



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 14, 2020

James McFadden
Director, Regulatory Affairs
Wellmark International, Inc.
1501 East Woodfield Rd., Suite 200 West
Schaumburg, IL 60173

Subject: Label Amendment – Adding required mitigation label information
Product Name: RF9908 SPOT ON FOR DOGS
EPA Registration Number: 2724-497
Application Date: 25 April 2019
Decision Number: 550712

Dear Mr. McFadden:

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable under FIFRA Section 3(c)(7)(A), subject to the following conditions:

1. You must submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
2. This registration is time-limited and expires on May 2, 2021.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
 - EPA Registration Number
 - Product name (brand name)
 - Lot #
 - Where purchased: internet, store, veterinarian
 - Active Ingredient(s)
 - Weight range for product
 - Date on which incident occurred. (mm/dd/yyyy)
 - State in which the incident occurred. (standard 2 letter abbreviation)
 - Registrant case #

- Species: dog, cat, other (specify)
 - Breed: (as reported by pet owner)
 - Age: months or years
 - Sex: M, F, or neutered
 - Weight: pounds
 - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 - Body System: neurological, dermatological, GI, respiratory, ocular, other
 - Major signs noted with separate column for each sign, using standard terminology
 - Time to Onset: (hours, days)
 - Treated by veterinarian: yes or no
 - First time product used: yes or no
 - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 - Any known precondition
 - EPA Severity Code: death, major, moderate, minor
 - Outcome: died, recovered, still treated, unknown
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
- All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - A summary table showing the number of dogs incidents for each severity code for each pet weight range on the product label, as applicable.
 - A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
 - Table showing number of incidents for each dog breed, where provided.
 - Table showing number of incidents in dogs for each clinical sign.
 - Table showing number of incidents in dogs for each organ system.

- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) 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.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). If you have any questions, please contact Dr. Helen Hull-Sanders by phone at 703-347-0243, or via email at hull-sanders.helen@epa.gov.

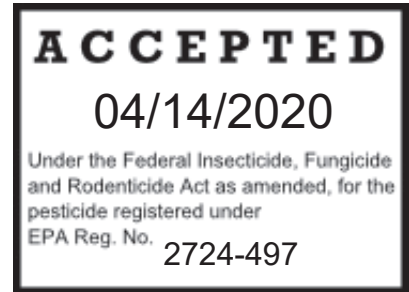
Sincerely,



Elizabeth Fertich
Product Manager 04
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

Text within braces { } denotes notes to reviewer.
Text within brackets [] denotes optional language.
Text within parentheses () is meant to be included on the label



RF9908 SPOT ON FOR DOGS

{Font size for word “Dog” in product name must be at least 75% the height of the largest letter in the primary brand name}

For Use Only on Dogs and Puppies 7-15 lbs [puppies, toys, & miniatures]/16-30 lbs [small dogs]/31-60 lbs [medium dogs]/over 60 lbs [large dogs] & 6 Months of Age or Older

{a large clear picture of a dog in the weight range for the product as packaged will appear on the front panel of the label}

{Front Panel}

ACTIVE INGREDIENTS:

Permethrin	45%
(S)-Methoprene	3%
OTHER INGREDIENTS:	52%
Total	100%

KEEP OUT OF REACH OF CHILDREN CAUTION

See back panel for additional First Aid and Precautionary Statements

Net Contents: Total 0.066 fl oz [1.95 ml] 3 – 0.022 fl oz (.65 ml) [applicators][tubes] [dogs 7-15 lbs]
 Total 0.102 fl oz [3 ml] 3-0.034 fl oz (1 ml) [applicators][tubes] [dogs 16-30 lbs]
 Total 0.204 fl oz [6 ml] 3-0.068 fl oz (2 ml) [applicators][tubes] [dogs 31-60 lbs]
 Total 0.303 fl oz [9 ml] 3-0.101 fl oz (3 ml) [applicators][tubes] [dogs >60 lbs]
 {other package sizes may be marketed from 1 to 12 doses but net contents will include individual size for tubes as well as total package contents}

EPA Reg. No. 2724-497
EPA Est. No. 2724-TX-1

{Lower right, Front panel}



{A minimum of 1.5cm x 1.5cm cat prohibition icon will be in a box in the lower right hand corner of the front panel in yellow with black images cat circled and line through it}

{back panel}

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS OR PUPPIES, WEIGHING [7-15 LBS [PUPPIES, TOYS, & MINIATURES]] [16-30 LBS [SMALL DOGS]] [31-60 LBS [MEDIUM DOGS]] [OVER 60 LBS [LARGE DOGS]] {as appropriate for package size} 6 MONTHS OF AGE OR OLDER. DO NOT USE ON CATS!

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

USE RESTRICTIONS: DO NOT ALLOW CHILDREN TO APPLY THIS PRODUCT. DO NOT USE ON CATS – MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately. Do not allow adults, children, or pets to touch treated area until dry. Do not apply to dogs/puppies less than 6 months of age or weighing less than [7] [16], [31], [60] {as appropriate for package size} lbs. Do not apply more than one [applicator] [tube] per treatment for one dog regardless of the dog's weight. Do not retreat more than once per [month] [30 days][4 weeks]. Do not allow your dog/puppy to ingest this product.

{back panel}

{Graphics for Each Step} {see below}

APPLICATION LANGUAGE FOR DOGS AND PUPPIES 7-15 LBS [PUPPIES, TOYS & MINIATURES], 16-30 LBS [SMALL], AND 31-60 LBS [MEDIUM]

APPLICATION METHOD



[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same.]

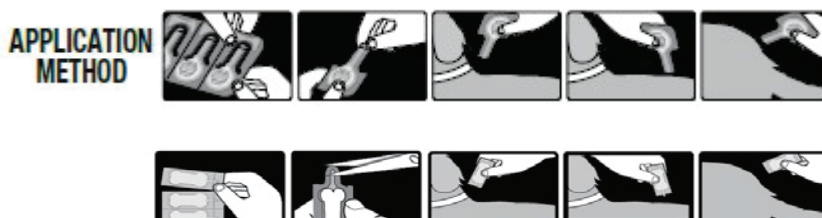
1. Bend at perforation and tear off first month's [applicator] [tube].
2. [Hold [applicator] [tube] and bend area of plastic at perforation, tear off and discard. Hold [applicator] [tube] upright and snap tip back, away from face and body of person and dog.] {OR} [Hold [applicator] [tube] and bend numbered area of plastic at perforation, tear off and discard. Hold [applicator] [tube] upright away from face and body of person and dog and use scissors to cut secure seal applicator tip.]
3. Position the tip of the [applicator] [tube] on the dog's back between the shoulder blades. Apply ½ of the contents of the tube and proceed with step 4.
4. Invert the [applicator] [tube] to an upright position. Position the tip of the [applicator] [tube] at the base of the tail and apply the remaining contents of the [applicator] [tube].
5. Do not reapply product for [30 days][one month] [4 weeks].

{Text within table represents optional dosage text in an alternate format – would be used in addition to above DFU}

IN TABLE FORMAT

DOG WEIGHT	SIZE	WHERE TO APPLY
7-15 lbs	0.022 fl oz (0.65 cc)	½ at neck, ½ at tail
16-30 lbs	0.034 fl oz (1 cc)	½ at neck, ½ at tail
31-60 lbs	0.068 fl oz (2 cc)	½ at neck, ½ at tail

APPLICATION LANGUAGE FOR DOGS AND PUPPIES OVER 60 LBS [LARGE]



1. Bend at perforation and tear off first month's [applicator] [tube].
2. [Hold [tube] [applicator] and bend area of plastic at perforation, tear off and discard. Hold [tube] [applicator] upright and snap tip back, away from face and body of person and dog.] { OR } [Hold [tube] [applicator] and bend numbered area of plastic at perforation, tear off and discard. Hold [tube] [applicator] upright away from face and body of person and dog and use scissors to cut secure seal [applicator][tube] tip.]
3. Position the tip of the [applicator] [tube] at the base of the dog's neck. Apply ⅓ of the contents of the [applicator][tube].
4. Invert the applicator to an upright position and move to the middle of the dog's back. Apply ½ of the remaining contents of the [applicator][tube].
5. Invert the [applicator][tube] to an upright position and move to the base of the dog's tail. Apply the remaining ⅓ of the contents of the [applicator] [tube].
6. Do not reapply product for [30 days][one month] [4 weeks].

{Text within table represents optional dosage text in an alternate format – would be used in addition to above DFU}

IN TABLE FORMAT

DOG WEIGHT	SIZE	WHERE TO APPLY
Greater than 60 lbs	0.101 fl oz (3 cc)	⅓ at neck, ⅓ at mid-back, ⅓ at tail

Note: DO NOT APPLY this product [or product name] to cats. This spot on product is intended for dogs only!

Although this product [or product name] is applied only between the shoulder blades and at the base of the tail [and in the middle of the back [over 60 lbs]], the dog's skin and hair oils carry the product over the entire body for protection against fleas, ticks, and flea eggs. This product [or product name] is most effective when used as part of a total flea and tick management program. Use other [Zodiac][Wellmark][Scratchex][Adams][Bio Spot] products registered for residential area control of these pests in conjunction with this treatment.

TREATMENT SCHEDULE			
Dosage: 1 [applicator] [tube] every [30 days][1 month][4 weeks] per dog			
Dog's Name	First Treatment Date	Second Treatment Date ([30 Days][1 month] [4 weeks] From 1 st)	Third Treatment Date ([30 Days] [1 month] [4 weeks] From 2 nd)

Reminder: I purchased RF9908 Spot On from: _____

NOTES: _____

{Treatment table can be expanded based on package size. [6 months]}

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. **Pesticide Storage:** Keep this product in its 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:** Do not reuse this container [empty applicator [tube]]. **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.

FIRST AID

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. • Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER: For additional information on this pesticide product (including human and veterinary concerns, medical emergencies or pesticide incidents), you may call [[1-800-950-4783] [1-800-234-2269] or a Poison Control Center], twenty-four [24] hours per day, seven [7] days per week.	

{First Aid statement paragraph format may be used if space is limited}

PRECAUTIONARY STATEMENTS

CAUTION

HAZARDS TO HUMANS: Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before use.

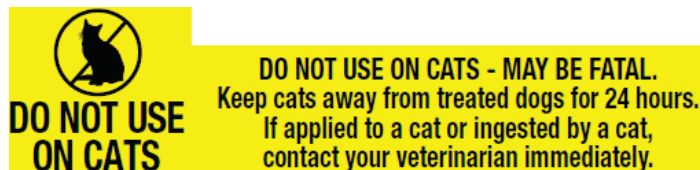
HAZARDS TO DOMESTIC ANIMALS: Do not use on dogs or puppies less than 6 months of age or weighing less than [7] [16], [31], [60] {as appropriate for package size} lbs. For external use ONLY on dogs and puppies. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing dogs. Sensitivities may occur after using ANY pesticide product for dogs. If signs of sensitivity occur, bathe your dog/puppy with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian IMMEDIATELY. In the event of an emergency, contact [1-800-950-4783][800-234-2269].

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.

{The Side Effects will appear in a box on the Back panel immediately above the cat warning box}

Side Effects: Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or [Brand] at [1-800-950-4783][800-234-2269].



{A minimum of 1.5cm x 1.5cm cat prohibition icon will be in a box immediately below the Side Effects box in the lower right hand corner of the back panel in yellow with black images cat circled and line through it}

[Manufactured for]
Wellmark International
1501 East Woodfield Road Suite 200W
Schaumburg, Illinois 60173
[Web site URL]
Made in USA

Questions? Call [[1-800-950-4783][800-234-2269]] Monday through Friday, [time]
[In case of emergency or for product use information, call [1-800-950-4783][800-234-2269]] or
visit our Web site: [URL]

{TEXT FOR [TUBE][APPLICATOR]}

[Product Name]

Permethrin 45%, S-methoprene 3%

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ ENTIRE LABEL BEFORE USING

EPA Reg No. 2724-497

Net Contents:

0.022 fl oz [.65 ml] [applicator][tube] [dogs 7-15 lbs]

0.034 fl oz [1 ml] [applicator][tube] [dogs 16-30 lbs]

0.068 fl oz [2 ml] [applicator][tube] [dogs 31-60 lbs]

0.101 fl oz [3 ml] [applicator][tube] [dogs >60 lbs]



**DO NOT USE
ON CATS**

For Use Only on Dogs/Puppies 7-15 lbs [puppies, toys, & miniatures]/16-30 lbs [small dogs]/31-60 lbs [medium dogs]/over 60 lbs [large dogs] & 6 Months of Age or Older

{Multiple package sizes}

Lot Number

Alternate Brand Names: ZODIAC® Groomers' Spot ON® Pack for Dogs
ZODIAC® Spot On® Flea & Tick Control for Small Dogs 16-30 lbs.
ZODIAC® Spot On® Flea & Tick Control for Medium Dogs 31-60 lbs.
ZODIAC® Spot On® Flea & Tick Control for Large Dogs Over 60 lbs.
ZODIAC® Spot On® Flea & Tick Control for Puppies, Toys & Miniature Dogs 7-15 lbs.

Topical Flea and Tick Treatment only for Dogs and Puppies 7-15 lbs [puppies, toys, & miniatures]/
16-30 lbs [small dogs]/31-60 lbs [medium dogs]/over 60 lbs [large dogs] six months and older
Contains [With] [Precor®], [Vigren®], [Insect Growth Regulator [IGR]], or [FGR® (Flea Growth Regulator)]
Easy and Convenient to Use

3 [Number] Month Supply [1 [applicator][tube] = [1 month][30 day][4 week] treatment]
3 [Number] [1 month][30 day][4 week] Flea & Tick Treatment
Four [Number] [Monthly][30 day][4 week] Treatments
[Once a Month][30 day][4 week] Flea and Tick Treatment
[Once a month] [Monthly][30 day][4 week] Flea and Tick [Prevention] [Treatment] [Control]
[30 day] [1 month] [4 weeks] Flea and Tick [Prevention] [Treatment] [Control]
3 [Number] Months treatment
Month 1 Month 2 Month 3 Month [#]
[Number] Convenient, Pre-filled [Applicators][Tubes]

[Each [applicator][tube]] Kills and Repels Fleas, Flea Larvae, and Ticks for up to [30 days] [1 month] [4 weeks]
Kills flea eggs
Kills Fleas Before they Lay Eggs
Kills [and repels] fleas, flea larvae, ticks [for up to [30 days] [1 month] [4 weeks]]
Kills Brown Dog Ticks, for up to [30 days] [1 month] [4 weeks]
Kills [fleas][and] [ticks] [by][through] contact
Protects against fleas and ticks]

[Contains Insect Growth Regulator [IGR] to kill flea eggs]
[Contains Insect Growth Regulator [IGR] to prevent reinfestation of fleas on your dog]
[Contains Insect Growth Regulator [IGR] to kill flea eggs and prevent reinfestation of fleas on your dog]
Prevents reinfestation of fleas on your dog
Prevents Flea Eggs from Developing into Biting Adults for up to [30 days] [1 month] [4 weeks]

This product [or product name] prevents eggs from developing into adult fleas for up to [30 days] [1 month] [4 weeks]
This product [or product name] also kills and repels ticks for up to [30 days] [1 month] [4 weeks]

Unique [applicator][tube] design [shape] helps prevent misapplication
Helps prevent misapplication with unique [applicator][tube]
Sold in sets of 3 [applicators][tubes], 1 [applicator][tube]/[month][30 days][4 weeks] for 3 months
Longer [applicator][tube] tip for easy application to long-haired dogs
Accu-Tip Dispenser
Pet Specifix™ [Applicator][tube]/EZ-Squeeze [Applicator][tube]