

OCT 23 2003

Michelle Foster  
Virbac AH, Inc.  
P.O. Box 162059  
Fort Worth, Texas 76161

Subject: Amended Label For:  
Permethrin-Pyriproxyfen Residual Shampoo For Dogs #1  
EPA Registration No. 2382-155  
Application dated June 19, 2003

Dear Ms. Foster:

The proposed amendment to the registration of the product cited above under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended revising the label in accordance with PR Notice 2001-1 is acceptable subject to the comment listed below. A stamped copy of the revised label is enclosed for your records.

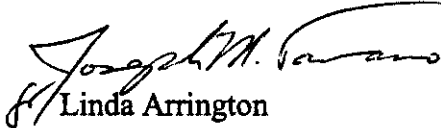
Add the following statements to the First Aid for IF SWALLOWED:

"Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person."

Submit two copies of the finished label before the product is released for shipment under this revised label.

If you have any questions please contact Joseph Tavano at (703) 305-6411.

Sincerely,

  
Linda Arrington  
Acting Product Manager 10  
Insecticide Branch  
Registration Division (7505C)



FRONT PANEL

**PERMETHRIN-PYRIPROXYFEN RESIDUAL\* SHAMPOO FOR DOGS #1**

(PreTect Flea & Tick Shampoo for Dogs and Puppies)  
[BABY POWDER SCENT]  
[SHAMPOO EVERY 2-4 WEEKS]  
[Permethrin immediately kills fleas and ticks, including ticks that transmit the organism that causes Lyme Disease]  
[Permethrin continues to repel and kill fleas for 9 days and ticks for 20 days]  
[Nylar® IGR sterilizes all new fleas and kills their eggs for 30 days]

**ACTIVE INGREDIENTS:**

Permethrin\*.....1.00%  
Pyriproxyfen..... 0.01%  
**OTHER INGREDIENTS**..... 98.99%  
**TOTAL**.....100.00%

\*Cis/trans ratio: Max. 55% (±) cis Min. 45% (±) trans

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See back panel for additional precautionary statements

EPA Reg. No. 2382-155

Net Wt. 8 oz. (237 mL)

Virbac AH, Inc.  
P.O. Box 162059  
Fort Worth, Texas 76161  
Tel. 8(00-338-3659

\*Patent pending

Nylar® is a registered trademark of Mclaughlin Gormley King Company.

BACK/SIDE PANEL

**READ ENTIRE LABEL BEFORE EACH USE**

**USE ONLY ON DOGS**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION**

**HAZARDS TO HUMANS:** Wash hands with soap and water after using.

**HAZARDS TO ANIMALS:** Do not treat puppies under 3 months of age. Consult a veterinarian before treating pregnant, nursing, sick, aged, debilitated or medicated dogs. Sensitivities may occur after using any pesticide product on pets. If signs of sensitivity occur, bathe pet with mild soap or a non-pesticidal shampoo and rinse with large quantities of water. If signs continue consult a veterinarian immediately. Wash hands with soap and water after using.

**[FIRST AID**

**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 further treatment advice.

**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 further treatment advice.

**IF SWALLOWED:** Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow.

**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.]

(Information in brackets is optional)

EPA Est. No. 11715-TN-1

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

OCT 23 2003

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

2382-155

## BACK/SIDE PANEL, CONTINUED

### DIRECTIONS FOR USE

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

Pyriproxyfen and permethrin, in this special formulation\*, are adsorbed onto, and stick tightly to hair and skin, even after complete rinsing, to provide long term residual efficacy against fleas and ticks. New fleas are repelled and killed for 9 days and ticks for 20 days after bathing. Lyme Disease ticks are also repelled and killed before they can feed and transmit disease.

The insect growth regulator (a synthetic flea hormone), [pyriproxyfen], sterilizes all fleas that jump onto the pet (even new fleas before they start laying eggs) and therefore kills all flea eggs. This action persists for 30 days and breaks the flea's life cycle by preventing the development of new fleas in the pet's environment and the build-up of reinfestation pressure. Because of the residual activity of the ingredients, it is not necessary to use an insecticidal dip or other topical or systemic pesticides or drugs to obtain extended control of fleas and ticks. The use of this shampoo on a regular basis, alone or in conjunction with initial environmental flea control measures (if needed) should suffice to provide complete and continuous effective flea and tick control on dogs.

**APPLICATION:** Wet the pet thoroughly with warm water.

Apply product onto its back at the rate of approximately 1 tablespoonful for each 5 lb. bodyweight (7.5 g per kg).

Massage well into the skin to obtain good lathering over the entire body. Allow lather to remain in contact for at least 10 minutes then rinse off. Allow pet to air dry or blow dry. Under flea and tick reinfestation pressure from the dog's environment, pet may be retreated as needed when new parasites are seen to persist on the dog, but not more frequently than once every 14 days.

### STORAGE AND DISPOSAL DIRECTIONS

**STORAGE:** Store in closed container in a cool dry area.

**DISPOSAL: If empty:** Do not reuse this container. Place in trash or offer for recycling if available.

**If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Lot No. on bottom of container

6/19/2003