

OCT 29 2004

Mr. Joe Dyer  
Virbac AH, Inc.  
3200 Meacham Blvd.  
Fort Worth, Texas 76137

Subject: Label Amendment  
Pesticidal Shampoo  
EPA File Number: 2382-25  
Application Dated: January 20, 2004

Dear Mr. Dyer:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, and Rodenticide Act, amended, is acceptable subject to the comments listed below:

It is the Agency's view that terms, such as "natural" are misleading health and safety claims and therefore constitute misbranding under section 2(Q)(1)(A) of FIFRA. Therefore, the use of "natural" and other similar claims is not permitted for any product registered under FIFRA.

Therefore, you must remove the following claims from your product labeling;

- Natural Flea & tick Shampoo for dogs.
- Natural Flea & tick shampoo for cats.

A stamped copy of the label is enclosed. Submit three copies of revised the final printed labeling prior to releasing product for shipment.

Sincerely,



Richard Gebken, Acting  
Team Leader (03)  
Insecticide Branch  
Registration Division (7505c)

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DRAFT LABEL  
Front Panel

PESTICIDAL SHAMPOO

- ◆ PARASITOLGY
- ◆ FLEA & TICK SHAMPOO FOR DOGS & CATS
- ◆ KILLS FLEAS TICKS & LICE
- ◆ EMOLIENT OATMEAL PESTICIDE SHAMPOO
- ◆ PESTICIDAL SHAMPOO
- ◆ FOR USE ON DOGS, CATS, PUPPIES & KITTENS
- ◆ NATURAL FLEA & TICK SHAMPOO FOR DOGS
- ◆ NATURAL FLEA & TICK SHAMPOO FOR CATS
- ◆ SHAMPOO FOR CATS
- ◆ OATMEAL FLEA & TICK SHAMPOO
- ◆ ECTO-SOOTHE SHAMPOO
- ◆ ECTO-SOOTHE SHAMPOO WITH SPHERULITES

**ACCEPTED  
with COMMENTS  
In EPA Letter Dated:**  
OCT 29 2004  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
7382-25

**ACTIVE INGREDIENTS:**

Pyrethrins: CAS #8003-34-7.....	0.05%
<sup>1</sup> Piperonyl Butoxide Technical: CAS #51-03-6.....	0.50%
<b>OTHER INGREDIENTS:</b> .....	<u>99.45%</u>
<b>TOTAL</b> .....	100.00%

<sup>1</sup>Equivalent to 0.4% (Butylcarbityl)(6-propylpiperonyl) ether and 0.1% related compounds.

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

Net Contents: 8 fl. oz. (237 mL)  
Net Contents: 13 fl. oz. (383 mL)

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Draft Label  
Side/Back Panel

**READ ENTIRE LABEL BEFORE EACH USE  
USE ONLY ON DOGS AND CATS**

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
CAUTION**

**HAZARDS TO HUMANS:** Harmful if swallowed. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after each use and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse. Avoid contamination of feed or foodstuffs.

**HAZARDS TO DOMESTIC ANIMALS: FOR USE ON DOGS AND PUPPIES, CATS & KITTENS.**  
Do not use on puppies or kittens under 12 weeks of age. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. Avoid contact with eyes and mouth of pet. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap or a non-pesticidal shampoo and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

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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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**If Swallowed**    ◦ Call a poison control center or doctor immediately for treatment advice.  
                          ◦ Have person sip a glass of water if able to swallow.  
                          ◦ Do not induce vomiting unless told to do so by a poison control center or doctor.  
                          ◦ Do not give anything by mouth to an unconscious person.

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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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Draft Label  
Side/Back Panel

**ENVIRONMENTAL HAZARDS**

This product is toxic to aquatic organisms. Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate.

**DIRECTION FOR USE**

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

**SHAKE WELL BEFORE USING**

Apply product to the back of the animal and massage well into the skin to obtain a good lathering of the entire body. Allow lather to remain in contact with the skin for 10 minutes. Rinse thoroughly with warm water and towel or blow dry. Do not repeat treatment more frequently than once weekly.

Ecto-Soothe, using Spherulites, represents a breakthrough in skin care technology.

\*SPHERULITES®: An exclusive and patented encapsulation system was developed by Virbac AH, Inc. to provide slow release of contents long after the shampoo is rinsed off. Oatmeal and glycerin are present in encapsulated (Spherulites) and free form. The patented encapsulated system does not include any pesticide ingredients, nor will it provide any increased pesticide effectiveness. The encapsulation system contents are only present for the purpose of soothing and moisturizing the animal's skin after use.

\*Spherulites only provide moisturizing for the animal's skin after use, and do not increase the effectiveness of the active pesticide ingredients.

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**STORAGE AND DISPOSAL**  
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**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.

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EPA Reg. No.: 2382-25

EPA Est. No.: 67517-MO-1

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

AVAILABLE THROUGH LICENSED VETERINARIANS ONLY

(lot number statements as needed)

MADE IN U.S.A. (label revision number) (product number)