



U.S. ENVIRONMENTAL PROTECTION AGENCY

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

EPA Reg. Number:

11556-143

Date of Issuance:

5/31/17

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
Expires: 05/31/2019

Name of Pesticide Product:

K9 Advantix II Large Dog

Name and Address of Registrant (include ZIP Code):

Todd Frank
Regulatory Affairs Consultant
Bayer U.S.
Animal Health Research & Development
P.O. Box 390
Shawnee Mission, KS 66201-0390

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:

Sincerely,

Gene Benbow, Acting Product Manager 4
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Date:

5/31/17

EPA Form 8570-6

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 05/31/2019.
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 an Agency letter dated 05/20/2013.
4. You are required to comply with the data requirements described in the DCI identified below:
 - a. Imidacloprid GDCI-129099-951
 - b. Permethrin GDCI-109701-1252
 - c. Permethrin GDCI-109701-1281
 - d. Pyriproxyfen GDCI-129032-1299

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: <http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

5. 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 CSFs:

- Basic CSF dated 09/02/2009

If you have any questions, please contact Helen Hull-Sanders by phone at 703-347-0243, or via email at hull-sanders.helen@epa.gov.

NOTE TO REVIEWER: Braces “{ }” indicate notes to reviewr. Brackets “[]” indicate alternate language.

{Front Panel}

K9 Advantix® II Large Dog

{The “Large Dog” text size will be 75% of the height of the largest letter in the primary brand name.}

{A large, clear picture of a dog in the weight range for the product will be on the front panel.}

Topical prevention and treatment of ticks, fleas, mosquitoes, biting flies, and lice for monthly use only on dogs and puppies 7 weeks of age and older, and weighing 21 - 55 lbs.

{Selected optional claims bulleted here from page 9 and/or 10}

•

ACTIVE INGREDIENTS	%
	By Weight
Imidacloprid.	8.80%
Permethrin*	44.00%
Pyriproxyfen.	0.44%
OTHER INGREDIENTS	46.76%
Total	100.00%

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

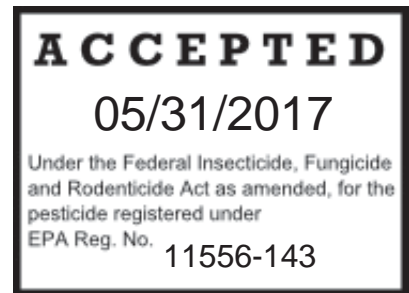
EPA Est. No. 11556-XXX-X

EPA Reg No. 11556-143

KEEP OUT OF REACH OF CHILDREN

WARNING

See back panel for Precautionary Statements, Restrictitons and First Aid.



{Icon Size 1.5 cm X 1.5 cm cat prohibition icon shall be placed in a box located at the lower right hand corner of the front panel in yellow with black images }

{Back Panel}

K9 Advantix® II Large Dog

Topical prevention and treatment of ticks, fleas, mosquitoes, biting flies, and lice for monthly use only on dogs and puppies 7 weeks of age and older, and weighing 21 - 55 lbs.

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Ticks, Fleas, Mosquitoes, Biting Flies and Lice on Dogs

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, 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 puppies under seven (7) weeks of age and weighing 21 - 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 animals. Individual sensitivities, may occur after using ANY pesticide product for dogs. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product.

{ A box labeled "Side Effects" will be immediately above the cat warning box on the back panel }

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 (such as lethargy or agitation) occur, consult your veterinarian or call 1-800-422-9874.

{ A "Fatality box" will be located immediately below the Side Effects box in the lower right hand corner of the back panel. The box will include 1.5cm X 1.5 cm cat prohibition icon and warning text in yellow and black images and text. }



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.

For consumer questions call 1-800-255-6826.

For medical emergencies call 1-800-422-9874.

ENVIRONMENTAL HAZARDS

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

{ Back Panel and Insert }

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 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 the poison control center or doctor. • Do not give anything 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. You may also contact 1-800-422-9874 for emergency medical treatment information. For consumer questions call 1-800-255-6826.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not contaminate feed or food.



HOW TO OPEN

K9 Advantix II Large na

[OPTION 1: INSTRUCTIONS FOR BLISTER PACK]

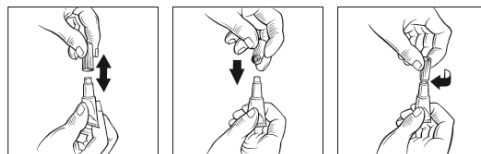
1. Being careful not to cut close to the blister cavities, take scissors and cut off one section of the card containing a single tube.
2. Take the separated section, and cut into the blister cavity across the small side, close to the cap of the tube.
3. Peel off the foil, and take out the tube.

[OPTION 2: INSTRUCTIONS FOR POUCH PACK]

1. Be sure tube is at bottom of pouch.
2. Using scissors, cut the pouch across the top and remove tube.

HOW TO APPLY

1. Remove applicator tube from the package. [Use scissors and peel down foil.]
2. Hold applicator tube in an upright position. Pull cap off tube.



3. Turn the cap around and place other end of cap back on tube.
4. Twist cap to break seal, then remove cap from tube.
5. The dog should be dry and standing for easy application. Evenly apply the entire contents of the K9 Advantix® II tube to four to six spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin.



6. Discard empty tube as described in Storage and Disposal.
7. In case of severe pest infestation, re-treatment is allowable after the initial application earlier than (4) four weeks. Do not retreat more often than once every seven (7) days not to exceed 4 weekly treatments. After pest control is attained, return to a monthly retreatment schedule.

Restrictions:

Do not allow children to apply product.
Avoid contact with treated area until dry.
Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.
Do not get this product in your dog's eyes, or allow your dog to ingest this product.
Do not bathe or allow dog to swim for 24 hours.

PRODUCT INFORMATION

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with K9 Advantix® II rapidly kills fleas and may reduce the incidence of this condition.

K9 Advantix® II kills existing fleas on dogs after initial application within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting at least four (4) weeks. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions.

K9 Advantix® II is waterproof and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight.

Monthly treatments are required for optimal control and prevention of fleas and ticks.

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. **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 1-800-422-9874 for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC, Animal Health Division warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer 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 additional information visit www.k9advantix.com

Net Contents: [1, 2, 4, 6] Tube(s) each 0.084 fl. oz. (2.5 mL)

{The sample package is only the one tube package size [Sample – Not for (Re)Sale]}

Manufactured For
Bayer HealthCare LLC
P.O. BOX 390
Animal Health Division
Shawnee Mission, Kansas 66201 USA

Made in Germany

{Back Panel and/or Bottom}

Lot No.

{Label on Individual Tube}

K9 Advantix[®] II Large Dog

8.8% imidacloprid
44.0% permethrin
0.44% pyriproxyfen

0.084 fl. oz. (2.5 mL)

EPA Reg. No. 11556-143

Keep out of reach of children

WARNING

DO NOT USE ON CATS

Read The Entire Label Before Use

BAYER

Lot No. 0000000

{OPTION 1: Label on blister pack; one card containing 1, 2, 3, 4, 5, or 6 tubes}
{OPTION 2: Label on pouch containing one tube}

{Additional label text for OPTION 2: THIS UNIT NOT FOR RETAIL SALE}

K9 Advantix[®] II Large Dog

For external use only on dogs and puppies 7 weeks and older and weighing 21 - 55 lbs.

See insert for complete product information.

8.8% imidacloprid
44.0% permethrin
0.44% pyriproxyfen

[X] - 0.084 fl. oz. (2.5 mL) Tube(s)

EPA Reg. No. 11556-143

BAYER

Lot No. 0000000



Do Not Use on Cats

NOTE TO REVIEWER: [Brackets indicate alternate language]

OPTIONAL MARKETING CLAIMS

1. For use on dogs and puppies 7 weeks of age and older and weighing 21 – 55 lbs
2. K9 Advantix[®] II contains [imidacloprid], [permethrin] and [an/the] [insect growth regulator] [IGR] [pyriproxyfen]
3. A single topical application remains effective for [a month][four (4) weeks]
4. Convenient, easy to apply topical solution
5. Once a month topical flea treatment for dogs 7 weeks of age or older and weighing 21 – 55 lbs
6. K9 Advantix[®] II is for the prevention and treatment of fleas, ticks, biting flies, mosquitoes, and lice on dogs 7 weeks of age and older and weighing 21 – 55 lbs
7. Repels and kills ticks, fleas and mosquitoes
8. For the treatment and prevention of flea infestations
9. One treatment prevents further flea infestations for [a month][four (4) weeks]
10. Kills fleas on dogs within 12 hours and continues to prevent infestations for [a month][four (4) weeks]
11. Repels and kills fleas before they lay eggs
12. Kills fleas within 12 hours of application
13. Controls existing flea infestations by rapidly killing adult fleas Prevents reinfestations by killing adult fleas before they lay eggs
14. Prevents flea eggs from hatching
15. Effectively breaks the flea life cycle
16. Flea adulticide, larvicide and oocide.
17. Prevents fleas on treated dogs from infesting (reinfesting) your home.
18. Effectively targets all [life] stages of [fleas] and [ticks]
19. 3-way flea protection [[kills] [controls] adults, larvae, and eggs]
20. Prevents development of fleas, flea eggs, pupae and larvae [for [a month][four (4) weeks]
21. Prevents development of all flea stages [for [a month][four (4) weeks]
22. Repels and kills all [life] stages of fleas
23. Prevents flea eggs [and flea larvae] from developing into [biting] [adult] fleas
24. Treatment with K9 Advantix[®] II rapidly kills fleas and may reduce the incidence of Flea Allergic Dermatitis [FAD]
25. Repels and kills ticks, including Deer ticks [vector of Lyme disease and anaplasmosis], American dog ticks [vector of Rocky Mountain spotted fever, tularemia and ehrlichiosis], Brown dog ticks [vector of ehrlichiosis, anaplasmosis, bartonellosis, canine hemoplasmosis, babesiosis and Rocky Mountain spotted fever], and Lone Star ticks [vector of ehrlichiosis and tularemia]
26. Repels and kills mosquitoes for up to four weeks that may transmit [heartworm disease] [Dirofilaria immitis], West Nile Virus
27. Repels and kills mosquitoes often before they have a chance to take a blood meal
28. [Prevents blood-feeding by] [Kills and repels] mosquitoes
29. Repels, and inhibits blood-feeding by biting flies
30. Repels, and prevents blood-feeding by biting flies
31. Repels [annoying][bothersome][nuisance] biting flies

32. Inhibits [annoying][bothersome][nuisance] biting flies
33. [Prevents][inhibits] blood-feeding by biting flies
34. Remains effective after bathing and/or swimming
35. Remains effective following swimming and/or shampooing
36. Kills [biting] [chewing] lice
37. For treatment and prevention of [biting] [chewing] lice [infestations]
38. Controls existing [biting] [chewing] lice infestations
39. 5-way protection [against fleas, ticks, biting flies, mosquitoes, and lice]
40. Treats, prevents and controls [biting] [chewing] lice [infestations]
41. Provides effective control of [biting] [chewing] lice [infestations]
42. Kills [biting] [chewing] lice and prevents further infestations
43. For treatment and prevention of infestations with [biting] [chewing] lice
44. Waterproof
45. Remains effective after exposure to rain or sunlight
46. Fragrance free