



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 12, 2021

Johnna Bridges
Senior Advisor, Regulatory
Elanco US Inc.
PO Box 708
2500 Innovation Way
Greenfield, IN 46140

Subject: PRIA Label Amendment – Change in Applicator Directions and Other Updates
Product Name: Cheristin for Cats
EPA Registration Number: 72642-10
Application Date: December 17, 2020
Decision Number: 569240

Dear Johnna Bridges:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, please contact Christopher M. Taylor by phone at 703-347-8857, or via email at taylor.christopher.m@epa.gov.

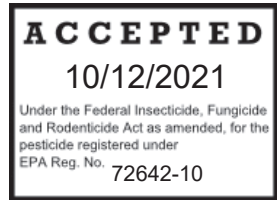
Sincerely,

A handwritten signature in black ink, appearing to read 'M. Walsh', with a stylized flourish at the end.

Michael Walsh
Product Manager 11
Invertebrate and Vertebrate Branch 2
Registration Division

Attachment

{NOTE TO REVIEWER: Alternative language in [brackets]; {Braces} indicate Note to Reviewer and will not be included on final label}



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] – 0.023 fl oz [0.7 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.

Manufactured for

Elanco US Inc.
2500 Innovation Way
Greenfield, IN 46140

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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]

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

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

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Spinetoram*	11.2%
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OTHER INGREDIENTS	88.8%
TOTAL	100.0%

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

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CAUTION

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

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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.

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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.

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.

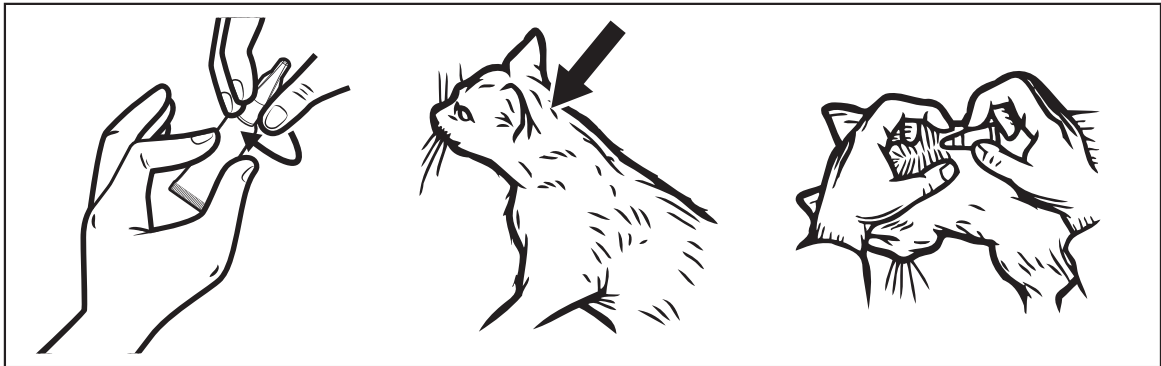
FREQUENCY OF APPLICATION

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 tray.
2. Hold applicator tube in an upright position.

3. Open applicator tube by twisting the nozzle tip.
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.
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.

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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.

0.023 fl oz [0.7 mL]

EPA Reg 72642-10

CAUTION

Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

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