

2517-80

09/25/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Sergeant's Pet Care Products
c/o Ms. Karen Warkentien
Lewis & Harrison
122 C Street, N.W., Suite 740
Washington, DC 20001

SEP 25 2008

Dear Ms. Warkentien:

Subject: Amendment – Update Storage & Disposal per PRN 2007-4 and
Revise per Efficacy review dated December 5, 2007

Sergeant's Cyphenothrin + IGR Squeeze-On for Dogs

EPA Reg. No. 2517-80

Your submission dated July 3, 2008

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(a), is acceptable provided that you:

1. Submit and/or cite all data or other material required for registration/reregistration of your product under FIFRA section 3(c)(5) or FIFRA section 4 when the Agency requires all registrants of similar products to submit such data.
2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
 - a. On the front panel claims, revise "Dogs can be bathed 24 hours after squeeze-on is applied" to read "Dogs can be bathed 24 hours after squeeze-on is applied".
 - b. In the Frequency of Application text, replace "[product brand name]" with the actual name of the product. The Agency notes that this "optional" text is the only label reference to the 4 week retreatment interval required for mosquito control. If this "optional" text section is not placed on the label, then text should be added somewhere on the label to clarify the one-month retreatment interval required for mosquito control.

A stamped copy of the label is enclosed for your records. Please forward to the Agency three copies of labeling bearing the above revisions, prior to release for shipment under the amended label.

Sincerely,

George LaRocca.
Product Manager 13
Insecticide Branch
Registration Division (7505P)

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Sergeant's Master Label

3 July 2008 Amend container language and incorporate 8 wk residual comments
Information in [] is optional. Page 1 of 6

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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]

Sergeant's Cyphenothrin+IGR Squeeze-On for Dogs

[(ABN) Sergeant's Gold Flea and Tick Squeeze-On for Dogs]

[(ABN) Sergeant's Gold Squeeze-On for Dogs]

[(ABN) SentryPro XFC [Extreme Flea Control] Squeeze-On for Dogs]

[(ABN) SentryPro XFC [Extreme Flea Control] Flea and Tick Squeeze-On for Dogs]



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

- [[Five] [5] Way Protection [Kills fleas, ticks, mosquitoes, flea eggs & flea larvae]]
- [Five Way Protection! Kills ticks, mosquitoes fleas, flea eggs & flea larvae]
- [5 Way Protection! Kills ticks, mosquitoes, fleas, flea eggs & flea larvae]

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

SEP 25 2008

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.**

2517-80

- [Specially Formulated for Dogs and Puppies]
- [Flea & Tick Control for Dogs & Puppies 12 weeks old and older]
- [For Dogs & Puppies (Over 12 Weeks of Age) and greater than 9 lbs]
- [For Dogs & Puppies (Over 12 Weeks of Age) 9 to 20 lbs]
- [For Dogs & Puppies (Over 12 Weeks of Age) 21 to 39 lbs]
- [For Dogs & Puppies (Over 12 Weeks of Age) 40 to 60 lbs]
- [For Dogs & Puppies (Over 12 Weeks of Age) 61 lbs and Over]
- [For Dogs [more than 9 lbs] or [9 lbs to 20 lbs] or [21 lbs to 39 lbs] or [40 lbs to 60 lbs] or [61 lbs and Over]]
- [[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] [61 lbs and over]
- [Apply once every [4 weeks] [month]!]
- [Up to [4 week] [5 week] [6week] [7 week] [8 week] Dose!]
- [Up to [1 Month Dose!] [2 month Dose!]]
- [(ICON Showing up to [4] [5] [6] [7] [8] 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] Calendar Stickers Inside!]
- [[Free] Brochure Inside!]
- [[Free] Brochure and Calendar Stickers Inside]
- [Patented Technology] [Patent pending technology]
- [Dogs can be bathed 24 hours after squeeze-on is applied.]

Sergeant's Master Label

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3 July 2008 Amend container language and incorporate 8 wk residual comments
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FRONT PANEL

DOG SQUEEZE ON Cyphenothrin & Pyriproxyfen

(Multiple species)

- [Kills all stages of the flea life cycle]
- [Kills fleas, ticks, mosquitoes, flea eggs, and flea larvae]
- [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] [Mosquitoes]
- [Kills Fleas, Ticks, Flea Eggs & Flea Larvae for up to [4 Weeks] [1 month]]
- [Works for up to [4][5][6][7] Weeks on fleas and ticks!]
- [Works for up to 8 Weeks on adult fleas and ticks!]
- [Protects for up to [4][5][6][7] Weeks on fleas and ticks!]
- [Protects for up to 8 Weeks on adult fleas and ticks!]
- [Up to [4] [5] [6] [7] Week Flea and Tick Treatment!]
- [Up to 8 Week Adult Flea and Tick Treatment!]
- [Up to [4] [5] [6] [7] Week Flea and Tick Control]
- [Up to 8 Week Adult Flea and Tick Control]
- [Up to [4] [5] [6] [7] Week Flea and Tick Protection!]
- [Up to 8 Week Adult Flea and Tick Protection!]
- [Up to [One] [Two] Month Flea and Tick Treatment]
- [Kills & Repels Fleas and Ticks for up to [4] [5] [6] [7] weeks!]
- [Kills & Repels Adult Fleas and Ticks for up to [8] weeks!]

(Flea and Flea eggs and Larval)

- [With Nylar® to Break Flea Life Cycle]
- [With Insect Growth Regulator to Break Flea Life Cycle]
- [With Nylar® Insect Growth Regulator which Breaks the Flea Life Cycle]
- [Dual Action [!]: Effectively Breaks the Flea Life Cycle [!]]
- [Dual Action [!]: Cyphenothrin with Nylar® 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] [5] [6] [7] weeks!]
- [Kills & Repels Adult Fleas for up to [8] weeks!]

(Ticks)

- [Kills and Detaches Ticks]
- [Prevents ticks from attaching and feeding in as little as [3 hours] after application]
- [Kills [& Repels] ticks in as little as 3 hours!]
- [Kills & Repels Ticks for up to [4] [5] [6] [7] [8] weeks!]
- [Kills & Repels Ticks (Including Deer Ticks) for up to 4 weeks]
- [Kills & Repels Deer Ticks (vector of Lyme Disease) for up to [4] [5] [6] [7] [8] weeks]
- [Kills & Repels Brown Dog Ticks [(*Rhipicephalus sanguineus*)] for up to [4] [5] [6] [7] [8] weeks!]
- [Kills & Repels American Dog Ticks [(*Dermacentor variabilis*)] for up to [4] [5] [6] [7] [8] weeks!]

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Sergeant's Master Label

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FRONT PANEL

**DOG SQUEEZE ON
Cyphenothrin & Pyriproxyfen**

(Mosquitoes)

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

***Note: Underscored Claims To Be Based on New as well as Existing Product Performance (Efficacy) Data**

{Ingredient Statement may be on front or back label}

ACTIVE INGREDIENTS:

Cyphenothrin (CAS# 39515-40-7)	40.00%
Pyriproxyfen (CAS# 95737-68-1)	2.00%

OTHER INGREDIENTS:58.00%

[TOTAL] 100.00%

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

[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.

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. 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. Cats that actively groom or engage in close physical contact with treated dogs may be at risk of serious harmful effects. Sensitivities may occur after using ANY pesticide product on pets. 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.

How to apply: Remove product tube from package. Holding tube with top end pointing up and away from face and body, [snap or] cut off top end. 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.

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BACK PANEL

DOG SQUEEZE ON Cyphenothrin & Pyriproxyfen

[Frequency of Application:

When used monthly, product breaks the flea life cycle and controls flea, tick and mosquito infestations. Research demonstrates that [product brand name] kills adult fleas and ticks for up to 8 weeks, also prevents development of flea egg and larval stages for up to nine weeks. A once monthly application is recommended where mosquito control is needed.]

(INSERT DIAGRAM THAT DEPICTS APPLICATION OF PRODUCT ON THE DOG)

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].

OR

{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].

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 3.0mL (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.]

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 25°C) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

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BACK PANEL

DOG SQUEEZE ON Cyphenothrin & Pyriproxyfen

DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling or reconditioning, if available and appropriate.

If empty: Do not reuse this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain

[Sergeant's Squeeze-On Flea & Tick Control with [Nylar® 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® 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 Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

In Case of Emergency, call: 1-800-781-4738 [For more information] [Visit us at:] [www.sergeants.com]
Non-Emergency call 1-800-224-PETS (7387) [Made in USA]

[Satisfaction Guaranteed!] [Please return for a refund if not completely satisfied!]

[Made in the USA For:] or [Manufactured by:]

[Distributed by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68130

EPA Reg. No. 2517-80
EPA Est. No. XXXXX-XX-XX
[lot, date & label code] [UPC CODE]

{END - BACK / SIDE PANEL}

TUBE / VIAL LABEL

Front Label

{Product Name}
[Box/Icon with Cat Image & Cross-Out],
Cyphenothrin 40.0% W/W, Pyriproxyfen 2.0% W/W
1.5 mL (or) 3.0 mL (or) 4.5 mL (or) 6.0 mL {label code}

Back Label

KEEP OUT OF REACH OF CHILDREN
CAUTION: Read directions and precautions before using.
EPA REG. No. 2517-80 {label code}