


2517-156

5/17/2013

1/9

 <p align="center">ENVIRONMENTAL PROTECTION AGENCY</p> <p align="center">Office of Pesticide Programs Registration Division (7504P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460-0001</p>	<p>EPA Registration No.</p> <p align="center">2517-156</p>	<p>Date of Issuance:</p> <p align="center">May 17, 2013</p>
<p align="center">NOTICE OF PESTICIDE:</p> <p align="center"><input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration</p> <p align="center">(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</p>	<p>Term of Issuance:</p> <p align="center">Conditional</p>	
	<p>Name of Pesticide Product:</p> <p align="center">Sergeant's Fipronil Multi-Dose for Dogs</p>	
<p>Name and Address of Registrant (include ZIP Code):</p> <p>Sergeant's Pet Care Products, Inc. 10077 South 143th Street Omaha, NE 68138-3710</p> <p>Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.</p>		
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.</p> <p>Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>This action is taken under the authority of section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.</p> <p align="center">Terms of Registration</p> <ol style="list-style-type: none"> EPA has registered the product listed above provided that the following changes are made to the label before you release the product for shipment: <ol style="list-style-type: none"> Revise the EPA Registration Number to read: "EPA Registration No 2517-156." This registration is time-limited and expires two years (2) from the date this product is first released for shipment. You must provide the Agency with a projected "release for shipment date", in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected "release for shipment date" until an actual release for shipment date is provided in writing. Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e., no alternate formulations or minor formulation amendments will be submitted and/or approved for this product, except to allow for alternate sources of any individual inert ingredient). You must submit the following data within the timeframe described below: Within sixteen (16) months of the date on this Notice of Registration, provide to the Agency acceptable data packages for Guideline Studies: OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage Stability). 		
<p>Signature of Approving Official:</p> <p align="center">Refer to Page #3</p> <p>Richard J. Gebken, Product Manager (10) Registration Division, Insecticide Branch</p>	<p>Date:</p> <p align="center">May 17, 2013</p>	

5. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on July 1, 2013. The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information (CBI) as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division (attn: Kaitlin Keller).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
 Product name (brand name)
 Lot#
 Where purchased: internet, store, Veterinarian
 Active Ingredient(s)
 Weight range for product
 Date on which incident occurred, (mm/dd/yyyy)
 State in which the incident occurred, (standard 2 letter abbreviation)
 Registrant case #
 Species: dog, cat, other (specify)
 Breed: (as reported by pet owner)
 Age: months or years
 Sex: M, F, or neutered
 Weight: pounds
 Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 Body System: neurological, dermatological, GI, respiratory, ocular, other Major signs noted
 Time to Onset: (hours, days)
 Treated by veterinarian: yes or no
 First time product used: yes or no
 Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 Any known precondition
 EPA Severity Code: death, major, moderate, minor
 Outcome: died, recovered, still treated, unknown

6. Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details:
- All minor dermal and ocular irritation reports.
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - Summary table for dogs and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - A summary table for s showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
 - A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
 - Table showing number of incidents for each dog breed.
 - Table showing number of incidents in dog for each clinical sign.
 - Table showing number of incidents in dog for each organ system.
 - Report aggregate incidents, but do not combine moderate and minor incidents.
7. If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary, EPA may take regulatory action.

3/9

8. Sergeant's Pet Care Products, Inc. must adequately address all of the mitigation actions identified in the Agency's *Generic Pet Spot-On Mitigation Plan* available at the following internet site:
<http://www.epa.gov/pesticides/health/spot-on-meetings.html>.
9. Enclosed is a copy of the data call-in (DCI) for fipronil.

You must submit and/or cite all data required for registration of your product under section 3(c)(5) of FIFRA when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for registration review of your product under FIFRA.

Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with all of the **Terms of Registration** stated above, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. If you have any questions concerning this action, please contact Mr. Richard J. Gebken at (703) 305-6701 or gebken.richard@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7504P)

Enclosures: *Label Stamped "Accepted with Comments," dated May 17, 2013*
 Copy of DCI for Fipronil

002517-00156 D470260

Sergeant's Master Label

16 May 2013 Revised Application
Information in [] is optional.

Version 13.1
Page 1 of 6

EPA No. 2517-RLA

49

[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[®] Ectoadvance[™] Spot On for Dogs]

[Meridian[®] Ectoadvance[™] for Dogs]

[Sergeant's[®] Ectoadvance[™] Spot On for Dogs]

[Sentry[®] Ectoadvance[™] Spot On for Dogs]

[Sergeant's[®] Ectoadvance[™] for Dogs]

[Sentry[®] Ectoadvance[™] for Dogs]

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 x 1.5 cm or as indicated]



ACCEPTED

May 17, 2013

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

EPA. Reg. No: 2517-156

Sergeant's Master Label

16 May 2013 Revised Application
Information in [] is optional.

Version 13.1
Page 2 of 6

EPA No. 2517-RLA

[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]!]

[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 3 to 132 lbs.]

[Convenient spot treatment]

[Easy to Use [Application]]

[Apply monthly]

6/9

Sergeant's Master Label

16 May 2013 Revised Application
Information in [] is optional.

Version 13.1
Page 3 of 6

EPA No. 2517-RLA

[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[**]:.....90.30%

TOTAL **100.00%**

[**diethylene glycol monoethyl ether]

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.

7/9

Sergeant's Master Label

16 May 2013 Revised Application
Information in [] is optional.

Version 13.1
Page 4 of 6

EPA No. 2517-RLA

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 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 x 1.5 cm 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]

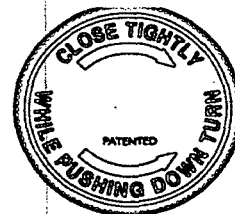
Sergeant's Master Label

16 May 2013 Revised Application
Information in [] is optional.

Version 13.1
Page 5 of 6

EPA No. 2517-RLA

[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.

FREQUENCY 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

9/9

Sergeant's Master Label

16 May 2013 Revised Application
Information in [] is optional.

Version 13.1
Page 6 of 6

EPA No. 2517-RLA

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:

Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

[BAR CODE AREA][Lot code]

EPA Reg. No. 2517-RLA

EPA Est. No. 2517-NE-1 [XXX-XX-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]

[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

