

2382-170

4-29-2004

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APR 29 2004

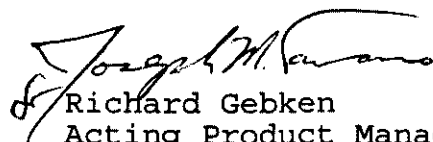
Joseph E. Dyer  
Virbac Inc.  
3200 Meacham Blvd.  
Fort Worth, Texas 76137

Subject: Revised Label For:  
Amitraz-Pyriproxyfen Flea And Tick Collar For Dogs #1  
EPA Registration No. 2382-170  
Application dated February 5, 2004

Dear Mr. Dyer:

The proposed amendment to the registration of the product cited above under The Federal Insecticide, Fungicide, and Rodenticide Act, as amended updating the label is acceptable. A stamped copy of the label is enclosed for your records.

Sincerely,



Richard Gebken  
Acting Product Manager 10  
Insecticide Branch  
Registration Division (7505C)



DRAFT LABEL  
Front Panel

AMITRAZ-PYRIPROXYFEN FLEA & TICK COLLAR FOR DOGS #1

- ◆ ANTIPARASITIC
- ◆ KILLS AND DETACHES TICKS FOR 3 MONTHS
- ◆ KILL TICKS ON DOGS FOR 3 MONTHS
- ◆ NYLAR® IGR STERILIZES FLEAS AND  
KILLS FLEA EGGS ON DOGS FOR 3 MONTHS
- ◆ TICK AND FLEA IGR COLLAR FOR DOGS

ACTIVE INGREDIENTS:

<sup>1</sup> Pyriproxyfen: CAS #95737-68-1..	0.5%
Amitraz: CAS #33089-61-1.....	9.0%
OTHER INGREDIENTS:.....	90.5%
TOTAL.....	100.0%

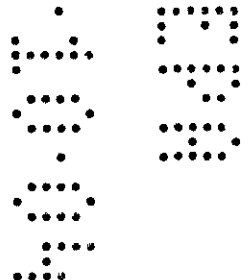
<sup>1</sup>Nylar® is a registered trademark of McLaughlin Gormley King Company.

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

**ACCEPTED**  
APR 29 2004  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under  
EPA Reg. No. 2382-170

CONTAINS ONE AMITRAZ-PYRIPROXYFEN COLLAR  
NET WT. 0.97 oz. (27.5g)  
NET WT. 1.5 oz (42g)  
Made in France

cc  
e  
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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:** Not intended for use on humans. Do not allow children to handle or play with this collar. Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Some humans may develop skin irritation through contact with collared pet. Remove collar, shampoo pet and consult physician if irritation persists. Wash thoroughly with soap and water after handling.

**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, 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 USE ON 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 a 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 is not registered in and must not be sold in the State of California.

**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. Temporary and reversible hyperglycemia was observed when the product was tested at 5 times the recommended dose.

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

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Draft Label  
Side/Back Panel

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.

The two active ingredients in this collar have different and complimentary functions. The IGR (synthetic flea hormone), pyriproxyfen, (NYLAR®), sterilizes all fleas that jump on the pet (even new fleas before they start laying eggs) and kills all flea eggs. Pyriproxyfen is continuously released from the collar, spreads over the pet in the natural oils of the haircoat and skin and adheres tightly to hair and skin to provide more than 3 months of continuous flea ovisterilant efficacy. This breaks the fleas life cycle by preventing the development of new fleas in the environment that would normally reinfest the pet. The ovicidal activity of pyriproxyfen starts immediately, reaches 100% effectiveness within 3 to 4 days and continues at 100% effectiveness as long as the collar is worn. The second active, amitraz, also spreads over the pet in the oil of its skin and haircoat where its activity starts within 24 hours to detach and kill existing ticks on the pet. Amitraz continues to prevent attachment and feeding and kills new ticks that may climb onto the pet for up to 90 days. The collar and its active ingredients are not affected by normal wetting such as rainfall, however, it is suggested the collar be removed before bathing. This collar should be replaced when new ticks are seen to persist on the pet. For optimal efficacy for tick control and flea prevention you should replace the collar every 3 months.

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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.: 2382-170

EPA Est. No.: 2382-FRA-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)

