



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: RF2185 CSO XM
EPA Registration Number: 2724-834
Application Date: May 10, 2024
Decision Number: 595819

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 Koger by phone at (202)-566-2288 or via email at koger.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

[] Optional Copy

ETOFENPROX	GROUP	3A	INSECTICIDE
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RF2185 CSO XM

Alternate brand names: []

Include "Cat" in product brand name and font size must be 75% of the size of the largest letter in the brand name

[For] use only on cats/kittens [over 2.5 lbs but under 5 lbs.][and weighing][5 lbs. and over] & 12 weeks of age or older

Only For use on cats/kittens weighing [5 lbs and over][> 2.5 lbs but < 5 lbs][over 2.5 lbs but Under 5 lbs] & 12 weeks of age or older

(General/Protection claims)

1 ml [cc] for cats [kittens] over 2.5 lbs but under 5 lbs.; 1.8 ml [cc] for cats 5 lbs. and over

Flea & Deer Tick [Protective] for cats [& kittens]

[Flea & deer tick] treatment for cats [& kittens]

[Special formula for cats/kittens][Superior flea prevention and treatment specially formulated for use on cats and kittens [12 weeks of age and older]

Spot On [Topical][Non-systemic] treatment for [cats/kittens]

Flea, Deer Tick, and Mosquito Treatment [Control][Prevention][Relief] for Cats & Kittens

3 in 1 [Protection][Treatment] (Fleas, Deer Ticks, and Mosquitoes)

[1 month][monthly][flea & deer tick,][protection

Monthly treatment for [fleas mosquitoes & deer ticks]

Flea [and deer tick][and mosquito] control for your cat

A smart approach to flea control

Keeps fleas, deer ticks, and mosquitoes under control

Controls flea, deer tick, and mosquito problems

[secure] flea, deer tick, and mosquito protection

Provide your cat with flea, deer tick, and mosquito protection, right from the start

Direct on-animal protection from fleas, deer ticks, and mosquitoes

Provides relief [protection] from fleas, deer ticks, and mosquitoes

Once-a-month [topical][Spot On] protection from fleas, and deer ticks,

ACCEPTED

Feb 28, 2025

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 2724-834

(Kills/Repels/Controls claims)

[Actively] Kills [Controls] [adult] fleas, deer ticks, and mosquitoes for [up to][4 weeks][1 month][per application]

[Actively] Kills [fleas][deer ticks][&][and][mosquitoes][by contact]Kills [and/or Repels] mosquitoes [for up to 18 days][by contact]

Controls fleas, deer ticks, and mosquitoes & [in your home]

[Kills deer ticks] (for up to 1 month [4 weeks]) [per application]

Starts killing fleas in 15 minutes

Protects your [cat][kitten] from fleas, deer ticks, and mosquitoes (which may transmit heartworm disease)

Effectively controls fleas, deer ticks, and mosquitoes

Kills [Controls] deer ticks that may transmit [][Lyme disease][and Cytauxzoonosis] for up to [1 month][4 weeks]

Protect your [cat] from [against] deer ticks that may transmit Lyme disease

Kills [and repels] mosquitoes that may transmit heartworm disease

Prevents mosquitoes from feeding on cats

Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation

Preventative treatment for fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation

Control highly irritating flea, deer tick, and mosquito [insect] bites

(More general claims)

When it comes to fleas and deer ticks, there's no room for compromise

[Brand] protecting pets for over 35 years

(Application claims)

[#] pack [# days'] [#] doses [1/2/3/4/5/6] months supply

One tube gives [1 month][4 weeks] of protection

[Pre-measured][Convenient][and][&][No mess][easy][simple] to [use][handle][apply] disposable applicator [tube]

Convenient [and effective], once-a-month [liquid][topical][Spot On] solution

Practical solution

Simple choice [flea & deer tick control]

A [One] simple application provides your cat with protection for up to [1 month]

Apply to one spot for head to tail (total body) flea protection [control]

Apply to 1 spot - spreads over the cat's [entire] body [from head to tail] through natural skin oils

Spreads naturally with cat's skin oils

[Plus] Contains a natural coat conditioner

[Once][One] Monthly Application

Easy to use [once] monthly application [liquid] prevents [and controls] fleas [& deer ticks]

Reapply [Repeat] [once] monthly

Repeat [treatment] every month

Monthly Control [Relief][treatment]

(Applicator claims)

Unique Applicator [tube] Shape [Design][helps prevents misuse on dogs][helps prevents misapplication on dogs]

Unique shape [only for cats & kittens 5 lbs and over][only for cats & kittens over 2.5 lbs but under 5 lbs]

Pet Specifix® Applicator Accu-Tip Dispenser

[New][X] Pro-cision Flo™ Applicators [tubes]

[New][Exclusive][Pinpoint][Applicator] for [pinpoint][exact][direct][easy][direct to skin] application

For pinpoint accuracy

Direct to your cat's skin

Easily penetrates hair

Easy to apply [identify][use] applicator [tube]

Cat head shape [applicator][tube] for cats [cat head = cats]

The right choice [applicator][tube] for the right pet

Make [Select] the right choice [applicator][tube][shape]

Choice [selection] is simple

Easy choice

Simple choice delivery system

Easy to use applicator [tube] [provides direct on-animal protection]

Longer Applicator [tube][tip] for easy application [to long-haired cats]

Longer tube [applicator][tip] is ideal for long-haired [cats]

Helps Prevent [misapplication on dogs] misuse on dogs with unique [specially designed] applicator [tube] design

Cat head shape prevents misuse [misapplication][on dogs]

Unique tube [applicator] design (cat shape) helps prevent misuse/misapplication [on dogs]

EZ-squeeze [Easy squeeze] tube [applicator][shape]

(Product Claims)

Odorless

Effective Control [Relief][Prevention]

Fast [Quick] acting [Relief]

Starts working by contact

Quick acting [treatment]

easy to use [apply]

[Flea prevention] Helps stop itching and scratching [from flea bites]

(Brand claims)

We () [Brand] put(s) your pet(s) first

Brand ...putting (your pet) pets first

Right choice = best defense

Perfect choice

Brand – caring & committed

Brand makes the choice simple

[Satisfaction guaranteed][Money-back guarantee]

(Formula claims)

Etofenprox provides a novel [smart] approach to flea, deer tick, and mosquito control

Advanced Formula [for cats & kittens]

Features [Contains] an [insecticide] adulticide to kill [and/or][control] adult fleas [deer ticks, and mosquitoes]

(FRONT PANEL)

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1) 40.0%

OTHER INGREDIENTS:..... 60.0%

Total 100.0%

KEEP OUT OF REACH OF CHILDREN

See back panel for additional Precautionary Statements

EPA Reg. No. 2724-834

EPA Est. No.

Batch/Lot No.

Net Contents:

READ ENTIRE LABEL BEFORE USE
USE ONLY ON CATS OR KITTENS 12 WEEKS OF AGE AND OLDER

[Specially formulated for cats [& kittens]] [For use on cats only] [Do not use on other animals]

INTRODUCTION:

[RF2185 CSO XM is a topically applied product specifically formulated for cats and kittens. It [This product] contains the highly effective flea, deer tick, and mosquito killing agent [Etofenprox][Brand Name], which kills biting adult fleas, deer ticks, and mosquitoes your cat may acquire from its surroundings. Each package contains enough product for xx monthly applications (xx days of protection [control]). RF2185 CSO XM provides relief from flea infestations for up to 1 month [4 weeks] by killing adult fleas on your cat or kitten.

After application, your cat's skin oils [disperse] carry RF2185 CSO XM over your cat's body for protection against biting adult fleas. [(product) may stain leather and suede fabrics for (24)(24 to 48) hours after application.] To completely kill the existing flea population, you may need to treat your home and your cat's bedding (home sprays, foggers), as well as your yard (yard spray/outdoor fogger) with traditional flea products approved for use on cats, around the home, or in your yard. RF2185 CSO XM can be used in conjunction with other [Brand] premise products. As with all flea products, they are [RF2185 CSO XM is] most effective when used as part of a total program aimed at reducing all stages of fleas in the cat's environment. [BRAND] products [They] are designed to complement each other in an integrated program for flea, deer tick, and mosquito management. To assure proper treatment, we recommend use of [Brand] products as directed to treat all pets in the household, as well as the indoor and outdoor home environments.]

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

USE RESTRICTIONS:

For indoor use only. Application of product on pets must only be done indoors.

USE ONLY ON CATS AND KITTENS 12 WEEKS OF AGE AND OLDER. (on the 2.5 - < 5 lb product – Do not apply to cats weighing less than 2.5 lbs.) [Do not apply to cats weighing less than 5 lbs.] Do not get this product in your cat's eyes or allow your cat to ingest this product. Do not use more than one applicator per cat and do not apply more than once every month.

[This product contains xx monthly dosages [one monthly dose], each [0.034 fl oz and][0.054 oz] (1 and 1.6 ml [cc])].

[1 ml [cc] [0.034 fl oz] dose for use only on cats and kittens over 2.5 lbs but under 5 lbs.

1.6 ml [cc] [0.054 oz] dose for use only on cats and kittens 5 lbs. and over (Same size applicators with different fill amounts)]]

[APPLICATION METHOD]

[Bend at perforation and tear off 1st month's applicator.] Hold [applicator] upright [and bend area of plastic at perforation, tear off and discard.] [Hold applicator upright] and snap tip back, away from face and body. Prior to application of the product, gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the tip of the [applicator] tube on the cat's exposed skin and squeeze out the [entire] contents of the [applicator] tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried. Repeat application once monthly.

ALTERNATE PACKAGING DIRECTIONS 1 (CAT-HEAD APPLICATOR)

[Bend at perforation and tear off 1st month's applicator.] Hold [applicator] upright and bend numbered area of plastic at perforation, tear off and discard. Hold applicator upright away from face and body and use scissors to cut secure seal applicator tip. Prior to application of the product, gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the tip of the [applicator] tube on the cat's exposed skin and squeeze out the [entire] contents of the [applicator] tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried. Repeat application once monthly.

ALTERNATE PACKAGING DIRECTIONS 2

Remove one applicator tube from the package and hold in an upright position (pointed away from your face). Hold bottom of tube with one hand. With other hand, snap cap off. Prior to application of the product, gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the tip of the [applicator] tube on the cat's exposed skin and squeeze out the [entire] contents of the [applicator] tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried. Repeat application once monthly.

ALTERNATE PACKAGING DIRECTIONS 3

1. Remove one applicator tube from the package and hold in an upright position pointed away from your face.
2. Pull off cap. Turn the cap around and place on top of tube.
3. Simply press cap down to break the seal of tube. Remove cap carefully.
4. Prior to application of the product, gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the tip of the tube on the cat's exposed skin and squeeze out the entire contents of the tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried.
5. Repeat application [once every month][once monthly].

STORAGE AND DISPOSAL: **Storage:** Store in a cool, dry place. Do not store unused applicators [tubes] separately from their packaging. **Container Disposal: If empty:** Do not reuse empty applicator [tube]. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for local disposal options. Do not pour or dispose of down the drain or sewer.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS: Repeated exposure to etofenprox can cause skin irritation.

HAZARDS TO ANIMALS: For External Use on Cats Only. **Do not use on kittens less than 12 weeks old.**

Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your cat/kitten with mild soap and rinse with large amounts of water. If signs continue, [please call 1-phone number or] consult a veterinarian immediately. Be careful not to get any product in the cat's mouth during application. For multiple cat households, prevent the cats from grooming each other until the product has dried.

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 an emergency or for product use information, call [800-234-2269] or visit our Web site:
[<https://www.adamspetcare.com>] [<https://www.zodiacpet.com>]

SIDE EFFECTS: Monitor your cat 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 East Woodfield Road 200W
Schaumburg, IL 60173
Made in USA

PRECOR® Insect Growth Regulator, **vIGRen®** Insect Growth Regulator, and ZODIAC® are registered trademarks of Wellmark International.

Adding a Dose Reminder section to appear as follows on the back panel:

First Monthly Application: Month _____ Day _____ Year _____
Second Monthly Application: Month _____ Day _____ Year _____
Third Monthly Application: Month _____ Day _____ Year _____
[Fourth Monthly Application: Month _____ Day _____ Year _____]

Optional marketing text for subregistrant

[TREATMENT SCHEDULE

Dosage: 1 applicator every 30 days per cat

Cat's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2nd)

NOTES: _____

REMINDER: I purchased [Brand Name] from _____]

[All text below represents one label statement with any selected line]

[Protect your family and cat from:]

[When your cat has fleas and ticks, your family and cat may be exposed to:]

Fleas that may cause:

Flea allergy dermatitis

Flea bite anemia

Tapeworm infestation

Deer ticks which may carry:

Lyme disease

To learn more about treating current infestations and preventing future outbreaks, please, visit our website: [URL]

[For more information, call our experts at 1-800-number (weekdays, 9am – 5 pm EST)]

To learn more, visit [URL]

Applicator/Tube:

Product Name

Etofenprox 40%

KEEP OUT OF REACH OF CHILDREN

Use only on cats/[kittens] 12 wks of age or older & [weighing](5 lbs & over) (over 2.5 lbs but under 5 lbs)

[READ DIRECTIONS BEFORE USING] (OPTIONAL if space allow)

EPA Reg No. 2724-834

Net Contents

[US Patent No. _____]