



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 13, 2017

J. Todd Frank
Regulatory Affairs Consultant
Bayer HealthCare LLC
Animal Health
P.O. Box 390
Shawnee Mission, KS 66201

Subject: Label Amendment – Addition of marketing claims and minor label revisions.
Product Name: K9 Advantix II Small Dog
EPA Registration Number: 11556-141
Application Date: August 19, 2016
Decision Number: 520651

Dear Mr. Frank:

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 Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a hand-drawn oval.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

Reason To Issue: Addition of optional text.

Date: 08/18/2016

Supersedes: 10/24/2013

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NOTE TO REVIEWER: [(Brackets and parentheses indicate alternate language)]

[Front Panel]

K9 Advantix® II Small Dog

Note: [The “Small Dog” text size will be 75% of the height of the largest letter in the primary brand name.]

Visual image of a dog within the weight range for product.

Topical prevention and treatment of ticks, fleas, mosquitoes, biting flies, and lice for monthly use only on (small) dogs and puppies 7 weeks of age and older and weighing 4 - 10 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	<u>46.76%</u>
Total	100.00%

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

EPA Est. No. 11556-XXX-X

EPA Reg No. 11556-141

KEEP OUT OF REACH OF CHILDREN

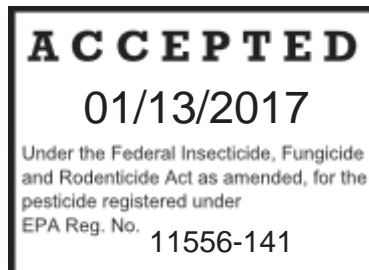
WARNING

See back panel for Precautionary Statements, Restrictions and First Aid.
For Directions for Use, Storage and Disposal, and First Aid, see package insert inside.



[Icon Size 1.5 cm X 1.5 cm, Background yellow with black text positioned in the lower right hand of package]

K9Advantix II Small mb



[Back Panel]

K9 Advantix® II Small Dog

Topical prevention and treatment of ticks, fleas, mosquitoes, biting flies, and lice for monthly use only on (small) dogs and puppies 7 weeks of age and older and weighing 4 - 10 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 weeks of age or weighing less than 4 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.

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.



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****[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.

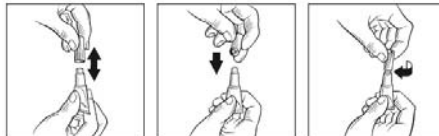
4. Repeat steps 1 to 3 for each tube.

[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. Use only on dogs. **DO NOT USE ON CATS** or on other animals. Do not apply to dogs weighing less than 4 lbs.
2. Remove applicator tube from the package. [Use scissors and peel down foil.]
3. Hold applicator tube in an upright position. Pull cap off tube.



4. Turn the cap around and place other end of cap back on tube.
5. Twist cap to break seal, then remove cap from tube.
6. The dog should be standing for easy application. Evenly apply the entire contents of the K9 Advantix® II tube to two to three 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. 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.



7. Discard empty tube as described in Storage and Disposal.
8. In cases of severe pest infestation, retreatment is allowable earlier than four (4) weeks. Do not retreat more often than once every seven (7) days. After pest control is attained, return to a monthly retreatment schedule.

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 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. 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

Reason To Issue: Addition of optional text.

Date: 08/18/2016

Supersedes: 10/24/2013

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Net Contents: Tube(s) each 0.014 fl. oz. (0.4 mL)

[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 Small Dog

8.8% imidacloprid

44.0% permethrin

0.44% pyriproxyfen

0.014 fl. oz. (0.4 mL)

EPA Reg. No. 11556-141

Keep out of reach of children

WARNING

DO NOT USE ON CATS

Read The Entire Label Before Use

BAYER

Lot No. 0000000

Reason To Issue: Addition of optional text.

Date: 08/18/2016

Supersedes: 10/24/2013

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[OPTION 1: Label on blister card; 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 Small Dog

For external use only on dogs and puppies 7 weeks and older and weighing 4 - 10 lbs.

See insert for complete product information.

8.8% imidacloprid

44.0% permethrin

0.44% pyriproxyfen

[X] - 0.014 fl. oz. (0.4 mL) Tube(s)

EPA Reg. No. 11556-141

BAYER

Lot No. 0000000



Do Not Use on Cats

NOTE TO REVIEWER: [(Brackets and parentheses indicate alternate language)]

OPTIONAL MARKETING CLAIMS

- For use on dogs and puppies 7 weeks of age and older
- K9 Advantix[®] II contains [imidacloprid], [permethrin] and [an/the] [insect growth regulator] [IGR] [pyriproxyfen]
- A single topical application remains effective for [(a month)(four (4) weeks)]
- Convenient, easy to apply topical solution
- Once a month topical flea treatment for dogs 7 weeks of age or older
- 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
- Repels and kills ticks, fleas and mosquitoes
- For the treatment and prevention of flea infestations
- One treatment prevents further flea infestations for [(a month)(four (4) weeks)]
- Kills fleas on dogs within 12 hours and continues to prevent infestations for [(a month)(four (4) weeks)]
- Repels and kills fleas before they lay eggs
- Kills fleas within 12 hours of application
- Controls existing flea infestations by rapidly killing adult fleas
- Prevents reinfestations by killing adult fleas before they lay eggs
- Prevents flea eggs from hatching
- Effectively breaks the flea life cycle
- Flea adulticide, larvicide and ovicide.
- Prevents fleas on treated dogs from infesting (reinfesting) your home.
- Effectively targets all [life] stages of [fleas] and [ticks]
- 3-way flea protection ([kills] [controls] adults, larvae, and eggs)
- Prevents development of fleas, flea eggs, pupae and larvae [for (a month)(four (4) weeks)]
- Prevents development of all flea stages [for (a month)(four (4) weeks)]
- Repels and kills all [life] stages of fleas
- Prevents flea eggs [and flea larvae] from developing into [(biting) (adult)] fleas
- Treatment with K9 Advantix[®] II rapidly kills fleas and may reduce the incidence of Flea Allergic Dermatitis [FAD]
- 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)
- Repels and kills mosquitoes for up to four weeks that may transmit (heartworm disease) (*Dirofilaria immitis*), West Nile Virus
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [(Prevents blood-feeding by) (Kills and repels)] mosquitoes
- Repels, and inhibits blood-feeding by biting flies

- Repels, and prevents blood-feeding by biting flies
- Repels [(annoying)(bothersome)(nuisance)] biting flies
- Inhibits [(annoying)(bothersome)(nuisance)] biting flies
- [(Prevents)(inhibits)] blood-feeding by biting flies
- Remains effective after bathing and/or swimming
- Remains effective following swimming and/or shampooing
- Kills [(biting) (chewing)] lice
- For treatment and prevention of [(biting) (chewing)] lice [infestations]
- Controls existing [(biting) (chewing)] lice infestations
- Treats, prevents and controls [(biting) (chewing)] lice [infestations]
- Provides effective control of [(biting) (chewing)] lice [infestations]
- Kills [(biting) (chewing)] lice and prevents further infestations
- For treatment and prevention of infestations with [(biting) (chewing)] lice
- Waterproof
- Remains effective after exposure to rain or sunlight
- Fragrance free