



### U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505C) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460

2724-790

EPA Reg. Number:

Date of Issuance:

OCT 0 3 2007

NOTICE OF PESTICIDE:

X Registration
Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

RF2062 MIST

Name and Address of Registrant (include ZIP Code):

Wellmark International 1501 E. Woodfield Road, Suite 200W Schaumburg, IL 60173-5417

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/reregistered 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 section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration 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.

(continued on page 2)

Signature of Approving Official:

Date:

See page #5.

OCT 03 2007

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

EPA Form 8570-6

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- 2. Make the following change to the label:
  - a. Change the product registration number to "EPA Reg. No. 2724-790"
  - b. Make the following label revisions:
    - 1. After an examination of the two (2) cited companion animal safety studies, EPA has concluded that these studies cannot be used as supporting safety data for dogs and cats. Delete all sections from this label pertaining to application of this product to dogs and cats. If Wellmark International wishes to register this product for use on dogs, puppies, cats and kittens at a later date, companion animal safety studies must be submitted as detailed in the companion animal safety review for this product. <sup>1</sup>
    - 2. Delete all text on the label that has been marked up with "strikethrough."
    - 3. On the 5<sup>th</sup> line of the optional marketing claims section, insert the word "may" immediately preceding the word "carry."
    - 4. Revise the Ingredient Statement section to read as follows:

# **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**	. <u>98.72%</u>
Total	
*Equivalent to 0.37% butylcarbityl (6-propylpiperonyl) ether	and 0.09% related
compounds.	
**Contains petroleum distillates.	

- 5. Delete the existing title block at the top of page 2 that starts with "READ ENTIRE LABEL..."
- 6. In the section starting with "HOW RF2062 WORKS:"
  - Replace the word "controls" with the word "kills" in the 1<sup>st</sup> sentence.
  - Delete the existing 2<sup>nd</sup> sentence, since this product is not intended for use in houses or yards.
- 7. Revise the introduction to the Directions for Use section by relocating the first three (3) sentences to their own lines for more prominence as follows:

### "DIRECTIONS FOR USE

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

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

SHAKE WELL ...."

<sup>&</sup>lt;sup>1</sup> For more detailed information, please refer to page 2 of 2 of the companion animal safety review for this product.

8. Per the REDs for pyrethrins, piperonyl butoxide and MGK® 264, add the following new subsection at the beginning of the Directions for Use section, immediately following the statement "It is a violation of..." This information must be placed in a text box as follows:

### General Precautions and Use Restrictions

- Apply this product only as specified on this label.
- Do not apply more than 1 time per day.
- Avoid spraying of genital areas.
- Do not apply this product in a way that will contact adults, 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 no apply when windy.
- 9. Replace the text at the beginning of the Directions for Use section, starting with "SHAKE WELL...," and insert it immediately following the statement starting with "Read and follow all directions..." as follows:
  - "READ ENTIRE LABEL BEFORE EACH USE. SHAKE WELL BEFORE USING. USE ONLY IN A WELL-VENTILATED AREA. USE ONLY ON [HORSES, PONIES]."
- 10. In the Storage and Disposal section, replace the word "Storage:" on the 2<sup>nd</sup> line with the words "Pesticide Storage:"
- 11. In the Storage and Disposal section, replace the word "Disposal:" on the 3<sup>rd</sup> line with the words "Pesticide Disposal:"
- 12. Insert the following new subsection at the end of the Storage and Disposal section: "Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerator, or, if allowed by state or local authorities, by burning. If burned, stay out of smoke."
- 13. Revise the section title that currently reads as "PRECAUTIONARY STATEMENTS, HAZARDS TO HUMANS-CAUTION" to read as "PRECAUTIONARY STATEMENTS, HAZARDS TO HUMANS AND DOMESTIC ANIMALS."
- 14. Replace the existing 4<sup>th</sup> and 5<sup>th</sup> sentences in the Precautionary Statements, Hazards to Humans and Domestic Animals section with: "Wash hands thoroughly with plenty of soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals." <sup>2</sup>

<sup>&</sup>lt;sup>2</sup> This revised label language is required since RF2062 MIST is a dermal sensitizer. For more detailed information, please refer to page 3 of 3 of the acute toxicity review for this product.



15. Replace the existing First Aid section (table) with:

FIRST AID	
If in Eyes:	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.
	Call a poison control center or doctor for further treatment advice.
If on Skin or Clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.
	<ul> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>
Have the product contain	ner or label with you when calling a poison control center, doctor
health concerns, medical e	for treatment. For additional information on this product (including mergencies or pesticide incidents), you may call 1-800-xxx-xxxx or the ation Center at 1-800-858-7378.
	ns petroleum distillate. Vomiting may cause aspiration

16. Per the REDs for pyrethrins, piperonyl butoxide and MGK® 264, replace the existing Precautionary Statements, Environmental Hazards section with: 4

"ENVIRONMENTAL HAZARDS: This product is toxic to aquatic organisms, including fish and invertebrates. Do not contaminate water when disposing of equipment wash-waters or 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."

- 17. Data deficiencies were identified for storage stability and corrosion characteristics in the product chemistry review for this product. Therefore, Wellmark International is obligated to submit a One Year Storage Stability (830.6317) study and a Corrosion Characteristics (830.6320) study on this product in support of this registration within one (1) year from the date of this registration.
- 18. Within forty-five (45) days from the date of this letter, you should submit a label amendment revising the "Warranty & Disclaimer" section in accordance with the guidance document entitled, "Guidance on Warranty Statements" and dated October 17, 2006. This update can be found at the following hyperlink: <a href="http://www.epa.gov/pesticides/regulating/labels/warranty.pdf">http://www.epa.gov/pesticides/regulating/labels/warranty.pdf</a>.
- 3. Submit two (2) copies of the revised final printed label for the record before the product is released for shipment.

<sup>4</sup> For more detailed information, please refer to page 84 of 108 of the pyrethrins RED.

<sup>&</sup>lt;sup>3</sup> Please note that the "1-800-xxx-xxxx" number listed must be available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.

Wellmark International should note that a notice of availability of EPA's reregistration eligibility decision (RED) document 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 MGK® 264.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label and hard copies of the efficacy, acute toxicity, companion animal safety and product chemistry reviews for this product are enclosed for your records.

/ or

Richard J. Gebken Product Manager (10) Insecticide Branch

Registration Division (7505P)

Enclosures: Label stamped "Accepted with Comments"

Efficacy Review for RF2062 MIST, dated October 1, 2007

Acute Toxicity Review for RF2062 MIST, dated September 17, 2007

Companion Animal Safety Review for RF2062 MIST, dated September 17, 2007

Product Chemistry Reviews for RF2062 MIST, dated September 19, 2007

002724-00790 D377058

# [] Indicate optional statements

# RF2062 MIST

#### **EFFECTIVE**

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

Kills and Repele: Ticks, fleas, lice, flies, mosquitoes and gnats

-Temporarily repels gnats, flies, mosquitoes-

Controls [Kills] [and repels] Lyme disease-carrying ticks [including /xodes scapularis][including-

these that carry [transmit] Lyme disease]

An effective spray mist that kills adult fleas

Contains pyrethrins, an adulticide

[Cosmetic grade solvent formulation]-

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

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

Strong floa 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%
Technical Piperonyl butoxide (CAS #51-03-6)*	
N-octyl bicycloheptene dicarboximide (CAS #113-48-4)	
OTHER INGREDIENTS:	<u>98</u> .72%
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

EPA Reg. No. 2724-EPA Est No.

Net Contents:

ACCEPTED
with COMMENTS
in EPA Letter Dated

Under the Federal Insecticide, Funginitie, and Rodenticide Act, an amended, for the pesticide registered under EPA Rec. No.



# READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON [DOGS, CATS, PUPPIES, KITTENS][HORSES, PONIES]

### **HOW RF2062 WORKS:**

RF2062-centrels ticks, lice, mosquitoes, gnats, fleas, house flies, stable flies, horn flies, and face flies. Effective flea centrel 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. 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 pecessary.

For Ticks: Make sure spray thoroughly wots individual-ticks.

### 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 cotten 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/viny 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.



### **IFOR 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. Storage: Store in a cool, dry area away from heat or open flame. Store away from children and animals. 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 or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

### PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS -CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

HAZARDS TO ANIMALS - GAUTION: 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 thise 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.

FIRST AID		
Call a poison control center or dector immediately for treatment advice.		
If in eyes	<ul> <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>	
If on skin or clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul>	
	ainer or label with you when calling a poison control center, doctor, or or treatment. You may also contact 1-800-[phone number] for emergency rmation.	

[Note: First Aid statement paragraph format may be used if space is limited.]

**ENVIRONMENTAL HAZARDS:** This product is toxic to fish. Do not apply directly to water. Do not apply where runoff is likely to occur.

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



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

Wellmark International 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] or visit our Web site: [URL]