

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 8, 2015

Mr. Prince Bamaze Regulatory Affairs Associate Sergeant's Pet Care Products, Inc. 10077 South 134<sup>th</sup> St Omaha, NE 68138

Subject: Notification per PRN 98-10 – Adding net contents options in addition to

correcting an accidental omission from the precautionary statement.

Product Name: Etofenprox/Nylar Spot-On Flea And Tick For Dogs & Puppies

EPA Registration Number: 2517-133 Application Date: February 18, 2015

Decision Number: 500553

Dear Mr. Bamaze:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

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

Sincerely,

Jennifer Urbanski, Ph.D.

Product Manager 04

Invertebrate & Vertebrate Branch 1 Registration Division (7505P) Office of Pesticide Programs

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**FRONT PANEL** 

**DOG SOUEEZE - 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]

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

NOTIFICATION 2517-133

The applicant has certified that no

changes, other than those reported to the Agency have been made to the

labeling. The Agency acknowledges

[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 Tov] Breed] Dogs]]

this notification by letter dated: [SentryPro Toy and Small Breed Flea and Tick Squeeze-On [for [Small [and Toy] Breed] Dogs]] 04/08/2015

[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 TM [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<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]]

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### **FRONT PANEL**

### **DOG SOUEEZE - 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 SOUEEZE – 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%
•	2.20%
OTHER INGREDIENTS:	
TOTAL	$1\overline{00.00\%}$

[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]

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][9][Nine][10][Ten][12][Twelve] 2.0 mL applicators. [for small dogs 4 to 10 lbs]

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][9][Nine][10][Ten][12][Twelve] 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, 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.

### 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.

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

**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 indicated]



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. 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.

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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.]

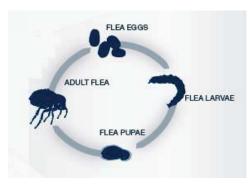
[Optional drawings that may or may not appear on finished label]







[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 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 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:]

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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]

TUBE / VIAL LABEL

Front Label Back Label

{Brand Name}

**For Dogs** [4-10][11-20] lbs >12 wks

Etofenprox 55.00%, Pyriproxyfen 2.20% 2.0 mL (**or**) 4.0 mL

0 mL (or) 4.0 mL {label code}

KEEP OUT OF REACH OF CHILDREN

CAUTION: Read directions and precautions before

using. Use scissors to open.

EPA REG. No. 2517-133 {label code}

**{END – TUBE/VIAL COPY}**