



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 12, 2016

Douglas Spilker
Manager, EPA Regulatory Affairs
Bayer HealthCare LLC, Animal Health Division
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 Cat
EPA Registration Number: 11556-152
Application Date: January 19, 2016
Decision Number: 513861

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. 11556-152
Decision No. 513861

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 black ink 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.

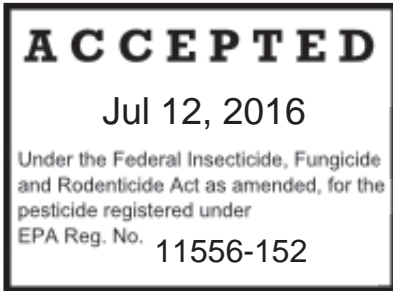
Date: 06/01/2016

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 Large Cat

Alternate Brand Names:

- [ExpertCare Flea Protection Large Cat]
- [ExpertCare Topical Flea Protection Large Cat]
- [ExpertCare Large Cat Flea Protection]
- [ExpertCare Large Cat Topical Flea Protection]

Once-A-Month Topical Flea Prevention and Treatment for Cats
For Use ONLY on Cats 8 Weeks and Older and Weighing Over 9 lbs.

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

Visual image of a Large Cat 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 | 90.44% |
| TOTAL | 100.00% |

EPA Est. No. 11556-XXX-X

EPA Reg No. 11556-152

KEEP OUT OF REACH OF CHILDREN

Reason To Issue: Minor label revisions.

Date: 06/01/2016

Supersedes: 11/01/13

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.

{Back Panel}

Advantage® II Large Cat

Once-A-Month Topical Flea Prevention and Treatment for Cats
For Use ONLY on Cats 8 Weeks and Older and Weighing Over 9 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 9 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:

Reason To Issue: Minor label revisions.

Date: 06/01/2016

Supersedes: 11/01/13

- Use only on cats or kittens 8 weeks and older and weighing over 9 lbs. Do not apply to cats or kittens weighing less than 9 lbs. Do not use on other animals.
- Do not apply more than one (1) tube per treatment, even for larger cats.
- Do not have contact or allow children to have contact with treated area until completely dry.

Net Contents: [1, 2, 3, 4, 6] Tube(s), each 0.027 fl. oz. (0.8 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 Bottom}

Lot No.

{ Back Panel and/or Insert }

Advantage® II Large Cat

Once-A-Month Topical Flea Prevention and Treatment for Cats
For Use ONLY on Cats 8 Weeks and Older and Weighing Over 9 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]

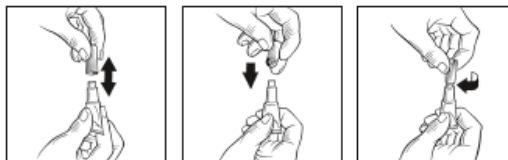
1. Being careful not to cut close to the blister cavities, take scissors and cut off one section of the card containing a single tube.
2. Take the separated section, and cut into the blister cavity across the small side, close to the cap of the tube.
3. Peel off the foil, and take out the tube.
4. Repeat 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 seven (7) 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 Large Cat kills fleas and may reduce the incidence of this condition.

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

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

Reason To Issue: Minor label revisions.

Date: 06/01/2016

Supersedes: 11/01/13

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 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.

| 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 9 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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Date: 06/01/2016

Supersedes: 11/01/13

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

RESTRICTIONS:

- Use only on cats or kittens 8 weeks and older and weighing over 9 lbs. Do not apply to cats or kittens weighing less than 9 lbs. Do not use on other animals.
- Do not apply more than one (1) tube per treatment, even for larger cats.
- 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 Large Cat

9.10% Imidacloprid

0.46% Pyriproxyfen

0.027 fl. oz. (0.8 mL)

EPA Reg. No. 11556-152

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 Large Cat

For external use only on cats and kittens 8 weeks and older and weighing over 9 lbs.

See insert for complete product information.

9.10% Imidacloprid

0.46% Pyriproxyfen

[1, 2, 3, 4 or 6] - 0.027 fl. oz. (0.8 mL) Tube(s)

EPA Reg. No. 11556-152

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 over 9 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 over 9 lbs
- Advantage II is for the prevention and treatment of fleas on cats 8 weeks of age and older and weighing over 9 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]

Reason To Issue: Minor label revisions.

Date: 06/01/2016

Supersedes: 11/01/13

- 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
- 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