## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 29, 2014

James Messina Sergeant's Pet Care Products, Inc. 10077 South 134<sup>th</sup> Street Omaha, NE 68138-3710

 Subject: Label Amendment – Acceptance of Master Labelling Submitted for Implementation of Pet Spot-On Mitigation Language
Product Name: Sergeant's Squeeze-On Flea & Tick Control for Dogs and Puppies EPA Registration Number: 2517-89
Application Date: December 5, 2013
Decision Number: 486619

Dear Mr. Messina:

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

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one 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.

This registration is now time-limited and expires two years from the date of this letter.

Please consider limiting the formulations of this product to one basic confidential statement of formula. The Agency may require this in the future and no additional alternate formulations or minor formulation amendments will be approved for this product in the future.

You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on January 1, 2015

The quarterly reports are due two months after the quarter ends. Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kable Davis).

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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

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 dogs 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 cats (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 dogs 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 dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Carlyn Petrella by phone at 703-347-0439, or via email at petrella.carlyn@epa.gov.

Sincerely,

Richard J. Ceede

Richard Gebken Product Manager 10 Invertebrate Vertebrate Branch 2 Office of Pesticide Programs Date: October 29, 2014

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## FRONT PANEL

SQUEEZE-ON FOR DOGS PERMETHRIN + PYRIPROXYFEN

Editor's Note: Text in [Brackets] are optional marketing statements any or all of which may be used on the final label.

### Sergeant's Squeeze-On Flea & Tick Control for Dogs and Puppies

For use ONLY on dogs [33[-][to] 66 lbs] [greater than 66 lbs] {OR}

For use ONLY on dogs [[&][and] puppies [7[-][to]15] [15[-][to]33] lbs and over [12 weeks][3 months] of age {OR}

ONLY For Dogs [33[-][to] 66 lbs] [greater than 66 lbs] {OR}

ONLY For Dogs & Puppies [12 weeks][3 months] or older [&][and] [7[-][to]15][15[-][to]33] lbs

[1.5 x 1.5 cm or as indicated]



[Monthly Flea, Tick & Mosquito Treatment] [Kills and Repels Fleas & Ticks for up to a Month] [Kills Flea Eggs and Larvae [For up to 63 days] [For up to 2 months] per application] [Kills Fleas, Ticks, and Mosquitoes [For up to 30 days] [For up to 1 month] per application] [Kills and Repels Mosquitoes!] [Kills and Repels Mosquitoes which may transmit heartworm disease] [Breaks Flea Life Cycle!] [Kills and Repels Deer Ticks which may transmit Lyme Disease] [[3 (or 4, 5, 6, 9, 12)] [three (or four, five, six, nine, twelve)] [month supply] [applications]] [Caring for pets since 1868] [Best if Used Year Round] ACCEPTED [Kills], [Protects Against], [Controls] Fleas, Flea Eggs and Larvae] 10/29/2014 [Kills], [Protects Against], Fleas, Ticks, Mosquitoes, Flea Eggs and Larvae] [5 Way Protection- Kills Fleas, Ticks, Mosquitoes, Flea Eggs and Larvae] Under the Federal Insecticide, Fungicide [Monthly Calendar Stickers Inside!] and Rodenticide Act as amended, for the [Kills & Repels fleas up to 1 month] pesticide registered under EPA Reg. No. [Kills flea eggs and larvae for up to 63 days] 2517-89 [Breaks Flea Life Cycle] [Protects against blood feeding mosquitoes (which may transmit heartworm disease) up to 4 weeks] [Kills and Repels Ticks for up to 4 weeks]

#### **ACTIVE INGREDIENTS:**

Permethrin [CAS #52645-53-1]*	
Pyriproxyfen [CAS #95737-68-1]	1.90%
OTHER INGREDIENTS:	
TOTAL	100.00%

\* Cis/trans ratio: Max 55% (±) cis and min 45% (±) trans

[Nylar® is a registered trademark of McLaughlin Gormley King Company. US Patent No. 5,942,525]

## KEEP OUT OF REACH OF CHILDREN CAUTION

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

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Net Contents: XX fl oz [XX mL(s)] [3][4][5][6][9][12]

[ - 0.034 fl oz (1.0 mL) applicators] [ - 0.051 fl oz (1.5 mL) applicators] [ - 0.101 fl oz (3.0 mL) applicators] [ - 0.152 fl oz (4.5 mL) applicators]

## BACK / SIDE PANEL

#### SQUEEZE-ON FOR DOGS PERMETHRIN + PYRIPROXYFEN

#### READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS 3 MONTHS OF AGE AND OLDER.

[Brand name][This product] is an effective and easy to use product. It prevents eggs from fleas on treated dogs from developing into biting adults for up to [2 months] [63 days]. [[Brand name][This product] also kills and repels mosquitoes and protects against blood feeding by mosquitoes (vectors of Heartworm) for up to 4 weeks.]

#### PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS. CAUTION.** Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

**HAZARDS TO DOMESTIC ANIMALS. FOR EXTERNAL USE ON DOGS ONLY.** Individual sensitivities, while rare, may occur after use with ANY pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant, or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product.

FIRST AID		
IF IN EYES	• 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.	
HOT LINE NUMBER		
Have the product	t container or label with you when calling a poison control center or doctor, or going	
for treatment Fo	r more information on this pesticide product (including health concerns, medical	

for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-781-4738.

PHYSICAL OR CHEMICAL HAZARDS: Combustible. Do not use or store near heat or open flame.

#### **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 DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on cats or animals other than dogs. Do not allow your dog to ingest this product. Do not use on puppies under 3 months of age or weighing less

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than [7][15][33][66] lbs. Use entire contents of tube vial on each dog. [Do not split one tube between dogs.] [Do not use multiple tubes on one dog.] Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied. Treated dogs should not be allowed to go swimming for 12 hours following treatment. Repeat application may be made if necessary, but do not apply more often than one every 4 weeks.

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. Signs of sensitivity to this product include skin sensitivity, increased itchiness, redness, rash, hair discoloration or hair loss at the application site. Dogs may also show "lethargy." If signs of sensitivity occur, bathe your dog 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 dog 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 dog and continue to monitor your dog for the next 24 hours.

#### [1.5 cm x 1.5 cm or as indicated]

DO NOT USE ON CATS. MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.

[**Only for Dogs Weighing Between 7 and 15 lbs.** Do not apply to dogs weighing less than 7 lbs. [including small dogs and puppies, 3 months or older]

**(For cartons containing 0.034 fl oz (1.0 mL) applicator tubes)** Apply one tube (0.034 fl oz) (1.0 mL) of this product as a spot or stripe to the dog's back between the shoulder blades.]

[Only For Dogs Weighing Between 15 and 33 lbs. Do not apply to dogs weighing less than 15 lbs {For cartons containing 0.051 fl oz (1.5 mL) applicator tubes} Apply one tube (0.051 fl oz) (1.5 mL) of this product as a spot or stripe to the dog's back between the shoulder blades.]

[Only For Dogs Weighing Between 33 and 66 lbs. Do not apply to dogs weighing less than 33 lbs {For cartons containing 0.051 fl oz (1.5 mL) applicator tubes} Apply one tube (0.051 fl oz) (1.5 mL) of this product as a spot or stripe to the dog's back between the shoulder blades and apply a second tube (0.051 fl oz) (1.5 mL) as a spot or stripe to the dog's back directly in front of the base of the tail.]

#### OR

[Only For Dogs Weighing Between 33 and 66 lbs. Do not apply to dogs weighing less than 33 lbs {For cartons containing 0.101 fl oz (3.0 mL) applicator tubes} Apply approximately half of the tube (0.051 fl oz) (1.5 mL) of this product as a spot or stripe to the dog's back between the shoulder blades and apply the rest of the tube's contents (0.051 fl oz) (1.5 mL) as a spot or stripe to the dog's back directly in front of the base of the tail.]

#### OR

[Only For Dogs Weighing Between 33 and 66 lbs. Do not apply to dogs weighing less than 33 lbs {For cartons containing 0.101 fl oz (3.0 mL) applicator tubes} Apply the entire tube (0.101 fl oz) (3.0 mL) as a continuous stripe on (to) the dog's back starting between the shoulder blades and ending directly in front of the base of the tail.]

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[Only For Dogs Weighing 66 lbs. and Over. Do not apply to dogs weighing less than 66 lbs {For cartons containing 0.051 fl oz (1.5 mL) applicator tubes} Apply one tube (0.051 fl oz) (1.5 mL) of this product as a stripe to the dog's back between the shoulder blades and apply a second tube (0.051 fl oz) (1.5 mL) continuing the stripe down the center of the dog's back and apply a third tube (0.051 fl oz) (1.5 mL) to the dog's back directly in front of the base of the tail.]

OR

[Only For Dogs Weighing 66 lbs. and Over. Do not apply to dogs weighing less than 66 lbs {For cartons containing 0.152 fl oz (4.5 mL) applicator tubes} Apply approximately half of the tube (0.076 fl oz) (2.25 mL) of this product as a spot or stripe to the dog's back between the shoulder blades and apply the rest of the tube's contents (0.076 fl oz) (2.25 mL) as a spot or stripe to the dog's back directly in front of the base of the tail]

OR

[Only For Dogs Weighing 66 lbs. and Over. Do not apply to dogs weighing less than 66 lbs {For cartons containing 0.152 fl oz (4.5 mL) applicator tubes} Apply the entire tube (0.152 fl oz) (4.5 mL) as a continuous stripe on (to) the dog's back starting between the shoulder blades and ending directly in front of the base of the tail.]

#### HOW TO APPLY:

**[FOR SARAN TUBES IN BLISTER CARD:** Remove product tube from package. Holding tube with notched end pointing up and away from face and body, snap or cut off narrow end at notches. Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin. Wrap tube and put in trash.]

OR

**[FOR FLAT CARD (doubled) UNIT-DOSE PACKAGING:** Separate cards along the perforated line. Holding separated card by its wide end with narrow end pointing up and away from face and body, cut along dotted line. Invert card over dog and use narrow end of the card to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin. Wrap card and put in trash.]

#### OR

**[FOR FLAT CARD UNIT DOSE PACKAGING:** (For push pin type applicator) Remove one product tube from (the) card. With cap end pointed up and away from face and body, depress cap to pierce tube end. Carefully remove cap, invert tube over dog, and with tube in close to dog's skin, squeeze tube to apply product. Wrap empty tube and put in trash.]

#### OR

[FOR FOLDING CARD OR TABBED CARD UNIT-DOSE PACKAGING: Remove product tab by tearing along perforation. Holding tab with tube end pointed up and away from face and body, cut along dotted line. Invert tab over dog and use narrow end of card to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin.]

#### OR

[FOR BLISTER CARD WITH TRI-LAYER TUBES: Remove product tube(s) from (the) package. Fold along perforation between tubes and tear off one (or more) tube(s). {Return unused tubes to package.} Holding tube with notched end pointing up and away from face and body, snap off (or cut) narrow end at notches. Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin.]

[\*\* FOR MULTI-DOSE PACKAGING: Withdraw (1.0 mL) (1.5 mL) (3.0 mL)(4.5 mL) of solution at a time. Apply entire given dose directly to the skin at the indicated locations.]

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[\*\* FOR DROPPER BOTTLE MULTI-DOSE PACKAGING: Insert dropper tube into insecticide solution, squeeze bulb and then release to fill tube barrel to (1.0 mL) (1.5mL) (3.0 mL) (4.5 mL) line. Position dropper tube end in dog's hair next to skin and squeeze bulb to apply all of the solution to the dog's skin as indicated for dog's size.]

#### [\*\* INTENTED FOR SALE TO VETERINARIANS ONLY]

#### 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°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. However, it is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of such factors as weather conditions, presence or absence of other materials, or the manner of application, all of which are beyond the control of Sergeant's.]] 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 disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[See Spanish insert inside package for directions for use and precautions.]

In Case of Emergency, call: 1-800-781-4738 [For more information] Non-Emergency, call: 1-800-224-PETS (7387) [Made in USA]

[Satisfaction Guaranteed!] [Please return for a refund if not completely satisfied!] [Sergeant's is committed to providing high quality products. If you have questions or comments about this product, please write: Sergeant's Consumer Response, P.O. Box 540399, Omaha, NE 68154-0339.] [lot, date & label code] [UPC CODE]

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

[BAR CODE AREA]

EPA Reg. No. 2517-89 EPA Est. No. XXXXX-XXXXX

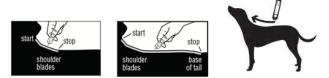
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[Optional graphics below may or may not appear anywhere on finished label]



TAT	Adult Flea	
-754	Flea eggs	<b>€</b>
っ	Flea Larvae	3
	Flea Pupae	
×	Ticks	
×	Brown Dog Tick	
×	Deer Tick	
₹.	Mosquitoes	$\bigotimes$





[[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 dog
- [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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# TUBE / VIAL LABEL

## **DOG SQUEEZE ON PERMETHRIN + PYRIPROXYFEN**

{Back Label}

{Front Label}	{Back Label}
	KEEP OUT OF REACH OF CHILDREN
{Brand Name}	CAUTION: Read directions and precautions
<b>For Dogs</b> $[x-y lbs] \ge [3 mos.][12 wks]$	before using.
Permethrin 45%, Pyriproxyfen 1.9%	EPA REG. No. 2517-89 {label code}
0.034 fl oz ( <b>or</b> ) 0.051 fl oz ( <b>or</b> )	
$0.101 \text{ fl oz } (\mathbf{or}) \ 0.152 \text{ fl oz} \qquad \{\text{label code}\}$	

{END TUBE / VIAL LABEL}