

11556-135

9/30/2002

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U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (H7505C)  
1200 Pennsylvania Avenue, NW  
Washington, D.C. 20460

EPA Reg. Number:

11556-135

Date of Issuance:

SEP 30 2002

Term of Issuance: **Conditional**

Name of Pesticide Product:

K9 Advantix™ 55

## NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

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

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A), provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Since you have agreed to generate/participate in the generation of data to address secondary permethrin incidents in cats exposed to treated dogs and to make additional label changes if necessary.
3. Make the following label changes:
  - a. We still consider the reference to a reduction in incidence of FAD an implied drug claim. However, we will allow the statement "Kills fleas which may cause flea allergy dermatitis (FAD)." Therefore, please replace the current paragraph with this statement.

Signature of Approving Official:

George T. LaRocca

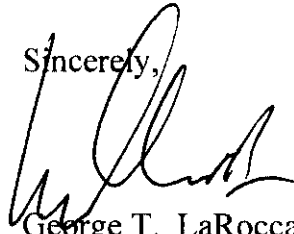
Date:

SEP 30 2002

- b. Either delete the retreatment instructions indicating not to retreat more than once per week or revise it to indicate that if retreatment is necessary, do not retreat more than once every three weeks.

Please refer to the A-79 enclosure for a further description of final printed labeling. 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 bearing amended labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. If you have any questions regarding this action, please contact Dr. William Sproat of my team at (703) 308-8587.

Sincerely,



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

Enclosure

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# K9 ADVANTIX™

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Topical prevention and treatment of ticks, fleas 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

### DO NOT USE ON CATS

#### 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 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

Imidacloprid; 1-[(6-Chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine	% By Weight
Permethrin*	8.0%
Inert Ingredients	44.0%
Total	47.2%
	100.0%

\*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.

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 Physicians:** Treat the patient symptomatically.

Manufactured For Bayer Corporation,  
Agriculture Division, Animal Health,  
Shawnee Mission, Kansas 66201 USA

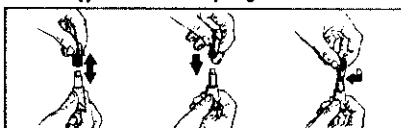


#### Directions for Use

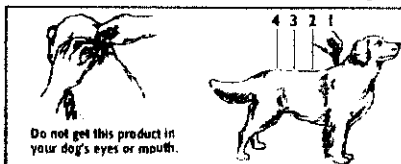
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not contaminate feed or food.

#### 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.

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 a can or other 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.

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EPA Reg. 11556-DEU-1  
EPA Reg. No. 11556-154

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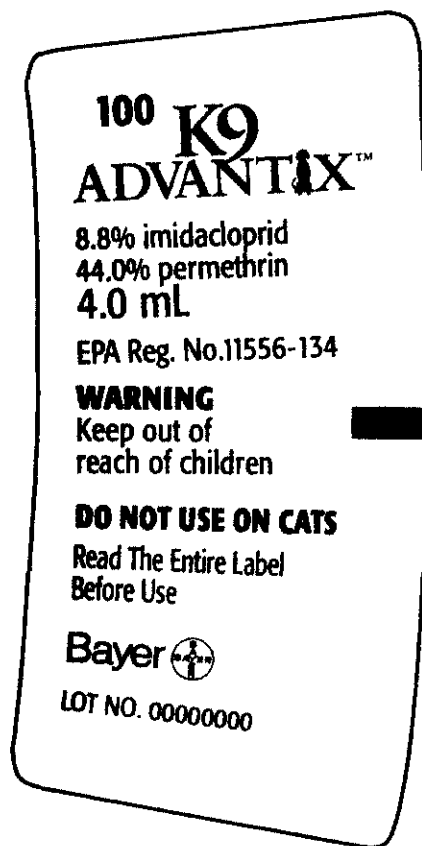
# K9 ADVANTIX™

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

**DO NOT USE ON CATS**

**Bayer** 

Foil Pouch-print area  
90 mm X 170 mm



Tube color is warm grey 3  
Tube cap is warm grey 5  
Type pms 653

This die is for the large tubes 4-packs  
74 mm x 140 mm

Four - 4.0 mL

00000000, 0541, R.0

# K9 ADVANTIX™ 100

8.8% imidacloprid/44.0% permethrin

For external use on dogs and puppies 7 weeks of age  
and older weighing over 55 lbs.

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**Bayer** 

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**Bayer** 

Use these calendar stickers  
to remind you when your dog is due  
for its next monthly application of



DO NOT USE ON CATS

Name: \_\_\_\_\_



DO NOT USE ON CATS

Name: \_\_\_\_\_



DO NOT USE ON CATS

Name: \_\_\_\_\_



DO NOT USE ON CATS

Name: \_\_\_\_\_



DO NOT USE ON CATS

Name: \_\_\_\_\_



DO NOT USE ON CATS

Name: \_\_\_\_\_