

2724-796

7/24/2009

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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Ms. Nancy Huebl  
Product Registration  
Wellmark International  
1501 Woodfield Road, Suite 200W  
Schaumburg, IL 60173

JUL 24 2009

SUBJECT: Application for Pesticide Notification (PRN 98-10)  
Request General Label Change (Marketing Claims)  
EPA Reg. No.2724-796  
Application Dated July 1, 2009

Dear Ms. Huebl:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 07/01/09 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Owen F. Beeder of my staff at 703-308-8899.

Sincerely,

Linda Arrington  
Notifications & Minor Formulations Team Leader  
Registration Division (7505P)  
Office of Pesticide Programs



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number Wellmark International/2724-796	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/RF2042 [CDSO]	PM # 13	
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: EPA Reg. No. _____ Product Name <u>NOTIFICATION</u> JUL 24 2009	

**Section - II**

Amendment - Explain below.  Final printed labels in response to Agency letter dated \_\_\_\_\_

Resubmission in response to Agency letter dated \_\_\_\_\_  "Me Too" Application

Notification - Explain below.  Other - Explain below.

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

Label notification to add marketing claim "New Formula" and move marketing text from DFU to precede DFU  
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:

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 Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted			

3. Location of Net Contents information  
 Label  Container

4. Size(s) Retail Container  
1.5/3/6/9 cc applicators

5. Location of Label Directions  
 On Label  
 On Label Accompanying Product

6. Manner in Which Label is Affixed to Product  
 Lithograph  
 Paper glued  
 Stenciled  Other printed on 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 Senior Registration Specialist	Telephone No. (Include Area Code) (847) 330-5376
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**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 Senior Registration Specialist
4. Typed Name Nancy Huebl	5. Date 01-Jul-09

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

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**Wellmark**

July 1, 2009

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: Richard Gebken, PM 13

SUBJECT: LABEL NOTIFICATION FOR RF2042 [CDSO]  
TO ADD MARKETING CLAIM/EPA REG. NO. 2724-796

Dear Mr. Gebken:

Per PRN 98-10, §II.K.5, enclosed is completed EPA Form 8570-1 and 2 copies of highlighted revised labeling for the above product (red is new text, blue strikethrough is deleted text). We are adding "New" as a marketing claim since this is the first etofenprox/S-methoprene dog topical and it was not included in the initial submission. The term will only be used on initial production or production within a six month timeframe. Additionally, we are moving a marketing general information paragraph out of the Directions for Use to precede the DFU and notating as optional text if spacing issues arise on the packaging.

This label change is submitted as a notification because it meets the requirements of PRN 98-10, §II.K.5. I have enclosed a self-addressed postcard for notification confirmation. If you have any questions please, call me directly at 847-330-5376. Thank you for your assistance in this matter.

Yours sincerely,  
WELLMARK INTERNATIONAL



Nancy Huebl  
Senior Registration Specialist  
[nhuebl@central.com](mailto:nhuebl@central.com)

enclosure

cc: J. McFadden/C. Elmi/C. Purcell

CC: J. McFadden/C. Elmi/C. Purcell  
Nancy Huebl  
Senior Registration Specialist  
nhuebl@central.com

JUL 24 2009

**RF2042 [CDSO]**

**For Small (5-15 lbs.), Medium (16-30 lbs.), Large (31-80 lbs.) and Extra Large (81 - 150 lbs.) Dogs [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]

[Aids in Control of Ticks for 3 weeks]

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]

[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 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)

[Non-Irritating][New (use for first production only or 6 months)][Formula]

[Water Resistant][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]

(Front or Back panel)

**ACTIVE INGREDIENTS:**

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

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

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

**OTHER INGREDIENTS:** ..... 61.4%

**TOTAL** ..... **100.0%**

\*Equivalent to minimum 4.00% butylcarbityl (6-propylpiperonyl ether) and 1.00% related compounds

**KEEP OUT OF REACH OF CHILDREN**

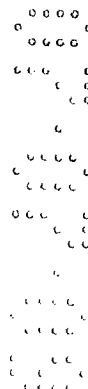
**CAUTION**

See Back Panel for [Ingredients and] Additional Precautionary Statements

**NET CONTENTS:** One 1.5 cc Applicator [tube] (Small Dogs)/  
 One 3.0 cc Applicator [tube] (Medium Dogs)  
 One 6.0 cc Applicator [tube] (Large Dogs)  
 One 9.0 cc Applicator [tube] (Extra Large Dogs)

EPA Reg. No. 2724-796

EPA Est. No:



## RF2042 [CDSO]

**IMPORTANT! Intended for Use on Dogs 6 Months of Age or Older**

**READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS. DO NOT USE ON OTHER ANIMALS!**

[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks 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.

~~RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.~~

RF2042 [CDSO] 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. 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 [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. RF2042 [CDSO] should be applied evenly to [two spots](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 RF2042 [CDSO] 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 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..
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 RF2042 [CDSO] 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 RF2042 [CDSO] 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 RF2042 [CDSO] 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 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.
- 6 Discard empty [tube][applicator] as described in Storage and Disposal

RF2042 [CDSO] 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 pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] 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 RF2042 [CDSO] from: \_\_\_\_\_ NOTES: \_\_\_\_\_  
Treatment table can be expanded based on package size. (6 months)

**STORAGE and DISPOSAL:** . **Pesticide Storage:** Store in a cool area away from children and animals. **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**

**DO NOT USE ON DOGS LESS THAN 6 MONTHS OLD.** For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

<b>FIRST AID</b>	
If in eyes	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 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

