



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

September 4, 2014

Mr. James B. Messina
Authorized Representative for
Pet Logic, LLC
c/o Exponent
1150 Connecticut Avenue, Suite 1100
Washington, DC 20036

Subject: Label Amendment – Acceptance of Master Labeling Submitted for Implementation of Pet Spot-On Mitigation
Product Name: ONE DROP ANTI-FLEA & TICK TREATMENT 2 FOR DOGS
EPA Registration Number: 69332-1
Application Date: December 5, 2013
Decision Number: 486773

Dear Mr. Messina:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with the following label revision provision(s):

Amendments to Dog Spot-On Product Registrations:

1. **This registration is now time-limited, and will expire 2 years from the date of this letter. More specifically, this registration will expire on September 4, 2016.**
2. If the Agency determines that future mitigation measures are necessary for all pet spot-on products, EPA will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.
3. Please consider limiting the formulations of this product to one basic confidential statement of formula. The Agency may require this in the future. In addition, it is possible that no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
4. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning October 1, 2014. Please flag any Confidential Business Information as such. Enhanced incident reporting and quarterly sales information should be submitted to the Product Manager. The following is a list of information that must be included in the quarterly reports for each incident:
 - 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.

Conditions of Acceptance/Amendments to Dog Spot-On Product Registrations, continued:

- 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 pre-condition.
- EPA Severity Code: Death, major, moderate, minor.
- Outcome: Died, recovered, still treated, unknown.

5. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- 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.
- Summary table for dogs 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 showing the number of dog incidents for each severity code for each pet weight range on the product label.
- 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 cat 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.

You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Copies of your updated master label stamped "Accepted" and the review for minimum weight treated are enclosed for your records. Please note that this letter does not supersede anything contained within the Agency's letter dated September 30, 2011 and the original conditions of acceptance detailed in the Agency's Notice of Registration dated April 4, 2000. The conclusion date for the subject time-limited product registration is September 4, 2016.

If you have any questions about this label review, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov or Mr. Richard Gebken at (703) 305-6701 or via e-mail at Gebken.Richard@epa.gov during the hours of 9:00 A.M. to 5:30 P.M. EST.

Sincerely,

A handwritten signature in black ink that reads "Richard J. Gebken". The signature is written in a cursive style with a large, stylized 'R' and 'G'.

Richard Gebken
Product Manager 10
Insecticide Branch
Office of Pesticide Programs
Date: September 4, 2014

Enclosures:

069332-00001 D486773

*Updated Master Label Stamped "Accepted," dated September 4, 2014
Review for Minimum Weight Treated, dated March 6, 2014*

Pet Logic, LLC Master Label

23 June 2014

Information in [] is optional.

v14.1

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EPA Reg. No. 69332-1

EPA SAL Apr 16, 2013

FRONT PANEL

DOG SQUEEZE ON PERMETHRIN ONLY PRODUCT

[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.]

ONE DROP ANTI-FLEA & TICK TREATMENT 2 FOR DOGS

For use ONLY on dogs and puppies over 6 months of age, 7 [-] [to] 33 lbs {OR}

For use ONLY on dogs over 33 lbs

THREE [ONE] MONTH SUPPLY

[1.5cm x 1.5cm on final or as indicated]



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

ACTIVE INGREDIENT:

Permethrin [CAS # 52645-53-1]*45.00%

OTHER INGREDIENTS:.....55.00%

TOTAL 100.00%

* Cis/trans ratio: max 55% ± cis and min 45% [±] trans

A C C E P T E D

09/04/2014

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 69332-1

KEEP OUT OF REACH OF CHILDREN

CAUTION

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

NET CONTENTS: X fl oz (X mL)

[Three] [One] 0.05 fl oz (1.5 mL). Tube[s] [(for use ONLY on Dogs 7 to 33 lbs)]

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

BACK PANEL

DOG SQUEEZE ON PERMETHRIN ONLY PRODUCT

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Hazards to Humans: CAUTION. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet.

Pet Logic, LLC Master Label

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Information in [] is optional.

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Hazards to Domestic Animals: For external use only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides; Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product.

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 treatment advice. |
|--------------------|--|

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.

PHYSICAL OR CHEMICAL HAZARDS

Combustible: Do not use or store near heat or open flame.

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 ALLOW CHILDREN TO APPLY PRODUCT.** TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on cats or animals other than dogs. Do not allow your dog to ingest this product. Do not use on puppies under 6 months of age or less than [7] [33] lbs. Use entire contents of tube vial on each dog. [Do not split one tube between dogs.] Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied. Treated dogs should not be allowed to go swimming for 12 hours following treatment. Repeat applications may be made as necessary, but do not apply at intervals less than 7 days.

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. 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." If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours.

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[1.5 cm x 1.5 cm on final]



DO NOT USE ON CATS. MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.

What the drops do: [Product Name] [This product] 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:

ONLY for dogs weighing 7 to 33 lbs and 6 months or older, the contents of this package provides a [3 months'] [1 month] supply. **Do not apply to dogs weighing less than 7 lbs.**

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]

ONLY for dogs weighing over 33 lb., the contents of this package provides a [3 months'] [1 month] supply. **Do not apply to dogs weighing less than 33 lbs.**

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 infestation is apparent.

Additional precautions to protect your family: Do not allow children to play with tubes. A dog 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 suggestions.]

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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 25°C) dry place out of reach of children and pets. Do not refrigerate. Protect from direct sunlight.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. **If empty:** 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.]

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

In Case of Emergency, call: 1-800-781-4738

Non-Emergency, call: 1-800-224-PETS (7387)

Made in USA

[Manufactured by:] [Distributed by:]

Pet Logics, LLC

Omaha, NE 68138-3710

EPA Reg. No. 69332-1

EPA Est. No. [63416-MN-1][XXX-XX-X]

{label code}

END - BACK / SIDE PANEL DOG SQUEEZE ON PERMETHRIN ONLY PRODUCT

[[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 dog
- [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 to avoid chance of ingestion
- [6] Do NOT split tubes between pets[and use the ENTIRE tube contents]

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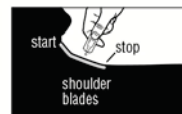
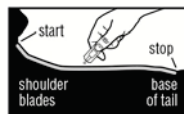
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[Satisfaction Guaranteed]

[If you are not satisfied, we will make it right with a replacement or refund.]

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

	Fleas	
	Ticks	




TUBE / VIAL LABEL

DOG SQUEEZE ON PERMETHRIN ONLY PRODUCT

Front Label

Back Label

 One Drop Anti-Flea & Tick Treatment 2 For Dogs [7-33][over 33] lbs \geq 6 months 0.05 fl oz (1.5 mL) or 0.10 fl oz (3 mL) Permethrin 45% {label code}	KEEP OUT OF REACH OF CHILDREN CAUTION: Read directions and precautions before using. EPA Reg. No. 69332-1 EPA Est. No. [63416-MN-1][XXX-XX-X] {label code}
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