

2724-485

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 24, 2012

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; Response to EPA Letter Dated November 2, 2011
RF9414 Shampoo, EPA Reg. No. 2724-485
Your Submission Dated November 14, 2011**

Dear Mr. McFadden:

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 label revision provision(s):

General Comment(s):

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

Optional Marketing Statements section comment(s):

2. Revise the 8th optional marketing statement to read "Contains pyrethrins, a botanical insecticide derived from Chrysanthemums."
3. Revise the 12th optional marketing statement to read "Contains [With][Plus] PRECOR® [vIGRen®] Insect Growth Regulator [IGR] plus pyrethrins [an adulticide] and piperonyl butoxide [a synergist]"
4. Delete the 16th optional marketing statement since it conflicts with the revised "Warranty & Disclaimer" section at the end of the subject label.

Ingredient Statement section comment(s):

5. In order to incorporate required label changes from the RED for piperonyl butoxide, you must:
 - Revise the listing of "Piperonyl Butoxide (CAS #51-03-6)" to read "Piperonyl Butoxide* (CAS #51-03-6)"
 - Add the following footnote to this section: "* (butylcarbityl)(6-propylpiperonyl) ether and related compounds"

Directions for Use section comment(s):

6. Revise the existing statement "USE ONLY ON CATS, KITTENS, DOGS, PUPPIES" to read "USE ONLY ON DOGS, CATS, AND PUPPIES OR KITTENS OLDER THAN 12 WEEKS OF AGE"
7. In order to facilitate inclusion of required language from the REDs for pyrethrins and piperonyl butoxide (updated label tables for pyrethrins/piperonyl butoxide combination products), insert the following new subsection immediately following the statement starting with "It is a violation of federal law to use ..." as follows:

USE RESTRICTIONS

- Apply this product only as specified on this label.
- Do not contaminate food or feedstuffs.
- **THIS PRODUCT IS FOR TOPICAL USE ONLY. DO NOT INDUCE.**
- Do not apply to pets (puppies or kittens) less than 12 weeks old.
- 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 apply more than 1 time per day.

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

- 8. Revise the 4th sentence to read "Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet."

Precautionary Statements, Hazards to Domestic Animals subsection comment(s):

- 9. Revise the subsection heading to read "**DOMESTIC ANIMALS**"
- 10. Revise the 1st sentence to read "Do not apply to pets (puppies or kittens) less than 12 weeks old."

Environmental Hazards Statement section comment(s):

- 11. In order to facilitate inclusion of required language from the REDs for pyrethrins and piperonyl butoxide (updated label tables for pyrethrins/piperonyl butoxide combination products), insert the following new subsection immediately following the "Precautionary Statements" subsections to read as follows:

"ENVIRONMENTAL HAZARDS

This product is toxic to aquatic organisms, including fish and invertebrates. Drift and run-off may be hazardous to aquatic organisms in water adjacent to treated areas. This product may contaminate water through run-off. This product has a potential for run-off for several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to produce run-off that contains this product.

This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash-waters or rinsate. See Directions of Use for additional precautions and requirements."

First Aid Statement section comment(s):

- 12. In order to facilitate inclusion of required language per the Agency's Label Review Manual (LRM), revise the 2nd sentence within the "**HOT LINE NUMBER**" subsection to read "For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-xxx-xxxx, twenty-four (24) hours per day, seven (7) days per week."
- 13. It is important to note that upon responding to this label review with an amended label, you must substitute the "1-800-xxx-xxxx" notation with a valid phone number that is available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.

Storage and Disposal Statement section comment(s):

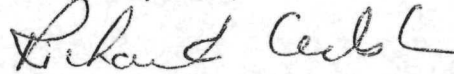
- 14. Revise the existing "**STORAGE:**" subsection to read "**PESTICIDE STORAGE:** Keep this product in its tightly closed original container when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals."
- 15. Revise the subsection heading "**DISPOSAL:**" subsection to read "**CONTAINER DISPOSAL:**"

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 section 12(a)(1)(E) of FIFRA. 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 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. 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 (7504P)

Enclosure:
002724-00485 D457654

Copy of label stamped "Accepted with Comments"

[] indicates optional text

RF-9414 SHAMPOO

Alternate brand names: ZODIAC® Flea & Tick Conditioning Shampoo for Puppies
ZODIAC® Oatmeal Conditioning Shampoo for Dogs & Puppies

[Protein] Conditioning flea and tick shampoo

For cats, kittens, dogs, puppies

Kills [adult] fleas, lice, ticks on contact

Prevents flea eggs from hatching for 28 days

Kills flea eggs [and flea larvae] for 28 days [to prevent reinfestation]

Controls adult fleas and ticks and provides long-lasting control of pre-adult fleas before they can bite

Pleasantly scented [Baby][“Fresh” scent]

⑧ Contains [With] natural pyrethrins

Shampoo [With][Contains] [natural soothing] aloe [vera][lanolin] and oatmeal Sensitive Skin Formula

Formulated with protein for increased groomability [luster]

⑫ Contains [With][Plus] PRECOR® [VIGRen®] Insect Growth Regulator [IGR] [plus pyrethrins, an adulticide]

Breaks the flea life cycle

Rich, creamy formula cleans and conditions

Leaves coat soft, shining [shiny], and manageable

~~Satisfaction 100% Guaranteed~~

ACTIVE INGREDIENTS:

(S)-Methoprene (CAS #65733-16-6).....0.10%

Pyrethrins (CAS #8003-34-7).....0.15%

Piperonyl Butoxide (CAS #51-03-6)1.8850%

OTHER INGREDIENTS:978.8725%

TOTAL 100.00%

A concentrated lathering shampoo enriched with oatmeal, coconut extract, lanolin, and aloe. Leaves the coat soft, shining, and manageable. The shampoo removes loose dandruff, dirt, and scales. PRECOR® Insect Growth Regulator provides 28 days of control of pre-adult fleas before they become biting adults.

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS

EPA Reg. No. 2724-485

EPA Est. No.

NET CONTENTS

ACCEPTED
With COMMENTS
In EPA Letter Dated:

January 24, 2012

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

2724-485

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**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON CATS, KITTENS, DOGS, 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.

[Brand Name] may be used full strength or diluted with 2 parts water. Thoroughly wet [animal] with warm water. Do not apply shampoo around eyes. Apply shampoo on head and ears, then lather; repeat procedure with neck, chest, middle and hind quarters, 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] thoroughly. For extremely dirty or scaly [animals], the above procedure may be repeated. Repeat every 7 to 10 days, if necessary, for adult flea relief. Flea egg hatch inhibition will last for 28 days. Do not use on puppies or kittens under 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.

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

STORAGE: Store in a cool area.

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.

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In case of emergency or for product use information call [phone number] or visit our web site:
[web site URL]

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 the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages, concerning the use 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.

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Wellmark International
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Made in USA

