

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 5, 2018

James McFadden, Ph.D. Director, Regulatory Affairs Wellmark International 1501 E. Woodfield Rd., Ste. 200 W Schaumburg, IL 60173

Subject: Label and CSF Amendment – Adding an alternate formula that makes this a foaming shampoo and adding alternate directions for use language related to the foaming shampoo.
 Product Name: RF-9414 SHAMPOO EPA Registration Number: 2724-485
 Application Date: October 6, 2017
 Decision Number: 534916; 534918

Dear Dr. McFadden:

The amended label and CSF referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Please note that the record for this product currently contains the following CSF(s):

- Basic CSF dated 01/07/2015
- Alternate CSF 1 dated 01/07/2015
- Alternate CSF 2 dated 10/06/2017

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act 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) list examples of statements EPA may consider false or misleading. In addition,

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regardless of whether a website is referenced on your product's label, claims made on the website may not 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 the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Sincerely,

Elizabeth Fertich Product Manager 4 Invertebrate & Vertebrate Branch 1 Registration Division (7505P) Office of Pesticide Programs

Enclosure

[] indicates optional text {} indicates a note to reviewer

ACCEPTED 04/05/2018

RF-9414 SHAMPOO

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2724-485

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

ACTIVE INGREDIENTS:

(S)-Methoprene (CAS #65733-16-6)		0.10%
Pyrethrins (CAS #8003-34-7)		0.15%
Piperonyl Butoxide* (CAS #51-03-6)		
OTHER INGREDIENTS:		
	TOTAL	100.00%

*(butylcarbityl)(6-propylpiperonyl) ether and related compounds

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 [*InfestStop™] provides 28 days of control of preadult 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

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS, CATS, AND PUPPIES OR KITTENS OLDER THAN 12 WEEKS OF AGE

PRECAUTIONARY STATEMENTS CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HUMANS: Harmful if absorbed through skin. Causes moderate eye irritation. 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. Remove and wash contaminated clothing before reuse.

DOMESTIC ANIMALS: Do not apply to pets (puppies or kittens) less than 12 weeks old.

FIRST AID		
Call a poison control center or doctor immediately for treatment advice.		
IF ON SKIN OR	Take off contaminated clothing.	
CLOTHING	 Rinse skin immediately with plenty of water for 15-20 minutes. 	
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. 	
HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-[234-2269/766-7661/950-4783] 24 hrs/ day, 7 days/wk.		

[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. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. This product has a potential to contaminate water through runoff. This product has a potential for runoff for several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product. This product is highly toxic to bees and other pollinating insects 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 or other pollinating insects are actively foraging 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 washwaters or rinsate.

DIRECTIONS FOR USE

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

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 INGEST.

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 one time per day.

[Brand Name] may be used full strength or diluted with 2 parts water. Thoroughly wet [the hair][the animal][your pet] with warm water. Do not apply shampoo around eyes. The total amount of shampoo to be applied is 1¹/₃ tablespoons for each 5 lbs of pet's weight. Estimate the total amount of shampoo needed for your pet, then apply shampoo along the back of the animal [pet]. Work well into coat starting at the head and working back. Spread lather to include head, neck, legs and feet. Continue to work lather in over the whole animal [pet] for 3 to 5 minutes (this is an important part of the grooming procedure). After lather has been worked in over the entire pet [animal], rinse [animal][pet] thoroughly with warm water. 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.

[Alternate Directions for Use for Foaming Formula]

Wet pet's coat thoroughly with water, then pump shampoo onto pet and rub shampoo into coat starting with head and working back and down. Use about 1-1/3 tablespoons for each 5 lbs. of pet's weight. Do not apply shampoo around eyes. Continue to work lather in over the whole animal [pet] for 3 to 5 minutes (this is an important part of the grooming procedure). Rinse pet with warm water and towel dry. 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.

STORAGE AND DISPOSAL

 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.
 PESTICIDE DISPOSAL AND CONTAINER HANDLING: 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.

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

WARRANTY AND CONDITIONS OF SALE: 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's no the extent consistent with applicable law, Seller's seller's liability or default, breach or failure under this label shall be limited to the amount of the purchase price.

PRECOR®, ZODIAC® and vIGRen® Insect Growth Regulator are registered trademarks of Wellmark International *InfestStop is a registered trademark of Central Garden & Pet Company

Wellmark International 1501 East Woodfield Road 200 W Schaumburg, IL 60173 Made in USA {Optional Marketing Claims}

[Protein] Conditioning flea and tick shampoo For cats, kittens, dogs, puppies over 12 weeks of age 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] Contains [With] pyrethrins, a botanical insecticide derived from chrysanthemums Shampoo [With][Contains] [natural soothing] aloe [vera][lanolin] and oatmeal Sensitive Skin Formula Formulated with protein for increased groomability [luster] Contains [With][Plus] PRECOR® [vIGRen®][*InfestStop™] Insect Growth Regulator [IGR] [plus] pyrethrins, an adulticide] and piperonyl butoxide [a synergist] Contains [*InfestStop™] an Insect Growth Regulator (IGR) to kill [flea eggs][flea larvae] and prevent [reinfestation] [flea development for up to 28 days] [Controls flea reinfestation for up to 28 days] [Kills flea eggs [flea larvae] and prevents flea egg hatch] for up to 28 days [With [S-Methoprene] [Precor®] [*InfestStop™] Insect Growth Regulator to Break Flea Life Cycle] [Plus][Contains][With] PRECOR® [vIGRen®][S-Methoprene][*InfestStop™], the first insect growth regulator for flea control [(S)-Methoprene][*InfestStop[™]] Insect Growth Regulator (IGR) interrupts the development of the flea life cycle [at the egg stage] [(S)-Methoprene][*InfestStop™] Insect Growth Regulator (IGR) prevents the development of flea eggs into adult fleas and [inhibits the development of flea eggs into adult fleas] Flea control for dogs [cats] with [PRECOR®][vIGRen®] [*InfestStop[™]] Insect Growth Regulator (IGR) [Kills][Prevents][Keeps] flea eggs from hatching for up to 28 days Breaks the flea life cycle [for up to 28 days] Rich, creamy formula cleans and conditions Leaves coat soft, shining [shiny], and manageable *(S)-Methoprene {Must occur on same panel wherever InfestStop™ is used}

{Precor® and vIGRen® are registered trademarks of Wellmark International that represent (S)methoprene}

Conditions and restores shine

[Rich][Deep] Conditioning

[Product name] gently cleanses your dog's coat while coconut replenishes skin's moisture for a fresh, healthy, clean.

Coconut helps create a rich lather while supporting a healthy and fresh coat.

[Coconut Extract Leaves coat soft, shining, and manageable]

Rich, creamy formula cleans and conditions

Lightly scented [Coconut], [fragrance]

Aloe replenishes skin's moisture for a fresh, healthy clean.

Aloe formula for sensitive skin

Aloe works to re-moisture, heal and soothe dry skin

Coconut formula for conditioning

Drip free foaming dispenser