

2382-185

02-15-2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

Jim Barron, Ph. D.
Managing Regulatory Consultant
Virbac AH Inc.
c/o Exponent, Inc.
1000 Centre Green Way Suite 200
Cary, NC 27513

FEB 15 2011

Subject: Effipro Topical Solution for Dogs, EPA Reg. No. 2382-185
Application Dated February 1, 2011
Decision: 445211

Dear Mr. Barron:

The labeling referred to above, submitted in connection with registration under the Federal insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, contingent upon acceptance of the conditions listed below:

1. All of the data and reporting requirements listed in the original Notice of Registration dated 14 January 2011 must be met.
2. The registration expiration date remains unchanged (i.e., two years from the date that the product is released for shipment).
3. On page 1 under the Precautionary Statements in the Hazards to Humans statement, add "or using the toilet." after "using tobacco."
4. On page 1 change "You may also contact the Hotline number 1-800-338-3669 for health concerns, emergency medical treatment information or pesticide incidents. To read "You may also contact the Hotline number 1-800-338-3669 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents."
5. On page 1, the net contents expressing the net volume of pesticide in the container must be expressed on the Front Panel of the label, in English units. Metric units may be expressed in addition to (immediately adjacent) to the English unit expression.
6. On page 3 in the Text for Foil of Blister package and the Text for Applicator Tube, the net volume must be expressed in English units, e.g., "0.017 fl. oz." Metric units may be expressed in addition to (immediately adjacent) to the English unit expression.
7. On page 3 change "For dog use only" to "Use only on dogs"

- 8. On page 4 change:
 - a. "Kills emerged adult fleas prior to egg laying" to "Kills newly emerged adult fleas prior to egg laying"
 - b. "Kills fleas that transmit diseases, including..." to read "Kills fleas that may transmit bartonellosis."
- 9. Delete "effective" from statement "easy to apply, effective control..."
- 10. On page 5 change the first statement to read "...aids in (the) control of sarcoptic mange mite infestations."
- 11. The basic CSF on file for this product is the only formulation that may be associated with this product registration. Modifications to the basic CSF and alternate CSFs are not permitted.

Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records. If you have any questions, you may contact Samantha Hulkower at (703) 603-0683 or at Hulkower.Samantha@epa.gov.

Sincerely,



Mark Suarez
Product Manager (11)
Insecticide Branch
Registration Division (7505P)

Enclosure: Copy of Label Stamped "Accepted with comments"

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{Master Label}

Virbac

EFFIPRO[®] TOPICAL SOLUTION FOR DOGS

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING 23 TO 44.9 LBS, WEIGHING 45 TO 88.9 LBS, WEIGHING 89 TO 132 lbs).

ACTIVE INGREDIENT:

Flipronil 9.6%

OTHER INGREDIENTS: 90.4%

TOTAL: 100.0%

**KEEP OUT OF REACH OF CHILDREN
CAUTION
READ ENTIRE LABEL BEFORE EACH USE**

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

FEB 15 2011

*Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
2382-185*

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

HAZARDS TO HUMANS

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 or using tobacco.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 8 weeks of age. 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.

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 1-800-338-3869 for health concerns, emergency medical treatment information or pesticide incidents.</p>	

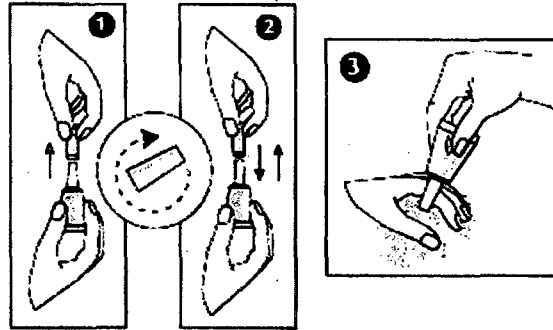
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

For killing 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 to **DOGS** or **PUPPIES** (8 weeks old or older) 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.



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.

STORAGE AND DISPOSAL

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

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

PESTICIDE /CONTAINER DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

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 risk 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 dogs and puppies 8 weeks old or older and medium dogs 23-44.9 lbs, large dogs 45-88.9 lbs, and extra large dogs 89-132 lbs.

Net Contents:

- 1, 6 or 36 single-dose applicator(s) per package. Each applicator contains 1.34 mL
- 6 single-dose applicators per package. Each applicator contains 2.68 mL
- 1 or 36 single-dose applicator(s) per package. Each applicator contains 4.02 mL

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

EPA Reg. No. 2382-185
EPA Est. No. 2382-FRA-1

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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
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
For dog use only

{Text for Foil of Blister package}

Virbac
EFFIPRO® Topical Solution for Dogs
Only for use (on dogs 23-44.9 lbs, on dogs 45-88.9 lbs, on dogs 89-132 lbs) / (1.34 mL, 2.68 mL, 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

{Text for Applicator Tube}

Virbac
EFFIPRO®
Topical Solution for Dogs
Only for use on dogs
23-44.9 lbs (45-88.9 lbs, 89-132 lbs)
1.34 mL (2.68 mL, 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

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 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
 - EFFIPRO® Topical Solution for Dogs is also approved for control of flea, tick, mosquito and chewing lice infestations in breeding, pregnant and lactating bitches.
 - EFFIPRO® Topical Solution for Dogs aids in control of sarcoptic mange infestations. Elimination of mites may require multiple monthly applications.
 - Aids in (the) control of sarcoptic mange infestations
 - For killing fleas, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks** (that 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 through one month (4 weeks)
 - Prevents flea and tick (re-)infestation for one month (4 weeks)
 - Kills fleas and ticks for one month (4 weeks)
 - Monthly application is recommended 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 emerged adult fleas prior to egg laying
- Kills fleas that may transmit diseases, including bartonellosis
- 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 one month (4 weeks)
- Kills fleas
- Easy to apply, effective control of fleas that lasts 1 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** (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 tick** (that may transmit ehrlichiosis), and **Lone Star ticks** (that may transmit hepatozoonosis) for 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 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 one month (4 weeks).
- Kills *Amblyomma americanum* (Lone Star ticks) for 4 weeks (for 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 infestations
- 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 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 (6 or 36) applicator(s) [tube(s)] 1.34 mL
- 6 applicators (tubes) 2.68 mL
- 1 (36) applicator(s) [tube(s)] 4.02 mL
- 1 (6, 36) month(ly) dose(s) (applications)
- 1 applicator (tube) 1 month(ly) dose
- 6 applicators (tubes) 6 monthly doses (applications)
- 36 applicators (tubes) 36 monthly doses (applications)
- 1 applicator containing 1.34 mL
- 6 applicators each containing 1.34 mL
- 36 applicators each containing 4.02 mL
- 6 applicators each containing 2.68 mL
- 1 applicator containing 4.02 mL
- 36 applicators each containing 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)

Dog Final master label as submitted on February 1st 2011