A332-3

05/09/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

> OTHCLOU PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MAY 0 9 2006

Mr. James Messina
Authorized Representative of Pet Logic, LLC.
Exponent
1730 Rhode Island Avenue, NW
Suite 1100
Washington, DC 20036

Dear Mr. Messina,

Subject: Label Amendment SPI #8208-55D EPA Reg. No. 69332-3 Submission dated November 30, 2005

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, is acceptable provided you:

- 1. Retain the following precautionary statement under the heading entitled "Hazards to Humans": "Repeated exposure to etofenprox can cause skin irritation."
- 2. Remove the precautionary statement: "Wear protective eyewear."

The Agency reviewed the storage stability and corrosion characteristics study submitted as a condition of registration and found the study to be acceptable. This study satisfies the product chemistry data requirements as described for GRN 830.6317 and GRN 830.6320. These data complete the product chemistry database for this product.

A copy of the stamped label is enclosed. Please submit a final printed label within 60 days of the receipt of this letter.

If you have any questions regarding these actions, please contact Kevin Sweeney at (703) 305-5063. Copies of the acute toxicology and product chemistry reviews are enclosed for your information and file. The Agency's data evaluation reviews for the studies submitted in

support of the spot-on pet use pattern together with the risk assessment will be sent to you shortly.

Sincerely, if ul George LaRocca

Product Manager 13 Insecticides Branch Registration Division (7505C)

Enclosure

NOTE TO REVIEWER: [brackets and italics indicate alternate language.] START CARTON / PACKAGE FRONT PANEL

# SPI #8208-55D

ETOFENPROX SPOT-ON

|SQUEEZE-ON||STRIPE-ON|

FLEA, [(Deer) or (Black Legged)] TICK, and MOSQUITO CONTROL FOR CATS

[for smaller cats over 2.2 lbs. and under 5 lbs.]

[For cats 5 lbs and over] [(for cats and kittens over 12 weeks of age and over 2.2 lbs.)

(for cats and kittens over 12 weeks of age)

WITH NYLAR®

[(ONE), (TWO), (THREE), ]MONTH SUPPLY OUICK ACTING & LONG LASTING

# ONE APPLICATION: (choose from the following)

- Monthly Protection
- Reapply Monthly
- Best when used year round
- Repels mosquitoes (for up to 30 days)
- BREAKS FLEA LIFE CYCLE (FOR UP TO 3 MONTHS) (90 DAYS)
- KILLS ADULT FLEAS FOR UP TO 28 DAYS (4 WEEKS) (1 MONTH) (per application)
- KILLS FLEA EGGS AND LARVAE (FOR UP TO 3 MONTHS) (90 DAYS) (per application)
- KILLS FLEAS, [(Deer) or (Black Legged)] TICKS, FLEA EGGS & LARVAE
- MONTHLY FLEA, [(Deer) or (Black Legged)] TICK, MOSQUITO, and FLEA EGG and LARVAE PROTECTION
- 5 WAY PROTECTION [Kills fleas, [(Deer) or (Black Legged)] Ticks, Flea Eggs & Larvae, and repels mosquitoes]
- Quick Acting, Long Lasting
- Specially formulated for Cats
- KILLS FLEAS and [(Deer) or (Black Legged)] TICKS for up to (4 WEEKS) (1 MONTH) (28 DAYS) (per application)
- KILLS FLEA EGGS AND LARVAE for up to (3 MONTHS) (90 DAYS) (per application)
- PREVENTS FLEA EGGS FROM DEVELOPING INTO BITING ADULTS FOR UP TO 90 DAYS (3 MONTHS) (per application)
- KILLS [*(Deer) or (Black Legged)*] TICKS FOR UP TO 28 DAYS (4 WEEKS) (1 MONTH) (per application) KILLS [*(Deer) or (Black Legged)*] TICKS [BEFORE THEY CAN] [THAT] TRANSMIT LYME DISEASE, FOR UP TO (4 WEEKS) (1 MONTH) (per application)
- PREVENTS MOSQUITOES THAT TRANSMIT WEST NILE VIRUS FROM FEEDING ON CATS FOR UP TO ONE MONTH (per application)

ACTIVE INGREDIENTS:

Etofenprox		55.00%
Pyriproxyfen		
INERT INGREDIENTS		42.80%
	TOTAL	100.00%

Nylar® is a Registered Trademark of the McLaughlin Gormley King Company

### KEEP OUT OF REACH OF CHILDREN CAUTION

# See [Side][Back] Panel For Additional Precautionary Statements

NET CONTENTS:

One [Two][Three] 0.7 ml applicators. [(for small cats between 2.2 lbs and 5 lbs)] One [Two][Three] 1.4 ml applicators. (for large cats over 5 lbs)

[Two] 0.7 ml applicators. (for large cats over 5 lbs)

with COMMENTS In EPA Letter Dated MA 0 9 2005 Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. (0933, 2-3)

ACCEPTED

### END CARTON / PACKAGE FRONT PANEL START CARTON / PACKAGE - BACK / SIDE PANEL

#### **READ ENTIRE LABEL BEFORE EACH USE**

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

HAZARDS TO HUMANS: Causes moderate eye irritation. Avoid contact with eyes and clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

HAZARDS TO DOMESTIC ANIMALS: For External Use Only. Do not use on pets under 12 weeks of age. Do not use on cats under 2.2 pounds. Consult a veterinarian before using this product on debilitated, aged, pregnant, or nursing animals. 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. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated animals.

### FIRST AID

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.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-224-PETS for emergency medical treatment information.

#### PHYSICAL-CHEMICAL HAZARDS:

Combustible: Do not use or store near heat or open flame.

### **DIRECTIONS FOR USE**

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

Do not get this product in your pet's eyes or mouth. Do no apply more often than once every 30 days. Use only on cats. Do not bathe pet with in the first 24 hours after squeeze-on has been applied. Households with more than one cat should not allow cats to groom each other until solution has dried.

#### FOR USE ON CATS:

Weighing 2.2 pounds to less than 5 pounds - Apply contents of one (0.7 ml) tube [vial] of Etofenprox Spot-On as a spot high on the back of the cat's neck behind its head.

Weighing 5 pounds or more - Apply contents of two (0.7 ml) tubes [vials] of Etofenprox Spot-On solution as a spot or stripe, starting high on the back of the cat's neck to in front of the shoulder blades.

Or Apply one (1.4 ml) tube [vial] of Etofenprox Spot-On solution as a spot or stripe, starting high on the back of the cat's neck to in front of the shoulder blades.

#### (INSERT DIAGRAHM THAT DEPICTS APPLICATION OF PRODUCT ON THE CAT)

#### HOW TO APPLY:

Remove product tube *[vial]* from the package. Holding tube *[vial]* with notched end pointing up and away from the face and body, cut or tear off the narrow end at the notches. While holding the animal with one hand, use the other hand to apply the solution. Invert the tube *[vial]* and use the narrow end to part the animal's hair while gently squeezing to apply to the animal's skin. Hold the animal for a few seconds to give the solution time to be absorbed into the animal's coat. When finished, wrap the tube *[vial]* in paper and put into the trash.

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store in a cool, dry place.

**Disposal:** Securely wrap original container is several layers of newspaper and discard in trash. Container Disposal: Do not reuse empty container. Wrap and put in trash.

In case of an emergency, call 1-800-224-PETS EPA Reg. No. 69332-3



# MANUFACTURED BY:

PET LOGIC, LLC P.O. BOX 18993 MEMPHIS, TN 38181

# END CARTON / PACKAGE - BACK / SIDEPANEL

TUBE / VIAL LABEL

SPI# 8208-55D

Etofenprox......55.00% Pyriproxyfen.....2.2%

KEEP OUT OF REACH OF CHILDREN CAUTION: Read directions and precautions before using.

EPA Reg. No. 69332-3

0.7 mL 1.4 mL