



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

EPA Reg. Number:

92334-1

Date of Issuance:

2/2/17

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
 Expires: 2/2/19

Name of Pesticide Product:

Evergreen II Spot On for Dogs

Name and Address of Registrant (include ZIP Code):

Robert Scharf, Managing Director
 Evergreen Animal health, LLC
 22655 Centennial Road
 Gretna, NE 68028

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:

Kable Bo Davis, Product Manager 03
 Invertebrate & Vertebrate Branch 1, Registration Division (7505P)

Date:

2/2/17

2. This registration is time-limited and expires 2/2/19.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. 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 cats and table for dogs 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, as applicable.
- 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, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- 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 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.

5. You are required to comply with the data requirements described in the DCI or EDSP Order identified below:
 - a. Imidacloprid GDCI-129099-951
 - b. Permethrin GDCI-109701-1252
 - c. Pyriproxyfen GDCI-129032-1299
 - d. Pyriproxyfen EDSP-129032-187

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

6. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
7. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 92334-1."
8. Submit one copy of the final printed label for the record before you release the product for shipment.

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.

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 04/19/2016

If you have any questions, you may contact Julie Breeden-Alemi at 703-347-0511 or via email at Breeden-Alemi.Julie@epa.gov.

Enclosure

[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 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	<u>56.92</u> %
TOTAL	100.00 %

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

**KEEP OUT OF REACH OF CHILDREN
WARNING**

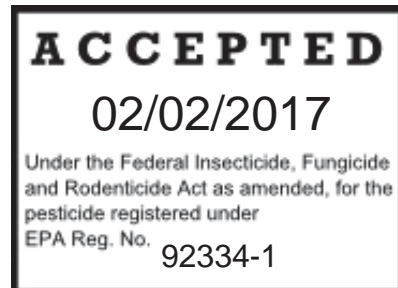
See First Aid and Directions for Use on back panel.

NET CONTENTS: [X fl oz (Y mL)]

[One] [Three] [Four] [Five] [Six] [Eight] [Ten] [Twelve] Tubes
[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)]

[1.5 cm x 1.5 cm cat prohibition icon]
DO NOT USE ON CATS

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



[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*]

*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]

[Back Panel of the Carton]

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.

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, although very rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Although uncommon, 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.]

[1.5 cm x 1.5 cm cat prohibition icon]
DO NOT USE ON CATS-MAY BE FATAL.
Keep cats away from treated dogs for 24 hours.
If applied to a cat or ingested by a cat, contact your veterinarian immediately.

[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.]

[Back Panel of the Carton]

PRODUCT INFORMATION

Evergreen II Spot On for Dogs rapidly kills fleas and may reduce the incidence 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 further flea infestation lasts at least four (4) weeks.

Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climate. Flea larvae in the dog's surroundings are killed following contact with an Evergreen II Spot On for Dogs treated dog. 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. For best results, use monthly treatments for flea and tick control.

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

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.

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.

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 per dog.

Do not apply more than 1 tube per treatment for dogs over 55 lbs. [This restriction 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

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.

[How to apply direction for aluminum/plastic tube container:]

How to Apply

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.

Discard empty tube as described in Storage and Disposal. In case of severe pest infestations, you are able to retreat your dog earlier than (4) four weeks. If infestation is severe at the initiation of treatment, once a week treatment is permitted not to exceed 4 weeks. After pest control has been successful, please return to a monthly retreatment schedule.

[Note to reviewer: A dog icon that shows the application may be added to this section "how to Apply"]



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: Call your local solid waste agency or 1-800-XXX-XXXX for disposal instructions.

Never place unused product down any indoor or outdoor drain.

[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
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)]

EPA Reg. No. 92334-1

Cat prohibition icon [Do not use on cats.]

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 weeks [for up to 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 up to one month] [for up to [four] [4] weeks]

- 31) Repels and Kills Ticks, Fleas & Mosquitoes [for up to one month] [for up to [four] [4] weeks]
- 32) Prevents fleas on dogs from infesting your home
- 33) Kills fleas on dogs within 12 hours and continues to prevent infestations for a month [for [four] [4] weeks]
- 34) Controls flea infestation for up to one month [for up to [four] [4] weeks]
- 35) Prevents development of fleas, flea eggs, larvae and pupae for up to one month [for up to [four] [4] weeks]
- 36) Prevents development of fleas for up to one month [for up to [four] [4] weeks]
- 37) Breaks flea life cycle for up to one month [for up to [four] [4] weeks]
- 38) Repels and kills mosquitoes for up to four weeks
- 39) Repels biting flies and prevents blood-feeding by biting flies
- 40) Water-proof
- 41) 5-way protection: Fleas, Ticks, Mosquitoes, Biting flies and Lice [insect icons may be used]
- 42) Kills chewing lice
- 43) Kills chewing lice & repels biting flies
- 44) Breaks the flea life cycle [graphic icon]
- 45) Easy to use Applicator [Image]
- 46) For Dogs and Puppies 7 weeks of age and older weighing [4-10 lbs] [11-20 lbs] [21-55 lbs] [over 55 lbs]
- 47) Small Dog [4-10 lbs]
- 48) Medium Dog [11-20 lbs]
- 49) Large Dog [21-55 lbs]
- 50) Extra Large Dog [over 55 lbs]
- 51) [For up to 1 month][4 weeks]: [Kills & Repels] [Repels & Kills] Fleas, Flea Eggs, Ticks and Mosquitoes
- 52) [For up to 1 month][4 weeks]: [Prevents] [Repels] Biting Flies and [prevents] [and] [&] [kills] Lice

[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	

Image of flea life cycle
Do Not Use on Cat prohibition icon
Tube, Tubes
Application procedures

[Alternate Brand Names:]

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