

12/11/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

Kelly R. Hoskins  
Director of Regulatory Affairs  
Sergeant's Pet Care Products, Inc.  
2625 South 158<sup>th</sup> Plaza  
Omaha, NE 68130-1770

DEC 11 2013

Subject: Label Amendment implementing label changes to pet spot-on products  
Etofenprox/Nylar Spot-On Flea and Tick for Dogs & Puppies  
EPA Reg. No 2517-133  
EPA Decision No. 478171

Dear Mr. Hoskins,

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is **acceptable**. With this letter, the label requirements listed in the EPA letter "Implementation of Label Changes to Pet Spot-On Products" dated September 30, 2011, are fulfilled. Please submit final printed labels to the Agency within 30 days of the date of this letter. If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants and may take regulatory action.

EPA also received your December 21 2012 request to replace the conditional time-limited registrations of 2517-127, 2517-128, 2517-129, 2517-130, 2517-131, 2517-132, and 2517-133 with an unconditional registrations and remove the enhanced reporting requirements. EPA has not yet made a decision on this action. Therefore, in the interim, the time-limited registration for 2517-133 is extended two years from the date of this letter. If registration extension requests are not received prior to that date, the registration of these products will expire. If a review of the previously submitted enhanced incident data indicates that there is a concern with any of these products, EPA may choose to take further regulatory action at that time.

Per the additional requirements of September 30, 2011 letter, you must continue to submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product, along with an analysis of the incidents reported. The quarterly reports are due two months after the quarter ends. 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 attention of Kaitlin Keller, Pesticide Reevaluation Division, Mail Code 7508P.

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


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.

•  
A stamped copy of the label is enclosed for your records. If you have any questions regarding this label, please contact Kaitlin Keller at (703) 308-8172 via email at [keller.kaitlin@epa.gov](mailto:keller.kaitlin@epa.gov).

Sincerely,



Richard Gebken  
Product Manager 10  
Insecticide Branch  
Registration Division (7504P)

Enclosure: Label stamped "Accepted"

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# Sergeant's Pet Care Products, Inc. Master Label

27 Sept 2013 Amendment  
Information in [ ] is optional.

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EPA Reg. No. 2517-133  
EPA SAL 7/12/2011  
Supersedes EPA Pending 4/19/2013

## 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]

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

#### [ABNs:]

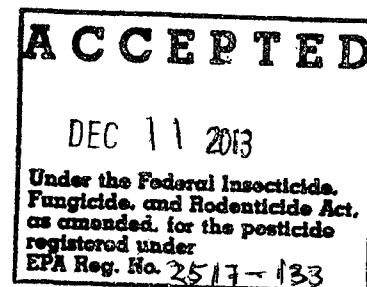
- [Sergeant's Toy Breed Flea and Tick Squeeze-On]
- [Sergeant's Toy Breed Flea and Tick Squeeze-On for Small Breed Dogs]
- [Sergeant's Toy Breed Flea and Tick Squeeze-On for Small and Toy Breed Dogs]
- [Sergeant's Small Breed Flea and Tick Squeeze-On [for [Small [and Toy] Breed] Dogs]]
- [SentryPro Toy 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 XTR [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)]
- [Sergeant's@ Evolve™ [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]



[1.5 cm x 1.5 cm on final or as above]

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]

- [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!]
- [(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™ [Technology]
- [DERMashield™ [Technology] [which] dries quickly to keep the product on the outer skin surfaces] [and contains [a vitamin] [vitamin E] to soothe skin]]



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## FRONT PANEL

## DOG SQUEEZE – ON Pyriproxyfen (NYLAR), Etofenprox

### (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]]
- [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]

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## FRONT PANEL

## DOG SQUEEZE – ON

**Pyriproxyfen (NYLAR), Etofenprox**

[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..... 55.00%  
Pyriproxyfen..... 2.20%

**OTHER INGREDIENTS:**..... 42.80%

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[s]] [Panel[s]] for Additional Precautionary Statements

NET CONTENTS: X fl oz [Y – X fl oz applicators]

[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 11 to 20 lbs]

## 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 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.

### 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.

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**BACK PANEL**

**DOG SQUEEZE – ON**

**Pyriproxyfen (NYLAR), Etofenprox**

## 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]. 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 pet 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 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.

[1.5cm x 1.5cm on final or as below]



Do Not Use On Cats. Keep cats away from treated dogs for 24 hours. Contact your veterinarian if applied to a cat or ingested by a cat (common signs of ingestion are excessive salivation and foaming at the mouth), 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. Use scissors to cut off the narrow end at the notches along the line.]

**How to apply:** While holding the animal 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 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][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.]

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# Sergeant's Pet Care Products, Inc. Master Label

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Information in [ ] is optional.

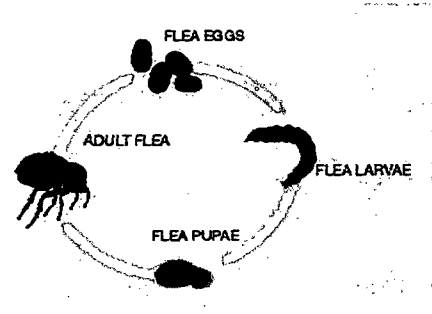
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[Optional drawings that may or may not appear on finished label]



[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 pets] [and use the ENTIRE [tube] [vial] [applicator] [pipette] contents]]

## STORAGE AND DISPOSAL

**PESTICIDE STORAGE:** Do not remove [tube][vial][applicator][pipette] 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 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 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. EPA Reg. No. 2517-133  
Omaha, NE 68138-3710 EPA Est. No. XXXXX-XX-XX  
[lot, date & label code] [UPC CODE]



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## TUBE / VIAL LABEL

### Front Label

### Back Label

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