

U.S. ENVIRONMENTAL PROTECTION AGENCY

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

2724-497

Date of Issuance:

2/23/17

NOTICE OF PESTICIDE:

X Registration Reregistration

(under FIFRA, as amended)

Term of Issuance:

EPA Reg. Number:

Conditional, Time-Limited

Expires: 02/23/2019

Name of Pesticide Product:

RF9908 Spot On for Dogs

Name and Address of Registrant (include ZIP Code):

Veronica Semetis Lawless Regulatory Affairs Specialist Wellmark International 1501 E Woodfield Rd, Suite 200 West 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:	
Sincerely,	Date:
Sincerely,	2/23/17
Gene Benbow, Acting Product Manager 4	
Invertebrate & Vertebrate Branch 1	
Registration Division (7505P)	
Office of Pesticide Programs	

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EPA Form 8570-6

- 2. The Agency has found your company to be in compliance with the terms and conditions for the subject product, and is extending the two-year registration restriction. This registration is time-limited and expires 02/23/2019.
- 3. Please note that the product is still subject to all other previously required conditions of registration. Your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information as stated in *an Agency letter dated 09/30/2011*.
- 4. You are required to comply with the data requirements described in the DCIs identified below:
 - a. Permethrin GDCI-109701-1252

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCIs listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-pesticide-re-evaluation-division

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 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.

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.

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

• Basic CSF dated 02/24/2011

If you have any questions, please contact Tim Ciarlo by phone at 703-347-8082, or via email at Ciarlo.Timothy@epa.gov.

ACCEPTED

02/23/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 2724-497

RF9908 SPOT ON FOR DOGS

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.

(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

(Representative picture of Dog)

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

[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:		
	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 7-15 lbs) 3-0.034 fl oz (1 ml) applicators (dogs 16-30 lbs) 3-0.068 fl oz (2 ml) applicators (dogs 31-60 lbs) 3-0.101 fl oz (3 ml) applicators (dogs >60 lbs)

EPA Reg. No. 2724-497 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. 		
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 near 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 and 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 LANGUAGE FOR DOGS AND PUPPIES 7-15 LBS [PUPPIES, TOYS & MINIATURES], 16-30 LBS [SMALL], AND 31-60 LBS [MEDIUM]

APPLICATION METHOD









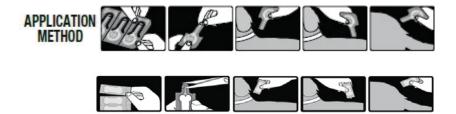


[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same.

- 1. Bend at perforation and tear off first month's applicator.
- 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.

IN TABLE FORMAT

IN TABLE I OKWAT			
DOG WEIGHT	SIZE	WHERE TO APPLY	
7-15 lbs	0.022 fl oz	½ at neck, ½ 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	½ at neck, ½ at tail	
	(2 cc)		



- 1. Bend at perforation and tear off first month's applicator.
- 2. Hold applicator and bend area of plastic at perforation, tear off and discard. Hold applicator upright and snap tip back, away from face and body of <u>person and dog</u>. OR Hold applicator and bend numbered area of plastic at perforation, tear off and discard. Hold applicator upright away from face and body of <u>person and dog</u>, and use scissors to cut secure seal applicator tip.
- 3. Position the tip of the applicator at the base of the dog's neck. Apply ♦ of the contents of the applicator.
- 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.
- 5. Invert the applicator to an upright position and move to the base of the dog's tail. Apply the remaining � of the contents of the applicator.
- 6. Do not reapply product for 30 days.

IN TABLE FORMAT

DOG WEIGHT	SIZE	WHERE TO APPLY
Greater than 60 lbs.	0.101 fl oz	1/3 at neck, 1/3 at mid-back, 1/3
	(3 cc)	at tail

Note: DO NOT APPLY this product [or product name] to cats. These flea drops are 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. [For additional control of fleas in and around the home, use [product names]

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

Reminder:	I purchased RF9908 Spot On from:	
NOTEC:		

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**: **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

Wellmark International 1501 East Woodfield Road Suite 200W Schaumburg, Illinois 60173 [Web site URL]

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: (URL)

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. 2724-497
Net Contents:



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