

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 27, 2017

Kim Huls Manager, Regulatory Affairs Bayer Healthcare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390

Subject: PRIA Label Amendment – Additional CRP option & Label Amendments

Product Name: Advantage II Small Cat EPA Registration Number: 11556-151 Application Date: 01-February-2017

Decision Number: 526111

Dear Ms. Huls:

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

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with FIFRA section 6. If you have any questions, please contact Dee Colby by phone at 703-347-8657, or via email at colby.deanna@epa.gov.

Sincerely,

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

Enclosure: Stamped Label

Reason To Issue: Alternate instructions for long neck tube

Date: 06/26/2017 Supersedes: 06/01/2016

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### MASTER LABEL for Advantage® II Small Cat EPA Reg No. 11556-151

### ACCEPTED

06/27/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 44550 454

11556-151

This label is divided into 3 sub-labels as follows:

Sub-label A: Cat and Ferret Sub-label B: Cat Only Sub-label C: Ferret Only\*

### **Alternate Brand Names:**

\*[Advantage II Ferret] to be used only with Sub-label C

### **SUB-LABEL A: Cat and Ferret Only Product**

NOTE TO REVIEWER: [Brackets indicate alternate language or notes to the EPA reviewer] Braces "{}" indicate location of text on container label

### **{Front Panel}**

For Use
ONLY on Cats 8
Weeks and
Older and
5 – 9 lbs. and
Ferrets 10 weeks
and older and 1
lb. or Greater

Visual image of a small cat within the weight range for product.

### Advantage® II Small Cat

Note: [The "Small Cat" text size will be 40% - 75% of the height of the largest letter in the primary brand name.]

[Selected optional claims bulleted here from OPTIONAL MARKETING CLAIMS]

Image of tube

[1, 2, 3, 4, or 6] monthly doses

Once-A-Month Topical Flea Prevention and Treatment [for Cats and Ferrets]
For Use ONLY on Cats 8 Weeks and Older and Weighing 5 - 9 lbs. or Ferrets 10 weeks and
Older and Weighing 1 lb. or Greater

Reason To Issue:	Alternate instructions for long neck tube	Date:	06/26/2017
		Supersedes:	: 06/01/2016
		LABEL A:	Cat and Ferret

ACTIVE INGREDIENTS	% By Weight
Imidacloprid	9.10%
Pyriproxyfen	0.46%
OTHER INGREDIENTS:	90.44%
TOTAL	100.00%

#### KEEP OUT OF REACH OF CHILDREN

### **CAUTION**

See back panel for First Aid, Precautionary Statements, and Directions for Use. For all information, including Storage and Disposal see insert inside carton.

### {Back Panel}

### Advantage® II Small Cat

Note: [The "Small Cat" text size will be  $4\overline{0}\%$  - 75% of the height of the largest letter in the primary brand name.]

Once-A-Month Topical Flea Prevention and Treatment [for Cats and Ferrets]
For Use ONLY on Cats 8 Weeks and Older and Weighing 5 - 9 lbs. or
Ferrets 10 weeks and Older and Weighing 1 lb. or Greater

### READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea Infestations on Cats and Ferrets

[Selected optional claims bulleted here from OPTIONAL MARKETING CLAIMS]

### 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 by mouth 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.

## 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 apply to cats or kittens under 8 weeks of age or weighing less than 5 lbs. or on kits (young ferrets) under 10 weeks of age or weighing less than 1 lb. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing cats or ferrets. Individual sensitivities may occur after using ANY pesticide product for cats or ferrets. If signs persist, or become more severe, consult a veterinarian immediately. If your cat or ferret is on medication, consult your veterinarian before using this or any other product.

**Side Effects (Cats):** 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.

**Side Effects (Ferrets):** Monitor your ferret after application. Side effects may include temporary changes in fecal consistency. If these or other side effects occur, consult your veterinarian or call 1-800-422-9874.

### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

### **RESTRICTIONS:**

- Use only on cats or kittens 8 weeks and older and weighing 5 9 lbs. and only on ferrets 10 weeks and older and weighing 1 lb. or greater. 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.
- Do not allow children to apply the product.
- Cats or ferrets should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].

See inside flap for HOW TO OPEN and HOW TO APPLY, or insert for full Directions for Use.

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

Net Contents: [1, 2, 3, 4, or 6] Tube(s), each 0.014 fl. oz. (0.4 mL)

EPA Est. No. 11556-XXX-X

EPA Reg No. 11556-151

Manufactured For

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

Made in Germany

[Sample – Not for Sale]

[Note to reviewer: cartons containing 1 or 2, individually pouched, tubes are completely labeled (all components) as the 3, 4 and 6 packs. The "Sample – Not for Sale" is used as optional text for the 1 or 2 packs only.]

{Any Panel}

Lot No.

### {Additionally, Inside Flap of Unit Carton for 1, 2, 3, 4, or 6 tubes}

### **DIRECTIONS FOR USE (continued from back panel)**

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 SHORT NECK TUBE POUCH]

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

### [OPTION 3: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

- 1. Be sure the tube is at the bottom of the pouch.
- 2. Use scissors to cut the pouch across the top, being careful not to cut the tube.
- 3. Remove the tube from the package.

### HOW TO APPLY

## [OPTION 1: INSTRUCTIONS FOR BLISTER PACK AND SHORT NECK TUBE POUCH]

- 1. Use only on cats or kittens 8 weeks and older and weighing 5-9 lbs. and only on ferrets 10 weeks and older and weighing 1 lb. or greater. Do not use on other animals.
- 2. Cats or ferrets should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].
- 3. Remove one [applicator tube] [pouch] from the carton. See "HOW TO OPEN" section.
- 4. Hold applicator tube in an upright position facing away from you and your cat's or ferret's face and eyes. Pull cap off tube.







- 5. Turn the cap around and place other end of cap back on tube.
- 6. Twist cap to break seal, then remove cap from tube.
- 7. 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 or ferret's eyes, or allow your cat or ferret to ingest this product. The product is bitter tasting and salivation may occur for a short time if the cat or ferret licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the cat or ferret to lick the product. Do not allow the product to run off.



- 8. Discard empty tube as described in Storage and Disposal.
- 9. 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. On cats, do not retreat more often than once every seven (7) days, not to exceed 4 weekly treatments. On ferrets, do not retreat more often than every 14 days, not to exceed 2 biweekly treatments. After flea control is attained, return to a monthly retreatment schedule.

### [OPTION 2: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

- 1. Use only on cats or kittens 8 weeks and older and weighing 5 9 lbs. and only on ferrets 10 weeks and older and weighing 1 lb. or greater. Do not use on other animals.
- 2. Cats or ferrets should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].
- 3. Remove one pouch from the carton. See "HOW TO OPEN" section.
- 4. Hold applicator tube in an upright position facing away from you and your cat's or ferret's face and eyes. Twist the tip of the applicator to break seal.





5. In order to ensure proper application, part the hair on the neck at the base of the skull. Place the tip of the tube against the cat's or ferret's skin.





- 6. Gently squeeze the tube to expel the entire contents of the tube directly on the skin.
- 7. Do not get this product in your cat's or ferret's eyes, or allow your cat or ferret to ingest this product. Do not allow the product to run off of the cat or ferret. The product is bitter tasting and salivation may occur for a short time if the cat or ferret licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the cat or ferret to lick the product.
- 8. Discard the empty tube as described in the Storage and Disposal section.
- 9. 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. On cats, do not retreat more often than once every seven (7) days, not to exceed 4 weekly treatments. On ferrets, do not retreat more often than every 14 days, not to exceed 2 biweekly treatments. Once the infestation is under control, return to a monthly treatment schedule.

For more information visit www.petbasics.com.

### {Insert}

### Advantage® II Small Cat

Note: [The "Small Cat" text size will be 40% - 75% of the height of the largest letter in the primary brand name.]

Once-A-Month Topical Flea Prevention and Treatment [for Cats and Ferrets]
For Use ONLY on Cats 8 Weeks and Older and Weighing 5 - 9 lbs. or Ferrets 10 weeks and
Older and Weighing 1 lb. or Greater

### READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea Infestations on Cats and Ferrets

[Selected optional claims bulleted here from OPTIONAL MARKETING CLAIMS]

ACTIVE INGREDIENTS	% By Weight
Imidacloprid	9.10%
Pyriproxyfen	0.46%
OTHER INGREDIENTS:	90.44%
TOTAL	100.00%

## KEEP OUT OF REACH OF CHILDREN CAUTION

### 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 by mouth 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.

## 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 5 lbs. or on kits (young ferrets) under 10 weeks of age or weighing less than 1 lb. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing cats or ferrets. Individual sensitivities may occur after using ANY pesticide product for cats or ferrets. If signs persist, or become more severe, consult a veterinarian immediately. If your cat or ferret is on medication, consult your veterinarian before using this or any other product.

**Side Effects (Cats):** 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. **Side Effects (Ferrets):** Monitor your ferret after application. Side effects may include temporary changes in fecal consistency. If these or other side effects occur, consult your

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

veterinarian or call 1-800-422-9874.

### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

### **RESTRICTIONS:**

- 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.
- Do not allow children to apply the product.

### **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 SHORT NECK TUBE POUCH]

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

### [OPTION 3: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

- 1. Be sure the tube is at the bottom of the pouch.
- 2. Use scissors to cut the pouch across the top, being careful not to cut the tube.
- 3. Remove the tube from the package.

### **HOW TO APPLY**

## [OPTION 1: INSTRUCTIONS FOR BLISTER PACK AND SHORT NECK TUBE POUCH]

- 1. Use only on cats or kittens 8 weeks and older and weighing 5 9 lbs. and only on ferrets 10 weeks and older and weighing 1 lb. or greater. Do not use on other animals.
- 2. Cats or ferrets should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].
- 3. Remove one [applicator tube] [pouch] from the carton. See "HOW TO OPEN" section.
- 4. Hold applicator tube in an upright position facing away from you and your cat's or ferret's face and eyes. Pull cap off tube.







5. Turn the cap around and place other end of cap back on tube.

6. Twist cap to break seal, then remove cap from tube.

7. 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 or ferret's eyes, or allow your cat or ferret to ingest this product. The product is bitter tasting and salivation may occur for a short time if the cat or ferret licks the product immediately after treatment.

Treatment at the base of the skull will minimize the opportunity for the cat or ferret to lick the product. Do not allow the product to run off.



- 8. Discard empty tube as described in Storage and Disposal.
- 9. 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. On cats, do not retreat more often than once every seven (7) days, not to exceed 4 weekly treatments. On ferrets, do not retreat more often than every 14 days, not to exceed 2 biweekly treatments. After flea control is attained, return to a monthly retreatment schedule.

### [OPTION 2: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

- 1. Use only on cats or kittens 8 weeks and older and weighing 5 9 lbs. and only on ferrets 10 weeks and older and weighing 1 lb. or greater. Do not use on other animals.
- 2. Cats or ferrets should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].
- 3. Remove one pouch from the carton. See "HOW TO OPEN" section.
- 4. Hold applicator tube in an upright position facing away from you and your cat's or ferret's face and eyes. Twist the tip of the applicator to break seal.





5. In order to ensure proper application, part the hair on the neck at the base of the skull. Place the tip of the tube against the cat's or ferret's skin.





- 6. Gently squeeze the tube to expel the entire contents of the tube directly on the skin.
- 7. Do not get this product in your cat's or ferret's eyes, or allow your cat or ferret to ingest this product. Do not allow the product to run off of the cat or ferret. The product is bitter tasting and salivation may occur for a short time if the cat or ferret licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the cat or ferret to lick the product.
- 8. Discard the empty tube as described in the Storage and Disposal section.
- 9. 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. On cats, do not retreat more often than once every seven (7) days, not to exceed 4 weekly treatments. On ferrets, do not retreat more often than every 14 days, not to exceed 2 biweekly treatments. After flea control is attained, return to a monthly treatment schedule.

### PRODUCT INFORMATION FOR CATS

[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 Small Cat kills fleas rapidly, within 12 hours, and may reduce the incidence of this condition.]

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

Advantage® II Small Cat kills adult fleas on cats quickly, within 12 hours, inhibits the development of immature flea life stages and prevents them from reaching the biting adult stage.

Advantage® II Small Cat is waterproof after 24 hours and remains effective following a shampoo treatment or after exposure to rain or sunlight.

Apply monthly treatments for optimal control and prevention of fleas.

To successfully prevent and control fleas, all cats must be treated with their own dose of Advantage® II Small Cat.

Apply according to label instructions, ensuring that the product is applied to the skin, not on top of the fur.

If your cat wears a decorative collar, it may be helpful to remove the collar before application, so it doesn't absorb the product.

Remember, your cat needs to be dry at the time Advantage® II Small Cat is applied and remains dry 24 hours after application.

Even indoor cats need protection against fleas because you or other pets in the household may bring fleas into the home. Fleas in your cat's environment can re-infest your cat. If you have a flea infestation, consider treating your home and yard with appropriate premise products to protect against fleas.

### PRODUCT INFORMATION FOR FERRETS

Advantage® II Small Cat kills the existing fleas on ferrets within 24 hours. Reinfesting fleas are killed 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 Small Cat provides multi-stage flea control effectively breaking flea life cycle stages for lasting control of flea populations.

Advantage® II Small Cat kills adult fleas on ferrets within 24 hours, inhibits the development of immature flea life stages and prevents them from reaching the biting adult stage.

Advantage® II Small Cat is waterproof after 24 hours and remains effective following a shampoo treatment or after exposure to rain or sunlight.

Apply monthly treatments 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.

[For more information visit www.petbasics.com.]

Manufactured For

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

Made in Germany

EPA Est. No. 11556-XXX-X EPA Reg No. 11556-151

# **{OPTION 1: Label on blister pack; one blister pack containing 1, 2, 3, 4, or 6 tubes} {OPTION 2: Label on pouch containing 1 tube}**

### Advantage® II Small Cat

For external use only on cats and kittens 8 weeks and older and weighing 5 - 9 lbs. or ferrets 10 weeks and older and weighing 1 lb. or greater

See insert for complete product information.

9.10% Imidacloprid

0.46% Pyriproxyfen

[1, 2, 3, 4, or 6]—Tube(s) - 0.014 fl. oz. (0.4 mL)

EPA Reg. No. 11556-151

THIS UNIT NOT FOR RETAIL SALE

**BAYER** 

### {Label on Individual Tube - label is colored coded to age and weight grouping}

Advantage® II Small Cat

9.10% Imidacloprid

0.46% Pyriproxyfen

0.014 fl. oz. (0.4 mL)

EPA Reg. No. 11556-151

Keep Out of Reach of Children

**CAUTION** 

Read The Entire Label Before Use

**BAYER** 

Lot No. 0000000

NOTE TO REVIEWER: [Brackets indicate alternate language]
[All claims apply to all sub-labels (A, B and C) however only language applicable to the species indicated in the sub-label will be used.]

### **OPTIONAL MARKETING CLAIMS** [Appearing on any panel]

- 1. For use on cats and kittens 8 weeks of age and older and weighing 5-9 lbs
- 2. For use on ferrets (and kits) 10 weeks of age and older and weighing 1 lb or greater
- 3. Advantage II contains imidacloprid and an insect growth regulator [IGR]
- 4. Advantage II contains imidacloprid and an insect growth regulator [IGR], pyriproxyfen
- 5. Advantage II contains imidacloprid [and][pyriproxyfen]
- 6. A single topical application remains effective for up to [4 weeks] [a month]
- 7. Convenient, easy-to-apply topical solution
- 8. Convenient, easy-to-apply and fragrance free [monthly] [topical solution]
- 9. Once a month topical flea prevention and treatment for cats 8 weeks of age or older and weighing 5 9 lbs [and ferrets 10 weeks of age and older and weighing 1 lb or greater]
- 10. Advantage II is for the prevention and treatment of fleas on cats 8 weeks of age and older and weighing 5 9 lbs [and ferrets 10 weeks of age and older and weighing 1 lb or greater]
- 11. For the prevention and treatment of flea infestations [on cats][ferrets]
- 12. One treatment prevents further flea infestations for up to [4 weeks] [a month]
- 13. Kills fleas within 12 hours on cats [, 24 hours on ferrets,] and continues to prevent infestations for up to [four weeks] [a month]
- 14. Kills fleas on cats within 12 hours [and on ferrets within 24 hours] of application
- 15. Stops existing flea infestations by killing adult fleas
- 16. Prevents reinfestations by killing adult fleas, so they can't lay eggs
- 17. Reinfesting fleas on cats are killed within 2 hours providing protection against further flea infestation
- 18. [Prevents] [Stops] flea eggs from hatching [into biting adults]
- 19. Effectively breaks the flea life cycle
- 20. [Kills] [Controls] flea life stages
- 21. Comprehensive flea prevention and treatment kills adult fleas, flea larvae, and flea eggs
- 22. 3-way protection against fleas [kills] [controls] adults, larvae, and eggs
- 23. [Prevents] [Stops] flea eggs from developing into [biting] [adult] fleas
- 24. Treatment of cats with Advantage II kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
- 25. Flea adulticide, larvicide, and ovicide
- 26. Kills flea eggs
- 27. Controls flea problems on cats [ferrets]
- 28. Advantage II may be used year-round for flea prevention
- 29. Contains an insect growth regulator (IGR) to kill flea eggs and prevent reinfestation

30. Monthly use of Advantage II on cats kills fleas which may cause [flea allergy dermatitis][flea bite hypersensitivity]

- 31. Controls existing flea infestations on your cat [or ferret] and prevents further infestations
- 32. Prevents fleas on treated cats [or ferrets] from reinfesting
- 33. Remains effective after bathing
- 34. Remains effective following shampooing
- 35. Waterproof, after 24 hours
- 36. Remains effective after exposure to rain or sunlight
- 37. Fragrance-free
- 38. In child-resistant packaging
- 39. Starts working through contact. [Fleas do not have to bite your cat to die.]
- 40. Cats or Kittens should be dry prior to application and remain dry for 24 hours after application [for product to work effectively]
- 41. Kills fleas, flea eggs and flea larvae
- 42. Prevents re-infestations on cats [ferrets]
- 43. Kills fleas and their eggs
- 44. Protects [cats] [ferrets] against fleas
- 45. Protects [cats] [ferrets] against flea infestations
- 46. Prevents [establishment of] new flea infestations on [cats] [ferrets] after application
- 47. Kills fleas that may cause transmission of tapeworms in [cats] [ferrets]
- 48. Kills fleas which may cause Flea Allergy Dermatitis and flea bite anemia
- 49. Prevents flea reinfestation [re-infestation] on [cats][ferrets]
- 50. Kills fleas that may cause a tapeworm infestation in cats[ferrets]
- 51. Protection from fleas for your cat [ferret] when applied monthly
- 52. Kills fleas even if your cat gets wet

### **Long Neck Applicator:**

[Note to reviewer: "New" will only be used 6 months from the date EPA is notified of first use]

- 53. New long-neck applicator
- 54. Long-neck makes it easy to get through fur to skin
- 55. New applicator makes it easy to get through long or thick fur and direct to skin

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### **SUB-LABEL B: Cat Only Product**

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

Braces "{}" indicate location of text on container label

### **{Front Panel}**

For Use
ONLY on Cats 8
Weeks and
Older Weighing
5 – 9 lbs.

Visual image of a small cat within the weight range for product.

### Advantage® II Small Cat

Note: [The "Small Cat" text size will be 40% - 75% of the height of the largest letter in the primary brand name.]

[Selected optional claims bulleted here from OPTIONAL MARKETING CLAIMS]

Image of tube

[1, 2, 3, 4, or 6] monthly doses

Once-A-Month Topical Flea Prevention and Treatment [for Cats] For Use ONLY on Cats 8 Weeks and Older and Weighing 5 - 9 lbs.

ACTIVE INGREDIENTS	% By Weight
Imidacloprid	9.10%
Pyriproxyfen	0.46%
OTHER INGREDIENTS:	90.44%
TOTAL	100.00%

### KEEP OUT OF REACH OF CHILDREN

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### **CAUTION**

See back panel for First Aid, Precautionary Statements, and Directions for Use. For all information, including Storage and Disposal see insert inside carton.

### {Back Panel}

### **Advantage® II Small Cat**

Note: [The "Small Cat" text size will be 40% - 75% of the height of the largest letter in the primary brand name.]

[Once-A-Month] Topical Flea Prevention and Treatment for Cats For Use ONLY on Cats 8 Weeks and Older and Weighing 5 - 9 lbs.

### READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea Infestations on Cats

[Selected optional claims bulleted here from OPTIONAL MARKETING CLAIMS]

### **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 by mouth 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.

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS

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**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 5 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.

#### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

#### **RESTRICTIONS:**

- Use only on cats or kittens 8 weeks and older and weighing 5 9 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.
- Do not allow children to apply the product.
- Cats should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].

See inside flap for HOW TO OPEN and HOW TO APPLY, or insert for full Directions for Use.

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

Net Contents: [1, 2, 3, 4, or 6] Tube(s), each 0.014 fl. oz. (0.4 mL)

EPA Est. No. 11556-XXX-X

EPA Reg No. 11556-151

Manufactured For

Bayer HealthCare LLC

Reason To Issue: Alternate instructions for long neck tube

Date: 06/26/2017 Supersedes: 06/01/2016 LABEL B: Cat Only

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### Animal Health Division P.O. BOX 390 Shawnee Mission, Kansas 66201 USA

Made in Germany

[Sample – Not for Sale]

[Note to reviewer: cartons containing 1 or 2, individually pouched, tubes are completely labeled (all components) as the 3, 4 and 6 packs. The "Sample – Not for Sale" is used as optional text for the 1 or 2 packs only.

{Any Panel}

Lot No.

### {Additionally, Inside Flap of Unit Carton for 1, 2, 3, 4, or 6 tubes}

### **DIRECTIONS FOR USE (continued from back panel)**

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 SHORT NECK TUBE POUCH]

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

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### [OPTION 3: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

- 1. Be sure the tube is at the bottom of the pouch.
- 2. Use scissors to cut the pouch across the top, being careful not to cut the tube.
- 3. Remove the tube from the package.

### **HOW TO APPLY**

## [OPTION 1: INSTRUCTIONS FOR BLISTER PACK AND SHORT NECK TUBE POUCH]

- 1. Use only on cats or kittens 8 weeks and older and weighing 5 9 lbs. Do not use on other animals.
- 2. Cats should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].
- 3. Remove one [applicator tube] [pouch] from the carton. See "HOW TO OPEN" section.
- 4. Hold applicator tube in an upright position facing away from you and your cat's face and eyes. Pull cap off tube.







- 5. Turn the cap around and place other end of cap back on tube.
- 6. Twist cap to break seal, then remove cap from tube.

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

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to run off.



- 7. Discard empty tube as described in Storage and Disposal.
- 8. 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. On cats, do not retreat more often than once every seven (7) days, not to exceed 4 weekly treatments. After flea control is attained, return to a monthly retreatment schedule.

### [OPTION 2: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

- 1. Use only on cats or kittens 8 weeks and older and weighing 5 9 lbs. Do not use on other animals.
- 2. Cats should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].
- 3. Remove one pouch from the carton. See "HOW TO OPEN" section.
- 4. Hold applicator tube in an upright position facing away from you and your cat's face and eyes. Twist the tip of the applicator to break seal.





5. In order to ensure proper application, part the hair on the neck at the base of the skull. Place the tip of the tube against the cat's skin.





6. Gently squeeze the tube to expel the entire contents of the tube directly on the skin.

Reason To Issue: Alternate instructions for long neck tube Date: 06/26/2017

Supersedes: 06/01/2016 LABEL B: Cat Only

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7. Do not get this product in your cat's eyes, or allow your cat to ingest this product. Do not allow the product to run off of the cat. 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.

- 8. Discard the empty tube as described in the Storage and Disposal section.
- 9. 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. On cats, do not retreat more often than once every seven (7) days, not to exceed 4 weekly treatments. Once the infestation is under control, return to a monthly treatment schedule.

For more information visit www.petbasics.com

### {Insert}

### **Advantage® II Small Cat**

Note: [The "Small Cat" text size will be 40% - 75% of the height of the largest letter in the primary brand name.]

Once-A-Month Topical Flea Prevention and Treatment [for Cats] For Use ONLY on Cats 8 Weeks and Older and Weighing 5 - 9 lbs.

### READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea Infestations on Cats

[Selected optional claims bulleted here from OPTIONAL MARKETING CLAIMS]

Reason To Issue: Alternate instructions for long neck tube

Date: 06/26/2017 Supersedes: 06/01/2016 LABEL B: Cat Only

ACTIVE INGREDIENTS	% By Weight
Imidacloprid	9.10%
Pyriproxyfen	0.46%
OTHER INGREDIENTS.	90.44%
TOTAL	100.00%

## KEEP OUT OF REACH OF CHILDREN CAUTION

#### **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 by mouth 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.

## 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 5 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.

### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

#### **RESTRICTIONS:**

- 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.
- Do not allow children to apply the product.

### **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 SHORT NECK TUBE POUCH]

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

### [OPTION 3: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

- 1. Be sure the tube is at the bottom of the pouch.
- 2. Use scissors to cut the pouch across the top, being careful not to cut the tube.
- 3. Remove the tube from the package.

#### **HOW TO APPLY**

## [OPTION 1: INSTRUCTIONS FOR BLISTER PACK AND SHORT NECK TUBE POUCH]

- 1. Use only on cats or kittens 8 weeks and older and weighing 5 9 lbs. Do not use on other animals.
- 2. Cats should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].
- 3. Remove one [applicator tube] [pouch] from the carton. See "HOW TO OPEN" section.
- 4. Hold applicator tube in an upright position facing away from you and your cat's face and eyes. Pull cap off tube.







- 5. Turn the cap around and place other end of cap back on tube.
- 6. Twist cap to break seal, then remove cap from tube.

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.



- 7. Discard empty tube as described in Storage and Disposal.
- 8. 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. On

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cats, do not retreat more often than once every seven (7) days, not to exceed 4 weekly treatments. After flea control is attained, return to a monthly retreatment schedule.

### [OPTION 2: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

- 1. Use only on cats or kittens 8 weeks and older and weighing 5 9 lbs. Do not use on other animals.
- 2. Cats should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].
- 3. Remove one pouch from the carton. See "HOW TO OPEN" section.
- 4. Hold applicator tube in an upright position facing away from you and your cat's face and eyes. Twist the tip of the applicator to break seal.





5. In order to ensure proper application, part the hair on the neck at the base of the skull. Place the tip of the tube against the cat's skin.





- 6. Gently squeeze the tube to expel the entire contents of the tube directly on the skin.
- 7. Do not get this product in your cat's eyes, or allow your cat to ingest this product. Do not allow the product to run off of the cat. 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.
- 8. Discard the empty tube as described in the Storage and Disposal section.
- 9. 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. On cats, do not retreat more often than once every seven (7) days, not to exceed 4 weekly

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treatments. Once the infestation is under control, return to a monthly treatment 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 Small Cat kills fleas and may reduce the incidence of this condition.]

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

Advantage® II Small Cat kills adult fleas on cats quickly, within 12 hours, inhibits the development of immature flea life stages and prevents them from reaching the biting adult stage.

Advantage® II Small Cat is waterproof after 24 hours and remains effective following a shampoo treatment or after exposure to rain or sunlight.

Apply monthly treatments for optimal control and prevention of fleas.

To successfully prevent and control fleas, all cats must be treated with their own dose of Advantage® II Small Cat.

Apply according to label instructions, ensuring that the product is applied to the skin, not on top of the fur.

If your cat wears a decorative collar, it may be helpful to remove the collar before application so it doesn't absorb the product.

Remember, your cat needs to be dry at the time Advantage® II Small Cat is applied and remains dry 24 hours after application.

Even indoor cats need protection against fleas because you or other pets in the household may bring fleas into the home. Fleas in your cat's environment can re-infest your cat. If you have a flea infestation, consider treating your home and yard with appropriate premise products to protect against fleas.

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### 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]

Manufactured For

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

Made in Germany

EPA Est. No. 11556-XXX-X EPA Reg No. 11556-151 Reason To Issue: Alternate instructions for long neck tube Date:

Date: 06/26/2017 Supersedes: 06/01/2016 LABEL B: Cat Only

# **{OPTION 1: Label on blister pack; one blister pack containing 1, 2, 3, 4, or 6 tubes} {OPTION 2: Label on pouch containing 1 tube}**

### Advantage® II Small Cat

For external use only on cats and kittens 8 weeks and older and weighing 5 - 9 lbs.

See insert for complete product information.

9.10% Imidacloprid

0.46% Pyriproxyfen

[1, 2, 3, 4, or 6] Tube(s) - 0.014 fl. oz. (0.4 mL) EPA Reg. No. 11556-151

THIS UNIT NOT FOR RETAIL SALE

**BAYER** 

Date: 06/26/2017 Supersedes: 06/01/2016

LABEL B: Cat Only

### {Label on Individual Tube – label is colored coded to age and weight grouping}

Advantage® II Small Cat

9.10% Imidacloprid

0.46% Pyriproxyfen

0.014 fl. oz. (0.4 mL)

EPA Reg. No. 11556-151

Keep Out of Reach of Children

**CAUTION** 

Read The Entire Label Before Use

**BAYER** 

Lot No. 0000000

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## **SUB-LABEL C: Ferret Only Product**

NOTE TO REVIEWER: [Brackets indicate alternate language or notes to the EPA reviewer] Braces "{}" indicate location of text on container label

## **{Front Panel}**

For Use
ONLY on Ferrets
10 Weeks and
Older and
1 lb. or Greater

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

## **Advantage® II Ferret**

Note: [The "Ferret" text size will be 40% - 75% of the height of the largest letter in the primary brand name.]

[Selected optional claims bulleted here from OPTIONAL MARKETING CLAIMS]

Image of tube

[1, 2, 3, 4, or 6] monthly doses

Once-A-Month Topical Flea Prevention and Treatment [for Ferrets] For Use ONLY on Ferrets 10 weeks and Older and Weighing 1 lb. or Greater

Reason To Issue: Alternate instructions for long neck tube Date:

Date: 06/26/2017 Supersedes: 06/01/2016 LABEL C: Ferret Only

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ACTIVE INGREDIENTS	% By Weight
Imidacloprid	9.10%
Pyriproxyfen	0.46%
OTHER INGREDIENTS:	90.44%
TOTAL	100.00%

## KEEP OUT OF REACH OF CHILDREN

### **CAUTION**

See back panel for First Aid, Precautionary Statements, and Directions for Use. For all information, including Storage and Disposal see insert inside carton.

## {Back Panel}

## Advantage® II Ferret

Note: [The "Ferret" text size will be 40% - 75% of the height of the largest letter in the primary brand name.]

[Once-A-Month] Topical Flea Prevention and Treatment for Ferrets For Use ONLY on Ferrets 10 weeks and Older and Weighing 1 lb. or Greater

## READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea Infestations on Ferrets

[Selected optional claims bulleted here from OPTIONAL MARKETING CLAIMS]

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#### 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 by mouth 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.

# 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 kits (young ferrets) under 10 weeks of age or weighing less than 1 lb. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing ferrets. Individual sensitivities may occur after using ANY pesticide product for ferrets. If signs persist, or become more severe, consult a veterinarian immediately. If your ferret is on medication, consult your veterinarian before using this or any other product.

**Side Effects:** Monitor your ferret after application. Side effects may include temporary changes in fecal consistency. If these or other side effects occur, consult your veterinarian or call 1-800-422-9874.

### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

### **RESTRICTIONS:**

• Use only on ferrets 10 weeks and older and weighing 1 lb or greater. Do not use on other animals.

Reason To Issue: Alternate instructions for long neck tube Date:

Date: 06/26/2017 Supersedes: 06/01/2016 LABEL C: Ferret Only

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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.
- Do not allow children to apply the product.
- Ferrets should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].

See inside flap for HOW TO OPEN and HOW TO APPLY, or insert for full Directions for Use.

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

Net Contents: [1, 2, 3, 4, or 6] Tube(s), each 0.014 fl. oz. (0.4 mL)

EPA Est. No. 11556-XXX-X

EPA Reg No. 11556-XXX

Manufactured for

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

Made in Germany

[Sample – Not for Sale]

[Note to reviewer: cartons containing 1 or 2, individually pouched, tubes are completely labeled (all components) as the 3, 4 and 6 packs. The "Sample – Not for Sale" is used as optional text for the 1 or 2 packs only.]

{Any Panel}

Lot No.

Date: 06/26/2017 Supersedes: 06/01/2016

LABEL C: Ferret Only

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## {Additionally, Inside Flap of Unit Carton for 1, 2, 3, 4, or 6 tubes}

## **DIRECTIONS FOR USE (continued from back panel)**

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 SHORT NECK TUBE POUCH]

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

## [OPTION 3: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

- 1. Be sure the tube is at the bottom of the pouch.
- 2. Use scissors to cut the pouch across the top, being careful not to cut the tube.
- 3. Remove the tube from the package.

### **HOW TO APPLY**

# [OPTION 1: INSTRUCTIONS FOR BLISTER PACK AND SHORT NECK TUBE POUCH]

- 1. Use only on ferrets 10 weeks and older and weighing 1 lb. or greater. Do not use on other animals.
- 2. Ferrets should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].
- 3. Remove one [applicator tube] [pouch] from the carton. See "HOW TO OPEN" section.
- 4. Hold applicator tube in an upright position facing away from you and your ferret's face and eyes. Pull cap off tube.

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- 5. Turn the cap around and place other end of cap back on tube.
- 6. 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 ferret's eyes, or allow your ferret to ingest this product. The product is bitter tasting and salivation may occur for a short time if the ferret licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the ferret to lick the product. Do not allow the product to run off.



- 7. Discard empty tube as described in Storage and Disposal.
- 8. 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. On ferrets, do not retreat more often than every 14 days, not to exceed 2 biweekly treatments. After flea control is attained, return to a monthly retreatment schedule.

## [OPTION 2: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

- 1. Use only on ferrets 10 weeks and older and weighing 1 lb. or greater. Do not use on other animals.
- 2. Ferrets should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].
- 3. Remove one [applicator tube] [pouch] from the carton. See "HOW TO OPEN" section.
- 4. Hold applicator tube in an upright position facing away from you and your ferret's face and eyes. Twist the tip of the applicator to break seal.

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5. In order to ensure proper application, part the hair on the neck at the base of the skull. Place the tip of the tube against the ferret's skin.





- 6. Gently squeeze the tube to expel the entire contents of the tube directly on the skin.
- 7. Do not get this product in your ferret's eyes, or allow your ferret to ingest this product. Do not allow the product to run off of the ferret. The product is bitter tasting and salivation may occur for a short time if the ferret licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the ferret to lick the product.
- 8. Discard the empty tube as described in the Storage and Disposal section.
- 9. 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. On ferrets, do not retreat more often than every 14 days, not to exceed 2 biweekly treatments. Once the infestation is under control, return to a monthly treatment schedule.

For more information visit www.petbasics.com

## {Insert}

## Advantage® II Ferret

Note: [The "Ferret" text size will be 40% - 75% of the height of the largest letter in the primary brand name.]

Once-A-Month Topical Flea Prevention and Treatment [for Ferrets] For Use ONLY on Ferrets 10 weeks and Older and Weighing 1 lb. or Greater

## READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea Infestations on Ferrets

[Selected optional claims bulleted here from OPTIONAL MARKETING CLAIMS]

ACTIVE INGREDIENTS	% By Weight
Imidacloprid	9.10%
Pyriproxyfen	0.46%
OTHER INGREDIENTS:	90.44%
TOTAL	100.00%

# KEEP OUT OF REACH OF CHILDREN CAUTION

Reason To Issue: Alternate instructions for long neck tube

Date: 06/26/2017 Supersedes: 06/01/2016 LABEL C: Ferret Only

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#### 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 by mouth 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.

# 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 kits (young ferrets) under 10 weeks of age or weighing less than 1 lb. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing ferrets. Individual sensitivities may occur after using ANY pesticide product for ferrets. If signs persist, or become more severe, consult a veterinarian immediately. If your ferret is on medication, consult your veterinarian before using this or any other product.

**Side Effects:** Monitor your ferret after application. Side effects may include temporary changes in fecal consistency. If these or other side effects 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.

## **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

#### **RESTRICTIONS:**

• Do not apply more than one (1) tube per treatment.

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• Do not have contact or allow children to have contact with treated area until completely dry.

• Do not allow children to apply the product.

## **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 SHORT NECK TUBE POUCH]

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

## [OPTION 3: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

- 1. Be sure the tube is at the bottom of the pouch.
- 2. Use scissors to cut the pouch across the top, being careful not to cut the tube.
- 3. Remove the tube from the package.

#### **HOW TO APPLY**

# [OPTION 1: INSTRUCTIONS FOR BLISTER PACK AND SHORT NECK TUBE POUCH]

- 1. Use only on ferrets 10 weeks and older and weighing 1 lb. or greater. Do not use on other animals.
- 2. Ferrets should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].
- 3. Remove one [applicator tube] [pouch] from the carton. See "HOW TO OPEN" section.
- 4. Hold applicator tube in an upright position facing away from you and your ferret's face and eyes. Pull cap off tube.

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- 5. Turn the cap around and place other end of cap back on tube.
- 6. Twist cap to break seal, then remove cap from tube.
- 7. 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 ferret's eyes, or allow your ferret to ingest this product. The product is bitter tasting and salivation may occur for a short time if the ferret licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the ferret to lick the product. Do not allow the product to run off.



- 8. Discard empty tube as described in Storage and Disposal.
- 9. 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. On ferrets, do not retreat more often than every 14 days, not to exceed 2 biweekly treatments. After flea control is attained, return to a monthly retreatment schedule.

## [OPTION 2: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

- 1. Use only on ferrets 10 weeks and older and weighing 1 lb. or greater. Do not use on other animals.
- 2. Ferrets should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].
- 3. Remove one [applicator tube] [pouch] from the carton. See "HOW TO OPEN" section.
- 4. Hold applicator tube in an upright position facing away from you and your ferret's face and eyes. Twist the tip of the applicator to break seal.

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5. In order to ensure proper application, part the hair on the neck at the base of the skull. Place the tip of the tube against the ferret's skin.





- 6. Gently squeeze the tube to expel the entire contents of the tube directly on the skin.
- 7. Do not get this product in your ferret's eyes, or allow your ferret to ingest this product. Do not allow the product to run off of the ferret. The product is bitter tasting and salivation may occur for a short time if the ferret licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the ferret to lick the product.
- 8. Discard the empty tube as described in the Storage and Disposal section.
- 9. 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. On ferrets, do not retreat more often than every 14 days, not to exceed 2 biweekly treatments. Once the infestation is under control, return to a monthly treatment schedule.

#### PRODUCT INFORMATION

Advantage® II Ferret kills the existing fleas on ferrets within 24 hours. Reinfesting fleas are killed 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 Ferrets provides multi-stage flea control effectively breaking flea life cycle stages for lasting control of flea populations.

Advantage® II Ferret kills adult fleas within 24 hours, inhibits the development of immature flea life stages and prevents them from reaching the biting adult stage.

Reason To Issue: Alternate instructions for long neck tube

Date: 06/26/2017 Supersedes: 06/01/2016 LABEL C: Ferret Only

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Advantage® II Ferret is waterproof after 24 hours and remains effective following a shampoo treatment or after exposure to rain or sunlight.

Apply monthly treatments 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.

[For more information visit www.petbasics.com]

Manufactured For

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

Made in Germany

EPA Est. No. 11556-XXX-X EPA Reg No. 11556-XXX

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# **{OPTION 1: Label on blister pack; one blister pack containing 1, 2, 3, 4, or 6 tubes} {OPTION 2: Label on pouch containing 1 tube}**

## Advantage® II Ferret

For external use only ferrets 10 weeks and older and weighing 1 lb. or greater

See insert for complete product information.

9.10% Imidacloprid

0.46% Pyriproxyfen

[1, 2, 3, 4, or 6] Tube(s) - 0.014 fl. oz. (0.4 mL) EPA Reg. No. 11556-XXX

THIS UNIT NOT FOR RETAIL SALE

**BAYER** 

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## {Label on Individual Tube - label is colored coded to age and weight grouping}

Advantage® II Ferret

9.10% Imidacloprid

0.46% Pyriproxyfen

0.014 fl. oz. (0.4 mL)

EPA Reg. No. 11556-151

Keep Out of Reach of Children

**CAUTION** 

Read The Entire Label Before Use

**BAYER** 

Lot No. 0000000