

2517-134

2/3/2011

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

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

FEB - 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 + Methoprene Dog Squeeze-On
EPA Reg. No. 2517-134
Submission dated January 19, 2011
Decision No: 443571

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. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment.

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 cursive script, appearing to read "Richard Gebken".

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

Enclosure: Sergeant's Fipronil + Methoprene Dog Squeeze-On, Stamped *Accepted*

Sergeant's Master Label

28 January 2011 Amendment
Information in [] is optional.

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FRONT PANEL

**DOG-SQUEEZE ON
FIPRONIL + METHOPRENE**

[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 + Methoprene Squeeze-On for Dogs

[ABNs]

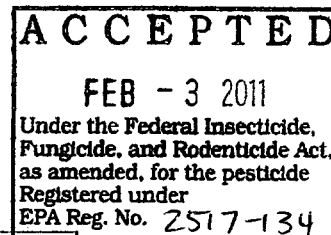
[(Sergeant's®) (Sentry®) FRONTIER GOLD (Spot On) for dogs]

[(Sergeant's®) (Sentry®) Ectoadvance (Spot On) for dogs]

[SentryProline (Spot On) for dogs]

[[SENTRY®] FIPROGUARD™ PLUS for dogs]

[[Sergeant's®] PRONYL OTC™ PLUS for dogs]



[Apply to puppies over 8 weeks old]

[Apply to puppies 8 weeks or older]



[Mosquitoes]

[Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]

[Adult Fleas]

[[Kills [adult] Fleas [for up to three months]]]

[Kills newly emerged adult Fleas before they lay eggs]

[Kills Adult Fleas, which may be a source of [flea allergy dermatitis] [, flea bite anemia]]

[Kills Fleas Up to [4 weeks] [1 month] [30 days]!]

[If dog is at high risk for flea reinfestation a once month application may be needed]

[Multiple Infestations]

[Kills chewing lice [and controls mites that may cause sarcoptic mange]]

[Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 8 weeks old [&] [and] older]

[Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes]]

[Kills fleas, ticks, [mosquitoes,] chewing lice, flea eggs, flea larvae [&] [and] [prevents the development of flea pupae]]

[Kills Fleas, Ticks [&] [and] [Mosquitoes]]

[Breaks the Flea Life Cycle [for up to three months]]

[Monthly flea, tick, [mosquito,] chewing lice and flea egg protection]

[Monthly flea, tick, [mosquito] and chewing lice protection]

[Kills fleas, ticks, [mosquitoes,] flea eggs, and chewing lice]

[[Seven] [7] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, flea eggs, flea larvae [&] [and] prevent the development of flea pupae]]

[[Six] [6] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, flea eggs [&] [and] flea larvae]

[[4 Week] [1 month] [30 day] [Flea [and] [&] Tick Treatment]

[[Four (4) Week] [1 month] [30 day] [Flea, Tick, and Chewing Lice Control]

[[Four [4] Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]

[Use [brand name] monthly to break the flea life cycle.]

[Use [brand name] monthly to control ticks and chewing lice]

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[Monthly flea, tick, [mosquito,] flea egg, flea larvae and chewing lice protection.]
[Once A Month Flea and Tick [Application][Treatment]
[[4 week] [1 month] [30 day] Flea and Tick [Application] [Treatment]!]
[Kills Fleas, [and] Ticks for up to [4 weeks] [1 month] [30 days]!]
[Kills Fleas, [and] Ticks [and Mosquitoes] for up to [4 weeks] [1 month]!]
[Kills Fleas, Ticks, Flea Eggs & Flea Larvae for up to [4 Weeks] [1 month] [30 days]]

[Ticks]

[Kills Ticks including those that may transmit Lyme disease]
[Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]
[Kills (deer) ticks [including those that may transmit Lyme Disease] [for up to [4 weeks] [1 month] [30 days] [per application]]
[Kills all stages of deer ticks]
[Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]
[Kills [brown dog ticks], [American dog ticks,] [and lone star ticks] [and deer ticks] [(*Rhipicephalus sanguineus*)] [for up to [4 weeks] [1 month] [30 days]]
[Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]

[Flea Eggs and Larvae]

[Controls flea reinfestation for up to [12 weeks] [3 months]]
[Kills adult fleas, flea eggs, flea larvae and prevents the development of pupae for up to [three months] [12 weeks].]
[Effectively controls all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]
[Effective against all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]
[If dog is at high risk for flea reinfestation a once month application may be needed]
[Prevents from developing, flea eggs [larvae] [pupae] for up to [3 months] [12 weeks]]
[With (S)-methoprene Insect Growth Regulator [IGR] which Breaks the Flea Life Cycle]
[With (S)-methoprene to Break Flea Life Cycle]
[With Insect Growth Regulator [IGR] to Break Flea Life Cycle]
[Dual Action [!]:Fipronil with (S)-methoprene IGR [insect growth regulator] Effectively Breaks the Flea Life Cycle]
[Dual Action [!]: Effectively Breaks the Flea Life Cycle [!]]
[Kills Flea Eggs & Flea Larvae for [up to 3 months] [up to 12 weeks]!]
[Prevents Flea Eggs From Developing Into Biting Adults]
[Prevents all stages of the flea life cycle from developing]
[Controls reinfestation of fleas for up to 3 months]
[Effective against all stages of the flea life cycle]
[Effectively controls all stages of the flea life cycle]

[All Others]

[For Dogs and Puppies 8 weeks of age or older]
[Controls mites that may cause sarcoptic mange]

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[For Dogs [up to 22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.]]

FRONT PANEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[Fast Acting] [Long Lasting]
 [Prevents reinfestation of listed pests for [4 weeks] [1 month]]
 [Easy to use [application]]
 [Apply monthly]
 [[A once monthly application required][Apply monthly to control] [for] chewing lice]
 [Rapid elimination of chewing lice infestations]
 [[Three] [3] 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 8 weeks of age or older]
 [[Free] Calendar Stickers Inside!]
 [Apply once every [4 weeks] [month] [30 days]!]
 [Waterproof]
 [Can be used on breeding, pregnant and lactating [bitches] [female] [dogs]]
 [[Free with purchase] [Free inside] Monthly Application Reminder [Magnet][inside]]
 [Can be used on puppies 8 weeks of age and older]
 [Convenient spot treatment]
 [Easy to Use [Application]]
 [Effective after bathing and exposure to water and sunlight]
 [For year-round protection, apply [**Brand name**] monthly]
 [Fipronil (9.8%) + (S)-methoprene (8.8%)]
 [Lift [here] for more information]
 [Contains Fipronil and (S)-methoprene[,] [-] the active ingredients used in Frontline Plus®*]
 [*[**Brand name**] is not manufactured by or distributed by Merial. Frontline Plus® is a registered trademark of Merial.]
 [U.S. Patent No. 5,567,429]
 [3 applications]
 [For year-round protection, apply [**Brand name**] monthly]
 [Effective after bathing and exposure to water and sunlight]
 [Stops and prevents infestation of listed pests for [4 weeks][1 month]]
 [Stops existing infestation and prevents establishment of additional infestation of listed pests]

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FRONT PANEL

**DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

[For use ONLY on dogs

[Up to 22 lbs]

[23-44 lbs]

[45-88 lbs]

[89-132 lbs]

[over 8 weeks of age]]

[For Dogs & Puppies 8 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%
(S)-methoprene	8.80%
OTHER INGREDIENT**:	81.40%
TOTAL	100.00%

[**diethylene glycol monoethyl ether]

**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 /SIDE PANEL

**DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

[[**brand name**]] contains Fipronil and S-Methoprene (insect growth regulator) (IGR) to effectively kill fleas and ticks [(including those that may transmit Lyme Disease).] [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 [1 month] [[4][four] weeks] on dogs.]

[**Brand name**]

**READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE.**



PRECAUTIONARY STATEMENTS

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

HAZARDS TO DOMESTIC ANIMALS. For external use only. Do not use on puppies under 8 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 treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs. Call 1-800-781-4738 for 24-hour assistance.

FIRST AID

If swallowed:	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If in eyes:	Flush eyes with plenty of water. Call a doctor if irritation persists.
If on skin:	Wash with plenty of soap and water. Get medical attention if irritation persists.

HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.

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BACK/SIDE PANEL

**DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

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 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 puppies under 8 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. Consult a veterinarian before using this product on debilitated, aged, or medicated dogs. Can be used on breeding, pregnant, or lactating dogs. Consult a veterinarian before using on dogs with known organ dysfunction. Dogs may experience some temporary irritation at the site of product application. Certain medications can interact with pesticides. 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.

{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 4 weeks.

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



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 for up to three months. Apply monthly if your dog is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks, [mosquitoes] and chewing lice. [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, 8 weeks or older]:

{For cartons containing 0.67 mL (0.023 fl oz) applicator tubes}

Apply one tube (0.67 mL)(0.023 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot on the dog's back between the shoulder blades.]

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BACK /SIDE PANEL

**DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

For Dogs Weighing 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.) [from the back of the neck to a point midway between the neck and tail.] [as a spot on the dog's back between the shoulder blades.]

For Dogs Weighing 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.) [from the back of the neck to a point midway between the neck and tail.] [as a spot on the dog's back between the shoulder blades.]

For Dogs Weighing 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.) [from the back of the neck to a point midway between the neck and tail.] [as a spot on the dog's back between the shoulder blades.]

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 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]

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BACK / SIDE PANEL

**DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

Distributed by:
Sergeant's Pet Care Products, Inc.
P.O. Box 540399
Omaha, NE 68154-0399
EPA Reg. No. 2517-134
EPA Est. No. 2517-TN-1 [XXXXXX-XX-XXX]

[BAR CODE AREA]

U.S. Patent No. 5,567,429

{END - BACK / SIDE PANEL}

OUTER PACKAGING OR FOLDED PANEL / FLAP OF FRONT OF PACKAGE

**DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

[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]

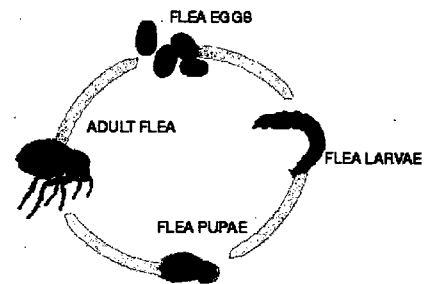
How to open

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

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.]

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



[Flea life cycle diagram] [Flea Life Cycle]

[Sample coloring and layout may be different on final label]

[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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OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE

**DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

[Brand name]

[3 Month [Treatment] [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] [Treatment] [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.]

- | | |
|---|---|
|  Adult Flea |  Adult Flea |
|  flea eggs |  flea eggs |
|  flea larvae |  flea larvae |
|  flea pupae |  flea pupae |
|  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 |

[Optional graphics above may or may not appear on finished label]

**{END - PACKAGE COPY} TUBE/VIAL LABEL DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

Front Label

Back Label

<p>{Brand Name}{cat graphic with line through} For dogs [up to X][X-Y] lbs Fipronil 9.8% w/w, (S)-methoprene 8.8% w/w 0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or) 0.136 fl oz {label code}</p>	<p>KEEP OUT OF REACH OF CHILDREN CAUTION: Read directions and precautions before using. Use scissors to open. EPA REG. No. 2517-134 {label code}</p>
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{END - TUBE/VIAL COPY}