

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

OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES

September 1, 2009

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

Dear Dr. McFadden:

Subject:

Label amendment

RF-9907 Flea Collar for Cats & Kittens

EPA Registration No. 2724-491 EPA Decision No. 415984 Submission Date: April 7, 2009

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable with the following comments:

- On page 2, under the statement "To minimize flea infestation, use appropriate products to...," add the following statement: "4. Only use EPA-registered products that are labeled for these uses."
- On page 2, revise the Storage and Disposal section to read as follows:

STORAGE AND DISPOSAL

Storage: Store in original unopened container, away from children.

Disposal: Do not reuse container or collar. Wrap in paper and dispose of in trash. If collar is temporarily removed, wrap in paper or plastic; do not allow children to have access to collar.

For consistency with other products and to increase prominence, it is also highly recommended that you place the Storage and Disposal text in a box.

• On page 3, delete the reference to the Web site and optional "[web site address]." In order to add a Web site reference to your label, you must provide the URL so that the Agency can review the referenced Web site. Please note that 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.

A stamped copy is enclosed for your records. Please submit two copies of your final printed labeling before you release the product for shipment. 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 FIFRA section 6(e). If you have any questions, please contact Julie Chao by phone at: (703) 308-8735, or by email at: chao.julie@epa.gov.

Sincerely,

John Hebert

Insecticide-Rodenticide Branch Registration Division (7505P)

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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]

Kills [Adult] Fleas & Ticks

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

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

Works in as little as [24 hours][1 day]

[Available through veterinarians]

PRECOR [vIGRen] breaks the flea life cycle

Works From Head to Tail [to kill fleas for up to 8 months and ticks for up to 6 months]

Satisfaction 100% Guaranteed or your money back

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

Kills fleas and kills flea eggs

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]

Effective against ticks

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

Flea protection for up to 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)	
OTHER INGREDIENTS:	
Total:	100.0%

DO NOT ALLOW CHILDREN TO PLAY WITH THIS COLLAR CAUTION

See Precautions on back

EPA Reg. No 2724-491

EPA Est. No.

Net Weight:

ACCEPTED With COMMENTS In EPA Letter Dated:

SEP - 1 2009 Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

4046

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.

- 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] or sooner if needed. Replace in [175 days][25 weeks][6 months] or sooner if needed. [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. Protection against fleas and flea eggs [hatch] will be achieved within a few days [48 hours], providing continuous protection for up to [35 weeks][245 days][8 months].
- 3. Replace collar every [35 weeks][245 days][8 months] or sooner if needed.

For Ticks:

- 1. Protection against adult and immature ticks will be achieved within a few days, providing continuous protection for up to [25 weeks][175 days][6 months].
- 2. Adult ticks will be killed over the entire pet. Dead ticks will fall off or may be easily removed.
- 3. Replace collar every [25 weeks][175 days][6 months] or sooner if needed.

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. NOTICE: This product contains propoxur, a chemical known to the State of California to cause cancer. (in red bold).

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	
Call a poison control	center or doctor immediately for treatment advice.
If swallowed	 Call a 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	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.
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 eye.
IN CASE OF EMERG	ENCY, CALL [1-800-XXX-XXXX] OR A POISON CONTROL
	product container or label with you when calling a poison control
center or doctor or go	ing for treatment.
NOTE TO PHYSICIA	N/VETERINARIAN: Contains an N-methyl carbamate that
inhibits cholinesterase inhibition are present.	e. *Atropine is antidotal only if symptoms of cholinesterase

6066

To the extent consistent with applicable law, 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 1501 East Woodfield Road 200W Schaumburg, IL 60173

100% satisfaction guaranteed or your money back. 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