

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 28, 2014

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

Subject: Label Amendment – Addition of Marketing Claims
Product Name: LC-2010-3 Fipronil and S-Methoprene for Cats
EPA Registration Number: 85495-1
Application Date: May 16, 2014
Decision Number: 491537

Dear Dr. Weatherston:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval **does not** supersede any of the pet mitigation and enhanced incident reporting requirements outlined in the Agency letters dated January 10, 2011 and June 26, 2013. You are reminded that this registration shall expire on June 26, 2015, unless the Agency receives a formal request to extend the registration for this product.

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

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). If you have any questions, please contact Carlyn Petrella by phone at 703-347-0439, or via email at petrella.carlyn@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard J. Gebken". The signature is fluid and cursive, with the first name "Richard" and last name "Gebken" clearly legible, and a middle initial "J." in between.

Richard Gebken
Product Manager 10
Insecticide Branch
Office of Pesticide Programs
Date: August 28, 2014

Master Label containing:

Sublabel A: Box Label

Sublabel B: Package Insert

Sublabel D: Labeling on the Pipette

Sublabel E: Stickers for Re-application Reminders

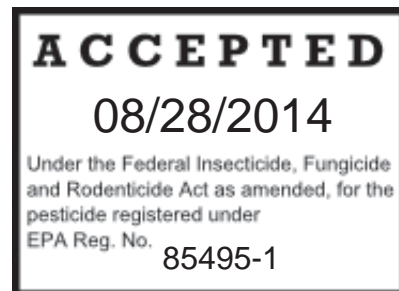
[] -- alternate verbiage

“Pipette/Vial/Tube/Applicator” can be used interchangeably

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%



KEEP OUT OF REACH OF CHILDREN
CAUTION

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

EPA Reg. No. 85495-1

Sublabel A: Box Label

[Front Panel of Box]

LC-2010-3
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
- Direct to skin [applicator][tube][vial][pipette]
- Bonus
- Buy “x” get “y” free
- Get “x%” free
- “X%” More Free
- Clip, Part, Squeeze
- [For Cats and Kittens 8 weeks of age or older]
- [Easy to use][applicator]
- Easier than ever applicator lets you **clip** the tip, **part** the fur [hair] and **apply** directly to the skin
- Easier than ever applicator lets you **clip** the tip, **part** the fur [hair] and **squeeze** directly onto the skin
- Clean cut [open][applicator!]
- No mess [open][applicator]
- Clip-tip design [applicator][!]
- [Contains the same active ingredients used in FRONTLINE® Plus for Cats. This product is not manufactured or distributed by Merial®, the makers of FRONTLINE® Plus for Cats. FRONTLINE® Plus for Cats is a registered trademark of Merial®.]

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

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

ACTIVE INGREDIENTS

Fipronil.....9.80%

(S)-methoprene.....11.80%

OTHER INGREDIENTS.....78.40%

TOTAL.....100.00%

(Picture of Cat that is
appropriate for size of cat)

KEEP OUT OF REACH OF CHILDREN

CAUTION

Contains 3-0.017 fl.oz (0.50 mL) pipettes/vials/tubes. Net weight 0.051 fl.oz.

[Contains 6-0.017 fl.oz (0.50 mL) pipettes/vials/tubes. Net weight 0.102 fl.oz.]

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

[Contains 2,4,5,12,24 - 0.017 fl.oz. (0.50 mL) pipettes/vials/tubes. Net weight 0.034
(0.068)(0.085)(0.204)(0.408) fl.oz.]

[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/vial/tube

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.
10077 South 134th Street
Omaha, NE
68138 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 USA

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

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.

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 1-888-908-TICK.

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 and less than 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.

For Cat use only.

FidoPharm, Inc.
10077 South 134th Street
Omaha, NE
68138 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 USA

Sublabel D: Labeling on the Pipette

Neck of pipette: Contains: fipronil 9.80%
(S)-methoprene 11.80%

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

Pet's Name:

lbs.