



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

2382-185

Date of Issuance:

4/15/16

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
Expires: 4/15/2018

Name of Pesticide Product:

EFFIPRO Topical Solution for
Dogs

Name and Address of Registrant (include ZIP Code):

Michelle Foster
Virbac AH, Inc.
3200 Meacham Boulevard
Fort Worth, TX 76137

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Kable Bo Davis, Product Manager 3
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)

Date:

4/15/16

2. The Agency has found your company to be in compliance with the terms and conditions for the subject product, and is extending the two-year registration restriction. This registration is time-limited and expires 4/15/2018.
3. Please note that the product is still subject to all other previously required conditions of registration. Your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information as stated in an Agency letter dated 1/14/11.
4. You are required to comply with the data requirements described in the DCI Order identified below:
 - a. Fipronil GDCI-129121-1305
 - b. Fipronil GDCI-129121-152

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: <http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

5. Submit one copy of the final printed label for the record before you release the product for shipment.

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.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 10/25/2010
- Alternate CSF 1 dated 10/25/10

If you have any questions, you may contact Julie Breeden at 703-347-0511 or via email at Breedden.Julie@epa.gov.

Enclosure

Front Panel

Optional Text Appears In Brackets

EFFIPRO[®] Topical Solution for Dogs

(Note: 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, WEIGHING 23 TO 44.9 LBS, WEIGHING 45 TO 88.9 LBS, WEIGHING 89 TO 132 LBS)

ACTIVE INGREDIENT

Fipronil9.6%

OTHER INGREDIENTS

90.4%

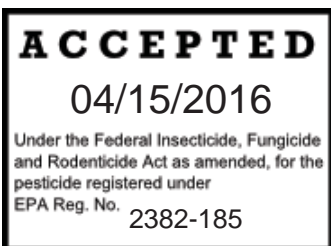
TOTAL

100.0%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

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

See [Back][or][Side] [Label[s]] [Panel[s]] for First Aid and Additional Precautionary Statements



Symbol on Front Panel (lower right hand corner)
(Note: Do not use on cats pictogram will be 1.5 x 1.5 cm)



[Net Contents:] 1, 3, 6 or 36 [single-dose] [applicator(s)] [application(s)] [per package] [Each applicator] [contains] (total #) fl oz (X mL), (# tubes)-(X fl oz (X mL) [applicators]
0.023 fl oz (0.67 mL), 0.045 fl oz (1.34 mL), 0.091 fl oz (2.68 mL), or 0.136 fl oz (4.02 mL) [of solution].

Back Panel

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 lbs. Individual sensitivities, while rare, may occur after using ANY pesticide product. Possible temporary irritation may occur at the site where EFFIPRO[®] Topical Solution for Dogs was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs.

Back Panel (single presentation on insert)

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. You may also contact the Hotline number 1-800-338-3659 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.</p>	

Back Panel (lower right hand corner)

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 [Registrant at 1-800-number].

Back Panel (lower right hand corner)



Note: Do not use on cats pictogram will be 1.5 x 1.5 cm (Must be yellow box with black text)

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.

SEE PACKAGE INSERT FOR PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE

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 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

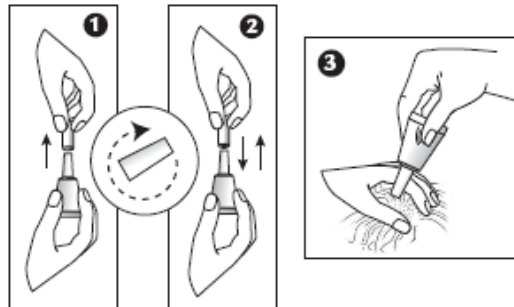
Do not use on dogs or puppies under 8 weeks of age, weighing less than 5 lbs. Do not allow children to apply product. DO NOT USE ON CATS, KITTENS, OR RABBITS. DO NOT USE ON OTHER ANIMALS.

Do not allow your dog to ingest this product. Do not split tubes between dogs. Do not double-dose or apply more than one tube on dogs weighing more than 132 lbs. Do not apply more often than once a [per] month [every 30 days]. Do not allow contact with treated area until completely dry.

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

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.
Deposit entire contents by squeezing the applicator at a single site on dog's skin.
Ensure that EFFIPRO® Topical Solution for Dogs is not applied superficially on dog's hair.



Insert

FREQUENCY OF APPLICATION

Research has shown that flea, tick and chewing lice infestations can be completely 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 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO® Topical Solution for Dogs. Avoid contact with treated area until dry.

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Back Panel (single presentation on 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.

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.]

How supplied: 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).

Net Contents:

1, 3, 6 or 36 single-dose applicator(s) per package. Each applicator contains 0.023 fl oz (0.67 mL), 0.045 fl oz (1.34 mL), 0.091 fl oz (2.68 mL), or 0.136 fl oz (4.02 mL) (of solution).

(Detachable) calendar (monthly application) reminder stickers (with illustration of dog or puppy)

Back Panel

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 Front Panel, Back Panel and Side Panel}

See package insert(s) for directions for use and frequency of application
Open resealable label for directions for use
Open resealable label for directions for use and storage and disposal
See back panel for additional precautionary statements (front panel in close proximity to the signal word)
See package insert(s) for frequency of application
See enclosed insert(s) for directions for use and storage and disposal
See enclosed insert(s) for directions for use
Photograph of dog or puppy
Lift here to open (LIFT HERE TO OPEN)
For Use on Dogs only
Use only on dogs

{Text for Foil of Blister package}

Virbac logo

EFFIPRO® Topical Solution for Dogs

Only for use (on dogs 5-22.9 lbs, on dogs 23-44.9 lbs, on dogs 45-88.9 lbs, on dogs 89-132 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 (9.6%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

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DO NOT USE ON CATS

CAT PROHIBITION ICON

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{Text for Applicator Tube}

Virbac logo

EFFIPRO® Topical Solution for Dogs

Only for use on dogs

**5-22.9 lbs (23-44.9 lbs, 45-88.9 lbs, 89-132 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 (9.6%)

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

MARKETING CLAIMS

[Multiple infestations]

- **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) (DOGS or PUPPIES) (8 weeks old or older) (weighing 5 to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 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.
- For killing fleas, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks** (that [which] may transmit [carry] Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPIES (8 weeks old or older) as follows: (followed by application directions).
- 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)
- Research has shown that flea, tick and chewing lice infestations can be completely 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 24 hours (for up to 7 days) and 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 sarcoptic mange mite infestations.
- Aids in (the) control of sarcoptic mange mite infestations
- Elimination of mites may require multiple monthly applications.
- Chewing lice infestations are rapidly eliminated
- Can be used on breeding, pregnant and lactating bitches
- May be used on puppies from 8 weeks of age
- Only for dogs and puppies 8 weeks old or older (weighing 5 to 22.9 lbs, 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 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)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.023 fl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.045 fl oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.091 fl oz (2.68 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.136 fl oz (4.02 mL)
- 1 (3, 6, 36) month(ly) dose(s) (applications)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.023 fl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.045 fl oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.091 fl oz (2.68 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.136 fl oz (4.02 mL)
- 1 applicator (tube) 1 month(ly) dose
- 3 applicators (tubes) 3 monthly doses (applications)
- 6 applicators (tubes) 6 monthly doses (applications)
- 36 applicators (tubes) 36 monthly doses (applications)
- 1 (3, 6, 36) applicator(s) containing 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]).
- Available from licensed veterinarians
- 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)