



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Michelle Foster
Virbac AH, Inc.
P.O. Box 162059
Fort Worth, TX 76161

MAY - 3 2012

Dear Ms. Foster:

Subject: Application for Pesticide Notification (PRN 98-10)
Revise per PR Notice 2007-4.
Otomite Plus
EPA Reg. No. 2382-116
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,

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

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



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2382-116	2. EPA Product Manager <i>R. Gebken</i>	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Otomite® Plus	PM# <i>#10</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: <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.

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 <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 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
Otomite® Plus
EPA Reg. No. 2382-116

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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- 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)

Sincerely,

Michelle Foster
Regulatory Specialist

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- ◆ OTIC
- ◆ VIRBAC ANIMAL HEALTH
- ◆ FOR TREATMENT OF EAR MITES IN DOGS,
CATS, PUPPIES AND KITTENS

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

²OTOMITE® PLUS is a registered trademark of Virbac AH, Inc.

Net Contents: 0.5 fl. oz. (14.7 mL)

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DRAFT LABEL
Side/Back Panel

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS AND CATS
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

HAZARDS TO HUMANS: Harmful if absorbed through the skin. Avoid contact with skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

HAZARDS TO DOMESTIC ANIMALS: FOR USE ON DOGS AND PUPPIES, CATS & KITTENS.
Do not use on puppies or kittens 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 on 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.

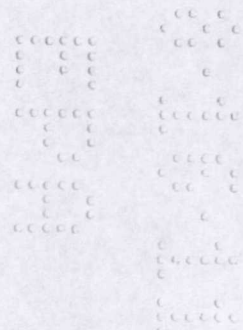
FIRST AID

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



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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.

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EPA Est. No.: 67517-M0-1

number)