



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

February 23, 2024

Arianna Shorey
Regulatory Consultant
Evergreen Animal Health
c/o Pyxis Regulatory Consulting Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332

Subject: Label Amendment - Registration Review Mitigation for Permethrin and
Pyriproxyfen
Product Name: EVERGREEN II SPOT ON FOR DOGS
EPA Registration Number: 92334-1
Application Date: December 22, 2020
Decision Numbers: 594825, 594826

Dear Arianna Shorey:

The Agency, in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with the Permethrin and Pyriproxyfen Interim Decisions, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

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 Assurance.

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 12 months from the date of this letter. After 12 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.

If you have any questions about this letter, please contact DeMariah Koger by phone at (202)-566-2288, or via email at Koger.demariah@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Linda Arrington", with a stylized flourish at the end.

Linda Arrington, Branch Chief
Risk Management and Implementation Branch 4
Pesticide Re-Evaluation Division
Office of Pesticide Programs

ENCLOSURE: Stamped label

{Front Panel of Carton}**Evergreen II Spot on for Dogs**

{Note to reviewer: The word "Dogs" in the product brand name will be at least 75% the height of the largest letter in the primary brand name.}

{Note to reviewer: Alternate Brand Names are listed at the end of this document on page 10.}

{Note to reviewer: A large clear picture of a dog in the weight range for the product as packaged will be included on the front panel.}

Monthly Topical Treatment of Fleas, Ticks, Mosquitoes, Biting Flies and Lice for Dogs

**For use only on dogs and puppies 7 weeks of age and older and [4-10 lbs] [11-20 lbs]
[21-55 lbs] [over 55 lbs]**

ACTIVE INGREDIENTS:

Imidacloprid 7.12 %

Permethrin* 35.6 %

Pyriproxyfen 0.36 %

OTHER INGREDIENTS 56.92 %

TOTAL 100.00 %

*cis/trans ratio: max 55% (±) cis and min 45% (±) trans

KEEP OUT OF REACH OF CHILDREN**WARNING**

See First Aid and Directions for Use on back panel.

NET CONTENTS:

[One [0.016 fl oz (0.48 mL)] [0.041 fl oz (1.2 mL)] [0.101 fl oz (3.0 mL)] [0.162 fl oz (4.8 mL)]
Tube]

[Three [0.048 fl oz (1.44 mL)] [0.123 fl oz (3.6 mL)] [0.303 fl oz (9.0 mL)] [0.486 fl oz (14.4
mL)] Tubes]

[Four [0.064 fl oz (1.92 mL)] [0.164 fl oz (4.8 mL)] [0.404 fl oz (12.0 mL)] [0.648 fl oz (19.2
mL)] Tubes]

[Five [0.080 fl oz (2.4 mL)] [0.205 fl oz (6.0 mL)] [0.505 fl oz (15.0 mL)] [0.81 fl oz (24.0 mL)]
Tubes]

[Six [0.096 fl oz (2.88 mL)] [0.246 fl oz (7.2 mL)] [0.606 fl oz (18.0 mL)] [0.97 fl oz (28.8 mL)]
Tubes]

[Eight [0.128 fl oz (3.84 mL)] [0.328 fl oz (9.6 mL)] [0.808 fl oz (24.0 mL)] [1.296 fl oz (38.4
mL)] Tubes]

[Ten [0.16 fl oz (4.8 mL)] [0.41 fl oz (12 mL)] [1.01 fl oz (30 mL)] [1.62 fl oz (48 mL)] Tubes]

[Twelve [0.192 fl oz (5.76 mL)] [0.492 fl oz (14.4 mL)] [1.21 fl oz (36 mL)] [1.94 fl oz (57.6
mL)] Tubes]

ACCEPTED

Feb 23, 2024

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 92334-1

{Note to reviewer: A 1.5 cm x 1.5 cm cat prohibition icon in a box will be placed in the lower right-hand corner of the front panel in yellow with black images}



{Front or Back Panel of the Carton}

Evergreen Animal Health, LLC
22655 Centennial Road
Gretna, Nebraska 68028

EPA Reg. No. 92334-1
EPA Est. No. XXXXX-XXX-XX

[Contains Imidacloprid, Permethrin, and Pyriproxyfen, the active ingredients found in K9Advantix II for Dogs* {OR}
Contains the active ingredients found in K9 ADVANTIX II FOR DOGS* {OR}
Compare to K9 Advantix® II for Dogs active ingredients* {OR}
Evergreen II Spot On for Dogs[This product] contains [the same] active ingredients [Imidacloprid, pyriproxyfen and permethrin,] used in K9 Advantix® II for Dogs* {OR}
Evergreen II Spot On for Dogs[This product] contains Imidacloprid, pyriproxyfen and permethrin, the active ingredients used in K9 Advantix® II for Dogs *

*This product is not manufactured or distributed by Bayer, the maker of K9Advantix® II for Dogs. [K9Advantix® II for Dogs is a registered trademark of Bayer.]

{Note to reviewer: When the above optional claim is used, all three statements included in this optional claim will be on the same panel.}

{Note to reviewer: Additional optional text/claims listed on pages 7 through 9.}

PRECAUTIONARY STATEMENTS**HAZARDS TO HUMANS**

WARNING: Causes substantial but temporary eye injury. Do not get in eyes or on skin or clothing. Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, and chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs only. Do not use on animals other than dogs. Do not use on dogs or puppies under seven weeks of age or weighing less than [4 lbs] [11 lbs] [21 lbs] [55 lbs]. Do not get this product in dog's eyes or mouth. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities may occur after using **ANY** pesticide product for dogs. If signs persist, or become more severe, consult a veterinarian immediately. If your dog is on medication, consult your veterinarian before using this or any other product. This product is not a substitute for prescribed Heartworm preventative.

{The age of the dog and the lowest weight of the dog for the product inside the carton will be stated together in all places on the label.}

ENVIRONMENTAL HAZARDS

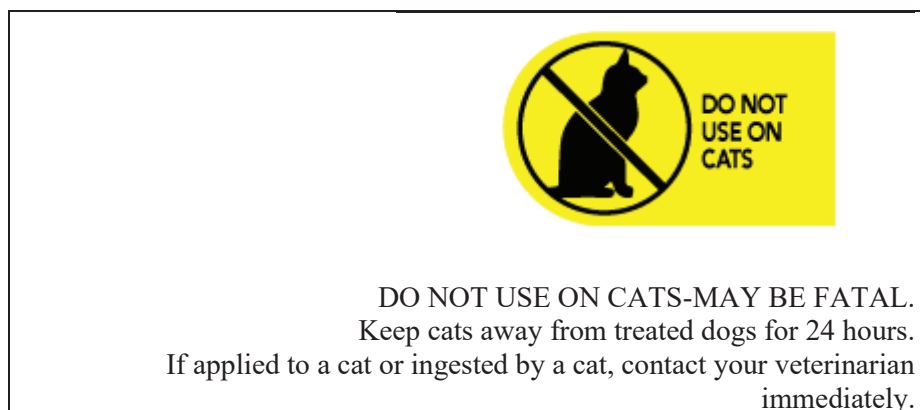
This product is extremely toxic to aquatic organisms, including fish and invertebrates. Do not add directly to water. Do not contaminate water when disposing of product packaging.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • 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 eye. • Call a poison control center or doctor for further treatment advice.
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-XXX-XXXX.	
NOTE TO PHYSICIAN OR VETERINARIAN	
Treat patient symptomatically	

Side Effects: Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-xxx-xxxx.

{Note to reviewer: A box labeled “Side Effects” will be placed immediately above the cat warning text box on the back panel of the carton.}

{Note to reviewer: A [1.5 cm x 1.5 cm] cat prohibition icon and warning text box will be located at the lower right hand corner of the back panel of the carton in yellow with black images and text.}



PRODUCT INFORMATION

Evergreen II Spot On for Dogs kills fleas that may be a source of flea allergy dermatitis (FAD), a hypersensitivity skin disorder which may be induced by the feeding activity of fleas. Evergreen II Spot On for Dogs kills existing fleas on dogs within 12 hours. Any other fleas that jump on the dog are killed within 2 hours. Protection against flea infestation lasts [four (4) weeks] [one (1) month]. Pre-existing pupae may continue to emerge for six (6) weeks or longer depending upon the climate.

{The time frame selected (i.e., weeks or month) will be used throughout the label and not alternate in order to maintain consistency.}

All life stages of fleas present on the dog are killed following contact with an Evergreen II Spot On for Dogs treatment. Evergreen II Spot On for Dogs is waterproof and will remain effective even after a shampoo treatment, after swimming or after exposure to rain or sunlight. Use monthly treatments for flea and tick control.

Monthly Topical Treatment of Fleas, Ticks, Mosquitoes, Biting Flies and Lice for Dogs

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.**

For indoor use only.

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS.

RESTRICTIONS

Do not use on cats.

Do not allow your dog to ingest this product.

Do not get this product in your dog's eyes.

Application of this product on dogs must only be done indoors.

Do not bathe dog for 24 hours after application.

Do not allow adults, children, or pets to touch the treated dog until liquid has dried.

Do not use on dogs under seven weeks of age or weighing less than [4 lbs] [11 lbs] [21 lbs] [55 lbs].

Do not apply more than 1 tube per treatment for one dog regardless of the dog's weight [, including dogs over 55 lbs.]. {the bracketed text will appear only on the package for dogs over 55 lbs.}

{Note to reviewer: either a plastic tube or aluminum tube will be chosen to use for the final product package}

{How to apply directions for plastic tube container:}

How to Apply

Dog must be dry at time of application and remain dry for 24 hours. The dog should be standing for the application. Remove tube from the package. Hold tube in a vertical upright position. Cut off top of tube with scissors. Part the hair at each spot until the skin is visible. Invert tube and place the open end of the tube on the skin of the dog. Squeeze tube to expel the entire content of liquid and apply the product evenly along the dog's back in 3 to 4 spots from the base of the skull to the base of the tail. Take care that liquid does not run off the dog. Avoid contact with treated area until dry.



{This icon will only be used for the spot application.}

{How to apply direction for aluminum/plastic tube container:}

How to Apply

Dog must be dry at time of application and remain dry for 24 hours. The dog should be standing for the application. Remove tube from the package. Hold tube in a vertical upright position. Screw [Pull] cap off of tube. While maintaining the tube in upright position, turn cap and puncture end of tube. Invert tube and apply the entire content of liquid to the skin of the dog evenly along the dog's back as a line from the base of the skull to the base of the tail. Take care that liquid does not run off the dog. Avoid contact with treated area until dry.

EPA Reg. No. 92334-1

{Note to reviewer: A dog icon that shows the application may be added to this section “how to Apply”}



[
{This icon will only be used for the line application.}

Discard empty tube as described in Storage and Disposal. In case of severe pest infestations, you are able to retreat your dog earlier than [four (4) weeks] [one (1) month]. If infestation is severe at the initiation of treatment, once a week treatment is permitted not to exceed more than 4 consecutive weeks. Such a retreatment regimen should occur only at the **initiation** of treatment with the product if infestation is severe. After pest control has been successful, please return to a monthly retreatment schedule.

STORAGE AND DISPOSAL

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

Storage: Store in a cool, dry place inaccessible to children and pets. Protect from freezing.

Pesticide Disposal and Container Handling: Nonrefillable container.

If empty: Do not reuse this container.

Place in trash or offer for recycling, if available.

If partly filled: Do not pour or dispose down-the-drain or sewer. Call your local solid waste agency or 1-800-XXX-XXXX for disposal instructions.

[LIMITED WARRANTY AND LIMITATION OF DAMAGES

Evergreen Animal Health, LLC warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW EVERGREEN MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Evergreen is authorized to do so except in writing with a specific reference to this warranty. To the extent consistent with applicable law, any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.]

[For consumer questions call 1-800-XXX-XXXX]

[For medical emergencies call 1-800-XXX-XXXX]

{**Tube Label**}

Evergreen II Spot On for Dogs

[4-10 lbs] [11-20 lbs] [21-55 lbs] [over 55 lbs] and 7 weeks & older

35.6% permethrin

7.12% imidacloprid

EPA Reg. No. 92334-1

0.36% pyriproxyfen

[0.016 fl oz (0.48 mL)] [0.041 fl oz (1.2 mL)] [0.101 fl oz (3.0 mL)] [0.162 fl oz (4.8 mL)]

{The correct net contents fl oz/mL will be on the corresponding tube}

EPA Reg. No. 92334-1



{Cat prohibition icon will be in black and white on tube}

Keep Out of Reach of Children

WARNING

Read Entire Label Before Use

Lot #

[For external use only]

{Note to reviewer: If there is still room on the tube, the phrase "For external use only" will be added to the tube label.}







{Optional/Alternate Claims, which may appear on carton}



- 1) For the prevention and treatment of Ticks, Fleas, Mosquitoes, Biting Flies and Lice on Dogs
- 2) Topical prevention and treatment of ticks, fleas and mosquitoes for dogs and puppies 7 weeks of age and older weighing [4-10 lbs] [11-20 lbs] [21-55 lbs] [over 55 lbs]
- 3) Preventative [treatment][control] of [ticks],[fleas], [mosquitoes][biting flies],and[lice] for monthly use on dogs and puppies 7 weeks of age and older weighing [4-10 lbs] [11-20 lbs] [21-55 lbs] [over 55 lbs]
- 4) Repels and kills [Kills and repels] ticks including Deer ticks [vector of Lyme disease], Brown dog ticks [vector of Ehrlichiosis], American dog ticks [vector of Rocky Mountain spotted fever], and Lone Star ticks [vector of Ehrlichiosis] for up to [four (4) weeks] [one month]
- 5) Evergreen II Spot On for Dogs contains imidacloprid, permethrin, and [an/the] [insect growth regulator] [IGR] pyriproxyfen
- 6) Evergreen II Spot On for Dogs contains [an] [the] [insect growth regulator] [IGR] [pyriproxyfen]
- 7) [One] [A] [single] [topical] application remains effective [for] [a month][four [4] weeks]
- 8) [One] [A] [single] [topical] application is effective [for] [a month][four [4] weeks]
- 9) Convenient [and easy] to [use] [apply] [Spot on [solution]] [topical [solution]]
- 10) Easy to [use] [apply] [Spot on [solution]] [topical [solution]]

- 11) [One] [A] [single] [topical] [application] prevents fleas [and flea [re-]infestations] [for] [a month][four [4] weeks]
- 12) [One] [A] [single] [topical] [application] prevents [fleas and] flea [re-]infestations [for] [a month][four [4] weeks]
- 13) [One] [A] [single] [topical] [application] prevents ticks [and tick [re-]infestations] [for] [a month][four [4] weeks]
- 14) [One] [A] [single] [topical] [application] prevents [ticks and] tick [re-]infestations [for] [a month][four [4] weeks]
- 15) Dead fleas don't bite
- 16) [Kills] [and] [repels] fleas before they lay eggs
- 17) Dead fleas don't lay eggs
- 18) Prevents flea egg hatching
- 19) [Flea adulticide] [Flea larvicide] [and] [Flea ovicide]
- 20) Flea adulticide, larvicide and ovicide
- 21) [Repels] [Inhibits] [annoying] [bothersome] nuisance biting flies [and] [fleas] [and] [ticks]
- 22) [Still] [Remains] effective after swimming [and] [shampooing]
- 23) [Kills] [and] [prevents] [biting] [chewing] lice
- 24) Prevents further infestations of [biting] [chewing] lice
- 25) Fragrance free
- 26) [Contains] no Fragrance
- 27) Monthly topical treatment kills and repels fleas, ticks and mosquitoes
- 28) Kills and repels all life stages of fleas
- 29) Repels and kills all stages of fleas
- 30) Kills and Repels Fleas, Ticks & Mosquitoes [for one month] [for [four] [4] weeks]
- 31) Repels and Kills Ticks, Fleas & Mosquitoes [for one month] [for [four] [4] weeks]
- 32) Kills fleas on dogs within 12 hours and continues to prevent infestations for [a month] [for [four] [4] weeks]
- 33) Controls flea infestation for [one month] [for [four] [4] weeks]
- 34) Prevents development of fleas, flea eggs, larvae and pupae for [one month] [for [four] [4] weeks]
- 35) Prevents development of fleas for [one month] [[four] [4] weeks]
- 36) Breaks flea life cycle for [one month] [[four] [4] weeks]
- 37) Repels and kills mosquitoes for [four (4) weeks] [one month]
- 38) Repels biting flies and prevents blood-feeding by biting flies
- 39) Water-proof
- 40) 5-way protection: Fleas, Ticks, Mosquitoes, Biting flies and Lice [insect icons may be used]
- 41) Kills chewing lice
- 42) Kills chewing lice & repels biting flies
- 43) Breaks the flea life cycle [graphic icon]
- 44) Easy to use Tube [Image]
- 45) For Dogs and Puppies 7 weeks of age and older weighing [4-10 lbs] [11-20 lbs] [21-55 lbs] [over 55 lbs]
- 46) Small Dog 7 weeks of age and older weighing 4-10 lbs {may be placed on any side of carton for appropriate dog age and weight range}

- 47) Medium Dog 7 weeks of age and older weighing 11-20 lbs {may be placed on any side of carton for appropriate dog age and weight range}
- 48) Large Dog 7 weeks of age and older weighing 21-55 lbs {may be placed on any side of carton for appropriate dog age and weight range}
- 49) Extra Large Dog 7 weeks of age and older weighing over 55 lbs {may be placed on any side of carton for appropriate dog age and weight range}
- 50) For [1 month][4 weeks]: [[Repels & Kills] [Kills & Repels] Fleas, Flea Eggs, Ticks and Mosquitoes],
- 51) [Prevents] [Repels] Biting Flies and [prevents] [and] [&] [kills] Lice
- 52) [One][Three][Four][Five][Six][Eight][Ten][Twelve] Month Supply* *(one tube = one month supply)

{Optional graphic images or icons:}

Fleas [Flea]	 FLEAS	
Flea eggs	 FLEA EGGS	
Ticks [Tick]	 TICKS	
Lice [Louse]	 LICE	
Repels Biting Flies [Biting Fly]	 REPELS BITING FLIES	
Mosquitoes [Mosquito]	 MOSQUITOES	

	
{Note to reviewer: example of the icon that will be used depending on the number of tubes in each carton}	
{Note to reviewer: example of the icon per Optional claim number 52 above}	

{Alternate Brand Names:}

{The word “Dog/s” will be 75% the height of the largest letter in the product name.}

Evergreen II Small Dog

Evergreen II Medium Dog

Evergreen II Large Dog

Evergreen II Extra Large Dog

Evergreen III Spot on for Dogs

Activate II for Dogs

Advance II For Dogs

Activate III for Dogs

Truveta III for Dogs

Activetix II for Dogs

Truветix III for Dogs

ActiGuard III for Dogs

Vetix III for Dogs

AvanTect II for Dogs

VanTect II for Dogs

Vantect II for Dogs

K9 Evergreen II Spot on for Dogs

K9 Evergreen III Spot on for Dogs

K9 Activate II for Dogs

K9 Advance II For Dogs

K9 Activate III for Dogs

K9 Truveta III for Dogs

K9 Activetix II for Dogs

K9 Truветix III for Dogs

K9 ActiGuard III for Dogs

K9 Vetix III for Dogs

K9 AvanTect II for Dogs

K9 VanTect II for Dogs

K9 Vantect II for Dogs