

2724-497

9/2/2014

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

September 2, 2014

Ms. Nancy Huebl  
Senior Registration Specialist  
Wellmark International  
1501 East Woodfield Road, Suite 200 West  
Schaumburg, IL 60173-5417

**Subject: Acceptance of Master Labeling Submitted for Implementation of Pet Spot-On Mitigation**

**Product Name: RF9908 SPOT ON**  
**EPA Registration Number: 2724-497**  
**Application Date: April 17, 2014**  
**Decision Number: 494642**

Dear Ms. Huebl:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with the following label revision provision(s):

Amendments to Dog Spot-On Product Registrations:

1. **This registration is now time-limited, and will expire 2 years from the date of this letter. More specifically, this registration will expire on September 2, 2016.**
2. If the Agency determines that future mitigation measures are necessary for all pet spot-on products, EPA will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.
3. Please consider limiting the formulations of this product to one basic confidential statement of formula. The Agency may require this in the future. In addition, it is possible that no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
4. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning October 1, 2014. Please flag any Confidential Business Information as such. Enhanced incident reporting and quarterly sales information should be submitted to the Product Manager. 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.

Conditions of Acceptance/Amendments to Dog Spot-On Product Registrations, continued:

- 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 pre-condition.
- EPA Severity Code: Death, major, moderate, minor.
- Outcome: Died, recovered, still treated, unknown.

5. 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.
- Summary 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.
- 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.
- Table showing number of incidents for each cat breed.
- 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.

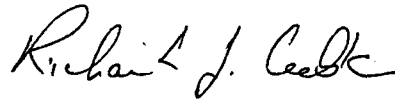
Should you wish to add/retain a reference to the company's website, smart phone/tablet app and/or a QR code reader on your product label, please be aware that the website, smart phone/tablet app and/or a QR code reader becomes labeling under FIFRA and is subject to review by the Agency. If the website, smart phone/tablet app, and/or a QR code reader is false or misleading, the product would be misbranded and unlawful to sell or distribute under section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website, smart phone/tablet app, and/or a QR code reader is referenced on a product's label, claims made on the website, smart phone/tablet app, and/or a QR code reader may not be 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, smart phone/tablet app, and/or a QR code reader contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website, smart phone/tablet app, and/or a QR code reader will be referred to EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

Copies of your updated master label stamped "Accepted" and the review for minimum weight treated are 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.

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Please note that this letter does not supersede anything contained within the Agency's letter dated September 30, 2011 and the original conditions of acceptance detailed in the Agency's letter dated January 30, 2004. The conclusion date for the subject time-limited product registration is September 2, 2016. If you have any questions about this label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at [Rodia.Carmen@epa.gov](mailto:Rodia.Carmen@epa.gov) or Mr. Richard J. Gebken at (703) 305-6701 or via e-mail at [Gebken.Richard@epa.gov](mailto:Gebken.Richard@epa.gov) during the hours of 9:00 A.M. to 5:30 P.M. EST.

Sincerely,



Richard Gebken  
Product Manager 10  
Insecticide Branch  
Office of Pesticide Programs  
Date: September 2, 2014

Enclosures: *Updated Master Label Stamped "Accepted," dated September 2, 2014*  
*Review for Minimum Weight Treated, dated August 27, 2012*

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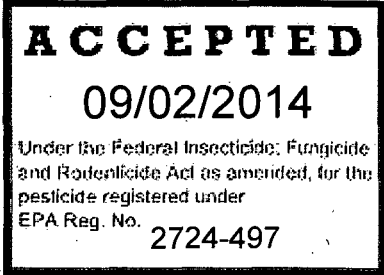
# RF9908 SPOT ON

Alternate Brand Names: ZODIAC® Groomers' Spot ON® Pack  
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)  
Prevents Flea Eggs from Developing into Biting Adults for up to 30 Days [3 Months]  
[Each applicator] Kills and Repels Fleas, Ticks and Mosquitoes for up to 30 Days  
Kills Fleas Before they Lay Eggs  
[Contains Insect Growth Regulator (IGR) to kill flea eggs]  
[Contains Insect Growth Regulator (IGR) to prevent reinfestation of fleas on your pet]  
[Contains Insect Growth Regulator (IGR) to kill flea eggs and prevent reinfestation of fleas on your pet]  
Kills flea eggs  
Prevents reinfestation of fleas on your pet  
[Number] Convenient, Pre-filled Applicators  
Easy and Convenient to Use  
3 [Number] Month Supply [1 applicator = 1 month treatment]  
3 [Number] month Flea & Tick Treatment  
Four [Number] Monthly Treatments  
Once a Month Flea, Tick and Mosquito Treatment.  
3 [Number] Month treatment  
Month 1 Month 2 Month 3 Month [#]  
Unique applicator design [shape] helps prevent misapplication on cats  
Helps prevent misapplication on cats with unique applicator  
Longer applicator tip for easy application to long-haired dogs  
Accu-Tip Dispenser  
Pet Specifix™ Applicator/EZ-Squeeze Applicator



<b>ACTIVE INGREDIENTS:</b>	
Permethrin [CAS #52645-53-1].....	45%
(S)-Methoprene [CAS #65733-16-6].....	3%
<b>OTHER INGREDIENTS:</b> .....	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)  
[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples\*]

EPA Reg. No. 2724-497  
EPA Est. No. 2724-TX-1



(Minimum size 1.5 cm X 1.5 cm)

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(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.] (if space available)</li> </ul>
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**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.

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)

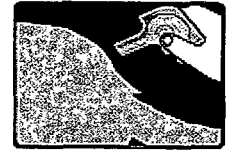
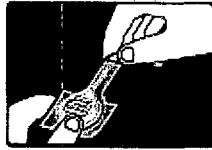
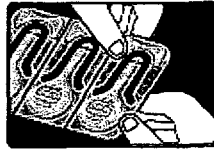
**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

This product [or product name] prevents eggs from developing into adult fleas for up to 30 days [3 months]. This product [or product name] also kills and repels ticks and mosquitoes for up to 30 days.

**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.

[Graphics for Each Step] (see below)

## APPLICATION METHOD



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## APPLICATION METHOD



[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples\*]

Remove pre-filled applicator(s) from package and hold in an upright position.

1. Gently press cap to break the seal of the applicator. [Simply twist cap to break the seal of the applicator.] Open applicator by carefully cutting the top of the tube.
2. [Carefully remove the cap.] Position the tip of the applicator on the dog's back between the shoulder blades. Apply half of the contents of the tube (0.5 cc) and proceed with steps 3 and 4.
3. Invert the applicator to an upright position and move to the dog's hindquarters. Position the tip of the applicator at the base of the tail and apply the remaining contents of the tube (0.5 cc).
4. Do not reapply product for 30 days.

[Alternate Packaging Directions 1][Application Method]

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

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.

[Alternate Packaging Directions 2]

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

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.

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]

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**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]. 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.

Copy: \_\_\_\_\_  
Product Code: \_\_\_\_\_  
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.



**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

[Alternate Language for dogs Over 60 lbs][W]

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

4 Month Supply [1 applicator = 1 month treatment]

Net Contents: 4 – 3 cc applicators

1. Remove pre-filled applicator(s) from package and hold in an upright position.
2. [Gently press cap to break the seal of the applicator.][Simply twist cap to break the seal of the applicator.] Open applicator by carefully cutting the top of the tube.
3. Position the tip of the applicator at the base of the dog's neck. Apply 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 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 1/3 of the contents of the applicator.
6. Do not reapply product for 30 days.

[Alternate Packaging Directions 1]

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.
3. Hold applicator upright and snap tip back, away from face and body.

[Alternate Packaging Directions 2]

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

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.

[Alternate Language for dogs of all sizes][W]

[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples\*]

Net Contents: 50 - 1 cc applicators

1. Remove pre-filled applicator(s) from package and hold in an upright position.
2. [Gently press cap to break the seal of the applicator.][Simply twist cap to break the seal of the applicator.] Open applicator by carefully cutting the top of the tube. [Carefully remove the cap.]
3. Apply as directed below.
4. Do not reapply product for 30 days.

[Alternate Packaging Directions 1]

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

Hold applicator upright and snap tip back, away from face and body.

[Alternate Packaging Directions 2]

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

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.



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MONTHLY [product name] APPLICATION

Application by Weight	# of 1 cc Tubes [applicators]	Where to Apply
Dogs 16 - 29 pounds	One tube [applicator]	½ tube [applicator] at base of neck ½ tube [applicator] at base of tail
Dogs 30 to 59 pounds	Two tubes [applicator]	1 tube [applicator] at base of neck 1 tube [applicator] at base of tail
Dogs 60 pounds +	Three tubes [applicator]	1 tube [applicator] at base of neck 1 tube [applicator] in middle of back 1 tube [applicator] at base of tail

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

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
Greater than 60 lbs.	0.101 fl oz (3 cc)	1/3 at neck, 1/3 at mid-back, 1/3 at tail