

# OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

September 5, 2025

Noelle Sanfilippo Regulatory Affairs Specialist Central Garden & Pet Company 1501 East Woodfield Road, 200W Schaumburg, Illinois 60173

Subject: Label Amendment - Registration Review Mitigation for Permethrin and (S)-

Methoprene

Product Name: RF9908 Spot On II for Dogs

EPA Registration Number: 89459-80

Case Number: 474531 Application Date: 3/9/2021

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 and (S)-Methoprene Interim Decisions, 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 and must be used at your next label printing. You must

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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 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 Alex McKee by phone at 202-566-1939, or via email at <a href="mailto:mckee.alex@epa.gov">mckee.alex@epa.gov</a>.

Sincerely,

Dana L. Friedman, Chief

Risk Management and Implementation Branch 1

Pesticide Re-Evaluation Division

Dana & Friedman

Office of Pesticide Programs

U.S. Environmental Protection Agency

**ENCLOSURE: Stamped label** 

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

Sep 05, 2025

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 89459-80

# RF9908 Spot On II for Dogs

Alternate brand name: Zodiac® Groomers' Spot On® Pack for Dogs



{A large, clear picture of a dog in the weight range for the product as packaged will be included in the final printed label.}

{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 weighing 7-17 lbs [puppies, toys, & miniatures]/18-35 lbs [small dogs]/36-55 lbs [medium dogs]/over 55 lbs [large dogs] & 6 Months of Age or Older

{Front Panel}

# **ACTIVE INGREDIENTS:**

| Permethrin [CAS #52645-53-1]     |       | 45%  |
|----------------------------------|-------|------|
| (S)-Methoprene [CAS #65733-16-6] |       | 3%   |
| OTHER INGREDIENTS:               |       | 52%  |
|                                  | Total | 100% |

# KEEP OUT OF REACH OF CHILDREN CAUTION

See back panel for First Aid and additional precautionary statements

Net Contents: 3–0.022 fl oz (0.65 mL) [applicators][tubes] (dogs 7-17 lbs)

3-0.044 fl oz (1.3 mL) [applicators][tubes] (dogs 18-35 lbs) 3-0.066 fl oz (1.95 mL) [applicators][tubes] (dogs 36-55 lbs) 3-0.110 fl oz (3.25 mL) [applicators][tubes] (dogs >55 lbs)

EPA Reg. No. 89459-80 EPA Est. No. 2724-TX-1 {Lower right, Front panel}



{A 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.}

{Back Panel}

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS OR PUPPIES 6 MONTHS OF AGE OR OLDER AND WEIGHING [7-17 LBS][18-35 LBS.][36-55 LBS.][>55 LBS.]. DO NOT USE ON CATS!

#### PRECAUTIONARY STATEMENTS

# HAZARDS TO HUMANS & DOMESTIC ANIMALS - CAUTION:

**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 reuse.

## **Domestic Animals:**

## DO NOT USE ON CATS!

May be toxic and potentially fatal if applied to or ingested by cats. Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided.

Do not use on puppies less than six months of age or weighing less than [7][18][36][55] pounds. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. 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.

# **FIRST AID**

| FIRST AID               |  |  |  |
|-------------------------|--|--|--|
| If on Skin or Clothing: | Take off contaminated clothing.  |  |  |
|                         | <ul> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul> |  |  |
|                         | • [Call a poison control center or doctor for treatment advice.] (if space         |  |  |
|                         | available)   |  |  |
|                         |  |  |  |

**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 [1-800-766-7661/1-800-234-2269 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}

### PHYSICAL OR CHEMICAL HAZARDS

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

**DIRECTIONS FOR USE**: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

{Use of either tube or applicator is optional but must be consistent throughout the label}

USE RESTRICTIONS: Do not apply to dogs/puppies weighing less than [7 lbs][18 lbs.][36 lbs.][55 lbs] Do not use more than one [applicator][tube] per dog/puppy regardless of the dog's weight. {not required for groomers pack}. For indoor use only. Application of product on pets must only be done indoors. Do not retreat more than once per month. Do not allow your dog/puppy to ingest this product.

Do not allow to enter indoor or outdoor drains. (No permita la entrada a desagües internos o externos.) Follow proper disposal procedures on this label. (Siga las indicaciones del etiquetado para el desecho apropiado del producto.)



{Back Panel}

{Graphics for Each Step (see below)}

# APPLICATION METHOD









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

# {APPLICATION LANGUAGE FOR DOGS AND PUPPIES 7-17 LBS [PUPPIES, TOYS & MINIATURES] AND 18-35 LBS [SMALL]}

- 1. Bend at perforation and tear off first month's [applicator] [tube].
- 2. {4 alternate statements}

[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.]

[Hold [applicator] [tube] and bend numbered area of plastic at perforation, tear off and discard. ]

[Hold applicator [tube] upright away from face and body, and use scissors to cut secure seal [applicator] [tube] 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 and 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][1 month][4 weeks].

Note: DO NOT APPLY [this product] [or product name] to cats. For use only on dogs.

# IN TABLE FORMAT

| IN IADEL I ONWAT |             |                      |
|------------------|-------------|----------------------|
| DOG WEIGHT       | SIZE        | WHERE TO APPLY       |
| 7-17 lbs         | 0.022 fl oz | ½ at neck, ½ at tail |
|                  | (0.65 mL)   |                      |

| DOG WEIGHT | SIZE        | WHERE TO APPLY           |
|------------|-------------|--------------------------|
| 18-35 lbs  | 0.044 fl oz | 1/2 at neck, 1/2 at tail |
|            | (1.3 mL)    |                          |

# {APPLICATION LANGUAGE FOR MEDIUM DOGS, 36-55 LBS AND LARGE DOGS, OVER 55 LBS}













- 1. Bend at perforation and tear off first month's [applicator] [tube].
- 2. {4 alternate statements}

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. 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, 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] [tube] 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 ½ of the contents of the [applicator] [tube].
- 6. Do not reapply product for [30 days][1 month][4 weeks].

### IN TABLE FORMAT

| DOG WEIGHT | SIZE | WHERE TO APPLY |
|------------|------|----------------|

| 36-55 lbs.           | 0.066 fl oz<br>(1.95 mL) | ⅓ at neck, ⅓ at mid-back, ⅓ at tail |  |
|----------------------|--------------------------|-------------------------------------|--|
|                      | •                        |                                     |  |
| DOG WEIGHT           | SIZE                     | WHERE TO APPLY                      |  |
| Greater than 55 lbs. | 0.110 fl oz              | ⅓ at neck, ⅓ at mid-back, ⅓ at tail |  |
|                      | (2.25 ml.)               |                                     |  |

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 [(medium dogs [36-55 lbs])] [(large dogs [over 55 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][[Adams][Bio Spot] products registered for residential area control of these pests in conjunction with this treatment. [For additional control of fleas in and around the home, use [product names] Do not use more than one tube per treatment regardless of dog's weight.

| TREATMENT SCHEDULE Dosage: One [applicator] [tube] every [30 days][month][4 weeks] per dog/puppy |  |   |  |
|--|--|---|--|
| First<br>Treatment<br>Date   | Second Treatment Date<br>([30 Days][1<br>month][4 weeks]<br>From 1 <sup>st</sup> ) | Third Treatment Date<br>([30 Days][1<br>month][4 weeks]<br>From 2 <sup>nd</sup> ) | Fourth Treatment Date<br>([30 Days][1<br>month][4 weeks]<br>From 3 <sup>rd</sup> ) |
|  |  |   |  |

Reminder: I purchased RF9908 Spot On II from:

{Treatment table can be expanded based on package size. (6 months)}

# {ALTERNATE DIRECTIONS FOR USE LANGUAGE FOR DOGS OF ALL SIZES PROFESSIONAL/GROOMERS PACK ONLY}

{Alternate applicator sizes permissible as long as dosage/ratios are maintained the same.} Do not dose more than 1 treatment per application, regardless of dog's size. Net Contents: 48-0.65 mL [applicators][tubes]

- 1. Bend at perforation and tear off first month's [applicator][tube].
- 2. {4 alternate statements}
  - [Hold [applicator][tube] and bend numbered area of plastic at perforation, tear off and discard.] [Hold [applicator][tube] upright away from face and body, and use scissors to cut secure seal [applicator][tube] tip].
  - [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.]
- 3. Apply as directed in table.
- 4. Do not reapply product for [30 days][1 month][4 weeks].













| Application by Weight                            | # of 0.65 mL [Tubes<br>][applicators]                      | Where to Apply   |
|--|--|--|
| Dogs 7 - 17 pounds & 6<br>months of age or older | One [tube] [applicators] 0.022 floz (0.65 mL)              | ½ [tube] [applicator] at base of neck ½ [tube] [applicator] at base of tail    |
| Dogs 18 -35 pounds &6 months of age or older     | Two [tubes] [applicators]0.044<br>fl oz (1.3 mL total)     | 1[ tube] [applicator] at base of neck<br>1[ tube] [applicator] at base of tail |
| Dogs 36-55 pounds &6 months of age or older      | Three [tubes] [applicators]<br>0.066 fl oz (1.95 mL total) | 1[ tube] [applicator] at base of neck 1[ tube] [applicator] in middle of back  |

|                             |                             | 1[ tube] [applicator] at base of tail   |
|-----------------------------|-----------------------------|---|
| Dogs Greater than 55 pounds | Five[ tubes] (applicators)  | 5 [tubes] [applicators] Distribute in 5 |
| & 6 months of age or older  | 0.110 fl oz (3.25 mL total) | spots down the middle of the back.      |

## STORAGE AND 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**: **If Empty**: Do not reuse this container [empty [applicator][tube]]. 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.

Made in USA

Central Garden & Pet Company 1501 East Woodfield Road Suite 200W Schaumburg, Illinois 60173 (www.central.com)

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

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 1-800-950-4783/234-2269.

{A box labeled Side Effects will be immediately above the cat warning box on the back panel}

(Lower right, Back panel)



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 1.5cm x 1.5cm cat prohibition icon and warning text in a box will be located at the lower right hand corner of the back panel in yellow with black images and text.}

## **{TEXT FOR TUBE/APPLICATOR}**

Product Name
Permethrin 45%, S-methoprene 3%
KEEP OUT OF REACH OF CHILDREN
CAUTION

[READ DIRECTIONS BEFORE USING] (if space permits)

EPA Reg No. 89459-80

Net Contents: [0.022 fl. oz. (0.65 mL)][0.044 fl. oz. (1.3 mL)][0.066 fl. oz. (1.95 mL)][0.110 fl. oz. (3.25 mL)]



For Use Only on Dogs and Puppies 7-17 lbs [puppies, toys, & miniatures]/18-35 lbs [small dogs]/36-55 lbs [medium dogs]/over 55 lbs [large dogs] & 6 Months of Age or Older

# {Optional Marketing Claims}

ITopicall Flea and Tick Treatment only for Dogs and Puppies six months and older Contains [With] Precor®, Vigren®, [Insect Growth Regulator (IGR)], or FGR® (Flea Growth Regulator)

Easy and Convenient to Use

Quick drying formula

3 [Number] Month Supply [1 [applicator][tube] = 1 month treatment]

3 [Number] month Flea & Tick Treatment

[Number] Monthly Treatments

Once a Month Flea and Tick Treatment

[Once a month] [Monthly] Flea and Tick [Prevention] [Treatment] [Control]

[28 day] [30 day] [1 month] [4 weeks] Flea and Tick [Prevention] [Treatment] [Control]

3 [Number] Month 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][4 weeks][1 month]

Kills flea eggs Kills Fleas Before they Lay Eggs

Kills [and repels] fleas, flea larvae, ticks [for up to [30 days][4 weeks][1 month]]

Kills Brown Dog Ticks, for up to [30 days][4 weeks][1 month]

Kills [fleas][and] [ticks] [bv][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 dogl

Prevents reinfestation of fleas on your dog

Prevents Flea Eggs from Developing into Biting Adults for up to [30 Days][4 weeks][1month]

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

This product [or product name] also kills and repels ticks for up to [30 days] [4 weeks][ 1month].

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 for 3 months

Longer [applicator][tube] tip for easy application to long-haired dogs

Accu-Tip Dispenser

Pet Specifix <sup>™</sup> Applicator/EZ-Squeeze Applicator