

PM-19

Reg # 11556-122

1910



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (H7505C)  
401 "M" St., S.W.  
Washington, D.C. 20460

EPA Reg. Number:

11556-122

Date of Issuance:

OCT 25 1996

NOTICE OF PESTICIDE:

Registration  
 Reregistration

Term of Issuance: Until Reregistration

Name of Pesticide Product:

Advantage 100

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Bayer Corporation  
Agriculture Div, 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/reregistration 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 or other material required for registration/reregistration of your product under FIFRA sec. 3(c)(5) or FIFRA sec. 4 when the Agency requires all registrants of similar products to submit such data.
2. Add the phrase EPA Registration No. "11556-122" to your label before you release the product-for shipment.

Signature of Approving Official:

DHE  
Dennis H. Edwards, JR Product Manager (19)  
Insecticide Branch Rodenticide Branch  
Registration Division (H7505C)

Date:

OCT 25 1996

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3. Delete the statement "Quickly eliminates the cause of flea allergy dermatitis," implied drug claim and is unacceptable.

4. Submit five (5) copies of your final printed labeling before you release the product for shipment. 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 sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

DHE

Dennis H. Edwards, Jr.  
Product Manager 19  
Insecticide-Rodenticide Branch  
Registration Division (7505C)

Enclosure

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Reason to Issue:

Date: 10/18/96  
Supersedes: 8/13/96

(Front Panel)

**Advantage™ 100**  
Flea Adulticide

ACCEPTED  
with COMMENTS  
in EPA Letter Dated

Once-A-Month Topical Flea Treatment  
For Dogs Over 55 lbs.

**OCT 25 1996**

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

For the Prevention and Treatment of Flea Infestations on Dogs

11556-122

- Available Only Through Licensed Practicing Veterinarians
- Kills 98-100% of the Fleas on Dogs Within One Day of Treatment
- 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 .....	<u>90.9%</u>
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 four months 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.

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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 4.0 mL Tubes

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

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

Reason to Issue:

Date: 10/18/96

Supersedes: 8/13/96

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(Back Panel)

## Advantage™ 100

Flea Adulticide

Fast

Effective

Once-A-Month Topical Flea Treatment for Dogs Over 55 lbs.

- Available only through licensed practicing veterinarians
- Kills fleas within 24 hours
- Prevents reinfestation for at least 4 weeks
- Quickly eliminates the cause of the flea allergy dermatitis
- Convenient, easy to apply

Four 4.0 mL Tubes

Reason to Issue:

Date: 10/18/96  
Supersedes: 8/13/96

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(Inside Left Panel)

Advantage™ 100

Flea Adulticide

Once-A-Month Topical Flea Treatment for Dogs Over 55 lbs.

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.



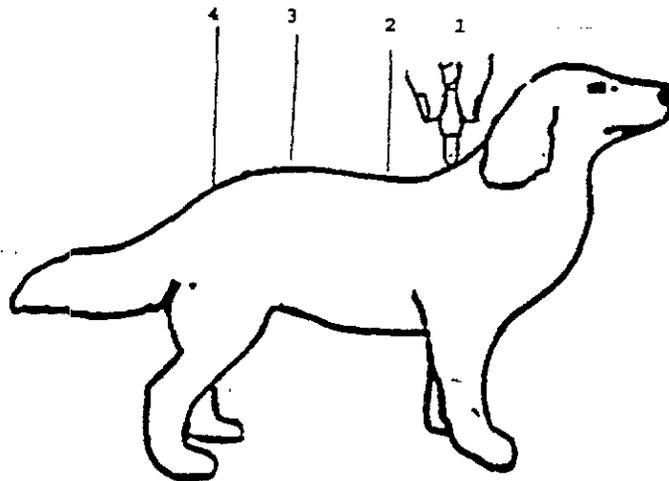
Reason to Issue:

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Supersedes: 8/13/96

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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 dispense 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.

Advantage™ will kill 98-100% of the fleas on dogs within one day of treatment and will continue to protect the dog from further flea infestation for at least four (4) weeks. Reinfestation from the emergence of new fleas in the environment may continue to occur for six weeks or longer after treatment is initiated.

Monthly treatments are required for optimal control and prevention of fleas.

Advantage remains efficacious following exposure to water or sunlight. Shampooing of the dog may shorten the duration of flea protection, therefore reapplication following shampooing is recommended. If re-treatment becomes necessary earlier than four weeks, do not re-treat more than once weekly.

Reason to Issue:

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Supersedes: 8/13/96

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(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-XXX

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(Label on Individual Tube)

Advantage™

9.1% Imidacloprid

4.0 mL

EPA Reg. No. 11556-XXX

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

BAYER

Lot No. 0000000

Reason to Issue:

Date: 10/18/96  
Supersedes: 8/13/96

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(Back of Blister Package)

40  
Four - 1/2 oz

**advantage™**  
9.1% Imidacloprid

For external use on  
dogs over 30 lbs. Bayer ⊕

55

40  
Four - 1/2 oz

**advantage™**  
9.1% Imidacloprid

For external use on  
dogs over 30 lbs. Bayer ⊕

55

40  
Four - 1/2 oz

**advantage™**  
9.1% Imidacloprid

For external use on  
dogs over 30 lbs. Bayer ⊕

55