



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

October 15, 2015

James McFadden, Ph.D.  
Directory, Regulatory Affairs  
Wellmark International  
1501 E. Woodfield Rd., Suite 200W  
Schaumburg, IL 60173

Subject: Notice of Extension of Conditional Registration until October 15, 2017 and Label Amendment  
Product Name: RF2042 (CDSO)  
EPA Registration Number: 2724-796  
Application Date: October 2, 2015  
Decision Number: 509776

Dear Dr. McFadden:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these

conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

This letter is also in reference to your request to extend the conditional, time-limited registration for the above-referenced registration. The above-referenced registration contains conditions calling for the registration to expire after two years. Additionally, your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information for the above-referenced registration.

The Agency has found your company to be in compliance with the terms and conditions for the subject product, and is therefore is granting the request to extend the two-year time-limited registration restriction. As such, the following change is being made to the terms and conditions for the product listed above:

- **The two-year time-limited registration restriction has been extended. The new expiration date for the registration listed above is October 15, 2017.**

Please note that the product is still subject to all other previously required conditions of registration. If your company wishes to remove the time limitations altogether, please submit to the Product Manager an amendment application for the product to change the terms and conditions of the registration. Please include with your submission a written rationale for the removal of the time limitation. As you remember, the Agency included this time limitation as a condition of registration for your product to allow for the post-market surveillance<sup>1</sup> of the product. Therefore, we recommend that you include in your rationale the following information, along with any additional information or analyses you think would be helpful to the Agency (e.g., tables, charts, information on stewardship activities, etc.):

- A summary and analysis of the incidents received associated with the product, including information on the following:
  - A comprehensive analysis of incident rates per doses distributed;
  - An analysis of historical incident trends since the products' release into the marketplace;
  - An analysis of historical incident trends by weight range of animal, breed, weight range of product, etc...
- If the product is also registered in the European Union or Canada, information on incident rates per doses distributed and trends in those countries.

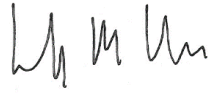
Please also note that requests to remove the expiration date condition are not subject to PRIA fees and do not have to be submitted under PRIA. However, these would also not be considered 90-day fast-track submissions, as the Agency requires time to fully evaluate the information provided. After receiving these submissions, the Agency will consider the incidents received since the initial registration; review the information and rationale provided; and make a decision on the request.

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<sup>1</sup> <http://www.epa.gov/pesticides/health/spot-on-meetings.html>

If you have any questions, please contact Jennifer Gaines at 703-305-5967 or via email at [gaines.jennifer@epa.gov](mailto:gaines.jennifer@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read 'Jennifer Urbanski', with a stylized, cursive script.

Jennifer Urbanski, PhD, Product Manager 4  
Invertebrate and Vertebrate Branch 1 (IVB1)  
Registration Division (7505P)  
Office of Pesticide Programs

Enclosure

## RF2042 [CDSO]

Font size for word "Dog" in product name must be at least 75% the height of the largest letter in the primary brand name

**Front Panel: For Use only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.), Large (56-80 lbs.), or Extra Large (81 lbs. and over) Dogs/Puppies & 10 weeks of age or older**

**[Flea & Tick [& Mosquito][Treatment] [and] Control only for Dogs and Puppies 10 weeks of age or older)] [weighing more than [6] lbs.(only required on smallest size dog packaging]**

Effective on indoor and outdoor dogs/puppies

([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

[10 weeks] up to [75 days][2.5 months]

[Starts Killing Fleas and Ticks within 15 minutes]

[Dual Action kills adult fleas and prevents flea development]

[Breaks Flea Life Cycle for [10 weeks] up to [75 days][2.5 months]

[Controls flea reinfestation for [10 weeks] up to [75 days][2.5 months]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]

(Indicated) for the treatment of adult ticks, tick nymphs and tick larvae of the *Rhipicephalus sanguineus* (Brown dog tick) which (can)(may) (carry)(transmit) Rocky Mountain Spotted Fever and Ehrlichiosis.

(Indicated) for the treatment and control of adult fleas, flea eggs, flea larvae, ticks, tick nymphs, tick larvae (immature ticks), and mosquitoes in dogs 10 weeks of age and older

Kills fleas, flea eggs, flea larvae, ticks, tick nymphs, tick larvae (immature ticks), and mosquitoes

Kills (Brown dog) [tick nymphs][and][kills][tick larvae][to prevent them from growing up into (biting, breeding) adults

Kills all stages of the (flea) (and) (tick) life cycle(s)

Breaks the (flea) (and) (tick) life cycle(s)

Kills all biting stages of ticks

Kills [tick nymphs][and][kills][tick larvae]

Kills adult (brown dog) ticks, nymphs and larvae

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 with dog's/puppy'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/puppies

[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**

Oct 15, 2015

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

(Front panel)



Picture < >, breed/size appropriate to package

**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%

\*(butyl carbityl) (6-propylpiperonyl ether) and related compounds

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

See Back Panel for Additional Precautionary Statements

NET CONTENTS: One: 0.05 fl oz (1.5 cc) Applicator [tube] (Toy Dogs)/0.10 fl oz (3.0 cc) Applicator [tube] (Small Dogs)/0.15 fl oz (4.5 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)/

EPA Reg. No. 2724-796

EPA Est. No.



(Minimum size 1.5 cm X 1.5 cm)

**(Back Panel)**

[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [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] treats fleas, ticks, and mosquitoes for up to one month and prevents flea eggs from developing for up to 2.5 months.]

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**IMPORTANT! READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS OR PUPPIES 10 WEEKS OF AGE OR OLDER. DO NOT USE ON OTHER ANIMALS!**

**USE RESTRICTIONS:**

- For indoor use only.
- Do not allow children to apply this product.
- Do not apply this product to puppies less than 10 weeks of age.
- Do not apply to dogs/puppies weighing less than 6 lbs. (only required for smallest size dog packaging)
- Do not allow your dog/puppy to ingest this product.
- Do not reapply this product for 30 days unless retreatment is required, but not sooner than 8 days after the initial treatment. Do not use more than one applicator/tube per dog/puppy and do not retreat more than 1 time per month.

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/puppy's eyes or mouth.

[(Note: Application assumes one applicator per dog/puppy per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

**ONLY FOR [TOY][SMALL][MEDIUM] DOGS/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/puppy should be standing for easy application. Apply RF2042 [CDSO] evenly to [two spots](toy dogs)[three spots](small or 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/puppy.
4. Do not spread RF2042 [CDSO] by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will 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. Discard empty [tube][applicator] as described in Storage and Disposal

[Note: Each package contains sufficient tubes/applicators for [X] applications]

**ONLY FOR [LARGE][EXTRA LARGE] DOGS/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/puppy 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/puppy. Do not apply more than 1 vial per application.
4. (Same as above)
5. (Same as above)

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 dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies 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/puppy			
Dog's/Puppy'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:** Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to 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**

**DO NOT USE ON PUPPIES LESS THAN 10 WEEKS OLD.** For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands 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 dog/puppy with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Some dogs/puppies may experience hair loss or temporary skin irritation at the application site. If signs persist or become more severe, contact veterinarian immediately and report incident to company at 1-800-xxx-xxxx.

FIRST AID	
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. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-XXX-XXXX, 24 hrs/day, 7 days/wk.	

**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.



Side Effects: 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 [Brand] at 1-800-number.



Wellmark International  
1501 E. Woodfield Road. 200W  
Schaumburg, Illinois 60173  
[adamsfleacontrol.com, biospot.com]  
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



For use only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.), Large (56-80 lbs.), or Extra Large (81 lbs. and over) Dogs/Puppies & 10 weeks of age or older