

2382-117

12/20/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

DEC 20 2011

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

Dear Ms. Foster:

Subject: Application for Pesticide Notification (PRN 98-10)
Revise per PR Notice 2007-4
Ecto-Soothe 3X Flea and Tick Shampoo for Dogs and Cats
EPA Reg. No. 2382-117
Your submission dated August 12, 2011

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated August 12, 2011 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds the action requested falls within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions regarding this letter, please contact Dana Pilitt, PhD of my staff at (703) 305-7071 or via e-mail at pilitt.dana@epa.gov.

Sincerely,

A handwritten signature in dark ink, appearing to read "Richard Gebken".

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



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number
2382-117

2. EPA Product Manager

R. Gebken

3. Proposed Classification

☐ None ☐ Restricted

4. Company/Product (Name)
Ecto-Soothe® 3X Flea and Tick Shampoo for Dogs and Cats

PM#

#10

5. Name and Address of Applicant (Include ZIP Code)

Virbac AH, Inc.
PO Box 162059
Fort Worth, TX 76161

☐ Check if this is a new address

6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:

☒ EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated _____

☒ Notification - Explain below.

☐ Final printed labels in response to
Agency letter dated _____

☐ "Me Too" Application.

☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

For the purposes, content and attachments to this Notification refer to the Cover Letter.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging

☐ Yes*
☐ No

Unit Packaging

☐ Yes
☐ No

Water Soluble Packaging

☐ Yes
☐ No

2. Type of Container

☐ Metal
☐ Plastic
☐ Glass
☐ Paper
☐ Other (Specify) _____

* Certification must
be submitted

If "Yes"
Unit Packaging wgt. No. per
container

If "Yes"
Package wgt. No. per
container

3. Location of Net Contents Information

☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions

☐ On Label
☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product

☐ Lithograph
☐ Paper glued
☐ Stenciled

☐ Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name
Michelle Foster

Title
Regulatory Specialist

Telephone No. (Include Area Code)
682-647-3545

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete.
I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or
both under applicable law.

6. Date Application
Received
(Stamped)

2. Signature

Michelle Foster

3. Title

Regulatory Specialist

4. Typed Name

Michelle Foster

5. Date

August 15, 2011



/ Virbac Corporation

August 12, 2011

Document Processing Desk
Office of Pesticide Programs (7508P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTENTION: Linda Arrington, Notifications & Minor Formulations Team Leader

Subject: Notification of label change per PR NOTICE 2007-4
Ecto-Soothe® 3X Flea and Tick Shampoo for Dogs and Cats
EPA Reg. No. 2382-117

Dear Ms. Arrington,

In accordance with 40 CFR 152.46, Virbac AH, Inc. submits herewith an application for pesticide notification for subject product. This submission allows for labeling changes per PR Notice 2007-4 to the side/back panel of the label. The labeling changes are noted below and clearly marked on the revised product label (see attachment).

"Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Revisions to side/back panel of the label in the "Storage and Disposal" section:

Added: Do not contaminate water, food, or feed, by storage and disposal.

Added: Pesticide before Storage

Replace "Disposal" statement with the following:

- Pesticide Disposal and Container Handling: Nonrefillable container. Do not reuse or refill this container. If Empty: Place in trash or offer for recycling, if available.
- If Partly Filled: Call your local solid waste agency for disposal instructions. Never place any unused product down any indoor or outdoor drain."

This product is in compliance with 40 CFR 156.140(a)(4) as the lot number is adhered to the product. This product is exempt from 40 CFR 156.144 through 156.156 due to the product's residential/household use. Additionally, this product is not a dilutable (liquid or solid) formulation.

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- 1) Cover Letter
- 2) Application for Pesticide Notification (EPA FORM 8570-1)
- 3) Revised Product Label with Changes Marked (one copy)
- 4) Revised Product Label (one copy)

Sincerely,

Michelle Foster
Regulatory Specialist

[illegible]

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Draft Label
Front Panel

ECTO-SOOTHE^{®2} 3X FLEA AND TICK SHAMPOO FOR DOGS AND CATS

- ♦ VIRBAC ANIMAL HEALTH
- ♦ PARASITOLOGY
- ♦ ECTO-SOOTHE^{®2} 3X
- ♦ KILLS TICKS, FLEAS & LICE
- ♦ EMOLLIENT OATMEAL PESTICIDAL SHAMPOO
- ♦ FOR USE ON DOGS, CATS, PUPPIES & KITTENS

ACTIVE INGREDIENTS:

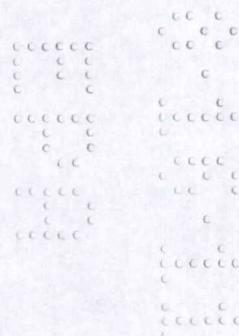
Pyrethrins: CAS #8003-34-7.....	0.15%
¹ Piperonyl Butoxide Technical: CAS #51-03-6.....	1.50%
n-Octyl bicycloheptene dicarboximide.....	0.50%
OTHER INGREDIENTS:	97.85%
TOTAL	100.00%

¹Equivalent to 1.2% (Butylcarbityl) (6-propylpiperonyl) ether and 0.3% related compounds.

²ECTO-SOOTHE is a registered trademark of Virbac AH, Inc.

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

Net Contents: 16 fl. oz. (473 mL)



HAZARDS TO HUMANS: Harmful if swallowed. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Avoid contamination of feed and foodstuffs.

Do not use on puppies or kittens under 12 weeks of age. Do not repeat treatment more often than once every 7 days. Avoid contact of product with eyes and mouth of pet. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. 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.

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.

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.

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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ENVIRONMENTAL HAZARDS

This product is toxic to aquatic organisms. Do 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 often than once every 7 days.

Ecto-Soothe[®] 3X, using Spherulites³, represents a breakthrough in skin care technology.

SPHERULITES: An exclusive and patented encapsulation system was developed by Virbac to provide slow release of contents long after the shampoo is rinsed off, Oatmeal and glycerin are present in encapsulated (Spherulites³) and free forms. The patented encapsulation 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.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in closed container in a cool dry area.

Pesticide Disposal and Container Handling: Nonrefillable container. Do not reuse or refill this container. **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 for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No.: 2382-117

EPA Est. No.: 67517-M0-1

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

Available Through Licensed Veterinarians Only
(lot number statements as needed)

Mfg. & Printed in U.S.A. (label revision number) (product number)

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