U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460	EPA Reg. Number: 2517-133	Date of Issuance: 12/11/15		
NOTICE OF PESTICIDE: <u>X</u> Registration Reregistration (under FIFRA, as amended)	Term of Issuance: Conditional, Time-Limited Expires: 12/11/2017 Name of Pesticide Product: Etofenprox/Nylar Spot-On Flea			
Name and Address of Registrant (include ZIP Code):         Mr. Kelly R. Hoskins         Sergeant's Pet Care Products, Inc.         10077 South 134 <sup>th</sup> Street         Omaha, NE 68138-3710				
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:				
<ol> <li>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.</li> </ol>				
Signature of Approving Official:	Date:			
Jennifer Urbanski Saunders, Product Manager 04 Invertebrate & Vertebrate Branch 1, Registration Division (7505P) EPA Form 8570-6	12/11/1	5		

- 2. The Agency has found your company to be in compliance with the terms and conditions for the subject product, and is extending the two-year registration restriction. This registration is time-limited and expires 12/11/2017.
- 3. Please note that the product is still subject to all other previously required conditions of registration. Your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information as stated in an Agency letter dated 9/30/11.
- 4. You are required to comply with the data requirements described in the DCI Orders identified below:
  - a. Etofenprox GDCI-128965-954
  - b. Etofenprox GDCI-128965-1041

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Orders listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: <u>http://www.epa.gov/oppsrtd1/contacts\_prd.htm</u>

5. Submit one copy of the final printed label for the record before you release the product for shipment.

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.

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.

If you have any questions, please contact Tim Ciarlo by phone at 703-347-8082, or via email at <u>Ciarlo.Timothy@epa.gov</u>.

Enclosure

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### FRONT PANEL

DOG SQUEEZE – ON

Pyriproxyfen (NYLAR), Etofenprox

[Optional text appears in brackets – the final label may include some or all of the optional text on front, back or side label panels] {Information is instructional}

### ETOFENPROX/NYLAR SPOT-ON FLEA AND TICK FOR DOGS & PUPPIES

{Market Label-the word Dog 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 dog in the respective weight range will be on the front panel of the label}

### [ABNs:]

[Sergeant's Toy Breed Flea and Tick Squeeze-On for [Toy Breed] Dogs]
[Sergeant's Toy Breed Flea and Tick Squeeze-On for Small Breed Dogs]
[Sergeant's Toy Breed Flea and Tick Squeeze-On for Small and Toy Breed] Dogs]]
[Sergeant's Small Breed Flea and Tick Squeeze-On [for [Small [and Toy] Breed] Dogs]]
[SentryPro Toy and Small Breed Flea and Tick Squeeze-On [for [Small [and Toy] Breed] Dogs]]
[SentryPro Small Breed Flea and Tick Squeeze-On [for [Small [and Toy] Breed] Dogs]]
[Sentry®Pro XFT [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]
[Sentry®Pro XFC+ [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]
[SentryPro® XFTC [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]
[SentryPro® XFTC [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]
[SentryPro® XFTC [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]



{1.5 cm x 1.5 cm on final or red & black as indicated below. Placement will be in the lower right hand quadrant.}

For use ONLY on Dogs [&][and] Puppies [4-10 lbs][11-20 lbs],12 weeks of age or older [OR] ONLY For Dogs & Puppies Over 12 Weeks of Age, [4 to 10 lbs] [11 to 20 lbs] {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]

[with Nylar®] [Pyriproxyfen]
[[Toy] [and] [small] breed formula]
[Gentle protection for [toy] [small] breed dogs]
[For toy and small breeds [4-10 lbs][11-20 lbs]]
[For toy breeds 4-10 lbs.] [For small breeds 11-20 lbs]
[Specially Formulated for Dogs and Puppies (over 12 weeks old)]
[Specially formulated for [toy breed[s]] [and] [small breed[s]] dogs]
[Apply once every [4 weeks] [1 month] [30 days]!]
[Up to [4 week] [1 Month] Dose!]

# **A C C E P T E D** 12/11/2015

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

2517-133

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# FRONT PANEL

# DOG SQUEEZE – ON Pyriproxyfen (NYLAR), Etofenprox

[(ICON Showing up to 4 Week Protection)] [(One) (Two) (Three) (Four) (XX) Applications] [Bonus] 33% more [now includes 4 [tubes] [vials] [applicators] [pipettes]]] [Three Applications {for cartons with 3 applicators}] and/or [3 Month Supply] or [12 Week Supply] [Four Applications {for cartons with 4 applicators}] and/or [4 Month Supply] or [16 Week Supply] [Best if used year round!] [Easy to Use Application] [[Free] [Brochure] [and] [Calendar] [Stickers] Inside!] [Patent pending technology] [odorless] [unscented] [fragrance free] [Dries quickly] [Quick drying formula] [Quick Drying] [Squeeze-On] [stays on and doesn't rub off] [Spreads by using the dog's natural skin oils] [with Vitamin E] [No oily residue] [Formulated] [with] DERMAshield<sup>TM</sup> [Technology] [DERMAshield<sup>TM</sup> [Technology] [which] dries quickly to keep the product on the outer skin surfaces] [and contains [a vitamin] [vitamin E] to soothe skin]]

# (Multiple species)

[Flea and Tick control] [Kills Fleas and Ticks] [for up to [30 days][4 weeks]] [Controls fleas, ticks, flea eggs & larvae] [Flea, Tick and Flea Egg Protection] [Flea & Tick Control for Dogs & Puppies 12 weeks old and older] [[Four] [4] Way Protection! [Kills ticks, fleas, flea eggs & flea larvae]] [[Five] [5] Way Protection! [Kills fleas, flea eggs, flea larvae, and ticks] [Repels mosquitoes] [Five in one protection [Kills fleas, flea eggs, flea larvae, and ticks] [Repels mosquitoes] [Kills all stages of the flea life cycle] [Kills fleas, ticks, flea eggs, and flea larvae] [Flea, tick, flea egg and larvae control] [Kills fleas, flea eggs, flea larvae, and ticks] [Repels mosquitoes] [Kills Fleas, Ticks, Flea Eggs & Flea Larvae for up to [4 Weeks] [1 month]] [Works for up to 4 Weeks on fleas and ticks!] [Protects for up to 4 Weeks on [adult] fleas and ticks!] [Up to 4 Week [One Month] [Adult] Flea and Tick [Control] [Protection!] [Treatment!]] [Kills [Adult] Fleas and Ticks for up to 4 weeks!]

# (Flea and Flea eggs and Larval)

[Kills [adult] fleas for up to [30 days] [4 weeks]]
[With [Nylar®] [Pyriproxyfen] to Break Flea Life Cycle]
[With Insect Growth Regulator to Break Flea Life Cycle]
[With [Nylar®] [Pyriproxyfen] Insect Growth Regulator which Breaks the Flea Life Cycle]
[Dual Action [!]: Effectively Breaks the Flea Life Cycle [!]]
[Dual Action [!]: Etofenprox with [Nylar®] [Pyriproxyfen] IGR Effectively Breaks the Flea Life Cycle]
[Prevents Flea Eggs From Developing Into Biting Adults]
[Controls reinfestation for up to (70 days) (10 weeks)]
[[Breaks Flea Life Cycle!] for up to (70 Days) (10 Weeks)]
[Kills Flea Eggs and Larvae for up to (70 Days) (10 Weeks) (per application)]
[Kills fleas that may cause flea allergy dermatitis, and flea bite anemia] [for up to [30 days] [4 weeks]]
[Prevents flea eggs from developing into biting adults for up to (10 weeks) (70 days) (per application)]
[Kills for up to [10 weeks] [70 days] [flea eggs][flea larvae]]

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# FRONT PANEL

DOG SQUEEZE – ON Pyriproxyfen (NYLAR), Etofenprox

[Kills fleas]

# (Ticks)

[Kills ticks [for up to [30 days] [4 weeks]]]
[Kills Ticks] [that may transmit Lyme Disease]
[Kills ticks including those that may transmit Lyme disease]
[Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]
[Kills Deer Ticks (vector of Lyme Disease) for up to 4 weeks]
[Kills deer ticks [before they can] [that] [transmit Lyme Disease,] [for up to [4 weeks] [1 month] [30 days]]]
[Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]
[Kills [brown dog ticks][(*Rhipicephalus sanguineus*)][for up to [4 weeks][1 month][30 days]]]
[Kills [American Dog Ticks][(*Dermacentor variabilis*)] for up to [4 weeks][1 month][30 days]!]

# (Mosquitoes)

[Repels mosquitoes]

[Repels mosquitoes] [for up to [28 days] [4 weeks] [1 month] !]

[Repels mosquitoes that may transmit heartworm]

[Repels mosquitoes that may transmit [heartworm] [from feeding on dogs] [for up to [one month] [30 days][ 4 weeks]]

[Repels Mosquitoes] [Prevents mosquitoes that transmit heartworm] [from feeding on dogs] [for up to [one month] [30 days][ 4 weeks]]

[Prevents mosquito blood feeding from mosquitoes which may transmit heartworm to dogs for up to four weeks.]

# **ACTIVE INGREDIENTS:**

Etofenprox	
Pyriproxyfen	
OTHER INGREDIENTS:	
TOTAL	100.00%

[Nylar<sup>®</sup> is a registered trademark of McLaughlin Gormley King Company]

# KEEP OUT OF REACH OF CHILDREN CAUTION

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

**Net Contents:** X fl oz [Y – X fl oz [tube][vial][applicator][pipette][s]] [1][One][2][Two][3][Three][4][Four][5][Five][6][Six][9][Nine][10][Ten][12][Twelve]

**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]

2.0 mL applicators. [for small dogs 4 to 10 lbs] 4.0 mL applicators. [for small dogs 11 to 20 lbs]

# {END - FRONT PANEL}

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**BACK PANEL** 

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DOG SQUEEZE – ON Pyriproxyfen (NYLAR), Etofenprox

# **{Product Name}** 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, using tobacco, or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS:** For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product.

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

**HAZARDS TO DOMESTIC ANIMALS**. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat a dog with more than one pesticide product at a time. Over dosing a dog can result in serious illness and even death. Use caution before using on medicated, debilitated, aged, pregnant, nursing dogs or dogs with known organ dysfunction. If the dog is exhibiting signs of and/or is being treated for skin dermatitis, use caution before applying any topical flea and tick control product.

### 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, and 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 1-800-781-4738 for emergency medical treatment information.

PHYSICAL OR 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 dog's eyes or mouth. Do not apply more often than [once a month] [once every 30 days]. Do not use on cats, rabbits or animals other than dogs. Do not allow your dog to ingest this product. Do not use on puppies under 12 weeks of age or less than [4][11] lbs. Use entire contents of [tube] [vial] [applicator] [pipette] on each dog. [Do not split one [tube][vial][applicator][pipette] between dogs.] Do not use multiple [tube][vial][applicator][pipette]s on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied. Best if used year round. Do not bathe dog within the first 24 hours after squeeze-on has been applied. Households with more than one pet should not allow dogs or cats to groom each other until solution has dried.

**SIDE EFFECTS:** Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, call your veterinarian or 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating

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application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours.

{1.5 cm x 1.5 cm on final or red & black as indicated below. Placement will be in the lower right hand quadrant.}



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

# {Outer Packaging}

**How to open:** Remove product [tube][vial][applicator][pipette][s] from the package. [Separate one [tube][vial][applicator][pipette] from the others.] [Holding the [tube][vial][applicator][pipette] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.] **OR** [Hold the [tube][vial][applicator][pipette] with notched end pointing up and away from the face and body, cut off the narrow the face and body. Use scissors to cut off the narrow end at the notches along the line.]

**How to apply:** While holding the dog 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 dog's hair while gently squeezing to apply to the dog's skin. Hold the dog for a few seconds to give the solution time to be absorbed into the dog's coat. When finished, wrap the [tube][vial][applicator][pipette] in paper and put into the trash.

# [Only for use on Dogs weighing 4 to 10 lbs. – Do not use on dogs less than 4 lbs.

Apply contents of one (2.0 mL) [tube][vial][applicator][pipette] of **[Product Name][Squeeze-on]** as a spot high on the back of the dog's neck behind its head and apply as a stripe to a point midway between the neck and the tail.]

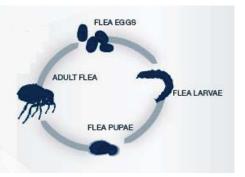
# [Only for use Dogs weighing 11 to 20 lbs. – Do not use two [tubes][vials][applicators][pipette]s on dogs greater than 20 lbs.

Apply contents of one (4.0 mL) [tube][vial][applicator][pipette] of [**Product Name][Squeeze-on]** as a spot high on the back of the dog's neck behind its head and apply as a stripe to a point midway between the neck and the tail.]

[Optional drawings that may or may not appear on finished label]



[Insert diagram that includes checklist with magnifying glass and checklist graphic]



[**Product name**][Sergeant's][Sentry][Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] [Checklist]

- Read the label completely and follow directions
- Weigh your dog
- Do NOT use Dog products on Cats
- Do NOT treat with more than one pesticide product at a time
- Separate animals after [treatment][application] to avoid chance of ingestion
- Do NOT split [tube][vial][applicator][pipette]s between dogs] [and use the ENTIRE [tube] [vial] [applicator] [pipette] contents]]

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## STORAGE AND DISPOSAL

**PESTICIDE STORAGE**: Do not remove [tube][vial][applicator][pipette] from the pack until ready to use. Store in a cool (below 77°F [25°C]), dry place out of reach of children. 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. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer.]] Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's 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, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's] [SENTRY] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

In Case of Emergency, call: 1-800-781-4738 [Coupon(s) inside or on outside of box] Non-Emergency, call: 1-800-224-PETS (7387) [Made in USA]

[Made in the USA For:] [Manufactured by:] [Distributed by:] Sergeant's Pet Care Products, Inc. Omaha, NE 68138-3710 [lot, date & label code] [UPC CODE] EPA Reg. No. 2517-133 EPA Est. No. XXXXX-XX-XX

# TUBE / VIAL LABEL

Front Label		Back Label	
<b>{Brand Name} For Dogs</b> [4-10][11-20] lbs		KEEP OUT OF REACH OF CHILDREN	
>12 wks		CAUTION: Read directions and precautions before	
Etofenprox 55.00%, Pyriproxyfen 2.20%	9	using. Use scissors to open.	
2.0 mL ( <b>or</b> ) 4.0 mL	{label code}	EPA REG. No. 2517-133	{label code}

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

{END - TUBE/VIAL COPY}