

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

Reregistration

<u>x</u> Registration

NOTICE OF PESTICIDE:

2382-115

EPA Reg.

Number:

Date of Issuance:

APR - 1 1996

Term of Issuance:

Conditional

Name of Pesticide Product:

Preventive L.A AquaSpray for Dogs

(under FIFPA, as amended)

Name and Address of Registrant (include 21P Code):

Virbac Inc., 32000 Meacham Blvd., 76137 Fort Worth, Texas

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:

- 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.
 - Make the following label changes:
 - a. Revise the EPA Registration Number to read, "EPA Reg. No. 2382 -115 ".
 - b. The acute toxicity data for EPA Registration No. 2382-90 (except for primary eye irritation) can be used in support of the subject product. The primary eye irritation study used in support of EPA File symbol 2382-REU can be used in support of the subject product (Tox. Category III). Revise the Hazards to Humans section similar to that labeled for EPA File Symbol 2382-90. However, for eye irritation, change the precaution to read: "Causes moderate eye irritation. Avoid contact with eyes and clothing".

Signature of Approving Official:

page 2 EPA Reg. No. 2382-115

- c. Under Directions for Use, chante the unit of measure from Metric to English.
- d. Revise the rate of application to read similar to that stated for EPA Reg. No. 2382-90 i.e,"This 16 oz. bottle should be sufficient for six applications at one month intervals to an average 30-35lb dog". The current instruction is confusing and may lead the user to apply the entire contents in one month.
- e. We assume the product will be marketed with a trigger spray attachment to spray the product (or make reference to use such an attachment for application). The Agency discourages the marketing of products for indoor general use unless they are applied from the original container. This minimizes the potential for consumers to pour the product into unlabeled containers such as Windex bottles to apply it. Please confirm.
- f. Add the wording "old" and "on animals undergoing drug or other pesticide treatment", to the statement "Consult a veterinarian before treating pregnant, nursing, sick or debilitated dogs".
- g. In the last sentence under Hazards to Animals change "consult a veterinarian if reaction persists" to read "immediately seek veterinary advice".
- 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.

virbac®

PREVENTIC™ L.A. AquaSpray for Dogs

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

ACTIVE INGREDIENT:

*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 Erlichiosis.

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.

dAZARDS 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 or debilitated dogs. 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 residueand consult a veterinarian if reaction persists.

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, applied once each month, should be sufficient to treat an average 45° lb. dog for three months or a 20 lb. dog for seven months. 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 95/12

ACCIDENTED

THE COMMENTS

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-APR - 1 1996

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