

2724 - 815

1/12/2012

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 12, 2012

Ms. Nancy Huebl
Wellmark International
1501 East Woodfield Road, Suite 200W
Schaumburg, Illinois 60173

Subject: Label Notification(s) of Alternate Brand Name per PRN 98-10

Dear Ms. Huebl:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice PRN 98-10 dated November 15, 2011 to add an alternate brand name for the following product(s):

RF2176 CDSO-K

EPA Reg. No. 2724-815

Alternate Brand Name(s):

**Kirkland Signature Water-Resistant Flea & Tick Control for Dogs
(Small 6-12 lbs, Medium 13-31 lbs, Large 32-79 and Extra Large 80 lbs and over)**

The Registration Division (RD) has conducted a review of this request to add Alternate Brand Name(s) and finds that the label change(s) requested falls within the scope of PRN-98-10 and has been found to be acceptable.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact Regina Foushee'-Smith at 703-605-0780.

Sincerely,

Richard J. Gebken
Product Manager
Insecticide Branch
Registration Division (7505P)



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-815	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/Rf2176 CDSO-K	PM # 10	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1501 East Woodfield Road, Suite 200W Schaumburg, Illinois 60173 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: NOTIFICATION EPA Reg. No. _____ Product Name <u>JAN 12 2012</u>	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application _____
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Notification of alternate brand name: Kirkland Signature Water-Resistant Flea & Tick Control for Dogs (Small 6-12 lbs, Medium 13-31 lbs, Large 32-79 lbs, & Extra Large 80 lbs & Over) - This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will be Packaged In:						2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packagin <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No				<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. .05/.10/.20/.30 fl o	No. per container 6	If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Glass	<input checked="" type="checkbox"/> Paper
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 0.05/0.10/0.20/0.30 fl oz		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product			
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled						<input checked="" type="checkbox"/> Other printed cardboard carton	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Nancy Huebl	Title Sr. Registration Specialist	Telephone No. (Include Area Code) 847-330-5376
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Nancy Huebl</i>	3. Title Sr. Registration Specialist	
4. Typed Name Nancy Huebl	5. Date 15-Nov-11	

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Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, Illinois 60173
847 330 5300
www.wellmarkinternational.com



November 16 , 2011

Document Processing Desk (NOTIF)
Office of Pesticide Programs 7504P
U.S. Environmental Protection Agency
Room S-4900 One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: R. Gebken, PM10

SUBJECT: PER PRN 98-10 NOTIFICATION OF ALTERNATE BRAND NAME
FOR RF2176 CDSO-K/EPA REG. NO. 2724-815

Dear Mr. Gebken:

Enclosed is a completed EPA Form 8570-1 and 1 copy of revised labeling for the above product. The label cover sheet details the change. The alternate brand name is: 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)

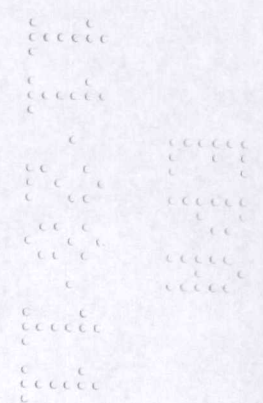
If you have any questions or if I can provide any further assistance, please, call me directly at 847/330-5376. Thank you for your assistance in this matter.

Yours sincerely,
WELLMARK INTERNATIONAL

Nancy Huebl
Sr. Registration Specialist
nhuebl@central.com

enclosure

cc: C. Elmi/H. Friedli



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RF2176 CDSO-K

NOTIFICATION

JAN 12 2012

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 6 months of age or older

Do not use more than one vial per dog

[Flea & Tick & Mosquito][Treatment] [and] Control only for Dogs 6 months of age or older

Effective on indoor and outdoor dogs

[(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]

Contains 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]

[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]

[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]

[Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[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)

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

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

Spreads naturally with dog'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

[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]

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1)30.0%

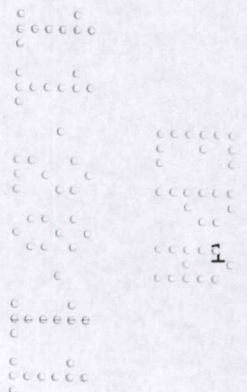
S-Methoprene (CAS # 65733-16-6)3.6%

Piperonyl Butoxide Technical (CAS # 51-03-6)*5.0%

OTHER INGREDIENTS:61.4%

TOTAL 100.0%

*butylcarbityl (6-propylpiperonyl ether) and related compounds

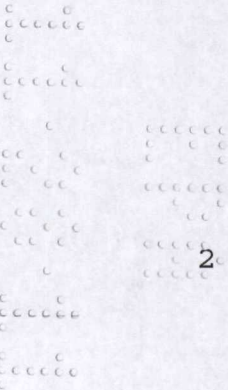


**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See Back Panel for [Ingredients and] Additional Precautionary Statements

- NET CONTENTS: (Number): 0.05 fl oz (1.5 cc) Applicator [tube] (Small/Toy 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. 2724-815
EPA Est. No.



RF2176 CDSO-K

**IMPORTANT! DO NOT USE ON DOGS LESS THAN 6 MONTHS OLD.
READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS. 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 skin, not to the hair. When applying, manually push aside dog'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 and do not retreat more than once per month. Do not get this product in dog's eyes or mouth. Do not allow your dog to ingest this product. (Small/toy size only - Do not apply to dogs weighing less than 6 lbs.)

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

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

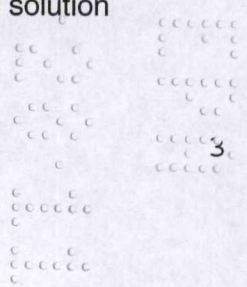
FOR [TOY][SMALL][MEDIUM] SIZE DOGS

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 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.
4. Do not spread RF2176 CDSO-K by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 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 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.



[Alternate Directions for Use for multi-tube application

- 3 The dog should be standing for easy application. Using the first applicator [tube], 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 applicator [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. Using the second applicator [tube], apply as indicated for first applicator [tube] except start application at base of tail and apply on top of the back to the shoulder.
- 4 Do not spread RF2176 CDSO-K by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 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.

Monthly treatments are required for optimal control and prevention of fleas.

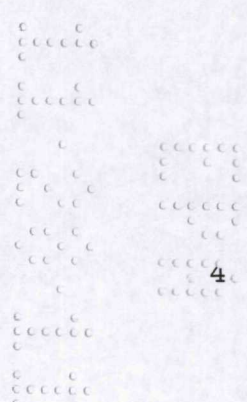
[The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with RF2176 CDSO-K rapidly kills fleas and may reduce the incidence of this condition.]

[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			
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 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 LESS THAN 6 MONTHS 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. ~~If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, please call 1-800-xxx-xxxx or consult a veterinarian immediately.~~ 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 with mild soap and rinse with large amounts of water. If signs persist or become more severe, call 1-88800-987~~xxx~~-4110~~xxx~~ or contact your veterinarian.

FIRST AID

If in eyes

- 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 1-800888-987~~XXX~~-4110~~XXXX~~ for emergency medical treatment information.

SIDE EFFECTS: Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or Wellmark at 1-88800-987~~xxx~~-4110~~xxx~~



DO NOT USE ON CATS.

Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

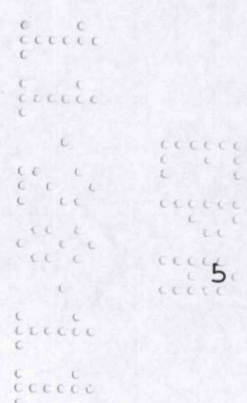
WARRANTY AND CONDITIONS OF SALE:

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 1-88800-987~~xxx~~-4110~~xxx~~.

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

[URL]
Made in USA



TEXT FOR INDIVIDUAL APPLICATOR

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. 2724-815

Net Contents

[ICON – DO NOT USE ON CATS]

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 6 months of age or older

