

69332-1

6.26.2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Susan Craft
Regulatory Affairs Specialist
Pet Logic LLC
c/o Sergeant's Pet Care Products
2625 S. 158th Plaza
Omaha, NE 68130-1770

JUN 26 2009

Subject: Label Notification(s) for Pesticide Registration Notices 2007-4 and 98-10
1. Warranty Statement

Dear Ms. Craft:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notices (PRN) 2007-4 and 98-10 dated June 1, 2009 for:

EPA Registration 69332-1

One Drop Anti-Flea & Tick Treatment 2

The Registration Division (RD) has conducted a review of this request for applicability under PR Notices 2007-4 and 98-10 and finds that the label changes requested falls within the scope of PR Notices 2007-4 and 98-10. The label has been date-stamped "Notification" and will be placed in our records.

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 nonrefillable 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 me directly at 703-305-6249 or Nicole Williams of my staff at 703-308-5551.

Sincerely,

A handwritten signature in black ink, appearing to be "Linda Arrington".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 69332-1	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) ONE DROP ANTI-FLEA & TICK TREATMENT 2	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Pet Logic LLC c/o Sergeant's Pet Care Products 2625 S. 158th Plz. Omaha, NE 68130-1770 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>NOTIFICATION</u> Product Name <u>JUN 26 2009</u>

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification to include updated storage and disposal per PR 2007-4: This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146 and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Notification to "Warranty & Disclaimer" section in accordance with the guidance documents entitled "Guidance on Warranty Statements" dated October 17, 2006.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" 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	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>Cardboard box</u>
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.7/1.4 mL	No. per container 3/4/6/12
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container See unit packaging info	5. Location of Label Directions <input checked="" type="checkbox"/> On label
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Susan Craft	Title Regulatory Specialist	Telephone No. (Include Area Code) 402-938-7021	
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 	3. Title Regulatory Specialist		
4. Typed Name Susan Craft	5. Date June 1, 2009		

Pet Logic LLC

P.O. Box 540224 · Omaha, NE 68154 · Telephone 402-938-7000 · Fax 402-938-7099

June 1, 2009

Document Processing Desk
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency (NOTIF)
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

SUBJECT: Product Name: ONE DROP ANTI-FLEA & TICK TREATMENT 2
EPA Reg. No. 69332-1
Notifications: per PR Notice 2007-4: storage and disposal update and warranty update in accordance with the guidance document entitled "Guidance on Warranty Statements" dated October 17, 2006.

Dear Mr. Gebken:

Pet Logic, LLC is submitting the following administrative documents in support of the Notification per PR Notice 2007-4 update storage and disposal and warranty update in accordance with the guidance documents entitled "Guidance on Warranty Statements" dated October 17, 2006.

- Application (EPA Form 8570-1)
- 2 copies of revised master label

If you have any questions, please contact me by phone at (402) 938-7021 or by email at scraft@sergeants.com.

Sincerely,

AUSA Craft

Susan Craft
Regulatory Affairs Specialist
Pet Logic LLC c/o Sergeant's Pet Care Products, Inc.

Enclosures

A 10x10 grid of 100 small squares, each containing a single character from the Chinese alphabet. The characters are arranged in a pattern that resembles a stylized '100' or a similar numerical representation.

One Drop Anti-Flea & Tick Treatment 2
EPA No. 69332-1
Notification dated 6/1/2009

PR Notice 98-10

"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 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 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 sections 12 and 14 of FIFRA."

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Pet Logic, LLC Master Label

26 May 2009 notif storage & disposal, warranty
Information in [] is optional.

EPA Reg. No. 69332-1
Page 1 of 4 EPA SAL February 9, 2007

FRONT PANEL DOG SQUEEZE ON PERMETHRIN ONLY PRODUCT

ONE DROP ANTI-FLEA & TICK TREATMENT 2

[(for Dogs up to 33 lbs)]

[(for Dogs over 33 lbs)]

THREE [ONE] MONTH SUPPLY

ONE APPLICATION: (choose from the following)

- Use only on dogs
- Kills and repels fleas and ticks quickly
- Kills and repels fleas and ticks for up to 4 weeks
- Protects for up to 4 weeks
- One easy application for effective control
- 3 [1] easy to use applicator[s]
- Pet Logic, LLC does not recommend use of any permethrin squeeze-on products on Chihuahuas

[Note to EPA: Label may contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial.]

ACTIVE INGREDIENT:

Permethrin (CAS #52645-53-1).....45.00%

OTHER INGREDIENTS.....55.00%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Side] [Back] Panel(s) For Additional Precautionary Statements

NET CONTENTS:

Three [One] 1.5 mL (0.05 fl.oz)Tube[s] [(for Dogs up to 33 lbs)]

Three [One] 3 mL(0.10 fl. oz) Tube[s] [(for Dogs over 33 lbs)]

NOTIFICATION

JUN 26 2009

Pet Logic, LLC Master Label

26 May 2009 notif storage & disposal, warranty
Information in [] is optional.

EPA Reg. No. 69332-1
Page 2 of 4 EPA SAL February 9, 2007

BACK PANEL DOG SQUEEZE ON PERMETHRIN ONLY PRODUCT

ONE DROP ANTI-FLEA & TICK TREATMENT 2

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

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 or ingested by cats.

What the drops do: {Product Name} kills and repels fleas and ticks on your dog for up to 4 weeks. It is also recommended that you use a product labeled to treat your dog's basket and favorite sleeping area.

How to Apply:

For dogs weighing up to 33 lb., the contents of this package provides a [3 months'] [1 month] supply.

1. Remove product tube from the package. Holding tube with top end pointing up and away from the face and body, cut off top end. 2. Use open end to part the dog's coat to expose the skin between the shoulder blades, at the nape of the neck. 3. Squeeze the entire contents of one tube onto exposed skin. If the dog's coat is subsequently wetted, such as when shampooing, the 4 week period of protection may be reduced.

[OR]

For dogs weighing over 33 lb., the contents of this package provides a 3 months' [1 month] supply.

1. Remove product tube from the package. Holding tube with top end pointing up and away from the face and body, cut off top end. 2. Use open end to part the dog's coat to expose the skin between the shoulder blades, at the nape of the neck, then squeeze approximately one-half the contents of one tube onto the exposed skin. 3. Next, part the dog's coat at the base of the tail, then squeeze the remaining contents of the tube onto exposed skin. If the dog's coat is subsequently wetted, such as when shampooing, the 4 week period of protection may be reduced.

Additional precautions to protect your dog: 1. Do not massage the drops into the dog's skin. Avoid applying to the dog's fur. 2. Do not administer any other flea control product to your dog during the 4 week period of protection. 3. Retreat after 28 days if reinfestation is apparent.

Additional precautions to protect your family: Do not allow children to play with tubes. A pet treated with this product should not sleep with people, particularly children, for 8 hours immediately following treatment. Do not handle the area of application for 3 to 6 hours following treatment.

[What else you must do: Treating your dog's basket and favorite sleeping areas with a suitable insecticidal product labeled for this use and vacuuming these areas regularly will also help to remove fleas and ticks. Consult your veterinarian for product recommendations.]

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Pet Logic, LLC Master Label

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PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Hazards to Humans: Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

Hazards to Domestic Animals: For external use only. Do not apply on dogs less than 6 months old. Repeat applications may be made as necessary, but do not apply at intervals less than 7 days. **DO NOT USE ON CATS.** Cats which actively groom or engage in close physical contact with recently treated dogs may be at risk of serious harmful effect. May be toxic and potentially fatal if applied or ingested by cats.

Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing or medicated animals. Consult a veterinarian before using this product on dogs with known organ dysfunction. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Signs of sensitivity to this product include skin sensitivity, increased itchiness, redness, rash, hair discoloration or hair loss at the application site. Dogs may also show "lethargy".

FIRST AID

If swallowed:	<ul style="list-style-type: none">• Call poison control center or 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:	<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 treatment advice.
If on skin:	<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.

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Pet Logic, LLC Master Label

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Information in [] is optional.

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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 1-800-781-4738 for emergency medical treatment information.

NOTE TO PHYSICIAN

Treat patient symptomatically.

Environmental Hazards: This product is extremely toxic to fish and aquatic organisms. Do not apply directly to any body of water. Treated dogs should not be allowed to go swimming for 12 hours following treatment.

Physical or Chemical Hazards: Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Pesticide Storage: Do not remove tube from the pack until ready to use. Store in a cool (below 25°C) dry place out of reach of children. Do not refrigerate. Protect from direct sunlight.

Pesticide 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.

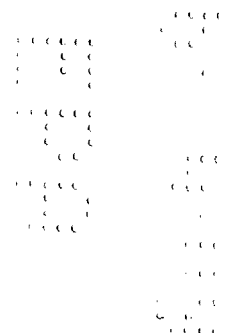
[WARRANTY

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.]

Sergeant's is committed to providing high quality products. If you have questions or comments about this product, please write: Pet Logics, LLC, P.O. Box 540244, Omaha, NE 68154-0244.



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Pet Logic, LLC Master Label

26 May 2009 notif storage & disposal, warranty
Information in [] is optional.

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Visit us at www.sergeants.com

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

Made in USA

Distributed by:

Pet Logics, LLC

PO Box 540224

Omaha, NE 68154-0244

EPA Reg. No. 69332-1

EPA Est. No. 63416-MN-1

{label code}

END - BACK / SIDE PANEL

TUBE / VIAL LABEL

Front Label

BANSECT® SQUEEZE-ON FLEA & TICK
CONTROL FOR DOGS

1.5 mL (or) 3 mL

Permethrin.....45.00%

{label code}

Back Label

KEEP OUT OF REACH OF CHILDREN

CAUTION: Read directions and precautions
before using.

EPA Reg. No. 69332-1

{label code}