

11556-118

11/21/2013

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

NOTIFICATION

NOV 21 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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

Subject: Notification to Add Alternate Brand Name and Marketing Claim
EPA Registration # 11556-118
Submission Date: November 4, 2013

Dear Mr. Frank:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 received November 4, 2013.

**ALTERNATE BRAND NAME:
DEFENSECARE FLEA PROTECTION LARGE CATS**

The Registration Division (RD) has reviewed these requests and finds that this action falls within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records. If you have any questions, please contact Jessica Rogala at (703) 347-0263 or via email at rogala.jessica@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "J. Rogala".

Jessica Rogala
Environmental Protection Specialist
Insecticide-Rodenticide Branch
Registration Division (7505P)



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11556-118	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Advantage 18 Topical Solution	PM# Team Number 01	
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 <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

Amendment - Explain below. Final printed labels in response to Agency letter dated _____

Resubmission in response to Agency letter dated _____ "Me Too" Application.

Notification - Explain below. Other - Explain below.

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

Notification per PR Notice 98-10:
 Addition of alternate brand name and optional text.
 E-mail Contact: todd.frank@bayer.com

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) _____
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* Certification must be submitted

3. Location of Net Contents Information
 Label Container

4. Size(s) Retail Container

5. Location of Label Directions
 On Label
 On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
 Lithograph
 Paper glued
 Stenciled Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name J. Todd Frank	Title Reg. Affairs Consultant	Telephone No. (Include Area Code) 913-268-2585
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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.

2. Signature 	3. Title Regulatory Affairs Consultant	6. Date Application Received (Stamped)
4. Typed Name J. Todd Frank	5. Date 11/01/2013	

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Bayer HealthCare

Via Federal Express

November 1, 2013

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/PM 01

Subject: Addition of alternate brand name and optional text:

- Advantage 9 Topical Solution (EPA Reg. No. 11556-116)
- Advantage 18 Topical Solution (EPA Reg. No. 11556-118)

Dear Ms. Eagle:

Please find enclosed, for the Agency's acceptance, two Applications for Pesticide Notification, one copy of the highlighted label, and ~~two~~ ^{one} copies of the unhighlighted labels for the subject products. **Note:** Similar applications have been made to R. Gebken, Team 10 for the K9 Advantix product line.

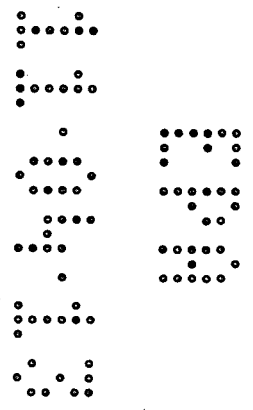
As allowed by PR Notice 98-10 Bayer HealthCare LLC Animal Health is adding Alternate Brand Name and other nonsubstantive changes via the enclosed Notifications.

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Bayer HealthCare LLC

Animal Health

P.O. Box 390
Shawnee Mission, KS
66201-0390



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If you have any questions, please do not hesitate to call (913) 268-2585.

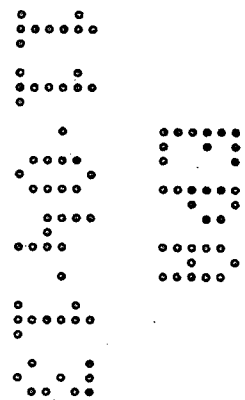
Sincerely,



J. Todd Frank
Regulatory Affairs Consultant
todd.frank@bayer.com

Enclosures:

- 1) Advantage 9 Topical Solution - Application w/att.
- 2) Advantage 18 Topical Solution - Application w/att.



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Reason To Issue: Addition of Alternate Brand Name, optional text and minor typographical revisions. Date: 10/31/2013
Supersedes: 08/20/2012

[Front Panel]

Advantage® 18 Topical Solution
Alternate Brand Names: **Advantage® for Large Cats;**
DefenseCare Flea Protection Large Cats

Once-A-Month Topical Flea Treatment for Cats and Kittens
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 on Cats

[Selected option claims]

- [One treatment prevents further flea infestation for up to four (4) weeks]
- [Kills fleas on cats within 12 hours]
- [Kills fleas before they lay eggs]
- [Convenient, easy to apply]
- [Waterproof]
- [Fragrance free]
- [From the makers of ExpertCare]

NOTIFICATION

NOV 21 2013

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

EPA Est. No. 11556-XXX-X

EPA Reg. No. 11556-118

- See Back Panel for First Aid and Precautionary Statements.
- For Directions For Use, and Storage and Disposal (instructions), see supplemental labeling inside.

KEEP OUT OF REACH OF CHILDREN
WARNING

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[Back Panel]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

WARNING: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. 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.

FIRST AID	
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 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 by mouth to an unconscious person.
If on Skin or Clothing	<ul style="list-style-type: none">• 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.
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 use on kittens under eight 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 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.

Reason To Issue: Addition of Alternate Brand Name, optional text and minor typographical revisions. Date: 10/31/2013
Supersedes: 08/20/2012

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.

RESTRICTIONS:

- Use only on cats 8 weeks and older. Do not use on other animals. Do not apply to kittens or cats weighing less than 9 lbs.
- 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.

Net Contents: Tubes(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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[Back Panel and/or insert]

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. Remove one applicator tube from the package.
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.
4. Twist cap to break seal, then remove cap from tube.
5. Part the hair in 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 of the tube 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.

[Visuals Depicting Application To Animal]

6. Discard empty tube as described in Storage and Disposal.
7. 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.

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PRODUCT INFORMATION

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

Advantage kills 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.

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

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.

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.

Reason To Issue: Addition of Alternate Brand Name, optional
text and minor typographical revisions.

Date: 10/31/2013

Supersedes: 08/20/2012

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[Label on Individual Tube]

Advantage® 18

9.1% Imidacloprid

0.027 fl. oz. (0.8 mL)

EPA Reg. No. 11556-118

WARNING

Keep Out of Reach of Children

Read The Entire Label Before Use

BAYER

Lot No. 0000000

Reason To Issue: Addition of Alternate Brand Name, optional text and minor typographical revisions. Date: 10/31/2013
Supersedes: 08/20/2012

[Label on ~~pouch~~ or blister card; (one card containing 1, 2, 3, 4, 5, or 6 tubes)]

Advantage® 18
Topical Solution

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

9.1% Imidacloprid

- 0.027 fl. oz. (0.8 mL)

EPA Reg. No. 11556-118

BAYER