



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Ms. Nancy Huebl Wellmark International 1501 East Woodfield Road, Suite 200 West Schaumburg, IL 60173

MAY 1 9 2011

Dear Ms. Huebl:

Subject: Application for Pesticide Notification (PRN 98-10)

Add Alternate Brand Names: Vet Kem Ovitrol X-Tend Flea & Tick Spray for Dogs

and Vet Kem Ovitrol X-Tend Flea & Tick Spray for Cats

RF2063 Pet Spray

EPA Reg. No. 2724-797

Your submission dated May 3, 2011

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated May 3, 2011 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds the action requested falls within the scope of PRN 98-10. The labels submitted with the application have been stamped "Notification" and will be placed in our records.

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 nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions regarding this letter, please contact Dana Pilitt, PhD of my staff at (703) 305-7071 or via e-mail at pilitt.dana@epa.gov.

Sincerely,

Richard Gebken Product Manager 10 Insecticide Branch

Registration Division (7505P)

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Please read instructions on re	everse before completing f	رسم <u>.</u>		Form /	Approved. OMB No. 2	2070-0060. Approval expires 2-28-95	
<b>⇔</b> EPA	Environmenta Washi	hington, DC 2046	60	X	jistration Amendment Other	OPP Identifier Number	
		Applicat	tion for Pesticide - Secti	بمستواط والمستان المتعادل أنشاب			
Company/Product Number     Wellmark International/272	24-797		2. EPA Product Manager R. Gebken	)T		3. Proposed Classification	
4. Company/Product (Name) Wellmark International/R	RF2063 Pet Spray		PM# 13			X None Restricted	
5. Name and Address of Applic Wellmark International 1501 East Woodfield Roa Schaumburg, Illinois 601	ad, Suite 200 West 73	Code)	6. Expedited Review (b)(i), my product is s EPA Reg. No. Product Name		ccordance with FIFRA iMOTIFIOATIO	Md labeling to:	
			Section - II				
Amendment - Explain below Resubmission in response X Notification - Explain below	se to Agency letter dated		Final p	l printed labe ncy letter dat Too" Applica er - Explain b	cation		
Explanation: Use additional page(s) if necessary. (For section I and section II.)  Notification of alternate brand names: Vet Kem Ovitrol X-Tend Flea & Tick Spray for Dogs, Vet Kem Ovitrol X-Tend Flea & Tick Spray for Cats  This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.							
			Section - III				
1. Material This Product Will	be Packaged In:			<del></del>			
Child-Resistant Packaging  Yes  No	Unit Packaging Yes X		Water Soluble Packagin Yes X No		2. Type of Container  Metal Plastic Glass		
* Certification must be submitted	If "Yes Unit Packaging wgt.			o. per ntainer	Paper Other (Speci	cify)	
3. Location of Net Contents Info	formation 4 ontainer	4. Size(s) Retail C 8, 16, 32 oz.	container	iner  5. Location of Label Directions  X On Label On Label Accompanying Product		•	
6. Manner in Which Label is Af	ffixed to Product	X Paper gl	plued ed	Other			
			Section - IV				
1. Contact Point (Complete	items directly below for ide	entification of in	dividual to be contacted, if nec	cessary, to	process this applicat	ion.)	
Name Nancy Huebl		Tit Sr	itle r. Registration Specialist		'	one No. (Include Area Code) 30-5376	
Certificati I certify that the statements I have made on this form and all atta acknowledge that any knowingly false or misleading statements under applicable law.			chments thereto are true, accurate			6. Date Application Received (Stamped)	
2. Signature  Maney Huebl		Sr	Title r. Registration Specialist	Registration Specialist			
4. Typed Name Nancy Huebl		1	5. Date 02-May-11				

ıational 1501 East Woodfield Road, Suite 200 West Schaumburg, Illinois 60173

847 330 5300 www.wellmarkinternational.com

# Wellmark

May 3, 2011

Document Processing Desk (NOTIF) Office of Pesticide Programs 7504P U.S. Environmental Protection Agency Room S-4900 One Potomac Yard 2777 South Crystal Drive Arlington, Virginia 22202-4501

ATTENTION: R. Gebken, PM10

SUBJECT:

PER PRN 98-10 NOTIFICATION OF ALTERNATE BRAND NAMES

FOR RF2063 PET SPRAY/EPA REG. NO. 2724-797

Dear Mr. Gebken:

Enclosed is a completed EPA Form 8570-1 and 1 copy of revised labeling for the above product. The label cover sheet details the change. The alternate brand names are: Vet Kem® Ovitrol® X-Tend™ Flea & Tick Spray for Dogs and Vet Kem® Ovitrol® X-Tend™ Flea & Tick Spray for Cats.

If you have any questions or if I can provide any further assistance, please, call me directly at 847/330-5376. Thank you for your assistance in this matter.

Yours sincerely,

WELLMARK INTERNATIONAL

Sr. Registration Specialist nhuebl@central.com

enclosure

CC:

C. Elmi/H. Friedli

# 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 [up to 10 weeks] up to [69 days] [2 months]

[One][1] Month Protection with 2 applications [Reapply every two weeks][Suitable for year-round 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 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)*	
OTHER INGREDIENTS.	
TOTAL	100.00%

<sup>\* (</sup>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.

# [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.

### 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.

2

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.

### 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. 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	<ul> <li>Call a poison control center or doctor for treatment advice.</li> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
Have the product of	container or label with you when calling a poison control center, doctor, or
veterinarian or goir	ng 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.

# 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

# **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

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 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.	97.48%
TOTAL	100.00%

<sup>\* (</sup>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.

. . . . . . . . .

# [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.

### 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.

6

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.

### 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. Repeated exposure to etofenprox can cause skin irritation.

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	<ul> <li>Call a poison control center or doctor for treatment advice.</li> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
Have the product c	ontainer or label with you when calling a poison control center, doctor, or

Have the product container or label with you when calling a poison control center, doctor, or veterinarian or going 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.

# **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 information, call 1-800-xxx-xxxx

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

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