

72642-3

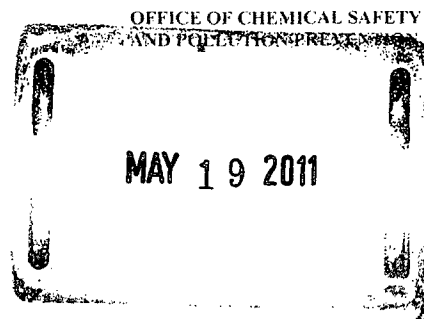
5/19/2011

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

Ms. Katherine Vannatta
Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140



Dear Ms. Vannatta:

Subject: Application for Pesticide Notification (PRN 98-10)
Comply with Agency pyrethroid labeling letter dated June 4, 2009
StandGuard Premise Insecticide
EPA Reg. No. 72642-3
Your submission dated May 13, 2010

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated May 13, 2010 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds the action requested 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.

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 regarding this letter, please contact Dana Pilitt, PhD of my staff at (703) 305-7071 or via e-mail at pilitt.dana@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Suarez".

A handwritten mark consisting of a vertical line with a horizontal crossbar, resembling a stylized "f" or a checkmark.

Mark Suarez
Product Manager 13
Insecticide 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 Elanco Animal Health/72642-3 | 2. EPA Product Manager Richard Gebken | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| Company/Product (Name) Elanco Animal Health/StandGuard Premise | PM# 13 | |
| Name and Address of Applicant (Include ZIP Code) Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140 <input checked="" 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 _____ | |

NOTIFICATION
MAY 19 2011

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 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 of label change per June 4, 2009, letter from Environmental Protection Agency. This notification is consistent with the guidance in the June 4, 2009 letter and the requirements of EPA's regulations at 40 CFR Part 156. No other changes have been made to the labeling or to the Confidential Statement of Formula for this product. I understand that it is a violation of 18 USC 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 Part 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

| | | | |
|--|--|---|---|
| Material This Product Will Be Packaged In: | | | |
| Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | 2. Type of Container <input type="checkbox"/> Metal <input checked="" 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 |
| Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container 8 oz (237 mL) | 5. Location of Label Directions <input checked="" type="checkbox"/> on the label |
| Manner in Which Label is Affixed to Product | | <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled | <input type="checkbox"/> Other _____ |

Section - IV

Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

| | | |
|-------------------------------|--|---|
| Name Katherine E. Vannatta | Title Principal Advisor, Regulatory Affairs | Telephone No. (Include Area Code) 317-277-3362 |
|-------------------------------|--|---|

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.

| | | |
|-------------------------------------|---|--|
| Signature | 3. Title Principal Advisor, Regulatory Affairs | 6. Date Application Received (Stamped) |
| Typed Name Katherine E. Vannatta | 5. Date 13 May 2010 | |



Elanco Animal Health

PO Box 708
2500 Innovation Way
Greenfield, IN 46140
(317) 276-2000

3046

13 May 2010

Document Processing Desk (NOTIF-PYRETHROID)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S04900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

PRN 2008-1

RE: EPA Registration Number 72642-3: Environmental Hazard and General Labeling for Pyrethroid Non-Agricultural Outdoor Products Notification

Elanco Animal Health is providing this notification of label change per the June 4, 2009 letter from the Environmental Protection Agency (Environmental Hazard and General Labeling for Pyrethroid Non-Agricultural Outdoor Products Notification). This notification is consistent with the guidance in the June 4, 2009 letter and the requirements of EPA's regulations at 40 CFR Part 156. No other changes have been made to the labeling or to the Confidential Statement of Formula for this product. I understand that it is a violation of 18 USC 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 Part 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 EPA and its implementing regulations. If there are any questions or concerns, please do not hesitate to contact me.

Sincerely,

Katherine E. Vannatta
Principal Advisor, Regulatory Affairs
317-277-3362 (phone)
317-997-0188 (mobile)
317-277-4755 (fax)
kevannatta@lilly.com

Handwritten notes and markings at the bottom right of the page.

ELANCO ^{ANIMAL HEALTH}

StandGuard

PREMISE INSECTICIDE
(For Agricultural Use Only)

A controlled release premise insecticide for use in and around livestock/poultry housing, pet kennels, railcars, trucks and trailers for control of flies, fleas, mosquitoes, ants, bees, wasps, crickets, pillbugs, scorpions, scabbugs, spiders, ticks and litter beetles.

Active Ingredient

Gamma-cyhalothrin:

Cyclopropanecarboxylic acid, 3-(2-chloro-3,3-trifluoro-1-propenyl)- 2,2-dimethyl, cyano (3-phenoxyphenyl) methyl ester

OTHER INGREDIENTS 99.1%

TOTAL 100.0%

Contains 0.5 pound of active ingredient per gallon

Contains petroleum distillates

Keep Out of Reach of Children
CAUTION

See Booklet for First Aid and Directions for Use including Storage and Disposal

EPA Reg. No. 72642-3

EPA Est. No. 34704-MS-2

064753 518 0L 45 00276625

(May 2010) Net Contents:

8 fl oz (237 mL)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes moderate eye irritation. Harmful if swallowed. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse.

Wear safety glasses or goggles, long-sleeved shirt, long pants, shoes and socks, and chemical resistant gloves. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

Skin exposure may also result in a sensation described as a tingling, itching, burning or prickly feeling. Onset may occur immediately to 4 hours after exposure and may last 2 to 30 hours, without damage. Wash exposed areas thoroughly with soap and water. Relief from skin sensation may be obtained by applying an oil-based cream.



ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish and aquatic organisms, and toxic to wildlife. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems. This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area. Apply this product only as specified on the label.

PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or an open flame.

Notice: Shake well before use. Avoid freezing. Read entire label. Use only according to label directions. Before using this product, read Warranty Disclaimer, Inherent Risks of Use, and Limitation of Remedies at the end of the label booklet. If terms are unacceptable, return at once unopened.

Elanco, StandGuard, and the diagonal color bar are trademarks of Eli Lilly and Company. Elanco Animal Health, A Division of Eli Lilly & Company Indianapolis, IN 46285

www.elanco.com
Questions or comments call 1-800-428-4441

NOTIFICATION

MAY 19 2011

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EIANCO ANEXO

StandGuard

PREMISE INSECTICIDE
(For Agricultural Use Only)

A controlled release premise insecticide for use in and around livestock/poultry housing, pet kennels, railcars, trucks and trailers for control of flies, fleas, mosquitoes, ants, bees, wasps, crickets, pillbugs, scorpions, sowbugs, spiders, ticks and litter beetles.

Keep Out of Reach of Children

CAUTION

Notice: Shake well before use. Avoid freezing. Read entire label. Use only according to label directions. Before using this product, read Warranty Disclaimer, Inherent Risks of Use, and Limitation of Remedies at the end of the label booklet. If terms are unacceptable, return at once unopened.

FIRST AID

If **swallowed**: Call a poison control center or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.

If in **eyes**: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after five minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Note to Physician: Induced vomiting as a first aid for this product may result in increased risk of chemical pneumonia or pulmonary edema caused by aspiration of the hydrocarbon solvent. Vomiting should only be induced under professional supervision.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-428-4441 for emergency medical treatment information.

DIRECTIONS FOR USE

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

For use as a general surface (non-food/non-feed areas), crack and crevice or spot treatment in and around livestock/ poultry housing, pet kennels, railcars, trucks and trailers. STANDGUARD insecticide can be reapplied at 21-day intervals if necessary.

STANDGUARD insecticide is intended for dilution with water for application using hand held or power operated application equipment as a coarse spray for crack and crevice or spot and general surface treatments. Application equipment that delivers low volume treatments may also be used to make crack and crevice or spot and general surface treatments. Fill the applicator tank with the desired volume of water and add STANDGUARD insecticide. Close and shake before use to ensure proper mixing. Shake or re-agitate applicator tank before use if application is interrupted. Make up only amount of treatment volume as required.

1. FLIES, FLEAS, MOSQUITOES, BEES AND WASP: Apply directly to walls, ceilings, window screens, and other insect resting areas as a residual surface treatment. May be used in and around equipment storage sheds; also see **OUTDOOR SURFACE USE**.

2. ANTS: Apply to ant trails around doors and windows and other places where ants are found. Apply barrier treatments to prevent infestations as directed in

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OUTDOOR SURFACE USE

For control of flies, fleas, mosquitoes, ants, bees, wasps, crickets, pillbugs, scorpions, sowbugs, spiders, ticks and other similar perimeter insect pests. Apply with either hand or power application equipment as a residual treatment to surface of buildings, screens, window frames, eaves and other similar areas. Also may be applied to lawn areas around non-residential buildings, refuse dumps and similar areas where these insect pests are active. Do not water the treated area to the point of run-off. Do not make applications during rain.

BARRIER TREATMENTS

To help prevent infestation of a building, apply a band 6 to 10 feet wide around and adjacent to the building. Also, treat the building foundation to a height of 2 to 3 feet where pests are active and may find an entry into the building. Apply as a coarse spray to thoroughly and uniformly wet the foundation and/or band area using 1-5 gallons of treatment solution applied to 800-1600 square feet.

NOTE: Do not use water-based sprays of STANDGUARD insecticide in conduits, motor housings, junction boxes, switch boxes, or other electrical equipment because of possible shock hazard. For best results thoroughly wash out sprayer and screen with water and detergent before using STANDGUARD insecticide.

- Let treated surfaces dry before allowing humans and pets to contact these surfaces.

- Do not use this product with oil.
- Do not allow applications to contact water inhabited by fish, such as aquariums and ornamental fish ponds that are located in and around structures being treated.

STORAGE AND DISPOSAL

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

Pesticide Storage: 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.

Container Disposal: 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 1/4 full with water and recap. Shake for 10 seconds. Pour rinse into application equipment or mix tank or store rinse for later use or disposal. Drain 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.

INTEGRATED PEST AND RESISTANCE MANAGEMENT

Flies, beetles 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 STANDGUARD insecticide, as well as other conventional insecticides.

- Apply STANDGUARD insecticide 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 STANDGUARD insecticide with other classes of insecticide (naturalys, phenyl pyrazoles, chloronicotylins, and organophosphates, etc.) during an insect pest season.

For advice concerning integrated pest management practices in relation to local conditions, consult resources in resistance management programs, your Cooperative Agricultural Extension Service or your Eianco Animal Health representative (1-800-428-4441).

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BARRIER TREATMENTS; also see **OUTDOOR SURFACE USE.**

3. SPIDERS AND CRICKETS: Apply as a coarse, low pressure spray to areas where these pests hide such as corners, storage areas, around water pipes, doors and windows, attics and eaves and baseboards. Pay particular attention to cracks and crevices; also see **OUTDOOR SURFACE USE.**

4. SOWBUGS AND PILLBUGS: Apply around doors and windows and other places where these pests may be found or where they may enter the premises. Treat storage areas and other locations. Apply barrier treatments to prevent infestations as directed in **BARRIER TREATMENTS;** also see **OUTDOOR SURFACE USE.**

5. LITTER BEETLES (Darkling, Hide and Carrion Beetles) in Animal Housing (such as Poultry Housing): To control adult litter beetles, apply STANDGUARD insecticide to walls and floors at each grow-out or sanitation procedure, before reintroduction of poultry or other animals. This will suppress beetles that escaped earlier treatment and will also help to delay the onset of further infestations. Pay attention to areas where beetles frequently occur, such as walls, supports, cages, stalls and around feeders; also see **LIVESTOCK/ POULTRY HOUSING STRUCTURES.**

| Pests | Active ingredient concentration | Dilution rate |
|---|---------------------------------|--|
| Flies (including House flies, stable flies, little house flies) | 0.0075% - 0.015% | 0.0075% 0.16 fl oz (5 mL) / gal water |
| Ants | | 0.5 fl oz (15 mL) / 3 gal water |
| Bees | | 0.015% |
| Fleas* | | 0.33 fl oz (10 mL) / gal water |
| Wasps | | 1.0 fl oz (30 mL) / 3 gal water |

Note: Typical premise spray rates are 1 gal of diluted spray to treat 500 – 1000 sq. ft.

* For outdoor use only and use at 0.015% rate only.

| Pests | Active ingredient concentration | Dilution rate |
|---|---------------------------------|---|
| Litter beetles** (including adults/immature stages of Darkling, Hide and Carrion beetles) | 0.03% | 0.03% 0.65 fl oz (20 mL) / gal water |
| Crickets | | 2.0 fl oz (60 mL) / 3 gal water |
| Mosquitoes | | |
| Pillbugs | | |
| Sowbugs | | |
| Scorpions | | |
| Spiders | | |
| Ticks | | |

Note: Typical premise spray rates are 1 gal of diluted spray to treat 500 – 1000 sq. ft.

** For control of light infestations of beetles, use 0.015% rate.

LIVESTOCK/POULTRY HOUSING STRUCTURES AND PET KENNELS

Apply as a general surface and/or crack and crevice treatment. Control is enhanced when interior and exterior perimeter applications are made in and around livestock, poultry and pet housing structures. Normal cleaning practices of the structure must also be followed along with applications of STANDGUARD insecticide to effectively control the crawling and flying insects listed in the table.

For poultry houses, apply to floor area (birds grown on litter) or to walls, posts and cage framing (birds grown in cages). Application should be made into cracks and crevices around insulation. Re-apply after each grow-out or sanitation procedure. Indoor control can be enhanced by making perimeter treatments around the outside of the building foundations to prevent immigrating beetles. Maintaining a year round treatment program will prevent background populations from reaching problem levels.

DO NOT make applications of STANDGUARD insecticide in areas where animals are present in the facility. Allow treated surfaces to dry completely before restocking the facility. **DO NOT** make applications to any animal feedstuffs, water or watering equipment. **DO NOT** contaminate any animal food, feed or water in and around livestock, poultry or pet housing when making applications.

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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.

LIMITATION 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:

- (1) 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 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. To the extent permitted by law, Elanco Animal Health shall not be liable for consequential or incidental damages or losses.

The terms of the Warranty Disclaimer 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.

TERMS AND CONDITIONS OF USE

If terms of the Warranty Disclaimer, Inherent Risks of Use, and Limitation of Remedies are not acceptable, return unopened package at once to the seller for a full refund of purchase price paid. Otherwise, use by the buyer or any other user constitutes acceptance of the terms under Warranty Disclaimer, Inherent Risks of Use and Limitations of Remedies.

WARRANTY DISCLAIMER

Elanco warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions, subject to the inherent risks previously stated. Elanco MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish and aquatic organisms, and toxic to wildlife. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems. This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area. Apply this product only as specified on the label.

PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or an open flame. Notice: Shake well before use. Avoid freezing. Read entire label. Use only according to label directions. Before using this product, read Warranty Disclaimer, Inherent Risks of Use, and Limitation of Remedies at the end of the label booklet. If terms are unacceptable, return at once unopened.

*Elanco, StandGuard, and the diagonal color bar are trademarks of Eli Lilly and Company
Elanco Animal Health
A Division of Eli Lilly & Company
Indianapolis, IN 46285
www.elanco.com
Questions or comments call 1-800-428-4441

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Cover

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