

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505C) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460

NOTICE OF PESTICIDE:

X Registration
Reregistration
(under FIFRA, as amended)

EPA	Reg.	Number:

Date of Issuance:

72642-10

JAN 17 2013

Term of Issuance:

Conditional

Spinetoram 11.2% Cats

Name and Address of Registrant (include ZIP Code):

Elanco Animal Health, A Division of Eli Lilly & Company 2500 innovation Way P.O. Box 708 Greenfield, IN 46140

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with section 3(c)(7)(A) of FIFRA provided that you:

- 1. Submit and/or cite all data required for registration of your product under section 3(c)(5) of FIFRA when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under section 4 of FIFRA.
- 2. Submit within 12 months of the date of issuance of this Registration Notice, acceptable guideline studies for Storage Stability study (OPPTS GLN: 830.6317) and Corrosion Characteristics study (OPTS GLN: 830.6320) for this product.
- 3. Change the product registration number to "EPA Reg. No. 72642-10" (continued on page 2)

Signature	٥f	Annro	vina	Official
Signature	OI.	ADDro	ving '	Omiciai:

See page 2

Date

JAN 17 2013

Mark Suarez, Product Manager (13)

Insecticide Branch, Registration Division (7504P)

EPA Form 8570-6

Conditions of acceptance

- 1. This registration is now time-limited and expires two years from the date of this letter.
- 2. Only one basic confidential statement of formula will be on file for this product at any one time; no alternate formulations or minor formulation amendments will be submitted or approved for this product.
- 3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning April 1, 2013.

The quarterly reports are due two months after the quarter ends. Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kaitlon Keller).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot #
Where purchased: internet, store, veterinarian
Active Ingredient(s)
Weight range for product

Date on which incident occurred. (mm/dd/yyyy)
State in which the incident occurred. (standard 2 letter abbreviation)
Registrant case #

Species: dog, cat, other (specify) Breed: (as reported by pet owner)

Age: months or years Sex: M, F, or neutered Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other Body System: neurological, dermatological, GI, respiratory, ocular, other

Major signs noted with separate column for each sign, using standard terminology

Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no

Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)

Any known precondition

EPA Severity Code: death, major, moderate, minor Outcome: died, recovered, still treated, unknown

4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported including all minor dermal and ocular irritation reports.
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.

Report aggregate incidents, but do not combine moderate and minor incidents.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. If EPA determines that future mitigation measures are necessary for all spot-on products, the Agency will inform registrants and if needed, EPA may take regulatory action. If you have any questions contact Driss Benmhend at 703-308-9525 or by e-mail at: Benmhend.driss@epa.gov.

Sincerely,

Mark Suarez

Product Manager 13, Insecticide Branch

Registration Division (7504P)

Enclosure: Label Stamped "with Comments"

Spinetoram 11.2% Cat Master Label Page 1 of 25

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

CARTON LABEL

FRONT PANEL

Spinetoram 11.2% Cat

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

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

Picture of Cat or Kitten

ACTIVE INGREDIENT

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 – 0.026 fl oz (0.77 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.

General use pesticide. For use only for further manufacture or repacking of a registered pesticide product for companion animals.

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

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, using tobacco or using the toilet. 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 or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. 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.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 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.

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

EPA Reg. No. 72642-RN EPA Est. No.

PACKAGE INSERT LABEL

Spinetoram 11.2% Cat

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 & 187166-15-0]	. 11.2%
OTHER INGREDIENTS	. 88.8%
TOTAL	

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 irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. 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 or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. 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.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 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.

DIRECTIONS FOR USE:

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

General use pesticide. For use only for further manufacture or repacking of a registered pesticide product for companion animals.

Read the entire label, directions for use and frequency of application each time before using this 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 and weighing 1.8 lbs or more. Do not use more than a single dose on cats weighing greater than 20 lbs.
- 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. For best results, apply at the base of the head, not between the shoulder blades. 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. Do not allow your cat to ingest this product. (There may be a small residual remaining in the tube after a full dose is expelled.)

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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. Spinetoram 11.2% Cat 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:

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

<u>If partly filled:</u> 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, EXPRESSED 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-RN EPA Est. No.

Applicator Labeling

Spinetoram 11.2% Cat Spinetoram 11.2%

Cats and Kittens 8 weeks & older

0.026 fl oz (0.77 mL)

EPA Reg. No 72642-RN

CAUTION Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

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Blister Labeling

Spinetoram 11.2% Cat Spinetoram 11.2%

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

0.026 fl oz (0.77 mL)

EPA Reg. No 72642-RN

CAUTION
Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

Page 10 of 25

(Calendar) Reminder Stickers

Place stickers on your calendar as a reminder to apply Spinetoram 11.2% Cat for cats and kittens 8 weeks of age and older.

Visit <u>www.elanco.com</u> to sign up and receive an email reminder from your cat when it is time to receive Spinetoram 11.2% Cat.

Graphic of calendar

Month 1 (Graphic)

Month 2 (Graphic)

Month 3 (Graphic)

Month 4 (Graphic) Month 5 (Graphic)

Month 6 (Graphic)

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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 only
- Kills fleas
- (Fast Acting) kills fleas on cats within 8 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)
- (Long Lasting) one treatment prevents further flea infestations through 6 weeks
- (Long Lasting) one treatment remains effective through 6 weeks
- (Long Lasting) remains effective through 6 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
- Long-lasting flea control through 6 weeks
- 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 only.
- One (applicator tube, size, package, dose, treatment, application) treats all (any) size(s)
 of cats and kittens 8 weeks of age and older only.
- 6 Pack
- Single Pack (Single dose, individual dose)
- Topical flea treatment
- Convenient
- Easy to apply (easy to use)
- Spinetoram, the active ingredient in Spinetoram 11.2% Cat, is a member of the spinosyn class of pesticide
- 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

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- weeks of age (and older) only
 (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.)

Spinetoram 11.2% Cat Sub-Label #1 Residential Page 13 of 25

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

CARTON LABEL

FRONT PANEL

Spinetoram 11.2% Cat

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

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

Picture of Cat or Kitten

ACTIVE INGREDIENT

 Spinetoram (CAS# 187166-40-1 & 187166-15-0)
 11.2%

 OTHER INGREDIENTS
 88.8%

 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 - 0.026 fl oz (0.77 ml) applicator

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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. Spinetoram 11.2% Cat 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, using tobacco or using the toilet. 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 or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. 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.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 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.

Manufactured for

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

EPA Reg. No. 72642-RN EPA Est. No.

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PACKAGE INSERT LABEL

Spinetoram 11.2% Cat

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 & 18	37166-15-0]	11.2%
OTHER INGREDIENTS		88.8%
	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 irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. 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 or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. 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.

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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 and weighing 1.8 lbs or more. Do not use more than a single dose on cats weighing greater than 20 lbs.
- 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. For best results, apply at the base of the head, not between shoulder blades. 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. Do not allow your cat to ingest this 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.

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Monthly application is recommended to prevent and treat flea infestations. Spinetoram 11.2% Cat starts working in 30 minutes, kills adult fleas before they 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:

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

<u>If partly filled:</u> 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, EXPRESSED 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-RN EPA Est. No.

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Applicator Labeling

Spinetoram 11.2% Cat Spinetoram 11.2%

Cats and Kittens 8 weeks & older

0.026 fl oz (0.77 mL)

EPA Reg. No 72642-RN

CAUTION Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

Blister Labeling

Spinetoram 11.2% Cat Spinetoram 11.2%

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

0.026 fl oz (0.77 mL)

EPA Reg. No 72642-RN

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 Spinetoram 11.2% Cat for cats and kittens 8 weeks of age and older.

Visit <u>www.elanco.com</u> to sign up and receive an email reminder from your cat when it is time to receive Spinetoram 11.2% Cat.

Graphic of calendar

Month 1 (Graphic)

Month 2 (Graphic)

Month 3 (Graphic)

Month 4 (Graphic) Month 5 (Graphic) Month 6 (Graphic)

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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 only
- Kills fleas
- (Fast Acting) kills fleas on cats within 8 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)
- (Long Lasting) one treatment prévents further flea infestations through 6 weeks
- (Long Lasting) one treatment remains effective through 6 weeks
- (Long Lasting) remains effective through 6 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
- Long-lasting flea control through 6 weeks
- 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 only.
- One (applicator tube, size, package, dose, treatment, application) treats all (any) size(s) of cats and kittens 8 weeks of age and older only.
- 6 Pack
- Single Pack (Single dose, individual dose)
- Topical flea treatment
- Convenient
- Easy to apply (easy to use)
- Spinetoram, the active ingredient in Spinetoram 11.2% Cat, is a member of the spinosyn class of pesticide
- 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) only
- (Flea infestations may vary) Monthly treatment (year-round) is recommended for optimal control

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and prevention of fleas
Satisfaction Guaranteed (Call 1-888-545-5973 if you have any questions.)

Spinetoram 11.2% Cat Sub-label #2 Commercial

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(label to be placed near discharge control valve, this statement can be removed from printed label)

Spinetoram 11.2% Cat

spinetoram

ACTIVE INGREDIENT

KEEP OUT OF REACH OF CHILDREN

CAUTION

ACCEPTED
with COMMENTS
In EPA Letter Dated
JAN 1 2013

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under FPA Reg. No.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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.

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DIRECTIONS FOR USE:

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

General use pesticide. For use only for the further manufacture or repacking of a registered pesticide product for companion animals.

STORAGE AND DISPOSAL:

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

Pesticide Storage: Store in original package only. In case of leak or spill, contain material with absorbent materials and dispose as waste.

Pesticide Disposal: Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Never pour unused product down the drain or on the ground.

Container Handling: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into manufacturing process or appropriate waste collection system. Fill the container about 10% full with water, and if possible, spray all sides while adding water. If practical, agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into a waste collection system. Repeat this rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures allowed by state and local authorities.

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

EPA Reg. No. 72642-RN EPA Est. No. 70996-CAN-002

NET (CO	NTEI	NTS:_				
(may	be	com	pleted	by	manual	entry)	