UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001

08 25 2011



2724-797

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Jim McFadden Sr. Regulatory Project Manager Wellmark International 1501 E. Woodfield Rd, Ste 200W Shaumburg, IL 60173 AUG 2 5 2011

Subject: Amended Reregistration Label Product Name: RF 2063 Pet Spray EPA Registration Number: 2724-797 EPA Decision Numbers: 417760

Dear Mr McFadden:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the above referenced product in connection with the Piperonyl Butoxide RED, and has concluded that your submission is acceptable.

NOTE: This product is **not** being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on <u>non-refillable</u> containers. The code may appear either on the label or durably marked on the container itself, and can be added by non-notification per PRN 98-10.

Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated November 14, 2008

A copy of your label stamped "Accepted" is enclosed along with copies of the acute toxicity and product chemistry reviews completed for the subject product. Products shipped after 12 months from the date of this amendment or the next printing of the label whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

If you have any questions about this letter, please contact Samantha Hulkower at 703-603-0683 or hulkower.samantha@epa.gov.

Sincerely,

Richard J. Gebken Product Manager (10) Insecticide Branch Registration Division (7504P)

Enclosures: Label stamped "Accepted," dated Acute Toxicity Review, dated May 7, 2010 Product Chemistry Review, dated September 29, 2010

SUBLABEL FOR DOGS

RF2063 PET SPRAY

Alternate brand name: Vet Kem® Ovitrol® X-Tend[™] Flea & Tick Spray for Dogs For Dogs and Puppies 10 weeks of age and older Contains Etofenprox, [to kill adult insects] *Plus* PRECOR® Insect Growth Regulator Kills [adult] fleas and ticks, repels [adults] mosquitoes Kills flea and ticks on contact [Kills flea eggs and larvae][Kills more than 90% of fleas in 1 day][Kills 80% of ticks in 1 day] [Flea & Tick [Treatment][and][Control] for Dogs and Puppies 10 weeksof age and older]

[Protects [Dogs] [Puppies] for up to [2] [Two] Weeks] [[2] Two Week Flea and Tick Treatment]

[Dual Action kills adult fleas and prevents flea development][Dual protection (against fleas and ticks)]

[Protects against blood feeding by mosquitoes] [Repels mosquitoes][for 2 weeks] Contains an Insect Growth Regulator (IGR) to [kill flea eggs] and prevent [reinfestation] flea development for [up to 10 weeks] up to [69 days] [2 months] [in Dogs] [In Puppies] [Breaks Flea Life Cycle for [up to 10 weeks] up to [69 days] [2 months]

[Controls flea reinfestation for Jup to 10 weeks] up to [69 days] [2 months]

[One][1] Month Protection with 2 applications [Reapply every two weeks][Suitable for yearround use]

Protects against fleas, ticks & mosquitoes for up to 2 weeks

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent reinfestation

Pets may be treatead indoors or outdoors

Effective in multi-pet households

Kills the Deer Tick, [Ixodes scapularis] which may transmit Lyme Disease

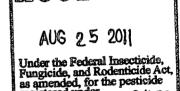
[With [S-Methoprene] [Precor®] Insect Growth Regulator to Break Flea Life

[Ready – To – Use [RTU] Spray] [Non-Aerosol]

[Satisfaction guaranteed or your money back]

ACTIVE INGREDIENTS:

Etofenprox (CAS #80844-07-1)	0.50%
(S)-Methoprene (CAS #65733-16-6)	
Piperonyl Butoxide (CAS #51-03-6)*	1.75%
OTHER INGREDIENTS.	<u>97.48%</u>
TOTAL	100.00%



registered under EPA Reg. No.

RPT

* (butylcarbityl) (6-propylpiperonyl) ether and related compounds

KEEP OUT OF REACH OF CHILDREN CAUTION

See Back Panel For Additional Precautionary Statements

NET CONTENTS:

EPA Reg. No. 2724-797 EPA Est. No.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS -CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Repeated exposure to etofenprox can cause skin irritation.

HAZARDS TO DOMESTIC ANIMALS - CAUTION: Do not use on puppies less than 10 weeks of age. For external use only. Drooling may be observed for a short period of time immediately following product application. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product 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.

FIRST AID		
If in eyes	 Call a poison control center or doctor for treatment advice. 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. 	
•	ntainer or label with you when calling a poison control center, doctor, or for treatment. You may also contact 1-800-XXX-XXXX for emergency	

medical treatment information.

PHYSICAL HAZARDS: Combustible. Do not use or store near heat or open flame.

[Brand Name] [Product Name] RF2063 PET SPRAY

With Etofenprox, [to kill adult insects] Plus [S-Methoprene] Precor® Insect Growth Regulator [to kill flea eggs and larvae]

IMPORTANT! READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS AND PUPPIES MORE THAN 10 WEEKS OLD

HOW RF2063 PET SPRAY WORKS:

RF2063 Pet Spray kills adult fleas, flea eggs, flea larvae, ticks, and repels mosquitoes. Flea eggs and larvae sprayed with **RF2063 Pet Spray** will not grow into adults.

[Product Name] combines the adult flea killing power of etofenprox with the long-lasting flea egg-killing power of [S-Methoprene] PRECOR® Insect Growth Regulator. This highly effective combination of ingredients provides quick relief from biting fleas and continuous killing of flea eggs laid on the animal, breaking the flea life cycle. The elimination of both adult fleas and flea eggs is important because adult fleas live on your pet, causing discomfort and skin irritation, while the vast number of eggs that they lay fall off and develop in your house. If fleas are already developing in your house, then use a [Brand Name] premise product. Effective flea control requires treatment of your pets, house, and yard.

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

USE RESTRICTIONS

The maximum application rate for this product is twice per month, and the second application must be made more than 8 days after the initial application.

SHAKE WELL BEFORE USING.

For Fleas and Ticks: A light, even coverage of the hair coat will provide effective flea control. Do not allow spray from application or damp dog/puppy to come into contact with painted or finished surfaces, including wood floors/furniture, leather/vinyl materials, or other surfaces of concern.

- 1. For best results, ruffle the coat while spraying against the natural lay of the hair. Cover dog's/puppy's eyes with hand. With a firm, fast stroke, spray head, ears, and chest. If you see a tick, spray it directly.
- 2. With cloth, rub on face around mouth, nose, and eyes. Then spray the neck, middle and hind quarters, finishing with legs and tail last. Avoid spraying rectum and genitals.
- 3. For all dogs, spray until damp, not saturated. Do not allow dogs/puppies to become chilled.
- 4. If your dog/puppy becomes reinfested with adult fleas or ticks from outside sources, [RF2063 Pet Spray] may be reapplied every two weeks after the initial application. Repeat every month for continuous home flea infestation prevention.

Recommended dosage: Note that the recommended dose is about 4 squeezes of the trigger sprayer [0.13 fluid ounce] per pound of body weight. Short-haired dogs/puppies will need less; more spray may be needed for long-haired dogs/puppies. In all cases, apply spray until the coat is damp, not saturated.

For Mosquitoes: A light, even coverage of the hair coat (as applied for flea control), will also provide effective repellency of mosquitoes.

RF2063 PET SPRAY is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential [area] [premise] control [(carpets, upholstery and pet bedding)] of these pests in conjunction with this treatment. Monthly premise treatments are required for optimal control and prevention of fleas.

The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies with RF2063 Pet Spray kills fleas and may reduce the incidence of this condition.

STORAGE and DISPOSAL: Pesticide Storage: Do not store near heat or open flame. Store away from children and animals. **Disposal: Nonrefillable container.** Do not reuse or refill this container. **If empty**: Place in trash or offer for recycling if available. **If partly filled**: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

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 use informnation, call 1-800-xxx-xxxx

Wellmark International 1501 E. Woodfield Rd., 200W Schaumburg, IL 60173 [URL]

PRECOR® Insect Growth Regulator is a registered trademark of Wellmark International. Made in USA

SUBLABEL FOR CATS

RF2063 PET SPRAY

Alternate brand name: Vet Kem® Ovitrol® X-Tend™ Flea & Tick Spray for Cats For Cats and Kittens 12 weeks of age and older]

Contains Etofenprox, [to kill adult insects] Plus PRECOR® Insect Growth Regulator Kills [adult] fleas and ticks, repels [adult] mosquitoes

Kills fleas and ticks on contact

[Kills flea eggs and larvae] [Kills more than 90% of fleas in 1 day] [Kills 80% of ticks in 1 day] [Flea & Tick [Treatment][and][Control] for Cats and Kittens 12 weeks of age and older] [Protects [Cats] [Kittens] for up to [3] [Three] Weeks] [Three (3) Week Flea and Tick Treatment1

[Dual Action kills adult fleas and prevents flea development] [Dual protection (against fleas and ticks)]

[Protects against blood feeding by mosquitoes] [Repels mosquitoes] [for 3 weeks] Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for [up to 11 weeks] up to [80 days] [2.5 months] [in Cats] [in Kittens]

[Breaks Flea Life Cycle for [up to 11 weeks] up to [80 days] [2.5 months]

[Controls flea reinfestation for [up to 11 weeks] up to [80 days] [2.5 months] [[Reapply monthly] [Suitable for year-round use]

Protects against fleas, ticks and mosquitoes for up to 3 weeks

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent reinfestation Kills the Deer Tick, [Ixodes scapularis] which may transmit Lyme Disease

[With [S-Methoprene] [Precor®] Insect Growth Regulator to Break Flea Life Cycle] [Ready - To - Use [RTU] Spray] [Non-Aerosol]

[Satisfaction guaranteed or your money back]

ACTIVE INGREDIENTS:

Etofenprox (CAS #80844-07-1)	0.50%
(S)-Methoprene (CAS #65733-16-6)	
Piperonyl Butoxide (CAS #51-03-6)*	1.75%
OTHER INGREDIENTS.	<u>97.48%</u>
TOTAL	100.00%

* (butylcarbityl) (6-propylpiperonyl) ether and related compounds

KEEP OUT OF REACH OF CHILDREN CAUTION

See Back Panel For Additional Precautionary Statements

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HAZARDS TO ANIMALS - CAUTION: Do not use on kittens less than 12 weeks of age. For external use only. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product 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. In some cases, excessive salivation and ear and paw flicking may occur; however, these effects are temporary and not harmful.

FIRST AID	
If in eyes	 Call a poison control center or doctor for treatment advice. 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.
	ntainer or label with you when calling a poison control center, doctor, or g for treatment. You may also contact 1-800-XXX-XXXX for emergency of formation.

PHYSICAL HAZARDS: Combustible. Do not use or store near heat or open flame.

[Brand Name] [Product Name] RF2063 PET SPRAY

With Etofenprox, [to kill adult insects] Plus Precor® [S-Methoprene] Insect Growth Regulator [to kill flea eggs and larvae]

IMPORTANT! READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON CATS AND KITTENS MORE THAN 12 WEEKS OLD

HOW RF2063 PET SPRAY WORKS:

RF2063 Pet Spray kills adult fleas, flea eggs, flea larvae, ticks, and repels mosquitoes. Flea eggs and larvae sprayed with **RF2063 Pet Spray** will not grow into adults.

[Product Name] combines the adult flea killing power of etofenprox with the long-lasting flea egg-killing power of [S-Methoprene] PRECOR® Insect Growth Regulator. This highly effective combination of ingredients provides quick relief from biting fleas and continuous killing of flea eggs laid on the animal, breaking the flea life cycle. The elimination of both adult fleas and flea eggs is important because adult fleas live on your pet, causing discomfort and skin irritation, while the vast number of eggs that they lay fall off and develop in your house. If fleas are already developing in your house, then use a [Brand Name] premise product. Effective flea control requires treatment of your pets, house, and yard.

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

USE RESTRICTIONS

The maximum application rate for this product is once per month

SHAKE WELL BEFORE USING.

For Fleas and Ticks: A light, even coverage of the hair coat will provide effective flea control. Do not allow spray from application or damp cat/kitten to come into contact with painted or finished surfaces, including wood floors/furniture, leather/vinyl materials, or other surfaces of concern.

- 1. For best results, ruffle the coat while spraying against the natural lay of the hair. Cover cat's/kitten's eyes with hand. With a firm, fast stroke, spray head, ears, and chest. If you see a tick, spray it directly.
- 2. With cloth, rub on face around mouth, nose, and eyes. Then spray the neck, middle and hind quarters, finishing with legs and tail last. Avoid spraying rectum and genitals.
- 3. For all cats, spray until damp, not saturated. Do not allow cats/kittens to become chilled.
- 4. If your cat/kitten becomes reinfested with adult fleas or ticks from outside sources, [RF2063 Pet Spray] may be reapplied every two weeks after the initial application. Repeat every month for continuous home flea infestation prevention.

Recommended dosage: Note that the recommended dose is about 4 squeezes of the trigger sprayer [0.13 fluid ounce] per pound of body weight. Short-haired cats/kittens will need less; more spray may be needed for long-haired cats/kittens. In all cases, apply spray until the coat is damp, not saturated.

For Mosquitoes: A light, even coverage of the hair coat (as applied for flea control), will also provide effective repellency of mosquitoes.

RF2063 PET SPRAY is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential [area] [premise] control [(carpets, upholstery and pet bedding)] of these pests in conjunction with this treatment. Monthly premise treatments are required for optimal control and prevention of fleas.

The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of cats/kittens with RF2063. Pet Spray kills fleas and may reduce the incidence of this condition.

STORAGE and DISPOSAL: Pesticide Storage: Do not store near heat or open flame. Store away from children and animals. **Disposal**: **Nonrefillable container.** Do not reuse or refill this container. **If empty**: Place in trash or offer for recycling if available. **If partly filled**: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

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In case of emergency or for product use information, call 1-800-xxx-xxxx

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