

73049-430

4.11.2007

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

NOTIFICATION

APR 11 2007

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Nasser Assaf, Ph.D.
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

SUBJECT: /Applications for Pesticide Notification – Warranty Statements, etc.
VBC Dinotefuran EPA Reg. No. 73049-430
Dinotefuran 0.5% cockroach Gel Bait Professional EPA Reg. No. 73049-441
Dinotefuran 0.5% Roach Bait Stations EPA Reg. No. 73049-442
Dinotefuran 0.2% Roach Bait Stations EPA Reg. No. 73049-443
Applications Dated October 25, 2006

Dear Dr. Assaf:

The Agency is in receipt of your Applications for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above products. The Registration Division (RD) has conducted a review of these requests for their applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The labels submitted with the application has been stamped "Notification" and will be placed in our records.

Because of the lateness of this review, we have accepted the labels submitted with the applications. However, at the next printing of these labels, please revise the first statement after "CONDITIONS:" to read "The directions for use of this product are believed to be adequate and must be followed carefully." (replaces "should" with "must") under the section heading "**IMPORTANT: READ BEFORE USE**". Please be advised that PRNs are provided as guidance; they are not considered regulation by the Agency. Therefore, the RD reserves the right to make the above determination and concludes that this action must be submitted by you at the next printing of the above labels.

If you have any questions, please me directly at 703-305-6249 or Terri Stowe of my staff at 703-305-6117.

Sincerely,

Linda Arrington
Notifications & Minor Formulations Team Leader
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 73049-430	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VBC Dinotefuran Technical	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048	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 _____	

NOTIFICATION
APR 11 2007

☐ Check if this is a new address

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

APR 11 2007

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

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152-46, and no other changes have been made to the labeling or the confidential statement of formula of 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 this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, 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 IN WARRANTY STATEMENT, EMERGENCY NUMBER & FORMULATORS STATEMENT CONSISTENT WITH 40 CSF156 PER PR NOTICE 98-10.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input 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 <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper, glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> 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 Assaf, Ph.D		Title Regulatory Manager, ESD		Telephone No. (Include Area Code) (847) 968-4244	
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 <i>N. ASSAF</i>		3. Title Regulatory Manager, ESD			
4. Typed Name Nasser Assaf, Ph.D		5. Date October 25, 2006			

VBC Dinotefuran Technical

FOR FORMULATION INTO INSECTICIDE PRODUCTS

Active Ingredient:

Dinotefuran, [N-methyl-N'-nitro-N''-((tetrahydro-3-furanyl)methyl)guanidine]..... 99.0%

Other Ingredients:..... 1.0%

Total:..... 100.0%

EPA Reg No. 73049-430

EPA Establishment

NOTIFICATION

APR 11 2007

KEEP OUT OF REACH OF CHILDREN

CAUTION

See side panels for additional precautionary statements

FIRST AID	
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 Swallowed:	<ul style="list-style-type: none"> • Call a poison control center or doctor 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 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 poison control center or doctor for treatment advice.
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.
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:

PRECAUTIONARY STATEMENTS
Hazards To Humans And Domestic Animals

CAUTION

Harmful if absorbed through the skin. Harmful if swallowed. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

Environmental Hazards

This pesticide is toxic to shrimp. 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 Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product 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.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

Dinotefuran and its degradate, MNG, have the properties and characteristics associated with chemicals detected in ground water. The high water solubility of dinotefuran, and its degradate MNG, coupled with its very high mobility, and resistance to biodegradation indicates that this compound has a strong potential to leach to the subsurface under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination. Periodic monitoring of shallow groundwater in the use area is recommended.

Physical Or Chemical Hazards

Do not use, pour, spill 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.

VBC Dinotefuran technical is intended for use only in the formulation of insecticide products used in the control of sucking, biting and chewing insects infesting cotton, leafy vegetables, fruiting vegetables, cucurbits, potatoes, grapes, head and stem brassica, turf and ornamental, domestic outdoor (lawn, perimeters, and ornamentals), and certain public health pests.

This product may be used to formulate products for specific use(s) not listed on the manufacturing product label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding the support of such uses(s).

STORAGE AND DISPOSAL

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

Pesticide Storage: Keep pesticide in original container. Do not put concentrate or dilute into food or drink containers. Store in a cool dry place. Do not store diluted spray. For help with any spill, leak, fire or exposure involving this material, call day or night 1-800-CLEANUP.

Pesticide Disposal: 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). Do not reuse container. Offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

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 should 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: 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. 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. Valent BioSciences Corporation disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

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