



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 11, 2015

Veronica Semetis Lawless  
Regulatory Affairs Specialist  
Wellmark International  
1501 East Woodfield Rd., Suite 200 West  
Schaumburg, IL 60173

Subject: PRIA Label Amendment – Addition of public health pest claims in addition to general label revisions.  
Product Name: RF9908 SPOT ON FOR DOGS  
EPA Registration Number: 2724-497  
Application Date: January 23, 2015  
Decision Number: 499382

Dear Ms. Lawless:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must 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 18 months from the date of this letter. After 18 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.

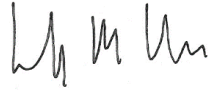
Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded 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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, please contact Jennifer Gaines at 703-305-5967 or via email at [gaines.jennifer@epa.gov](mailto:gaines.jennifer@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read 'Jennifer Urbanski', with a stylized flourish at the end.

Jennifer Urbanski, PhD, Product Manager 4  
Invertebrate and Vertebrate Branch 1 (IVB1)  
Registration Division (7505P)  
Office of Pesticide Programs

Enclosure

**ACCEPTED**

06/11/2015

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**

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 Specific™ 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 7-15 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**

<b>If on Skin or Clothing:</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>HOT LINE NUMBER:</b> 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.]

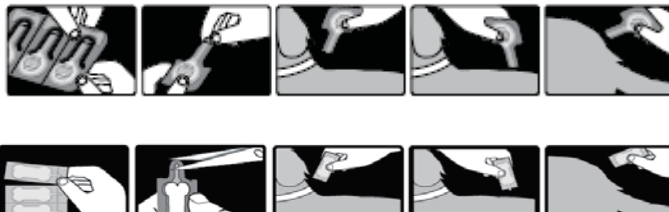
1. Bend at perforation and tear off first month's applicator.
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard]. [Hold applicator] [tube] upright and snap tip back, away from face and body of person and dog. **OR** Hold applicator [tube] and bend numbered area of 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**

DOG WEIGHT	SIZE	WHERE TO APPLY
7-15 lbs	0.022 fl oz (0.65 cc)	½ at neck, ½ at tail
16-30 lbs	0.034 fl oz (1 cc)	½ at neck, ½ at tail
31-60 lbs.	0.068 fl oz (2 cc)	½ at neck, ½ at tail

**APPLICATION LANGUAGE FOR DOGS AND PUPPIES OVER 60 LBS [LARGE]**

**APPLICATION METHOD**



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 person and dog. OR Hold applicator and bend numbered area of plastic at perforation, tear off and discard. Hold applicator 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 at the base of the dog's neck. Apply  $\frac{1}{3}$  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  $\frac{1}{2}$  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  $\frac{1}{3}$  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 (3 cc)	1/3 at neck, 1/3 at mid-back, 1/3 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 1 <sup>st</sup> )	Third Treatment Date (30 Days From 2 <sup>nd</sup> )

Reminder: I purchased RF9908 Spot On from: \_\_\_\_\_

NOTES: \_\_\_\_\_

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