

11556-120

04/05/2002

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Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95

	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 11556-120	2. EPA Product Manager Deborah McCall	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Advantage 55 for Dogs	PM#	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation, Animal Health, Agriculture Division P.O. Box 390 Shawnee Mission, KS 66201 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>NOTIFICATION</u> Product Name <u>APR - 5 2002</u>	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

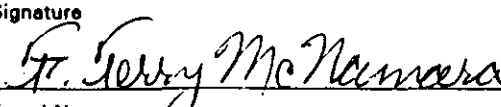
Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Please see attached explanation for details.

Section - III

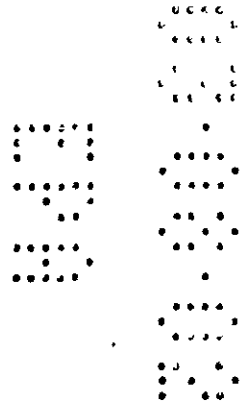
1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Package wgt	No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product			<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name F. Terry McNamara	Title Director, Preclinical Dev. & EPA Reg. Affairs	Telephone No. (Include Area Code) (913) 266-2588
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		8. Date Application Received (Stamped)
2. Signature 	3. Title Director, Preclinical Development & EPA Regulatory Affairs	(Braille area)
4. Typed Name F. Terry McNamara	5. Date 3/4/02	

Attachment for Application for Pesticide Registration
Advantage[®] 55 for Dogs, EPA Reg. No. 11556-120

Enclosed with this application are five (5) copies of final printed labels for Bayer's Advantage[®] 55 for Dogs product (EPA Reg. No. 11556-120). This label is for a new package size (1 tube). The revision is being made by Notification as per PR Notice 98-10 which allows for a change in package size under section II.B "Changes in Packaging and Related Labeling Statements." The enclosed label is identical to the currently approved labels for the 4-tube and 6-tube package sizes for Advantage 55 for Dogs. The only change from the existing label is the net contents statement for the 1-tube package, specifically "One 2.5 mL Tube". Except for the net contents statement, no other changes have been made to the label.



NOTIFICATION
APR - 5 2002

advantage

Once-a-month topical flea treatment for dogs and puppies
7 weeks and older and 21-55 lbs.

55

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea Infestations on Dogs

- Available only through licensed practicing veterinarians
- One treatment prevents further flea infestation for at least four weeks
- Kills 98-100% of the fleas on dogs within 12 hours
- Kills fleas before they lay eggs

Active Ingredient

Imidacloprid, 1-[(6-Chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine 9.1%

Inert Ingredients 90.9%

Total 100.0%

% By Weight

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 puppies under seven 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. For consumer questions call 1-800-255-6826. For medical emergencies call 1-877-258-2280.

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.



Manufactured for Bayer Corporation,
Agriculture Division, Animal Health,
Shawnee Mission, Kansas 66201 USA • Made in Germany

One 2.5 mL Tube

0652, R4
EPA Est. 043995-MJ-001 EPA Reg. No. 11556-120

effective



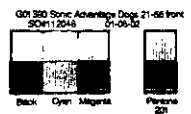
fast

advantage

(imidacloprid)
Topical Solution

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

Once-a-month topical flea treatment
for dogs and puppies 7 weeks
and older and 21-55 lbs.



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Once-a-month topical flea treatment for dogs and puppies 7 weeks and older and 21-55 lbs. 55

The successive feeding activity 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.

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.

For the prevention and treatment of flea infestation on dogs and puppies 7 weeks and older and 21-55 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 dogs. Do not use on other animals.
2. Remove one applicator tube from the package.

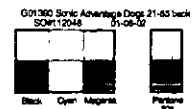
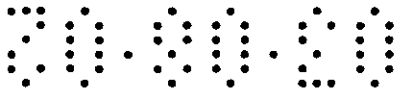
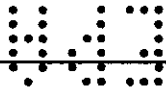


3. Hold applicator tube in an upright position. Pull cap off tube.
4. Turn the cap around and place other end of cap back on tube.

5. Twist cap to break seal, then remove cap from tube.



6. 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.
7. Discard empty tube as described in Storage and Disposal.



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