

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

February 21, 2012

James B. Messina,
Principal Regulatory Consultant
(Authorized Agent for Sergeant's Pet Care Products, Inc.)
Exponent
Center for Chemical Regulation and Food Safety
1150 Connecticut Avenue, N.W.
Suite 1100
Washington, DC 20036

Subject: Revise CRP labeling (Net Content, Opening and directions).

- Sergeant's Fipronil Squeeze-On for Dogs EPA Reg. No. 2517-136
- Sergeant's Fipronil + Methoprene Squeeze-On for Dogs EPA Reg. No. 2517-134
- Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs EPA Reg. No. 2517-140
- Sergeant's Fipronil + Nylar Squeeze-On for Dogs EPA Reg. No. 2517-141
- Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs EPA Reg. No. 25 17-142
- Sergeant's Fipronil + Cyphenothrin + NyJar Squeeze-On for Dogs EPA Reg. No. 2517-143

Applications dated September 26, 2011

Dear Mr. Messina:

The above referenced labeling for each of the subject products, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable:

Please note that we have approved the amended labels for these products with the understanding that they are consistent with the Agency's previously stamped accepted ones; and other than the revisions stated in your applications (dated September 26, 2011), no other changes have been made to the labeling and/or the Confidential Statement of Formula (CSF).

See enclosed copy of the stamped label for your record. If you have any questions concerning this action please contact me or Dr. B.A. Akinlosotu (703-605-0653 or via email Akinlosotu.bonaventure@epa.gov).

Sincerely,

Richard Gebken,

Product Manager 10

Insecticide Branch

Registration Division (7505P)

26 Sep 2011- Amendment Information in [ ] is optional.

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FRONT PANEL

DOG SQUEEZE ON

FIPRONIL+METHOPRENE

[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 + Methoprene Squeeze-On for Dogs

[ABNs][(Sergeant's®) (Sentry®) FRONTIER GOLD (Spot On) for dogs]

ACCEPTED

[ABNs][(Sergeant's®) (Sentry®) Ectoadvance (Spot On) for dogs]

FEB 2 1 2012

[ABNs][SentryProline (Spot On) for dogs]

Under the Federal Insecticide, Fungicide,

[ABNs][[SENTRY®] FIPROGUARD<sup>TM</sup> PLUS for dogs] [ABNs][[Sergeant's®] PRONYL OTC<sup>TM</sup> PLUS for dogs] and Rodenticide Act, as amended, for the

[ABNs][[Sergeant's®][SENTRY®] AdvanSpot Plus (Spot On) for dogs]

pesticide registered under:

[Apply to puppies over 8 weeks old]

[Apply to pupples 8 weeks or older]

EPA Reg. No: 2517-134

[Mosquitoes]

[Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]

[Chewing Lice]

[Kills chewing lice]

[Rapid elimination of chewing lice infestation]

[[A once monthly application required][Apply monthly to control] [for] chewing lice]

[Adult Fleas]

[[Kills [adult] Fleas [for up to three months]]

[Kills newly emerged adult Fleas before they lay eggs]

[Kills Adult Fleas, which may be a source of [flea allergy dermatitis] [, flea bite anemia]]

[Kills Fleas Up to [4 weeks] [1 month] [30 days]!]

[If dog is a high risk for flea reinfestation a once month application may be needed]

[Multiple Infestations]

[Kills chewing lice [and controls mites that may cause sarcoptic mange]]

[Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 8 weeks old [&] [and] older]

[Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes]]

[Kills fleas, ticks, [mosquitoes], chewing lice, flea eggs, flea larvae [&] [and] [prevents the development of flea pupae]]

[Kills Fleas, Ticks [&] [and] [Mosquitoes]]

[Breaks the Flea Life Cycle [for up to three months]]

[Monthly flea, tick, [mosquito], chewing lice and flea egg protection]

[Monthly flea, tick, [mosquito] and chewing lice protection]

[Kills fleas, ticks, [mosquitoes], flea eggs, and chewing lice]

[[Seven] [7] [Six] [6][Five[5] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,]

chewing lice, flea eggs, [&][and]flea larvae [&] [and] prevent the development of flea pupae]]

[[Six] [6] [Five] [5] [Four] [4] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,]

chewing lice, [&][and]flea eggs [&] [and] flea larvae]

[[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!]

[[Four (4) Week] [1 month] [30 day] [Flea, Tick, and Chewing Lice Control]

[[Four [4] Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]

[Use [Full or Partial Brand Name] monthly to break the flea life cycle.]

26 Sep 2011- Amendment Information in [ ] is optional.

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FRONT PANEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[Use [Full or Partial Brand Name] monthly to control ticks and chewing lice]

[Monthly flea, tick, [mosquito,] flea egg, flea larvae and chewing lice protection.]

[Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]]

[Kills Fleas, [and] [&] Ticks for up to [4 weeks] [1 month] [30 days]!]

[Kills Fleas, [and] [&] Ticks [and Mosquitoes] for up to [4 weeks] [1 month]!]

[Kills Fleas, Ticks, Flea Eggs [and] [&] Flea Larvae for up to [4 Weeks] [1 month] [30 days]]

#### [Ticks]

[Kills Ticks including those that may transmit Lyme disease]

[Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]

[Kills [all stages of] 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]!]

### [Flea Eggs and Larvae]

[Controls flea reinfestation for up to [12 weeks] [3 months]]

[Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae for up to [three months] [12 weeks].]

[Effectively controls all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]

[Effective against all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]

[If dog is a high risk for flea reinfestation a once month application may be needed]

[Prevents from developing, flea eggs [larvae] [pupae] for up to [3 months] [12 weeks]]

[With (S)-methoprene Insect Growth Regulator [IGR] which Breaks the Flea Life Cycle]

[With (S)-methoprene to Break Flea Life Cycle]

[With Insect Growth Regulator [IGR] to Break Flea Life Cycle]

[Dual Action [!]: Fipronil with (S)-methoprene IGR [insect growth regulator] Effectively Breaks the Flea Life Cycle]

[Dual Action [!]: Effectively Breaks the Flea Life Cycle [!]]

[Kills Flea Eggs & Flea Larvae for [up to 3 months] [up to 12 weeks]!]

[Prevents Flea Eggs From Developing Into Biting Adults]

[Prevents all stages of the flea life cycle from developing]

[Controls reinfestation of fleas for up to 3 months]

[Effective against all stages of the flea life cycle]

[Effectively controls all stages of the flea life cycle]

### [All Others]

[For Dogs and Puppies 8 weeks of age or older]

[Can be used on puppies 8 weeks of age and older]

[Specially Formulated for Dogs and Puppies 8 weeks of age or older]

[For Dogs [up to 22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.]

[Fast Acting] [Long Lasting]

[Convenient spot treatment]

[Easy to Use [Application]]

[Best if used year round!]

26 Sep 2011- Amendment Information in [ ] is optional.

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EPA No. 2517-134

FRONT PANEL

EPA SAL 3 Feb 2011

**DOG SQUEEZE ON** FIPRONIL+METHOPRENE

[For year-round protection, apply [Full or Partial Brand Name] monthly] [(ICON Showing [4 week] [1 month] [30 day] Protection)] [Apply monthly] [Prevents reinfestation of listed pests for [4 weeks] [1 month]] [Apply once every [4 weeks] [month] [30 days]!] [4 Week Dose!] [1 Month Dose!] [30 Day Dose!] [One Application] [Two Applications] [Three Applications] [Four Applications] [Five Applications [Six Applications] [12 Applications] [24 Applications] and/or [1 Month Supply] [2 Month Supply [3 Month Supply] [4 Month Supply] [5 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] [Controls mites that may cause sarcoptic mange] [Waterproof] [Effective after bathing and exposure to water and sunlight] [Can be used on breeding, pregnant, and lactating [bitches] [female] [dogs]] [[Free] Calendar Stickers Inside!] [[Free with purchase] [Free inside] Monthly Application Reminder [Magnet][inside]] [Fipronil (9.8%) + (S)-methoprene (8.8%)] [Contains Fipronil and (S)-methoprene[,] [-] the [same] active ingredients used in Frontline Plus® for dogs\*] [\*[Full or Partial Brand Name] is not manufactured by or distributed by Merial. Frontline Plus® is a registered trademark of Merial.] [Full or Partial Brand Name] is a registered trademark of Sergeant's Pet Care Products, Inc.] [[1][2][3][4][5][6][12][24] Applications] [Stops and prevents infestation of listed pests for [4 weeks][1 month]]

[Stops existing infestation and prevents establishment of additional infestation of listed pests]

[Lift [here] for more information]

[For use ONLY on dogs [&] [and] puppies] [Up to 22 lbs]

[up to 22 lbs.] [For Dogs 23[-] [to] 44 lbs.]

[For Dogs & Puppies 8 weeks or older and]

[23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs]

[For Dogs 45[-] [to] 88 lbs.] [For Dogs 89[-] [to] 132 lbs.]

[over 8 weeks of age]]

**ACTIVE INGREDIENTS:** 

(S)-methoprene......8.80% OTHER INGREDIENT:......81.40% TOTAL 100.00%

## KEEP OUT OF REACH OF CHILDREN CAUTION

See [Back][or][Side] [Label Panel[s]] for Additional Precautionary Statements Net Contents: [1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four] 0.023 fl oz (0.67 ml) applicators

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four] 0.045 fl oz (1.34 ml) applicators

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[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four] 0.091 fl oz (2.68 ml) applicators

[[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four] 0.136 fl oz (4.02 ml) applicators

{END - FRONT PANEL}

**BACK /SIDE PANEL** 

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[[Full or Partial Brand Name] contains Fipronil and S-Methoprene (insect growth regulator) (IGR) to effectively kill fleas and ticks [(including those that may transmit Lyme disease).] [The active ingredients in [Full or Partial Brand Name] feature a sustained release formula developed for fast acting [and long lasting] control of fleas, ticks, [mosquitoes] and chewing lice for up to [1 month] [[4][four] weeks] on dogs.]

## READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE.

#### 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 only. Do not use on puppies under 8° weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs. Call 1-800-781-4738 for 24-hour assistance.

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:	Flush eyes with plenty of water. Call a doctor if irritation persists.
If on skin:	Wash with plenty of soap and water. Get medical attention if irritation persists.

#### 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.

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**BACK /SIDE PANEL** 

**DOG SQUEEZE ON** FIPRONIL+METHOPRENE

#### **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. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

Do not use on puppies under 8 weeks of age. 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. Consult a veterinarian before using this product on debilitated, aged, or medicated dogs. Can be used on breeding, pregnant, or lactating dogs. Consult a veterinarian before using on dogs with known organ dysfunction. Dogs may experience some temporary irritation at the site of product application. Certain medications can interact with pesticides. Sensitivities may occur after using ANY pesticide product on dogs. 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.

{Outer Packaging}

How to open: Remove product tubes [vial] from the package. [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 lines.

How to apply: 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. Do not apply more often than once every 4 weeks.

[Optional drawings that may or may not appear anywhere on finished label]









For Dogs Weighing up to 22 lbs. [including small dogs and puppies, 8 weeks or older]: {For cartons containing 0.67 mL (0.023 fl oz) applicator tubes}

Apply one tube (0.67 mL)(0.023 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

For Dogs Weighing 23 [-] [to] 44 lbs.:

{For cartons containing 1.34 mL (0.045 fl oz) applicator tube}

Apply one tube (1.34 mL)(0.045 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

For Dogs Weighing 45 [-] [to] 88 lbs.:

{For cartons containing 2.68 mL (0.091 fl oz) applicator tube}

Apply one tube (2.68 mL)(0.091 floz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

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**BACK /SIDE PANEL** 

DOG SQUEEZE ON FIPRONIL+METHOPRENE

For Dogs Weighing 89 [-] [to] 132 lbs.:

{For cartons containing 4.02 mL (0.136 fl oz) applicator tube}

Apply one tube (4.02 mL)(0.136 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

FREQUENCY OF APPLICATION

Use [Full or Partial Brand Name] monthly for complete control of flea, tick, [and] chewing lice, [and mosquito] infestations. [Studies show that] [Full or Partial Brand Name] kills adult fleas for up to three months. Apply monthly if your dog is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks[,] [mosquitoes] and chewing lice. [Full or Partial Brand Name] [This product] remains effective even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for [30 days] [4 weeks].

STORAGE AND DISPOSAL

**PESTICIDE STORAGE:** Do not remove tube from the pack until ready to use. Store in a cocl (below 77°F [/][25°C]) dry place inaccessible to children and pets. Do not refrigerage. 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] [U.S. Patent No. 5,567,429]

Distributed by: Sergeant's Pet Care Products, Inc. P.O. Box 540399 Omaha, NE 68154-0399

[BAR CODE AREA][Lot code] EPA Reg. No. 2517-134 EPA Est. No. 2517-TN-1 [XXX-XX-XXX]

{END - BACK / SIDE PANEL}

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Information in [ ] is optional.

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OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE

DOG SQUEEZE ON

FIPRONIL+METHOPRENE

[How to Apply - May contain graphics illustrating product use, e.g., dog 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.

## How to Apply

- 1. Invert tube over dog and use open end to part dog's hair.
- 2. Squeeze tube firmly to apply all of the solution to the dog's skin [as a spot [on] [to] the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

[Optional drawings that may or may not appear anywhere on finished label]

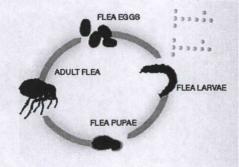






[Flea life cycle diagram] [Flea Life Cycle] [Sample coloring and layout may be different on final label]





[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 pet
- [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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DOC COUFE Z

OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE

DOG SQUEEZE ON

FIPRONIL+METHOPRENE

#### [Full or Partial Brand Name]

[1][2][3][4][5][6][12][24][Month [Application] Tracker]

[For year-round protection, apply [Full or Partial Brand Name] monthly.]

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

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

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

[calendar stickers with Full or Partial Brand Name] [Place stickers on your calendar as a reminder to reapply [Full or Partial Brand Name] in 30 days.]

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

[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 [Full or Partial Brand Name]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

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

n fleas

s flea eggs

flea pupae

7 flea larvae

Adult Flea

ticks

Deer Tick

Brown Dog Tick

Lone Star Tick

\* American Dog Tick

\* chewing lice

>> mosquitoes

**fleas** 

flea eggs

flea pupae

flea larvae

Adult Flea

ticks

Deer Tick

Brown Dog Tick

Lone Star Tick

Marican Dog Tick

chewing lice

mosquitoes

{END - PACKAGE COPY} TUBE/VIAL LABEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

{Front Label}

{Back Label}

KEEP OUT OF REACH OF CHILDREN

CAUTION: Read directions and precautions before

{Brand Name} [cat graphic with line through] For dogs [up to X][X-Y] lbs Fipronil 9.8% w/w, (S)-methoprene 8.8% w/w

0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or) 0.136 fl oz {label code}

using. Use scissors to open. EPA REG. No. 2517-134

{label code}