

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

EPA Reg. Number:

MAY 1 7 2004

69332-3

Term of Issuance: Conditional

Name of Pesticide Product: SPI #8208-55D

**NOTICE OF PESTICIDE:** 

x Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Pet Logic, LLC P.O. Box 18993

Memphis, TN 38181

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 pasticide 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)(C) since you agreed in your letter dated April 29, 2004 that:

- 1. You will submit/cite all data required for registration/reregistration of your product under FIFRA section 3 (c)(5) or 4(a) when the Agency requires all registrants of similar products to submit such data.
- 2. You will submit the listed data below, conducted in accordance with the 40 CFR Part 158 test guidelines referred to below:

Title of Study	Guideline Reference Numbers	Date Due
One-year Storage Stability Study	830.6317	September 1, 2005
Corrosion Characteristics Study	830.6320	September 1, 2005

The registrant is required to generate a one year storage stability study for the subject product under warehouse conditions. It is recommended that observations be made at 0, 3, 6, 9, and 12 months. The corrosion characteristics study may be conducted concurrently. An accelerated study will not substitute for a one year study under warehouse conditions.

Signature of Approving Officier

May 19, 2004

EPA Form 8570-6

- 3. You will make additional changes to the labeling, if necessary, as result of our reviews of the pending studies on the animal safety of etofenprox to cats and the studies related to operator exposure and dislodgeability of etofenprox from the haircoat of cats.
- 4. You will make the following label changes before you release the product for shipment:
  - a. Add the phrase "EPA Registration No. 69332-3 to the product label.
  - b. Under Precautionary Statement "Hazards to Humans", add the following statement:
  - "Repeated exposure to etofenprox can cause skin irritation."
  - c. Remove the statement "Gentle Formula" from the label.
- 5. Submit three (3) copies of your final printed labeling before releasing the product for shipment.
- 6. The revised basic Confidential Statement of Formula dated March 25, 2004 is acceptable and is the basic CSF of Record.

You should note that if you fail to satisfy any of the conditions imposed on this registration, e.g., you fail to submit the required data by the specified deadlines or the data submitted were not generated in accordance with applicable test guidelines, EPA may issue notice to cancel this use under FIFRA 6(e).

Finally, once the required data have been submitted and evaluated, EPA will entertain an application to amend the registration of the subject product to allow unconditional use on cats.

A stamped copy of your product label is attached.

Sincerely,

George LaRocca Product Manager 13 Registration Division (7505C) Insecticides Branch

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 QUICK ACTING & LONG LASTING

# ONE APPLICATION: (choose from the following)

- · Monthly Protection
- Reapply Monthly
- 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
- Gentle Formula
- · 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

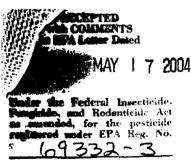
# KEEP OUT OF REACH OF CHILDREN CAUTION

See Side 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 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.

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

EPA Est. No.

515

# 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