

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460 EPA Registration No.

2517-133

Date of Issuance:

APR 3 0 2010

NOTICE OF PESTICIDE:

☑ Registration ☐ Reregistration

(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

Term of Issuance:

Conditional Registration Expires April 30, 2012

Name of Pesticide Product: Etofenprox/Nylar Spot-on Flea and

Tick for Dogs and Puppies

Name and Address of Registrant (include ZIP Code):

Sergeant's Pet Care Products, Inc. 2625 South 158th Plaza Omaha, NE 68130

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 labour 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 sec. 3(c)(7)(a) provided that:

- 1. This registration is time-limited and expires two years from the date this product is first released for shipment.
 - You must provide the Agency with a projected release for shipment date within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing.
- 2. Only one confidential statement of formula (basic) will be filed for this product; no alternate formulation or minor formulation statements may be submitted or approved for this product.
- 3. Make the following changes to the label:
 - a. All marketing statements and references to "mosquitoes" throughout the draft label must be deleted because the submitted efficacy study do not support these claims. West Nile virus and heartworm claims must also be removed
 - b. On page one of the label, because all "mosquito" references are not permitted, you must correct the marketing statements that refer to "[Five] [5] Way Protection" to "[Four] [4] Way Protection..."

- c. The claim "New [formula]" may appear on product produced for 6 months from the date of first distribution only.
- d. Revise the EPA Registration Number to read: "EPA Registration No. 2517-133.
- e. Remove the phrase "Before they can..." made with reference to transmission of disease by ticks. There are no data to support this claim.
- f. Of the three statements proposed, you may use: "Some dogs may experience temporary startle effects when this product is applied." in the Precautionary Statements section of the label.
- g. Change the second weight class for dogs from 10-20lbs to 11-20lbs.
- 4. All of the product chemistry data requirements for this product have been satisfied, except for OPPTS Guidelines 830.6317 and 830.6320, Storage Stability and Corrosion Characteristics studies, respectively. Within on-year of the date of this registration you must submit these data including interim reports made at 0, 3, 6, 9, and 12 month intervals.
- 5. You must submit enhanced incident reports for this product on a quarterly basis beginning July 1, 2010. Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (ATTN: Kimberly Nesci).

The following is a list of information needed by EPA to better characterize these incidents:

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

- 6. 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 dogs 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 cats (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 dogs 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 dog incidents for each severity code for each pet weight range on the product label.
 - A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
 - Table showing number of incidents for each dog breed.
 - Table showing number of incidents in dogs for each clinical sign.
 - Table showing number of incidents in dogs for each organ system.
 - Report aggregate incidents, but do not combine moderate and minor incidents.
- 7. You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for reregistration of your product under FIFRA section 4.
- 8. The basic Confidential Statement of Formula dated April 28, 2010 is acceptable, and is the basic CSF of record, superseding all previously submitted CSFs. As stated above, only one confidential statement of formula (basic) will be filed for this product; no alternate formulation or minor formulation statements may be submitted or approved for this product.

9. The acute toxicity profile for this product is as follows:

Route of Exposure	Toxicity Category	
Acute oral toxicity	IV	
Acute dermal toxicity	ľV	
Acute inhalation toxicity	IV	
Primary eye irritation	III	
Primary skin irritation	IV	
Dermal sensitization	Negative	

A stamped copy of the label and copies of the Data Evaluation Records (DERs) are included for your file. Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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. If you have any questions concerning this registration, please contact Kevin Sweeney at (703) 305-5063.

Signature of Approving Official:	Date:
Herry Anne and O	APR 3 0 2010
Richard Gepken, Product Manager (10)	
Registration Division Insecticide Branch	

EPA Form 8570-6

29 April 2010

Information in | | is optional.

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EPA Reg. No. 2517-RGG EPA SAL

FRONT PANEL

DOG SQUEEZE - ON

Pyriproxyfen (NYLAR), Etofenprox

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

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

{ABN: Sergeant's Toy Breed Flea and Tick Squeeze-On}

{ABN: Sergeant's Toy Breed Flea and Tick Squeeze-On for small breed dogs}

{ABN: Sergeant's Toy Breed Flea and Tick Squeeze-On for small and toy breed dogs}

{ABN: Sergeant's Small Breed Flea and Tick Squeeze-On}

{ABN: Sergeant's Small Breed Flea and Tick Squeeze-On for small breed dogs}

{ABN: Sergeant's Small Breed Flea and Tick Squeeze-On for small and toy breed dogs}

{ABN: SentryPro Toy and Small Breed Flea and Tick Squeeze-On}

{ABN: SentryPro Toy and Small Breed Flea and Tick Squeeze-On for dogs}

{ABN: SentryPro Toy and Small Breed Flea and Tick Squeeze-On for small and toy breed dogs}

{ABN: SentryPro Small Breed Flea and Tick Squeeze-On for Dogs}

{ABN: SentryPro Small Breed Flea and Tick Squeeze-On for small breed dogs}

{ABN: SentryPro Small Breed Flea and Tick Squeeze-On for small and toy breed dogs}

{ABN. Sergeant's® Evolve (4) Flea and Tick Squeeze-On for Dogs (and Puppies)}

{ABN: Sergeant's® Evolve (10) Flea and Tick Squeeze-On for Dogs (and Puppies)}

{ABN: SentryPro® XFTC (4) Flea and Tick Squeeze-On for Dogs (and Puppies)}

{ABN: SentryPro® XFTC (10) Flea and Tick Squeeze-On for Dogs (and Puppies)}

[One Application:(choose from the following)]

[with nylar®]

• [(One) (Two) (Three) (Four) (XX) Applications]

• [Bonus] 33% more [now includes 4 tubes]

[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]

• [Breaks the flea life cycle for up to (70 Days) (9 Weeks)]

[Controls reinfestation for up to (70 days) (9 weeks)]

[For toy breeds 4-10 lbs.]

[For small breeds 10-20 lbs.]

[For toy and small breeds [4-10][10-20] lbs.]

[Specially formulated for small breed[s] dogs]

[Specially formulated for toy breed[s] [dogs]]

[Specially formulated for [toy breed[s]] and [small breed[s]] dogs]

[Toy] [and] [small] breed formula]

[Gentle protection for [toy] [small] breed dogs]

[5 Way Protection]

[Controls fleas, ticks, flea eggs & larvae]

• [Kills Fleas, Ticks, Flea Eggs, Larvae] [and] [repels mosquitoes [for up to one month] [for up to 4 weeks]]

[Flea, tick, flea egg and larvae control]

[Kills fleas and ticks for up to [30 days] [4 weeks]]

[Kills ticks [for up to [30 days] [4 weeks]]]

• [Kills Ticks] [Before they can] [that] [transmit Lyme Disease

[Kills [adult] fleas for up to [30 days] [4 weeks]]

• [Kills Fleas and Ticks] [for up to [30 days][4 weeks]]

[Flea, Tick and Flea Egg Protection]

[Repels mosquitoes [for up to one month] [for up to 4 weeks]]

• [Flea and Tick control]

• [Kills fleas that may cause flea allergy dermatitis, and flea bite anemia] [for up to [30 days] [4 weeks]]

• [Kills Flea Eggs and Larvae for up to (9 weeks) (70 days) (per application)]

ACCEPTED
with COMMENTS

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

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- [Prevents flea eggs from developing into biting adults for up to (9 weeks) (70 days) (per application)]
- [Repels mosquitoes that may transmit [heartworm] [West Nile virus] [from feeding on dogs] [for up to [one month] [30 days] [4 weeks]]
- [Repels Mosquitoes] [Prevents mosquitoes that transmit West Nile virus and heartworm] [from feeding on dogs] [for up to [one month] [30 days] [4 weeks]]

FRONT PANEL

DOG SQUEEZE - ON Pyriproxyfen (NYLAR), Etofenprox

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

NET CONTENTS:

[One] [Two][Three][Four][Five][Six] 2.0 mL applicators. [for small dogs 4 to 10 lbs] [One] [Two][Three][Four][Five][Six] 4.0 mL applicators. [for small dogs 10 to 20 lbs]

6/9

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Information in [] is optional.

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BACK PANEL

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, or using tobacco.

HAZARDS TO DOMESTIC ANIMALS: For External Use Only. Do not use on dogs under 13 weeks of age. Consult a veterinarian before using this product on debilitated, aged, medicated, 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.

[Some dogs may startle when a room temperature squeeze-on is applied.][Some dogs may experience temporary startle effects when a squeeze-on's are applied.]

[Some dogs may experience temporary startle effects when squeeze-on's are applied.]

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 pet's eyes or mouth. Do not apply more often than [once a month] [once every 30 days]. Use only on Dogs. FOR EXTERNAL USE ON DOGS ONLY. Do not use on puppies less than 13 weeks of age. Weigh your dog to be sure you are applying the right dose formulated for the weight of your pet. Do not treat your pet with more than one pesticide product at a time. Over dosing your animal can result in serious illness and even death. Best if used year round. Do not bathe pet with in 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. DO NOT USE ON CATS or animals other than dogs. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied. Cats or dogs that actively groom or engage in close physical contact with treated dogs may be at risk of serious harmful effects. If your dog is exhibiting signs of and/or are being treated for skin dermatitis, talk to your vet before applying any topical flea and tick control product. Sensitivities may occur after using ANY pesticide product on pets. It is recommended to separate treated dogs from other household pets for 24 hours after treatment has been applied. If signs of sensitivity occur, bathe your dog with mild soap and rinse with large amounts of water.

FOR USE ON DOGS:

Weighing 4 TO 10 LBS. - Apply contents of one (2.0 mL) tube [vial] 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

(INSERT DIAGRAM THAT DEPICTS APPLICATION OF PRODUCT ON THE DOG)

FOR USE ON DOGS:

Weighing 10 TO 20 LBS. - Apply contents of one (4.0 mL) tube [vial] 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.

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(INSERT DIAGRAM THAT DEPICTS APPLICATION OF PRODUCT ON THE DOG)

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.

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BACK PANEL

DOG SQUEEZE - ON Pyriproxyfen (NYLAR), Etofenprox

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or 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. Do not refrigerate. Protect from direct sunlight.

PESTICIDE DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling or reconditioning, if available and appropriate. **If empty:** Do not reuse this container. 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 Sergeant's Pet Care Products, Inc..]] Sergeant's Pet Care Products, Inc. is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's Pet Care Products, Inc. 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 Pet Care Products, Inc., 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.]

In Case of Emergency, call: 1-800-781-4738

Non-Emergency call: 1-800-224-PETS (7387)

[For more information] [Visit us at:] www.sergeants.com

Made in USA

Distributed by:

Sergeant's Pet Care Products, Inc. PO Box 540224 Omaha, NE 68154 {END - BACK / SIDE PANEL} EPA Reg. No. 2517-XX EPA Est. No. XXXXXXX {date & label code}

TUBE / VIAL LABEL

Front Label Back Label

{Product Name}		KEEP OUT OF REACH OF CHIL	DREN
Etofenprox55.0% W/W		CAUTION: Read directions and precautions before	
Pyriproxyfen2.2% W/W	i i	using.	
[2.0][4.0] mL {lal	oel code}	EPA REG. No. 2517-XX	{label code}