

PM 4

11556-120

12/23/97

1/9



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 10
EPA Reg. No. 11556-117
Advantage 20
EPA Reg. No. 11556-119
Advantage 55
EPA Reg. No. 11556-120
Advantage 100
EPA Reg. No. 11556-122
**Amended Labels: Revised Restriction for Application on Puppies; 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. Revise the use on puppies to a minimum age of seven weeks or older.
2. 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 black ink, reading "Elizabeth T. Haebeler".

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

Enclosures

Reason to Issue: Revised to puppy age restriction and pupae statement

Date: 12/10/97
Supersedes: 4/15/97

2/4

(Front Panel)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

Advantage® 55
(imidacloprid) Topical Solution

DEC 23 1997

Once-A-Month Topical Flea Treatment
For 21 - 55 lb. Dogs

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

1556-120 DEC 23 1997

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% |

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 puppies under six 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.

Reason to Issue: Revised to puppy age restriction and pupae statement

Date: 12/10/97
Supersedes: 4/15/97

3/9

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 2.5 mL Tubes

EPA Est. 11556-DEU-1
EPA Reg. No. 11556-120

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

Reason to Issue: Revised to puppy age restriction and pupae statement

Date: 12/10/97
Supersedes: 4/15/97

4/9

(Back Panel)

Advantage® 55

(imidacloprid) Topical Solution
Fast
Effective

Once-A-Month Topical Flea Treatment for 21 - 55 lb. Dogs

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

Four 2.5 mL Tubes

(Inside Left Panel)

Advantage® 55

(imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment for 21 - 55 lb. Dogs

For the Prevention and Treatment of Flea Infestations on Dogs

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.



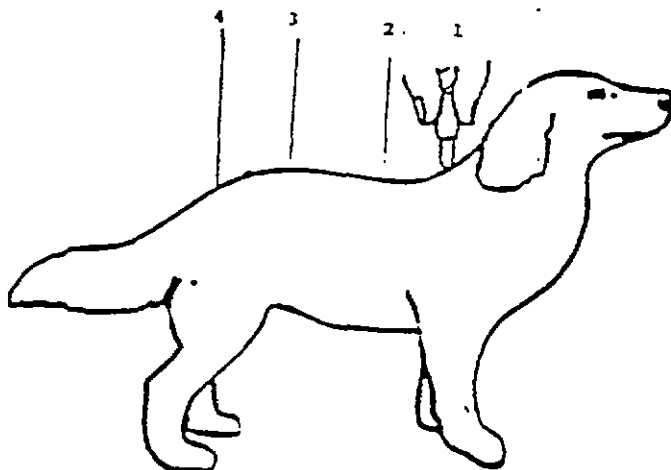
4. Turn the cap around and place other end of cap back on tube.



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.



Do not get this product in your pet's eyes or mouth.

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.

Reason to Issue: Revised to puppy age restriction and pupae statement

Date: 12/10/97
Supersedes: 4/15/97

7/4

(Inside Right Panel)

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. 11556-120

Reason to Issue: Revised to puppy age restriction and pupae statement

Date: 12/10/97
Supersedes: 4/15/97

2/9

(Label on Individual Tube)

Advantage®

9.1% Imidacloprid

2.5 mL

EPA Reg. No. 11556-120

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

BAYER

Lot No. 0000000

Reason to Issue: Revised puppy age restriction and add pupae statement.

Date: 12/10/97
Supersedes: 4/15/97

4/9

(Back of Blister Package)

