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

Term of Issuance: Unconditional

Name of Pesticide Product:

Sergeant's® Bifenthrin + Nylar 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 134<sup>th</sup> Street

Omaha, NE 68138-3710

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. 2517-138."
  - 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) 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.

Signature of Approying Official:

Richard Gehken Product Manager

Insecticide Branch/Registration Division (7505P)

Date

January 11, 2013

- d) Delete the statement "{Ingredient Statement may 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.
- e) General tick 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 the following claims:
  - "Kills Fleas & Ticks for 15 days/2 weeks"
  - "Kills for 15 days/2 weeks Fleas and Ticks"
  - "Kills Ticks for 15 days/2 weeks"
  - "Kills ... flea eggs for 30 days and flea larvae for 30 days"
  - "Kills flea eggs and flea larvae"
  - "Kills flea eggs and flea larvae for 30 days/1 month"
  - "Sterilizes (All New) Fleas and Kills Their Eggs For 30 Days"
  - "Breaks the Flea Life Cycle"
  - "Fast Acting"
  - "Kills Flea Eggs and flea larvae for 30 days"
  - "Complete Protection Against All Stages of the Flea Life Cycle"
  - "Prevents/Controls Reinfestation for up to 30 Days"
- f) Revise the following optional marketing claims:
  - Replace "Repels mosquitoes for up to 15 days/2 weeks" with "Repels mosquitoes for up to 7 days/1 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"
- g) The following alternate brand names are not acceptable and must be deleted from the label:
  - "[Sergeant's® Evolve™(30) (Complete) Flea and Tick Shampoo for Dogs]"
  - "[(Sergeant's®) (Sentry®) VetSpot™ (Plus) (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 (Plus) (Flea and Tick) (Shampoo) for dogs]"

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- 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 <a href="www.alexander.bewanda@epa.gov">www.alexander.bewanda@epa.gov</a> or (703) 305-7460.

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Information in [ ] is optional.

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#### ERONT PANEL

DOG SHAMROO Bifenthrin/Nylar Shampoo

### Sergeant's® Bifenthrin + Nylar Shampoo for Dogs

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

[ABNs]

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

[Sergeant's® EvolveTM (30) (Complete) Flea and Tick Shampoo for Dogs]

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

[Sentry®Pro Flea and Tick Shampoo for Dogs]

[(Sergeant's®) (Sentry®) VetSpot<sup>TM</sup> (Plus) (Flea and Tick) (Shampoo) for dogs]

[(Sergeant's®) (Sentry®) Ectoadvance<sup>TM</sup> (Flea and Tick) (Shampoo) for dogs]

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

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

[Apply to puppies over 12 weeks old]

[Apply to puppies 12 weeks or older]

ACCEPTED
with COMMENTS
In EPA Letter Dated
JAN | 1 2013

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

[Optional Marketing Claims]

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

[Active against fleas]

[Active against ticks]

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

[Kills for 30 days Flea eggs flea larvae]

[Kills Fleas [for [15 days] [2 weeks]], Ticks [for [7 days] [1 week]], [flea eggs [for 30 days]] [and] [flea

larvae [for 30 days]]

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

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

[Prevents blood feeding by mosquitoes for up to [15 days][2 weeks]]

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

[Kills fleas, ticks, flea eggs and (flea) larvae]

[Kills flea eggs and (flea) larvae for (30 days) (1 month)]

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

[Kills newly emerged adult Fleas before they lay eggs]

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

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

[Sterilizes (All New) Fleas And Kills Their Eggs For 30 Days]

[Breaks The Flea Life Cycle!]

[Kills Ticks That May Carry Lyme disease]

[pH Balanced For Pet's Coat]

[Fast Acting]

[Cleans]

[Deodorizes]

[Conditions]

[Contains [Pyriproxyfen] [Nylar®] Insect Growth Regulator (IGR)]

[Kills Flea Eggs [and] [flea larvae] For 30 Days]

[Kills Fleas [&] [and] Ticks]

[For Dogs]

[Do Not Use on Cats]



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Information in [ ] is optional.

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[Cleans, Deodorizes and Conditions]

[One Step Hassle Free Protection!]

[Complete Protection Against All Stages of the Flea Life Cycle]

[Prevents Reinfestation for up to 30 Days]

[Controls Reinfestation for up to 30 days]

[Kills Fleas, Ticks & Flea Eggs While Grooming Your Pet]

[Specially Formulated for Dogs and Puppies (over 12 weeks old)]

[Caring.For\_Your\_Pets\_since\_1868]\_

[The Only Flea and Tick Protection You Need For Your Dog!]

[[Specific Fragrance noted here] Scent]

{Ingredient Statement may be on front or back label}

#### **ACTIVE INGREDIENTS:**

 Bifenthrin
 0.05%

 Pyriproxyfen
 0.01%

 OTHER INGREDIENTS:
 99.94%

 [TOTAL
 100.00%]

## KEEP OUT OF REACH OF CHILDREN CAUTION

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

**NET [WEIGHT] [CONTENTS]** 

XXX oz (XXX mL)

#### BACK PANEL

DOG SHAMPOO Bifenthrin/Nylar Shampoo [withOatmeal]

### 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 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]]

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#### IMPORTANT CONSUMER INFORMATION

[[Product Name] [This product] kills fleas [for [15 days][2 weeks]] [, ticks for [7 days][1 week] [, and repels mosquitoes and prevents blood feeding [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 insect growth regulator (IGR) that sterilizes new fleas and kills their eggs for 30 days.]

### 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.



information.

	FIRST AID
IF IN EYES:	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
IF ON SKIN OR CLOTHING:	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
	HOT LINE NUMBER
	act container or label with you when calling a poison control center or doctor or ment. You may also contact 1-800-781-4738 for emergency medical treatment

#### **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 in pounds. 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 adult fleas and ticks for up to [15 days] [2 weeks], while the IGR continues to break the flea life cycle for 30 days [to prevent the reinfestation process]. To maintain maximum effectiveness against both fleas and ticks, repeat (or reapply) every 30 days.

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[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 fl oz	Up to 7 lb		
1 fl oz	Over 7 lbs to 14 lbs		
2 fl oz	Over 14 lbs to 28 lbs		
3 fl oz	Over 28 lbs to 42 lbs		
4 fl oz	Over 42 lbs to 56 lbs		
5 fl oz	Over 56 lbs to 70 lbs		
6 fl oz	Over 70 lbs to 84 lbs		
7 fl oz	Over 84 lbs to 98 lbs		
8 fl oz	Over 98 lbs to 112 lbs		
9 fl oz	Over 112 lbs To 126 lbs		
10 fl 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.

#### [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:]

Sergeant's Pet Care Products, Inc.

Omaha, NE 68138

EPA Reg. No. 2517-XX

EPA Est. No. XXXXX-XX-XX

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

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Information in [ ] is optional.

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{END - BACK / SIDE PANEL}

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



Adult Flea



flea eggs



flea larvae



ticks



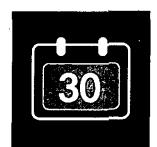
mosquitoes



fleas



flea eggs



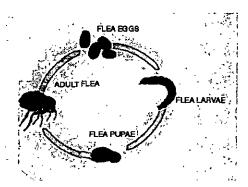
7 flea larvae



ticks



mosquitoes



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