

11556-125

11/7/2012

1/12

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



NOV 07 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:
11556-125, Advantage II Medium Dog ✓
11556-127, Advantage II Large Dog
11556-128, Advantage II Small Dog
11556-130, Advantage II Extra Large Dog

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

As a reminder, **this registration is time-limited and expires January 17, 2013**. You must apply to extend the expiration and/or to change the terms of this registration.

Per the implementation of label changes for pet spot on products, the Agency has reviewed a copy of the print ready label.

A stamped copy of the labeling is enclosed for your records. If you have any questions regarding this label, please contact Autumn Metzger at (703) 305-5314.

Sincerely,

A handwritten signature in black ink that reads "Venus Eagle".

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

2/12

Reason To Issue: Revise according to EPA "Implementation of Label Changes to Pet Spot-On Products" document Date: 09/25/12 Supersedes: 03/26/12 and 09/15/10

NOTE TO REVIEWER: [(Brackets and parentheses indicate alternate language)]

[Front Panel]

Advantage® II Medium Dog

Once-A-Month Topical Treatment for Fleas and Lice For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 11 - 20 lbs.

[Selected optional claims bulleted here from page 10 and/or 11]

- •
•
•

Table with 2 columns: Active Ingredients, % By Weight. Rows include Imidacloprid (9.10%), Pyriproxyfen (0.46%), Other Ingredients (90.44%), and Total (100.00%).

EPA Est. 11556-XXX-X

EPA Reg. No. 11556-125

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for Precautionary Statements. For Directions for Use, Storage and Disposal, and First Aid see package insert inside.

ACCEPTED NOV 07 2012

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

DO NOT USE ON CATS

Icon size 1.5cm x 1.5cm



EPA. Reg. No: 11556-125

3/12

Reason To Issue: Revise according to EPA "Implementation of Label Changes to Pet Spot-On Products" document

Date: 09/25/12
Supersedes: 03/26/12 and 09/15/10

[Back panel]

Advantage® II Medium Dog

Once-A-Month Topical Treatment for Fleas and Lice
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 11 - 20 lbs.

READ THE ENTIRE LABEL BEFORE EACH USE
For the Prevention and Treatment of Flea and Lice Infestations [on Dogs]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and warm water after handling.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 7 weeks of age or weighing less than 11 lbs. 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 dogs. If signs persist, or become more severe, consult a veterinarian immediately. If your dog is on medication, consult your veterinarian before using this or any other product.

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



For consumer questions call 1-800-255-6826.
For medical emergencies call 1-800-422-9874.

RESTRICTIONS:

- Use only on dogs 7 weeks and older and weighing 11 – 20 lbs. Do not use on other animals.

4/12

Reason To Issue: Revise according to EPA "Implementation of Label Changes to Pet Spot-On Products" document
Date: 09/25/12
Supersedes: 03/26/12 and 09/15/10

- 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 0.034 fl. oz. (1.0 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

5/12

Reason To Issue:	Revise according to EPA "Implementation of Label Changes to Pet Spot-On Products" document	Date:	09/25/12
		Supersedes:	03/26/12 and 09/15/10

[Back Panel and/or Insert]

Advantage® II Medium Dog

Once-A-Month Topical Treatment for Fleas and Lice
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 11 - 20 lbs.

READ THE ENTIRE LABEL BEFORE EACH USE
For the Prevention and Treatment of Flea and Lice Infestations [on Dogs]

DIRECTIONS FOR USE

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

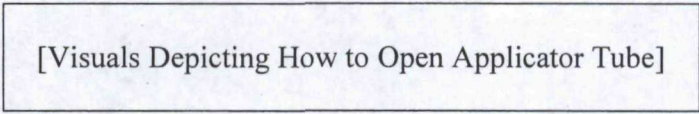


HOW TO OPEN

1. Being careful not to cut close to the blister cavities, take scissors and cut off one section of the card containing a single tube.
2. Take the separated section, and cut into the blister cavity across the small side, close to the cap of the tube.
3. Peel off the foil, and take out the tube.
4. Repeat steps 1 to 3 for each tube.

HOW TO APPLY

1. Remove one applicator tube from the package. See "HOW TO OPEN" section.
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. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. *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.

Reason To Issue: Revise according to EPA "Implementation of Label Changes to Pet Spot-On Products" document

Date: 09/25/12
Supersedes: 03/26/12 and 09/15/10

6/12

[Visuals Depicting Application To Animal]

6. Discard empty tube as described in the Storage and Disposal section.
7. Under normal conditions the product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every seven (7) days. After flea control is obtained, return to a monthly retreatment schedule.

PRODUCT INFORMATION

The successive feeding activity of fleas on dogs frequently elicits a hypersensitivity skin disorder known as flea allergy dermatitis (FAD) or flea bite hypersensitivity. Treatment of dogs with Advantage® II Medium Dog rapidly kills fleas within 12 hours which may reduce the incidence of this condition.

Advantage® II Medium Dog kills existing fleas on dogs within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting for four (4) weeks. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions.

Fleas, flea eggs, and flea larvae in the dog's environment are killed following contact with an Advantage® II Medium Dog treated dog. Advantage® II Medium Dog provides multi-stage flea control effectively breaking all flea life-cycle stages for quick and lasting control of flea populations.

Advantage® II Medium Dog kills adult fleas quickly, within 12 hours, inhibits the development of immature flea life stages and prevents them from reaching the biting adult stage.

Advantage® II Medium Dog kills [(biting) (chewing)] lice that infest dogs and puppies, and prevents further infestations.

Advantage® II Medium Dog 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.

7/12

Reason To Issue:	Revise according to EPA "Implementation of Label Changes to Pet Spot-On Products" document	Date:	09/25/12
		Supersedes:	03/26/12 and 09/15/10

KEEP OUT OF REACH OF CHILDREN

CAUTION

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS**

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and warm water after handling.

FIRST AID	
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 to an unconscious person.
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 On Skin	<ul style="list-style-type: none"> • Wash with plenty of soap and water.
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 consumer 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 7 weeks of age or weighing less than 11 lbs. 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 dogs. If signs persist, or become more severe, consult a veterinarian immediately. If your dog is on medication, consult your veterinarian before using this or any other product.

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.

8/12

Reason To Issue: Revise according to EPA "Implementation of Label Changes to Pet Spot-On Products" document
Date: 09/25/12
Supersedes: 03/26/12 and 09/15/10

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



For consumer questions call 1-800-255-6826.
For medical emergencies call 1-800-422-9874.

RESTRICTIONS:

- Use only on dogs 7 weeks and older and weighing 11 – 20 lbs. Do not use on other animals.
- 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.

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. To the extent consistent with applicable law, 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.

9/12

Reason To Issue: Revise according to EPA "Implementation of Label Changes to Pet Spot-On Products" document
Date: 09/25/12
Supersedes: 03/26/12 and 09/15/10

[Label on Individual Tube]

Advantage[®] II Medium Dog

9.10% Imidacloprid

0.46% Pyriproxyfen

0.034 fl. oz. (1.0 mL)

EPA Reg. No. 11556-125

Keep Out of Reach of Children

CAUTION

Read The Entire Label Before Use

BAYER

Lot No. 0000000

6/12

Reason To Issue: Revise according to EPA "Implementation of Label Changes to Pet Spot-On Products" document

Date: 09/25/12
Supersedes: 03/26/12 and 09/15/10

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

Advantage® II Medium Dog

For external use only on dogs and puppies 7 weeks and older and weighing 11 - 20 lbs.

9.10% Imidacloprid

0.46% Pyriproxyfen

[X] - 0.034 fl. oz. (1.0 mL)

EPA Reg. No. 11556-125

BAYER



Reason To Issue: Revise according to EPA "Implementation of Label Changes to Pet Spot-On Products" document
Date: 09/25/12
Supersedes: 03/26/12 and 09/15/10

11/12

NOTE TO REVIEWER: [(Brackets and parentheses indicate alternate language)]

OPTIONAL MARKETING CLAIMS

- For use on dogs and puppies 7 weeks of age and older
- Advantage II contains [imidacloprid], and [an/the] [insect growth regulator] [IGR] [pyriproxyfen]
- A single topical application remains effective for [4 weeks] [a month]
- Convenient, easy-to-apply topical solution
- Convenient, easy-to-apply and fragrance free [monthly] [topical solution]
- Once a month topical flea treatment for dogs 7 weeks of age or older
- Advantage II is indicated for the prevention and treatment of fleas on dogs 7 weeks of age and older
- For the treatment and prevention of flea [and lice] infestations
- One treatment prevents further flea infestations for [4 weeks] [a month]
- Kills fleas on dogs within [12] hours and continues to prevent infestations for [four weeks] [a month]
- Kills fleas before they lay eggs
- Larval flea stages in the dog's environment are killed following contact with an Advantage II treated dog
- Kills larval stages of fleas in the dog's environment
- Kills fleas within [12] hours of application
- Stops existing flea infestations by killing adult fleas
- Prevents [Stops] reinfestations by killing adult fleas before they lay eggs
- [Prevents] [Stops] flea eggs from hatching [into biting adults]
- Effectively breaks the flea life cycle
- Effectively targets all [life] stages of [fleas]
- [Kills] [Controls] all flea life stages
- 3-way flea protection ([kills] [controls] adults, larvae, and eggs)
- [Prevents] [Stops] flea eggs [and flea larvae] from developing into [(biting) (adult)] fleas
- Treatment with Advantage II rapidly kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
- Flea adulticide, larvicide, and ovcide
- Kills flea eggs
- Controls highly [irritating] [annoying] [flea] [insect] bites
- Controls flea problems
- Provides flea protection
- Controls existing fleas and flea eggs [(plus) (and)] [prevents] future flea infestations in the home
- Starts working through contact

12/12

Reason To Issue: Revise according to EPA "Implementation of Label Changes to Pet Spot-On Products" document

Date: 09/25/12
Supersedes: 03/26/12 and 09/15/10

- Use flea [prevention][protection] year-round
- Contains an insect growth regulator (IGR) to kill flea eggs and prevent re-infestation
- Monthly use of Advantage II kills fleas which may cause ([flea allergy dermatitis][flea bite hypersensitivity])
- Multi-stage flea control
- Prevents fleas on treated dogs from infesting (reinfesting) your home
- Kills fleas which may serve as intermediate hosts for tapeworms
- Kills [(biting) (chewing)] lice
- For treatment and prevention of [(biting) (chewing)] lice [infestations]
- Stops 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
- Remains effective after bathing and/or swimming
- Remains effective following swimming and/or shampooing
- Waterproof
- Remains effective after exposure to rain or sunlight
- Fragrance-free
- [In child-resistant packaging]