

2517-136

3/31/2011

1049



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

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

MAR 31 2011

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

Subject: Label Amendment to Sergeant's Fipronil Dog Squeeze-On
EPA Reg. No. 2517-136
Submission dated March 17, 2011
Decision No: 447010

"Sergeant's Fipronil
Squeeze-On for Dogs"
BA 5/26/2011

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,

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

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

Sergeant's Master Label

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Information in [] is optional.

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FRONT PANEL

**DOG SQUEEZE ON
FIPRONIL**

[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 Fipronil 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™ for dogs]

[[Sergeant's®] PRONYL OTC™ for dogs]

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

ACCEPTED
MAR 31 2011
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide Registered under EPA Reg. No. 2517-136

[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] [and] [, flea bite anemia]]

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

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

[Multiple Bugs]

[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, ticks, chewing lice [&] [and] mosquitoes]

[Kills Fleas, Ticks and Mosquitoes]

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

[Monthly flea, tick, mosquito, and chewing lice [application] [treatment]]

[[Four][4] Way [Action][Effectiveness][Control] to kill fleas, ticks, mosquitoes, and chewing lice]

[[4 Week] [1 month] [30 day] [Flea and Tick [Application] [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]

[Kills Fleas and Ticks for up to [4 weeks] [1 month] [30 days]!]

[Once A Month Flea and Tick [Application] [Treatment]]

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

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

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FRONT PANEL

DOG SQUEEZE ON FIPRONIL

[Ticks]

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

[All Others]

- [For Dogs and Puppies 8 weeks of age or older]
- [For Dogs [up to 22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.]]
- [Fast Acting]
- [Long Lasting]
- [Prevents infestation of listed pests for [1 month][4 weeks]]
- [Convenient spot treatment]
- [Apply monthly]
- [[A once monthly application required] [Apply monthly to control] [for] chewing lice]
- [Rapid elimination of chewing lice infestations]
- [Controls mites that may cause sarcoptic mange]
- [[Three] [3] Applications] and/or [3 Month Supply] or [12 Week Supply]
- [Best if used year round!]
- [(ICON Showing 4 Week Protection)]
- [4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
- [Easy to Use [Application]]
- [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]
- [Effective after bathing and exposure to water and sunlight]
- [For year-round protection, apply **[Brand name]** monthly]
- [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]
- [Fipronil (9.7%)]
- [Contains Fipronil[,] [-] the active ingredient used in Frontline Top Spot®*]
- [***[Brand name]** is not manufactured by or distributed by Merial. Frontline Top Spot® is a registered trademark of Merial.]
- [3 applications]
- [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

[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 INGREDIENT:

Fipronil9.70%

OTHER INGREDIENT[**]:.....90.30%

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:

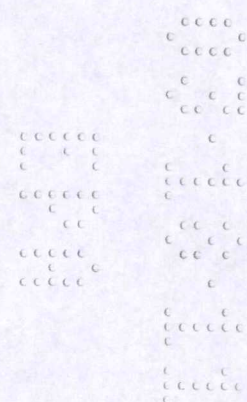
[3] [three] 0.023 fl oz (0.67 mL) applicators

[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**

[[**brand name**]] contains Fipronil to effectively kill fleas and ticks [(including those that may transmit Lyme Disease).] [The active ingredient in [**brand name**] features a sustained release formula developed for fast acting [and long lasting] control of fleas, ticks, mosquitoes and chewing lice for up to [1 month] [[four][4] weeks] on dogs.]
[**Brand Name**]

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON DOGS AND PUPPIES OVER 8 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 may transmit Lyme disease. Kills brown dog ticks, American dog ticks, and lone star ticks. Prevents flea reinfestation for [[4][four] weeks] [[1][one] month] [30 days].]

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:	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 treatment advice.
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**

DIRECTIONS FOR USE

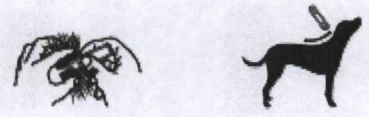
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **DO NOT ALLOW CHILDREN TO APPLY PRODUCT.** TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY.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

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]

80f9

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BACK /SIDE PANEL

**DOG SQUEEZE ON
FIPRONIL**

Distributed by:

Sergeant's Pet Care Products, Inc.

P.O. Box 540399

Omaha, NE 68154-0399

EPA Reg. No. 2517-136

EPA Est. No. 2517-TN-1 [XXXXXX-XX-XXX]

[BAR CODE AREA]

{END - BACK / SIDE PANEL}

OUTER PACKAGING

DOG SQUEEZE ON FIPRONIL

[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

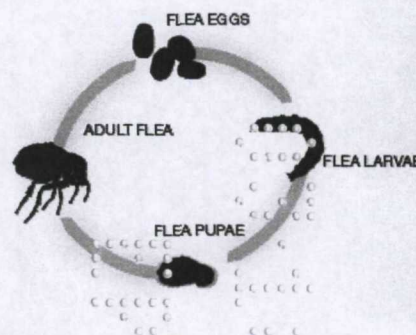
1. Invert tube over dog and use open end to part dog's hair.
2. Squeeze tube firmly to apply all of the solution to the dog's skin [as a spot to the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

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

9099

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OUTER PACKAGING COPY

**DOG SQUEEZE ON
FIPRONIL**

[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


 Brown Dog Tick


 Lone Star Tick


 Deer Tick


 American Dog Tick


 Chewing Lice


 Mosquito


 Adult Flea


 Brown Dog Tick

 Lone Star Tick

 Deer Tick

 American Dog Tick

 Chewing Lice

 Mosquito

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

{END - OPTIONAL PACKAGE COPY}

TUBE/VIAL LABEL

DOG SQUEEZE ON

FIPRONIL

Front Label

Back Label

{Brand Name}[cat graphic with line through]

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

Fipronil 9.7% 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.

EPA REG. No. 2517-136

{label code}

{END - TUBE/VIAL COPY}