

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,

A handwritten signature in blue ink that reads "Venus Eagle". The signature is fluid and cursive, with a long horizontal line extending to the right.

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

Reason To Issue: Revise according to EPA "Implementation of Label Changes to Pet Spot-On Products" document, dated 9/30/11 (Rec'd 10/11/11) Date: 08/20/2012 Supersedes: 07/17/2012, 02/22/12 & 08/27/2010

[Front Panel]

Advantage[®] 9 Topical Solution
Alternate Brand Name: **Advantage[®] for Small Cats**

Once-A-Month Topical Flea Treatment for Cats and Kittens
For Use Only on Cats 8 Weeks and Older and Weighing 2 to 9 lbs.

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
- 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. 11556-116

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

**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:

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) 02/22/12 & 08/27/2010

[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 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 kittens under eight weeks of age or weighing less than 2 lbs As with any product consult your veterinarian before using this product on debilitated aged pregnant or nursing cats Individual sensitivities while rare may occur after using ANY pesticide product for cats 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 cat 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 hypersalivation, 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.

RESTRICTIONS:

- Use only on cats 8 weeks and older. Do not use on other animals. Do not apply to kittens or cats weighing less than 2 lbs.
- Do not apply more than one (1) tube per treatment.
- Do not have contact or allow children to have contact with treated area until completely dry.

Net Contents: Tube(s) each 0.014 fl. oz. (0.4 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.

[Visuals Depicting How to Open Applicator 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. 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 cat's eyes or allow your cat to ingest this product.* 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. Do not allow the product to run off.

[Visuals Depicting Application To Animal]

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 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 cat's surroundings are killed following contact with an Advantage treated cat.

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

Advantage® 9
Topical Solution

For external use only on cats and kittens 8 weeks and older and weighing 2 to 9 lbs.

9.1% Imidacloprid

- 0.014 fl. oz. (0.4 mL)

EPA Reg. No. 11556-116

BAYER