

11556-120

9/13/2010

1089



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 13 2010

Subject: Notification of the addition of a Net Contents heading and the optional text [Sample-not for (re)sale] for Advantage® 55 Topical Solution (EPA Reg. # 11556-120)

Dear Ms. McKinney Hunt:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 8/27/2010 for the product Advantage® 55 Topical Solution (EPA Reg. # 11556-120). 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. Urbanski".

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

2009

 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 11556-120	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Advantage 55 Topical Solution	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
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NOTIFICATION

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

NON PRIA ACTION. Please see attached for more detail.

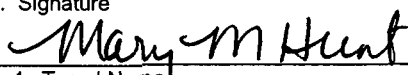
AUG 2010

Enclosed for Agency acceptance is a draft label for Advantage 55 Topical Solution (EPA Reg. No. 11556-120). The proposed revisions are the addition of 1) Net Contents heading and 2) optional text: [Sample-not for (re)sale].

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"/> 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
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 8-27-2010	



Bayer HealthCare Animal Health

August 27, 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

Attn: Venus Eagle, PM Team 1

**SUBJECT: Notification of Label Revision to
Advantage® 9 Topical Solution, EPA Reg. No. 11556-116
Advantage® 10 Topical Solution, EPA Reg. No. 11556-118
Advantage® 18 Topical Solution, EPA Reg. No. 11556-117
Advantage® 20 Topical Solution, EPA Reg. No. 11556-119
Advantage® 55 Topical Solution, EPA Reg. No. 11556-120
*Advantage® 100 Topical Solution, EPA Reg. No. 11556-122***

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

Dear Ms. Eagle:

Please find enclosed for the Agency's acceptance a Notification (EPA Form 8570-1 and attachment) and draft label dated August 27, 2010 for each subject product.

The proposed label revisions are the addition of the "Net Contents" heading and the optional text: [Sample-not for (re)sale].

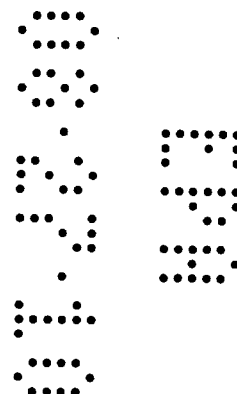
Thank you for your assistance with this notification process, and please contact me at 913-268-2311 or mary.hunt.b@bayer.com if you have any questions or need further information.

Respectfully,

BAYER HEALTHCARE LLC
ANIMAL HEALTH DIVISION

Mary McKinney Hunt
Regulatory Specialist

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



50f9

Reason To Issue: Add "Net Contents" heading and optional text: [Sample-not for (re)sale]

Date: 08/27/2010
Supersedes: 01/05/10

Note to Reviewer: [Brackets and parentheses indicate alternate language]

NOTIFICATION

SEP 13 2010

Advantage® 55 Topical Solution

Once-A-Month Topical Flea and Lice Treatment For Dogs
and Puppies 7 Weeks and Older and 21-55 lbs.

READ THE ENTIRE LABEL BEFORE EACH USE

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

- One treatment prevents further flea infestation for at least four (4) weeks
- Kills fleas on dogs within 12 hours
- Kills fleas before they lay eggs
- Convenient, easy to apply
- Kills [(biting) (chewing)] lice
- For treatment and prevention of [(biting) (chewing)] lice [infestations]
- Controls existing [(biting) (chewing)] lice infestations
- Dual protection (against fleas and lice)
- Treats, prevents and controls [(biting) (chewing)] lice [infestations]
- Provides effective control of [(biting) (chewing)] lice [infestations]
- Kills [(biting) (chewing)] lice and prevents further infestations
- For treatment and prevention of infestations with [(biting) (chewing)] lice
- Waterproof
- Fragrance free

	<u>% By Weight</u>
Active Ingredient	
Imidacloprid	9.1%
Other Ingredients	<u>90.9%</u>
Total	100.0%

EPA Reg. No. 11556-120

EPA Est. No. 11556-DEU-1

KEEP OUT OF REACH OF CHILDREN

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

6099

WARNING
See Below for First Aid and Precautionary Statements

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS: Causes eye irritation. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. 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 puppies under seven 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. For consumer questions call 1-800-255-6826. For medical emergencies call 1-800-422-9874.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

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 swallowed: Call 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 on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

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 APPLY

1. Use only on dogs. Do not use on other animals.

70f9

2. Remove one applicator tube from the package.

[Visuals Depicting How to Open Applicator Tube]

3. Hold applicator tube in an upright position. Pull cap off 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. The entire contents of the Advantage tube should be applied 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 Storage and Disposal.
8. In case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not retreat more often than once every seven days. After flea control is attained, return to a monthly retreatment schedule.

GENERAL INFORMATION

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

Advantage kills fleas on dogs 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.

Larval flea stages in the pet's surroundings are killed following contact with an Advantage treated pet.

9089

Reason To Issue: Add "Net Contents" heading and optional text: [Sample-not for (re)sale]

Date: 08/27/2010
Supersedes: 01/05/10

Advantage 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.

Storage: Store in a cool, dry place.

Disposal: 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

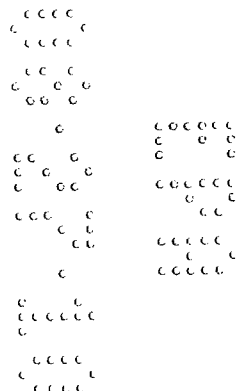
Bayer HealthCare LLC, Animal Health Division warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and 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.

Net Contents: XX0.084 fl. oz. (2.5 mL) Tubes

[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



Reason To Issue: Add "Net Contents" heading and optional text: [Sample-not for (re)sale]

Date: 08/27/2010
Supersedes: 01/05/10

9089

[Label on Individual Tube]

Advantage® 55

9.1% Imidacloprid

0.084 fl. oz. (2.5 mL)

EPA Reg. No. 11556-120

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

BAYER

Lot No. 0000000

