

72642-9

6/7/2011

10/15



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

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

Katherine A. Meyer
Elanco Animal Health
PO Box 708
2500 Innovation Way
Greenfield, IN 46140

JUN 7 - 2011
NOTIFICATION

Subject: Notification of minor label changes
EPA Registration Number: 72642-9
Decision: 445748

NOTIFICATION
JUN 7 - 2011

Dear Ms. Meyer:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration (PRN)98-10 dated February 18, 2011, 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,

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

Enclosures: Copy of Label Stamped "Notification"

Explanation Continued:

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations 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 sections 12 and 14 of FIFRA."

Signature Katherine A. Meyer
Katherine A. Meyer

Date 18 Feb. 2011

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

CARTON LABEL

FRONT PANEL

Assurity™

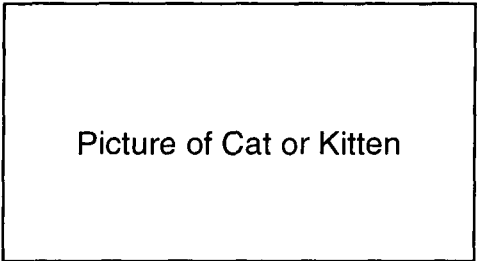
spinetoram

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

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

NOTIFICATION

JUN 7 - 2011



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

60915

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 irritation. 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.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

70915

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

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

80415

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

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OTHER INGREDIENTS 60.4%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION

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HAZARDS TO DOMESTIC ANIMALS

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- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 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.

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.

110415

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.

120f15

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

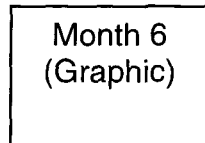
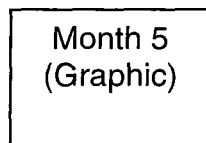
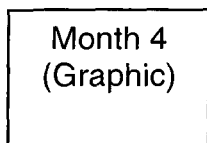
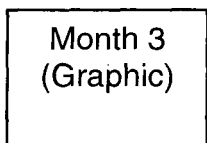
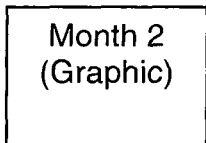
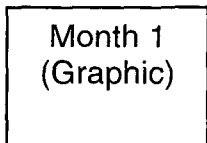
Lot No.

(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.assurity4cats.com to sign up and receive an email reminder from your cat when it is time to receive Assurity™

Graphic of calendar



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]
- 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)

OK SAH

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 L899 INSECTICIDE, is a member of the spinosyn class of pesticide
- The only spinetoram-based product for use on cats [can include up to 6 months]
- 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.)