



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 12, 2018

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

Subject: Label Amendment – submitted with registration extension  
Product Name: EFFIPRO Topical Solution for Dogs  
EPA Registration Number: 2382-185  
Application Date: 15-Jan-2018  
Decision Number: 537708

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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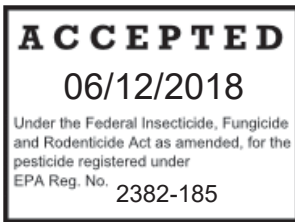
with FIFRA section 6. If you have any questions, you may contact Dr. Breeden-Alemi at 703-347-0511 or via email at [Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov).

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



Front Panel and Insert [Back Panel] [Side Panel]  
 [Optional Text Appears In Brackets]

# EFFIPRO<sup>®</sup> 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}

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

<b>ACTIVE INGREDIENT</b>	
Fipronil .....	9.6%
<b>OTHER INGREDIENTS</b> .....	90.4%
<b>TOTAL</b> .....	100.0%

Large, clear picture of a dog in the appropriate weight range for the product as packaged

## KEEP OUT OF REACH OF CHILDREN CAUTION

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

**Front Panel-** {Note to reviewer: A 1.5 x 1.5 cm cat prohibition icon in a box will be 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. 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.** Do not use on puppies under 8 weeks of age, weighing less than [5][23][45][89] lbs. Individual sensitivities, while rare, may occur after using ANY pesticide product. Possible temporary irritation may occur at the site where EFFIPRO<sup>®</sup> Topical Solution for Dogs was applied. If signs of sensitivity occur, bathe your dog with mild soap or shampoo and rinse with large amounts of water. If signs continue, contact 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 or aged dogs, or dogs known to be sensitive to pesticide products. This product is not a substitute for prescribed heartworm preventative.

FIRST AID	
<b>IF SWALLOWED</b>	<ul style="list-style-type: none"> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
<b>IF IN EYES</b>	<ul style="list-style-type: none"> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF ON SKIN OR CLOTHING</b>	<ul style="list-style-type: none"> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents twenty-four (24) hours per day, seven (7) days per week.	

{Note to reviewer: A box labeled "Side Effects" will be immediately above the cat warning box in the lower right hand corner of 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: A 1.5 cm x 1.5 cm cat prohibition icon and warning text will be in a box in 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**

#### **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 of age 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. Do not bathe your dog within the first 24 hours after the product has been applied. 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 under 8 weeks of age, weighing less than [5][23][45][89] lbs. Do not allow children to apply product. **DO NOT USE ON CATS, KITTENS, 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 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, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may [which may] transmit [carry] Lyme disease), mosquitoes and chewing lice; apply only to dogs or puppies as follows:

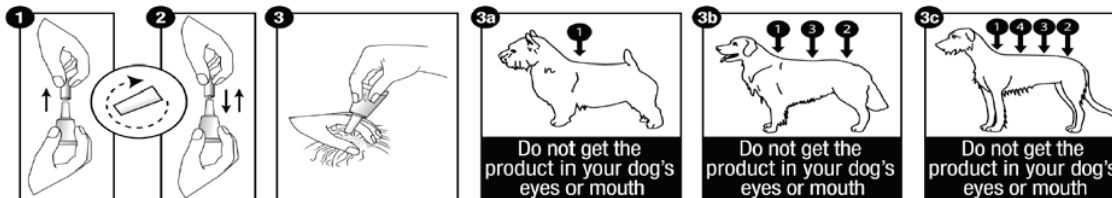
#### **APPLICATION DIRECTIONS**

Your dog must be dry at the time of application and remain dry for 24 hours after application. Ensure that EFFIPRO® Topical Solution for Dogs is not applied superficially on dog's hair.

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.

(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 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.



**Insert**

#### **FREQUENCY OF APPLICATION**

Flea, tick and chewing lice infestations can be controlled with monthly applications of EFFIPRO® Topical Solution for Dogs.  
**Fleas:** EFFIPRO® Topical Solution for Dogs can kill 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.  
**Ticks:** EFFIPRO® Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.  
**Chewing Lice:** EFFIPRO® Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.  
**Mosquitoes:** When applied monthly, EFFIPRO® Topical Solution for Dogs can kill mosquitoes within 48 hours (for up to 28 days).

**Back Panel**

**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.

**Insert**

**[LIMITED WARRANTY AND DISCLAIMER**

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risks of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.]

[Detachable calendar monthly application reminder stickers with illustration of dog or puppy]

**Back Panel and Insert**

EPA Reg. No. 2382-185

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

VIRBAC AH, INC.  
PO BOX 162059  
FORT WORTH, TX 76161  
1-800-338-3659

Made in France  
EFFIPRO® is a registered trademark of Virbac S.A.  
Questions or comments?  
Call: 1-800-338-3659

**{Text for Foil of Blister package}**

*{Virbac logo}*

EFFIPRO® Topical Solution for Dogs

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

0.023 fl oz [0.67 mL] {or} 0.045 fl oz [1.34 mL] {or} 0.091 fl oz [2.68 mL] {or} 0.136 fl oz [4.02 mL]

Contains fipronil (9.6%)

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See full label for additional directions

EPA Reg. No. 2382-185

**DO NOT USE ON CATS**

{CAT PROHIBITION ICON}

**{Text for Applicator}**

*{Virbac logo}*

EFFIPRO® Topical Solution for Dogs

Only for use on dogs ≥ 8 wks &

5-22.9 lbs [23-44.9 lbs] [45-88.9 lbs] [89-132 lbs]

0.023 fl oz [0.67 mL] {or} (0.045 fl oz [1.34 mL]{or} 0.091 fl oz

[2.68 mL]{or} 0.136 fl oz [4.02 mL])

Contains fipronil (9.6%)

**KEEP OUT OF REACH**

**OF CHILDREN**

**CAUTION**

See full label for additional directions

EPA Reg. No. 2382-185

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

**DO NOT USE ON CATS**

{CAT PROHIBITION ICON}

{Lot number}

**OPTIONAL MARKETING CLAIMS**

**[Multiple infestations]**

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- **For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice.**
  - EFFIPRO® 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 lbs], [23 to 44.9 lbs], [45 to 88.9 lbs], [89 to 132 lbs].
  - **For easy and convenient application, EFFIPRO® Topical Solution for Dogs is available in sizes for small dogs and puppies 8 weeks old or older and 5 to 22.9 lbs (0.023 fl oz) [(0.67 mL)], medium dogs 23-44.9 lbs (0.045 fl oz) [(1.34 mL)], large dogs 45-88.9 lbs (0.091 fl oz) [(2.68 mL)], and extra-large dogs 89-132 lbs (0.136 fl oz) [(4.02 mL)].**
  - EFFIPRO® Topical Solution for Dogs is also approved for control of flea, tick, mosquito and chewing lice infestations in breeding, pregnant and lactating bitches.
  - 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 and ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, and bartonellosis.
  - Kills fleas, ticks, mosquitoes and chewing 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 with monthly applications of EFFIPRO® Topical Solution for Dogs.
- Fleas:** EFFIPRO® Topical Solution for Dogs can kill 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.
- Ticks:** EFFIPRO® Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.
- Chewing Lice:** EFFIPRO® Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.
- Mosquitoes:** When applied monthly, EFFIPRO® Topical Solution for Dogs can kill mosquitoes within 48 hours (for up to 28 days).

#### [Fleas]

- Kills newly emerged adult fleas prior to egg laying
- Kills fleas that may transmit bartonellosis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit diseases, including bartonellosis, tularemia and tapeworm infestations.
- Kills fleas that may transmit diseases, including bartonellosis and tularemia
- 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)
- East to apply, flea control that lasts up to 1 (one) month (4 weeks)
- EFFIPRO® Topical Solution for Dogs kills fleas on your dog
- Kills adult fleas which may cause Flea Allergy Dermatitis (FAD)
- Kills fleas which (that) may cause flea-bite anemia
- Fleas do not have to bite to die
- EFFIPRO® 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)

#### [Ticks]

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (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 *Amblyomma americanum* (Lone Star ticks) for 4 weeks (for up to one month).
- Effective monthly application against ticks

#### [Mosquitoes]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days

#### [All others]

- EFFIPRO® Topical Solution for Dogs aids in (the) control of mite infestations that may cause sarcoptic mange.
- Control of mites may require multiple monthly applications.
- Chewing lice infestations are rapidly eliminated
- Can be used on breeding, pregnant and lactating bitches
- Only for dogs and puppies 8 weeks old or older weighing [5 to 22.9 lbs], [23 to 44.9 lbs],[45 to 88.9 lbs], [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 (applications)
- Convenient to use (easy to apply)
- Once monthly application
- Single application lasts 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® Topical Solution for Dogs is effective after bathing, shampooing, water immersion, or sunlight exposure.
- Waterproof (remains effective after bathing and swimming)