

85495-1

6/26/2013

1/16



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Iain Weatherston, Ph.D.
Agent for FidoPharm Inc.
J&T Associates LLC
4061 North 156th Drive
Goodyear, AZ 85395

JUN 26 2013

Subject: LC-2010-3 Fipronil and S-Methoprene for Cats
EPA Reg. No. 85495-1
Amendment dated 6/8/2013 to incorporate pet spot-on mitigation label language and transfer the product manufacturing site
EPA Decision No. 480096

Dear Dr. Weatherston,

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is **acceptable**. With this letter, the transfer of the manufacturer of LC-2010-3 Fipronil and S-Methoprene for Cats to Sergeant's Pet Care Products, Inc. facility in Omaha, Nebraska and corresponding label changes are accepted. Additionally, the label requirements listed in the EPA letter "Implementation of Label Changes to Pet Spot-On Products" dated September 30, 2011, are fulfilled. Please submit final printed labels to the Agency within 30 days of the date of this letter. If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants and may take regulatory action. The time-limited registration for this product is extended to one-year from the date of this letter. If a registration extension request is not received prior to that date, the registration of this product will expire. If a review of the previously submitted enhanced incident data indicates that there is a concern with this product, EPA may choose to take further regulatory action at that time.

Per the additional requirements of September 30, 2011 letter, you must continue to submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product, along with an analysis of the incidents reported. The quarterly reports are due two months after the quarter ends. Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the attention of Kaitlin Keller, Pesticide Reevaluation Division, Mail Code 7508P.

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

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

- All incidents should be reported including all minor dermal and ocular irritation reports.
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for cats (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 dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.

- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

A stamped copy of the label is enclosed for your records. If you have any questions regarding this label, please contact Kaitlin Keller at (703) 308-8172 via email at keller.kaitlin@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7504P)

Enclosure: Label stamped "Accepted"

4/16

Master Label containing:

Sublabel A: Box Label

Sublabel B: Package Insert

Sublabel D: Labeling on the Pipette

Sublabel E: Stickers for Re-application Reminders

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

ACTIVE INGREDIENTS

Fipronil.....9.8%

(S)-methoprene.....11.8%

OTHER INGREDIENTS.....78.4%

TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN

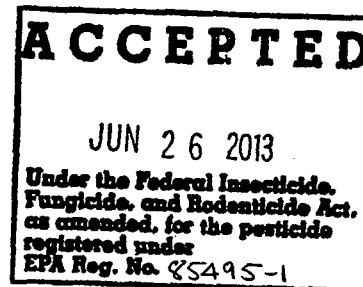
CAUTION

Contains 3-0.017 fl.oz. (0.50 mL) pipettes

[Contains 6-0.017 fl.oz. (0.50 mL) pipettes

[Contains 1-0.017 fl.oz. (0.50 mL) pipette]

EPA Reg. No. 85495-1



Sublabel A: Box Label**[Front Panel of Box]**

LC-2010-3
 [Alternative Brand Names]
 [PetArmor™ Plus]
 [TrustGard™ Plus]
 [Velcera® Fipronil Plus]
 For Cats

3 (Drawing of pipette/vial/tube)
 [Alternate Packaging]
 [6 (Drawing of pipette/vial/tube)]
 [1 (Drawing of pipette/vial/tube)]
 [2 (Drawing of pipette/vial/tube)]
 [4 (Drawing of pipette/vial/tube)]
 [5 (Drawing of pipette/vial/tube)]
 [12 (Drawing of pipette/vial/tube)]
 [24 (Drawing of pipette/vial/tube)]
 Pipette[s]

Kills fleas, flea eggs, ticks, chewing lice & mosquitoes

- Fast action
- Kills ticks, including ticks that may transmit Lyme Disease
- Waterproof
- Lasting control

Only for Cats and Kittens 8 weeks or older and \geq 1.5 lbs..

ACTIVE INGREDIENTS

Fipronil.....9.8%

(S)-methoprene.....11.8%

OTHER INGREDIENTS.....78.4%

TOTAL.....100.0%

(Picture of Cat)

KEEP OUT OF REACH OF CHILDREN
CAUTION

Contains 3-0.017 fl.oz (0.50 mL) pipettes

[Contains 6-0.017 fl.oz (0.50 mL) pipettes]

[Contains 1-0.017 fl.oz. (0.50 mL) pipette]

[Contains 2,4,5,12,or 24 0.017 fl.oz. (0.50 mL) pipettes/vials/tubes]

Compare to Frontline® Plus same active ingredients*

*This product is not manufactured or distributed by Merial, the makers of Frontline® Plus

[Back Panel of Box]

LC-2010-3 [or other approved alternate brand name] For Cats

LC-2010-3 [or other approved alternate brand name] For Cats acts fast and is an effective, 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. Do not use more than one tube per animal per month.

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 this product. READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON CATS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Do not allow your cat to ingest this product. Apply LC-2010-3 [or other approved alternate brand name] For Cats ONLY to cats and kittens aged 8 weeks or older and ≥ 1.5 lbs., including on breeding, pregnant, and lactating queens, as indicated below for control of fleas, flea eggs, ticks, chewing lice, and mosquitoes. If your cat weighs more than 20 lbs., discuss dosing with your veterinarian. Do not use more than one tube per animal per month.

How to Apply

Drawing of a pipette

Drawing of treating animal

1. Open the child resistant package according to the directions on the back of the sealed inner package for each pipette.
2. Snap the tip of the pipette away from you as shown
3. Part the cat's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of LC-2010-3 [or other approved alternate brand name] For Cats is contained in a single spot on the cat's skin. Be sure to squeeze the pipette thoroughly so that the entire contents are applied.

Do not apply the product superficially to the cat's hair. Use only one pipette during each application.

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

Do not allow your cat to ingest this product.

Frequency of Application

Fleas: According to research studies, adult fleas, flea eggs and flea larvae are killed, and all flea stages' development prevented, for up to six weeks following an application of fipronil plus (S)-methoprene. If, however, your cat or kitten is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply once every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-3 [or other approved alternate brand name] For Cats for thirty (30) days.

Please note that there is no need to reapply following your cat's exposure to bathing or water immersion, as LC-2010-3 [or other approved alternate brand name] For Cats remains effective in those conditions.

Side Effects:

Monitor your cat after application. Infrequent 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 XXXXX [FidoPharm or name of other distributor] at 1-888-908-TICK

FidoPharm, Inc.
PO Box 1060
Yardley, PA19067-9060 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

Made in XXXXXX

[Top Panel of Box]

LC-2010-3 [or other approved alternate brand name] For Cats

Only for cats and kittens 8 weeks or older and ≥ 1.5 lbs..

3 (Drawing of pipette)
[6 (Drawing of pipette)]
[1 (Drawing of pipette)]
[2 (Drawing of pipette/vial/tube)]
[4 (Drawing of pipette/vial/tube)]
[5 (Drawing of pipette/vial/tube)]
[12 (Drawing of pipette/vial/tube)]
[24 (Drawing of pipette/vial/tube)]

Pipette[s]

[Bottom Panel of Box]

For Cat use only

[Right side panel of Box]

LC-2010-3 [or other approved alternate brand name] For Cats

Only for cats and kittens 8 weeks or older and ≥ 1.5 lbs.

3 (Drawing of pipette)
[6 (Drawing of pipette)]
[1 (Drawing of pipette)]
[2 (Drawing of pipette/vial/tube)]
[4 (Drawing of pipette/vial/tube)]
[5 (Drawing of pipette/vial/tube)]
[12 (Drawing of pipette/vial/tube)]

[24 (Drawing of pipette/vial/tube)]

Pipette[s]

[Left side panel of Box]

Lot Number:

3 (Drawing of pipette)

[6 (Drawing of pipettes)]

[1 (Drawing of pipette)]

[2 (Drawing of pipette/vial/tube)]

[4 (Drawing of pipette/vial/tube)]

[5 (Drawing of pipette/vial/tube)]

[12 (Drawing of pipette/vial/tube)]

[24 (Drawing of pipette/vial/tube)]

Pipette[s]

Sublabel B: Package Insert**LC-2010-3 [or other approved alternate brand name] For Cats****Only For use on cats and kittens 8 weeks or older and \geq 1.5 lbs.**

LC-2010-3 [or other approved alternate brand name] For Cats is a topical application for fast action and lasting control of fleas, flea eggs, ticks, chewing lice, and mosquitoes.

ACTIVE INGREDIENTS

Fipronil.....	9.8%
(S)-methoprene.....	11.8%
OTHER INGREDIENTS.....	78.4%
TOTAL.....	100.0%

Compare to Frontline® Plus same active ingredients*

KEEP OUT OF REACH OF CHILDREN**CAUTION**

LC-2010-3 [or other approved alternate brand name] For Cats acts fast is an effective, lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes on cats and kittens. When used as directed, LC-2010-3 [or other approved alternate brand name] For Cats can stop infestations of fleas, ticks, and chewing lice, and help to prevent re-infestation on cats and kittens, including on breeding, pregnant, and lactating queens.

Specifically, LC-2010-3 [or other approved alternate brand name] For Cats 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.

LC-2010-3 [or other approved alternate brand name] For Cats 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. Do not allow children to apply this product. READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON CATS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Do not allow your cat to ingest this product. Apply LC-2010-3 [or other approved alternate brand name] For Cats ONLY to cats and kittens aged 8 weeks or older and ≥ 1.5 lbs., including on breeding, pregnant, and lactating queens, as indicated below for control of fleas, flea eggs, ticks, chewing lice, and mosquitoes. If your cat weighs more than 20 lbs., discuss dosing with your veterinarian. Do not use more than one tube per month per animal.

How to Apply

Drawing of a pipette

Drawing of treating animal

1. Open the child resistant package according to the directions on the back of the sealed inner package for each pipette.
2. Snap the tip of the pipette away from you as shown.
3. Part the cat's hair and place the tip of the pipette to the skin level behind the neck and between the shoulders. Ensure that the entire application of LC-2010-3 [or other approved alternate brand name] For Cats is contained in a single spot on the cat's skin. Be sure to squeeze the pipette thoroughly so that the entire contents are applied.

Do not apply the product superficially to the cat's hair. Use only one pipette during each application.

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

Frequency of Application

Fleas: According to research studies, adult fleas, flea eggs, and flea larvae are killed, and all flea stages development prevented for up to six weeks following an application of fipronil plus (S)-methoprene. If, however, your cat or kitten is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply once every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-3 [or other approved alternate brand name] For Cats for thirty (30) days.

Please note that there is no need to reapply following your cat's exposure to bathing or water immersion, as LC-2010-3 [or other approved alternate brand name] For Cats remains effective in those conditions.

Storage and Disposal

Do not contaminate water food, or feed by storage or disposal.

Storage. Store unused application pipettes in the original child-resistant container and outer box only, out of reach of children and animals.

Pesticide Disposal. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Container Disposal. Nonrefillable container. **If empty:** Do not reuse this container. Place in trash or offer for recycling if available.

First Aid

Have the product container or label with you when calling a poison control center or doctor, or if going for treatment.

If Swallowed: Immediately call a poison control center or doctor for treatment advice. Have the person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the 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. Call a poison control center or doctor for treatment advice.

If on Skin: Rinse skin with plenty of soap and water. Get medical attention if irritation persists.

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, or using tobacco.

Hazards to Domestic Animals.

For external use only. Do not use on kittens under 8 weeks of age or < 1.5 lbs.

Sensitivities may occur after using ANY pesticide product for pets. 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.

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.

Side Effects:

Monitor your cat after application. Infrequent 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 XXXXX [FidoPharm or name of distributor] at 1-888-9089-TICK

For Cat use only.

* This product is not manufactured or distributed by Merial, the makers of Frontline® Plus

FidoPharm, Inc.
PO Box 1060
Yardley, PA19067-9060 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

Made in XXXXXX

Sublabel D: Labeling on the Pipette

Neck of pipette: Contains: fipronil (9.8%)
s-methoprene (11.8%)

Body of pipette: **FidoPharm**
0.017 fl.oz.
LC-2010-3 [or other approved alternate brand name] For
Cats

For cats and kittens 8 weeks or older and ≥ 1.5 lbs. only

**KEEP OUT OF REACH OF CHILDREN
CAUTION.**

See package insert for directions for use

EPA Reg. No. 85495-1

Sublabel E: Stickers for Re-application Reminders

LC-2010-3
[or other approved alternate brand name]
For Cats
Care Card

Kills Fleas, Ticks, Chewing Lice, & Mosquitoes

Picture of Cat

Month 1

Drawing of paw
<hr/>
Date of Application

Month 2

Drawing of paw
<hr/>
Date of Application

Month 3

Drawing of paw
<hr/>
Date of Application

[Month 4

Drawing of paw
<hr/>
Date of Application

Month 5

Drawing of paw
<hr/>
Date of Application

Month 6

Drawing of paw
<hr/>
Date of Application

]

Place sticker on your calendar or refrigerator to remind yourself to apply LC-2010-3 [or other approved alternate brand name] For Cats to your cat.

Pet's Name:

lbs.