2382-186

07-20-2011



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

> OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

> > July 20, 2011

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

Subject: Effipro Topical Solution for Cats, EPA Reg. No. 2382-186 Application Dated February 1, 2011 Decision: 446146

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, subject to the comments 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. 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.

A copy of the Agency's Child Resistant Packaging Data review is enclosed. 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 Clayton Myers at (703) 347-8874 or at myers.clayton@epa.gov.

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Sincerely,

Granda alutander for 1

Richard Gebken Product Manager Insecticide Branch Registration Division (7505P)

Enclosures:

Copy of Label Stamped "Accepted with comments" Agency Child-Resistant Packaging Review

{Master Label}

ACCEPTED With COMMENTS In EPA Letter Dated: JUL 2 0 2011 Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

2382 - 186

EFFIPRO[®] TOPICAL SOLUTION FOR CATS

FOR USE ONLY ON CATS AND KITTENS 8 WEEKS OLD OR OLDER

ACTIVE INGREDIENT:

Virbac

Fipronii		
OTHER	INGREDIENTS:	
TOTAL:		

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. Do not use on kittens 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 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.

FIRST AID	
 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. 	
 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. 	
 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. 	ссес ссес с
	 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 do Do not give anything by mouth to an unconscious person. 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 call a poison control center or doctor for treatment advice. Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

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) 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.

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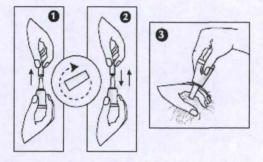
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Push cap down to break seal.

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[®] Topical Solution for Cats is not applied superficially on cat's hair.



FREQUENCY OF APPLICATION

3

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.

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.

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. 2382-186 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

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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 (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

EFFIPRO® Topical Solution For Cats Only for use on cats / 0.017 fl oz (0,5 mL) Contains fipronil (9.6%) KEEP OUT OF REACH OF CHILDREN CAUTION See full label for additional directions EPA Reg. No. 2382-186

{Text for Applicator Tube}

Virbac EFFIPRO® Topical Solution For Cats Only for use on cats 0.017 fl oz (0.5 mL) Contains fipronil (9.6%) KEEP OUT OF REACH OF CHILDREN CAUTION See full label for additional directions EPA Reg. No. 2382-186

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 flocs, or 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

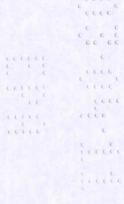
[All others]

- 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])

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- 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 oz0.5 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)

Cat Final master label as submitted on March 4, 2011







FOR USE ONLY ON CATS AND KITTENS 8 WEEKS OLD OR OLDER

For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice. • Easy and convenient application.

- Waterproof (remains effective after bathing and swimming).
- Kills newly emerged adult fleas prior to egg-laying.
- Kills fleas that may transmit bartonellosis.
- · Kills fleas that may cause Flea Allergy Dermatitis (FAD) or flea-bite anemia.
- · 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, anaplasmosis and cytauxzoonosis).
- · Kills mosquitoes.
- · Chewing lice infestations are rapidly eliminated.
- · Can be used on breeding, pregnant and lactating queens.

EFFIPRO® Topical Solution for Cats contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice.

ACTIVE INGREDIENT:

Fipronil		
OTHER ING	REDIENTS:	
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

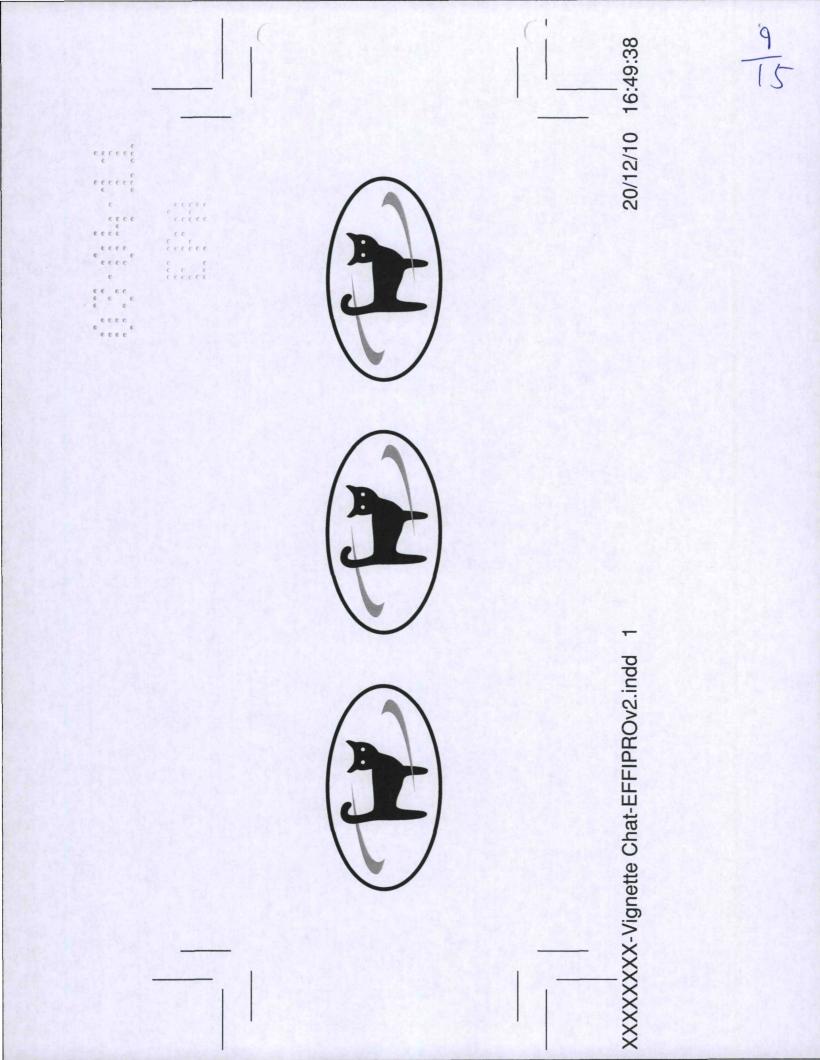
Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

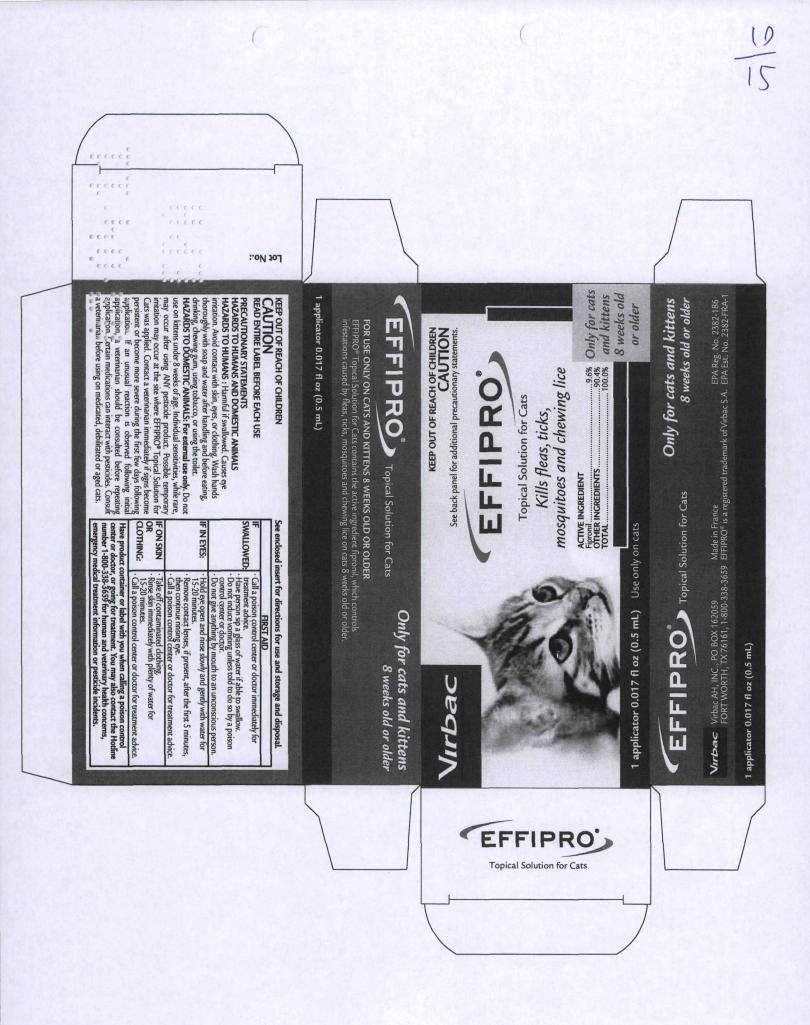
HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on kittens 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 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.

FIRST AID				
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.				
 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. 				
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.				

eterinary health concerns, emergency medical treatment information or pesticide incidents.





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