

85495-2

12/14/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

December 14, 2011

Iain Weatherston, PhD  
(Agent for LoradoChem, Inc.)  
J & T Associates  
4061 North 156<sup>th</sup> Drive  
Goodyear, AZ 85395

Subject: Revise basic Confidential Statement of Formula (CSF) to "add new site for manufacture."

LC-2010-1 Fipronil for Cats: EPA Reg. No. 86230-1  
LC-2010-2 Fipronil for Dogs: EPA Reg. No. 86230-2  
LC-2010-3 Fipronil & S-Methoprene for Cats: EPA Reg. No. 86230-3 (85495-1)  
LC-2010-4 Fipronil & S-Methoprene for Dogs: EPA Reg. No. 86230-4 (85495-2)

Submissions dated August 04, 2011

Dear Dr. Weatherston:

The above referenced labeling, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

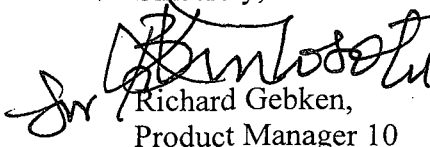
For each of the subject products, the revised accepted basic CSF dated 08/04/11 supersedes that of 06/29/2010, and all previously accepted ones. We have included copies of the revised CSF in the records for the products.

In the labeling for each product, replace "Inert Ingredients" with "***Other Ingredients***"

Please note that we have approved the amended labeling for the subject products with the understanding that the labels are consistent with the Agency's previously stamped accepted ones; and other than the above stated revisions, no other changes have been made to the labeling and/or the CSF.

For your records, you have been sent (via email) copies of our reviews (CRP and Prod. Chem.). Also, see enclosed copy of the stamped label for each product. If you have any questions concerning this action please contact me or Dr. B.A. Akinlosotu at (703) 605-0653.

Sincerely,



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

**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-2010-4 FIPRONIL and S-METHOPRENE FOR DOGS**

**ACTIVE INGREDIENTS**

Fipronil..... 9.8%

(S)-methoprene..... 8.8%

(Picture of dog)

*Other* INERT INGREDIENTS..... 81.4%

TOTAL..... 100.0%

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

EPA Reg. No. ~~86230-4~~  
85495-2

**ACCEPTED  
With COMMENTS  
In EPA Letter Dated:  
DEC 14 2011**

**Under the Federal Insecticide, Fungicide  
and Rodenticide Act, As amended, for the  
pesticide Registered under EPA Reg. No:**

**85495-2**

**Sublabel A: Box Label**

**[Front Panel of Box]**

**LC-2010-4**  
**[Alternate Brand Names]**  
**[PetArmor™ Plus]**  
**[TrustGard™ Plus]**  
**[Velcera® Fipronil Plus]**  
**For Dogs**

3 (Drawing of pipette)  
[Alternate Packaging]  
[6 (Drawing of pipette)]  
[1 (Drawing of pipette)]  
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 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 INGREDIENTS**

Fipronil..... 9.8%

(S)-methoprene..... 8.8%

(Picture of dog)

**INERT INGREDIENTS.....81.4%**

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

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

[Contains 3-0.023 fl.oz (0.67 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

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[Contains 3-0.136 fl.oz (4.02 mL) pipettes]

Or

[Contains 6-0.023 fl.oz (0.67 mL) pipettes]

Or

[Contains 6-0.045 fl.oz. (1.34 mL) pipettes]

Or

[Contains 6-0.091 fl.oz. (2.68 mL) pipettes]

Or

[Contains 6-0.136 fl.oz (4.02 mL) pipettes]

Or

[Contains 1-0.023 fl.oz (0.67 mL) pipette]

Or

[Contains 1-0.045 fl.oz. (1.34 mL) pipette]

Or

[Contains 1-0.091 fl.oz. (2.68 mL) pipette]

Or

[Contains 1-0.136 fl.oz (4.02 mL) pipette]

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

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-2010-4 [or other approved alternate brand name] For Dogs

LC-2010-4 [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, flea eggs, 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-2010-4 [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, flea eggs, 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-2010-4 [or other approved alternate brand names] 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-2010-4 [or other approved alternate brand names] 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, flea eggs and flea larvae are killed for up to three months following an application of fipronil plus (S)-methoprene. 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-2010-4 [or other approved alternate brand name] For Dogs for thirty (30) days.

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

EPA Reg. No. 86230-4

EPA Est. No. XXXXX-XXX-XX

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

Made in XXXXXX

**[Top Panel of Box]**

**LC-2010-4 [or other approved alternate brand name] For Dogs**

[Only use on dogs and puppies up to 22 lbs. 8 weeks or older]	3 (Drawing of pipette)
Or	[6 (Drawing of pipette)]
[Only use on dogs 23-44 lbs. 8 weeks or older]	[1 (Drawing of pipette)]
Or	pipette[s]
[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-2010-4 [or other approved alternate brand name] Fipronil and S-Methoprene For Dogs

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[Only use on dogs and puppies up to 22 lbs. 8 weeks or older]      3 (Drawing of pipette)  
 Or      [6 (Drawing of pipette)]  
 [Only use on dogs 23-44 lbs. 8 weeks or older]      [1 (Drawing of pipette)]  
 Or      pipette[s]  
 [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)  
                                  [6 (Drawing of pipette)]  
                                  [1 (Drawing of pipette)]  
                                  Pipette[s]



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**Sublabel B: Package Insert**

**LC-2010-4 [or other approved alternate brand name] For Dogs**

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

LC-2010-4 [or other approved alternate brand name] For Dogs 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.....	8.8%
<b>INERT INGREDIENTS.....</b>	<b>81.4%</b>
<b>TOTAL.....</b>	<b>100.0%</b>

Compare to Frontline® Plus same active ingredients\*

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

LC-2010-4 [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, flea eggs, ticks, chewing lice, and mosquitoes on dogs and puppies. When used as directed, LC-2010-4 [or other approved alternate brand name] For Dogs can stop infestations of fleas, ticks, and chewing lice and help to prevent reinfestation on dogs and puppies, including on breeding, pregnant and lactating bitches. LC-2010-4 [or other approved alternate brand name] For Dogs aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

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

LC-2010-4 [or other approved alternate brand name] For Dogs 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 DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Apply LC-2010-4 [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, flea eggs, 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-2010-4 [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-2010-4 [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, flea eggs and flea larvae are killed for up to three months following an application of fipronil plus (S)-methoprene. 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-2010-4 [or other approved alternate brand name] For Dogs for thirty (30) days.

Please note that there is no need to reapply following your dog's exposure to bathing or water immersion, as LC-2010-4 [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

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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.

**Application Options for Different Sizes of Dogs**

LC-2010-4 [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® Plus

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

EPA Reg. No. 86230-4

EPA Est. No. XXXXXX-XXX-XX

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

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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-2010-4 [or other approved alternate brand name] 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 E: Stickers for Re-application Reminders

## LC-2010-4 [or other approved alternate brand name] 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

[ 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-2010-4 [or other approved alternate brand name] For Dogs to your dog

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