

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505P)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

EPA Reg. Number: 2724-797

Term of Issuance:

Date of Issuance:

JUN 0 4 2009

NOTICE OF PESTICIDE:

X Registration

Reregistration

Conditional

Name of Pesticide Product:

RF2063 Pet Spray

(Under FIFRA as amended)

Name and Address of Registrant (include ZIP Code):

Wellmark International

1501 E. Woodfield Road

Suite 200W

Schaumburg, IL 60173

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to ' and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7) (A) provided you:

- 1. You will submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
- 2. Submit the listed data below, conducted in accordance with the 40 CFR Part 158 test guidelines referred to below:

Title of Study	OPPTS Guideline	Due Date
One-year Storage Stability Study	830.6317	August 1, 2010
Corrosion Characteristics Study	830.6320	August 1, 2010

You are required to generate a one year storage stability study for the subject product under warehouse conditions. It is recommended that observations be made at 0, 3, 6, 9, and 12 months. The corrosion characteristics study may be conducted concurrently. An accelerated study will not substitute for a one year study under warehouse conditions.

Richard Gebken, Product Manager (13), RD/IB (7505P)

Date:

Date:

JUN 0 4 2009

- 3. You will make the following label changes before you release the product for shipment:
  - a) Add the phrase "EPA Registration No. 2724-797"
  - b) Remove all references to puppies and kittens.
  - c) Remove: Kills fleas that may transmit Tapeworm (*Dipylidium caninum*)
  - d) Remove: "For ticks: Make sure spray thoroughly wets individual ticks." This directive may lead to overapplication of the product. Combine the directions for ticks with the directions for mosquitoes or fleas.

#### Dog sub-label:

Change the "Hazards to Animals" age restriction to read: "Do not use on dogs less than 6 months of age."

Changes to claims:

<u>Kills [adult] fleas and ticks, kills and repels [adults] mosquitoes</u>: The kills fleas and ticks claims are acceptable. The kills mosquitoes claim is unacceptable. The repels mosquitoes claim is acceptable.

Kills and repels the Deer Tick, [Ixodes scapularis] which may transmit Lyme Disease: The kills claim is acceptable, but the repels claim is unacceptable as repellence data were not presented.

#### Cat sub-label:

Change the "Hazards to Animals" age restriction to read: "Do not use on cats less than 6 months of age."

Changes to claims:

<u>Kills [adult] fleas and ticks, kills and repels [adults] mosquitoes</u>: The tick claim is acceptable. The kills mosquitoes claim is unacceptable. The repels mosquitoes claim is acceptable.

[Protects [Cats and Kittens] for up to [4][Four] weeks][One month] [Four (4) week flea and tick treatment]: Unacceptable. Longest tick efficacy demonstrated was 25 days in vitro, and flea efficacy was 23 days—both of which are less than 4 weeks. Therefore maximum claim for flea and tick protection should be 3 weeks.

[Protects against blood feeding by mosquitoes] [Repels mosquitoes] [for 1 month] Unacceptable. 95% repellence is only demonstrated through day 21, so the maximum claim for repellence should be 3 weeks.

Contains an insect growth regulator (IGR) to kill flea eggs and prevent flea development for [more than 12 weeks] up to [85 days] [3 months] [in cats and kittens]: Unacceptable. The maximum efficacy for preventing flea development was day 80. Thus, the maximum claim is [up to 11 weeks] [up to 80 days] [2.5 months].

[Breaks flea life cycle for [more than 12 weeks] up to [85 days] [3 months]: Unacceptable. The maximum efficacy for preventing flea development was day 80. Thus, the maximum claim is [up to 11 weeks] [up to 80 days] [2.5 months].

[Controls flea reinfestation for [more than 12 weeks] up to [85 days] [3 months]: Unacceptable. The maximum efficacy for preventing flea development was day 80. Thus, the maximum claim is [up to 11 weeks] [up to 80 days] [2.5 months].

[One][1] Month protection, [reapply monthly] [suitable for year-round use]: Claim of 1 month protection is not acceptable since efficacy for ticks and mosquito repellence is only 3 weeks.

<u>Protects against fleas, ticks and mosquitoes for up to 4 weeks</u>: Unacceptable. The maximum claim for ticks and mosquitoes would be 3 weeks.

<u>Kills and repels the Deer Tick, [Ixodes scapularis]</u> which may transmit Lyme <u>Disease</u>: The kills claim is acceptable, but the repels claim is unacceptable as repellence data were not presented.

- c.) Change "Storage" to read "Pesticide Storage" in the "Storage and Disposal Statement".
- 4. The basic Confidential Statement of Formula (CSF) dated November 14, 2008 is acceptable and is the CSF of record.
- 5. Submit three (3) copies of your final printed labeling.

A stamped copy of the label and the data evaluation reviews are enclosed for your records. If you have any questions, please contact Kevin Sweeney at (703)-305-5063 or by email sweeney.kevin@epa.gov

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Product Manager 13

Registration Division (7505P)

Insecticide Branch

Enclosure

#### SUBLABEL FOR DOGS

# **RF2063 PET SPRAY**

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, kills and 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 weeks old and older] [Protects [Dogs and 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 and 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 and repels the Deer Tick, [Ixodes scapularis] which may transmit Lyme Disease [Kills fleas that may transmit tapeworm (Dipylidium caninum)]

[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	True to the second seco

<sup>\*</sup> Equivalent to 1.40% (butylcarbityl) (6-propylpiperonyl) ether and 0.35% related compounds

# KEEP OUT OF REACH OF CHILDREN CAUTION

See Back Panel For Additional Precautionary Statements

NET CONTENTS:

EPA Reg. No. 2724-XXX EPA Est. No.

ACCEPTED
with COMMENTS
In EPA Letter Dated
JUN 0 4 2009
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No.

## [Brand Name] [Product Name] RF2063 PET SPRAY

With Etofenprox, [to kill adult insects] Plus 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 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: A light, even coverage of the hair coat will provide effective flea control. Do not allow spray from application or damp dog to come into contact with painted or finished surfaces, including wood floors/furniture, leather/vinyl materials, or other surfaces of concern. For best results, ruffle the coat while spraying against the natural lay of the hair. Cover dog's eyes with hand. With a firm, fast stroke, spray head, ears, and chest. With cloth, rub into 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. Apply at the rate of 1 or 2 squeezes of the trigger sprayer [0.10 fluid ounce] per pound of body weight. For larger dogs, spray until damp, not saturated. Do not allow dogs to become chilled. Repeat every month for continuous home flea infestation prevention. If your dog becomes reinfested with adult fleas from outside sources, [RF2063 Pet Spray] may be reapplied every two weeks. Continue applications (once every two weeks) for continuous home flea infestation prevention.

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

For Ticks: Make sure spray thoroughly wets individual ticks.

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 with RF2063 Pet Spray kills fleas and may reduce the incidence of this condition.

**STORAGE and DISPOSAL:** 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 puppies less than 10 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.

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> </ul>
	<ul> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
	container or label with you when calling a poison control center, doctor, or ing for treatment. You may also contact <b>1-800-XXX-XXXX</b> for emergency t 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**

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, kills and repels [adults] 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 old and older]

[Protects [Cats and Kittens] for up to [4] [Four] Weeks][One month] [Four (4) 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 1 month]

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

[more than 12 weeks] up to [85 days] [3 months] [in Cats and Kittens]

[Breaks Flea Life Cycle for [more than 12 weeks] up to [85 days] [3 months]

[Controls flea reinfestation for [more than 12 weeks] up to [85 days] [3 months]

[One][1] Month Protection, [Reapply monthly] [Suitable for year-round use]

Protects against fleas, ticks and mosquitoes for up to 4 weeks

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

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

[Kills fleas that may transmit Tapeworm (Diplylidium caninum)]

[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)	0.27%
Piperonyl Butoxide (CAS #51-03-6)*	1.75%
OTHER INGREDIENTS	97,48%
TOTAL	100.00%

<sup>\*</sup> Equivalent to 1.40% (butylcarbityl) (6-propylpiperonyl) ether and 0.35% related compounds

# KEEP OUT OF REACH OF CHILDREN CAUTION

See Back Panel For Additional Precautionary Statements

**NET CONTENTS:** 

EPA Reg. No. 2724-XXX EPA Est. No.

## [Brand Name] [Product Name] RF2063 PET SPRAY

With Etofenprox, [to kill adult insects] Plus Precor® 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 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: A light, even coverage of the hair coat will provide effective flea control. Do not allow spray from application or damp cat to come into contact with painted or finished surfaces, including wood floors/furniture, leather/vinyl materials, or other surfaces of concern. For best results, ruffle the coat while spraying against the natural lay of the hair. Cover cat's eyes with hand. With a firm, fast stroke, spray head, ears, and chest. With cloth, rub into 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. Apply at the rate of 1 or 2 squeezes of the trigger sprayer [0.10 fluid ounce] per pound of body weight. For larger cats, spray until damp, not saturated. Do not allow cats to become chilled. Repeat every month for continuous home flea infestation prevention.

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

For Ticks: Make sure spray thoroughly wets individual ticks.

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 with RF2063 Pet Spray kills fleas and may reduce the incidence of this condition.

**STORAGE and DISPOSAL: 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>
•	t container or label with you when calling a poison control center, doctor, or bing for treatment. You may also contact <b>1-800-XXX-XXXX</b> for emergency of 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

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