



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

February 28, 2025

Noelle Sanfilippo
Regulatory Affairs Specialist
Wellmark International
1501 East Woodfield Road, 200W
Schaumburg, Illinois 60173

Subject: Label Amendment - Registration Review Mitigation for Etofenprox
Product Name: RF2042 (CDSO) FOR DOGS
EPA Registration Number: 2724-796
Application Date: May 3, 2024
Decision Number: 595763

Dear Noelle Sanfilippo:

The Agency, in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with the Etofenprox Interim Decision, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

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 Assurance.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling and must be used at your next label printing. 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 12 months from the date of this letter. After 12 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.

If you have any questions about this letter, please contact DeMariah Cotton by phone at (202)-566-2288 or via email at cotton.demariah@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Linda Arrington", with a stylized flourish at the end.

Linda Arrington, Branch Chief
Risk Management and Implementation Branch 4
Pesticide Re-Evaluation Division
Office of Pesticide Programs

ENCLOSURE: Stamped label

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

ETO FENPROX	GROUP	3A	INSECTICIDE
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RF2042 (CDSO) for DOGS

{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:	61.4%
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}

EPA Reg. No. 2724-796

EPA Est. No.

ACCEPTED

Feb 28, 2025

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



{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.

Application of product on pets must only be done indoors

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 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: 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:** Do not pour or dispose down the drain or sewer. Call your local solid waste agency for local disposal options.

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	<ul style="list-style-type: none">• 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.
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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.

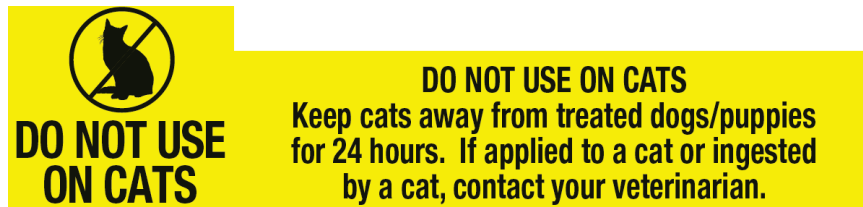
WARRANTY AND CONDITIONS OF SALE:

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}



{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]