

2517-80

9/22/2009

10/8



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 22, 2009

Mr. Kelly R. Hoskins,
Manager of Technical Affairs
Sergeant's Pet Products, Inc.
2625 South 158th Plaza
Omaha, NE 68130-1770

Subject: Amended Labeling, Response to EPA Letter Dated September 24, 2008, New Label Claims and Revised Directions for Use Sergeant's® Cyphenothrin + IGR Squeeze-On for Dogs, EPA Reg. No. 2517-80 Your Submission Dated September 16, 2009

Dear Mr. Hoskins:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with the following label revision provision(s):

General Comment:

- 1. Delete all text throughout the label marked with "strikethrough."

New Labeling Claims section comment(s):

- 2. Delete new labeling claims #1 and #10, since they are comparative statements and insinuate heightened efficacy.
- 3. Clarify what "[Formulated] [with] DERMAsield™ [Technology]" specifically means or delete new labeling claim #8, since it is considered misleading to the consumer.

Precautionary Statements section, Hazards to Humans subsection comment(s):

- 4. Revise the 4th sentence in this subsection to read: "Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet."

Storage and Disposal section comment(s):

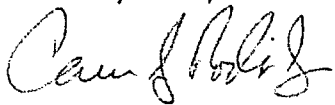
- 5. Replace "PESTICIDE DISPOSAL:" subsection with: "CONTAINER DISPOSAL: If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain."

A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

2 of 8

If you have any questions about this label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely Yours,

For 

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments"
002517-00080 D420319

3078

Sergeant's Master Label

20 August 2009 Amendment
Information in [] is optional.

Page 1 of 6

EPA No. 2517-80
EPA SAL 25 September 2008

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]
- [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.]

ACCEPTED
With COMMENTS
 In EPA Letter Dated:
September 22, 2009
 Under the Federal Insecticide, Fungicide
 and Rodenticide Act, As amended, for the
 pesticide Registered under EPA Reg. No:
2517-80

4098

Sergeant's Master Label

20 August 2009 Amendment
Information in [] is optional.

Page 2 of 6

EPA No. 2517-80
EPA SAL 25 September 2008

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!]
- ~~[New and Improved] [formula]~~
- [for dogs with Sensitive Skin]
- [with] [Skin Protection Technology]
- [Quick Drying] [formula]
- [with Vitamin E]
- [No oily residue]
- [Fragrance Free]
- [Formulated] [with] DERMAsield™ [Technology]
- [A skin soothing formula]
- ~~[Ultimate post fighting power in a new formula]~~
- [Controls reinfestation for 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!]

50f8

Sergeant's Master Label

20 August 2009 Amendment
Information in [] is optional.

Page 3 of 6

EPA No. 2517-80
EPA SAL 25 September 2008

FRONT PANEL

DOG SQUEEZE ON
Cyphenothrin & Pyriproxyfen

(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!]

(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

6088

Sergeant's Master Label

20 August 2009 Amendment
Information in [] is optional.

Page 4 of 6

EPA No. 2517-80
EPA SAL 25 September 2008

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. 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. 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.

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 by calling 1-800-781-4738.

7098

Sergeant's Master Label

20 August 2009 Amendment
Information in [] is optional.

Page 5 of 6

EPA No. 2517-80
EPA SAL 25 September 2008

BACK PANEL

DOG SQUEEZE ON
Cyphenothrin & Pyriproxyfen

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.

Frequency of Application:

[When used monthly, {product name} breaks the flea life cycle and controls flea, tick and mosquito infestations.] [Research demonstrates that {product name} kills adult fleas and ticks for up to 8 weeks, also prevents development of flea egg and larval states 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.]

8098

Sergeant's Master Label

20 August 2009 Amendment
Information in [] is optional.

Page 6 of 6

EPA No. 2517-80
EPA SAL 25 September 2008

BACK-PANEL

DOG SQUEEZE-ON
Cyphenothrin & Pyriproxyfen

STORAGE AND DISPOSAL

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

PESTICIDE 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.

PESTICIDE 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 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]

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

[Distributed by:]

Sergeant's Pet Care Products, Inc.

PO Box 540399

Omaha, NE 68154-0399

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

Back 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}

KEEP OUT OF REACH OF CHILDREN

CAUTION: Read directions and precautions before using.

EPA REG. No. 2517-80

{label code}