

2382-117

12-14-2011

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



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 14, 2011

Ms. Michelle Foster,
Regulatory Specialist
Virbac AH, Inc.
3200 Meacham Boulevard
Fort Worth, TX 76137-4611

**Subject: Amended Labeling; Response to PRNs 98-10, 2007-1 and 2007-4
Ecto-Soothe® 3X Flea and Tick Shampoo for Dogs and Cats, EPA Reg. No. 2382-117
Your Submission Dated October 4, 2011**

Dear Ms. Foster:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with the following label revision provision(s):

General Comment(s):

1. Delete all text throughout the label marked with "~~strikethrough~~."

Optional Marketing Statements section comment(s):

2. Revise the 6th optional marketing statement to read "FOR USE ON DOGS, CATS, AND PUPPIES & KITTENS (OLDER THAN 12 WEEKS OF AGE)"

Ingredient Statement section comment(s):

3. To facilitate inclusion of required label language from the REDs for pyrethrins, piperonyl butoxide, and MGK 264 insecticide synergist (updated label table for pyrethrins/piperonyl butoxide/MGK 264 insecticide synergist combination products), you must revise the listing of "Piperonyl Butoxide Technical: CAS #51-03-6" to read "Piperonyl Butoxide: CAS #51-03-6" and revise the 1st footnote to read "(Butylcarbityl) (6-propylpiperonyl) ether and related compounds."

Precautionary Statements, HAZARDS TO HUMANS subsection comment(s):

4. Revise this subsection to read "Harmful if swallowed or absorbed through the skin. Avoid contact with skin, eyes, or clothing. Causes moderate eye irritation. Wash hands thoroughly with plenty of soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet."

Precautionary Statements, HAZARDS TO DOMESTIC ANIMALS subsection comment(s):

5. Revise the 1st sentence within this subsection to read "Do not apply to pets less than 12 weeks of age."

Precautionary Statements, First Aid Statement subsection comment(s):

6. Revise the "**HOT LINE NUMBER**" subsection to read "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."

Precautionary Statements, Environmental Hazards Statement subsection comment(s):

7. Revise the "**ENVIRONMENTAL HAZARDS**" subsection to read:

"This product is toxic to aquatic organisms, including fish and invertebrates. Drift and run-off may be hazardous to aquatic organisms in water adjacent to treated areas. This product may contaminate water through run-off. This product has a potential for run-off for several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to produce run-off that contains this product."

Precautionary Statements, Environmental Hazards Statement subsection comment(s):

"This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash-waters or rinsate. See Directions of Use for additional precautions and requirements."

Directions for Use section comment(s):

8. To facilitate inclusion of required label language from the REDs for pyrethrins, piperonyl butoxide, and MGK 264 insecticide synergist (updated label table for pyrethrins/piperonyl butoxide/MGK 264 insecticide synergist combination products), you must insert the following new subsection immediately following the statement "**It is a violation of Federal law to ...**" as follows:

USE RESTRICTIONS

- Apply this product only as specified on this label.
- Do not contaminate of food or feedstuffs.
- Do not apply this product to pets (puppies or kittens) less than 12 weeks old.
- Do not apply more than 1 time per week.

9. Insert the following text statement immediately following the "**USE RESTRICTIONS**" subsection above as follows:
"**USE THIS PRODUCT ONLY ON DOGS, CATS, AND PUPPIES & KITTENS (OLDER THAN 12 WEEKS OF AGE).**"

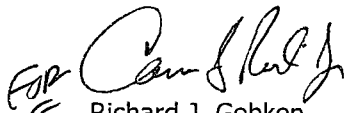
Storage and Disposal Statement section comment(s):

10. Revise the existing "**Pesticide Storage:**" subsection to read "**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."
11. Insert the following text statement immediately following the revised "**Pesticide Storage:**" subsection above as follows: "**Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."
12. Revise the subsection heading "**Pesticide Disposal and Container Handling:**" to read "**Container Disposal:**"

A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

If you have any questions regarding the label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely yours,



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

Enclosure: Copy of label stamped "Accepted with Comments"
002382-00117 D456786

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Draft Label
Front Panel

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

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

ACTIVE INGREDIENTS:

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

~~Equivalent to 1.2% (Butylcarbityl) (6-propylpiperonyl) ether and 0.34%~~
related compounds.

ECTO-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:

8 fl. Oz. (237 mL)
16 fl. oz. (473 mL)
[1 Gallon] 128 fl.oz. (3.79L)

ACCEPTED
With COMMENTS
In EPA Letter Dated:
December 14, 2011
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:

2382-117

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 eyes, skin or clothing.
Avoid contamination of feed and foodstuffs.

User Safety Recommendations:

Users should wash hands with plenty of soap and water before eating, drinking, chewing gum, using tobacco or using the toilet. 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 pets less than 12 weeks old. 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

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- | | |
|------------------------|---|
| If In Eyes | <ul style="list-style-type: none">◦ 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 | <ul style="list-style-type: none">◦ 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 | <ul style="list-style-type: none">◦ 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 or veterinary treatment information.

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Deleted: Avoid contamination of feed and foodstuffs.
Deleted: use on puppies or kittens under 12 weeks of age
Deleted: medicated,
Deleted: ANY
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Deleted: or a non-pesticidal shampoo

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic organisms, including fish and invertebrates. Do not contaminate water when disposing of equipment, washwater, or rinsate. See Directions for Use for additional precautions and requirements.

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DIRECTION FOR USE

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

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, using Spherulites' Microcapsules, represents a breakthrough in skin care technology.

SPHERULITES' Microcapsules An exclusive 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

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increased pesticide effectiveness. The encapsulation system contents are only present for the purpose of soothing and moisturizing the animal's skin after use. Spherulites' Microcapsules 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

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: 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.

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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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October 4, 2011