

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SEP 2 4 2007

Mary McKinney Hunt Pesticide Regulatory Manager Bayer HealthCare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390

RE: Proposed Label Revision, to remove the word "only" from a proposed statement

EPA Reg. No.: 11556-119

Date of Submission: September 10, 2007

Dear Ms. Hunt:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated September 10, 2007, for the product Advantage 20 Topical Solution. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Joyce Edwards of my staff at 703-308-5479.

Linda Arrington

Notifications & Minor Formulations Team Leader

Registration Division (7505P)

Office of Pesticide Programs

Please read instructions on reverse before	Form App	Form Approved. OMB No. 2070-0060. Approval expires 2-28-95				
SEPA Environn	United States nental Protection Ag Washington, DC 20460	jency		tration dment	OPP Identifier Number	
Application for Pesticide - Section I						
1. Company/Product Number 11556-119		EPA Product Manager Venus Eagle		3. Pro	posed Classification	
Company/Product (Name) Advantage 20 Topical Solution		PM# Team 1			THOUSE THE STATE OF THE STATE O	
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 Check if this is a new address		6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No				
0/100 // 0/10 /		Product NameSection - II				
Amendment - Explain below. Resubmission in response to Agence Notification - Explain below.		Final printed labels in repsonse to Agency letter dated			NOTIFICATION SEP 2 4 2007	
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Enclosed for Agency acceptance is the draft label for Advantage 9 Topical Solution (EPA Reg. No. 11556-116). The only label revision is the removal of the word, "only," in the following statement: Available "only" through licensed practicing veterinarians. The proposed statement is: "Available through licensed practicing veterinarians." Please see attachment for further detail.						
Section - III						
1. Material This Product Will Be Packaged In:						
Child-Resistant Packaging Yes No If "Yes" No. per		Vater Soluble Packaging 2. Typ Yes No ''Yes" No. per		of Container Metal Plastic Glass Paper		
* Certification must be submitted		kage wgt container	r E	Other (Specify)		
3. Location of Net Contents Information 4. Size(s) Re Label Container		tail Container 5. Location of Label Direction			ns	
6. Manner in Which Label is Affixed to Product Lithor Paper Stend		graph Other				
Section - IV						
1. Contact Point (Complete items directly	below for identification of inc	dividual to be contacted,	if necessary, to	process this	application.)	
Name Mary McKinney Hunt		Title 1 Pesticides Regulatory Manager		1	Telephone No. (Include Area Code) (913) 268-2311	
•		on I attachments thereto are true, accurate and complete, ment may be punishable by fine or imprisonment or			6. Dete Application Received (Sxamped)	
2. Signature Mary Mikenney Hurt		3. Title Pesticide Regulatory Managerr				
4. Typed Name Mary McKinney Hunt		Sept. 10, 2007				

NOTIFICATION SEP 2 4 2007

ATTACHMENT FOR OPP APPLICATION FOR PESTICIDE NOTIFICATION Page 1 of 1

Advantage 20 Topical Solution, EPA Reg. No. 11556-119 September 10, 2007

Enclosed for Agency acceptance is a draft label for Advantage 20 Topical Solution, EPA Reg. No. 11556-119.

The only proposed change is the removal of the word, "only."

from: Available only through licensed practicing veterinarians.

to: Available through licensed practicing veterinarians.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46 and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

ACCEPTED

MAR 10 2006

Under the Rederal Insecticide, Pungicide, and Rodenticide Act, as amended, for the pesticide Registered under EPA Reg. No. 1556

Once-a-month topical flea treatment for dogs and pupples 7 weeks and older and i 1-20 lbs.

READ THE ENTIRE LABEL BEFORE EACH USE.

For the Prevention and Treatment of Flea Infestations on Dogs

- Available of the through licensed practicing veterinarians
 Kills 98-300% 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 Imidacloprid; I-(6-Chloro-3-pyridinyl) methyl)-N-nitro-2- imidazolidinimine... Other Ingredients.

% By Weight .. 9.1%

90.9% 100.0%

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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 Animais

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 1-877-258-2220.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If swallowed: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.

To Physician: Treat the patient symptomatically.

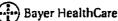
Directions for Use

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.





Manufactured For Bayer HealthCare LLC, Animal Health Division, Shawnee Mission, Kansas 66201 USA

Baver the Bayer Cross and Advantage are trademarks of Bayer

- 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. 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 expel the entire contents of the tube directly on the skin. 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 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 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

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.

Disposal: If empty: Do not reuse container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or 1-877-258-2280 for disposal instructions. Never place unused product down any indoor or outdoor drain.

Limited Warranty and Limitation of Damages

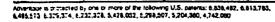
Bayer HealthCare LLC, Animal Health Division warrants that this material conforms to the chemical description on the label, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY CTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer is authorized to do so except 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.

C 2005 Bayer HealthCare LLC 01406278

00837893-03299-J/01791722-053998, R.S. EPA Est. 11558-0EU-1

Made in Germany EPA Reg. No. 11856-119

To receive monthly email application reminders, go to www.nofless.com











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For the Prevention and Treatment of Flee Infestations on Dogs

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KEEP OUT OF REACH OF CHILDREN

WARNING

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Precautionary Statements

Hazenths to Humans: Ca

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Bayer

Six 0.034 floz (1.0 ml) Tubes

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SIX 0.034 fl oz (1.0 ml) Tubes &

Convanient, opsy to apply

Avaitable only through licensed ordeviolag vetering Kills 88-1825s of Pass within 12 hours

for Dogs and Puppies Topical Flea Treatmer

Once-A-Month

7 Weeks and Older

and 11-20 lbs.

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