

2382-117

4/7/2014

1/5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 7, 2014

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

Subject: Amended Reregistration Label
Product Name: Ecto-Soothe 3X Flea and Tick Shampoo for Dogs and Cats
EPA Registration Number: 2382-117
EPA Decision Numbers: 410980, 412216, 414509, 483202

Dear Ms. Foster,

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the above referenced product in connection with the Pyrethrins, Piperonyl Butoxide, and MGK 264 REDs, and has concluded that your submission is acceptable.

NOTE: This product is not being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

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 or durably marked on the container itself, and can be added by non-notification per PRN 98-10.

Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

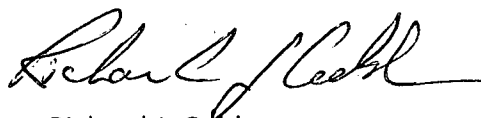
- Basic CSF, dated September 13, 2012
- Alternate CSF #1, dated September 13, 2012
- Alternate CSF #2, dated September 13, 2012
- Alternate CSF #3, dated September 13, 2012
- Alternate CSF #4, dated September 13, 2012

2/5

A copy of your label stamped "Accepted" is enclosed along with copies of the acute toxicity and product chemistry reviews completed for the subject product. Products shipped after 12 months from the date of this amendment or the next printing of the label whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

If you have any questions about this letter, please contact Julie Chao at (703) 308-8735 or chao.julie@epa.gov.

Sincerely,



Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

Enclosures: *Label stamped "Accepted"*
Acute Toxicity Review, dated January 27, 2014
Product Chemistry Review, dated January 8, 2013

3/5

Master Label
Front Panel

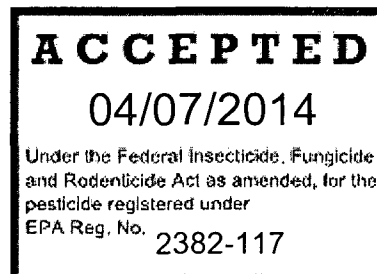
ECTO-SOOTHE® 3X FLEA AND TICK SHAMPOO FOR DOGS AND CATS

- KILLS TICKS, FLEAS & LICE
- EMOLLIENT OATMEAL PESTICIDAL SHAMPOO
- FOR USE ON DOGS, CATS, AND PUPPIES & KITTENS OLDER THAN 12 WEEKS OF AGE

ACTIVE INGREDIENTS

Pyrethrins.....	0.15%
Piperonyl Butoxide*.....	1.50%
n-Octyl bicycloheptene dicarboximide.....	0.48%
OTHER INGREDIENTS.....	97.87%
TOTAL.....	100.00%

*(Butylcarbityl)(6-propylpiperonyl) ether and related compounds.



KEEP OUT OF THE REACH OF CHILDREN

CAUTION

**SEE BACK PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS**

Net Contents:

8 fl. Oz. (237 mL)

16 fl. oz. (473 mL)

[1 Gallon] 128 fl. oz. (3.79L)

4/5

Master Label
Side/Back Panel

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS AND CATS OLDER THAN 12 WEEKS OF AGE
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

HAZARDS TO HUMANS: Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

User Safety Recommendations:

Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

HAZARDS TO DOMESTIC ANIMALS: Do not apply to dogs or cats less than 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 medicated, debilitated, aged, pregnant or nursing animals. Sensitivities may occur after using any pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

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 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 treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center, doctor, or veterinarian. For additional information on this product, including health concerns, medical emergencies, pesticide incidents, or veterinary treatment information, you may call 1-800-345-4735, twenty-four (24) hours per day, seven (7) days per week.	

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic organisms, including fish and invertebrates. Run-off may be hazardous to aquatic organisms in water adjacent to treated areas. See Directions for Use for additional precautions and requirements.

Master Label
Side/Back Panel

DIRECTION FOR USE

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

USE RESTRICTIONS

- Apply this product only as specified on this label.
- Do not contaminate food or feedstuffs.
- Do not apply this product to dogs or cats less than 12 weeks old.
- Do not apply more than 1 time per week.
- Do not apply directly into sewers or drains, or to any area like a gutter where drainage to storm sewers, water bodies, or aquatic habitats can occur. Do not allow the product to enter any drain during or after application.

USE THIS PRODUCT ONLY ON DOGS, CATS, AND PUPPIES & KITTENS OLDER THAN 12 WEEKS OF AGE

APPLICATION INSTRUCTIONS

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 apply more than 8 fl. oz. of product to pet per application. Do not repeat treatment more often than once every 7 days.

Ecto-Soothe® 3X Flea and Tick Shampoo for Dogs and Cats uses Spherulites Microcapsules. SPHERULITES Microcapsules, an 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 (SPHERULITES Microcapsules) and free forms. The 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.

STORAGE AND DISPOSAL

Pesticide Storage: Store product in its tightly closed original container when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

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 unused product down any indoor or outdoor drain.

EPA Reg. No. 2382-117

EPA Est. No. 67517-MO-1

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