

#### U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

Washington, D.C. 20460

NOTICE OF PESTICIDE:

X Registration
Reregistration

(under FIFRA, as amended)

EPA Reg. Number:

Date of Issuance:

69332-1

1/27/17

Term of Issuance:

Conditional, Time-Limited Expires: 01/27/2019

Name of Pesticide Product:

ONE DROP ANTI-FLEA & TICK TREATMENT 2 FOR DOGS

Name and Address of Registrant (include ZIP Code):

Mr. Kelly R. Hoskins PetLogic, Inc. PO Box 540224 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 section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

**Signature of Approving Official:** 

Date:

1/27/17

Kable Bo Davis, Product Manager 03

Invertebrate & Vertebrate Branch 1, Registration Division (7505P)

EPA Form 8570-6

- 2. The Agency has found your company to be in compliance with the terms and conditions for the subject product, and is extending the two-year registration restriction. This registration is time-limited and expires 01/27/2019.
- 3. Please note that the product is still subject to all other previously required conditions of registration. Your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information as stated in the amendment letter dated 09/04/2014.
- 4. You are required to comply with the data requirements described in the DCI and EDSP Orders identified below:
  - a. Permethrin GDCI-109701-1252
  - b. Permethrin GDCI-109701-1281
  - c. Permethrin GDCI-109701-1113
  - d. Permethrin EDSP-109701-83
  - e. Permethrin EDSP-109701-84
  - f. Permethrin EDSP-109701-85
  - g. Permethrin EDSP-109701-86
  - h. Permethrin EDSP-109701-87
  - i. Permethrin EDSP-109701-88
  - j. Permethrin EDSP-109701-89
  - k. Permethrin EDSP-109701-90
  - 1. Permethrin EDSP-109701-91
  - m. Permethrin EDSP-109701-92

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI and EDSP Orders listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1

5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Page 3 of 3 EPA Reg. No. 69332-1 Decision No. 517836

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 07/25/2012
- Alternate CSF 1 dated 09/18/2015

If you have any questions, you may contact Elizabeth Fertich at 703-347-8560 or via email at fertich.elizabeth@epa.gov.

Enclosure

27 MAY 2016 2YR EXT Information in [ ] is optional.

Page 1 of 6

EPA Reg. No. 69332-1 EPA SAL 09/04/2014

#### 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

{Market Label - the word dog will be at least 40-75% in height of the largest letter in the primary brand name.} {Market Label - a large clear picture of a dog in the respective weight range will be on the front panel of the label}

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

 $\{Market\ Label\ \hbox{- one of the statements above will be placed prominently on the front panel}\}$ 

{box only designates Vet Only language}

{SUBLABEL: FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION}

### FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION

For use in veterinarian clinics, animal shelters, grooming facilities and boarding kennels. Not for residential use. Do not repackage.

[Ideal for shelter use when under direct supervision of veterinarian]

[Professional Roll Pack]

[Convenient roll pack for in clinic use]

[Convenient roll pack for animal facility use]

[For use only by licensed veterinarians]

#### THREE [ONE] MONTH SUPPLY

{1.5 cm x 1.5 cm on final or red & black as indicated below. Placement will be in the lower right hand quadrant.}

#### **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





01/27/2017

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

° 69332-1

27 MAY 2016 2YR EXT V16.1 EPA Reg. No. 69332-1 Information in [ ] is optional. Page 2 of 6 EPA SAL 09/04/2014

#### **ACTIVE INGREDIENT:**

# KEEP OUT OF REACH OF CHILDREN CAUTION

See [Side] [Back] [Insert] [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)]

**OR** {box only designates Vet Only language}

Net Contents: X fl oz X count [Y – X fl oz [tube][vial][applicator][pipette][s]]

[Thirty-five] 35[Fifty][50][Seventy-five][75][One hundred][100] [One hundred sixty][160]

**{END – FRONT PANEL}** 

#### **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.

**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.

<sup>\*</sup> Cis/trans ratio: max 55% [ $\pm$ ] cis and min 45% [ $\pm$ ] trans

27 MAY 2016 2YR EXT V16.1 EPA Reg. No. 69332-1 Information in [ ] is optional. Page 3 of 6 EPA SAL 09/04/2014

**OR** {box only designates Vet Only language}

**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. Use caution before using on medicated, debilitated, aged, pregnant, nursing dogs or dogs with known organ dysfunction. If the dog is exhibiting signs of and/or is being treated for skin dermatitis, use caution before applying any topical flea and tick control product.

	FIRST AID	
If in eyes:	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> </ul>	
	• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.	
	<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>	
	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.

27 MAY 2016 2YR EXT V16.1 EPA Reg. No. 69332-1 Information in [ ] is optional. Page 4 of 6 EPA SAL 09/04/2014

#### [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.]

27 MAY 2016 2YR EXT V16.1 EPA Reg. No. 69332-1 Information in [ ] is optional. Page 5 of 6 EPA SAL 09/04/2014

#### 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.]

Sergeant's 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 Logic, 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** 

27 MAY 2016 2YR EXT EPA Reg. No. 69332-1 Information in [ ] is optional. Page 6 of 6 EPA SAL 09/04/2014

[[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]

#### [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]

<b>7</b>	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 ≥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}