

2517-136

2/21/2012

10410



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

February 21, 2012

James B. Messina,
Principal Regulatory Consultant
(Authorized Agent for Sergeant's Pet Care Products, Inc.)
Exponent
Center for Chemical Regulation and Food Safety
1150 Connecticut Avenue, N.W.
Suite 1100
Washington, DC 20036

Subject: Revise CRP labeling (Net Content, Opening and directions).

- Sergeant's Fipronil Squeeze-On for Dogs
EPA Reg. No. 2517-136
- Sergeant's Fipronil + Methoprene Squeeze-On for Dogs
EPA Reg. No. 2517-134
- Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs
EPA Reg. No. 2517-140
- Sergeant's Fipronil + Nylar Squeeze-On for Dogs
EPA Reg. No. 2517-141
- Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs
EPA Reg. No. 2517-142
- Sergeant's Fipronil + Cyphenothrin + NyJar Squeeze-On for Dogs
EPA Reg. No. 2517-143

Applications dated September 26, 2011

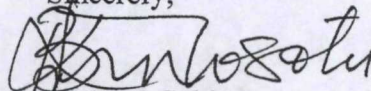
Dear Mr. Messina:

The above referenced labeling for each of the subject products, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable:

Please note that we have approved the amended labels for these products with the understanding that they are consistent with the Agency's previously stamped accepted ones; and other than the revisions stated in your applications (dated September 26, 2011), no other changes have been made to the labeling and/or the Confidential Statement of Formula (CSF).

See enclosed copy of the stamped label for your record. If you have any questions concerning this action please contact me or Dr. B.A. Akinlosotu (703-605-0653 or via email Akinlosotu.bonaventure@epa.gov).

Sincerely,



SR

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

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 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 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]

[FiproSpot (Topical) for Dogs (and puppies)]

[EctoSpot (Topical) for Dogs (and puppies)]

[Ectopronil (Topical) for Dogs (and puppies)]

[EctoAdvance (Topical) for Dogs (and puppies)]

[F-Pronil (Topical) for Dogs (and puppies)]

[Meridian Animal Health]

[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]

[Chewing Lice]

[Kills chewing lice]

[Rapid elimination of chewing lice infestation]

[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 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, 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] [Three] [3] Way [Action][Effectiveness][Control] to kill, ticks, [mosquito,] and chewing lice]

ACCEPTED
FEB 21 2012
Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:
EPA. Reg. No: 2517-136



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[[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, [Mosquitoes] and Chewing Lice Control]
 [Kills Fleas and Ticks for up to [4 weeks] [1 month] [30 days]!]
 [Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]]
 [Use **Full or Partial Brand Name**] monthly to control ticks and chewing lice]
 [Monthly flea, tick, [mosquito], and chewing lice protection.]
 [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]!]

[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] [per application]]
 [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]!]

[All Others]

[For Dogs and puppies 8 weeks of age or older]
 [Can be used on puppies 8 weeks of age and older]
 [Specially Formulated 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]
 [Convenient spot treatment]
 [Easy to Use [Application]]
 [Best if used year round!]
 [For year-round protection, apply **Full or Partial Brand Name**] monthly]
 [(ICON Showing 4 Week Protection)]
 [Apply monthly]
 [Prevents infestation of listed pests for [1 month][4 weeks]]
 [Apply once every [4 weeks] [month] [30 days]!]
 [4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
 [One Application][Two Applications][Three Applications][Four Applications][Five Applications][Six Applications][Twelve Applications][Twenty-Four Applications] and/or [1 Month Supply][2 Month Supply][3 Month Supply][4 Month Supply][5Month Supply][6 Month Supply][12 Month Supply][24 Month Supply] or [4 Week Supply][8 Week Supply][12 Week Supply][16 Week Supply][Twenty Week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply]
 [[A once monthly application required][Apply monthly to control] [for] chewing lice]
 [Controls mites that may cause sarcoptic mange]
 [Waterproof]
 [Effective after bathing and exposure to water and sunlight]
 [Can be used on breeding, pregnant and lactating [bitches] [female] [dogs]]
 [[Free] Calendar Stickers Inside!]

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[[Free with purchase] [Free inside] Monthly Application Reminder [Magnet][inside]]
[Fipronil (9.7%)]
[Contains Fipronil[,] [-]the [same] active ingredient used in Frontline® Top Spot* for dogs*]

[***[Full or Partial Brand Name]** is not manufactured by or distributed by Merial. Frontline® Top Spot is a registered trademark of Merial.]

[[**[Full or Partial Brand Name]** is a trademark of **[Company Name]**]]

[[1][2][3][4][5][6][12][24] 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]

FRONT PANEL

DOG SQUEEZE ON FIPRONIL

[For use ONLY on dogs [&] [and] puppies]	[For Dogs & Puppies 8 weeks or older and]
[Up to 22 lbs]	[up to 22 lbs.]
[23[-] [to] 44 lbs]	[For Dogs 23[-] [to] 44 lbs.]
[45[-] [to] 88 lbs]	[For Dogs 45[-] [to] 88 lbs.]
[89[-] [to] 132 lbs]	[For Dogs 89[-] [to] 132 lbs.]
[over 8 weeks of age]]	

ACTIVE INGREDIENT:

Fipronil9.70%

OTHER INGREDIENT:90.30%

TOTAL **100.00%**

KEEP OUT OF REACH OF CHILDREN

CAUTION

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

Net Contents:

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]
0.023 fl oz (0.67 mL) applicators

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]
0.045 fl oz (1.34 mL) applicators

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]
0.091 fl oz (2.68 mL) applicators

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]
0.136 fl oz (4.02 mL) applicators

{END - FRONT PANEL}

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BACK /SIDE PANEL

**DOG SQUEEZE ON
FIPRONIL**

[[**Full or Partial Brand Name**]] contains Fipronil to effectively kill fleas and ticks [(including those that may transmit Lyme disease).] [The active ingredient in [**Full or Partial 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] [[4][four] weeks] on dogs.]

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE.



[[**Full or Partial Brand Name**]] for dogs provides [[four] [three] 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. 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.

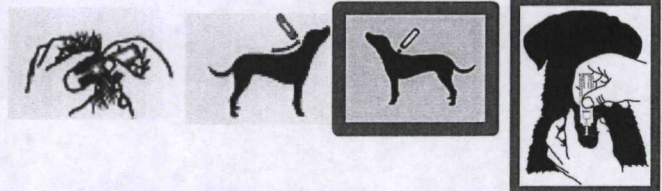
DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS. Do not use on puppies under 8 weeks of age. Use entire contents of tube [vial] on each dog. [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.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

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 anywhere on finished label]



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] [to] the dog's back between the shoulder blades.]

For Dogs Weighing 23 [-] [to] 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] [to] the dog's back between the shoulder blades.]

For Dogs Weighing 45 [-] [to] 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] [to] the dog's back between the shoulder blades.]

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BACK /SIDE PANEL

**DOG SQUEEZE ON
FIPRONIL**

For Dogs Weighing 89[-] [to] 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] [to] the dog's back between the shoulder blades.]

FREQUENCY OF APPLICATION

Use [Full or Partial Brand Name] monthly for complete control of flea, tick [and] chewing lice [and mosquito] infestations. [Studies show that] [Full or Partial 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. [Full or Partial Brand Name] [This product] remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for [30 days] [4 weeks].

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]

Distributed by:
Sergeant's Pet Care Products, Inc.
P.O. Box 540399
Omaha, NE 68154-0399

[BAR CODE AREA][Lot code]
EPA Reg. No. 2517-136
EPA Est. No. 2517-TN-1 [XXX-XX-XXX]

{END - BACK / SIDE PANEL}

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OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE

**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.] Hold the tube *[vial]* with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

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 [on] [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 anywhere on finished label]



[Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your pet
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after treatment to avoid chance of ingestion
- [6] Do NOT split tubes between pets[and use the ENTIRE tube contents]

[Full or Partial Brand Name]

[1][2][3][4][5][6][12][24] [Month [Treatment] [Application] Tracker]

[For year-round protection, apply [Full or Partial Brand Name] monthly.]

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

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth][8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

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

[calendar stickers with Full or Partial Brand Name] [Place stickers on your calendar as a reminder to reapply [Full or Partial 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 [Full or Partial Brand Name]. Press the

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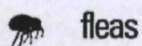
EPA No. 2517-136
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button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

OUTER PACKAGING OR INSERT COPY

DOG SQUEEZE ON FIPRONIL

[Optional graphics below may or may not appear anywhere on finished label]



fleas



Adult Flea



ticks



Deer Tick



Brown Dog Tick



Lone Star Tick



American Dog Tick



chewing lice



mosquitoes



fleas



Adult Flea



ticks



Deer Tick



Brown Dog Tick



Lone Star Tick



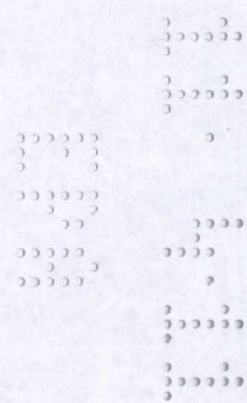
American Dog Tick



chewing lice



mosquitoes



{END - OPTIONAL INSERT OR PACKAGE COPY}

TUBE/VIAL LABEL

DOG SQUEEZE ON FIPRONIL

Front Label

Back Label

<p>{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}</p>	<p>KEEP OUT OF REACH OF CHILDREN CAUTION: Read directions and precautions before using. Use scissors to open. EPA REG. No. 2517-136 {label code}</p>
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{END - TUBE/VIAL COPY}