

11556-122

9.24.2007

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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

SEP 24 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.: 11556-122  
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 100 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.

Sincerely,

A handwritten signature in cursive script that reads "Linda Arrington".

*LA*  
Linda Arrington  
Notifications & Minor Formulations Team Leader  
Registration Division (7505P)  
Office of Pesticide Programs



United States  
Environmental Protection Agency  
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 11556-122	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Advantage 100 Topical Solution	PM# Team 1	
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

**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.

**NOTIFICATION**

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**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:				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	Metal Plastic Glass Paper Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	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	
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 Mary McKinney Hunt	Title Pesticides Regulatory Manager	Telephone No. (Include Area Code) (913) 262-2211
<b>Certification</b> 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.		6. Date Application Received <b>(Stamped)</b>
2. Signature <i>Mary McKinney Hunt</i>	3. Title Pesticide Regulatory Manager	
4. Typed Name Mary McKinney Hunt	5. Date Sept. 10, 2007	

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**NOTIFICATION**

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ATTACHMENT FOR OPP  
APPLICATION FOR PESTICIDE NOTIFICATION  
Page 1 of 1

**Advantage 100 Topical Solution, EPA Reg. No. 11556-122  
September 10, 2007**

Enclosed for Agency acceptance is a draft label for Advantage 100 Topical Solution, EPA Reg. No. 11556-122.

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.**

11556-122

03/10/2006

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ACCEPTED



MAR 10 2006
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide Registered under EPA Reg. No. 11556-122

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

READ THE ENTIRE LABEL BEFORE EACH USE.

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

Table with 2 columns: Active Ingredient, Other Ingredients, Total and % By Weight (9.1%, 90.9%, 100.0%)

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

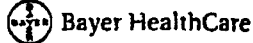
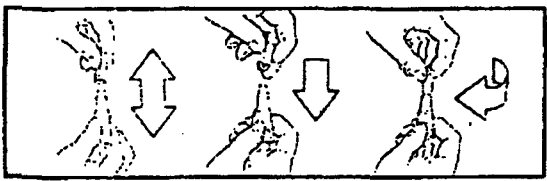
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison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

- Use only on dogs. Do not use on other animals.
Remove one applicator tube from the package.



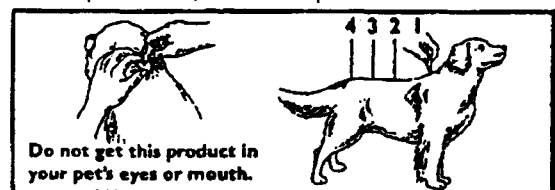
Manufactured For Bayer HealthCare LLC, Animal Health Division, Shawnee Mission, Kansas 66201 USA
Bayer, the Bayer Cross and Advantage are trademarks of Bayer

Advantage is protected by one or more of the following U.S. patents: 6,638,462, 6,619,783, 6,495,573, 6,329,374, 6,292,329, 5,428,032, 5,298,607, 5,204,360, 4,742,060

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- Hold applicator tube in an upright position. Pull cap off tube.
Turn the cap around and place other end of cap back on tube.
Twist cap to break seal, then remove cap from tube.



- 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.
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 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.
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.

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

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 OTHER 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.

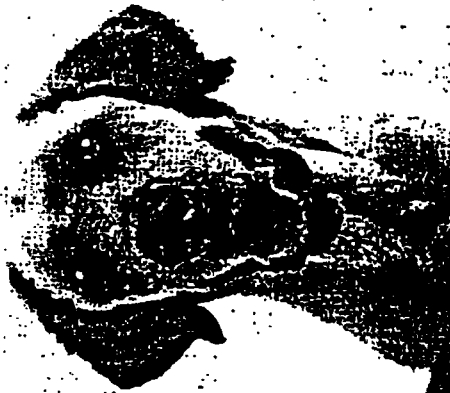
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D1405778
Made in Germany

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

For Dogs and Puppies  
7 Weeks and Older  
and Over 55 lbs.

advantage<sup>®</sup>

advantage<sup>®</sup>



Once-A-Month  
Topical Flea Treatment  
for Dogs and Puppies  
7 Weeks and Older  
and Over 55 lbs.

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

6  
Pkt.  
SIX 0.135 fl oz (4.0 ml) Tubes

Name: \_\_\_\_\_

advantage<sup>®</sup> 100

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

For the Prevention and Treatment of Flea Infestations on Dogs

- Available only through licensed practicing veterinarians
- Kills 99-100% of the flea 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, (1*S*)-*trans*-3-(imidazolyl)methyl-4-nitro-2-hydroxybenzoylamine 9.11%  
Other Ingredients 90.89%  
Net 100.0%

## KEEP OUT OF REACH OF CHILDREN WARNING

See below for First Aid and Precautionary Statements.  
For Children see First Aid and other labeling, see supplemental labeling sheets.

### 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 water before eating, drinking, or using tobacco. Do not consume food or feed.

**Hazards to Domestic Animals:** For animal use only. Do not use on puppies under seven weeks of age. As with any product, avoid your veterinarian before using this product on debilitated, aged, pregnant or nursing animals, lactating animals, with rats, may occur after using other flea products for pets. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is an herbivore, consult your veterinarian before using this or any other product.

For consumer questions call 1-800-525-0228.  
For medical emergencies call 1-877-258-2288.

### First Aid

Wash the product container or label with you when using a poison control center or doctor or going for treatment. If in eyes: Hold eye open and flush 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. Wash skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.

In Pregnancy: Avoid the product approximately.

EPA Reg. No. 11000-302-1 EPA Reg. No. 11000-520



Six 0.135 fl oz (4.0 ml) Tubes

91707170-000109, R,2

Made in Germany

www.bayerusa.com

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Keep the Bayer Cross and Advantage logos trademarks of Bayer




Lot No. \_\_\_\_\_



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**Advantage 100**  
9.1% Imidacloprid  
0.135 fl oz (4.0 ml)  
EPA Reg. No. 11556-122  
**WARNING**  
Keep out of reach of children  
Read The Entire Label Before Use

 Bayer

**01224137** ■  
00412498171749, R.4  
LOT NO.