

2382-124

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

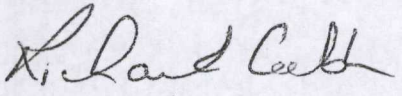
Dear Ms. Foster:

Subject: Application for Pesticide Notification (PRN 98-10)
Revise per PR Notice 2007-4
Preventic LA IGR
EPA Reg. No. 2382-124
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.

Sincerely,


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

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

 Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2382-124	2. EPA Product Manager <i>M. Suarez</i>	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Preventic L.A. IGR	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: NOTIFICATION EPA Reg. No. _____ Product Name _____ DEC 20 2011	

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	No. per container	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 Michelle Foster	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
Preventic LA IGR
EPA Reg. No. 2382-124

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.

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NOTIFICATION

DEC 20 2011

FRONT PANEL

PREVENTIC L.A. IGR

- ◆ RESIDUAL FLEA OVISTERILANT AND TICK KILLER SPRAY FOR DOGS
- ◆ LONG ACTING FLEA & TICK SPRAY WITH NYLAR^{®2} IGR FOR DOGS
- ◆ QUICK ACTING/IMMEDIATE FLUSHING RESIDUAL FLEA & TICK SPRAY FOR DOGS
- ◆ LONG ACTING FLEA & TICK SPRAY WITH PERMETHRIN AND PYRIPROXYFEN
- ◆ KILLS FLEAS FOR 2 MONTHS
- ◆ KILLS TICKS, INCLUDING LYME VECTORS, FOR 1 MONTH
- ◆ NYLAR^{®2} IGR STERILIZES FLEAS (KILLS FLEA EGGS) FOR 3 MONTHS

ACTIVE INGREDIENT:

¹ Permethrin: CAS #52645-53-1	2.00%
Pyriproxyfen: CAS #95737-68-1 (NYLAR ^{®2})	0.05%
OTHER INGREDIENTS:	<u>97.95%</u>
TOTAL	100.00%

¹ cis/trans isomer ratio: Min 35% (+/-) cis and Max 65% (+/-) trans

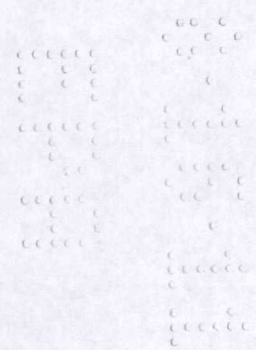
² NYLAR is a Registered Trademark of McLaughlin Gormley King & Company

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE SIDE/BACK PANEL FOR
ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents: 8 fl. oz. (237 mL)
16 fl. oz. (473 mL)



SIDE/BACK PANEL

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS
DO NOT USE ON CATS

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

HAZARD TO HUMANS: Caused moderate eye irritation. Avoid contact with eyes or clothing. Avoid breathing spray mist. Use only in a well ventilated area. Avoid contamination of food. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove contaminated clothing and wash before reuse.

HAZARDS TO ANIMALS:

DO NOT USE ON CATS. DO NOT USE ON DOGS UNDER 6 MONTHS OF AGE. Do not spray in eyes, face or genitalia. Until dry do not confine treated dog in area without adequate cross ventilation.

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 or a non-pesticidal shampoo and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID

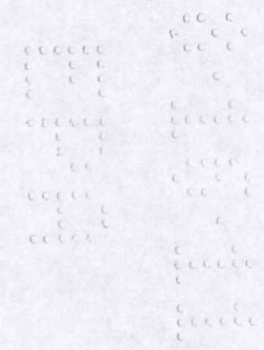
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If In Eyes ° Hold eye open and rinse slowly and gently with water for 15-20 minutes.
 ° Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.
 ° Call a poison control center or doctor for treatment advice.
=====

HOT LINE NUMBER

=====
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-345-4735 for emergency medical treatment information.
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PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.



SIDE/BACK PANEL

DIRECTIONS FOR USE

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

Spray over entire haircoat making sure the coat is thoroughly wetted to the skin. Spray against the lay of the hair, ruffling the coat on long-haired dogs. Weight of dog, length of hair, and density of coat will determine amount of spray to be applied to wet the skin (average dose approximately 7.5g/kg). Eight ounces (8 oz.) of product should be sufficient for two applications at a two month interval to an average 30-35 lb. dog. Lighter applications will reduce period of effectiveness and require more frequent treatments. Allow dog to air dry or blow dry. Do not towel dry. Do not spray in eyes, face or genitalia. Do not use on dogs under 12 weeks of age. Do not apply more often than once a month.

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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 an area away from heat and open flame.

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.: 2382-124

EPA Est. No.: 67517-M0-1

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

AVAILABLE THROUGH LICENSED VETERINARIANS ONLY

(lot number statements as needed)
Mfg. & Printed in U.S.A. (label revision number) (product number)

