

PM-17

Reg # 11556-120

19 10



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-
120

Date of Issuance:

MAR 8 1996

NOTICE OF PESTICIDE:

 X Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Name of Pesticide Product:

Advantage™ 55

Name and Address of Registrant (include ZIP Code):

Bayer Corporation
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 unconditionally registered in accordance with FIFRA sec. 3(c)(5). Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If EPA determines, at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

2. Add the phrase EPA Registration No. "11556-120" to your label before you release the product for shipment.

Signature of Approving Official:

DNE

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

Date:

MAR 8 1996

3. Make the following labeling revisions.

a. Revise the statement "Do not use on puppies 8 weeks of age" to "Do not use on puppies under four months of age."

b. After the statement "Shampooing of the dog may shorten the duration of flea protection, therefore reapplication following shampooing is recommended." add the sentence "If re-treatment becomes necessary earlier than four weeks, do not re-treat more than once weekly."

c. Add the statements "As with any product consult your Veterinarian before using this product on debilitated, aged, pregnant or nursing animals." and "If your animal is on medication consult your veterinarian before using this or any product." to your Hazards to Domestic Animals paragraph.

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

Reason to Issue: To Initiate EPA Product Label

Date: 1/11/96

Supersedes: 12/14/95

ACCEPTED
with COMMENTS
in EPA Letter Dated

(Front Panel)

MAA 8 1898

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

11552-170

Advantage™ 55 Flea Adulticide

Once-A-Month Topical Flea Treatment
For Dogs Over 20 lbs.

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 One Day of Treatment
- One Treatment Prevents Further Flea Infestation For At Least Four Weeks
- Kills Fleas Before They Lay Eggs

DHE
3/18/96

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 8 weeks of age.

Reason to Issue: To Initiate EPA Product Label

4 9 10
Date: 1/11/96

Supersedes: 12/14/95

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 patients 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: To Initiate EPA Product Label

Date: 1/11/96

Supersedes: 12/14/95

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(Back Panel)

Advantage™ 55

Flea Adulticide

Fast

Effective

Once-A-Month Topical Flea Treatment for Dogs Over 20 lbs.

- Kills fleas within 24 hours
- Prevents reinfestation for at least 4 weeks
- Convenient, easy to apply

Four 2.5 mL Tubes

Reason to Issue: To Initiate EPA Product Label

Date: 1/11/96

Supersedes: 12/14/95

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(Inside Left Panel)

Advantage™ 55

Flea Adulticide

Once-A-Month Topical Flea Treatment for Dogs Over 20 lbs.

For Prevention and Treatment of Flea Infestation 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

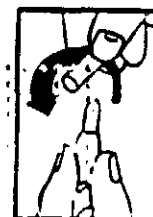
1. Use only on dogs. Do not use on other animals.
2. Remove applicator tube(s) from the package. One applicator tube is required for dogs weighing 21-55 lbs.

Two applicator tubes are required for dogs weighing over 55 lbs.

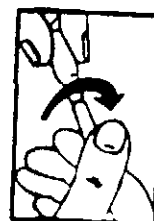
3. Hold applicator tube in an upright position. Pull cap off tube.



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: To Initiate EPA Product Label

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6. The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube twice to apply the solution directly on the skin.

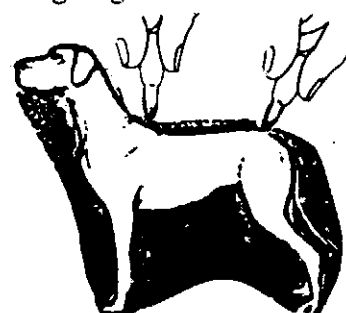
For dogs weighing over 55 lbs. the second tube should be applied on the top of the rump. Part the hair until the skin is visible and apply the solution directly on the skin as described above.

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

Apply one tube for dogs weighing 21-55 lbs



Apply two tubes for dogs weighing over 55 lbs.

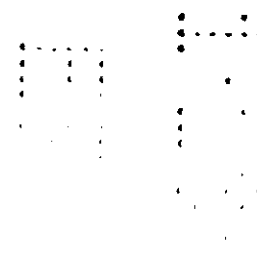


7. Discard empty tube(s) as described in Storage and Disposal.

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.

Shampooing of the dog may shorten the duration of flea protection, therefore reapplication following shampooing is recommended.



Reason to Issue: To Initiate EPA Product Label

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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. 11556-120

Reason to Issue: To Initiate EPA Product Label

9916
Date: 1/11/96

Supersedes: 12/14/95

(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: To Initiate EPA Product Label

Date: 1/11/96

Supersedes: 12/14/95

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(Back of Blister Package)

