

PM 4

11556-118

12/23/97

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

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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Subject: Advantage 9  
EPA Reg. No. 11556-116  
Advantage 18  
EPA Reg. No. 11556-118  
**Amended Labels: Revised Restriction for Application on Kittens; Addition  
of Statement on Pre-Existing Pupae.**  
Submissions were received at EPA on December 16, 1997

DEC 23 1997

Dear Mr. McNamara,

The amended labels referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, have undergone review and are conditionally acceptable provided that you:

1. Provide EPA with data on the incidence of adverse reactions in puppies, kittens, dogs and cats, after six months of relabeled product being available in veterinary clinics. Data should specify breeds where applicable.

Stamped copies of the conditionally approved labels are enclosed for your records.

Sincerely,

A handwritten signature in cursive script that reads "Elizabeth T. Haeberer".

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

Enclosures

Reason To Issue: Revised kitten age restriction and add pupae statement. Date: 12/10/97  
Supersedes: 4/15/97

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ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

(Front Panel)

DEC 23 1997

**Advantage® 18**  
(imidacloprid) Topical Solution

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended for the pesticide  
registered under EPA Reg. No.  
11536-118 DEC 23 1997

Once-A-Month Topical Flea Treatment for Cats Over 9 lbs  
For the Prevention and Treatment of Flea Infestations

- Available Only Through Licensed Practicing Veterinarians
- Kills 98-100% of the Fleas on Cats Within 12 Hours
- One Treatment Prevents Further Flea Infestation For Up to 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%

KEEP OUT OF REACH OF CHILDREN

WARNING

See Below for Statements of Practical Treatment 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. If your animal is on medication, consult your veterinarian before using this or any other product.

#### STATEMENTS OF PRACTICAL TREATMENT

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.

Four 0.8 mL Tubes

EPA Est. 11556-DEU-1  
EPA Reg. No. 11556-118

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

(Back Panel)

## Advantage® 18

(imidacloprid) Topical Solution

Fast

Effective

) Once-A-Month Topical Flea Treatment for Cats Over 9 lbs.

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

Four 0.8 mL Tubes

(Inside Left Panel)

Advantage® 18

(imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment for Cats

For the Prevention and Treatment of Flea Infestation on Cats Over 9 lbs

### DIRECTIONS FOR USE

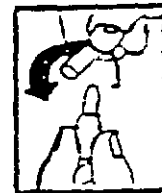
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

### 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.



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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.

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 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 condition.

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.

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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. **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.

EPA Est. 11556-DEU-1

EPA Reg. No. 11556-118

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(Label on Individual Tube)

Advantage®

9.1% Imidacloprid

0.8 mL

EPA Reg. No. 11556-118

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

BAYER

Lot No. 0000000



Reason To Issue:

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(Back of Blister Package)

BEST AVAILABLE IMAGE

