

2382-104

09/08/2011

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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

SEP 08 2011

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

Subject: Notification of label change per PR NOTICE 2007-4
Preventic Tick Collar for Dogs
EPA Reg. #2382-104
Submission date: August 12, 2011

Dear Ms. Foster:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated August 12, 2011, for the product Preventic Tick Collar for Dogs, EPA Reg. #2382-104. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 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 call me directly at 703-308-0139 or britton.wade@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Wade Britton", with a long horizontal flourish extending to the right.

Wade Britton
Registration Division (7505P)
Office of Pesticide Programs

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2382-104	2. EPA Product Manager J. Hebert	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Preventic Tick Collar for Dogs	PM# #7	
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 NOTIFICATION	

Section - II

SEP 08 2011

<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	If "Yes" Unit Packaging wgt. No. per container		<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" Package wgt. No. per container	1		
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
Preventic Tick Collar for Dogs
EPA Reg. No. 2382-104

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.

DRAFT LABEL
Front Panel

PREVENTIC TICK COLLAR FOR DOGS

NOTIFICATION

SEP 08 2011

- ◆ 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)

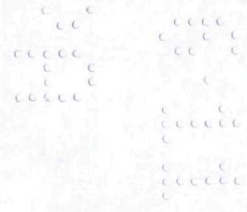
ACTIVE INGREDIENTS:

Amitraz: CAS# 33089-61-1.....	9.0%
OTHER INGREDIENTS:.....	91.0%
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)



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.

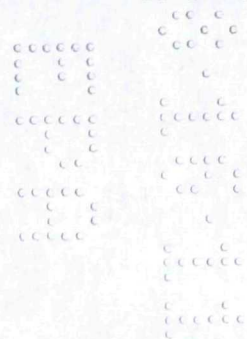
Do not use on puppies under 12 weeks of age. Consult a veterinarian before using on debilitated, aged, medicated, pregnant or nursing animals. Do not treat collared dogs with other monoamine oxidase inhibitors, or with tricyclic antidepressants, selective serotonin reuptake inhibitors, or pressor agents.

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.



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.

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- 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

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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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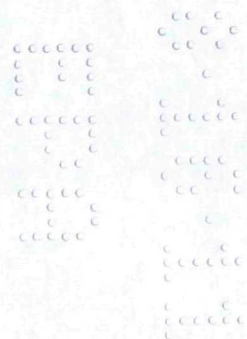
DIRECTIONS FOR USE

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.



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-1
EPA Est. No.: 83680-TX-1
EPA Est. No.: 85440-TX-1
OR EPA Est. No.: 2382-FRA-1
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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)

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