



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 14, 2016

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

Subject: Label Amendment – Acceptance of Updated Label for Cat Spot-On Mitigation
Product Name: Sergeant's PreTect Squeeze-On Flea Control for Cats and Kittens
EPA Registration Number: 2517-88
Application Date: November 24, 2015
Decision Number: 486765

Dear Mr. Messina:

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable under FIFRA Section 3(c)(7)(B), subject to the following conditions:

1. You must submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
2. This registration is time-limited and expires two years from the date of this letter.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. 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
4. 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 cats 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 dogs (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 cats 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 cat incidents for each severity code for each pet weight range on the product label, as applicable.
 - A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range, as applicable.
 - Table showing number of incidents for each cat breed, where provided.
 - Table showing number of incidents in cats for each clinical sign.

- Table showing number of incidents in cats for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. You are required to comply with the data requirements described in the DCI or EDSP Order identified below:
 - a. Pyriproxyfen GDCI-129032-1299
 - b. Pyriproxyfen EDSP-129032-186
 - c. Pyriproxyfen EDSP-129032-187

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

http://www.epa.gov/oppsrrd1/contacts_prd.htm

6. Be aware that proposed data requirements have been identified in a Work Plan or proposed DCI. For more information on these proposed data requirements, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:
http://www.epa.gov/oppsrrd1/contacts_prd.htm

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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Your release for shipment of the product constitutes acceptance of these conditions. If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). If you have any questions, please contact Mr. Carmen J. Rodia, Jr. by phone at (703) 306-0327, or via email at Rodia.Carmen@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Gebken", written in a cursive style.

Richard Gebken
Product Manager 10
Invertebrate & Vertebrate Branch 2
Office of Pesticide Programs

Enclosure: Stamped "Accepted" Master Label, dated April 14, 2016

Sergeant's Master Label

07 April 2016 Mitigation
Information in [] is optional.

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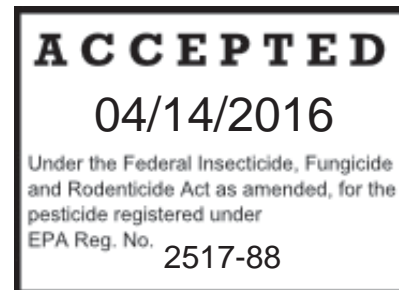
[Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels.]

Sergeant's PreTect Squeeze-On Flea Control for Cats and Kittens

For use ONLY on cats [and kittens] 6 lbs and over and 12 weeks or older

{Optional Marketing Statements}

- [Breaks The Flea Life Cycle!]
- [Best when used year round]
- [Prevents Flea Reinfestation for up to 3 months]
- [Kills Flea Eggs!]
- [Special Formula for Cats and Kittens]
- [Each Application protects for 3 months!]
- [Economical Solution to Flea Control]
- [Kills Flea Eggs for Three Months [per application]]
- [Kills Hatching Flea Eggs for Three Months [per application]]
- [Prevents Flea Eggs from Developing into Biting, Breeding, Adults for up to Three Months [per application]]
- [Prevents Fleas on Treated Cats for Three Months [per application]]
- [Aids in the Control of Flea Populations!]
- [Easy to Apply Squeeze-On Formulation!]
- [Prevents New Fleas from Growing up to Bite!]
- [Easy to Apply!]
- [[3 month], [6 month], [12 month] Supply]



KEEP OUT OF REACH OF CHILDREN CAUTION

See Back Panel for Additional Precautionary Statements

Net Contents: X fl oz

[One][Two][Three][Four]
0.047 fl oz (1.4 mL) applicator

ACTIVE INGREDIENT:

Pyriproxyfen2.20%

OTHER INGREDIENTS:.....97.80%

TOTAL 100.00%

PURPOSE:

Sergeant's PreTect Squeeze-On is an effective easy to use product. This product prevents eggs from fleas on treated cats from developing into biting adults for three months. As with all flea control products, Sergeant's PreTect Squeeze-On should be used as a part of a program aimed at reducing flea populations. For existing flea infestations, a premise treatment including an adulticide and larvicide should be used prior to treating your pet with Sergeant's PreTect Squeeze-On. Consult your veterinarian or entomologist or retailer for program recommendations.

Sergeant's PreTect Squeeze-On Flea Control for Cats and Kittens

Sergeant's Master Label

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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. Avoid contact with eyes and clothing. Wear protective eyewear. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco.

HAZARDS TO DOMESTIC ANIMALS: For external use on cats only. Individual sensitivities, while rare, may occur after using ANY pesticide product on cats. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Certain medications can interact with pesticides. Do not treat your cat with more than one pesticide at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant, or nursing animals. Consult a veterinarian before using on cats with known organ dysfunction.

FIRST AID

If In Eyes:	Hold eye open and rinse slowly and gently with soap and water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
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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 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 6 lbs. Use entire contents of tube on each cat. [Do not split one tube 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. Do not get this product in your cat's eyes or mouth. Repeat applications may be made if necessary, but do not apply more often than once every 3 weeks. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

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.

Sergeant's Master Label

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FOR SARAN TUBES IN BLISTER CARD: Remove product tube from package. Holding tube with notched end pointing up and away from face and body, cut off narrow end at notches. Invert tube over cat or kitten and use open end to part cat's or kitten's hair. Apply contents of one tube of Sergeant's PreTect Squeeze-On solution as a spot or stripe, starting high on the back of the cat's or kitten's neck behind its head. Wrap tube and put in trash. Repeat application in 3 months.

BLISTER CARD WITH TRI-LAYER TUBES: Remove product tube(s) from package. Fold along perforation between tubes and tear off one tube. [Return unused tubes to package.] Holding tube with notched end pointing up and away from face and body, snap off narrow end at notches. Invert tube over cat or kitten and use open end to part cat's or kitten's hair. Squeeze tube firmly to apply contents of one tube of Sergeant's PreTect Squeeze-On solution as a spot or stripe, starting high on the back of the cat's or kitten's neck behind its head. Wrap tube and put in trash. Repeat Application in 3 months.

STORAGE AND DISPOSAL

STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F/[/][25°C]), dry place that is inaccessible to children and pets. Do not refrigerate and protect from freezing. Protect from direct sunlight.

CONTAINER DISPOSAL: If empty: Do not reuse this container. Place in trash or 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.

NOTICE OF WARRANTY

Sergeant's Pet Care Products, Inc. makes no warranty of merchantability, fitness for a particular purpose, or otherwise, expressed or implied concerning this product or its uses which extend beyond the use of the product under normal conditions in accordance with the statement made on this label.

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)

Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

EPA Reg. No. 2517-88
EPA Est. No. XXXX-XX-XXX
{date & label code}

TUBE / VIAL LABEL

Front Label

Sergeant's PreTect Squeeze-On Flea Control for Cats and
Kittens \geq 12 wks & over 6 lbs
Pyriproxyfen 2.2%
0.047 fl oz [1.4 mL] {label code}

Back Label

KEEP OUT OF REACH OF CHILDREN
CAUTION: Read directions and
precautions before using.
EPA REG. NO. 2517-88 {label code}