

2517-147

5/1/2014

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 1, 2014

Mr. James Messina
Authorized Representative of
Sergeant's Pet Care Products, Inc.
c/o Exponent
1150 Connecticut Avenue, Suite 1100
Washington, DC 20036-4127

**Subject: Acceptance of Updated Master Labeling
Sergeant's® Fipronil + Etofenprox + Pyriproxyfen Spot On for Cats, EPA Reg. No. 2517-147
Your Submission Dated July 10, 2013 & E-Resubmission Dated April 30, 2014**

Dear Mr. Messina:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

A copy of your updated master label stamped "Accepted" is enclosed for your records. Please note that this letter does not supersede anything contained within the Agency's letter dated September 30, 2011 and the original conditions of acceptance detailed in the Agency's letter dated August 18, 2011. If you have any questions about this label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov or Mr. Richard J. Gebken at (703) 305-6701 or via e-mail at Gebken.Richard@epa.gov during the hours of 9:00 A.M. to 5:30 P.M. EST.

Sincerely Yours,

Handwritten signature of Carmen J. Rodia, Jr. in black ink.

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

Enclosures: Updated Master Label Stamped "Accepted," dated May 1, 2014
Efficacy Review #1, dated December 30, 2013
Efficacy Review #2, dated April 7, 2014

002517-00147 D480769

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FRONT PANEL

CAT SPOT ON

FIPRONIL + ETOFENPROX + 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 + Etofenprox + Pyriproxyfen Spot On for Cats

[ABNs]

- [Sergeant's® Ectoadvance™ II [Spot On] for Cats]
- [Ectoadvance™ Plus II [Spot On] for Cats]
- [Sergeant's® Advanspot Plus II [Spot On] for Cats]
- [Sentry® Advanspot Plus II [Spot On] for Cats]
- [SENTRY® PRONYL OTC™ Max III for Cats]
- [SENTRY® FIPROGUARD™ Max III for Cats]
- [PetArmor® Max III for Cats]
- [Sergeant's® PetArmor® Max III for Cats]
- [PetArmorPro™ Advanced III for Cats]
- [Sergeant's® PetArmorPro™ Advanced III for Cats]
- [PetArmorPro™ Advanced Ticks III for Cats]
- [Sergeant's® PetArmorPro™ Advanced Ticks III for Cats]
- [VetSpot Plus III for Cats]
- [VetSpot Advanced III for Cats]

ACCEPTED
May 1, 2014
Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

EPA. Reg. No: 2517-147

For use ONLY on cats [[&] [and] kittens] over 1.5 lbs and 12 weeks of age or older [OR]
ONLY for cats [[&] [and] kittens] 12 weeks of age or older and over 1.5 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]

- [Starts killing fleas in [as little as][just] [15 minutes][1 hour][after application]]
- [Starts to kill fleas in [as little as][just] [15 minutes][1 hour][after application]]
- [Quickly kills fleas]
- [Kills fleas [fast]]
- [Prevents and controls reinfestations]
- [Controls flea reinfestation [for up to six weeks]]
- [Kills Fleas [Up to [4] [6] weeks]!]
- [[Brand Name] kills adult fleas for up to six weeks]
- [Kills Fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]
- [If cat is a high risk for flea reinfestation a once month application [may be][is] needed]
- [Kills immature fleas [for up to 3 months]]

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[[Starts killing][Starts to kill] [adult] fleas [in as little as] [in just] [15 minutes] [1 hour]]
[[Starts killing] [Starts to kill] newly emerged fleas [in as little as] [in just] [15 minutes][1 hour]
before they lay eggs]
[Kills fleas which may be a source of [flea allergy dermatitis) [flea bite anemia] [tapeworm]]

[Flea Eggs and Larvae]

[Stops [and prevents] infestations]
[Prevents and controls reinfestations]
[Controls flea reinfestation for up to 6 weeks]
[[Brand Name] prevents development of all flea stages for up to 6 weeks]
[[Brand Name] kills adult fleas, flea eggs, [and] flea larvae [and prevents pupae] for up to six
weeks]
[Prevents all immature flea stages (flea eggs, flea pupae and flea larvae)]
[Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)]
[Prevents Flea Eggs From Developing Into Biting Adults]
[Kills flea eggs [and larvae] for up to [3 months] [12 weeks]]
[Kills Flea Eggs & Flea Larvae [for up to 3 months]!]
[Kills all stages of the flea life cycle]
[Triple Action [!]: Effectively Breaks the Flea Life Cycle[!]]
[[With][Contains] Pyriproxyfen to Break Flea Life Cycle]
[[With][Contains] Insect Growth Regulator to Break Flea Life Cycle]
[[With][Contains] Pyriproxyfen Insect Growth Regulator which Breaks the Flea Life Cycle]
[Triple Action [!]:Fipronil and Etofenprox with Pyriproxyfen IGR] [Effectively Breaks the Flea
Life Cycle]]
[[Seven][Six] [Five][7][6] [5]Way Protection [Kills fleas, ticks, [mosquitoes,] chewing lice, flea
eggs, [and] flea larvae [and prevents flea pupae]]]

[Ticks]

[Quickly kills ticks]
[Kills ticks [fast]]
[Kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis,
babesiosis, and anaplasmosis]
[Kills Ticks [for Up to [4 weeks][1 month][30 days]!]
[Kills American Dog Ticks for up to [4 weeks][1 month][30 days]]
[Kills Ticks (Including 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]!]
[Kills [Brown], [American] [and Lone Star] dog ticks for up to [4 weeks][1 month][30 days]]
[Kills Deer Ticks (which may transmit Lyme disease) for up to [4 weeks] [1 month] [30 days]]
[Kills Ticks including those that may transmit Lyme disease]
[(Starts killing ticks in as little as 15 minutes)]
[Starts killing ticks in [as little as] [just] [15 minutes] [1hour] [after application]]
[[Starts killing] [Starts to kill] ticks [in as little as] [in just] [15 minutes] [1 hour] including those
that [may transmit][may cause] Lyme disease]

[Multiple Infestations]

[Quickly kills fleas and ticks]
[Kills fleas and ticks [fast]]
[Starts killing fleas and ticks in [as little as] 1 hour]

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[Kills fleas and ticks in [24 hours] [1 day]]
[Starts to kill fleas and ticks in an hour, continues to kill for [1 month][30 days][4 weeks]]
[Controls reinfestation for up to [4 weeks][30 Day] [1 Month]]
[Contols infestation and reinfestation for up to [4 weeks] [30 days] [1 month]]
[Kills Fleas and Ticks for up to [4 weeks!] [30 days!] [1 month!]]
[[4 Week] [30 Day] [1 Month] [Flea and Tick Treatment]]
[Once A Month Flea and Tick Treatment]
[[Four (4) Week] [30 Day] [1 Month] [Flea, Tick, [Mosquito] and Chewing Lice Control]]
[Monthly flea, tick, [mosquito] and chewing lice protection]
[Kills fleas, ticks, [mosquitoes,] and chewing lice]
[Kills fleas, ticks, [&] chewing lice [& mosquitoes]]
[[Four [4][Three][3] Way Pest Protection]
[Flea & Tick Control for Cats & Kittens 12 weeks old or older]
[**Brand Name**] [This product] provides convenient and effective flea, tick, [and] chewing lice
[and mosquito] control for cats and kittens [12 weeks or older]]
[When used monthly [Brand Name] completely breaks the flea life cycle and controls tick and
chewing lice infestations.]

[All Others]

[Brand Name][This product] is a trademark of [Company Name]
[Fipronil (9.8%) + Etofenprox (15.0%) + Pyriproxyfen (2.2%)]
[For Cats and Kittens 12 weeks of age or older]
[Specially Formulated for Cats and Kittens [12 weeks or older]]
[Fast Acting] [Long Lasting]
[Waterproof][Water resistant]
[Cats can be bathed 24 hours after treatment]
[ICON Showing [4 Week] [1 month] [30 Day] Protection]
[4 Week Dose!][1 Month Dose!] [30 Day Dose!]
[Apply once every [4 weeks] [month] [30 days]!]
[Best [if] [when] used year round!]
[Easy to Use Application]
[Convenient to use]
[[1][2][3][4][5][6][12][24] [Application][Dose] [Treatment][tube][vial][applicator][pipette](s)]
[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]
[[Free] [Brochure] [and] [Calendar Stickers] Inside!]
[[Free with purchase] [Free inside] Monthly Application Reminder [Magnet] [clip] [insert]]
[Patent Pending]
[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][!]]

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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] [Label[s]] [Panel[s]] For Additional Precautionary Statements

NET CONTENTS: X fl oz [Y – 0.017 fl oz [tube][vial][applicator][pipette](s)]
[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]
0.017 fl oz [0.50 ml] [tube][vial][applicator][pipette](s)

BACK/SIDE PANEL CAT SPOT ON FIPRONIL+ETOFENPROX+PYRIPROXYFEN

[Brand Name][This product] contains Fipronil, Etofenprox and [the insect growth regulator] [IGR] Pyriproxyfen to effectively kill fleas, ticks, [mosquitoes] and chewing lice. The active ingredients in [Brand Name][this product] features a sustained-release formula developed for fast-acting [and long-lasting] control of fleas, ticks, [mosquitoes] and chewing lice [for 30 days] [1 month] [4 weeks] 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 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.

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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.

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 1.5 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.

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(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][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

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[and mosquito] infestations. [Brand Name][This product] 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. [[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][1 month] [4 weeks].

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)
[Made in USA]

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

[BAR CODE AREA]

EPA Reg. No. 2517-147
EPA Est. No. XXXXX-XX-XXX

{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.]

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

[Brand Name]

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

[For year-round protection, apply [Brand Name] monthly.]

[Pet's Name (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)

[Monthly reminder card]

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

[calendar stickers with **Brand Name**]

[Place stickers on your calendar as a reminder to reapply [Brand Name] in [30 days] [1 month].]

[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.]

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{END - OPTIONAL INSERT OR PACKAGE COPY}

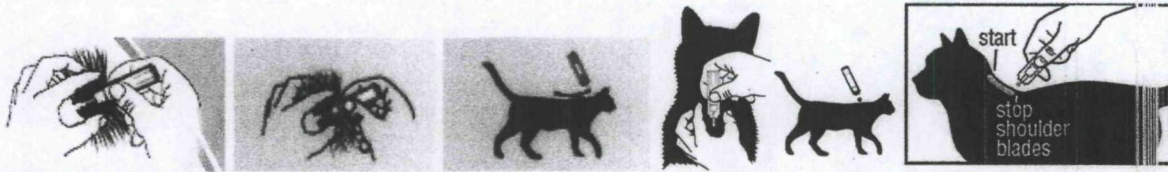
[TUBE] [VIAL] LABEL

Front Label

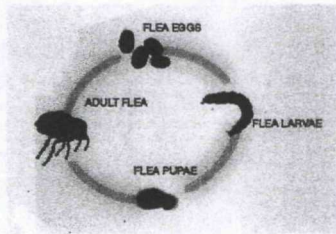
Back Label









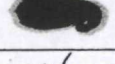









<p>{Brand Name} Cats ≥12 wks & 1.5 lbs Fipronil 9.8%, Etofenprox 15%, Pyriproxyfen 2.2% 0.017 fl oz [0.50 mL] {label code}</p>	<p>KEEP OUT OF REACH OF CHILDREN CAUTION: Read directions and precautions before using. Use scissors to open. EPA REG. No. 2517-147 {label code}</p>
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[Optional graphics below may or may not appear anywhere on finished label]



[Flea life cycle diagram] [Flea Life Cycle][Sample coloring and layout may be different on final label]



	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	
	Flea Pupae	
	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	






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	Chewing Lice	
	Lone Star Tick	
	Mosquitoes	