

2517-147

02-21-2012

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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. 2517-147
- Sergeant's Fipronil + Etofenprox Spot-On for Cats
EPA Reg. No. 2517-148

Applications dated September 26, 2011

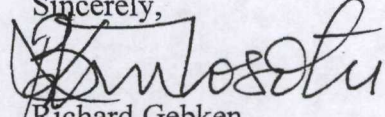
Dear Mr. Messina:

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,



Sr

Richard Gebken,
Product Manager 10
Insecticide Branch
Registration Division (7505P)

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Sergeant's[®] Master Label

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Information in [] is optional.

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[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.]

FRONT PANEL

CAT SPOT ON

FIPRONIL + ETOFENPROX + PYRIPROXYFEN

Sergeant's Fipronil + Etofenprox + Pyriproxyfen Spot-On for Cats

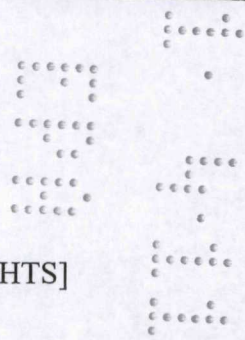
ACCEPTED
FEB 21 2012

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

EPA. Reg. No: 2517-147

[ABNs:]

- [(Sergeant's[®]) (Sentry[®]) FRONTIER GOLD (Spot On) for cats]
- [(Sergeant's[®]) (Sentry[®]) Ectoadvance[™] (Spot On) for cats]
- [(Sergeant's[®]) (Sentry[®]) Frontspot[™] (Spot On) for cats]
- [(Sergeant's[®]) (Sentry[®]) Firstline (Spot On) for cats]
- [(Sergeant's[®]) (Sentry[®]) Frontedge (Spot On) for cats]
- [(Sergeant's[®]) (Sentry[®]) Frontguard[™] (Spot On) for cats]
- [(Sergeant's[®]) (Sentry[®]) FRONTPRONIL (Spot On) for cats]
- [(Sergeant's[®]) (Sentry[®]) FIPROLINE (Spot On) for cats]
- [(Sergeant's[®]) (Sentry[®]) Advanspot (Spot On) for cats]



[Apply to kittens over 12 weeks old]

[Apply to kittens 12 weeks or older]

[For use ONLY on cats [[&][and] kittens 12 weeks or older]OF ALL WEIGHTS]

[For use ONLY on cats][of ALL weights][over 12 weeks of age]

[Mosquitoes]

- [•Kills mosquitoes]

[Chewing Lice]

- [•Kills chewing lice]
- [•Fast Action against chewing lice infestations]

[Adult Fleas]

- [• [Full or Partial Brand Name] 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]]
- [• [Full or Partial Brand Name] kills adult fleas for up to six weeks]
- [•If cat is a high risk for flea reinfestation a once month application may be needed]
- [•Prevents and controls reinfestations]

[Flea Eggs and Larvae]

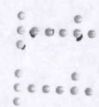
- [•Stops and prevents infestations]
- [•Controls flea reinfestation for up to 6 weeks]
- [• [Full or Partial Brand Name] kills adult fleas, flea eggs, [and] flea larvae [and prevents pupae] for up to six weeks]

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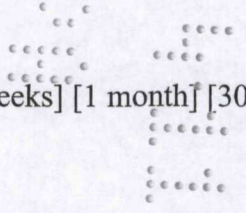
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- [Full or Partial Brand Name] prevents development of all flea stages for up to 6 weeks]
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)]
- If cat is a high risk for flea reinfestation a once month application may be needed]
- Kills flea eggs [larvae] for up to [3 months] [12 weeks]]
- [Seven][Six] [Five][7][6] [5]Way Protection [Kills fleas, ticks, [mosquitoes,] chewing lice, 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]
- Triple Action [!]:Fipronil and Etofenprox with Pyriproxyfen IGR] [Effectively Breaks the Flea Life Cycle]]
- Triple 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]

- [(Full or Partial Brand Name) 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]]
- 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]]
- [Four [4][Three][3] Way Pest Protection]
- When used monthly [Full or Partial Brand Name] 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!]
- Starts to kill fleas and ticks in an hour, continues to kill for a month]
- Kills [fleas] in 4 hours [and] [ticks in one hour]]
- [[Full or Partial Brand Name] kills fleas in 4 hours and Dermacentor ticks in one hour]
- Kills ticks in 1 hour]
- Kills fleas and ticks in [24 hours] [1 day]]
- Starts killing fleas and ticks in as little as 1 hour]

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Sergeant's® Master Label

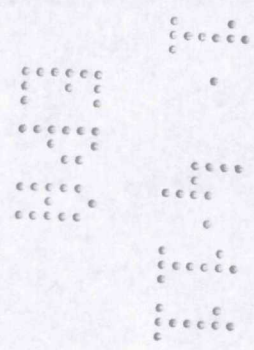
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[All Others]

- [•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 Application][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][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]
- [• 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]]
- [•Patent Pending]
- [•[1][2][3][4][5][6][12][24] Applications]



ACTIVE INGREDIENTS:

Fipronil	9.80%
Etofenprox.....	15.00%
Pyriproxyfen.....	2.20%
OTHER INGREDIENT[**].....	73.00 %
TOTAL:	100.00%

[**diethylene glycol monoethyl ether]

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Side] [or] [Back] Panel 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

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[BACK/SIDE CARTON LABEL - MASTER LABEL]

[Full or Partial Brand Name] contains Fipronil, Etofenprox and [the insect growth regulator] [IGR] Pyriproxyfen to effectively kill fleas, ticks, [mosquitoes] and chewing lice. The active ingredients in [Full or Partial Brand Name] features 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 only. Do not use on kittens under 12 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.] If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. If your pet has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. Call 1-800-224-PETS [7387] for 24-hour assistance.

FIRST AID

If In Eyes	<ul style="list-style-type: none"> • 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 further treatment advice.
If On Skin Or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none"> • Call a poison control center or 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.

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.

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
READ ENTIRE LABEL BEFORE EACH USE.

FOR EXTERNAL USE ON CATS ONLY. Do not use on kittens under 12 weeks of age. Use entire contents of tube [vial] on each cat. [Do not split tubes between cats.] [Do not use multiple tubes on one cat.] 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. **Best if used year round.** Consult a veterinarian before using this product on debilitated, aged, medicated cats. Consult a veterinarian before using on cats with known organ dysfunction. Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied. Cats and dogs that actively groom or engage in close physical contact with treated cat may be at risk of serious harmful effects. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your pet for the next 24 hours.

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 by calling 1-800-781-4738.

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



[{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.

FREQUENCY OF APPLICATION

Use [Full or Partial Brand Name] monthly for complete control of flea, tick [and] chewing lice [and mosquito] infestations. [Full or Partial Brand Name] kills fleas for up to six weeks, and flea eggs, [and] flea larvae [and prevents flea pupae] for up to 12 weeks.

Apply monthly, if your pet 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] kills mosquitoes within 24 hours for up to 14 days, and within 48 hours for up to 28 days.] [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.

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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 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)
[Made in USA]

Distributed by:
Sergeant's Pet Care Products, Inc.
P.O. Box 540399
Omaha, NE 68154-0399
EPA Reg. No. 2517-147
EPA Est. No. XXXXX-XX-XXX

[BAR CODE AREA]

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{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.]



[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.

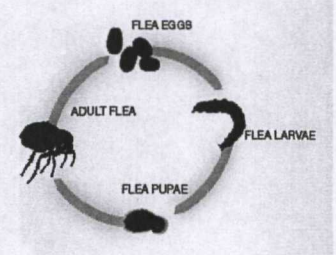
How to Apply:

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 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 the finished label]



[Flea life cycle diagram]



[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]

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[Full or Partial Brand Name]

[Monthly reminder card]

[Apply [Full or Partial Brand Name] 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)]

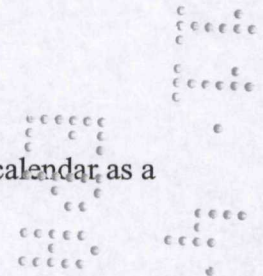
[Ninth [dose] [Treatment] (Empty blank for owner to fill in date)]

[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)]

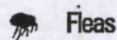
[calendar stickers with Full or Partial Brand Name] [Place stickers on your calendar as a reminder to reapply [Full or Partial Brand Name] in 30 days.



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

Enclosed for your convenience is an application reminder magnet. Push the (reset) button to start the clock. After 30 days the magnet will flash (and beep) reminding you to reapply [Full or Partial Brand Name]. 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 which may or may not appear anywhere on the finished label]



Fleas



Fleas



Ticks



Ticks



Mosquitoes



Mosquitoes



Chewing Lice



Chewing Lice

{END - OPTIONAL INSERT OR PACKAGE COPY}

[TUBE] [VIAL] LABEL

Front Label

Back Label

{Brand Name} [For use only on cats/kittens
12 weeks or older]

Fipronil 9.8% w/w, Etofenprox 15% w/w,

Pyriproxyfen 2.2% w/w

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.

EPA REG. No. 2517-147

{label code}

