2724-796

06-29-2009



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Mr. James McFadden Regulatory Project Manager Wellmark International 1501 E. Woodfield Road Suite 200W Schaumberg, IL 60173

JUN 2 9 2009

Dear Mr. McFadden:

Subject: Fast-Track Label Amendment Product Name: RF2042 EPA Registration No. 2724-796 Application dated June 4, 2009

The label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, is acceptable.

A stamped copy of the label is enclosed for your records. Submit two copies of the revised finished labeling within 60 days of the receipt of this letter. If you have any questions, please contact Kevin Sweeney at (703) 305-5063. Thank you for your cooperation in this matter.

Sincerely,

Product Manager 13 Registration Division (7505P) Insecticide Branch

Enclosure

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 6 months of age or and Puppies 10 weeks

[Flea & Tick [& Mosquito][Treatment] [and] Control for Dogs 6 months of age or and Puppies	i 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 week	s
[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]	0003 0003 0004
[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]	ſ
[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)]	c cc c
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Kills the Deer Tick, which may transmit Lyme Disease Kills and Repels mosquitoes (a major carrier of canine heartworm)	c
[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]	cccc
Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]	6 6 6 6 6 6 6 6 6 6
Spreads naturally with dog's movement (skin and hair oils)	c c c c
[Non-Irritating][Formula]	C C C C C C
[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)	

Etofenprox (CAS # 80844-07-1)	
S-Methoprene (CAS # 65733-16-6)	
Piperonyl Butoxide (CAS # 51-03-6)*	5.0%
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

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EPA Est. No.

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RF2042 [CDSO]

IMPORTANT! Intended for Use on Dogs 6 Months & 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 doa'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 6 6 6 6 6 6 the dog.
- 4. Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's/pt/pp//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.. с с ссссс
- 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

- Bend at perforation and tear off first applicator [tube]. [(Note multi-application pack)] 1
- Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold 2 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 3 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.]

Pet's Name	Clust Transforment Data			
Pet's Name First Treatment Date		Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)	
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			6.8.8.6.8.C	

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 <u>DOGS</u> PUPPIES LESS THAN <u>6 MONTHS OLD10 WEEKS OF AGE</u>. 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.

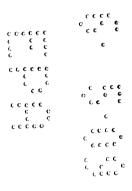
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FIRST AID	······································		
If in eyes		gently with water for 15-20 minutes. after first 5 minutes, then continue rinsi or for treatment advice.	ing
	roduct container or label with you when or You may also contact 1-800-XXX-XXXX for e		

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



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