

2517-140

08-03-2011

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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

AUG - 3 2011

Sergeant's Pet Care Products, Inc.  
c/o Mr. James Messina, Exponent, Inc.  
1150 Connecticut Avenue, NW  
Washington, DC 20036

Subject: Amendment to Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs  
To change Signal Word and Precautionary Statements  
EPA Reg. No. 2517-140  
Submission dated March 9, 2011  
Decision No: 446380

Dear Mr. Messina:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable *subject to the comment below*. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment.

- Per the Acute Toxicity review, dated June 28, 2011, the request to reclassify this product as a dermal sensitizer is denied. Therefore, the following statement must be reinstated on page 4 in the Hazards to Humans section:

"Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."

Please be reminded that this product is still subject to the terms outlined in the Notice of Registration dated January 13, 2011, and that this amendment does not address or fulfill any of those requirements. A stamped copy of the label is enclosed for your records. If you have any questions regarding this action, please contact Rosanna Louie-Juzwiak at (703) 308-0037.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

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

Enclosure: Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs, Stamped *Accepted with Comments*

# Sergeant's® Master Label

13 January 2011  
Information in [ ] is optional.

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EPA SAL

## FRONT PANEL

## DOG SQUEEZE ON FIPRONIL+CYPHENOTHHRIN

[Optional text appears in brackets – the final product label may include some or all of the optional text on front, back or side label panels. **The CRP required text will not change.**]

### Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs

#### [ABNs]

[(Sergeant's®) (Sentry®) EctoAdvance™ (Spot On) for dogs]  
[(Sergeant's®) (Sentry®) FiproGuard™ (Spot On) for dogs]

[Apply to puppies over 12 weeks old]  
[Apply to puppies 12 weeks or older]



#### [Mosquitoes]

[[Kills mosquitoes] [within 24 hours for up to the first 7 days after application, and within 48 hours for up to 28 days]  
[Kills mosquitoes]

#### [Fleas]

[[Kills adult fleas (starts killing in as little as 1 hour) [for up to 3 months]]  
[Kills newly emerged adult fleas (starts killing in as little as 1 hour) before they lay eggs]  
[Kills fleas, which may be a source of flea allergy dermatitis] [or flea bite anemia]]  
[Kills fleas (starts killing in as little as 1 hour)]  
[Kills fleas (starts killing in as little as 1 hour) Up to [4 weeks] [1 month] [30 days]!]  
[If dog is at high risk of flea reinfestation, apply once a month]

ACCEPTED  
with COMMENTS  
In EPA Letter Dated:  
AUG - 3 2011

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 2517-140

#### [Multiple Infestations]

[Kills chewing lice and controls mites that may cause sarcoptic mange]  
[Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 12 weeks old [&] [and] older]  
[Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], [and] Chewing lice [&] [and] [Mosquitoes]]  
[Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], [and] kills Mosquitoes], [and kills chewing lice]]  
[Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], and kills chewing lice & mosquitoes]  
[Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], mosquitoes, and chewing lice]]  
[Monthly flea, tick, mosquito, and chewing lice application]  
[[4 Week] [1 month] [30 day] [Flea and Tick Application]  
[[Four (4) Week] [1 month] [30 day] [Flea, Tick, Mosquito and Chewing Lice Application]  
[Kills Fleas (starts killing in as little as 1 hour) and Ticks (starts killing in as little as 1 hour) for up to [4 weeks] [1 month] [30 days]!]  
[Once A Month Flea and Tick Application]  
[Use [brand name] monthly to control Ticks (starts killing in as little as 1 hour) and chewing lice]

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**FRONT PANEL**

**DOG SQUEEZE ON  
FIPRONIL+CYPHENOTHRIIN**

[Monthly flea, tick, mosquito, and chewing lice protection.]  
[Starts killing fleas and ticks in as little as 1 hour] [and continues to kill for a month]  
[Flea & Tick Control for Dogs & Puppies 12 weeks old and older]

## [Ticks]

[Kills Ticks (starts killing in as little as 1 hour) including those that may transmit Lyme disease]  
[Kills ticks (starts killing in as little as 1 hour) for Up to [4 weeks] [1 month] [30 days]:]  
[Kills] Deer Ticks [that may transmit Lyme Disease,] for up to [4 weeks] [1 month] [30 days]  
[Kills Ticks (starts killing in as little as 1 hour)]  
[Kills Deer Ticks for up to [4 weeks] [1 month] [30 days]]  
[Kills [Brown Dog Ticks] [(*Rhipicephalus sanguineus*)], [American Dog Ticks,] [and Lone Star Ticks] (in as little as 1 hour) [and deer ticks] for up to [4 weeks] [1 month] [30 days]]  
[Kills [Brown Dog Ticks], [(*Rhipicephalus sanguineus*)] (starts killing in as little as 1 hour) for up to [4 weeks] [1 month] [30 days]]  
[Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]  
[Prevents and controls reinfestation of listed pests for [30 days][1 month]]  
[Kills ticks that may transmit Lyme disease, Rocky Mountain Spotted fever, ehrlichiosis, babesiosis, and anaplasmosis]

## [All Others]

[For Dogs and Puppies 12 weeks of age or older]  
[Controls mites that may cause sarcoptic mange]  
[For Dogs [up to 22 lbs], [23-44 lbs], [45-88 lbs], [89-132 lbs]]  
[Fast Acting] [Long Lasting]  
[Remains effective, even after bathing, water immersion, or exposure to sunlight]  
[Easy to Use [Application]]  
[Rapidly eliminates infestations of chewing lice]  
[Three Applications] and/or [3 Month Supply] or [12 Week Supply]  
[Best if used year round!]  
[(ICON Showing [4 week] [1 month] [30 day] Protection)]  
[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]  
[Specially Formulated for Dogs and Puppies 12 weeks of age or older]  
[[Free] Calendar Stickers Inside!]  
[Monthly application reminder card inside]  
[Apply once every [4 weeks] [month] [30 days]!]  
[Waterproof]  
[Can be used on puppies 12 weeks of age and older]  
[[Convenient spot application][Convenient][to use]]

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**FRONT PANEL**

**DOG SQUEEZE ON  
FIPRONIL+CYPHENOTHRIN**

[Fipronil (9.8%) + Cyphenothrin (5.2%)]  
[Lift [here] for more information]  
[For year-round protection, apply [**Brand name**] monthly]

[[Free with purchase] [Free inside] Monthly Application Reminder [Magnet]][inside]]  
[Patent(s) Pending]

[[3] Applications]  
[For use ONLY on dogs]  
    [Up to 22 lbs]  
    [23-44 lbs]  
    [45-88 lbs]  
    [89-132 lbs]  
    [over 12 weeks of age]

**[For Dogs & Puppies 12 weeks or older] [and] [up to] 22 lbs.]**  
**[For Dogs 23-44 lbs.]**  
**[For Dogs 45-88 lbs.]**  
**[For Dogs 89-132 lbs.]**

**ACTIVE INGREDIENTS:**

Fipronil .....	9.80%
Cyphenothrin .....	5.2%
<b>OTHER INGREDIENTS[*]: .....</b>	<b>85.0%</b>
<b>TOTAL</b>	<b>100.00%</b>

[\*Diethylene glycol monoethyl ether, Vitamin E nicotinate]

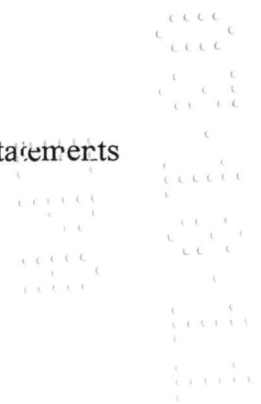
**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

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

**NET CONTENTS:**  
    [3] [three] 0.023 fl oz (0.67 mL) applicators  
    [3] [three] 0.045 fl oz (1.34 mL) applicators  
    [3] [three] 0.091 fl oz (2.68 mL) applicators  
    [3] [three] 0.136 fl oz (4.02 mL) applicators

**{END - FRONT PANEL}**



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**BACK PANEL**

**DOG SQUEEZE ON  
FIPRONIL+CYPHENOTHRIN**

[[**Brand name**] contains Fipronil and Cyphenothrin to effectively kill Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)] [(including those that may transmit Lyme Disease)], and kills mosquitoes and chewing lice. [The active ingredients in [**brand name**] feature a sustained release formula developed for fast acting [and long lasting] control of fleas, ticks mosquitoes and chewing lice for up to 30 days on dogs.]



### READ ENTIRE LABEL BEFORE EACH USE.

### USE ONLY ON DOGS AND PUPPIES OVER 12 WEEKS OF AGE.

[[**Brand name**] for dogs provides four way protection that kills fleas, ticks, mosquitoes and chewing lice. Controls mites that may cause sarcoptic mange. Kills deer ticks that transmit Lyme disease. Kills brown dog ticks, American dog ticks, and lone star ticks.]

### PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS. CAUTION.** Causes moderate eye irritation . Do not get in eyes or on clothing. Harmful if swallowed. Harmful if absorbed through skin. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

**HAZARDS TO DOMESTIC ANIMALS.** For external use only. Do not use on puppies under 12 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, pregnant, nursing, debilitated or aged dogs. Call 1-800-781-4738 for 24-hour assistance.

### FIRST AID

<b>If In Eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>If On Skin Or Clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If Swallowed</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>

### 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

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**BACK PANEL**

**DOG SQUEEZE ON  
FIPRONIL+CYPHENOTHHRIN**

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **DO NOT ALLOW CHILDREN TO APPLY PRODUCT.** TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL [AND ENCLOSED DIRECTIONS] BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

**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 tubes 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. Certain medications can interact with pesticides. 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 application 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 dog 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 dogs. Dogs may experience some temporary irritation at the site of product application. 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 tubes [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.

**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. Do not apply more often than once every [30 days] [month].

[Optional drawings that may or may not appear on finished label]



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**BACK PANEL**

**DOG SQUEEZE ON  
FIPRONIL+CYPHENOTHRIN**

## FREQUENCY OF APPLICATION

Use [**brand name**] monthly for complete control of flea, tick [and] chewing lice [and mosquito] [infestations]. [Studies show that] [**brand name**] kills adult fleas (starts killing in as little as 1 hour) for up to three months. Apply monthly if your pet is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks, mosquitoes and chewing lice. [**Brand name**] kills mosquitoes within 24 hours for up to the first 7 days after application, then within 48 hours for up to 28 days. [**Brand name**] remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for 30 days.

**For Dogs Weighing up to 22 lbs. [including small dogs and puppies, 12 weeks or older]:**  
**{For cartons containing 0.67 mL (0.023 fl oz) applicator tubes}**

Apply one tube (.67 mL)(0.023 fl oz) [as a spot to the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

**For Dogs Weighing [Between] 23-44 lbs.**

**{For cartons containing 1.34 mL (0.045 fl oz) applicator tube}**

[Apply one tube (1.34 mL)(0.045 fl oz)] [as a spot to the dog's back between the shoulder blades.] [from the back of the neck to a point midway between the neck and tail].

**For Dogs Weighing [Between] 45-88 lbs.**

**For cartons containing 2.68 mL (0.091 fl oz) applicator tube}**

Apply one tube (2.68 mL)(0.091 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].

**For Dogs Weighing [Between] 89-132 lbs.**

**For cartons containing 4.02 mL (0.136 fl oz) applicator tube}**

Apply one tube (4.02 mL)(0.136 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].

## 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 inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

**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.

## [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

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**BACK PANEL**

**DOG SQUEEZE ON  
FIPRONIL+CYPHENOTHRI**

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  
Non-Emergency, call: 1-800-224-PETS (7387)

[Coupon(s) inside or on outside of box]  
[Made in USA]

Distributed by:  
Sergeant's Pet Care Products, Inc.  
P.O. Box 540399  
Omaha, NE 68154-0399  
EPA Reg. No. 2517-140  
EPA Est. No. XXXXX-XX-XXX

[BAR CODE AREA]

{END - BACK / SIDE PANEL}

**OPTIONAL OUTER PACKAGING**

**DOG SQUEEZE ON  
FIPRONIL+CYPHENOTHRI**

**[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]**

## [Application Instructions] [Directions for Use]

### How to open

1. Remove product tubes [vial] from the package.
2. 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.

### How to apply [Optional drawings that may or may not appear on finished label]

1. Invert tube over dog and use open end to part dog's hair.
2. Squeeze tube firmly to apply all of the solution to the dog's skin [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.]





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**OPTIONAL OUTER PACKAGING**

**DOG SQUEEZE ON  
FIPRONIL+CYPHENOTHIN**

[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 application to avoid chance of ingestion
- Do NOT split tubes between pets]

## [Brand name]

[3] [Month [Application] Tracker]

[For year-round protection, apply [Brand name] monthly.]

[Pet's Name (Empty blank for owner to fill in name)]

[First] [1st] [Second] [2nd] [Third] [3rd]

[Dose] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)]

[calendar stickers with brand name]

[Place stickers on your calendar as a reminder to reapply [brand name] [in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand name]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]



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## OPTIONAL OUTER PACKAGING

## DOG SQUEEZE ON FIPRONIL+CYPHENOTHRIN

 Adult Flea

 Adult Flea

 flea eggs

 flea eggs

 flea larvae

 flea larvae

 flea pupae

 flea pupae

 ticks

 ticks

 Brown Dog Tick

 Brown Dog Tick

 Deer Tick

 Deer Tick

 American Dog Tick

 American Dog Tick

 chewing lice

 chewing lice

 Lone Star Tick

 Lone Star Tick

 mosquitoes

 mosquitoes

{END - OPTIONAL INSERT OR PACKAGE COPY}

## TUBE/VIAL LABEL

## DOG SQUEEZE ON FIPRONIL+ CYPHENOTHRIN

Front Label

Back Label

{Brand Name}[cat graphic with line through]

For dogs [up to X lbs][X-Y lbs]

Fipronil 9.8% w/w, Cyphenothrin 5.2% w/w

0.023 fl oz (or) 0.045 fl oz(or) 0.091 fl oz (or)

0.136 fl oz {label code}

KEEP OUT OF REACH OF CHILDREN

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

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{label code}