



2382-116



11 | 28 | 2012  
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

1/4

OFFICE OF  
CHEMICAL SAFETY  
AND POLLUTION PREVENTION

NOV 28 2012

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

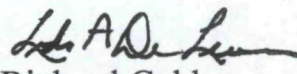
Subject: Amended Labeling/AI Percentage Change in Approved CSF  
Otomite® Plus  
EPA Registration Number: 2382-116  
Application Dated: September 25, 2012  
Decision: 470603

Dear Ms. Foster:

The label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

If you have any questions, please contact Melody Banks on 703 305-5413 or via E-mail @ banks.melody@epa.gov.

Sincerely,

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

Enclosure: Stamped Accepted Copy of Product Label



2/4

Front Panel

OTOMITE®<sup>2</sup> PLUS

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

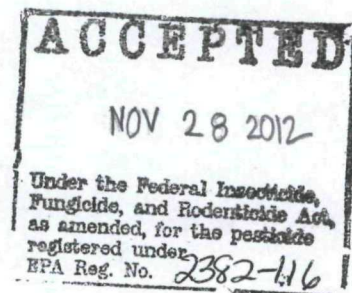
ACTIVE INGREDIENTS:

Pyrethrins: CAS #8003-34-7.....	0.15%
<sup>1</sup> Piperonyl Butoxide Technical: CAS #51-03-6.....	1.50%
n-Octyl bicycloheptene dicarboximide.....	0.48%
OTHER INGREDIENTS:.....	97.87%
TOTAL.....	100.00%

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

<sup>2</sup>OTOMITE® PLUS 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: 0.5 fl. oz. (14.7 mL)



3/4

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. Avoid contamination of feed and foodstuffs.

User Safety Recommendations:

Users should wash hands with plenty of soap and water before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

**HAZARDS TO DOMESTIC ANIMALS: FOR USE ON DOGS AND PUPPIES, CATS & KITTENS.**  
Do not apply to pets less than 12 weeks old.

Consult a veterinarian before using this product on medicated, debilitated, aged, 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 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 800-345-4745 for emergency medical or veterinary treatment information.

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic organisms, including fish and invertebrates. Do not contaminate water when disposing of equipment, washwater, or rinsate. See Directions for Use for additional precautions and requirements.



4/4

Side/Back Panel

**DIRECTION FOR USE**

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

APPLICATION INSTRUCTIONS

**SHAKE WELL BEFORE USING**

Cleanse ear thoroughly with a low pH ear cleanser, like Epi-Otic. Place sufficient Otomite Plus in each ear to wet external ear canal, approximately at the rates, for each pound bodyweight, of 1 drop (maximum 15) for dogs and 2 drops (maximum 10) for cats. 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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Do not contaminate water, food, or feed by storage and disposal.

**Pesticide Storage:** Store in a cool dry area.

**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 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)