

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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PM-13

Reg # 2382-115

193

300/5306061  
18/2

20 SEP 1996

Dr. Thomas A. Miller  
Virbac, Inc.  
3200 Meqacham Blvd  
Fort Worth, Texas 76137

Dear Dr. Miller:

Subject: Citation of Primary eye irritation study Conducted on File Symbol 2382-REI to support reg. no. 2382-115.  
Reg. No. 2382-115  
Preventic L.A. AquaSpray for Dogs  
Your Letter Dated April 19, 1996

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 modifications. A stamped copy is enclosed for your records.

1. In your letter you stated that you felt that the Agency was citing the wrong primary eye irritation study to determine the precautionary labeling for your product. You continued to state that, in doing so, unwarranted precautionary statements were required for the product label. The primary eye irritation study you mentioned was conducted on file symbol 2382-REI.

An April 1, 1996, letter to you from the Agency stated that the acute toxicity data from Reg. No. 2382-90 (with the exception of the primary eye irritation study) would be used to support the Reg. No. 2382-115. This letter also stated that the primary eye irritation would be supported by data conducted using file symbol 2382-REI. You have not received the authority to cite the primary eye irritation study conducted on file symbol 2382-REI. Thus,

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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the statement "Causes moderate eye irritation. Avoid contact with eyes and clothing" is required.

2. Since the product is not limited to veterinarians, but sold through them to the consumer, we recommend you add the U.S. equivalent measurements in addition to metric.

Sincerely Yours,

George T. LaRocca  
Product Manager 13  
Insecticide-Rodenticide Branch  
Registration Division (7505C)

393.  
  
virbac®

# PREVENTIC™ L.A. AquaSpray for Dogs

Kills fleas and Ticks for 1 Month  
Kills *Ixodes* Lyme Disease Ticks

**ACTIVE INGREDIENT:**

Permethrin: [(3-Phenoxyphenyl) methyl  
(±)cis-trans-3-(2,2-dichloroethenyl)-2,2-  
dimethylcyclopropanecarboxylate]\*.. 2.0%

INERT INGREDIENTS ..... 98.0%

TOTAL.....100.0%

\*cis-trans isomer ratio: Min. 35% (+/-) cis  
Max. 65% (+/-) trans

## CAUTION

KEEP OUT OF REACH OF  
CHILDREN

See back panel for additional  
precautionary statements and  
directions

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

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

Kills Fleas and Ticks for 1 month and  
kills *Ixodes* Ticks, the vector of Lyme  
Disease and Ehrlichiosis.

**PRECAUTIONARY STATEMENT**

**HAZARDS TO HUMANS AND DOMESTIC  
ANIMALS CAUTION**

**HAZARDS TO HUMANS:** Avoid breathing spray  
mist. Avoid contamination of food. Wash exposed  
skin with soap and water after using.

**HAZARDS TO ANIMALS: DO NOT USE ON  
CATS.** Do not use on pups under 3 months of age.  
Consult a veterinarian before treating pregnant,  
nursing, sick, old or debilitated dogs or dogs  
undergoing drug or other pesticide treatment. Do  
not spray in eyes, face or on genitalia. In the event  
of adverse reaction, shampoo dog with a non-  
pesticidal shampoo to remove pesticide residue and  
immediately seek veterinary advice.

**DIRECTIONS FOR USE:** It is a violation of Federal  
law to use this product in a manner inconsistent with  
its labelling. Spray over entire haircoat making sure  
the coat is wetted to the skin. Spray against the lay  
of the hair, ruffling the coat on long-haired dogs.  
Weight of dog, length of hair and density of coat will  
determine amount of spray to be applied to wet to  
the skin (average dose approximately 7.5 g/kg).  
The contents of this bottle should be sufficient for  
three applications at one month intervals to a 45 lb.  
dog or seven applications, repeated at the same  
interval, to 20 lb. dog. Lighter applications will  
reduce the period of effectiveness and require more  
frequent treatments. Allow dog to air dry or blow dry.  
Do not towel dry.

**STORAGE AND DISPOSAL**

**STORAGE:** Store in a cool dry area.

**DISPOSAL:** Do not reuse empty container. Wrap  
in several layers of newspaper and discard in trash.  
EPA Reg. No. 2382-115, EPA Est. No. 2382-IN-1  
Lot no. on bottom of container 96/04

ACCEPTED  
with COMMENTS  
in EPA Letter Dated

20 SEP 1996

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

2382-115