

11556-144

11/19/2013

1114



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Mr. J. Todd Frank  
Bayer HealthCare LLC  
Animal Health Division  
P.O. Box 390  
Shawnee Mission, KS 66201-0390

NOV 19 2013

Subject: Label Notification(s) for Pesticide Registration Notice 98-10.

Dear Mr. Frank:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 October 25 2013, for the following product(s):

**K9 Advantix II Extra Large Dog      EPA Reg. No. 11556-144**

The Registration Division (RD) has conducted a review of this request for applicability under PR Notice 98-10 and finds that the label change(s) requested falls within the scope of PRN 98-10. The label has been date-stamped "Notification" and will be placed in our records.

If you have any questions, please contact Linda A. DeLuise at 703-305-5428.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard J. Gebken".

Richard J. Gebken  
Product Manager (10)  
Insecticide Branch  
Registration Division (7504P)

2114

Print Form

	United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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**Application for Pesticide - Section I**

<b>1. Company/Product Number</b> 11556-144	<b>2. EPA Product Manager</b> Richard Gebken	<b>3. Proposed Classification</b> <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
<b>4. Company/Product (Name)</b> • K9 Advantix II Extra Large Dog	<b>PM#</b> Team Number 10	
<b>5. Name and Address of Applicant (Include ZIP Code)</b> Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390  <input type="checkbox"/> Check if this is a new address		<b>6. Expedited Review.</b> In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar to _____ in composition and labeling to: <input checked="" type="checkbox"/> EPA Reg. No. <u>                    </u> <b>NOV 19 2013</b> Product Name <u>                    </u>

**Section - II**

<input type="checkbox"/> Amendment - Explain below.  <input type="checkbox"/> Resubmission in response to Agency letter dated _____  <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application.  <input type="checkbox"/> Other - Explain below.
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**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Notification per PR Notice 98-10:  
 Addition of optional text.

E-mail Contact: todd.frank@bayer.com

**Section - III**

<b>1. Material This Product Will Be Packaged In:</b>			
<b>Child-Resistant Packaging</b> <input type="checkbox"/> Yes* <input type="checkbox"/> No	<b>Unit Packaging</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>Water Soluble Packaging</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>2. Type of Container</b> <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted If "Yes" Unit Packaging wgt.    No. per container		If "Yes" Package wgt    No. per container	
<b>3. Location of Net Contents Information</b> <input type="checkbox"/> Label <input type="checkbox"/> Container		<b>4. Size(s) Retail Container</b>	<b>5. Location of Label Directions</b> <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
<b>6. Manner in Which Label is Affixed to Product</b> <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

**Section - IV**

**1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)**

<b>Name</b> J. Todd Frank	<b>Title</b> Reg. Affairs Consultant	<b>Telephone No. (Include Area Code)</b> 913-268-2585
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<p style="text-align: center;"><b>Certification</b></p> <p>I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.</p>	<b>6. Date Application Received (Stamped)</b> Received _____ (Stamped) _____ _____ _____ _____ _____ _____ _____ _____
<b>2. Signature</b> 	<b>3. Title</b> Regulatory Affairs Consultant
<b>4. Typed Name</b> J. Todd Frank	<b>5. Date</b> 10/25/2013

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# Bayer HealthCare

Via Federal Express

October 25, 2013

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken/PM 10

Subject: Addition of optional text:

- ~~K9 Advantix II Small Dog; EPA Reg. No. 11556-141~~
- ~~K9 Advantix II Medium Dog; EPA Reg. No. 11556-142~~
- ~~K9 Advantix II Large Dog; EPA Reg. No. 11556-143~~
- K9 Advantix II Extra Large Dog; EPA Reg. No. 11556-144

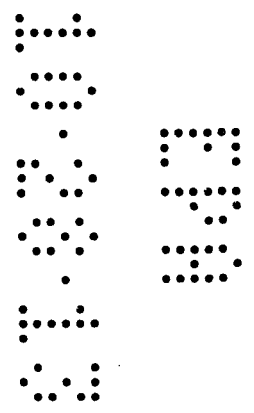
Bayer HealthCare LLC  
Animal Health  
P.O. Box 390  
Shawnee Mission, KS  
66201-0390

Dear Mr. Gebken:

Please find enclosed four Applications for Pesticide Notification. For each of the subject products we have included <sup>two</sup> ~~four~~ (2) copies, one highlighted label and ~~one~~ (1) unhighlighted.

Bayer Animal Health is adding the optional text, 'store use only,' to the subject labels. As you may recall, Bayer originally submitted a notification on August 9, 2013 for alternate brand names and this additional text; however that package was rejected based upon unacceptable alternate brand names. Therefore this is the identical submission, but without any alternate brand names as allowed by PR Notice 98-10.

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."



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If you have any questions, please do not hesitate to call (913) 268-2585.

Sincerely,



J. Todd Frank  
Regulatory Affairs Consultant  
[todd.frank@bayer.com](mailto:todd.frank@bayer.com)

Enclosures:

- 1) K9 Advantix Small Dog - Application w/att.
- 2) K9 Advantix Medium Dog - Application w/att.
- 3) K9 Advantix Large Dog - Application w/att.
- 4) K9 Advantix Extra Large Dog - Application w/att.

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

### K9 Advantix® II Extra 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 over 55 lbs.

[Selected optional claims bulleted here from page 9 and/or 10]

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- 
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**NOTIFICATION**

**NOV 19 2013**

Active Ingredients	% By Weight
Imidacloprid. ....	8.80%
Permethrin* .....	44.00%
Pyriproxyfen. ....	0.44%
Other Ingredients .....	46.76%
<b>Total</b> .....	<b>100.00%</b>

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

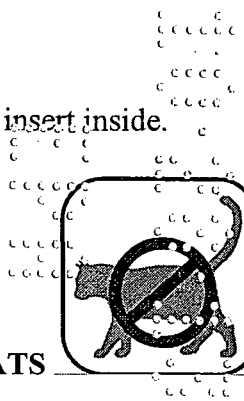
EPA Est. No. 11556-DEU-1

EPA Reg No. 11556-144

**KEEP OUT OF REACH OF CHILDREN**

### WARNING

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



**DO NOT USE ON CATS**

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### K9 Advantix® II Extra 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 over 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. 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, while rare, 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, although very rare, 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.

<b>FIRST AID</b>	
<b>If in Eyes:</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If Swallowed:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything to an unconscious person.</li> </ul>
<b>If on Skin or Clothing:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15 – 20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>HOT LINE NUMBER</b>	
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.	
<b>NOTE TO PHYSICIAN</b>	
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.

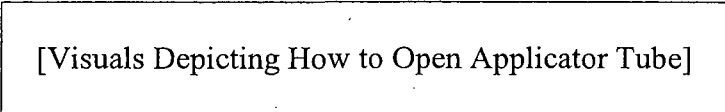
3. Peel off the foil, and take out the tube.
4. Repeat steps 1 to 3 for each tube.

**[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.
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. The entire contents of the K9 Advantix® II tube should be applied evenly 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. 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.

Larval flea stages in the dog's surroundings are killed following contact with a K9 Advantix® II treated dog.

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.

For dogs over 55 lbs., do not apply more than 1 tube per treatment.

**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.petparents.com](http://www.petparents.com)

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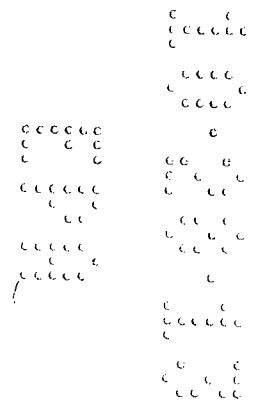
Net Contents: [X] Tube(s) each 0.135 fl. oz. (4.0 mL)

[Sample – Not for (Re)Sale]

[Store Use Only]

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

Made in Germany



(Label on Individual Tube)

### K9 Advantix<sup>®</sup> II Extra Large Dog

8.8% imidacloprid  
44.0% permethrin  
0.44% pyriproxyfen

0.135 fl. oz. (4.0 mL)

EPA Reg. No. 11556-144

#### WARNING

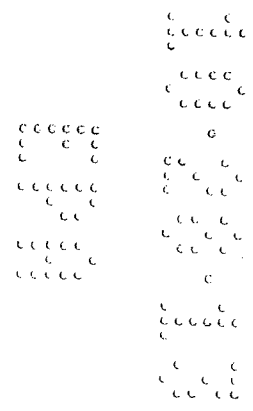
Keep out of reach of children

**DO NOT USE ON CATS**

Read The Entire Label Before Use

**BAYER**

Lot No. 0000000



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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 Extra Large Dog

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

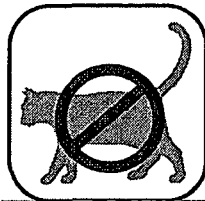
- 8.8% imidacloprid
- 44.0% permethrin
- 0.44% pyriproxyfen

[X] - 0.135 fl. oz. (4.0 mL) Tube(s)

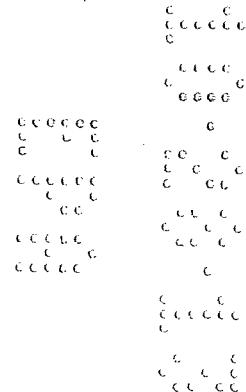
EPA Reg. No. 11556-144

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 indicated 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
- Larval flea stages in the dog's surroundings are killed following contact with a K9 Advantix® II treated dog
- Kills larval stages of fleas in the dog's environment following contact with K9 Advantix® II treated dog
- 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), American dog ticks (vector of Rocky Mountain spotted fever), Brown dog ticks (vector of Ehrlichiosis), and Lone Star ticks (vector of Ehrlichiosis) for up to four weeks
- Repels and kills mosquitoes for up to four weeks

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- 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
- 5-way protection (against fleas, ticks, biting flies, mosquitoes, and lice)
- 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

