

#### U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

69332-3

Date of Issuance:

32-3 7/18/16

NOTICE OF PESTICIDE:

X Registration
Reregistration

(under FIFRA, as amended)

Term of Issuance:

**EPA Reg. Number:** 

Conditional, Time-Limited

Expires: 7/18/2018

Name of Pesticide Product:

SPI #8208-55D

Name and Address of Registrant (include ZIP Code):

Mary Hunt Managing Regulatory Consultant for Pet Logic, LLC. c/o Exponent, Inc. 1150 Connecticut Ave, Suite 1100 Washington, DC 20036

**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 pesticide is hereby registered 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 section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:	Date:
Meridith M. Fry, Ph.D., Product Manager 4	7/18/16
Invertebrate & Vertebrate Branch 1 (IVB1)	
Registration Division (7505P), Office of Pesticide Programs	

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- 2. This registration is time-limited and expires 7/18/2018.
- 3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
  - EPA Registration Number
  - Product name (brand name)
  - Lot #
  - Where purchased: internet, store, veterinarian
  - Active Ingredient(s)
  - Weight range for product
  - Date on which incident occurred. (mm/dd/yyyy)
  - State in which the incident occurred. (standard 2 letter abbreviation)
  - Registrant case #
  - Species: dog, cat, other (specify)
  - Breed: (as reported by pet owner)
  - Age: months or years
  - Sex: M, F, or neutered
  - Weight: pounds
  - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
  - Body System: neurological, dermatological, GI, respiratory, ocular, other
  - Major signs noted with separate column for each sign, using standard terminology
  - Time to Onset: (hours, days)
  - Treated by veterinarian: yes or no
  - First time product used: yes or no
  - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
  - Any known precondition
  - EPA Severity Code: death, major, moderate, minor
  - Outcome: died, recovered, still treated, unknown
- 4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
  - All incidents should be reported including all minor dermal and ocular irritation reports.
  - Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

- A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for cats showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range, as applicable.
- Table showing number of incidents for each cat breed, where provided.
- Table showing number of incidents in cats for each clinical sign.
- Table showing number of incidents in cats for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

- 5. You are required to comply with the data requirements described in the DCI identified below:
  - a. Pyriproxyfen GDCI-129032-1299
  - b. Ethofenprox GDCI-128965-954
  - c. Ethofenprox GDCI-128965-1041

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://www.epa.gov/oppsrrd1/contacts\_prd.htm

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

• Basic CSF dated 03/04/2016

If you have any questions, please contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Enclosure

23 December 2015 Mitigation Information in [ ] is optional.

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#### FRONT PANEL

**CAT SOUEEZE - ON** 

Pyriproxyfen (NYLAR), Etofenprox

Editors Note: Optional proposed text appears in brackets – the final label may include some or all of the optional text]

#### **SPI #8208-55D for Cats**

{Market Label-the word Cat will be at least 40-75% in height of the largest letter in the primary brand name.} {Market Label-a large clear picture of a cat in the respective weight range will be on the front panel of the label

For use ONLY on smaller cats and kittens 3 to 5 lbs and over 12 weeks of age {OR}

For use ONLY on cats [and kittens] 6 lbs and over and 12 weeks or older

{Market Label-one of the statements above will be placed prominently on the front panel}

{box only designates Vet Only language}

{SUBLABEL: FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION }

#### FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION

For use in veterinarian clinics, animal shelters, grooming facilities and boarding kennels. Not for residential use. Do not repackage.

[Ideal for shelter use when under direct supervision of veterinarian]

[Professional Roll Pack]

[Convenient roll pack for in clinic use]

[Convenient roll pack for animal facility use]

[For use only by licensed veterinarians]

[[Etofenprox] Spot-On [Squeeze-On] [Stripe-On]]

[Flea, (Deer) Or (Black Legged) Tick, And Mosquito Control For Cats] [With Nylar®]

[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]
- [Specially formulated for Cats]
- [Kills Fleas, (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]]

## ACCEPTED

Jul 18, 2016

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 69332-3

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- [Kills (Deer) Or (Black Legged) Ticks For Up To [28 Days] [4 Weeks] [1 Month] [Per Application]]
- [Kills (Deer) Or (Black Legged) Ticks That May Transmit Lyme Disease, For Up To [4 Weeks] [1 Month] [Per Application]]
- [Prevents Mosquitoes [That May Transmit West Nile Virus] From Feeding On Cats For Up To One Month (per application)]
- [Improved formula]
- [Now a squeeze-on that] [leaves] [No oily residue]
- [Cats can't rub off on furniture leaving oily residue behind.]
- [No oily residue (on your cat's coat)]
- [Odorless] [unscented] [fragrance free]
- [Quick drying]
- [No pesticide smell]
- [Dries quickly] [Quick drying formula] [Dries quickly] [Quick Drying]
- [Squeeze-On] [stays On and doesn't rub off]
- [Who says a squeeze-on has to smell bad to work well]
- [Improved Technology]
- [Spreads using the cats natural skin oils]
- [Bonus] 33% More [now includes 4 tubes]
- [with (Clear Dry) (Technology) (Formula) (base)]
- [Kills (and repels) mosquitoes that may transmit heartworm]
- [Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]
- [Monthly Flea, Tick and Mosquito Treatment]
- [Direct to skin [tube][vial][applicator][pipette]]
- [Easy to Use] [tube][vial][applicator][pipette]]
- [Clean cut [open] [tube][vial][applicator][pipette]]
- [No-mess [open] [tube][vial][applicator][pipette]]
- [Clip-tip design [tube][vial][applicator][pipette][!]]

[One Applications][Two Applications][Three Applications][Four Applications][Five Applications][Six Applications][Twelve Applications][24 Applications] and/or [1 Month Supply][2 Month Supply]
[3 Month Supply][4 Month Supply][5 Month Supply][6 Month Supply][12 Month Supply][24 Month Supply] or [4 Week Supply][8 Week Supply][12 Week Supply][16 Week Supply][20 Week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply]

[Save Now!]

[Value Size]

[Club Size]

[Bonus Size]

[Club Pack]

[Great Value]

[Better Value]

[Bonus Pack]

[(x) + (x) bonus pack!]

[Buy more and save!]

[Buy X Get Y Free]

[Buy 3 get 1 free]

[(x)% (More) (Free)!]

[33% more free]

- [(x) Dose(s) Free!]
- [(x) Day(s) (Free)!]
- [(x) Month(s) Free!]
- [(x) Day(s) of treatment- Free!]

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- [(x) Tube(s) Free!]
- [(x) Applicator(s) Free!]
- [(x) Application(s) Free!]

#### **ACTIVE INGREDIENTS:**

Etofenprox	55.00%
Pyriproxyfen	
OTHER INGREDIENTS:	
TOTAL	100.00%

[Nylar® is a registered trademark of McLaughlin Gormley King Company]

# KEEP OUT OF REACH OF CHILDREN CAUTION

See [Insert] [Back][or][Side] [Label[s]][ Panel[s]] for Additional Precautionary Statements

NET CONTENTS: X fl. oz. [(X ml)]
[One] [Two][Three] [Four] [Five] [Six]

0.024 fl oz [(0.7 mL)] [tube][vial][applicator][pipette](s)]. [(for small cats 3 - 5 lbs)] [(for large cats 6 lbs and over)]

0.047 fl oz [(1.4 mL)] [tube][vial][applicator][pipette](s)]. [(for large cats 6 lbs and over)]

**OR** {box only designates Vet Only language}

Net Contents: X fl oz X count [Y – X fl oz [tube][vial][applicator][pipette][s]]

[Thirty-five] 35[Fifty][50][Seventy-five][75][One hundred][100] [One hundred sixty][160]

BACK PANEL

**CAT SQUEEZE – ON** 

Pyriproxyfen (NYLAR), Etofenprox

{Brand Name}

## READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON CATS AND KITTENS OVER 12 WEEKS OF AGE

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**HAZARDS TO HUMANS: CAUTION.** Causes moderate eye irritation. Avoid contact with eyes and clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation.

**HAZARDS TO DOMESTIC ANIMALS:** For external use on cats only. Individual sensitivities, while rare, may occur after using any pesticide product on cats. Certain medications can interact with pesticides. Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant, or nursing cats. Consult a veterinarian before using on cats with known organ dysfunction.

**OR** {box only designates Vet Only language}

**HAZARDS TO DOMESTIC ANIMALS**. For external use on cats only. Individual sensitivities, while rare, may occur after using any pesticide product on cats. Certain medications can interact with pesticides. Do not treat a cat with more than one pesticide product at a time.

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Over dosing a cat can result in serious illness and even death. Use caution before using on medicated, debilitated, aged, pregnant, nursing cats or cats with known organ dysfunction. If the cat is exhibiting signs of and/or is being treated for skin dermatitis, use caution before applying any topical flea and tick control product.

PHYSICAL OR CHEMICAL HAZARDS: Combustible: Do not use or store near heat or open flame.

	FIRST AID	
If In Eyes:	Hold eye open and rinse slowly and gently with soap and 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.	
HOT LINE NUMBER		
	oduct container or label with you when calling a poison control center or doctor, treatment. You may also contact 1-800-781-4738 for emergency medical formation.	

#### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on animals other than cats. Do not allow your cat to ingest this product. Do not use on kittens under 12 weeks of age. Do not apply to cats weighing less than [3][6] lbs. [Do not split one tube between cats.] Do not get this product in your cat's eyes or mouth. Do not apply more often than once every 30 days. Do not bathe cat within 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.

Side Effects: Monitor your cat after application. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application such as redness, scratching, rash, hair discoloration or hair loss or other signs of discomfort. If signs of sensitivity occur, bathe your cat with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your cat for the next 24 hours.

#### FOR USE ONLY ON CATS:

Weighing 3 to 5 lbs - Do not apply product to cats weighing less than 3 lbs. Apply contents of one (0.024 fl oz [0.7 mL]) [tube] [vial] [applicator] [pipette] of {Brand Name} as a spot high on the back of the cat's neck behind its head. Do not double dose cat.

Weighing 6 lbs and over - Do not apply product to cats weighing less than 6 lbs Apply contents of two (0.024 fl oz [0.7 mL]) [tube] [vial] [applicator] [pipette](s) of {Brand Name} 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 (0.047 fl oz [1.4 mL]) [tube] [vial] [applicator] [pipette] of {Brand Name} solution as a spot or stripe, starting high on the back of the cat's neck to in front of the shoulder blades. Do not double dose cat.

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#### **HOW TO APPLY:**

Remove product [tube] [vial] [applicator] [pipette] from the package. Holding[tube] [vial] [applicator] [pipette] 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 cat with one hand, use the other hand to apply the solution. Invert the [tube] [vial] [applicator] [pipette] and use the narrow end to part the cat's hair while gently squeezing to apply directly to the cat's skin. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat. When finished, wrap the [tube] [vial] [applicator] [pipette] in paper and put into the trash.

### [[Clip. Part. Squeeze.]

Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea and tick protection where it needs to be.]

[Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy][Spot On] [Squeeze-On] [Topical] Checklist

- [1] Read the label completely and follow directions
- [2] Weigh your cat
- [3] Do NOT use Dog products on Cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment][application] to avoid chance of ingestion
- [6] Do NOT split [tube][vial][applicator][pipette]s between pets][and use the entire [tube][vial][applicator][pipette] contents]

#### STORAGE AND DISPOSAL

**PESTICIDE 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 and pets. Do not refrigerate. Protect from direct sunlight.

**PESTICIDE DISPOSAL AND CONTAINER HANDLING:** Nonrefillable container. Do not reuse or refill this container. **If Empty**: Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

#### [WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. [[The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks inherently associated with the use of this product. Unintended consequences may result because of such factors as weather conditions, presence or absence of other materials, or the manner of application, all of which are beyond the control of Pet Logic, LLC .]] Pet Logic, LLC is committed to providing high quality products. To the extent consistent with applicable law, Pet Logic, LLC makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Pet Logic, LLC, the manufacturer, or the Seller disclaims any liability whatsoever for special, incidental, or consequential damages resulting from the use of this product. To the extent consistent with the law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[Sergeant's Care Pet Products, Inc. is committed to providing high quality products. If you have questions or comments about this product, please write: Sergeant's Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

23 December 2015 Mitigation Information in [ ] is optional.

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In Case of Emergency, call: 1-800-781-4738 Non-Emergency, call: 1-800-224-PETS (7387)

[Made in USA]

[Distributed by:][Manufactured by:]

Pet Logic, LLC, A Division of Sergeant's Pet Care Products, Inc.

Omaha, NE 68138-3710

EPA Reg. No. 69332-3 EPA Est. No. XX-XX-XXX

{date & label code}

{END - BACK / SIDE PANEL}

#### **{START – OPTIONAL PACKAGE}**

CAT SQUEEZE - ON

Pyriproxyfen (NYLAR), Etofenprox

[Optional graphics below may or may not appear on finished label]

publiai grapilies below iliay	or may not appear on missied label]	
Total	Adult Flea	
Toto	Fleas	
755-	Flea eggs	
つ	Flea Larvae	<b>3</b>
*	Ticks	<b>8</b>
*	Deer Tick	8
*	Black Legged Tick	<b>®</b>
7	Mosquitoes	<u> </u>

[Optional graphics below may or may not appear on finished label]

























23 December 2015 Mitigation Information in [ ] is optional.

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#### TUBE / VIAL LABEL

Front Label Back Label

 {Brand Name for Cats}
 KEEP OUT OF REACH OF CHILDREN

 [3 to 5 lbs][6 lbs & over] ≥ 12 wks
 CAUTION: Read directions and precautions before

Etofenprox 55% us

Pyriproxyfen 2.2% EPA REG. No. 69332-3 {label code}

{EPA REG No may be on either the front or back label}