

72642-9

11/03/2010

1/16



U.S. ENVIRONMENTAL PROTECTION AGENCY

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

EPA Registration No.

72642-O

Date of Issuance:

NOV 3 2010

NOTICE OF PESTICIDE: [X] Registration
[ ] Reregistration

(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

L899 Insecticide

Name and Address of Registrant (include ZIP Code):

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

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 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 FIFRA sec. 3(c)(7)(a) provided that you:

(See comments on pages 2-5)

A copy of your label stamped "Accepted with Comments" is enclosed for your records.

Signature of Approving Official:

Refer to Page 5

Mark Suarez, Product Manager (13)
Registration Division, Insecticide Branch

Date:

NOV 3 2010

1. Make the following label changes:
  - On the first page change the , after 12 to a – so that it is more clear you are referring to the number of applicators and not the fl oz size, “1, 2, 3, 4, 6, 8, 12 – 0.019 fl oz (0.57 ml) applicator(s)”
  - Under Hazards to Humans sections change “Causes moderate eye damage” to “Causes moderate eye irritation.”
  - Change the final paragraph in the first aid statements to read, “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 info.”
  - Change the 5<sup>th</sup> marketing statement to read as follows, “For the prevention and treatment of flea infestations [*Ctenocephalides felis*] on cats (and kittens) 8 weeks of age or older”
  - Delete optional marketing claim, “Unique mode of action”
  - Change the optional marketing statement, “The only spinetoram-based product for use on cats” to “The only spinetoram-based product for use on cats [can include up to 6 months]”
  
2. This registration is time-limited and expires **two years** from the date this product is first released for shipment.

You must provide the Agency with a projected release for shipment date in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing.

3. 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.
  
4. You must submit the following data within the timeframes described below:
  - 1 year storage stability (Guideline 830.6317) and corrosion characteristics (830.6320) data at 0, 3, 6, 9, and 12 months in both electronic and hard copies.
  - In accordance with the revised 40 CFR Part 158 data requirements, an immunotoxicity study is required for all food and non-food use chemicals. Since Spinosad and spinetoram are considered toxicologically identical and since the toxicity data of these pesticides can be used interchangeably the immunotoxicity study is required on only one of these compounds.
  
5. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning January 1, 2011.

Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager (Mark Suarez, PM 13). Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci).

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

6. 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 cats 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 dogs (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 cats 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 cat incidents for each severity code for each pet weight range on the product label (if applicable).
  - A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range (if applicable).
  - Table showing number of incidents for each cat breed, where provided.
  - Table showing number of incidents in cats for each clinical sign.
  - Table showing number of incidents in cats for each organ system.
  - Report aggregate incidents, but do not combine moderate and minor incidents.
7. You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for reregistration of your product under FIFRA section 4.
  8. You revise the EPA Registration Number to read: "EPA Registration No. 72642-9" on page 1 of the label.


If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

As a reference to the company's website is included on your label, please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance. As an alternative, you may refer consumers to the company's phone number or email address.

Two copies of the finished labeling must be submitted prior to releasing the product for

shipment. 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. A copy of your label stamped "Accepted with Comments" is enclosed for your records.

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

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

Enclosure: Copy of label stamped "Accepted with Conditions"  
DP 372448 Companion Animal Study DER; DP 372447 Product Chemistry Review; DP 376658 Occupational and Residential Exposure Risk Assessment for Use as a Spot-on for Cats and Kittens; DP 372446 Acute Toxicology Study; DP 371967 Efficacy Review; DP 376415 Human Health Risk Assessment

ACCEPTED  
with COMMENTS  
In EPA Letter Dated:

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

NOV 3 2010  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
72642-9

CARTON LABEL

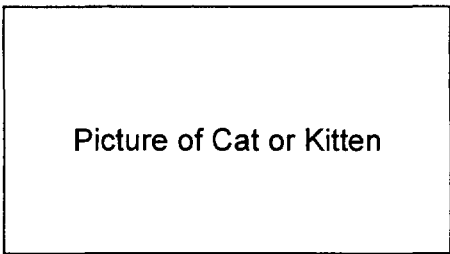
FRONT PANEL

# L899 INSECTICIDE

## 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.



<b>ACTIVE INGREDIENT</b>	
Spinetoram (CAS# 187166-40-1 & 187166-15-0) .....	39.6%
<b>OTHER INGREDIENTS</b> .....	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. L899 INSECTICIDE 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 LABELING

# L899 INSECTICIDE

## 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

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HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION**

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**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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- Do not induce vomiting unless told to by a poison control center or doctor.
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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.

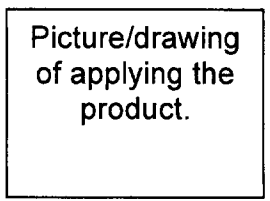
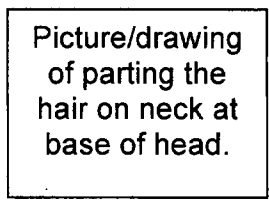
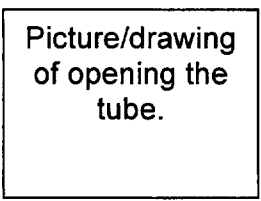
Read the entire label, directions for use and frequency of application each time before using the product. For external use on cats and kittens only.

**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.



Monthly application is recommended to prevent and treat flea infestations. L899 INSECTICIDE 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-O  
EPA Est. No.

12/16

Applicator Labeling

**L899 INSECTICIDE**

Spinetoram 39.6%

Cats and Kittens 8 weeks & older

0.019 fl oz (0.57 mL)

EPA Reg. No 72642-O

CAUTION

Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

Blister Labeling

**L899 INSECTICIDE**

Spinetoram 39.6%

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

0.019 fl oz (0.57 mL)

EPA Reg. No 72642-O

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 L899 INSECTICIDE for cats and kittens 8 weeks of age and older.

Visit [www.assurity.com](http://www.assurity.com) to sign up and receive an email reminder from your cat when it is time to receive L899 INSECTICIDE

Graphic of calendar

Month 1  
(Graphic)

Month 2  
(Graphic)

Month 3  
(Graphic)

Month 4  
(Graphic)

Month 5  
(Graphic)

Month 6  
(Graphic)

### 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 L899 INSECTICIDE, 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.)