

11556-146

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

NOTIFICATION

FEB 06 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

J. Todd Frank
Bayer HealthCare LLC, Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201-0390

Subject: Notification to remove pests from the label
Credo SC Insecticide
EPA Registration # 11556-146
Submission Date: November 22, 2013

Dear Jane M. Miller :

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 received November 22, 2013. The Registration Division (RD) has reviewed these requests and finds that this action falls 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 contact Jessica Rogala at (703) 347-0263 or via email at rogala.jessica@epa.gov.

Sincerely,

Jessica Rogala
Environmental Protection Specialist
Insecticide-Rodenticide Branch
Registration Division (7505P)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11556-146	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Credo SC Insecticide	PM# Team Number 01	
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 <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.)

Notification per PR Notice 98-10:

Remove pests from label and minor updates as allowed by PR Notice 98-10. See attached letter.

E-mail Contact: todd.frank@bayer.com

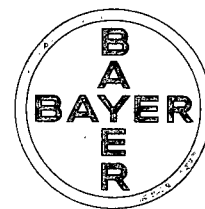
Section - III

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"/> On Label <input type="checkbox"/> On Labeling accompanying product	
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 J. Todd Frank	Title Reg. Affairs Consultant	Telephone No. (Include Area Code) 913-268-2585
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.		8. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Consultant	
4. Typed Name J. Todd Frank	5. Date 11/21/2013	

Bayer HealthCare



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November 21, 2013

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

Attention: Ms. Venus Eagle/PM 01

Subject: Remove pests from label and minor updates:

- Credo SC Insecticide (EPA Reg. No. 11556-146)

Dear Ms. Eagle:

Please find enclosed, for the Agency's acceptance an Applications for Pesticide Notification, one copy of the highlighted label, and ~~three~~ ^{one} copies of the unhighlighted labels for the subject product.

As allowed by PR Notice 98-10 Bayer HealthCare LLC Animal Health is deleting the uses for ants and the related directions for use. Other nonsubstantive changes were made via the enclosed Notification.

"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."

If you have any questions, please do not hesitate to call (913) 268-2585.

Sincerely,

J. Todd Frank
Regulatory Affairs Consultant
todd.frank@bayer.com

Enclosures:

- 1) Credo SC Insecticide - Application w/att.

Bayer HealthCare LLC

Animal Health

P.O. Box 390
Shawnee Mission, KS
66201-0390

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Reason to Issue: Remove pests from label and update
Warranty and Conditions of Sale Sections.
Added copy right symbol to brand name.

Date: 11/19/2013
Supersedes: 03/27/2008
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Note to Reviewer: Brackets [] and parentheses () denote optional language

Credo® SC Insecticide

For (effective) control of [(darkling beetles) (lesser mealworms)] and [hide beetles] in and around poultry [(housing) (structures) (facilities) (buildings) (barns)].

-
-
-
-

[Selected optional label claims bulleted here from pages 8 -10.]

ACTIVE INGREDIENT:

Imidacloprid [CAS 1328261-41-3] 42.8%

OTHER INGREDIENTS 57.2%

Total: 100.0%

Contains 4.38 pounds of imidacloprid per gallon, or 526 grams
AI/liter.

Shake well before using.

EPA Reg. No. 11556-146

EPA Est. No. TBD

STOP - Read the label before use.

Keep out of reach of children.

CAUTION

PRECAUCION AL USUARIO: Si usted no puede leer o entender inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.

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

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FIRST AID	
If Swallowed:	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 the poison control center or doctor. Do not give anything by mouth to an unconscious person.
If In Eyes:	Hold eyelids 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 On Skin or Clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of soap and 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. For emergency medical treatment call 1-800-422-9874. For customer service or to obtain product information, including the MSDS, call 1-800-633-3796.	
NOTE TO PHYSICIAN	
No specific antidote is available. Treat the patient symptomatically.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if swallowed or absorbed through skin. Avoid contact with skin; eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Keep children or pets away from treated area until dry.

Personal Protective Equipment

All pesticide handlers (mixers and applicators) must wear long-sleeved shirt and long pants, socks, shoes, and chemical – resistant gloves made of waterproof material. After the product is diluted in accordance with label directions for use, shirt, pants, socks, shoes must be worn.

ENVIRONMENTAL HAZARDS

This product is highly toxic to aquatic invertebrates. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash waters. Apply this product only as specified on this label.

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DIRECTIONS FOR USE

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

IMPORTANT: Read the entire Directions for Use, Conditions of Sale and Disclaimer of Warranties and Limitations of liability before using this product.

Conditions of Sale: The directions on this label were determined through research to be appropriate for the correct use of this product. This product has been tested under different environmental conditions both indoors and outdoors similar to those that are ordinary and customary where the product is to be used. Insufficient control of pests or plant injury may result from the occurrence of extraordinary or unusual conditions, or from failure to follow label directions. In addition, failure to follow label directions may cause injury to animals, man, and damage to the environment. To the extent permitted by applicable law, Bayer offers, and the buyer accepts and uses, this product subject to the conditions that extraordinary or unusual environmental conditions, or failure to follow label directions are beyond the control of Bayer and are, therefore, the responsibility of the buyer.

Do not formulate this product into other end-use products.

[(DARKLING BEETLE) (LESSER MEALWORM)] [AND HIDE BEETLE] CONTROL IN AND AROUND POULTRY [(HOUSING) (STRUCTURES) (FACILITIES) (BUILDINGS) (BARN)]

Use [(Credo SC Insecticide) (this product)] as a general surface, spot, or crack and crevice treatment to floors, walls and support beams of [(poultry) (broiler) (turkey) (caged egg layer) (breeder)] [(housing) (structures) (facilities) (buildings) (barns)]. **Do not apply when birds are present.** Cover or remove exposed feed and water from the area to be treated. Allow treated surfaces to dry before restocking/reintroducing [(birds) (animals)] into the [(house) (structure) (facility) (building) (barn)].

MIXING AND APPLICATION RATES: Determine the [(area) (number of square feet (ft²))] to be treated. Refer to Mixing Table below for amount of [(Credo SC Insecticide) (this product)] to be used. Mix the required amount of [(Credo SC Insecticide) (this product)] with the [(appropriate) (desired)] amount of water and apply as a spray. Fill the sprayer tank with ½ of the water [(required) (needed) (necessary) (desired)] for the treatment. Begin agitating the water and add the required amount of product to the tank. Continue mixing and add the remaining water. Maintain sufficient agitation during product application to ensure a uniform spray. Prepare a fresh spray mixture before each treatment.

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MIXING TABLE FOR Credo SC Insecticide

Pests to Control	Credo SC Insecticide Per 1,000 ft²	Gallons of Water Per 1,000 ft²
Darkling Beetles [Hide Beetles]	3 fl. oz.* (90 mL*)	½ -2 gallons

* Equivalent to 45 grams of imidacloprid a.i./1,000 ft²

CONVERSION KEY: 128 fl oz = 1 gal, 16 fl oz = 1 pint, 8 pints = 1 gal, 1 fl oz = 29.5 mL

WHEN TO APPLY: Apply [(between flocks) (after each grow-out) (following de-caking) (to new litter following clean-out) (following sanitation procedures) (prior to placement of a new flock)].

HOW TO APPLY:

Band Application: When darkling beetles are concentrated in certain areas, such as under feed or water lines, or along the perimeter walls, it may not be [(necessary) or (desirable)] to treat the entire [(floor area) (litter surface)] of a [(poultry) (broiler) (turkey) (caged egg layer) (breeder)] house. In these situations, certain portions [of the house] [or "bands"] may be treated. For example, [(apply) (spray)] diluted Credo SC Insecticide [(on) (to)]: a 3-foot wide band of litter [surface] under all of the [(feed) (water)] lines in the house; a 3-foot wide band of litter [surface] adjacent to the side and end walls; and the lower [(section) (portion)] of the walls, including 1 foot up onto wood surfaces above the [concrete] foundation. Be sure to measure the [(actual) (surface) (area) (square feet)] to be treated in order to determine the [amount] [quantity] of [(Credo SC Insecticide) (this product)] [(needed) (required) (necessary)] for the [(application) (treatment)].

Whole House Application: When darkling beetle infestation is severe, the entire house may need to be treated. Apply diluted [(Credo SC Insecticide) (this product)] as a broadcast spray to the litter covering the entire floor area, especially to litter under feed and water lines, as well as to the lower sections of walls, including 1 foot up onto wood surfaces above the concrete foundation.

FOR BEST RESULTS: In houses with support beams, treat the litter surface around each support post, and 1 foot up each post. Also apply diluted spray to cracks and crevices around wall insulation, where beetles have been seen or can find harborage.

[INSECTICIDE ROTATION] [INTEGRATED PEST MANAGEMENT (IPM)] [RESISTANCE MANAGEMENT]

Darkling beetles, like all insects, have the ability to develop resistance to insecticides. When a single chemical class is used [(continuously) (flock after flock) (year after year) (time after time)], this [(enhances) (increases) (maximizes)] the [(likelihood) (probability) (certainty) (chance)] that resistance to that chemical class will develop. [(Credo SC Insecticide) (this product)] contains

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imidacloprid, which belongs to the class of chloronicotinyl insecticides. [(Credo SC Insecticide) (this product)] should be used in a [(rotational) (insecticide rotation)] program with other [classes of] insecticides [(such as) (including, but not limited to)] [pyrethroids] [(such as) (Tempo® products) (Tempo® SC Ultra products)] [organophosphates] [spinosyns], to prevent [the development of] resistance and [(preserve) (prolong) (protect) (maintain) (increase)] the product's [(useful life) (usefulness) (effectiveness) (efficacy) (longevity) (value)] for darkling beetle control.

- Read and follow ALL label directions when [(using) (applying) (treating with)] [(Credo SC Insecticide) (this product)] or any other insecticide [product].
- Do not use [(Credo SC Insecticide) (this product)] or any other insecticide [product] at [(less) (lower)] than the specified label rate. This exposes the insects to a [(sub-lethal) (non-killing)] dose and [(hastens) (speeds up) (accelerates) (favors) (increases)] the development of resistance.
- Use [(other) (Integrated Pest Management) (IPM)] [(strategies) (tactics) (practices) (measures)] in addition to [(insecticide) (chemical)] [(applications) (treatments)] to [(manage) (control)] darkling beetle populations.

[Contact] [Talk to] your [local] Bayer [Animal Health] representative or your [local] Cooperative Extension Service for advice concerning the use of [(Credo SC Insecticide) (this product)] and [(appropriate) (helpful) (suitable)] [(resistance management) (insecticide rotation)] [(strategies) (tactics) (practices) (measures)].

[NOTE: When pest exclusion at possible entry points is desired, supplement Credo SC Insecticide [litter] treatments with [targeted] [(applications) (treatments)] of [(pyrethroid) (insecticides)] [such as (Tempo® SC Ultra) or (Tempo® 20 WP)] to the building perimeter, foundation, doors and windows, utility entry points, and other places where pests may enter the structure. Read and follow all label directions for use of [(these other) (companion)] products.]

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area. Handle and open container in a manner as to prevent spillage. If the container is leaking, invert to prevent leakage. If container is leaking or material spilled for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Absorb spilled material with absorbing type compounds and dispose of as directed for pesticide below. In spill or leak incidents, keep unauthorized people away. You may contact the Bayer Emergency Response Team for decontamination procedures or any other assistance that may be necessary. The Bayer Kansas City Emergency Response Telephone No. is 1-800-414-0244, or contact Chemtrec at 800-424-9300.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site

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(in the treatment area) or at an approved waste disposal facility.

Residue Removal: Triple rinse as follows: Empty remaining contents into application equipment or mix tank and drain for 10 seconds after flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this process two more times.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

Limited Warranty and Limitation of Damages: Bayer HealthCare LLC, Animal Health Division warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER 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, and no agent of Bayer is authorized to make or modify any warranties beyond those contained herein. Any damages arising from breach of this warranty shall be limited to direct damages and shall not include special, incidental or consequential damages resulting from the use or handling of this product.

NET CONTENTS:

Crredo and TEMPO is a registered trademark of Bayer.

Manufactured for:

Bayer HealthCare, LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201
<http://www.bayer-ah.com/livestock.cfm>

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Additional/Alternative Marketing Claims

Formula:

- One dose formula
- No dust
- Quick mix (liquid) formula
- Specifically formulated for control of darkling beetles
- Specifically formulated for the poultry industry
- Quick mix and spray formula
- Mix & Go (liquid) formula
- One dose mix-and-go (liquid) formula
- Formulated to meet the needs of poultry operations
- Darkling beetle control (product) designed (formulated) specifically for poultry producers
- Darkling beetle control (liquid) formula
- Easy to apply, hard on darkling beetle (formula)
- Quick Mix and Apply (Product)
- Contains [(imidacloprid) (a chloronicotinyl insecticide)]

Benefits:

- Controls darkling beetles that may [(carry) (spread) (transmit)] poultry disease-causing organisms
- Controls darkling beetles that may damage [(buildings) (ceilings) (insulation) (walls)]
- Controls darkling beetles that can feed on grain
- Controls both [(darkling beetle) (lesser mealworm)] [and hide beetle] larvae and adults
- Effective against both [(darkling beetle) (lesser mealworm)] [and hide beetle] larvae and adults
- Stop (reduce) (alleviate) (take out) the risks darkling beetles [(pose) (bring)]
- Stop the damage and risks that darkling beetles cause
- Stop darkling beetles from [(taking)(eating)] your profitability
- Reduce darkling beetle risk(s)
- Reduce risks that darkling beetles [(pose) (bring)]
- Reduce impact on neighboring communities
- Reduce darkling beetles' negative impact on [poultry] [(production) (performance)]

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Application:

- Effective control of [(darkling beetles) (lesser mealworms)] [and hide beetles]
- [(Targeted) (Banded)] [(application) (treatment)] delivers effective [(darkling beetle) (lesser mealworm)] [and hide beetle] control
- One dose – effective, (easy) (simple) to use
- [(Focused) (Targeted) (Strategic)] band [(treatment) (application)]
- Allows labor saving band [(treatment) (application)]
- Broadcast or banded treatment (application)
- Less time consuming (band) [(application) (treatment)]
- Easy and flexible treatment (options)
- Time Saving Band Application
- Mix and spray – fast and flexible treatment technology
- Credo SC can be applied as either a band or broadcast (spray) treatment
- Controls even pyrethroid [(spinosad) (organophosphate)] resistant [(darkling beetle) (lesser mealworm)] [and hide beetle]
- Use less insecticide (per house/building/barn) with a banded application
- Less insecticide – [(targeted) (banded)] [(application) (treatment)]
- Easy and targeted control of [(darkling beetle) (hide beetle) (lesser mealworm)]
- [(Protection) (Control)] exactly where you need it
- Flexible application for any poultry operation
- Save time, labor and money with [(targeted) (focused)] band application
- Banded application saves time, labor and money; Provides effective control
- Apply [(treatment) (control)] right where you need it
- Easy (One) Dose Technology
- One dose, mix, and spray – Quick and Easy
- Target [(darkling beetles) (lesser mealworms)] [and hide beetles]

General:

- The active ingredient in Credo SC (imidacloprid) has been proven to provide effective control of [(darkling beetles) (lesser mealworms)] [and hide beetles]
- Controls darkling beetle adults and larvae
- The solution to [(darkling beetle) (lesser mealworm)] [and hide beetle] control
- [(Control) (Reduce)] darkling beetles that can [(spread) (carry)] disease causing organisms

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Rotation Benefits:

- Rotate with [(Tempo) (Tempo Ultra)] to manage (darkling beetle) resistance
- Team up with Credo SC and [(Tempo) (Tempo Ultra)]
- [(Manage) (Prevent)] resistance - rotate (with) (between) Credo SC & [(Tempo) (Tempo Ultra)]
- Team up with the Rotation (Combination): Credo SC & [(Tempo) (Tempo Ultra)]
- [(Prevent) (Manage)] resistance with the rotation (combination) (products) (team): Credo SC & [(Tempo) (Tempo Ultra)]
- Rotation (Team) Technology
- The Credo SC & [(Tempo) (Tempo Ultra)] Team [(prevents) (manages)] resistance
- For maximum results, Team up with the Rotation Combination