

11556-128

09-18-2007

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U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (7505C)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

EPA Reg. Number:  
11556-128

Date of Issuance:  
SEP 18 2007

NOTICE OF PESTICIDE:

Registration  
 Reregistration

(under FIFRA, as amended)

Term of Issuance:  
Conditional

Name of Pesticide Product:  
Advantage Plus 10 for Dogs

Name and Address of Registrant (include ZIP Code):  
Bayer HealthCare LLC, Animal Health Division  
P.O. Box 390  
Shawnee Mission, KS 66201-0390

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product when the Agency requires all registrants of similar products to submit such data.
2. Make the following label changes before you release the product for shipment:
  - a. Revise the EPA Registration Number to read, "EPA Reg. No. 11556-128".
3. The data requirements for storage stability (830-6317) and corrosion characteristics (830-6320) have not been satisfied, and must be submitted within eighteen months of the date of this letter.

Signature of Approving Official:

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

Date:

SEP 18 2007

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4. Submit one copy of the revised final printed label for the record before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

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

Enclosure

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

(Front Panel)

Advantage<sup>®</sup> Plus 10

Topical Solution

Once-A-Month Topical Treatment for Fleas and Lice  
On Dogs and Puppies 7 Weeks and Older and 10 lbs. and Under

READ ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea and Lice Infestations on Dogs

- Available through licensed practicing veterinarians
- For use on dogs and puppies 7 weeks of age and older
- Advantage Plus contains [imidacloprid], and [an/the] [insect growth regulator] [IGR] [pyriproxyfen] [Nylar<sup>®</sup>]\*
- A single topical application remains effective for at least 4 weeks
- Convenient, easy to apply topical solution
- Once a month topical flea treatment for dogs 7 weeks of age or older
- Advantage Plus is indicated for the prevention and treatment of fleas on dogs 7 weeks of age and older
- For the treatment and prevention of flea infestations
- One treatment prevents further flea infestations for at least 4 weeks
- Kills 98-100% of the fleas on dogs within 12 hours and continues to prevent infestations for at least four weeks
- Kills fleas before they lay eggs
- Larval flea stages in the dog's surroundings are killed following contact with an Advantage Plus treated dog
- Kills larval stages of fleas in the pet's environment
- Kills 98-100% of fleas within 12 hours of application
- Stops existing flea infestations by killing adult fleas
- Prevents reinfestations by killing adult fleas before they lay eggs
- Prevents flea eggs from hatching
- Effectively breaks the flea life cycle
- Effectively targets all [life] stages of [fleas]
- 3-way flea protection ([kills] [controls] adults, larvae, and eggs)
- Prevents flea eggs [and flea larvae] from developing into [(biting) (adult)] fleas
- Treatment with Advantage Plus rapidly kills fleas and may reduce the incidence of Flea Allergic Dermatitis [FAD]

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated:**  
**SEP 18 2007**  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
11556-128

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- Flea adulticide, larvicide, and ovicide
- Prevents fleas on treated dogs from infesting (reinfesting) your home
- Kills fleas often before they bite and may reduce the risk of Canine Vector Borne Diseases (CVBD)
- 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 (odor) free
- In child-resistant packaging

\*NYLAR® - Registered trademark of McLaughlin Gormley King Co.

<u>Active Ingredients</u>	<u>% By Weight</u>
Imidacloprid; [CAS 138261-41-3] .....	9.10%
Pyriproxyfen; [CAS 95737-68-1] .....	0.46%
Other Ingredients .....	<u>90.44%</u>
Total .....	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Below for First Aid and Precautionary Statements

PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS

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

Reason To Issue: Minor Updates

Date: 09/17/07  
Supersedes: 07/10/07

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### HAZARDS TO DOMESTIC ANIMALS

For external use only.

Do not use on puppies under 7 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

**IF SWALLOWED:** 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:** 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:** Wash with plenty of soap and water.

**TO PHYSICIAN:** Treat the patient symptomatically.

([Four] [Six]) 0.014 fl. oz. (0.4 mL) Tubes

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

Manufactured For  
Bayer HealthCare LLC  
Animal Health Division  
Shawnee Mission, Kansas 66201 USA

Made in Germany

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(Back Panel)

## Advantage<sup>®</sup> Plus 10

Topical Solution  
Fast  
Effective  
Multi-Stage Flea Control

Once-A-Month Topical Treatment for Fleas and Lice on  
Dogs and Puppies 7 Weeks and Older and 10 lbs. and Under

- Available through licensed practicing veterinarians
- Kills fleas within 12 hours
- Kills reinfesting fleas within 2 hours
- Prevents reinfestation for up to 4 weeks
- Convenient, easy to apply
- Kills adults, larvae, and eggs
- Kills chewing lice
- Waterproof
- In child-resistant packaging

READ ENTIRE LABEL BEFORE EACH USE

([Four] [Six]) 0.014 fl. oz. (0.4 mL) Tubes

Reason To Issue: Minor Updates

Date: 09/17/07

Supersedes: 07/10/07

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(Leaflet)

Advantage<sup>®</sup> Plus 10

Topical Solution

Once-A-Month Topical Treatment for Fleas and Lice on  
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For the Prevention and Treatment of Flea and Lice Infestations on Dogs.

<u>Active Ingredients</u>	<u>% By Weight</u>
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Pyriproxyfen; [CAS 95737-68-1] .....	0.46%
Other Ingredients .....	<u>90.44%</u>
Total .....	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

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PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS

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

Reason To Issue: Minor Updates

Date: 09/17/07

Supersedes: 07/10/07

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### HAZARDS TO DOMESTIC ANIMALS

For external use only.

Do not use on puppies under 7 weeks of age.

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### FIRST AID

**IF SWALLOWED:** 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:** 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:** Wash with plenty of soap and water.

**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 OPEN [4-Pack]

1. To open the blister, prepare blister card piece containing only one cavity/tube by cutting off a section of the blister card.
2. Do not cut close to the blister cavities.
3. Cut into the blister cavity across the small side close to the cap of the tube.
4. Peel off the cover foil and take out the tube.
5. Repeat steps 1 to 4 for each tube.

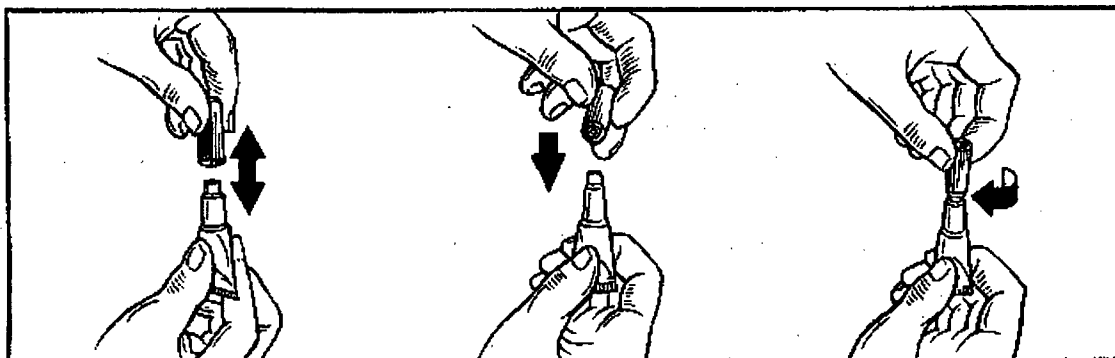
HOW TO OPEN [6-Pack]

1. Take a pair of scissors and cut blister card in the center of the long side into two equal portions with 3 cavities/tubes each.
2. Do not cut close to the blister cavities.
3. The two halves of the blister card can now be separated into 3 pieces with one cavity/tube each.
4. To open the blister, prepare blister card piece containing only one cavity/tube.
5. Cut into the blister cavity across the small side close to the cap of the tube.
6. Peel off the cover foil and take out the tube.
7. Repeat steps 4 to 6 for each tube.



HOW TO APPLY

1. Use only on dogs. Do not use on other animals.
2. Remove one applicator tube from the package. See "HOW TO OPEN" section.

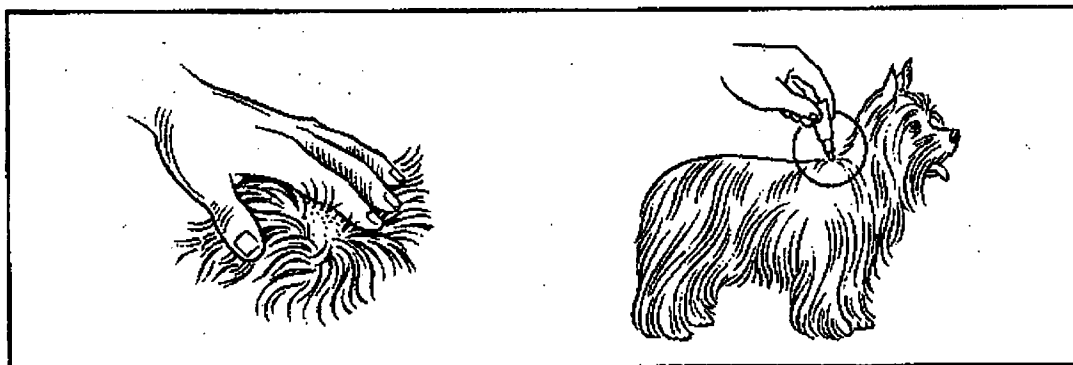


3. Hold applicator tube in an upright position. Pull cap off tube.
4. Turn the cap around and place other end of cap back on tube.

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5. Twist cap to break seal, then remove cap from tube.
6. 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 twice to expel the entire contents directly on the skin.

Do not get this product in your pet's eyes or mouth.



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

The successive feeding activity of fleas on pets frequently elicits a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with Advantage® Plus rapidly kills fleas and reduces the incidence of this condition.

Advantage® Plus kills 98-100% of the existing fleas on pets 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.

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

Advantage® Plus kills adult fleas quickly, inhibits the development of immature flea life stages and prevents them from reaching the biting adult stage.

Reason To Issue: Minor Updates

Date: 09/17/07  
Supersedes: 07/10/07

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Advantage<sup>®</sup> Plus is waterproof and remains efficacious 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.

**If Empty:** Do not reuse 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.

EPA Est. 11556-DEU-1

EPA Reg. No. 11556-REI

Manufactured for Bayer HealthCare LLC  
Animal Health Division  
Shawnee Mission, Kansas 66201 USA

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Date: 09/17/07  
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(Label on Individual Tube)

Advantage<sup>®</sup> Plus 10

9.10% Imidacloprid

0.46% Pyriproxyfen

0.014 fl. oz. (0.4 mL)

EPA Reg. No. 11556-REI

CAUTION

Keep Out of Reach of Children

Read The Entire Label Before Use.

BAYER

Lot No. 0000000