



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):

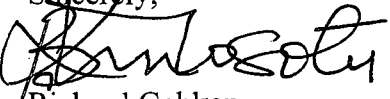
- Submitted data was adequate to support efficacy claims for repellence against *Culex*, and *Aedes*. The general mosquito claims are accepted conditionally, pending the registrant's submission of appropriate data to support claims for *Anopheles*.
- Kill claims for mosquitoes were not supported and 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,

for 

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. 2517-130
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 (30%)

- [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 [61] [+] Flea and Tick Squeeze-On for Dogs]
- [ABN][Sentry®Pro XTR [61] [+] Flea and Tick Squeeze-On for Dogs]
- [ABN][Sentry®Pro XFT [61] [+] Flea and Tick Squeeze-On for Dogs]
- [ABN][Sentry®Pro XFTC [61] [+] Flea and Tick Squeeze-On for Dogs]
- [ABN][Sentry®Pro XFC+ [61] [+] 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) [61 lbs and over] [more than 61 lbs]]
- [For Dogs [61 lbs and over] [more than 61 lbs]]
- [For use ONLY on Dogs [61 lbs and over] [more than 61 lbs] 12 weeks of age or older]
- [[12][15][18][21][24][32][52] Week Supply For Dogs weighing [[61 lbs and over] [more than 61 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] [Fragrance Free]
- [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]]

ACCEPTED
With COMMENTS
In EPA Letter Dated:
JUL 14 2011
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:
2517-130

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

Sergeant's Master Label

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FRONT PANEL

DOG SQUEEZE ON
Cyphenothrin & Pyriproxyfen

ACTIVE INGREDIENTS:

Cyphenothrin (CAS# 39515-40-7)	30.00%
Pyriproxyfen (CAS# 95737-68-1)	2.00%

OTHER INGREDIENTS*:	68.00%
[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]

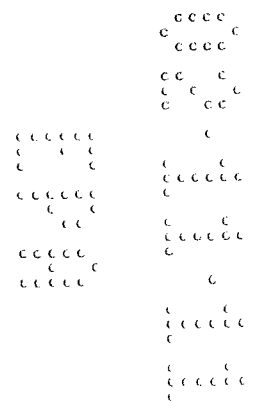
KEEP OUT OF REACH OF CHILDREN

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] (0.20 fl oz) 6.0 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.

FIRST AID	
IF IN EYES	<ul style="list-style-type: none"> • 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.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • 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.
IF SWALLOWED	<ul style="list-style-type: none"> • 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.
HOT LINE NUMBER	
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 same 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 may experience temporary startle effects when any product is applied.] Sensitivities may occur after using ANY pesticide product on dogs. 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.]

Sergeant's Master Label

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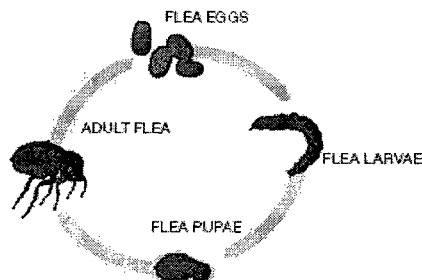
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BACK PANEL

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 61 lbs and Over:

{For cartons containing four 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 contents of the other two tubes (1.5 mL) (0.05 fl oz) from the back of the neck to a point midway between the neck and tail.]

OR

{For cartons containing two 3.0 mL (0.10 fl oz) applicator tubes}

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

OR

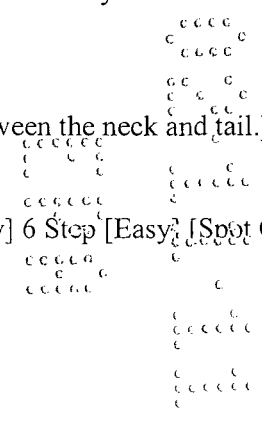
{For cartons containing one 6.0 mL (0.20 fl oz) applicator tubes}

[Apply one tube (6.0 mL)(0.20 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]



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Sergeant's Master Label

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BACK PANEL

DOG SQUEEZE ON 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. 2517-130
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

<p>{Brand Name}{cat graphic with line through} For dogs [up to X][X-Y] lbs Cyphenothrin 30.00% w/w, Pyriproxyfen 2.00% w/w 1.5 mL (or) 3.0 mL (or) 6.0 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. 2517-130 {label code}</p>
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{END - TUBE/VIAL COPY}