

73049-467

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



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

11/1/13

Valent BioSciences Corp.
Nasser Assaf
Manager, Product Safety & Regulatory Affairs
870 Technology Way
Liberty, IL 60048

Subject: Amended label adding pollinator protection language
Product Name: Darlex Insecticide
EPA Reg. No. 73049-467
EPA Decision No. 482409
Submission dated August 21, 2013

Dear Mr. Assaf:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act is acceptable. A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. See 40 CFR 156.10(a)(6).

Under 40 CFR 152.130(d), EPA may establish dates by which all product distributed or sold by the registrant must bear revised labeling. The following paragraphs set forth the schedule for ensuring that that your product bears revised labeling within a reasonable time period.

- Any product released for shipment after 2/28/14 must bear the new label.

If these conditions are not complied with, EPA will take appropriate action against this registration. If you have any questions please contact Marianne Lewis at 703 308-8043 or lewis.marianne@epa.gov.

Regards,

A handwritten signature in cursive script that reads "Venus Eagle".

Venus Eagle, Product Manager (01)
Insecticide-Rodenticide Branch
Registration Division (7505P)

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ACCEPTED

11/1/13

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

DARLEX® INSECTICIDE

Alternate brand name: NA811

EPA Reg. No: 73049-467

- ◆ 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

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.)

EPA Reg. No. 73049-467

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN CAUTION

SEE NEXT PAGE [side panel] FOR PRECAUTIONARY STATEMENTS

FIRST AID	
If Swallowed:	<ul style="list-style-type: none"> ▪ Call a poison control center or doctor immediately 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 doctor. ▪ Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
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.	

NET CONTENTS : [1 pint, 1 quart, 2 quarts, 1 gallon, 1.5 gallons]

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 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.
- 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.

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

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.

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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.

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 [0.25] 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] [With] 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].

Interior [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 spinosyns to minimize or prevent [the development of] resistance and to maintain its effectiveness in controlling darkling beetles and other listed insects.

[In order to avoid re-infestation after clean out, apply targeted applications to the exterior of the building perimeter, foundation, doors and windows, and other places where pests may enter the building. Do not allow this product to contact plants in bloom if bees are foraging the treatment area.]

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[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, or fences, may be treated by spraying the cavity where ants are nesting or the wood surface.

Not for use in control of red imported fire ants, native fire ants, pharaoh ants, or harvester ants or carpenter 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

To avoid wastes, use all material in this container by application according to label instructions. If waste cannot be avoided, offer remaining product to a waste facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

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.

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Master Label

October 29, 2013
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