



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 27, 2017

Michelle Foster
Associate Manager, Regulatory Affairs
Research & Development/Virbac Corporation
3200 Meacham Boulevard
Fort Worth, TX 76137

Subject: Label Amendment – Clarifications to Directions for Use and various revisions
Product Name: Effipro Plus Topical Solution for Cats
EPA Registration Number: 2382-188
Application Date: 12-Dec-16
Decision Number: 524878

Dear Ms. Foster:

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, you may contact Julie Breeden-Alemi at 703-347-0511 or via email at Breeden-Alemi.Julie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to be '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

Master Label

[Optional Text Appears In Brackets. The final label may include some or all of the optional text on the front, back, side panels, or insert.]

Front Panel and Insert [Back Panel] [Side Panel]

Virbac logo

EFFIPRO Plus™ Topical Solution for Cats

(Note to reviewer: font size of Cats will be 40% of the size of the largest letter in the brand name on the front panel)

Front Panel- Large, clear picture of a cat in the appropriate weight range for the product as packaged

FOR USE ONLY ON CATS AND [&] KITTENS 8 WEEKS OLD OR OLDER WEIGHING 1.5 LBS AND OVER

ACTIVE INGREDIENTS

Fipronil..... 9.58%

Pyriproxyfen..... 11.65%

OTHER INGREDIENTS..... 78.77%

TOTAL..... 100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

Front Panel- See Back Panel for First Aid and Additional Precautionary Statements

See Insert for Directions for Use

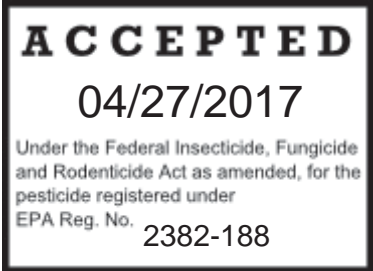
(OR)

See Back Panel for First Aid, Additional Precautionary Statements and Directions for Use

Front Panel

3 Applicators

[Net Contents:] 0.051 fl oz (1.5 mL), 3- 0.017 fl oz (0.5 mL) applicators



Back Panel and Insert

READ ENTIRE LABEL BEFORE EACH USE PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed or absorbed through the skin. Causes moderate 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 cats ONLY. Do not use on cats or kittens less than 8 weeks of age, weighing less than 1.5 lbs. Individual sensitivities, while rare, may occur after using ANY pesticide product. Cats may experience some possible temporary irritation at the site of product application. If signs of sensitivity occur bathe your cat with mild soap and shampoo and rinse with large amounts of water. If signs continue, contact a veterinarian immediately. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant, or nursing cats, or cats known to be sensitive to pesticide products.

FIRST AID	
IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or 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	<ul style="list-style-type: none"> • 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 OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
<p>Have product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including human and veterinary health concerns, medical emergencies or pesticide incidents), you may call 1-800-338-3659, twenty-four (24) hours per day, seven (7) days per week.</p>	

(Note to reviewer: A box labeled "Side Effects" will be placed in the lower right hand corner of the back panel.)

Side Effects: Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or contact Virbac at 1-800-338-3659.

Insert [Back Panel]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. **FOR EXTERNAL USE ON CATS AND KITTENS ONLY.** For use ONLY on CATS and KITTENS 8 weeks old or older weighing at least 1.5 lbs. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

RESTRICTIONS

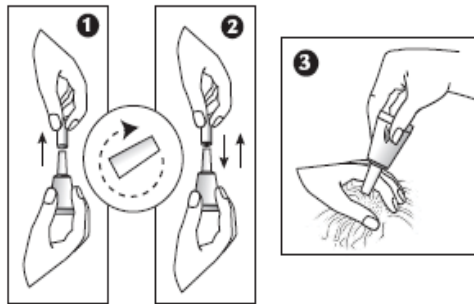
Do not use on cats or kittens less than 8 weeks of age weighing less than 1.5 lbs. Do not allow children to apply product. DO NOT USE ON DOGS, PUPPIES, OR RABBITS. DO NOT USE ON OTHER ANIMALS. Do not allow your cat to ingest this product. Do not apply more than one applicator to one cat per treatment regardless of the cat's weight. Do not apply more often than once a [per] month. In multiple cat households, do not allow cats to groom each other until the product has dried. Do not allow contact with treated area until completely dry. Do not bathe your cat within the first 24 hours after the product has been applied.

To kill fleas, flea eggs, flea larvae, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks [that may transmit Lyme disease], [mosquitoes], and chewing lice; apply as follows:

APPLICATION DIRECTIONS

1. Remove one applicator from packaging. Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip. Push cap down to break seal. Remove cap prior to treatment application.
3. Part cat's hair between shoulder blades until skin is visible. Place applicator tip directly against exposed skin. Deposit entire contents by squeezing the applicator at a single site on cat's skin.

Ensure that EFFIPRO PLUS™ Topical Solution for Cats is not applied superficially on cat's hair.



Insert

FREQUENCY OF APPLICATION

[EFFIPRO PLUS™ Topical Solution for Cats] [will kill] [Kills] fleas, ticks and chewing lice when applied monthly.

Fleas: [EFFIPRO PLUS Topical Solution for Cats] [can control][Controls] fleas [for] up to six weeks. Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis [(FAD)], or if reinfestation is likely. [EFFIPRO PLUS Topical Solution for Cats] [can control][Controls] flea eggs and larvae for up to three months [90 days].

Ticks: [EFFIPRO PLUS Topical Solution for Cats] [can kill][Kills] ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewing Lice: [EFFIPRO PLUS Topical Solution for Cats] [can kill][Kills] chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

[Mosquitoes:] When applied monthly, [EFFIPRO PLUS Topical Solution for Cats] [can kill][Kills] mosquitoes within 48 hours (for up to 28 days).]

Back Panel or Bottom Panel and Insert

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container.

If empty: Place in trash or offer for recycling. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[Back Panel] [Bottom Panel] [Insert]

[LIMITED WARRANTY AND DISCLAIMER

VIRBAC warrants this product only if it is used, stored and handled in accordance with the label instructions. The buyers and users are solely responsible for all risks of use and handling of this product when such use and handling are contrary to or differ from the label instructions. To the extent permitted by applicable law, any damages arising from a breach of this warranty shall be limited to direct damages only and shall not include any type of consequential damages.]

Insert

[Detachable calendar monthly application reminder stickers with illustration of cat or kitten]

**Back Panel and Insert**

EPA Reg. No. 2382-188

EPA Est. No. [2382-FRA-1] [47420-DEU-1]

Virbac AH, Inc.
 PO Box 162059
 Fort Worth, TX 76161
 1-800-338-3659
 Made in France
 [Questions or comments? Call: 1-800-338-3659]

Insert

© 2017 Virbac Corporation. All Rights Reserved. EFFIPRO PLUS™ is a trademark of Virbac S.A.

Foil of Blister package

Virbac logo

EFFIPRO PLUS™ Topical Solution for Cats

Only for use on cats & kittens ≥ 8 wks and [&] ≥ 1.5 lbs

0.017 fl oz [0.5 mL]

Contains fipronil (9.58%) and [&] pyriproxyfen (11.65%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-188

Applicator

Virbac logo

EFFIPRO PLUS™ Topical Solution for Cats

Only for use on cats & kittens ≥ 8 wks and [&] ≥ 1.5 lbs

0.017 fl oz [0.5 mL]

Contains fipronil (9.58%) and [&] pyriproxyfen (11.65%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-188

EPA Est. No. [2382-FRA-1]

OPTIONAL MARKETING CLAIMS- ALTERNATE VARIATIONS APPEAR IN BRACKETS

The final label may include some or all of the optional text within each claim.

Multiple infestations

- [For] [convenient], [quick-acting], [long-lasting], [effective] control of [fleas], [flea eggs], [flea larvae], [ticks], [mosquitoes] [and] [chewing] [lice]
- [For] [convenient], [quick-acting], [long-lasting], [effective] control of [fleas], [ticks], [mosquitoes] [and] [chewing] [lice]
- [EFFIPRO PLUS™ Topical Solution for Cats] contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, [mosquitoes] and chewing lice
- [EFFIPRO PLUS™ Topical Solution for Cats] contains the active ingredient pyriproxyfen, which controls reinfestation caused by flea eggs and flea larvae
- Persistent flea and tick efficacy for up to one month [4 weeks] [30 days]
- Prevents flea and tick [re] infestation for up to one month [4 weeks]
- Effective monthly application for fleas and ticks
- Effective monthly application against fleas and ticks
- Kills fleas and ticks for up to one month [4 weeks]
- Kills fleas, ticks, [mosquitoes] and [chewing] lice
- Kills fleas, ticks and lice
- Kills fleas, flea eggs, flea larvae, [and] ticks, [mosquitoes] and [chewing] lice
- Apply monthly for control and prevention of fleas and ticks
- Protects against fleas and ticks for up to one month
- EFFIPRO PLUS™ Topical Solution for Cats will kill fleas, ticks and chewing lice when applied monthly

Fleas

- **Fleas:** [EFFIPRO PLUS™ Topical Solution for Cats] [can control][Controls] fleas for up to six weeks. Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis [(FAD)], or if reinfestation is likely. [EFFIPRO PLUS Topical Solution for Cats] [can control][Controls] flea eggs and larvae for up to three months [(90 days)].
- Kills newly emerged adult fleas prior to egg-laying
- Kills fleas that may transmit [bartonellosis], [tularemia] [and] [tapeworm] [infestations]
- Kills [fleas], [flea eggs] [and] [flea larvae]
- Prevents development of all flea stages [flea eggs, flea pupae and flea larvae] for up to [3 months] [90 days]
- Kills flea eggs for up to [3 months] [90 days]
- Sterilizes and kills fleas
- Sterilizes fleas for up to [3 months] [90 days]
- Prevents all flea stages [adult fleas, flea eggs, flea pupae and flea larvae]
- Prevents development of all flea stages [flea eggs, flea pupae and flea larvae] for up to [3 months] [90 days]
- With pyriproxyfen (IGR)* to break flea life cycle [*insect growth regulator]
- Dual Action[!]: fipronil and pyriproxyfen [IGR] effectively breaks the flea life cycle
- Kill fleas that may cause Flea Allergy Dermatitis [(FAD)] or flea-bite anemia
- Effective monthly control of adult fleas
- Kills fleas
- Easy to apply, control of fleas that lasts for up to 1 month [4 weeks]
- Protects your cat from fleas for up to one month [4 weeks]
- Protects from fleas for up to one month [4 weeks]
- Kills adult fleas for up to one month [4 weeks]
- Apply monthly [all year] for control and prevention of fleas
- Regular [monthly] use breaks the flea life cycle
- EFFIPRO PLUS™ Topical Solution for Cats [rapidly] kills fleas that may cause Flea Allergy Dermatitis [(FAD)]
- EFFIPRO PLUS™ Topical Solution for Cats kills fleas on your cat
- Kills adult fleas that may cause Flea Allergy Dermatitis [(FAD)]
- Kills fleas that may cause flea-bite anemia
- Fleas do not have to bite to die
- Protects your cat from flea infestations that may cause flea-bite anemia
- The successive feeding activity of fleas on cats may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis [(FAD)]
- Protects cats [and kittens 8 weeks old or older weighing 1.5 lbs and over] from fleas for up to one month [4 weeks]
- Prevents flea [re] infestation for up to one month [4 weeks]
- Prevents flea eggs from hatching or developing into larvae or adult stages for up to [90 days] [3 months]

Ticks

- Ticks: [EFFIPRO PLUS™ Topical Solution for Cats] [can kill][Kills] ticks for a month or longer. Apply monthly where tick control is consistently needed.
- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks [including those that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, anaplasmosis and cytauxzoonosis]
- Kills all stages of the Deer tick that may transmit Lyme disease
- Kills ticks, including those that may transmit Lyme disease
- Kills ticks including Deer ticks [that may transmit Lyme disease], American dog ticks [that may transmit Rocky Mountain Spotted Fever], Brown dog ticks [that may transmit ehrlichiosis], and Lone Star ticks [that may transmit hepatozoonosis] for up to one month [4 weeks]
- Kills ticks including Deer ticks [that may transmit Lyme disease], American dog ticks [that may transmit Rocky Mountain Spotted Fever] and Brown dog ticks [that may transmit ehrlichiosis] for up to one month [4 weeks]
- Kills Brown dog ticks [*Rhipicephalus spp.*], American dog ticks [*Dermacentor variabilis*], Deer ticks [*Ixodes spp.*], and Lone Star ticks [*Amblyomma americanum*] for up to one month [4 weeks]
- Kills Lone Star ticks [*Amblyomma americanum*] for up to 4 weeks [for up to one month]
- Protects cats [and kittens 8 weeks old or older weighing 1.5 lbs and over] from ticks for up to one month
- Kills ticks

Mosquitoes

- Mosquitoes: When applied monthly, [EFFIPRO PLUS™ Topical Solution for Cats] [can kill][Kills] mosquitoes within 48 hours (for up to 28 days).
- Kills mosquitoes
- Kills mosquitoes for up to 28 days

Lice

- Chewing Lice: [EFFIPRO PLUS™ Topical Solution for Cats] [can kill][Kills] chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.
- Chewing lice infestations are rapidly eliminated
- Kills lice

All others

- For use only on cats and kittens 8 weeks old or older weighing 1.5 lbs and over
- Begins working upon application
- Once monthly application
- Single application lasts up to 4 weeks [one month]
- Easy and convenient application [applications]
- Easy to apply spot-on [topical] application
- Convenient, easy to apply
- Convenient to use [easy to apply]
- Convenient to use [easy to apply] topical application

- Convenient topical application [for cats]
- Easy, spot-on [topical] application
- Quick-drying, non-greasy
- Remains effective after exposure to sunlight
- Remains effective after bathing
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Remains effective even after bathing
- Remains effective after exposure to rain and sunlight
- Still works after bathing, or exposure to sunlight
- EFFIPRO PLUS™ Topical Solution for Cats is effective after bathing, shampooing, water immersion, or sunlight exposure.
- Still works after exposure to sunlight
- Waterproof [remains effective after bathing and swimming]
- Waterproof
- Illustration of flea life cycle
- Illustration of flea
- Illustration of tick
- Picture or illustration of a cat or kitten in weight range of product as packaged