



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

January 19, 2022

Prince M. Bamaze  
Regulatory Affairs  
Sergeant's Pet Care Products, LLC  
10077 South 134<sup>th</sup> Street  
Omaha, NE 68138

Subject: Label Amendment – Agency initiated revisions and 2-year registration extension  
Product Name: LC-2010-3 Fipronil and S-Methoprene for Cats  
EPA Registration Number: 85495-1  
Application Date: 8/22/2017; 3/2/2021  
Decision Number: 532814; 581289

Dear Mr. Bamaze:

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable under FIFRA Section 3(c)(7)(A), subject to the following conditions:

1. You must submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
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 05/30/2023.**
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. 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
4. 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 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.
  - A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
  - Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
  - 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.
  - A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label, as applicable.
  - 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, as applicable.
  - Table showing number of incidents for each cat breed, where provided.

- Table showing number of incidents in cats for each clinical sign.
- Table showing number of incidents in cats for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

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

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) 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.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). If you have any questions, please contact Kaitlin Saunders by phone at 202-566-2890, or via email at [Saunders.Kaitlin@epa.gov](mailto:Saunders.Kaitlin@epa.gov).

Sincerely,



Elizabeth Fertich  
Product Manager 4  
Invertebrate-Vertebrate Branch 1  
Registration Division  
Office of Pesticide Programs

Enclosure

**Master Label containing:**

**Sublabel A: Box Label**

**Sublabel B: Package Insert**

**Sublabel C: Labeling on the tube/vial**

**Sublabel D: Stickers for Re-application Reminders**

Supersedes EPA SAL 08/28/2014

{The CRP required text and format will not change from that used in SAUE testing.}

Text in [ ] is optional verbiage

Text in { } is instructional

Text in ( ) is additional information used in the label

{A statement of purpose of the product and the duration per application, indicated in the optional claims section will be included on the front panel}

**LC-2010-3 Fipronil and S-Methoprene for Cats**

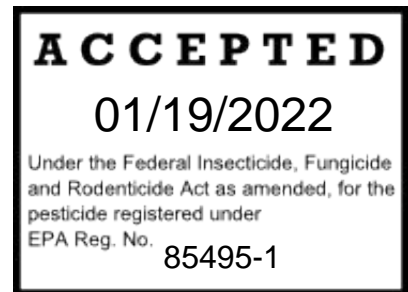
**ACTIVE INGREDIENTS**

Fipronil.....9.80%

(S)-Methoprene.....11.80%

**OTHER INGREDIENTS.....78.40%**

**TOTAL 100.00%**



**EPA Reg. No. 85495-1**

**Sublabel A: Box Label**

**{Front Panel of Box}**

**LC-2010-3 Fipronil and S-Methoprene For Cats**

{Market Label: The word 'Cat' will be 40-75% in height of the largest letter in the primary brand name}  
{A large, clear, age and weight appropriate picture of a cat will be on the front panel}

[1][2][3][4][5][6][12][24] [vial] [tube] [s]

[1][2][3][4][5][6][12][24] [Applications] [Month Supply]

{The statement below will appear prominently in a box on the market label on front panel as required}

**Only For Use on cats and kittens 8 weeks or older and  
[weighing] 1.5 lbs. or over**

**ACTIVE INGREDIENTS**

Fipronil.....	9.80%
(S)-methoprene.....	11.80%
OTHER INGREDIENTS.....	78.40%
TOTAL	100.00%

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

See Back Label for Additional Precautionary Statements.

{or}

See Insert for First Aid and Storage and Disposal

**Net Contents:**

1 - 0.017 fl. oz (0.50 mL) [tube][vial]  
0.034 fl. oz (1.00 mL), 2 - 0.017 fl. oz (0.50 mL) [tubes][vials]  
0.051 fl. oz (1.50 mL), 3 - 0.017 fl. oz (0.50 mL) [tubes][vials]  
0.068 fl. oz (2.00 mL), 4 - 0.017 fl. oz (0.50 mL) [tubes][vials]  
0.085 fl. oz (2.50 mL), 5 - 0.017 fl. oz (0.50 mL) [tubes][vials]  
0.102 fl. oz (3.00 mL), 6 - 0.017 fl. oz (0.50 mL) [tubes][vials]  
0.204 fl. oz (6.00 mL), 12 - 0.017 fl. oz (0.50 mL) [tubes][vials]  
0.408 fl. oz (12.00 mL), 24 - 0.017 fl. oz (0.50 mL) [tubes][vials]

## {Back Panel of Box}

{Product Name}

{{Product Name} {or} [This product] acts fast (starts [killing][working] within 48 hours after application) on fleas, ticks, and mosquitoes, and is an effective, [30-days] [1 month] [4 weeks] lasting, waterproof, and easy-to-use application for control of fleas, flea eggs, ticks (including all stages of American Dog ticks, Brown Dog ticks, Deer ticks and Lone Star ticks), chewing lice, and mosquitoes ONLY on cats and kittens 8 weeks or older and  $\geq 1.5$  lbs.]

### **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. Carefully follow all precautionary statements and Directions for Use.

For topical application only. Apply {Product Name} ONLY to cats and kittens aged 8 weeks or older and  $\geq 1.5$  lbs., including on breeding, pregnant, and lactating queens, for control of fleas, flea eggs, ticks, chewing lice, and mosquitoes. Cat must be dry at time of application and remain dry for 24 hours after application. Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.

### **Restrictions:**

Do not allow children to apply this product.

Do not touch the area where the application was made until it is dry.

Do not apply the product superficially to the cat's hair.

Do not bathe or allow water immersion for 24 hours after application.

Do not reapply for [4 weeks] [a month] [30 days].

Do not allow your cat to ingest this product.

Do not use on dogs, rabbits or other animals.

Do not use on cats or kittens under 8 weeks of age or less than 1.5 lbs.

Do not apply more than one [tube] [vial] per treatment for one cat regardless of cat's weight.

{Optional graphics to illustrate "how to Apply"}



{CRP: One of the following terms: "tube" or "vial" will be used consistently throughout the label.}

### **How to open:**

1. Remove product [tube][vial][s] from the package
2. [Separate one [tube][vial] 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][vial] over cat and use open end to part cat's hair.
2. Part the cat's hair and place the tip of the [tube][vial] behind the neck and between the shoulders. Ensure that the entire application of [Brand name] [this product] is contained in a single spot on the cat's skin. Be sure to squeeze the [tube][vial] thoroughly so that the entire contents are applied.

**Frequency of Application**

**Fleas:** For control of fleas apply once every [4 weeks] [month] [30 days].

**Ticks:** Each application kills ticks for [one month] [4 weeks] [30 days]. For control of ticks, apply once every [4 weeks] [month] [30 days].

**Chewing Lice:** Each application kills chewing lice for [one month] [4 weeks] [30 days]. For control of chewing lice, apply once every [4 weeks] [month] [30 days].

**Mosquitoes:** For control of mosquitoes, apply once every [4 weeks] [month] [30 days].

[Do not reapply {Product Name} {or} [This product] for [30 days] [4 weeks] [one month], including following your cat's exposure to bathing or water immersion, as {Product Name} remains effective in those conditions.]

{Side Effects box will be located on the lower right-hand corner of the back label panel}

<p><b>Side Effects:</b> Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting and/or diarrhea have been reported. If these or other side effects occur, consult your veterinarian or call [FidoPharm] {Name of distributor} at 1-xxx-xxx-xxxx</p>
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FidoPharm, Inc.  
P.O. Box 540399  
Omaha, NE 68154-0399 USA

EPA Reg. No. 85495-1

EPA Est. No. XXXXX-XX-XX

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{Drawing of telephone receiver} Questions? Comments? 1-888-908-TICK

**{Top Panel of Box}**

{Product Name}

[Only for use on cats and kittens 8 weeks or older and  $\geq 1.5$  lbs.]

[1][2][3][4][5][6][12][24] [vial] [tube] [s]

[1][2][3][4][5][6][12][24] [Applications] [Month Supply]

**{Bottom Panel of Box}**

[For Use on Cats Only]

**{Right side panel of Box}**

{Product Name}

[Only for use on cats and kittens 8 weeks or older and  $\geq 1.5$  lbs.]

[1][2][3][4][5][6][12][24] [vial] [tube] [s]

[1][2][3][4][5][6][12][24] [Applications] [Month Supply]

**{Left side panel of Box}**

Lot Number:

[1][2][3][4][5][6][12][24] [vial] [tube] [s]

[1][2][3][4][5][6][12][24] [Applications] [Month Supply]



**Sublabel B: Package Insert**

{Product Name}

**Only For Use on cats and kittens 8 weeks or older and  
[weighing] 1.5 lbs. or over**

{Product Name} {or} [This product] is a topical application for fast action (starts [killing][working] within 48 hours after application) on fleas, ticks, and mosquitoes, and [30-days] [1 month] [4 weeks] lasting control of fleas, flea eggs, ticks, chewing lice, and mosquitoes.

**ACTIVE INGREDIENTS**

Fipronil.....	9.80%
(S)-methoprene.....	11.80%
OTHER INGREDIENTS.....	<u>78.40%</u>
TOTAL	100.00%

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

[{Product Name} {or} [This product] acts fast (starts [killing][working] within 48 hours after application) on fleas, ticks, and mosquitoes, and is an effective, [30-days] [1 month] [4 weeks] lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes on cats and kittens 8 weeks or older and  $\geq 1.5$  lbs. When used as directed, {Product Name} {or} [This product] can control infestations of fleas, ticks, and chewing lice, and help to prevent re-infestation on cats and kittens 8 weeks or older and  $\geq 1.5$  lbs, including on breeding, pregnant, and lactating queens.]

Specifically, {Product Name} {or} [This product] kills, controls and prevents infestations of:

- 1) Adult fleas, flea eggs, and flea larvae, including fleas which could cause flea allergy dermatitis, and can prevent the further development of fleas at the egg, larvae and pupae stages.
- 2) Brown Dog tick, the American Dog tick, the Lone Star tick, and the Deer tick (that may transmit Lyme Disease), at all stages; and
- 3) Chewing lice infestations.
- 4) Kills mosquitoes.

{Product Name} {or} [This product] contains the active ingredient fipronil and the insect growth regulator (IGR) (S)-methoprene.

**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. Carefully follow all precautionary statements and Directions for Use.

For topical application only. Apply {Product Name} {or} [This product] ONLY to cats and kittens aged 8 weeks or older and  $\geq 1.5$  lbs., including on breeding, pregnant, and lactating queens, for control of fleas, flea eggs, ticks, chewing lice, and mosquitoes. Cat must be dry at time of application and remain dry for 24 hours after application. Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.

### Restrictions:

- Do not allow children to apply this product.
- Do not touch the area where the application was made until it is dry.
- Do not apply the product superficially to the cat's hair.
- Do not bathe or allow water immersion for 24 hours after application.
- Do not reapply for [4 weeks] [a month] [30 days].
- Do not allow your cat to ingest this product.
- Do not use on dog, rabbits or other animals.
- Do not use on cats or kittens under 8 weeks of age or less than 1.5 lbs.
- Do not apply more than one [tube] [vial] per treatment for one cat regardless of cat's weight.

{Optional graphics to illustrate "how to Apply"}



{CRP: One of the following terms: "tube" or "vial" will be used consistently throughout the label.}

### How to open:

1. Remove product [tube][vial][s] from the package
2. [Separate one [tube][vial] 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][vial] over cat and use open end to part cat's hair.
2. Part the cat's hair and place the tip of the [tube][vial] behind the neck and between the shoulders. Ensure that the entire application of [Brand name] [this product] is contained in a single spot on the cat's skin. Be sure to squeeze the [tube][vial] thoroughly so that the entire contents are applied.

### Frequency of Application

**Fleas:** For control of fleas apply once every [4 weeks] [month] [30 days].

**Ticks:** Each application kills ticks for [one month] [4 weeks] [30 days]. For control of ticks, apply once every [4 weeks] [month] [30 days].

**Chewing Lice:** Each application kills chewing lice for [one month] [4 weeks] [30 days]. For control of chewing lice, apply once every [4 weeks] [month] [30 days].

**Mosquitoes:** For control of mosquitoes, apply once every [4 weeks] [month] [30 days].

[Do not reapply {Product Name} {or} [This product] for [30 days] [4 weeks] [one month]].

[Do not reapply {Product Name} {or} [This product] for [30 days] [4 weeks] [one month], including following your cat's exposure to bathing or water immersion, as {Product Name} {or} [This product] remains effective in those conditions.]

**Side Effects:** Monitor your cat after application. side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting and/or diarrhea have been reported. If these or other side effects occur, consult your veterinarian or call [FidoPharm] {Name of distributor} at 1-xxx-xxx-x x x x .

#### STORAGE AND DISPOSAL

**PESTICIDE STORAGE:** Do not remove [tube][vial] 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.

**PESTICIDE DISPOSAL AND CONTAINER HANDLING:** Non-refillable container. Do not reuse or refill this container. **If empty:** 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.

#### 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:	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:	Take off contaminated clothing. Rinse skin immediately with plenty of water. 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.

## PRECAUTIONARY STATEMENTS

### **Hazards to Humans. Caution.**

Harmful if swallowed. Causes moderate 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 cats or kittens under 8 weeks of age and less than 1.5 lbs. Sensitivities may occur after using ANY pesticide product for cats. While temporary irritation at the application area may occur, if signs of continued sensitivity occur, consult a veterinarian immediately. Should any unusual reactions to the application occur, do not reapply before consulting with a veterinarian. Certain medications can interact with pesticides. Consult with your veterinarian before using this product on medicated, debilitated, or aged cats. Call 1-888-908-TICK for 24-hour assistance. This product is not a substitute for prescribed heartworm preventative

### **Physical or Chemical Hazards**

**Flammable:** Keep away from heat and open flame.

### **Warranty**

To the extent consistent with applicable law, Sellers make no warranty, express or implied, concerning the use of this product other than as indicated on the labeling. Buyer assumes all risk of use and handling of the product when such use and handling are contrary to the label instructions.

FidoPharm, Inc.  
P.O. Box 540399  
Omaha, NE 68154-0399 USA

EPA Reg. No. 85495-1

EPA Est. No. XXXXX-XXX-XX

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{Drawing of telephone receiver} Questions? Comments? 1-888-908-TICK

**Sublabel C: Labeling on the [Tube] [Vial]**

**Neck of tube/vial:** Contains: fipronil 9.80%  
(S)-methoprene 11.80%

**Body of tube/vial:**

{Product Name}  
0.017 fl.oz.  
ONLY for cats and kittens 8 weeks or older and  $\geq$  1.5 lbs.

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

Read entire label before using. Use scissors to open

**EPA Reg. No. 85495-1**

{Lot Code is engraved on the crimp portion of tubes}  
{EPA Reg. No. may be on either the front or back label}

**Sublabel D: Stickers for Re-application Reminders**

**Care Card**

Kills Fleas, Flea Eggs, Ticks, Chewing Lice, & Mosquitoes

Picture of Cat

Month 1

Drawing of paw
_____
Date of Application

Month 2

Drawing of paw
_____
Date of Application

Month 3

Drawing of paw
_____
Date of Application

[ Month 4

Drawing of paw
_____
Date of Application

Month 5

Drawing of paw
_____
Date of Application

Month 6

Drawing of paw
_____
Date of Application

] Place sticker on your calendar or refrigerator to remind yourself to apply {Product Name} to your cat.

Cat's Name: \_\_\_\_\_ lbs.

## {Optional marketing statements}

{Active ingredients comparison statement will appear on the same label panel as the corresponding disclaimer indicated with a (\*)}

- [Contains the same active ingredients used in FRONTLINE® Plus for Cats.][\*]
- [\*] This product is not manufactured or distributed by Boehringer Ingelheim Animal Health, the makers of FRONTLINE® Plus for Cats. FRONTLINE® Plus for Cats is a registered trademark of Boehringer Ingelheim Animal Health.]

[[Brand name] is a registered trademark of Sergeant's Pet Care Products, Inc.]

- Kills fleas, flea eggs, ticks, chewing lice & mosquitoes
- Fast action (starts [killing][working] within 48 hours after application) on fleas, ticks, and mosquitoes.
- Kills ticks, including ticks that may transmit Lyme Disease
- Waterproof
- [30-days] [1 month] [4 weeks] Lasting control

{note to reviewer: X&Y is based on the number of tubes/vials or %. When additional [tube][vial] is provided, the extra tube (or vial) will not cover or distract consumer from required text. X&Y will not exceed the allowable net contents}

- Bonus
- Buy "x" get "y" free
- Get "x%" free
- "X%" More Free
- Clip, Part, Squeeze
- Easy to use applicator
- Easier than ever [!]You **clip** the tip, **part** the fur [hair] and **apply [squeeze]** directly to [onto] the skin
- Clean cut [open] [tube][vial]!
- No mess [open] [tube][vial]
- Clip-tip design [tube][vial]!

{The statement below may be used in addition to the required language}

- Only for cats and kittens 8 weeks [of age] or older and [weighing] 1.5 lbs. or over