

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Nance Huebl Senior Registration Specialist Wellmark International 1501 East Woodfield Road, Suite 200W Schaumburg, IL 60173

JUL 3 0 2009

SUBJECT:

Application for Pesticide Notification - Clarify Animal Weight Ranges per South Dakota

RF2042 [CDSO]

EPA Reg. No. 2724-796

Application Dated May 27, 2009

Dear Ms. Huebl:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 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 requested falls within the scope of this PRN. The label submitted with the application has been date-stamped "Notification" and will be placed in our records.

If you have any questions, please contact me directly at (703) 305-6249 or Terri Stowe of my staff at (703) 305-6117.

Sincerely,

Linda Arrington

Notifications & Minor Formulations Team Leader

Registration Division (7505P)

Office of Pesticide Programs

ricase tead misa dicaons on re	everse before completing	form.	<u></u>	Form A	pproved. OMB No. 207	0-0060. Approval expires 2-28-95✓	
⊕ EPA		United States Ital Protection Shington, DC 20460	•	х	Registration Amendment Other	OPP Identifier Number	
		Applicati	on for Pesticide - Secti	on I			
1. Company/Product Number		7 17 7110 4111	2. EPA Product Manager			3. Proposed Classification	
Wellmark International/272	4-796		R. Gebken/K. Sweene			or reposed classification	
4. Company/Product (Name) Wellmark International/RF2042 [CDSO]			PM# 13				
Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1501 Fast Woodfield Road, Suite 200W		IP Code)	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to:				
1501 East Woodfield Road, Suite 200W Schaumburg, Illinois 60173			EPA Reg. No. NOTIFICATION				
Condumbary, Illinois Con	75		Product Name			210	
Check if this is a new address			Product Name JUL 3 0 2009				
			Section - II				
Amendment - Explain belong Resubmission in respons			Agenc	orinted labe y letter date oo" Applica			
X Notification - Explain belo	w.		Other	- Explain be	elow.		
Per request of S. Dakota, c This notification is consiste labeling or the confidential EPA. I further understand t	ent with the provisions of statement of formula of the that if this notification is r	es to avoid overlar PR Notice 98-10 a his product. I unde not consistent with	etion II.) of same size in two different and EPA regulations at 40 CF erstand that it is a violation of the terms of PR Notice 98-10 er sections 12 and 14 of FIFR	R 152.46, 18 U.S.C. D and 40 C	and no other changes Sec. 1001 to willfully a	s have been made to the make any false statement to	
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Material This Product Will Child-Resistant Packaging	be Packaged In: Unit Packaging		Section - III Water Soluble Packaging		2. Type of Container		
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Wellmark International

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





May 27, 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]

EPA REG. NO. 2724-796

PER SOUTH DAKOTA REQUEST/CLARIFY SIZE RANGES

Dear Mr. Gebken:

Per PRN 98-10, §II.N. 2 & 3, 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). This change was requested by the State of South Dakota to clarify the weight ranges to avoid overlap (5-15 lb , 15-30 lb, etc.). Therefore, the minimum weight in the three large sizes has been increased by one lb to avoid overlap (16-30 lb, 31-80 lb, 81 to 150 lb). This requires only a change to the size claim, there were no other changes made to the label.

This label change is submitted as a notification because it meets the requirements of PRN 98-10, §II.N. 2 & 3 and: (2) are consistent with 40 CFR Part 156; and (3) involve no change in the ingredients statement, signal word, use classification, precautionary statements, statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use. 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

Lancy Aluelil

Nancy Huebl

Senior Registration Specialist

nhuebl@central.com

enclosure

cc: J. McFadden/C. Elmi/H. Friedli



RF2042 [CDSO]

For Small (5-15 lbs.), Medium (165-30 lbs.), Large (310-80 lbs.) and Extra Large (810 to 150 lbs.) Dogs/Puppies

[Flea & Tick [& Mosquito][Treatment] [and] Control for Dogs and Puppies 10 weeks old and 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][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)	
Piperonyl Butoxide (CAS # 51-03-6)*	
OTHER INGREDIENTS:	
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.

3 3 3

> 2) 12 1 1

RF2042 [CDSO]

IMPORTANT! Intended for Use on Dogs & Puppies 10 Weeks of Age or Older READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS OR PUPPIES. DO NOT USE ON OTHER ANIMALS!

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/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 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 AND 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 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/puppy's skin and hair oils will naturally 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. 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 AND PUPPIES

- 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
- 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/puppy's skin and hair oils will naturally 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 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 1

		EATMENT SCHEDULE applicator every 30 days per dog	1
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 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 PUPPIES LESS THAN 10 WEEKS OF AGE. 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, agea; 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.

3

FIRST AID	
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing Call a poison control center or doctor for treatment advice.
	oduct container or label with you when calling a poison control center or doctor or going for treatment. so 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