

2724-497

08/26/2013

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 26, 2013

Ms. Nancy Huebl
Wellmark International
1501 E. Woodfield Rd, Suite 200W
Schaumburg, IL 60173

Subject: Label Notification(s) for Pesticide Registration Notice 98-10

Dear Ms. Huebl:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated May 22, 2013 for the following product(s):

RF9908 Spot-On

EPA Reg. No. 2724-497

The Registration Division (RD) has conducted a review of this request for applicability under PR Notice 98-10 and finds that the label change(s) requested falls within the scope of PRN 98-10. The label has been date-stamped "Notification" and will be placed in our records.

If you have any questions, please contact Linda A. DeLuise at 703-305-5428.

Sincerely,

A handwritten signature in black ink, appearing to read "R. J. Gebken".

Richard J. Gebken
Product Manager (PM10)
Insecticide Branch
Registration Division (7504P)



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-497	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/RF9908 Spot On	PM # 10	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1501 East Woodfield Road, Suite 200W Schaumburg, Illinois 60173 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical to a previously registered product and labeling to: NOTIFICATION EPA Reg. No. _____ Product Name _____ AUG 26 2013	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Label notification to add graphics (for already approved text) and small miscellaneous additions. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will be Packaged in:						2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		Water Soluble Packagin <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. 1-3 cc	No. per container 1-50	If "Yes" Unit Packaging wgt.	No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 1-3 cc, 1-50/container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product			
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input checked="" type="checkbox"/> Other outer printed cardboard carton			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Nancy Huebl	Title Senior Registration Specialist	Telephone No. (Include Area Code) 847-330-5376
2. Signature <i>Nancy Huebl</i>		3. Title Senior Registration Specialist
4. Typed Name Nancy Huebl		5. Date 22-May-13
<p>Certification</p> <p>I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.</p>		6. Date Application Received (Stamped)

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Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, Illinois 60173
847 330 5300
www.wellmarkinternational.com



May 22, 2013

Document Processing Desk (NOTIF)
Office of Pesticide Programs 7504P
U.S. Environmental Protection Agency
Room S-4900 One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: Richard Gebken, PM 10

SUBJECT: LABEL NOTIFICATION TO ADD GRAPHICS (FOR ALREADY APPROVED TEXT)
FOR RF9908 SPOT ON/EPA REG. NO. 2724-497

Dear Mr. Gebken:

Enclosed is completed EPA Form 8570-1 and 2 copies of highlighted revised labeling for the above product (red is new text, blue strikethrough is deleted text). This label change is submitted per PRN 98-10, §II, M, 2 which allows "graphics which present the same use directions already approved by EPA in narrative form" as a notification. Additionally, small specific additions were included (phone numbers, EPA Est No). If you have any questions please, call me directly at 847-330-5376. Thank you for your assistance in this matter.

Yours sincerely,
WELLMARK INTERNATIONAL

A handwritten signature in cursive script that reads "Nancy Huebl".

Nancy Huebl
Senior Registration Specialist
nhuebl@central.com

enclosure

cc: J. McFadden/C. Elmi/H. Friedli

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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, & Miniatures Under 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(s) Flea Eggs] [to][and] Prevent Reinfestation
 [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 Specific™ Applicator
 EZ-Squeeze Applicator

NOTIFICATION
AUG 26 2013

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)
 [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



**DO NOT USE
 ON CATS**

(Minimum size 1.5 cm X 1.5 cm)

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:	<ul style="list-style-type: none"> • 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)
<p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-950-4783 [1-800-766-7661/1-800-234-2269 or a Poison Control Center] for emergency medical treatment.</p>	

[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 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF9908 Spot On from: _____ NOTES: _____
Treatment table can be expanded based on package size. (6 months)

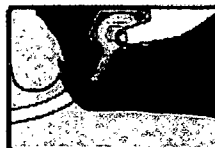
DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

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



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: Store in a cool, dry area in a location out of reach of children and pets.
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-~~xxx-xxx~~) Monday through Friday, [time]
[In case of emergency or for product use information, call (1-800-950-4783/234-2269 ~~phone number~~) 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 ~~phone number~~.



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

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[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 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 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