

12/11/2013

1/9



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Michelle Foster
Regulatory Specialist
Virbac AH, Inc.
3200 Meacham Blvd.
Fort Worth, TX 76137

DEC 11 2013

Subject: Label Amendment implementing label changes to pet spot-on product
Effipro Topical Solution for Dogs
EPA Reg. No 2382-185
EPA Decision No. 485692

Dear Ms. Foster,

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is **acceptable**. With this letter, the label requirements listed in the EPA letter "Implementation of Label Changes to Pet Spot-On Products" dated September 30, 2011, are fulfilled. Please submit final printed labels to the Agency within 30 days of the date of this letter. If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants and may take regulatory action. This registration is now time-limited and expires two years from the date of this letter.

Per Virbac's August 22, 2013 2Q 2013 enhanced incident report submission, it is our understanding that this product is not currently marketed by Virbac. If Virbac intends to market this product in the future, the additional requirements of September 30, 2011 must be fulfilled. These requirements include the submission of final printed labels, quarterly enhanced incident reports, and quarterly sales information in doses sold for this product, along with an analysis of the incidents reported. The quarterly reports are due two months after the quarter ends. Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the attention of Kaitlin Keller, Pesticide Re-evaluation Division, Mail Code 7508P.

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot #
Where purchased: internet, store, veterinarian
Active Ingredient(s)
Weight range for product

Date on which incident occurred. (mm/dd/yyyy)
State in which the incident occurred. (standard 2 letter abbreviation)
Registrant case #

Species: dog, cat, other (specify)
Breed: (as reported by pet owner)
Age: months or years
Sex: M, F, or neutered
Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other
Body System: neurological, dermatological, GI, respiratory, ocular, other
Major signs noted with separate column for each sign, using standard terminology
Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no
Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
Any known precondition
EPA Severity Code: death, major, moderate, minor
Outcome: died, recovered, still treated, unknown

Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported including all minor dermal and ocular irritation reports.
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.

- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

A stamped copy of the label is enclosed for your records. If you have any questions regarding this label, please contact Kaitlin Keller at (703) 308-8172 via email at keller.kaitlin@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7504P)

Enclosure: Label stamped "Accepted"

4/9

ACCEPTED
DEC 11 2013
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 2382-185

{Master Label}

Virbac

EFFIPRO[®] TOPICAL SOLUTION FOR DOGS

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
READ ENTIRE LABEL BEFORE EACH USE**

**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, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Symbol on Front Panel/ Symbol and text on Back panel. Side Effects on back panel immediately above Cat warning box.



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.

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].

Do not use on puppies under 8 weeks of age or 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[®] 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.

	<ul style="list-style-type: none"> 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.</p> <p>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>	

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.

DO NOT USE ON CATS.

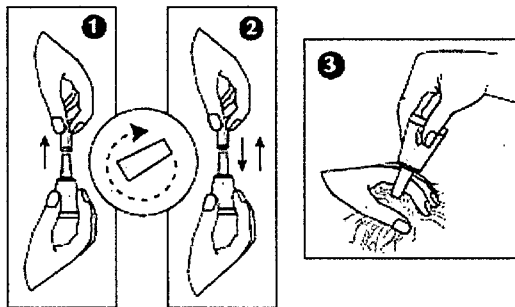
FOR EXTERNAL USE ON DOGS ONLY. Do not use on dogs under 8 weeks of age FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING) (5 TO 22.9 LBS, [WEIGHING] 23 TO 44.9 LBS, [WEIGHING] 45 TO 88.9 LBS, [WEIGHING] 89 TO 132 lbs). Do not allow your dog to ingest this product. Do not split tubes between dogs. Do not use multiple tubes on one dog. 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.

Do not apply more often than once a [per] month [every 30 days].

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

- Remove one applicator from packaging. Hold applicator upright and remove cap.
- Invert cap and place other end back onto applicator tip. Push cap down to break seal. Remove cap prior to treatment application. 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.

4/9

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 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)

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
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
EFFIPRO® Topical Solution for Dogs
Only for use (on dogs 5 to 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
EPA Reg. No. 2382-185
DO NOT USE ON CATS
CAT PROHIBITION ICON

7/9

{Text for Applicator Tube}

Virbac
EFFIPRO®

Topical Solution for Dogs

Only for use on dogs

5 to 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

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)
- Easy 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)