



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505P)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

EPA Reg. Number: 2724-796
Date of Issuance: MAR 10 2009

Term of Issuance: Conditional

Name of Pesticide Product: RF2042[CDSO]

NOTICE OF PESTICIDE:
 Registration
 Reregistration

(Under FIFRA as amended)

Name and Address of Registrant (include ZIP Code):
Wellmark International
1501 E. Woodfield Road
Suite 200W
Schaumburg, IL 60173

Notes: 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.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

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.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7) (A) provided you:

1. You will submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 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.
2. Submit the listed data below, conducted in accordance with the 40 CFR Part 158 test guidelines referred to below:

Title of Study	OPPTS Guideline	Due Date
One-year Storage Stability Study	830.6317	June 1, 2010
Corrosion Characteristics Study	830.6320	June 1, 2010

You are required to generate a one year storage stability study for the subject product under warehouse conditions. It is recommended that observations be made at 0, 3, 6, 9, and 12 months. The corrosion characteristics study may be conducted concurrently. An accelerated study will not substitute for a one year study under warehouse conditions.

Signature of Approving Official: *Richard Gebken*
Richard Gebken, Product Manager (13), RD/IB (7505P)

Date: MAR 10 2009

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3. You will make the following label changes before you release the product for shipment:

- a) Add the phrase "EPA Registration No. 2724-796"
- b) Add the signal word 'CAUTION' to the front panel of the label.
- c) Change "Each tube [applicator] kills fleas and ticks for 3 to 4 weeks and kills and repels mosquitoes for 3-4 weeks." to read: "Each tube [applicator] kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3-4 weeks."
- d) Aids in control of ticks for up to 30 days [one month] should be revised to "for 3 weeks."
- e) [Starts killing fleas and ticks within minutes][Kills more than 90% of fleas in 8 hours]—Revise to 'within 15 minutes.' The second claim is unacceptable, as 90% of fleas are not killed until 48 hours.
- f) Non-Irritating/Coat Conditioning Formula—Non-irritating is acceptable, but a coat conditioning claim might not be allowed: implied use of a pesticide for some purpose other than killing pests, 40 CFR 156.10.
- g) Remove "Sold by [Vets][Veterinarians] for over 30 years." Etofenprox has only been used on pets for a short time.
- h) Remove: "If necessary, dog may be retreated on week after the initial treatment but do not retreat more than once per month" Please see the companion animal safety study review. If a related statement remains on the label it should: "Do not reapply the 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." This statement must be removed or changed as directed above everywhere it appears on the label.
- i) Remove: [Kills fleas that may transmit Tapeworm (*Dipylidium caninum*)]
- j) Remove: "Based on testing, accidental exposure to cats will not cause serious harmful effects." and "Can be used in households with dogs and cats." Please see the Companion Animal Safety Study recommendations.
- k) Change the highest dose (Extra Large Dogs) from 8.0 cc to 9.0 cc to be consistent with dose titration in your studies. There is no evidence that a lower dose will be efficacious.
- l.) Change 'Storage' to read 'Pesticide Storage.' in the 'Storage and Disposal Statement'

m) Precautionary Statements

i. First Aid Statements: Add:

“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 poison control center or doctor for treatment advice.”

ii. Add the following to the general precautionary statement:

“Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or suing tobacco. Repeated exposure to etofenprox can cause skin irritation.

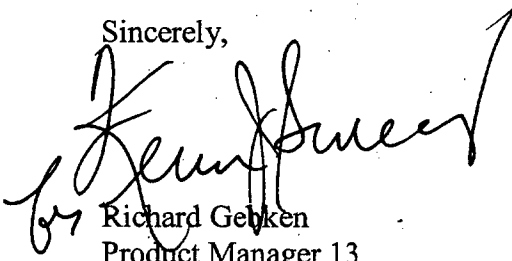
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.”

4. The basic Confidential Statement of Formula (CSF) dated August 15, 2008 is acceptable and is the CSF of record.

5. Submit three (3) copies of your final printed labeling.

A stamped copy of the label and the data evaluation reviews are enclosed for your records. If you have any questions, please contact Kevin Sweeney at (703)-305-5063 or by email sweeney.kevin@epa.gov

Sincerely,



for
 Richard Gebken
 Product Manager 13
 Registration Division (7505P)
 Insecticide Branch

Enclosure

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RF2042 [CDSO]

For Small (5-15 lbs.), Medium (15-30 lbs.), Large (30-80 lbs.) and Extra Large (80 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 to 4 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 up to [30 days] [One month]]

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 minutes][Kills more than 90% of Fleas in 8 hours]

[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)

[Kills fleas that may transmit Tapeworm (*Dipylidium caninum*)]

[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][Coat Conditioning 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

[Can be used in households with dogs and cats]

[Based on testing, accidental exposure to cats will not cause serious harmful effects]

[Fresh][Clean][[Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

Sold by [Vets][Veterinarians] for over 30 years

[Satisfaction guaranteed or your money back]

**ACCEPTED
with COMMENTS
In EPA Letter Dated
MAR 10 2009**

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
2724-796**

(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

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 8.0 cc Applicator [tube] (Extra Large Dogs)

EPA Reg. No. 2724-XXX

EPA Est. No.

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 to 4 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]

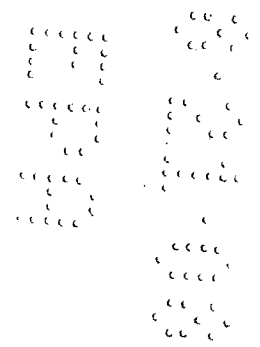
FOR [SMALL][MEDIUM] SIZE DOGS AND PUPPIES

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.
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
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/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.
- 6 Discard empty [tube][applicator] as described in Storage and Disposal

If necessary, dog may be retreated one week after the initial treatment but do not retreat more than once per month.

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.]

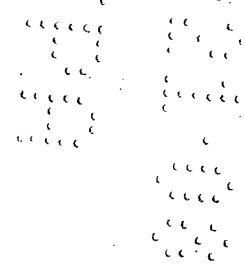
TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF2042 [CDSO] from: _____ NOTES: _____
Treatment table can be expanded based on package size. (6 months)

STORAGE and DISPOSAL: . **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

DO NOT USE ON PUPPIES LESS THAN 10 WEEKS OF AGE. For external use only. 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.



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

