

11556-122

1/7/2010

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



OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

January 7, 2010

Douglas A. Spilker  
Bayer HealthCare, LLC  
Animal Health Division  
P.O. Box 390  
Shawnee Mission, KS 66201-0390

Dear Dr. Spilker,

Subject: Label Notifications per Pesticide Registration Notice 98-10

The Agency is in receipt of your Applications for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10, dated December 7, 2009, for the following products:

- Advantage 9 Topical Solution, EPA Registration Number 11556-116
- Advantage 10 Topical Solution, EPA Registration Number 11556-117
- Advantage 18 Topical Solution, EPA Registration Number 11556-118
- Advantage 20 Topical Solution, EPA Registration Number 11556-119
- Advantage 55 Topical Solution, EPA Registration Number 11556-120
- Advantage 100 Topical Solution, EPA Registration Number 11556-122

The Registration Division has conducted a review of these requests for their applicability under PRN 98-10, and finds that the actions requested fall within the scope of PRN 98-10. The information submitted with the applications has been stamped "Notification" and will be placed in our records. If you have any questions, please contact me directly at 703-308-8735 or email me at [chao.julie@epa.gov](mailto:chao.julie@epa.gov).

Sincerely,

A handwritten signature in cursive script that reads "Julie A. Chao".

Julie A. Chao  
Insecticide-Rodenticide Branch  
Registration Division (7505P)  
Office of Pesticide Programs

Please read instructions on reverse before completing form.

Form Approved. 2070-0060

Print Form



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

**Application for Pesticide - Section I**

<b>1. Company/Product Number</b> 11556-122	<b>2. EPA Product Manager</b> Venus Eagle	<b>3. Proposed Classification</b> <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
<b>4. Company/Product (Name)</b> Advantage 100 Topical Solution	<b>PM#</b> 01	
<b>5. Name and Address of Applicant (Include ZIP Code)</b> 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	<b>6. Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: <input checked="" type="checkbox"/> 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.

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

See attachment (1p.) for more information.  
Contact: doug.spilker.b@bayer.com

**NOTIFICATION**

**JAN - 7 2010**

**Section - III**

<b>1. Material This Product Will Be Packaged In:</b>				<b>2. Type of Container</b>	
<b>Child-Resistant Packaging</b> <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	<b>Unit Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>Water Soluble Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	<input type="checkbox"/> Plastic
<b>* Certification must be submitted</b>	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
<b>3. Location of Net Contents Information</b> <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		<b>4. Size(s) Retail Container</b> 1/4/6-4.0mL tbe		<b>5. Location of Label Directions</b> <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
<b>6. Manner in Which Label is Affixed to Product</b> <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

**Section - IV**

<b>1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)</b>		
<b>Name</b> Douglas A. Spilker, Ph.D.	<b>Title</b> Manager, EPA Reg. Affairs	<b>Telephone No. (Include Area Code)</b> 913-268-2751
<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.		<b>6. Date Application Received (Stamped)</b>
<b>2. Signature</b> 	<b>3. Title</b> Manager, EPA Reg. Affairs	
<b>4. Typed Name</b> Douglas A. Spilker, Ph.D.	<b>5. Date</b> 7 Dec 2009	



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Reason To Issue: Show additional package size.

Date: 01/05/10

Supersedes: 10/29/08

Note to Reviewer: [Brackets and parentheses indicate alternate language]

**NOTIFICATION**

**Advantage® 100 Topical Solution**

**JAN - 7 2010**

Once-A-Month Topical Flea and Lice 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 and Lice Infestations on Dogs

- One treatment prevents further flea infestation for at least four (4) weeks
- Kills fleas on dogs within 12 hours
- Kills fleas before they lay eggs
- Convenient, easy to apply
- Kills [(biting) (chewing)] lice
- For treatment and prevention of [(biting) (chewing)] lice [infestations]
- Controls existing [(biting) (chewing)] lice infestations
- Dual protection (against fleas and lice)
- Treats, prevents and controls [(biting) (chewing)] lice [infestations]
- Provides effective control of [(biting) (chewing)] lice [infestations]
- Kills [(biting) (chewing)] lice and prevents further infestations
- For treatment and prevention of infestations with [(biting) (chewing)] lice
- Waterproof
- Fragrance free

	<u>% By Weight</u>
Active Ingredient	
Imidacloprid . . . . .	9.1%
Other Ingredients . . . . .	<u>90.9%</u>
Total . . . . .	100.0%

**EPA Reg. No. 11556-122**

**EPA Est. No. 11556-DEU-1**

**KEEP OUT OF REACH OF CHILDREN**

[For Directions For Use, and Storage and Disposal (instructions),  
see supplemental labeling inside]

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### 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 1-800-422-9874.

#### 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 a 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.

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2. Remove one applicator tube from the package.

[Visuals Depicting How to Open Applicator Tube]

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.

[Visuals Depicting Application To Animal]

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.

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

7. Discard empty tube as described in Storage and Disposal.
8. In case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not retreat more often than once every seven days. After flea control is attained, return to a monthly retreatment schedule.

#### **GENERAL INFORMATION**

The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with Advantage kills fleas and may reduce the incidence of this condition.

Advantage kills fleas on dogs 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.

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Advantage is waterproof and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight.

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

#### **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**Storage:** Store in a cool, dry place.

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

**If partly filled:** Call your local solid waste agency or 1-800-422-9874 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. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, 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.

[One] [Four] [Six] 0.014 fl. oz. (0.4 mL) Tubes

**OPTIONAL CLAIM FOR THE ONE TUBE PACKAGE: [Sample – Not for (Re)Sale]**

Manufactured For

Bayer HealthCare LLC

Animal Health Division

P.O. Box 390

Shawnee Mission, Kansas 66201 USA

Made in Germany

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[Label on Individual Tube]

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

Lot No. 0000000