



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 18, 2014

Ms. Michelle Foster
Regulatory Specialist
Virbac Animal Health, Inc.
3200 Meacham Boulevard
Fort Worth, TX 76137-4611

Subject: Label Amendment – Acceptance of Master Labeling Submitted for Implementation of Pet Spot-On Mitigation
Product Name: Pyriproxyfen 10% Spot On for Cats
EPA Registration Number: 2382-173
Application Date: September 26, 2013
Decision Number: 483967

Dear Ms. Foster:

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 Cat 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 18, 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: Cat, cat, other (specify).
 - Breed: (As reported by pet owner)
 - Age: Months or years.

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

- Sex: M, F, or neutered.
- Weight: Pounds.
- 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 cats 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 cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for cats 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 cat incidents for each severity code for each pet weight range on the product label.
- A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range.
- Table showing number of incidents for each cat breed.
- Table showing number of incidents in cats for each clinical sign.
- Table showing number of incidents in cats for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

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 (1) 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 section 2(gg) of FIFRA and its implementing regulation at 40 CFR §152.3. 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 with section 6(e) of FIFRA.

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 12, 2000. The conclusion date for the subject time-limited product registration is September 18, 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 or Mr. Richard J. Gebken at (703) 305-6701 or via e-mail at Gebken.Richard@epa.gov during the hours of 9:00 A.M. to 5:30 P.M. EST.

Sincerely,

A handwritten signature in black ink that reads "Richard J. Gebken". The signature is written in a cursive style with a large initial 'R' and 'G'.

Richard Gebken
Product Manager 10
Insecticide Branch
Office of Pesticide Programs
Date: September 18, 2014

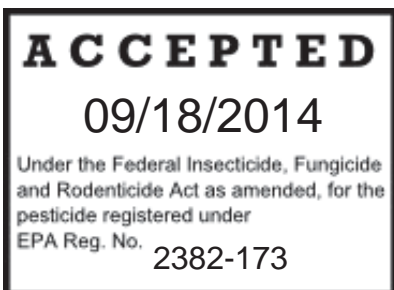
Enclosures:

Updated Master Label Stamped "Accepted," dated September 18, 2014
Review for Minimum Weight Treated, dated June 4, 2014

002382-00173 D483967

Front Panel

Pyriproxyfen 10% Spot On for Cats
For use ONLY on cats or kittens 3 months of age and older.
For use ONLY on cats or kittens weighing 1.5 lbs. and over.
[Nylar® IGR sterilizes fleas and (kills) flea eggs for 3 months]



ACTIVE INGREDIENT
Pyriproxyfen10.00%
OTHER INGREDIENTS.....90.00%
TOTAL.....100.00%

KEEP OUT OF REACH OF CHILDREN
CAUTION

Large, clear picture of appropriate species of cat

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 0.69 mL (0.021 fl. oz.) pipettes
Virbac AH, Inc.
P.O.Box 162059
Fort Worth, Texas 76161

Nylar® is a registered trademark of McLaughlin Gormley King Company

Back Panel

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 DOMESTIC ANIMALS: Do not use on kittens less than three months of age. Do not use on cats or kittens weighing less than 1.5 lbs. Do not allow your cat to ingest this product. 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.

Back Panel, continued

SIDE EFFECTS: Possible temporary irritation may occur at the site where Pyriproxyfen 10% Spot On for Cats was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following initial application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating application. In addition, if your pet experiences an adverse event, contact a veterinarian immediately and report incident to Virbac AH, Inc. at 1-800-338-3659.

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

For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-345-4735, twenty-four (24) hours per day, seven (7) days per week.

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

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON CATS OR KITTENS 3 MONTHS OF AGE OR OLDER.

DO NOT USE ON CATS OR KITTENS WEIGHING LESS THAN 1.5 LBS.

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 cat's 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: Keep this product in its tightly closed original container, when not in use. Store in a cool dry (preferably locked) area, inaccessible to children and animals.

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.