



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: RF2176 CDSO-K FOR DOGS
EPA Registration Number: 2724-815
Application Date: May 8, 2024
Decision Number: 595800

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 carets < > is not optional, but is replaceable

{Front Panel}

ETOFPENPROX	GROUP	3A	INSECTICIDE
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RF2176 CDSO-K for Dogs

Alternate brand name: Kirkland Signature Water-Resistant Flea & Tick Control for Dogs [Small 6-12 lbs], [Medium 13-31 lbs,][Large 32-79 lbs,] and [Extra Large 80 lbs & Over]



{A large, clear picture of a dog in the weight range for the product as packaged will be included in the final printed label.}

{Text for "Dog" in the product name must be at least 75% of the size of the largest letter in the Brand Name}

Front panel - For Use Only on [Small/Toy (6-12 lbs.)], [Medium (13-31 lbs.)], [Large (32-79 lbs.)] {and } [Extra Large (80 lbs and over)] Dogs/Puppies 10 weeks of age or older

[Flea & Tick [& Mosquito]][Treatment] [and] Control only for Dogs/Puppies 10 weeks of age or older] and weighing [6-12 lbs.][13-31 lbs.][32-79 lbs.][80 lbs. and over].

ACTIVE INGREDIENTS:

Etofenprox	30.0%
S-Methoprene.....	3.6%
Piperonyl Butoxide *	5.0%
OTHER INGREDIENTS:	<u>61.4%</u> TOTAL
	100.0%

*butylcarbityl (6-propylpiperonyl ether) and related compounds

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See Back Panel for First Aid and Additional Precautionary Statements

NET CONTENTS: (3 or 6): 0.05 fl oz (1.5 mL) [Applicator] [tube] (Small/Toy Dogs)
..... 0.10 fl oz (3.0 mL) [Applicator] [tube] (Medium Dogs)
..... 0.20 fl oz (6.0 mL) [Applicator] [tube] (Large Dogs)
..... 0.30 fl oz (9.0 mL) [Applicator] [tube] (Extra Large Dogs)

EPA Reg. No. 2724-815

EPA Est. No.:

Lot No.:



{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.}

ACCEPTED

Feb 28, 2025

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 2724-815

{Back Panel}

[<RF2176 CDSO-K for Dogs>]

**IMPORTANT! DO NOT USE ON DOGS/PUPPIES LESS THAN 10 WEEKS OLD OR LESS THAN [6][13][32][80] POUNDS. READ ENTIRE LABEL [AND INSERT(S)] BEFORE EACH USE. USE ONLY ON DOGS/PUPPIES. DO NOT USE ON ANIMALS OTHER THAN DOGS!
DO NOT ALLOW CHILDREN TO APPLY PRODUCT.**

INTRODUCTION:

[Brand – Adams, Adams Plus] Water-Resistant Flea & Tick Control for Dogs prevents flea eggs from developing into adult fleas for up to 2.5 months. [Brand] Water-Resistant Flea & Tick Control for Dogs also controls fleas and ticks for up to 1 month and kills and repels mosquitoes for 4 weeks.

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

To prevent harm to you and your dog, read entire label before each use. Follow all directions and precautionary statements carefully. Dog must be dry at time of application and remain dry for 24 hours after application. Use entire contents of [applicator] [tube] on each dog. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

<RF2176 CDSO-K for Dogs> 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.

USE RESTRICTIONS:

For indoor use only. Application of product on pets must only be done indoors. Do not use on dogs/puppies less than 10 weeks old or less than [6][13][32][80] lbs. Do not use more than one [applicator] [tube] per dog/puppy regardless of the dog's weight and do not retreat more than once per [month] [4 weeks][30 days]. Do not get this product in dog's/puppy's eyes or mouth. Do not allow your dog/puppy to ingest this product. Do not use on cats. If applied to a cat or ingested by a cat, contact your veterinarian. Do not allow children to apply this product. Do not bathe or allow dog to swim for 24 hours after application.

{Note: Application assumes one applicator per dog/puppy per application}

{Note: Each package contains sufficient [tubes][applicators] for [3][6] applications}

ONLY FOR [[TOY]/[SMALL] (6-12 lbs.)], [[MEDIUM] (13-31 lbs.)] DOGS/PUPPIES 10 WEEKS OF AGE OR OLDER

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 dry and standing for easy application. Apply <RF2176 CDSO-K for Dogs> evenly to [two spots]{toy/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 [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/puppy.
4. Do not spread <RF2176 CDSO-K for Dogs> by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will [over time] distribute the application over the entire dog/puppy, brushing the dog/puppy 12 to 24 hours after application will help to distribute the material over the

skin.

5. Do not retreat more than once per [month][4 weeks][30 days].
6. Discard empty [tube][applicator] as described in STORAGE and DISPOSAL.

[Each package contains sufficient [tubes]][applicators] for [3][6] applications]

ONLY FOR [[LARGE] (32-79 lbs.)], [[EXTRA LARGE] (80 lbs and over)] DOGS 10 WEEKS OF AGE OR OLDER

- 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 dry and standing for easy application. Apply <RF2176 CDSO-K for Dogs > 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/puppy.

Monthly treatments are required for 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 <RF2176 CDSO- K for Dogs > kills fleas that may cause this condition.

[<RF2176 CDSO-K for Dogs > is water resistant at 24 hrs after application and remains efficacious following exposure to rainfall or swimming.24 hours after application.] Note: Dog must remain dry during and 24 hours after application.

[TREATMENT SCHEDULE			
Dosage: Apply 1 [applicator] [tube] [every 30 days][monthly][every 4 weeks] per dog/puppy			
Dog's/Puppy's Name	First [Month][Treatment Date]	Second [Month][Treatment Date] [[([30 Days][4 weeks][1 month] From 1 st)]	Third [Month][Treatment Date] [[([30 Days][4 weeks] [1 month] From 2 nd)]

[Reminder: I purchased <RF2176 CDSO-K> from: _____ {Treatment table can be expanded based on package size, but will not exceed 6 months.} NOTES: _

STORAGE and DISPOSAL: Pesticide Storage: Store [applicators][tubes] in a cool, dry (preferably locked) area away from children and animals. **Container Handling : 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 AND DOMESTIC ANIMALS - CAUTION

HAZARDS TO HUMANS: 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. Remove and wash contaminated clothing before reuse. Repeated exposure to Etofenprox can cause skin irritation.

HAZARDS TO ANIMALS: DO NOT USE ON DOGS/PUPPIES LESS THAN 10 WEEKS OLD OR LESS THAN [6][13][32][80] POUNDS.

For external use only. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated dogs. Sensitivities may occur after using ANY pesticide product for dogs. Some sensitive dogs/puppies may experience temporary skin irritation such as itching or redness at the application site. If signs of sensitivity occur, bathe your dog/puppy with mild soap and rinse with large amounts of water. If signs persist or become more severe, call 1-888-987-4110 or contact your veterinarian. This product is not a substitute for prescribed heartworm preventative. 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.

FIRST AID	
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 to 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 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 1-888-987-4110, 24 hours/day, 7 days/week .	

SIDE EFFECTS: Monitor your dog/puppy 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 Wellmark at 1-888-987-4110.
{This box will appear in lower right hand corner of back panel}

{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.}

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 1-888-987-4110.

Wellmark International
1501 E. Woodfield Road. 200W
Schaumburg, Illinois 60173
Made in USA

{TEXT FOR INDIVIDUAL TUBE/APPLICATOR}

<Product name>

Etofenprox 30%, S-Methoprene 3.6%, Piperonyl Butoxide 5% KEEP

OUT OF REACH OF CHILDREN

CAUTION

FOR EXTERNAL USE ONLY

READ DIRECTIONS BEFORE USING EPA

Reg No. 2724-815

Net Contents [0.05][0.10][0.20][0.30] fl. oz.

[ICON – DO NOT USE ON CATS]

For Use Only on [Small/Toy (6-12 lbs.)], [Medium (13-31 lbs.)], [Large (32-79 lbs.)] {and} [Extra Large (80 lbs and over)] Dogs/Puppies 10 weeks of age or older

{OPTIONAL TEXT FOR PACKAGE INSERTS}

{OPTIONAL INSERT 1}

Dear Valued [Store Customer],

Thank you for your purchase of [Product Name]. [Brand – Adams, Adams Plus] wants the best for your dog, and we are pleased to share with you some great tips on using the product. f

- A. The <Product Name> comes in 4 different sizes so that the right amount of protection from fleas and ticks is applied to your size dog. Weigh your dog before applying <Product Name> and be sure that the product you purchased is the right size for your dog. Do not apply this product to dogs/puppies younger than 10 weeks or weighing less than [6][13][32][80] pounds. If you have questions, please call 1-888-987-4110 to talk to a product specialist.
- B. Apply <Product Name> evenly to the dog's back in spots starting at the top of the back from the shoulders to the base of the tail. Use two spots for toy dogs; three spots for medium dogs, and 4 or 5 spots for large and extra-large dogs. At each spot, be sure to apply the product to your dog's skin, not to the surface of your dog's hair coat. For complete instructions on application, please read the package label.
- C. <Product Name> contains lanolin as a coat conditioner. The lanolin helps the product spread over the dog and acts as a coat conditioner as well. After the product has dried, you may brush through your dog's fur with a brush or comb for distribution of the product and coat conditioning lanolin. Because of the initial effect of the lanolin, keep treated dogs off furniture until the product has dried.
- D. Sensitivities may occur after the use of any topically applied product. A dog's skin is a complex organ, and your dog's skin may be generally sensitive to topical products. Monitor your dog after application, and if you have questions about best results or if your dog experiences a reaction after application, please call 1-888-987-4110 to talk to a product specialist.
- E. When applying <Product Name> make sure not to get this product in your dog's/puppy's eyes or mouth. If you are concerned that your dog may have an oral exposure to <Product Name> please call 1-888-987-4110 to talk to a product specialist.
- F. In households with dogs and cats, the cat will often groom the dog as well as itself. Separate treated dogs from cats for 24 hours after treatment to minimize [reduce potential] oral exposure to your cat.
- G. Treatment of fleas on your dog does not address the 95-99% of the flea population that lives in your house and yard. So even after your dog is treated with <Product Name> and adult fleas are killed, flea eggs may continue to hatch in your home for up to two months. Treat your yard and home for fleas with treatments that contain an Insect Growth Regulator, which kills flea eggs. Over time, treatment of your dog and its environment will eliminate fleas from your home.

{OPTIONAL INSERT/CARD 2}

STOP. Please read this insert/card and the entire instructions before using this product.

[Brand Name] wants the best for your dog, and we are pleased to share with you some great tips for using the product.

- Use <Product Name> only as directed.
- Brush your dog's coat 24 hours after application.
- Apply away from furniture and carpeting.
- Consult a veterinarian before using if your dog is aged, pregnant, nursing, or taking other medication.

[Contact a product specialist at 1-888-987-4110 with any questions.]

{OPTIONAL MARKETING CLAIMS}

[Effective on indoor and outdoor dogs/puppies (10 weeks of age or older and weighing [6-12 lbs.][13-31 lbs.][32-79 lbs.][81 lbs and over])]

[[3][6] [monthly][4 weeks][30 days] treatments) [3][6] Months Supply [applications]

[Each [tube] [applicator] [kills fleas & ticks for up to 4 weeks and [kills and repels mosquitoes for 4 weeks]]

[Protects for up to [Four/4] Weeks][One month][30 days]

[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][4 weeks][1 month]

[Dual Action kills adult fleas and prevents flea development]

[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)]] Convenient,

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

] Spreads [over time] with dog's/puppy's movement (through skin and hair oils)]

[Formula][Contains lanolin for coat conditioning]

[Water Resistant 24 hours after application. Note: dog must remain dry during and 24 hours after application] [to keep killing fleas and ticks in humid and wet conditions]

[Long Lasting (up to one month)][Kills Fleas and Ticks by Contact]

[Easy to use] Longer [applicator][tube] tip for easy application to long-haired dogs/puppies (10 weeks of age or older and weighing [6-12 lbs.][13-31 lbs.][32-79 lbs.][81 lbs and over])

[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]

{IGR Claims:}

[Contains [*InfestStop™] [an Insect Growth Regulator (IGR) to kill flea eggs [and larvae]] and prevent flea development for [10 weeks] up to [75 days][2.5 months]]

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

An important step in breaking the flea life cycle

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

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

*InfestStop/Infestop™

[Plus][Contains][With] PRECOR® [vIGRen®][S-Methoprene][*InfestStop™], an insect growth regulator for flea control

[(S)-Methoprene][*InfestStop™] Insect Growth Regulator (IGR) interrupts the development of the flea life cycle [at the egg stage]

[(S)-Methoprene][*InfestStop™] Insect Growth Regulator (IGR) prevents the development of flea eggs into adult fleas and [inhibits the development of flea eggs into adult fleas]

Flea control for dogs with [PRECOR®][vIGRen®] [*InfestStop™] Insect Growth Regulator (IGR)

[Kills][Prevents][Keeps] flea eggs from hatching for up to [75 days][2.5 months][10 weeks]

***(S)-Methoprene {Must occur on same panel wherever InfestStop™ is used}**