

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 15, 2014

Ms. Nancy Huebl Senior Registration Specialist Wellmark International 1501 East Woodfield Road, Suite 200 West Schaumburg, IL 60173-5417

Subject: Label Amendment – Acceptance of Master Labeling Submitted for Implementation of Pet Spot-On Mitigation & Direct Response to Unacceptable Notification Dated October 9, 2014 Product Name: RF2181 KD A/T COMBO EPA Registration Number: 2724-826 Application Date: October 15, 2014 Decision Number: 496313

Dear Ms. Huebl:

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

Amendments to Dog Spot-On Product Registrations:

- 1. This registration is now time-limited, and will expire 2 years from the date of this letter. More specifically, this registration will expire on October 15, 2016.
- 2. If the Agency determines that future mitigation measures are necessary for all pet spot-on products, EPA will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.
- 3. Please consider limiting the formulations of this product to one basic confidential statement of formula. The Agency may require this in the future. In addition, it is possible that no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
- 4. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning January 1, 2015. Please flag any Confidential Business Information as such. Enhanced incident reporting and quarterly sales information should be submitted to the Product Manager. The following is a list of information that must be included in the quarterly reports for each incident:
  - EPA Registration Number
  - Product name (brand name)
  - Lot #
  - Where purchased: Internet, store, veterinarian.
  - Active ingredient(s)
  - Weight range for product
  - Date on which incident occurred. (mm/dd/yyyy)
  - State in which the incident occurred. (Standard 2 letter abbreviation)
  - Registrant case #
  - Species: Dog, cat, other (specify).
  - Breed: (As reported by pet owner)
  - Age: Months or years.
  - Sex: M, F, or neutered.

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

- 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 pre-condition.
- EPA Severity Code: Death, major, moderate, minor.
- Outcome: Died, recovered, still treated, unknown.
- 5. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
  - All incidents should be reported, including all minor dermal and ocular irritation reports.
  - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
  - Summary table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multipet households).
  - A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
  - A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
  - A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
  - Table showing number of incidents for each dog breed.
  - Table showing number of incidents in dogs for each clinical sign.
  - Table showing number of incidents in dogs for each organ system.
  - Report aggregate incidents, but do not combine moderate and minor incidents.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act 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 FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) list 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 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 the EPA's Office of Enforcement and Compliance.

Please note that this letter does not supersede anything contained within the original conditions of acceptance detailed in the Agency's Notice of Registration dated November 8, 2012. The conclusion date for the subject time-limited product registration is October 15, 2016. Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. If you have any questions, please contact Mr. Carmen J. Rodia, Jr. by phone at (703) 306-0327, or via e-mail at *Rodia.Carmen@epa.gov*.

Sincerely,

Richard J. Ceede

Richard Gebken Product Manager 10 Insecticide Branch Office of Pesticide Programs Date: October 15, 2014

Enclosure:

Updated Master Label Stamped "Accepted," dated October 15, 2014

# RF2181 KD A/T COMBO

[Text for "Dog" in the product name must be at least 75% of the size of the largest letter in the Brand Name]

Front panel - For Use Only on Toy/Small (6-12 lbs.), Medium (13-31 lbs.), Large (32-79 lbs.) and Extra Large (80 lbs and over) Dogs/Puppies 10 weeks of age or older

(Representative picture of dog)

Do not use more than one vial per dog/puppy

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

Spot-On Flea & Tick Control only for Dogs & Puppies 10 Weeks of age or older

#### **General Claims:**

Effective on indoor and outdoor dogs/puppies

([1][3][4[[6] monthly treatments) [1][3][4][6] Months Supply[applications] [24][48] doses Every 30 days logo

Spreads 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]

#### **Efficacy Claims:**

Each tube [cartridge][vial] [application] [kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]

[Aids in Control of Ticks for up to 30 days]

Kills Brown Dog Ticks (for)(28 days)(30 days)(1 month)(4 weeks)

Kills Deer Ticks (that may carry Lyme disease)(for)(28 days)(30 days)(1 month)(4 weeks)(on dogs)

Kills Fleas (that may transmit tapeworm)(for)(28 days)(30 days)(1 month)(4 weeks)(on dogs)

Kills fleas that may cause flea allergy dermatitis (and flea bite anemia)(for)(28 days)(30 days)(1 month)(4 weeks)(on dogs)

Helps [Keep][Prevent] Fleas & Ticks from [coming back][returning]

Prevents flea eggs from developing into biting adults (for)(up to)(30 days)(1 month)(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]

[Starts Killing Fleas and Ticks within 15 minutes]

[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 on your dog/puppy

Prevents (and controls) re-infestation(s) on your dog/puppy

Kills fleas before they have a chance to lay eggs

### **IGR Claims:**

[Contains [\*InfestStop<sup>™</sup>] 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<sup>™</sup>] [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 on your dog/puppy for [more than 10 weeks] up to [75 days][2.5 months]

[With [\*InfestStop<sup>™</sup>][S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle] \*InfestStop/\*Infestop<sup>™</sup> logo

Prevents flea eggs from hatching

Prevents flea eggs from developing into biting adults (for)(up to)(30 days)(1 month)(4 weeks)

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

**A C C E P T E D** 10/15/2014

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2724-826

### **Applicator Claims**

Contemporary design

[brand name] [Applicator] helps to prevent getting liquid on [your] hands

Helps keep liquid off hands

[brand name] [Applicator] tip parts hair to help [liquid][application] get down to [the][your][dog's/puppy's] skin Tip parts hair

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

Includes reusable 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

#### 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)	
S-Methoprene (CAS # 65733-16-6)	
Piperonyl Butoxide (CAS # 51-03-6)*	
OTHER INGREDIENTS:	
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: (Number): ......0.05 fl oz (1.5 cc) Applicator [tube] (Toy/Small Dogs) .....0.10 fl oz (3.0 cc) Applicator [tube] (Medium Dogs) .....0.20 fl oz (6.0 cc) Applicator [tube] (Large Dogs) .....0.30 fl oz (9.0 cc) Applicator [tube] (Extra Large Dogs)

EPA Reg. No. 2724-826 EPA Est. No.



# SUBLABEL A – APPLICATOR DEVICE PACKAGE

### 1. DIRECTIONS FOR USE WITH APPLICATOR **RF2181 KD 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! DO NOT ALLOW CHILDREN TO APPLY PRODUCT.

### [Back Panel]

### **INTRODUCTION:**

[RF2181 KD A/T COMBO ] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2181 KD A/T COMBO also [kills fleas and ticks for 3 weeks] [controls fleas and ticks for up to 1 month] 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 –That's because it doesn't just kill adult fleas and ticks, it also prevents reinfestation on your dog/puppy by knocking out flea eggs and larvae that could hatch later on. Plus, it kills and repels mosquitoes.

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.

The RF2181 KD 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.

**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. \*If necessary, product can be reapplied at 8 or more days after the initial application. Do not use more than one vial [tube][cartridge] per dog and do not retreat more than once per month. Do not get this product in dog's/puppy's eyes or mouth. Do not allow your dog/puppy to ingest this product. Do not apply to dogs/puppies weighing less than 6 lbs (required for smallest size only).

RF2181 KD 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.

[(Note: Application now assumes one tube[vial][cartridge] per dog/puppy per application)] [Note: Each package contains sufficient tubes/applicators for [X] applications]

### [DFU Set No. 1] FOR [TOY/SMALL][MEDIUM] SIZE DOGS/PUPPIES To apply the [RF2181 KD A/T COMBO ] treatment, use one disposable liquid cartridge [tube][vial][for each application] with the applicator device.

[bullets may be used instead of numbers]

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/Small dogs/puppies) [three] (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 RF2181 KD A/T COMBO by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will 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. RETREATMENT [REAPPLICATION] (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] applications]

## FOR [LARGE][EXTRA LARGE] DOGS/PUPPIES

[bullets may be used instead of numbers]

1 ...

2 ...

- 3 ...
- 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 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 RF2181 KD A/T COMBO by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will 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]

RF2181 KD 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 RF2181 KD A/T COMBO rapidly kills fleas and may reduce the incidence of this condition.] [RF2181 KD 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 <sup>st</sup> )	Third Treatment Date (30 Days From 2 <sup>nd</sup> )

Reminder: I purchased RF2181 KD A/T COMBO from: \_\_\_\_\_

NOTES:\_

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

**STORAGE and DISPOSAL:** Pesticide Storage: Store [tubes][vials][cartridges] together 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

**HAZARDS TO HUMANS:** 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.

### HAZARDS TO ANIMALS: DO NOT USE ON DOGS/PUPPIES LESS THAN 10 WEEKS OLD. For

external use only. Consult a veterinarian before using this product on debilitated, aged, pregnant, or nursing animals. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated animals. Sensitivities may occur after using ANY pesticide product for pets. Some sensitive dogs may experience temporary skin irritation such as itching or redness at the application site. If signs of sensitivity occur, bathe your dog/puppy with mild soap and rinse with large amounts of water. If signs persist or become more severe, call 1-800-brand phone number or contact your veterinarian immediately.

FIRST AID	
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> </ul>
	Remove contact lenses, if present, after first 5 minutes, then continue rinsing
	<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
Have the pro	oduct container or label with you when calling a poison control center or doctor or going
for treatme information.	nt. You may also contact 1-800-XXX-XXXX for emergency medical treatment

**SIDE EFFECTS:** Monitor your dog/puppy 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 Wellmark at 1-800-brand phone number.



### 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 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-XXX Net Contents XXX fl oz

For Use Only on Toy/Small (6-12 lbs.), Medium (13-31 lbs.), Large (32-79 lbs.), and Extra Large (80 lbs. and over) Dogs/Puppies 10 Weeks of age or older





[DISPOSE]





[CLOSE]

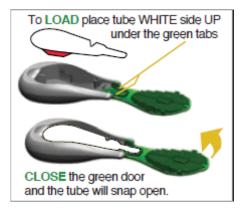


Alternate Sets of ICONS for the RF2181 KD A/T COMBO [ICON SET 1] [OPEN]

**[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
Cilck 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)



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

## [DFU Set No. 2] DIRECTIONS FOR USE FOR DIRECT APPLICATION TO DOG/PUPPY

### **USE RESTRICTIONS:**

Apply this product once every 30 days unless a retreatment is necessary. \*If necessary, product can be reapplied at 8 or more days after the initial application. Do not use more than one vial [tube][cartridge] per dog and do not retreat more than once per month. Do not get this product in dog's/puppy's eyes or mouth. Do not allow your dog/puppy to ingest this product. Do not apply to dogs/puppies weighing less than 6 lbs (required for smallest size only).

RF2181 KD 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.

[(Note: Application now assumes one applicator per animal per application)] [Note: Each package contains sufficient tubes/applicators for [X] applications]

### [bullets may be used instead of numbers]

### 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 RF2181 KD A/T COMBO evenly to [two spots](toy/small dogs/puppies)[three spots](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 RF2181 KD A/T COMBO by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will 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 RF2181 KD 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 RF2181 KD A/T COMBO by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will 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.

RF2181 KD 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 RF2181 KD A/T COMBO rapidly kills fleas and may reduce the incidence of this condition.] [RF2181 KD A/T COMBO is water resistant and remains efficacious following exposure to rainfall or swimming.]

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

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

# SUB-LABEL B FOR REFILLPACKAGE (For use with applicator device or direct application to dog/puppy without applicator device)

(Front Panel) [Product Name]

Front panel - For Use Only on Toy/Small (6-12 lbs.), Medium (13-31 lbs.), Large (32-79 lbs.) and Extra Large (80 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/Puppies 10 weeks of age or older

#### **ACTIVE INGREDIENTS:**

Etofenprox (CAS # 80844-07-1)	
S-Methoprene (CAS # 65733-16-6)	
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-XXX EPA Est No.

NET CONTENTS:



### [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! DO NOT ALLOW CHILDREN TO APPLY PRODUCT.

[RF2181 KD A/T COMBO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2181 KD 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 –. That's because it doesn't just kill adult fleas and ticks, it also prevents reinfestation on your dog/puppy 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 RF2181 KD 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. \*If necessary, product can be reapplied at 8 or more days after the initial application. Do not use more than one vial [tube][cartridge] per dog and do not retreat more than once per month. Do not get this product in dog's/puppy's eyes or mouth. Do not allow your dog/puppy to ingest this product. Do not apply to dogs/puppies weighing less than 6 lbs (required for smallest size only).

RF2181 KD 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]

[bullets may be used instead of numbers]

# 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 RF2181 KD A/T COMBO evenly to [two spots](toy/small dogs/puppies)[three spots](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 RF2181 KD A/T COMBO by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will 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 RF2181 KD 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 RF2181 KD A/T COMBO by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will 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.

RF2181 KD 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 RF2181 KD A/T COMBO rapidly kills fleas and may reduce the incidence of this condition.] [RF2181 KD 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 <sup>st</sup> )	Third Treatment Date (30 Days From 2 <sup>nd</sup> )	
Pomindar: I purchased PE2191 KD A/T COMPO from:				

Reminder: I purchased RF2181 KD 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