

11556-135

2/5/2010

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Douglas A. Spilker, Ph.D.
Product Registration
Bayer HealthCare, LLC
P.O. Box 390
Shawnee Mission, KS 66201-9390

FEB 5 2010

SUBJECT: Application for Pesticide Notification (PRN 98-10)
Request General Label Change Statement and Larger Product Size
EPA Reg. No. 11556-132, 11556-133, 11556-135 and 11556-134
Application Dated December 7, 2009

Dear Registrant:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 12/07/09 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Owen F. Beeder of my staff at 703-308-8899.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Arrington".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

2011

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11556-135	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) K9 Advantix 55	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) 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	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: <input checked="" type="checkbox"/> EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION FEB - 5 2010
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See attachment (1p.) for more information.
Contact: doug.spilker.b@bayer.com

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	<input checked="" type="checkbox"/> Glass	
				<input checked="" type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1/4/6-2.5mL tbe		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Douglas A. Spilker, Ph.D.	Title Manager, EPA Reg. Affairs	Telephone No. (Include Area Code) 913-268-2751
Certification 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.		6. Date Application Received (Stamped)
2. Signature 	3. Title Manager, EPA Reg. Affairs	
4. Typed Name Douglas A. Spilker, Ph.D.	5. Date 7 Dec 2009	

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Attachment to:
OPP APPLICATION FOR PESTICIDE – NOTIFICATION

Section II – Explanation:

Bayer HealthCare, Animal Health Division, is notifying the Agency that we plan to produce the product in a third package size, a single tube pack (1-pack), in addition to the current 4- and 6-pack configurations. This is noted on page one of this application form. The packaging and labeling scheme for this size is identical to that used for the other two pack sizes of this product, except for the number of tubes contained.

We are also notifying the Agency, pursuant to PR Notice 98-10, that we will be adding the following optional text to final printed labeling of the appropriate size product, as needed:

[“Sample – Not for Resale”]

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 proposed for the labeling or the confidential statement of formula for this product. Bayer understands that it is a violation of 18 U.S. C. Sec. 1001 to willfully make any false statement to EPA. Bayer further understands 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 Bayer may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

40211

Reason To Issue: Show additional package size.

Date: 01/06/10
Supersedes: 09/15/08
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NOTE TO REVIEWER: [(Brackets and parentheses indicate alternate language)]

K9 Advantix[®] 55

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

READ THE ENTIRE LABEL BEFORE EACH USE

DO NOT USE ON CATS

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

- For use on dogs and puppies 7 weeks of age and older
- 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 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 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 (4) weeks
- Kills fleas on dogs within 12 hours and continues to prevent infestations for [(a month) (four (4) weeks)]
- Kills and repels fleas before they lay eggs
- Larval flea stages in the dog's surroundings are killed following contact with a K9 Advantix[®] treated dog
- For the treatment and prevention of flea infestations
- One treatment prevents further flea infestations for [(a month) (four (4) weeks)]
- Controls existing flea infestations by killing adult fleas
- Prevents reinfestations by killing adult fleas before they lay eggs
- Prevents fleas on treated dogs from infesting (reinfesting) your home.
- Treatment with K9 Advantix kills fleas and may reduce the incidence of Flea Allergy Dermatitis (FAD)

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- Repels and kills mosquitoes for up to four (4) weeks
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [(Prevents blood-feeding by) (Kills and repels)] mosquitoes
- Remains effective after bathing and swimming [(for a month) (for up to four weeks)]
- Repels biting flies
- 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
- 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
- Remains effective after exposure to rain or sunlight
- Waterproof
- Fragrance free

Active Ingredients	% By Weight
Imidacloprid	8.8%
Permethrin*	44.0%
Other Ingredients	<u>47.2%</u>
Total	100%

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

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KEEP OUT OF REACH OF CHILDREN

WARNING

[For Directions for Use, and Storage and Disposal (instructions), see supplemental labeling inside.]


See below for first aid and precautionary statements.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS

Causes substantial but temporary eye injury. Do not get in eyes or on skin nor clothing. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. 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. 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 pets. 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.

DO NOT USE ON CATS	
Due to their unique physiology and inability to metabolize certain compounds, this product must not be used on cats. If applied to a cat, or ingested by a cat which actively grooms a recently treated dog, this product may have serious harmful effects. If this occurs contact your veterinarian immediately.	

For consumer questions call 1-800-255-6826. For medical emergencies call 1-800-422-9874.

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ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not add directly to water. Do not contaminate water when disposing of product or packaging.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in eyes: 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: Call 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 by mouth to an unconscious person.

If on skin or clothing: 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.

To Physician: Treat the patient symptomatically.

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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 APPLY

1. Use only on dogs. DO NOT USE ON CATS or on other animals.
2. Remove applicator tube from the package.

[Visuals Depicting How to Open Applicator Tube]

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[®] tube should be applied evenly to three or four 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.

[Visuals Depicting Application To Animal]

Do not get this product in your dog's eyes or mouth.

7. Discard empty tube as described in Storage and Disposal.

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GENERAL INFORMATION

Kills fleas which may cause flea allergy dermatitis (FAD).

K9 Advantix[®] kills existing fleas on dogs within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting 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[®] treated dog.

K9 Advantix[®] 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.

Storage: Store in a cool, dry place. Protect from freezing. **Disposal:** Nonrefillable container. **If empty:** Do not reuse or refill 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.

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[One] [Four] [Six] 0.084 fl. oz. (2.5 mL) Tubes

OPTIONAL CLAIM FOR THE ONE TUBE PACKAGE: [Sample – Not for (Re)Sale]

EPA Est. 11556-DEU-1
EPA Reg. No. 11556-135

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

Made in Germany

110911

Reason To Issue: Show additional package size.

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(Label on Individual Tube)

K9 Advantix[®] 55

8.8% imidacloprid
44.0% permethrin

0.084 fl. oz. (2.50 mL)

EPA Reg. No. 11556-135

WARNING

Keep out of reach of children
DO NOT USE ON CATS

Read The Entire Label Before Use

BAYER

Lot No. 0000000

NOTIFICATION

FEB - 5 2010