



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 Smoke Generator
EPA Registration Number: 773-56
Received Date: 6/28/2021
Decision Number: 580516

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® SMOKE GENERATOR

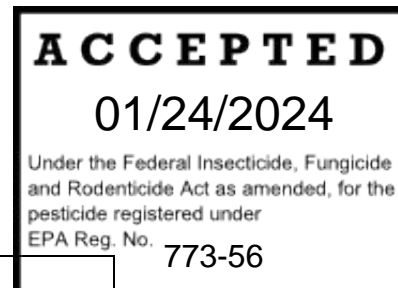
For the control of *Aspergillus fumigatus* in cleaned poultry and turkey hatchery equipment prior to the introduction of eggs, including empty hatcher cabinets, settlers, coolers and egg and chick handling equipment.

ACTIVE INGREDIENT:

Imazalil (enilconazole):1-(2-(2,4-Dichlorophenyl)-2-(2-propenyloxy)ethyl)-1H-imidazole.....16.0% w/w

OTHER INGREDIENTS..... 84.0%

[Minimum] 5 grams Imazalil (enilconazole) per canister **TOTAL**.... ..100.0% w/w



**KEEP OUT OF REACH OF CHILDREN
DANGER - PELIGRO**
See [back] [other] [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. • 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: 24 – 1.27 oz (24 – 35.9g) canisters

Manufactured for:
Intervet Inc. (d/b/a Merck Animal Health)
2 Giralda Farms
Madison, NJ 07940

EPA Reg. No. 773-56
EPA Est. No. 39775-GBR-01

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[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 canisters.)

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

(OUTER CARTON LABEL (cont'd))**ENVIRONMENTAL HAZARDS**

This chemical is toxic to fish.

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

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. Wearing long sleeved shirt, long pants, shoes, socks, and chemical resistant gloves (barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton, selection category C). The unignited content of the canister contains a strong oxidizing agent which may cause irreversible eye damage.

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. 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 elastomeric half mask respirator with organic vapor (OV) cartridges; OR a NIOSH-approved full face respirator with OV cartridges; OR a gas mask with OV canisters; OR a powered air-purifying respirator with OV cartridges. During early re-entry handlers must wear a long-sleeved shirt, long pants, shoes, socks, chemical resistant gloves, and a full-face respirator with a protection factor (PF) of 50.

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: Flammable. 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: such as empty hatcher cabinets, settlers, coolers and egg and chick handling equipment. Imazalil will dramatically reduce the levels of *Aspergillus fumigatus* in treated areas. Each canister contains sufficient Imazalil and smoke generating material to cover an enclosure of 400 to 500 cubic feet.

This product may not be used when egg or poultry are present. Treatment of the hatchery equipment should be the final step prior to introduction of the eggs. Do not remove canisters from the container except for immediate use. After equipment has been thoroughly cleaned and disinfected, place a smoke canister of Imazalil on a noncombustible surface. Keep everyone, except applicators, out of treatment

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site prior to and during application. Before starting, the area to be treated must be closed off to prevent air currents from diluting smoke. Ventilation ducts may be treated, but fans must be shut off. Ignite the wick of the canister. The treatment site must be vacated immediately after lighting the smoke canister. Within 60 seconds, the canister will be through smoking. The smoke must be allowed to settle and contact the surfaces for no less than ½ hour but preferably up to at least 12 hours before fumigated equipment and areas are used.

Do not enter or allow others to enter the treated area if smoke is still visible. Do not reenter the unventilated area for at least 12 hours. For ventilated areas, do not enter or allow others to enter the treated areas for at least 2 hours, provided that at least 9 air exchanges have occurred during that period. If no mechanical ventilation is used, do not enter or allow others to enter the treated areas for at least 12 hours after application is complete. Early entry is permitted only in an emergency or to operate ventilation equipment, provided that the person is wearing personal protective equipment required for such entry (see PPE requirements on this label.) After the ventilation requirements have been met, workers entering the treatment area to remove canisters must wear chemical resistant gloves.

Post signs at the entrances to the hatchery before the application begins and keep the signs in place until the mechanical ventilation period is over or, if no mechanical ventilation is used, for at least 12 hours after application is complete. The signs must contain the following word in a size that can easily be read: Danger/Peligro, Do Not Enter/No Enter.

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.

(Note to reviewer: Product is non-dilutable.)

STORAGE: Store in a cool, dry place. Storage temperature should not exceed 100°F.

PESTICIDE DISPOSAL: Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to the label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Offer empty canisters 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.

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.

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

[Product of Janssen Research]

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[Made in the United Kingdom]

[Take Time, Observe Label Directions - graphic]

(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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2-(2-propenyloxy)ethyl)-1H-imidazole.....16.0% w/w

OTHER INGREDIENTS.....84.0%

Contains [minimum] 5 grams Imazalil (enilconazole) **TOTAL.** ..100.0% w/w

KEEP OUT OF REACH OF CHILDREN
DANGER - PELIGRO
See outer container label for use directions, additional precautionary statements and First Aid.

Net contents: 1.27 oz. (35.9 g)

Manufactured for:

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

2 Giralda Farms

Madison, NJ 07940

EPA Reg. No. 773-56

EPA Est. No. 39775-GBR-01

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[Take Time, Observe Label Directions - graphic]

[Merck Animal Health logo]

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