

PMU3

2382-123

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:

2382-123

Date of Issuance:

SEP 30 1998

Term of Issuance:

Conditional

NOTICE OF PESTICIDE:

Registration
 Reregistration

Name of Pesticide Product:

Ecto- Soothe
Permethrin Shampoo
for Dogs

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Virbac Inc.
P.O. Box 162059
Fort Worth, Texas 76161

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label changes:

- a. Revise the EPA Registration Number to read, "EPA Reg. No. ". 2382-123
- b. In accordance with PR Notice 96-6 add appropriate reapplication statement. refer to Notice for examples. delete "Repeat shampoo when new fleas and ticks are seen on pet.".

Signature of Approving Official:

Linda A. DeLuise for George La Rocca

Date:

September 30, 1998

2673

c. Change "In the event of an adverse reaction, shampoo dog thoroughly with a non-pesticidal shampoo or with white bar soap to remove residues. Consult a veterinarian if reaction persists." to read "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."

d. Under Precautionary Statements add "ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not apply directly to any body of water. Do not contaminate water when disposing of equipment washwater."

e. The Agency has reviewed your response and concludes that the domestic animal safety study (MRID 43531801) still remains inadequate and unacceptable because of major study deficiencies. However, based on the domestic animal safety study (MRID 436191108) which used Max Tox principles the domestic animal data requirements for registration of this product is satisfied. Since the animals used in this study were all cats replace the statement "Do not treat puppies under 12 weeks of age." to "do not treat dogs under 6 months of age."

3. Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

A copy of the domestic animal safety study is enclosed for your records.

Enclosures

Enlarged 150%

virbac®

ECTO-SOOTHE®

PERMETHRIN SHAMPOO FOR DOGS

KILLS TICKS up to 20 days

AND FLEAS up to 9 days

**Emollient oatmeal shampoo with residual
pesticidal properties for use on dogs.**

**Effective against Fleas & Ticks including Ixodidae
responsible for the transmission of Lyme Disease**

ACTIVE INGREDIENTS:

Permethrin [(3-phenoxyphenyl) methyl (±)-cis, trans-3-(2,2-di-chloroethenyl) -2,2-dimethylcyclopropanecarboxylate]*	1.0%
INERT INGREDIENTS.....	99.0%
TOTAL.....	100.00%

*Cis/trans ratio: Max. 55% (±) cis
Min. 45% (±) trans

CAUTION

KEEP OUT OF REACH OF CHILDREN

**See back panel for additional precautionary
statements.**

Net Wt. 8 fl. oz. (237 mL)

Made in U.S.A. by

virbac®, inc. P.O. Box 162059

Fort Worth, Texas 76161

ACCEPTED
with COMMENTS
in EPA Letter Dated

SEP 30 1998

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

2382-123

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON DOGS

**PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS
AND DOMESTIC ANIMALS CAUTION** Remove contaminated
clothing and wash hands after using. Wear rubber gloves if
repeated frequent exposure to the concentrate is likely (i.e. grooming
service). **DO NOT USE ON CATS.** Do not treat puppies under 12
weeks of age. Consult a veterinarian before use on pregnant or
nursing bitches or on old, sick or debilitated animals or on animals
under other drug or pesticide treatment. In the event of adverse
reaction, shampoo dog thoroughly with a non-pesticidal shampoo.
If reaction persists or becomes more severe consult a veterinarian
immediately.

STORAGE AND DISPOSAL DIRECTIONS

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

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

DIRECTIONS FOR USE

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

Data show that this product, when used as directed, in addition to
being effective against existing fleas and ticks on the dog, provides
residual efficacy against reinfestation for up to 9 days against new
fleas and for up to 20 days against new ticks (depending on the
level of reinfestation pressure from the environment). Post-
shampoo exposure to additional pesticides (e.g., dipping or spray-
ing) should not therefore be needed.

Shake well before using. Wet the dog thoroughly with warm water.
Apply product onto the back of the dog at the rate of approximately
1 teaspoonfull for each pound bodyweight (2 g per kg). Massage
well into the skin to obtain good lathering over the entire body.
Allow lather to remain in contact for at least 10 minutes then rinse
off. Allow dog to air dry or blow dry. Repeat shampoo when new
fleas and ticks are seen on pet.

EPA Reg. No. 2382-REG

EPA Est. No. 2382-IN-1

Sold Only By Veterinarians.

Lot No. on bottom of container

96/05

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