

2382-104

05-14-2004

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

MAY 14 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Joseph E. Dyer
Regulatory Agent for
virbac AH Inc.
3200 Meacham Blvd.
Forth Worth, TX 76137

Subject: Label Amendment: First Aid, etc.
Preventic Tick Collar for Dogs (Amitraz).
EPA Reg. No. 2382-104
Submission dated January 20, 2003

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 comments:

- 1) The statements under Do not apply to cats heading on page 2 do not apply to cats.....The heading should be moved to under the Directions for Use.
- 2) Replace "Keep out of reach of children" with "Do not allow children to play with the collar".

A stamped copy "accepted with comments" 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 that reads "Akiva Abramovitch".

Akiva Abramovitch, Ph.D.

Chemist

Insecticide-Rodenticide Branch
Registration Division (7505C)

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DRAFT LABEL
Front Panel

PREVENTIC TICK COLLAR FOR DOGS

- ◆ ANTIPARASITIC
- ◆ 25" COLLAR
- ◆ ADJUSTABLE - ONE SIZE FITS MOST DOGS
- ◆ TICK COLLAR FOR DOGS
- ◆ KILLS AND DETACHES TICKS FOR 3 MONTHS
- ◆ KILL TICKS FOR 3 MONTHS

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

MAY 14 2004

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:	<u>91.0%</u>
TOTAL	100.0%

**KEEP OUT OF THE REACH OF CHILDREN
CAUTION
SEE BACK PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS**

NET CONTENTS: ONE COLLAR
NET WT. 0.97 oz. (27.5g)

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 thoroughly with soap and water after handling and before eating, drinking, chewing gum, 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 this product 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.

NOTICE: This product contains an ingredient know 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.

NOTE TO VETERINARIAN: If a dog ingests the 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.

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 eyes.
 - 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.
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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 800-345-4735 for emergency medical treatment information.

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DIRECTION FOR USE

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

Place the 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. The collar must be worn tightly enough to contact skin and so 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 or offer for recycling, if available.

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EPA Reg. No.: 2382-104

EPA Est. No.: 2382-TX-1

Manufactured For
Virbac AH, Inc.
Fort Worth, TX 76161
800-338-3659

AVAILABLE THROUGH LICENSED VETERINARIANS ONLY

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