

11556-152

9/27/2010

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SEP 27 2010

Mary McKinney Hunt
Bayer HealthCare LLC
Animal Health Division
PO Box 390
Shawnee Mission, KS 66201

Subject: Notification of the addition of the EPA Registration Number and the optional text [Sample-not for (re)sale] for Advantage II Large Cat (EPA Reg. # 11556-152)

Dear Ms. McKinney Hunt:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 9/15/2010 for the product Advantage II Large Cat (EPA Reg. # 11556-152). The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The Confidential Statement of Formula (CSF) and/or label submitted with the application has (have) been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-347-0156 or urbanski.jennifer@epa.gov.


Sincerely,

Jennifer Urbanski
Registration Division (7505P)
Office of Pesticide Programs

20812

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060

 EPA	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other:	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 11556-152	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Advantage II Large Cat	PM# 01/Team 1	
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division PO Box 390 Shawnee Mission, KS 66201 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

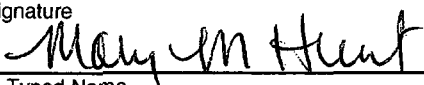
Section - II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below
Explanation: Use additional page(s) if necessary. (For Section I and Section II.)	
NOTIFICATION SEP 27 2010	
NON PRIA ACTION. Please see attached for more detail.	
Enclosed for Agency acceptance is a draft label for Advantage II Large Cat (EPA Reg. No. 11556-152). The proposed revisions are the addition of the EPA Reg. No. and added the optional text: [Sample-not for (re)sale] for package sizes (SKUs).	

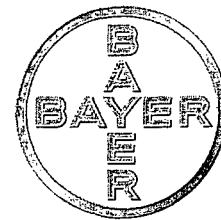
Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
* Certification must be submitted			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Mary M. Hunt	Title Pesticide Registrations Manager	Telephone No. (include Area Code) 913-260-2311
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both, under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Pesticide Registrations Manager	
4. Typed Name Mary M. Hunt	5. Date 9-15-2010	

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Bayer HealthCare Animal Health

September 15, 2010

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Ms. Venus Eagle, Team 1

SUBJECT: Notification of Label Revision to
Advantage II Kitten, EPA Reg. No. 11556-150
Advantage II Small Cat, EPA Reg. No. 11556-151
Advantage II Large Cat, EPA Reg. No. 11556-152

Bayer HealthCare LLC
Animal Health
P.O. Box 390
Shawnee Mission, KS 66201-0390

Dear Ms. Eagle:

Please find enclosed for the Agency's review and acceptance, a Notification (EPA Form 8570-1 and attachment) and draft label dated September 15, 2010 for each subject product.

The proposed revisions are the addition of the EPA Registration Number and the addition of optional text, [Sample-not for (re)sale], to all package sizes (SKUs).

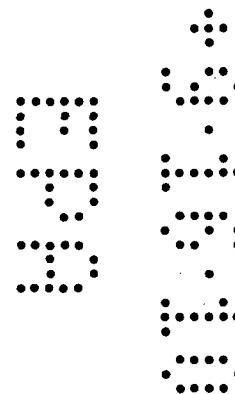
Thank you for your assistance with this notification process, and please contact me at 913-268-2311 or mary.hunt.b@bayer.com if you have any questions or need further information.

Respectfully,

BAYER HEALTHCARE LLC
ANIMAL HEALTH DIVISION

Mary McKinney Hunt
Pesticides Regulatory Manager

- Encl: (3) 8570-1 Application for Pesticide Notification
- (3) Attachment to Application for Pesticide Notification
- (3) Draft Label (3 cc each)
- (3) Highlighted Label (1 cc each)



5 of 12

Reason To Issue: Added EPA Reg. No. and optional text
[Sample-not for (re)sale] for all SKUs

Date: 09/15/2010
Supersedes: 06/17/10

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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NOTIFICATION

SEP 27 2010

<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. ~~11556-152~~

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.]

leaf 12

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

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Reason To Issue: Added EPA Reg. No. and optional text
[Sample-not for (re)sale] for all SKUs

Date: 09/15/2010
Supersedes: 06/17/10

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 Large Cat rapidly 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 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.

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.

9 of 12

Reason To Issue: Added EPA Reg. No. and optional text
[Sample-not for (re)sale] for all SKUs

Date: 09/15/2010
Supersedes: 06/17/10

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: XX 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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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 ovide
- 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
- 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

Reason To Issue: Added EPA Reg. No. and optional text
[Sample-not for (re)sale] for all SKUs

Date: 09/15/2010
Supersedes: 06/17/10

12 of 12

(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