

2517-137



3/13/2014
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

1/11

MAR 13 2014

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Kelly R. Hoskins
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-1710

Subject: Label Notification(s) for Pesticide Registration 98-10

Dear Ms. Hoskins:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated for February 10, 2014 for:

Alternate Brand Names

PetArmor® for Cats
Sergeant's® PetArmor® for Cats

The Registration Division (RD) has conducted a review of this request for applicability Under PRN 2007-4 and finds that the label change(s) requested falls within the scope of PRN-2007-4. The label has been date-stamped "Notification" and will be placed in our records.

EPA Registration Number: 2517-137 Sergeant's Fipronil Squeeze-On for Cats

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact Melody Banks on 703 305-5413 or via E-mail at banks.melody@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

Richard Gebken
Product Manager
Insecticide Branch
Registration Division (7504P)

<h1 style="margin: 0;">EPA</h1> <p style="text-align: center; margin: 0;">United States Environmental Protection Agency Washington, DC 20460</p>	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 2517-137	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sergeant's Pet Care Products, Inc. / Sergeant's Fipronil Spot-On for Cats		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical to a pesticide already registered to: EPA Reg. No. MAR 13 2014 Product Name _____
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134 th Street Omaha, NE 68138-1710 <input type="checkbox"/> Check if this is a new address		

Section II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated XX-XX-XX <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below.
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Explanation: Use additional page(s) if necessary. (For section I and Section II.) This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 USC Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PRN 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sec 12 and 14 of FIFRA. Please see cover letter for details.

Label notification alternate brand names. Please see cover letter for details.

Section III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If "Yes" Unit Packaging wgt. 0.017 fl oz (0.50 ml)	No. per Container 1,2,3,4,5,6, 12,24 vials	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag
*Certification must be submitted		3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.017 fl oz (0.05 ml)	
5. Location of Label Directions <input type="checkbox"/> On Can <input checked="" type="checkbox"/> On Labeling accompanying product				6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kelly R. Hoskins	Title Director of Regulatory Affairs	Telephone No. (Include Area Code) 402-938-7079

Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature BY: <i>Kelly R. Hoskins</i>	3. Title Director of Regulatory Affairs	
4. Typed Name: Kelly R. Hoskins	5. Date: 2/10/2014	

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Sergeant's Master Label

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Information in [] is optional.

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FRONT PANEL

**CAT SPOT ON
FIPRONIL**

[Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels. The CRP required text will not change.]

Sergeant's Fipronil Spot-On for Cats NOTIFICATION

MAR 13 2014

[ABNs:]

[Sergeant's® Frontier Gold Spot On for Cats]

[Sergeant's® Frontier Gold for Cats]

[Sentry® Frontier Gold Spot On for Cats]

[Sentry® Frontier Gold for Cats]

[Sergeant's® Ectoadvance Spot On for Cats]

[Sergeant's® Ectoadvance for Cats][Sentry® Ectoadvance Spot On for Cats]

[Sentry® Ectoadvance for Cats]

[Sergeant's® Gold FrontSpot Spot On for Cats]

[Sergeant's® Gold FrontSpot for Cats]

[Sentry® Gold FrontSpot Spot On for Cats]

[Sentry® Gold FrontSpot for Cats]

[Sentry® Proline Spot On for Cats]

[Sentry® Proline for Cats]

[SENTRY® FIPROGUARD™ for Cats]

[FIPROGUARD™ for Cats]

[Sergeant's® PRONYL OTC™ for Cats]

[PRONYL OTC™ for Cats]

[Sergeant's® AdvanSpot Spot On for Cats]

[Sergeant's® AdvanSpot for Cats]

[Sentry® AdvanSpot Spot On for Cats]

[Sentry® AdvanSpot for Cats]

[FiproSpot Topical for Cats and Kittens]

[FiproSpot for Cats and Kittens]

[FiproSpot Topical for Cats]

[FiproSpot for Cats]

[EctoSpot Topical for Cats and Kittens]

[EctoSpot for Cats and Kittens]

[EctoSpot Topical for Cats]

[EctoSpot for Cats]

[Ectopronil Topical for Cats and Kittens]

[Ectopronil for Cats and Kittens]

[Ectopronil Topical for Cats]

[Ectopronil for Cats]

[EctoAdvance Topical for Cats and Kittens]

[EctoAdvance for Cats and Kittens]

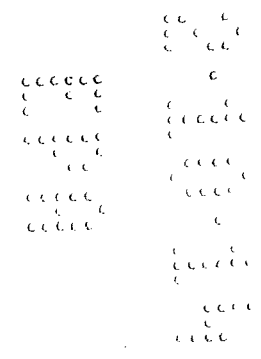
[EctoAdvance Topical for Cats]

[EctoAdvance for Cats]

[F-Pronil Topical for Cats and Kittens]

[F-Pronil for Cats and Kittens]

[F-Pronil Topical for Cats]



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[F-Pronil for Cats]

[Meridian Animal Health]

[PetArmor® for cats]

[Sergeant's® PetArmor® for cats]

[For use ONLY on cats [[&] [and] kittens] over 1.5 lbs and over 8 weeks of age] [OR]
[Only for cats [[&] [and] kittens] over 8 weeks of age and over 1.5 lbs]

[Apply to kittens over 8 weeks old]
[Apply to kittens 8 weeks or older]

[Mosquitoes]

[Kills mosquitoes within 24 hours for up to 14 days] [and within 48 hours for up to 28 days]

[Chewing Lice]

[Kills chewing lice]
[Rapid elimination of chewing lice infestation]
[Fast Action against chewing lice infestations]

[Fleas]

[Kills adult fleas [for up to six weeks]]
[Kills Fleas [Up to 4 weeks] [1 month] [30 days]!]
[If cat is a high risk for flea reinfestation apply once a month]
[Kills fleas which may be a source of flea allergy dermatitis] [or flea bite anemia]

[Ticks]

[Kills ticks including those that may transmit Lyme disease]
[Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]
[Kills deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days] [per application]]
[Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]] [Kills [brown dog ticks], [(*Rhipicephalus sanguineus*)] [American dog ticks,] [and lone star ticks] [,][and deer ticks] [for up to [4 weeks] [1 month] [30 days]]]
[Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]

[Multiple Infestations]

[Flea [&] [and] Tick Control for Cats [&] [and] Kittens 8 weeks old and older]
[Kills fleas, ticks, [mosquitoes] [&] [and] chewing lice]
[Kills fleas, ticks, chewing lice [&] [and] [mosquitoes]]
[Monthly flea, tick, [mosquito] and chewing lice protection]
[Four] [4] [Three] [3] Way [Action] [Effectiveness] [Control] [kills fleas, [mosquitoes,] ticks, and chewing lice]
[[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!]
[[Four (4) Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]
[Once A Month Flea and Tick Treatment]
[Use [Brand name][this product] monthly to control ticks and chewing lice]
[Monthly flea, tick, [mosquito], and chewing lice protection.]
[Kills Fleas and Ticks for up to [4 weeks] [1 month] [30 days]!]
[[Brand name][This product]provides convenient and effective flea, tick, chewing lice [and] [mosquito] control for cats and kittens over 8 weeks of age.]

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[All Others]

[Cats and Kittens 8 weeks of age or older]
 [Can be used on kittens 8 weeks of age and older]
 [Specially Formulated on Cats and Kittens Over 8 Weeks Old]
 [Fast Acting] [Long Lasting]
 [Easy to Use [Application]]
 [Best if used year round!]
 [Apply monthly]
 [Once a month treatment]
 [For year-round protection, apply [Brand name][this product] monthly]
 [(ICON Showing [4 Week] [1 month] [30 day] Protection)]
 [Apply once every [4 weeks] [month] [30 days]!]
 [4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
 [[One][1][Two][2][Three] [3][4][Four][5][Five] [Six][6][Twelve][12][Twenty-Four][24]]Applications] and/or
 [1 Month Supply][2 Month Supply][3 Month Supply][Four Month Supply][Five Month Supply][6 Month
 Supply][12 Month Supply][24 Month Supply] or [4 Week Supply][8 Week Supply][12 Week Supply][16
 Week Supply][20 week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply]
 [Waterproof]
 [Effective even after bathing]
 [Effective after bathing and exposure to water and sunlight]
 [Can be used on breeding, pregnant and lactating [queens], [female] [cats]]
 [[Free] Calendar Stickers Inside!]
 [Monthly application reminder inside]
 [[Free with purchase] [Free inside] Monthly Application Reminder [Magnet][clip] [inside]]
 [Fipronil (9.7%)]
 [Contains [the] [same] active ingredient used in [FRONTLINE® Top Spot® for Dogs (or any ABN)]
 [FRONTLINE® brand products].*]
 [Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® brand products], contains
 [the] [same] active ingredient.*]
 [Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® brand products], contains
 [the] [an] [same] active ingredient fipronil.*]
 [[Brand Name] [products] [This product] contains(s) fipronil, [the] [an] [same] active ingredient used in
 [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® brand products].*]
 [[Brand Name] [products] [This product] contains(s) fipronil, compared to [the] [an] [same] active ingredient
 used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® brand products].*]
 [[*][Brand Name][This product] is not manufactured or distributed by [Merial®] [Company name], the makers
 of [FRONTLINE® Top Spot® for Dogs (or any ABN)][FRONTLINE® brand products].]
 [[Brand Name][This product][Frontline®] [Frontline® TopSpot®] is a registered trademark of [Merial®]
 [Company name].]
 [[1][2][3][4][5][6][12][24] applications]
 [Stops and prevents infestation of listed pests for [4 weeks][1 month]]

ACTIVE INGREDIENT:

Fipronil.....9.70%

OTHER INGREDIENT:.....90.30%

TOTAL 100.00%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

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

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Net Contents: X fl oz | Y - 0.017 fl oz (0.50 ml) applicator(s)
[1][One][2][Two][3] [Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]

{END - FRONT PANEL}

BACK PANEL/SIDE PANEL

CAT SPOT ON FIPRONIL

[[Brand name]][this product] contains Fipronil to effectively kill fleas and ticks ((including those that may transmit Lyme disease)). [The active ingredients in [Brand name]][this product] feature a sustained release formula developed for fast acting [and long lasting] control of fleas, ticks, [mosquitoes] and chewing lice for [1 month][4 weeks] on cats.]

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON CATS AND KITTENS OVER 8 WEEKS OF AGE

[[Brand name]][this product] provides [[four] [three] way] protection that kills fleas, ticks, [mosquitoes] and chewing lice. Kills deer ticks that may transmit Lyme disease. Kills brown dog ticks, American dog ticks, and lone star ticks. Prevents flea reinfestation for [[4][four] weeks] [[1] [one]month] [30 days].]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on cats only. Individual sensitivities, while rare, may occur after using any pesticide product on cats. Certain medications can interact with pesticides. Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, or aged cats. Can be used on breeding, pregnant, or lactating [cats] [female cats] [queens]. Consult a veterinarian before using on cats with known organ dysfunction.

FIRST AID

If swallowed:	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. 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.
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:	Wash with plenty of soap and water. Get medical attention if irritation persists.

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.

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STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F/[25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: If empty: Non-refillable container. Do not reuse or refill this container. 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] [SENTRY] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

In Case of Emergency, call: 1-800-781-4738
Non-Emergency, call: 1-800-224-PETS (7387)

[Coupon(s) inside or on outside of box]
[Made in USA]

[Distributed by:][Manufactured by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

[BAR CODE AREA][Lot code]
EPA Reg. No. 2517-137
EPA Est. No. XXX-XX-XXX

{END - BACK / SIDE PANEL}

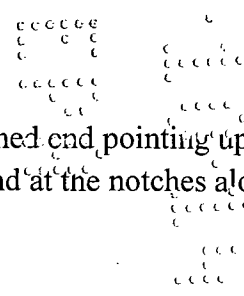
OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE **CAT SPOT ON FIPRONIL**

[How to Apply - May contain graphics illustrating product use, e.g., cat with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

[Application Instructions] [Directions for Use]

How to Open:

1. Remove product tubes [vial] from the package.
2. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.



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How to Apply:

1. Invert tube over cat and use open end to part cat's hair.
2. Apply contents of one tube [vial] of {Brand Name} [as a stripe, starting high [on] [to] the back of the cat's neck to in front of the shoulder blades] [as a spot between the shoulder blades]. Squeeze tube firmly to apply all of the solution to the cat's skin.]

[Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist

- [1] Read the label completely and follow directions
- [2] Weigh your cat
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment] [application] to avoid chance of ingestion
- [6] Do NOT split tubes between pets] [and use the ENTIRE tube contents]

[Brand name]

[3] [Month [Treatment] [Application] Tracker]

[For year round protection apply [Brand name][this product] monthly.]

[Pet's Name (Empty blank for owner to fill in name)]

[First][1st]Second][2nd]Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth][8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

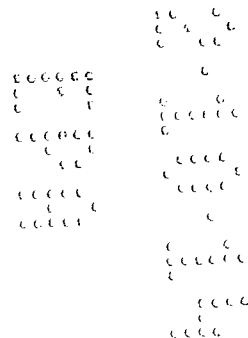
[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[calendar stickers with [Brand name][this product] [Place stickers on your calendar as a reminder to reapply [Brand name][this product] in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Monthly reminder card]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand name][this product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

















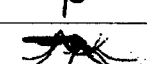



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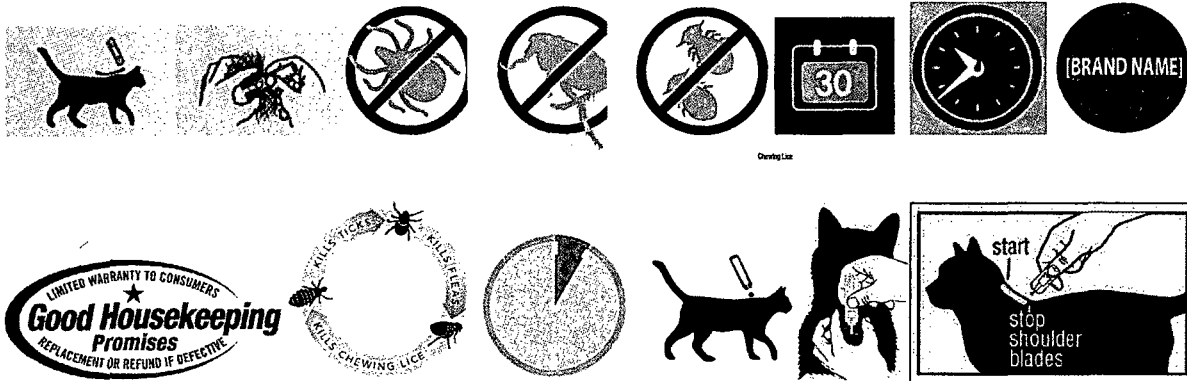
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[Optional graphics below may or may not appear anywhere on finished label]

	Fleas	
	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	
	Chewing Lice	
	Lone Star Tick	
	Mosquitoes	
	Mite	



{END - OPTIONAL PACKAGE COPY}

TUBE/VIAL LABEL **CAT SPOT ON FIPRONIL**

Front Label	Back Label
<p>{Brand Name}</p> <p>For Cats over 1.5 lbs ≥8 wks</p> <p>Fipronil 9.7%</p> <p>0.017 fl oz {label code}</p>	<p>KEEP OUT OF REACH OF CHILDREN</p> <p>CAUTION: Read directions and precautions before using. Use scissors to open.</p> <p>EPA REG. No. 2517-137 {label code}</p>

{END - TUBE/VIAL COPY}