



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 16, 2015

Michelle Foster
Virac AH, Inc.
3200 Meacham Blvd.
Ft. Worth, TX 76137

Subject: Label Amendment – Revising Label to Comply with Spot On Mitigation
Product Name: EFFIPRO TOPICAL SOLUTION FOR CATS
EPA Registration Number: 2382-186
Application Date: September 28, 2015
Decision Number: 509684

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, please contact me by phone at (703) 306-0415, or via email at davis.kable@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

ACCEPTED

10/16/2015

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2382-186

Front Panel

Virbac logo

EFFIPRO[®] TOPICAL SOLUTION FOR CATS

FOR USE ONLY ON CATS AND KITTENS 8 WEEKS OLD OR OLDER AND WEIGHING 1.5 LBS. AND OVER

ACTIVE INGREDIENT

Fipronil.....9.59%

OTHER INGREDIENTS 90.41%

TOTAL..... 100.00%

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

Back Panel

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. Do not use on kittens under 8 weeks of age or weighing less than 1.5 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 Cats 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 cats.

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

Side Effects: Monitor your cat 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 (single presentation on insert)

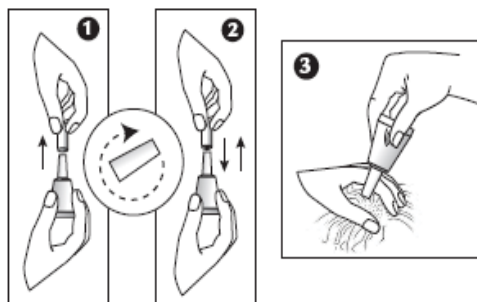
DIRECTIONS FOR USE

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 CAT, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS 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 [which] may transmit [carry] Lyme disease), mosquitoes, and chewing lice; apply to CATS or KITTENS (8 weeks old or older and weighing 1.5 lbs. and over) 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 cat'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 cat's skin.
Ensure that EFFIPRO® Topical Solution for Cats is not applied superficially on cat's hair.



Insert

FREQUENCY OF APPLICATION

EFFIPRO® Topical Solution for Cats will kill fleas, ticks and chewing lice completely when applied monthly.

Fleas: EFFIPRO® Topical Solution for Cats can control fleas for up to six weeks. Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely.

Ticks: EFFIPRO® Topical Solution for Cats can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® Topical Solution for Cats can kill mosquitoes within 24 hours (for up to 14 days), and within 48 hours (for up to 28 days).

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

Back Panel (single presentation on insert)

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.

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 cat or kitten).

Front Panel

Net Contents: 1, 3, 6 or 36 single-dose applicator(s) per package. Each applicator contains 0.017 fl oz (0.5 mL) of solution.

Back / Side Panel

EPA Reg. No. 2382-186
EPA Est. No. 2382-FRA-1
EPA Est. No. 74720-DEU-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

Use only on cats
For Use on Cats only
Only for cats and kittens 8 weeks old or older and weighing 1.5 lbs. and over
(1, 3, 6 or 36) applicator(s) 0.017 fl oz (0.5 ml)

Photograph of cat or kitten

Lift here to open (LIFT HERE TO OPEN)

Text for Foil of Blister package

Virbac logo
EFFIPRO® Topical Solution for Cats
**Only for use on cats 8 weeks old or older
and weighing 1.5 lbs. and over
0.017 fl oz (0.5 mL)**
Contains fipronil (9.59%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-186

Text for Applicator Tube

Virbac logo
EFFIPRO® Topical Solution for Cats
**Only for use on cats 8 weeks old or older
and weighing 1.5 lbs. and over
0.017 fl oz (0.5 mL)**
Contains fipronil (9.59%)
**KEEP OUT OF REACH
OF CHILDREN**
CAUTION
See full label for additional directions
EPA Reg. No. 2382-186
EPA Est. No. 2382-FRA-1

MARKETING CLAIMS

[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, ticks, mosquitoes and chewing lice for CATS and KITTENS 8 weeks old or older.**
- EFFIPRO® Topical Solution for Cats contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice (on cats) (8 weeks old or older).
- For killing fleas, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks**, (which/that may carry (transmit) Lyme disease), mosquitoes and chewing lice; apply to CATS or KITTENS (8 weeks old or older) as follows: (followed by application directions).
- EFFIPRO® Topical Solution for Cats is also approved for control of flea, tick, mosquito and chewing lice infestations in breeding, pregnant and lactating queens.
- Persistent flea and tick efficacy for up to one month (4 weeks) (30 days)
- Prevents flea and tick (re-)infestation for up to one month (4 weeks)
- Effective monthly application for (on) fleas and ticks
- Effective monthly application for cats (and kittens) against fleas and ticks
- Kills fleas and ticks for up to one month (4 weeks)
- Kills fleas, ticks, mosquitoes and chewing lice
- Apply monthly for control and prevention of fleas and ticks
- Protects against fleas and ticks for up to one month
- EFFIPRO® Topical Solution for Cats will kill fleas, ticks and chewing lice completely when applied monthly.
Fleas: EFFIPRO® Topical Solution for Cats can control fleas for up to six weeks. Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis, or if reinfestation is likely.
Ticks: EFFIPRO® Topical Solution for Cats can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.
Mosquitoes: When applied monthly, EFFIPRO® Topical Solution for Cats can kill mosquitoes within 24 hours (for up to 14 days), and within 48 hours (for up to 28 days).
Notes: Wait at least 30 days before re-application of EFFIPRO® Topical Solution for Cats. Avoid contact with treated area until dry.

[Fleas]

- Kills newly emerged adult fleas prior to egg-laying
- Kills fleas that may transmit bartonellosis
- Kills fleas that transmit bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit diseases, including bartonellosis, tapeworm and tularemia
- Kills fleas that may transmit diseases, including bartonellosis, tularemia and tapeworm infestations
- Kills fleas that may transmit diseases, including bartonellosis and tularemia
- Kill fleas that may cause Flea Allergy Dermatitis (FAD) or flea-bite anemia
- Effective monthly control of adult fleas
- Kills fleas
- Easy to apply, control of (for) fleas that lasts (at least) 1 month (4 weeks)
- Easy to apply, flea control that lasts (at least) 1 month (4 weeks)
- Protects (your cat and kitten 8 weeks of age or older) from fleas for up to one month (4 weeks)
- Protects from fleas for up to one month (4 weeks)
- Kills adult fleas for up to one month (4 weeks)
- Monthly applications (all year) are recommended for control and prevention of fleas
- Regular (monthly) use breaks the flea life cycle
- EFFIPRO® Topical Solution for Cats (rapidly) kills fleas that may cause Flea Allergy Dermatitis (FAD)
- EFFIPRO® Topical Solution for Cats kills fleas on your cat
- 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
- Protects your cat from flea infestation that may cause flea-bite anemia
- The successive feeding activity of fleas on cats may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis (FAD)
- Protects cats and kittens over 8 weeks of age from fleas for at least one month (4 weeks)
- Prevents flea (re-)infestation for at least one month (4 weeks)

[Ticks]

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (which [that] may transmit [carry] Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, anaplasmosis and cytauxzoonosis)
- Kills ticks including those that may transmit Lyme disease
- Kills ticks including Deer ticks (which [that] may transmit Lyme disease), American dog ticks (which [that] may transmit Rocky Mountain Spotted Fever), Brown dog ticks (which [that] may transmit ehrlichiosis), and Lone Star ticks (which [that] may transmit hepatozoonosis) for up to one month (4 weeks)
- Kills ticks including Deer ticks (which [that] may transmit Lyme disease), American dog ticks (which [that] may transmit Rocky Mountain Spotted Fever) and Brown dog ticks (which [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 up to 4 weeks (for up to one month)
- Protects from ticks for up to one month

[Mosquitoes]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days

[All others]

- Chewing lice infestations are rapidly eliminated
- Can be used on breeding, pregnant and lactating queens
- May be used only on kittens from 8 weeks of age
- Begins working upon application
- Once monthly application
- Single application lasts 4 weeks (one month)
- Easy and convenient application (applications)
- Easy to apply spot-on (topical) application
- Convenient, easy to apply
- Convenient to use (easy to apply)
- Convenient to use (easy to apply) topical application
- Convenient topical application (for cats)
- Easy, spot on (topical) application
- Quick drying, non-greasy
- Available from licensed veterinarians
- 1 (3, 6, 36) applicator(s) (tube[s]) of 0.017 fl oz (0.5 mL)
- 1 (3, 6, 36) applicator(s) (tube[s]) 0.017 fl oz (0.5 mL)
- 1 (3, 6, 36) month(ly) dose(s) (application[s])
- 1 applicator (tube) 1 month(ly) dose
- 3 applicators (tubes) 3 (monthly) doses
- 6 applicators (tubes) 6 (monthly) doses
- 36 applicators (tubes) 36 (monthly) doses
- 1 applicator containing 0.017 fl oz 0.5 mL
- 3 (6,36) applicators each containing 0.017 fl oz (0.5 mL)
- Remains effective after exposure to sunlight
- Remains effective after bathing
- 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, or exposure to sunlight
- EFFIPRO® Topical Solution for Cats is effective after bathing, shampooing, water immersion, or sunlight exposure.
- Still works after exposure to sunlight
- Waterproof (remains effective after bathing and swimming)