


2724-815

10/11/2011

10 of 10

	<p align="center"><b>U.S. ENVIRONMENTAL PROTECTION AGENCY</b> Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460</p>	<p>EPA Registration No. <b>2724-815</b></p>	<p>Date of Issuance: <b>OCT 11 2011</b></p>
<p align="center"><b>NOTICE OF PESTICIDE:</b></p> <p align="center"> <input checked="" type="checkbox"/> Registration  <input type="checkbox"/> Reregistration         </p> <p align="center">(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</p>		<p>Term of Issuance: <b>Conditional Registration</b></p> <hr/> <p>Name of Pesticide Product: <b>RF2176 CDSO-K</b></p>	
<p>Name and Address of Registrant (include ZIP Code): <b>Wellmark International</b> <b>1501 E. Woodfield Road</b> <b>Suite 200W</b> <b>Schaumburg, IL 60173</b></p>			
<p><b>Note:</b> Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.</p>			
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.</p> <p>Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(a) provided that:</p> <ol style="list-style-type: none"> <li>1. This registration is time-limited and expires two years from the date this product is first released for shipment.             <ol style="list-style-type: none"> <li>a. You must provide the Agency with a projected release for shipment date within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing.</li> </ol> </li> <li>2. The basic Confidential Statement of Formula (CSF) dated June 15, 2011 is the CSF of record and supersedes all previously accepted CSFs. All of the product chemistry data requirements for this product have been satisfied.</li> <li>3. Make the following changes to the label:             <ol style="list-style-type: none"> <li>a. Submit a revised label addressing all changes described below <u>no later than six months</u></li> </ol> </li> </ol>			

from the date of this registration notice. If EPA does not receive a label with these changes within that time frame, the Agency will consider whether further regulatory action is necessary to ensure your products continue to meet the standard for registration set forth in the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA").

**i. Label changes**

- a. Revise the EPA Registration Number to read: "EPA Registration No. 2724-815".
- b. Make the following changes on the **Front Panel**

Include the word "dog" in your product's brand name and increase the size of the word "dog" to at least 75% the height of the largest letter in the primary brand name.

Include the word "only" when referring to dog size and age and place this restriction in a box prominently on the front panel. Examples: "Only for use on dogs larger than 55 lbs."; "Use only on dogs weighing 35 – 45 lbs."; and "Only for use on puppies 8 weeks and older."

Place a large, clear picture of a dog in the weight range for the product as packaged on the front panel of the label.

Place a [1.5 cm x 1.5 cm] cat prohibition icon in a box located at the lower right hand corner of the front panel in yellow with black images. If the box itself is yellow, or a yellow and black icon may blend into the box, propose an alternate color scheme.

- c. Make the following changes to the **Back Panel**

Place a [1.5 cm x 1.5 cm] cat prohibition icon and warning text in a box located at the lower right hand corner of the back panel in yellow with black images and text. If the box itself is yellow, or a yellow and black icon may blend into the box, propose an alternate color scheme. Please note that this language can, but is not required to, replace other cat warning language present on any product label. The text must read as follows:

"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."

Place a box on the back panel labeled "Side Effects" immediately above the cat warning box. Either include the language below or propose your own side effects language based on incident reports, companion animal safety data, and/or clinical trials, if available. *"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 [Registrant at 1-800-number].” Please note that the Agency prefers product-specific warnings, where available, but understand that some registrants were requesting more specific guidance. In the event that you want to provide alternate or varying language please discuss your reasons for the change.

- d. Make the following changes to the Directions for Use  
Repeat the word “dog” throughout the directions for use.  
Include the word “only” when referring to dog size and age restrictions.

To avoid overdose for dogs larger than 55 lbs, please provide specific language which instructs consumers to not double-dose animals larger than the upper weight limit on the package for the largest size dogs.

On the smallest package size, please include a lower weight limit which corresponds to the lower limit of the dose ranges based on animals tested in your supporting companion animal study. Include the language “Do not apply to dogs weighing less than [insert weight] lbs” where [insert weight] is replaced with the lowest weight in pounds of the animals tested in your supporting companion animal study.  
Include the language, “Do not allow your dog to ingest this product.”

- e. Applicator Vial  
Place weight and age restrictions on the immediate container for the vial and/or the vial itself.  
Place a cat prohibition icon on the immediate container for the vial and/or the vial itself.

- 4. You must submit enhanced incident reports for this product on a quarterly basis beginning January 1, 2012. Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (ATTN: Kimberly Nesci).

The following is a list of information needed by EPA to better characterize these incidents:

- EPA Registration Number
- Product name (brand name)
- Lot #
- Where purchased: internet, store, veterinarian
- Active Ingredient(s)
- Weight range for product
  
- Date on which incident occurred. (mm/dd/yyyy)
- State in which the incident occurred. (standard 2 letter abbreviation)
- Registrant case #
  
- Species: dog, cat, other (specify)
- Breed: (as reported by pet owner)

Age: months or years  
Sex: M, F, or neutered  
Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other  
Body System: neurological, dermatological, GI, respiratory, ocular, other  
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 precondition  
EPA Severity Code: death, major, moderate, minor  
Outcome: died, recovered, still treated, unknown

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.

A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.

Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).

A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.

A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.

A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.

Table showing number of incidents for each dog breed.

Table showing number of incidents in dogs for each clinical sign.

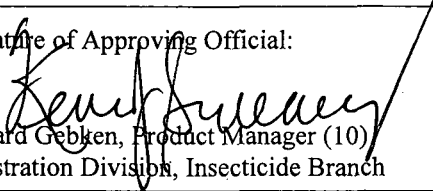
Table showing number of incidents in dogs for each organ system.

Report aggregate incidents, but do not combine moderate and minor incidents.

- 5. You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for reregistration of your product under FIFRA section 4.
- 6. Two copies of the finished labeling must be submitted prior to releasing the product for shipment. Submit the following with the finished labeling:
  - a. Master labels as they will appear when printed on product boxes for all product dose ranges.
  - b. Copies of any package inserts that may be provided in product packaging (including such things as monthly reminder stickers and additional directions for use).
  - c. Images of vial packaging and labeling (actual empty vial can be provided instead, but it is not required).

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is included for your file. If you have any questions concerning this registration, please contact Kevin Sweeney at (703) 305-5063.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

Signature of Approving Official:  
  
 Richard Gebken, Product Manager (10)  
 Registration Division, Insecticide Branch

Date:  
 OCT 11 2011

# RF2176 CDSO-K

[Text for "Dog" must be same size as 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

**Front panel – ICON - DO NOT USE ON CATS!**

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

**ACCEPTED  
with COMMENTS  
In EPA Letter Dated  
Oct 11 2011**  
**Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
2724-815**

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**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%
<b>OTHER INGREDIENTS:</b>	<b>61.4%</b>
<b>TOTAL</b>	<b>100.0%</b>

\*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)

# 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 retreat more than once per month. Do not use more than one tube/vial/cartridge per dog. Do not get this product in dog'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

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.

[Back Panel] DO NOT USE ON CATS

Keep cats away from treated dogs for 24 hours. If applied or ingested, contact your veterinarian immediately.

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

[The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets 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 <sup>st</sup> )	Third Treatment Date (30 Days From 2 <sup>nd</sup> )

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 1-800-xxx-xxxx or contact your veterinarian.

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

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.

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

