen Research.



Schering-Plough Animal Health

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EPA Reg. No. 773-55

EPA Est. No 6175-LA-1

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CARTON LABEL right side

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER**

Corrosive, causes irreversible eye damage. Harmful or fatal if swallowed. Harmful if absorbed through skin or inhaled. Avoid breathing spray mist and contact with skin. Do not get in eyes, wear goggles or face shield. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

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TAKE TIME



OBSERVE LABEL DIRECTIONS

CLINAFARM is a registered trademark of Johnson & Johnson. CF-15

20724609 Rev. xxxx