



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 13, 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; Addition of *InfestStop™ to Subject Label
RF2164 A/T COMBO, EPA Reg. No. 2724-811
Your Submission Dated October 8, 2012**

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):

General Comment(s):

1. Delete all text throughout the label marked with "strikethrough."

Generic Pet Spot-On Mitigation comment(s):

2. To facilitate inclusion of generic spot-on mitigation language in order to reduce adverse incidents, Wellmark International must do the following:
 - At the top of page 1 of 16, immediately following the "Brand Name," revise the 1st listed statement to read "[Include "Dog" in product name and Text for "Dog" must be the same size as the largest letter in the Brand Name]"
 - Within all of the minimum treatment weights that are listed at the top of page 1 of 16, revise all listings of the word "only" to read "ONLY."
 - At the bottom of page 3 of 16, a cat prohibition icon must be placed on the front panel of the subject label in a box at the same size as any marketing icons. The background of the box containing the cat prohibition icon must be yellow with black text.
 - The existing cat prohibition language that is currently listed at the top of page 4 of 16 is acceptable; however, it must be accompanied by a cat prohibition icon and must also appear in a yellow box with black text.
 - Wellmark International should use the word "ONLY" when referring to dog size and age. In addition, this information must appear on the front panel. **Weight/Age Restrictions:** Ranges must appear on product vials.
 - List potential side effects in plain language on the product label based on incidents most commonly seen. This must appear on the back panel, not only on package inserts, so consumers can make choices based on potential side effects. If any commonly seen side effect would warrant veterinary care, Wellmark International must provide instructions on what to do (e.g., in case of x, contact veterinarian immediately and report incident to company at 1-866-xxxx). **Please Note:** For consumer ease the Agency is considering standard terminology.

Directions for Use section comment(s), top of page 4 of 16:

3. At the top of page 4 of 16, revise the statement starting with "IMPORTANT! DO NOT Use on ..." to read "IMPORTANT! READ ENTIRE LABEL BEFORE EACH USE. FOR USE ONLY ON DOGS OR PUPPIES (10 WEEKS OF AGE OR OLDER). DO NOT USE ON OTHER ANIMALS!" and relocate this revised statement to appear on the subject label immediately following the statement "It is a violation of ..."

Directions for Use, USE RESTRICTIONS subsection comment(s), bottom of page 4 of 16:

- 4. In order to maintain consistency with other Wellmark International products, revise the existing "USE RESTRICTIONS" subsection to read as follows:

USE RESTRICTIONS	
<ul style="list-style-type: none"> • For indoor use only. • Apply this product once every 30 days unless a retreatment is necessary. Do not make the repeat treatment sooner than 8 days after the initial treatment. Do not retreat more than once per month. • Do not apply this product to puppies less than 10 weeks of age, and do not apply this product to other animals! 	

Directions for Use, Subsection-Specific comment(s):

- 5. At the top of page 5 of 16, revise the statement "FOR [TOYS][SMALL][MEDIUM] SIZE DOGS/PUPPIES" to read "FOR USE ONLY ON [TOYS][SMALL][MEDIUM] SIZE (OVER 6 POUNDS) DOGS OR PUPPIES (OVER 10 WEEKS OF AGE OR OLDER)"
- 6. Within the "APPLY [icon]" subsection, revise the 3rd sentence to read "Press [circle] [[round] thumb pad] on [color-green] door [number-once] at each of [two] (Toy Dogs (Over 6 Pounds) or Puppies (Over 10 Weeks of Age)) [three] (Small Dogs (Over 6 Pounds) or Puppies (Over 10 Weeks of Age or Older)) (Medium Dogs (Over 6 Pounds) or Puppies (Over 10 Weeks of Age or Older)) evenly placed spots between the shoulder and the base of the tail."
- 7. At the top of page 6 of 16, revise the statement "FOR [LARGE][EXTRA LARGE] DOGS/PUPPIES" to read "FOR USE ONLY ON [LARGE][EXTRA LARGE] SIZE DOGS OR PUPPIES (OVER 10 WEEKS OF AGE OR OLDER)"

Directions for Use, USE RESTRICTIONS subsection comment(s), bottom of page 5 of 16:

- 8. In order to maintain consistency with other Wellmark International products, revise the existing "USE RESTRICTIONS" subsection to read as follows:

USE RESTRICTIONS	
<ul style="list-style-type: none"> • For indoor use only. • Apply this product once every 30 days unless a retreatment is necessary. Do not make the repeat treatment sooner than 8 days after the initial treatment. Do not retreat more than once per month. • Do not apply this product to puppies less than 10 weeks of age, and do not apply this product to other animals! 	

Storage & Disposal section comment(s), bottom of page 6 of 16:

- 9. Revise the existing "Pesticide Storage:" subsection to read "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."
- 10. Revise the subsection heading "Disposal:" to read "Container Disposal:"

Precautionary Statements, Hazards to Humans and Domestic Animals subsection comment(s), page 7 of 16:

- 11. Revise the statement "DO NOT USE ON DOGS/PUPPIES LESS THAN 10 WEEKS OLD" to read "DO NOT USE ON DOGS OR PUPPIES LESS THAN 6 POUNDS or 10 WEEKS OF AGE"
- 12. Revise the existing 4th sentence within this subsection to read "Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet."

First Aid section comment(s), middle of page 7 of 16:

- 13. Revise the existing 2nd sentence within the "HOT LINE NUMBER:" subsection to read "For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-xxx-xxxx, twenty-four (24) hours per day, seven (7) days per week."¹

¹ Please note that the "1-800-xxx-xxxx" must be substituted with a valid phone number that is available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.

Directions for Use, USE RESTRICTIONS subsection comment(s), top of page 11 of 16:

14. In order to maintain consistency with other Wellmark International products, revise the existing "USE RESTRICTIONS" subsection to read as follows:

USE RESTRICTIONS	
<ul style="list-style-type: none"> • For indoor use only. • Apply this product once every 30 days unless a retreatment is necessary. Do not make the repeat treatment sooner than 8 days after the initial treatment. Do not retreat more than once per month. • Do not apply this product to puppies less than 10 weeks of age, and do not apply this product to other animals! 	

Directions for Use, Subsection-Specific comment(s):

15. At the top of page 11 of 16, revise the statement "FOR [TOYS][SMALL][MEDIUM] SIZE DOGS/PUPPIES" to read "FOR USE ONLY ON [TOYS][SMALL][MEDIUM] SIZE (OVER 6 POUNDS) DOGS OR PUPPIES (OVER 10 WEEKS OF AGE OR OLDER)"

16. Within the 3rd enumerated text statement, revise the 2nd sentence to read "Apply RF2164 A/T COMBO evenly to [two spots](toy dogs (over 6 pounds) or puppies (over 10 weeks of age or older))[three spots](small or medium dogs (over 6 pounds) or puppies (over 10 weeks of age or older)) on the top of the back from the shoulder to the base of the tail."

17. In the middle of page 11 of 16, revise the statement "FOR [LARGE][EXTRA LARGE] DOGS/PUPPIES" to read "FOR USE ONLY ON [LARGE][EXTRA LARGE] SIZE DOGS OR PUPPIES (OVER 10 WEEKS OF AGE OR OLDER)"

Optional Marketing Statements comment(s), top of page 13 of 16:

18. Revise the 2nd optional marketing statement to read "Spot-On Flea & Tick Control for Dogs and Puppies (10 Weeks of Age or Older)"

NET CONTENTS section comment(s), middle of page 13 of 16:

19. Revise the 1st listed statement to read "One 0.05 fl oz (1.5 cc) [vial][tube][cartridge] (Toy Dogs (Over 6 Pounds) or Puppies (Over 10 Weeks of Age))"

20. Revise the 2nd listed statement to read "One 0.10 fl oz (3.0 cc) [vial][tube][cartridge] (Small Dogs (Over 6 Pounds) or Puppies (Over 10 Weeks of Age))"

21. Within the 3rd listed statement, replace "(Medium Dogs/Puppies)" with "(Medium Dogs or Puppies (Over 10 Weeks of Age))"

22. Within the 4th listed statement, replace "(Large Dogs/Puppies)" with "(Large Dogs or Puppies (Over 10 Weeks of Age))"

Directions for Use section comment(s), top of page 14 of 16:

23. At the top of page 4 of 16, revise the statement starting with "IMPORTANT! DO NOT Use on ..." to read "IMPORTANT! READ ENTIRE LABEL BEFORE EACH USE. FOR USE ONLY ON DOGS OR PUPPIES (10 WEEKS OF AGE OR OLDER). DO NOT USE ON OTHER ANIMALS!" and relocate this revised statement to appear on the subject label immediately following the statement "It is a violation of ..."

Directions for Use, USE RESTRICTIONS subsection comment(s), bottom of page 14 of 16:

24. In order to maintain consistency with other Wellmark International products, revise the existing "USE RESTRICTIONS" subsection to read as follows:

USE RESTRICTIONS	
<ul style="list-style-type: none"> • For indoor use only. • Apply this product once every 30 days unless a retreatment is necessary. Do not make the repeat treatment sooner than 8 days after the initial treatment. Do not retreat more than once per month. • Do not apply this product to puppies less than 10 weeks of age, and do not apply this product to other animals! 	

Directions for Use, Subsection-Specific comment(s):

- 25. At the top of page 15 of 16, revise the statement "**FOR [TOYS][SMALL][MEDIUM] SIZE DOGS/PUPPIES**" to read "**FOR USE ONLY ON [TOYS][SMALL][MEDIUM] SIZE (OVER 6 POUNDS) DOGS OR PUPPIES (OVER 10 WEEKS OF AGE OR OLDER)**"
- 26. At the middle of page 15 of 16, revise the statement "**FOR [LARGE][EXTRA LARGE] DOGS/PUPPIES**" to read "**FOR USE ONLY ON [LARGE][EXTRA LARGE] SIZE DOGS OR PUPPIES (OVER 10 WEEKS OF AGE OR OLDER)**"

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.

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,



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

Enclosures: *Label stamped "Accepted with Comments," dated March 13, 2013*
Review for Minimum Treatment Weight, dated March 12, 2013

RF2164 A/T COMBO

[Include "Dog" in product name and Text for "Dog" must be at least 75% of 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

Front Panel - For Use Only on Dogs/Puppies 10 Weeks of age or older
[Flea & Tick & Mosquito][Treatment][and] Control]

Spot-On Flea & Tick Control for Dogs & 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 [over time] 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]

ACCEPTED
With COMMENTS
In EPA Letter Dated:
March 13, 2013
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:
2724-811

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 35% 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 larvae]] and prevent flea development for [more than 10 weeks] up to [75 days][2.5 months]]

[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

[Plus][Contains][With] PRECOR® [vIGRen®][S-Methoprene][*InfestStop™], the first insect growth regulator for flea control

[(S)-Methoprene][*InfestStop™] Insect Growth Regulator (IGR) interrupts the development of the flea life cycle [at the egg stage]

[(S)-Methoprene][*InfestStop™] Insect Growth Regulator (IGR) prevents the development of flea eggs into adult fleas and [inhibits the development of flea eggs into adult fleas]

Flea control for dogs with [PRECOR®][vIGRen®] [*InfestStop™] Insect Growth Regulator (IGR)

[Kills][Prevents][Keeps] flea eggs from hatching for up to [75 days][2.5 months][more than 10 weeks]

*(S)-Methoprene (Must occur on same panel wherever InfestStop™ is used)

Applicator Claims

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

Thermofom 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

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

Ampoule
 Cartridge
 Packet
 Pod
 Refill
 Tube
 Vial

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 [Ingredients and] 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.

[ICON – DO NOT USE ON CATS]

SUBLABEL A – APPLICATOR DEVICE PACKAGE

8/20

1. DIRECTIONS FOR USE WITH APPLICATOR

RF2164 A/T COMBO

~~IMPORTANT! DO NOT Use on Dogs/Puppies LESS THAN 10 Weeks OLD.
READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS AND PUPPIES. DO NOT USE ON OTHER ANIMALS!~~

[Back Panel]

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 immediately.

[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 [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. 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:

Apply this product once every 30 days unless a retreatment is necessary. Do not make the retreatment sooner than 8 days after the initial treatment. 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 [TOY][SMALL][MEDIUM] SIZE DOGS/PUPPIES

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/puppies) [three] (Small Dogs/puppies) (Medium dogs/puppies) 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 [over time] 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.]

6. USE RESTRICTIONS (2 Alt. statements)

- 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.

- If necessary, product can be reapplied, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.

[Note: Each package contains sufficient cartridges/tubes/vials for [X] application.s]

FOR [LARGE][EXTRA LARGE] DOGS/PUPPIES

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 [over time] 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			
Pet'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:** Store in a cool area away from children and animals. Liquid Cartridge [vial][tube] **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.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

DO NOT USE ON DOGS/PUPPIES LESS THAN 10 WEEKS OLD. For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash 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. |
|-------------|--|

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX for emergency medical treatment information.

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:xx 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

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

EPA Reg. No. 2724-811

Net Contents

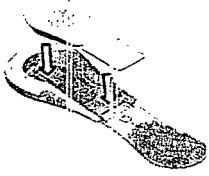
[ICON – DO NOT USE ON CATS]

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]

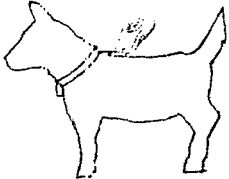
[LOAD]



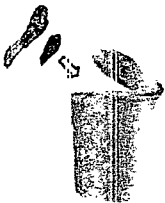
[CLOSE]



[APPLY]



[DISPOSE]



[ICON SET 2] ALTERNATE ICONS 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

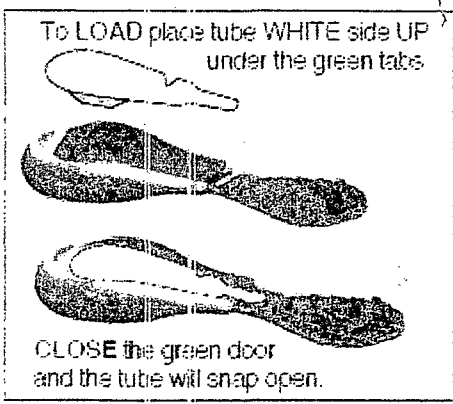
Click tube under
green holding tabs.

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)



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

Use finger scoop to lift OPEN door

To LOAD place tube WHITE side UP under the green 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 open green door and drop empty tube into trash

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

[2. DIRECTIONS FOR USE FOR DIRECT APPLICATION TO DOG/PUPPY]

USE RESTRICTIONS:

Apply this product once every 30 days unless a retreatment is necessary. Do not make the retreatment sooner than 8 days after the initial treatment. 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 [TOY][SMALL][MEDIUM] SIZE DOGS/PUPPIES

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 [over time] 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 [LARGE][EXTRA LARGE] DOGS/PUPPIES

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 [over time] 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.]

[TREATMENT SCHEDULE			
Dosage: 1 [cartridge] [tube][vial] every 30 days per dog/puppy			
Pet'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)]

17/20

SUB-LABEL B FOR REFILL PACKAGE

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

(Front Panel)

[Product Name]

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

Spot-On Flea & Tick Control for Dogs/Puppies

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

[ICON – DO NOT USE ON CATS]

(Back Panel)

~~IMPORTANT! DO NOT Use on Dogs/Puppies LESS THAN 10 Weeks OLD.
READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS/PUPPIES. DO NOT
USE ON OTHER ANIMALS!~~

[Back Panel]

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 immediately.

[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. 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:

Apply this product once every 30 days unless a retreatment is necessary. Do not make the retreatment sooner than 8 days after the initial treatment. 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 [TOY][SMALL][MEDIUM] SIZE DOGS/PUPPIES

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 [over time] 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 [LARGE][EXTRA LARGE] DOGS/PUPPIES

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 [over time] 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.]

[TREATMENT SCHEDULE Dosage: 1 [cartridge] [tube][vial] every 30 days per dog/puppy			
Pet'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-xxx or contact your veterinarian if your pet is experiencing an adverse event.

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