# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 6, 2014

Kelly R. Hoskins Director of Regulatory Affairs Sergeant's Pet Care Products, Inc. 10077 South 134<sup>th</sup> St Omaha, NE 68138

Subject: Label Notification per PRN 98-10 – Addition of Marketing Statements

"[Satisfaction Guaranteed] [If you are not satisfied, we will make it right with a

replacement or refund.]"

Product Name: Sergeant's Fipronil + Pyriproxyfen Spot On for Cats

EPA Registration Number: 2517-146 Application Date: October 21, 2014

Decision Number: 496699

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,

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

Office of Pesticide Programs

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FRONT PANEL CAT SPOT ON

FIPRONIL + PYRIPROXYFEN

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

## Sergeant's Fipronil + Pyriproxyfen Spot On for Cats

[ABNs:]

[Sergeant's® PRONYL OTC® PLUS for Cats] [SENTRY® FIPROGUARD® PLUS for Cats] [[Sergeant's®] Pet Armor OTC® PLUS for Cats]

[[Sergeant's®] Fast Act OTC® PLUS for Cats]

NOTIFICATION

2517-146

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:

11/06/2014

For use ONLY on cats [[&] [and] kittens] over 3.5 lbs and over 12 weeks of age [OR] Only for cats [[&] [and] kittens] over 12 weeks of age and over 3.5 lbs

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

### [Mosquitoes]

[Kills mosquitoes]

### [Chewing Lice]

[Kills chewing lice]

[Fast Action against chewing lice infestations]

#### [Adult Fleas]

[[Brand name][This product] kills adult fleas for up to six weeks]

[Kills Fleas [Up to [4] [6] weeks]!]

[Kills Fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]

[Stops and prevents reinfestation]

[Controls flea reinfestation [for up to six weeks]]

[[Brand name][This product] kills adult fleas for up to six weeks]

[If cat is a high risk for flea reinfestation a once a month application may be needed]

[Dual Action [!]:Fipronil and Pyriproxyfen Effectively Break the Flea Life Cycle]

[Prevents and controls reinfestations]

#### [Flea Eggs and Larvae]

[Stops and prevents infestations]

[Controls flea reinfestation for up to 6 weeks]

[[Brand name][This product] kills adult fleas, flea eggs, [and] flea larvae [and prevents pupae] for up to six weeks]

[[Brand name][This product] prevents development of all flea stages for up to 6 weeks]

[Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)]

[If cat is a high risk for flea reinfestation a once monthly application may be needed]

[Kills flea eggs [and] [larvae] [and prevents pupae] for up to [3 months] [12 weeks]]

[[Seven] [Six] [Five] [7] [6] [5] Way Protection [Kills fleas, ticks, [mosquitoes,] chewing lice,

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flea eggs, [and] flea larvae [and prevents flea pupae]]

[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 all stages of the flea life cycle]

[Kills Flea Eggs & Flea Larvae [for up to 3 months]!]

[Prevents Flea Eggs From Developing Into Biting Adults]

[Prevents and controls reinfestations]

#### [Ticks]

[Kills Ticks including those that may transmit Lyme disease]

[Kills Ticks [for Up to 4 weeks]!]

[Kills Deer Ticks (which may transmit Lyme disease) for up to [4 weeks] [1 month] [30 days]]

[Kills Ticks (Including Deer Ticks) for up to 4 weeks]

[Kills American Dog Ticks for up to 4 weeks]

[Kills [Brown], [American] [and Lone Star] dog ticks for up to 4 weeks]

[Kills American Dog Ticks [(Dermacentor variabilis)] for up to 4 weeks!]

### [Multiple Infestations]

[[Brand name][This product] provides convenient and effective flea, tick, [and] chewing lice [and mosquito] control for cats and kittens [12 weeks or older] ]

[Controls reinfestation for up to 4 weeks]

[Flea & Tick Control for Cats & Kittens 12 weeks old or older]

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

[[Four][4][Three] [3] Way Pest Protection]

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

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

[[4 Week] [Flea and Tick Treatment]]

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

[When used monthly [Brand name][this product] completely breaks the flea life cycle and controls tick and chewing lice infestations.]

[Once A Month Flea and Tick Treatment]

[Kills Fleas and Ticks for up to 4 weeks!]

#### [All Others]

[Stops and prevents infestations]

[For Cats and Kittens 12 weeks of age or older]

[Fast Acting]

[Cats can be bathed 24 hours after treatment]

[Waterproof]

[Long Lasting]

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

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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 Cats and Kittens [12 weeks or older]]

[[Free] Calendar Stickers Inside!]

[[Free] Brochure Inside!]

[[Free] Brochure and Calendar Stickers Inside]

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

[Convenient to use]

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

[1][2][3][4][5][6][12][24][Month [Treatment] [Application] Tracker]

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

[Fipronil (9.8%)]

[[Brand Name][This product] is a registered trademark of [Company name].]

[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.]

### **ACTIVE INGREDIENTS:**

Fipronil	9.80%
Pyriproxyfen	2.20%
OTHER INGREDIENT [*]	
TOTAL	100.00%

[\*diethylene glycol monoethyl ether]

# 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] [tube][vial][applicator][pipette](s) [1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]

BACK/SIDE PANEL CAT SPOT ON FIPRONIL + PYRIPROXYFEN

[Brand name] [This product] contains fipronil and [the insect growth regulator] [IGR] pyriproxyfen to effectively kill fleas, ticks, [mosquitoes] and chewing lice. The active

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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 30 days] on cats [and kittens 12 weeks or older].

# READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON CATS AND KITTENS OVER 12 WEEKS OF AGE.

#### PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS. CAUTION.** Causes moderate eye irritation. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Harmful if swallowed. Harmful if absorbed through skin.

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, aged, pregnant or nursing cats. Consult a veterinarian before using on cats with known organ dysfunction.

FIRST AID			
If In Eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>		
If On Skin Or Clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>		
If Swallowed	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>		
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.

#### **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 12 weeks of age. Do not apply to cats weighing less than 3.5 lbs. Use entire contents of [tube][vial][applicator][pipette] on each cat. [Do not split one [tube] [vial] [applicator] [pipette] between two cats.] Do not double-dose cats. Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.

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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](s) 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} [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]. 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 [tube][vial][applicator][pipette] 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. [Brand Name] [This product] kills fleas for up to six weeks, and flea eggs, flea larvae [and prevents flea pupae] for up to 90 days / 3 months.

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] kills mosquitoes within 24 hours for up to 14 days, and within 48 hours for up to 28 days.] [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.

#### STORAGE AND DISPOSAL

**PESTICIDE STORAGE:** Do not remove [tube][vial][applicator][pipette] 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

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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.]

[Distributed by:][Manufactured by:] [Made in USA]

Sergeant's Pet Care Products, Inc. [BAR CODE AREA]

Omaha, NE 68138-3710

EPA Reg. No. 2517-146 In Case of Emergency, call: 1-800-781-4738 EPA Est. No. XXXXX-XXXX Non-Emergency, call: 1-800-224-PETS (7387)

### **(START - OPTIONAL INSERT OR PACKAGE COPY)**

[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](s) 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][vial][applicator][pipette] 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 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

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- [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 [tube][vial][applicator][pipette]s between pets][and use the entire [tube][vial][applicator][pipette] contents]

### [Brand Name]

[Monthly reminder card]

[Apply [Brand name][this product] monthly for continuous protection against fleas, ticks, flea eggs, flea larvae [and] chewing lice [and mosquitoes].]

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

[First [dose] [Treatment] (Empty blank for owner to fill in date)]

[Second [dose] [Treatment] (Empty blank for owner to fill in date)]

[Third [dose] [Treatment] (Empty blank for owner to fill in date)]

[Fourth [dose] [Treatment] (Empty blank for owner to fill in date)]

[Fifth [dose] [Treatment] (Empty blank for owner to fill in date)]

[Sixth [dose] [Treatment] (Empty blank for owner to fill in date)]

[Seventh [dose] [Treatment] (Empty blank for owner to fill in date)]

[Eighth [dose] [Treatment] (Empty blank for owner to fill in date)]

[Ninth [dose] [Treatment] (Empty blank for owner to fill in date)]

[Tenth [dose] [Treatment] (Empty blank for owner to fill in date)]

[Eleventh [dose] [Treatment] (Empty blank for owner to fill in date)]

[Twelfth [dose] [Treatment] (Empty blank for owner to fill in date)]

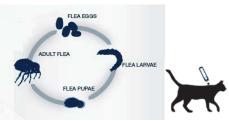
[calendar stickers with [Brand name]] [Place stickers on your calendar as a reminder to reapply [Brand name][this product] in 30 days.

[Monthly Application Reminder Magnet (image of reminder magnet)

Enclosed for your convenience is an application reminder magnet. Push the (reset) button to start the clock. After 30 days the magnet will flash (and beep) reminding you to reapply [Brand name][this product]. This application reminder can be used for future treatments. Just press the reset button and in another 30 days the reminder magnet will flash (and beep) reminding you to reapply.]

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





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Poli	Adult Flea	
Total	Fleas	
136	Flea eggs	
つ	Flea Larvae	3
	Flea Pupae	
*	Ticks	8
*	Brown Dog Tick	8
*	Deer Tick	
*	American Dog Tick	<b>S</b>
*	Chewing Lice	<b>(%)</b>
*	Lone Star Tick	<b>®</b>
7	Mosquitoes	

























## **(END - OPTIONAL INSERT OR PACKAGE COPY)**

TUBE / VIAL LABEL CAT SPOT ON FIPRONIL + PYRIPROXYFEN

{Front Label} {Back Label}

{Brand Name}KEEP OUT OF REACH OF CHILDRENFor Cats ≥ 3.5 lb & 12 wksCAUTION: Read directions and precautionsFipronil 9.8%, Pyriproxyfen 2.2%before using. Use scissors to open.0.017 fl oz [0.50 mL] {label code}EPA REG. No. 2517-146{label code}

**END TUBE / VIAL LABEL** 

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