

11556-132

12-16 2003

7/12

Mr. F.T. McNamara
Bayer Corporation
P.O. Box 390
Shawnee Mission, KS 66201-0390

DEC 16 2003

Dear Mr. McNamara:

Subject: Amendment - add repels fleas claim
K9 Advantix 10
EPA Registration No. 11556-132
Your submission dated November 26, 2003

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(a), is acceptable provided that you:

1. Submit and/or cite all data or other material required for registration/reregistration of your product under FIFRA section 3(c)(5) or FIFRA section 4 when the Agency requires all registrants of similar products to submit such data.
2. Submit two (2) copies of your final printed labeling before you release the product for shipment.

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

A stamped copy of the label is enclosed for your records.

Sincerely,

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

Enclosure

Reason To Issue: Add flea repellency claim.

Date: 10/01/03

Supersedes: 08/14/02

(Front Panel of Outer Box)

K9 Advantix™ 10

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

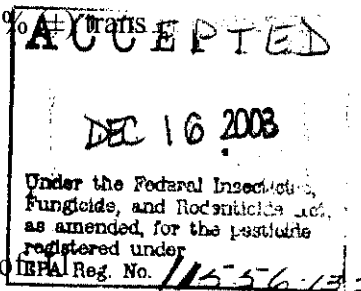
READ THE ENTIRE LABEL BEFORE EACH USE

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

- Available only 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
- Remains effective after bathing and swimming

Active Ingredients	% By Weight
Imidacloprid; 1-[(6-Chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine . . .	8.8%
Permethrin*	44.0%
Inert Ingredients	47.2%
Total	100%

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



Reason To Issue: Add flea repellency claim.

Date: 10/01/03

Supersedes: 08/14/02

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

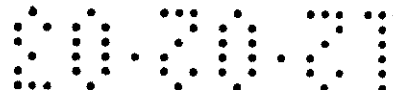
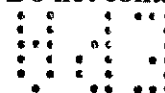


Due to their unique physiology and inability to metabolize certain compounds, this product must not be used on cats. If applied to a cat, or ingested by a cat which actively grooms a recently treated dog, this product may have serious harmful effects. If this occurs contact your veterinarian immediately.

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

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.



Reason To Issue: Add flea repellency claim.

4/12
Date: 10/01/03

Supersedes: 08/14/02

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 0.4 mL Tubes

EPA Est. 11556-DEU-1

EPA Reg. No. 11556-132

Manufactured For

Bayer Corporation

Agriculture Division

Animal Health

Shawnee Mission, Kansas 66201 USA

Made in Germany

5/12

Reason To Issue: Add flea repellency claim.

Date: 10/01/03

Supersedes: 08/14/02

(Back Panel of Outer Box)

K9 Advantix™ 10

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

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

DO NOT USE ON CATS

Four 0.4 mL Tubes

6/12

Reason To Issue: Add flea repellency claim.

Date: 10/01/03

Supersedes: 08/14/02

(Top Panel of Outer Box)

K9 ADVANTIX™ 10

DO NOT USE ON CATS

(Side Panel of Outer Box)

- Available only 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

843

00-20-21

1/12

Reason To Issue: Add flea repellency claim.

Date: 10/01/03

Supersedes: 08/14/02

(Package Insert)

K9 Advantix™ 10

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

Read The Entire Label Before Use

DO NOT USE ON CATS

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ENVIRONMENTAL HAZARDS

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FIRST AID

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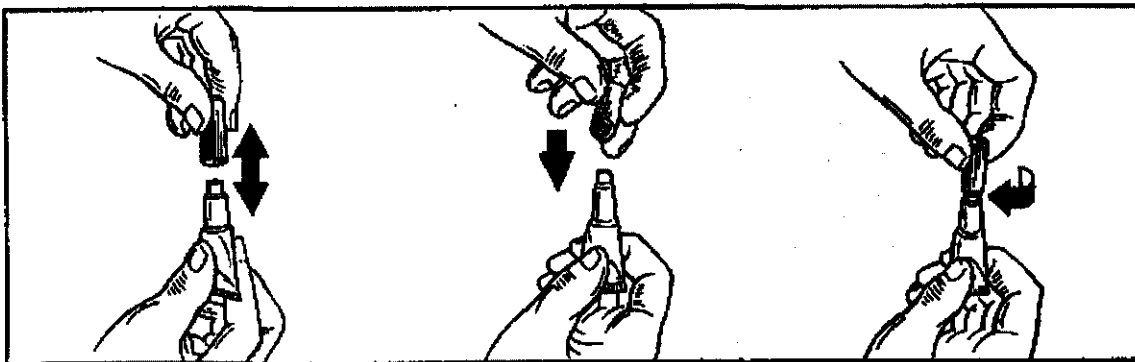
To Physician: Treat the patient symptomatically.

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.
2. Remove applicator tube from the package.

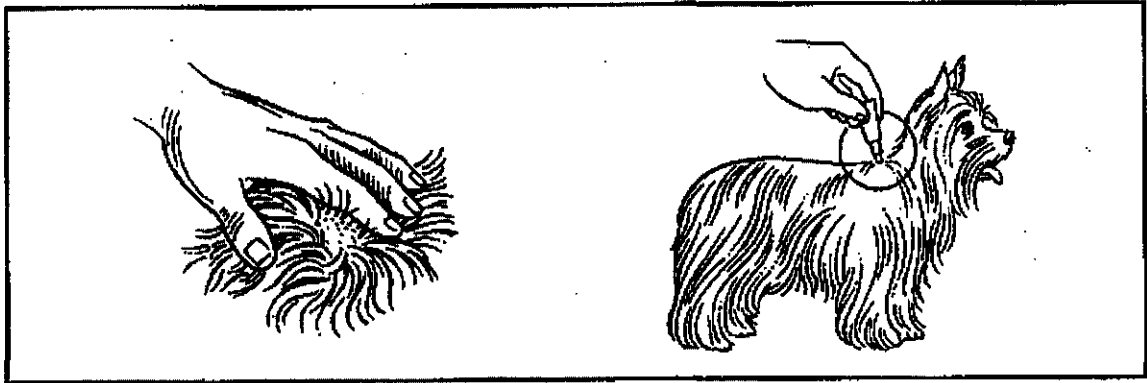


3. Hold applicator tube in an upright position. Pull cap off tube.
4. Turn the cap around and place other end of cap back on tube.
5. Twist cap to break seal, then remove cap from tube.

Reason To Issue: Add flea repellency claim.

10/12
Date: 10/01/03
Supersedes: 08/14/02

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 twice 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.

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.

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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.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer Corporation, Agriculture Division, Animal Health warrants that this material conforms to the chemical description on the label. BAYER CORPORATION MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer Corporation 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. 11556-132

Reason To Issue: Add flea repellency claim.

Date: 10/01/03

Supersedes: 08/14/02

(Label on Individual Tube)

K9 Advantix™ 10

8.8% imidacloprid

44.0% permethrin

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

