

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

2724-796	
2/2 4 -/90	

EPA Reg. Number:

Date of Issuance:

9/30/21

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X Registration
Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

RF2042 (CDSO) FOR DOGS

Name and Address of Registrant (include ZIP Code):

James McFadden, Ph.D. Wellmark International 1501 East Woodfield Road Suite 200 West Schaumburg, IL 60173

Note: 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 section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:	Date:
Elbala Latura	9/30/21
Elizabeth Fertich, Product Manager 4	
Invertebrate & Vertebrate Branch 1	
Registration Division (7505P)	
Office of Pesticide Programs	

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- 2. Consistent with the guidance on Pet Spot-On Enhanced Reporting Implementation (updated Aug. 2019), the Agency has reviewed your request to remove the two-year registration expiration date and has found your company to be in compliance with the terms and conditions for the subject product. Further, the Agency has reviewed a sample of enhanced reporting using EPA's standardized templates, as described in Condition 3. hereafter, and concluded that the use of the standardized templates for enhanced reporting for this product will considerably improve pharmacovigilance and thus the continued safety of this product. Therefore, the Agency is removing the two-year registration expiration date for this product. The product remains subject to all other previously required conditions of registration, including the submission of enhanced incident reports and sales information as stated in the amendment letter dated 10/31/13 and amended below to require continued use of the standardized templates.
- 3. The Agency has reviewed your request to change the terms of your registration from quarterly to annual submission of enhanced incident and sales reports using EPA's standardized templates. Based on an initial screening of sample enhanced reports, the sample submission was determined to be adequate and the templates were successfully used. Therefore, the condition of quarterly submission of enhanced incident and sales reports is hereby amended to annual submission with continued use of these standardized templates. You must submit enhanced incident and sales reports for this product to the Agency every 12 months from the date the product is first released for shipment, or from the end date in the last quarterly enhanced reporting submission. The initial released-for-shipment date must be provided to the Product Manager, once known. The enhanced reporting submission should be addressed to the Product Manager's attention and must use the standardized, electronic templates available on the EPA website through the following links: Enhanced Incident Reporting Template, Sales Reporting Template. Submissions must be received by the Agency no later than 60 days following the completion of the 12-month period. If the product is not marketed or sold, you must submit to the Product Manager a letter to this effect every 12 months in lieu of the enhanced incident and sales reports. Please follow appropriate procedures and flag any Confidential Business Information as such.
- 4. You are required to comply with the data requirements described in the DCI identified below:
 - a. PBO GDCI-67501-26641

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1

5. Submit one copy of the final printed label for the record before you release the product for shipment.

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

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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.

If you fail to satisfy these terms and conditions, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

Basic CSF dated 01/26/2018

If you have any questions, please contact Kaitlin Saunders by phone at 703-347-8454, or via email at Saunders.Kaitlin@epa.gov.

Enclosure

Text within braces { } denotes notes to reviewer.

Text within brackets [] denotes optional language.

Text within parentheses () is meant to be included on the label

Text within brackets < > is replaceable, but not optional

RF2042 (CDSO) for DOGS

ACCEPTED

09/30/2021

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 2724-796

{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 [& Mosquito][Treatment] [and] Control only for Dogs and Puppies 10 weeks of age or older and weighing [6-12 lbs.][13-31 lbs.][32-55 lbs.] [56-80 lbs.][81 lbs. and over]]

{Front panel}



{A large, clear picture of a dog in the weight range for the product as packaged will be on the front panel}

ACTIVE INGREDIENTS:

Etofenprox	30.0%
S-Methoprene	3.6%
Piperonyl Butoxide *	5.0%
OTHER INGREDIENTS:	
TOTAL	100.0%

^{*(}butyl carbityl) (6-propylpiperonyl ether) and related compounds

KEEP OUT OF REACH OF CHILDREN CAUTION

See Back/Side Panel for First Aid and Additional Precautionary Statements

NET CONTENTS:

[One][Three][Four][Six]: 0.05 fl oz (1.5 cc) Applicator [tube(s)] (Toy Dogs)] [[One][Three][Four][Six]: 0.10 fl oz (3.0 cc) Applicator [tube(s)] (Small Dogs)] [One][Three][Four][Six]: 0.15 fl oz (4.5 cc) Applicator [tube(s)] (Medium Dogs)] [One][Three][Four][Six]: 0.20 fl oz (6.0 cc) Applicator [tube(s)] (Large Dogs)] [One][Three][Four][Six]: 0.30 fl oz (9.0 cc) Applicator [tube(s)] (Extra Large Dogs)]

{Net Contents to include total package volume}

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{A 1.5cm x 1.5cm cat prohibition icon will be in a box in the lower right hand corner of the front panel in yellow with black images.}

{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 for 4 weeks and kills and repels mosquitoes for 4 weeks.] <[RF2042 [CDSO]> treats fleas, 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 AND WEIGHING [6-12 lbs.] [13-31 lbs.][32-55 lbs.][56-80 lbs.][81 lbs. and over]. 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][13][32][56][81] .lbs.

Do not allow your dog/puppy to ingest this product.

Do not apply more than one [applicator][tube] per treatment for one dog regardless of the dog's weight.

Do not reapply this product for 30 days unless retreatment is required, but not sooner than 8 days after the initial treatment.

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. Dog must be dry at the time of application and remain dry for 24 hours after application.

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

[Note: Each package contains [tubes]/[applicators] for [][1][3][4][6] applications]
ONLY FOR [TOY][SMALL][MEDIUM] DOGS/PUPPIES 10 WEEKS OF AGE OR OLDER AND
WEIGHING [6-12 lbs.][13-31 lbs.][32-55 lbs.]

- 1. Bend at perforation and tear off first applicator [tube]. {(Skip for single dose package.)}
- 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 [1][3][4][6] applications]
ONLY FOR [LARGE][EXTRA LARGE] DOGS/PUPPIES 10 WEEKS OF AGE AND OLDER
AND WEIGHING [56-80 lbs.][81 lbs. AND OVER]

- 1. Bend at perforation and tear off first applicator [tube]. {(Skip for single dose package.)}
- 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.
- 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

<RF2042 [CDSO]> is most effective when used as part of a total flea management program. Use other [Brand Name] products registered for residential area control of fleas in conjunction with this treatment. Apply monthly for control 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]> kills fleas which may be a source of flea allergy dermatitis.]

[<RF2042 [CDSO]> is water resistant (dog must be dry during and 24 hours after application) 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 1st)	Third Treatment Date (30 Days From 2 nd)
			NOTEC

Reminder: I pu	rchased RF2042 [CDSO] from	om:	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. **Pesticide Disposal and Container Handling**: Nonrefillable container. Do not reuse or refill this container. **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 - CAUTION

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.

HAZARDS TO DOMESTIC ANIMALS DO NOT USE ON PUPPIES LESS THAN 10 WEEKS OLD OR WEIGHING LESS THAN [6-12][13-31][32-55][56-80][81 AND OVER] LBS.

For external use on dogs or puppies only. This product is not a substitute for prescribed heartworm preventative. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or dogs on medication. Sensitivities may occur after using ANY pesticide product for dogs. 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 1-800-234-2269.

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.
Have the pro	oduct container or label with you when calling a poison control center or doctor or going

Have the product container or label with you when calling a poison control center or doctor or going for treatment. **HOTLINE** For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-234-2269, 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 1-800-234-2269.

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.

{A box labeled Side Effects will be immediately above the cat warning box on the back panel}



DO NOT USE ON CATS

Keep cats away from treated dogs/puppies for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

{A 1.5cm x 1.5cm cat prohibition icon and warning text in a box will be located at the lower right hand corner of the back panel in yellow with black images and text.}

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 ENTIRE LABEL BEFORE EACH USE For external use only.
EPA Reg. No.
Net Contents
Batch/Lot no.:



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

{Optional Marketing Claims}

Effective on indoor and outdoor dogs/puppies 10 weeks of age and older and weighing [6-12 lbs.]

[13-31 lbs.][32-55 lbs.][56-80 lbs.][81 lbs. and over]

[1][3][4[[6] monthly treatments)

[1][3][4][6] Months Supply

Each tube [applicator] [kills fleas for 4 weeks] and [kills and repels mosquitoes for 4 weeks]

[Protects for up to [Four/4] Weeks][One month]

[One month][Four/4 Week [Flea][Mosquito] Treatment]

[Controls fleas, and mosquitoes for up to one month]

[Monthly treatment for control of fleas, and mosquitoes]

[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 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, mosquitoes, flea eggs and flea larvae]

[Indicated] for the treatment and control of adult fleas, flea eggs, flea larvae, and mosquitoes in dogs 10 weeks of age and older and weighing [6-12 lbs.] [13-31 lbs.] [32-55 lbs.] [56-80 lbs.] [81 lbs. and over]

Kills fleas, flea eggs, flea larvae, and mosquitoes

Kills all stages of the flea life cycle

Breaks the flea life cycle

Kills and Repels mosquitoes (that may transmit canine heartworm)

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

Spreads by dog's/puppy's movement through skin and hair oils

[Formula][Contains lanolin for coat conditioning]

[Water Resistant] [to keep killing fleas in humid and wet conditions](Dog must be dry during and 24 hours after application).

[Kills Fleas by Contact]

[Easy to use] Longer applicator tip for easy application to long-haired dogs/puppies 10 weeks of age and older and weighing [6-12 lbs.] [13-31 lbs.][32-55 lbs.][56-80 lbs.][81 lbs. and over]

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

[Reapply monthly]

[Suitable for year-round use]

[1][3][4][6][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]