



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

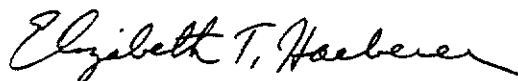
Dear Mr. McNamara,

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

3/4

advantage
(imidacloprid)
Topical Solution

Once-a-month topical flea treatment for cats and kittens
8 weeks and older and under 9 lbs.

9

READ THE ENTIRE LABEL BEFORE EACH USE
For the Prevention and Treatment of Flea Infestations

- Available only through licensed practicing veterinarians
- One treatment prevents further flea infestation for up to four weeks
- Kills 98-100% of the fleas on cats 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 kittens under eight 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.

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.

11556-116

Bayer

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



Four 0.4 mL Tubes

0326, R3

EPA Est. 11556-DEU-1 EPA Reg. No. 11556-116

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

Once-a-month topical flea treatment for cats and kittens 8 weeks and older and under 9 lbs.

(imidacloprid)
Topical Solution

advantage



Effective

RECEIVED
JUN 16 1998
LABEL COORDINATION

4/4



Once-a-month topical flea treatment for cats and kittens 8 weeks and older and under 9 lbs.

9

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 for up to 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.

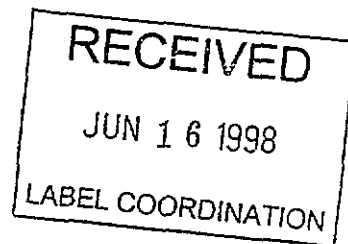
Storage: Store in a cool, dry place.

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 Limitations 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.



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

For the Prevention and Treatment of Flea Infestation on Cats and Kittens 8 Weeks and Older and Under 9 lbs.

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 cats. Do not use on other animals.
2. Remove one 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. Part the hair in the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube twice to expel the entire contents of the tube directly on the skin. Do not get this product in your pet's eyes or mouth. The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the cat to lick the product.



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

