

86230-1

12/14/2011

1/19



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 156th 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.

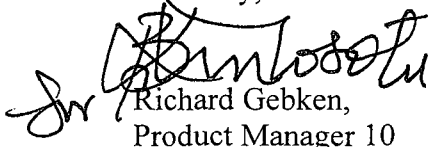
For each of the subject products, the revised accepted basic CSF dated 08/04/11 supersedes that of 06/29/2010, and all previously accepted ones. We have included copies of the revised CSF in the records for the products.

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)

3/14

055766

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%

to "Other"

ACCEPTED
 DEC 14 2011
**Under the Federal Insecticide, Fungicide,
 and Rodenticide Act, as amended, for the
 pesticide registered under:**

EPA. Reg. No. 86230-1

KEEP OUT OF REACH OF CHILDREN
CAUTION
 Contains 3-0.017 fl.oz. (0.50 mL) pipettes
 [Contains 6-0.017 fl.oz. (0.50mL) pipettes]
 [Contains 1-0.017 fl. oz. (0.50mL) pipette]

EPA Reg. No. 86230-1

4/14
056

Sublabel A: Box Label

[Front Panel of Box]

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

3 (Drawing of Pipette)
[Alternate Packaging]
[6 (Drawing of Pipette)]
[1 (Drawing of Pipette)]
Pipette[s]

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
[Contains 6-0.017 fl.oz. (0.50 mL) pipettes]
[Contains 1-0.017 fl. oz. (0.50 mL) pipette]

Compare to Frontline® Top Spot same active ingredient*

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

05776 5/14
66

Back Panel of Box

LC-2010-1 [or other approved alternate brand name] 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.

0581 6/14
06

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. 86230-1

EPA Est. No. XXXXXX-XX-XX

©2011 LoradoChem, Inc. All rights reserved.

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

Made in XXXXXXX

[Top Panel of Box]

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

Only for cats and kittens 8 weeks or older.

3 (Drawing of pipette)
[6(Drawing of pipette)]
[1(Drawing of pipette)
Pipette[s]

[Bottom Panel of Box]

For Cat use only

7/14

059 11 60

[Right side panel of Box]

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

3 (Drawing of pipette)
[6 (Drawing of pipette)]
[1 (Drawing of pipette)]
Pipette[s]

[Left side panel of Box]

Lot Number:

3 (Drawing of pipette)
[6 (Drawing of pipette)]
[1 (Drawing of pipette)]
Pipette[s]

8/14

0606
66

Sublabel B: Package Insert

LC-2010-1 [or other approved alternate brand name] 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.

061, 9/14
06

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.

10/19
0627
66

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.

063³ 11/14
20

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

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

EPA Reg. No. 86230-1

EPA Est. No. XXXXX-XXX-XX

©2011 LoradoChem, Inc. All rights reserved.

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

Made in XXXXXX

12/14

0641
66

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] 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

13/14

0651
66

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] For
Cats

KEEP OUT OF REACH OF CHILDREN

CAUTION

See package insert for directions for use.

EPA Reg. No. 86230-1

14/14

066 1
66

Sublabel E: Stickers for Re-application Reminders

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

[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-2010-1 [or other approved alternate brand name] For Cats to your cat.

Pet's Name:

lbs.