

65331-8

05/11/2012

1/22



U S ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (7505C)  
1200 Pennsylvania Avenue NW  
Washington D C 20460

EPA Reg  
Number

65331 8

Date of Issuance

05/11/2012

Term of Issuance

Conditional

Name of Pesticide Product

Tradename for Dogs

## NOTICE OF PESTICIDE

x Registration

Reregistration

(under FIFRA as amended)

Name and Address of Registrant (include ZIP Code)

Merial Ltd  
3239 Satellite Blvd  
Duluth GA 30096

Note Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant the above named pesticide is hereby registered under the Federal Insecticide Fungicide and Rodenticide Act

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment the Administrator on his motion may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is registered in accordance with FIFRA sec 3(c)(7)(A) contingent on the following

- 1 Make the following labeling changes before releasing the product for shipment
  - a Revise the EPA Registration Number to read EPA Registration No 65331 8

Signature of Approving Official

Date

See page 4

May 11 2012

Richard Gebken  
Product Manager (RM 10)  
Insecticide Branch  
Registration Division (MC 7505P)

- b Delete the marketing claim *Available [through Veterinarians] [from a licensed veterinary professional] [from a licensed veterinarian]*
  - c State the full net contents for multiple packages
  - d Remove/delete the claim *Kills flea eggs and larvae* throughout label
  - e Change mites to *Sarcoptic mange mites*
  - f State the lower weight limit on blister pack etc
  - g Delete the statement *The killing of fleas and ticks is important in the prevention of disease transmission by these parasites*
  - h Under the subtitle *Alternate marketing text for carton or insert* (pgs 13 – 18) see mark up corrections on the label and revise accordingly
- 2 This registration is time limited and expires two years from the date this product is first released for shipment
- You must provide the Agency with a projected release for shipment date in writing within 30 days of the date of this Notice of Registration (NOR) The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing
- 3 Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e. no alternate formulations or minor formulation amendments will be submitted and/or approved for this product except to allow for alternate sources of any individual inert ingredient)
- 4 Submit the following data within the timeframe described below
- Within sixteen (16) months of the date on this NOR Guideline Studies OPPTS 830 6320 (Corrosion Characteristics) and OPPTS 830 6317 (Storage Stability)***
- Within twelve (12) months of the date on this NOR - Guideline Study OPPTS 830 1650 (Description of the formulation process)***
- 5 You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on July 1 2012

The quarterly reports are due two months after the end of each quarter Please flag any Confidential Business Information (CBI) as such Enhanced incident reporting should be submitted to the Product Manager Quarterly sales information should be submitted to the Registration Division Immediate Office (attn Kimberly Nesci)

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

- 6 Along with the enhanced incident reporting you must submit an analysis of all incidents seen to include the following details
- a All minor dermal and ocular irritation reports
  - b 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
  - c A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure
  - d Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g. multi pet households)
  - e 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
  - f A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label
  - g 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
  - h Table showing number of incidents for each dog breed
  - i Table showing number of incidents in dogs for each clinical sign
  - j Table showing number of incidents in dogs for each organ system
  - k Report aggregate incidents but do not combine moderate and minor incidents

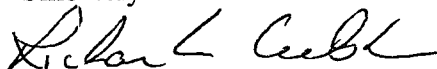
- 1 You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data and submit acceptable responses required for re registration (registration review) of your product under FIFRA section 4

This NOR was issued with the understanding that you will ensure that the labeling for this product (a) is consistent with that of the cited me too product (Effitix Tropical Solution for Dogs EPA Reg Nos 2382 187) and (b) conforms to the mitigation measures stated in the Agency's letter ( Implementation of Label Changes to Pet Spot on Products ) to you dated 09/30/2011 Also if EPA determines that future mitigation measures are necessary for all pet spot on products the Agency will inform all registrants concerned If mitigation measures are necessary EPA may take regulatory action

Copy of the finished labeling must be submitted prior to releasing the product for shipment If you fail to comply with the above stated conditions the registration will be subject to cancellation in accordance with FIFRA sec 6(e) and/or automatically expire Your release for shipment of the product constitutes your acceptance of these conditions

A copy of your label stamped Accepted with Comments is enclosed for your records If you have any questions concerning this action please contact me or Dr B A Akinlosotu via (703) 605 0653 or alinlosotu.bonaventure@epa.gov

Sincerely



Richard Gebken  
Product Manager (RM 10)  
Insecticide Branch  
Registration Division (MC 7505P)

Enclosures  
Stamped Label

5/22

Reason to Issue Product Registration

Date 05/09/12  
Supersedes 10/06/11

**Draft Master Label**

Includes label text for four different applicator sizes corresponding to four dog weight ranges, and including a 1x, 3x and 6x applicator presentation. Due to space limitations the layout of the 1x hanging card may differ from the 3x and 6x cartons (NOTE The 1x hanging card will not utilize a carton or compliance cards, so all required information will be located on the Insert, blister pack or pipette for the 1x presentation) Optional text appears in brackets

(For alternate marketing text to use on carton insert or 1X hanging card see pages 13 18)

(CARTON FRONT PANEL)

[1][3][6]  
monthly  
dose(s)

**FRADENAME™ for dogs**

~~Available [through veterinarians][from a licensed veterinary professional][from a licensed veterinarian]~~  
[From the makers of FRONTLINE®]

Picture of  
representative  
size dog

Fast Acting long lasting control of fleas ticks lice biting flies and mosquitoes for use on (Dogs  
x Puppies ONLY 12 weeks or older and up to 22 9 lbs)  
Dogs ONLY 23 – 44 9 lbs)  
Dogs ONLY 45 – 88 9 lbs)  
Dogs ONLY 89 – 132 lbs)

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

For First Aid and other precautionary statements refer to product package insert

**ACTIVE INGREDIENTS**

Fipronil 6 01%  
Permethrin\* 44 88%

**OTHER INGREDIENTS**

**TOTAL** 49 11%  
100 0%

\*cis trans ratio max 55% (+ / ) cis and min 45 % (+ / ) trans

**ACCEPTED  
with COMMENTS  
In EPA Letter Dated  
MAY 11 2012**

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

**65331-8**

Contains 1 3 or 6 [(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))] applicators

— Need full net contents for multiple pkgs

Do Not Use on  
Cats  
Pictogram

(CARTON BACK PANEL)

**READ THE ENTIRE LABEL BEFORE EACH USE****For the treatment and prevention of Fleas, Ticks, Mosquitoes, Biting Flies, and Lice on Dogs**

Repels and kills (fleas) (and) 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)]

Kills ticks which may transmit Lyme disease Canine Ehrlichiosis, Anaplasmosis Rocky Mountain spotted fever Hepatozoonosis Babesiosis or cause tick paralysis]

**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 on dogs ONLY

DO NOT USE ON CATS PICTOGRAM

DO NOT USE ON CATS IF INGESTED BY A CAT THAT HAS ACTIVELY GROOMED A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS IF THIS OCCURS CONTACT YOUR VETERINARIAN IMMEDIATELY

Do not use on dogs under 12 weeks of age 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 and persist 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 Call 1 800 660 1842 for 24 hour assistance

**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 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 ONLY** Do not use on dogs under 12 weeks of age Do not split applicators between dogs Do not use multiple applicators 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

(CARTON BACK PANEL)(Cont d)

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

For use in DOGS (12 weeks old or older) To repel and kill fleas ticks and mosquitoes to kill lice and to aid in control of mites to repel and prevent blood feeding by biting flies Apply monthly according to the following directions

Open the child resistant packaging according to the instructions found on the inside front panel of the carton Hold applicator upright away from face and body snap applicator tip to open For small dogs (12 weeks or older) and weighing up to 22.9 lbs Part the dog's hair above the shoulder blades at the base of the neck Place the applicator tip just above the skin and squeeze Apply entire contents of the applicator in a single spot directly onto the dog's skin Do not apply on top of the haircoat For medium dogs 23.44-9 lbs or large dogs 44.88-9 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 For extra large dogs 89-132 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 Avoid contact with treated area until dry

**Frequency of Application**

Fleas ticks, (biting and chewing) lice infestations can be controlled with monthly applications of **TRADENAME™** for Dogs Biting flies and mosquitoes are (also) repelled by **TRADENAME™** for Dogs

**TRADENAME™** for Dogs can start killing adult fleas within 6 hours and lasts for (up to) a month Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD) or if reinfestation is likely

**TRADENAME™** for Dogs can kill ticks for (up to) a month Apply monthly where tick control is consistently needed

**TRADENAME™** for Dogs can kill biting and chewing lice for (up to) a month Apply monthly where lice control is consistently needed

**TRADENAME™** for Dogs aids in (the) control of (sarcoptic mange)/(mite infestations that may cause sarcoptic mange)

When applied monthly, **TRADENAME™** 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)

Wait at least 30 days before re application of **TRADENAME™** for Dogs Avoid contact with treated area until dry **TRADENAME™** remains effective even after bathing, water immersion or exposure to sunlight

Merial Limited  
4239 Satellite Blvd  
Duluth GA 30096 4640 USA

MADE IN FRANCE

EPA Reg No 65331 I  
EPA Est No 65331 FR 2

Satisfaction  
Guaranteed  
Graphic

Please call our experts at  
1 800 660 1842 if you have any  
questions or comments about flea  
tick mosquito biting fly and lice  
control or **TRADENAME™**

(CARTON INSIDE FRONT PANEL)(Cont d)

(Instructions for the 3x/6x blister pack)

**How to Apply TRADENAME™ for dogs**

Pictogram  
indicating how to  
remove applicator

Pictogram  
indicating how to  
open applicator

Pictogram  
indicating where to  
apply on the dog

**Step 1 To Remove Applicator**

Lift and remove the plastic tab to expose foil backing then peel away the foil Or use scissors to open

**Step 2 Open Applicator**

Hold upright with foil side toward you and snap applicator tip

**Step 3 Apply Tradename ™ for dogs**

a) For small dogs (12 weeks or older) and weighing up to 22.9 lbs Part the dog's hair above the shoulder blades at the base of the neck Place the applicator tip just above the skin and squeeze Apply entire contents of the applicator in a single spot directly onto the dog's skin Do not apply on top of the haircoat b) For medium dogs 23.44.9 lbs or large dogs 44.88.9 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 c) For extra large dogs 89.132 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 Avoid contact with treated area until dry

Questions or Comments?  
Call 1 800 660 1842  
Monday Friday 8am 8pm EST



9/22

(INSIDE CARTON FLAPS)

**TRADENAME™ for dogs**

(Rapidly/Quick/Quickly/Fast Acting)(Starts rapidly killing fleas in (as little as) 6 hours), and kills ticks for (up to) a month

**TRADENAME™ for dogs** provides efficacy against fleas and ticks with a rapid (quick) onset of activity (in) (as little as) (6 hour) [The active ingredients in TRADENAME™ provide for fast acting (and long lasting) control of fleas ticks chewing lice and mosquitoes (for at least 30 days) on dogs ]

**[ PICTOGRAMS (icon with slash through) ]**

Adult Flea  
Adult Tick  
Tick nymph  
Tick larvae  
Chewing Lice  
Mosquitoes  
Biting Flies  
Mites

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10/22

(PACKAGE INSERT FRONT)

**IRADENAME™ for dogs**

For use ONLY on dogs &amp; puppies 12 weeks or older

Convenient fast acting, long lasting spot on treatment for treatment and control of fleas, ticks, mosquitoes, biting flies and chewing lice

**ACTIVE INGREDIENTS**

Fipronil	6.01%
Permethrin*	44.88%

**OTHER INGREDIENTS**

49.11%

**TOTAL**

100.00%

\*cis/trans ratio max 55% (±) cis and min 45% (±) trans

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

See below for First Aid and Precautionary Statements

**IRADENAME™ for dogs**Starts rapidly killing fleas in (as little as) 6 hours and all stages of ticks for an entire month including **Deer ticks, Brown Dog ticks, American Dog ticks, and Lone Star ticks**

- Kills ticks which may transmit **Lyme Disease, canine Ehrlichiosis, Anaplasmosis, Rocky Mountain Spotted Fever, Hepatozoonosis, Babesiosis** or cause **tick paralysis**
- Kills and repels fleas, ticks, biting flies, chewing lice and mosquitoes
- Effectively (Kills)(Stops)(Controls) existing infestations and prevents re infestations of fleas and ticks
- Kills adult fleas ~~flea eggs & flea larvae~~
- Kills fleas which may cause flea allergy dermatitis
- Eliminates infestations with chewing lice
- Aids in control of sarcoptic mange infestations
- Can be used on dogs and puppies 12 weeks or older
- [Can also be used on breeding, pregnant and lactating bitches]
- Fast acting (in) (as little as) (6 hours)
- Long lasting for 1 month against fleas and ticks
- Waterproof
- Convenient to use

**DO NOT USE ON CATS**Do not use on cats  
pictogram

~~Available [Through Veterinarians] [from a licensed veterinary professional]~~  
~~[from a licensed veterinarian]~~

**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. For external use on dogs only. Do not use on cats or rabbits. Do not use on other animals.

**DO NOT USE ON CATS**

11/22

(PACKAGE INSERT FRONT)(Cont d)

**FOR EXTERNAL USE ON DOGS ONLY** Do not use in dogs under 12 weeks of age Do not split pipettes between dogs Do not use multiple pipettes 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

To kill and repel all stages of fleas and ticks biting flies mosquitoes and chewing lice apply topically to the skin of dogs or puppies (12 weeks or older) as follows

(Instructions for the 1x hanging card/carton)

**How to Apply TRADENAME™ for dogs**

Pictogram indicating how to remove applicator

**Step 1 To Open, use scissors** to cut along dotted line of hanging card then pull apart plastic and remove the applicator

Pictogram indicating how to open applicator

**Step 2 Open Applicator**  
Hold upright with foil side toward you and snap applicator tip

Pictogram indicating where to apply on the dog

**Step 3 Apply TRADENAME™ for dogs**

a) For small dogs (12 weeks or older) and weighing up to 22.9 lbs Part the dog's hair above the shoulder blades at the base of the neck Place the applicator tip just above the skin and squeeze Apply entire contents of the applicator in a single spot directly onto the dog's skin Do not apply on top of the haircoat b) For medium dogs 23.44.9 lbs or large dogs 44.88.9 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 c) For extra large dogs 89.132 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 Avoid contact with treated area until dry

**Questions or Comments?**  
**Call 1 800 660 1842**  
**Monday Friday 8am 8pm EST**

12/22

(PACKAGE INSERT BACK)

#### **FREQUENCY OF APPLICATION**

A monthly application of **TRADENAME™** kills and repels fleas all stages of ticks mosquitoes, biting flies, and chewing lice. Do not apply more than once a month. Research demonstrates that **TRADENAME™** kills adult fleas, flea eggs, and flea larvae for up to one month. **TRADENAME™** remains effective even after bathing, water immersion, or exposure to sunlight.

#### **PESTICIDE STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**STORAGE** Store unused product in original container only in a cool, dry place, out of reach of children and animals.

**PESTICIDE DISPOSAL** If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

**CONTAINER DISPOSAL** If empty: Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling, if available.

#### **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 on dogs ONLY. Do not use on cats. If ingested by a cat that has actively groomed a recently treated dog, this product may have serious harmful effects. If this occurs, contact your veterinarian immediately. Do not use on dogs under 12 weeks of age. 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. Call 1-800-660-1842 for 24-hour assistance.

(PACKAGE INSERT BACK)(Cont d)

<b>FIRST AID</b>	
<b>IF SWALLOWED</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice</li> <li>• Have a person sip a glass of water if able to swallow</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor</li> <li>• Do not give anything by mouth to an unconscious person</li> </ul>
<b>IF IN EYES</b>	<ul style="list-style-type: none"> <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>
<b>IF ON SKIN OR CLOTHING</b>	<ul style="list-style-type: none"> <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>
<b>Have product container or label with you when calling a poison control center or doctor, or going for treatment, or call 1-800-660-1842 for 24-hour assistance</b>	

#### **How Supplied**

For easy and convenient application, TRADENAME™ for Dogs is available in sizes for small dogs and puppies ONLY 12 weeks or older and up to 22 9 lbs medium dogs 23 44 9 lbs large dogs 45 88 9 lbs and extra large dogs 89 132 lbs

#### **WARRANTY**

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label To the extent consistent with applicable law buyer assumes all risk of use and handling of this material when such use and handling are contrary to the label instructions

EPA Reg No 65331 I

#### **Merial Limited**

239 Satellite Blvd  
Duluth GA 30096 4640 USA

**TRADENAME™** is a trademark of Merial

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14/22

(COMPLIANCE CARD)

(FRONT)

See other side for more

**TRADENAME™ for dogs**

Some tips and other information

DO NOT USE ON CATS

To successfully control fleas ticks chewing lice mosquitoes, biting flies and mites all dogs must be treated with their own dose of **TRADENAME™**

*Sarcoptic mange*

Tick  
pictogram

Flea eggs  
larvae, and  
adult flea  
pictogram

Pipette  
pictogram

Chewing lice  
pictogram

Apply according to label instructions ensuring the product is applied to the skin. It must be applied above the shoulder blades at the base of the neck. Do not apply on top of the haircoat. It may be helpful to remove the collar before application so it doesn't absorb the product.

Remember your dog needs to be dry at the time **TRADENAME™** is applied and remain dry 24 hours after application.

Verify applicator is empty after applying to your dog.

Even indoor dogs need flea and tick control because you or other dogs in the household may bring fleas and ticks into the home.

Mosquito  
pictogram

Biting fly  
pictogram

(BACK)

Calendar reminder stickers

Do not use on  
cats pictogram

To ensure continued protection of your dog, use these stickers as a reminder to apply and re-purchase **TRADENAME™**.

After treating your pet for the first time, peel off the sticker and place on your calendar that day.

Place the remaining stickers on your calendar as a reminder to apply **TRADENAME™** monthly.

Don't forget to re-purchase!

6 months  
Use all 6 stickers

months

5 stickers that read: Apply  
**TRADENAME™** with the 6<sup>th</sup> sticker  
Re-purchase **TRADENAME™**

QUESTIONS? Contact your veterinarian or call our technical experts at 1 800 660 1842 Monday-Friday, 8am-8pm. For more information, visit **www.TRADENAME™.com**  
**TRADENAME™** is a trademark of Merial.

15/22

(LABEL ON INDIVIDUAL APPLICATOR)

**TRADENAME™ for dogs**

6.01% fipronil  
44.88% Permethrin

Application to  
dog pictogram

EPA Reg. No. 65331-1

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

Lot No.

Do not use on  
cats pictogram

16/22

Reason to Issue Product Registration

Date 05/09/12

Supersedes 10/06/11

(LABEL ON BLISTER PACK)

**TRADENAME™ for dogs**

(S, M L XL)

*Lower wt limit?*

(For dogs and puppies ONLY 12 weeks or older and up to 22 9 lbs )

(For dogs ONLY 23 – 44 9 lbs )

(For dogs ONLY 45 – 88 9 lbs )

(For dogs ONLY 89 – 132 lbs )

Do not remove applicator until ready to use

EPA Reg No 65331 I

(0 034 fl oz )

(0 068 fl oz )

(0 135 fl oz )

(0 203 fl oz )

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

Read the entire label before use

Lot No





17/22

**Alternate marketing text for carton or insert**

**TRADENAME™ for dogs** [starts rapidly killing fleas and ticks within 6 hour providing a convenient effective treatment for fleas and (all stages of) ticks] **TRADENAME™** kills and repels fleas mosquitoes biting flies chewing lice and all stages of ticks ONLY for (dogs and puppies 12 weeks or older and up to 22.9 lbs)(dogs weighing 23 – 44.9 lbs)(dogs weighing 45 – 88.9 lbs)(dogs weighing 89 – 132 lbs)

[Multiple Infestations]

- Starts rapidly killing fleas and all stages of ticks (in) (as little as) (6 hours) including Deer ticks Brown dog ticks, American dog ticks, and Lone Star ticks
- Kills and repels ticks mosquitoes and biting flies
- Repels and kills mosquitoes for up to four weeks
- Kills ticks which may transmit Lyme Disease canine Ehrlichiosis Anaplasmosis Rocky Mountain Spotted Fever Hepatozoonosis, Babesiosis or cause tick paralysis
- (Kills)(Stops)(Controls) existing infestations and prevents re infestations of fleas and ticks
- Fast acting starts killing fleas and ticks (in)(as little as) (6 hours)
- Long lasting for (1 month against ticks)(and)(3 months against fleas)
- Re infestation of fleas ticks and mosquitoes (biting, chewing) lice and biting flies is prevented for a (one) month or longer
- 8 way protection against fleas ticks tick larvae tick nymphs mosquitoes biting flies lice, and mites
- ~~The killing of fleas and ticks is important in the prevention of disease transmission by these parasites.~~
- After application **TRADENAME™** spreads naturally over the dog's body to provide (full body) (all over) protection against fleas ticks mosquitoes biting flies and chewing lice
- **TRADENAME™** provides ongoing protection against fleas ticks mosquitoes, biting flies and chewing lice [for at least one month (30 days)]
- Effective monthly treatment of fleas and ticks
- Easy fast effective control of fleas and ticks that lasts at least 1 month (30 days)
- Using the (patented)(trademark) applicator **TRADENAME™** is specially designed to spread naturally over the dog's body providing effective control of fleas and ticks
- Prevents reinfestation (of fleas)(of ticks) for up to one month
- Monthly treatment is recommended for optimal control and prevention of fleas and ticks
- Proven treatment technology for (the control of) flea(s)(infestations) (ticks) (mosquitoes) (biting flies) (and chewing lice)
- **TRADENAME™** uses (different)(multiple) modes of action to kill (ticks)(fleas)(mosquitoes)(chewing lice)(sarcoptic mange mites)(biting flies)
- For convenient quick acting long lasting control of fleas, ticks mosquitoes and lice
- (When) Applied topically on a monthly basis **TRADENAME™** for Dogs repels and kills fleas ticks and mosquitoes, kills (biting chewing) lice, aids in control of mites and repels (and inhibits blood feeding) by biting flies and mosquitoes
- **TRADENAME™** for Dogs contains the active ingredients fipronil and permethrin which control infestations caused by fleas ticks and lice, repel (against) biting flies and repel and kill mosquitoes
- Kills fleas, ticks lice and mosquitoes repels biting flies and mosquitoes  
Repels and kills fleas and ticks  
Repels fleas, ticks, biting flies and mosquitoes
- For the control and prevention of flea [and lice] infestations  
Flea tick (biting and chewing) lice infestations can be controlled with monthly applications of **TRADENAME™** for Dogs
- Helps to relieve your dog's pain (discomfort) by controlling flea tick and lice infestations

- Biting flies and mosquitoes are (also) repelled by **TRADENAME**™ for Dogs
- Monthly application against fleas ticks and mosquitoes
- Kills fleas ticks and mosquitoes for (up to) one month
- Monthly application is recommended for control and prevention of fleas ticks and mosquitoes
- Long lasting flea tick and mosquito control for your pet
- **TRADENAME**™ for Dogs is indicated for the prevention and control of fleas ticks mosquitoes and lice on dogs 12 weeks of age and older
- Kills fleas ticks mosquitoes lice and aids in control of mites
- Kills and repels fleas ticks and mosquitoes

[Fleas]

- ~~• Kills and repels all stages of fleas~~
- Prevents fleas on treated dogs from infesting your home
- Kills fleas on dogs within (in) (as little as) (6 hour) and continues to prevent infestations for a month
- Larval flea stages in the dog's environment (surroundings) are killed following contact with a **TRADENAME**™ treated dog — *specific date/duration, etc*
- Kills fleas (before they lay eggs) (that may transmit ~~disease, including~~ bartonellosis and tapeworm disease)
- Kills fleas which may cause flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD) Treatment of dogs with **TRADENAME**™ rapidly kills fleas and may reduce the incidence of this condition
- **TRADENAME**™ kills existing fleas on dogs within (6 hours)
- Re infesting fleas are killed within (6 hours) with protection against further flea infestation lasting at least four weeks Pre existing pupae in the environment may continue to emerge for six weeks or longer depending upon climatic conditions
- ~~• Repels and kills all life stages of fleas.~~
- Prevents fleas on treated dogs from infesting your home
- Kills fleas on dogs within (6 hours) and continues to prevent infestations for a month
- Approximately 95% of the flea population in a household infestation are immature flea stages that live in the dog's environment
- ~~• (Regular use) protects against all stages of the flea life cycle~~
- May reduce the incidence of flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD) Treatment of dogs with **TRADENAME**™ rapidly kills fleas and may reduce the incidence of FAD
- **TRADENAME**™ is useful for dogs susceptible to flea allergy dermatitis (FAD)
- Regular use of **TRADENAME**™ breaks the flea life cycle
- Kills (newly emerged) fleas (before they lay eggs) for up to 12 weeks
- **TRADENAME**™ for Dogs can kill adult fleas in 6 hours (and lasts) for (up to) 12 weeks 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
- Kills fleas (within 6 hours) that may transmit bartonellosis (tularemia) (and tapeworm)
- Kills fleas (within 6 hours) that may transmit ~~diseases, including~~ bartonellosis (tularemia) (and tapeworm infestations)
- Kills fleas (within 6 hours) that may transmit ~~diseases including~~ bartonellosis and tularemia
- ~~• Rapid kill of fleas is important in the prevention of disease transmission by (these) parasites~~
- Acts to kill fleas that may transmit ~~disease such as~~ 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
- **TRADENAME™** for Dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- Kills adult fleas for up to 3 months (12 weeks) ?
- Kills fleas
- Easy to apply control of (for) fleas that lasts up to 3 months (12 weeks) ?
- **TRADENAME™** for Dogs kills fleas on your dog
- Once a month topical flea control for dogs 12 weeks of age or older
- **TRADENAME™** for Dogs is indicated for the prevention and control of fleas on dogs 12 weeks of age and older
- One application prevents further flea infestations for up to (12 weeks) ([three] months)
- Monthly treatment (all year) is recommended for control and prevention of fleas
- Provides ongoing protection against fleas ~~and the diseases they may transmit for three months~~
- Stops existing flea infestations by rapidly killing adult fleas
- Kills fleas before they lay eggs
- Stops existing flea infestations by killing adult fleas
- Prevents [Stops] re infestations by killing adult fleas (before they lay eggs)
- Treatment with **TRADENAME™** rapidly kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
- ~~Controls flea problems~~ on your dog ?
- Provides flea protection [prevention] [protection] year round
- ~~**TRADENAME™** for Dogs controls flea infestation that may lead to painful skin irritation and bacterial infection~~

[Ticks]

- ~~Kills all stages of ticks infesting dogs.~~
- (Rapidly)(kills)(ticks)(~~including those~~)(vectors)(which may cause)(which may transmit) Lyme disease (Ehrlichiosis) (Anaplasmosis) (Babesiosis) (Tick Paralysis) (Rocky Mountain Spotted Fever) (Southern Tick Associated Rash Illness), and (Hepatozoonosis)
- Kills ticks for (up to)(at least) 4 weeks
- **TRADENAME™ for dogs** rapidly kills all stages of ticks including deer ticks brown dog ticks American dog ticks and lone star ticks
- Kills and repels ticks
- Kills the vectors that may transmit Lyme disease Rocky Mountain spotted fever ehrlichiosis hepatozoonosis and heartworm disease
- Ticks **TRADENAME™** for Dogs can kill ticks for (up to) a [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) 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)
- Monthly application against ticks

[Mosquitoes and biting flies] *Data for 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 **TRADENAME™** 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 mosquitoes (*Culex* spp *Ochlerotatus* spp *Aedes* spp) which may be (a) vector(s) of heartworm (*Dirofilaria immitis*) for one month
- Repels and prevents blood feeding by biting flies

[Lice and Mites]

- (For treatment of)(Treats and controls)(Provides effective control of)(For treatment of infestations with)(Kills)(Stops existing) chewing lice (infestations)
- Kills chewing lice
- Lice **TRADENAME™** for Dogs can kill biting and chewing lice for (up to) a [one] month Apply monthly where lice control is consistently needed
- Mites (**TRADENAME™** for Dogs) aids in (the) control of mites (that may cause sarcoptic mange)
- **TRADENAME™** for Dogs aids in (the) control of mite infestations (that may cause sarcoptic mange)
- (When applied monthly ) **TRADENAME™** for Dogs aids in (the) control of sarcoptic mange
- Aids in (the) control of sarcoptic mange mite infestations
- Kills chewing and biting lice
- (Also) Kills lice and aids in control of mites
- Eliminates infestations with chewing lice
- Aids in control of sarcoptic mange infestations 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 control of [(biting) (chewing)] lice (infestations)

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- Kills [(biting) (chewing)] lice and prevents further infestations
- For control and prevention of (infestations with) [(biting) (chewing)] lice
- ~~(For treatment of)(Kills) sarcoptic mange mites~~

[Miscellaneous]

**TRADENAME™** is waterproof and remains effective following bathing shampooing swimming (water immersion) or after exposure to rain or sunlight

- [Can also be used on breeding, pregnant and lactating bitches]
- Convenient topical treatment for dogs who enjoy the outdoors
- (Convenient)(to use)(Easy to apply) spot on application
- Persistent (sustained) efficacy through 30 days
- Protects for (at least) one month
- Convenient (easy to apply) topical treatment (with [patented] applicator)(that allows application down to the skin)
- (Patented) applicator (trademark) for easy application directly to the skin
- Quick drying
- For easy and convenient application **TRADENAME™** for Dogs is available in sizes for small dogs (12 weeks old or older) and up to 22.9 lbs (0.034 fl oz)(1.0 ml) medium dogs 23.44.9 lbs (0.068 fl oz) (2.0 ml) large dogs 45.88.9 lbs (0.135 fl oz) (4.0 ml) and extra large dogs 89.132 lbs (0.203 fl oz) (6.0 ml)
- Easy spot on (topical) application
- Guaranteed effective for (at least) one month
- New (combination)(formula for your dog(s))(first six months)
- Non greasy
- (Formulated) for dogs that (enjoy)(love) the outdoors
- Waterproof
- Tested on puppies from 12 weeks of age
- Convenient to use
- (1)(3)(6) applicator(s) (1.0 ml 2.0 ml 4.0 ml 6.0 ml)
- (1)(3)(6) applicator(s) (0.034 fl oz 0.068 fl oz, 0.135 fl oz, 0.203 fl oz)
- (1)(3)(6) applicator(s) (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) applicator(s)(each) containing (0.034 fl oz [1.0mL] 0.068 fl oz [2.0 mL], 0.135fl oz [4.0 mL] 0.203 fl oz [6.0 mL])
- (1)(3)(6) applicator(s)
- (1)(3)(6) monthly dose(s) [application(s)]
- (1)(3)(6) applicator(s)
- This product is only for use on dogs 12 weeks of age or older up to 22.9 lbs (weighing 23 to 44.9 lbs weighing 45 to 88.9 lbs weighing 89 to 132 lbs)
- Up 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(s)
- Stops existing infestations and prevents establishment of new infestations
- Convenient topical treatment for dogs
- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents (re )infestation for one month
- Once monthly application
- **TRADENAME™** is brought to you by the makers of FRONTLINE®
- Quick drying non greasy
- (Convenient) (to use) Easy (to apply) spot on (topical) application
- ~~Fragrance (odor) free~~
- No noticeable odors

6 months from NBR

- Easy to use applicator makes treatment simple (trouble free, smooth) and comfortable for you and your pet
- Convenient easy to apply topical solution
- Convenient, easy to apply and ~~and fragrance free topical solution~~
- Starts working by (on) contact
- (In) child resistant packaging
- Convenient (to use), easy to apply (topical solution)
- 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
- ~~Available from licensed 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 Merial logo
- Picture or illustration of the primary package (applicators)