

2382-89

11-09-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 9, 2010

Ms. Michelle Foster,
Regulatory Affairs Specialist
Virbac AH, Inc.
3200 Meacham Boulevard
Fort Worth, TX 76137-4611

**Subject: Label Notification(s); Pesticide Registration Notification (PRN) 98-10
PYRE-SECT DIP, EPA Reg. No. 2382-89
Your Submission Dated September 23, 2010**

Dear Ms. Foster:

The Agency is in receipt of your application for Pesticide Notification under Pesticide Registration Notification (PRN) 98-10, dated September 23, 2010, for the referenced product. The Registration Division 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.

Please be reminded that 40 CFR §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/PRN 98-10) or durably marked on the container itself.

The label submitted with this application has been time-stamped "Notification," and will be placed within the administrative file for this product. If you have any questions, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely yours,

A handwritten signature in black ink, which appears to read "Richard J. Gebken", is written over the typed name.

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)



Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060

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 2382-89	2. EPA Product Manager PM# 10	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Pyre-sect Dip		
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.

NOTIFICATION

NOV - 9 2010

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:				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 <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container			
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 Affairs Spec.	Telephone No. (Include Area Code) 682-647-3545
2. Signature 		6. Date Application Received (Stamped) 9/23/10
3. Title Regulatory Affairs Specialist		
4. Typed Name Michelle Foster		
5. Date 9/23/10		



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:

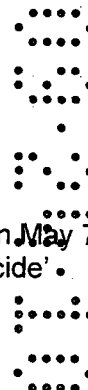
According to the Label Review Manual, Chapter 13: Storage and Disposal; "use of a toll-free number or website is optional"; therefore, 1-800-CLEANUP has been removed from our labels. We understand notification is not required for such a change, but we wanted to maintain a record.

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.



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

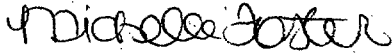
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The contents and attachments to this notification include the following:

- 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)

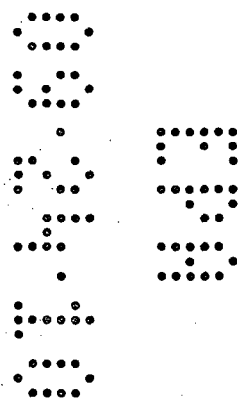
If there are any questions regarding this notification, please contact me at 682-647-3545 or via email at mfooster@virbacus.com.

Sincerely,



Michelle Foster
Registration Specialist

Enclosures



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6.

copy

A collection of 15 small, stylized drawings of various insects, including beetles, flies, and bees, arranged in a grid-like pattern. The drawings are simple line art illustrations, some showing the insects from the side and others from the top or bottom. They are arranged in a roughly rectangular grid, with some insects appearing in pairs or small groups.

Draft Label
Side/Back Panel

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS AND CATS

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 eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip glass of water if able to swallow. Do not induce vomiting unless told to do so by a 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.

HOTLINE 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 800-345-4735 for emergency medical treatment information.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

HAZARDS TO HUMANS: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Avoid contact with skin. Wear protective eyewear (face shield or goggles), long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves made of any waterproof material. Remove contaminated clothing and wash before reuse. Avoid contamination of food/feed.

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. User should remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing. User should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

HAZARDS TO DOMESTIC ANIMALS: FOR USE ON DOGS AND PUPPIES, CATS & KITTENS.

Do not apply to pets less than 12 weeks of age. Do not reapply more often than once every 7 days.

Consult a veterinarian before applying this product on medicated, debilitated, aged, 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.

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Draft Label
Side/Back Panel

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

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

DIRECTIONS FOR USE

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

Do not use on horses or foals intended for slaughter. Do not apply over cuts, wounds, or irritated skin. Do not apply near eyes and mouth. Apply sparingly around ears.

SHAKE WELL BEFORE USING:

DILUTION: To kill fleas ticks and lice, thoroughly mix 1/2 oz (1 tablespoon) of dip with 1 gallon of warm water. For use under more severe reinfestation pressure, dilute at the rate of 1 fl. oz. (2 tablespoons) per gallon. Do not dilute more dip than will be used in a 24 hour period.

APPLICATION: Dip should be applied to dry or damp (not wet) coat. Sponge, dip or spray animal with the diluted concentrate making sure all areas are soaked to the skin. Let animal drip dry. Do not submerge the animals nose, mouth or eyes. DO NOT RINSE OFF! Do not reapply product for 7 days. Do not use on puppies or kittens under 12 weeks of age.

STORAGE AND DISPOSAL

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

Pesticide Storage: Do not use or store near heat or open flame. Store in a cool, dry place (preferably locked) inaccessible to children and pets. Protect from freezing.

Pesticide/Container Disposal: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No.: 2382-89

EPA Est. No.: 67517-M0-1

Manufactured By
Virbac AH, Inc.
Fort Worth, TX 76161
1-800-338-3659

Made in U.S.A.

(lot number statements as needed)

(label revision number)

(product number)