

11556-116

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.

Sincerely,

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

Attachment to:
OPP APPLICATION FOR PESTICIDE – NOTIFICATION

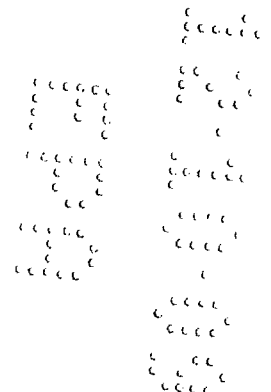
Section II – Explanation:

Bayer HealthCare, Animal Health Division, is notifying the Agency that we plan to produce the product in a third package size, a single tube pack (1-pack), in addition to the current 4- and 6-pack configurations. This is noted on page one of this application form. The packaging and labeling scheme for this size is identical to that used for the other two pack sizes of this product, except for the number of tubes contained.

We are also notifying the Agency, pursuant to PR Notice 98-10, that we will be adding the following optional text to final printed labeling of the appropriate size product, as needed:

["Sample – Not for Resale"]

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 proposed for the labeling or the confidential statement of formula for this product. Bayer understands that it is a violation of 18 U.S. C. Sec. 1001 to willfully make any false statement to EPA. Bayer further understands 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 Bayer may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.



Reason To Issue: Show additional package size.

Date: 01/05/10

Supersedes: 09/05/08

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

NOTIFICATION

JAN - 7 2010

Advantage® 9 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

- One treatment prevents further flea infestation for up to four (4) weeks
- Kills 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%

EPA Reg. No. 11556-116

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]

WARNING

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.

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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.

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3. Hold applicator tube in an upright position. Pull cap off tube.

[Visuals Depicting How to Open Applicator 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. Part the hair on 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 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.
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 cats with Advantage kills fleas and may reduce the incidence of this condition.

Advantage kills fleas on cats 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

Reason To Issue: Show additional package size.

Date: 01/05/10

Supersedes: 09/05/08

[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

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