

11556-152

3/28/2013

1/12



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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Douglas Spilker
Bayer HealthCare LLC, Animal Health Division
PO Box 390
Shawnee Mission, KS 66201

MAR 28 2013

Dear Mr. Spilker:

Subject: Amendments to add new child resistant packaging
Advantage II Large Cat
EPA Registration No. 11556-152
Decision Numbers: 473345
Submission Dates: December 14, 2012

The label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy of the label is enclosed for your records. Please submit two copies of your final printed labeling before you release the product for shipment. If you have any questions regarding these labels, please contact Dr. Jennifer Urbanski at 703-347-0156 or urbanski.jennifer@epa.gov.

Sincerely yours,

A handwritten signature in black ink that reads "Venus Eagle". The signature is written in a cursive style and is followed by a long horizontal line.

Venus Eagle
Product Manager (01)
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure- Stamped Label and Science Review (DP408177)

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Reason To Issue: New child-resistant packaging proposal.

Date: 02/14/13

Supersedes: 12/12/12,
11/28/12 and 09/25/12

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

[Front 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.

[Selected optional claims bulleted here from page 10 and/or 11]

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-

<u>Active Ingredients</u>	<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. 11556-152

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for Precautionary Statements.

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

ACCEPTED

MAR 28 2013

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

Page 1 of 11

EPA. Reg. No: _____

11556-152

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11/28/12 and 09/25/12

[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 or clothing. Wash hands thoroughly with soap and warm water after handling. 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, while rare, 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, although very rare, 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. 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.

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Net Contents: Tube(s), each 0.027 fl. oz. (0.8 mL)

[Sample - Not for (Re)Sale]

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

Made in Germany

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Reason To Issue: New child-resistant packaging proposal.

Date: 02/14/13

Supersedes: 12/12/12,

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[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.

[Visuals Depicting How to Open Applicator Tube]

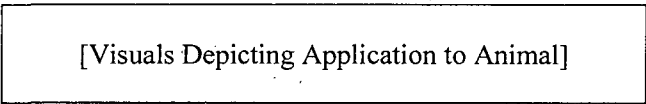
3. Turn the cap around and place other end of cap back on tube.

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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.

Fleas, eggs and larvae in the cat's surroundings are killed following contact with an Advantage® II Large Cat treated cat. Advantage® II Large Cat provides multi-stage flea control effectively breaking all 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.

Apply monthly treatments for optimal control and prevention of fleas.

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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 thoroughly with soap and warm water after handling. 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	<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, while rare, 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, although very rare, 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. 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.petparents.com

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Reason To Issue: New child-resistant packaging proposal.

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[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

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Reason To Issue: New child-resistant packaging proposal.

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

[Additional label text for OPTION 2: THIS UNIT NOT FOR RETAIL SALE]

Advantage[®] II Large Cat

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

9.10% Imidacloprid

0.46% Pyriproxyfen

[X] - 0.027 fl. oz. (0.8 mL) Tube(s)

EPA Reg. No. 11556-152

BAYER

11/12

Reason To Issue: New child-resistant packaging proposal.

Date: 02/14/13
Supersedes: 12/12/12,
11/28/12 and 09/25/12

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
- 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
- Advantage II is indicated for the prevention and treatment of fleas on cats 8 weeks of age and older
- 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 fleas before they lay eggs
- Larval flea stages in the cat's environment are killed following contact with an Advantage II treated cat
- 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] all 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 ovcide
- Kills flea eggs
- Controls flea problems
- Provides flea protection
- Controls existing fleas and flea eggs plus [and] [prevents] future flea infestations
- Advantage II may be used year-round for flea [prevention][protection]

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- 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 infesting (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