

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 134th 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 Gold Squeeze-On for Dogs
EPA Registration Number: 2517-94
Application Date: December 5, 2013
Decision Number: 486617

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).

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

Sergeant's Master Label

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FRONT PANEL

DOG SQUEEZE-ON PERMETHRIN

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

Sergeant's Gold Squeeze-On for Dogs

[ABNs:]

[SENTRY PRO Squeeze-On for Dogs]

[SENTRY PRO Squeeze-On for Dogs and Puppies]

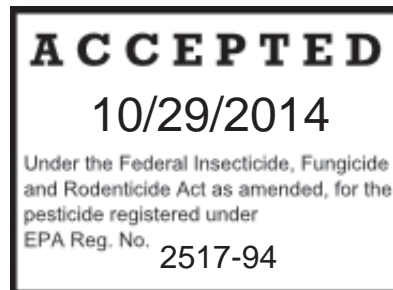
[Sergeant's Gold Squeeze-On for Dogs and Puppies]

[Sergeant's PreTect Squeeze-On for Dogs]

[Sergeant's Squeeze-On for Dogs and Puppies]

[Sergeant's Squeeze-On Flea, Tick and Mosquito Control for Dogs]

[Sergeant's SEVEN WAY Squeeze-On Protection for Dogs]



[1.5 x 1.5 cm on final or as indicated]

For use ONLY on dogs [33[-] [to] 66 lbs] [greater than 66 lbs] {OR}
For use ONLY on dogs [[&][and] puppies 7[-] [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] 33 lbs

Optional Marketing Statements:

[Citrus Scent]

[Flea and Tick Control for Dogs and Puppies 3 Months [12 Weeks] of Age or Older]

[Kills and Repels [Adult] Fleas [For] up to 5 Weeks [Per Application]]

[Kills, Repels, and Prevents Re-Infestation of Fleas for up to 5 Weeks!]

[Kills and Repels Ticks for up to 6 Weeks [Per Application]!]

[Kills and Repels Brown Dog Ticks (*Rhipicephalus Sanguineus*) for up to 6 Weeks [Per Application]!]

[Monthly Flea, Tick, Lice & Mite Application [Treatment]!]

[Flea, Tick, Lice and Mite Control [Protection] [Treatment]!]

[Kills and Repels Mosquitoes [on Dogs]]

[Kills and Repels Fleas and Ticks for up to 5 Weeks [Per Application]!]

[3 [4] [5] [6] [9] [12]] Month Supply [Applications]]

[Triple Pest Protection][Fleas][Ticks][Mosquitoes]

[Flea, Tick & Mosquito Treatment]

[Seven Way Pest Protection][Fleas][Ticks][Mosquitoes][Lice][Mites][Flea Eggs and Larvae]

[Five Way Pest Protection][Kills Fleas, Ticks, Mosquitoes, Flea Eggs and Larvae]

[Kills Fleas for up to 5 Weeks and Ticks for up to 6 Weeks]

[Kills Fleas, Ticks, Mosquitoes, Lice & Mites on Dogs]

[Repels and Kills Ticks on Dogs]

[Promotes Proper Removal of Ticks from Dogs]

[A Quick, Easy, and Effective Way to Kill and Remove Ticks from Dogs]

[Kills and Repels The Deer Tick (A Vector of Lyme Disease) for up to 6 Weeks!]

[Kills and Repels Ticks Including The Brown Dog Tick and Deer (A Vector of Lyme Disease)] for up to 6 Weeks!]

[Kills and Repels Ticks (Known to Be A Carrier of Lyme Disease)]

[Breaks The Flea Life Cycle!]

[Kills and Repels Adult Fleas for up to 5 Weeks [Per Application]!]

[Stops Flea Eggs from Hatching!]

[Controls Reinfestation!]

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Information in [] is optional.

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[Kills, Repels and Prevents Reinfestation of Ticks, Including Brown Dog Ticks and *Ixodes* Spp. Which May be Vectors of Lyme Disease, for up to 6 Weeks.]
[Kills Flea Eggs & Larvae for up to [123 Days] [4 Months]]
[Kills Flea Eggs for up to [123 Days] [4 Months]]
[Kills Larvae for up to [123 Days] [4 Months]]
[Prevents Flea Eggs from Developing Into Biting Adults]

ACTIVE INGREDIENTS:

Permethrin[CAS #52645-53-1]* 45.00%
Pyriproxyfen [CAS #95737-68-1] 1.90%

OTHER INGREDIENTS: 53.10%

[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

NET CONTENTS: XXX fl oz (XXX mL)

[THREE] [FOUR] [SIX] [TWELVE]
[0.05 fl oz (1.5 mL)] [0.10 fl oz (3.0 mL)] [0.15 fl oz (4.5 mL)] [0.20 fl oz (6.0 mL)]Tubes

{END – FRONT PANEL}

BACK/SIDE/OTHER PANEL

**DOG SQUEEZE-ON
PERMETHRIN**

[Apply Once Every Month] [Can be applied monthly [if needed]]

**READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES 12 WEEKS OF AGE & OLDER.**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION: Wash 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 on dogs only. Individual sensitivities, while rare, may occur after using 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 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.

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.

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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 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 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 12 weeks of age or weighing less than [7][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.

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 x 1.5 cm on final or as indicated below]



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.

Frequency of Application:

[When used monthly, {product name} controls flea and tick infestations.] A once monthly application is recommended where mosquito control is needed.

[Only for Dogs Weighing Between 7 and 33 lbs. Do not apply to dogs weighing less than 7 lbs.:

(0.05 fl oz (1.5mL) applicator tube) Apply one 0.05 fl oz (1.5mL) tube of this product as a spot or stripe to the dog's back between the shoulder blades.]

[Only for Dogs Weighing between 33lbs. & 66 lbs. Do not apply to dogs weighing less than 33 lbs.:

(0.05 fl oz (1.5mL) applicator tube) Apply one tube 0.05 fl oz (1.5mL) of this product as a spot or stripe to the dog's back between the shoulder blades and apply a second tube 0.05 fl oz (1.5mL) as a spot or stripe to the dog's back directly in front of the base of the tail.

OR

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(0.11 fl oz (3.0mL) applicator tube) Apply approximately half of the tube 0.05 fl oz (1.5mL) of this product as spot or stripe to the dog's back between the shoulder blades and apply the rest of the tube's contents 0.05 fl oz (1.5mL) as a spot or stripe to the dog's back directly in front of the base of the tail.

OR

(0.11 fl oz (3.0mL) applicator tube) Apply the entire tube 0.11 fl oz (3.0mL) as a continuous strip on the dog's back starting between the shoulder blades and ending directly in front of the base of the tail.]

[Only for Dogs Weighing 66 lbs. and Over. Do not apply to dogs weighing less than 66 lbs.:

(0.05 fl oz (1.5mL) applicator tube) Apply one tube 0.05 fl oz (1.5mL) of this product as a spot or stripe to the dog's back between the shoulder blades and apply a second and a third tube (0.05 fl oz (1.5mL) tubes) continuing the strip down the center of the dog's back and apply a fourth tube 0.05 fl oz (1.5mL) to the dog's back directly in front of the base of the tail.

OR

(0.22 fl oz (6.0 mL) applicator tube) Apply approximately half of the tube 0.11 fl oz (3.0mL) 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 0.11 fl oz (3.0mL) as a spot or a stripe to the dog's back directly in front of the base of the tail.

OR

(0.22 fl oz (6.0 mL) applicator tube) Apply the entire tube (0.22 fl oz (6.0 mL) as a continuous stripe on 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 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 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 (1.5 mL)(3.0 mL)(6.0 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 (1.5mL)(3.0 mL)(6.0 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.]

[INTENDED FOR SALE TO VETERINARIANS ONLY]**

To Kill and Help Remove Visible Ticks on Dogs:

Open vial/tube and apply a drop directly onto the tick or ticks then apply remainder onto the dog as per usage directions on this label. Wait 15 minutes and if the TICK has not backed off or fallen off, carefully remove tick with tweezers or comb making sure to remove entire tick. Clean wound, apply antiseptic and cover with a bandaid if needed. Tube is not resealable. Do not reseal tube. Discard after use as directed in Disposal instructions on this label.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 25⁰C) dry place inaccessible to children. Do not refrigerate. Protect from direct sunlight.

PESTICIDE DISPOSAL AND CONTAINER HANDLING. Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or for disposal instructions. Never place unused product down any indoor or outdoor drain

[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, and prevents reinfestations for up to 5 weeks. Sergeant's Gold Squeeze-On for Dogs kills and repels ticks for up to 6 weeks, and kills mosquitoes, lice and mites on dogs.

[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.]

[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 68154-0399.]

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

In Case of Emergency, call: 1-800-781-4738 [Coupon(s) inside or outside of box]

Non-Emergency, call: 1-800-224-PETS (7387) [Made in USA] [Manufactured in USA]

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[Made in the USA For:] or [Manufactured by:]
[Distributed by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

EPA Reg. No. 2517-94
EPA Est. No. XXXXX-XX-XX
[lot, date & label code] [UPC CODE]

{END - BACK / SIDE PANEL}

[OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGING]

[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] [application] for 24 hours to avoid chance of ingestion
- [6] Do NOT split tubes between dogs [and use the ENTIRE tube contents.]

[Brand Name]

[For year-round protection, apply [Brand Name][this product] monthly.]
[Dog's Name (Empty blank for owner to fill in name)]
[Dose] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)
[calendar stickers with [Brand Name]
[Place stickers on your calendar as a reminder to reapply [Brand Name] [in 30 days.]
[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]

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








	Adult Flea	
	Flea eggs	
	Flea Larvae	
	Flea Pupae	
	Ticks	

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	Brown Dog Tick	
	Deer Tick	
	Chewing Lice	
	Mosquitoes	
	Mite	




{END - BACK / SIDE PANEL}

TUBE / VIAL LABEL

DOG SQUEEZE -ON PERMETHRIN

Front Label

Back Label

<p></p> <p>Brand Name For Dogs [x-y lbs.] ≥[12 wks] [3 mos] Permethrin 45% 0.05 fl oz (or) 0.10 fl oz (or) 0.15 fl oz {label code}</p>	<p>KEEP OUT OF REACH OF CHILDREN CAUTION: Read directions and precautions before using. Use scissors to open. EPA REG. No. 2517-94 {label code}</p>
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