



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Kelly R. Hoskins Director of Regulatory Affairs Sergeant's Pet Care Products, Inc. 2625 South 158<sup>th</sup> Plaza Omaha, NE 68130-1770 JAN 1 3 2014

Subject:

Sergeant's submission implementing pet spot-on mitigation label changes to

Sergeant's Fipronil + Pyriproxyfen Spot On for Cats

EPA Decision No. 478170 EPA Reg. No 2517-146

Dear Mr. Hoskins,

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is **acceptable**. With this letter, the label requirements listed in the EPA letter "Implementation of Label Changes to Pet Spot-On Products" dated September 30, 2011, are fulfilled and the time-limited registration for this product is hereby extended two years from the date of this letter. If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants and may take regulatory action.

It is our understanding that this product is not currently marketed by Sergeant's. If Sergeant's intends to market this product in the future, the additional requirements of September 30, 2011 must be fulfilled. These requirements include the submission of final printed labels, quarterly enhanced incident reports, and quarterly sales information in doses sold for this product, along with an analysis of the incidents reported. The quarterly reports are due two months after the quarter ends. Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the attention of Kaitlin Keller, Pesticide Re-evaluation Division, Mail Code 7508P.

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 with separate column for each sign, using standard terminology

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

Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported including 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 cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs 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 dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

A stamped copy of the label is enclosed for your records. If you have any questions regarding this label, please contact Kaitlin Keller at (703) 308-8172 via email at keller.kaitlin@epa.gov.

Sincerely

Richard Gebken Product Manager 10 Insecticide Branch

Registration Division (7504P)

Enclosure: Label stamped "Accepted"

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FRONT PANEL

CAT SPOT ON

FIPRONIE + PYRIPROXYFÉN

[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<sup>®</sup>] Fast Act OTC<sup>®</sup> PLUS for Cats]

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.

\*\*ACCEPTED\*\*

[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,

With COMMENTS
In EPA Letter Dated:

Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

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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][12 Month Supply][12 Week Supply][12

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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][!]]

#### **ACTIVE INGREDIENTS:**

Fipronil	9.80%
Pyriproxyfen	
OTHER INGREDIENT [*]	
TOTAL	$1\overline{00.00\%}$

[\*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 ingredients in [Brand name][this product] feature a sustained-release formula developed for fastacting [and long-lasting] control of fleas, ticks, [mosquitoes] and chewing lice [for 30 days] on cats [and kittens 12 weeks or older].

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### 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 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

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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 EPA Est. No. XXXXX-XXX In Case of Emergency, call: 1-800-781-4738 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
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment][application] to avoid chance of ingestion

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• [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)]

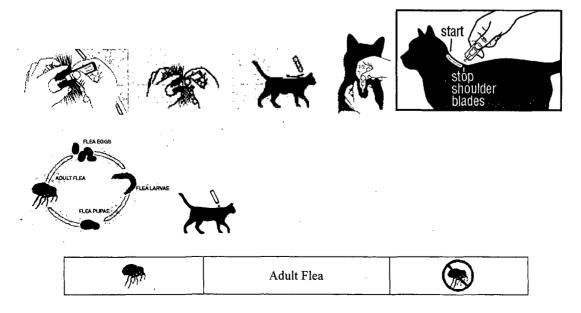
[Twelfth [dose] [Treatment] (Empty blank for owner to fill in date)]

[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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		uperseues El 2x I chui.
Total	Fleas	
yer.	Flea eggs	<b>&amp;</b>
つ	Flea Larvae	3
	Flea Pupae	
*	Ticks	
*	Brown Dog Tick	
*	Deer Tick	
*	American Dog Tick	
*	Chewing Lice	<b>(*)</b>
*	Lone Star Tick	
<b>**</b>	Mosquitoes	8







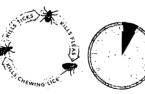


















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 	1.5		¥			3.	11.		*	~"

FIPRONIL + PYRIPROXYFEN

{Front Label}

{Back Label}

{Brand Name}
For Cats $\geq 3.5$ lb & 12 wks
Fipronil 9.8%, Pyriproxyfen 2.2%
0.017 fl oz [0.50 mL] {label code}

KEEP OUT OF REACH OF CHILDREN CAUTION: Read directions and precautions before using. Use scissors to open.

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{label code}

{END TUBE / VIAL LABEL}