



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 22, 2015

Ms. Kelly Hoskins
Director of Regulatory Affairs
Sergeant's Pet Care Products, Inc.
10077 South 134th St
Omaha, NE 68138

Subject: Label Notification per PRN 98-10 – Adding optional text and graphics.
Product Name: Sergeant's Fipronil Spot-On for Cats
EPA Registration Number: 2517-137
Application Date: December 12, 2014
Decision Number: 498495

Dear Ms. Hoskins:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, you may contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Jennifer Gaines" followed by a small mark that appears to be "bn".

Kable Bo Davis, Product Manager 03
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Sergeant's Master Label

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Information in [] is optional.

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FRONT PANEL

CAT SPOT ON FIPRONIL

[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. The CRP required text will not change.]

Sergeant's Fipronil Spot-On for Cats

[ABNs:]

- [Sergeant's[®] Frontier Gold Spot On for Cats]
- [Sergeant's[®] Frontier Gold for Cats]
- [Sentry[®] Frontier Gold Spot On for Cats]
- [Sentry[®] Frontier Gold for Cats]
- [Sergeant's[®] Ectoadvance Spot On for Cats]
- [Sergeant's[®] Ectoadvance for Cats]
- [Sentry[®] Ectoadvance Spot On for Cats]
- [Sentry[®] Ectoadvance for Cats]
- [Sergeant's[®] Gold FrontSpot Spot On for Cats]
- [Sergeant's[®] Gold FrontSpot for Cats]
- [Sentry[®] Gold FrontSpot Spot On for Cats]
- [Sentry[®] Gold FrontSpot for Cats]
- [Sentry[®] Proline Spot On for Cats]
- [Sentry[®] Proline for Cats]
- [SENTRY[®] FIPROGUARD™ for Cats]
- [FIPROGUARD™ for Cats]
- [Sergeant's[®] PRONYL OTC™ for Cats]
- [PRONYL OTC™ for Cats]
- [Sergeant's[®] AdvanSpot Spot On for Cats]
- [Sergeant's[®] AdvanSpot for Cats]
- [Sentry[®] AdvanSpot Spot On for Cats]
- [Sentry[®] AdvanSpot for Cats]
- [FiproSpot Topical for Cats and Kittens]
- [FiproSpot for Cats and Kittens]
- [FiproSpot Topical for Cats]
- [FiproSpot for Cats]
- [EctoSpot Topical for Cats and Kittens]
- [EctoSpot for Cats and Kittens]
- [EctoSpot Topical for Cats]
- [EctoSpot for Cats]
- [Ectopronil Topical for Cats and Kittens]
- [Ectopronil for Cats and Kittens]
- [Ectopronil Topical for Cats]
- [Ectopronil for Cats]
- [EctoAdvance Topical for Cats and Kittens]
- [EctoAdvance for Cats and Kittens]
- [EctoAdvance Topical for Cats]
- [EctoAdvance for Cats]
- [F-Pronil Topical for Cats and Kittens]

NOTIFICATION

2517-137

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

01/22/2015

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[F-Pronil for Cats and Kittens]

[F-Pronil Topical for Cats]

[F-Pronil for Cats]

[Meridian Animal Health]

[PetArmor® for cats]

[Sergeant's® PetArmor® for cats]

For use ONLY on cats [[&] [and] kittens] over 1.5 lbs and over 8 weeks of age [OR]
Only for cats [[&] [and] kittens] over 8 weeks of age and over 1.5 lbs

[Apply to kittens over 8 weeks old]

[Apply to kittens 8 weeks or older]

[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]

[Rapid elimination of chewing lice infestation]

[Fast Action against chewing lice infestations]

[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] [or flea bite anemia]

[Ticks]

[Kills ticks including those that may transmit Lyme disease]

[Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]

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

[Kills American Dog Ticks [(*Dermacentor variabilis*)] 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]

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

[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][this product] 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]!]

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[[Brand name][This product]provides convenient and effective flea, tick, chewing lice [and] [mosquito] control for cats and kittens over 8 weeks of age.]

[All Others]

[Cats and Kittens 8 weeks of age or older]

[Can be used on kittens 8 weeks of age and older]

[Specially Formulated on Cats and Kittens Over 8 Weeks Old]

[Fast Acting] [Long Lasting]

[Easy to Use [Application]]

[Best if used year round!]

[Apply monthly]

[Once a month treatment]

[For year-round protection, apply [Brand name][this product] monthly]

[(ICON Showing [4 Week] [1 month] [30 day] Protection)]

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

[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[[One][1][Two][2][Three] [3][4][Four][5][Five] [Six][6][Twelve][12][Twenty-Four][24]]Applications] and/or [1 Month Supply][2 Month Supply][3 Month Supply][Four Month Supply][Five 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]

[Waterproof]

[Effective even after bathing]

[Effective after bathing and exposure to water and sunlight]

[Can be used on breeding, pregnant and lactating [queens], [female] [cats]]

[[Free] Calendar Stickers Inside!]

[Monthly application reminder inside]

[[Free with purchase] [Free inside] Monthly Application Reminder [Magnet][clip] [inside]]

[Fipronil (9.7%)]

[Contains [the] [same] active ingredient used in [FRONTLINE® Top Spot® for Cats (or any ABN)]

[FRONTLINE® brand products].*]

[Compare to [FRONTLINE® Top Spot® for Cats (or any ABN)] [FRONTLINE® brand products], contains [the] [same] active ingredient.*]

[Compare to [FRONTLINE® Top Spot® for Cats (or any ABN)] [FRONTLINE® brand products], contains [the] [an] [same] active ingredient fipronil.*]

[[Brand Name] [products] [This product] contains(s) fipronil, [the] [an] [same] active ingredient used in [FRONTLINE® Top Spot® for Cats (or any ABN)] [FRONTLINE® brand products].*]

[[Brand Name] [products] [This product] contains(s) fipronil, compared to [the] [an] [same] active ingredient used in [FRONTLINE® Top Spot® for Cats (or any ABN)] [FRONTLINE® brand products].*]

[[*][Brand Name][This product] is not manufactured or distributed by [Merial®] [Company name], the makers of [FRONTLINE® Top Spot® for Cats (or any ABN)][FRONTLINE® brand products].]

[[Brand Name][This product][Frontline®] [Frontline® TopSpot®] is a registered trademark of [Merial®] [Company name].]

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

[Stops and prevents infestation of listed pests for [4 weeks][1 month]]

[Direct to skin [tube][vial][applicator][pipette]]

[Easy to Use] [tube][vial][applicator][pipette]]

[Clean cut [open] [tube][vial][applicator][pipette]]

[No-mess [open] [tube][vial][applicator][pipette]]

[Clip-tip design [tube][vial][applicator][pipette][!]]

[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]

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ACTIVE INGREDIENT:

Fipronil 9.70%

OTHER INGREDIENT:..... 90.30%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

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

Net Contents: X fl oz [Y - 0.017 fl oz (0.50 ml) [applicator] [tube][vial][pipette][s]]
[1][One][2][Two][3] [Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]

{END - FRONT PANEL}

BACK PANEL/SIDE PANEL

CAT SPOT ON FIPRONIL

[[Brand name]][this product] contains Fipronil to effectively kill fleas and ticks [(including those that may transmit Lyme disease)]. [The active ingredients in [Brand name]][this product] feature a sustained release formula developed for fast acting [and long lasting] control of fleas, ticks, [mosquitoes] and chewing lice for [1 month][4 weeks] on cats.]

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON CATS AND KITTENS OVER 8 WEEKS OF AGE

[[Brand name]][this product] 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 your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, or aged cats. Can be used on breeding, pregnant, or lactating [cats] [female cats] [queens]. Consult a veterinarian before using on cats with known organ dysfunction.

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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.
HOT LINE 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. **DO NOT ALLOW CHILDREN TO APPLY PRODUCT.** TO PREVENT HARM TO YOU AND YOUR 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 double-dose cats. Use entire contents of [tube] [vial] [applicator] [pipette] on each cat. [Do not split one [tube] [vial] [applicator] [pipette] between two cats.] Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.

Side Effects: Monitor your cat after application. [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 your cat with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your cat for the next 24 hours.

[{Outer Packaging}]

How to open: Remove product tube[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: While holding the cat with one hand, use the other hand to apply the solution. Invert the tube[vial][applicator][pipette] and use the narrow end to part the cat's hair. Apply contents of one [tube][vial][applicator][pipette] of [Brand name][this product] [as a stripe, starting high on the back of the cat's neck to in front of the shoulder blades] [as a spot between the shoulder blades].

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Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat. When finished, wrap the [tube][vial][applicator][pipette] in paper and put into the trash. Only one applicator per treatment is needed.

FREQUENCY OF APPLICATION

Use [Brand name][this product] monthly for complete control of flea, tick [and] chewing lice [and mosquito] infestations. [Studies show that] [Brand name][this product] kills adult fleas for up to six weeks. Apply monthly if your cat is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks[,] [mosquitoes] and chewing lice. [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]. [[Brand name][this product] can be used on breeding, pregnant and lactating (queens) (female cats).]

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:][Manufactured by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

[BAR CODE AREA][Lot code]
EPA Reg. No. 2517-137
EPA Est. No. XXX-XX-XXX

{END - BACK / SIDE PANEL}

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OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE

**CAT SPOT ON
FIPRONIL**

[How to Apply - May contain graphics illustrating product use, e.g., cat with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

[[Clip. Part. Squeeze.]]

Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea and tick protection where it needs to be.]

[Application Instructions] [Directions for Use]

How to Open:

1. Remove product tube[vial]from the package.
2. [Separate one tube from the others.] Hold the tube 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 cat and use open end to part cat's hair.
2. Apply contents of one [tube][vial][applicator][pipette] of {Brand Name} [as a stripe, starting high [on] [to] the back of the cat's neck to in front of the shoulder blades] [as a spot between the shoulder blades]. Squeeze [tube][vial][applicator][pipette] firmly to apply all of the solution to the cat's skin.]

[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 cat
- [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] [application] to avoid chance of ingestion
- [6] Do NOT split tubes between pets] [and use the ENTIRE tube contents]

[Brand name]

[3] [Month [Treatment] [Application] Tracker]

[For year round protection apply [Brand name][this product] monthly.]

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

[Cat's Weight (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)

[Application date][Date of Application]

[calendar stickers with [Brand name][this product]

[Place stickers on your calendar as a reminder to reapply [Brand name][this product] in 30 days.]

[Place sticker on your calendar or [refrigerator] to remind yourself to apply [Brand name][this product] to your cat]

[Monthly Application Reminder Magnet (image of reminder magnet)]

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[Monthly reminder card]



















[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 [Brand name][this product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[33% more free]

[Bonus Size]

[Buy 3 get 1 free]

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

	Fleas	
	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	
	Chewing Lice	
	Lone Star Tick	
	Mosquitoes	
	Mite	



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{END - OPTIONAL PACKAGE COPY}

TUBE/VIAL LABEL

CAT SPOT ON FIPRONIL

Front Label

Back Label

<p>{Brand Name} For Cats over 1.5 lbs \geq 8 wks Fipronil 9.7% 0.017 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. 2517-137 {label code}</p>
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{EPA REG No may be on either the front or back label}

{END – TUBE/VIAL COPY}