

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

July 14, 2011

James B. Messina,
Principal Regulatory Consultant
(Authorized Agent for Sergeant's Pet Care Products, Inc.)
Exponent
Center for Chemical Regulation and Food Safety
1150 Connecticut Avenue, N.W.
Suite 1100
Washington, DC 20036

Subject: Add mosquito claims, update labeling per Agency's request in NOR, etc.

Cyphenothrin + Pyriproxyfen Squeeze-on for Dogs (20%) EPA Reg. No. 2517-129

Cyphenothrin + Pyriproxyfen Squeeze-on for Dogs (30%) EPA Reg. No. 2517-130

Applications dated February 11, 2011

Dear Mr. Messina:

The above referenced labeling, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the following comments:

Overall Review of Label Claims and Directions (Please see enclosed Agency's "Efficacy Reviews" dated July 1, 2011 for more details):

- Submitted data was adequate to support efficacy claims for repellence against *Culex*, and *Aedes*. The general mosquito claims are accepted conditionally, pending the registrant's submission of appropriate data to support claims for *Anopheles*.
- Kill claims for mosquitoes were not supported and must be removed or changed to "repel".
- There are a number of claims present on the label for repellence of fleas and/or ticks. No data has been submitted or cited to support these claims in this or previous applications (approval of such claims initially was an

oversight on the part of the Agency). Thus, unless the registrant submits or cites data demonstrating repellence (i.e., 90% or greater prevention of animal attachment and feeding by fleas or ticks) for these species, all claims related to repellence for fleas and ticks must be removed.

Please note that we have approved the amended labeling for this products with the understanding that the labels are consistent with the Agency's previously stamped accepted ones; and other than the revisions stated in your applications (dated February 11, 2011), no other changes have been made to the labeling and/or the Confidential Statement of Formula (CSF).

See enclosed copy of the stamped label for your record. If you have any questions concerning this action please contact Dr. B.A. Akinlosotu at (703) 605-0653.

Sincerely

Richard Gebken,

Product Manager 10

Insecticide Branch

Registration Division (7505P)

Sergeant's Master Label

February 2011 Amendment Information in [] is optional.

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EPA No. 2517-129 EPA SAL 30 April 2010

FRONT PANEL

DOG SQUEEZE ON

Cyphenothrin & Pyriproxyfen

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

Cyphenothrin+Pyriproxyfen Squeeze-On for Dogs (20%)

[ABN][Sergeant's [Plus] [Flea and Tick] Squeeze-On for Dogs [and Puppies Over 12 Weeks Old]]

[ABN][Sergeant's Gold® [Plus] [Flea and Tick] Squeeze-On for Dogs [and Puppies Over 12 Weeks Old]]

[ABN][SentryPro XFC [Flea and Tick] Squeeze-On for Dogs [and Puppies Over 12 Weeks Old]]

[ABN][Sergeant's Evolve [11] [21] [40] Flea and Tick Squeeze-On for Dogs]

[ABN][Sentry®Pro XTR [11] [21] [40] Flea and Tick Squeeze-On for Dogs]

[ABN][Sentry®Pro XFT [11] [21] [40] Flea and Tick Squeeze-On for Dogs]

[ABN][Sentry®Pro XFTC [11] [21] [40] Flea and Tick Squeeze-On for Dogs]

[ABN][Sentry®Pro XFC+ [11] [21] [40] Flea and Tick Squeeze-On for Dogs]



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

[Specially Formulated for Dogs and Puppies (over 12 weeks old)]

[Flea & Tick Control for Dogs & Puppies 12 weeks old and older]

[For Dogs & Puppies (Over 12 Weeks of Age) [greater than 9 lbs] [9 to 20 lbs] [21 to 39 lbs] [40 to 60 lbs]]

[For Dogs [more than 9 lbs] or [9 lbs to 20 lbs] or [21 lbs to 39 lbs] or [40 lbs to 60 lbs]

[For use ONLY on Dogs [greater than 9 lbs] [9 - 20 lbs] [21 - 39 lbs] [40 - 60 lbs] 12 weeks of age or older]

[[12][15][18][21][24][32][52] Week Supply For Dogs weighing [more than 9 lbs], [9 to 20 lbs], [21 to 39 lbs], [40 to 60 lbs]]

[Apply once every [4 weeks] [1 month] [30 days]!]

[Up to [4 week] [1 Month] Dose!]

[(ICON Showing up to 4 Week Protection)]

[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] [U.S. and Foreign patent pending technology]

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

[Quick Drying] [formula]

[with Vitamin E] [No oily residue]

[Fragrance Free]

[Formulated] [with] DERMAshieldTM [Technology]

[DERMAshieldTM [Technology] [which] dries quickly to keep the product on the outer skin surfaces] [and

contains [a vitamin] [vitamin E] to soothe skin]]

(Multiple species)

[[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, [mosquitoes,] flea eggs, and flea larvae]

[Kills fleas, flea eggs, flea larvae, ticks, mosquitoes]

[Kills fleas [in as little as 1 hour], [and] [ticks] [in as little as 3 hours], [mosquitoes] [flea eggs & flea lar vae]

[Kills [and Repels] Fleas [in as little as 1 hour] Ticks [in as little as 3 hours]]

[Kills Fleas, Ticks, [Mosquitoes] 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!]]

ACCEPTED

With COMMENTS

In EPA Letter Dated:

Under the Federal Insecticide, Fungicide

and Rodenticide Act, As amended, for the

pesticide Registered under EPA Reg. No:

2517-17-9

JUL 1 4 2011

sergeant's Master Label

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[Kills & Repels [Adult] Fleas and Ticks for up to 4 weeks!]

FRONT PANEL

DOG SQUEEZE ON Cyphenothrin & Pyriproxyfen

(Flea and Flea eggs and Larval)

[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 [!]: Cyphenothrin with [Nylar®] [Pyriproxyfen] IGR Effectively Breaks the Flea Life Cycle]

[Prevents Flea Eggs From Developing Into Biting Adults]

[[Breaks Flea Life Cycle!] for up to 9 weeks]

[Controls reinfestation for up to 9 weeks!]

[Kills Flea Eggs & Flea Larvae for up to [63 days], [9 weeks]!]

[Kills for up to [9 weeks] [63 days] [flea eggs][flea larvae]]

[Kills [& Repels] fleas in as little as 1 hour!]

[Kills & Repels Fleas for up to 4 weeks!]

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

(Ticks)

[Kills and Detaches Ticks]

[Kills [& Repels] ticks in as little as 3 hours!]

[Prevents ticks from attaching and feeding in as little as [3 hours] after application]

[Kills [and] [&] [repels] ticks including those that may transmit Lyme disease]

[Kills [and] [&] [repels] Ticks for Up to [4 weeks] [1 month] [30 days]!]

[Kills & Repels Deer Ticks (vector of Lyme Disease) for up to 4 weeks]

[Kills [and] [&] [repels] deer ticks [before they can] [that] [transmit Lyme Disease,] [for up to [4 weeks] [1 month] [30 days]]]

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

[Kills [and] [&] [repels] [brown dog ticks] [(Rhipicephalus sanguineus)] [for up to [4 weeks] [1 month] [30 days]]]

[Kills [&] [and] [Repels] 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 [30 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 mosquitoes from blood feeding, which may transmit viruses such as West Nile Virus and heartworm to dogs for up to four weeks.

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FRONT PANEL

DOG SQUEEZE ON

Cyphenothrin & Pyriproxyfen

ACTIVE INGREDIENTS:

 Cyphenothrin (CAS# 39515-40-7)
 20.00%

 Pyriproxyfen (CAS# 95737-68-1)
 2.00%

 OTHER INGREDIENTS*:
 78.00%

 [TOTAL
 100.00%]

*(Diethylene glycol monoethyl ether, [vitamin E nicotinate])

[Nylar® is a registered trademark of McLaughlin Gormley King Company. U.S. Patent No. 5,942,525]

KEEP OUT OF REACH OF CHILDREN CAUTION

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

NET [WEIGHT] [CONTENTS]

XXX fl oz (XXX mL)

[THREE][FOUR][SIX][TWELVE] (0.05 fl oz) 1.5 mL Tubes [THREE][FOUR][SIX][TWELVE] (0.10 fl oz) 3.0 mL Tubes [THREE][FOUR][SIX][TWELVE] (0.15 fl oz) 4.5 mL Tubes



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BACK PANEL

DOG SQUEEZE ON Cyphenothrin & Pyriproxyfen

[Apply Once Every Month] [Can be applied monthly [if needed]]

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS AND PUPPIES OVER 12 WEEKS OF AGE. DO NOT USE ON CATS

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Harmful if swallowed or absorbed through skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for further treatment advice. Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Have person sip a glass of water if able to do so. Do not give anything by mouth to an unconscious person. 		FIRST AID
 Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. IF Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Have person sip a glass of water if able to do so. Do not give anything by mouth to an unconscious person. 	IF IN EYES	• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
 Do not induce vomiting unless told to do so by a poison control center or doctor. Have person sip a glass of water if able to do so. Do not give anything by mouth to an unconscious person. 	OR	Rinse skin immediately with plenty of water for 15-20 minutes.
HOT LINE NUMBER		 Do not induce vomiting unless told to do so by a poison control center or doctor. Have person sip a glass of water if able to do so. Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going for	***	

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-781-4738.

NOTE TO PHYSICIAN OR VETERINARIAN

Treat patient symptomatically

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON CATS. May be toxic and potentially fatal if applied to or ingested by cats. FOR EXTERNAL USE ON DOGS ONLY. Do not use on puppies under 12 weeks of age. [Do not split one tube between [dogs].] [Do not use multiple tubes on one [dog].] Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. 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. [Best if used year round]. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant, or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. 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 and dogs that actively groom or engage in close physical contact with treated dog may be at risk of serious harmful effects. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur immediately feed your dog and continue to monitor your pet for the next 24 hours. If symptoms persist call 1-800-781-4738 to talk to a veterinarian. Cats exhibiting these rame symptoms from ingestion should be taken to the veterinarian immediately. 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. [Some dogs máy experience temporary startle effects when any product is applied.] Sensitivities may occur after using ANY pesticide product on degs. If signs of sensitivity occur bathe your dog with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately by calling 1-800-781-4738.

{Outer Packaging}

How to open: Remove product tube[s] [vial] from the package. [Separate one tube from the others.] [Holding the 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.]

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BACK PANEL

DOG SQUEEZE ON

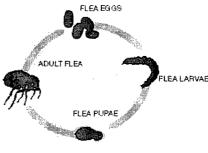
Cyphenothrin & Pyriproxyfen

How to apply: Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin, as directed below. Repeat application may be made if necessary, but do not apply more often than once every 4 weeks.

[Optional drawings that may

or may not appear on finished label]







Frequency of Application:

[When used monthly, {product name} breaks the flea life cycle and controls flea and tick infestations.]

For Dogs Weighing Between 9 and 20 lbs

{For cartons containing one 1.5 mL (0.05 fl oz) applicator tubes}

Apply one tube (1.5 mL)(0.05 fl oz) [as a spot to the dog's back between the shoulder blades] or [from the back of the neck to a point midway between the neck and tail].

For Dogs Weighing Between 21 and 39 lbs

{For cartons containing two 1.5 mL (0.05 fl oz) applicator tubes}

[Apply two tubes (1.5 mL)(0.05 fl oz) as a spot on the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

OR

{For cartons containing one 3.0 mL (0.10 fl oz) applicator tube}

[Apply one tube (3.0 mL)(0.10 fl oz) as a spot or stripe to the dog's back between the shoulder blades.] or [from the back of the neck to a point midway between the neck and tail.]

For Dogs Weighing Between 40 and 60 lbs

{For cartons containing three 1.5 mL (0.05 fl oz) applicator tubes}

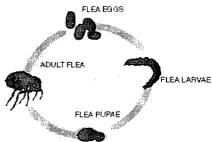
[Apply two tubes (1.5 mL)(0.05 fl oz) as a spot or stripe to the dog's back between the shoulder blades and apply the third tube from the back of the neck to a point midway between the neck and tail].

{For cartons containing one 4.5 mL (0.15 fl oz) applicator tube}

[Apply one tube (4.5 mL)(0.15 fl oz) from the back of the neck to a point midway between the neck and tail]. (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]



Sergeant's Master Label

February 2011 Amendment Information in [] is optional.

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BACK PANEL SQUEEZE ON

DOG

Cyphenothrin & Pyriproxyfen

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove tube 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.

[Sergeant's Squeeze-On Flea & Tick Control with [[Nylar®] [Pyriproxyfen] Insect Growth Regulator] is an effective and easy to use product.] [Sergeant's Squeeze-On Flea & Tick Control with [Nylar® Insect Growth Regulator] prevents eggs from fleas on treated dogs from developing into biting adults for up to 63 days] [9 weeks]. [As with all flea and tick control products, [Sergeant's Squeeze-On Flea and Tick Control] [with] [[Nylar®] [Pyriproxyfen] Insect Growth Regulator] should be used as part of a program aimed at reducing flea populations in the dog's environment (bedding, carpets, kennel, yard).] [Consult your retailer for program recommendations.]

[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:] or [Manufactured by:] [Distributed by:]

Sergeant's Pet Care Products, Inc.

EPA Reg. No. 2517-129

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]
For dogs [up to X] [X-Y] lbs
Cyphenothrin 20.00% w/w, Pyriproxyfen 2.00% w/w
1.5 mL (or) 3.0 mL (or) 4.5 mL {label code}

KEEP OUT OF REACH OF CHILDREN.

CAUTION: Read directions and precautions before using. Use scissors to open.

EPA REG. No. 2517-129 {label code}

{END - TUBE/VIAL COPY}