

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 20, 2015

Kelly R. Hoskins Sergeant's Pet Care Products, Inc. 10077 South 134th Street Omaha, NE 68138

Subject: Label Amendment – Correcting lower limit for weight restrictions

Product Name: Sergeant's Fipronil Multi-Dose for Dogs

EPA Registration Number: 2517-156 Application Date: August 10, 2015

Decision Number: 508046

Dear Mr. Hoskins:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, please contact me by phone at (703) 306-0415, or via email at davis.kable@epa.gov.

Sincerely,

Kable Bo Davis, Product Manager 3 Invertebrate and Vertebrate Branch 1 Registration Division (7505P) Office of Pesticide Programs

Enclosure

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[Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels.]

Sergeant's Fipronil Multi-Dose for Dogs

[ABN(s):]

[Meridian® EctoadvanceTM Spot On for Dogs]

[Meridian® EctoadvanceTM for Dogs]

[Sergeant's® EctoadvanceTM Spot On for Dogs]

[Sentry® EctoadvanceTM Spot On for Dogs]

[Sergeant's® EctoadvanceTM for Dogs]

[Sentry® EctoadvanceTM for Dogs]

ACCEPTED

08/20/2015

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 0547450

2517-156

FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION

For use in veterinarian clinics, animal shelters, grooming facilities and boarding kennels. Not for residential use. Keep product in its original container. Do not repackage.

[For use ONLY on dogs [&] [and] puppies 5 to 132 lbs. and over 8 weeks of age] [ONLY For Dogs & Puppies 8 weeks or older [&][and] 5 to 132 lbs.]

[Ideal for shelter use when under direct supervision of veterinarian]

[Multi-dose bottle]

[Convenient multi-dose bottle for in clinic use]

[Convenient multi-dose bottle for animal facility use]

[Accurate and convenient dosing for all sizes of dogs]

[Weigh dog for accurate dosing]

[For use only by licensed veterinarians [on animals in their control or under their immediate supervision]]

[Multi-Dose Package [Weigh dog and determine appropriate application rate using chart]] [Location of cat icon: lower righthand corner of label]

{1.5 cm x 1.5 cm on final or as indicated}



[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]

[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]!]

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[If dog is a high risk for flea reinfestation a once monthly application may be needed] [Starts [killing][to kill] fleas in [an][1][one]hour]

[Ticks]

[Kills ticks including those that may transmit Lyme disease]

[Kills [all stages of] deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days] [per application]]

[Starts [killing][to kill] ticks in [an][1][one]hour]

[Kills ticks [including] [brown dog ticks] [(*Rhipicephalus sanguineus*)] [American dog ticks,] [(*Dermacentor variabilis*)] [and] [lone star ticks][,][and deer ticks] [for up to [4 weeks] [1 month] [30 days]]

[Multiple Infestations]

[Kills chewing lice [and aids in control of sarcoptic mange mites]]

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

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

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

[[Four] [4] [Three] [3] Way [Action][Effectiveness][Control] to kill, ticks, [mosquito,] and chewing lice]

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

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

[Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice] [Application] [Treatment]]

[Use [Brand Name] monthly to control ticks and chewing lice]

[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]!]

[Starts [killing][to kill] fleas and ticks in [an][1][one]hour]

[All Others]

[For Dogs and Puppies 8 weeks of age or older]

[Can [use][apply] [on][to] puppies 8 weeks of age and older]

[Specially Formulated for Dogs and Puppies 8 weeks of age or older]

[For Dogs [from 5 to 132 lbs.]

[Convenient spot treatment]

[Easy to Use [Application]]

[Apply monthly]

[Apply once every [4 weeks] [month] [30 days]!]

[Waterproof]

[Effective after bathing and exposure to water and sunlight]

[Can be used on breeding, pregnant and lactating [bitches] [female] [dogs]]

ACTIVE INGREDIENT:

Fipronil	9.70%
OTHER INGREDIENT[**]:	
TOTAL	100 00%

[**diethylene glycol monoethyl ether]

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KEEP OUT OF REACH OF CHILDREN CAUTION

[See [Back][Label] for Additional Precautionary Statements]

Net Contents: [3.38 fl oz (100 ml)] [8.45 fl oz (250 ml)]

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

[[Brand Name] for dogs provides [[four] [three] way] protection that kills fleas, ticks, [mosquitoes] and chewing lice. Aids in control of sarcoptic mange mites. 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 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 a dog with more than one pesticide product at a time. Over dosing a dog can result in serious illness and even death. Use caution before using on medicated, debilitated, aged, pregnant, nursing dogs or dogs with known organ dysfunction. If the dog is exhibiting signs of and/or is being treated for skin dermatitis, use caution before applying any topical flea and tick control product.

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.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL

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OR UNDER THEIR IMMEDIATE SUPERVISION. DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND THE 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 the dog to ingest this product. Do not use on puppies under 8 weeks of age. Weigh dog to be sure you are applying the right dose formulated for the weight of the dog. Instruct the dog owner to separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

Side Effects: Instruct the owner to monitor the dog after application. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed dog and continue to monitor 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 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 immediately call 1-800-781-4783. If dog has an unusual reaction to the initial application, evaluate the [situation][dog's condition] before repeating application.

{1.5 cm x 1.5 cm on final or as indicated}



DO NOT USE ON CATS. Instruct the owner to keep cats away from treated dogs for 24 hours. Evaluate [the situation][the condition of the cat] if applied to a cat or ingested by a cat, [common signs of ingestion are excessive salivation and foaming at the mouth].

[For use only by licensed veterinarians on dogs in their control or under their immediate supervision]

[CRP text found on top of cap: WHILE PUSHING DOWN TURN CLOSE TIGHTLY][Graphic may or may not appear anywhere on the label]

How to Apply

Weigh dog or puppy 8 weeks and older, to determine appropriate application rate using the following chart:



Weight/Application Amount		
Only for dogs weighing:	Apply:	
5 [-][to] 20 lbs	(0.6 ml) or (0.6 cc)	
21 [-][to] 44 lbs	(1.4 ml) or (1.4 cc)	
45 [-][to] 88 lbs	(2.8 ml) or (2.8 cc)	
89 [-][to] 132 lbs	(4.0 ml) or (4.0 cc)	

Application to be made using commercially available 5 mL (syringe must have 0.2 mL graduations), luer tip disposable syringe without needle. Use of non-sterile syringe is acceptable since applications are topical. Use syringe [(not included)] to measure and withdraw the appropriate amount of solution by inserting the syringe into the top of the bottle. Refer to table above for application rates. Part the dog's hair, and apply entire amount directly to the skin of the dog, as directed below. Do not apply more often than once every 4 weeks. When finished using product, replace the cap.

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FREOUENCY OF APPLICATION

[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: Keep product in its original container. Do not repackage. Store in a cool (below 77°F [/][25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

SYRINGE DISPOSAL: Do not reuse the syringe. Only discard empty syringes; do not discard syringes containing product. Discard disposable syringe in accordance with State and Local regulations.

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) [Made in USA]

[Distributed by:] [Manufactured by:] [BAR CODE AREA][Lot code]

Sergeant's Pet Care Products, Inc. EPA Reg. No. 2517-156

Omaha, NE 68138-3710 EPA Est. No. [XXX-XXX]

[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 the 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 for 24 hours after treatment to avoid chance of ingestion
- [6] Not for residential use]

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

