



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 13, 2015

James McFadden, PhD
Director, Regulatory Affairs
Wellmark International
1501 E Woodfield Road, Suite 200W
Schaumburg, IL 60173

Subject: PRIA Label Amendment – submission of acute toxicity data to revise signal word from “WARNING” to “CAUTION” (due to primary eye irritation)
Product Name: RF2112 Shampoo
EPA Registration Number: 2724-806
Application Date: 12/29/14
Decision Number: 498674

Dear Dr. McFadden:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

As noted in the Acute Toxicity memo dated 3/20/2015 (DP 425895), the primary eye irritation study submitted did not support any changes to the signal word or precautionary statements.

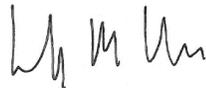
A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 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.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Autumn Metzger at 703-305-5314, or Metzger.autumn@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jennifer Urbanski', with a stylized, cursive script.

Jennifer Urbanski, PhD, Product Manager 4
Invertebrate and Vertebrate Branch 1 (IVB1)
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

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)*1.14%
S-Methoprene (CAS #65733-16-6).....0.10%

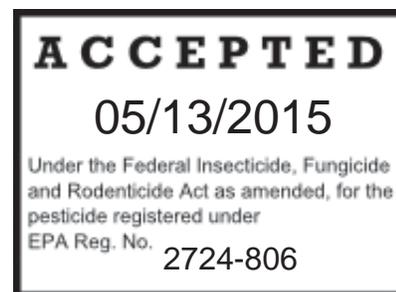
OTHER INGREDIENTS:98.66%
TOTAL 100.00%

* (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)

[] indicates optional text

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 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 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 the first 5 minutes, then continue rinsing eye.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-[phone number] for emergency medical 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
<ul style="list-style-type: none">○ 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 disposal instructions. Never place unused product down any indoor or outdoor drain.

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]