

2724-811

4/23/2013

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 23, 2013

Mr. James J. McFadden, Ph.D.
Senior Regulatory Project Manager
Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, IL 60173-5417

**Subject: Amending Labeling; Response to EPA Letter Dated September 30, 2011
RF2164 A/T COMBO, EPA Reg. No. 2724-811
Your Submission Dated April 2, 2012 & E-Mail Resubmission Dated April 22, 2013**

Dear Mr. McFadden

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 two (2) years from the date of this letter. More specifically, this registration will expire on April 23, 2015.**
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 April 1, 2013. 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 (Attn: Katlin Keller). 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.

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

- 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., multi-pet 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.

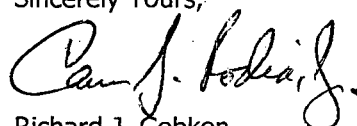
Should you wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not be substantially differ from those claims approved through the registration process. Therefore, should the Agency find, or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

Copies of your label stamped "Accepted with Comments" as well as a review for minimum treatment weight are enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

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If you have any questions about this label review, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely Yours,

For


Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

Enclosures: *Label stamped "Accepted with Comments," dated April 23, 2013*
Review for Minimum Treatment Weight, dated March 12, 2013

002724-00811 D469103

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RF2164 A/T COMBO

[Include "Dog" in product name and the Text for "Dog" must be the same size as the largest letter in the Brand Name]

Front Panel - For Use ONLY on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.), Large (56 - 80 lbs.) and Extra Large (81 lbs. and over) Dogs/Puppies (10 Weeks of age or older)

**Front Panel - For Use ONLY on Dogs (Over 6 lbs) & Puppies (10 Weeks of age or older)
[Flea & Tick [& Mosquito][Treatment] [and] Control]
Spot-On Flea & Tick Control ONLY for Dogs (Over 6 lbs) & Puppies (10 Weeks of age or older)**

General Claims:

5 size categories provide [smaller] weight ranges to improve [maintain][deliver] efficacy [performance][flea and tick][control][protection] on [for] your dog/puppy
Effective on indoor and outdoor dogs/puppies
(1)[3][4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses
Spreads naturally with dog's/puppy's movement (skin and hair oils)
[Formula][Contains lanolin for coat conditioning]
[Water Resistant] [to keep killing fleas and ticks in humid and wet conditions]
[Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]
[Fresh][Clean][Scent][Smell]
[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar
[Satisfaction guaranteed or your money back]
[Patent Pending]
[Can be used in households with dogs and cats]

Efficacy Claims:

Each tube [cartridge][vial] [application] [kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]
[Protects for up to [Four/4] Weeks][One month][Four/4 Week [Flea][Tick][Mosquito] Treatment]
[Controls fleas, ticks and mosquitoes for up to one month][Monthly treatment for control of fleas, ticks and mosquitoes]
[Aids in Control of Ticks for up to 30 days]
[Starts Killing Fleas and Ticks within 15 minutes]
[Kills 85% of ticks within 48 hours][Kills more than 50% of fleas in 2 hours]
[Dual Action kills adult fleas and prevents flea development]
[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]
Kills the Deer Tick, which may transmit Lyme Disease
Kills and Repels mosquitoes (the major carrier of canine heartworm)
Monthly application for most effective protection

IGR Claims:

[Contains [InfestStop™] an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for [more than 10 weeks] up to [75 days][2.5 months]
[Contains [InfestStop™] [an Insect Growth Regulator (IGR) to kill flea eggs and larvae]
[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]
An important step in breaking the flea life cycle
[Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]
[With [InfestStop™][S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]
InfestStop/Infestop™ logo

ACCEPTED
With COMMENTS
In EPA Letter Dated:
April 23, 2013
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:

2724-011

Applicator Claims

[applicator]
 contemporary design
 [brand name] [Applicator] helps to prevent getting liquid on [your] hands
 [brand name] [Applicator] tip parts hair to help [liquid][application] get down to [the][your][dog's/puppy's] skin
 Ergonomically contoured [ergonomic][shape][design] for easy handling [ease of use] [easy use]
 For use with [only][brand name][disposable][liquid dispensing] tubes [pods] [vials] [cartridges]
 [brand name] [applicator][has][provides][allows for][delivers] better grip
 [brand name][provides] re-closable [re-sealable] packaging for [easy] storage
 Closing [the][brand name][applicator] door automatically opens the [disposable][liquid dispensing] tube
 [pod][vial][cartridge]
 [brand name] [Applicator] [will not drip after opening]
 [brand name] [Applicator] Won't drip when set down as you go fetch the [your] dog/puppy
 Includes unique [brand] applicator
 Puts the liquid on your dog/puppy – not your hands
 Directs the liquid onto your dog [/puppy] – not your hands
 Directs the liquid onto your dog [/puppy] – away from your hands
 Applies liquid to your dog's [/puppy's] skin – not yours
 Helps prevent applying the wrong spot-on [dose] [product] on [to] the wrong pet
 Convenient, easy to use ACCU-TIP [Applicator] [DISPENSER]
 [Easy to use] Longer applicator tip for easy application to long-haired dogs/puppies

Thermoform claims

[disposable][liquid dispensing] tube [cartridge][vial][pod]
 (Note tube/vial/cartridge/pod used interchangeably)
 [brand name][disposable][liquid dispensing] [tube][vial][pod] tip [helps][to] spread out liquid [on your][dog/puppy]
 Unique [cartridge] [tube][vial][pod] with flow control
 [no drip][no mess][application][tube][cartridge][vial][pod]

Promotional Package Copy

One month [dose] free
 One free month supply [dose] included
 Bonus pack
 Free [applicator][tube][vial][cartridge][pod][inside]
 Designed not to drip when set on top of the counter, or table, or other flat surface.
 For use with [brand] applicator
 Applicator [device] not included
 [brand] Refill Pack [brand][applicator [device] not included]

Refill Claims

For use [only] with [brand name][Applicator]
 ([1][3][4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses
 Easy to use [convenient] refills
 [Can be used with] [Use with] [Brand Name] applicator
 [Brand Name (e.g., Adams or Bio Spot, Smart Shield)] [Applicator] [Refills][Refill Pack]
 [Refill Pack] [for][Brand Name] Applicator
 [tube][cartridge][vial][pod] refill pack [refills]
 Refills [Refill Pack] available
 [refill][tube][cartridge][vial][pod] design

Applicator name options (applicator device is used in text)

Applicator
 Tool
 Device
 Applicator Device
 Application Tool

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The moform name options (tube, cartridge and vial are used in the text)

- Ampoule
- Cartridge
- Packet
- Pod
- Refill
- Tube
- Vial

(Front panel)

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1)	30.0%
S-Methoprene (CAS # 65733-16-6)	3.6%
Piperonyl Butoxide (CAS # 51-03-6)*	5.0%

OTHER INGREDIENTS: 61.4%

TOTAL 100.0%

*(butyl carbityl) (6-propylpiperonyl ether) and related compounds

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See Back Panel for Additional Precautionary Statements

NET CONTENTS:

- One: 0.05 fl oz (1.5 cc) [vial][tube][cartridge] (Toy Dogs)/[and Puppies]
- 0.10 fl oz (3.0 cc) [vial] [tube][cartridge] (Small Dogs)/[and Puppies]
- 0.15 fl oz (4.5 cc) [vial][tube][cartridge] (Medium Dogs)/[and Puppies]
- 0.20 fl oz (6.0 cc) [vial][tube][cartridge] (Large Dogs)/[and Puppies]
- 0.30 fl oz (9.0 cc) [vial][tube][cartridge] (Extra Large Dogs)[and Puppies]

EPA Reg. No. 2724-811
EPA Est. No.



**DO NOT USE
ON CATS**

Minimum of 1.5 cm X 1.5 cm

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SUB LABEL A – APPLICATOR DEVICE PACKAGE

1. DIRECTIONS FOR USE WITH APPLICATOR RF2164 A/T COMBO

[Back Panel]

[RF2164 A/T COMBO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2164 A/T COMBO also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.]

Effective flea & tick control for your dog/puppy.

[brand] provides flea and tick protection for dogs/puppies for up to 30-days – and protection from flea reinfestation beyond. That’s because it doesn’t just kill adult fleas and ticks, it also prevents reinfestation by knocking out flea eggs and larvae that could hatch later on. Plus, it kills and repels mosquitoes.

A unique, convenient applicator for you. The new [brand] Applicator is specially designed to make applying flea and tick control easier, more precise -- and neater – than ever before. You simply insert the appropriate [brand] tube [vial][cartridge] for your dog/puppy into the applicator, close it and squeeze to apply. The applicator’s ergonomic, contoured shape [design] makes it easy to grip and a built-in fin [tip] [comb] helps to spread [part] the [your] dog’s/puppy’s hair to allow the liquid to more readily [better] reach [apply] the [to] [your dog’s/puppy’s] skin. The tube [vial][cartridge] is sealed inside, so you can be confident that the liquid goes onto your dog/puppy – and not your hand. Plus, if the applicator is laid down on a table, counter or other flat surface, it won’t run out or drip.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **IMPORTANT! READ ENTIRE LABEL BEFORE EACH USE. FOR USE ONLY ON DOGS/PUPPIES (10 WEEKS OF AGE OR OLDER) DO NOT USE ON OTHER ANIMALS!** Read and follow all directions and precautions on this product label. [If you choose to apply directly to dog without using the applicator device, read and follow the Directions for Use For Direct Application to Dog on this package.]

USE RESTRICTIONS

THIS PRODUCT IS FOR INDOOR USE ONLY.

Do not apply this product to puppies less than 10 weeks of age, and do not apply this product to other animals!

Do not apply this product to dogs/puppies weighing less than 6 lbs. (for smallest size dog package only)

Do not allow your dog/puppy to ingest this product.

Apply this product once every 30 days unless a retreatment is necessary. Do not make the repeat retreatment sooner than 8 days following the initial treatment. Do not use more than one tube [vial][cartridge] per dog/puppy and do not retreat more than once per month.

RF2164 A/T COMBO works by application directly to the dog’s/puppy’s skin, not to the hair. When applying, use applicator device tip to push aside dog’s/puppy’s hair to allow direct application to the skin. Do not get this product in dog’s/puppy’s eyes or mouth. [(Note: Application now assumes one tube[vial][cartridge] per dog/puppy per application)]

The RF2164 A/T COMBO provides a unique applicator device that allows dog/puppy owners to treat their dogs/puppies more securely, and dispose of liquid cartridges [tubes][vials] with less mess.

[Note: Each package contains sufficient cartridges/tubes/vials for [X] applications]

[DFU Set No. 1]

FOR USE ONLY ON [TOY] (OVER 6 LBS) [SMALL][MEDIUM] SIZE DOGS/PUPPIES (10 WEEKS OF AGE OR OLDER)

To apply the [RF2164 A/T COMBO] treatment, use one disposable liquid cartridge [tube][vial][for each application] with the applicator device.

1. OPEN [icon]

Use finger scoop to lift open [color, e.g. green] door.

2. LOAD [icon] (2 alternate statements)

-[To Load, place tube [cartridge][vial] white side up into the open applicator with front of tube placed under tab on door]

-[To Load, place tube [cartridge][vial] white side up into the [open] applicator with tip end of tube placed under [color][U-shaped] tab on door]

[Ensure that tube [cartridge][vial] fits securely in the applicator.]

3. CLOSE [icon]

Gently close the [color, e.g. green] door [and] the tube will snap open.

4. APPLY [icon]

The dog/puppy should be standing for easy application. To apply, use [front edge of applicator] [tip] to part hair and get next to dog's/puppy's skin. Press [circle] [[round] thumb pad] on [color-green] door [number-once] at each of [two] (Toy dogs (Over 6 lbs) or puppies(10 weeks of Age or Older) [three] (Small Dogs/puppies (10 weeks of Age or Older) (Medium dogs/puppies (10 weeks of Age or Older) evenly placed spots between the shoulder and the base of the tail. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy. Do not spread RF2164 A/T COMBO by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after treatment will help to distribute the material over the skin.

5. DISPOSE [icon]

[When finished, hold applicator device over trash.] To dispose of empty tube, open [color, e.g. green] door and drop empty tube into trash or offer for recycling if available. [Close applicator device door and store in original package.]

[Note: Each package contains sufficient cartridges/tubes/vials for [X] applications]

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FOR USE ONLY ON [LARGE][EXTRA LARGE] DOGS/PUPPIES (1 WEEKS OF AGE OR OLDER)

- 1 ...
- 2 ...
- 3 ...
- 4 APPLY [icon]

The dog should be standing for easy application. To apply, use [front edge of applicator][tip] to part hair and get next to dog's/puppy's skin. Press [circle] [[round] thumb pad] on [color][green] door [number-once] at each of four or five evenly placed spots between the shoulder to the base of the tail.

Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy. Do not spread RF2164 A/T COMBO by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after treatment will help to distribute the material over the skin.

- 5 ...
- 6 ...

[Note: Each package contains sufficient cartridges/tubes/vials for [X] applications]

RF2164 A/T COMBO is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies with RF2164 A/T COMBO rapidly kills fleas and may reduce the incidence of this condition.] [RF2164 A/T COMBO is water resistant and remains efficacious following exposure to rainfall or swimming.]

[TREATMENT SCHEDULE			
Dosage: 1 [cartridge] [tube][vial] every 30 days per dog/puppy			
Dog's/Puppy's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF2164 A/T COMBO from: _____

NOTES: _____

Treatment table can be expanded based on package size. (6 months)]

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. Liquid Cartridge [vial][tube] **Container Disposal: If empty:** Do not reuse cartridge [vial] [tube]. Place in trash or 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.

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

DO NOT USE ON DOGS LESS THAN 6 LBS OR PUPPIES LESS THAN 10 WEEKS OF AGE. For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your dog/puppy with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

Some dogs/puppies may experience hair loss or temporary skin irritation at the application site. If signs persist or become more severe, contact veterinarian immediately and report incident to company at 1-800-XXX-XXXX.

FIRST AID

- | | |
|------------|--|
| If in eyes | <ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after first 5 minutes, then continue rinsing • Call a poison control center or doctor for treatment advice. |
|------------|--|

HOT LINE NUMBER: Have the 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 health concerns, medical emergencies or pesticide incidents), you may also call 1-800-XXX-XXXX 24 hours/day, 7 days/week.

WARRANTY AND CONDITIONS OF SALE:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-x:xxx or contact your veterinarian if your pet is experiencing an adverse event.

Wellmark International
1501 E. Woodfield Road. 200W
Schaumburg, Illinois 60173

[URL]

Made in USA

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 [Brand name] at [phone number].



**DO NOT USE
ON CATS**

DO NOT USE ON CATS
Keep cats away from treated dogs/puppies for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

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TEXT FOR LIQUID TUBE/CARTRIDGE/VIAL

Product name

Etofenprox 30%, (S)-Methoprene 3.6%, Piperonyl Butoxide 5%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[READ DIRECTIONS BEFORE USING] (if space permits)

EPA Reg. No. 2724-811

Net Contents



**DO NOT USE
ON CATS**

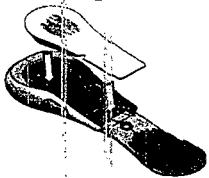
For Use: Only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.), Large (56 -80 lbs.), and Extra Large (81 lbs. and over) Dogs/Puppies (10 Weeks of age or older)

Alternate Sets of ICONS for the RF2164 A/T COMBO

[ICON SET 1]

[OPEN]

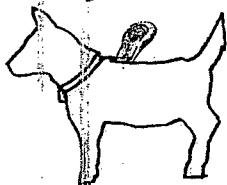
[LOAD]



[CLOSE]



[APPLY]



[DISPOSE]



[ICON SET 2] ALTERNATE ICON FOR DIRECTIONS FOR USE (will be specific to dog's/puppy's size)

With green door facing down
Push two side buttons
to OPEN door

To LOAD Place tube with
WHITE side UP into applicator

Click tube under
green holding tabs.

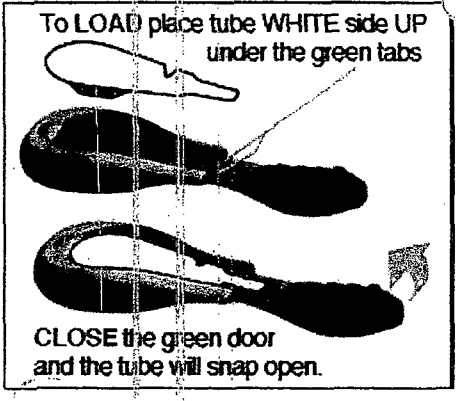
Close the green door and
the tube will snap open.

To APPLY Use Tip to part fur
and get next to dog's skin.
Press circle on green door
once at each of # spots
between shoulders
and tail

DISPOSE of empty tube
Push two side buttons to
open green door and
drop empty tube
into trash

("#Spots" is a variable dependent on size)
Door color may change based on brand.
(Alternate LOAD icon)

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[ICON SET 3] ALTERNATE ICONS FOR DIRECTIONS FOR USE (will be specific to dog's/puppy's size)



("#Spots" is a variable dependent on size)
Door color may change based on brand.

15/20

2. DIRECTIONS FOR USE OR DIRECT APPLICATION TO DOG/PUPPY

USE RESTRICTIONS

THIS PRODUCT IS FOR INDOOR USE ONLY.

Do not apply this product to puppies less than 10 weeks of age, and do not apply this product to other animals!

Do not apply this product to dogs/puppies weighing less than 6 lbs. (for smallest size dog package only)

Do not allow your dog/puppy to ingest this product.

Apply this product once every 30 days unless a retreatment is necessary. Do not make the repeat retreatment sooner than 8 days following the initial treatment. Do not use more than one tube [vial][cartridge] per dog/puppy and do not retreat more than once per month.

RF2164 A/T COMBO works by application directly to the dog's/puppy's skin, not to the hair. When applying, manually push aside dog's/puppy's hair to allow direct application to the skin. Do not get this product in dog's/puppy's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR USE ONLY ON [TOY] (OVER 6 LBS)[SMALL][MEDIUM] SIZE DOGS/PUPPIES (10 WEEKS OF AGE OR OLDER)

1. [Bend at perforation and tear off first applicator [tube].]
2. [Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.]] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog/puppy should be standing for easy application. Apply RF2164 A/T COMBO evenly to [two spots](toy dogs (over 6 lbs) or puppies (10 weeks of age or older))[three spots](small or medium dogs/puppies (10 weeks of age or older)) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.
4. Do not spread RF2164 A/T COMBO by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
5. Discard empty [tube][applicator] as described in Storage and Disposal
6. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days following the initial treatment. Do not retreat more than once per month.

[Note: Each package contains sufficient tubes/applicators for [X] applications]

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FOR USE ONLY ON [LARGE, EXTRA LARGE] DOGS OR PUPPIES (10 WEEKS OF AGE OR OLDER)

1. [Bend at perforation and tear off first applicator [tube].]
2. [[Hold applicator [tube]][and bend area of plastic at perforation, tear off and discard.]]
Hold applicator [tube] upright and snap tip back, away from face and body
3. The dog/puppy should be standing for easy application. Apply RF2164 A/T COMBO evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.
4. Do not spread RF2164 A/T COMBO by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
5. Discard empty [tube][applicator] as described in Storage and Disposal
6. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days following the initial treatment. Do not retreat more than once per month.

RF2164 A/T COMBO is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies with RF2164 A/T COMBO rapidly kills fleas and may reduce the incidence of this condition.] [RF2164 A/T COMBO is water resistant and remains efficacious following exposure to rainfall or swimming.]

[TREATMENT SCHEDULE			
Dosage: 1 [cartridge] [tube][vial] every 30 days per dog/puppy			
Dog's/Puppy's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF2164 A/T COMBO from: _____

NOTES: _____

Treatment table can be expanded based on package size. (6 months)]

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SUB-LABEL B FOR REFILL PACKAGE

(For use with applicator device or direct application to dog/puppy without applicator device)

(Front Panel)

[Product Name]

[Include "Dog" in product name and the Text for "Dog" must be the same size as the largest letter in Brand Name]

Front Panel - For Use Only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.), Large (56 -80 lbs.), and Extra Large (81 lbs. and over) Dogs/Puppies (10 Weeks of age or older)

[Flea & Tick [& Mosquito][Treatment] [and] Control]

Spot-On Flea & Tick Control ONLY for Dogs (Over 6 lbs)/Puppies (10 Weeks of Age or Older)

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1)	30.0%
S-Methoprene (CAS # 65733-16-6)	3.6%
Piperonyl Butoxide (CAS # 51-03-6)*	5.0%
OTHER INGREDIENTS:	61.4%
TOTAL	100.0%

*(butyl carbityl) (6-propylpiperonyl ether) and related compounds

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See Back Panel for Additional Precautionary Statements

EPA Reg. No. 2724-811

EPA Est. No.

NET CONTENTS:

- One 0.05 fl oz (1.5 cc) [vial][tube][cartridge] (Toy Dogs (Over 6 lbs)/Puppies)(10 Weeks of Age or Older)
- One 10 fl oz (3.0 cc) [vial] [tube][cartridge] (Small Dogs/Puppies)/(10 Weeks of Age or Older)
- One 15 fl oz (4.5 cc) [vial][tube][cartridge] (Medium Dogs/Puppies)/ (10 Weeks of Age or Older)
- One 20 fl oz (6.0 cc) [vial][tube][cartridge] (Large Dogs/Puppies) (10 Weeks of Age or Older)
- One 30 fl oz (9.0 cc) [vial][tube][cartridge] (Extra Large Dogs) (10 Weeks of Age or Older)



**DO NOT USE
ON CATS**

Minimum of 1.5 cm X 1.5 cm

(Back Panel)

[Back Panel]

[RF2164 A/T COMBO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2164 A/T COMBO also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.]

[Effective flea & tick control for your dog/puppy.

[brand] provides flea and tick protection for dogs/puppies for up to 30-days – and protection from flea reinfestation beyond. That’s because it doesn’t just kill adult fleas and ticks, it also prevents reinfestation by knocking out flea eggs and larvae that could hatch later on. Plus, it kills and repels mosquitoes.]

[Note: full directions for use to be used if space allows]

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **IMPORTANT! READ ENTIRE LABEL BEFORE EACH USE. FOR USE ONLY ON DOGS (OVER 6 LBS) OR PUPPIES 10 WEEKS OF AGE OR OLDER. DO NOT USE ON OTHER ANIMALS!**

Read and follow all directions and precautions on this product label.

[To apply the RF2164 A/T COMBO treatment with the [Brand Name] applicator, use one disposable liquid cartridge [tube][vial][for each application] with the applicator device.]

[Remove one refill tube [cartridge][vial] from the package and insert into opened [brand name] applicator device. Make application according to label directions supplied with the [brand name] applicator device.] If you need directions for application, please call 1-800-XXX-XXXX.

[However, if you choose to apply directly to dog/puppy without using the applicator device, read and follow the Directions for Use For Direct Application to Dog /Puppy on this package.]

(DIRECTIONS FOR USE FOR DIRECT APPLICATION TO DOG/PUPPY)

[USE RESTRICTIONS

THIS PRODUCT IS FOR INDOOR USE ONLY.

Do not apply this product to puppies less than 10 weeks of age, and do not apply this product to other animals!

Do not apply to dogs/puppies weighing less than 6 lbs. (for smallest size dog package only)

Do not allow your dog/puppy to ingest this product.

Apply this product once every 30 days unless a retreatment is necessary. Do not make the retreatment sooner than 8 days following the initial treatment. Do not use more than one tube per dog/puppy and do not retreat more than once per month.

RF2164 A/T COMBO works by application directly to the dog’s/puppy’s skin, not to the hair. When applying, manually push aside dog’s/puppy’s hair to allow direct application to the skin. Do not get this product in dog’s/puppy’s eyes or mouth.

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[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR USE ONLY ON [TOY (OVER 6 LBS)][SMALL][MEDIUM] SIZE DOGS OR PUPPIES (10 WEEKS OF AGE OR OLDER)

1. [Bend at perforation and tear off first applicator [tube].]
2. [Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.]]
Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog/puppy should be standing for easy application. Apply RF2164 A/T COMBO evenly to [two spots](toy dogs/puppies)[three spots](small or medium dogs/puppies) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.
4. Do not spread RF2164 A/T COMBO by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin.
5. Discard empty [tube][applicator] as described in Storage and Disposal
6. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR USE ONLY ON [LARGE][EXTRA LARGE] DOGS/PUPPIES (10 WEEKS OF AGE OR OLDER)

1. [Bend at perforation and tear off first applicator [tube].]
2. [Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.]]
Hold applicator [tube] upright and snap tip back, away from face and body
3. The dog/puppy should be standing for easy application. Apply RF2164 A/T COMBO evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.
4. Do not spread RF2164 A/T COMBO by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
5. Discard empty [tube][applicator] as described in Storage and Disposal
6. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.

RF2164 A/T COMBO is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies with RF2164 A/T COMBO rapidly kills fleas and may reduce the incidence of this condition.] [RF2164 A/T COMBO is water resistant and remains efficacious following exposure to rainfall or swimming.]

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[TREATMENT SCHEDULE Dosage: 1 [cartridge] [tube][vial] every 30 days per dog/puppy			
Dog's/Puppy's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF2164 A/T COMBO from: _____

NOTES: _____

Treatment table can be expanded based on package size. (6 months)]]

(Precautionary/First Aid and Storage/Disposal) text included)

WARRANTY AND CONDITIONS OF SALE:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx or contact your veterinarian if your pet is experiencing an adverse event.

Wellmark International
1501 East Woodfield Road 200W
Schaumburg, Illinois 60173

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 [Brand name] at [phone number].



DO NOT USE ON CATS
Keep cats away from treated dogs/puppies for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.