

### U S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460

NOTICE OF PESTICIDE:

X Registration
 Reregistration

EPA Reg. Date of Issuance: NOV 2 2 2006

Term of Issuance: Conditional

Name of Pesticide Product: Sergeant's Cypernothrin + Methoprene Squeeze- On for Dogs

(Under F1FRA as amended)

Name and Address of Registrant (include ZIP Code): Sergeant's Pet Care Products, Inc.

2637 South 158 Plaza, Suite 100

Omaha, NE 68130-1703

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 **conditionally** registered in accordance with FIFRA sec.  $3(c_1(7))(A)(B)$  provided that :

- 1. You will submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
- 2. You submit as you agreed the data listed below conducted in accordance with 40CFR Part 158 test guidelines or agreed upon protocols:

Title of Study Guideline Reference Date

Number

Cyphenothrin-specific
Pislodgeability Study (dogs)

NA

Within 9 months of acceptance of protocol\*

Efficacy Study of a Cyphenothrin 810-1000,3000, Spot-On Against fleas, ticks and 3300 Mosquitoes

Protocol submitted within one month of Notice of Registration. Study submitted within 9 months of acceptance of protocol.\*

Signature of Approving Official:

Date:

November 22,2006

page 2

EPA Reg. No. 2517-90

\*You must submit a protocol prior to conducting the efficacy for Agency review and approval. We note that the protocol for Cyphenothrin dislodgeability study is currently under review.

- 3. You will make the following label changes before you release the product for shipment:
- a. Revise the EPA Registration Number to read "EPA Registration Number 2517-90.".
- b. Under Directions for Use replace "as a continuous stripe on the dog's back starting between the shoulder blades and ending directly in front of the base of the dog's tail" with "from the back of the neck to a point midway between the neck and tail". Make the same change to the directions beginning, "apply the contents of the other tube along the dog's back …".
- c. The net contents must be expressed in terms of U.S. liquid units or measurements also. It is recommended that the application rates also include US units of measurement.
- d. Under Precautionary Statements change "Avoid contact with eyes or clothing." to "Avoid contact with skin, eyes or clothing."
- e. Under Precautionary Statements add "Harmful if swallowed or absorbed through skin.".

f. Under First Aid add

FIRST AID			
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.		
If swallowed	<ul> <li>Immediately call a poison control center or doctor.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give any liquid to the person.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>		

page 3

EPA Reg. No. 2517-90

#### ACUTE TOXICITY REVIEW

STUDY	MRID	CATEGORY	CLASSIFICATION
Acute Oral	46166103	III	Acceptable
Acute Dermal	46166104	III	Acceptable
Acute Inhalation		IV	Waived
Eye Irritation	46166105	III	Acceptable
Dermal Irritation	46166106	IV	Acceptable
Dermal Sensitization	46166107	Negative	Acceptable

- g. Under advertising bullets delete "combines effectiveness with gentleness". Heightened efficacy claims or implied safety claims are not acceptable.
- h. Delete "Pleasant and Fresh Scent or Fragrance" since there is no fragrance in the formulation.
- i. Move the paragraph beginning, "For External Use on Dogs Only ... etc." under the Directions for Use section on the label.
- j. Delete "Water Proof formula". No data was submitted to support this claim.
- 3. You must generate studies corresponding to guidelines 830.6317 (one year storage stability) and 830.6320 (corrosion characteristics). The observations must be3 made at 0, 3, 6, 9, and 12 months intervals. The results must be submitted to the Agency along with and electronic format also.
- 4. Please submit three (3) copies of your final printed labeling before releasing the product for shipment. 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 Linda A. DeLuise of my team at (703) 305-5428.

## [CARTON LABEL - DRAFT MASTER LABEL COPY] Sergeant's Cyphenothrin+Methoprene Squeeze-On for Dogs

### • DO NOT USE ON CATS [Box/Icon with Cat Image and Cross-Out]

[ Pleasant Fresh Scent [or][Fragrance]]

[• Flea & Tick Control for Dogs & Puppies 12 weeks old and older]

[12 week], [16], [20], [24] [32 [36] [26] [52] Week Supply

For Dogs weighing [greater than 9 lbs], [9 to 20 lbs], [21 to 39 lbs] [40 to 60 lbs] [61 lbs and over]

[• Four Way Protection: [Kills] [fleas], [ticks], [mosquitoes], and [flea eggs]

[Works up to [4] [Four] Weeks on fleas and ticks!]

[Protects for up to [4] [Four] Weeks against [fleas] [ticks]!]

[Kills [For Up To 4 Weeks:] fleas and ticks, [For up to 4 Weeks]

[Kills Flea eggs for up to one month]

[ Four Way Protection [Kills fleas, ticks, mosquitoes and flea eggs]

[ • Four Way Protection! Kills fleas, ticks, mosquitoes and flea eggs]

[•4 Way Protection! Kills fleas, ticks, mosquitoes and flea eggs]

[• [Four (4) Week] [Flea and Tick Control]]\*

[• With methoprene an Insect Growth Regulator which Breaks the Flea Life Cycle]\*

[• With methoprene to Break Flea Life Cycle]\*

[• With Insect Growth Regulator to Break Flea Life Cycle]\*

[• Dual Action [!]: Cyphenothrin with methoprene IGR Effectively Breaks the Flea Life Cycle]\*

[ • Dual Action [!]: Effectively Breaks the Flea Life Cycle[!]]\*

[• For Dogs & Puppies (Over 12 Weeks of Age) greater than 9 lbs.]

[ For Dogs & Puppies (Over 12 Weeks of Age) 9 to 20 lbs.]

[• For Dogs & Puppies (Over 12 Weeks of Age) 21 to 39 lbs.]

[• For Dogs & Puppies (Over 12 Weeks of Age) 40 to 60 lbs.]

[• For Dogs & Puppies (Over 12 Weeks of Age) 60 lbs and Over]

[• Three Applications {for cartons with 3 applicators}.] and/or [3 Month Supply] or [12 Week Supply]

[• For Dogs [greater than 9 lbs.] or [9 lbs. to 20 lbs.] or [21 lbs. to 39 lbs.] or [40 lbs. To 60 lbs.] or [60 lbs. and Over]

[• Breaks Flez Life Cycle!]\*[for up to 1 month]

[Controls Flea reinfestation for up to 4 weeks]

[ Best if used year round!]

[• Kills & Repels Fleas Up to [4 weeks]!]

- [Kills [& repels] fleas in as little as 1 hour!]
- [[Kills [& repels] ticks in as little as 3 hours!]
- [Kills [and Repels] mosquitoes]
- [Kills [and Repels] for 1 [One] Month [30 days]]
  - [Fleas (in as little as 1 hour],]
  - [Ticks [in as little as 3 hours]]
  - [flea eggs]
  - [flea larvae]

ACCEPTED with COMMENTS In EPA Letter Dated:

NOV 2 2 2006

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

- [• Prevents ticks from attaching and feeding in as little as 3 hours after application]
- [ Kills and Detaches Ticks]
- [• Easy to Use Application]
- [ Specially Formulated for Dogs and Puppies]
- [• 4 Week Protection against fleas and ticks!]
- [• Reminder Calendar Stickers Inside!]
- [• Patented Technology [combines effectiveness with gentleness!]]
- [• Kills Flea Eggs for 30 days]
- [ Prevents Flea Eggs From Developing Into Biting Adults]\*
- [• Kills & Repels Ticks for up to [4 weeks][!]]\*
- [• Kills & Repels Deer Ticks (vector of Lyme Disease) for up to 4 weeks!]\*
- [• Kills & Repels Ticks (Including Deer Ticks) for up to 4 weeks!]\*
- [• Kills & Repels Brown Dog Ticks [(Rhipicephalus sanguineus)] for up to 4 weeks!]\*
- [• Kills & Repels American Dog Ticks [(Dermacentor variabilis)] for up to 4 weeks!]\*
- [• Apply once every [4 weeks]!]\*
- [• [4 week][1month] Flea and Tick Treatment!]\*
- [• Kills & Repels Fleas and Ticks for up to 4 weeks!]\*
- [• Kills Fleas and Flea Eggs for up to 4 Weeks]\*
- [• Kills [& Repels] [for four [4] Weeks] Fleas [in as little as 1 hour], and ticks [in as little as 3 hours] [for up to 4 weeks]]

[(ICON Showing 4 Week Protection)]

- [• May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]
- [] Denotes Optional Statements and/or Images that May be Used on Front, Back or Side Label Panels
- [\* Denotes claims to be based on new as well as existing product performance (efficacy) Data)]

[Ingredient Statement may be on front or back label]

#### **ACTIVE INGREDIENTS:**

Cyphenothrin (CAS# 39515-40-7)	40.0%
(S)-Methoprene (CAS#65733-16-6)	2.3%
OTHER INGREDIENTS:	<u>57.7%</u>
TOTAL:	100.0%

### KEEP OUT OF REACH OF CHILDREN CAUTION

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

NET CONTENTS: [THREE][SIX][TWELVE] 1.5 ml Tubes [THREE][SIX][TWELVE] 3.0 ml Tubes [THREE][SIX][TWELVE] 4.5 ml Tubes [THREE][SIX][TWELVE] 6.0 ml Tubes

EPA Registration N	umber: 2517-	EPA Establishment	Number:	

### [BACK/SIDE CARTON LABEL - MASTER LABEL]

# READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS AND PUPPIES OVER 12 WEEKS OF AGE. DO NOT USE ON CATS

### 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. Best if used year round. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant, or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. DO NOT USE ON CATS or animals other than dogs. Cats that actively groom or engage in close physical contact with treated dogs may be at risk of serious harmful effects. Sensitivities may occur after using ANY pesticide product on pets. If signs of sensitivity occur bathe your dog with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

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>			
HOTLINE 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 1-800-224-PETS for emergency medical treatment information.				
	NOTE TO PHYSICIAN OR VETERINARIAN  Treat patient symptomatically			

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. DO NOT USE ON CATS. May be toxic and potentially fatal if applied to or ingested by cats.

How to apply: Remove product tube from package. Holding tube with top end pointing up and away from face and body, [snap or] cut off top end. 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, as directed below. Repeat application may be made if necessary, but do not apply more often than once every 4 weeks.

### [BACK/SIDE CARTON LABEL - MASTER LABEL]

### For Dogs Weighing Between 9 and 20 lbs.: {For cartons containing 1.5 ml applicator tubes}

[Apply one tube (1.5 ml) as a spot or stripe to the dog's back between the shoulder blades.] - or - [Apply one tube (1.5 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 dog's tail.]

### For Dogs Weighing Between 21 and 39 lbs. {For cartons containing 3.0 ml applicator tubes}

[Apply one tube (3.0 ml) as a spot or stripe to the dog's back between the shoulder blades.] - or - [Apply one tube (3.0 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 dog's tail.]

### For Dogs Weighing Between 40 and 60 lbs. {For cartons containing one 4.5 ml applicator tube}

[Apply one tube (4.5 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 dog's tail.]

### For Dogs Weighing 60 lbs. and Over: {For cartons containing at least two 3.0 ml applicator tubes, or at least one 6.0 ml applicator tube}

[Apply the first tube (3.0 ml) as a spot to the dog's back between the shoulder blades and apply the contents of the other tube (3.0 ml each) along the dog's back extending to directly in front of the base of the tail.] - or - [Apply one tube (6.0 ml) as a continuous stripe on the dog's back starting between the shoulder blades and ending directly in from of the base of the dog's tail.]

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**STORAGE:** Do not remove tube from the pack until ready to use. Store in a cool (below 25°C) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

**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 or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

[Sergeant's Squeeze-On Flea & Tick Control with methoprene is an effective and easy to use product.] [Sergeant's Squeeze-On Flea & Tick Control with methoprene prevents eggs from fleas on treated dogs from developing into biting adults for 30 days.] [As with all flea and tick control products, Sergeant's Squeeze-On Flea and Tick Control with methoprene should be used as part of a program aimed at reducing flea populations in the dog's environment (bedding, carpets, kennel, yard).] [Consult your retailer for program recommendations.]

### [BACK/SIDE CARTON LABEL - MASTER LABEL]

#### www.sergeants.com

MADE IN USA

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.

[Satisfaction Guaranteed!] [ Please return for a refund if not completely satisfied!]

In Case of Emergency, call 1-800-224-PETS.

[WARRANTY: SERGEANT'S PET CARE, INC. MAKES NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY 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 STATEMENTS MADE ON THIS LABEL.]

Made in the USA For: Sergeant's Pet Care Products, Inc. Omaha, NE 68130 EPA Reg. No. 2517 -XX EPA Est. No. XXXXX -XX -XXX

[BAR CODE AREA]

### [TUBE/APPLICATOR LABEL]

#### FRONT PANEL -

Sergeant's Squeeze-On Flea & Tick Control with methoprene, Insect Growth Regulator, [Box/Icon with Cat Image and Cross-Out], [1.5 ml] or [3.0 ml] or [4.5 ml] or [6.0 ml], Cyphenothrin 40.0% W/W, (S)-Methoprene 2.3% W/

#### **BACK PANEL -**

READ DIRECTIONS/PRECAUTIONS BEFORE USING.

CAUTION: KEEP OUT OF REACH OF CHILDREN

EPA REG. NO. 2517-XX