



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 26, 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 Dogs
EPA Registration Number: 2382-189
Application Date: 12-Dec-16
Decision Number: 524877

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 Dogs

(Note to reviewer: font size of Dogs 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 dog in the appropriate weight range for the product as packaged

**FOR USE ONLY ON DOGS AND [&] PUPPIES 8 WEEKS OLD OR OLDER WEIGHING [5 TO [-] 22.9][23 TO [-] 44.9]
[45 TO [-] 88.9] [89 TO [-] 132] LBS**

ACTIVE INGREDIENTS

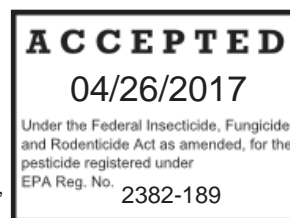
Fipronil.....	9.78%
Pyriproxyfen.....	2.94%
OTHER INGREDIENTS	87.28%
TOTAL	100.00%

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- (Note to reviewer: A 1.5 cm x 1.5 cm cat prohibition icon in a box will be located in the lower right hand corner of the front panel in yellow with black images.)



Front Panel

3 Applicators
[Net Contents:] [0.069][0.135][0.273][0.408] fl oz ([2.01][4.02][8.04][12.06] mL),
3-[0.023][0.045][0.091][0.136] fl oz ([0.67][1.34][2.68][4.02] 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 dogs ONLY. Do not use on dogs or puppies less than 8 weeks of age, weighing less than [5][23][45][89] lbs. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. If your dog 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 on medicated, debilitated, aged dogs, or dogs 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.

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.

(Note to reviewer: A box labeled "Side Effects" will be placed immediately above the cat warning box on the back panel.)

Side Effects: Monitor your dog 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.

Back panel-Lower right hand corner (Note to reviewer: Do not use on cats pictogram will be A 1.5 cm x 1.5 cm cat prohibition icon and warning text box will be located at the lower right hand corner of the back panel in yellow with black images and text.)

Insert- front page



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 immediately.

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 DOGS AND PUPPIES ONLY.** For use ONLY on DOGS and PUPPIES 8 weeks old or older weighing at least [5][23][45][89] lbs. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

RESTRICTIONS

Do not use on dogs or puppies less than 8 weeks of age weighing less than [5][23][45][89] lbs. Do not allow children to apply product. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS. Do not allow your dog to ingest this product. Do not split applicators between dogs. Do not apply more than one applicator to one dog per treatment regardless of the dog's weight. Do not use on pregnant or lactating dogs. Do not apply more often than once a [per] month [every 30 days]. Do not allow contact with treated area until completely dry. Do not bathe your dog 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:

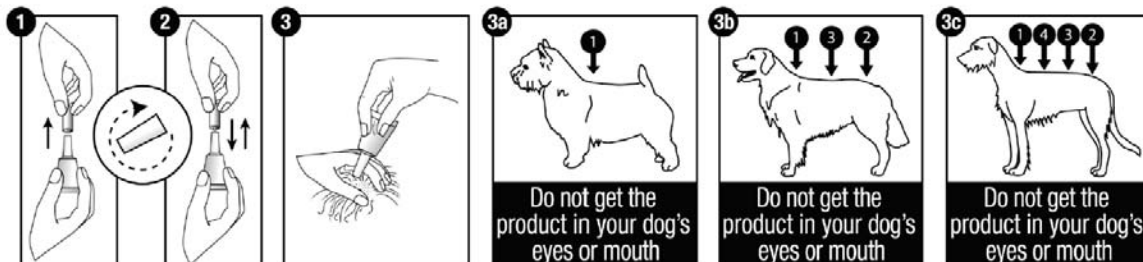
APPLICATION DIRECTIONS

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 dog's hair between shoulder blades until skin is visible. Place applicator tip directly against exposed skin.

(Note to reviewer: there will be a separate insert for each SKU. The appropriate application directions and image (3a, 3b or 3c) will be included for the corresponding weight range of the dog.)

- 3a. **For use only on small dogs and puppies 8 weeks old or older weighing 5 to [-] 22.9 lbs-** Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. **For use only on medium dogs and puppies 8 weeks old or older weighing 23 to [-] 44.9 lbs-** Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3b. **For use only on large dogs and puppies 8 weeks old or older weighing 45 to [-] 88.9 lbs-** Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. **For use only on extra-large dogs and puppies 8 weeks old or older weighing 89 to [-] 132 lbs-** Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty.

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



Insert

FREQUENCY OF APPLICATION

Flea, tick and chewing lice infestations can be controlled with monthly applications of EFFIPRO PLUS™ Topical Solution for Dogs.

Fleas: Kills adult fleas for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis [(FAD)], or if reinfestation is likely. Controls flea eggs for up to [three months] 12 weeks [90 days].

Ticks: Kills ticks for up to a month. Apply monthly where tick control is consistently needed.

Chewing Lice: Kills chewing lice for up to a month. Apply monthly where chewing lice control is consistently needed.

[Mosquitoes: When applied monthly, 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 dog or puppy]



Back Panel and Insert

EPA Reg. No. 2382-189

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

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Foil of Blister package

Virbac logo

EFFIPRO PLUS™ Topical Solution for Dogs

Only for use on dogs & puppies ≥ 8 wks and [5 to [-] 22.9] [23 to [-] 44.9] [45 to [-] 88.9] [89 to [-] 132] lbs

[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]

Contains fipronil (9.78%) and [&] pyriproxyfen (2.94%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

DO NOT USE ON CATS

CAT PROHIBITION ICON

EPA Reg. No. 2382-189

Applicator

Virbac logo

EFFIPRO PLUS™ Topical Solution for Dogs

Only for use on dogs & puppies ≥ 8 wks and [5 to [-] 22.9] [23 to [-] 44.9], [45 to [-] 88.9], [89 to [-] 132] lbs

[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]

Contains fipronil (9.78%) and [&] pyriproxyfen (2.94%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

DO NOT USE ON CATS

CAT PROHIBITION ICON

EPA Reg. No. 2382-189

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

EPA Reg. No. 2382-189

April 21, 2017

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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], [ticks], [mosquitoes] and [chewing lice]
 - [For] [convenient], [quick-acting], [long-lasting], [effective] control of [fleas], [flea eggs], [flea larvae], [ticks], [mosquitoes] and [chewing lice]
 - [EFFIPRO PLUS™ Topical Solution for Dogs] contains the active ingredient fipronil, which controls infestations caused by [fleas], [ticks], [mosquitoes] and [chewing lice] on dogs or puppies 8 weeks old or older weighing [5 to 22.9] [23 to 44.9] [45 to 88.9][89 to 132] [lbs]
 - [EFFIPRO PLUS™ Topical Solution for Dogs] contains the active ingredient pyriproxyfen, which controls [re]infestations caused by flea eggs and flea larvae on dogs or puppies 8 weeks old or older [weighing [5 to 22.9][23 to 44.9][45 to 88.9][89 to 132] lbs]
 - [For] [easy] and [convenient] application, EFFIPRO PLUS™ Topical Solution for Dogs is available in sizes for small dogs or puppies 8 weeks old or older weighing 5 to 22.9 lbs [(0.023 fl oz)] [(0.67 mL)], medium dogs or puppies 8 weeks old or older weighing 23-44.9 lbs [(0.045 fl oz)] [(1.34 mL)], large dogs or puppies 8 weeks old or older weighing 45-88.9 lbs [(0.091 fl oz)] [(2.68 mL)], and extra-large dogs or puppies 8 weeks old or older weighing 89-132 lbs [(0.136 fl oz)] [(4.02 mL)]
 - Persistent flea and tick efficacy for up to one month [4 weeks]
 - Prevents flea and tick [re-]infestation for up to one month [4 weeks]
 - Kills fleas and ticks for up to one month [4 weeks]
 - Apply monthly for control and prevention of fleas and ticks
 - Kills fleas and ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, bartonellosis and hepatozoonosis
 - Kills fleas, [flea eggs, flea larvae], [ticks], [mosquitoes] and [chewing lice]
 - Kills fleas, [flea eggs, flea larvae], [ticks], [mosquitoes] and [lice]
 - Kills fleas, ticks and lice
 - Effective monthly control of fleas and ticks
 - Effective monthly application for fleas and ticks
 - Effective monthly application for dogs against fleas and ticks
 - Single application kills fleas and ticks
 - Single application lasts 4 weeks [one month]
 - Flea, tick and chewing lice infestations can be controlled on dogs with monthly application[s] [of EFFIPRO PLUS™ Topical Solution for Dogs].
- Fleas:** [EFFIPRO PLUS™ Topical Solution for Dogs can kill] [Kills] adult fleas, flea eggs and flea larvae for up to three months [90 days] [3 months] [12 weeks]. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely.
- Ticks:** [EFFIPRO PLUS™ Topical Solution for Dogs [can kill] [Kills] ticks for up to a month. Apply monthly where tick control is consistently needed.
- Chewing Lice:** [EFFIPRO PLUS™ Topical Solution for Dogs [can kill] [Kills] chewing lice for up to a month. Apply monthly where chewing lice control is consistently needed.
- Mosquitoes:** When applied monthly, [EFFIPRO PLUS™ Topical Solution for Dogs] [can kill] [Kills] mosquitoes within 48 hours (for up to 28 days))

Fleas

- Kills newly emerged adult fleas prior to egg laying
- Kills fleas, flea eggs and flea larvae
- Sterilizes and kills [adult] fleas
- 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
- Kills fleas that may transmit bartonellosis
- Kills fleas that may transmit [bartonellosis], [tularemia] [and] [tapeworm]
- Kills fleas that may transmit [bartonellosis], [tularemia] [and] [tapeworm infestations]
- Kills fleas that may cause Flea Allergy Dermatitis [(FAD)] or flea-bite anemia
- Effective monthly application against fleas
- Effective monthly control of fleas
- Kills adult fleas for up to one month [4 weeks]
- Kills fleas
- Easy to apply, control of [for] fleas that lasts [1 month] [4 weeks]
- Easy to apply, flea control that lasts up to [1] [one] [month] [4 weeks]
- EFFIPRO PLUS™ Topical Solution for Dogs kills fleas on your dog
- 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
- EFFIPRO PLUS™ Topical Solution for Dogs rapidly kills fleas that may cause FAD [(Flea Allergy Dermatitis)]
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis [(FAD)]
- Prevents flea eggs from hatching or developing into larvae or adult stages [for up to] [90 days] [12 weeks] [3 months]
- For the control and prevention of flea, flea egg, flea pupae, flea larvae, [and lice] infestations
- Effective against all stages of the flea life cycle
- Kills adult fleas, flea eggs, and flea larvae for up to three months [12 weeks], however, if your dog is susceptible to Flea Allergy Dermatitis [(FAD)] it is recommended to use monthly
- Kills fleas, flea eggs, and flea larvae

- One application prevents further flea infestations for up to 12 weeks [three months]. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis [(FAD)], or if reinfestation is likely.
- Stops existing flea infestations by killing adult fleas, flea eggs, and flea larvae

Ticks

- 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 and anaplasmosis]
- 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 [one month]
- Effective monthly application against ticks

Mosquitoes

- Kills mosquitoes
- Kills mosquitoes for up to 28 days

Lice and Mites

- EFFIPRO PLUS™ Topical Solution for Dogs aids in [the] control of sarcoptic mange mite infestations
- Aids in [the] control of sarcoptic [mange] [mite] infestations
- Aids in [the] control of sarcoptic mites
- Elimination of sarcoptic mange mites may require multiple monthly applications
- Chewing lice infestations are rapidly eliminated

All others

- For Use on Dogs ONLY
- Use ONLY on dogs
- May be used on puppies from 8 weeks of age weighing at least 5 lbs.
- Only for dogs and puppies 8 weeks old or older weighing [5 to 22.9] [23 to 44.9] [45 to 88.9] [89 to 132] lbs
- Easy, spot-on [topical] application
- Convenient topical application for dogs
- Easy to apply spot-on [topical] application
- [Quick-drying], [non-greasy]
- [Convenient], [easy to apply]
- Easy and convenient application[s]
- Convenient to use [easy to apply]
- Once monthly application
- Single application lasts up to 4 weeks [1 month] [one month]
- Remains effective after exposure to sunlight
- Remains effective after bathing and swimming
- 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, swimming or exposure to sunlight
- Still works after exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- EFFIPRO PLUS™ Topical Solution for Dogs is effective after bathing, shampooing, water immersion, or sunlight exposure
- Waterproof [remains effective after bathing and swimming]
- Waterproof
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog or puppy in weight range of product as packaged
- Picture or illustration of the Virbac logo
- Picture or illustration of the primary package applicator