

86230-2

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:

86230-2

Date of Issuance:

JAN 10 2011

NOTICE OF PESTICIDE:

Registration  
 Reregistration  
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

LC-2010-2 Fipronil for Dogs

Name and Address of Registrant (include ZIP Code):

**LoradoChem, Inc.**  
**Cira Centre, 12<sup>th</sup>. 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

EPA Form 8570-6

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2. Make the following change to the label:
  - a. Change the product registration number to "EPA Reg. No. 86230-#2"
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.

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- 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:

- a. This product has met the requirements for Child Resistant Packaging (CRP). however, the Agency reserves the right to reevaluate the associated data if:
  - i. an incident report shows any problems in human, and/or
  - ii. epidemiological evidence indicates a problem once the products reach the marketplace.
- b. 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.
- c. 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. 86230-2 / DECISION 429489

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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-2010-2 FIPRONIL FOR DOGS**

**ACTIVE INGREDIENT**

Fipronil.....9.7%

**INERT INGREDIENTS.....90.3%**

**TOTAL.....100.0%**

(Picture of dog)

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

Contains X-0.0XX fl.oz. (X.xx mL) pipette(s)

**EPA Reg. No. 86230-E**

**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.  
86230-2

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**Sublabel A: Box Label**

**[Front Panel of Box]**

LC-2010-2  
[Alternate Brand Names]  
[PetArmor™]  
[TrustGard™]  
[Velcera® Fipronil]

FIPRONIL FOR DOGS

3 (Drawing of pipette)  
Pipettes

Kills fleas, ticks, chewing lice & Mosquitoes

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

[Only use on dogs and puppies up to 22 lbs. 8 weeks or older]

Or

[Only use on dogs 23-44 lbs. 8 weeks or older]

Or

[Only use on dogs 45-88 lbs.]

Or

[Only use on dogs 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

**ACTIVE INGREDIENT**

Fipronil.....9.7%

(Picture of dog)

INERT INGREDIENTS.....90.3%

TOTAL.....100.0%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

[Contains 3-0.023 fl.oz (0.067 mL) pipettes]

Or

[Contains 3-0.045 fl.oz. (1.34 mL) pipettes]

Or

[Contains 3-0.091 fl.oz. (2.68 mL) pipettes]

Or  
[Contains 3-0.136 fl.oz (4.02 mL) pipettes]  
[Label identifiers that will be used to identify each respective package size contained within the box.]

Compare to Frontline® Top Spot same active ingredient\*

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

**[Back Panel of Box]**

LC-2010-2 [or other approved alternate brand name] Fipronil For Dogs  
LC-2010-2 [or other approved alternate brand name] For Dogs acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes [ONLY on dogs and puppies weighing up to 22 lbs. and 8 weeks or older.]

Or ... [ONLY on dogs weighing 23-44 lbs. and 8 weeks or older.]

Or ... [ONLY on dogs weighing 45-88 lbs.]

Or ... [ONLY on dogs weighing 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

**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 DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Apply LC-2010-2 [or other approved alternate brand name] For Dogs ONLY to dogs and puppies aged 8 weeks or older, including on breeding, pregnant, and lactating bitches, as indicated below 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:

**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 dog's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of LC-2010-2 [or other approved alternate brand name] For Dogs is contained in a single spot on the dog's skin. Be sure to squeeze the pipette thoroughly so that the entire contents are applied.

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

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

LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

**Frequency of Application**

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy 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-2010-2 [or other approved alternate brand name] For Dogs for thirty (30) days.

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

EPA Reg. No. 86230-E

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-2010-2 [or other approved alternate brand name] FIPRONIL FOR DOGS

[Only use on dogs and puppies up to 22 lbs. 8 weeks or older]	3 (Drawing of pipette)
Or	Pipettes
[Only use on dogs 23-44 lbs. 8 weeks or older]	
Or	
[Only use on dogs 45-88 lbs.]	
Or	
[Only use on dogs 89-132 lbs.]	
[Label identifiers that will be used to identify each respective package size contained within the box.]	

**[Bottom Panel of Box]**

For Dog use Only

**[Right side panel of Box]**

LC-2010-2 [or other approved alternate brand name] Fipronil For Dogs

[Only use on dogs and puppies up to 22 lbs. 8 weeks or older]	3 (Drawing of pipette)
Or	Pipettes
[Only use on dogs 23-44 lbs. 8 weeks or older]	
Or	
[Only use on dogs 45-88 lbs.]	
Or	
[Only use on dogs 89-132 lbs.]	
[Label identifiers that will be used to identify each respective package size contained within the box.]	

**[Left side panel of Box]**

Lot Number:	3 (Drawing of pipette)
	pipettes



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**Sublabel B: Package Insert**

LC-2010-2 [or other approved alternate brand name] Fipronil For Dogs

**Only for use on dogs and puppies 8 weeks or older**

LC-2010-2 [or other approved alternate brand name] FOR DOGS is a topical application for fast action and lasting control of fleas, ticks, chewing lice and mosquitoes.

**ACTIVE INGREDIENT**

Fipronil.....	9.7%
<b>INERT INGREDIENTS.....</b>	<b>90.3%</b>
<b>TOTAL.....</b>	<b>100.0%</b>

Compare to Frontline® Top Spot same active ingredient\*

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

LC-2010-2 [or other approved alternate brand name] For Dogs acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes on dogs and puppies. When used as directed, LC-2010-2 [or other approved alternate brand name] For Dogs can stop infestations of fleas, ticks, chewing lice, and mosquitoes and help to prevent re-infestation on dogs and puppies, including on breeding, pregnant and lactating bitches. LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Specifically, LC-2010-2 [or other approved alternate brand name] For Dogs 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 (including ticks that may transmit Lyme Disease), at all stages;
- 3) Chewing lice infestations;
- 4) Kills mosquitoes.

LC-2010-2 [or other approved alternate brand name] FOR DOGS 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**

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ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Apply LC-2010-2 [or other approved alternate brand name] For Dogs ONLY to dogs and puppies aged 8 weeks or older, including on breeding, pregnant, and lactating bitches, 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 dog's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of LC-2010-2 [or other approved alternate brand name] For Dogs is contained in a single spot on the dog's skin. Be sure to squeeze the applicator thoroughly so that the entire contents are applied.

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

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

LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

### Frequency of Application

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply 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-2010-2 [or other approved alternate brand name] For Dogs for thirty (30) days.

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Please note that there is no need to reapply following your dog's exposure to bathing or water immersion, as LC-2010-2 [or other approved alternate brand name] For Dogs 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 puppies 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 dogs. 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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**Application Options for Different Sizes of Dogs**

LC-2010-2 [or other approved alternate brand name] For Dogs comes in four different packages for different-sized dogs and puppies eight (8) weeks or older:

- \* Up to 22 lbs.
- \* 23 to 44 lbs.
- \* 45 to 88 lbs.
- \* 89 to 132 lbs.

**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.

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

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

EPA Reg. No. 86230-E  
Or

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-2010-2 [or other approved alternate brand name]  
Fipronil For Dogs

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: [Dogs up to 22 lbs. – 0.023 fl.oz.]  
Or  
[Dogs 23-44 lbs. – 0.045 fl.oz.]  
Or  
[Dogs 45-88 lbs. – 0.091 fl.oz.]  
Or  
[Dogs 89-132 lbs. – 0.136 fl.oz.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

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**  
                                 [0.023 fl.oz.]  
                                 Or  
                                 [0.0045 fl.oz.]  
                                 Or  
                                 [0.091 fl.oz.]  
                                 Or  
                                 [0.136 fl.oz.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

LC-2010-2 [or other approved alternate brand name]  
FIPRONIL For Dogs

[For Dogs up to 22 lbs.]

Or

[For Dogs 23-44 lbs.]

Or

[For Dogs 45-88 lbs.]

Or

[For Dogs 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

See package insert for directions for use.

**EPA Reg. No. 86230-E**

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

**LC-2010-2**  
[or other approved alternate brand name]  
**Fipronil for Dogs**  
**Care Card**

Kills Fleas, Ticks, Chewing Lice, & Mosquitoes

Picture of Dog

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-2010-2 [or other approved alternate brand name] For Dogs to your dog

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