


2517-155

5/17/2013

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 <p style="text-align: center;">ENVIRONMENTAL PROTECTION AGENCY</p> <p style="text-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 style="text-align: center;">2517-155</p>	<p>Date of Issuance:</p> <p style="text-align: center;">May 17, 2013</p>
<p>NOTICE OF PESTICIDE:</p> <p><input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration</p> <p>(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</p>	<p>Term of Issuance:</p> <p style="text-align: center;">Conditional</p>	<p>Name of Pesticide Product:</p> <p style="text-align: center;">Sergeant's Fipronil Multi-Dose for Cats</p>
<p>Name and Address of Registrant (include ZIP Code): 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 style="text-align: center;">Terms of Registration</p> <ol style="list-style-type: none"> 1. 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"> a. Revise the EPA Registration Number to read: "EPA Registration No 2517-155." 2. 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. 3. 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). 4. 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 style="text-align: center;">Refer to Page #3</p> <p>Richard J. Gebken, Product Manager (10) Registration Division, Insecticide Branch</p>	<p>Date:</p> <p style="text-align: center;">May 17, 2013</p>	

1. 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

2. Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details:
 - a. All minor dermal and ocular irritation reports.
 - b. 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.
 - c. A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - d. Summary table for dogs and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - e. 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.
 - f. A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
 - g. 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.
 - h. Table showing number of incidents for each dog breed.
 - i. Table showing number of incidents in dog for each clinical sign.
 - j. Table showing number of incidents in dog for each organ system.
 - k. Report aggregate incidents, but do not combine moderate and minor incidents.
3. 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.

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4. 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>.
5. 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

002517-00155 D470265

Sergeant's Master Label

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

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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 Cats

[ABNs:]

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

[Sergeant's® Ectoadvance™ for Cats]

[Sentry® Ectoadvance™ Spot On for Cats]

[Sentry® Ectoadvance™ for Cats]

[Meridian® Ectoadvance™ Spot On for Cats]

[Meridian® Ectoadvance™ for Cats]

ACCEPTED
May 17, 2013
Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:
EPA. Reg. No: 2517-155

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 cats [[&] [and] kittens] over 1.5 lbs. and over 8 weeks of age]
[Only for cats [[&] [and] kittens] over 8 weeks of age and over 1.5 lbs.]

[Ideal for shelter use when under direct supervision of veterinarian]
[Multi-dose bottle] [Multi-Dose Package]
[Convenient multi-dose bottle for in clinic use]
[Convenient multi-dose bottle for animal facility use]
[Accurate and convenient dosing for all sizes of cats]
[For use only by licensed veterinarians [on animals in their control or under their immediate supervision]

[Mosquitoes]

[Kills mosquitoes] [within 24 hours for up to 14 days] [and within 48 hours for up to 28 days]

[Chewing Lice]

[Kills chewing lice]

[Fleas]

[Kills adult fleas [for up to six weeks]]
[Kills Fleas Up to [4 weeks] [1 month] [30 days]!]
[If cat is a high risk for flea reinfestation apply once a month]
[Kills fleas which may be a source of flea allergy dermatitis] [and] [flea bite anemia]]

[Ticks]

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

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[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]

[Flea [&] [and] Tick Control for Cats [&] [and] Kittens 8 weeks old and older]
[Kills fleas, ticks, [mosquitoes] [&] [and] chewing lice]
[Monthly flea, tick, [mosquito] and chewing lice protection]
[Four] [4] [Three] [3] Way [Action] [Effectiveness] [Control] [kills fleas, [mosquitoes,] ticks, 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 and Tick Treatment]
[Use [**Brand Name**] monthly to control ticks and chewing lice]
[Kills Fleas and Ticks for up to [4 weeks] [1 month] [30 days]!]
[**(Brand Name)** provides convenient and effective flea, tick, chewing lice [and] [mosquito] control for cats and kittens over 8 weeks of age.]

[All Others]

[For Cats and Kittens 8 weeks of age or older]
[Can [use][apply] [on][to] kittens 8 weeks of age and older]
[Specially Formulated for Cats and Kittens Over 8 Weeks Old]
[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 [queens], [female] [cats]]

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 CATS AND KITTENS OVER 8 WEEKS OF AGE**

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[[**Brand Name**]] for cats provides [[four] [three] [way]] protection that kills fleas, ticks, [mosquitoes] and chewing lice. 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 cats only. Individual sensitivities, while rare, may occur after using any pesticide product on cats. Certain medications can interact with pesticides. Do not treat a cat with more than one pesticide product at a time. Over dosing a cat can result in serious illness and even death. Use caution before using on medicated, debilitated, aged, pregnant, nursing cats, or cats with known organ dysfunction. If the cat 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.

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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 CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on rabbits or animals other than cats. Do not allow your cat to ingest this product. Do not use on kittens under 8 weeks of age. Do not apply to cats weighing less than 1.5 lbs. Do not over dose cat. Instruct the cat owner to separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.

Side Effects: Instruct the owner to monitor the cat after application. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed the cat and continue to monitor the cat for the next 24 hours. [Some cats may experience temporary startle effects when any product is applied.] Cats 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 the cat 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 1-800-781-4738. If the cat has an unusual reaction to the initial application, evaluate the cat's condition before repeating application.

[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

Weight/Application Amount	
Only for cats and kittens 8 weeks or older and over 1.5 lbs.	
Weight:	Apply:
All sizes (weights)	(0.50 mL) or (0.50 cc)

Application to be made using commercially available ≥ 1 mL (syringe must have 0.1 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 cat's hair, and apply entire amount directly to the skin of the cat, as directed below. Do not apply more often than once every 4 weeks. When finished using product, replace the cap.

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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 this 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

[Coupon(s) inside or on outside of box]

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]

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

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[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 cat
- [3] Do NOT use cat products on dogs
- [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	