

72642-3

08/10/2009

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

AUG 10 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 72642-3

StandGuard Premise

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,

A handwritten signature in black ink that reads "Rachel C. Halloran".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs



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 Kimberly Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Elanco Animal Health/StandGuard® Premise	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Elanco Animal Health 2001 W. Main Street Greenfield, IN 46140 <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 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:				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 the label	
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 Sonya Gissendanner		Title Regulatory Associate	
		Telephone No. (Include Area Code) 317-651-4127	
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.			6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Associate	
4. Typed Name Sonya Gissendanner		5. Date 14 January 2009	

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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

Kimberly 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 StandGuard Premise® (72462-3)

Elanco Animal Health is providing in this notification, updates to storage and disposal statements for StandGuard Premise® (72462-3). 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 (Gissendannersj@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:

ELANCO AN1330

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.

Active Ingredient

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

OTHER INGREDIENTS

TOTAL

Contains 0.5 pound

ingredient per gallon

Contains petrole

**Keep Out of
Reach of Children
CAUTION**

ELANCO AN1330

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.

PRECAUTIONARY STATEMENTS

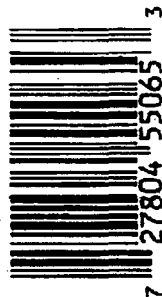
**HAZARDS TO HUMANS AND
DOMESTIC ANIMALS**

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.



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

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish and aquatic organisms, and toxic to wildlife. Do not apply directly to water, or 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. 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

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 WASPS: 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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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.**

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.

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 0.5 fl oz (15 mL) / 3 gal water
Ants		
Bees		0.015% 0.33 fl oz (10 mL) / gal water
Fleas*		1.0 fl oz (30 mL) / 3 gal water
Wasps		

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.

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.

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.

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 2.0 fl oz (60 mL) / 3 gal water
Crickets		
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.

- 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 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. 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 (naturalytes, phenyl pyrazoles, chloronicotinyls, 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 Elanco Animal Health representative (1-800-428-4441).

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish and aquatic organisms, and toxic to wildlife. Do not apply directly to water, or 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. 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.

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.

*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

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.

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