



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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

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

MAR 4 2008

Dear Dr. Spilker:

Subject: Labeling Amendment; Label Claim Revisions  
Advantage 9 Topical Solution  
EPA Registration No. 11556-116  
Date Submitted: February 15, 2008

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable with the following provisions:

1. Revise the claim "*Kills 98-100% of the fleas on cats within 12 hours*" to read "*Kills fleas on cats within 12 hours.*"
2. On page 3 of the label, revise the sentence "*Treatment of pets with Advantage rapidly kills fleas and may reduce the incidence of this condition.*" to read "*Treatment of cats with Advantage kills fleas and may reduce the incidence of this condition.*"
3. On page 3 of the label, revise the sentence "*Advantage kills 98-100% of the fleas on pets within 12 hours.*" to read "*Advantage kills fleas on cats within 12 hours.*"

A stamped copy is enclosed for your records. Please submit one (1) final printed copy for the referenced label, incorporating the above changes, before releasing the product for shipment. If you have any questions regarding this letter, please contact me at (703) 306-0415.

Sincerely,

Kable Bo Davis  
Entomologist  
Insecticide-Rodenticide Branch  
Registration Division (7505P)

Enclosure

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

**Advantage® 9**  
**(imidacloprid) Topical Solution**

Once-A-Month Topical Flea Treatment for Cats and  
Kittens 8 Weeks and Older and 9 lbs. and Under.

**READ THE ENTIRE LABEL BEFORE EACH USE**

For the Prevention and Treatment of Flea Infestations on Cats

- Available only through licensed practicing veterinarians
- One treatment prevents further flea infestation for up to four (4) weeks
- Kills 98-100% of the fleas on cats within 12 hours
- Kills fleas before they lay eggs
- Convenient, easy to apply
- Waterproof
- Remains effective after exposure to rain or sunlight
- Fragrance free

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

**KEEP OUT OF REACH OF CHILDREN**

[For Directions For Use and other labeling, see supplemental labeling inside]

**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.

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated:**

**MAR 4 2008**

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

11556-116

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## HAZARDS TO DOMESTIC ANIMALS

**For external use only.** Do not use on kittens under eight 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.

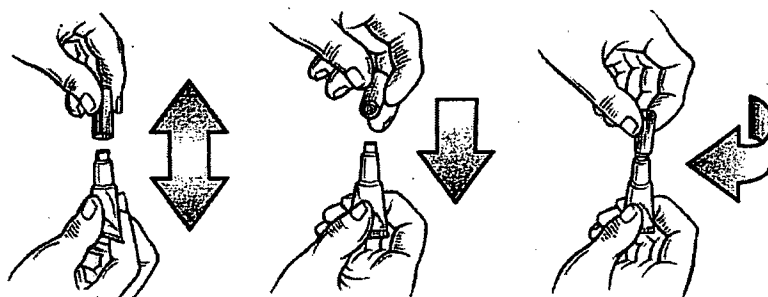
## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

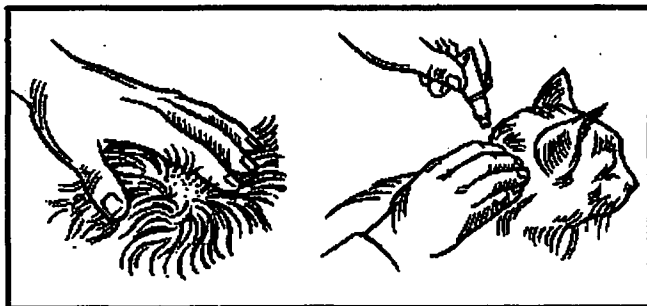
## HOW TO APPLY

1. Use only on cats. 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. Part the hair in the neck at the base of the skull 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. The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the cat to lick the product.
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 is waterproof and 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 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.

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

EPA Est. 11556-DEU-1

EPA Reg. No. 11556-116

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® 9

9.1% Imidacloprid

0.014 fl. oz. (0.4 mL)

EPA Reg. No. 11556-116

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

BAYER

Lot No. 0000000