

2382-117

10/18/2010

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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):

**Ecto- Soothe® 3X Flea      EPA Registration Number 2382-117  
and Tick Shampoo for  
Dogs and Cats**

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,

A handwritten signature in black ink, appearing to read "Richard J. Gebken".

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



307



*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:

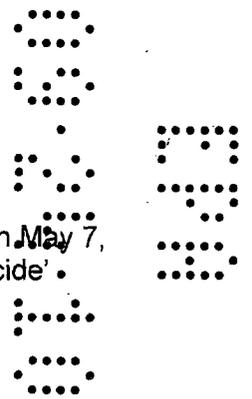
According to the Label Review Manual, Chapter 13: Storage and Disposal; "use of a toll-free number or website is optional"; therefore, 1-800-CLEANUP has been removed from our labels. We understand notification is not required for such a change, but we wanted to maintain a record.

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.



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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)

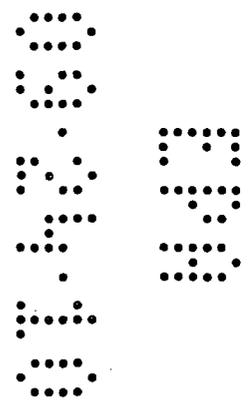
If there are any questions regarding this notification, please contact me at 682-647-3545 or via email at [mfoster@virbacus.com](mailto:mfoster@virbacus.com).

Sincerely,



Michelle Foster  
Registration Specialist

Enclosures



Draft Label  
Front Panel

ECTO-SOOTHE® 3X FLEA AND TICK SHAMPOO FOR DOGS AND CATS

- ◆ VIRBAC ANIMAL HEALTH
- ◆ PARASITOLOGY
- ◆ ECTO-SOOTHE® 3X
- ◆ KILLS TICKS, FLEAS & LICE
- ◆ EMOLLIENT OATMEAL PESTICIDAL SHAMPOO
- ◆ FOR USE ON DOGS, CATS, PUPPIES & KITTENS

ACTIVE INGREDIENTS:

Pyrethrins: CAS #8003-34-7.....	0.15%
<sup>1</sup> Piperonyl Butoxide Technical: CAS #51-03-6.....	1.50%
n-Octyl bicycloheptene dicarboximide.....	0.50%
<b>OTHER INGREDIENTS:</b> .....	<u>97.85%</u>
<b>TOTAL</b> .....	<b>100.00%</b>

<sup>1</sup>Equivalent to 1.2% (Butylcarbityl) (6-propylpiperonyl) ether and 0.3% related compounds.

<sup>2</sup>ECTO-SOOTHE is a registered trademark of Virbac AH, Inc.

KEEP OUT OF THE REACH OF CHILDREN  
CAUTION  
SEE BACK PANEL FOR ADDITIONAL  
PRECAUTIONARY STATEMENTS

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

**NOTIFICATION**  
**OCT 18 2010**

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Draft Label  
Side/Back Panel

**ENVIRONMENTAL HAZARDS**

This product is toxic to aquatic organisms. Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate.

**DIRECTION FOR USE**

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

**SHAKE WELL BEFORE USING**

Apply product to the back of the animal and massage well into the skin to obtain a good lathering of the entire body. Allow lather to remain in contact with the skin for 10 minutes. Rinse thoroughly with warm water and towel or blow dry. Do not repeat treatment more often than once every 7 days.

Ecto-Soothe® 3X, using Spherulites®, represents a breakthrough in skin care technology.

**SPHERULITES®** An exclusive and patented encapsulation system was developed by Virbac to provide slow release of contents long after the shampoo is rinsed off, Oatmeal and glycerin are present in encapsulated (Spherulites®) and free forms. The patented encapsulation system does not include any pesticide ingredients, nor will it provide any increased pesticide effectiveness. The encapsulation system contents are only present for the purpose of soothing and moisturizing the animal's skin after use.

Spherulites® only provide moisturizing for the animal's skin after use, and do not increase the effectiveness of the active pesticide ingredients.

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**STORAGE AND DISPOSAL**
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**Storage:** Store in closed container in a cool dry area.

**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.: 2382-117

EPA Est. No.: 67517-MO-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)  
Page 3 of 3  
September 23, 2010

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