724-254

911/2009

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 Dog Collar for Flea Control EPA Registration No. 2724-254 EPA Decision No. 415983 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, 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,

in Helen

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

Enclosure

DOG COLLAR FOR FLEA CONTROL

Alternate Brand Names: ZODIAC® Tick Collar for Dogs VET KEM® Tickaway™ Tick Collar for Dogs

Works in as little as [24 hours][1 day] Kills Fleas and Ticks in less than [24 hours][1 day] Works From Head to Tail to Kill Fleas and Ticks for up to 5 Months [Available through Veterinarians] [For [all][large][small][medium] dogs and puppies with necks up to (number of inches)] [Snip notch at replacement month] [Unique Dating Feature] Works even after temporary wetting Temporary wetting will not reduce effectiveness [Protects from fleas and ticks for up to 5 Months] **Kills Fleas & Ticks** Kills [adult] fleas which may cause flea bite anemia Kills [adult] fleas which may cause flea allergy dermatitis Kills [adult] fleas which may transmit tapeworms Kills fleas up to 5 months [21 weeks][150 days][Kills fleas for 4 months] Aids in the control of fleas and ticks for up to 5 months Kills [Controls][immature and adult] ticks up to 5 months [21 weeks][150 days][Kills ticks for 4 months] [Integrated][One-piece][Unique][plastic] buckle [design] Effective against ticks 100% Satisfaction Guaranteed or your money back (Descriptor) Red/Blue/Green/Clear/White

ACTIVE INGREDIENT:

Propoxur (CAS #114-26-1)	
OTHER INGREDIENTS:	<u>90%</u>
Total:	100%

DO NOT ALLOW CHILDREN TO PLAY WITH THIS COLLAR CAUTION

See Precautions on back

EPA Reg. No. 2724-254 EPA Est. No. 2724-TX-1

NET WEIGHT

ACCEPTED

With COMMENTS

In EPA Letter Dated: <u>SEP - 1</u> 2009 Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

2724-254

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS/PUPPIES [APPLY ONLY 1 COLLAR AT A TIME]

[ONE SIZE FITS ALL – TRIM TO SIZE (See Directions On Back)

This collar is designed to fit 99% of all dogs. In rare instances (for example, well developed St. Bernards or Mastiffs), the collar may be too short. If found short for your dog, return to address on top panel for full purchase price refund.]

DIRECTIONS FOR USE:

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

- Buckle collar around dog's/puppy's neck. [Thread flat end of the collar through buckle hole and tighten as necessary, so that at least two 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 dog's/puppy's leg or lower jaw through the collar, yet loose enough to be rotated about the neck. [Generally, if used on large dogs, two or three fingers should fit between the collar and dog's/puppy's neck.]
- 2. Leave 2-3 extra inches on the collar for adjustment, cut off excess length and dispose of in trash.
- 3. Check periodically and adjust fit if necessary, especially when puppies are rapidly growing.
- 4. May be used in addition to regular collar. Replace collar when effectiveness diminishes. [To release the collar, squeeze buckle between thumb and finger and pull sharply.]

WHAT TO EXPECT:

For Fleas:

- 1. This [brand name] collar is designed to kill adult fleas.
- 2. Protection against fleas will be achieved within a few days, providing continuous protection for up to 5 months [4 months].
- 3. Replace collar every 5 [4 months] months or sooner if needed.

For Ticks:

- 1. Ticks are tougher to kill than fleas and are killed more slowly.
- 2. Protection against adult and immature ticks will be achieved within a few days, providing continuous protection for up to 5 months. [for 4 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 5 months [4 months] or sooner if needed.

STORAGE and DISPOSAL: Storage: Store in original unopened container away from children. **Disposal**: Do not reuse container or used collar. Dispose of in trash.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS-CAUTION: Do not get dust or collar in mouth, harmful if swallowed. Do not get dust in eyes, will cause temporary pupillary constriction.* The dust released by this collar is a cholinesterase inhibitor. **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 handle this collar. Dust will form on this collar during storage. Avoid contact with skin or clothing. 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 dogs. Do not use on puppies under 12 weeks of age. Do not use this product on dogs simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. 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 pet with mild soap and rinse with large amounts of water.

FIRST AID	
Call a poison contr	ol center or doctor immediately for treatment advice
If swallowed	 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 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.
If on skin or clothing	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.
	container or label with you when calling a poison control center or doctor, or going for ay also contact 1-800-[phone number] for emergency medical treatment information.
	CIAN/VETERINARIAN: Contains an N-methyl Carbamate that inhibits cholinesterase. natropine are antidotal only if symptoms of cholinesterase inhibition are present.

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. In case of emergency or for product use information, call [phone number] or visit our Web site: [web site address] [For information or in an emergency, call (phone number) See top panel of box for details of unconditional guarantee If not satisfied, send used collar and indication of purchase price paid to (company name/address)]

VET KEM®, Tickaway™, and ZODIAC® are trademarks of Wellmark International.

Made in USA