

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

January 30, 2024

Lisa Adamson Control Solutions, Inc. 5903 Genoa-Red Bluff Pasadena, TX 77507-1041

Electronic Transmittal: ladamson@controlsolutionsinc.com

Subject: Label Amendment – Changes Required by the Imazalil

Interim Registration Review Decision

Product Name: Imazalil 13.8 EC

EPA Registration Number: 53883-327

Received Date: 12/8/2021 Decision Number: 581202

Dear Lisa Adamson:

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

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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,

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

Enclosure:

ACCEPTED

01/30/2024

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

53883-327

IMAZALIL 13.8 EC

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

Active ingredient:	
Imazalil (CAS No. 35554-44-0)	13.8%
Other Ingredients	86.2%
Total	100.0%

Keep Out of Reach of Children DANGER

See back [side] panel for additional Precautionary Statements

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NET CONTENTS: (_750_ mL)

FIRST AID

	TINOTAID
If in Eyes	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 treatment advice.
If Swallowed	Immediately call a poison control center or doctor for treatment advice.
	Have person sip a glass of water if able to swallow.
	Do not induce vomiting unless told to do so by a poison control center or a
	doctor.
	Do not give anything by mouth to an unconscious person.
If on Skin	Take off contaminated clothing.
or Clothing	 Immediately rinse skin with plenty of water for 15-20 minutes.
	Call a poison control center or doctor for treatment advice.
If Inhaled	Move person to fresh air.
	• If person is not breathing, call 911 or an ambulance, then give artificial
	respiration, preferably by mouth-to-mouth, if possible.
	Call a poison control center or doctor for further treatment advice.
Have the produ	ct container or label with you when calling the poison control center or doctor or

Have the product container or label with you when calling the poison control center or doctor or going for treatment. You may also contact SafetyCall[®] International at (866) 897-8050 for emergency medical treatment information.

PRECAUTIONARY STATEMENTS Hazards to Humans & 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. Thoroughly wash hands with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTION EQUIPMENT PPE

Some materials that are chemical-resistant to this product are nitrile rubber, neo-prene rubber and butyl rubber. All mixers, loaders, applicators and other handlers must wear long-sleeved shirt and long pants, shoes plus socks and chemical-resistant apron when mixing/loading, cleaning up spills, cleaning equipment, or otherwise exposed to the concentrate.

Handlers entering the treated area before the ventilation period is over must wear long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves and wear a minimum of 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.

DIRECTIONS FOR USE

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

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 a 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 or 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.

Use this product for the control of *Aspergillus* organisms in cleaned poultry and turkey hatchery equipment (empty hatchery cabinets, setters, coolers, storerooms, handling equipment) prior to introduction of the eggs. IMAZALIL 13.8 EC CANNOT BE USED WHEN EGGS AND POULTRY ARE PRESENT. Imazalil 13.8 EC reduces the levels of Aspergillus organisms and spores in treated areas. Imazalil 13.8 EC should be diluted before use and product should be used within 24 hours .To make 1 gallon of a 1:100 dilution, add 1.28 fluid ounces (36mL) of IMAZALIL 13.8 EC to one gallon of clean water (optimal temperature 110°F) to provide an antifungal concentration of 0.15% active ingredient. To assure proper efficacy, the area or equipment to be treated must be clean and closed off from outside air currents before treatment. Shut off fans before treating ventilation ducts.

The diluted product is to be applied by using a spray application directly to areas (including walls, floors and equipment) with spray devices (including pump-up, hose end applicator). Apply to treatment area at the rate of 1/2 fluid ounce diluted product per 150 cubic feet (1mL per 10 cubic feet). Spray all surfaces until thoroughly wet and ensure good contact of Imazalil 13.8 EC with surface areas. Vacate the treated area immediately after the application is complete.

Allow the surfaces to completely dry. Do not reenter the unventilated area for 12 hours. For ventilated areas, do not reenter treated areas for at least 2 hours, provided that at least 1 air exchange has occurred during that period. Use spray, Imazalil 13.8 EC, as an adjunct to normal disinfection.

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.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when cleaning equipment or disposing of equipment wash waters or rinsate. Apply this product only as specified on the label. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product

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to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PHYSICAL / CHEMICAL HAZARDS:

Combustible. Do not use or store this product near heat or open flame.

{For non-refillable containers (5 gallons or less in capacity):}

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store upright at room temperature. Avoid exposure to extreme temperatures. In case of spillage or leakages, soak up with an absorbent material such as sand, sawdust, earth, Fuller's earth, etc. Dispose of with chemical waste.

PESTICIDE DISPOSAL: Pesticide, spray mixture or rinse water that cannot be used according to label instructions must be disposed of at or by an approved waste disposal facility.

CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 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 for recycling if available. If recycling is not available: then dispose of container in a sanitary landfill or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

{Per PR Notice 2007-4 the batch code/lot number will appear on the label or container.}

LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather, presence of other materials or other influencing factors in the use of the product, which are beyond the control of Control Solutions, Inc. or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold Control Solutions, Inc. and Seller harmless for any claims relating to such factors.

Control Solutions, Inc. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Control Solutions, Inc., and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, CONTROL SOLUTIONS, INC. MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS

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Control Solutions, Inc. and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of Control Solutions, Inc.

Manufactured for: Control Solutions, Inc. 5903 Genoa-Red Bluff Pasadena, TX 77507-1041

[] Denotes alternate/optional language

^{ } Denotes language that does not appear on the market labeling