

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 6, 2023

Noelle Sanfilippo Regulatory Affairs Specialist Wellmark International 1501 East Woodfield Road, 200W Schaumburg, Illinois 60173

Subject: Registration Review Label Mitigation for Permethrin

Product Name: SPI Residual Flea and Tick Spray for Dogs

EPA Registration Number: 2724-586

Application Date: 12/14/2020 Decision Number: 568737

Dear Noelle Sanfilippo:

The Agency, in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with the Permethrin Interim Decision and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

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, 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 Assurance.

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 12 months from the date of this letter. After 12 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently

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approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

If you have any questions about this letter, please contact Carolyn Smith by phone at (202) 566-2273, or via email at smith.carolyn@epa.gov.

Sincerely,

Kelly Sherman

Chief, Risk Management & Implementation Branch III

Pesticide Re-evaluation Division Office of Pesticide Programs

Enclosure

SPI RESIDUAL FLEA AND TICK SPRAY FOR DOGS

Spray Residually Kills Ticks and Fleas on Dogs Water Based

ACTIVE INGREDIENTS:

Pyrethrins (CAS #8003-34-7)	0.056%
Permethrin *(CAS #52645-53-1)	
OTHER INGREDIENTS:	
TOTAL	100.000%

^{*}cis-trans isomer ratio: Min. 35% (+ or -) cis Max. 65% (+ or -) trans

KEEP OUT OF REACH OF CHILDREN CAUTION See Side Panel For Additional Precautionary Statements

EPA REG. NO	2724-586
EPA EST. NO.	

NET WEIGHT:____

ACCEPTED

12/06/2023

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2724-586

READ ENTIRE LABEL BEFORE EACH USE FOR USE ON DOGS ONLY

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS CAUTION

Harmful if absorbed through skin. Harmful if inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

FIRST AID		
IF ON SKIN OR	Take off contaminated clothing.	
CLOTHING	Rinse skin immediately with plenty of water for 15-20 minutes.	
	Call a poison control center or doctor for treatment advice.	
IF INHALED	Move person to fresh air.	
	• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.	
	Call a poison control center or doctor for further treatment advice.	
Have the product container or label with you when calling a poison control center or doctor, or		
going for treatment. information.	You may also contact 1-800-XXX-XXXX for emergency medical treatment	

PHYSICAL OR CHEMICAL HAZARDS

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperature above 130°F may cause bursting.

DIRECTIONS FOR USE

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

USE RESTRICTIONS:

For indoor use only.

DO NOT use on Kittens or Cats.

DO NOT use on puppies under 12 weeks of age.

DO NOT spray in face, eyes, or on genitalia.

For thin/short-haired dogs, to apply at the maximum rate, spray for 2 seconds for each lb of animal weight. For heavy/long-haired dogs, to apply at the maximum rate, spray for 8 seconds for each lb of animal weight.

USE INSTRUCTIONS:

HOLD CONTAINER UPRIGHT. SHAKE WELL BEFORE USING.

Application of product on pets must only be done indoors. Spray dog from a distance of 8-12 inches. Start spraying at the tail, moving the dispenser rapidly and making sure the dog's entire body is covered, including the legs and under the body. Fluff the hair as you spray so the spray will penetrate to the skin. The spray should wet the ticks thoroughly. Apply at the rate of 2 seconds per pound of body weight for thin or short-haired dogs and up to 8 seconds per pound of body weight for heavy or long-haired dogs. Reapply after 2 weeks, if necessary. This product will kill fleas up to 14 days on dogs. It will kill ticks for 4 days on dogs.

Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals, 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 rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in a cool, dry area away from heat or open flame. **PESTICIDE DISPOSAL AND CONTAINER HANDLING:** Do not puncture or incinerate! **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for local disposal options. Do not pour or dispose of down-the-drain or sewer.

In case of emergency or for product use information call 1-800-xxx-xxxx (distributors may elect to use their own phone numbers and hours of operation).

WARRANTY: 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, express 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.

Wellmark International 1501 East Woodfield Road 200W Schaumburg, Illinois 60173 [URL] Made in USA