



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

EPA , Number: 2517-139

Date of Issuance:

JAN 1 1 2013

Term of Issuance:
Unconditional

Name of Pesticide Product:

Sergeant's® Bifenthrin Shampoo for Dogs

NOTICE OF PESTICIDE:

X Registration Reregistration

(Under FIFRA as amended)

Name and Address of Registrant (include ZIP Code):

Sergeant's Pet Care Products, Inc.

10077 South 134th Street

Omaha, NE 68138-3710

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is <u>unconditionally</u> registered in accordance with FIFRA sec. 3(c)(5). Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3).

- 1. You will make the following label changes before you release the product for shipment:
 - a) Revise the EPA Registration Number to read "EPA Reg. No. 2517-139."
 - b) Revise Precautionary Statements to read as follows:

"Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, and chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse."

- c) The following alternate brand names are not acceptable and must be deleted from the label:
- [Sergeant's® Silver (Skip-Flea®) (Flea) and Tick Shampoo for Dogs]
- [Sergeant's® (Sentry®) VetSpotTM (Flea and Tick) (Shampoo for dogs]
- [(Sergeant's®) (Sentry®) Ectoadvance™ (Flea and Tick) (Shampoo for dogs]
- Sentry®Proline (Flea and Tick) (Shampoo) for dogs]

[Sentry®Vet (Flea and Tick) (Shampoo) for dogs]

Signature of Approving Official:

Richard Gebken Product Manager

Insecticide Branch/Registration Division (7505P)

Date

ganuary 11, 2013

- d) General thek claims (not supported because no American Dog Tick data were submitted or cited). All killing claims against ticks must either be species specific or qualified to exclude American Dog Ticks. All general claims of 15 day and/or 2 week efficacy must be revised to only include fleas. Tick efficacy is not supported for this duration. Also, all claims against flea egg/larvae and breaking of the flea life cycle are unsupported by the submitted data and must be removed from the label. Based on the result of the efficacy review, delete or revise the following claims:
 - Delete "[Repels and prevents blood feeding by mosquitoes for up to 2 weeks]"
 - Delete "[Repels mosquitoes [for up to [15 days] [2 weeks]]"
 - Replace "[Prevents blood feeding of mosquitoes for up to [15 days][2 weeks]]" with "[Prevents blood feeding of mosquitoes for up to [7 days][1 weeks]]"
 - Delete "Kills Fleas & Ticks for 15 days/2 weeks"
 - Delete "Kills for 15 days/2 weeks Fleas and Ticks"
 - Delete "Kills Ticks for 15 days/2 weeks"
 - Replace "Repels and prevents blood feeding by mosquitoes for up to 2 weeks" with "Repels and prevents blood feeding by mosquitoes for up to 1 weeks"
 - Replace "Repels mosquitoes for up to 15 days/2 weeks" with "Repels mosquitoes for up to 7 days/1 weeks"
 - Replace "[Active against ticks]" with "[Active against ticks (except American dog)]"
 - Replace "[Kills Ticks for [7days][1 week]]" with "[Kills Ticks except American dog ticks for [7days][1 week]]"
 - Delete "[Kills brown dog ticks [Rhipicephalus sanguineus] for up to
 [15 days][2 weeks] [which may carry Rocky Mountain spotted fever]"
 - Replace "[Kills [Fleas] [and] [Ticks] for [7 days] [1 week]]" with
 "[Kills Fleas and Ticks (except American dog) for [7 days][1 week]]"
 - Replace "[Kills Fleas & Ticks While Grooming Your Pet]" with "[Kills Fleas & Ticks (except American dog) While Grooming Your Pet]"
 - Delete "[[Specific fragrance noted here] Scent]"
 - Replace "[Kills Fleas and Ticks on Dogs]" with "[Kills Fleas and Ticks (except American dog) on Dogs]"
 - Replace "[Do not use on cats]" with "Do not use on cats"
- e) An application rate must be added to the label, equivalent to the dosing of 2.5mg ai/kg animal, expressed in some minimal rate statement: expression in teaspoons and/or fluid ounces of shampoo per 10 lbs of animal weight is preferred, rather than a weight measurement, which would be impractical for a user to measure.
- f) Delete the statement "{Ingredient Statement may be on front or back label}", as specified in 40 CFR §156.10(g)(2)(i) and Chapter 5, Section III.A of the Agency's Label Review Manual, the "Ingredient Statement" must appear on the front panel of the label, preferably immediately below the product name.

- 2. Within one year from the date of this registration conduct and submit a one year storage stability (830.6317) and corrosion characteristics (830.6320) study with observations be made at 0, 6, 9, and 12 month intervals.
- 3. Per 40 CFR 156.10(a)(6), submit one copy of your final printed labeling before releasing the product for shipment. As defined in 40 CFR 152.3, "final printed labeling" means the "label or labeling of the product when distributed or sold". Clearly legible reproductions or photo reductions will be accepted for unusual labels. Note that a clean copy of the master label in most cases does not meet the definition of final printed labeling. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

If you have any questions regarding this action, please contact BeWanda Alexander at www.alexander.bewanda@epa.gov or (703) 305-7460.

- [Sergeant's® Silver (Skip-Flea®) (Flea) and Tick Shampoo for Dogs]
- [Sergeant's® (Sentry®) VetSpotTM (Flea and Tick) (Shampoo for dogs]
- [(Sergeant's®) (Sentry®) Ectoadvance™ (Flea and Tick) (Shampoo for dogs]
- Sentry®Proline (Flea and Tick) (Shampoo) for dogs]
- [Sentry®Vet (Flea and Tick) (Shampoo) for dogs]

Srgeant's® Master Lab

19 Dec 2012

Version 12.1

Information in [] is optional.

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FRONT PANEL

DOG SHAMPOO
Bifenthrin Shampoo

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

Sergeant's® Bifenthrin Shampoo for Dogs

[ABNs]

[Sergeant's® Skip-Flea® (Flea) and Tick Shampoo for Dogs]

[Sergeant's® Silver (Skip-Flea®) (Flea) and Tick Shampoo for Dogs]

[Sentry® [XFT] Flea and Tick Shampoo for Dogs]

[Sergeant's® Bansect® Flea and Tick Shampoo for Dogs]

[Sentry® Value Flea & Tick Shampoo for Dogs]

[(Sergeant's®) (Sentry®) VetSpotTM (Flea and Tick) (Shampoo for dogs]

[(Sergeant's®) (Sentry®) EctoadvanceTM (Flea and Tick) (Shampoo for dogs]

[Sentry®Proline (Flea and Tick) (Shampoo) for dogs]

[Sentry®Vet (Flea and Tick) (Shampoo) for dogs]

[Apply to puppies over 12 weeks old] [Apply to puppies 12 weeks or older]

[Optional Marketing Claims]

[Kills adult fleas for [15 days][2 weeks]]

[Kills Fleas for [15 days] [2 weeks]]

[Active against fleas]

[Active against ticks]

[Kills Ticks for [7 days] [1 week]]

[[Kills adult Fleas [for up to [15 days] [2 weeks]].]

[Cleans, deodorizes [and] conditions]

[Repels and prevents blood feeding by mosquitoes for up to 2 weeks]

[Repels mosquitoes [for up to [15 days] [2 weeks]]

[Prevents blood feeding of mosquitoes for up to [15 days][2 weeks]][Kills ticks that may carry Lyme disease]

[Kills black-legged ticks, lone star ticks, brown dog ticks, and deer ticks]

[Kills brown dog ticks [Rhipicephalus sanguineus] for up to [15 days][2 weeks] [which may carry Rocky Mountain spotted fever]

[Kills fleas, source of flea allergy dermatitis [,flea bite anemia] and tapeworm infestations]

[Kills [Fleas] [and] [Ticks] for [7 days][1 week]]

[Original Formula]

[pH Balanced For Pet's Coat]

[Cleans]

[Deodorizes]

[Kills Fleas Up to [[15 days] [2 weeks]!]

[Conditions]

[Kills Fleas & Ticks While Grooming Your Pet]

[Caring For Your Pets since 1868]

[[Specific fragrance noted here] Scent]

[Kills Fleas and Ticks on Dogs]

[Do not use on cats]

ACCEPTED
with COMMENTS
In EPA Letter Dated
JAN 1 1 2013

Under the Federal Insecticide, Fungicide, and Rodenticide Act. as amended, for the pesticide registered under EPA Peg. No.

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[Ingredient Statement may be on front or back label]

ACTIVE INGREDIENTS:

OTHER INGREDIENTS:99.95%

[TOTAL 100.00%]

KEEP OUT OF REACH OF CHILDREN CAUTION

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

NET [WEIGHT] [CONTENTS]

XXX fl oz (XXX mL)

BACK PANEL

DOG SHAMPOO Bifenthuin Shampoo

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS.

[Kills fleas for up to [15 days] [2 weeks] [and] ticks for up to [7 days][1 week]]

[Kills fleas and ticks]

[Kills the ticks that may carry Lyme disease]

[pH balanced for pet's coat]

[Cleans and deodorizes]

[Repels mosquitoes and prevents blood feeding for up to [15 days] [2 weeks]]

IMPORTANT CONSUMER INFORMATION

[PURPOSE: [PRODUCT NAME] kills fleas [for [15 days][2 weeks]] and ticks for [7 days][1 week] [, and repels and prevents blood feeding by mosquitoes [for up to [15 days] [2 weeks]] while it cleans and deodorizes in one easy and convenient step. This rich, conditioning, non-staining formula contains a highly effective flea and tick killing ingredient combined with an excellent pH balanced shampoo.]

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

FOR EXTERNAL USE ON DOGS ONLY. Do not use on puppies under 12 weeks of age. Do not treat your dog with more than one pesticide product at a time. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing dogs. Sensitivities may occur after using ANY pesticide product for dogs. If signs of sensitivity occur bathe your dog with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately by calling 1-800-781-4783. DO NOT USE ON CATS.

Srgeant's® Master Lab.

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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 treatment advice. 	
IF ON SKIN OR CLOTHING:	 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. 	
	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.

Weigh and determine your dog's body weight. Do not use on puppies under 12 weeks of age. Wet dog's coat thoroughly. [Use the reference table below as a guide to determine the amount of [PRODUCT NAME] [shampoo] to use on your dog.] [Use ½ oz of [PRODUCT NAME] [shampoo] for every 7 pounds of dog body weight.] Starting at the head and working back, work up a lather with this quick lathering formula, being sure that the lather is worked thoroughly into dog's coat down to the skin. Allow lather to stand five minutes, then rinse completely and towel dry. Kills fleas and ticks quickly and continues to kill fleas for up to [15 days] [2 weeks] and ticks for [7 days][1 week]. To maintain maximum effectiveness, repeat (or reapply) every [15 days] [2 weeks].

[Optional table]

Use ½ oz of [PRODUCT NAME] [shampoo] for every 7 pounds of dog body weight (lbs).			
Amount of shampoo fluid ounces (fl oz)	Dog's body weight in pounds (lb)		
½ 0Z	Up to 7 lb		
1 oz	Over 7 lbs to 14 lbs		
2 oz .	Over 14 lbs to 28 lbs		
3 oz	Over 28 lbs to 42 lbs		
4 oz	Over 42 lbs to 56 lbs		
5 oz	Over 56 lbs to 70 lbs		
6 oz	Over 70 lbs to 84 lbs		
7 oz	Over 84 lbs to 98 lbs		
8 oz .	Over 98 lbs to 112 lbs		
9 oz	Over 112 lbs to 126 lbs		
10 oz	Over 126 lbs to 140 lbs		

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store only in original container in a cool, dry area inaccessible to children and pets and away from heat and 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 for disposal instructions. Never place unused product down any indoor or outdoor drain.

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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, Omaha, NE 68138.]

In Case of Emergency, call: 1-800-781-4738

Non-Emergency call 1-800-224-PETS (7387)

[Made in USA]

[Distributed by:] [Manufactured by:]

EPA Reg. No. 2517-RGO

Sergeant's Pet Care Products, Inc.

EPA Est. No. XXXXX-XX-XX

Omaha, NE 68138

[lot, date & label code] [UPC CODE]

[END - BACK / SIDE PANEL]

[Each optional graphics below may or may not appear anywhere on the label]



fleas



ticks



mosquitoes



fleas



ticks



mosquitoes

