

PM 03

2382-25

8/25/99

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United States Environmental Protection Agency

Olivier Elfassy
Virbac® Inc.
P.O. Box 162059
Fort worth TX 76161

AUG 25 1999

Subject: Re-submission of a Label amendment in response to a July 15, 1998 EPA letter
Submission dated: June 4, 1999
Product Name: Pesticidal Shampoo
Registration Number: 2382-25

Dear Ms. Elfassy,

The Agency has re-visited your complete regulatory jacket. Based upon your rebuttal of the Agency's May 12, 1999 denial, and your description in the letter, the desired intent is not expressed clearly on the label. Therefore, the potential for false and misleading claims clearly exists without any qualifying language. The "conditional accepted" language below, provides the qualifying language to avoid potential misleading claims.

The labeling referenced above, and submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable subject to the comments listed below.

- 1. All statements "Spherulites" should be footnoted with the following language:

"* Spherulites only provides moisturizing for the animal's skin after use, and does not increase the effectiveness of the active pesticide ingredients."

- 2. The statement "Spherulites, an exclusive and patented encapsulation system containing oatmeal and glycerine was developed by Allerderm to provide slow release of contents long after the shampoo is rinsed off. Oatmeal and glycerin are present in encapsulated (Spherulites) and free forms." This statement should be additionally clarified with the following statement:

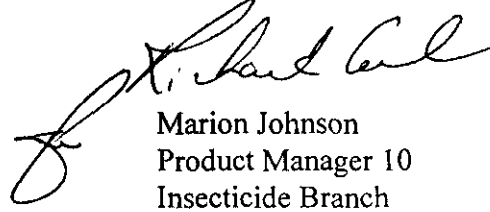
"The patented encapsulation system does not include any pesticide ingredients, nor will it provide any increased pesticide effectiveness. The encapsulated system contents are only present for the purpose of soothing and moisturizing the animal's skin after use."

CONCURRENCES

SYMBOL ▶	H7505C							
SURNAME ▶	RGEBKEN							
DATE ▶	Aug 25, 1999							

Five copies of the finished labeling must be submitted prior to releasing the product for shipment. These final printed labels may be submitted to the Agency by notification as outlined in PR Notice 98-10. If you have any questions in reference to this letter, you may contact Richard Gebken at (703) 305-6701.

Sincerely,



Marion Johnson
Product Manager 10
Insecticide Branch
Registration Division (7505C)

Enclosure

virbac®

PESTICIDAL SHAMPOO

(Natura Flea & Tick Shampoo for Dogs, Natura Flea & Tick Shampoo for Cats, Oatmeal Flea & Tick Shampoo, Healthy Companion Flea & Tick Blaster Shampoo with Oatmeal, Ecto-Soothe Shampoo, Ecto-Soothe Shampoo with

Spherulites, Team Patrol Flea & Tick Shampoo)

KILLS TICKS, FLEAS & LICE

Pesticidal shampoo for use on dogs, cats, puppies and kittens

ACTIVE INGREDIENTS:

Pyrethrins..... 0.05%

Piperonylbutoxide technical*..... 0.50%

OTHER INGREDIENTS..... 99.45%

*Equivalent to 0.4% (Butylcarbityl) (6-propylpiperonyl) ether and 0.1% related compounds.

KEEP OUT OF REACH OF CHILDREN.
CAUTION

See back panel for additional precautionary statements

EPA Reg. No. 2382-25

EPA Est. No. 2382-IN-1

Net Contents 8 fl. oz. (237 mL)

Virbac

P.O. Box 162059

Fort Worth, Texas 76161

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS AND CATS. PRECAUTIONARY STATEMENT HAZARDS TO HUMANS AND DOMESTIC ANIMALS. CAUTION.

HAZARDS TO HUMANS: Harmful if swallowed. Avoid contact with eyes. Avoid contamination of feed or foodstuffs. Wash exposed skin with soap and water.

HAZARDS TO ANIMALS: Do not use on puppies or kittens under 12 weeks old. Consult a veterinarian before treating debilitated, aged, medicated, pregnant or nursing animals. Avoid contact of product with eyes and mouth of pet. Sensitivities may occur after using any pesticide product on 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.

FIRST AID: In case of contact, immediately flush eyes with plenty of water and get medical treatment if irritation persists.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to aquatic organisms. Do not apply directly to water or contaminate water by cleaning of equipment or disposal of wastes.

DIRECTIONS 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 at least 10 minutes. Rinse thoroughly with warm water and towel or blow dry. Do not repeat treatment more frequently than once weekly.

STORAGE AND DISPOSAL DIRECTIONS

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

DISPOSAL: Do not reuse empty container. Wrap container in newspaper and put in trash.

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

[* SPHERULITES: an exclusive and patented encapsulation system containing oatmeal and glycerin was developed by Allerderm to provide slow release of contents long after the shampoo is rinsed off. Oatmeal and glycerin are present in encapsulated (Spherulites) and free forms.]

Available through licensed veterinarians only. Lot No. on bottom

of container

(817)831-5039 89/06

ACCEPTED
with COMMENTS
In EPA Letter Dated:
AUG 25 1999

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

2382-25

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