

2724-797

11/1/2010

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

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

Mr. James McFadden
Regulatory Project Manager
Wellmark International
1501 E. Woodfield Road
Suite 200W
Schaumburg, IL 60173

NOV 1 2010

Dear Mr. McFadden:

Subject: Label Amendment
Product Name: RF2063 Pet Spray
EPA Registration No. 2724-797
Application dated February 24, 2010

The label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, is acceptable provided you:

1. Add the following statement under the "Hazards to Domestic Animals" heading on the dog sub-label: "Drooling may be observed for a short period of time immediately following product application."
2. This registration is now time-limited and expires two years from the date of this letter.
3. Please consider limiting the formulations of this product to one basic confidential statement of formula. The Agency may require this in the future and no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
4. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning January 1, 2011.

Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot #

Where purchased: internet, store, veterinarian
Active Ingredient(s)
Weight range for product

Date on which incident occurred. (mm/dd/yyyy)
State in which the incident occurred. (standard 2 letter abbreviation)
Registrant case #

Species: dog, cat, other (specify)
Breed: (as reported by pet owner)
Age: months or years
Sex: M, F, or neutered
Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other
Body System: neurological, dermatological, GI, respiratory, ocular, other
Major signs noted with separate column for each sign, using standard terminology
Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no
Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
Any known precondition
EPA Severity Code: death, major, moderate, minor
Outcome: died, recovered, still treated, unknown

5. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported including all minor dermal and ocular irritation reports.
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

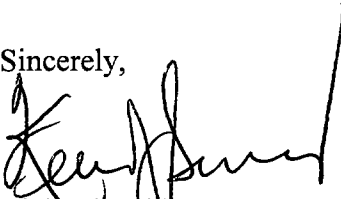
- Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- A summary table for cats showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label (if applicable).
- A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight

range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range (if applicable).

- Table showing number of incidents for each cat breed, where provided.
- Table showing number of incidents in cats for each clinical sign.
- Table showing number of incidents in cats for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

A stamped copy of the label and DERs are enclosed for your records. The confirmatory tick efficacy data are acceptable. Submit two copies of the revised finished labeling within 60 days of the receipt of this letter. If you have any questions, please contact Kevin Sweeney at (703) 305-5063. Thank you for your cooperation in this matter.

Sincerely,


Richard Gebken
Product Manager 10
Registration Division (7505P)
Insecticide Branch

Enclosure

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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, 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 of 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 treated 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).....	0.27%
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

NET CONTENTS:

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

**ACCEPTED
with COMMENTS
In EPA Letter Dated
NOV 1 2010**
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act,
 as amended, for the pesticide
 registered under EPA Reg. No.
2724-797

[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 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.

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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 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.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • 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.
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]

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

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SUBLABEL FOR CATS

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, 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).....	0.27%
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

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® 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 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.

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 style="list-style-type: none"> • 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.
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]

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