

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 + S-Methoprene Spot-On for Cats EPA Registration Number: 2517-135 Application Date: December 12, 2014 Decision Number: 498483

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,

ennifer Daines In

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+METHOPRENE

[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 + Methoprene Spot-On for Cats

[ABNs:] [Sergeant's[®] Frontier Gold Plus Spot On for Cats] [Sergeant's[®] Frontier Gold Plus for Cats] [Sentry[®] Frontier Gold Plus Spot On for Cats] [Sentry[®] Frontier Gold Plus for Cats] [Sergeant's[®] Ectoadvance Plus Spot On for Cats] [Sergeant's[®] Ectoadvance Plus for Cats] [Sentry[®] Ectoadvance Plus Spot On for Cats] [Sentry[®] Ectoadvance Plus for Cats] [Sentry[®] Proline Plus Spot On for Cats] [Sentry[®] Proline Plus for Cats] [SENTRY[®] FIPROGUARDTM PLUS for Cats] [FIPROGUARDTM PLUS for Cats] [Sergeant's[®] PRONYL OTCTM PLUS for Cats] [PRONYL OTCTM PLUS for Cats] [Sergeant's[®] AdvanSpot Plus Spot On for Cats] [Sergeant's[®] AdvanSpot Plus for Cats] [Sentry[®] AdvanSpot Plus Spot On for Cats] [Sentry[®] AdvanSpot Plus for Cats] [PetArmor® Plus for cats] [Sergeant's® PetArmor® Plus for cats]

NOTIFICATION

2517-135 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

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]

[Adult Fleas]

[Kills adult fleas [for up to six weeks]] [Kills Fleas [Up to [4] [6] weeks]!] [Kills fleas which may be a source of flea allergy dermatitis] [or flea bite anemia]

Version 14.3 12 DEC 2014 Notification EPA Reg. No. 2517-135 EPA SAL 9/11/2013 & Notification 3/13/2014 Information in [] is optional. Page 2 of 9 Supersedes pending Amendment 3/06/2014 [Ticks] [Kills ticks including those that may transmit Lyme disease] [Kills Ticks for Up to [4 weeks] [1 month] [30 days]!] [Kills Deer Ticks (that may carry Lyme disease) 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, flea eggs, ticks, chewing lice [&] [and] [mosquitoes] [Kills fleas, ticks, [mosquitoes,] chewing lice, flea eggs, [and] flea larvae [and prevents the development of flea pupae]] [Breaks the Flea Life Cycle] [Monthly flea, tick, [mosquito,] chewing lice, and flea egg protection] [Monthly flea, tick, [mosquito] and chewing lice protection] [Kills fleas, ticks, [mosquitoes,] flea eggs, and chewing lice] [[Seven] [7] [Six] [6] Way [Action] [Effectiveness] [Control] [kills fleas, ticks, [mosquitoes,] chewing lice, flea eggs, flea larvae and prevents the development of flea pupae]] [[Six] [6] [Five] [5] Way [Action] [Effectiveness] [Control] [kills fleas, ticks, [mosquitoes,] chewing lice, flea eggs & flea larvae] [[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!] [[Four (4) Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control] [Use [Brand name][this product] monthly to break the flea life cycle.] [[Four (4) Week] [1 month] [30 day] [Flea, Tick and Chewing Lice Control] [Use [Brand name][This product] monthly to control ticks and chewing lice] [Monthly flea, tick, [mosquito,] flea egg, flea larvae and chewing lice protection.] [[4 week] [1 month] [30 day] Flea and Tick Treatment!] [Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]] [Kills Fleas and Ticks for up to [4 weeks] [1 month] [30 days]!] [Kills Fleas, Ticks, Flea Eggs & Flea Larvae for up to [4 Weeks] [1 month] [30 days]] [Brand name][This product provides convenient and effective flea, tick, [and] chewing lice [and] [mosquito] control for cats and kittens over 8 weeks of age] [Controls reinfestation of fleas for up to six weeks] [Flea Eggs and Larvae]

[Flea Eggs and Larvae]
[Controls flea reinfestation [for up to six weeks]]
[Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae [for up to six weeks]]
[Kills all stages of the flea (adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]
[If cat is at high risk for flea reinfestation apply once a month]
[Kills flea eggs [larvae] [and prevents the development of pupae] for up to six weeks]
[With (S)-methoprene [Insect Growth Regulator] [IGR] which Breaks the Flea Life Cycle]
[With [Insect Growth Regulator] [IGR] to Break Flea Life Cycle]
[Dual Action [!]: Fipronil with (S)-methoprene [insect growth regulator] [IGR] Effectively Breaks the Flea Life Cycle]
[Dual Action [!]: Effectively Breaks the Flea Life Cycle[!]]
[Kills Flea Eggs & Flea Larvae [for up to six weeks]!]
[Prevents Flea Eggs From Developing Into Biting Adults]

Version 14.3 EPA Reg. No. 2517-135 12 DEC 2014 Notification EPA SAL 9/11/2013 & Notification 3/13/2014 Information in [] is optional. Page 3 of 9 Supersedes pending Amendment 3/06/2014 [All Others] [For Cats and Kittens 8 weeks of age or older [Can be used on kittens 8 weeks of age and older [Specially Formulated for 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] [Apply once every [4 weeks] [month] [30 days]!] [4 Week Dose!] [1 Month Dose!] [30 Day Dose!] [One Application][Two Applications][Three Applications][Four Applications][Five Applications][Six Applications][Twelve Applications][24 Applications] and/or [1 Month Supply][2 Month Supply][3 Month Supply][4 Month Supply][5 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 (9.8%) + (S)-methoprene (11.8%)] [Contains [the] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Cats (or any ABN)] [FRONTLINE® Plus for Cats (or any ABN)] [FRONTLINE® brand products].*]] [Compare to [FRONTLINE® Top Spot® for Cats (or any ABN)] [FRONTLINE® Plus for Cats (or any ABN)] [FRONTLINE® brand products], contains [the] [same] active ingredient(s).*] [Compare to [FRONTLINE® Top Spot® for Cats (or any ABN)] [FRONTLINE® Plus for Cats (or any ABN)] [FRONTLINE® brand products], contains [the] [an] [same] active ingredient fipronil.*] [Compare to [FRONTLINE® Top Spot® for Cats (or any ABN)] [FRONTLINE® Plus for Cats (or any ABN)] [FRONTLINE® brand products], contains [the] [an] [same] active ingredient (S)-Methoprene.*] [Compare to [FRONTLINE® Top Spot® for Cats (or any ABN)] [FRONTLINE® Plus for Cats (or any ABN)] [FRONTLINE® brand products], contains [the] [same] active ingredients fipronil and (S)-Methoprene.*] [Brand Name] [products] [This product] contain(s) fipronil, [the] [an] [same] active ingredient used in [FRONTLINE® Top Spot® for Cats (or any ABN)] [FRONTLINE® Plus for Cats (or any ABN)] [FRONTLINE® brand products].*] [Brand Name] [products] [This product] contain(s) fipronil, compared to [the] [an] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Cats (or any ABN)] [FRONTLINE® Plus for Cats (or any ABN)] [FRONTLINE® brand products].*] [Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, [the] [same] active ingredients used in [FRONTLINE® Plus for Cats (or any ABN)] [FRONTLINE® brand products].*] [Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, compared to [the] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Cats (or any ABN)] [FRONTLINE® Plus 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® Plus for Cats (or any ABN)] [FRONTLINE® brand products].] [[Brand Name][This product][Frontline®] [Frontline® TopSpot®] is a registered trademark of [Merial®]

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[Company name].]

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

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

[Lift [here] for more information]

[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	
(S)-methoprene	
OTHER INGREDIENT:	
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(s)][tubes][vials][pipettes]] [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+METHOPRENE

[[Brand name][This product] contains Fipronil and S-Methoprene (insect growth regulator) (IGR) to effectively kill fleas (all stages) 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 only.]

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON CATS AND KITTENS OVER 8 WEEKS OF AGE

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

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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.

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:	Flush eyes with plenty of water. Call a doctor if irritation persists.			
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

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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]. 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 $77^{\circ}F[/][25^{\circ}C]$) 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)

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

{END - BACK / SIDE PANEL}

[Coupon(s) inside or on outside of box] [Made in USA] [U.S. Patent No. 5,567,429]

[BAR CODE AREA] EPA Reg. No. 2517-135 EPA Est. No. XXXXX-XX-XXX

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{START - OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE}

[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[*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]

[Monthly reminder card]

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

[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.]

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[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)]

[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]

Toto	Adult Flea	
Toto	Fleas	
-736-	Flea eggs	S
っ	Flea Larvae	3
	Flea Pupae	
-	Ticks	
*	Brown Dog Tick	
*	Deer Tick	
*	American Dog Tick	
「	Chewing Lice	8
*	Lone Star Tick	
I	Mosquitoes	



[Flea life cycle diagram] [Flea Life Cycle]



{END - OPTIONAL PACKAGE COPY }

TUBE/VIAL LABEL	CAT SPOT ON
	FIPRONIL+METHOPRENE
{Front Label}	{Back Label}
{Brand Name}	KEEP OUT OF REACH OF CHILDREN
For Cats over 1.5 lbs \geq 8wks	CAUTION: Read directions and precautions
Fipronil 9.8%, (S)-methoprene 11.8%	before using. Use scissors to open.
0.017 fl oz {label code}	EPA REG. No. 2517-135 {label code}
{EPA REG No may be on either the front or back label}	
{END – TUBE/VIAL LABEL}	