



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

March 28, 2024

Evergreen Animal Health
c/o Brien O'Loughlin, Agent
Pyxis
4110 136th St. Ct. NW
Gig Harbor, WA 98332

Subject: Label Notification per PRN 98-10 – adding 2 vial packaging
Product Name: Evergreen II Spot On for Dogs
EPA Registration Number: 92334-1
Application Date: 2/23/2024
Case Number: 501609

Dear Brien O'Loughlin:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "NOTIFICATION" and placed in our records.

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 (FIFRA) 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.

If you have any questions, please contact Autumn Metzger at 202-566-2830 or at Metzger.autumn@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Beth Fertich", followed by the word "for" written in a smaller, simpler script.

Beth Fertich, Product Manager 04 Invertebrate
& Vertebrate Branch 1 Registration Division
(7505P)
Office of Pesticide Programs

NOTIFICATION

92334-1

() = text included on label

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

[] = optional

{ } = notes to reviewer

EPA Reg. No. 92334-1

{Front Panel of Carton}

03/28/2024

Evergreen II Spot on for Dogs

{Note to reviewer: The word "Dogs" in the product brand name will be at least 40-75% the height of the largest letter in the primary brand name.}

{Note to reviewer: Alternate Brand Names are listed at the end of this label}

{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 for Fleas, Ticks, Mosquitoes, Biting Flies and Lice on 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	<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:

- [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]
- [Two [0.032 fl oz (0.96 mL)] [0.082 fl oz (2.4 mL)] [0.202 fl oz (6.0 mL)] [0.324 fl oz (9.6 mL)] Tubes]
- [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]

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{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 K9 Advantix 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][Brand name] 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] [Brand name] contains Imidacloprid, pyriproxyfen and permethrin, the active ingredients used in K9 Advantix® II for Dogs *

*This product is not manufactured or distributed by Elanco US, Inc., the maker of K9 Advantix® II for Dogs. [K9 Advantix® II for Dogs is a registered trademark of Elanco.]

{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 8 through 9.}

{EPA Reg. No. and EPA Est. No. will be found either on front, back panel or side panel of carton}

[EPA Reg. No. 92334-1]

[EPA Est. No.]

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EPA Reg. No. 92334-1

{Back Panel of the Carton}

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.}



**DO NOT
USE ON
CATS**

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.

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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. Use only on dogs or puppies seven weeks of age or older and weighing 4-10 lbs [11-20 lbs] [21-55 lbs] [over 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.

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 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}

PRODUCT INFORMATION

Evergreen II Spot On for Dogs[This product] [Brand name] 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[This product] [Brand name] 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

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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 [Brand name] treatment. Evergreen II Spot On for Dogs[This product] [Brand name] 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 for Fleas, Ticks, Mosquitoes, Biting Flies and Lice on Dogs

{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.

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



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

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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. Do not bathe dog for 24 hours after application.

{Note to reviewer: Storage and Disposal language will be located either on the back of the carton or on a side panel.}

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place inaccessible to children and pets. Protect from freezing. ^[] _[SEP]

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.

Do not pour or dispose down-the-drain or sewer.

[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]

[If you have questions or comments about this product, please write:

Evergreen Animal Health, LLC

22655 Centennial Road

Gretna, Nebraska 68028]

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

[In case of emergency, call 1-800-775-9416]

[Non-emergency, call 1-xxx-xxx-xxxx]

{EPA Reg. No. and EPA Est. No. will be found either on front, back panel or side panel of carton}

[EPA Reg. No. 92334-1]

[EPA Est. No.]

{SIDE PANELS OF CARTON}

{Note to reviewer: Storage and Disposal language will be located either on the back of the carton or on a side panel. EPA Reg. No. and EPA Est. No. will be found either on back panel or side panel of carton }

Evergreen II Spot on for Dogs – ~~4/4/2023~~2/23/2024
~~4/9/2020~~4/4/2023]

[LAST EPA APPROVAL DATE-

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EPA Reg. No. 92334-1

[Evergreen II Spot On for Dogs][Brand Name]

[EPA Reg. No. 92234-1]

[EPA Est. No.]

Lot/Batch Number

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{Tube Label}

Evergreen II Spot On for Dogs[Brand name]

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)]

{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.}

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

- 1) For the prevention and treatment of Ticks, Fleas, [Flea Eggs,] Mosquitoes, Biting Flies and Lice on Dogs
- 2) Topical prevention and treatment for ticks, fleas and mosquitoes on 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] for 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[brand name] contains imidacloprid, permethrin, and [the insect growth regulator] [IGR] pyriproxyfen
- 6) Evergreen II Spot On for Dogs[Brand Name] 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 to use [and easy to 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 [Flea Eggs], [Ticks] & [Mosquitoes] for one month [for four [4] weeks]
- 31) Repels and Kills Ticks, [Fleas],[Flea Eggs] & Mosquitoes for one month [for four [4] weeks]
- 32) Repels and Kills [Kills and Repels] Fleas, [Flea Eggs], [Ticks] [,&] Mosquitoes [,&] [lice]
- 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 one month [four] [4] weeks]

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- 35) Prevents development of fleas, flea eggs, larvae and pupae for one month [four [4] weeks]
- 36) Prevents development of fleas for one month [[four] [4] weeks]
- 37) Breaks flea life cycle for one month [[four] [4] weeks]
- 38) Repels and kills mosquitoes [for four (4) weeks][one month]
- 39) Repels biting flies and prevents blood-feeding by biting flies
- 40) Water-proof
- 41) 5-way protection [Controls: 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 Tube {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 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}
- 48) 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}
- 49) 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}
- 50) 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}
- 51) Protects For 1 month[4 weeks]: Repels & Kills [Kills & Repels] Fleas, Flea Eggs, Ticks and Mosquitoes
- 52) Prevents [Repels] Biting Flies and [prevents] [and] [&] [kills] Lice
- 53) One[Two][Three][Four][Five][Six][Eight][Ten][Twelve] Month[s] Supply* *(one tube = one month supply)
- 54) Club Pack –4 dose + 4 dose[=][8 month supply] [5 dose + 5 dose][=] [10 month supply][6 dose + 6 dose] [=] [12 month supply][1 year supply]
- 55) Twin Pack –4 dose + 4 dose[=][8 month supply] [5 dose + 5 dose][=][10 month supply] [6 dose + 6 dose][=][12 month supply][1 year supply]
- 56) Small Dog 4-10 lbs 7 weeks of age and older
- 57) Medium Dog 11-20 lbs 7 weeks of age and older
- 58) Large Dog 21-55 lbs 7 weeks of age and older
- 59) X-Large Dog Over 55 lbs 7 weeks of age and older
- 60) X-Large Dog Over 55 lbs 7 weeks of age and older















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{Optional graphic images or icons:}




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

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

{Alternate Brand Names:}

{The word “Dog/s” will be 40-75% 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
- 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 Truветix III for Dogs
- K9 ActiGuard III for Dogs
- K9 Vetix III for Dogs
- K9 AvanTect II for Dogs