

# 10/11/2002 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION. PESTICIDES AND TOXIC SUBSTANCES

OCT | | 2002

Mr. Bill Washburn
Pet Logic, L.L.C.
P.O. Box 18993
Memphis, TN 38181-0993

Subject:

Amendment Adding Cat Precautions and Updating First Aid and Disposal

Statements per PR Notices 2001-1 and 2001-6

One Drop Anti flea & Tick Treatment 2

EPA Reg. No. 69332-1

Your Submission Dated July 9, 2002

Dear Mr. Washburn:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments below. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

- 1. As agreed at the April 19, 2001 meeting concerning permethrin dog spot-on products, all of the important cat information should be placed in a box under the Precautionary Statements to help draw the consumer's attention to this information.
- 2. In accordance with PR Notice 96-6, you must revise the statement regarding use of the product on debilitated, aged or medicated animals to include pregnant or nursing animals. The revised statement should read: "Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing or medicated animals."
- 3. Since this product has been registered for more than 2 ½ years, you should delete the "New" claim on the front panel, unless it has been less than 6 months since the product's introduction.

If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely,

Susan L. Stanton, for George T. LaRocca

Product Manager (13)

Insecticide Branch

Registration Division (7505C)

Enclosure

#### [FRONT PANEL]

#### ONE DROP ANTI-FLEA & TICK TREATMENT 2

DO NOT USE ON CATS



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	#52	64	5-	53	-1)	) .		٠						•	•		•	45%	
OTHER INGREDIEN	NTS:								•	`.									55%	
																			100%	

## Reep 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

ACCEPTED
with COMMENTS
In EPA Letter Dated;

OCT 1 1 2002

[BACK PANEL]

READ THE ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS.

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 69332-1

## 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 6 months old. 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 group or engage in close physical contact with recently treated dogs may be at the deficient as a marrial addition. 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	<ul> <li>Call poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by poison</li> </ul>
	control center or doctor.
	<ul> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 19</li> <li>20 minutes.</li> </ul>
	<ul> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
	Call a poison control center or doctor for treatment advice.
If on skin	Take off contaminated clothing.
	<ul> <li>Rinse skin immediately with plenty of water for 15 - 20 minutes.</li> </ul>
	Call a poison control center or doctor for treatment advice.
	HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-877-757-4943 for emergency medical treatment information.

#### NOTE 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 2 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.

DO NOT USE ON CATS. May be toxic and potentially fatal if applied or ingested by cats.

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 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.

#### STORAGE AND DISPOSAL

**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: If empty: Do not reuse this container. Place in trash or offer for recycling if available. If partly filled: Call you local solid waste agency or 1-800-CLEANUP for disposal instructions. Never placed unused product down any indoor or outdoor drain.



For customer questions call 901-362-1950, between the hours of 8:00 a.m. - 4:00 p.m. CST, Monday - Friday.

In case of an emergency call 1-877-757-4943, 24 hours a day.

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

Lot No.:

EPA Reg. No. 69332-1 EPA Est. 11715-TN-1

> Manufactured for Pet Logic, L.L.C. 4242 B.F. Goodrich Blvd. Memphis, TN 38118

#### [PRINTED ON TUBE(S)]

ONE DROP ANTI-FLEA & TICK TREATMENT2 1.5 ml / 3 ml EPA Reg. No. 69332-1

### Keep Out of Reach of Children CAUTION

DO NOT USE ON CATS
Read the entire label before use.

C:/Regulatory/SPI Labels/69332 Labels/69332-1 Amended(rev. 7/09/2002)