

72642-5

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 72642-5 StandGuard Pour On

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. Holloman

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



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Elanco Animal Health/72642-5	2. EPA Product Manager Kim Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Elanco Animal Health/StandGuard® Pour-on	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	Metal Plastic Glass Paper 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 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 Margaret Gillis	Title Regulatory Associate	Telephone No. (include Area Code) 317-651-5375
2. Signature <i>Margaret Gillis</i>		6. Date Application Received (Stamped)
3. Title Regulatory Associate		
4. Typed Name Margaret Gillis		5. Date 14 Jan 2009
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 both under applicable law.		

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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)278-2000

March 20, 2009

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

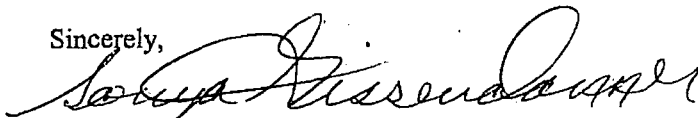
RE: PRN 2007-4 Updates for StandGuard Pour-on® (72462-5)

Elanco Animal Health is providing in this notification, updates to storage and disposal statements for StandGuard Pour-on® (72462-5). 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

Enclosures:

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NOTIFICATION

APR 10 2009

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Remove contaminated clothing and wash before re-use. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Wear rubber or non-permeable protective gloves when applying this product. Data indicate this product to be a contact allergenic. Do not apply this product to the face of cattle.

FIRST AID

If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If in eyes:

- Hold eye 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.
- Call a poison control center or doctor for treatment advice.

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 a poison control center or doctor.
- Do not give anything to an unconscious person.

Have 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.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish. 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. Apply the product only as specified on this label.

PHYSICAL AND CHEMICAL HAZARDS

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

YL9480DEAMB (V01-06-2009) / 00283422

StandGuard Pour-on Insecticide

COVER



DIRECTIONS FOR USE

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

READY TO USE: No dilution necessary. Do not apply to lactating or dry dairy cows. Do not apply this product to the face of beef cattle and calves.

Apply to	Target Insect	Dosage
Beef cattle	Horn flies, lice	Apply product along the backline at the rate of: More than 600 lbs: 15 mLs (½ fl. oz.) Less than 600 lbs: 10 mLs (¼ fl. oz.)

For horn flies, repeat treatment as needed, however do not apply more than once every two weeks and do not apply more than four times within any 6-month period.

SPECIAL NOTE: StandGuard pour-on Insecticide is not recommended for veal calves. StandGuard pour-on Insecticide is not effective in controlling cattle grubs. Therefore, this product can be used on cattle at any time of the year without fear of host-parasite reactions commonly associated with grub treatments. StandGuard pour-on Insecticide should be used in an integrated pest management system which may involve repeat treatments and the use of other pest control practices. Continual exposure of horn flies to a single class of insecticide (eg. pyrethroids or organophosphates) may lead to the development of resistance to that class of insecticide. In order to reduce the possibility of horn flies developing resistance, it is important to rotate, on a seasonal basis, the class of insecticide used and/or the method of horn fly control. For advice concerning current control practices with relation to specific local conditions, consult resources in resistance management programs, your Cooperative Agricultural Extension agent or your Elanco Animal Health representative at 1-800-428-4441.

STORAGE AND DISPOSAL

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

Pesticide 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.

TERMS AND CONDITIONS OF USE

If terms of the following 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 Limitation 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 set forth below. ELANCO ANIMAL HEALTH MAKES NO OTHER EXPRESSED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

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.

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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 the buyer or user of the product bought, or
- (2) Replacement of the 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 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.

NOTIFICATION
APR 10 2009