

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

2724-49	7
2/2 1- 7/	/

EPA Reg. Number:

Date of Issuance:

8/12/22

X Registration
Reregistration

(under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product:

RF9908 Spot On for Dogs

Name and Address of Registrant (include ZIP Code):

Noelle S. Sanfilippo Regulatory Affairs Specialist Central Garden & Pet Company 1501 E. Woodfield Road, Suite 200W Schaumburg, IL 60173

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:	Date:
Elberal Falul	8/12/22
Elizabeth Fertich, Product Manager 04	
Invertebrate & Vertebrate Branch 1	
Registration Division (7505P)	
Office of Pesticide Programs	

Page 2 of 3 EPA Reg. No. 2724-497 Decision No. 576770; 571948

- 2. Consistent with the guidance on Pet Spot-On Enhanced Reporting Implementation (updated Aug. 2019), the Agency has reviewed your request to remove the two-year registration expiration date and has found your company to be in compliance with the terms and conditions for the subject product. Further, the Agency has reviewed a sample of enhanced reporting using EPA's standardized templates, as described in Condition 3. hereafter, and concluded that the use of the standardized templates for enhanced reporting for this product will considerably improve pharmacovigilance and thus the continued safety of this product. Therefore, the Agency is removing the two-year registration expiration date for this product. The product remains subject to all other previously required conditions of registration, including the submission of enhanced incident reports and sales information as stated in the amendment letter dated 10/31/12 and amended below to require continued use of the standardized templates.
- 3. The Agency has reviewed your request to change the terms of your registration from quarterly to annual submission of enhanced incident and sales reports using EPA's standardized templates. Based on an initial screening of sample enhanced reports, the sample submission was determined to be adequate and the templates were successfully used. Therefore, the condition of quarterly submission of enhanced incident and sales reports is hereby amended to annual submission with continued use of these standardized templates. You must submit enhanced incident and sales reports for this product to the Agency every 12 months from the date the product is first released for shipment, or from the end date in the last quarterly enhanced reporting submission. The initial released-for-shipment date must be provided to the Product Manager, once known. The enhanced reporting submission should be addressed to the Product Manager's attention and must use the standardized, electronic templates available on the EPA website through the following links: Enhanced Incident Reporting Template, Sales Reporting Template. Submissions must be received by the Agency no later than 60 days following the completion of the 12-month period. If the product is not marketed or sold, you must submit to the Product Manager a letter to this effect every 12 months in lieu of the enhanced incident and sales reports. Please follow appropriate procedures and flag any Confidential Business Information as such.
- 4. You are required to comply with the data requirements described in the DCI identified below:
 - a. Permethrin GDCI-109701-1113

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1

5. Submit one copy of the final printed label for the record before you release the product for shipment.

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

Page 3 of 3 EPA Reg. No. 2724-497 Decision No. 576770; 571948

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.

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of 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.

If you fail to satisfy these terms and conditions, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 08/28/2018
- Alternate CSF 1 dated 08/28/2018
- Alternate CSF 2 dated 08/28/2018
- Alternate CSF 3 dated 08/28/2018

If you have any questions, you may contact Robert Mitchell at 202-566-2842 or via email at mitchell.robert@epa.gov.

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

ACCEPTED

08/12/2022

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2004 400

2724-497

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 and puppies 7-15 lbs]Total 0.102 fl oz [3 ml] 3-0.034 fl oz (1 ml) [applicators][tubes] [dogs and puppies 16-30 lbs]Total 0.204 fl oz [6 ml] 3-0.068 fl oz (2 ml) [applicators][tubes] [dogs and puppies 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. For indoor use only. Application of product on pets must only be done indoors.

{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]

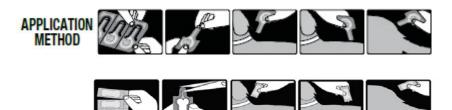
- at the base of the tail and apply the remaining contents of the [applicator] [tube].
- 5. Do not reapply product for [30 days][one month] [4 weeks].

{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	1/2 at neck, 1/2 at tail
	(0.65 cc)	
16-30 lbs	0.034 fl oz	½ at neck, ½ at tail
	(1 cc)	
31-60 lbs	0.068 fl oz	1/2 at neck, 1/2 at tail
	(2 cc)	

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 % 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	⅓ at neck, ⅓ at mid-back, ⅓ at tail
	(3 cc)	

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.

Dos	· · · · - ·	ATMENT SCHEDULE e] every [30 days][1 month][4	l 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:			

{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 local disposal options. Do not dispose of down the drain or sewer.

FIRST AID

If on Skin or Clothing:	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].



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.

{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
[www.zodiacpet.com][adamsfleacontrol.com]
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: [www.zodiacpet.com][adamsfleacontrol.com]

{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 and puppies 7-15 lbs] 0.034 fl oz [1 ml] [applicator][tube] [dogs and puppies 16-30 lbs] 0.068 fl oz [2 ml] [applicator][tube] [dogs and puppies 31-60 lbs] 0.101 fl oz [3 ml] [applicator][tube] [dogs >60 lbs]



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]