2724-49

3/31/2003



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES 15

MAR 3 | 2003

Nancy Huebl Wellmark International 1100 East Woodfield Road, Suite 500 Schaumburg, Illinois 60173

Subject: EPA Reg. N0.:2724-491 RF-9907 Flea Collar for Cats & Kittens Label Amendment (PRN 2001-6) Your facsimile dated March 4, 2003

Dear Ms. Huebl:

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 provisions:

* The phrase "Satisfaction 100% guaranteed" is not acceptable as a stand-alone claim. It must either be substantiated to describe how it is guaranteed, such as "Satisfaction 100% guaranteed or your money back", or the statement must be removed.

A stamped copy is enclosed for your records. Please submit one (1) final printed copy for the above mentioned label before releasing the product for shipment.

If you have any questions regarding the review, please contact Stephanie Nguyen at 703-605-0702.

Sincerely,

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Daniel C. Kenny Product Manager (01) Insecticide-Rodenticide Branch Registration Division (7505C)

Enclosure

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ACCEPTED with COMMENTS In EPA Letter Dated: MAR 3 | 2003

[] indicates optional statements

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No.

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RF-9907 FLEA COLLAR FOR CATS & KITTENS. Alternate brand Names: ZODIAC® Flea & Tick Collar for Cats,

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.

[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-plece 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)	
(S)-Methoprene (CAS # 65733-16-6)	
OTHER INGREDIENTS:	
Totai:	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.

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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 improperty, 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.

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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 scap and rinse with large amounts of water.

FIRST AID	
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 on skin or	Take off contaminated clothing.
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 eye.
	 [Call a poison control center or doctor for treatment advice.]
IN CASE OF EMERGEN	CY, CALL [1-800-XXX-XXXX] OR A POISON CONTROL
	uct container or label with you when calling a poison control
	ETERINARIAN: *Atropine is antidotal only if symptoms of

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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