

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.

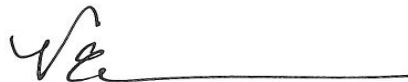
The above-referenced registrations contain conditions calling for the registrations to expire two years from the date the products are first released for shipment (i.e., January 17, 2013). Additionally, your company is required to adhere to the spot on label mitigation, submit quarterly enhanced incident 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. 11556-150

Reason To Issue: Minor label revisions Date: 06/01/2016
 Supersedes: 11/01/13

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 Kitten

Alternate Brand Names:

- [ExpertCare Flea Protection Kitten]
- [ExpertCare Topical Flea Protection Kitten]
- [ExpertCare Kitten Flea Protection]
- [ExpertCare Kitten Topical Flea Protection]

Once-A-Month Topical Flea Prevention and Treatment for Cats
 For Use ONLY on Cats 8 Weeks and Older and Weighing 2 – 5 lbs.

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

Visual image of a kitten 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. No. 11556-XXX-X

EPA Reg No. 11556-150

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for Precautionary Statements, Restrictions and First Aid.

Reason To Issue: Minor label revisions.

Date: 06/01/2016

Supersedes: 11/01/13

For Directions for Use, Storage and Disposal, and First Aid see package insert inside.

{Back Panel}

Advantage® II Kitten

Once-A-Month Topical Flea Prevention and Treatment for Cats
For Use ONLY on Cats 8 Weeks and Older and Weighing 2 - 5 lbs.

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea Infestations

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. Keep out of reach of children. Do not contaminate feed or food.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not apply to cats or kittens under 8 weeks of age or weighing less than 2 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing cats. Individual sensitivities may occur after using ANY pesticide product for cats. If signs persist, or become more severe, consult a veterinarian immediately. If your cat is on medication, consult your veterinarian before using this or any other product.

Side Effects: Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as hypersalivation, 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.

For consumer questions call 1-800-255-6826.

For medical emergencies call 1-800-422-9874.

RESTRICTIONS:

- Use only on cats or kittens 8 weeks and older and weighing 2 – 5 lbs. Do not apply to cats or kittens weighing less than 2 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: [1, 2, 3, 4 or 6] Tube(s), each 0.0078 fl. oz. (0.23 mL)

Reason To Issue: Minor label revisions.

Date: 06/01/2016

Supersedes: 11/01/13

[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 Bottom }

Lot No.

Reason To Issue: Minor label revisions.

Date: 06/01/2016

Supersedes: 11/01/13

{Back Panel and/or Insert}

Advantage® II Kitten

Once-A-Month Topical Flea Prevention and Treatment for Cats
For Use ONLY on Cats 8 Weeks and Older and Weighing 2 - 5 lbs.

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea Infestations

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]

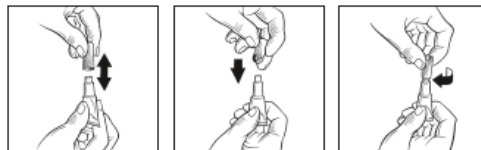
1. Being careful not to cut close to the blister cavities, take scissors and cut off one section of the card containing a single tube.
2. Take the separated section, and cut into the blister cavity across the small side, close to the cap of the tube.
3. Peel off the foil, and take out the tube.
4. Repeat 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. Part the hair on the neck at the base of the skull 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 cat's eyes, or allow your cat to ingest this product. The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment.* Treatment at the base of the skull will minimize the opportunity for the cat to lick the product. Do not allow the product to run off.



6. Discard empty tube as described in Storage and Disposal.
7. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) weeks. Do not retreat more often than once every fourteen (14) days. After flea control is attained, return to a monthly retreatment schedule.

PRODUCT INFORMATION

The successive feeding activity of fleas on cats frequently elicits a hypersensitivity skin disorder known as flea allergy dermatitis (FAD) or flea bite hypersensitivity. Treatment of cats with Advantage® II Kitten kills fleas and may reduce the incidence of this condition.

Advantage® II Kitten kills the existing fleas on cats 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® II Kitten provides multi-stage flea control effectively breaking flea life-cycle stages for lasting control of flea populations.

Advantage® II Kitten 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 Kitten is waterproof and remains effective following a shampoo treatment or after exposure to rain or sunlight.

Apply monthly treatments 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 or clothing. Wash hands after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Keep out of reach of children. Do not contaminate feed or food.

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 customer questions call 1-800-255-6826.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not apply to cats or kittens under 8 weeks of age or weighing less than 2 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing cats. Individual sensitivities may occur after using ANY pesticide product for cats. If signs persist, or become more severe, consult a veterinarian immediately. If your cat is on medication, consult your veterinarian before using this or any other product.

Side Effects: Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as hypersalivation, 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.

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

RESTRICTIONS:

- Use only on cats or kittens 8 weeks and older and weighing 2 -5 lbs. Do not apply to cats or kittens weighing less than 2 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. 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.

For more information visit www.petbasics.com

Reason To Issue: Minor label revisions.

Date: 06/01/2016

Supersedes: 11/01/13

{Label on Individual Tube}

Advantage[®] II Kitten

9.10% Imidacloprid

0.46% Pyriproxyfen

0.0078 fl. oz. (0.23 mL)

EPA Reg. No. 11556-150

Keep Out of Reach of Children

CAUTION

Read The Entire Label Before Use

BAYER

Lot No. 0000000

Reason To Issue: Minor label revisions.

Date: 06/01/2016

Supersedes: 11/01/13

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

{OPTION 2: Label on pouch containing 1 tube}

Advantage[®] II Kitten

For external use only on cats and kittens 8 weeks and older and weighing 2 -5 lbs.

See insert for complete product information.

9.10% Imidacloprid

0.46% Pyriproxyfen

[1, 2, 3, 4 or 6] - 0.0078 fl. oz. (0.23 mL) Tube(s)

EPA Reg. No. 11556-150

THIS UNIT NOT FOR RETAIL SALE

BAYER

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

OPTIONAL MARKETING CLAIMS [Appearing on any panel]

- For use on cats and kittens 8 weeks of age and older and weighing 2 – 5 lbs
- Advantage II contains [imidacloprid], [and an/the] [insect growth regulator] [IGR] [pyriproxyfen]
- A single topical application remains effective for up to [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 prevention and treatment for cats 8 weeks of age or older and weighing 2 – 5 lbs
- Advantage II is for the prevention and treatment of fleas on cats 8 weeks of age and older and weighing 2 – 5 lbs
- For the prevention and treatment of flea infestations
- One treatment prevents further flea infestations for up to [4 weeks] [a month]
- Kills fleas on cats within [12] hours and continues to prevent infestations for up to [four weeks] [a month]
- Kills larval stages of fleas following contact with an Advantage II treated cat
- Kills fleas within [12] hours of application
- Stops existing flea infestations by killing adult fleas
- Prevents reinfestations by killing adult fleas before they lay eggs
- Reinfesting fleas are killed within 2 hours with protection against further flea infestation
- [Prevents] [Stops] flea eggs from hatching [into biting adults]
- Effectively breaks the flea life cycle
- [Kills] [Controls] flea life stages
- Comprehensive flea prevention and treatment
- 3-way flea protection ([kills] [controls]) adults, larvae, and eggs
- [Prevents] [Stops] flea eggs from developing into [(biting) (adult)] fleas
- Treatment with Advantage II kills fleas and may reduce the incidence of flea allergic dermatitis [FAD] or flea bite hypersensitivity
- Flea adulticide, larvicide, and ovicide
- Kills flea eggs
- Controls flea problems
- Advantage II may be used year-round for flea [prevention]
- Contains an insect growth regulator (IGR) to kill flea eggs and prevent re-infestation
- Monthly use of Advantage II kills fleas and may prevent ([flea allergy dermatitis][flea bite hypersensitivity])
- Controls existing flea infestations on your cat and prevents further infestations
- Prevents fleas on treated cats from reinfesting

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- Remains effective after bathing
- Remains effective following shampooing
- Waterproof
- Remains effective after exposure to rain or sunlight
- Fragrance-free
- In child-resistant packaging
- Starts working through contact