

73049-467

09/23/2011

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



OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

SEP 23 2011

Nasser Assaf  
Regulatory Manager, ESD  
Valent BioSciences Corp.  
870 Technology Way  
Libertyville, IL 60048

Subject: Darlex Insecticide – Notification for Alternate Brand Name (NA811)  
EPA Reg. No. 73049-467  
Notification Application Dated September 14, 2011

Dear Mr. Assaf:

The Agency has received your Application for Pesticide Notification under Pesticide Registration Notices (PRN) 98-10, dated September 14, 2011, for the product Darlex Insecticide, EPA Reg. No. 73049-467. The Registration Division (RD) has reviewed this request and finds that the actions requested fall within the scopes of PR Notice 98-10. The information submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at (703) 308-8043 or email [lewis.marianne@epa.gov](mailto:lewis.marianne@epa.gov)

Sincerely,

A handwritten signature in black ink that reads "Marianne Lewis".

Marianne Lewis  
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 73049-467	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Darlex Insecticide	PM# 01	
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

<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  
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 ALTERNATE BRAND NAME PER PR NOTICE 98-10 II A. Alternate Name: NA811  
-No other changes have been made to the label.

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
* 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"/> on label	
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 Manager, Product Safety and Regulatory Affairs	Telephone No. (Include Area Code) (847) 968-4844 e-mail: nassef.assaf@valent.com
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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 NA ASSAF	3. Title Manager, Product Safety and Regulatory Affairs
4. Typed Name Nasser Assaf, Ph.D.	5. Date September 14, 2011



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

September 14, 2011

Document Processing Desk (NOTIF)  
Insecticide Branch  
Registration Division (7504P)  
Office of Pesticide Programs  
US Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

ATTN: Venus Eagle  
Product Manager 01  
Insecticide-Rodenticide Branch

SUBJECT: APPLICATION FOR PESTICIDE – NOTIFICATION (Alternate Brand Name)  
Darlex® Insecticide; EPA Reg. No. 73049-467

Dear Ms. Eagle:

Valent BioSciences Corporation would like to add an alternate brand name to EPA Registration number 73049-467 of: NA811. This name is being used for research purposes only and will not be on any consumer product. No other changes have been made to the label.

The primary name of the product is to remain as Darlex Insecticide.

Enclosed:  
Application for Pesticide Registration  
Draft Labeling (2 copies)

Two (2) copies of revised labeling are enclosed. Additions are noted in highlighted, underlined italics. Deletions (if any) are shown struck through.

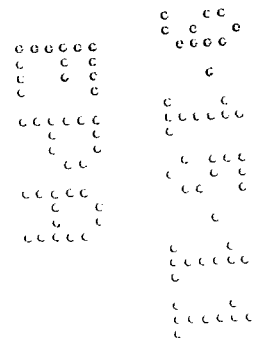
Please contact me at (847) 968-4844 or e-mail to: [Nasser.Assaf@valent.com](mailto:Nasser.Assaf@valent.com) if you have any questions or need additional information regarding this submission.

Sincerely,

*MAASSAF*  
Nasser Assaf, Ph.D.  
Regulatory Manager, ESD

Enclosures

cc: VBC regulatory file



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**DARLEX™ INSECTICIDE****NOTIFICATION****SEP 23 2011**Alternate brand name: NA811

- ◆ FOR USE IN, AND ALONG THE OUTSIDE PERIMETER OF POULTRY HOUSES TO CONTROL DARKLING BEETLES & HIDE BEETLES
- ◆ CONTROLS BOTH ADULTS AND LARVAE
- ◆ FOR [BOTH] BROADCAST [OR] [AND] [SPOT] [BAND] APPLICATIONS
- ◆ EASY TO USE [MIX AND SPRAY]
- ◆ CAN BE USED IN WHOLE [POULTRY] HOUSE APPLICATIONS
- ◆ [ECONOMICAL]
- ◆ [KILLS BEETLES]
- ◆ SPECIALLY FORMULATED FOR THE POULTRY INDUSTRY
- ◆ ONE BOTTLE TREATS up to 10,000 [21,000, 42,500, 85,000] SQUARE FEET
- ◆ [EXCELLENT] RESIDUAL [KILLING POWER] [ACTIVITY]
- ◆ [PROVEN PERFORMANCE]

Active Ingredient:

*Clothianidin .....	23.60%
Other Ingredients:.....	76.40%
Total .....	100.00%

\*(E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine

Contains 2.13 lbs active ingredient per gallon

EPA Reg. No. 73049-467

EPA Est. No.

**KEEP OUT OF REACH OF CHILDREN  
CAUTION  
SEE NEXT PAGE FOR PRECAUTIONARY STATEMENTS**

**PRECAUCION AL CONSUMIDOR:** Si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.

**(TO THE USER:** If you cannot read English, do not use this product until the label has been fully explained to you.)

<b>FIRST AID</b>	
<b>If Swallowed:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>HOT LINE NUMBER</b>	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-877-315-9819.	
<b>NOTE TO PHYSICIAN</b>	
Contains petroleum distillate - vomiting may cause aspiration pneumonia.	

NET CONTENTS : [1 pint, 1 quart, 2 quarts, 1 gallon]

**PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS & DOMESTIC ANIMALS**

**CAUTION:** Harmful if swallowed. Wash thoroughly with soap and water after handling.

**PERSONAL PROTECTIVE EQUIPMENT (PPE)**

Some of the materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category A on an EPA chemical-resistance category selection chart.

**Applicators and other handlers must wear:** long-sleeved shirt and long pants, shoes plus socks and chemical-resistant gloves made of any waterproof material.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables are available, 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.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- 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.

**ENVIRONMENTAL HAZARDS**

This product is toxic to aquatic invertebrates. Do not apply when weather conditions favor drift from treated areas. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwater or rinsate.

**DIRECTIONS FOR USE**

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

**Shake well before using.**

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

Do not apply this product in any way that will contact workers or other persons either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

Poultry producers should use a range of management practices to reduce the possibility of insecticide resistance and to help minimize the build-up and carry-over of populations of darkling beetles and other insect pests. Contact your local Cooperative Extension Service for advice concerning the use of this product and appropriate [helpful, suitable] resistance management [insecticide rotation] strategies [tactics, practices, measures.]

Darlex insecticide controls Darkling Beetles, (also known as Lesser Mealworm[s] [Beetles]) and Hide Beetles in Poultry Housing [Structures, Facilities, Buildings, Barns]. This product can be used as a crack & crevice, general surface, or spot treatment applied to walls, floors, and support [posts] [beams] of poultry [broiler, turkey, caged egg layer, breeder] housing [structures, facilities, buildings, barns].

**Do not apply when birds are present** and do not expose poultry to direct spray. Exposed water and feed [troughs] [lines] must be covered or removed from the area before treatment begins. Once completed, allow surfaces to dry completely before restocking. Do not apply as a fog or space-spray. Fresh bedding material must be put into the house prior to restocking.

**Read and follow ALL label directions when using [applying, treating with] this product.**

Do not use DARLEX at less [lower] than the label rate. By using less than the specified rate, insects are exposed to sub-lethal doses, which may not kill the insect but can [increase] [speed-up] the development of resistance.

**When To Apply:** Apply between flocks [after each grow-out, following de-caking] [approximately every 45 days] following clean-out and sanitation procedures, but prior to placement of a new flock. It may be advisable to treat houses before removing litter to prevent possible infestation of nearby residences.

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**Mixing Instructions:** Mix 4 ounces in ½ to 2 gallons of water to treat 1000 sq. feet of floor, wall, litter, or roost surface]. Be sure to accurately measure the actual surface area [square feet] to be treated in order to determine [how much] [the quantity of] Darlex [is] needed [required] [necessary] for the application [treatment]. To prepare the diluted spray, fill the sprayer tank with half the total water to be used, add the appropriate amount of Darlex, then add the remaining water while agitating or mixing.

To apply 4 oz Darlex per 1000 sq ft		
Sq. ft. of area to be Treated	Fluid Ounces of Darlex Needed	Total Volume of Water
500	2 oz	¼ to 1 gallon
5,000	20 oz	2.5 to 10 gallons
10,000	40 oz.	5 to 20 gallons
15,000	60 oz.	7.5 to 30 gallons
20,000	80 oz.	10 to 40 gallons

Make certain that sufficient agitation is maintained throughout the application to ensure a uniform spray. Prepare a fresh spray mixture before each treatment.

**NOTE:** Adding disinfectants to insecticide tank mixes may affect insecticidal activity.

#### APPLICATION METHODS:

**Band Application** – Darkling beetles often crowd under feeders, water lines or along perimeter walls, lying buried in the litter. Under these circumstances, it may be sufficient [desirable] to treat the primary areas of beetle infestation within a poultry [broiler, turkey, caged egg layer, breeder] house. Under these conditions, [targeted] [selected] areas of the house, 3-5 ft wide bands may be treated. Beetles can also infest structures behind insulation in walls; Darlex can be applied as a spot treatment inside wall voids or as a crack and crevice application to target these infestations.

For band application, apply diluted product to a 3-5 foot wide swath of floor area, making sure to get under all the water and/or feed lines in the house. Continue applying a 3-5 foot swath along the inside perimeter of [all] [the side and end] walls including the entire surface of all footings and 1-2 feet up on to the walls support beams and wood surfaces above the [concrete] [foundation] [footings].

**[Broadcast] [Whole House] Application** – Whenever an infestation is severe, it may be necessary to treat the entire house by applying the diluted product as a broadcast spray. Spray Darlex on the entire floor, paying particular attention to areas beneath feed and water lines, as well as to the lower sections of walls up to 1 foot on wood surfaces above the foundation. Fresh bedding must be put into the house prior to restocking.

**For Best Results** – In houses with support beams, treat around the base of each support post and 1 foot up each post. Apply dilute spray to cracks and crevices around insulation where beetles have been seen or can find harborage. To prevent movement of beetle infestations to houses and nearby residences, it may also be desirable to treat manure before it is relocated from the poultry house

Use Darlex as part of an integrated pest management program to extend the efficacy of insect control products and to help minimize the build-up and carry-over of resistant insect populations. Darkling beetles have the ability to develop resistance to insecticides. When one class of chemistry is used [flock after flock, year after year, time after time], the likelihood that insects will develop resistance and become more difficult to control, greatly increases. This product contains clothianidin, a neonicotinoid insecticide which should be used in a rotational [insecticide rotation] program with other [classes of] insecticides such as pyrethroids, organophosphates or spinosid, to minimize or prevent [the development of] resistance and to maintain its effectiveness in controlling darkling beetles and other listed insects.

**[NOTE:** In order to avoid re-infestation after clean out, to apply targeted applications to the exterior of the building perimeter, foundation, doors and windows, and other places where pests may enter.]

**[Darlex may be used to control crickets and nuisance ants in, and along the outside perimeter of animal housing**

Darlex may be used to control crickets and nuisance ants in, and along the outside perimeter of animal housing. Mix ½ to 1 ounce of Darlex per gallon of water. Apply as a spot treatment, banded application, or crack & crevice application at the base of the structure foundation, or at entry points such as doors, vents, eaves or utility penetrations. In building

interiors, apply only as a crack & crevice or void application. If desired, spot or drench treatments may be made to soil around the structure exterior where ants nest. Aboveground ant nests in wood posts, decks, fences or trees, may be treated by spraying the cavity where ants are nesting or the wood surface.

Note: not for use in control of red imported fire ants, native fire ants, pharaoh, or harvester ants.]

### STORAGE AND DISPOSAL

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

#### PESTICIDE STORAGE

Store in a dry place away from excessive heat.

Do not store near food or feed.

Store in original container only.

To close package, replace and tighten cap to form an airtight seal.

#### 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:** Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying.

[Containers 5 gallons or under]

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 solvent used to dilute the product for use 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 or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

[Containers over 5 gallons]

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with solvent used to dilute the product for use. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store for later use or disposal. Repeat this procedure two more times. Offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, 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.

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Darlex is a trademark of Valent BioSciences Corporation

Valent BioSciences Corporation  
Environmental Science Division  
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