

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

February 21, 2012

James B. Messina,
Principal Regulatory Consultant
(Authorized Agent for Sergeant's Pet Care Products, Inc.)
Exponent
Center for Chemical Regulation and Food Safety
1150 Connecticut Avenue, N.W.
Suite 1100
Washington, DC 20036

Subject: Revise CRP labeling (Net Content, Opening and directions).

- Sergeant's Fipronil Spot-On for Cats EPA Reg. No. 2517-137
- Sergeant's Fipronil + Methoprene Spot-On for cats EPA Reg. No. 2517-135
- Sergeant's Fipronil + Etofenprox + Methoprene Spot-On for Cats EPA Reg. No. 2517-145
- Sergeant's Fipronil + Pyriproxyfen Spot-On for Cats EPA Reg. No. 2517-146
- Sergeant's Fipronil + Etofenprox + Pyriproxyfen Spot-On for Cats EPA Reg. No. 25 17-147
- Sergeant's Fipronil + Etofenprox Spot-On for Cats EPA Reg. No. 2517-148

Applications dated September 26, 2011

Dear Mr. Messina:

The above referenced labeling for each of the subject products, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable:

Please note that we have approved the amended labels for these products with the understanding that they are consistent with the Agency's previously stamped accepted ones; and other than the revisions stated in your applications (dated September 26, 2011), no other changes have been made to the labeling and/or the Confidential Statement of Formula (CSF).

See enclosed copy of the stamped label for your record. If you have any questions concerning this action please contact me or Dr. B.A. Akinlosotu (703-605-0653 or via email Akinlosotu.bonaventure@epa.gov).

Sincerely

Richard Gebken,

Product Manager 10 Insecticide Branch

Registration Division (7505P)

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FRONT PANEL

CAT SPOT ON

FIPRONIL+METHOPRENE

ACCEPTED

Under the Federal Insecticide, Fungicide,

and Rodenticide Act, as amended, for the pesticide registered under:

EPA. Reg. No: 25/7-/35

FEB 2 1 2012 -

[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®) (Sentry®) Frontier Gold (Spot On) for cats]

[ABNs][(Sergeant's®) (Sentry®) Ectoadvance (Spot On) for cats]

[ABNs][SentryProline (Spot On) for cats]

[ABNs][[SENTRY®] FIPROGUARDTM PLUS for cats]

[ABNs][[Sergeant's] PRONYL OTCTM PLUS for cats]

[ABNs][[Sergeant's®][SENTRY®] AdvanSpot Plus (Spot On) for cats]

[For use ONLY on cats [[&] [and] kittens] OF ALL WEIGHTS over 8 weeks of age]

[For use ONLY on cats] [of ALL weights][over 8 weeks of age]

[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]

[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 [Full or Partial Brand Name] monthly to break the flea life cycle.]

[[Four (4) Week] [1 month] [30 day] [Flea, Tick and Chewing Lice Control]

[Use [Full or Partial Brand Name] monthly to control ticks and chewing lice]

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FRONT PANEL

CAT SPOT ON FIPRONIL+METHOPRENE

[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]]

[(Full or Partial Brand Name) 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]

[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]!]

[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 (S)-methoprene to Break 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]

[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]

[(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 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] [12 Month Supply] [13 Month Supply] [14 Month Supply] [15 Month Supply] [16 Month Supply] [17 Month Supply] [18 Month Supply

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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]

FRONT PANEL

CAT SPOT ON

FIPRONIL+METHOPRENE

[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 Fipronil[,] and (S)-methoprene [,] [-]the [same] active ingredients used in Frontline Plus® for cats*]

[* [Full or Partial Brand Name] is not manufactured by or distributed by Merial. Frontline Plus® is a registered trademark of Merial.]

[Full or Partial Brand Name] is a registered trademark of Sergeant's Pet Care Products, Inc.]

[[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]

ACTIVE INGREDIENTS:

 Fipronil
 9.80%

 (S)-methoprene
 11.80%

 OTHER INGREDIENT:
 78.40%

 TOTAL
 100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

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

Net Contents:

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four] 0.017 fl oz (0.50 mL) applicators

{END - FRONT PANEL}

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BACK PANEL

CAT SPOT ON FIPRONIL+METHOPRENE

[[Full or Partial Brand Name] 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 [Full or Partial Brand Name] 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

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 only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged cats. Call 1-800-781-4738 for 24-hour assistance

| 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. | | | |
| | 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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BACK PANEL

CAT SPOT ON

FIPRONIL+METHOPRENE

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. FOR EXTERNAL USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS. Do not use on kittens under 8 weeks of age. Use entire contents of tube [vial] on each cat. [Do not split one tube between cats.] [Do not use multiple tubes on one cat.] Consult a veterinarian before using this product on debilitated, aged, or medicated cats. Can be used on breeding, pregnant, or lactating [cats] [female cats] [queens]. Consult a veterinarian before using on cats with known organ dysfunction. Cats may experience some temporary irritation at the site of product application. Certain medications can interact with pesticides. Sensitivities may occur after using ANY pesticide product on cats. If signs of sensitivity occur bathe your cat with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

{Outer Packaging}

How to open: Remove product tube(s) [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] and use the narrow end to part the cat's hair. Apply contents of one tube [vial] of [Full or Partial 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] in paper and put into the trash. Only one applicator per treatment is needed.

[Optional diagram may or may not appear anywhere on the finished label]







FREQUENCY OF APPLICATION

Use [Full or Partial Brand Name] monthly for complete control of flea, tick [and] chewing lice [and mosquito] infestations. [Studies show that] [Full or Partial Brand Name] 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. [Full or Partial Brand Name] 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].

[(Full or Partial Brand Name) can be used on breeding, pregnant and lactating (queens) (female cats).]

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BACK PANEL

CAT SPOT ON

FIPRONIL+METHOPRENE

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] [U.S. Patent No. 5,567,429]

Distributed by: Sergeant's Pet Care Products, Inc. P.O. Box 540399 Omaha, NE 68154-0399

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

{END - BACK / SIDE PANEL}

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ADULT FLEA

LEA LARVAE

{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.]

[Application Instructions] [Directions for Use] How to Open:

- 1. Remove product tube(s) [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.

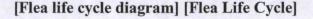
2. Apply contents of one tube [vial] of {Full or Partial Brand Name} [as a stripe, starting high [on] [to] the back of the cat's neck to in front of the shoulder blades] [as a spot between the shoulder blades]. Squeeze tube firmly to apply all of the solution to the cat's skin.]

[Optional diagram may or may not appear anywhere on finished label]









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

[Full or Partial Brand Name]

[Monthly reminder card]

[3 Month [Treatment] [Application] Tracker]

[For year round protection apply [Full or Partial Brand Name] monthly.]

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

[First][1st][Second][2nd][Third][3rd][Fourth][4^{th}][Fifth][5^{th}][Sixth][6^{th}][Seventh][7^{th}][Eighth][8^{th}][Ninth][9^{th}][Tenth][10^{th}][Eleventh][11^{th}][Twelfth][12^{th}]

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[Dose] [Treatment] [Application] (Empty blank for owner to fill in date) (Date: MM/DD/YY)] **{OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE}**

[calendar stickers with Full or Partial Brand Name] [Place stickers on your calendar as a reminder to reapply [Full or Partial Brand Name] in 30 days.]

[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 [Full or Partial Brand Name]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

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

| n fleas | | fleas | | 3 3 |
|-----------------------|-----------------|-------------------|--------|---|
| s flea eggs | & | flea eggs | | 9 |
| n flea pupae | | flea pupae | 333333 | |
| 7 flea larvae | 3 | flea larvae | 939999 | |
| Adult Flea | | Adult Flea | 33333 | 2222 |
| ticks | (S) | ticks | | 3 |
| Deer Tick | | Deer Tick | | ; , , , , |
| Brown Dog Tick | | Brown Dog Tick | | |
| Lone Star Tick | 8 | Lone Star Tick | | |
| * American Dog Tick | ® | American Dog Tick | | |
| * chewing lice | (| chewing lice | | |
| mosquitoes mosquitoes | ⊗ | mosquitoes | | |
| CENT OPTIONAL D | A CW A CE CORVA | | | |

{END - OPTIONAL PACKAGE COPY }

TUBE/VIAL LABEL

CAT SPOT ON FIPRONIL+METHOPRENE

| {Front Label} | | {Back Label} | | |
|---|--------------------------|--|--------------|--|
| {Brand Name} [For use only on | | KEEP OUT OF REACH OF CHILDREN | | |
| cats/kittens 8 weeks or older] | | CAUTION: Read directions and precautions | | |
| Fipronil 9.8% w/w, (S)-methoprene 11.8% | | before using. Use scissors to open. | | |
| w/w | 0.017 fl oz {label code} | EPA REG. No. 2517-135 | {label code} | |
| {END - TUE | BE/VIAL COPY} | | | |