

2382 - 104

10/23/2007

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

OCT 23 2007

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Joseph E. Dyer  
Regulatory Affair  
virbac Inc  
3200 Meacham Blvd  
Forth Worth, TX 76161

Subject: Label Amendment: Correct 18" collar net weight, etc.  
Preventic Tick Collar for Dogs (Amitraz).  
EPA Reg. No. 2382-104  
Submission dated July 25, 2007

Dear Mr. Dyer:

The revised labeling referenced to above, submitted in connection with the registration under the Federal Insecticide, fungicide, and Rodenticide Act (FIFRA) as amended, is accepted with the following comment.

1) Change to Ingredient in Active Ingredients- singular since you have only one a.i.-amitraz.

A stamped copy "accepted" of the label is enclosed for your records. Please submit two (2) copies of the final printed label for our records before releasing the product to market. If you have any questions please call me at (703) 308-8328.

Sincerely yours

A handwritten signature in black ink, appearing to read "Akiva Abramovitch".

Akiva Abramovitch, Ph.D.  
Chemist

Insecticide-Rodenticide Branch  
Registration Division (7505P)

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}
- ANTI PARASITIC
- 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 {I.E., FOR CARTON CONTAINS TWO COLLARS}
- ADJUSTABLE FOR DOGS UP TO 60 LBS

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated:**  
**OCT 23 2007**

**Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.**  
2382-104

ACTIVE INGREDIENTS:

Amitraz: CAS# 33089-61-1..... 9.0%

OTHER INGREDIENTS:..... 91.0%

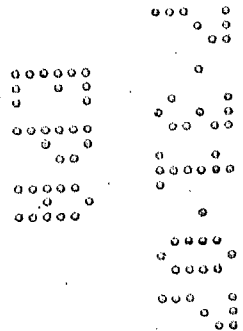
TOTAL..... 100.0%

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.

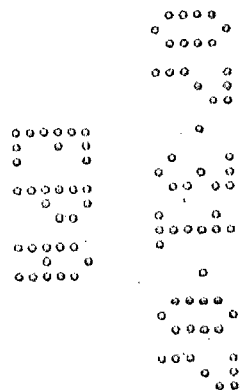
Do not use on puppies under 12 weeks of age. Consult a veterinarian before using on debilitated, aged, medicated, pregnant or nursing animals. Do not treat collared dogs with other monoamine oxidase inhibitors, or with tricyclic antidepressants, selective serotonin reuptake inhibitors, or pressor agents.

Sensitivities may occur after using ANY pesticide product for pets. Remove at first sign of irritation or adverse reaction, bath 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

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 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.

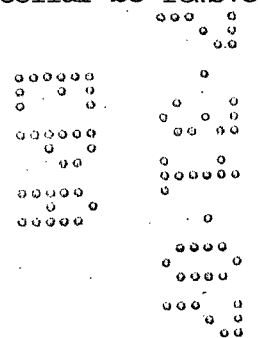
DIRECTIONS FOR USE

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.



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Draft Label  
Side/Back Panel

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STORAGE AND DISPOSAL

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Storage: Store in original container in locked storage area.

Disposal: 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

OR 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)

