

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



AUG 29 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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

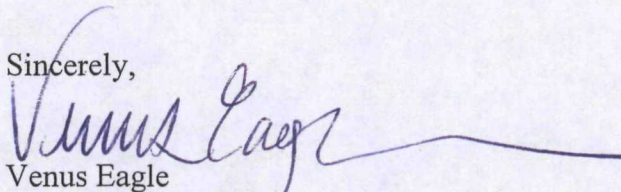
Dear Dr. Spilker:

Subject: Amendment to update labels per spot on mitigation letter sent by the Agency dated September 30, 2011
EPA Registration Nos./Product name:
11556-116, Advantage 9 Topical Solution (small cats)
11556-117, Advantage 10 Topical Solution (small dogs)
11556-118, Advantage 18 Topical Solution (large cats)
11556-119, Advantage 20 Topical Solution (medium dogs)
11556-120, Advantage 55 Topical Solution (large dogs)
→ 11556-122, Advantage 100 Topical Solution (extra large dogs)

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide, as amended are acceptable.

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,



Venus Eagle
Product Manager 01
Insecticide-Rodenticide Branch
Registration Division (7505P)

Reason To Issue: Revise according to EPA "Implementation Date: 08/20/2012
of Label Changes to Pet Spot-On Products" Supersedes: 07/17/2012,
document, dated 9/30/11 (Rec'd 10/11/11) 03/01/2012 & 08/27/2010

[Front Panel]

Advantage® 100 Topical Solution

Alternate Brand Name: **Advantage for Extra Large Dogs**

Once-A-Month Topical Flea and Lice Treatment
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 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 Est. No. 11556-XXX-X | EPA Reg. No. 11556-122 |

- See Back Panel for First Aid and Precautionary Statements.
- For Directions For Use, and Storage and Disposal (instructions), see supplemental labeling inside.

Icon size 1.5cm x 1.5cm



**KEEP OUT OF REACH OF CHILDREN
WARNING**

ACCEPTED
AUG 29 2012

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

EPA. Reg. No: 11556-122

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[Back Panel]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

WARNING: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. 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.

| FIRST AID | |
|---|--|
| If In Eyes: | <ul style="list-style-type: none"> • 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: | <ul style="list-style-type: none"> • Call a 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 | <ul style="list-style-type: none"> • 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. |
| HOT LINE NUMBER | |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies call 1-800-422-9874. For customer questions call 1-800-255-6826. | |
| NOTE TO PHYSICIAN | |
| Treat the patient symptomatically. | |

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 dogs. 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.

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Side Effects: Monitor your dog after application. Side effects, although very rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy) occur, consult your veterinarian or call 1-800-422-9874.

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

Icon size 1.5cm x 1.5 cm



RESTRICTIONS:

- Use only on dogs 7 weeks and older and weighing over 55 lbs. Do not use on other animals.
- Do not apply more than one (1) tube per treatment, even for larger dogs.
- Do not have contact or allow children to have contact with treated area until completely dry.

Net Contents: [X] Tube(s) each 0.135 fl. oz. (4.0 mL)
[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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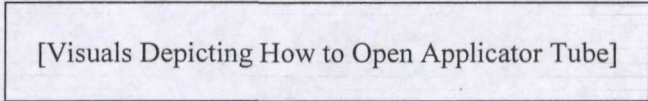
[Back Panel and/or insert]

DIRECTIONS FOR USE

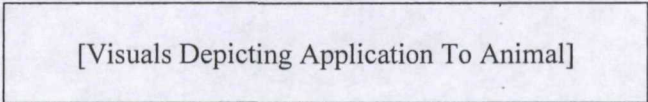
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HOW TO APPLY

- 1. Remove one applicator tube from the package.
- 2. Hold applicator tube in an upright position facing away from you and your pet's face and eyes. Pull cap off tube.



- 3. Turn the cap around and place other end of cap back on tube.
- 4. Twist cap to break seal, then remove cap from tube.
- 5. 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 dog's eyes or allow your dog to ingest this product.* Do not allow the product to run off.



- 6. Discard empty tube as described in Storage and Disposal.
- 7. 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.

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PRODUCT INFORMATION

The successive feeding activity of fleas on dogs 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 dog s surroundings are killed following contact with an Advantage treated dog

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

Pesticide Storage Store in a cool dry place inaccessible to children and pets **Pesticide Disposal and Container Handling** 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

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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

8/8

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[Label on blister card; one card containing 1, 2, 3, 4, 5 or 6 tubes]

Advantage® 100
Topical Solution

For external use only on dogs and puppies 7 weeks and older and weighing over 55 lbs.

9.1% Imidacloprid

[X] - 0.135 fl. oz. (4.0 mL)

EPA Reg. No. 11556-122

BAYER

