

11556-135

6/30/2008

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

JUN 30 2008

Dear Dr. Spilker:

Subject: Amendment - Revise claims
K9 Advantix 55
EPA Reg. No. 11556-135
Your submission dated April 18, 2008

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(A), is acceptable provided the following revisions are incorporated prior to release for shipment:

1. Revise "at least" to read "for up to" when used in reference to the duration of effectiveness.
2. Remove "rapidly" where it indicates the time required for the product to be effective.
3. Delete any and all references to "Canine Vector Borne Diseases (CVBD)". This is an open ended claim and is unacceptable.
4. Revise "for a full month" to read "for up to a month".

A stamped copy of the label is enclosed for your records. Please submit 3 copies of the revised amended labeling as soon as it becomes available.

Sincerely,

George LaRocca.
Product Manager 13
Insecticide Branch
Registration Division (7505P)

Reason To Issue: Elaboration of current marketing claims.

Date: 04/15/08
Supersedes: 02/22/08
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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

- Available only through licensed practicing veterinarians
- For use on dogs and puppies 7 weeks of age and older
- A single topical application remains effective for at least 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 98-100% of the fleas on dogs within 12 hours and continues to prevent infestations for at least 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 at least four (4) weeks
- Controls existing flea infestations by rapidly killing adult fleas
- Prevents reinfestations by killing adult fleas before they lay eggs
- Prevents fleas on treated dogs from infesting (reinfesting) your home.

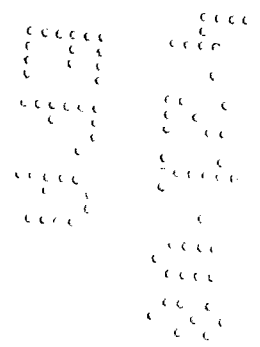
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**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

JUN 3 0 2008

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
11556-735**

- Treatment with K9 Advantix rapidly kills fleas and may reduce the incidence of Flea Allergy Dermatitis (FAD)
- Because K9 Advantix repels ticks, year-round use of K9 Advantix may reduce the risk of Canine Vector Borne Diseases (CVBD)
- Repels and kills fleas often before they bite and may reduce the risk of Canine Vector Borne Diseases (CVBD)
- K9 Advantix repels and kills fleas often before they bite and may reduce the risk of Canine Vector Borne Diseases (CVBD)
- Repels and kills mosquitoes that may transmit Canine Vector Borne Diseases (heartworm disease)
- K9 Advantix repels and kills mosquitoes that may transmit Canine Vector Borne Diseases (heartworm disease)
- 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 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
- 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



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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

KEEP OUT OF REACH OF CHILDREN

WARNING

[For Directions for Use and other labeling, 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.

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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.

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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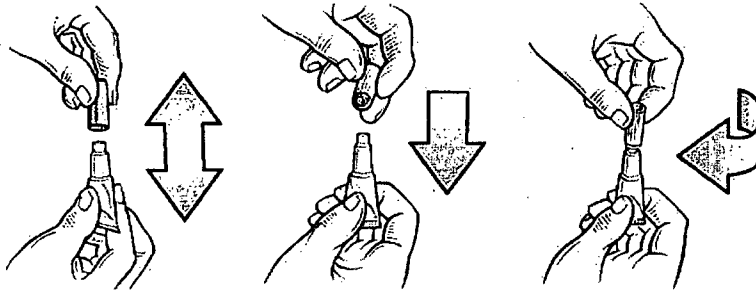
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DIRECTIONS FOR USE

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

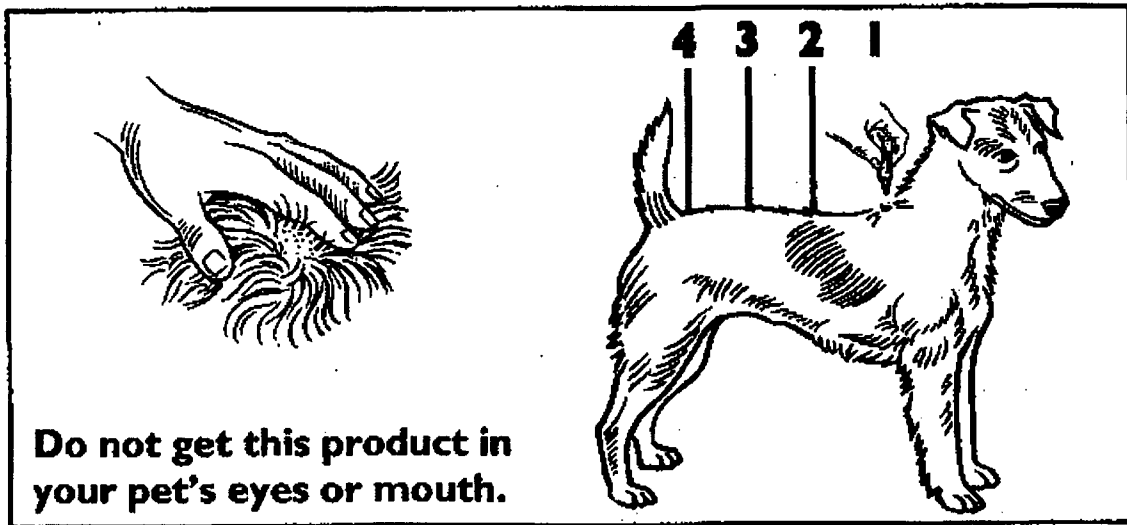
HOW TO APPLY

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



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.



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

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

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[®] is waterproof and remains efficacious following a shampoo treatment, swimming or after exposure to rain or sunlight.

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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. **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 1-800-422-9874 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.

Four (Six) 0.084 fl. oz. (2.5 mL) Tubes

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

9099

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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