



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 19, 2018

Michelle Foster
Associate Manager, R.A.
Virbac AH, Inc.
PO Box 162059
Fort Worth, TX 76161

Subject: Notification per PRN 2008-1 –Minor changes
Product Name: OTOMITE PLUS EAR MITICIDE
EPA Registration Number: 2382-116
Application Date: 3/29/2018
Decision Number: 540154

Dear Ms. Foster:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 2008-1 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 2008-1 and finds that the action requested falls within the scope of PRN 2008-1.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Elizabeth Fertich", is written over the word "Fertich" in the typed name below.

Elizabeth Fertich, Product Manager 04
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Front Panel (~~Sticker~~ Base label)

Optional text appears in brackets. The final label may include some or all of the optional text on the front panel, back panel or booklet.

Otomite Plus® Ear Miticide

- [OTIC]
- [FOR THE TREATMENT OF EAR MITES IN DOGS, CATS, PUPPIES AND KITTENS]

NOTIFICATION

2382-116

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

07/19/2018

ACTIVE INGREDIENTS

Pyrethrins..... 0.15%

Piperonyl Butoxide*..... 1.50%

n-Octyl bicycloheptene dicarboximide..... 0.48%

OTHER INGREDIENTS..... 97.87%

TOTAL..... 100.00%

*Equivalent to 1.2% (Butylcarbityl) (6-propylpiperonyl) ether and 0.3% related compounds

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

**SEE ~~BACK PANEL~~ BOOKLET FOR ADDITIONAL
PRECAUTIONARY STATEMENTS**

Net Contents: 0.5 fl oz (14.7 mL)

Side/Back Panel: Base label (adheres to the bottle and is underneath the visible panel) and (visible panel of the attached booklet)

[Otomite Plus® Ear Miticide]

See booklet for additional Precautionary Statements, First Aid and Directions for Use

EPA Reg. No. 2382-116

EPA Est. No. 47000-IA-1

Manufactured for Virbac AH, Inc.

PO Box 162059

Fort Worth, TX 76161

(800) 338-3659

[label revision number]

[OPEN]

Side/Back Panel (Attached ~~outsert~~ booklet label)

**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, eyes, 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.

EPA Reg. No. 2382-116

~~November 11, 2016~~ March 23, 2018

Page 1 of 2

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 eye. 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 product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-338-3659 for emergency medical or veterinary treatment information.

NOTE TO PHYSICIAN: Contains petroleum distillates. Vomiting may cause aspiration pneumonia.

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.

PHYSICAL OR CHEMICAL HAZARDS: Contains Petroleum Distillates

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 an ear cleanser, like EPI-OTIC® Advanced Ear Cleanser, in accordance with the directions for use. Place sufficient OTOMITE PLUS® Ear Miticide 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 [2] weeks, discontinue treatment and consult a veterinarian. If it is necessary to reuse an ear cleaner, re-treat afterwards with OTOMITE PLUS Ear Miticide.

Side/Back Panel (Sticker label) and (Attached outsert label)

STORAGE AND DISPOSAL: 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.

EPA Reg. No. 2382-116 ——— EPA Est. No. 47000-IA-1

Manufactured for

Virbac AH, Inc.

PO Box 162059

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(800) 338-3659

[label revision number]

Note to reviewer: lot number will appear on bottle

EPA Reg. No. 2382-116

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Page 2 of 2