

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 19, 2015

Nancy Huebl Sr. Registration Specialist Central Garden & Pet Company 1501 E. Woodfield Rd., Suite 200W Schaumburg, IL 60173

Subject: Notification per PRN 98-10 – Alternate Brand Name

Product Name: RF9908 Spot On II for Dogs

EPA Registration Number: 89459-80

Application Date: 7/27/2015 Decision Number: 507460

Dear Ms. Huebl:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The alternate brand name Zodiac® Groomers' Spot On® Pack for Dogs has been added to the product record.

If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

Kable Bo Davis, Product Manager 3 Invertebrate and Vertebrate Branch 1 Registration Division (7505P)

Office of Pesticide Programs

# **RF9908 Spot On II for Dogs**

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

NOTIFICATION

89459-80

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

08/19/2015

[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]		45%
(S)-Methoprene [CAS #65733-16-6]		3%
OTHER INGREDIENTS:		52%
	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-xxx80 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 LINE NUMBER. For additional information on this posticide product (including human and vatorings)		

**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 ½ 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 (1.95 cc)	1/₃ at neck, 1/₃ at mid-back, 1/₃ at tail
	(1.95 00)	

WHERE TO APPLY
z ⅓ at neck, ⅓ at mid-back, ⅓ at tail
0

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 <sup>st</sup> )	2 <sup>nd</sup> )	3 <sup>rd</sup> )

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-xx80
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