


2517-131

04-30-2010

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	<p align="center">U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460</p>	<p>EPA Registration No. 2517-131</p>	<p>Date of Issuance: APR 30 2010</p>
<p align="center">NOTICE OF PESTICIDE:</p> <p align="center"> <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration </p> <p align="center">(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</p>		<p>Term of Issuance: Conditional Registration Expires April 30, 2012</p> <hr/> <p>Name of Pesticide Product: Cyphenothrin Squeeze-On for Dogs (20%)</p>	
<p>Name and Address of Registrant (include ZIP Code):</p> <p>Sergeant's Pet Care Products, Inc. 2625 South 158th Plaza Omaha, NE 68130</p>			
<p><i>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.</i></p>			
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.</p> <p>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.</p> <p>This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(a) provided that:</p> <ol style="list-style-type: none"> 1. This registration is time-limited and expires two years from the date this product is first released for shipment. You must provide the Agency with a projected release for shipment date within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing. 2. Only one confidential statement of formula (basic) will be filed for this product; no alternate formulation or minor formulation statements will be submitted or approved for this product. 3. All marketing statements and references to "mosquitoes" throughout the draft label, including the statement "a once monthly application is recommended where mosquito control is needed" on page 5, must be deleted because the submitted efficacy study does not support these claims. 4. On page one of the label, because all "mosquito" references are not permitted, you must correct the marketing statements that refer to "[Three] [3] Way Protection" to "[Two] [2] Way Protection..." 			

5. Revise the section "Frequency of Application" from "[When used monthly, {product name} breaks the flea life cycle and controls flea, tick and mosquito infestations.] [Research demonstrates that {product name} kills adult fleas and ticks for up to 8 weeks, also prevents development of flea egg and larval states for up to nine weeks.] A once monthly application is recommended where mosquito control is needed." to "A once monthly application is recommended where mosquito control is needed."

6. For labeling clarity, for the alternate brand names options listed on page one, you must include the full brand name "and Puppies Over 12 Weeks Old," or do not include "and Puppies" in the alternate brand names without the "over 12 weeks old" statement.

7. The following words contained in the alternate brand names must be deleted from page one of the label because misleading product names are not acceptable:

"Advance"

"VetSpot"

"AdvanSpot"

8. On page one of the label, the marketing statement "with Skin Protection Technology" must be deleted because misleading claims are not permitted.

9. The claim "New [formula]" may appear on product produced for 6 months from the date of first distribution only.

10. On page two of the label, delete "Vitamin E acetate" from the Ingredient Statement Panel, because this is not one of the ingredients in the formulation.

11. Remove "[Formulated] [with] DERMASHIELD™ [Technology]" must be deleted because misleading claims are not permitted.

12. As a condition of registration for this product, the following data must be submitted within the respective timeframes:

a) Data to fulfill OPPTS Guideline 830.1800 – Enforcement Analytical Method, must be submitted within 45 days from the date of this registration:

b) Within one year from the date of this registration, you must submit the results corresponding to OPPTS Guidelines 830.6317 and 830.6320, Storage Stability and Corrosion Characteristics studies, respectively, including interim reports made at 0, 3, 6, 9, and 12 month intervals.

c). To confirm that there are no additional dermal or eye irritation concerns from this formulation, the following studies must be submitted within six months of the date of this registration:

OPPTS Guideline 870.2400 - Acute Eye Irritation

OPPTS Guideline 870.2500 - Acute Dermal Irritation

13. You must submit enhanced incident reports for this product on a quarterly basis beginning July 1, 2010. 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: Kimberly Nesci).

The following is a list of information needed by EPA to better characterize these incidents:

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

14. Along with the enhanced incident reporting, you must submit an analysis quarterly, comparing any incidents associated with the new product to the incidents associated with the existing product (EPA Registration Number 2517-85) to demonstrate if there is any reduction in the number of pet incidents, to include the following details:

- You must include the number of doses sold during the reporting quarter.
- 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 showing number of incidents (misuse or secondary exposure) 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 for dogs showing number of incidents for each severity code for these weight ranges: <5, 5-9, 9-20, 21-39, 40-60, 61-80, 80-100, >100 pounds. The weight ranges were picked to follow the weight ranges on their product label and should be changed if the product weight range changes.
- 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.

15. You must submit and/or cite all data required for registration of your product under FIFRA Section 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.

16. Revise the EPA Registration Number to read: "EPA Registration No. 2517-131" on page five of the label.

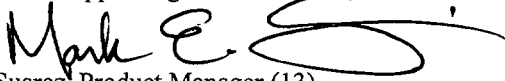
Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A copy of your label stamped "Accepted with Comments" is enclosed for your records.

If you have any questions concerning this action, please contact Rosanna Louie at (703) 308-0037.

Enclosure:

- Cyphenothrin Squeeze-On for Dogs (20%) Label, Stamped *Accepted with Comments*

Signature of Approving Official:


 Mark Suarez, Product Manager (13)
 Registration Division, Insecticide Branch

Date:

APR 30 2010

Sergeant's Master Label

26 January 2010

Information in [] is optional.

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FRONT PANEL

DOG SQUEEZE-ON

Cyphenothrin

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

Cyphenothrin Squeeze-On for Dogs (20%)

[ABNs]

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

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

[Sergeant's VetSpot™ [Flea and Tick] Squeeze-On for Dogs [and Puppies]]

[Sergeant's AdvanSpot™ [Flea and Tick] Squeeze-On for Dogs [and Puppies]]

[Sergeant's Silver® Advance [Flea and Tick] Squeeze-On for Dogs [and Puppies]]

[Sergeant's Silver® [Flea and Tick] Squeeze-On for Dogs [and Puppies]]

[Sentry XFC [Flea and Tick] Squeeze-On for Dogs [and Puppies]]

(*over 12 weeks old)

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



- [[Three] [3] Way Protection [Kills fleas, ticks & mosquitoes]]
- [Three in one Protection! [Kills fleas, ticks & mosquitoes]]
- [Specially Formulated for Dogs and Puppies (over 12 weeks old)]
- [Flea & Tick Control for Dogs & Puppies 12 weeks old and older]
- [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 [more than 9 lbs] or [9 lbs to 20 lbs] or [21 lbs to 39 lbs] or [40 lbs to 60 lbs]]
- [[12][15][18][21][24][32][52] Week Supply For Dogs]
- [Monthly flea and tick control]
- [Works for up to 4 Weeks!]
- [Protects for up to 4 Weeks!]
- [Apply every [4 weeks] [1 month]!]
- [Up to 4 week Dose!]
- [Up to 1 Month Dose!]
- [(ICON Showing up to 4 Week Protection)]
- [Three Applications {for cartons with 3 applicators}] and/or [3 Month Supply] or [12 Week Supply]
- [Four Applications {for cartons with 4 applicators}] and/or [4 Month Supply] or [16 Week Supply]
- [Best if used year round!]
- [Easy to Use Application]
- [Patented Technology] [Patent pending technology]
- [Dogs can be bathed 24 hours after squeeze-on is applied.]
- [New] [formula]
- [with] [Skin Protection Technology]
- [Quick Drying] [formula]
- [with Vitamin E]
- [No oily residue]
- [Fragrance Free]
- [Formulated] [with] DERMASHIELD™ [Technology]

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

APR 30 2010

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
2517-131**

Sergeant's Master Label

26 January 2010

Information in [] is optional.

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FRONT PANEL

DOG SQUEEZE ON

Cyphenothrin

(Multiple species)

- [Kills fleas, ticks and mosquitoes]
- [Kills [and Repels] Fleas [in as little as 1 hour] Ticks [in as little as 3 hours] [Mosquitoes]
- [Protects for up to 4 Weeks on fleas and ticks!]
- [Protects for up to 4 Weeks on adult fleas and ticks!]
- [Up to 4 Week Flea and Tick Treatment!]
- [Up to 4 Week Adult Flea and Tick Treatment!]
- [Up to 4 Week Flea and Tick Control]
- [Up to 4 Week Adult Flea and Tick Control]
- [Up to 4 Week Flea and Tick Protection!]
- [Up to 8 Week Adult Flea and Tick Protection!]
- [Up to [One] Month Flea and Tick Treatment]
- [Kills & Repels Fleas and Ticks for up to 4weeks!]
- [Kills & Repels Adult Fleas and Ticks for up to 4 weeks!]

(Fleas)

- [Kills [& Repels] fleas in as little as 1 hour!]
- [Kills & Repels Fleas for up to 4 weeks!]
- [Kills & Repels Adult Fleas for up to 4 weeks!]

(Ticks)

- [Kills and Detaches Ticks]
- [Prevents ticks from attaching and feeding in as little as [3 hours] after application]
- [Kills [& Repels] ticks in as little as 3 hours!]
- [Kills & Repels Ticks for up to 4 weeks!]
- [Kills & Repels Ticks (Including Deer Ticks) for up to 4 weeks]
- [Kills & Repels Deer Ticks (vector of Lyme Disease) 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!]

(Mosquitoes)

- [Kills [and Repels] mosquitoes [for up to [28 days] [4 weeks] [1 month]!]

***Note: Underscored 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).....20.00%

OTHER INGREDIENTS*:80.00%

[TOTAL] 100.00%

*(Diethylene glycol monoethyl ether, [vitamin E acetate], [vitamin E nicotinate])

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)
[THREE][FOUR][SIX][TWELVE] (0.05 fl oz) 1.5 mL Tubes

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

BACK PANEL

DOG SQUEEZE ON
Cyphenothrin

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

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. Harmful if swallowed or absorbed through skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID	
IF IN EYES	<ul style="list-style-type: none">• 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.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none">• 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 style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to do so.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
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.	
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.
FOR EXTERNAL USE ON DOGS ONLY. Do not use on puppies under 12 weeks of age. Weigh your dog to be sure you are applying the right dose formulated for the weight of your pet. Do not treat your pet with more than one pesticide product at a time. Over dosing your animal can result in serious illness and even death. **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. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied. Cats and dogs that actively groom or engage in close physical contact with treated dog may be at risk of serious harmful effects. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur immediately feed your dog and continue to monitor your pet for the next 24 hours. If symptoms persist call 1-800-781-4738 to talk to a veterinarian. Cats exhibiting these same symptoms from ingestion should be taken to the veterinarian immediately. If your dog is exhibiting signs of and/or are being treated for skin dermatitis, talk to your vet before applying any topical flea and tick control product.

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Information in [] is optional.

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BACK PANEL

DOG SQUEEZE ON
Cyphenothrin

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 by calling 1-800-781-4738.

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.

Frequency of Application:

[When used monthly, {product name} breaks the flea life cycle and controls flea, tick and mosquito infestations.] [Research demonstrates that {product name} kills adult fleas and ticks for up to 8 weeks, also prevents development of flea egg and larval states for up to nine weeks.] A once monthly application is recommended where mosquito control is needed.

(INSERT DIAGRAM THAT DEPICTS APPLICATION OF PRODUCT ON THE DOG)

For Dogs Weighing Between 9 and 20 lbs

{For cartons containing one 1.5 mL (0.05 fl oz) applicator tubes}

Apply one tube (1.5 mL)(0.05 fl oz) [as a spot to the dog's back between the shoulder blades] or [from the back of the neck to a point midway between the neck and tail].

For Dogs Weighing Between 21 and 39 lbs

{For cartons containing two 1.5 mL (0.05 fl oz) applicator tubes}

[Apply two tubes (1.5 mL)(0.05 fl oz) as a spot on the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

OR

{For cartons containing one 3.0 mL (0.10 fl oz) applicator tube}

[Apply one tube (3.0 mL)(0.10 fl oz) as a spot or stripe to the dog's back between the shoulder blades.] or [from the back of the neck to a point midway between the neck and tail].

For Dogs Weighing Between 40 and 60 lbs

{For cartons containing three 1.5 mL (0.05 fl oz) applicator tubes}

[Apply two tubes (1.5 mL)(0.05 fl oz) as a spot or stripe to the dog's back between the shoulder blades and apply the third tube from the back of the neck to a point midway between the neck and tail].

OR

{For cartons containing one 4.5 mL (0.15 fl oz) applicator tube}

[Apply one tube (4.5 mL)(0.15 fl oz) from the back of the neck to a point midway between the neck and tail].

STORAGE AND DISPOSAL

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

PESTICIDE 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.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling or reconditioning, if available and appropriate.

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 for disposal instructions. Never place unused product down any indoor or outdoor drain

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BACK PANEL

DOG SQUEEZE ON Cyphenothrin

[Sergeant's Cyphenothrin Squeeze-On for Dogs is an effective and easy to use product.] [As with all flea and tick control products, [Sergeant's Cyphenothrin Squeeze-On for Dogs] should be used as part of a [an overall] [complete] program [aimed at] [to] [intended to] [reduce] reducing flea populations in the dog's environment (bedding, carpets, kennel, yard).] [Consult your retailer for program recommendations.]

[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, P.O. Box 540399, Omaha, NE 68154-0399.]

In Case of Emergency, call: 1-800-781-4738 [For more information] [Visit us at:] [www.sergeants.com]
Non-Emergency call 1-800-224-PETS (7387) [Made in USA]

[Made in the USA For:] or [Manufactured by:]

[Distributed by:]
Sergeant's Pet Care Products, Inc.
PO Box 540399
Omaha, NE 68154-0399

EPA Reg. No. 2517-XX

EPA Est. No. XXXXX-XX-XX

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

{END - BACK / SIDE PANEL}

TUBE / VIAL LABEL

Front Label

{Product Name}
[Box/Icon with Cat Image & Cross-Out],
Cyphenothrin 20.0% W/W
1.5 mL (or) 3.0 mL (or) 4.5 mL {label code}

Back Label

KEEP OUT OF REACH OF CHILDREN
CAUTION: Read directions and precautions before
using.
EPA REG. No. 2517-XX {label code}