



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 15, 2016

Douglas A. Spilker
Manager, EPA Regulatory Affairs
Bayer HealthCare, LLC
Animal Health
P. O. Box 390
Shawnee Mission, KS 66201-0390

Subject: Label Amendment – Response to Agency’s letter dated 12/21/2015
Product Name: Advantage II Large Dog
EPA Registration Number: 11556-127
Application Date: January 19, 2016
Decision Number: 513854

Dear Mr. Spilker:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

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

Page 2 of 2
EPA Reg. No. 11556-127
Decision No. 513854

with FIFRA section 6. If you have any questions, please contact Rita Kumar by phone at (703) 308-8291, or via email at kumar.rita@epa.gov.

Sincerely,

A handwritten signature in cursive script that reads "Rita Kumar" followed by a stylized flourish.

Venus Eagle, Product Manager 01
Insecticide-Rodenticide Branch 3
Registration Division (7505P)
Office of Pesticide Programs

Reason To Issue: Minor label revisions.

Date: 06/07/2016

Supersedes: 02/14/13

NOTE TO REVIEWER: [(Brackets and parentheses indicate alternate language or notes to the EPA reviewer)]

Braces “{ }” indicate location of text on container label

{Front Panel}

Advantage® II Large Dog

ACCEPTED

Jul 15, 2016

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 11556-127

Once-A-Month Topical Treatment for Fleas and Lice
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 21-55 lbs.

Note: [The “Large Dog” text size will be 75% of the height of the largest letter in the primary brand name.]

Visual image of a dog within the weight range for product.

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

-
-

ACTIVE INGREDIENTS

%
By Weight

Imidacloprid	9.10%
Pyriproxyfen	0.46%
OTHER INGREDIENTS.	<u>90.44%</u>
TOTAL.	100.00%

EPA Est. 11556-XXX-X

EPA Reg. No. 11556-127

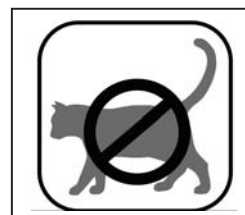
KEEP OUT OF REACH OF CHILDREN

CAUTION

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

DO NOT USE ON CATS

[Icon Size 1.5 cm X 1.5 cm, Background yellow with black text
positioned in the lower right hand of package.]



Reason To Issue: Minor label revisions.

Date: 06/07/2016

Supersedes: 02/14/13

{Back panel}

Advantage® II Large Dog

Once-A-Month Topical Treatment for Fleas and Lice
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 21-55 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 and clothing. Wash hands after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 7 weeks of age or weighing less than 21 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities 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 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 21 – 55 lbs. Do not use on other animals.

Reason To Issue: Minor label revisions.

Date: 06/07/2016

Supersedes: 02/14/13

- 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: [X] Tube(s) each 0.085 fl. oz. (2.5 mL)

[Sample – Not for Sale]

[Note to reviewer: 1 and 2 packages are completely labeled (all components) as the 4 and 6 packs. The “Sample – Not for Sale” is only used for the 1 or 2 packs]

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

Made in Germany

{ Back Panel and/or Insert }

Advantage® II Large Dog

Once-A-Month Topical Treatment for Fleas and Lice
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 21-55 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

[OPTION 1: INSTRUCTIONS FOR BLISTER PACK]

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.

[OPTION 2: INSTRUCTIONS FOR POUCH PACK]

1. Be sure tube is at bottom of pouch.
2. Using scissors, cut the pouch across the top and remove tube.

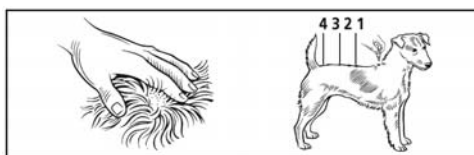
HOW TO APPLY

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. Apply the entire contents of the tube 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.*



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 retreat more often than once every seven (7) days. After flea control is attained, 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 Large Dog rapidly kills fleas within 12 hours which may reduce the incidence of this condition.

Advantage® II Large 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.

Advantage® II Large Dog provides multi-stage flea control effectively breaking flea life-cycle stages for quick and lasting control of flea populations.

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

Reason To Issue: Minor label revisions.

Date: 06/07/2016

Supersedes: 02/14/13

Advantage® II Large 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.

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes and clothing. Wash hands after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

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 OR CLOTHING:	• 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 21 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities may occur after using ANY pesticide product for dogs. If signs persist, or become more severe, consult a veterinarian

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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 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 21-55 lb. 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.

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Supersedes: 02/14/13

For more information visit www.petbasics.com

Reason To Issue: Minor label revisions.

Date: 06/07/2016

Supersedes: 02/14/13

{Back Panel and/or Bottom}

Lot. No. 000000

{Label on Individual Tube}

Advantage[®] II Large Dog

9.10% Imidacloprid

0.46% Pyriproxyfen

0.085 fl. oz. (2.5 mL)

EPA Reg. No. 11556-127

Keep Out of Reach of Children

CAUTION

Read The Entire Label Before Use

BAYER

Lot No. 0000000

Reason To Issue: Minor label revisions.

Date: 06/07/2016

Supersedes: 02/14/13

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

[OPTION 2: Label on pouch containing one tube]

Advantage® II Large Dog

For external use only on dogs and puppies 7 weeks and older and weighing 21 - 55 lbs.

See insert for complete product information.

9.10% Imidacloprid

0.46% Pyriproxyfen

[X] - 0.085 fl. oz. (2.5 mL) Tube(s)

EPA Reg. No. 11556-127

THIS UNIT NOT FOR RETAIL SALE

BAYER



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

OPTIONAL MARKETING CLAIMS

- For use on dogs and puppies 7 weeks of age and and Weighing 21-55 lb
- 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 and Weighing 21-55 lb
- Advantage II is for the prevention and treatment of fleas on dogs 7 weeks of age and older and Weighing 21-55 lb
- 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 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 [life] stages of fleas after application
- [Kills] [Controls] 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 ovicide
- Kills flea eggs
- Controls highly [irritating] [annoying] [flea] [insect] bites
- Controls flea problems
- Provides flea protection
- Starts working through contact
- Use for flea [prevention] year-round
- Contains an insect growth regulator (IGR) to kill flea eggs and prevent re-infestation

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Supersedes: 02/14/13

- Monthly use of Advantage II kills fleas which may cause ([flea allergy dermatitis][flea bite hypersensitivity])
- Multi-stage flea control
- 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