

2382-116

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
OTOMITE® PLUS, EPA Reg. No. 2382-116
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, appearing to read "Richard Gebken".

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



Virbac Corporation

September 23, 2010.

NOTIFICATION

NOV - 9 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:

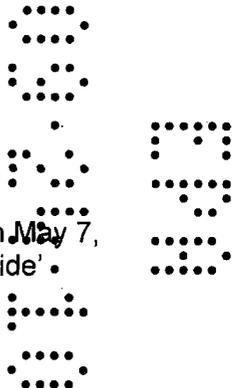
According to the Label Review Manual, Chapter 13: Storage and Disposal; "use of a toll-free number or website is optional"; therefore, 1-800-CLEANUP has been removed from our labels. We understand notification is not required for such a change, but we wanted to maintain a record.

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

4
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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)

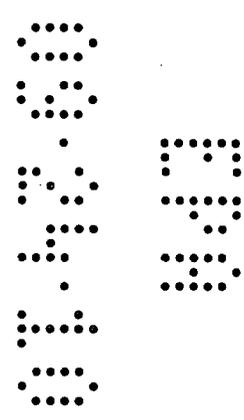
If there are any questions regarding this notification, please contact me at 682-647-3545 or via email at mfoster@virbacus.com.

Sincerely,



Michelle Foster
Registration Specialist

Enclosures



Draft Label
Side/Back Panel

DIRECTION FOR USE

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

Cleanse ear thoroughly with a low pH ear cleanser, like Epi-Otic. Place sufficient Otomite Plus in each ear to wet external ear canal. Spread product inside ear canal by massaging the ear. Re-treat at least every 7 days, depending on the severity of the condition, but not more frequently than twice a week. If condition does not resolve in two weeks, discontinue treatment and consult a veterinarian. If it is necessary to reuse an ear cleaner, re-treat afterwards with Otomite Plus.

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STORAGE AND DISPOSAL
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Storage: Store 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.: 2382-116

EPA Est. No.: 67517-M0-1

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

Sold only by Veterinarians
Available Through Licensed Veterinarians Only

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

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