

71829-2

04/04/2000

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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:

71829-2

Date of Issuance:

APR - 4 2000

Term of Issuance: Conditional

Name of Pesticide Product:

One-Drop Anti-Flea & Tick  
Treatment

## NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Bilaurand Laboratories, Ltd  
Lancaster Road, Carnaby Industrial Est.  
Bridlington, East Yorkshire  
United Kingdom YO15 306

**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 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. 71829-2".
  - b. Under HAZARDS TO DOMESTIC ANIMALS, change the second sentence to read, "Do not apply on dogs less than 6 months old." OR supply the Agency with animal safety information to support the 4 week claim.

Signature of Approving Official:

George T. LaRocca, Product Manager 13

Date:

APR - 4 2000

3. The Agency is reevaluating the acute toxicity database used to support this registration. Once this reevaluation is complete, you may be subject to additional compensation requirements.
4. Submit two (2) copies of your final printed label before you release the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

If you have any questions regarding this action, please contact Linda Werrell of my team at (703) 308-8033. A stamped copy of the label is enclosed for your records.

Sincerely



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

Enclosure

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**[FRONT PANEL]****ONE DROP ANTI-FLEA & TICK TREATMENT,**Optional marketing statements:

New [to be featured on label for no more than 6 months from date of product introduction]

Kills and repels fleas and ticks quickly

One easy application for effective control

Protects for up to 4 weeks

For animal treatment only

[Note to EPA: Label may contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial.]

**ACTIVE INGREDIENT:**

Permethrin (CAS #52645-53-1) ..... 45%

**OTHER INGREDIENTS:** ..... 55%

100%

**Keep Out of Reach of Children****CAUTION**

See back/other panel(s) for additional Precautionary Statements.

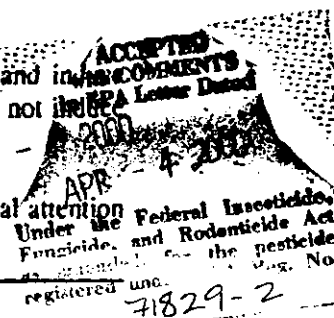
**NET CONTENTS THREE 1.5 ml Tubes / THREE 3 ml Tubes****[BACK PANEL]****READ THE ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS.****PRECAUTIONARY STATEMENTS****Hazards to Humans and Domestic Animals****CAUTION****Hazards to Humans:** Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.**Hazards to Domestic Animals:** For external use only. Do not apply on dogs less than 4 weeks of age. Repeat applications may be made as necessary, but do not apply at intervals less than 7 days. **DO NOT USE ON CATS.** Cats which actively groom or engage in close physical contact with recently treated dogs may be at risk of toxic exposure. Consult a veterinarian before using this product on debilitated, aged, or medicated animals. Consult a veterinarian before using this product on dogs with known organ dysfunction. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Signs of sensitivity to this product include skin sensitivity, increased itchiness, redness, rash, hair discoloration or hair loss at the application site. Dogs may also show "lethargy".**FIRST AID****If Swallowed:** Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger or, if available, administer syrup of ipecac. Do not induce vomiting or give anything by mouth to an unconscious person.**If In Eyes:** Flush with plenty of water. Get medical attention. If irritation persists.**If on Skin:** Remove contaminated clothing and wash with plenty of soap and water. Get medical attention.

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If symptoms or irritation develops.

To Physician: Treat patient symptomatically.

**Environmental Hazards:** This product is extremely toxic to fish and aquatic organisms. Do not apply directly to any body of water. Treated dogs should not be allowed to go swimming for 12 hours following treatment.

**Physical or Chemical Hazards:** Do not use or store near heat or open flame.

What the drops do:

One Drop Anti-Flea & Tick Treatment, kills and repels fleas and ticks on your dog for up to 4 weeks. It is recommended that you also use a product labeled to treat your dog's basket and favorite sleeping areas.

### DIRECTIONS FOR USE

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

**Storage:** Do not remove tube from the pack until ready to use. Store in a cool (below 25°C) dry place out of reach of children. Do not refrigerate. Protect from direct sunlight.

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

**How to use the drops:** [VERSION A - when packaged in THREE 1.5 ml Tube container]

For dogs weighing up to 33 lb. (15 kg.), the contents of this package provides a 3 months' supply.

1. Only open the tube immediately prior to use by holding upright and twisting the cap off, taking care not to squeeze the tube.
2. Part the dog's coat to expose the skin between the shoulder blades, at the nape of the neck.
3. Squeeze the entire contents of one tube onto the exposed skin.

For dogs weighing over 33 lb. (15 kg.)

Apply as in 1-3 above, then:

4. Open a second tube and apply by parting the dog's coat at the base of the tail, then squeeze the entire contents of the second tube onto the exposed skin.

**How to use the drops:** [VERSION B - when packaged in THREE 3 ml Tube container for large dogs only]

For dogs weighing over 33 lb. (15 kg.), the contents of this package provides a 3 months' supply.

1. Only open the tube immediately prior to use by holding upright and twisting the cap off, taking care not to squeeze the tube.
2. Part the dog's coat to expose the skin between the shoulder blades, at the nape of the neck, then squeeze approximately one-half the contents of one tube onto the exposed skin.
3. Next, part the dog's coat at the base of the tail, then squeeze the remaining contents of the tube onto the exposed skin.

[Note to EPA: Label may contain graphics illustrating product use. e.g., removing cap from tube, parting dog's coat, applying product to dog's skin, etc.]

If the dog's coat is subsequently wetted, such as when shampooing, the 4 week period of protection

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may be reduced.

**Additional precautions to protect your dog:**

1. Do not massage the drops into the dog's skin. Avoid applying to the dog's fur.
2. Do not administer any other flea control product to your dog during the 4 week period of protection.
3. Re-treat after 28 days if reinfestation is apparent.

**Additional precautions to protect your family:**

Do not allow children to play with tubes. A pet treated with this product should not sleep with people, particularly children, for the 8 hours immediately following treatment. Do not handle the area of application for 3 to 6 hours following treatment.

**What else you must do:**

Treating your dog's basket and favorite sleeping areas with a suitable insecticidal product labeled for this use and vacuuming these areas regularly will also help to remove fleas and ticks. Consult your veterinarian for product recommendations.

**NOTICE:** Buyer assumes all responsibility for safety and use not in accordance with directions.

Lot No.: \_\_\_\_\_

Manufactured in the United Kingdom.

Manufactured by  
**Bilaurand Laboratories, Ltd.**  
Bridlington, East Yorkshire, UK

**[PRINTED ON TUBES(S)]**

**ONE DROP ANTI-FLEA & TICK TREATMENT**

1.5 ml / 3 ml

EPA Reg. No. 71829-\_\_\_\_\_

Keep Out of Reach of Children

**CAUTION**

Read the entire label before use.