

11556-120

9/18/2008

1/6

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



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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

SEP 18 2008

Dear Dr. Spilker:

Subject: Amendment of label to revise according to EPA's letter of 3/4/08, PR Notice
2007-4 and other minor changes
Advantage® 55 Topical Solution
EPA Registration No. 11556-120
Your Submissions Dated 9/5/08

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide, as amended are acceptable provided you make the following changes before you release the product for shipment:

On page 4, the first statement, "If re-treatment becomes necessary earlier..." is a mandatory statement and cannot be included under "General Information." This statement needs to be moved into the "Directions for Use" area.

It is also recommended that you move the EPA Reg. Number and EPA Est. Numbers to the first page.

A stamped copy of the labeling is enclosed for your records. Please submit one final printed copy of the labeling before releasing the product for shipment. If you have any questions regarding this label, please contact Autumn Metzger at (703) 305-5314.

Sincerely,

A handwritten signature in black ink, appearing to read "John D. Hebert".

John D. Hebert
Product Manager 7
Insecticide-Rodenticide Branch
Registration Division (7505P)

2/6

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

Advantage® 55 Topical Solution

Once-A-Month Topical Flea and Lice Treatment For Dogs
and Puppies 7 Weeks and Older and 21-55 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%

KEEP OUT OF REACH OF CHILDREN

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

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

SEP 18 2008

**Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:**

11556-120

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.

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.

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.

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.

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: 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.

Four [or six] 0.084 fl. oz (2.5 mL) Tubes

EPA Est. 11556-DEU-1
EPA Reg. No. 11556-120

Manufactured For
Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, Kansas 66201 USA

Made in Germany

[Label on Individual Tube]

Advantage® 55

9.1% Imidacloprid

0.084 fl. oz. (2.5 mL)

EPA Reg. No. 11556-120

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

BAYER

Lot No. 0000000