

72642-2

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 02, 2011

Ms. Katherine A. Meyer,
Associate Consultant, Regulatory Affairs
Elanco Animal Health
PO Box 708
2500 Innovation Way
Greenfield, IN 46140

Subject: Notification to add "house fly larvae"
Product Name: Elector PSP Insect Control Agent
EPA Registration Number: 72642-2
Date of Application: January 11, 2011

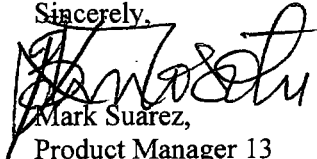
Dear Ms. Meyer:

The Agency is in receipt of your above referenced application for Pesticide Notification under Pesticide Registration (PR) Notice 98-10, for the subject product. The Registration Division (RD), after conducting a review of your request for its applicability, finds that the action(s) requested fall(s) within the scope of the aforementioned PR Notice.

Please note that we have approved the amended labeling for this product with the understanding that it is consistent with the Agency's previously stamped accepted label(s); and other than the above stated, no other changes have been made to the labeling and/or the Confidential Statement of Formula (CSF).

The CSF and/or label submitted with the application have/has been stamped "Notification" and will be placed in our records. If you have any questions regarding this letter, please contact Dr. B. A. Akinlosotu at (703) 605-0653.

Sincerely,


Mark Suarez,
Product Manager 13
Insecticide Branch
Registration Division (7505P)



Elanco Animal Health

PO Box 708
2500 Innovation Way
Greenfield, IN 46140

317.276.2000

January 11, 2011

Notifications Coordinator
U.S. EPA – OPP – RD
Document Processing Desk [NOTIF]
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

SUBJECT: Notification of Changes to Label Verbiage
COMPANY: Elanco Animal Health, A Division of Eli Lilly & Company, Indianapolis, Indiana 46285
CONTACT: Katherine A. Meyer, Associate Consultant, Regulatory Affairs
PRODUCT: Elector® PSP Insect Control Agent /72642-2

Dear Paul Mastradone:

On behalf of Elanco Animal Health, I am submitting for your review this notification to change the verbiage on the Elector® PSP Insect Control Agent label.

These changes are allowed per PRN 98-10, II B:

1. The pest being added is "house fly larvae," houseflies in this life stage are not considered a public health pest.
2. Elanco has and will maintain efficacy data against house fly larvae.
3. The pest matches the type of product registered – insect/insecticide.
4. This pest occurs at sites already on the approved label.
5. The dosage, frequency, concentration or method of the application are not changed.
6. The addition of this pest to the label does not increase the exposure of the pesticide to humans or the environment.
7. House fly larvae are not subject to quarantine by USDA/APHIS.

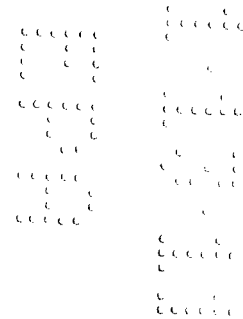
This notification submission, in addition to this letter, includes:

- A fully executed Application for Pesticide Form [8570-1] containing the mandated certification statement.
- One copy of the current stamped approved label
- Two copies of the new draft label, one marked up to show the changes, and a clean one for PPIS.

If you require further information or have any questions, please do not hesitate to contact me at 317-433-2167 or by e-mail at meyer_katherine_a@lilly.com.

Sincerely,

Katherine A. Meyer



Explanation Continued:

"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 section 12 and 14 of FIFRA."

Signature Katherine A. Meyer Date 11 Jan 2011
Katherine A. Meyer

Front Panel
ELANCO*

AH0495-___

ELECTOR® PSP INSECT CONTROL AGENT LOGO*

- Control of darkling beetles, hide beetles, house flies (adults and larvae), stable flies, little house flies (*Fannia canicularis*) in and around agricultural animal premises.
- Control of northern fowl mites (*Ornithonyssus sylviarum*) infesting poultry.

ACTIVE INGREDIENT

Spinosad (A mixture of spinosyn A and spinosyn D).....	44.2%
OTHER INGREDIENTS.....	55.8%
TOTAL.....	100.0%

Keep Out of Reach of Children

NOTIFICATION

CAUTION

MAR 02 2011

Elanco Animal Health, A Division of Eli Lilly and Company
Indianapolis, IN 46285
www.elanco.com

To report adverse effects or obtain additional product information, call 1-800-428-4441

Net Contents: 8 oz (237 mL)

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

(Label Booklet Cover-Back Panel)

ELANCO* AH0495-____

ELECTOR® PSP INSECT CONTROL AGENT LOGO*

- Control of darkling beetles, hide beetles, house flies (adults and larvae), stable flies, little house flies (*Fannia canicularis*) in and around agricultural animal premises.
- Control of northern fowl mites (*Ornithonyssus sylviarum*) infesting poultry.

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.

Notice: Shake Well Before Use. Avoid Freezing. Read the entire label before using. Use only according to label directions. See Directions for Use including storage and disposal inside label booklet.

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

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Net Contents: 8 oz (237 mL)

Peel Back Logo

(Label Booklet: Page 1 through end)

ELECTOR® PSP INSECT CONTROL AGENT LOGO*

- Control of darkling beetles, hide beetles, house flies (adults and larvae), stable flies, little house flies (*Fannia canicularis*) in and around agricultural animal premises.
- Control of northern fowl mites (*Ornithonyssus sylviarum*) infesting poultry.

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 or 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 livestock premises, including but not limited to poultry houses, beef and dairy barns, feedlots, stables, corrals and housing structures.
- This product may be used as a direct treatment to control Northern Fowl mites infesting poultry.
- 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.
- 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 fog or space spray.

APPLICATIONS

TO CONTROL	APPLICATION
✓ House flies (adults and larvae) Stable flies Little house flies	<ul style="list-style-type: none"> • 2 fl. oz. (60 mL) Elector PSP in 10 gallons of water will treat 5,000 – 10,000 ft². Use enough water in a directed spray to contact flies and their resting surfaces. Spray thoroughly, but do not allow run-off to occur.
Darkling beetles Hide beetles	<ul style="list-style-type: none"> • Use enough water to ensure thorough coverage of the area treated, especially litter, along feed and water lines, walls and support beams. Use a sprayer of appropriate design that is equipped to effectively apply low to moderate volumes of spray. <ul style="list-style-type: none"> ○ Low volume spray: Up to 15 gallons of diluted spray applied to 20,000 ft². ○ Moderate volume spray: Up to 40 gallons of diluted spray applied to 20,000 ft². • 2 fl. oz. (60 mL) of product treats 5,000 ft² (8 fl. oz. of product treats 20,000 ft²). • For severe infestations, 4 fl. oz. of product may be used to treat 5,000 ft² (16 fl. oz. treats 20,000 ft²).
Northern fowl mite (<i>Ornithonyssus sylviarum</i>)	<ul style="list-style-type: none"> • Dilute 3 fl. oz. of product in 10 gallons of water. • Apply 1 gallon of coarse spray per 100 birds under high pressure (no less than 100 – 125 psi), directed toward the vent area.

Egg Producing Poultry

Northern Fowl Mite: Re-application may occur every 14 days as needed. Spray birds in cages with a high pressure (100 – 125 psi) spray. Spray should be applied at the rate of 1 gallon per 100 birds. For optimum efficacy, direct spray toward vent area of chicken. Ensure adequate coverage.

Poultry Houses

✓ **House Flies (adults and larvae), Stable Flies and Little house flies:** Treat areas where flies rest: pay attention to side walls, the ends of buildings, upper sides of posts, crossbeams, and manure. Spray in ✓ early morning when flies are resting. Use enough water in a directed spray to contact flies and their resting surfaces thoroughly, but do not allow run-off to occur. Do not contaminate feedstuffs, 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 lines 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.

9/10

Livestock Housing ✓

House Flies (adults and larvae), Stable Flies and Little house flies: Apply to vertical and overhead surfaces where flies may congregate. Feeders, 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, manure, stanchions, pipes, window and doors, and other areas where flies 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 nuisance levels. ✓

INTEGRATED PEST AND RESISTANCE MANAGEMENT

This product is a member of a unique class of insect control agents (spinosyns) with no pre-existing levels of resistance to any other insect control agents and can be rotated with all other classes, such as synthetic pyrethroids and organophosphates. House flies, stable flies, little house flies and other insects have demonstrated the ability to develop resistance to insect control products. Continual exposure of flies 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 pest 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.

Pesticide Storage:	Store in original container only, tightly closed in a secure place. Keep out of reach of children and domestic animals. In case of leak or spill, remove with absorbent materials and dispose of as waste.
Pesticide Disposal:	Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility
Container Handling:	Nonrefillable container. Do not reuse 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 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 procedure two more times. Then dispose of empty 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. To the extent consistent with applicable law all such risks are assumed by the buyer.

LIMITATIONS OF REMEDIES

To the extent consistent with applicable law all 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:

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

To the extent consistent with applicable law all Elanco Animal Health shall not be liable 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 Warranty Disclaimer of this Limitation of Remedies in any manner.

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