

U.S. ENVIRONMENTAL PROTECTION AGENCY

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

NOTICE OF PESTICIDE:

X Registration
Reregistration
(under FIFRA, as amended)

EPA Reg. Number:

Date of Issuance:

89459-80

7/2/15

Term of Issuance:

Conditional, Time-Limited

Name of Pesticide Product:

RF9908 Spot On II for Dogs

Name and Address of Registrant (include ZIP Code):

Central Garden & Pet Company 1501 East Woodfield Road, Suite 200 West Schaumburg, IL 60173

ATTN: Veronica Semetis Lawless

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.

EPA Form 8570-6

- 2. This registration is time-limited and expires two years from the date this product is first released for shipment. You provided the Agency with a projected release for shipment date of September 1, 2015. Therefore, the expiration date for this registration is September 1, 2017.
- 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 dog 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.

- 5. You are required to comply with the data requirements described in the DCI identified below:
 - a. Permethrin GDCI-109701-1252
 - b. Permethrin GDCI-109701-1281

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://www.epa.gov/oppsrrd1/contacts_prd.htm

- 6. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 89459-80."
- 7. 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 of statements EPA may consider false or misleading. In addition, regardless of whether a website is

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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.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Only one basic confidential statement of formula will be on file for this product at any one time; no alternate formulations or minor formulation amendments will be submitted or approved for this product. Please note that the record for this product currently contains the following CSF:

• Basic CSF dated February 2, 2015

If you have any questions, please contact Julie Chao by phone at (703) 308-8735, or via email at chao.julie@epa.gov.

Jennifer Urbanski, Ph.D., Product Manager 04 Invertebrate & Vertebrate Branch 1 Registration Division (7505P)

Enclosure

RF9908 Spot On II 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 7-17 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

Topical 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 = 1 month treatment]

3 [Number] month Flea & Tick Treatment

Four [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

ACCEPTED

7/2/2015

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2017 200

89459-80

[Each applicator] Kills and Repels Fleas, Flea Larvae, and Ticks for up to 30 Days

Kills flea eggs

Kills Fleas Before they Lay Eggs

Kills [and repels] fleas, flea larvae, ticks [for up to 30 days]

Kills Brown Dog Ticks, for up to 30 days

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

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

Unique applicator design [shape] helps prevent misapplication

Helps prevent misapplication with unique applicator

Sold in sets of 3 applicators, 1 applicator/month for 3 months

Longer applicator tip for easy application to long-haired dogs

Accu-Tip Dispenser

Pet Specifix[™] Applicator/EZ-Squeeze Applicator

(Front Panel)

ACTIVE INGREDIENTS:

Permethrin	[CAS #52645-53-1]	1]	45%
(S)-Methopre	ene [CAS #65733-	3-16-6]	3%

OTHER INGREDIENTS:		<u>52%</u>
	Total	100%

KEEP OUT OF REACH OF CHILDREN CAUTION

See back panel for additional precautionary statements

Net Contents: 3–0.022 fl oz (.65 ml) applicators (dogs 7-17 lbs)

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

EPA Reg. No. 89459-xxx EPA Est. No. 2724-TX-1 (Lower right, Front panel)



(Minimum size 1.5 cm X 1.5 cm)

(back panel)

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS OR PUPPIES 6 MONTHS OF AGE OR OLDER. 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 use.

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. 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

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.] (if space available) 	
HOT I WE MUMBED . E		

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 RESTRICTIONS: Do not apply to dogs/puppies weighing less than 7 lbs (for smallest size dog package only). Do not use more than one tube per dog/puppy [not required for groomers pack]. Do not retreat more than once per month. Do not allow your dog/puppy to ingest this product.

(back panel)

[Graphics for Each Step] (see below)

APPLICATION METHOD









[Alternate applicator 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. 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] 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.

Note: DO NOT APPLY this product [or product name] to cats. These flea drops are intended for dogs only!

IN TABLE FORMAT

DOG WEIGHT	SIZE	WHERE TO APPLY
7-17 lbs	0.022 fl oz	½ at neck, ½ at tail
	(0.65 cc)	

DOG WEIGHT	SIZE	WHERE TO APPLY
18-35 lbs	0.044 fl oz	½ at neck, ½ at tail
	(1.3 cc)	

[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. 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 tip.
- 3. Position the tip of the applicator [tube] at the base of the dog's neck. Apply $\frac{1}{3}$ 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 $\frac{1}{3}$ of the contents of the applicator [tube].
- 6. Do not reapply product for 30 days.

IN TABLE FORMAT

DOG WEIGHT	SIZE	WHERE TO APPLY
36-55 lbs.	0.066 fl oz	⅓ at neck, ⅓ at mid-back, ⅓ at tail
	(1.95 cc)	

DOG WEIGHT	SIZE	WHERE TO APPLY
Greater than 55 lbs.	0.110 fl oz	1/₃ at neck, 1/₃ at mid-back, 1/₃ at tail
	(3.25 cc)	

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] and 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][Scratchex][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 double dose dogs larger than 55 lbs."

TREATMENT SCHEDULE Dosage: One applicator [tube] every 30 days per dog/puppy			
First	Second Treatment Date	Third Treatment Date	Fourth Treatment Date
Treatment	(30 Days From	(30 Days From	(30 Days From
Date	1 st)	2 nd)	3 rd)

Reminder: I purchased RF9908 Spot On II from:

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

[ALTERNATE LANGUAGE FOR DOGS OF ALL SIZES] [PROFESSIONAL/GROOMERS PACK]

[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same.] "Do NOT double dose dogs larger than 55 lbs."

Net Contents: 48- 0.65cc applicators

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













MONTHLY [product name] APPLICATION

Application by Weight	# of 0.65cc Tubes	Where to Apply
	[applicators]	,
Dogs 7 - 17 pounds	One tube [applicators] 0.022	½ tube [applicator] at base of neck
	fl oz (0.65 cc)	½ tube [applicator] at base of tail
Dogs 18 -35 pounds	Two tubes [applicators]0.044	1 tube [applicator] at base of neck
	fl oz (1.3 cc total)	1 tube [applicator] at base of tail
Dogs 36-55 pounds	Three tubes [applicators]	1 tube [applicator] at base of neck
	0.066 fl oz (1.95 cc total)	1 tube [applicator] in middle of back
		1 tube [applicator] at base of tail
Dogs Greater than 55	Five tubes (applicators)	5 tubes [applicators] Distribute in 5
pounds	0.110 fl oz (3.25 cc 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 disposal instructions. Never place unused product down any indoor or outdoor drain.

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.

(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.

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-xx
Net Contents:



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