

2382-155

12/20/2011

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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

DEC 20 2011

Ms. Michelle Foster  
Virbac AH, Inc.  
P.O. Box 162059  
Fort Worth, TX 76161

Dear Ms. Foster:

Subject: Application for Pesticide Notification (PRN 98-10)  
Revise per PR Notice 2007-4  
Permethrin-Pyriproxyfen Residual Shampoo for Dogs #1  
EPA Reg. No. 2382-155  
Your submission dated August 12, 2011

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated August 12, 2011 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds the action requested 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.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions regarding this letter, please contact Dana Pilitt, PhD of my staff at (703) 305-7071 or via e-mail at [pilitt.dana@epa.gov](mailto:pilitt.dana@epa.gov).

Sincerely,

Richard Gebken  
Product Manager 10  
Insecticide Branch  
Registration Division (7505P)



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

Print Form



United States  
Environmental Protection Agency  
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2382-155	2. EPA Product Manager <i>M. Suarez</i>	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Permethrin-Pyriproxyfen Residual Shampoo for Dogs #1	PM# <i>#13</i>	
5. Name and Address of Applicant (Include ZIP Code) Virbac AH, Inc. PO Box 162059 Fort Worth, TX 76161 <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: <input checked="" type="checkbox"/> EPA Reg. No. _____ Product Name _____	

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.

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

For the purposes, content and attachments to this Notification refer to the Cover Letter.

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
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	Other (Specify) _____	
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 <i>Michelle Foster</i>	Title Regulatory Specialist	Telephone No. (Include Area Code) 682-647-3545
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 <i>Michelle Foster</i>	3. Title Regulatory Specialist	
4. Typed Name Michelle Foster	5. Date <i>August 15, 2011</i>	





*Virbac Corporation*

August 12, 2011

Document Processing Desk  
Office of Pesticide Programs (7508P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

**ATTENTION: Linda Arrington, Notifications & Minor Formulations Team Leader**

Subject: Notification of label change per PR NOTICE 2007-4  
Permethrin-Pyriproxyfen Residual Shampoo for Dogs #1  
EPA Reg. No. 2382-155

Dear Ms. Arrington,

In accordance with 40 CFR 152.46, Virbac AH, Inc. submits herewith an application for pesticide notification for subject product. This submission allows for labeling changes per PR Notice 2007-4 to the side/back panel of the label. The labeling changes are noted below and clearly marked on the revised product label (see attachment).

*"Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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 the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, 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."*

Revisions to side/back panel of the label in the "Storage and Disposal" section:

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

Added: Pesticide before Storage

Replace "Disposal" statement with the following:

- Pesticide Disposal and Container Handling: Nonrefillable container. Do not reuse or refill this container. If Empty: Place in trash or offer for recycling, if available.
- If Partly Filled: Call your local solid waste agency for disposal instructions. Never place any unused product down any indoor or outdoor drain."

This product is in compliance with 40 CFR 156.140(a)(4) as the lot number is adhered to the product. This product is exempt from 40 CFR 156.144 through 156.156 due to the product's residential/household use. Additionally, this product is not a dilutable (liquid or solid) formulation.



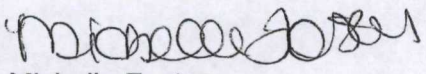
Ms. Linda Arrington  
Page 2 of 2  
August 12, 2011

The contents and attachments to this notification include the following:

- 1) Cover Letter
- 2) Application for Pesticide Notification (EPA FORM 8570-1)
- 3) Revised Product Label with Changes Marked (one copy)
- 4) Revised Product Label (one copy)

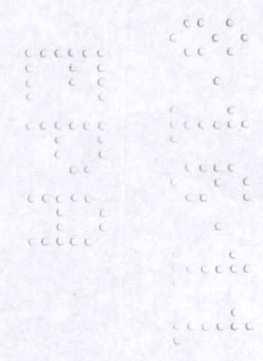
If there are any questions regarding this notification, please contact me at (682)647-3545 or via email at [mfoster@virbacus.com](mailto:mfoster@virbacus.com).

Sincerely,



Michelle Foster  
Regulatory Specialist

Enclosures





FRONT PANEL

**PERMETHRIN-PYRIPROXYFEN RESIDUAL<sup>1</sup> SHAMPOO FOR DOGS #1**

- ◆ PERMETHRIN IMMEDIATELY KILLS FLEAS AND TICKS, INCLUDING TICKS THAT TRANSMIT THE ORGANISM THAT CAUSES LYME DISEASE
- ◆ PERMETHRIN CONTINUES TO REPEL AND KILL FLEAS FOR 9 DAYS AND TICKS FOR 20 DAYS
- ◆ PYRIPROXYFEN IGR, NYLAR<sup>®3</sup>, STERILIZES ALL NEW FLEAS AND KILLS THEIR EGGS FOR 30 DAYS
- ◆ EMOLLIENT OATMEAL SHAMPOO FOR RESIDUAL KILLING AND CONTROL OF TICKS, FLEAS AND THEIR EGGS ON DOGS AND PUPPIES

**ACTIVE INGREDIENT:**

<sup>2</sup> Permethrin: CAS #52645-53-1 (Nylar <sup>®3</sup> ).....	1.00%
Pyriproxyfen: CAS #95737-68-1.....	0.01%

<b>OTHER INGREDIENTS:</b> .....	<u>98.99%</u>
<b>TOTAL</b> .....	<b>100.00%</b>

<sup>1</sup> Patent Pending

<sup>2</sup> Cis/trans isomer ratio: Max. 55% (+/-) cis and Min. 45% (+/-) trans

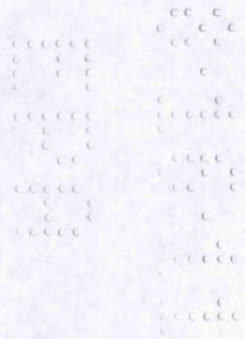
<sup>3</sup> NYLAR<sup>®</sup> a registered trademark of McLaughlin Gormley King Company

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**SEE SIDE/BACK PANEL FOR  
ADDITIONAL PRECAUTIONARY STATEMENTS**

NET CONTENTS: 8 fl. oz. (237 mL.)





SIDE/BACK PANEL

**READ ENTIRE LABEL BEFORE EACH USE  
USE ONLY ON DOGS**

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
CAUTION**

**HAZARDS TO HUMANS:** May cause eye irritation. Do not get in eyes, on skin or clothing. Avoid breathing spray mist. Avoid contamination of food or foodstuffs. Wear gloves or mitt when applying the product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse.

**HAZARDS TO ANIMALS: DO NOT USE ON CATS. DO NOT TREAT PUPPIES UNDER 12 WEEKS OF AGE.**

Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant, or nursing animals.

Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

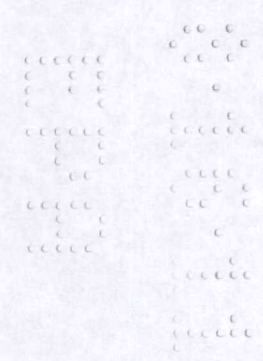
=====  
**FIRST AID**  
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- If In Eyes**
  - Hold eye open and rinse slowly and gently with water for 15-20 minutes.
  - Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.
  - Call a poison control center or doctor for treatment advice.

- 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.

=====  
**HOT LINE NUMBER**  
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Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-XXX-XXXX for emergency medical treatment information.





7/7

SIDE/BACK PANEL

DIRECTIONS FOR USE

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

Pyriproxyfen and permethrin in this special formulation<sup>2</sup>, are absorbed onto, and stick tightly to hair and skin, even after complete rinsing, to provide long term residual efficacy against fleas and ticks. New fleas are repelled and killed for 9 days and ticks for 20 days after bathing. Lyme disease ticks are also repelled and killed before they can feed and transmit disease. The insect growth regulator (a synthetic flea hormone), pyriproxyfen, sterilizes all fleas that jump onto the dog (even new fleas before they start laying eggs) and therefore kills all flea eggs. This action persists for 30 days and breaks the flea's life cycle by preventing the development of new fleas in the dog's environment and the build-up of reinfestation pressure.

Because of the residual activity of the ingredients, it is not necessary to use an insecticidal dip or other topical or systemic pesticides or drugs to obtain extended control of fleas and ticks. The use of this shampoo on a regular basis, alone or in conjunction with initial environmental flea control measures (if needed), should suffice to provide complete and continuous effective flea and tick control on dogs.

APPLICATION: SHAKE WELL BEFORE USING. Wet the dog thoroughly with warm water. Apply product onto its back at the rate of approximately 1 tablespoonful for each 5 lb. body weight (7.5g/kg.). Massage well into the skin to obtain good lathering over the entire body. Allow lather to remain in contact for at least 10 minutes then rinse off. Allow dog to air dry or blow dry. Under flea and tick reinfestation pressure from the dog's environment, the dog may be retreated when new parasites are seen to persist on the dog, but not more often than once every 14 days.

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STORAGE AND DISPOSAL
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Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store in original container in a cool, dry place inaccessible to children and pets.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. If Empty: Place in trash or offer for recycling, if available. If Partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No.: 2382-155

EPA Est. No.: 67517-M0-1

Manufactured By
Virbac AH, Inc.
Fort Worth, TX 76161
800-338-3659

(lot number statements as needed)

Mfg. & Printed in U.S.A. (label revision number) (product number)

