

2724-491

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



OFFICE OF
PREVENTION, PESTICIDES,
AND TOXIC SUBSTANCES

SEP 23 2008

James McFadden
Wellmark International
1501 E. Woodland Rd., Suite 200W
Schaumburg, IL 60173

Dear Dr. McFadden:

Subject: Label amendment in response to propoxur RED and efficacy DCI
RF 9907 Flea Collar for Cats and Kittens
EPA Registration No. 2724-491
Submission Date: December 12, 2007

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided you make the following changes before you release the product for shipment bearing the amended labeling:

- Revise the warranty statement so it reads, "**To the extent consistent with applicable law, Seller makes no warranty...**"
- **NOTE:** The alternate brand name "ZODIAC Breakaway Flea & Tick Collar for Cats and Kittens" is acceptable and has been noted in the Agency's records.
- **NOTE:** Should you wish to add/retain a reference to the company's website on your label, the website then becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not 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 contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

- Delete the following claims:

- “Kills flea eggs”
- “..including those carrying Lyme disease”
- “Kills [deer] ticks (including Ixodes scapularis), [up to 6 months][including those carrying Lyme disease] which may transmit Lyme disease [borreliosis]”
- “Effective against [vectors, ticks, Ixodes scapularis] which may transmit Lyme disease [borreliosis]”
- “Controls [Kills] Lyme disease [borreliosis]-carrying ticks”
- “Kills immature [fleas] and flea eggs”
- “Protection [control of] against immature and flea eggs”
- “PRECOR [vIGRen®] is Prevention”
- “Long-lasting protection”
- “Ring of Prevention [Protection] against flea build-up in your home”
- “Quick [Fast] acting [action][killing] for fleas”
- “Kills [Adult][Fleas][Fast] & Ticks [including those carrying Lyme disease]”
- “Temporary wetting will not reduce effectiveness”
- “[Ovicidal] -kills flea eggs [before they hatch] for [245 day][35 weeks][8 months][to prevent reinfestation]”
- “Prevents flea build-up in your home by killing fleas and flea eggs before they hatch”
- “This [brand name] collar is designed to kill flea eggs”
- “This collar begins working to kill fleas and flea eggs as soon as it is placed around the cat's neck”
- “Protection against fleas and flea eggs [hatch] will be achieved within a few days [48 hours], providing continuous protection for [35 weeks][245 days][8 months]”
- “Full protection against adult and immature ticks will be achieved within a few days, providing continuous protection for [25 weeks][175 days][up to 6 months]”
- “Collar does not need replacement if cat becomes wet.”

- Revise the following:

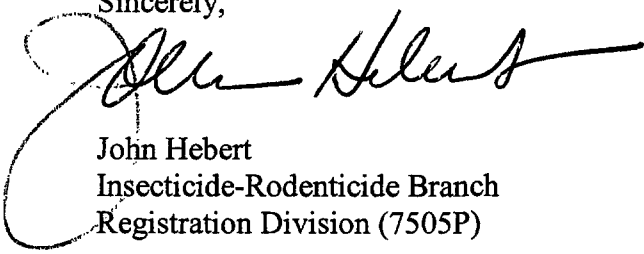
- “[245 days][35 weeks][8 months] protection [control of] against immature and adult fleas and flea eggs” to read “ up to [21 weeks][150 days][5 months] protection [control of] against adult fleas”
- “[175 days][25 weeks][6 months] protection [control of] against ticks” to read “ up to [21 weeks][150 days][5 months] protection [control of] against ticks”
- “Kills immature [fleas] and adult fleas and flea eggs up to [35 weeks][245 days][8 months]” to read “Kills adult fleas up to [21 weeks][150ays][5 months]”
- protection [control of] against immature and adult fleas and flea eggs” to to read “up to [21 weeks][150 days][5 months] protection [control o] against adult fleas”

- “ Replace in [245 days][35 weeks][8 months] for continuous protection from adult fleas and flea egg hatch” to read “Replace in [21 weeks][150 days][5 months] or sooner if needed for continuous protection from adult fleas and adult flea emergence”
- “ Replace in [175 days][25 weeks][6 months] for continuous protection from ticks” to read “Replace in [21 weeks][150 days][5 months] or sooner if needed for continuous protection from ticks”
- Revise “This [brand name] collar is designed to kill adult fleas and flea eggs” to read “This [brand name] collar is designed to kill adult fleas and prevent adult flea emergence”
- “Replace collar every [35 weeks][245 days][8 months] to help control adult flea infestations on your pet” to read “Replace collar every [21 weeks][150 days][5 months] or sooner to help control adult fleas on your pet”
- “Replace collar every [25 weeks][175 days][6 months] for continuous protection from ticks” to read “Replace collar every [21 weeks][150 days][5 months] or sooner for continuous protection from ticks”
- Satisfaction 100% Guaranteed and 100% satisfaction guaranteed to “Satisfaction 100% Guaranteed or your money back” and “100% satisfaction guaranteed or your money back.”

Approval of this labeling amendment does not constitute approval of your application for reregistration of this product. Product reregistration is currently pending and future labeling amendments and/or additional data may be required.

You must submit one (1) copy of the final printed label before you release the product for shipment. Products shipped after 12 months from the date of this Notice or the next printing of the label whichever occurs first, must bear the new revised label. A stamped copy of the label is enclosed for your records. Should you have any questions, please contact Julie Chao at 703-308-8735 or chao.julie@epa.gov.

Sincerely,



John Hebert
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

[] indicates optional statements

RF-9907 FLEA COLLAR FOR CATS & KITTENS

**Alternate brand Names: ZODIAC® Flea & Tick Collar for Cats,
ZODIAC® Flea & Tick Collar for Cats & Kittens,
ZODIAC® Breakaway® Flea & Tick Collar for Cats & Kittens**

VET KEM® Breakaway® Plus Flea & Tick Collar for Cats

with [Plus] PRECOR® [vIGRen®] Insect Growth Regulator [IGR][Kills flea eggs]
Plus IGR Kills Flea Eggs

Kills [Adult] Fleas [Fast] & Ticks [(including those carrying Lyme disease)]

[245 days][35 weeks][8 months] protection [control of] against immature and adult fleas and flea eggs

[175 days][25 weeks][6 months] protection [control of] against ticks

PRECOR [vIGRen®] is Prevention

Long Lasting Protection

Ring of Prevention [Protection] against flea build-up in your home

PRECOR [vIGRen] breaks the flea life cycle

Works From Head to Tail

Quick [Fast] acting [action] [killing] for Fleas

Satisfaction 100% Guaranteed

Temporary wetting will not reduce effectiveness

[Ovicidal] - kills flea eggs [before they hatch] for [245 days][35 weeks][8 months][to Prevent Reinfestation]

Prevents flea build-up in your home by killing fleas and flea eggs before they hatch

For cats of all sizes

[Unique one-piece buckle design][Integrated one-piece buckle]

[Unique breakaway design]

[Integrated plastic buckle] [Breakaway Collar][Expandable Collar][Stretch Band]

Kills [deer] ticks (including *Ixodes scapularis*), [up to 6 months][including those carrying Lyme disease] which may transmit Lyme disease [*borreliosis*]

Effective against [vectors, ticks, *Ixodes scapularis*] which may transmit Lyme disease [*borreliosis*]

Controls [Kills] Lyme disease [*borreliosis*]-carrying ticks

Kills immature [fleas] and adult fleas and flea eggs up to [35 weeks][245 days][8 months]

Flea protection for 8 months

Kills ticks up to [175 days][25 weeks][6 months]

(FRONT OR BACK PANEL)

ACTIVE INGREDIENTS:

Propoxur (CAS #114-26-1)..... 10.0%

(S)-Methoprene (CAS # 65733-16-6)..... 2.1%

OTHER INGREDIENTS: 87.9%

Total: 100.0%

DO NOT ALLOW CHILDREN TO PLAY WITH THIS COLLAR

CAUTION

See Precautions on back

EPA Reg. No 2724-491

Net Weight:

EPA Est. No.

**ACCEPTED
With COMMENTS
In EPA Letter Dated:
SEP 23 2008**

Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

2724-491

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON CATS AND KITTENS 12 WEEKS OF AGE AND OLDER**

DIRECTIONS FOR USE:

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

1. Buckle collar around cat's neck. [Thread flat end of the collar through buckle hole and tighten as necessary, so that at least 2 ridges are covered by the buckle. Since the plastic buckle is molded into the collar, the possibility of neck irritation and buckle failure is reduced.] Fit collar snug enough to prevent placement of the cat's leg or lower jaw through the collar, yet loose enough to be rotated about the neck.
2. Leave 1-2 extra inches on the length of the collar for adjustment, cut off excess, and dispose of in trash.
3. Check periodically and adjust fit if necessary, especially when kittens are rapidly growing.
4. Replace in [245 days][35 weeks][8 months] for continuous protection from adult fleas and flea egg hatch. Replace in [175 days][25 weeks][6 months] for continuous protection from ticks. [To release the collar, squeeze buckle between thumb and finger and pull sharply.] Collar does not need replacement if cat becomes wet.

[UNIQUE FEATURE: This collar is designed to stretch under the weight of an average sized adult cat. It helps the cat to free itself ("breakaway") if the collar gets snagged on a fixed object. If the collar is fitted improperly, so that it is loose enough for a cat to work the collar over its leg or jaw, this release feature may not stretch adequately to allow the extra room necessary for the cat to free itself.]

To minimize flea infestation use appropriate products to:

1. Treat the pet
2. Treat the indoor environment, especially where pets spend time resting
3. Treat the outdoor environment when necessary

STORAGE and DISPOSAL: Collar should be left in place once fitted on cat. If collar is temporarily removed, do not set it on wood or other surfaces. **Storage:** Store in original unopened package away from children. **Disposal:** Do not reuse container or reuse collar. Dispose of in trash.

WHAT TO EXPECT:

For Fleas:

1. This [brand name] collar is designed to kill adult fleas and flea eggs.
2. This collar begins working to kill fleas and flea eggs as soon as it is placed around the cat's neck.
3. Protection against fleas and flea eggs [hatch] will be achieved within a few days [48 hours], providing continuous protection for [35 weeks][245 days][8 months].
4. Replace collar every [35 weeks][245 days][8 months] to help control adult flea infestations on your pet.

For Ticks:

1. Ticks are tougher to kill than fleas and are killed more slowly.
2. Full protection against adult and immature ticks will be achieved within a few days, providing continuous protection for [25 weeks][175 days][up to 6 months].
3. Adult ticks will be killed over the entire pet. Dead ticks will fall off or may be easily removed.
4. Replace collar every [25 weeks][175 days][6 months] for continuous protection from ticks.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS-CAUTION: Do not get dust or collar in mouth. Harmful if swallowed or absorbed through skin. Do not get dust in eyes, will cause temporary constriction of the pupils*. The dust released by this collar is a cholinesterase inhibitor. Avoid contact with skin, eyes or clothing.

Humans: Do not open package until ready to use. Do not allow children to play with this collar. Pesticidal dust will form on this collar during storage. Wash hands thoroughly with soap and water after handling collar.

Animals: Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant, or nursing cats. Do not use on kittens under 12 weeks of age. Do not use this product on cats simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting** drugs or pesticides (eg. carbaryl or propoxur etc.). However, flea and tick collars may be immediately replaced. When collar is first worn, observe neck area every few days for irritation. Remove collar at the first sign of irritation or adverse reaction. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your cat with mild soap and rinse with large amounts of water.

FIRST AID	
If swallowed	<ul style="list-style-type: none"> • Call poison control center or doctor immediately for treatment advice. • 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.
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 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. • [Call a poison control center or doctor for treatment advice.]
<p>IN CASE OF EMERGENCY, CALL [1-800-XXX-XXXX] OR A POISON CONTROL CENTER. Have the product container or label with you when calling a poison control center or doctor or going for treatment.</p>	
<p>NOTE TO PHYSICIAN/VETERINARIAN: *Atropine is antidotal only if symptoms of cholinesterase inhibition are present.</p>	

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

Wellmark International
Schaumburg, IL 60173

100% satisfaction guaranteed. For product use information, call [1-800-XXX-XXXX] or visit our website [internet address].

**For information on cholinesterase inhibition please call our 800 number or consult your veterinarian.

Breakaway®, VET KEM®, ZODIAC®, PRECOR® and vIGRen® Insect Growth Regulator are registered trademarks of Wellmark International.

Made in USA