

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

AUG 1 0 2009

Ms. Sonya Gissendanner Elanco Animal Health 2001 W. Main Street Greenfield, IN 46140

Subject: Label Notification(s) for Pesticide Registration Notice 2007-4

Dear Registrant,

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 dated March 20, 2009 for:

## EPA Registration 72642-2 Elector PSP Premise Insect Control Agent

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and finds that the label change(s) requested falls within the scope of PRN-2007-4. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact me directly at 703-305-6249 or Banza Djapao of my staff at 703-305-7269.

Sincerely, Rachel C. Helloman

Linda Arrington

Notifications & Minor Formulations Team Leader

Registration Division (7505P)

Office of Pesticide Programs

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Please read instructions on reverse before completing form. Form Approved, OMB No. 2070-0060, Approval expire **OPP Identifier Number** Registration **United States \$EPA Environmental Protection Agency Amendment** Washington, DC 20460 Other Application for Pesticide - Section I 1. Company/Product Number 2. EPA Product Manager 3. Proposed Classification Elanco Animal Health/72642-2 Kim Nesci None Restricted 4. Company/Product (Name) PM# Elanco Animal Health/Elector® PSP 13 5. Name and Address of Applicant (Include ZIP Code) 6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling Elanco Animal Health 2001 W. Main Street EPA Reg. No. Greenfield, IN 46140 Check if this is a new address **Product Name** Section - II Amendment - Explain below. Final printed labels in repsonse to Agency letter dated "Me Too" Application. Resubmission in response to Agency letter dated \_ Notification - Explain below. Other - Explain below. Explanation: Use additional page(s) if necessary. (For section I and Section II.) 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. Section - III 1. Material This Product Will Be Packaged In: Child-Resistant Packaging Unit Packaging Water Soluble Packaging 2. Type of Container Matel Yes Yes Yes Plastic Nο Nο No Glass Paper If "Yes" If "Yes" No. per No. per \* Certification must Unit Packaging wgt. Package wgt Other (Specify) container container be submitted 3. Location of Net Contents Information 5. Location of Label Directions 4. Size(s) Retail Container on the label 6. Manner in Which Label is Affixed to Product Other Lithograph Paper glued Stenciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Name Title Telephone No. (Include Area Code) 317-651-5375 0000 Margaret Gillis Regulatory Associate 6: Date Application Certification S Received I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment cross (Stamped) both under applicable law. อาดออัว 2. Signature 3. Title Regulatory Associate

5. Date

14 Fan 2009

Typed Name
 Margaret Gillis



Elanco Animal Health A Division of Eli Lilly and Company PO Box 708 2001 W. Main Street Greenfield, IN.46140 (317)276-2000

March 20, 2009

Kim Nesci Product Manager #13 U.S. EPA - OPP - BPPD One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202

RE: PRN 2007-4 Updates for Elector® PSP Premise Insect Control Agent (72462-2)

Elanco Animal Health is providing in this notification, updates to storage and disposal statements for Elector<sup>®</sup> PSP Premise insect Control Agent (72462-2). This change is represented in the attached label by highlights to the changed portion of the label. [PR Notice 2007-4: IV(A)]

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.

We appreciate the opportunity to work with you to ensure our product labeling is fully compliant with the requirements of the EPA and its implementing regulations. If there are any questions, please contact me by e-mail (gissendanners)@lilly.com) or by telephone at (317) 651-4127.

Sincerely,

Sonya Gissendanner Regulatory Associate

Elanco Animal Health

2001 W. Main St.

Greenfield, IN 46143

(317) 651-4127

Enclosures:

NOTIFICATION 40F

# ELECTOR® PSP

#### PREMISE INSECT CONTROL AGENT

Control of house flies, stable flies, little house flies (Fannia canicularis), darkling beetles and hide beetles in and around agricultural animal promises.

#### **ENVIRONMENTAL HAZARDS**

This product is highly toxic to molluscs. 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 cleaning or disposing of equipment washwaters. Apply this product only as specified on this label.

#### DIRECTIONS FOR USE

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

Read all Directions for Use carefully before applying.

Notice: Shake well before use. Avoid freezing.

#### MIXING FOR APPLICATIONS THAT REQUIRE DILUTION

This product is intended to be mixed with water and applied as a coarse, low-pressure spray. Fill the tank of the sprayer with water to about ½ of the total spray volume required. Start agitation and add the required amount of product. Continue mixing and agitation while filling the spray tank to the required spray volume. Maintain sufficient agitation during the application to ensure uniformity of the spray. Prepare spray fresh for each use.

#### **GENERAL NOTICE**

- This product may be applied as a general surface spray or a crack and crevice application. Applications may be made in and around poultry and ilvestock premises, including but not limited to poultry houses, beef and dairy barns, foodiots, stables, corrats and housing structures.
- Control is enhanced when interior and exterior perimeter applications
  are made in and around livestock and poultry structures. Normal
  sanitation practices of the structure consistent with good animal husbandry
  should be followed to enhance effectiveness of insect control agents.
- Do not apply dilutions for premise treatment directly onto poultry or livestock. Lactating and non-lactating dairy and beef cattle, swine, sheep and poultry may be present at the time of premise treatment. Horses not intended for human consumption may also be present at the time of premise treatment.
- Cover or remove exposed feed and water from the area being treated.
- Do not use in milking rooms.
- Do not apply as a log or space spray.

#### **APPLICATIONS**

TO CONTROL	APPLICATION
House liles Stable files Little house tiles	2 ft. oz. (60 mL) Elector PSP in 10 gallons of water will treat 5,000 - 10,000 ft. Use enough water in a directed spray to contact flies and their resting surfaces. Spray moroughly, but do not allow run-off to occur.
Darkling beetles Hide beetles	Use enough water to ensure thorough coverage of the properties of specially litter, along feed and water lines, waits and support beams. Use a sprayer of appropriate dealign that is equipped to effectively apply low to moderate volumes of spray.  Low volume spray: Up to 15 gallons of diluted spray applied to 20,000 tif.  Moderate volume spray: Up to 40 gallons of diluted spray applied to 20,000 tif.  I loz. (60mL) of product treats 5,000 fif (8 fl. oz. of product may be used to troat 5,000 fif.).

NOTE: One captul of product equals 2 ounces. Rinse cap after use and pour rinsate into spray tank.

#### **Poultry Houses**

House Files, Stable Files and Little House Files: Treat areas where files rost: pay attention to side walls, the ends of buildings, upper sides of posts, and crossbeams. Spray in early morning when files are resting. Use enough water in a directed spray to contact files and their rosting surfaces thereughly, but do not allow run-off to occur. Do not contaminate feedstulls, water or watering and feeding equipment with premise treatment. Re-application may occur every 7 to 10 days as needed, or when fly populations reach nuisance levels.

Darkling Beetles and Hide Beetles: Apply to floor area, especially to litter around feed and water flnes and to walls and support beams, but do not allow run-off to occur. Application should also be made into cracks and crevices around insulation, and where pests have been seen or can find harborage. Reapply after each grow-out or sanitation procedure. Indoor control can be enhanced by making perimeter treatments to the outside of building foundations to prevent migrating adult beetles.

### Livestock Housing

House Files, Stable Files and Little House Files: Apply to vertical and overhead surfaces where files may congregate. Feadors, waterers and feedcarts should be covered before application to prevent contamination. Do not contaminate feedstuffs or water with premise treatment. Pay attention to animal areas including fence railings, alleyways, stanchions, pipes, window and doors, and other areas where files congregate. Spray in early morning when flies are resting. Re-application may occur every 7 to 10 days as needed, or when fly populations reach nulsance levels.

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#### INTEGRATED PEST AND RESISTANCE MANAGEMENT

This product is a member of a unique class of insect control agents (spinosyns) with no pro-oxisting levels of resistance to any other insect control agents and can be rotated with all other classes, such as synthetic pyrothroids and organophosphates. House files, stable files, little house files and other insects have demonstrated the ability to develop resistance to insect control products. Continual exposure of files and other insects to a single class of insecticide may lead to the development of resistance to that class of insecticide. The following resistance management strategy will help ensure the prolonged usefulness of this product, as well as other conventional insecticides:

- Apply this product and other insect control agents only according to label directions.
- Do not use less than the labeled rate of any insect control product.
- Include multiple control tactics (cultural and/or biological controls)
   Within an integrated Pest Management Program.
- Rotate this product with other classes of insecticides (synthetic pyrethroid, organophosphate) during a fly season.

For advice concerning integrated peat management practices in relation to specific local conditions, consult resources in resistance management programs, your Cooperative Agricultural Extension Service, or your Elanco Animal Health representative (800-428-4441).

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal Notice: Shake well before use. Avoid freezing.

	Pesticide Slorage:	Store in original container, tightly closed, in a secure place. Keep out of the reach of children and domestic animals, in case of leak or spill, contain material and dispose as waste.	
The second secon	Container Disposal:	Nonrefillable container. Do not rouse or refill this container. Offer for recycling, if available. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rineate into application equipment or mix tank or store rineate for later use or disposal. Orain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility. Triple rinse empty container. Then dispose of empty bag/container in a sanitary landfill, or, if allowed by state and local authorities, by burning, if burned, stay out of smoke.	

#### INHERENT RISKS OF USE

It is impossible to eliminate all risks associated with the use of this product. Lack of performance or other unintended consequences may result because of such factors as use of the product contrary to label instructions, abnormal conditions, presence of other materials, the manner of application, or other factors which are beyond the control of Elanco Animal Health or the seller. All such risks are assumed by the buyer.

#### LIMITATIONS OF REMEDIES

The exclusive remedy for losses or damages resulting from this product (including claims based on contract, negligence, strict liability, or other legal theories), shall be limited to, at Elanco Animal Health's election, one of the following:

- Refund of purchase price paid by buyer or user for product bought, or
- (2) Replacement of amount of product used.

Elanco Animal Health shall not be flable for losses or damages resulting from the handling or use of this product unless Elanco Animal Health is promptly notified of such loss or damage in writing. In no case shall Elanco Animal Health be liable for consequential or incidental damages or losses.

The terms of the Warranty Disclaimer above and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Elanco Animal Health or the seller is authorized to vary or exceed the terms of the Warranty Disclaimer of this Limitation of Remedies in any manner.

Elanco Animal Health, A Division of Eli Lilly and Company Indianapolis, IN 46285 www.elanco.com Questions or comments call 1-800-428-4441.

EPA Reg. No.: 72642-2 EPA Est. No.: 37429-GA-02

\*Elanco®, Elector® PSP Premise Insect Control Agent, and the diagonal color bar are trademarks of Eli Lilly and Company.

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