



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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

June 17, 2008

Ms. Nancy Huebl, Senior Registration Specialist  
Wellmark International  
1501 E. Woodfield Road, Suite 200 West  
Schaumburg, IL 60173-5417

**Subject: Final Labeling, Wellmark Response to Conditional Registration  
RF2066 SHAMPOO, EPA Reg. No. 2724-792  
Your Submission Dated May 16, 2008**

Dear Ms. Huebl:

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

General Statement:

1. Delete all text on the label that has been marked up with "strikethrough."
2. The words "**INSECTICIDE SHAMPOO**" must be displayed prominently on the front panel of this label, immediately following the brand name, in bold-faced, capital lettering to indicate to the consumer that this product is an insecticidal shampoo.
3. Delete the reference to the "[web site URL]" currently found at the bottom of page 3. This reference is considered collateral labeling.

Optional Marketing Claims section comment(s):

4. On the 2<sup>nd</sup> optional marketing claim, delete the words "[Specially formulated]" since these words imply heightened efficacy. Insert the words "over 12 weeks of age" immediately following the word "puppies." Otherwise, this statement will be inconsistent with and a detraction from the General Precautions and Use Restrictions section.
5. On the 3<sup>rd</sup> optional marketing claim, delete the word "[Soothing]" since it implies a medical claim.
6. On the 4<sup>th</sup> optional marketing claim, delete the words "Punch/Colada" and delete the statement "[scent descriptors, use singly or in combination]" If you intend to put this statement back on the label at a later date, you can submit an amendment that clearly articulates why this statement is necessary.
7. Delete the 5<sup>th</sup> and 8<sup>th</sup> optional marketing claims since they imply a medical claim.

Optional Marketing Claims section comment(s), continued:

- 8. On the 7<sup>th</sup> optional marketing claim, delete the word "[Gentle]" since it is an implied safety claim and it also detracts from the Precautionary Statements.
- 9. Delete the 13<sup>th</sup> optional marketing claim since this statement contradicts the revised Warranty and Disclaimer section.

Ingredient Statement section comment(s):

- 10. Revise the ingredient listed as "Piperonyl Butoxide (CAS #51-03-6)\*" to read: "Piperonyl Butoxide: Technical (CAS #51-03-6)\*"

Directions for Use section comment(s):

- 11. In the last sentence in the General Precautions and Use Restrictions subsection, replace the misspelled word "veterinariam" with the correctly spelled word "veterinarian."

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

- 12. Revise the section title to read: "Hazards to Humans and Domestic Animals."
- 13. Delete the subsection title "**HUMANS:**" in the 1<sup>st</sup> line of this section.

First Aid Statement section comment(s):

- 14. Insert the statement "Call a poison control center or doctor for further treatment advice." as a 3<sup>rd</sup> bullet under the lines (rows) in this section titled "**If in eyes:**" and "**If on skin or clothing:**"
- 15. Replace the 2<sup>nd</sup> sentence from the last statement in this section with: "**For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-xxx-xxxx.**"<sup>1</sup>

Storage and Disposal Statement section comment(s):

- 16. Replace the "**Pesticide Storage:**" statement with: "Store this product in a cool, dry (preferably locked) area that is inaccessible to pets and children."
- 17. Per updates to PR Notice 2007-4, replace the "**Pesticide/Container Disposal:**" statement with: "**Disposal: If empty:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. **If partially filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain."

Warranty and Disclaimer section comment(s):

- 18. In the 3<sup>rd</sup> sentence, insert the word "the" immediately preceding the word "purchase."

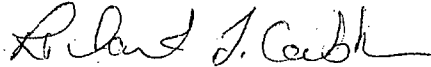
Wellmark International should note that a notice of availability of EPA's reregistration eligibility decision (RED) document for products containing pyrethrins was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42387-42389). In addition, EPA's RED for products containing 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 piperonyl butoxide.

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<sup>1</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.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. 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 FIFRA section 6(e). 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](mailto:Rodia.Carmen@epa.gov).



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

Enclosure: Copy of label stamped "Accepted with Comments"

002724-00792 D393885

[ ] indicates optional text

# RF2066 SHAMPOO

- Kills [adult] [biting] fleas, ticks, [which may transmit Lyme disease] through contact
- ~~[Specially formulated] For cats, kittens, dogs, and puppies~~
- Conditioning [~~Seething~~] flea, tick shampoo
- Pleasant [Wave/Spice/Leaf/Blossom/Bloom/Breeze/Ocean/Moonlight/Tropical/~~Punch/Celada~~ (scent descriptors, use singly or in combination)][Fresh][scent][fragrance][to overcome dog/cat odors]
- ~~Seething relief from itchy or irritated skin~~
- Contains [With] pyrethrins
- ~~[Gentle][Emollient] Shampoo [with[coconut extract]~~
- ~~[Designed for] Sensitive Skin [Formula]~~
- Contains [features coconut] conditioners [extract]
- Cleans, Freshens, Beautifies, Deodorizes [in one easy step]
- Rich, creamy formula cleans and conditions
- [Coconut Extract Leaves coat soft, shining, and manageable]
- ~~Satisfaction Guaranteed or your money back~~

### ACTIVE INGREDIENTS:

Pyrethrins (CAS #8003-34-7) .....	0.05%
Piperonyl Butoxide (CAS #51-03-6)* .....	0.50%

<b>OTHER INGREDIENTS:</b> .....	<u>99.45%</u>
<b>TOTAL</b>	<b>100.00%</b>

\* 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. 2724-792

EPA Est. No.

NET CONTENTS

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated**  
*June 17, 2008*  
 Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act,  
 as amended, for the pesticide  
 registered under EPA Reg. No.  
2724-792

**READ ENTIRE LABEL BEFORE EACH USE**

**USE ONLY ON DOGS, CATS, KITTENS, OR PUPPIES 12 weeks of age or older**

**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.**

<b>General Precautions and Use Restrictions</b>	
<ul style="list-style-type: none"> <li>o Apply this product only as specified on this label.</li> <li>o <b>DO NOT</b> apply to pets less than 12 weeks of age.</li> <li>o Consult a veterinarian before applying this product on debilitated, aged, pregnant or nursing animals. Certain medicines can interact with pesticides. Consult a veterinarian before using on medicated animals. Sensitivities may occur after using <b>ANY</b> 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.</li> </ul>	

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. Do not apply more than once per week for control of adult fleas and ticks. Treat animal bedding/quarters with an approved product labeled for that use at the same time that [pet][dog/cat/puppy/kitten] is treated with [Brand Name].

**PRECAUTIONARY STATEMENTS**

**CAUTION**

**HAZARDS TO HUMANS**

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

<b>FIRST AID</b>	
Call a poison control center or doctor immediately for treatment advice.	
If in eyes	<ul style="list-style-type: none"> <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 style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul>
Have the product container or label with you when calling a poison control center or doctor, 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.]

**STORAGE AND DISPOSAL**

**Pesticide Storage:** Store in a cool area.

**Pesticide/Container 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 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]

**Warranty and Disclaimer**

Note: Seller warrants that this product complies with the specifications expressed in this label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, expressed 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 or default, breach or failure under this label shall be limited to the amount of purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

Wellmark International  
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Schaumburg, IL 60173

Made in USA

~~[web site URL]~~