

11556134

09/05/2007

1/14



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

SEP 5 2007

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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

Subject: Amendment – Add Waterproof claims
K9 Advantix 100
EPA Reg. No. 11556-134
Your submission dated April 13, 2007

Dear Ms. Hunt:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable subject to the comments listed below. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

1. It has come to our attention that the precautionary statements have to be upgraded based on the toxicity categories assigned to this product. Therefore revise the Precautionary Statement to read as follows:

“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.”
2. Replace “Inert Ingredients” with “Other Ingredients” in the Ingredients statement.
3. The data submitted to support the waterproof claim appears to confirm the water repellency, however the data is incomplete. Submit to the Agency within 3 months of this letter the complete data including raw data sheets. Please see enclosed efficacy review dated August 8, 2007.

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4. Change "waterproof" to "water repellent" throughout the labeling.
5. Add "To the extent consistent with applicable law" to the beginning of the sentence "Bayer makes no other express or implied warranty ... etc" and "Any damages arising from a breach of this warranty shall be limited etc." in the Limited Warranty statement.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions regarding this action, please contact BeWanda Alexander of my team at (703) 305-7460.

Sincerely,
BeWanda Alexander for
George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505C)

Enclosure

3/14

Reason To Issue: Add waterproof and other minor changes.

Date: 04/12/07

Supersedes: 10/03/06

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

(Front Panel of Outer Box)

K9 Advantix® 100

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

READ THE ENTIRE LABEL BEFORE EACH USE

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

- Available through licensed practicing veterinarians
- 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 for up to four weeks
- Kills 98-100% of the fleas on dogs within 12 hours and continues to prevent infestations for at least four 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
- Repels and kills mosquitoes for up to four weeks
- Waterproof
- Remains effective after bathing and swimming [(for a full 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

**ACCEPTED
with COMMENTS
In EPA Letter Dated
SEP 5 2007**
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.

11556-134

4/14

Reason To Issue: Add waterproof and other minor changes.

Date: 04/12/07

Supersedes: 10/03/06

Active Ingredients	%
	By Weight
Imidacloprid	8.8%
Permethrin*	44.0%
Inert Ingredients	<u>47.2%</u>
Total	100%
* cis/trans ratio: Max 55% (±) cis and min 45% (±) trans	

KEEP OUT OF REACH OF CHILDREN

WARNING

See below for first aid and precautionary statements.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

Causes eye irritation. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wash hands thoroughly with soap and warm water after handling.

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.

5/14

Reason To Issue: Add waterproof and other minor changes.

Date: 04/12/07

Supersedes: 10/03/06

For consumer questions call 1-800-255-6826. For medical emergencies call 1-877-258-2280.

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.

Four (Six) 0.135 fl. oz. (4.0 mL) Tubes

EPA Est. 11556-DEU-1
EPA Reg. No. 11556-134

Manufactured For
Bayer HealthCare LLC
Animal Health Division
Shawnee Mission, Kansas 66201 USA

Made in Germany

6/14

Reason To Issue: Add waterproof and other minor changes.

Date: 04/12/07

Supersedes: 10/03/06

(Back Panel of Outer Box)

K9 Advantix[®] 100

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

- Repels and kills ticks including those that may transmit Lyme disease
- Kills 98-100% of fleas within 12 hours
- Repels and kills mosquitoes
- Repels biting flies

DO NOT USE ON CATS

Four (Six) 0.135 fl. oz. (4.0 mL) Tubes

7/14

Reason To Issue: Add waterproof and other minor changes.

Date: 04/12/07

Supersedes: 10/03/06

(Top Panel of Outer Box)

K9 ADVANTIX[®] 100
DO NOT USE ON CATS

(Side Panel of Outer Box)

- Available through licensed practicing veterinarians
 - Convenient, easy to apply
-

(Side Panel of Outer Box)

**SEE PACKAGE INSERT FOR COMPLETE
PRODUCT INFORMATION**

- Repels and kills ticks
- Kills 98-100% of fleas within 12 hours
- Repels and kills mosquitoes
- Repels biting flies

8/14

Reason To Issue: Add waterproof and other minor changes.

Date: 04/12/07

Supersedes: 10/03/06

(Package Insert)

K9 Advantix[®] 100

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

Read The Entire Label Before Use
DO NOT USE ON CATS

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

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- Kills 98-100% of the fleas on dogs within 12 hours and continues to prevent infestations for at least four 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
- Repels and kills mosquitoes for up to four weeks
- Waterproof
- Remains effective after bathing and swimming [(for a full month) (for up to four weeks)]
- Repels biting flies
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9/14

Reason To Issue: Add waterproof and other minor changes. Date: 04/12/07
Supersedes: 10/03/06

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KEEP OUT OF REACH OF CHILDREN

WARNING

See below for first aid and precautionary statements.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS**

Causes eye irritation. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wash hands thoroughly with soap and warm water after handling.

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 1-877-258-2280.

10/14

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Date: 04/12/07

Supersedes: 10/03/06

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.

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.

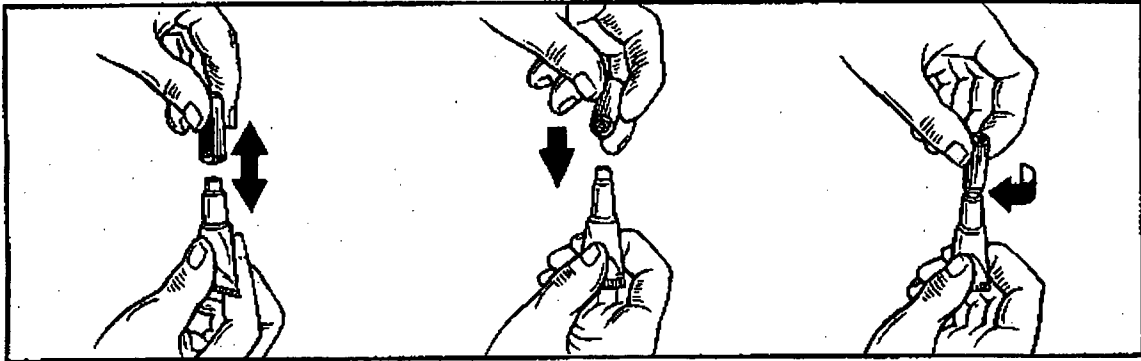
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Reason To Issue: Add waterproof and other minor changes.

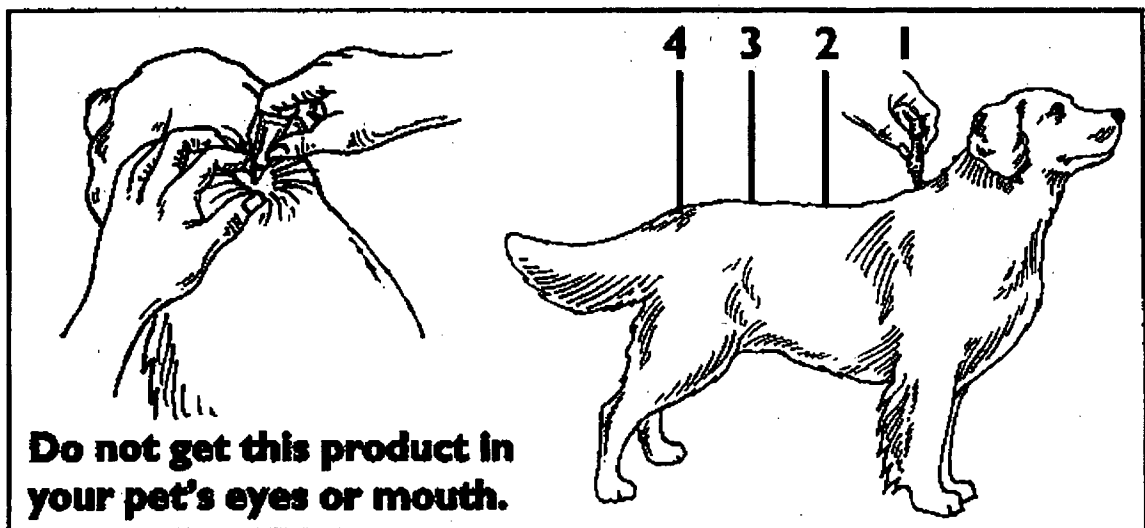
Date: 04/12/07

Supersedes: 10/03/06

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. 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.



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

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Reason To Issue: Add waterproof and other minor changes.

Date: 04/12/07

Supersedes: 10/03/06

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

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™ rapidly kills fleas and may reduce the incidence of this condition.

K9 Advantix® kills 98-100% of the 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® treated dog.

K9 Advantix® remains efficacious 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.

If re-treatment becomes necessary, do not re-treat more than once every week.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in a cool, dry place. Protect from freezing. **Pesticide Disposal: 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 1-800-255-6826 for disposal instructions. Never place unused product down any indoor or outdoor drain.

13/14

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Date: 04/12/07

Supersedes: 10/03/06

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC, Animal Health Division warrants that this material conforms to the chemical description on the label. 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. 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.

EPA Est. 11556-DEU-1

EPA Reg. No. 11556-134

14/14

Reason To Issue: Add waterproof and other minor changes.

Date: 04/12/07

Supersedes: 10/03/06

(Label on Individual Tube)

K9 Advantix[®] 100

8.8% imidacloprid

44.0% permethrin

0.135 fl. oz. (4.0 mL)

EPA Reg. No. 11556-134

WARNING

Keep out of reach of children

DO NOT USE ON CATS

Read The Entire Label Before Use

BAYER

Lot No. 0000000