

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

SEP 6 2011

Michelle Foster 3200 Meacham Blvd. Fort Worth, TX 76137

Subject:

Notification per PRN 98-10 and PRN 2007-4

EPA Reg. No. 2382-173

Pyriproxyfen 10% Spot On for Cats

Date of Submission: August 15, 2011

Dear Ms. Foster:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration (PRN) 98-10 for the abovementioned product. The Registration Division (RD) has conducted a review of this request and finds that the actions requested fall within the scope of PRN 98-10 and PRN 2007-4. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have questions regarding this letter, please contact Olga Odiott at (703) 308-9369.

Sincerely,

Mark Suarez

Product Manager 13 Insecticide Branch

Registration Division (7505P)

2096

Print Form

Form Approved, OMB No. 2070-0060 Please read instructions on reverse before completing form. **OPP Identifier Number** United States Registration **Environmental Protection Agency** Amendment Washington, DC 20460 Other Application for Pesticide - Section I 2. EPA Product Manager 1. Company/Product Number 3. Proposed Classification R. Gebken 2382-173 Restricted 4. Company/Product (Name)
Pyriproxyfen 10% Spot On for Cats #10 5. Name and Address of Applicant (Include ZIP Code) 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling Virbac AH, Inc. to: PO Box 162059 Fort Worth, TX 76161 EPA Reg. No. Check if this is a new address Product Name Section - II Amendment - Explain below. Final printed labels in response to Agency letter dated Resubmission in response to Agency letter dated "Me Too" Application. × Notification - Explain below. Other - Explain below. Explanation: Use additional page(s) if necessary. (For section I and Section II.) For the purposes, content and attachments to this Notification refer to the Cover Letter. Section - III 1. Material This Product Will Be Packaged In: Water Soluble Packaging Child-Resistant Packaging Unit Packaging 2. Type of Container Yes' Yes Yes Plastic No No No Glass If "Yes" No. per If "Yes" No. per container Paper * Certification must container Unit Packaging wgt. Package wgt Other (Specify) be submitted 3. Location of Net Contents Information 4. Size(s) Retail Container 5. Location of Label Directions On Label Container On Labeling accompanying product 6. Manner in Which Label is Affixed to Product Lithograph Other Paper glued Stenciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Title Regulatory Specialist Name Telephone No. (Include Area Code) Michelle Foster 682-647-3545 6. Date Application Certification Received 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 statement may be punishable by fine or imprisonment of c c c (Stamped) both under applicable law. 3. Title 2. Signature Regulatory Specialist 5. Date 4. Typed Name Michelle Foster



August 15, 2011

Document Processing Desk Office of Pesticide Programs (7508P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

ATTENTION: Linda Arrington, Notifications & Minor Formulations Team Leader

Subject:

Notification of label change per PR NOTICE 2007-4

Pyriproxyfen 10% Spot On for Cats

EPA Reg. No. 2382-173

Dear Ms. Arrington,

In accordance with 40 CFR 152.46, Virbac AH, Inc. submits herewith an application for pesticide notification for subject product. This submission allows for labeling changes per PR Notice 2007-4 to the side/back panel of the label. The labeling changes are noted below and clearly marked on the revised product label (see attachment).

"Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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 the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, 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."

Revisions to side/back panel of the label in the "Storage and Disposal" section:

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

Added: Pesticide before Storage

Replace "Disposal" statement with the following:

- Pesticide Disposal and Container Handling: Nonrefillable container. Do not reuse or refill this container. If Empty: Place in trash or offer for recycling, if available.
- If Partly Filled: Call your local solid waste agency for disposal instructions. Never place any unused product down any indoor or outdoor drain."

This product is in compliance with 40 CFR 156.140(a)(4) as the lot number is adhered to the product. This product is exempt from 40 CFR 156.144 through 156.156 due to the product residential/household use. Additionally, this product is not a dilutable (liquid or solid) formulation.

Ms. Linda Arrington
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The contents and attachments to this notification include the following:

- 1) Cover Letter
- 2) Application for Pesticide Notification (EPA FORM 8570-1)
- 3) Revised Product Label with Changes Marked (one copy)
- 4) Revised Product Label (one copy)

If there are any questions regarding this notification, please contact me at (682)647-3545 or via email at mfoster@virbacus.com.

Sincerely,

Michelle Foster

Regulatory Specialist

Enclosures

NOTIFICATION

Front of card

SEP 0 6 2011

Pyriproxyfen 10% Spot On for Cats

[Nylar® IGR sterilizes fleas and (kills) flea eggs for 3 months]

ACTIVE INGREDIENTS

Pyriproxyfen	10.00%
OTHER INGREDIENTS	
TOTAL	100.00%.

KEEP OUT OF REACH OF CHILDREN CAUTION

See back panel for additional precautionary statements.

EPA Reg. No. 2382-173

EPA Est. No. 2382-TX-1 or EPA Est. No. 2382-FRA-01

Contains four 0.6 9 (0.021 fl.oz.) pipettes Manufactured by Virbac AH, Inc. P.O.Box 162059 Fort Worth, Texas 76161 Telephone 817-831-5030

Nytar® is a registered trademark of McLaughlin Gormley King Company

Back of card

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON CATS
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

HAZARDS TO HUMANS: Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using toilet.

HAZARDS TO ANIMALS: Do not use on kittens less than three months. 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 pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

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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.

If in Eyes: 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. Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-345-4735 for emergency medical treatment information.

DIRECTION FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Pyriproxyfen (Nylar) IGR sterilizes all fleas and (kills) their eggs for up to 3 months. This action breaks the flea life cycle and prevents the development of new fleas in the pet's environment that might reinfest the pet. Remove the cap of the pipette. Part the hair between the shoulder blades. Squeeze the pipette firmly to empty the entire contents directly on the skin at the base of the neck. Care should be taken in keeping the pipette in contact with the skin.

Avoid contact with treated area until dry. Reapply every three months. Efficacy is not reduced by bathing, water immersion, or exposure to sunlight.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in a cool dry area, inaccessible to children and pets. **PESTICIDE DISPOSAL AND CONTAINER HANDLING:** Nonrefillable container. Do not reuse or refill this container. **If Empty:** 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.

Lot no.

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