

2517-147

08/18/2011

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs

Registration Division (7505C)

1200 Pennsylvania Avenue NW

Washington, D.C. 20460

EPA Reg. Number: 2517-147

Date of Issuance: 08/18/2011

Term of Issuance: **Conditional**

Name of Pesticide Product: **Sergeant's Fipronil + Etofenprox + Pyriproxyfen Spot On for Cats**

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Sergeant's Pet Care Products, Inc.
2625 South 158th Plaza
Omaha, NE 68130-1770

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/reregistered 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 registered in accordance with FIFRA sec 3(c)(7)(A), contingent on the following:

1. Make the following labeling changes before you release the product for shipment:
 - a. Revise the EPA Registration Number to read: "EPA Registration No. 2517-147".
 - b. Revise the signal word to "Caution".

Signature of Approving Official:

See page 4
 Richard Gebken,
 Product Manager (RM 10)
 Insecticide Branch
 Registration Division (MC 7505P)

Date:

August 18, 2011

- c. Delete the ABN "**VetSpot**"; implies / could be confused with FDA approved product.
 - d. Under subtitle "[Multiple Infestations]", revise claim to read [**Three [3] Way Protection**]; only three (3) active ingredients on label.
2. This registration is time-limited and expires two years from the date this product is first released for shipment.

You must provide the Agency with a projected "release for shipment date", in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected "release for shipment date" until an actual release for shipment date is provided in writing.

3. Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e., no alternate formulations or minor formulation amendments will be submitted and/or approved for this product, except to allow for alternate sources of any individual inert ingredient).
4. You must submit the following data within the timeframes described below:
 Within sixteen (16) months of the date on this Notice of Registration, provide to the Agency acceptable data packages for Guideline Studies: OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage Stability).
5. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on October 1, 2011.

The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information (CBI) as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci).

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
- 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 precondition

EPA Severity Code: death, major, moderate, minor

Outcome: died, recovered, still treated, unknown

6. Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details:
 - a. All minor dermal and ocular irritation reports.
 - b. Summary table for cats 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.
 - c. A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - d. Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - e. A summary table for cats 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.
 - f. A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label (if applicable).
 - g. A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range (if applicable).
 - h. Table showing number of incidents for each cat breed, where provided.
 - i. Table showing number of incidents in cats for each clinical sign.
 - j. Table showing number of incidents in cats for each organ system.
 - k. Report aggregate incidents, but do not combine moderate and minor incidents.

- 7. You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for re-registration (registration review) of your product under FIFRA section 4.

If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary, EPA may take regulatory action.

Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with the above stated conditions, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. If you have any questions concerning this action, please contact Dr. B. A. Akinlosotu via (703) 605-0653 or akinlosotu.bonaventure@epa.gov.

Sincerely,



Richard Gebken,
 Product Manager (RM 10)
 Insecticide Branch
 Registration Division (MC 7505P)

Enclosures
 Stamped Label

Sergeant's[®] Master Label

29 June 2011

Version 10.3

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Information in [] is optional.

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[Optional text appears in brackets-the final label may include some or all of the optional text on the front, back or side label panels.]

FRONT PANEL

CAT SPOT ON

FIPRONIL + ETOFENPROX + PYRIPROXYFEN

Sergeant's Fipronil + Etofenprox + Pyriproxyfen Spot On for Cats

[ABNs:]

- [(Sergeant's[®]) (Sentry[®]) VetSpot[™] (Spot On) for cats]
- [(Sergeant's[®]) (Sentry[®]) FRONTIER GOLD (Spot On) for cats]
- [(Sergeant's[®]) (Sentry[®]) Ectoadvance[™] (Spot On) for cats]
- [(Sergeant's[®]) (Sentry[®]) Frontspot[™] (Spot On) for cats]
- [(Sergeant's[®]) (Sentry[®]) Firstline (Spot On) for cats]
- [(Sergeant's[®]) (Sentry[®]) Frontedge (Spot On) for cats]
- [(Sergeant's[®]) (Sentry[®]) Frontguard[™] (Spot On) for cats]
- [(Sergeant's[®]) (Sentry[®]) FRONTPRONIL (Spot On) for cats]
- [(Sergeant's[®]) (Sentry[®]) FIPROLINE (Spot On) for cats]
- [(Sergeant's[®]) (Sentry[®]) Advanspot (Spot On) for cats]

**ACCEPTED
With COMMENTS
In EPA Letter Dated:
AUG 18 2011
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:**

2517-147

- [Apply to kittens over 12 weeks old]
- [Apply to kittens 12 weeks or older]
- [For use ONLY on cats [[&][and] kittens 12 weeks or older]OF ALL WEIGHTS]
- [For use ONLY on cats][of ALL weights][over 12 weeks of age]

[Mosquitoes]

- [•Kills mosquitoes]

[Adult Fleas]

- [• [Full or Partial Brand Name] kills adult fleas for up to six weeks]
- [•Kills Fleas [Up to [4] [6] weeks]!]
- [•Kills Fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]
- [•Stops and prevents reinfestation]
- [•Controls flea reinfestation [for up to six weeks]]
- [• [Full or Partial Brand Name] kills adult fleas for up to six weeks]
- [•If cat is a high risk for flea reinfestation a once month application may be needed]
- [•Prevents and controls reinfestations]

[Flea Eggs and Larvae]

- [•Stops and prevents infestations]
- [•Controls flea reinfestation for up to 6 weeks]
- [• [Full or Partial Brand Name] kills adult fleas, flea eggs, [and] flea larvae [and prevents pupae] for up to six weeks]
- [•[Full or Partial Brand Name] prevents development of all flea stages for up to 6 weeks]
- [•Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)]
- [•If cat is a high risk for flea reinfestation a once month application may be needed]

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- [•Kills flea eggs [larvae] for up to [3 months] [12 weeks]]
- [• [Seven][Six] [Five][7][6] [5]Way Protection [Kills fleas, ticks, [mosquitoes,] chewing lice, flea eggs, [and] flea larvae [and prevents flea pupae]]]
- [•With Pyriproxyfen Insect Growth Regulator which Breaks the Flea Life Cycle]
- [•With Pyriproxyfen to Break Flea Life Cycle]
- [•With Insect Growth Regulator to Break Flea Life Cycle]
- [•Triple Action [!]:Fipronil and Etofenprox with Pyriproxyfen IGR] [Effectively Breaks the Flea Life Cycle]]
- [•Triple Action [!]: Effectively Breaks the Flea Life Cycle[!]]
- [•Kills all stages of the flea life cycle]
- [•Kills Flea Eggs & Flea Larvae [for up to 3 months]!]
- [•Prevents Flea Eggs From Developing Into Biting Adults]
- [•Prevents and controls reinfestations]

[Ticks]

- [•Kills Ticks including those that may transmit Lyme disease]
- [•Kills Ticks [for Up to 4 weeks]!]
- [•Kills Deer Ticks (which may transmit Lyme disease) for up to [4 weeks] [1 month] [30 days]]
- [•Kills Ticks (Including Deer Ticks) for up to 4 weeks]
- [•Kills American Dog Ticks for up to 4 weeks]
- [•Kills [Brown], [American] [and Lone Star] dog ticks for up to 4 weeks]
- [•Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to 4 weeks!]

[Multiple Infestations]

- [(Full or Partial Brand Name) provides convenient and effective flea, tick, [and] chewing lice [and mosquito] control for cats and kittens [12 weeks or older]]
- [•Controls reinfestation for up to 4 weeks]
- [• Flea & Tick Control for Cats & Kittens 12 weeks old or older]
- [•Kills fleas, ticks,[&] chewing lice [& mosquitoes]]
- [•Kills fleas, ticks, [mosquitoes,] and chewing lice]
- [•Monthly flea, tick, [mosquito] and chewing lice protection]
- [•[Four][Three] [4][3] Way Protection]
- [•[4 Week] [Flea and Tick Treatment]]
- [•[Four (4) Week] [Flea Tick, [Mosquito] and Chewing Lice Control]]
- [•When used monthly [Full or Partial Brand Name] completely breaks the flea life cycle and controls tick and chewing lice infestations.]
- [•Once A Month Flea and Tick Treatment]
- [•Kills Fleas and Ticks for up to 4 weeks!]
- [•Starts to kill fleas and ticks in an hour, continues to kill for a month]
- [•Kills [fleas] in 4 hours [and] [ticks in one hour]]
- [[Full or Partial Brand Name] kills fleas in 4 hours and Dermacentor ticks in one hour]
- [•Kills ticks in 1 hour]
- [•Kills fleas and ticks in [24 hours] [1 day]]
- [•Starts killing fleas and ticks in as little as 1 hour]

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[All Others]

- [•Stops and prevents infestations]
- [•For Cats and Kittens 12 weeks of age or older]
- [•Fast Acting]
- [•Cats can be bathed 24 hours after treatment]
- [•Waterproof]
- [•Long Lasting]
- [•Fast Action against chewing lice infestations]
- [• Three Applications] [3 Month Supply] [12 Week Supply]
- [• Best if used year round!]
- [• (ICON Showing 4 Week Protection)]
- [• 4 Week Dose!]
- [• 1 Month Dose!]
- [• Easy to Use Application]
- [• Specially Formulated for Cats and Kittens [12 weeks or older]]
- [• [Free] Calendar Stickers Inside!]
- [• [Free] Brochure Inside!]
- [• [Free] Brochure and Calendar Stickers Inside]
- [• Apply once every [4 weeks] [month] [30 days]!]
- [• Convenient to use]
- [• [Free with purchase] [Free inside] Monthly Application Reminder [Magnet] [clip] [insert]]
- [•Patent Pending]
- [•3 applications]

ACTIVE INGREDIENTS:

| | |
|----------------------------------|----------------|
| Fipronil | 9.80% |
| Etofenprox..... | 15.00% |
| Pyriproxyfen..... | 2.20% |
| OTHER INGREDIENT[**]..... | 73.00 % |
| TOTAL: | 100.00% |

[**diethylene glycol monoethyl ether]

**KEEP OUT OF REACH OF CHILDREN
WARNING**

See [Side] [or] [Back] Panel For Additional Precautionary Statements

NET CONTENTS:

[3][Three] 0.017 fl oz [0.50 ml] applicators

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[BACK/SIDE CARTON LABEL - MASTER LABEL]

[Full or Partial Brand Name] contains Fipronil, Etofenprox and [the insect growth regulator] [IGR] Pyriproxyfen to effectively kill fleas, ticks, [mosquitoes] and chewing lice. The active ingredients in [Full or Partial Brand Name] features a sustained-release formula developed for fast-acting [and long-lasting] control of fleas, ticks, [mosquitoes] and chewing lice [for 30 days] on cats [and kittens 12 weeks or older].

**READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON CATS AND KITTENS OVER 12 WEEKS OF AGE.**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. WARNING. Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Harmful if swallowed. Harmful if absorbed through skin.

HAZARDS TO DOMESTIC ANIMALS. For external use only. Do not use on kittens under 12 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. [Some cats may experience temporary startle effects when any product is applied.] If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. If your pet 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 animals. Call 1-800-224-PETS [7387] for 24-hour assistance.

| 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 further treatment advice. |
| If On Skin Or Clothing | <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. |
| If Swallowed | <ul style="list-style-type: none"> • Call a 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. |
| HOT LINE NUMBER | |
| <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-781-4738.</p> | |

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL BEFORE EACH USE.

FOR EXTERNAL USE ON CATS ONLY. Do not use on kittens under 12 weeks of age. 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. **Best if used year round.** Consult a veterinarian before using this product on debilitated, aged, medicated cats. Consult a veterinarian before using on cats with known organ dysfunction. Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied. Cats and dogs that actively groom or engage in close physical contact with treated cat may be at risk of serious harmful effects. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your pet for the next 24 hours.

Sensitivities may occur after using ANY pesticide product on cats. If signs of sensitivity occur bathe your cat with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately by calling 1-800-781-4738.

[Optional diagram may or may not appear on the finished label]



[[Outer Packaging]]

How to open: Remove product tubes [vial] from the package. Separate one tube from the others. Holding the tube [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

How to apply: While holding the cat with one hand, use the other hand to apply the solution. Invert the tube [vial] and use the narrow end to part the cat's hair. Apply contents of one tube [vial] of {Full or Partial Brand Name} [as a stripe, starting high on the back of the cat's neck to in front of the shoulder blades] [as a spot between the shoulder blades]. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat. When finished, wrap the tube [vial] in paper and put into the trash. Only one applicator per treatment is needed.

FREQUENCY OF APPLICATION

Use [Full or Partial Brand Name] monthly for complete control of flea, tick [and] chewing lice [and mosquito] infestations. [Full or Partial Brand Name] kills fleas for up to six weeks, and flea eggs, [and] flea larvae [and prevents flea pupae] for up to 12 weeks.

Apply monthly, if your pet 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] kills mosquitoes within 24 hours for up to 14 days, and within 48 hours for up to 28 days.] [Full or Partial Brand Name] remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for 30 days.

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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 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)
[Made in USA]

Distributed by:

Sergeant's Pet Care Products, Inc.
P.O. Box 540399
Omaha, NE 68154-0399
EPA Reg. No. 2517-RUT
EPA Est. No. XXXXX-XX-XXX

[BAR CODE AREA]

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{START - OPTIONAL INSERT OR PACKAGE COPY}

[• 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. Holding the tube [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

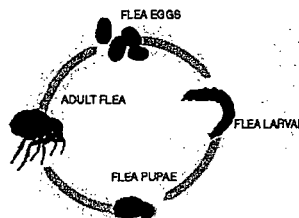
How to Apply:

1. Invert tube over cat and use open end to part cat's hair.
2. Apply contents of one tube [vial] of {Full or Partial Brand Name} [as a stripe, starting high on 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.]

[Optional diagram may or may not appear on the finished label]



[Flea life cycle diagram]



[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]

[Full or Partial Brand Name]

[Monthly reminder card]

[Apply [Full or Partial Brand Name] monthly for continuous protection against fleas, ticks, flea eggs, flea larvae [and] chewing lice [and mosquitoes].]

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

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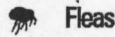
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[First [dose] [Treatment] (Empty blank for owner to fill in date)]
 [Second [dose] [Treatment] (Empty blank for owner to fill in date)]
 [Third [dose] [Treatment] (Empty blank for owner to fill in date)]
 [calendar stickers with Full or Partial Brand 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 to
 start the clock. After 30 days the magnet will flash (and beep) reminding you to reapply [Full or
 Partial Brand Name]. This application reminder can be used for future treatments. Just press the
 reset button and in another 30 days the reminder magnet will flash (and beep) reminding you to
 reapply.]

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



Fleas



Fleas



Ticks



Ticks



Mosquitoes



Mosquitoes



Chewing Lice



Chewing Lice

{END - OPTIONAL INSERT OR PACKAGE COPY}

[TUBE] [VIAL] LABEL

Front Label

Back Label

| | |
|---|---|
| <p>{Brand Name} [For use only on cats/kittens 12 weeks or older] Fipronil 9.8% w/w, Etofenprox 15% w/w, Pyriproxyfen 2.2% w/w 0.017 fl oz [0.50 mL] {label code}</p> | <p>KEEP OUT OF REACH OF CHILDREN WARNING: Read directions and precautions before using. Use scissors to open. EPA REG. No. 2517-RUT {label code}</p> |
|---|---|