

2724-404

02-13-2004

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States Environmental Protection Agency Washington, DC 20460

Registration Amendment Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Name: Wellmark International 2724-404
2. EPA Product Manager: L. Arrington
3. Proposed Classification: [X] None [] Restricted
4. Company/Product Name: Wellmark International, Tracoon RF-322 Ovicidal Pump Spray (RF 9606)
5. Name and Address of Applicant/Registrant: Wellmark International, 1100 East Woodfield Road, Suite 500, Schaumburg, Illinois 60195
6. Expedited Review: [] In accordance with FIFRA Section 3(C)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name

Section - II

[] Amendment - Explain below
[] Resubmission in response to Agency letter dated
[X] Notification - Explain below
[] Final printed labels in response to Agency letter dated
[] "Me Too" Application
[] Other - Explain below

NOTIFICATION FEB 13 2004

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

Notification per PRN 98-10 (Changes in Packaging & Related Labeling Statements) to cover additional packaging size-gallon refill only for 1 pt spray bottle. 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.

Section - III

1. Material This Product Will be Packaged In: Child-Resistant Packaging, Unit Packaging, Water Soluble Packaging, 2. Type of Container: Plastic, 3. Location of Net Contents: Label, 4. Size(s) Retail Container: 8 oz, 16 oz, 1 gallon, 5. Location of Label Directions: On Label, 6. Manner in Which Label is Affixed to Product: Paper glued

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: Regulatory Specialist, Telephone No.: (847) 330-5376

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received

(Stamped)

2. Signature: Nancy Huebl, 3. Title: Regulatory Specialist, 4. Typed Name: Nancy Huebl, 5. Date: 26-Jan-04

[] Indicate optional statement

ZOECON® RF-322 OVICIDAL PUMP SPRAY

Alternate Brand Name: ZODIAC® PreStrike™ Mosquito Repellent for Dogs

EFFECTIVE

For dogs, puppies, cats, kittens, horses, ponies

[FOR 1 PT. BOTTLE] [A REFILL FOR 1 PT. [PRODUCT VALUE] [PER 4 BOTTLES] [FOR 1 PT. BOTTLE]

Kills and Repels: Ticks, fleas, lice, flies, mosquitoes and gnats

Kills fleas before they mature into adults

Kills flea eggs

Effectively breaks the flea life cycle

Controls [Kills] [and repels] Lyme disease-carrying ticks [including *Ixodes scapularis*][including those that carry Lyme disease]

Reduces bot infestation by killing botfly eggs

Prevents botfly eggs from hatching

An effective spray mist that kills adult fleas, plus prevents eggs from developing into biting adults

No need to pump, spray in any position, even upside down

Contains PRECOR® Insect Growth Regulator, plus pyrethrins, an adulticide

Prevents [Stops] flea eggs from becoming full grown for 63 days [9 weeks][2 months][with PRECOR® [vIGRen®] Insect Growth Regulator]

One treatment works for 63 [9 weeks][2 months] days [against flea eggs][to keep flea eggs from hatching]

Keeps working to keep flea eggs from hatching for 63 days [9 weeks][2 months] with PRECOR [vIGRen] Insect Growth Regulator

[RF 9606] cosmetic-grade solvent formulation]

[Rapid action][quick acting][fast acting] formula

Quickly kills [repels] [expels] adult fleas plus kills their hatching eggs for up to 63 days [9 weeks][2 months] on your dog [puppy, cat, kitten, horse, pony]

Strong flea repellent action that you can see

One [single] treatment works for 63 days [9 weeks][2 months] to keep flea eggs from hatching

Provides 63 days [9 weeks][2 months] protection against fleas

Stops flea egg development, preventing further infestations for up to 63 days [9 weeks][2 months]

[63 days][9 weeks][2 months] protection

Protects for [63 days][9 weeks][2 months]

Satisfaction 100% guaranteed

Rapidly rid your animal of pesky biting fleas and ticks for up to 63 days [9 weeks][2 months]

Kills fleas and ticks for up to 63 days [9 weeks][2 months] reducing itching and scratching

Pleasant [name of scent] scent

Egg stop formula

EPA Reg. No. 2724-404

EPA Est No.

ACTIVE INGREDIENTS:

(S)-Methoprene (CAS #65733-16-6)	0.27%
Pyrethrins (CAS #8003-34-7)	0.20%
Piperonyl butoxide (CAS #51-03-6)	0.37%
N-octyl bicycloheptene dicarboximide (CAS #113-48-4)	0.62%
OTHER INGREDIENTS	98.54%
TOTAL	100.00%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See Back Panel For Additional Precautionary Statements

Net Contents: 1 pt [1 gallon]

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON [DOGS, CATS, PUPPIES, KITTENS][HORSES, PONIES]

[Using a dedicated non-household funnel, carefully pour into 1 pt. (product name) spray bottle only. Use as directed below.] (text for 1 gallon size only)

HOW ZOECON RF-322 WORKS:

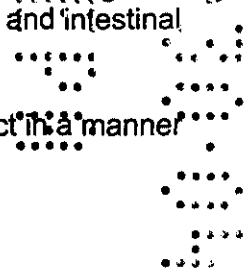
RF-322 controls ticks, lice, mosquitoes, gnats, fleas, house flies, stable flies, horn flies, face flies, flea larvae and horse bots. Botfly eggs and flea eggs sprayed with RF-322 will not hatch into adults.

Zoecon RF-322 combines the adult flea killing power of pyrethrins with the long-lasting egg-killing power of PRECOR® [VIGRen®] Insect Growth Regulator. This highly effective combination of ingredients provides quick relief from biting fleas and continuous killing of flea eggs laid on the animal, breaking the flea life cycle. The elimination of both adult fleas and flea eggs is important because adult fleas live on your pet, causing discomfort and skin irritation, while the vast number of eggs that they lay fall off and develop in your house. [If fleas are already developing in your house then {premise product} and {yard product} should also be used.] Effective flea control requires treatment of your pets, house, and yard.

Zoecon RF-322 contains PRECOR [VIGRen] Insect Growth Regulator which effectively kills botfly eggs that have been glued to the hairs on the forelegs, shoulders, and faces of horses by adult botflies (*Gastrophilus* spp.). If left untreated, botfly larvae emerge from these eggs and are taken into the mouth of the horse. After botfly larvae are swallowed they attach to the stomach and small intestinal linings in tremendous numbers where they can remain for months before passing out in the feces. Adult botflies emerge from pupae in the soil to begin the cycle all over again. Botflies have been implicated as a cause of some stomach and intestinal conditions in horses.

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

SHAKE WELL BEFORE USING.



FOR DOGS AND CATS

For Fleas: A light, even coverage of the hair coat will provide effective flea control. Do not allow spray from application or damp animal to come into contact with painted or finished surfaces including wood floors/furniture, leather/vinyl materials, or other surfaces of concern. For best penetration [results] ruffle the coat while spraying against the natural lay of the hair. Cover animal's eyes with hand. [ICON] With a firm fast stroke, spray head, ears and chest. With cloth, rub into face around mouth, nose, and eyes. Then spray the neck, middle and hind quarters, finishing with legs and tail last. Avoid spraying rectum and genitals. Apply at the rate of 1 or 2 squeezes of the trigger sprayer [0.10 fluid ounce] per pound of body weight. For larger dogs, spray until damp, not saturated. Do not allow animals, cats in particular, to become chilled. Repeat every 2 months for continuous home flea infestation prevention. If your pet becomes reinfested with adult fleas from outside sources, [Brand Name] may be reapplied weekly.

For Ticks: Make sure spray thoroughly wets individual ticks.

FOR PUPPIES AND KITTENS

For Fleas: Leaving the eyes, nose, and mouth exposed, treat puppies and kittens weighing less than 3 pounds by wrapping the animal in a towel that has been lightly sprayed with [Brand Name], for 5 to 10 minutes. Or lightly spray a brush or cotton ball and work thoroughly into the hair coat. Fleas may then be removed from the coat by picking or combing. Puppies and kittens over 3 pounds may be treated the same as dogs and cats as described above. Repeat every 2 months for continuous home flea infestation prevention. If your pet becomes reinfested with adult fleas from outside sources, [Brand Name] may be reapplied weekly. Do not allow animal to become chilled. Do Not Use On Puppies and Kittens Under 12 Weeks of Age.

[FOR HORSES AND PONIES

For Flies: Remove excess dirt and dust by brushing coat. Apply spray directly to horse's coat giving particular attention to legs, shoulders, flanks, neck and topline. To treat face, dampen a cloth with spray and rub on face and head, being careful to avoid eyes. Repeat every 2 months for continuous fly infestation prevention. If your horse/pony becomes reinfested, [Brand Name] may be reapplied weekly. This product is not to be used on horses destined for slaughter.]

[FOR PREVENTION OF HATCH OF HORSE BOTFLY EGGS: Spray any infested areas directly at the first sign of visible eggs, paying particular attention to legs, shoulders, flanks, neck, and topline. Spray to the point of dampness but not to the point of run-off of the spray. For a high degree of botfly egg control, spray animals every 3-5 days during the botfly season.]

STORAGE and DISPOSAL: Do not contaminate water, food or feed by storage or disposal.

Storage: Do not store near heat or open flame. Store away from children and animals.

Disposal: If empty: Do not reuse this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS -CAUTION: Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes, or clothing. May cause dermal sensitization (skin allergy).

HAZARDS TO ANIMALS - CAUTION: Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Some cats may be sensitive to products containing pyrethrins. Excessive salivation and ear and paw flicking may occur; however, these effects are temporary and not harmful. May cause dermal sensitization (skin allergy).

FIRST AID	
Call a poison control center or doctor immediately for treatment advice.	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
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.
If swallowed	<ul style="list-style-type: none"> • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center, doctor, or veterinarian or going for treatment. You may also contact 1-800-[phone number] for emergency medical treatment information.	

[Note: First Aid statement paragraph format may be used if space is limited.]

PHYSICAL HAZARDS: Combustible. Do not use or store near heat or open flame.

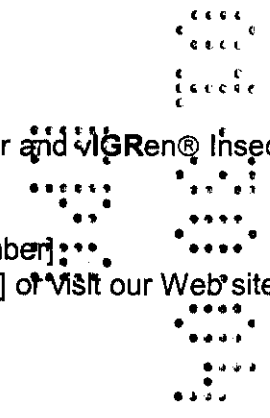
WARRANTY AND CONDITIONS OF SALE: Seller makes no warranty, expressed or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

Wellmark International
Schaumburg, IL 60173

Made in USA

PreStrike™, ZODIAC®, ZOECON®, PRECOR® Insect Growth Regulator and VigRen® Insect Growth Regulator are trademarks of Wellmark International.

For more information, [or in case of emergency (24 hrs)] call [phone number].
In case of emergency or for product use information, call [phone number] or visit our Web site:
[URL]



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Wellmark

January 23, 2004

Document Processing Desk (NOTIF)
Office of Pesticide Programs 7504C
U.S. Environmental Protection Agency
Room 266A Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

ATTENTION: L. Arrington

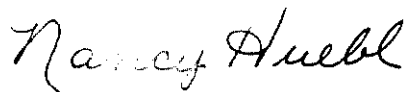
SUBJECT: NOTIFICATION OF LABEL CHANGE PER PRN 98-10
FOR RF-322 OVICIDAL PUMP SPRAY (RF9606)/EPA REG. NO. 2724-404

Dear Ms. Arrington:

Enclosed is a completed EPA Form 8570-1 and 1 copy of a highlighted label (new text is red). The label change involves the addition of a marketing claim and text relating to an additional packaging size (meets criteria of PRN 98-10, §II, E – changes in packaging and related labeling statements) – a one gallon refill only for the one pint spray bottle (for product sold into the equine market where a larger size container is desired but a sprayer gallon container is not practical). I have enclosed a self-addressed postcard for notification confirmation.

If you have any questions or if I can provide any further assistance, please, call me directly at 847/330-5376. Thank you for your assistance in this matter.

Yours sincerely,
WELLMARK INTERNATIONAL



Nancy Huebl
Regulatory Specialist

enclosure

cc: C. Eimi/J. Richardson