

	United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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**Application for Pesticide - Section I**

1. Company/Product Number 2382-116	2. EPA Product Manager Joe Tavano	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Otomite Plus	PM#	
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: EPA Reg. No. _____ Product Name _____

**Section - II**

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
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September 7, 2001  
**NOTIFICATION**  
 SEP 30 2003

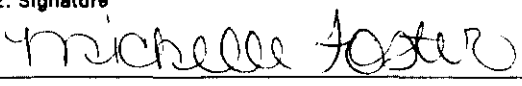
**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Notification of label change relative to PR Notice 2001-6. This notification is consistent with the guidance in PR Notice 2001-6 and the requirements of EPA's regulations at 40 CFR 156.10 and 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 guidance of PR Notice 2001-6 and the requirements of 40 CFR 156.10 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.

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If "Yes" Unit Packaging wgt. _____ No. per container _____	If "Yes" Package wgt _____ No. per container _____	<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 oz		5. Location of Label Directions <input checked="" type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph 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 Registration Specialist	Telephone No. (include Area Code) 800-338-3659 x3545	
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 	3. Title Registration Specialist		
4. Typed Name Michelle Foster	5. Date 9/12/03		

# 300%

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

**Hazards to Humans:** Harmful if absorbed through skin. Avoid contact with 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 each handling.

**Hazards to Domestic Animals:** Do not use on pets under 12 weeks of age. Consult a veterinarian before treating pregnant, nursing, aged, debilitated or medicated animals. Sensitivities may occur after using any pesticide product for pets. If signs of sensitivity occur, wash treated area with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

**FIRST AID:**

**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.

O T I C



## Otomite Plus®

FOR THE TREATMENT OF  
EAR MITES IN DOGS, CATS,  
PUPPIES AND KITTENS

**ACTIVE INGREDIENTS:**

Pyrethrins ..... 0.15%  
Piperonyl butoxide, technical\* ..... 1.50%  
n-Octyl bicycloheptene

dicarboximide ..... 0.50%  
**OTHER INGREDIENTS** ..... 97.85%

**TOTAL** ..... 100.00%

\*Equivalent to 1.2% (butyl-carbityl) (6-propyl-piperonyl) ether and 0.3% related compounds.

### CAUTION

KEEP OUT OF REACH OF CHILDREN

See Side Panel For Additional Precautionary Statements

Net 0.5 fl. oz. (14.7 mL)



**STORAGE AND DISPOSAL:**

**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 or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

**DIRECTIONS 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 2 weeks, discontinue treatment and consult your veterinarian. If it is necessary to reuse an

ear cleaner, re-treat afterwards with Otomite Plus.

EPA Reg. No. 2382-116 EPA Est. No. 67517-MO-1

Sold only by veterinarians.

Virbac AH, Inc. • P.O. Box 162059 • Fort Worth, Texas 76161 • (800) 338-3659  
OTOMITE PLUS is a registered trademark of Virbac AH, Inc.



250920-07

# SPOT UV

### SPECIFICATIONS

**Component Number:** 250920 **Revision Number:** -07

**Description:** Label for Otomite Plus Ear Treatment (.5 oz.) U.S.

**Product Number:** 601712

**Label Size:** Width: 3" Height: 1-3/8" Corner Radius: 1/8"

**Material:** Clear label, permanent adhesive with clear over-laminate.

**Function:** Must adhere to bottle without lifting. Corners should not lift.

### FOURTH PROOF

**Revision Date:** 1/30/03

**Color(s):** 2 Colors -

■ Pantone Ref Blue

■ Pantone 2975 CV

NOTIFICATION  
SEP 3 0 2003

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