

2382-155

10/18/2010

10e7



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Michelle Foster
Virabac AH, Inc.
P.O. Box 162059
Fort Worth, Texas 76161

OCT 18 2010

Subject: Label Notification(s) for Pesticide Registration Notice 98-10

Dear Ms. Foster:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated September 23, 2010 for the following product(s):

Permethrin- Pyriproxyfen **EPA Registration Number 2382-155**
Residual Shampoo for Dogs #1

The Registration Division (RD) has conducted a review of this request for applicability under PR Notice 98-10 and finds that the label change(s) requested falls within the scope of PRN 98-10. The label has been date-stamped "Notification" and will be placed in our records.

If you have any questions, please contact Linda A. DeLuise at 703-305-5428.

Sincerely,

RJ Richard J. Gebken
Product Manager
Insecticide Branch
Registration Division (7504P)

Please read instructions on reverse before completing form.

Form Approved, UMB No. 2070-0060

Print Form



United States Environmental Protection Agency Washington, DC 20460

Registration Amendment Other (checked)

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 2382-155
2. EPA Product Manager
3. Proposed Classification: None (checked), Restricted
4. Company/Product (Name): Permethrin-Pyriproxyfen Residual Shampoo for Dogs #1
5. Name and Address of Applicant: Virbac AH, Inc., PO Box 162059, Fort Worth, TX 76161
6. Expedited Review: EPA Reg. No. OCT 18 2010, Product Name

Section - II

Amendment - Explain below. Resubmission in response to Agency letter dated. Notification - Explain below. Final printed labels in response to Agency letter dated. "Me Too" Application. 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 dated September 23, 2010.

Section - III

1. Material This Product Will Be Packaged In: Child-Resistant Packaging, Unit Packaging, Water Soluble Packaging, 2. Type of Container: Metal, Plastic, Glass, Paper, Other (Specify)
3. Location of Net Contents Information: Label (checked), Container
4. Size(s) Retail Container
5. Location of Label Directions: On Label (checked), 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: Michelle Foster, Title: Regulatory Affairs Spec., Telephone No.: 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)
cccccc
cccccc
cccccc
cccccc
cccccc
cccccc
cccccc
cccccc
cccccc

2. Signature: Michelle Foster
3. Title: Regulatory Affairs Specialist
4. Typed Name: Michelle Foster
5. Date: 9/23/10

3097



Virbac Corporation

September 23, 2010

Document Processing Desk
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: Linda Arrington

Subject: Notification of removal of 1-800-CLEANUP number

Dear Ms. Arrington:

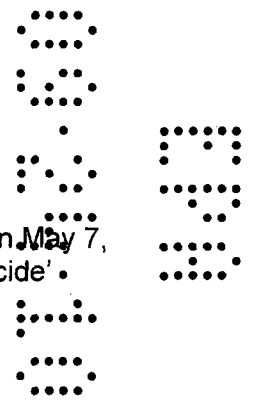
According to the Label Review Manual, Chapter 13: Storage and Disposal; "use of a toll-free number or website is optional"; therefore, 1-800-CLEANUP has been removed from our labels. We understand notification is not required for such a change, but we wanted to maintain a record.

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.

Enclosed are the following revised products labels.

- Ecto-Soothe® 3X Flea and Tick Shampoo for Dogs and Cats, EPA Reg. No. 2382-117
- FlyPel, EPA Reg. No. 2382-132
- Zema IGR Premise Spray, EPA Reg. No. 2382-183
- Preventic L.A. IGR, EPA Reg. No. 2382-124
- Otomite® Plus, EPA Reg. No. 2382-116
- Permethrin-Pyriproxyfen Residual Shampoo for Dogs #1, EPA Reg. No. 2382-155
- Pet-Guard Gel Forte, EPA Reg. No. 2382-92
- Pyre-sect Dip, EPA Reg. No. 2382-89
- Yard Spray Concentrate, EPA Reg. No. 2382-122

One additional change was made to the Pyre-sect Dip label. This label was submitted on May 7, 2009 in response to an MGK-326 RED reregistration deficiency letter. The word, 'Pesticide' was inadvertently left off and has been added before 'Storage' in the STORAGE AND DISPOSAL section to comply with the required verbiage in PR Notice 2007-4 .



4097


Ms. Linda Arrington
Page 2 of 2
September 23, 2010

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)

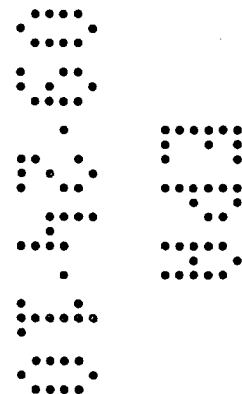
If there are any questions regarding this notification, please contact me at 682-647-3545 or via email at mfooster@virbacus.com.

Sincerely,



Michelle Foster
Registration Specialist

Enclosures



FRONT PANEL

PERMETHRIN-PYRIPROXYFEN RESIDUAL¹ 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^{®3}, 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:

Permethrin: CAS #52645-53-1 (Nylar ^{®3}).....	1.00%
Pyriproxyfen: CAS #95737-68-1.....	0.01%
OTHER INGREDIENTS:.....	98.99%
TOTAL.....	100.00%

¹ Patent Pending

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

³ NYLAR[®] 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.)

NOTIFICATION

OCT 18 2010

```

cccc
e cccc
c cc
c c c
cccc
c
cccccc
c c c
c c c c
c c c
cccc
c
cccccc
cccc
cccc
cccc
c
cccc
cccc
cccc

```

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.

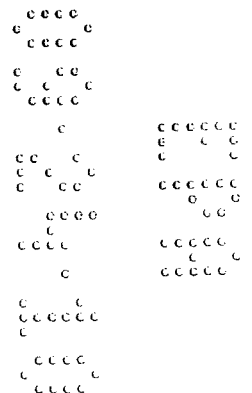
=====
FIRST AID
=====

- 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
=====

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.
=====



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, 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.

=====
STORAGE AND DISPOSAL
=====

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

DISPOSAL: If Empty: Do not reuse this container. 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.

Deleted: or 1-800-CLEANUP

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)

