

11556-152

6.24.2010

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

11556-152

Date of Issuance:

JUN 24 2010

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

FROM: June 24, 2010
TO: see comment #1

Name of Pesticide Product:

Advantage II Large Cat

Name and Address of Registrant (include ZIP Code):

Attention: Dr. Doug Spilker
Bayer HealthCare, LLC
P.O. Box 390
Shawnee Mission, KS 66201

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that:

1. This registration is time-limited and expires two years from the date this product is first released for shipment. You must provide the Agency with a projected release for shipment date in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing.
2. Only one basic confidential statement of formula will be on file for this product at any one time; no alternate formulations or minor formulation amendments will be submitted or approved for this product.

Signature of Approving Official:

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

Date:

JUN 24 2010

3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning July 1, 2010.

Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci).

The following is a list of information that must be included in the quarterly reports for each incident:

- a. EPA Registration Number
 - b. Product Name (brand name)
 - c. Lot Number
 - d. Where Purchased: Internet, Store, Veterinarian
 - e. Active Ingredient(s)
 - f. Weight Range for Product
 - g. Date on which incident occurred (mm/dd/yyyy).
 - h. State in which the incident occurred (standard 2 letter abbreviation).
 - i. Registrant Case Number
 - j. Species: Dog, Cat, Other (specify)
 - k. Breed: (as reported by pet owner)
 - l. Age: Months or Years
 - m. Sex: Male, Female
 - n. Weight: Pounds
 - o. Primary Route of Exposure: Dermal, Oral, Other Animal, Inhalation, Other
 - p. Body System: Neurological, Dermatological, GI, Respiratory, Ocular, Other
 - q. Major Signs: Separate Column for Each Sign, Using Standard Terminology
 - r. Time to Onset: Hours, Days
 - s. Treated By Veterinarian: Yes or No
 - t. First Time Product Used: Yes or No
 - u. Misuse: Use on Incorrect Species, Overdose, Too Frequent Dosing, Other (describe)
 - v. Any Known Precondition
 - w. EPA Severity Code: Death, Major, Moderate, Minor
 - x. Outcome: Died, Recovered, Still Being Treated, Unknown
4. You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for reregistration of your product under FIFRA Section 4.
5. Revise the EPA Registration Number to read "EPA Registration No. 11556-152" on the first page of the label.
6. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- a. All incidents should be reported including all minor dermal and ocular irritation reports.
 - b. Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be as follows: 1) ocular, 2) oral and 3) dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - c. A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - d. Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - e. A summary table for cats showing number of incidents for each severity code for following age ranges: 1) <3 months, 2) 3 – 6 months, 3) 6 – 9 months, 4) 9 – 12 months, 5) 1 year, 6) 2 years, 7) 3 years, 8) 4 years, 9) 5 years, 10) 6 years, 11) 7 years, 12) 8 years, 13) 9 years, 14) 10 years, 15) 11 years, 16) 12 years, 17) 13 years, 18) 14 years, 19) 15 years and 20) >15 years.
 - f. A summary table showing the number of cats incidents for each severity code for each pet weight range on the product label, if applicable.
 - g. A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range, if applicable.
 - h. Table showing number of incidents for each cat breed, where provided.
 - i. Table showing number of incidents in cats for each clinical sign.
 - j. Table showing number of incidents in cats for each organ system.
 - k. Report aggregate incidents, but do not combine moderate and minor incidents.
7. The Agency reserves the right, in the future, to require the addition of a section of label that lists the most common side effects, based on the submission of incident data.
8. The required storage stability (830-6317) and corrosion characteristics (830-6320) data were submitted to the Agency on May 12, 2010 and are currently under review (D378289). If the data are deemed unacceptable, additional storage stability and corrosion characteristics data must be submitted and deemed acceptable.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. If you have any questions regarding this notice, please contact Kable Bo Davis at (703) 306-0415 or davis.kable@epa.gov.

Venus Eagle, PM (01)
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure- Stamped Label

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

Advantage® II Large Cat

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

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea Infestations

[Selected optional claims bulleted here from page 6 and/or 7]

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**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

JUN 24 2010

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

11556-152

<u>Active Ingredients</u>	<u>% By Weight</u>
Imidacloprid	9.10%
Pyriproxyfen	0.46%
Other Ingredients	<u>90.44%</u>
Total	100.00%

EPA Reg No. 11556-RLE

EPA Est. No. 11556-DEU-1

KEEP OUT OF REACH OF CHILDREN

CAUTION

[See back panel for First Aid.]

[For Directions For Use, and Storage and Disposal (instructions),
see supplemental labeling inside.]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS: 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 use on kittens under 8 weeks of age. 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.

If your cat is experiencing an adverse event, contact your veterinarian and, call 1-800-422-9874.

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.	

DIRECTIONS FOR USE

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

HOW TO OPEN

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.



HOW TO APPLY

1. Use only on cats and kittens. Do not use on other animals.
2. Remove one applicator tube from the package. See "HOW TO OPEN" section.
3. Hold applicator tube in an upright position. Pull cap off tube.

[Visuals Depicting How to Open Applicator Tube]

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

[Visuals Depicting Application to Animal]

6. 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 mouth. 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.
7. Discard empty tube as described in Storage and Disposal.
8. Under normal conditions, the product is effective for a month. However, in cases of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not

retreat more often than once every seven (7) days. After flea control is attained, return to a monthly retreatment schedule.

ADDITIONAL INFORMATION

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

Advantage® II 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 treated cat. Advantage® II provides multi-stage flea control effectively breaking all flea life-cycle stages for lasting control of flea populations.

Advantage® II 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 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.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place.

Pesticide Disposal and Container Handling: Nonrefillable container. **If Empty:** Do not reuse 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.

Reason To Issue: Propose registration

Date: 06/17/10

Supersedes: 11/24/09

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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.

Net Contents: [(One)(Four)(Six)] Tube(s) - 0.027 fl. oz. (0.8 mL) each

OPTIONAL CLAIM FOR THE ONE TUBE PACKAGE: [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

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

OPTIONAL MARKETING CLAIMS

- 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]

Reason To Issue: Propose registration

Date: 06/17/10

Supersedes: 11/24/09

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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
- 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

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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-RLE

Keep Out of Reach of Children

CAUTION

Read The Entire Label Before Use

BAYER

Lot No. 0000000