



### U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460 EPA Registration No.

2517-130

Date of Issuance:

APR 3 0 2010

#### **NOTICE OF PESTICIDE:**

☑ Registration ☐ Reregistration

(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

Term of Issuance:

Conditional Registration Expires April 30, 2012

Name of Pesticide Product:

Cyphenothrin + Pyriproxyfen Squeeze-On for Dogs (30%)

Name and Address of Registrant (include ZIP Code):

Sergeant's Pet Care Products, Inc. 2625 South 158<sup>th</sup> Plaza Omaha, NE 68130

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 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)(7)(a) provided that:

- 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 "[Five] [5] Way Protection" to "[Four] [4] Way Protection..."

- 5. Remove the statement "[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.]" The claim is not supported by the data on file with the Agency.
- 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 two 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 three 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. Remove the claim "[Sergeant's Squeeze-On Flea & Tick Control with [Nylar® Insect Growth Regulator] prevents eggs from fleas on treated dogs from developing into biting adults for up to 63 days] [9 weeks]." The claim is not supported by the data on file with the Agency.
- 13. 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

14. 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

- 15. 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 2517-90) 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.
- 16. 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.
- 17. Revise the EPA Registration Number to read: "EPA Registration No. 2517-130" on page six 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.

- Cyphenothrin + Pyriproxyfen Squeeze-On for Dogs (30%) Label, Stamped Accepted with Comments				
Signature of Approving Official:	Date:			
May 8	APR 3 0 2010			

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

26 January 2010

Information in [ ] is optional.

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EPA No. 2517-XX RGN

#### IERKONNICIPANNICIL

DOG SQU**HY**AE ON Gypherothalis Byalpasyter

[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+Pyriproxyfen Squeeze-On for Dogs (30%)

#### [ABNs]

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

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

[Sergeant's VetSpot<sup>TM</sup> [Plus] [Flea and Tick] Squeeze-On for Dogs [and Puppies]]

[Sergeant's AdvanSpot<sup>TM</sup> [Plus] [Flea and Tick] Squeeze-On for Dogs [and Puppies]]

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

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

[SentryPro 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]

- DO NOT USE ON CATS
- [[Five] [5] Way Protection [Kills fleas, ticks, mosquitoes, flea eggs & flea larvae]]
- [Five Way Protection! Kills ticks, mosquitoes fleas, flea eggs & flea larvae]
- [5 Way Protection! Kills ticks, mosquitoes, fleas, flea eggs & flea larvae]
- [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) 61 lbs and Over]
- [For Dogs [61 lbs and Over]]
- [[12][15][18][21][24][32][52] Week Supply For Dogs weighing [61 lbs and over]
- [Apply once every [4 weeks] [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]
- [[Free] Calendar Stickers Inside!]
- [[Free] Brochure Inside!]
- [[Free] Brochure and Calendar Stickers Inside]
- [Patented Technology] [Patent pending technology]
- [Dogs can be bathed 24 hours after squeeze-on is applied.]

ACCEPTED
with COMMENTS
In EPA Letter Dated:

APR 3 0 2010

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

26 January 2010

Information in [ ] is optional.

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#### INCONTERANTEL.

DOG SQUEEZE ON Cyphenothein & Pyriproxyfer

#### (Multiple species)

- [Kills all stages of the flea life cycle]
- [Kills fleas, ticks, mosquitoes, flea eggs, and flea larvae]
- [Kills fleas [in as little as 1 hour], [and] [ticks] [in as little as 3 hours] [mosquitoes], [flea eggs & flea larvae]
- [Kills [and Repels] Fleas [in as little as 1 hour] Ticks [in as little as 3 hours] [Mosquitoes]
- [Kills Fleas, Ticks, Flea Eggs & Flea Larvae for up to [4 Weeks] [1 month]]
- [Works for up to 4 Weeks on fleas and ticks!]
- [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 4 Week Adult Flea and Tick Protection!]
- [Up to One Month Flea and Tick Treatment]
- [Kills & Repels Fleas and Ticks for up to 4 weeks!]
- [Kills & Repels Adult Fleas and Ticks for up to 4 weeks!]
- [New ] [formula]
- [with] [Skin Protection Technology]
- [Quick Drying] [formula]
- [with Vitamin E]
- [No oily residue]
- [Fragrance Free]
- [Formulated] [with] DERMAshield<sup>TM</sup> [Technology]

#### (Flea and Flea eggs and Larval)

- [With Nylar® to Break Flea Life Cycle]
- [With Insect Growth Regulator to Break Flea Life Cycle]
- [Dual Action [!]: Effectively Breaks the Flea Life Cycle [!]]
- [Dual Action [!]: Cyphenothrin with S-Methoprene IGR Effectively Breaks the Flea Life Cycle]
- [Prevents Flea Eggs From Developing Into Biting Adults]
- [Breaks Flea Life Cycle!] for up to 9 weeks]
- [Controls reinfestation for up to 9 weeks!]
- [Kills Flea Eggs & Flea Larvae for up to [63 days], [9 weeks]!]
- [Kills for up to [9 weeks] [63 days]] [flea eggs][flea larvae]
- [Kills [& Repels] fleas in as little as 1 hour!]
- [Kills & Repels Fleas for up to 4 weeks!]

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Information in [ ] is optional.

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#### ERONTEPANIEL

DOGSQUEE*7AL*ON Cyphenothdin&Pydproxyfed

#### (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)	30.00%
Pyriproxyfen (CAS# 95737-68-1)	2.00%
OTHER INGREDIENTS*:	<u>68.00%</u>
[TOTAL	100.00%]

<sup>\*(</sup>Diethylene glycol monoethyl ether, [vitamin E acetate], [vitamin E nicotinate])

[Nylar® is a registered trademark of McLaughlin Gormley King Company. U.S. Patent No. 5,942,525]

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

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Information in [ ] is optional.

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ODANIFIC

DOG SQUEEZE ON Cyphenothan & Pyriproxyfer

[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> <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 further 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>
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>Have person sip a glass of water if able to do so.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
	HOT LINE NUMBER
for treatment. Fo	t container or label with you when calling a poison control center or doctor, or going r more information on this pesticide product (including health concerns, medical sesticide 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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BACKEPANELA

DOG SQÚIEZZE ON Cyphenotháin & Pyráproxyfen

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 61 lbs and Over:

#### {For cartons containing four 1.5 mL (0.05 fl oz) applicator tubs}

[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 contents of the other two tubes (1.5 mL) (0.05 fl oz) from the back of the neck to a point midway between the neck and tail.]

#### OR

#### {For cartons containing two 3.0mL (0.10 fl oz) applicator tubes}

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

#### OR

#### {For cartons containing one 6.0 mL (0.20 fl oz) applicator tubes}

[Apply one tube (6.0 mL)(0.20 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 for disposal instructions. Never place unused product down any indoor or outdoor drain

[Sergeant's Squeeze-On Flea & Tick Control with [Nylar® Insect Growth Regulator] is an effective and easy to use product.] [Sergeant's Squeeze-On Flea & Tick Control with [Nylar® Insect Growth Regulator] prevents eggs from fleas on treated dogs from developing into biting adults for up to 63 days] [9 weeks]. [As with all flea and tick control products, [Sergeant's Squeeze-On Flea and Tick Control] [with] [Nylar® Insect Growth Regulator] 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.]

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Information in [ ] is optional.

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#### BACK PANIEL

NO <u>IVEFU</u>OS DOUL Cydraed A nirdonadyd

#### **[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:]

EPA Reg. No. 2517-XX

Sergeant's Pet Care Products, Inc.

PO Box 540399

EPA Est. No. XXXXX-XX-XX

Omaha, NE 68154-0399

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

#### {END - BACK / SIDE PANEL}

#### TUBE/VIAL LABEL

Fron	+	T	ah	ام
$r_{1}om$	Ł	1.	/AII	CI

#### Back Label

{Product Name}	KEEP OUT OF REACH OF CHILDREN
[Box/Icon with Cat Image & Cross-Out],	CAUTION: Read directions and precautions before
Cyphenothrin 30.0% W/W, Pyriproxyfen 2.0% W/W	using.
6.0 mL {label code}	EPA REG. No. 2517-XX {label code}