

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.

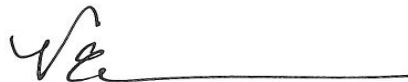
The above-referenced registrations contain conditions calling for the registrations to expire two years from the date the products are first released for shipment (i.e., January 17, 2013). Additionally, your company is required to adhere to the spot on label mitigation, submit quarterly enhanced incident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

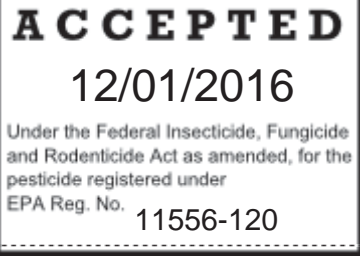
- **The 2-year time-limited registration restriction has been extended an additional two (2) years. Therefore the new expiration date for the subject product registrations is now January 17, 2019.**

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 'Venus Eagle', 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



Reason To Issue: Update Label.

Date: 02/22/2016
Supersedes: 08/20/2012

[Front panel]

Advantage® 55 Topical Solution
Alternate Brand Name: **Advantage for Large Dogs**

Note: [The “Large Dogs” 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.

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

READ THE ENTIRE LABEL BEFORE EACH USE

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

[Selected option claims]

- One treatment prevents further flea infestation for at least four (4) weeks
- Kills fleas on dogs within 12 hours
- Kills fleas before they lay eggs
- Convenient, easy to apply
- Kills [(biting) (chewing)] lice
- For treatment and prevention of [(biting) (chewing)] lice [infestations]
- Controls 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
- Waterproof
- Fragrance free

	% By Weight
ACTIVE INGREDIENT:	
Imidacloprid	9.1%
OTHER INGREDIENTS:	90.9%
Total	100.0%
EPA Est. No. 11556-XXX-X	EPA Reg. No. 11556-120

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

Icon size 1.5cm x 1.5cm



DO NOT USE ON CATS

[Icon Size 1.5 cm X 1.5 cm, Background yellow with black text]

KEEP OUT OF REACH OF CHILDREN

WARNING

[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. Do not get in eyes or on clothing. 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.	

Reason To Issue: Update Label.

Date: 02/22/2016

Supersedes: 08/20/2012

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under seven weeks of age. 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 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.

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



RESTRICTIONS:

- Use only on dogs 7 weeks and older and weighing 21 to 55 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.

Net Contents: [X] Tube(s) each 0.084 fl. oz. (2.5 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

[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. The dog should be standing for easy application. The entire contents of the Advantage tube should be applied 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. 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.

Reason To Issue: Update Label.

Date: 02/22/2016

Supersedes: 08/20/2012

PRODUCT INFORMATION

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with Advantage kills fleas and may reduce the incidence of this condition.

Advantage kills fleas on dogs 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.

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.

Reason To Issue: Update Label.

Date: 02/22/2016

Supersedes: 08/20/2012

[Label on Individual Tube]

Advantage® 55

9.1% Imidacloprid

0.084 fl. oz. (2.5 mL)

EPA Reg. No. 11556-120

Keep Out of Reach of Children

WARNING

Read The Entire Label Before Use

BAYER

Lot No. 0000000

Reason To Issue: Update Label.

Date: 02/22/2016

Supersedes: 08/20/2012

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

Advantage® 55
Topical Solution

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

9.1% Imidacloprid

See leaflet for complete information

[X] - 0.084 fl. oz. (2.5 mL)

[THIS UNIT NOT FOR RETAIL SALE]

EPA Reg. No. 11556-120

BAYER

