

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 15, 2014

Michelle Foster
Regulatory Affairs Manager
Virbac AH, Inc.
3200 Meacham Blvd.
Forth Worth, TX 76137

Subject: Label Amendment – Agency Initiated Spot-On Mitigation Language
Product Name: Effipro Plus Topical Solution for Cats
EPA Registration Number: 2382-188
Application Date: May 16, 2014
Decision Number: 491534

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**.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. 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.

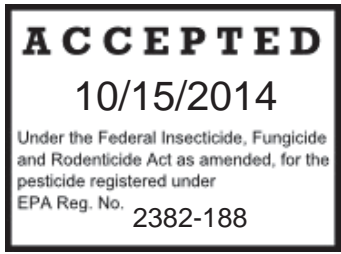
A copy of your updated master label stamped “Accepted” is enclosed for your records. Please note that this letter does not supersede anything contained within the Notice of Registration dated July 6, 2012. Based upon your written request dated May 19, 2014, the time-limited registration for this product has been extended 2 years from the date of this letter. More specifically, the registration for this product will expire October 15, 2016.

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 with FIFRA section 6(e). If you have any questions, please contact Carlyn Petrella by phone at 703-347-0439, or via email at petrella.carlyn@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Richard J. Gebken". The signature is written in a cursive style with a large initial 'R' and a distinct 'G'.

Richard Gebken
Product Manager 10
Insecticide Branch
Office of Pesticide Programs
Date: October 15, 2014



EFFIPRO[®] Plus TOPICAL SOLUTION FOR CATS

(Note: font size of Cats will be 40% of the size of the largest letter in the brand name on the front panel)

Front, back and side panels

Optional Text Appears In Brackets

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

Front Panel

ACTIVE INGREDIENTS

Fipronil.....9.5%
 Pyriproxyfen.....11.5%

OTHER INGREDIENTS.....79.0%

TOTAL.....100.0%

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

Picture of Cat

Back Panel

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed or absorbed through the skin. Causes moderate 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 cats ONLY. Do not use on kittens under 8 weeks of age or weighing less than 1.5 lbs. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Possible temporary irritation may occur at the site where EFFIPRO[®] Plus 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 this product on debilitated, aged, pregnant, or nursing animals.

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.</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>	

Back Panel (lower right hand corner)

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.

Insert)

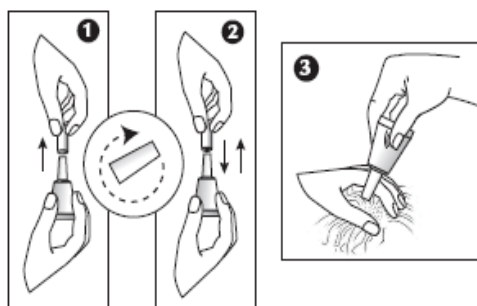
DIRECTIONS FOR USE

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 DOGS, PUPPIES, OR RABBITS. DO NOT USE ON OTHER ANIMALS.

FOR EXTERNAL USE ON CATS AND KITTENS ONLY. Do not use on cats and kittens under 8 weeks of age or weighing less than 1.5 lbs. Do not allow your cat to ingest this product. Do not use more than one application per cat per month. For killing fleas, flea eggs, flea larvae, 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 only to CATS or KITTENS 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.
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® Plus Topical Solution for Cats is not applied superficially on cat's hair.



Insert

FREQUENCY OF APPLICATION

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

Fleas: EFFIPRO® Plus 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. EFFIPRO® Plus Topical Solution for Cats can control flea eggs (and larvae) for up to three months (90 days).

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

Chewing Lice: EFFIPRO® Plus Topical Solution for Cats can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® Plus 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® Plus 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.

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.

(Detachable) calendar (monthly application) reminder stickers with (illustration of cat or kitten).

EPA Reg. No. 2382-188
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. in the United States.
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
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 and kittens
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® Plus 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 (9.5%) and pyriproxyfen (11.5%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-188

Text for Applicator Tube

Virbac logo
EFFIPRO® Plus 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 (9.5%) and pyriproxyfen (11.5%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-188

MARKETING CLAIMS

[Multiple infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice for cats and kittens 8 weeks old or older.
- 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® Plus Topical Solution for Cats contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice on cats or kittens 8 weeks old or older.
- EFFIPRO® Plus Topical Solution for Cats contains the active ingredient pyriproxyfen, which controls reinfestation caused by flea eggs, flea larvae on cats or kittens 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).
- Persistent flea and tick efficacy for up to one month (4 weeks) (30 days) on cats and kittens
- Prevents flea and tick (re-)infestation for up to one month (4 weeks) on cats and kittens
- Effective monthly application for (on) fleas and ticks on cats and kittens
- Effective monthly application for cats and kittens against fleas and ticks
- Kills fleas and ticks for up to one month (4 weeks) on cats and kittens
- Kills fleas, ticks, mosquitoes and chewing lice
- Kills fleas, ticks, mosquitoes and lice
- Kills, fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice
- Kills, fleas, flea eggs, flea larvae, ticks, mosquitoes and lice
- Apply monthly for control and prevention of fleas and ticks on cats and kittens
- Protects against fleas and ticks for up to one month on cats and kittens
- EFFIPRO® Plus Topical Solution for Cats will kill fleas, ticks and chewing lice on cats and kittens when applied monthly.
- **Fleas:** EFFIPRO® Plus Topical Solution for Cats can control fleas, flea eggs and flea larvae for up to (six weeks) on cats and kittens. Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis, or if reinfestation is likely.
- **Ticks:** EFFIPRO® Plus Topical Solution for Cats can kill ticks for a month or longer on cats and kittens. Apply monthly where tick control is consistently needed.
- **Mosquitoes:** When applied monthly, EFFIPRO® Plus Topical Solution for Cats can kill mosquitoes within 24 hours (for up to 14 days), and within 48 hours (for up to 28 days) on cats and kittens.
- **Notes:** Wait at least 30 days before re-application of EFFIPRO® Plus 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 may transmit bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit (bartonellosis), (tularemia) (and) (tapeworm)
- Kills fleas that may transmit (bartonellosis), (tularemia) (and) (tapeworm infestations)
- Kills fleas that may transmit bartonellosis and tularemia
- Kills fleas, flea eggs and flea larvae
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days) on cats and kittens
- Kills flea eggs for up to (3 months) (90 days) on cats and kittens
- Sterilizes and kills fleas on cats and kittens
- Sterilizes fleas for up to (3 months) (90 days) on cats and kittens
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae) on cats and kittens
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days) on cats and kittens
- With pyriproxyfen (IGR)* to break flea life cycle * insect growth regulator
- Dual Action(!): fipronil and pyriproxyfen (IGR) effectively breaks the flea life cycle
- Kill fleas that may cause Flea Allergy Dermatitis (FAD) or flea-bite anemia
- Effective monthly control of adult fleas on cats and kittens
- Kills fleas
- Easy to apply, control of (for) fleas that lasts for up to 1 month (4 weeks) on cats and kittens
- Protects your cat or 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) on cats and kittens
- Kills adult fleas for up to one month (4 weeks) on cats and kittens
- Apply monthly (all year) for control and prevention of fleas on cats and kittens
- Regular (monthly) use breaks the flea life cycle on cats and kittens
- EFFIPRO® Plus Topical Solution for Cats (rapidly) kills fleas that may cause Flea Allergy Dermatitis (FAD)
- EFFIPRO® Plus 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 or kitten 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 up to one month (4 weeks)
- Prevents flea (re-)infestation for up to one month (4 weeks) on cats and kittens

- Prevents flea eggs from hatching or developing into larvae or adult stages (for up to 90 days (3 months)) on cats and kittens

[Ticks]

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (including those 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 may transmit Lyme disease), American dog ticks (which may transmit Rocky Mountain Spotted Fever), Brown dog ticks (which may transmit ehrlichiosis), and Lone Star ticks (which may transmit hepatozoonosis) for up to one month (4 weeks) on cats and kittens
- Kills ticks including Deer ticks (which may transmit Lyme disease), American dog ticks (which may transmit Rocky Mountain Spotted Fever) and Brown dog ticks (which may transmit ehrlichiosis) for up to one month (4 weeks) on cats and kittens
- 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) on cats and kittens
- Kills Lone Star ticks (*Amblyomma americanum*) for up to 4 weeks (for up to one month) on cats and kittens
- Protects cats and kittens 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
- May be used only on kittens from 8 weeks of age
- Begins working upon application
- Once monthly application
- Single application lasts up to 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® Plus 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)