

11556-132

9/16/2010

10/12



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SEP 16 2010

Ms. Mary M. Hunt
Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201-0390

Subject: Label Notification(s) for Pesticide Registration Notice 2007-4

Dear Ms. Hunt:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice PRN 2007-4 dated August 27, 2010 for the following product:

K9 Advantix 10

EPA Reg. No. 11556-132

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and finds that the label change(s) requested falls within the scope of PRN 2007-4. 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 cursive script, appearing to read "Linda A. DeLuise".

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

2012

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060

 EPA	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other:	OPP Identifier Number
--	---	--	-----------------------

Application for Pesticide - Section I

1. Company/Product Number 11556-132	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) K9 Advantix 10	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division PO Box 390 Shawnee Mission, KS 66201 <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: 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 _____
<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.)

NON PRIA ACTION. Please see attached for more detail.

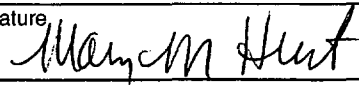
Enclosed for Agency acceptance is a draft label for K9 Advantix 10 (EPA Reg. No. 11556-132). The proposed revisions are the addition of 1) Net Contents heading and 2) optional text: [Sample-not for (re)sale].

Section - III

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

Section - IV

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

Name Mary M. Hunt	Title Pesticide Registrations Manager	Telephone No. (include Area Code) 913-268-2311
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) o o o o o o o o o o o o o o o o
2. Signature 		
3. Title Pesticide Registrations Manager		
4. Typed Name Mary M. Hunt		5. Date 8-27-2010

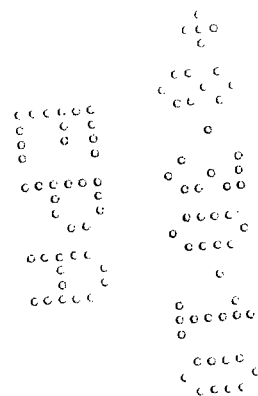
Bayer Health Care, Animal Health Division
K9 Advantix 10
EPA Reg. No. 11556-132
August 27, 2010

Section II Explanation

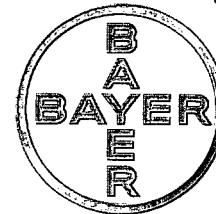
Enclosed for Agency acceptance is a draft label for K9 Advantix 10, EPA Reg. No. 11556-132.

The proposed revisions are the addition of 1) the "Net Contents" heading and 2) optional text: [Sample-not for (re)sale].

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. 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.



40912



Bayer HealthCare Animal Health

August 27, 2010

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 13

SUBJECT: Notification of Label Revision to
K9 Advantix 10, EPA Reg. No. 11556-132
K9 Advantix 20, EPA Reg. No. 11556-133
K9 Advantix 55, EPA Reg. No. 11556-135
K9 Advantix 100, EPA Reg. No. 11556-134

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

Dear Mr. Gebken:

Please find enclosed for the Agency's review and acceptance, a Notification (EPA Form 8570-1 and attachment) and draft label dated August 27, 2010 for each subject product.

The proposed revisions are the addition of the "Net Contents" heading and the optional text: [Sample-not for (re)sale

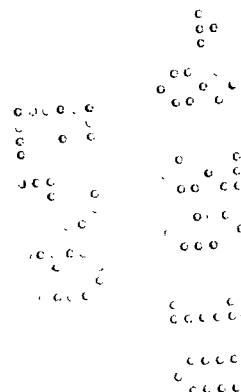
Thank you for your assistance with this notification process, and please contact me at 913-268-2311 or mary.hunt.b@bayer.com if you have any questions or need further information.

Respectfully,

BAYER HEALTHCARE LLC
ANIMAL HEALTH DIVISION

Mary McKinney Hunt
Pesticides Regulatory Manager

- Encl: (4) 8570-1 Application for Pesticide Notification
(4) Attachment to Application for Pesticide Notification
(4) Draft Label (1 cc each)
(4) Highlighted Label (1 cc each)



509/2

Reason To Issue: Add "Net Contents" heading and optional text:
[Sample-not for (re)sale]

Date: 08/27/2010
Supersedes: 01/06/10
Page 1 of 8

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

NOTIFICATION

K9 Advantix[®] 10

SEP 16 2010

Topical prevention and treatment of ticks, fleas, mosquitoes, biting flies, and lice for monthly use on [small] dogs and puppies 7 weeks of age and older, weighing 10 lbs. and under.

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)

Reason To Issue: Add "Net Contents" heading and optional text:
[Sample-not for (re)sale]

Date: 08/27/2010
Supersedes: 01/06/10
Page 2 of 8

- 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

Reason To Issue: Add "Net Contents" heading and optional text:
[Sample-not for (re)sale]

Date: 08/27/2010
Supersedes: 01/06/10
Page 3 of 8

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.

80 of 12

Reason To Issue: Add "Net Contents" heading and optional text:
[Sample-not for (re)sale]

Date: 08/27/2010
Supersedes: 01/06/10
Page 4 of 8

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.

90612

Reason To Issue: Add "Net Contents" heading and optional text:
[Sample-not for (re)sale]

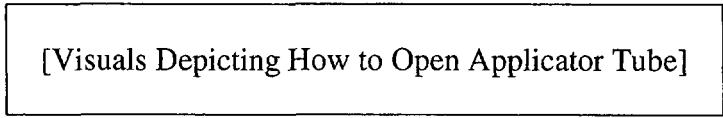
Date: 08/27/2010
Supersedes: 01/06/10
Page 5 of 8

DIRECTIONS FOR USE

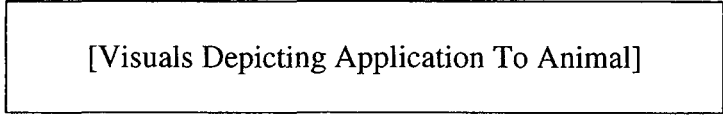
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
Do not contaminate feed or food.

HOW TO APPLY

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



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. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin.



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

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

100612

Reason To Issue: Add "Net Contents" heading and optional text:
[Sample-not for (re)sale]

Date: 08/27/2010
Supersedes: 01/06/10
Page 6 of 8

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.

110912

Reason To Issue: Add "Net Contents" heading and optional text:
[Sample-not for (re)sale]

Date: 08/27/2010
Supersedes: 01/06/10
Page 7 of 8

~~Net Contents: XX 0.014 fl. oz. (0.4 mL) Tubes~~

~~[Sample - Not for (Re) Sale]~~

EPA Est. 11556-DEU-1
EPA Reg. No. 11556-132

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

Made in Germany

120912

Reason To Issue: Add "Net Contents" heading and optional text:
[Sample-not for (re)sale]

Date: 08/27/2010
Supersedes: 01/06/10
Page 8 of 8

(Label on Individual Tube)

K9 Advantix[®] 10

8.8% imidacloprid
44.0% permethrin

0.014 fl. oz. (0.4 mL)

EPA Reg. No. 11556-132

WARNING

Keep out of reach of children
DO NOT USE ON CATS

Read The Entire Label Before Use

BAYER

Lot No. 0000000