

2724-790

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1/7



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 10, 2009

Mr. James J. McFadden, Ph.D.
Regulatory Project Manager
Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, IL 60173-5417

**Subject: Amending Labeling, Addition of Uses on Dogs Cats, Puppies and Kittens
RF2062 MIST, EPA Reg. No. 2724-790
Your Submission Dated November 7, 2008**

Dear Mr. McFadden

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with the following provision(s):

General Statement:

1. Delete all text throughout the label marked with "strikethrough."

Optional Marketing Statements section comment(s):

2. On the 1st, 2nd, 3rd, 4th, 8th and 9th optional marketing statements, delete all text marked with "strikethrough" since RF2062 MIST is **NOT** a repellent product.

Ingredient Statement section comment(s):

3. Revise the line reading "**OTHER INGREDIENTS:**" to read: "**OTHER INGREDIENTS:****"
4. Insert the following text as a 2nd footnote in this section: "**Contains petroleum distillates."
5. In the subsection starting with "**HOW RF2062 WORKS:**," delete the existing 2nd sentence. RF2062 MIST does not "control" fleas.

Directions for Use section comment(s):

6. To facilitate inclusion of language from the REDs for pyrethrins, piperonyl butoxide and MGK® 264, replace the existing "**General Precautions and Use Restrictions**" section with the following:

General Precautions and Use Restrictions

- Apply this product only as specified on this label.
- Do not apply to pets (puppies and kittens) less than 12 weeks old.
- Avoid spraying of genital areas.
- Consult a veterinarian before applying this product on medicated, debilitated, aged, pregnant or nursing animals.
- 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.
- Do not use this product on horses destined for slaughter.
- Do not apply more than 1 time per day.
- Except when applying to pets, do not apply this product in a way that will contact adults or children, either directly or through drift.
- Remove birds and cover fish aquariums before spraying application.

Directions for Use, "FOR PUPPIES AND KITTENS" subsection comment(s):

- 7. Insert the following statement as a new 1st sentence in this subsection: "Do not apply to pets (puppies and kittens) less than 12 weeks old."
- 8. Delete the existing last sentence in this subsection.

Directions for Use, "FOR PET'S SLEEPING QUARTERS" subsection comment(s):

- 9. Insert the following statement immediately preceding the existing 4th sentence in this subsection: "Do not allow pets to reoccupy sleeping quarters until treated surfaces have thoroughly dried."

Directions for Use, "FOR HORSES AND PONIES" subsection comment(s):

- 10. In the 1st sentence of this subsection, replace the word "control" with the word "kill."

Storage and Disposal Statement section comment(s):

- 11. To facilitate inclusion of language from PR Notice 2007-4, replace the 1st part of the "Pesticide/Container Disposal:" subsection with: "Pesticide/Container Disposal: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available." In the "If partly filled:" portion of this subsection, replace the word "partly" with the word "partially."

Precautionary Statements, Hazards to Humans and Domestic Animals section comment(s):

- 12. Revise the subsection header to read: "HAZARDS TO DOMESTIC ANIMALS – CAUTION:"
- 13. Replace the existing 1st sentence in this subsection with: "Do not apply to pets (puppies and kittens) less than 12 weeks old."

First Aid section comment(s):

- 14. Delete the existing 1st row under the "FIRST AID" section title starting with "Call a poison control..."
- 15. To facilitate inclusion of language from the acute toxicity review completed for this product, insert the statement "Call a poison control center or doctor for further treatment advice." as a 3rd bullet in the rows starting with "If in Eyes:" and "If on Skin or Clothing:"
- 16. Revise the 2nd sentence on the existing 4th row to read: "For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-xxx-xxxx." It is important to note that the "1-800-xxx-xxxx" phone number listed in this revised 2nd sentence should be available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.
- 17. To facilitate inclusion of language from the acute toxicity review completed for this product, insert the following "Note to Physician" as a new 4th row into this section as follows: "Note to Physician: Contains petroleum distillates. Vomiting may cause aspiration pneumonia."

Wellmark International should note that a notice of availability of EPA's RED for products containing pyrethrins was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42387-42389). In addition, EPA's RED for products containing piperonyl butoxide was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42385-42386). Further, EPA's RED for products containing MGK® 264 was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42381-42383). As a result, additional data and/or labeling changes may be required for products containing pyrethrins, piperonyl butoxide and/or MGK® 264.

Should you wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under FIFRA 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) lists 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 be substantially differ from those claims approved through the registration process. Therefore, should the Agency find, or if it is

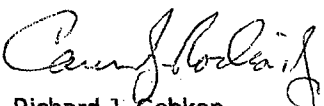
3/7

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 EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

A copy of your label stamped "Accepted with Comments" is enclosed for your records along with a hard copy of the acute toxicology data evaluation record (DER) pertaining to Wellmark International's rebuttal to the companion animal safety data requirement as well as a revised data waiver request for acute inhalation toxicity data for this product. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

If you have any questions about this label review, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely Yours,


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

*Enclosures: Label stamped "Accepted with Comments"
Copy of acute toxicology DER, dated February 23, 2009*

002724-00790 D402652

4/7

[] Indicate optional statements

RF2062 MIST

EFFECTIVE

[Insecticide, ~~Repellent~~ & Deodorant] for dogs, puppies, cats, kittens, horses, ponies

~~Kills and Repels:~~ Ticks, fleas, lice, flies, mosquitoes and gnats

~~Temporarily repels gnats, flies, mosquitoes~~

~~[Kills][and repels] Lyme disease-carrying ticks [including Ixodes scapularis][including those that may carry [transmit]-Lyme disease]~~

An effective spray mist that kills adult fleas

Contains pyrethrins, an adulticide

[Rapid action][quick acting][fast acting] formula

Quickly kills ~~[repels][expels]~~ adult fleas on your dog [puppy, cat, kitten]

~~Strong flea repellent action that you can see~~

Rapidly rids your animal of pesky biting fleas and ticks

Kills fleas and ticks reducing itching and scratching

Pleasant [floral] scent

ACTIVE INGREDIENTS:

Pyrethrins (CAS #8003-34-7) 0.20%

Piperonyl butoxide, Technical (CAS #51-03-6)* 0.46%

N-octyl bicycloheptene dicarboximide (CAS #113-48-4) 0.62%

OTHER INGREDIENTS: 98.72%

TOTAL 100.00%

*Equivalent to 0.37% Butylcarbityl (6-propylpiperonyl) ether and 0.09% related compounds

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See Back Panel For Additional Precautionary Statements

EPA Reg. No. 2724-790

EPA Est No.

Net Contents:

ACCEPTED
With COMMENTS
In EPA Letter Dated:

March 10, 2009

Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:

2724-790

5/7

HOW RF2062 WORKS:

RF2062 kills ticks, lice, mosquitoes, gnats, fleas, house flies, stable flies, horn flies, and face flies. ~~Effective flea control requires treatment of your pets, house, and yard with appropriate EPA-registered products for these applications.~~

DIRECTIONS FOR USE

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

General Precautions and Use Restrictions
<ul style="list-style-type: none">• Apply this product only as specified on this label.• Do not apply more than one time per day.• Avoid spraying of genital areas.• Do not apply this product in a way that will contact adults, <u>or</u> children, or pets either directly or through drift.• Remove pets, birds, and cover fish aquariums before spraying application.• Do not apply directly to or near water, storm drains or drainage ditches. Do not apply when windy.

Read and follow all directions and precautions on this product label.

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON [DOGS, CATS, PUPPIES, KITTENS][HORSES, PONIES]
SHAKE WELL BEFORE USING. Use only in a well ventilated area.

FOR DOGS AND CATS

For Fleas: A light, even coverage of the hair coat will provide effective flea control. Do not allow spray from application or damp animal to come into contact with painted or finished surfaces, including wood floors/furniture, leather/vinyl materials, or other surfaces of concern. For best penetration [results] ruffle the coat while spraying against the natural lay of the hair. Cover animal's eyes with hand. With a firm fast stroke, to get a proper spray mist, spray head, ears, and chest until damp. Then spray neck, middle and hind quarters, finishing with legs last. With cloth, rub into face around mouth, nose, and eyes. For best penetration of spray to the skin, direct spray against the natural lay of the hair. On long haired dogs, rub your hand against the lay of the hair, spraying the ruffled hair directly behind the hand. 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 animals, cats in particular, to become chilled. [Brand Name] may be reapplied weekly, if necessary.

For Ticks: Make sure spray thoroughly wets individual ticks.

6/7

FOR PUPPIES AND KITTENS

For Fleas: Leaving the eyes, nose, and mouth exposed, treat puppies and kittens weighing less than 3 pounds by wrapping the animal in a towel that has been lightly sprayed with [Brand Name], for 5 to 10 minutes . Or lightly spray a brush or cotton ball and work thoroughly into the hair coat. Fleas may then be removed from the coat by picking or combing. Puppies and kittens over 3 pounds may be treated the same as dogs and cats as described above. [Brand Name] may be reapplied weekly, if necessary. Do not allow animal to become chilled. ~~Do Not Use On Puppies and Kittens Under 12 Weeks of Age.~~

FOR PET'S SLEEPING QUARTERS

The pet's bedding should be sprayed, making sure the area beneath the bedding is also sprayed. Do not allow spray from application to come into contact with painted or finished surfaces, including wood floors/furniture, leather/vinyl materials, or other surfaces of concern. After spray has dried, remove old pet bedding and replace with fresh bedding. Treat pets with [Brand Name] flea and tick control products before allowing pets to enter treated areas. Repeat weekly, if necessary.

[FOR HORSES AND PONIES

For Flies: To control stable flies, horse flies, deer flies, and face flies, first remove excess dirt and dust by brushing coat. Apply spray to legs, shoulders, flanks, neck, top line and other body areas commonly attacked by these flies. To treat face, dampen a cloth with spray and rub on face and head, being careful to avoid eyes. [Brand Name] may be reapplied weekly, if necessary. This product is not to be used on horses destined for slaughter.]

STORAGE and DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Do not transfer contents to other containers. **Pesticide Storage:** Store in a cool, dry area away from heat or open flame. Store away from children and animals. **Pesticide/Container Disposal: If empty:** Do not reuse this container. 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 AND DOMESTIC ANIMALS - CAUTION:~~ Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash hands 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. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

HAZARDS TO ANIMALS - CAUTION: ~~Do not treat animals under 12 weeks of age.~~ Do not over saturate, especially on cats. Avoid spraying of genital areas. 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. Some cats may be sensitive to products containing pyrethrins. Excessive salivation and ear and paw flicking may occur; however, these effects are temporary and not harmful.

7/7

FIRST AID	
Call a poison control center or doctor immediately 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, doctor, or veterinarian 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.]

ENVIRONMENTAL HAZARDS: This product is toxic to aquatic organisms, including fish and invertebrates. Do not contaminate water when disposing of rinsate. See Directions for Use for additional precautions and requirements. Do not apply directly to or near water. Drift and run-off may be hazardous to fish in water adjacent to treated areas.

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

WARRANTY AND CONDITIONS OF SALE: To the extent consistent with applicable law, Seller makes no warranty, expressed or implied, concerning the use and handling of this product other than indicated on the label. To the extent consistent with applicable law, Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

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Schaumburg, IL 60173

Made in USA

For more information, [or in case of emergency (24 hrs)] call [phone number]
In case of emergency or for product use information, call [phone number]
Web site: [URL]