

Pm 03

2382-117

8/25/99

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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: Ecto-soothe 3X Flea and Tick Shampoo for Dogs and Cats
Registration Number: 2382-117

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:

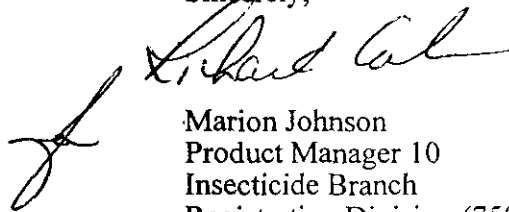
"* Spherulites only provides moisturizing for the animal's skin after use, and does not increase the effectiveness of the active pesticide ingredients."

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."

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®

**ECTO-SOOTHE® 3x Flea and
Tick Shampoo for Dogs and
Cats**

(Ecto-Soothe 3x Shampoo, Ecto-Soothe 3x
Shampoo with Spherulites)

KILLS TICKS, FLEAS & LICE

**Emollient oatmeal pesticidal shampoo
for use on dogs, cats, puppies and
kittens**

ACTIVE INGREDIENTS:

Pyrethrins..... 0.15%
Piperonyl butoxide technical*..... 1.50%
n-Octyl bicycloheptene dicarboximide..... 0.50%

OTHER INGREDIENTS..... 97.85%

*Equivalent to 1.2% (Butylcarbityl) (6-propylpiperonyl) ether and
0.3% related compounds.

KEEP OUT OF REACH OF

CHILDREN.

CAUTION

See back panel for additional precautionary
statements

EPA Reg. No. 2382-117

EPA Est. No. 2382-IN-1

**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. Wet the animal thoroughly with warm water. Apply
product to the back of the animal and massage coat well, adding
more water as needed, to obtain a good lathering over its entire
body. Amount of shampoo required will depend on the size of the
pet and density of its coat. 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 every 14 days.

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 3X, using spherulites, represents a breakthrough
in skin care technology.]

[* SPHERULITES: an exclusive and patented encapsulation
system containing oatmeal and glycerin was developed by
Allerterm 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.

Virbac

P.O. Box 162059

Ft. Worth, TX 76161

9906
Phone number: (817) 531-5030

**ACCEPTED
with COMMENTS
In EPA Letter Dated:
AUG 25 1991**

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
2382-117**

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