

73049-450

02/25/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

February 25, 2010

Nassar A. Assaf
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

Subject: Label Notification per Pesticide Registration Notices 2007-4 and 98-10

Dear Dr. Assaf:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notices (PRNs) 2007-4 and 98-10, dated July 29, 2009, for EPA Registration Number 73049-450: Dinotefuran Fly Bait.

The Registration Division (RD) has conducted a review of this request for applicability under PRNs 2007-4 and 98-10, and finds that the label changes requested fall within the scope of PRNs 2007-4 and 98-10. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label or durably marked on the container itself, and can be added by non-notification per PRN 98-10.

If you have any questions, please contact me directly at 703-308-8735 or email me at chao.julie@epa.gov.

Sincerely,

A handwritten signature in cursive script that reads "Julie A. Chao".

Julie A. Chao
Insecticide-Rodenticide Branch
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73049-450	2. EPA Product Manager Rita Kumar	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Dinotefuran Fly Bait	PM# IRB	
5. Name and Address of Applicant (Include ZIP Code) Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

Amendment - Explain below. Final printed labels in response to Agency letter dated _____

Resubmission in response to Agency letter dated _____ "Me Too" Application.

Notification - Explain below. Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of label change per PR-Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.
 Notification of change to disposal statements.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container

3. Location of Net Contents Information
 Label Container

4. Size(s) Retail Container
1, 2, 3, 5, 10, 15, 20, 30, 40, or 50 lbs.

5. Location of Label Directions

6. Manner in Which Label is Affixed to Product
 Lithograph
 Paper glued
 Stenciled Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Nasser A. Assaf, Ph.D.	Title Regulatory Manager, ESD	Telephone No. (Include Area Code) (847) 968-4844
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Certification
 I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature N.A. ASSAF	3. Title Regulatory Manager, ESD
4. Typed Name Nasser A. Assaf, Ph.D.	5. Date July 29, 2009



870 TECHNOLOGY WAY
LIBERTYVILLE, IL 60048 - 800-323-9597

September 27, 2009

Document Processing Desk
Registration Division
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

ATTN: Rita Kumar
Insecticide Rodenticide Branch

SUBJECT: APPLICATION FOR PESTICIDE LABEL NOTIFICATION –
No PRIA Service Fee Required
Submission of Revised Labeling Per:
- PR-Notice 2007-4, Container Disposal
Dinotefuran Fly Bait; EPA Reg. No. 73049-ULN

Dear Ms. Kumar:

This application for label notification for the above subject product is being submitted to comply with the PR Notice 2007-4, Labeling Revisions Required by the Final Rule "Pesticide Management and Disposal; Standards for Pesticide Containers and Containment Revision of Container Disposal.

The following underlined italic text has been added to the label:
If empty: *Non-refillable container.* Do not reuse *or refill* this container.

Two (2) copies of revised draft labeling with changes clearly marked are enclosed. Additions are noted in underlined italics. Deletions are shown struck through.

If you need additional information or have any questions regarding this submission, please do not hesitate to contact me at (847) 968-4844 or e-mail to: Nasser.assaf@valent.com.

Sincerely,

Nasser A. Assaf, Ph.D.
Regulatory Manager, ESD

Enclosures
cc: VBC Regulatory File

Dinotefuran Fly Bait

- *[For Control Of Houseflies In Industrial, Commercial And Agricultural Settings*
- *For Pest Management, Professionals, Livestock And Poultry Producers, [And Commercial Use]*
- *Ready To Use [Scatter Bait]*
- *Can Be Used [For Use] In Fly Bait Stations*
- *Attracts And Kills Houseflies*
- *Four [4] Ounces Treats 500 Square Feet*
- *Contains [(Z)-9 Tricosene] Fly Sex Attractant [Muscamone@] [Pheromone]*
- *For The Control Of Nuisance Houseflies In And Around Livestock, And Poultry Facilities And Stables*
- *Use Around Commercial Food Producing Facilities, Restaurants And Dumpsters]*

Active Ingredients:

Dinotefuran, [N-methyl-N'-nitro-N''-(tetrahydro-3-furanyl)	
methyl) guanidine]	0.50%
(Z)-9-tricosene.....	0.04%
Other Ingredients:	<u>99.46%</u>
Total:	100.00%

EPA Reg No.: 73049-450

EPA Establishment No.: XXXXX-XX-X

KEEP OUT OF REACH OF CHILDREN

CAUTION

See side panels 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 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. • Have person sip a glass of water if able to swallow. • 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.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. In case of medical emergencies or health and safety inquiries or in case of fire, leaking or damaged containers, information may be obtained by calling 1-877-315-9819.	

NET CONTENTS: [1, 2, 3, 5, 10, 15, 20, 30, 40 or 50 lb(s)]

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PRECAUTIONARY STATEMENTS
Hazards To Humans And Domestic Animals

CAUTION

Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Environmental Hazards

This pesticide is toxic to shrimp. Do not apply directly to water, areas where surface water is present or to intertidal areas below the mean high water mark. Drift or run off from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwaters.

This product is highly toxic to bees exposed to direct treatment. Do not apply this product if bees are actively foraging in the treatment areas.

DIRECTIONS FOR USE

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

READ ENTIRE LABEL, USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS, AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.

GENERAL USE RESTRICTIONS

[Dinotefuran Fly Bait] [Brand Name] fly bait should not be used inside homes, or any place where children or animals might be present. [Do not spread granules or use bait stations within reach of children or animals.] Do not apply this product in a way that will contact workers or other persons.

Do not apply where poultry or animals, especially dogs and young calves, can pick it up or lick it. Do not use on edible product areas of food processing plants or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed. Do not use as a scatter bait indoors. Do not use as a scatter bait in food/feed areas of food/feed handling establishments. Do not use around commercial dumpsters, which are not enclosed.

GENERAL INFORMATION

[Dinotefuran Fly Bait] [Brand Name] is an effective fly bait formula that contains Muscamone fly attractant.

Baits can be an important tool in the overall management of housefly populations. An integrated approach is recommended which includes: sanitation, manure management, physical barriers, sprays, mechanical traps and periodic rotation of baits with different modes of action.

APPLICATION PROCEDURES

SCATTER BAIT

Where to Apply

[Dinotefuran Fly Bait] [Brand Name] may be used around the outside of milking parlors, broiler houses, kennels, canneries, beverage processing plants, meat and poultry processing plants, food processing plants and refuse dumpsters associated with these establishments and the walkways of caged layer houses. Do not use around commercial dumpsters, which are not enclosed. May also be used in fenced or otherwise enclosed areas inaccessible to children and around the outside of restaurants, supermarkets, commissaries and bakeries.

Methods of Application

Scatter [Dinotefuran Fly Bait] [Brand Name] fly bait granules [directly from container] onto desired locations. Scatter granules evenly on [dry, level] surfaces, avoid placing bait in piles. Apply at a rate of 1/4 pound per 500 square feet of area. Re-apply as bait is consumed to maintain control. Start applications at the beginning of the season to help keep housefly populations manageable. Avoid application to windy areas as houseflies will avoid these areas; apply bait in several locations, concentrating on areas where houseflies are a problem.

BAIT STATIONS

Where to Apply

[Dinotefuran Fly Bait] [Brand Name] stations may be used in housefly infested areas such as in and around milking parlors and broiler houses, caged layer houses, canneries, beverage processing plants, food processing plants, meat and poultry processing plants, kennels, stables, refuse dumpsters, warehouses, loafing sheds, swine facilities, broiler houses, and feed lots. May also be used in and outside the non-food/feed areas of restaurants, barns, taverns, supermarkets, commissaries and bakeries.

Methods of Application

Use [Dinotefuran Fly Bait] [Brand Name] fly bait in any commercial fly bait station secured at least 4 feet above the ground. One bait station should be positioned in each 250 square feet of area with up to 2.0 ounces of bait per station. Place Bait stations in areas inaccessible to food-producing animals, pets and children. Concentrate bait station placements in areas where houseflies are a problem including dumpsters, stables, trash piles or other areas that attract houseflies. Avoid placing bait stations in windy areas as houseflies will avoid bait stations that move. Re-apply as bait is consumed to maintain control.

STORAGE AND DISPOSAL

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

Storage: Store in a cool dry place away from heat or open flame and inaccessible to children.

Disposal: *If empty:* Non-refillable container. Do not reuse *or refill* this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency [or 1-877-315-9819] for disposal instructions. Never place unused product down any indoor or outdoor drain.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions of Sale and Limitation of Warranty and Liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following, Conditions of Sale and Limitation of Warranty and Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Valent BioSciences Corporation. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, VALENT BIOSCIENCES CORPORATION MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Valent BioSciences Corporation is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, any warranties having been made, express or implied, are not applicable if this product has been used contrary to label directions, under abnormal conditions, or under conditions not reasonably foreseeable to Valent BioSciences Corporation, and buyer assumes the risk of any such use to the extent permitted by law. To the extent consistent with applicable law, Valent BioSciences Corporation disclaims any liability

whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT VALENT BIOSCIENCES CORPORATION'S ELECTION, THE REPLACEMENT OF PRODUCT.

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Alternate warranty statements:

[WARRANTY AND CONDITIONS OF SALE

To the extent consistent with applicable law, Seller makes no warranty, expressed or implied, concerning the use of the product other than indicated on the label. To the extent consistent with applicable law, Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.]

[] Denotes alternate text in addition to any subset of the directions for use.

Muscamone is a registered trademark of Wellmark International

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02-0805/R2