

## 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: RF2112 SHAMPOO EPA Registration Number: 2724-806 Application Date: May 9, 2024

Decision Number: 595811

## 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

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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 <a href="mailto:cotton.demariah@epa.gov">cotton.demariah@epa.gov</a>.

Sincerely,

Linda Arrington, Branch Chief

Risk Management and Implementation Branch 4
Pesticide Re-Evaluation Division

Office of Pesticide Programs

ENCLOSURE: Stamped label

# ETOFENPROX GROUP 3A INSECTICIDE

# **RF2112 SHAMPOO**

Alternate brand name: Vet Kem® Ovitrol® X-Tend™ Flea & Tick Shampoo for Dogs and Cats

#### **ACTIVE INGREDIENTS:**

Etofenprox (CAS #80844-07-1)		0.10%
Piperonyl Butoxide (CAS #51-03-6)*		
S-Methoprene (CAS #65733-16-6)		
OTHER INGREDIENTS:		
	TOTAL	100.00%

<sup>\* (</sup>butylcarbityl) (6-propylpiperonyl) ether and related compounds

Leaves coat soft and shining [while removing dandruff, dirt and scales]. The shampoo removes loose dandruff, dirt, and scales.

# KEEP OUT OF REACH OF CHILDREN WARNING

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS

EPA Reg. No. 2724-806 EPA Est. No.

NET CONTENTS Oz. (12, 24) Gallons (1)

ACCEPTED

Feb 28, 2025

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

EPA Reg. No. 2724-806

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS WARNING

Causes substantial but temporary eye irritation. Avoid contact with skin or clothing. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). Wash 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. Wear long-sleeved shirt and long pants, socks, shoes, and waterproof gloves. Repeated exposure to etofenprox can cause skin irritation.

FIRST AID		
Call a poison control center or doctor for treatment advice.		
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> </ul>	
	<ul> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>	
If on skin or	Take off contaminated clothing.	
clothing	<ul> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul>	
Have the product container or label with you when calling a poison control center or		
doctor, or going	ng for treatment. You may also contact 1-800-[phone number] for	
emergency m	edical treatment information.	

[Note: First Aid statement paragraph format may be used if space is limited.]

# **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. FOR TOPICAL USE ONLY. DO NOT INGEST.

# READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON CATS AND KITTENS 12 weeks of age or older USE ONLY ON DOGS AND PUPPIES 10 weeks of age or older

### **Use Restrictions**

- For indoor use only.
- o Application of product on pets must only be done indoors.
- Apply this product only as specified on this label
- DO NOT apply to cats less than 12 weeks of age (or) dogs less than 10 weeks of age (or as appropriate for dog only or cat only shampoos).
- Consult a veterinarian before applying this product on debilitated, aged, pregnant or nursing animals. Certain medicines can interact with pesticides. Consult a veterinarian before using on medicated animals. Sensitivities may occur after using **ANY** pesticide for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

Thoroughly wet [the hair][the animal][your pet/dog/cat/puppy/kitten] with warm water. Use [Brand Name] full strength. Do not apply shampoo around the eyes. Apply ¼ tablespoon\*\* shampoo for each 1 lb of pet's [cat's/dog's/kitten's/puppy's] weight. Starting with the head and ears, lather; then continue to work lather in for 3 to 5 minutes to the neck, chest, middle and hindquarters, and finishing legs last (this is an important part of the grooming procedure). Rinse [animal][pet][cat/dog/puppy/kitten] thoroughly with warm water. For extremely dirty or scaly animals [pets][cat/dog/puppy/kitten], remove excess dirt and dust by brushing coat first, then shampoo. For dogs, do not repeat applications unless, at least, 8 days apart. For cats, do not repeat applications unless, at least, 14 days apart and do not apply more than twice per month. Treat animal bedding/quarters with an approved product labeled for that use at the same time that [pet][dog/cat/puppy/kitten] is treated with [Brand Name] Shampoo.

\*\*Do not use food utensils such as tablespoons for food purposes after use with pesticides.

# STORAGE AND DISPOSAL

**Pesticide Storage:** Store in a cool, dry (preferably locked) area that is inaccessible to pets and children.

**Pesticide Disposal and Container Handling**: Non-refillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available. **If partially filled:** Call your local solid waste agency for local disposal options. Do not pour or dispose of down the drain or sewer.

### Dog claims:

Kills [adult] [biting] fleas, ticks, through contact [including the Deer tick, which may carry Lyme disease] [On Dogs] [Kills Deer Ticks, which may carry Lyme Disease] For dogs and puppies over 10 weeks of age Dogs can be shampooed weekly/once per week

### **Cat Claims**

For cats and kittens over 12 weeks of age Cats can be shampooed bi-weekly/every other week Kills [adult] [biting] fleas, ticks, through contact

#### Dog and Cat claims:

For [use on] Dogs and Cats, Puppies and Kittens Kills adult fleas and ticks through contact

Effective in multi-pet households

Effectively kills fleas and ticks

Kills fleas that may transmit tapeworm (*Dipylidium caninum*)

Provides immediate relief from fleas and ticks

Kills fleas and aids in the control of ticks

Kills flea eggs

Prevents flea egg hatch for 1 month [4 weeks]

Prevents flea eggs from hatching for 1 month [4 weeks]

Breaks the flea life cycle

Conditioning flea and tick shampoo; Rich [Deep] Conditioning

Pleasant [scent][fragrance] [to overcome dog/cat odors]

Contains [With] [Etofenprox][to kill adult insects] [Plus] [S-Methoprene][Precor][Insect Growth Regulator] [Dual action kills adult fleas and prevents flea development][Dual protection (against fleas and ticks)]

[Emollient] Shampoo [with [coconut extract] [aloe][aloe vera], and [lanolin]

[Contains] [Conditions][Moisturizes] [coat][skin] with [aloe][aloe vera], coconut extract and lanolin

Contains [features coconut] conditioners [extract]

[Cleans][Freshens][Beautifies][Deodorizes][Conditions] [in one easy step]

Rich, creamy formula cleans, deodorizes and conditions

[Coconut Extract Leaves coat soft, shining, and manageable]

With coconut conditioners

Give hair coat a brighter luster

Fresh Citrus Fragrance; [Clean] Fresh Scent

Contains [\*InfestStop™] an Insect Growth Regulator (IGR) to kill [flea eggs] and prevent [reinfestation] [flea development for up to [28 days][1 month][4 weeks]]

Controls flea reinfestation for up to [28 days] [1 month][4 weeks]

[Kills flea eggs [flea larvae] and prevents flea egg hatch]

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

[Plus][Contains][With] PRECOR® [vIGRen®][S-Methoprene][\*InfestStop™], the first 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 [cats] with [PRECOR®][vIGRen®] [\*InfestStop™] Insect Growth Regulator (IGR)

[Kills][Prevents][Keeps] flea eggs from hatching for up to [28 days] [1 month][4 weeks]

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

In case of emergency or for product use information, call [phone number]

# **Warranty and Disclaimer**

Note: Seller warrants that this product complies with the specifications expressed in this label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, expressed 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 or 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.

Wellmark International 1501 East Woodfield Road 200 W Schaumburg, IL 60173 [web site URL]