

2517-141

02/15/2013

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

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 15, 2013

Mr. James Messina
Authorized Representative of Sergeant's Pet Care Product, Inc.
c/o Exponent
1150 Connecticut Ave. NW, Suite 1100
Washington, DC 20036

Subject: Application for Pesticide Amendment
Sergeant's Fipronil + Nylar Squeeze-On for Dogs
EPA Reg. No. 2517-141
Your Submission Dated September 28, 2012
Decision No: 470238

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 contact Driss Benmhend at 703-308-9525 or by e-mail at: Benmhend.driss@epa.gov.

Sincerely,

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

Enclosure: *Label stamped "Accepted"*

Sergeant's® Master Label

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Information in [] is optional.

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FRONT PANEL DOG SQUEEZE ON FIPRONIL+NYLAR

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

Sergeant's Fipronil + Nylar Squeeze-On for Dogs

[ABNs]

- [Sergeant's® FRONTIER GOLD for Dogs]
- [Sergeant's® FRONTIER GOLD Spot On for Dogs]
- [Sentry® FRONTIER GOLD for Dogs]
- [Sentry® FRONTIER GOLD Spot On for Dogs]
- [Sergeant's® Ectoadvance™ Spot On for Dogs]
- [Sergeant's® Ectoadvance™ for Dogs]
- [Sentry® Ectoadvance™ Spot On for Dogs]
- [Sentry® Ectoadvance™ for Dogs]
- [SENTRY® FIPROGUARD® PLUS for Dogs]
- [SENTRY® FIPROGUARD® II for Dogs]
- [Sergeant's® PRONYL OTC® PLUS for Dogs]
- [Sergeant's® PRONYL OTC® II for Dogs]

ACCEPTED
with COMMENTS
In EPA Letter Dated
FEB 15 2013

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
2517-141



[1.5 cm x 1.5 cm on final]

[For use ONLY on dogs [&] [and] puppies](OR) [ONLY For Dogs & Puppies 12 weeks or older [&][and]
 [6-][to] 22 lbs] [6-][to] 22 lbs]
 [23-] [to] 44 lbs] [23-] [to] 44 lbs]
 [45-] [to] 88 lbs] [45-] [to] 88 lbs]
 [89-] [to] 132 lbs] [89-] [to] 132 lbs]
 [and over 12 weeks of age]

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

[Mosquitoes]

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

[Chewing Lice]

[Kills chewing lice]
[Rapid elimination of chewing lice infestations]

[Fleas]

[[full or partial brand name] prevents development of all flea stages for up to [63 days] [9 weeks].]
[Prevents all flea stages (adult fleas, flea eggs, and flea larvae)]
[If dog is at high risk for flea reinfestation a once a month application may be needed]
[Kills flea eggs [and][larvae] [and][prevents pupae development] for up to [63 days][9 weeks]]

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[With Pyriproxyfen Insect Growth Regulator which Breaks the Flea Life Cycle]
 [With Pyriproxyfen to Break Flea Life Cycle]
 [With Insect Growth Regulator to Break Flea Life Cycle]
 [Dual Action (!): Fipronil with Pyriproxyfen IGR Effectively Breaks the Flea Life Cycle]
 [Dual Action (!): Effectively Breaks the Flea Life Cycle(!)]
 [Kills Fleas for up to [4 weeks!] [2 months!]]

[Ticks]

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

[Multiple Infestations]

[Flea & Tick Control for Dogs & Puppies 12 Weeks Old and Older]
 [Kills fleas, flea eggs, ticks, chewing lice & [mosquitoes]]
 [Kills fleas, ticks, [mosquitoes], chewing lice, flea eggs, larvae, and prevents pupae development]
 [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]
 [[4 Week] [Flea and Tick & Treatment]]
 [[Seven] [7] [Six][6][Five][5]Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, flea eggs, flea larvae [&] [and] prevent the development of flea pupae]]
 [[Six] [6] [Five][5][Four][4]Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, flea eggs [&] [and] flea larvae]
 [[Four (4) Week] [Flea, Tick, [Mosquito] and Chewing Lice Control]
 [Kills Flea Eggs & Flea Larvae for up to [63 days], [9 weeks]!]
 [Prevents Flea Eggs From Developing Into Biting Adults]
 [Kills Fleas, Ticks, Flea Eggs & Flea Larvae for up to 4 Weeks]
 [4 week Flea and Tick Treatment!]
 [Once A Month Flea and Tick Treatment]
 [Kills Fleas and Ticks for up to 4 weeks!]
 [When used monthly [full or partial brand name] completely breaks the flea life cycle and controls tick and chewing lice infestations.]
 [Prevents and controls reinfestations of listed pests for up to [1 month] [4 weeks]]
 [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]!]

[All Others]

[For Dogs and Puppies 12 weeks of age or older]

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[For Dogs [6 to 22 lbs], [23-44 lbs], [45-88 lbs], [89-132 lbs]]
 [Fast Acting]
 [Waterproof]
 [Long Lasting]
 [Apply monthly]
 [A once monthly application is required for chewing lice.]
 [Apply monthly to control chewing lice.]
 [Controls mites that may cause sarcoptic mange]
 [One Application][Two Applications][Three Applications][Four Applications][Five Applications][Six Applications][12 Applications][24 Applications] and/or [1 Month Supply][2 Month Supply][3 Month Supply][4 Month Supply][5 Month Supply][6 Month Supply][12 Month Supply][24 Month Supply] or [4 Week Supply][8 Week Supply][12 Week Supply][16 Week Supply][20 Week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply]
 [Best if used year round!]
 [(ICON Showing 4 Week Protection)]
 [4 Week Dose!]
 [1 Month Dose!]
 [Easy to Use Application]
 [Specially Formulated for Dogs and Puppies over 12 weeks old]
 [[Free] Calendar Stickers Inside!]
 [Patented Technology]
 [Apply once every [4 weeks] [month]!]
 [Effective after bathing and exposure to water and sunlight]
 [[Free with purchase] [Free inside] Monthly Application Reminder [Magnet]]
 [[1][2][3][4][5][6][12][24] Applications]
 [Fipronil (9.8%) + [Pyriproxyfen] (2.0%)]
 [US and Foreign patents pending]
 [Lift [here] for more information]
 [For year round protection, apply (full or partial brand name) monthly]
 [Full or Partial Brand Name] is a trademark of:[Company Name]
 [Maximize the power of fipronil [with Brand Name]]

ACTIVE INGREDIENTS:

Fipronil.....	9.8%
Pyriproxyfen	2.0%
OTHER INGREDIENTS[*]:	88.2%
TOTAL	100.0%

[*diethylene glycol monoethyl ether, vitamin E nicotinate]

[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] [Label [Panel][s] for Additional Precautionary Statements]

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NET CONTENTS: X fl oz [Y – X fl oz applicators]

[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]

[0.045 fl oz (1.34 mL) applicators]

[0.091 fl oz (2.68 mL) applicators]

[0.136 fl oz (4.02 mL) applicators]

[END OF FRONT PANEL]

BACK PANEL

DOG SQUEEZE ON FIPRONIL+NYLAR

[BACK/SIDE CARTON LABEL - MASTER LABEL]

[full or partial brand name] contains fipronil and the insect growth regulator (IGR) pyriproxyfen to effectively kill fleas, ticks [(including those that may transmit Lyme disease)], and kill[s] flea eggs, flea larvae, [mosquitoes] and chewing lice. The active ingredients in [full or partial 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.

READ ENTIRE LABEL BEFORE EACH USE.

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

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 on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. 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. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product.

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"> • Call a poison control center or 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.

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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 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.** Do not use on rabbits or animals other than dogs. Do not allow your dog to ingest this product. Do not use on puppies under 12 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. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

Side Effects: Monitor your dog after application. 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. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If signs persist or become more severe within a few days of application, consult a veterinarian immediately by calling 1-800-781-4783. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application.

[1.5 cm x 1.5 cm on final]



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. Contact your veterinarian if applied to a cat or ingested by a cat [common signs of ingestion are excessive salivation and foaming at the mouth.

[{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. Repeat application may be made if necessary, but do not apply more often than once every [4 weeks][30 days].

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



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Only For Dogs Weighing 6 [-][to] 22 lbs. Do not apply to dogs weighing less than 3 lbs. [including small dogs and puppies, only 12 weeks or older]

{For cartons containing .67 ml (0.023 fl. oz.) applicator tubes}
 Apply one tube (.67 ml)(0.023 fl. oz.) [as a spot [on][to] the dog's back between the shoulder blades][from the back of the neck to a point midway between the neck and tail].

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

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

Only For Dogs Weighing 89[-][to] 132 lbs. Do not use two tubes on dog greater than 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][to] the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

FREQUENCY OF APPLICATION

Use [full or partial brand name] monthly for complete control of flea, tick [and] chewing lice [and to kill mosquitoes] [infestations]. If your dog is at high risk for flea reinfestation [, or in a highly infested environment], apply monthly. Apply monthly to control ticks, [mosquitoes] and chewing lice. [[Full or partial brand name] kills mosquitoes within 24 hours for up to the first 7 days after treatment, then within 48 hours for up to 28 days.] [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 [4 weeks][30 days].

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

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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

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

[Made in USA]

Distributed by:

Sergeant's Pet Care Products, Inc.

Omaha, NE 68138-3710

EPA Reg. No. 2517-141

EPA Est. No. XXXXX-XX-XXX

{END - BACK / SIDE PANEL}

[BAR CODE AREA]

**[OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE
FIPRONIL DOG SQUEEZE ON]**

[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.]

[{Outer Packaging}]

[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.]

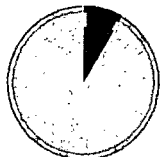
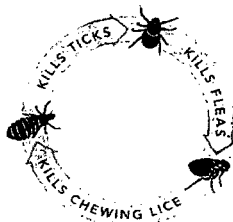


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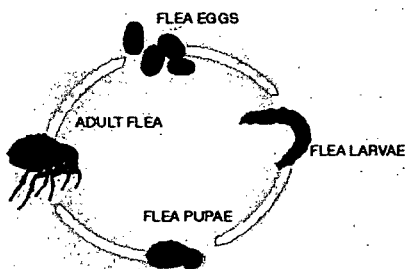
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[Flea life cycle diagram] [Flea Life Cycle][Sample coloring and layout may be different on final label]



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

- [1] Read the label completely and follow directions
- [2] Weigh your dog
- [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 button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

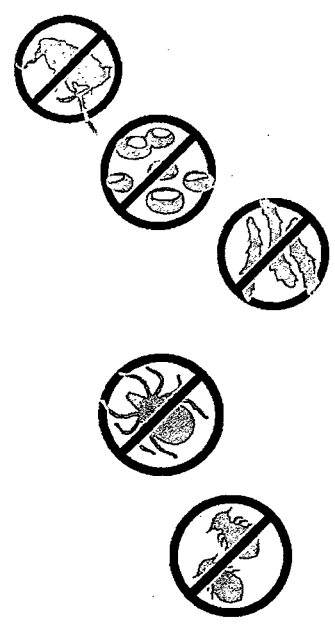
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- | | |
|-----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
|  Adult Flea |  Adult Flea |
|  flea 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 |
|  Mite |  Mite |



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

{END - OPTIONAL INSERT OR PACKAGE COPY}

TUBE/VIAL LABEL	DOG SQUEEZE ON FIPRONIL+NYLAR
-----------------	----------------------------------

Front Label	Back Label
<p>{Brand Name} </p> <p>For Dogs [X-Y lbs.]</p> <p>Fipronil 9.8% w/w, Pyriproxyfen 2.0% w/w</p> <p>0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or)</p> <p>0.136 fl oz {label code}</p>	<p>KEEP OUT OF REACH OF CHILDREN</p> <p>WARNING: Read directions and precautions before using. Use scissors to open.</p> <p>EPA REG. No. 2517-141 {label code}</p>