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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

7/12/2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Mr. James Messina Authorized Representative for Sergeant's Pet Care Products, Inc. Exponent 1150 Connecticut Avenue, NW Suite 1100 Washington, DC 20036

JUL 12 2011

Dear Mr. Messina,

Subject: Label Changes through Amendment and Notification Product Name: Etofenprox/Nylar Spot-on Flea and Tick for Dogs and Puppies EPA Reg. No. 2517-133 Submissions dated May 10, 2010 and February 11, 2011

The labeling above, submitted in accordance with the Federal Insecticide, Rodenticide and Fungicide Act, as amended, is acceptable provided you:

1. Remove claims referring to "kill" for mosquitoes as the submitted data do not support these claims. Revise the claims as follows:

a. [Five] [5] Way Protection! [Kills fleas, flea eggs, flea larvae and ticks.] [Repels mosquitoes.]

b. Five in one protection [Kills fleas, flea eggs, flea larvae, and ticks.] [Repels mosquitoes.]

c. Kills fleas, flea eggs, flea larvae, and ticks. Repels mosquitoes.

d. Change: "Kills mosquitoes" to "Repels mosquitoes' everywhere it appears on the label.

e. Remove [Kills [and] [&] Repels [mosquitoes] [within 24 hours]

f. Remove references to West Nile virus because dogs do not get this disease.

g. The remaining claims are acceptable provided they are modified where necessary as specified above.

2. Delete [Dogs can be bathed 24 hours after squeeze-on is applied.]

3. Retain the statement: "Some dogs may experience temporary startle effects when this product is applied."

4. Submit a study conducted with *Anopheles sp.* mosquitoes within 12 months. *Anopheles quadrimaculatus* is the preferred species. Consult EPA before initiating the study.

The alternate brand names appearing on the label are acceptable. A stamped copy of the label is enclosed for your records. Please contact Kevin Sweeney at (703) 305-5063 if you have questions or concerns.

(

rely, Riehard Gebken Product Manager ゝ Insecticide Branch Registration Division (7505P)

Enclosure

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

February 2011 Amendment Information in [] is optional.

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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]

## 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 [for [small [and toy] breed] 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 [small [and toy] breed] dogs]]
[ABN] Sentry®Pro XFT [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]
[ABN] Sentry®Pro XFC [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]
[ABN] Sentry®Pro XFC+ [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]
[ABN] SentryPro® XFTC [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]
[ABN] SentryPro® XFTC [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]
[ABN] SentryPro® XFTC [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]
[ABN] SentryPro® XFTC [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]
[ABN] SentryPro® XFTC [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]
[ABN] SentryPro® XFTC [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]
[ABN] SentryPro® XFTC [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]
[ABN] SentryPro® XFTC [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]



#### DO NOT USE ON CATS [Box/Icon with Cat Image and Cross-Out]

<ul> <li>[with Nylar®] [Pyriproxyfen]</li> <li>[[Toy] [and] [small] breed formula]</li> <li>[Gentle protection for [toy] [small] breed dogs]</li> <li>[For toy and small breeds [4-10 lbs][11-20 lbs]]</li> <li>[For toy breeds 4-10 lbs.] [For small breeds 11-20 lbs]</li> <li>[Specially Formulated for Dogs and Puppies (over 13 weeks old)]</li> <li>[Specially formulated for [toy breed[s]] [and] [small breed[s]] dogs]</li> <li>[For Dogs &amp; Puppies (Over 13 Weeks of Age) [4 to 10 lbs] [11 to 20 lbs]]</li> <li>[For use ONLY on Dogs [4-10 lbs][11-20 lbs]13 weeks of age or older]</li> <li>[Apply once every [4 weeks] [1 month] [30 days]!]</li> <li>[Up to [4 week] [1 Month] Dose!]</li> <li>[(ICON Showing up to 4 Week Protection)]</li> <li>[(One) (Two) (Three) (Four) (XX) Applications] [Bonus] 33% more [now includes 4 tubes]]</li> <li>[Three Applications {for cartons with 3 applicators}] and/or [3 Month Supply] or [12]</li> </ul>	with C In EFA Under the F Fungicide, ar as amended, registered ur 25	
[Best if used year round!] [Easy to Use Application]		
[[Free] [Brochure] [and] [Calendar] [Stickers] Inside!] [Patent pending technology]		( ( ( ( ( ( ( (
[Dogs can be bathed 24 hours after squeeze-on is applied.] [odorless] [unscented] [fragrance free] [Dries quickly] [Quick drying formula] [Quick Drying]	ιιιίι ι υ ι ι ι ι ι ι ι ι ι ι ι ι ι	ι ι ι ι ι ι ι ι ι ι ι
[Squeeze-On] [stays on and doesn't rub off] [Spreads by using the dog's natural skin oils] [with Vitamin E] [No oily residue]	ιιίι ι ί ιιί	
[With Vitanini E] [No only restate] [Formulated] [with] DERMAshield <sup>™</sup> [Technology] [DERMAshield <sup>™</sup> [Technology] [which] dries quickly to keep the product on the out contains [a vitamin] [vitamin E] to soothe skin]]	er skin surfa	( ( (

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# FRONT PANEL

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## 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 13 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, ticks and mosquitoes]] [Five in one protection [Kills fleas, flea eggs, flea larvae, ticks and 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, ticks, mosquitoes] [Kills Fleas Ticks] [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 [1]: Effectively Breaks the Flea Life Cycle [1]] [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]
 [Kills fleas for up to 4 weeks!]

 [Kills Adult Fleas for up to 4 weeks!]
 [Kills Adult Fleas for up to 4 weeks!]

 (Ticks)
 [Kills ticks [for up to [30 days] [4 weeks]]]

 [Kills Ticks] [that] [transmit Lyme Disease]
 [Kills Ticks]

 [Kills ticks
 [Kills ticks

 [Kills land] ticks including those that may transmit Lyme disease]
 [Kills [and] Ticks for Up to [4 weeks] [1 month] [30 days]!]

 [Kills Deer Ticks (vector of Lyme Disease) for up to 4 weeks]
 [Kills [and] deer ticks [before they can] [that] [transmit Lyme Disease,] [for up to [4 weeks] [1 month] [30

days]]]

[Kills [and] Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]

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## FRONT PANEL

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

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[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)

[Kills [and Repels] mosquitoes]

[[Kills [and] [&] [Repels] mosquitoes] [within 24 hours]

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

[Kills ([and] [&] repels) mosquitoes that may transmit heartworm]

[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]]

[Prevents mosquito blood feeding from mosquitoes which may transmit viruses such as West Nile Virus and 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 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 11 to 20 lbs]* 

Sergeant's Pet Care Products, Inc. Master Label

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**BACK PANEL** 

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**DOG SOUEEZE - ON** 

Pyriproxyfen (NYLAR), Etofenprox

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## {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 on dogs. [Some dogs may experience temporary startle effects when this product is applied.] If signs of sensitivity occur, bathe your dog with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately by calling 1-800-781-4738.

#### 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. If signs of sensitivity occur, bathe your dog with mild soap and rinse with large amounts of water.

#### {Outer Packaging}

How to open: Remove product tube[s] [vial] from the package. [Separate one tube from the others.] [Holding tue tube [vial] 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] 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 tuke fviul? and use the narrow end to part the animal's hair while gently squeezing to apply to the animal's skin. Held 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.

#### 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.

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BACK PANEL

**Pyriproxyfen (NYLAR), Etofenprox** Weighing 11 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. [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 pet
- Do NOT use Dog products on Cats
- Do NOT treat with more than one pesticide product at a time
- Separate animals after treatment to avoid chance of ingestion
- Do NOT split tubes between pets]

#### 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. Do not refrigerate. Protect from direct sunlight.

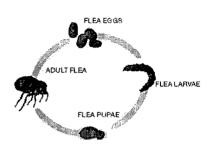
**PESTICIDE DISPOSAL AND CONTAINER HANDLING:** Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor 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 damáges. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the compurchase 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]<sup>(')</sup> Non-Emergency, call: 1-800-224-PETS (7387) [Made in USA]



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**DOG SOUEEZE – ON** 

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[Made in the USA For:] or [Manufactured by:] [Distributed by:]			
Sergeant's Pet Care Products, Inc.	EPA Reg. No. 2517-133		
P.O. Box 540399	EPA Est. No. XXXXX-XX-XX		
Omaha, NE 68154-0399	[lot, date & label code] [UPC CODE]		
{END - BACK / SIDE PANEL}			

TUBE / VIAL LABEL

Front Label		Back Label	
{Brand Name}[cat graphic with line through]		KEEP OUT OF REACH OF CHILDREN	
For dogs [up to X][X-Y] lbs		CAUTION: Read directions and precautions before	
Etofenprox 55.00% w/w, Pyriproxyfen 2.20% w/w		using. Use scissors to open.	
2.0 mL (or) 4.0 mL	{label code}	EPA REG. No. 2517-133	{label code}
{END – TUBE/VIAL COPY}			

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