



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 17, 2015

Mr. Kelly Hoskins
LoredoChem, Inc.
1020 Stoney Hill Road, Suite 200
Yeardley, PA 19067

Subject: Label Amendment – Additional marking claims; clarification of directions for use
Product Name: LC-2010-2 FIPRONIL FOR DOGS
EPA Registration Number: 86230-2
Application Date: March 3, 2015
Decision Number: 502168

Dear Mr. Hoskins:

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 affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

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.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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

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with FIFRA section 6. If you have any questions, please contact me by phone at (703) 306-0415, or via email at davis.kable@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a hand-drawn oval.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

Sergeant's Master Label

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Information in [] is optional.

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FRONT PANEL

DOG SQUEEZE ON FIPRONIL

[Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels.] “Pipette/Vial/Tube/Applicator” can be used interchangeably

LC-2010-2 FIPRONIL FOR DOGS

[ABNs:]

[PetArmor™ for Dogs]

[TrustGard™ for Dogs]

[Velcera® Fipronil for Dogs]

[Sergeant's® Pet Armor for Dogs]

[Pet Armor for Dogs]

[[1][2][3][4][5][6][12][24](Drawing of
pipette/vial/tube/applicator)]
[1.5cm x 1.5cm on final or as indicated]



[Only use on dogs and puppies 5-22 lbs. 8 weeks or older]

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

[Only use on dogs 45-88 lbs.]

[Only use on dogs 89-132 lbs.]

[Picture of a dog that is the appropriate for the size of dog for each weight range]

{box only designates Vet Only language}

{**SUBLABEL: FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION**}

FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION

For use in veterinarian clinics, animal shelters, grooming facilities and boarding kennels.
Not for residential use. Do not repackage.

[Ideal for shelter use when under direct supervision of veterinarian]

[Professional Roll Pack]

[Convenient roll pack for in clinic use]

[Convenient roll pack for animal facility use]

[For use only by licensed veterinarians]

[Ticks]

[Kills ticks, including ticks that may transmit Lyme Disease]

[Mosquitoes]

[Kills mosquitoes]

[Multiple Infestations]

[Kills fleas, ticks, chewing lice & Mosquitoes]

[All Others]

[For Dogs and puppies 8 weeks of age or older]

[Can be used on puppies 8 weeks of age and older]

[Specially Formulated for Dogs and Puppies 8 weeks of age or older]

[For Dogs [4 to 22 lbs.],[5 to 22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.]]

[Fast Acting] [Long Lasting]

[Easy to Use [Application]]

[[Easy to use] [applicator]]

ACCEPTED

08/17/2015

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 86230-2

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[Easy-to-use topical application]
[Apply monthly]
[Once a month treatment]
[For year-round protection, apply [Brand name][this product] monthly]
[(ICON Showing [4 Week] [1 month] [30 day] Protection)]
[Apply once every [4 weeks] [month] [30 days]!]
[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
[[One][1][Two][2][Three] [3][4][Four][5][Five] [Six][6][Twelve][12][Twenty-Four][24]]Applications] and/or
[1 Month Supply][2 Month Supply][3 Month Supply][Four Month Supply][Five Month Supply][6 Month
Supply][12 Month Supply][24 Month Supply] or [4 Week Supply][8 Week Supply][12 Week Supply][16 Week
Supply][20 week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply]
[Waterproof]
[Effective even after bathing]
[Effective after bathing and exposure to water and sunlight]
[Can be used on breeding, pregnant and lactating [queens], [female] [cats]]
[[Free] Calendar Stickers Inside!]
[Monthly application reminder inside]
[[Free with purchase] [Free inside] Monthly Application Reminder [Magnet][clip] [inside]]
[Fipronil (9.7%)]
[Contains the same active ingredient used in [Fipaira for Dogs (or any approved ABN)].*]
[Compare to [Fipaira for Dogs (or any approved ABN)], contains the same active ingredient.*]
[Compare to [Fipaira for Dogs (or any approved ABN)], contains the same active ingredient fipronil.*]
[[Brand Name] [products] [This product] contains(s) fipronil, the same active ingredient used in [Fipaira for
Dogs (or any approved ABN)].*]
[[Brand Name] [products] [This product] contains(s) fipronil, compared to the same active ingredient used in
[Fipaira for Dogs (or any approved ABN)].*]
[[*][Brand Name][This product] is not manufactured or distributed by [Merial®] [Company name], the makers
of [Fipaira for Dogs (or any approved ABN)].]
[[Brand Name][This product][Fipaira] is a trademark of [Merial®] [Company name].]
[[Brand Name] is a registered trademark of Sergeant's Pet Care Products, Inc.]
[[1][2][3][4][5][6][12][24] Applications]
[Stops and prevents infestation of listed pests for [4 weeks][1 month]
[Stops existing infestation and prevents establishment of additional infestation of listed pests]
[[S][Small] (5 to 22 lbs)] [[M][Medium] (23-44lbs.)] [[L][Large] (45-88 lbs.)] [[XL][Extra Large] (89-132 lbs.)]
[[For Small Dogs 5-22 lbs.] [For Medium Dogs 23-44 lbs.] [For Large Dogs 45-88 lbs.] [For Extra Large Dogs
89-132 lbs.]]
[Direct to skin [tube][vial][applicator][pipette]]
[Direct to dog's skin [applicator][tube][vial][pipette]]
[Easy to Use] [tube][vial][applicator][pipette]]
[Clean cut [open] [tube][vial][applicator][pipette]]
[No-mess [open] [tube][vial][applicator][pipette]]
[Clip-tip design [tube][vial][applicator][pipette]!]
[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]
[Save Now!]
[Value Size]
[Club Size]
[Bonus Size]
[Club Pack]
[Great Value]
[Better Value]
[Bonus Pack]
[(x) + (x) bonus pack!]

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[Buy more and save!]

[Buy X Get Y Free]

[Buy 3 get 1 free]

[(x)% (More) (Free)!]

[33% more free]

[(x) Dose(s) Free!]

[(x) Day(s) (Free)!]

[(x) Month(s) Free!]

[(x) Day(s) of treatment- Free!]

[(x) Tube(s) Free!]

[(x) Applicator(s) Free!]

[(x) Application(s) Free!]

[Clip, Part, Squeeze]

[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]

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

ACTIVE INGREDIENT:

Fipronil..... 9.70%

OTHER INGREDIENTS: 90.30%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Insert] [Back][or][Side] [Label[s]] [Panel[s]] for Additional Precautionary Statements

Net Contents: X fl. oz. [Y – 0.0xx fl oz (x ml)] [tube] [vial] [applicator] [pipette]]

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]

OR {box only designates Vet Only language}

Net Contents: X fl oz X count [Y – X fl oz [tube][vial][applicator][pipette][s]]

[Thirty-five] 35[Fifty][50][Seventy-five][75][One hundred][100] [One hundred sixty 160]

[0.023 fl oz (0.67 mL)][0.045 fl oz (1.34 mL)][0.091 fl oz (2.68 mL)][0.136 fl oz (4.02 mL)]

[tube] [vial] [applicator] [pipette[s]]

{END - FRONT PANEL}

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BACK/SIDE PANEL

DOG SQUEEZE ON FIPRONIL

LC-2010-2 [or other approved alternate brand name] For Dogs
[Brand Name][This product] 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 5- 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. If your dog weighs more than 132 lbs., discuss dosing with your veterinarian.]
Do not use more than one tube/vial/pipette per dog 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 DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Do not allow your dog to ingest this product. Apply [Brand Name][This product] ONLY to dogs and puppies aged 8 weeks or older and 5–22 lbs. [23-44 lbs.] [45-88 lbs.] [89-132 lbs.], 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.

{Outer Packaging} {Drawing of pipette/vial/tube/applicator} {Drawing of treating animal}

How to apply:

1. Remove product {pipette/vial/tube/applicator} from the package
2. [Separate one {pipette/vial/tube/applicator} from the others.] Hold the {pipette/vial/tube/applicator} with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.
3. Part the dog's hair and place the tip of the {pipette/vial/tube/applicator} behind the neck and between the shoulders. Ensure that the entire application of [Brand Name][This product] is contained in a single spot on the dog's skin. Be sure to squeeze the {pipette/vial/tube/applicator} thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one {pipette/vial/tube/applicator} during each application. Do not touch the area where the application was made until it is dry.

[Brand Name][This product] also aids in the control of sarcoptic mange infestations.

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 [Brand Name][This product] for thirty (30) days.

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Side Effects: Monitor your dog 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 [LoradoChem or name of distributor] at 1-888-908-TICK.

{ 1.5 cm x 1.5 cm on final or as indicated }



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

©2013 LoradoChem, Inc. All rights reserved. [Made in USA]
(Drawing of telephone receiver) Questions? Comments? 1-888-908-TICK

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

[BAR CODE AREA][Lot code]
EPA Reg. No. 86230-2
EPA Est. No. [XXX-XX-XXX]

{END - BACK/SIDE PANEL}

TUBE/VIAL LABEL

DOG SQUEEZE ON FIPRONIL

{Front Label}

{Icon as indicated}

{Back Label}

{Brand Name} For Dogs [X-Y] lbs \geq 8 wks Fipronil 9.7% 0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or) 0.136 fl oz {label code}	 KEEP OUT OF REACH OF CHILDREN CAUTION: Read directions and precautions before using. Use scissors to open. EPA REG. No. 86230-2 {label code}
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{EPA REG No may be on either the front or back label}

{END - TUBE/VIAL LABEL}

PACKAGE INSERT

DOG SQUEEZE ON FIPRONIL

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

Only for use on dogs and puppies 8 weeks or older and 5-22 lbs. [23-44 lbs.] [45-88 lbs.] [89-132 lbs.]
[Brand Name][This product] is a topical application for fast action and lasting control of fleas, ticks, chewing lice and mosquitoes.

ACTIVE INGREDIENT:

Fipronil.....9.70%

OTHER INGREDIENTS:90.30%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[Brand Name][This product] 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, [Brand Name][This product] 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. [Brand Name][This product] also aids in the control of sarcoptic mange infestations.

Specifically, [Brand Name][This product] kills, controls and prevents infestations of:

- 1) Newly emerged adult fleas prior to egg-laying, including fleas which could cause flea allergy

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dermatitis;

- 2) Brown Dog tick, the American Dog tick, the Lone Star tick, and the Deer tick (including ticks that may transmit Lyme Disease);
- 3) Chewing lice infestations;
- 4) Kills mosquitoes.

[Brand Name][This product] 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 DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Do not allow your dog to ingest this product. Apply [Brand Name][This product] ONLY to dogs and puppies aged 8 weeks or older and 5-22 lbs. [23-44 lbs.] [45-88 lbs.] [89-132 lbs.], 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/vial/tube} {Drawing of treating animal}

1. Remove product {pipette/vial/tube/applicator} from the package
2. [Separate one {pipette/vial/tube/applicator} from the others.] Hold the {pipette/vial/tube/applicator} with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.
3. Part the dog's hair and place the tip of the {pipette/vial/tube/applicator} behind the neck and between the shoulders. Ensure that the entire application of [Brand Name][This product] is contained in a single spot on the dog's skin. Be sure to squeeze the {pipette/vial/tube/applicator} thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one {pipette/vial/tube/applicator} during each application. Do not touch the area where the application was made until it is dry.

[Brand Name][This product] also aids in the control of sarcoptic mange infestations.

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 [Brand Name][This product] for thirty (30) days.

Side Effects: Monitor your dog 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 [LoradoChem or name of distributor] at 1-888-908-TICK.

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{ 1.5 cm x 1.5 cm on final or as indicated }



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

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, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product.

OR {box only designates Vet Only language}

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat a dog with more than one pesticide product at a time. Over dosing a dog can result in serious illness and even death. Use caution before using on medicated, debilitated, aged, pregnant, nursing dogs or dogs with known organ dysfunction. If the dog is exhibiting signs of and/or is being treated for skin dermatitis, use caution before applying any topical flea and tick control product.

FIRST AID

If swallowed:	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a 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 eye. Call a poison control center or doctor for treatment advice.
If on skin:	Wash with plenty of soap and water. Get medical attention if irritation persists.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.

Physical or Chemical Hazards

Flammable: Keep away from heat and open flame.

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Application Options for Different Sizes of Dogs

[Brand Name][This product] comes in four different packages for different-sized dogs and puppies eight (8) weeks or older:

* 5 to 22 lbs.

* 23 to 44 lbs.

* 45 to 88 lbs.

* 89 to 132 lbs. If your dog weighs more than 132 lbs., discuss dosing with your veterinarian.]

Do not use more than one pipette/vial/tube per dog per month

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F [/][25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[**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]

[If you have questions or comments about this product, please write: [Sergeant's] [SENTRY] [LoradoChem, Inc.] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

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

[Distributed by:] [Manufactured by:]
LoradoChem, Inc.
10077 South 134th Street
Omaha, NE 68138 USA

[BAR CODE AREA][Lot code]
EPA Reg. No. 86230-2
EPA Est. No. [XXX-XX-XXX]

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{**END - Package Insert**}

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SUB LABEL – STICKERS FOR RE-APPLICATION REMINDERS DOG SQUEEZE ON FIPRONIL

LC-2010-2

[or other approved alternate brand name]

**For Dogs
Care Card**

Kills Fleas, Ticks, Chewing Lice, & Mosquitoes

{Picture of a Dog}

Month 1, Month 2, Month 3, Month 4, Month 5, Month 6

Drawing of paw
<hr/>
Date of Application

Place sticker on your calendar or refrigerator to remind yourself to apply [Brand Name][This product] to your dog

Pet's Name: lbs.

{END – SUB LABEL - STICKERS}