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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

DEC 1 1999

Lee Tharrington
Unicorn Laboratories
12385 Automobile Blvd.
Clearwater, FL 33762

Dear Mr. Tharrington:

Subject: Labeling Amendment

Unicorn 30 Day Flea & Tick Treatment

EPA Reg. No. 28293-293

Your submission dated 19 August 1999

The labeling amendment referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide, Act, as amended, has been received, and reviewed, and the labeling is acceptable subject to the comments listed below. Please submit three (3) copies of your final printed labeling incorporating the changes prior to releasing your product for shipment. A stamped accepted with comments copy is enclosed for your records.

1. It is highly recommended that you update your "First Aid Statements" to read:

## IF SWALLOWED:

- -Call a poison control center or doctor immediately for treatment
- -Have person sip a glass of water if able to swallow.
- -Do not induce vomiting unless told by a poison control center.

## IF ON SKIN:

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- -Take off contaminated clothing.
- -Rinse skin immediately with plenty of water for 15-20 minutes.
- -Call a poison control center or doctor for treatment advice.

## IF IN EYES:

- -Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- -Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- -Call a poison control center or doctor for treatment advice.
- 2. You should also include the following general information either near the first aid statement or emergency phone number: "Have the product container or label with you when calling a poison control center or doctor or going for treatment."
- 3. We have received several reports of incidents involving secondary exposure to

cats via permethrin treated dogs with these type concentrated products; therefore, we recommend addition of the following statements following "Do Not Use on Cats" under Precautionary Statements:

May be toxic if applied to or ingested by cats. Cats which actively groom or engage in close physical contact with recently treated dogs may be at risk of toxic exposure".

- 4. We recommend moving the statement (or adding) "Important! Do Not Use on Cats. This Product is For Use on Dogs Only" to the stop of the front panel.
- 5. We recommend you add the statement "Do not Use on Puppies Less Than Six Months Old" to the front panel since you identify use on puppies on the front panel.

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Sincerely,

ArGeorge T. LaRocca

Product Manager (13)

Insecticide Branch

Registration Division (7505C)

## UNICORN 30 DAY Flea & Tick Treatment

[] Indicates alternate or optional wording to clarify packaging.

For Dogs and Puppies

Kills and Repels Fleas and Ticks for up to 30 Days.

Easy and convenient to use Kills and repels the deer tick which may carry Lyme Disease Kills fleas before they lay eggs

## **ACTIVE INGREDIENT:**

Permethrin \*..... 45% INERT INGREDIENTS:.... 55% 100% \* CAS #52645-53-1

## KEEP OUT OF REACH OF CHILDREN CAUTION

See side/back panel for Additional Precautionary Statements.

NET CONTENTS:1 cc [0.03 oz] [1 mL] 2 cc [0.06 oz] [2 mL]

Manufactured by:

Unicorn Laboratories 12385 Automobile Blvd. Clearwater, FL 33762 Phone: (727) 578-4545

EPA REG. NO. 28293-293 (8/19/99 AMD draft)

ACCEPTED with COMMENTS In EPA Letter Dated: DEC 1 1999

Under the Federal Insecticide, Fungicide, and Rodenticide Act, na amended, for the pesticide EPA EST. NO. 62478 FL-1A 44616-MO-1B Súbščript used is first letter of run code on container.

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS. [IMPORTANT! DO NOT USE ON CATS. THIS PRODUCT IS FOR USE ON DOGS ONLY]

#### PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Humans - Harmful if swallowed or absorbed through skin. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Animals - DO NOT USE ON CATS. Do not use on puppies less than six months old. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals, or animals on medication. 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.

## **Environmental Hazards:**

This product is toxic to fish. Do not add directly to water. Do not contaminate water when disposing of product or packaging.

## First Aid

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting. Do not give anything by mouth to an unconscious person. Avoid alcohol.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF IN EYES: Flush with plenty of water. Call a physician if irritation persists.

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As with all flea and tick products, this product is most effective when used as part of a total program aimed at reducing fleas and ticks in your pet's environment. Be sure to treat the animal's bedding and the areas they frequent with products registered for these uses.

EPA REG. NO. 28293-293 (8/19/99 AMD draft)

EPA EST. NO.62478-FL-1A 44616-MO-1B Subscript used is first letter of run code on container.

## **DIRECTIONS FOR USE**

(To be used on 1cc packaging for Dogs & Puppies 30 lbs and under) [3 Month Supply for dogs & puppies 30 lbs. & UNDER]

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

This product contains three [month supply] [monthly dosages], each 1 cc, [1 mL] [0.03 fl. oz.] for Dogs and Pupples 30 pounds and under. [Apply the full contents of a single applicator tube between the dog's shoulder blades.]

#### DO NOT USE ON CATS.

Remove applicator tube from package and hold in an upright position. Press cap down to break the seal of tube [Twist or cut off top of applicator tube]. Remove cap carefully. Position the tip of the tube on the dog's back between the shoulder blades and squeeze out the [entire] contents of the tube.

Reapply every 30 days.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal. Store in a cool, dry place. Do not reuse empty tube. Wrap and discard in trash.

EPA REG. NO. 28293-293 (8/19/99 AMD draft)

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EPA EST. NO. 62179-FL-1A 44616-MO-1B Subscript used is first letter of run code on container.

#### **DIRECTIONS FOR USE**

(To be used on 2cc packaging for Dogs & Puppies over 30 lbs.) [3 month supply for dogs & puppies OVER 30 lbs.]

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

This product contains three [month supply] [monthly dosages], each 2 cc, [2 mL] [0.06 fl. oz.] for Dogs and Puppies over 30 pounds.

[Apply one-half of the applicator tube's contents between the dog's shoulder blades, the second one-half of the applicator tube's contents to the base of the dog's tail.]

## DO NOT USE ON CATS.

Remove applicator tube from package and hold in an upright position. Press cap down to break the seal of tube. [Twist or cut off top of applicator tube.] Remove cap carefully. Position the tip of the tube on the dog's back between the shoulder blades and squeeze out [one-half of] the contents of the [applicator] tube [until the contents level reaches the ½ mark on the tube].

Invert the applicator tube upright and go to the dog's tail. [Next,] position the tip of the [applicator] tube at the base of the tail and [squeeze out] [apply] the remaining contents of the tube to [on] the base of the dog's tail. Reapply every 30 days.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal. Store in a cool, dry place. Do not reuse empty tube. Wrap and discard in trash.

EPA REG. NO. 28293-293 (8/19/99 AMD draft)

EPA EST. NO. 62478-FL-1A 44616-MO-1B Subscript used is first letter of run code on container.

## SUGGESTED MINIMAL LABELING FOR EACH INDIVIDUAL TUBE

("")= According to outer container used.

# UNICORN 30 DAY Flea & Tick Treatment

ACTIVE INGREDIENT:	
Permethrin*	45%
*CAS #52645-53-1	<u>55%</u> 100%

CAUTION: KEEP OUT OF REACH OF CHILDREN
Refer to container ("box", "card") for full Precautionary Statements and Directions for Use.
[Read Label Before Use]

EPA Reg. No. 28293-293 EPA Est. No. 62478-FL-1

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EPA REG. NO. 28293-293 (8/19/99 AMD draft)

EPA EST. NO. 624/8-FL-1A 44616-MO-1B Subscript used is first letter of run code on container.