

JAN - 5 2005

Mr. James Messina
Consultant for Pet Logic, LLC
Exponent
1730 Rhode Island Avenue, Suite 1100
Washington, DC 20036

Dear Mr. Messina:

Subject: Amendment- Remove Irritation Statement, Additional
Efficacy Data
SPI #8208-55D
EPA Registration Number 69332-3
Your submission dated June 29, 2004

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(a), is acceptable provided that you:

1. Submit and/or cite all data or other material required for registration/reregistration of your product under FIFRA section 3(c)(5) or FIFRA section 4 when the Agency requires all registrants of similar products to submit such data.

2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

a) Reinstate in italics "Deer or Black Legged" before the pest claim Tick on the front panel of the labeling. The new efficacy data did not support a general tick claim on cats. As indicated in our August 24, 2004 letter and product performance review for a general tick control claim on cats to be considered you were to submit additional *in vivo* study data on cats and *in vitro* data with clipped hair removed from treated and untreated cats against Lone Star ticks and American dog ticks at a minimum. Only the label rate treatment should be tested because this is the rate that will be applied. The number of replicates should be at least five for the treatment. We also question the value of the additional efficacy data on fleas since it does not support the current label claims. Refer to the enclosed efficacy review.

b) Reinstate the label text "repeated exposure to etofenprox can cause skin irritation.". We will evaluate your rationale and supporting information to remove this precautionary statement when the other data required as a condition of registration for etofenprox technical are submitted and reviewed.

c) The other label changes are acceptable.

3. Submit two (2) copies of your final printed labeling before you release the product for shipment.

A stamped copy of the label is enclosed for your records.

If you have any questions in regard to this letter please feel free to contact me at 703-305-6100.

Sincerely yours,

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

Enclosure

3 8 5

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, 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
QUICK ACTING & LONG LASTING

ACCEPTED
with COMMENTS
in EPA Letter Dated

JAN - 5 2005

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

09382-3

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, TICKS, FLEA EGGS & LARVAE
- MONTHLY FLEA, TICK, MOSQUITO, and FLEA EGG and LARVAE PROTECTION
- 5 WAY PROTECTION [Kills fleas, Ticks, Flea Eggs & Larvae, and repels mosquitoes]
- Quick Acting, Long Lasting
- Specially formulated for Cats
- KILLS FLEAS and 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 TICKS FOR UP TO 28 DAYS (4 WEEKS) (1 MONTH) (per application)
KILLS 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.....	2.20%
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)*

END CARTON / PACKAGE FRONT PANEL

4 8 5

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. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. ~~Repeated exposure to etofenprox can cause skin irritation.~~

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 not 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 in 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

EPA Est. No.

575

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