



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

EPA Reg. Number:

72642-10

Date of Issuance:

3/1/17

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
 Expires: 03/01/2019

Name of Pesticide Product:

Cheristin™ for cats

Name and Address of Registrant (include ZIP Code):

Aaron Johnson
 Elanco Animal Health
 2500 Innovation Way
 Greenfield, IN 46410

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 section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Michael Walsh, Product Manager 11
 Invertebrate and Vertebrate Branch 2,
 Registration Division (7505P)

Date:

3/1/17

2. The Agency has found your company to be in compliance with the terms and conditions for the subject product and is extending the two-year registration restriction. This registration is time-limited and expires 03/01/2019.
3. Please note that the product is still subject to all other previously required conditions of registration. Your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information as stated in the initial registration notice dated 1/17/13.
4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to retain a reference to the company's website on your label, then 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) list 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.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSF:

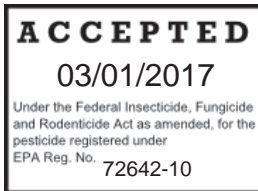
- Basic CSF dated 05/11/2015

If you have any questions, please contact Debra Rate by phone at (703) 306-0309, or via email at rate.debra@epa.gov.

Attachment

Cheristin™ for cats

Alternative language in [brackets]



CARTON LABEL

FRONT PANEL

Cheristin™ for cats

{Note to Reviewer: Size of the word cats will be at least 75% the height of the largest letter in the primary brand name.}

spinetoram

[Alternate Brand Name: Spinetoram 11.2% Cat]

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 AND WEIGHING 1.8 LBS [POUNDS] OR MORE

[Marketing claims: see lists at the end of the label.]

Large, Clear Picture of Cat or Kitten within the Age and Weight Range for the Product.

ACTIVE INGREDIENT

Spinetoram* 11.2%

OTHER INGREDIENTS 88.8%

TOTAL 100.0%

*CAS #s 187166-40-1 and 187166-15-0

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE BACK PANEL FOR FIRST AID AND ADDITIONAL PRECAUTIONARY STATEMENTS

READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

CONTENTS

[1] [one] [2] [two] [3] [three] [4] [four] [6] [six] [8] [eight] [12] [twelve] – 0.026 fl oz [0.77 ml] applicator[s]

BACK PANEL**DIRECTIONS FOR USE**

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

Do not allow children to apply product. Do not allow children to come in contact with the treated animal until after the application has dried. Do not use on cats or kittens <8 weeks of age and weighing <1.8 lbs [pounds]. Do not double dose cats. Do not allow your cat to ingest this product.

More detailed directions for use, including storage and disposal, 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. Cheristin™ for cats starts working in 30 minutes and continues killing fleas for a full month after application.

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

CAUTION. 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. As with any product, consult your veterinarian before using the product on medicated, debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides. In multiple cat households, do not allow the cats to groom each other until the product has dried.

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 inappetence 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.

{Note to Reviewer: The "Side Effects" box will be located at the lower right hand corner of the back panel.}

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 by mouth 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. 72642-10
EPA Est. No.

PACKAGE INSERT LABEL

Cheristin™ for cats

{Note to Reviewer: Size of the word cats will be at least 75% the height of the largest letter in the primary brand name.}

spinetoram

[Alternate Brand Name: Spinetoram 11.2% Cat]

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ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE AND OLDER AND WEIGHING 1.8 LBS [POUNDS] OR MORE

ACTIVE INGREDIENT

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Read the entire label, directions for use and frequency of application each time before using the product. Do not allow children to apply product. Do not allow children to come in contact with the treated animal until after the application has dried. Do not use on cats or kittens <8 weeks of age and weighing <1.8 lbs [pounds]. Do not double dose cats. Do not allow your cat to ingest this product.

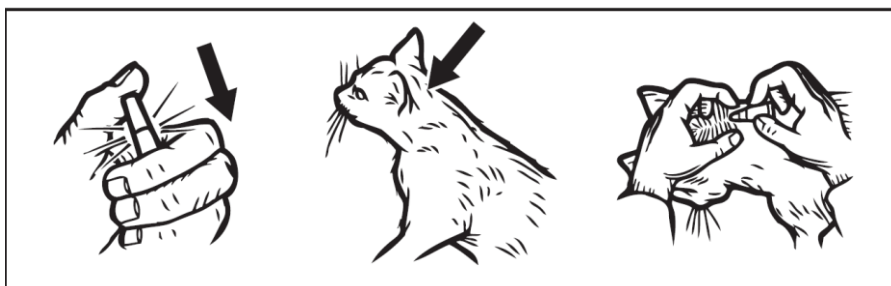
FREQUENCY OF APPLICATION

To kill fleas and prevent reinfestations, apply one applicator tube, once a month, to cats and kittens 8 weeks of age and older and weighing 1.8 lbs [pounds] or more as follows:

HOW TO APPLY

1. Remove one applicator tube from the blister package.
2. Hold applicator tube in an upright position.

3. 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.
4. 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 cat'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.]
5. Discard empty applicator tube in the trash.



Monthly application is recommended to prevent and treat flea infestations. Cheristin™ for cats starts working in 30 minutes 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 inaccessible to children and animals.

Pesticide Disposal:

Call your local solid waste agency 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, 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. 72642-10
EPA Est. No.

Applicator Labeling

Cheristin™ for cats

spinetoram 11.2%

[Alternate Brand Name: Spinetoram 11.2% Cat]

Cats and Kittens 8 weeks & older and \geq 1.8 lbs.

0.026 fl oz [0.77 mL]

EPA Reg 72642-10

CAUTION

Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

Blister Labeling

Cheristin™ for cats
spinetoram 11.2%
[Alternate Brand Name: Spinetoram 11.2% Cat]

Only for Cats and Kittens 8 weeks of age and older and [weighing] 1.8 lbs. [pounds] or more

0.026 fl oz [0.77 mL]

EPA Reg. No 72642-10

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 Cheristin™ for cats only to cats and kittens 8 weeks of age and older and [weighing] 1.8 lbs. [pounds] or more.

Visit www.Cheristin4Cats.com to sign up and receive an email reminder from your cat when it is time to receive Cheristin™ for cats.

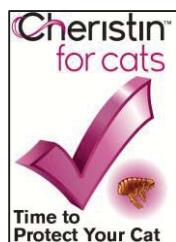
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

Graphic of calendar

[Time to protect your cat]

[Visit your veterinarian for more Cheristin for cats]

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*] and only for use on cats [and kittens] 8 weeks of age or older and weighing 1.8 lbs. [pounds] or more
- 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 for cats and kittens 8 weeks of age and older and weighing 1.8 lbs. [pounds] or more
- 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 dose size for all cats/ kittens 8 weeks of age and older and weighing 1.8 lbs. [pounds] or more.
- One [applicator tube] [size] [package] [dose] [treatment] [application] treats [all] [any] size(s) of cats and kittens 8 weeks of age and older and weighing 1.8 lbs. [pounds] or more.
- 6 [six] [applications] [applicator tubes] [individual doses] [topical applicators]
- Single Pack [Single dose] [individual dose]
- Topical flea treatment
- Convenient
- Easy to apply [Easy to use]
- Spinetoram, the active ingredient in Cheristin™ for cats, is a member of the spinosyn

class of pesticide

- Protects cats and kittens 8 weeks of age and older and weighing 1.8 lbs. [pounds] or more from fleas [for one month]
- One size application is effective for all sizes [weight ranges] of cats and kittens 8 weeks of age and older and weighing 1.8 lbs. [pounds] or more
- [Flea infestations may vary] Monthly treatment [year-round] is recommended for optimal control and prevention of flea infestations