

72642-9

01-04-2011

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

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Iain Weatherston, Senior Regulatory Consultant
Technology Sciences Group Inc
4061 North 156th Drive
Goodyear, AZ 85395

NOTIFICATION

JAN - 4 2011

Subject: Notification of primary brand name change
EPA Registration Number: 72642-9
Date of Submission: November 5, 2010

Dear Mr. Weatherston:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration (PRN)98-10 dated November 5, 2010, for the abovementioned product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions regarding this letter, please Samantha Hulkower at (703) 603-0683 or Hulkower.Samantha@epa.gov.

Sincerely,

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

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

Enclosures: Copy of Label Stamped "Notification"

	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number <p style="text-align: center;">72642-9</p>	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Elanco Animal Health / Assurity	PM# <p style="text-align: center;">13</p>	
5. Name and Address of Applicant (Include ZIP Code) Elanco Animal Health (A Division of Eli Lilly & Co. 2500 Innovation Way, P.O. Box 708, 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.

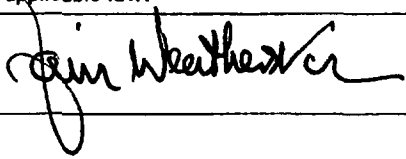
Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of a PRIMARY BRAND NAME
 '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 wilfully 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 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) <u>cardboard</u>	
* 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"/> _____	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph Paper glued 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 Iain Weatherston	Title Senior Managing Consultant	Telephone No. (Include Area Code) (623)-535-4060
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 Senior Managing Consultant	
4. Typed Name Iain Weatherston	5. Date <p style="text-align: center;">November 5, 2010</p>	

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Technology Sciences Group Inc.

4061 N. 156th Drive
Goodyear, AZ 85395
Direct: (623)-535-4060
Cell: 217-9013
E-Mail: iweatheraton@tsgusa.com

Iain Weatherston Ph.D.
Senior Managing Consultant

November 5, 2010

Paul Mastradone
Notifications Team Leader
U.S. EPA – OPP – RD – IB
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Notification of primary brand name
Company: Elanco Animal Health, A Division of Eli Lilly & Company, Indianapolis, Indiana 46285
Contact: Iain Weatherston, Ph.D., Senior Managing Consultant, Technology Sciences Group Inc. (contact information as per letterhead)
Product: L899 Insecticide [EPA Reg. No. 72642-9]

Dear Mr. Mastradone:

As agent for, and on behalf of Elanco Animal Health I am submitting for your review this Notification to add the **primary brand name** to the subject product. This addition of the new brand name **Assurity™** is being done in compliance with the conditions outlined in PRN 98-10.

In addition to this letter, the Notification is comprised of:

- A fully executed Application for Pesticide Registration [EPA form 8570-1]
- Certification statement (included on the 8750-1- form)
- One copy of the stamped approved label dated November.
- A copy of the draft label marked up to show the changes
- A clean copy of the label containing the new primary brand name.

If you have any questions, or require further information please do not hesitate to contact me at iweatherston@tsgusa.com or by phone at 623-535-4060.

Sincerely,

Washington, D.C.
1150 18th St., NW, Suite 1000
Washington, D.C. 20036
Phone: (202) 223-4392

California
712 Fifth St., Suite A
Davis, CA 95616
Phone: (530) 757-1245

Canada
275 Slater St., Suite 900
Ottawa, Ontario K1P 5H9
Phone: (613) 247-6285

Marketing claims: see lists at the end of the draft labels.
Alternative language in (parentheses)

CARTON LABEL

FRONT PANEL

Assurity™

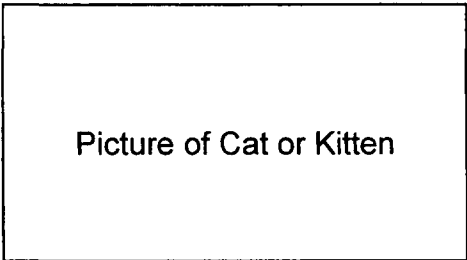
NOTIFICATION

JAN - 4 2011

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF FLEA INFESTATIONS FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

Marketing claims: see lists at the end of the draft labels.



ACTIVE INGREDIENT

Spinetoram (CAS# 187166-40-1 & 187166-15-0) 39.6%

OTHER INGREDIENTS 60.4%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS

READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

CONTENTS

1, 2, 3, 4, 6, 8, 12, 0.019 fl oz (0.57 ml) applicator

BACK PANEL

DIRECTIONS FOR USE

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

More detailed directions for use are included in the box. Read the entire label, directions for use and frequency of application each time before using this product.

For prevention and treatment of fleas, part the hair on the neck at the base of the head and apply the contents of the applicator tube to a single spot on the skin of the cat. Do not apply on the surface of the cat's hair coat. Place the empty applicator tube in the trash.

Monthly application is recommended to prevent and treat flea infestations. Assurity™ starts working in 30 minutes, kills adult fleas before they lay eggs and continues killing fleas for a full month after application.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION**

HAZARDS TO HUMANS

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

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age. As with any product, consult your veterinarian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides. Sensitivities, such as, hair sparseness or hair loss or skin irritation or discoloration or salivation may occur. If sensitivities occur or persist, contact your veterinarian. If you have questions regarding the use of this product consult your veterinarian, your cat's healthcare expert. For technical assistance or to report an adverse reaction, call 1-888-545-5973.

FIRST AID

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 the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

For more information on human-related medical first aid, call Rocky Mountain Poison Control at 1-888-767-5023. Have the product container or label with you when calling a poison control center or doctor for

treatment.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-O
EPA Est. No.

PACKAGE INSERT LABEL

Assurity™

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF FLEA INFESTATIONS FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 & 187166-15-0] 39.6%

OTHER INGREDIENTS 60.4%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION

HAZARDS TO HUMANS

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

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age. As with any product, consult your veterinarian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides. Sensitivities, such as, hair sparseness or hair loss or skin irritation or discoloration or salivation may occur. If sensitivities occur or persist, contact your veterinarian. If you have questions regarding the use of this product consult your veterinarian, your cat's healthcare expert. For technical assistance or to report an adverse reaction, call 1-888-545-5973.

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- 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.
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- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

For more information on human-related medical first aid, call Rocky Mountain Poison Control at 1-888-767-5023. Have the product container or label with you when calling a poison control center or doctor for treatment.

DIRECTIONS FOR USE:

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

Read the entire label, directions for use and frequency of application each time before using the product. For external use on cats and kittens only.

FREQUENCY OF APPLICATION

To kill fleas and prevent reinfestations, apply to cats and kittens 8 weeks of age and older as follows:

HOW TO APPLY

1. Use only on cats and kittens 8 weeks of age and older. Do not use on other animals.
2. Remove one applicator tube from the blister package.
3. Hold applicator tube in an upright position,
4. Press cap down until it clicks (indicating the tube has been punctured). Hold upright and remove cap. Check to be sure there is an opening at the tip of tube.
5. Part the hair on the neck at the base of the head until the skin is visible. Place the tip of the tube directly above the skin and squeeze the tube 2-4 times to expel the contents of the tube directly on the skin. Avoid getting the product in your pet's eyes or mouth. Treatment at the base of the head will minimize the opportunity for the cat to directly lick the product. (There may be a small residual remaining in the tube after a full dose is expelled.)
6. Discard empty applicator tube in the trash.

Picture/drawing
of opening the
tube.

Picture/drawing
of parting the
hair on neck at
base of head.

Picture/drawing
of applying the
product.

Monthly application is recommended to prevent and treat flea infestations. Assurity™ starts working in 30 minutes, kills adult fleas before the lay eggs and continues killing fleas for a full month after application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage:

Store in original package in a cool dry place.

Pesticide Disposal:

Call your local solid waste agency or 1-800-CLEANUP or equivalent organization for disposal instructions. Unless otherwise instructed place in trash. Never pour unused product down the drain or on the ground.

Container Handling:

If empty: Non-refillable container. Do not reuse this container. Place in the trash, or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATIONS OF LIABILITY

By using, buying or handling this product, users or buyers accept the following conditions, disclaimer of warranties and limitations of liability. The directions for use of this product are believed to be adequate and must be followed carefully. All risks of product use or handling are assumed by the user or buyer. No agent of Elanco is authorized to make, extend or modify any warranties. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW ELANCO MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. ELANCO DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. To the extent consistent with applicable law the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, is limited to the purchase price paid or replacement of the product.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

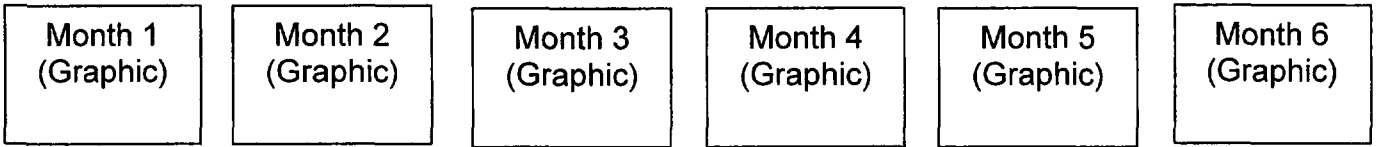
EPA Reg. No. 72642-9
EPA Est. No.

(Calendar) Reminder Stickers

Place stickers on your calendar as a reminder to apply Assurity™ for cats and kittens 8 weeks of age and older.

Visit www.assurity.com to sign up and receive an email reminder from your cat when it is time to receive Assurity™

Graphic of calendar



Applicator Labeling

Assurity™
Spinetoram 39.6%

Cats and Kittens 8 weeks & older

0.019 fl oz (0.57 mL)

EPA Reg. No 72642-9

CAUTION
Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

12
14

Blister Labeling

Assurity™
Spinetoram 39.6%

For Cats and Kittens 8 weeks of age (and older)

0.019 fl oz (0.57 mL)

EPA Reg. No 72642-9

CAUTION
Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

Optional Marketing Claims

- Once-a-month
- Topical
- Topical Solution
- Single topical (spot-on) application
- For the prevention and treatment of flea infestations [*Ctenocephalides felis*] on cats (and kittens 8 weeks of age or older)
- Kills fleas
- (Fast Acting) kills fleas on cats within 8 hours
- (Fast Acting) kills 98-100% of the fleas within 12 hours
- (Fast Acting) starts killing fleas in 30 minutes
- (Fast Acting) starts working in 30 minutes
- Kills fleas which may cause flea allergy dermatitis (FAD)
- Kills fleas before they lay eggs
- Kills adult fleas before they lay eggs
- (Long Lasting) one treatment prevents further flea infestations through 8 (6, 7) weeks
- (Long Lasting) one treatment remains effective through 8 (6, 7,) weeks
- (Long Lasting) remains effective for up to 8 (7) weeks
- (Long Lasting) one treatment prevents further flea infestations for up to 8 (7) weeks
- (Long Lasting) one treatment remains effective for up to 8 (7,) weeks
- (Long Lasting) one treatment kills fleas and prevents reinfestation for up to 8 (7) weeks
- (Long Lasting) remains effective through 8 (6, 7) weeks
- Fragrance-free
- Quick-drying
- Non-greasy
- Formulated (exclusively) for cats and kittens 8 weeks of age (and older)
- Kills fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*, *Francisella tularensis*
- Kills fleas that may carry and transmit bartonellosis, tapeworm and tularemia
- For indoor and outdoor cats and kittens
- Kills fleas that may cause anemia
- One application provides 100% flea control from 24 hours through 50 (37) days
- Long-lasting flea control for up to 8 (7) weeks
- Long-lasting flea control through 8 (6, 7) weeks
- New mode of action [can say for 6 months]
- Novel mode of action [can include up to 6 months]
- Unique mode of action
- The primary target of action of spinetoram on insects is an activation of nicotinic acetylcholine receptors (nAChRs).
- Spinetoram does not interact with known insecticidal binding sites of other nicotinic or GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodienes.
- Insects in contact with spinetoram show involuntary muscle contractions and tremors resulting from activation of motor neurons.
- Prolonged spinetoram-induced hyperexcitation results in prostration and paralysis resulting in death of fleas.
- Topical application
- One size for all cats/ kittens 8 weeks of age and older.

- One (applicator tube, size, package, dose, treatment, application) treats all (any) size(s) of cats and kittens 8 weeks of age and older.
- 6 Pack
- Single Pack (Single dose, individual dose)
- Topical flea treatment
- Convenient
- Easy to apply (easy to use)
- Spinetoram, the active ingredient in Assurity™ is a member of the spinosyn class of pesticide
- The only spinetoram-based product for use on cats
- Protects cats and kittens 8 weeks of age (and older) (all sizes) from fleas (for one month)
- One size application is effective for all (any) sizes (weight ranges) of cats and kittens 8 weeks of age (and older)
- (Flea infestations may vary) Monthly treatment (year-round) is recommended for optimal control and prevention of fleas
- Satisfaction Guaranteed (Call 1-888-545-5973 if you have any questions.)