

2724-815

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 10, 2013

Mr. James J. McFadden, Ph.D.
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
RF2176 CDSO-K, EPA Reg. No. 2724-815
Your Submission Dated October 16, 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."

Directions for Use, USE RESTRICTIONS subsection comment(s), top of page 3 of 6:

2. Insert the following text immediately following the existing 2nd sentence to read "Do not use on dogs/puppies less than 10 weeks old."

Storage and Disposal section comment(s), middle of page 4 of 6:

3. Within the "**Pesticide Storage:**" subsection, you must revise the existing 1st sentence to read "Store applicators in a cool, dry (preferably locked) area away from children and animals."

Precautionary Statements, Hazards to Humans subsection comment(s), middle of page 4 of 6:

4. Within the 3rd sentence of this subsection, insert the word "hands" immediately following word "Wash."

First Aid section comment(s), bottom of page 4 of 6:

5. Revise the 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 1-888-987-4110, twenty-four (24) hours per day, seven (7) days per week."

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.

A copy of your label stamped "Accepted with Comments" is 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,

RJG


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

Enclosure: *Label stamped "Accepted with Comments," dated January 10, 2013*
002724-00815 D471756

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RF2176 CDSO-K

Alternate brand name: Kirkland Signature Water-Resistant Flea & Tick Control for Dogs (Small 6-12 lbs, Medium 13-31 lbs, Large 32-79 lbs, and Extra Large 80 lbs & Over)

[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 Small/Toy (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

Do not use more than one vial per dog/puppy

[Flea & Tick & Mosquito][Treatment] [and] Control only for Dogs/Puppies 10 weeks of age or older

Effective on indoor and outdoor dogs/puppies

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

Each tube [applicator] [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 (a major carrier of canine heartworm)

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

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]

[Easy to use] Longer applicator tip for easy application to long-haired dogs/puppies

[Fresh][Clean][[Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

Alternate Applicator claims: Unique applicator [tube] with flow control

[no drip][no mess][application][applicator][tube]

**ACCEPTED
With COMMENTS
In EPA Letter Dated:
January 10, 2013
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:**

2724-815

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)**

RF2176 CDSO-K

IMPORTANT! DO NOT USE ON DOGS/PUPPIES LESS THAN 10 WEEKS OLD. READ ENTIRE LABEL [AND INSERT(S)] BEFORE EACH USE. USE ONLY ON DOGS/PUPPIES. DO NOT USE ON OTHER ANIMALS! DO NOT ALLOW CHILDREN TO APPLY PRODUCT.

INTRODUCTION:

[Brand] Water-Resistant Flea & Tick Control for Dogs prevents flea eggs from developing into adult fleas for up to 2.5 months. [Brand] Water-Resistant Flea & Tick Control for Dogs also controls fleas and ticks for up to 1 month and kills and repels mosquitoes for 3 to 4 weeks.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS:

RF2176 CDSO-K 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. If necessary, product can be reapplied at 8 or more days after the initial application. Do not use more than one tube/vial/cartridge per dog/puppy 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. (Small/toy size only - Do not apply to dogs/puppies weighing less than 6 lbs.)

[(Note: Application now assumes one applicator per dog/puppy 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 RF2176 CDSO-K evenly to [two spots][toy/small dogs][three spots][medium dogs) 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 RF2176 CDSO-K 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 to 24 hours after application will help to distribute the material over the skin.
5. Do not retreat more than once per month.
6. Discard empty [tube][applicator] as described in STORAGE and DISPOSAL.

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

FOR [LARGE][EXTRA LARGE] DOGS

- 1 Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
- 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 RF2176 CDSO-K 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.

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 RF2176 CDSO-K rapidly kills fleas and may reduce the incidence of this condition.]

[RF2176 CDSO-K is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator 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 RF2176 CDSO-K from: _____ NOTES: _____
Treatment table can be expanded based on package size. (6 months)

STORAGE and DISPOSAL: **Pesticide Storage:** Store applicators together in a cool area away from children and animals. **Container Disposal: If empty:** Do not reuse container [tube][applicator]. 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/puppies 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 1-888-987-4110 or contact your veterinarian.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15 to 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 1-888-987-4110 for emergency medical treatment information.	

OPTIONAL TEXT FOR PACKAGE INSERTS
OPTIONAL INSERT 1

Dear Valued [Store Customer],

Thank you for your purchase of [Product Name]. [Brand] wants the best for your dog, and we are pleased to share with you some great tips on using the product for the best results.

- A. The [Product Name] comes in 4 different sizes so that the right amount of flea and tick protection is applied to your size dog. Weigh your dog before applying [Product Name] and be sure that the product you purchased is the right size for your dog. Do not apply this product to dogs/puppies younger than 10-weeks. If you have questions, please call 1-888-987-4110 to talk to a product specialist.
- B. For best results, apply [Product Name] evenly to the dog's back in spots starting at the top of the back from the shoulders to the base of the tail. Use two spots for toy dogs; up to 5 could be used for large dogs. At each spot, be sure to apply the product to your dog's skin, not to the surface of your dog's hair coat. For complete instructions on application, please read the package label.
- C. [Product Name] contains lanolin as a coat conditioner. The lanolin helps the product spread over the dog and acts as a coat conditioner as well. After the product has dried, you may brush through your dog's fur with a brush or comb for distribution of the product and coat conditioning lanolin. Because of the initial effect of the lanolin, keep treated dogs off furniture until the product has dried.
- D. Sensitivities may occur after the use of any topically applied product. A pet's skin is a complex organ, and your pet's skin may be generally sensitive to topical products. Monitor your dog after application, and if you have questions about best results or if your dog experiences a reaction after application, please call 1-888-987-4110 to talk to a product specialist.
- E. When applying [Product Name] make sure not to get this product in your dog's/puppy's eyes or mouth. If you are concerned that your dog may have an oral exposure to [Product Name] please call 1-888-987-4110 to talk to a product specialist.
- F. In households with dogs and cats, the cat will often groom the dog as well as itself. Separate treated dogs from cats for 24 hours after treatment to minimize [reduce potential] oral exposure to your cat.
- G. Treatment of fleas on your pet does not address the 95-99% of the flea population that lives in your house and yard. So even after your dog is treated with [Product Name] and adult fleas are killed, flea eggs may continue to hatch in your home for up to two months. For best results, treat your yard and home for fleas with treatments that contain an Insect Growth Regulator, which kills flea eggs. Over time, treatment of your pet and its environment will eliminate fleas from your home.

OPTIONAL INSERT 2

STOP. Please read this insert/card and the entire instructions before using this product.

[Brand Name] wants the best for your dog/pet, and we are pleased to share with you some great tips for using the product.

- Use [Product Name] only as directed.
- For best results, brush your dog's/pet's coat 24 hours after application.
- Apply away from furniture and carpeting.
- Consult a veterinarian before using if your dog/pet is aged, pregnant, nursing, or taking other medication.