

U.S. ENVIRONMENTAL PROTECTION AGENCY

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

NOTICE OF PESTICIDE:

X Registration
Reregistration
(under FIFRA, as amended)

****	~	
LPA	Keg.	Number

Date of Issuance:

2724-792

APR 2 6 2008

Term of Issuance:

Conditional

Name of Pesticide Product:

RF2066 SHAMPOO

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 #4.

APR 2 6 2008

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

EPA Form 8570-6

- 2. Make the following change(s) to the label:
 - a. Change the product registration number to "EPA Reg. No. 2724-792"
 - b. Make the following label revisions:

Optional Marketing Claims section comment(s):

- 1. On the 1st optional marketing claim, replace the word "carry" with the word "transmit" and replace the word "on" with the word "through."
- 2. Delete the 2nd optional marketing claim since it is broad, ambiguous and therefore false and misleading.
- 3. On the 3rd optional marketing claim, delete the words "[Specially formulated]" since these words imply heightened efficacy. In addition, insert the words "over 12 weeks of age" immediately following the word "puppies."
- 4. Delete the 4th, 6th and 14th optional marketing claims since they imply heightened efficacy.
- 5. Delete the 5th optional marketing claim since these statements contradict the Directions for Use.
- 6. Delete the 10th, 11th, 12th and 13th optional marketing claims since they are implied safety claims.

Directions for Use section comment(s):

7. As required by the REDs for pyrethrins and piperonyl butoxide, add the following new subsection 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 contaminate of food or feedstuffs.
- **DO NOT** apply to pets less than 12 weeks of age.
- Consult a veterinarian before applying this product on debilitated, aged, pregnant or nursing animals. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated animals.
- Sensitivities may occur after using ANY pesticide 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.
- 8. Revise the 7th sentence in this section with: "Do not apply more than once per week for the control of adult fleas and ticks."
- 9. Add the following text at the end of this Directions for Use: "Animal bedding/quarters should be treated with an approved product labeled for that use at the same time that [animal][pet][dog/cat/puppy/kitten] is treated with [Brand Name]."

<u>Precautionary Statements, Hazards to Humans and Domestic Animals section</u> comment(s):

- 10. Replace the existing 4th sentence in the **HUMANS** subsection with: "Wash hands thoroughly with plenty of soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet."
- 11. Delete the 2nd paragraph starting with "ANIMALS:" since this text has been moved to the new "General Precautions and Use Restrictions" subsection listed/added in Item #9.

Storage and Disposal section comment(s):

12. Place the Storage and Disposal Statement within a solid text box to increase its prominence. Within the text box, the Storage and Disposal heading should be placed on the top and in a central position above the Storage and Disposal Statement. Replace this section with:

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry, well-ventilated (preferably locked) that is inaccessible to pets and children.

Pesticide Disposal: If empty: Do not reuse or refill this container. Place in trash or offer for recycling if available. If partially filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drains.

General comment(s):

- 13. Within one (1) year from the date of this registration, 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. ¹
- 14. Within forty-five (45) days from the date of this letter, Wellmark International 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: http://www.epa.gov/pesticides/regulating/labels/warranty.pdf. When resubmitting, the subtitle "Warranty & Disclaimer" should be added to clarify the intent of the language contained within.
- 15. Delete the reference to the "[web site URL]" currently found at the bottom of page 3. This reference is considered collateral labeling.
- 3. You must submit two (2) copies of the revised 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 FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

¹ For more detailed information, please refer to page 2 of 2 of the product chemistry review for this product

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). As a result, additional data and/or labeling changes may be required for products containing pyrethrins and/or piperonyl butoxide.

A copy of your label stamped "Accepted with Comments" is enclosed for your records along with hard copies of the efficacy, acute toxicity, companion animal safety and product chemistry reviews for this product.

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*.

Richard J. Gebken Product Manager (10) Insecticide Branch

Registration Division (7505P)

Kland J. Call

Enclosures: Label stamped "Accepted with Comments"

Efficacy Review, dated April 14, 2008 Acute Toxicity Review, dated April 9, 2008

Companion Animal Safety Review, dated April 8, 2008 Product Chemistry Review, dated March 11, 2008

002724-00792 D347721

[] indicates optional text

RF2066 SHAMPOO

Kills [adult] [biting] fleas, ticks, [which may carry Lyme disease] on contact

2 - [kills] [biting] adult fleas, ticks [which can carry numerous diseases] --

-[Specially formulated]-For cats, kittens, dogs, and pupples

4 Highly [and rapidly] effective Conditioning [Seething] floa, tick champeo

5 -Pleasant [Wave/Spice/Leaf/Blossom/Bloom/Breeze/Ocean/Moonlight/Tropical/Punch/Colada (coont-descriptors, use singly or in combination)][Frosh][ccont][fragrance][to-overcome-dog/cat-odere]

6 Soothing rollof from bug bitos which can cause itchy or irritated skin

7 Contains [With] pyrethrins

[Gentle][Emollient] Shampoo [with[coconut extract]

[Designed for] Sensitive Skin [Formula]

Ontains [features econut] conditioners [extract]

(I -Cleans, Freshens, Beautifies, Deodorizes [in one easy step]

12 Rich, creamy formula cleans and conditions-

12 [Coconut Extract Leaves coat soft; shining; and manageable

14 Satisfaction Guaranteed or your money back

ACTIVE INGREDIENTS:

Pyrethrins (CAS #8003-34-7)	***************************************	0.05%
Piperonyl Butoxide (CAS #51-03-6)*		
OTHER INGREDIENTS:		
	TOTAL	

^{*} Equivalent to 0.40% of (butylcarbityl) (6-propylpiperonyl) ether and 0.10% of related compounds

A concentrated lathering shampoo enriched with coconut extract. Leaves coat soft and shining. The shampoo removes loose dandruff, dirt, and scales.

KEEP OUT OF REACH OF CHILDREN CAUTION

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS

EPA Reg. No. 2724-xxx EPA Est. No.

NET CONTENTS

ACCEPTED with COMMENTS in EPA Letter Dated

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No.

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS, CATS, KITTENS, OR PUPPIES

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. FOR TOPICAL USE ONLY. DO NOT INGEST.

Thoroughly wet [the hair][the animal][your pet/dog/cat/puppy/kitten] with warm water. Use [Brand Name] full strength. Do not apply shampoo around the eyes. Apply 1 1/3 tablespoons shampoo for each 5 lbs of pet's [cat's/dog's/kitten's/puppy's] weight to the head and ears, then lather; repeat procedure with the neck, chest, middle and hindquarters, and finishing legs last. Continue to work lather in for 3 to 5 minutes (this is an important part of the grooming procedure), then rinse [animal][pet][cat/dog/puppy/kitten] thoroughly with warm water. For extremely dirty or scaly animals [pets][cat/dog/puppy/kitten], the above procedure may be immediately repeated. Repeat as necessary but do not apply more than once per week, for control of adult fleas and ticks. Do not use on puppies or kittens less than 12 weeks old.

PRECAUTIONARY STATEMENTS CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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

ANIMALS: Do not use on puppies or kittens less than 12 weeks old. Consult a veterinarian before using this product on debilitated, aged, animals on medication, 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.

FIRST AID	
Call a poison	control center or doctor immediately for treatment advice.
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.
If on skin or clothing	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.
doctor, or goi	duct container or label with you when calling a poison control center or ng for treatment. You may also contact 1-800-[phone number] for edical treatment information.

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

STORAGE AND DISPOSAL

STORAGE: Store in a cool area. **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.

In case of emergency or for product use information, call [phone number]

To the extent consistent with applicable law, Seller makes no warranty, expressed or implied, concerning the use 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.

Wellmark International 1501 East Woodfield Road 200 W Schaumburg, IL 60173

Made in USA

[web site URL]