

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 11, 2014

Ms. Michelle Foster Regulatory Specialist Virbac Animal Health, Inc. 3200 Meacham Boulevard Fort Worth, TX 76137-4611

Subject: Label Amendment – Acceptance of Master Labeling Submitted for Implementation of Pet Spot-On Mitigation Product Name: EFFITIX® PLUS Topical Solution for Dogs EPA Registration Number: 2382-192 Application Date: May 16, 2014 Decision Numbers: 491714 & 493758

Dear Ms. Foster:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with the following label revision provision(s):

Amendments to Dog Spot-On Product Registrations:

1. This registration is now time-limited, and will expire 2 years from the date of this letter. More specifically, this registration will expire on September 11, 2016.

- 2. If the Agency determines that future mitigation measures are necessary for all pet spot-on products, EPA will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.
- 3. Please consider limiting the formulations of this product to one basic confidential statement of formula. The Agency may require this in the future. In addition, it is possible that no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
- 4. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning October 1, 2014. Please flag any Confidential Business Information as such. Enhanced incident reporting and quarterly sales information should be submitted to the Product Manager. 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.

#### Conditions of Acceptance/Amendments to Dog Spot-On Product Registrations, continued:

- 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 pre-condition.
- EPA Severity Code: Death, major, moderate, minor.
- Outcome: Died, recovered, still treated, unknown.
- 5. 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.
  - Summary table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multipet 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.

Copies of your updated master label stamped "Accepted" and the review for minimum weight treated are enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) 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 section 2(gg) of FIFRA and its implementing regulation at 40 CFR §152.3. 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 section 6(e) of FIFRA.

Please note that this letter does not supersede anything contained within the original conditions of acceptance detailed in the Agency's letter dated February 21, 2013. The conclusion date for the subject time-limited product registration is September 11, 2016. If you have any questions about this label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at <u>Rodia.Carmen@epa.gov</u> or Mr. Richard J. Gebken at (703) 305-6701 or via e-mail at <u>Gebken.Richard@epa.gov</u> during the hours of 9:00 A.M. to 5:30 P.M. EST.

Sincerely,

Richard J. Ceede

Richard Gebken Product Manager 10 Insecticide Branch Office of Pesticide Programs Date: September 11, 2014

Enclosures: Updated Master Label Stamped "Accepted," dated September 11, 2014 Review for Minimum Weight Treated, dated June 23, 2014 002382-00192 D491714 & D493758

# EFFITIX<sup>®</sup> PLUS TOPICAL SOLUTION FOR DOGS

(Note: font size of Dogs 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 DOGS OR PUPPIES 8 WEEKS OF AGE OR OLDER, (WEIGHING 5 TO 10.9 LBS., WEIGHING 11 TO 22.9 LBS., WEIGHING 23 TO 44.9 LBS., WEIGHING 45 TO 88.9 LBS., WEIGHING 89 TO 132 LBS.).

#### Front Panel

#### **ACTIVE INGREDIENTS**

Fipronil..... 6.0% 

#### 

\* cis/trans ratio: maximum 55% (±) cis and minimum 45% (±) trans



## **KEEP OUT OF REACH OF CHILDREN** CAUTION

Large, clear picture of appropriate species of dog

Symbol on Front Panel (lower right hand corner) (Note: Do not use on cats pictogram will be 1.5 x 1.5 cm)



**Back Panel** 

## READ ENTIRE LABEL BEFORE EACH USE PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### HAZARDS TO HUMANS

Harmful if swallowed or absorbed through the skin. 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. Remove and wash contaminated clothing before reuse.

#### HAZARDS TO DOMESTIC ANIMALS

#### For external use on dogs ONLY.

#### Back Panel

Do not use on dogs or puppies less than 8 weeks of age, weighing less than 5 lbs. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products.

#### Symbol and text on Back panel (lower right hand corner)

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 contact Virbac at 1-800-338-3659.



(Note : Do not use on cats pictogram will be 1.5 x 1.5 cm)(Must be yellow box with black text) DO NOT USE ON CATS- MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.

#### Back Panel (single presentation on insert)

FIRST AID	
IF SWALLOWED	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> </ul>
	<ul> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything to an unconscious person.</li> </ul>
IF IN EYES	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
IF ON SKIN OR CLOTHING	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
Have product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including human and veterinary health concerns, medical emergencies or pesticide incidents), you may call 1-800-345-4735, twenty-four (24) hours per day, seven (7) days per week.	

#### Inside flap (single presentation insert only)

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labelling. USE ONLY ON DOGS OR PUPPIES 8 WEEKS OF AGE OR OLDER, WEIGHING AT LEAST 5 LBS. 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. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

#### DO NOT USE ON CATS.

FOR EXTERNAL USE ON DOGS and PUPPIES ONLY. Do not use on dogs or puppies under 8 weeks of age. Do not use on dogs or puppies weighing less than 5 lbs. Do not allow your dog to ingest this product. Do not split tubes between dogs. Do not use multiple tubes on one dog. Do not use two applicators for dogs weighing more than 132 lbs. 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.

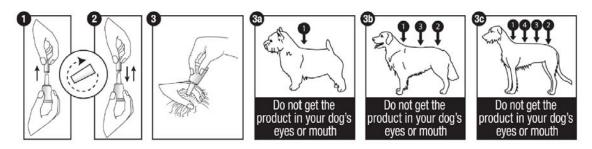
Do not apply more often than once a [per] month [every 30 days].

For use ONLY on DOGS or PUPPIES 8 weeks of age or older, weighing at least 5 lbs. To repel and kill fleas, ticks, and mosquitoes; to kill flea eggs, pupae and larvae, lice, and to aid in control of mites; to repel and prevent blood feeding by biting flies. Apply monthly according to directions for use.

#### APPLICATION DIRECTIONS

- 1. 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 until skin is visible.
- Place applicator tip directly against exposed skin.
- 3a. For use only on small dogs and puppies (8 weeks of age or older), weighing (5 to 10.9 lbs.) or weighing (11 to 22.9 lbs.) Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For use only on medium dogs weighing (23 to 44.9 lbs.) or large dogs weighing (45 to 88.9 lbs.) Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For use only on extra-large dogs weighing (89 to 132 lbs.) Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty.

Ensure that EFFITIX® Plus Topical Solution for Dogs is not applied superficially on dog's hair.



#### Insert

#### FREQUENCY OF APPLICATION

Fleas, flea eggs, flea pupae, flea larvae, ticks, [biting and chewing] and lice infestations can be controlled with monthly applications of EFFITIX<sup>®</sup> Plus Topical Solution for Dogs. Biting flies and mosquitoes are [also] repelled by EFFITIX<sup>®</sup> Plus Topical Solution for Dogs.

Fleas: EFFITIX<sup>®</sup> Plus Topical Solution for Dogs can start killing adult fleas within 6 hours and lasts for [up to] three months against adult fleas, flea eggs and flea larvae. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.

Ticks: EFFITIX<sup>®</sup> Plus Topical Solution for Dogs can kill ticks for at least a month. Apply monthly where tick control is consistently needed.

Lice: EFFITIX<sup>®</sup> Plus Topical Solution for Dogs can kill biting and chewing lice for [up to] a month. Apply monthly where lice control is consistently needed.

Mites: EFFITIX<sup>®</sup> Plus Topical Solution for Dogs aids in [the] control of [sarcoptic mange]/[mite infestations that may cause sarcoptic mange].

**Biting flies and Mosquitoes**: When applied monthly, EFFITIX<sup>®</sup> Plus Topical Solution for Dogs [prevents blood feeding by] [and] [repels] biting flies and mosquitoes for up to 4 weeks [a [one] month]. Kills mosquitoes for up to four weeks [a [one] month]. **Notes**: Wait at least 30 days before re-application of EFFITIX<sup>®</sup> Plus Topical Solution for Dogs. Avoid contact with treated area until

Notes: Wait at least 30 days before re-application of EFFITIX<sup>®</sup> Plus Topical Solution for Dogs. 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.

**PESTICIDE STORAGE:** Keep this product in its tightly closed original container, , when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

**PESTICIDE /CONTAINER DISPOSAL: If empty:** Nonrefillable. 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.

#### Inside Flap (single presentation on insert)

#### LIMITED WARRANTY AND DISCLAIMER

VIRBAC warrants this product only if it is used, stored and handled in accordance with the label instructions. The buyers and users are solely responsible for all risks of use and handling of this product when such use and handling are contrary to or differ from the label instructions. To the extent permitted by applicable law, any damages arising from a breach of this warranty shall be limited to direct damages only and shall not include any type of consequential damages.

How supplied: For easy and convenient application, EFFITIX<sup>®</sup> Plus Topical Solution for Dogs is available in sizes for toy dogs and puppies 8 weeks of age or older and weighing 5 to 10.9 lbs. (0.017 oz.)/(0.5 mL), small dogs weighing11 to 22.9 lbs. (0.034 fl. oz.)/(1.0 mL), medium dogs weighing 23-44.9 lbs. (0.068 fl. oz.)/(2.0 mL), large dogs weighing 45-88.9 lbs. (0.135 fl. oz.)/(4.0 mL), and extra-large dogs weighing 89-132 lbs. (0.203 fl. oz.)/(6.0 mL).

Net Contents: 1 (3, 6 or 36) single-dose applicator(s) per package containing 0.5 mL, (1mL, 2mL, 4mL or 6mL)/ 0.017 fl. oz. (0.034 fl. oz., 0.068 fl. oz., 0.135 fl. oz., 0.203 fl. oz.) (of solution).

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

#### Back Panel (single presentation on side panel)

EPA Reg. No. 2382-192 EPA Est. No. 2382-FRA-1 VIRBAC AH, INC. PO BOX 162059 FORT WORTH TX 76161 1-800-338-3659

Made in France EFFITIX<sup>®</sup> is a trademark of Virbac S.A. Questions or comments? Call: 1-800-338-3659

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## {Text for Front Panel, Back Panel, Inside Flap and Side Panel}

See package insert(s) for directions for use and frequency of application See package insert for directions for use and storage and disposal 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 Lift here to open (LIFT HERE TO OPEN) For Use on Dogs ONLY Use ONLY on dogs See inside flap for directions for use

## Text for Foil of Blister package

Virbac logo EFFITIX® Plus Topical Solution For Dogs Only for use on dogs and puppies 8 weeks of age or older (5 to 10.9 lbs,11 to 22.9 lbs, 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs) (0.017 oz, 0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (0.5 mL, 1.0 mL, 2.0 mL, 4.0 mL, 6.0mL) Contains fipronil (6.0%), permethrin (44.88%), and pyriproxyfen (1.8%) KEEP OUT OF REACH OF CHILDREN CAUTION See full label for additional directions EPA Reg. No. 2382-192 DO NOT USE ON CATS CAT PROHIBITION ICON

## **Text for Applicator Tube**

Virbac logo EFFITIX® Plus Topical Solution For Dogs Only for use on dogs and puppies 8 weeks of age or older (5 to 10.9 lbs., 11 to 22.9 lbs., 23-44.9 lbs., 45-88.9 lbs., 89-132 lbs.) (0.017 fl. oz., 0.034 fl. oz., 0.068 fl. oz., 0.135 fl. oz., 0.203 fl. oz.) [(0.5 mL (1.0 mL, 2.0 mL, 4.0 mL, 6.0mL)] Contains fipronil (6.0%), permethrin (44.8%), and pyriproxyfen (1.8%) KEEP OUT OF REACH OF CHILDREN CAUTION See full label for additional directions EPA Reg. No. 2382-192 DO NOT USE ON CATS CAT PROHIBITION ICON

## **MARKETING CLAIMS**

#### [Multiple infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea pupae, flea larvae, ticks, mosquitoes, and lice.
- [When] Applied topically on a monthly basis, EFFITIX<sup>®</sup> Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea larvae, [biting, chewing] lice, aids in the control of sarcoptic mites, and repels [and inhibits blood feeding by] biting flies and mosquitoes.
- [When] Applied topically on a monthly basis, EFFITIX<sup>®</sup> Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea larvae, [biting, chewing] lice, aids in the control of mites that may cause sarcoptic mange, and repels [and inhibits blood feeding by] biting flies and mosquitoes.
- For easy and convenient application, EFFITIX<sup>®</sup> Plus Topical Solution for Dogs is available in sizes for toy dogs and puppies (8 weeks old or older) and weighing 5 to 10.9 lbs. [0.17 fl. oz.][0.5 mL], small dogs weighing 11 to 22.9 lbs. [0.034 fl. oz.][1.0 mL], medium dogs weighing 23-44.9 lbs. [0.068 fl. oz.] [2.0mL], large dogs weighing 45-88.9 lbs. [0.135 fl. oz.] [4.0 mL], and extra-large dogs weighing 89-132 lbs. [0.203 fl. oz.] [6.0 mL].
- EFFITIX<sup>®</sup> Plus Topical Solution for Dogs contains the active ingredients fipronil, permethrin, and pyriproxyfen which control infestations caused by fleas, flea eggs, flea pupae, flea larvae, ticks and lice; repel [against] biting flies, and repel and kill mosquitoes.
- Kills fleas, flea eggs, flea larvae, ticks, lice and mosquitoes, repels biting flies and mosquitoes
- Repels and kills fleas and ticks
- Repels fleas, ticks, biting flies and mosquitoes
- Kills and repels ticks
- For the control and prevention of flea, flea egg, flea pupae, flea larvae, [and lice] infestations

- Research has shown that flea, flea egg, flea pupae, flea larvae, tick (biting and chewing) lice infestations, can be controlled with monthly applications of EFFITIX<sup>®</sup> Plus Topical Solution for Dogs. Biting flies and mosquitoes are [also] repelled by EFFITIX<sup>®</sup> Plus Topical Solution for Dogs.
- Effective monthly application against fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Kills fleas, flea eggs, flea larvae, ticks and mosquitoes for up to one month
- Monthly application is recommended for control and prevention of fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Long lasting flea, flea egg, flea pupae, flea larvae, tick and mosquito control for your pet
- EFFITIX<sup>®</sup> Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, flea larvae, ticks, biting flies, mosquitoes, and lice on dogs 8 weeks of age or older, weighing at least 5 lbs.
  - Helps to relieve your dog's pain [discomfort] by controlling flea, flea egg, flea pupae, flea larvae, tick and lice infestations
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, anaplasmosis, ehrlichiosis, hepatozoonosis and heartworm disease.
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of sarcoptic mites
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of mites that may cause sarcoptic mange
- Kills and repels fleas, ticks, and mosquitoes.

#### [Fleas]

- Fleas: EFFITIX<sup>®</sup> Plus Topical Solution for Dogs can kill adult fleas in 6 hours and adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis [FAD], or if reinfestation is likely.
- Kills newly emerged adult fleas prior to egg laying
- Fleas, flea eggs, and flea larvae in the dog's environment are killed following contact with EFFITIX<sup>®</sup> Plus Topical Solution for Dogs
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to [3 months] [90 days]
- Dual Action: fipronil and permethrin to kill adult fleas and pyriproxyfen to kill flea eggs and flea larvae
- With pyriproxyfen (IGR)\* to break [the] flea life cycle \*insect growth regulator
- Kills fleas [within 6 hours] that may transmit bartonellosis, [tularemia] [and tapeworm]
- Kills fleas [within 6 hours] that may transmit the following diseases: bartonellosis, [tularaemia] [and tapeworm infestations]
- Kills fleas [within 6 hours] that may transmit the following diseases: bartonellosis and tularemia
- Rapid kill of fleas is important in the prevention of the following diseases: bartonellosis and tularemia
- Acts to kill fleas that may transmit the following disease: bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms [Dipylidium caninum]
- · Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills (adult) fleas [within 6 hours] that may cause Flea Allergy Dermatitis [FAD] [or] [flea-bite anemia]
- Fleas do not have to bite to die
- Controls highly [irritating] [annoying] [flea] bites
- EFFITIX<sup>®</sup> Plus 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]
- EFFITIX<sup>®</sup> Plus Topical Solution for Dogs kills fleas and may reduce the incidence of Flea Allergy Dermatitis [FAD]
- Kills fleas which [that] may cause flea-bite anemia
- Effective monthly application against fleas, flea eggs, flea pupae, and flea larvae
- Effective monthly control of fleas, flea eggs, flea pupae, and flea larvae
- Kills adult fleas for up to one month [4 weeks]
- Prevents flea eggs from hatching or developing into larvae or adult stages [for up to [90 days] [3 months]]
- Kills adult fleas, flea eggs, and flea larvae for up to three months [12 weeks] however if your dog is susceptible to Flea Allergy Dermatitis (FAD) it is recommended to use monthly
- Kills fleas, flea eggs, and flea larvae
- EFFITIX® Plus Topical Solution for Dogs kills fleas, flea eggs, flea pupae, and flea larvae on your dog
- Once a month topical flea control for dogs and puppies 8 weeks old or older, weighing no less than 5 lbs.
- EFFITIX<sup>®</sup> Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, and flea larvae on dogs and puppies 8 weeks old or older, weighing no less than 5 lbs.
- One application prevents further flea infestations for up to [12 weeks] [three months]. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
  - Monthly treatment [all year] is recommended for control and prevention of fleas, flea eggs, flea pupae, and flea larvae
- Provides ongoing protection against fleas and the following diseases: bartonellosis,[tularemia][and tapeworm infestations] they may transmit for one month
- Stops existing flea infestations by rapidly killing adult fleas, flea eggs, and flea larvae
- Kills fleas before they lay eggs
- Stops existing flea infestations by killing adult fleas, flea eggs, and flea larvae
- Prevents [Stops] re-infestations by killing adult fleas (before they lay eggs)
- Treatment with EFFITIX<sup>®</sup> Plus Topical Solution for Dogs rapidly kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
- Controls flea problems
- Provides flea protection
- Use flea [prevention] [protection] year-round

[Ticks]

- Ticks: EFFITIX<sup>®</sup> Plus Topical Solution for Dogs can kill ticks for [up to] at least [one] month. Apply monthly where tick control is consistently needed.
- Kills and repels 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 and anaplasmosis], 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 and anaplasmosis], 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 Lone Star ticks (*Amblyomma americanum*) for 4 weeks [for up to one month].
- Effective monthly application against ticks

#### [Mosquitoes and biting flies]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days [four weeks] [a [one] month]
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, EFFITIX<sup>®</sup> Plus Topical Solution for Dogs [prevents blood feeding by] [and] [repels] biting flies and mosquitoes for [up to] 4 weeks [a [one] month]
- Repels and kills mosquitoes for up to four [4] weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents [inhibits] blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [[Prevents blood-feeding by] [Kills and repels]] mosquitoes
- Repels biting flies
- Repels [[annoying][bothersome][nuisance]] biting flies
- Inhibits [[annoying][bothersome ][nuisance]] biting flies
- [[Prevents][inhibits]] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitos [*Culex spp, Ochlerotatus spp, Aedes spp*] which may vector heartworm [*Dirofilaria immitis*] for one month

#### [Lice and Mites]

- Lice: EFFITIX<sup>®</sup> Plus Topical Solution for Dogs can kill biting and chewing lice for a [one] month. Apply monthly where lice control is consistently needed.
- Mites: [EFFITIX<sup>®</sup> Plus Topical Solution for Dogs] aids in [the] control of mites that may cause sarcoptic mange.
- Mites: [EFFITIX<sup>®</sup> Plus Topical Solution for Dogs] aids in [the] control of sarcoptic mites
- EFFITIX® Plus Topical Solution for Dogs aids in (the) control of mites that may cause sarcoptic mange.
- [When applied monthly], EFFITIX® Plus Topical Solution for Dogs aids in [the] control of sarcoptic mange.
- Aids in [the] control of sarcoptic mange mite infestation
- Kills chewing and biting lice
- [Also] Kills lice and aids in control of mites that may cause sarcoptic mange
- [Also] Kills lice and aids in control of sarcoptic mites
- Controls existing chewing/biting lice infestations
- Kills [[biting] [chewing]] lice
- For control and prevention of [[biting] [chewing]] lice [infestations]
- Stops existing [[biting] [chewing]] lice infestations
- Prevents and controls [[biting] [chewing]] lice [infestations]
- Provides effective control of [[biting] [chewing]] lice [infestations]
- Kills [[biting] [chewing]] lice and prevents further infestations
- For control and prevention of [infestation][with] [[biting] [chewing]] lice

#### [Others]

- 1 (3, 6, 36) applicator(s) (tube[s]) 0.5 mL (1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)
- 1 (3, 6, 36) applicator(s) (tube[s]) 0.017 fl. oz. (0.034 fl. oz., 0.068 fl. oz., 0.135 fl. oz., 0.203 fl. oz.)
- 1 (3, 6, 36) applicator(s) (tube[s]) 0.017 fl. oz. [0.5 mL], (0.034 fl. oz. [1.0 mL], 0.068 fl. oz. [2.0 mL], 0.135 fl. oz. [4.0 mL], 0.203 fl. oz. [6.0 mL])
- 1 (3, 6, 36) applicator(s) (tube[s]) (each) containing 0.017 fl. oz. [0.5mL] (0.034 fl. oz. [1.0 mL], 0.068 fl. oz. [2.0 mL], 0.135 fl. oz. [4.0 mL], 0.203 fl. oz. [6.0 mL])
- 1 (3, 6, 36) applicator(s) (tube[s])
- 1 (3, 6, 36) monthly dose(s) (application[s])
- 1 (3, 6, 36) applicator(s) (tube[s]) 1 (3, 6, 36) month(ly) dose(s) (application(s)
- DO NOT USE ON CATS
- This product is for use only on dogs and puppies 8 weeks of age or older and (weighing 5 to 10.9 lbs., weighing 11 to 22.9 lbs., weighing 23 to 44.9 lbs., weighing 45 to 88.9 lbs., weighing 89 to 132 lbs.)
- Easy and convenient application [applications]
- Remains effective for a [one] month [4 weeks] for fleas, flea eggs, flea larvae, flea pupae, ticks, mosquitoes and biting flies
- Stops existing infestations and prevents establishment of new infestations for fleas and ticks
- Reinfestation of fleas, ticks and mosquitoes, [biting, chewing] lice and biting flies is prevented for a [one] month

- Convenient topical treatment for dogs •
- Quick onset of activity .
- Persistent efficacy through 30 days •
- Prevents [re-]infestation for one month .
- Once monthly application
- Quick drying, non-greasy
- [Convenient] [to use] Easy [to apply] spot-on [topical] application
- Fragrance [odor] free No noticeable odors
- Single application lasts 4 weeks [one month] [30 days]
- Easy to use applicator makes treatment simple [trouble free, smooth]
- Convenient, easy to apply topical solution
- Convenient, easy to apply and fragrance free topical solution
- Starts working by [on] contact
- [In] child-resistant packaging •
- Convenient [to use], easy to apply [topical solution]
- EFFITIX® Plus Topical Solution for Dogs remains effective after bathing, shampooing, water immersion, or sunlight . exposure.
- Waterproof [remains effective after bathing and swimming] for up to four weeks [a month] [one month]
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight
- Remains effective even after bathing [and swimming] •
- Remains effective after exposure to rain and/or sunlight .
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing [and swimming] [[for a month] [for one month] [for up to four weeks]] •
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Sold by veterinarians •
- Illustration of flea life cycle
- Illustration of tick life cycle .
- Illustration of mosquito life cycle
- Illustration of mite life cycle .
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito Illustration of mite
- Illustration of louse
- Picture or illustration of a dog [or puppy]
- Picture or illustration of the Virbac logo •
- Picture or illustration of the primary package [applicator tubes]