

73049-430

06-25-2010

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JUN 25 2010

Name Dr. Nasser Assaf
Manager, Product Safety and Regulatory Affairs

Company Valent BioSciences Corporation
Address 870 Technology Way
Libertyville, IL 60048

Subject: Notification: Minor label additions/corrections
Updated container disposal statement per PR Notice 2007-4
Updated warranty statement
VBC Dinotefuran Technical
EPA Registration Number 73049-430
Your submission pin punched April 27, 2010

Dear Dr. Assaf:

The Agency is in receipt of your Application dated April 15, 2010 for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 and PRN 2007-4 for the product VBC Dinotefuran Technical. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10, and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me at 703-308-8291 or send an e-mail.

Sincerely,

Rita Kumar

Rita Kumar
Senior Regulatory Specialist
Insecticide-Rodenticide Branch
Registration Division (7505P)
Office of Pesticide Programs
E-mail: kumar.rita@epa.gov



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73049-78	2. EPA Product Manager Rita Kumar	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VBC Dinotefuran Technical	PM# 01 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 _____	

NOTIFICATION

JUN 25 2010

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.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Label Notification - No Fee; e-mail: Nasser.Assaf@valent.com; Fax: (925) 817-5160
See Self Certifications statements on cover letter.

Changes include:

- Revise Storage & Disposal Statements in Compliance with PR Notice 2007-4,
- Updated warranty statement in agreement with US EPA OPP Guidance on Warranty Statements (Oct. 17, 2006)
- No other changes have been made to the label other than those clearly marked.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted				<input checked="" type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container		<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 to 55 gallons		5. Location of Label Directions <input checked="" type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input checked="" 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 A. Assaf, Ph.D		Title Manager, Product Safety and Regulatory Affairs	
		Telephone No. (Include Area Code) (847) 968-4788	
<p align="center">Certification</p> <p>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.</p>			
2. Signature 		3. Title Manager, Product Safety and Regulatory Affairs	
4. Typed Name Nasser A. Assaf, Ph.D		5. Date April 15, 2010	
6. Date Application Received (Stamped)			



April 15, 2010

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NOTIFICATION
JUN 25 2010
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Document Processing Desk (NOTIF)
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
- PR-Notice 98-10, Warranty Statement update
VBC Dinotefuran Technical; EPA Reg. No. 73049-430

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 and US EPA OPP Guidance on Warranty Statements (Oct. 17, 2006) among other minor changes which are clearly marked.

VBC Dinotefuran Technical; EPA Reg. No. 73049-430, is for indoor, manufacturing use only.

Due to the limited space on EPA Form 8570-1, Section II, the self certification statements are as follows:

PR Notice 2007-4, Labeling Revisions Required by the Final Rule "Pesticide Management and Disposal 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.

US EPA OPP Guidance on Warranty Statements (Oct. 17, 2006)

This notification is consistent with the provisions of PR Notice 98-10 and the EPA regulations at 40 CFR 152.46, and 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 this notification is not consistent with the

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Enclosures
cc: VBC Regulatory File

NOTIFICATION
JUN 25 2010

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%
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EPA Reg No. 73049-430

EPA Establishment

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 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 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 treatment advice.
HOT LINE NUMBER	
<p>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.</p>	

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.

Products formulated from this technical material will require registration with the U.S. Environmental Protection Agency (EPA).

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 your local solid waste agency [or 1-877-318-9819 (day or night)].

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: ~~Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Do not reuse container.~~ Offer for recycling *if available*, or reconditioning *if appropriate*, 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. or by other procedures approved by state and local authorities.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of 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, disclaimer of warranties and limitations of 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, Valent BioSciences Corporation disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

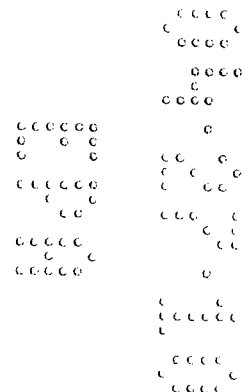
LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED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

[Or alternate text

Note [Notice]: Seller warrants that this product complies with the specifications expressed in this label. To the extent consistent with applicable law, seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability or default, breach or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, seller shall have no liability for consequential damages.]

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Valent BioSciences Corporation
Environmental Science Division
870 Technology Way
Libertyville, IL 60048
02-0791/R2



JUN 25 2010

For Formulation Into Insecticide Products

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

Other Ingredients:..... 1.0%

Total:	100.0%
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EPA Reg No. 73049-430

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NET CONTENTS:

A collection of 25 small, stylized line drawings of various birds, including sparrows, finches, and songbirds, arranged in a grid-like fashion. The drawings are simple and elegant, capturing the essence of each bird's form and posture. They are arranged in a grid-like fashion, with some birds facing left and others facing right, creating a balanced and visually appealing composition.

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Container Disposal: Nonrefillable container. Do not reuse or refill this container. Triple-rinse (or equivalent). ~~Do not reuse container.~~ Offer for recycling if available, or reconditioning if appropriate, 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.~~ or by other procedures approved by state and local authorities.

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By using this product, user or buyer accepts the following conditions, disclaimer of warranties and limitations of liability:

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

[Or alternate text

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