

86230-1

01-10-2011

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

86230-1

Date of Issuance:

JAN 10 2011

NOTICE OF PESTICIDE:

Registration
 Reregistration

Term of Issuance:

Conditional

Name of Pesticide Product:

LC-2010-1
Fipronil for Cats

Name and Address of Registrant (include ZIP Code):

LoradoChem, Inc.
Cira Centre, 12th. Floor
29202 Arch Street
Philadelphia, PA 19104-2891

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 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 conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

(continued on page 2)

Signature of Approving Official:

See page 3

Richard J. Gebken, Product Manager (10)
Insecticide Branch, Registration Division (7505P)

Date:

JAN 10 2011

- 2. Make the following change to the label:
 - a. Change the product registration number to "EPA Reg. No. 86230-1"
- 3. Agency requirements with respect to the continued registration:
 - a. The registration for this product is time-limited and expires two years from the date this product is released for shipment bearing the revised language. You must provide the Agency with a projected release for shipment date within 30 days of the date of this letter. The Agency will calculate the expiration date based on the projected release date until an actual release date is provided in writing.
- 4. Reporting of incident data for this product:
 - a. 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, 2010. The quarterly reports are due two months after each 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 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
- b. **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 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 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 (if applicable).
- 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 (if applicable).
- 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.

5. Other Comments:

- This product has met the requirements for Child Resistant Packaging (CRP). however, the Agency reserves the right to reevaluate the associated data if:
 - an incident report shows any problems in human, and/or
 - epidemiological evidence indicates a problem once the products reach the marketplace.
- Consider limiting the formulations of each product to one basic confidential statement of formula, if applicable. The Agency may require this in the future. It is possible that no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
- If the Agency determines that future mitigation measures are necessary for all pet spot-on products, you will be informed, and be expected to comply. If mitigation measures are necessary, the Agency may take appropriate regulatory actions.

6. You must submit two copies of the revised final printed labels (Master label and Production Copies) for all sizes for the Agency records, before the product is released for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Richard J. Gebken



Product Manager (10)
Insecticide Branch
Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments"

[EPA REG. NO. 86230-1 / DECISION 429282]

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Master Label containing:

Sublabel A: Box Label

Sublabel B: Package Insert

Sublabel C: Labeling on the Child Resistant Package

Sublabel D: Labeling on the Pipette

Sublabel E: Stickers for Re-application Reminders

**LC-2010-1
Fipronil For Cats**

ACTIVE INGREDIENT

Fipronil.....	9.7%
INERT INGREDIENTS.....	90.3%
TOTAL.....	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Contains 3-0.017 fl.oz. (0.50 mL) pipette(s)

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

JAN 10 2011

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
86230-1

EPA Reg. No. 86230-R

Sublabel A: Box Label

[Front Panel of Box]

LC-2010-1
[Alternate Brand Names:]
[PetArmor™]
[TrustGard™]
[Velcera® Fipronil]
Fipronil For Cats

3 (Drawing of Pipette)
Pipettes

Kills fleas, ticks, chewing lice & mosquitoes

- Easy-to-use topical application
- Fast action and lasting control of fleas, ticks, and chewing lice
- Kills ticks, including ticks that may transmit Lyme Disease
- Kills mosquitoes
- Waterproof

Only for cats and kittens 8 weeks or older.

ACTIVE INGREDIENT

Fipronil.....9.7%

(Picture of Cat)

INERT INGREDIENTS.....90.3%

TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

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

Compare to Frontline® Top Spot same active ingredient*

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

Back Panel of Box

LC-2010-1 [or other approved alternate brand name] Fipronil For Cats

LC-2010-1 [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, 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.

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. Apply LC-2010-1 [or other approved alternate brand name] For Cats ONLY to cats and kittens aged 8 weeks or older, including on breeding, pregnant, and lactating queens, as indicated below for control of fleas, ticks, chewing lice, and mosquitoes:

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-2010-1 [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 are killed for up to six weeks following an application of fipronil. 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-2010-1 [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-2010-1 [or other approved alternate brand name] For Cats remains effective in those conditions.

LoradoChem, Inc.
Circa Center, 12th Floor
2929 Arch Street
Philadelphia, PA 18104-2891 USA

EPA Reg. No. 86230-R

EPA Est. No. 87688-IND-01

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(Drawing of telephone receiver) Questions? Comments?
1-888-908-TICK

Made in India

[Top Panel of Box]

LC-2010-1 [or other approved alternate brand name] Fipronil for Cats

Only for cats and kittens 8 weeks or older.

3 (Drawing of pipette)
pipettes

[Bottom Panel of Box]

For Cat use only

[Right side panel of Box]

LC-2010-1 [or other approved alternate brand name] Fipronil For Cats
Only for cats and kittens 8 weeks or older

3 (Drawing of pipette)
pipettes

[Left side panel of Box]

Lot Number:

3 (Drawing of pipette)
pipettes

Sublabel B: Package Insert

LC-2010-1 [or other approved alternate brand name] Fipronil For Cats

Only for use on cats and kittens 8 weeks or older

LC-2010-1 [or other approved alternate brand name] for Cats is a topical application for fast action and lasting control of fleas, ticks, chewing lice, and mosquitoes.

ACTIVE INGREDIENT

Fipronil.....9.7%

INERT INGREDIENTS.....90.3%

TOTAL.....100.0%

Compare to Frontline® Top Spot same active ingredient*

KEEP OUT OF REACH OF CHILDREN

CAUTION

LC-2010-1 [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, ticks, chewing lice and mosquitoes on cats and kittens. When used as directed, LC-2010-1 [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-2010-1 [or other approved alternate brand name] For Cats kills, controls and prevents infestations of:

- 1) newly emerged adult fleas prior to egg-laying, including fleas which could cause flea allergy dermatitis;
- 2) Brown Dog tick, the American Dog tick, the Lone Star tick, and the Deer tick (that may transmit Lyme Disease), at all stages;
- 3) Chewing lice infestations;
- 4) Kills Mosquitoes.

LC-2010-1 [or other approved alternate brand name] For Cats contains the active ingredient fipronil.

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. Apply LC-2010-1 [or other approved alternate brand name] For Cats ONLY to cats and kittens aged 8 weeks or older, including on breeding, pregnant, and lactating queens, as indicated below for control of fleas, ticks, chewing lice, and mosquitoes:

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-2010-1 [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 are killed for up to six weeks following an application of fipronil. 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-2010-1 [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-2010-1 [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 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. 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.

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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.

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

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EPA Reg. No. 86230-R

EPA Est. No. 87688-IND-01

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(Drawing of telephone receiver) Questions? Comments?
1-888-908-TICK

Made in India

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Sublabel C: Labeling on the Child Resistant Package

Top of lidding foil: Dotted line with representation of a scissors
Company Name: LoradoChem
Product Name: LC-2010-1 [or other approved alternate brand name]
Fipronil For Cats

Graphic picture of the pipette

Instructions: **To Open Package:**
Cut across the top
as shown.
Peel down the foil
completely before
removing pipette.

Species and amount: Cat – 0.017 fl oz

Lot number: Lot No: XXXX

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Sublabel D: Labeling on the Pipette

Neck of pipette: Contains: fipronil (9.7%)

Body of pipette: **LoradoChem**
0.017 fl.oz.
LC-2010-1 [or other approved alternate brand name]
Fipronil For Cats

KEEP OUT OF REACH OF CHILDREN

CAUTION

See package insert for directions for use.

EPA Reg. No. 86230-R

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Sublabel E: Stickers for Re-application Reminders

LC-2010-1
[or other approved alternate brand name]
Fipronil For Cats
Care Card

Kills Fleas, 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

Place sticker on your calendar or refrigerator to remind yourself to apply LC-2010-1 [or other approved alternate brand name] For Cats to your cat.

Pet's Name: _____ lbs.