



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

January 24, 2024

Mr. Micah Reynolds
Consultant for Merck Animal Health
TSG
1150 18th Street, Ste 1000
Washington, DC 20036
Electronic Transmittal: micah.reynolds@tsgconsulting.com

Subject: Label Amendment – Changes Required by the Imazalil
Interim Registration Review Decision
Product Name: Clinafarm EC
EPA Registration Number: 773-55
Received Date: 6/28/2021
Decision Number: 580515

Dear Micah Reynolds:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the Registration Review of the above referenced product in connection with the Imazalil Interim Registration Review Decision, and has concluded that your submission is acceptable.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Pursuant to 40 CFR 156.10(a)(6) you must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 12 months from the date of this letter. After 12 months, you may only distribute or sell this product if it bears this new revised

labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Megan Snyderman by phone at 202-566-0639 or via email at snyderman.megan@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read 'J. Gayoso', is centered on the page.

Jose Gayoso, Senior Regulatory Advisor
Reevaluation Branch
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure:

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

(OUTER CARTON LABEL)

CLINAFARM® EC

[Emulsifiable Concentrate]

[For the control of *Aspergillus fumigatus* in cleaned poultry and turkey hatchery equipment prior to the introduction of eggs, including empty hatcher cabinets, settlers, coolers and egg and chick handling equipment.] (or)

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

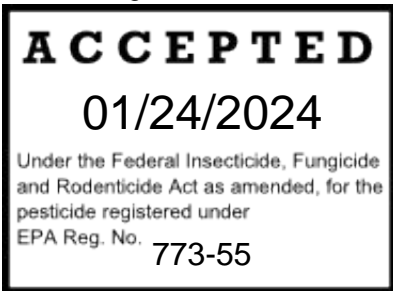
ACTIVE INGREDIENT:

Imazalil (enilconazole):1-(2-(2,4-Dichlorophenyl)-

2-(2-propenyloxy)ethyl)-1H-imidazole.....14.4% w/w

OTHER INGREDIENTS..... 85.6%

TOTAL.....100.0% w/w



**KEEP OUT OF REACH OF CHILDREN
DANGER**

See [back] [other] [side] panel for additional precautionary statements [and directions for use].

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. Have person sip a glass of water if able to swallow. 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.
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.
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	
HOT LINE NUMBER	
Have the product container or label with you when calling the poison control center or doctor or going for treatment. For incidents involving humans, call 1-800-680-9206. 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 US pints) bottles

[Manufactured for:]

Intervet Inc. (d/b/a Merck Animal Health)

2 Giralda Farms

Madison, NJ 07940

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EPA Reg. No. 773-55

EPA Est. No. [618-LA-1]

Rev. XX/XX]

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

[Lot/Batch No.] (Note to reviewer: the lot or batch number may also or alternatively be stamped directly on the outer carton or the individual bottles.)

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

Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Harmful if absorbed through skin. Harmful if inhaled. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing spray mist. Wear goggles, face shield, or safety glasses.

PERSONAL PROTECTIVE EQUIPMENT

Some materials that are chemical-resistant to this product are made of barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride or viton. If you want more options, follow the instructions for category C on an EPA chemical-resistance category selection chart.

All handlers must wear long-sleeved shirt and long pants, shoes plus socks, chemical resistant gloves, and chemical resistant apron when mixing/loading, cleaning up spills, cleaning equipment, or otherwise exposed to concentrate. Handlers using handheld foggers must wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges and combination R or P filter; OR a NIOSH-approved gas mask with OV canisters; OR a NIOSH-approved powered air-purifying respirator with OV cartridges and combination HE filters.

Handlers entering the treated area before the ventilation period is over must wear a long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves and wear a minimum of a NIOSH-approved respirator with a particulate filtering facepiece respirator with any R or P filter; OR a NIOSH-approved powered air-purifying respirator with HE filters.

USER SAFETY REQUIREMENTS

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

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

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

GENERAL PRECAUTIONS AND RESTRICTIONS

Do not apply this product in a way that will contact workers or other persons. Only protected handlers may be in the area during application.

For the control of *Aspergillus fumigatus* in cleaned poultry and turkey hatchery equipment prior to the introduction of eggs. Equipment would include empty hatcher cabinets, settlers, coolers, storerooms, and egg and chick handling equipment. CLINAFARM® EC will dramatically reduce the levels of infectious organisms and spores in treated areas.

This product may not be used when eggs or poultry are present. 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

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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. When applying imazalil in hatchery facilities using a handheld fogger, a respirator with a protection factor (PF) of 10 is required. Do not re-enter unventilated area for at least 12 hours. For ventilated areas, do not re-enter treated areas for at least 2 hours, provided that at least 5 air exchanges have occurred during that period. CLINAFARM® EC is compatible with other commonly used disinfectants such as quaternary ammonium compounds, glutaraldehyde, formaldehyde, and phenolic compounds.

Using a program that conforms to OSHA's requirements (see 29 CFR Part 1910.134), employers must verify that any handler who uses a respirator is:

- Fit-tested and fit-checked,
- Trained, and
- Examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as physical exam, might be necessary. The initial evaluation must be done before respirator use begins. Handlers must be reexamined by a qualified medical practitioner if their health status, respirator style, or use-conditions change.

Upon request by local/state/federal/tribal enforcement personnel, employers must provide documentation demonstrating how they have complied with these requirements.

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 HANDLING: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer empty bottles for recycling, if available, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities. If outer carton is contaminated and cannot be reused, offer for recycling if available or place in trash, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(Optional Warranty Statement)

[NOTICE OF WARRANTY

To the extent consistent with applicable law, Merck Animal Health makes no warranty of merchantability, fitness for any purpose, or otherwise, expressed or implied, concerning this product or its uses which extend beyond the use of the product under normal conditions in accord with the statements made on this label.]

[Product of Janssen Research]

[CLINAFARM® is a registered trademark of Johnson & Johnson CF-15]

[CLINAFARM® is a trademark owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.]

[Take Time, Observe Label Directions - graphic]

[Merck Animal Health logo]

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

(BOTTLE LABEL)

(UNIT PACK LABEL, FULL TEXT WILL APPEAR ON OUTER SHIPPER CARTON)

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Net contents: 1.58 US pints (750mL)

[Manufactured for:]

Intervet Inc. (d/b/a Merck Animal Health)

2 Giralda Farms

Madison, NJ 07940

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[Take Time, Observe Label Directions - graphic]

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[See bottom for [Lot] [Batch] [Control] [number]