

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



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

December 1, 2016

Mr. Todd Frank/ Mr. Bruce Martin
Bayer Animal Health Development
P.O. Box 390
Shawnee Mission, KS 66201-0390

Subject: Notice of Extension of Conditional Registrations until January 17, 2019

Dear Mr. Frank and Mr. Martin:

This letter is in reference to your request dated November 18, 2016 to extend the following conditional time-limited registrations:

Advantage 9 Topical Solution	EPA Reg. No. 11556-116
Advantage 10 Topical Solution	EPA Reg. No. 11556-117
Advantage 18 Topical Solution	EPA Reg. No. 11556-118
Advantage 20 Topical Solution	EPA Reg. No. 11556-119
Advantage 55 Topical Solution	EPA Reg. No. 11556-120
Advantage 100 Topical Solution	EPA Reg. No. 11556-122
Advantage II Medium Dog	EPA Reg. No. 11556-125
Advantage II Large Dog	EPA Reg. No. 11556-127
Advantage II Small Dog	EPA Reg. No. 11556-128
Advantage II Extra Large Dog	EPA Reg. No. 11556-130
Advantage II Kitten	EPA Reg. No. 11556-150
Advantage II Small Cat	EPA Reg. No. 11556-151
Advantage II Large Cat	EPA Reg. No. 11556-152

Also, the Agency is in receipt of Mr. Martin's 10/7/16 and 10/28/16 letters requesting to remove the time limitations.

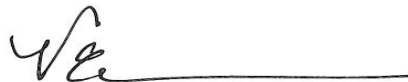
The above-referenced registrations contain conditions calling for the registrations to expire two years from the date the products are first released for shipment (i.e., January 17, 2013). Additionally, your company is required to adhere to the spot on label mitigation, submit quarterly enhanced incident reports and quarterly sales information for each of the above registrations.

The Agency has found Bayer in compliance with the terms and conditions for the subject products. The Agency contacted Mr. Martin on 11/19/16 and relayed that it is not in a position to use the incident and quarterly reporting data to make a regulatory decision on Bayer's request to remove the time-limitation from these registrations and therefore is granting the request to extend the 2-year time-limited registration restriction. As such, the following change is being made to the terms and conditions of the products listed above:

- **The 2-year time-limited registration restriction has been extended an additional two (2) years. Therefore the new expiration date for the subject product registrations is now January 17, 2019.**

Please note that these products are still subject to all other previous required conditions of registration. If you have any questions, please contact the product manager, Venus Eagle, at eagle.venus@epa.gov or (703) 308-8045.

Regards,

A handwritten signature in black ink, appearing to read 'Ve', followed by a horizontal line extending to the right.

Venus Eagle, Product Manager 01
Invertebrate and Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

ACCEPTED
 12/01/2016
 Under the Federal Insecticide, Fungicide
 and Rodenticide Act as amended, for the
 pesticide registered under
 EPA Reg. No. 11556-127

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

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	<u>% By Weight</u>
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.

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- 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.

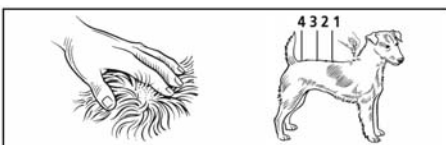
HOW TO APPLY

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.

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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:	<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 OR CLOTHING:	<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 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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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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- 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