

2382-104

3/6/2014

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

NOTIFICATION

MAR 06 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Michelle Foster
Virbac AH, Inc.
3200 Meacham Blvd.
Forth Worth, TX 76137

Subject: Notification to delete a marketing claim and to revise text
EPA Registration No. 2382-104
Primary Brand Name: PREVENTIC TICK COLLAR FOR DOGS
Submission Date: February 21, 2014

Dear Ms. Foster:

The Agency is in receipt of your Application for Pesticide Notification under PRN 98-10 dated and finds that 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. If you have any questions, please contact Gene Benbow at (703) 347-0235 or via email at benbow.gene@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Gene Benbow", written over a horizontal line.

Gene Benbow
Wildlife Biologist
Insecticide-Rodenticide Branch
Registration Division (7505P)

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United States
Environmental Protection Agency
Washington, DC 20460

| | |
|-------------------------------------|--------------|
| <input type="checkbox"/> | Registration |
| <input type="checkbox"/> | Amendment |
| <input checked="" type="checkbox"/> | Other |

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|---|---|---|
| 1. Company/Product Number 2382-104 | 2. EPA Product Manager Reuben Baris | 3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Preventic Tick Collar for Dogs | PM# Team 7 | |
| 5. Name and Address of Applicant (Include ZIP Code) Virbac AH, Inc. 3200 Meacham Blvd. Fort Worth, TX 76137 <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"/> 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.)

Notification revised labeling per PR Notice 98-10.
This notification is consistent with the provisions of PR Notice 98-10 and the 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.

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 |
| * Certification must be submitted | | If "Yes" Unit Packaging wgt. No. per container | If "Yes" Package wgt. No. per container | <input type="checkbox"/> Glass | <input type="checkbox"/> Paper |
| | | | | <input type="checkbox"/> Other (Specify) _____ | |
| 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"/> | |
| 6. Manner in Which Label is Affixed to Product | | <input type="checkbox"/> Lithograph Paper glued <input type="checkbox"/> Stenciled | | <input type="checkbox"/> Other _____ | |

Section - IV

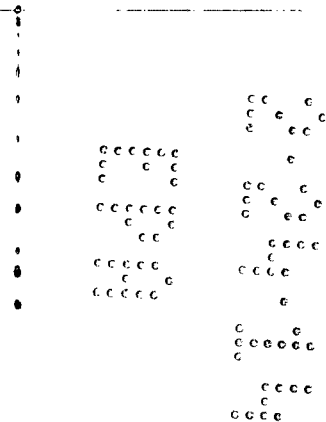
| | | | | | |
|--|--|--|---|---|--|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | | | | |
| Name Michelle Foster | | Title Associate Manager, Regulatory Affairs | | Telephone No. (Include Area Code) 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 Associate Manager, Regulatory Affairs | | |
| 4. Typed Name Michelle Foster | | 5. Date February 21, 2014 | | | |



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February 21, 2014

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202



Subject: Notification for revised label for
PREVENTIC® Tick Collar for Dogs, EPA Reg. No. 2382-104

Virbac AH, Inc. is herewith filing a notification to the Registration Division to for Preventic Tick Collar for Dogs.

The contents and attachments to this submission include the following:

- 1) Cover Letter
- 2) Application for Pesticide (EPA Form 8570-1)
- 3) Marked up label
- 4) New label for stamping

Please return the new stamped label to my attention at the below address.

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

Sincerely,

Michelle Foster
Associate Manager, Regulatory Affairs
Virbac AH, Inc.
3200 Meacham Blvd.
Fort Worth, TX 76137

Need label + cover letter -
2-28-14

Enclosures

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DRAFT LABEL
Front Panel

PREVENTIC TICK COLLAR FOR DOGS

- ◆ USE ONLY ON DOGS
- ◆ DO NOT USE ON CATS {PICTURE OF CAT WITH DIAGONAL LINE DRAWN THROUGH CAT}
- ◆ ANTIPARASITIC
- ◆ FITS NECKS UP TO 18"
- ◆ FITS NECKS UP TO 25"
- ◆ KILLS AND DETACHES TICKS FOR 3 MONTHS
- ◆ ADJUSTABLE - ONE SIZE FITS MOST DOGS
- ◆ ADJUSTABLE FOR DOGS OVER 60 LBS.
- ◆ TICK COLLAR FOR DOGS
- ◆ 90 DAY TICK COLLAR FOR DOGS
- ◆ KILL TICKS FOR 3 MONTHS
- ◆ KILL TICKS FOR 90 DAYS
- ◆ THE ONE THAT KILLS AND DETACHES TICKS
- ◆ FOR DOGS UP TO 60 LBS
- ◆ FOR DOGS OVER 60 LBS
- ◆ SIX MONTHS OF TICK PREVENTION {I.E., FOR CARTON CONTAINS TWO COLLARS}
- ◆ INDIVIDUAL COLLARS NOT TO BE SOLD SEPARATELY
- ◆ ADJUSTABLE FOR DOGS UP TO 60 LBS
- ◆ 18" AVAILABLE FOR DOGS UP TO 60 LBS (THIS WILL BE ON THE 25" COLLAR IFC)
- ◆ 25" AVAILABLE FOR DOGS OVER 60 LBS (THIS WILL BE ON THE 18" COLLAR IFC)

NOTIFICATION

MAR 06 2014

ACTIVE INGREDIENTS:

| | |
|--|--------------|
| —Amitraz: CAS# 33089-61-1 | 9.0% |
| OTHER INGREDIENTS+..... | <u>91.0%</u> |
| TOTAL..... | 100.0% |

KEEP OUT OF THE REACH OF CHILDREN
CAUTION

SEE BACK PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS AND DIRECTIONS

DO NOT ALLOW CHILDREN TO PLAY WITH THE COLLAR
DO NOT OPEN UNTIL READY TO USE

FOR DOGS UP TO 60 LBS.: NET CONTENTS: ONE 18" COLLAR - NET. WT.: 0.652 OZ. (18.5g)
 FOR DOGS UP TO 60 LBS.: NET CONTENTS: 2(TWO) 18" COLLARS - NET. WT.: 1.304 OZ. (37g)
 FOR DOGS OVER 60 LBS.: NET CONTENTS: ONE 25" COLLAR - NET. WT.: 0.97 OZ. (27.5g)
 FOR DOGS OVER 60 LBS.: NET CONTENTS: 2(TWO) 25" COLLARS - NET. WT.: 1.94 OZ. (55g)

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Draft Label
Side/Back Panel

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS. DO NOT USE ON CATS

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

HAZARDS TO HUMANS: Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water before eating, drinking, chewing gum, or using tobacco.

This collar is intended for use as an acaracide generator and is not to be taken internally by man or animal. Not intended for use on humans. Do not allow children to handle or play with this collar.

Some humans may develop skin irritation through contact with collared pet. Remove collar, shampoo pet and consult physician if irritation persists.

HAZARDS TO DOMESTIC ANIMALS: FOR USE ON DOGS ONLY. DO NOT USE ON CATS.

Do not use on puppies under 12 weeks of age. Consult a veterinarian before using on debilitated, aged, medicated, pregnant or nursing animals. Do not treat collared dogs with other monoamine oxidase inhibitors, or with tricyclic antidepressants, selective serotonin reuptake inhibitors, or pressor agents.

Sensitivities may occur after using ANY pesticide product for pets. Remove at first sign of irritation or adverse reaction, bathe dog with mild soap or non-pesticidal shampoo and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

DO NOT APPLY TO CATS. There is a risk of collar breakage and ingestion if collar is worn by unattended dogs that play by mouthing each other in the neck area. If collar is missing from a dog, search for, retrieve and recover the entire collar. Immediately consult a veterinarian if dog is depressed or if ingestion is suspected.

NOTE TO VETERINARIAN: If a dog ingests this collar and exhibits intoxication (primary sign is severe depression), induce vomiting, administer non-oily laxative, activated charcoal or enema. Provide supportive therapy until collar fragments are voided. If dog cannot be roused, Yohimbine, 0.1mg/kg by intravenous injection is antidotal. Repeat as needed.

NOTICE: This product contains an ingredient known to the State of California to cause birth defects or other reproductive harm. Wash hands thoroughly after applying this product. Dispose of as instructed below.

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Draft Label
Side/Back Panel

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FIRST AID

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- 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.

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HOT LINE NUMBER

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Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment. You may also contact 1-800-345-4735 for emergency medical treatment information.

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DIRECTIONS FOR USE

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

DO NOT USE ON CATS {PICTURE OF CAT WITH DIAGONAL LINE DRAWN THROUGH CAT}

Application Instructions: Place this collar around the dog's neck, adjust for proper fit and buckle in place. Cut off and dispose of excess length. Do not allow dogs to play with cut-off excess. Do not apply both collars at once. The collar must be worn tightly enough to contact skin and so that the dog cannot remove it.

Activity against ticks starts within 24 hours and continues as long as the collar is worn (up to 90 days). Ticks present in the dogs environment that may reappear on the dog will not attach and will be killed in less than 24 hours. Replace collar when effectiveness diminishes. The effectiveness of the collar is not diminished by normal wetting such as rainfall, however, it is suggested that the collar be removed before bathing. This product does not control fleas.

7/7

Draft Label
Side/Back Panel

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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 original container in locked storage area. Store away from food and pet food.

Pesticide Disposal and Container Handling: Do not reuse empty pouch or box. Wrap pouch and put in trash collection.

When discarding cut off end and used collar, wrap in newspaper and place in trash collection.

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EPA Reg. No.: 2382-104

EPA Est. No.: ~~2382-TX-179975-IL-2~~

EPA Est. No.: ~~83680-TX-1 86169-MO-1~~

EPA Est. No.: ~~85440-TX-1~~

EPA Est. No.: 2382-FRA-1

Made in France
Manufactured For
Virbac AH, Inc.
~~Consumer Brands Division~~
P.O. BOX 162059
Fort Worth, TX 76161
(800) 338-3659

AVAILABLE THROUGH LICENSED VETERINARIANS ONLY

(lot number statements as needed)
(label revision number) (product number)