

11556-130

9/27/2010

10012



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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

SEP 27 2010

Subject: Notification of the addition of the agency required changes (letter dated 4/29/2010) and the optional text [Sample-not for (re)sale] for Advantage II Extra Large Dog (EPA Reg. # 11556-130)

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 Extra Large Dog (EPA Reg. # 11556-130). 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,

A handwritten signature in black ink, appearing to read "J M U".

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

2012

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060



EPA

United States
Environmental Protection Agency
Washington, DC 20460

- Registration
- Amendment
- Other:

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11556-130	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Advantage II Extra Large Dog	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	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 _____	

Check if this is a new address

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

NOTIFICATION

SEP 27 2010

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

NON PRIA ACTION. Please see attached for more detail.

Enclosed for Agency acceptance is a draft label for Advantage II Extra Large Dog (EPA Reg. No. 11556-130). The proposed revisions are in accordance with Agency letter dated 4/29/2010 and added the optional text: [Sample-not for (re)sale].

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
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"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

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) 913-268-2311
2. Signature <i>Mary M Hunt</i>		3. Title Pesticide Registrations Manager
4. Typed Name Mary M. Hunt		5. Date 9-15-2010
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)

40A12



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 Small Dog, EPA Reg. No. 11556-128
Advantage II Medium Dog, EPA Reg. No. 11556-125
Advantage II Large Dog, EPA Reg. No. 11556-127
*Advantage II Extra Large Dog, EPA Reg. No. 11556-130***

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 required changes in accordance with Agency letter dated 4/29/2010, and the addition of optional text, [Sample-not for (re)sale], to all package sizes (SKUs).

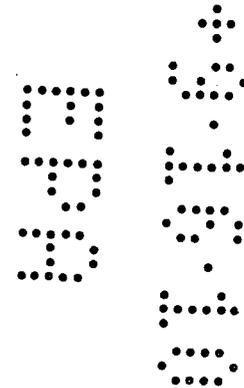
Thank you for your assistance with this notification process, and please contact me at 913-268-2311 or mary.hunt.b@bayer.com if you have any questions or need further information.

Respectfully,

BAYER HEALTHCARE LLC
ANIMAL HEALTH DIVISION

Mary McKinney Hunt
Pesticides Regulatory Manager

- Encl: (4) 8570-1 Application for Pesticide Notification.
(4) Attachment to Application for Pesticide Notification
(4) Draft Label (3 cc each)
(4) Highlighted Label (1 cc each)



50412

Reason To Issue: Revised per EPA letter 4/29/10, and added optional text: [Sample-not for (re)sale] Date: 09/15/2010 Supersedes: 04/28/10

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

Advantage® II Extra Large Dog

Once-A-Month Topical Treatment for Fleas and Lice
On Dogs and Puppies 7 Weeks and Older and Weighing Over 55 lbs

READ ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea and Lice Infestations [on Dogs]

[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. 11556-130

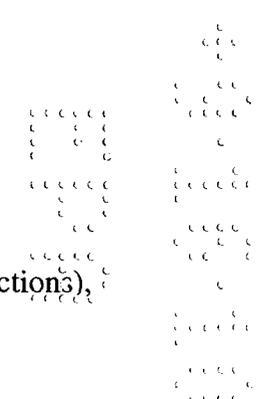
EPA Est. 11556-DEU-1

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]



0012

Reason To Issue: Revised per EPA letter 4/29/10, and added optional text: [Sample-not for (re)sale] Date: 09/15/2010 Supersedes: 04/28/10

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.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 7 weeks of age. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Individual sensitivities, while rare, may occur after using ANY pesticide product for pets. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product.

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 consumer questions call 1-800-255-6826.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

DIRECTIONS FOR USE

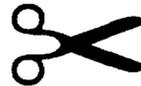
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

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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 dogs. 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. The dog should be standing for easy application. Apply the entire contents of the tube evenly to three or four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog. Do not get this product in your pet's eyes or mouth.
7. Discard empty tube as described in the Storage and Disposal section.

80912

- 8. Under normal conditions the product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every seven (7) days. After flea control is obtained, return to a monthly retreatment schedule.

ADDITIONAL INFORMATION

The successive feeding activity of fleas on dogs frequently elicits a hypersensitivity skin disorder known as flea allergy dermatitis (FAD) or flea bite hypersensitivity. Treatment of dogs with Advantage® II Extra Large Dog rapidly kills fleas within 12 hours which may reduce the incidence of this condition.

Advantage® II Extra Large Dog kills existing fleas on dogs within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting for 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, flea eggs, and flea larvae in the dog's environment are killed following contact with an Advantage® II Extra Large Dog treated pet. Advantage® II Extra Large Dog provides multi-stage flea control effectively breaking all flea life-cycle stages for quick and lasting control of flea populations.

Advantage® II Extra Large Dog 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 Extra Large Dog kills [(biting) (chewing)] lice that infest dogs and puppies, and prevents further infestations.

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

Monthly treatments are required 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 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.

90412

Reason To Issue: Revised per EPA letter 4/29/10, and added optional text: [Sample-not for (re)sale] Date: 09/15/2010 Supersedes: 04/28/10

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. To the extent consistent with applicable law, 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.

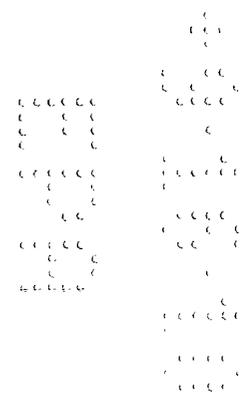
Net Contents: XX Tubes, each 0.135 fl. oz. (4.0 mL)

~~[Sample-not for (re)sale]~~

EPA Est. 11556-DEU-1
EPA Reg. No. 11556-130

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

Made in Germany



100912

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

OPTIONAL MARKETING CLAIMS

- For use on dogs and puppies 7 weeks of age and older
- Advantage II contains [imidacloprid], and [an/the] [insect growth regulator] [IGR] [pyriproxyfen]
- A single topical application remains effective for [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 treatment for dogs 7 weeks of age or older
- Advantage II is indicated for the prevention and treatment of fleas on dogs 7 weeks of age and older
- For the treatment and prevention of flea [and lice] infestations
- One treatment prevents further flea infestations for [4 weeks] [a month]
- Kills fleas on dogs within [12] hours and continues to prevent infestations for [four weeks] [a month]
- Kills fleas before they lay eggs
- Larval flea stages in the dog's environment are killed following contact with an Advantage II treated dog
- Kills larval stages of fleas in the dog's environment
- Kills fleas within [12] hours of application
- Stops existing flea infestations by killing adult fleas
- Prevents [Stops] reinfestations by killing adult fleas before they lay eggs
- [Prevents] [Stops] flea eggs from hatching [into biting adults]
- Effectively breaks the flea life cycle
- Effectively targets all [life] stages of [fleas]
- [Kills] [Controls] all flea life stages
- 3-way flea protection ([kills] [controls] adults, larvae, and eggs)
- [Prevents] [Stops] flea eggs [and flea larvae] from developing into [(biting) (adult)] fleas
- Treatment with Advantage II rapidly kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
- Flea adulticide, larvicide, and oviicide
- Kills flea eggs
- Controls highly [irritating] [annoying] [flea] [insect] bites
- Controls flea problems
- Provides flea protection
- Controls existing fleas and flea eggs [(plus) (and)] [prevents] future flea infestations in the home
- Starts working through contact

120912

Reason To Issue: Revised per EPA letter 4/29/10, and added optional text: [Sample-not for (re)sale] Date: 09/15/2010 Supersedes: 04/28/10

(Label on Individual Tube)

Advantage® II Extra Large Dog

9.10% Imidacloprid

0.46% Pyriproxyfen

0.135 fl. oz. (4.0 mL)

EPA Reg. No. 11556-130

CAUTION

Keep Out of Reach of Children

Read The Entire Label Before Use

BAYER

Lot No. 0000000

