



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JUN 25 1998

F. T. McNamara
Bayer Corporation
Agricultural Division, Animal Health
P.O. Box 390
Shawnee Mission, KS 66201-0390

Subject: Advantage 9 for Cats
EPA Reg. No. 11556-116

Advantage 18 for Cats
EPA Reg. No. 11556-118

Advantage 10 for Dogs
EPA Reg. No. 11556-117

Advantage 20 for Dogs
EPA Reg. No. 11556-119

Advantage 55 for Dogs
EPA Reg. No. 11556-120

Advantage 100 for Dogs
EPA Reg. No. 11556-122

Revised Labels
Received at EPA June 18, 1998


Dear Mr. McNamara,

The subject labels have been reviewed and will be acceptable if the following claim modification is made on each of the labels. Delete "The successive feeding activities.....reduces the incidents of this condition." The following statement may be used as a replacement:

"The successive feeding activities of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with Advantage rapidly kills fleas and may reduce the incidence of this condition."

Two copies of each final printed label should be submitted to the Agency prior to shipment of the products. Stamped copies of the subject labels are enclosed for your files.

Sincerely,



Elizabeth T. Haebener
Insecticide - Rodenticide Branch
Registration Division (7505C)

Enclosures

RECEIVED

JUN 16 1998

LABEL COORDINATION

Four color process
Match pantone 201
& varnish

Size: 78/20/145 mm

For Dogs and Puppies
7 Weeks and Older and 21-55 lbs.

78/20/145

effective



Convenient, easy to apply



fast

READ ENTIRE LABEL
BEFORE EACH USE

advantage®

(Imidacloprid)
Topical Solution

Once-a-month topical
flea treatment for dogs
and puppies 7 weeks and
older and 21-55 lbs.

- Available only through licensed practicing veterinarians
- Kills fleas within 12 hours
- Prevents reinfestation for at least 4 weeks
- Convenient, easy to apply

Kills fleas within 12 hours

Name:

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advantage®

Once-a-month topical flea
treatment for dogs and
puppies 7 weeks and older
and 21-55 lbs.

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For the Prevention and Treatment of Flea Infestations on Dogs

- Available only through licensed practicing veterinarians
- Kills 98-100% of the fleas on dogs within 12 hours
- One treatment prevents further flea infestation for at least four weeks
- Kills fleas before they lay eggs

| Active Ingredient | % By Weight |
|---|-------------|
| Imidacloprid; 1-[(6-chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine | 9.1% |
| Inert Ingredients | 90.9% |
| Total | 100.0% |

KEEP OUT OF REACH OF CHILDREN WARNING

See Below for First Aid and Precautionary Statements.
For Directions for Use and other labeling, see supplemental labeling inside

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 water after handling. Keep out of reach of children. Do not contaminate feed or food.

Hazards to Domestic Animals

For external use only. Do not use on puppies under seven weeks of age. 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 AMT 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. Call 1-800-255-6826 for 24 hour assistance.

First Aid

If in eyes: Hold eyelids open and flush with plenty of water.
Get medical attention if irritation persists.
If swallowed: Call a physician or Human Contact Center.
If on skin: Wash with plenty of soap and water.
To Physician: Treat the patient symptomatically.



854303 0



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

Made in Germany

Four 2.5 mL Tubes

EPA Est. 11554-BEM-1 PM Reg. No. 11554-120

Lot No.:

ACCEPTED
with COMMENTS
In EPA Letter Dated:

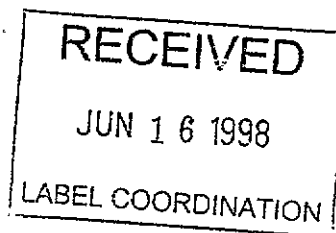
JUN 25 1998
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
11554-120

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**Once-a-month topical flea treatment for dogs and puppies
7 weeks and older and 21-55 lbs.**



Read entire label before each use

For the Prevention and Treatment of Flea Infestations on Dogs

- Available only through licensed practicing veterinarians
- One treatment prevents further flea infestation for at least four weeks
- Kills 98-100% of the fleas on dogs within 12 hours
- Kills fleas before they lay eggs

Active Ingredient

Imidacloprid, 1-[(6-chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine

% By Weight

9.1%

Inert Ingredients

90.9%

Total

100.0%

**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. Keep out of reach of children. Do not contaminate feed or food.

Hazards to Domestic Animals

For external use only. Do not use on puppies under seven weeks of age. 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. Call 1-800-255-6826 for 24 hour assistance.

First Aid

If in eyes: Hold eyelids open and flush with plenty of water. Get medical attention if irritation persists.

If swallowed: Call a physician or Poison Control Center.

If on skin: Wash with plenty of soap and water.

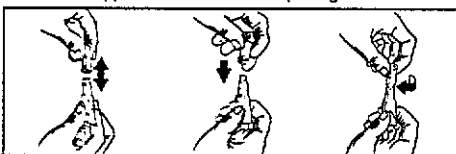
To Physician: Treat the patient symptomatically.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

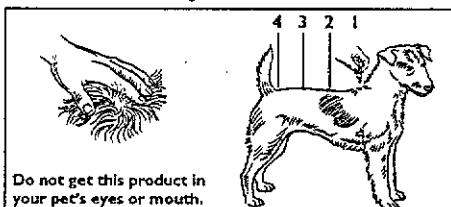
How to Apply

1. Use only on dogs. Do not use 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 Advantage® 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 pets frequently elicits a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with Advantage® rapidly kills fleas and reduces the incidence of this condition.

Advantage® kills 98-100% of the existing fleas on pets 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 pet's surroundings are killed following contact with an Advantage® treated pet.

Advantage® 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.

If re-treatment becomes necessary earlier than four weeks, do not re-treat more than once weekly.

Storage and Disposal

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

Storage: Store in a cool, dry place.

Pesticide Disposal: Securely wrap original container in several layers of newspaper and discard in trash.

Container Disposal: Do not reuse empty container. Wrap container and put in trash.

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.



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

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EPA Est. 11554-DEU-1
EPA Reg. No. 11554-120

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