

PM 03

2724-169

3/31/98

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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MAR 31 1998

Eileen Valenta  
Wellmark International  
1000 Tower Lane  
Bensonville, IL 60106

Subject: Vet-Kem Kemolate Emulsifiable Liquid  
EPA Registration No. 2724-169  
Amendment dated January 5, 1998

Dear Ms. Valenta:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable provided that you:

1. Submit two copies of your final printed labeling before you release the product for shipment.
2. Refer to comment #2 in our March 26, 1998 letter regarding labeling for EPA Reg. No. 2724-262.
3. Expand the front panel statement to read "Do Not Use on Cats or Other Animals."
4. Delete "The solution may be stored or used for 30 days." The use of concentrated pesticides that are to be diluted and stored by homeowners can result in increased exposure and adverse effects due to improper storage of the diluted product in an unmarked container.
5. The age limitation, reapplication restriction, and container precaution should appear below the directions for fleas and ticks and sarcoptic mange. As currently labeled, it appears that these precautions pertain only to the flea and tick directions.
6. Under Hazards to Animals, correct "...30 a few days..." to "...within 30 days before or after..."

7. Under Precautionary Statements, replace "Causes eye and skin irritation with  
"Causes substantial but temporary eye irritation." Also, add "Wear safety glasses" to the

SYMBOL	applicator precaution statement.					
SURNAME						
DATE						

8. We note use of tablespoons for dilution. Is a measuring utensil marketed with the product? We recommend adding the following precaution under Directions for Use: "Food utensils such as tablespoons or measuring cups should not be used for food purposes after use with insecticides."

A review of our files for the subject product indicates that we are lacking an acceptable domestic animal safety study. In 1988 we issued a Special DCI to Zoecon Corp (later Sandoz and now Wellmark International) requesting a domestic animal safety study on dogs and cats for the subject product. This was due to large number of adverse effects associated with use of this product on pets, especially cats. This concern was first identified in the 1986 Registration Standard for products containing phosmet. We asked for a cholinesterase study in the dog and cat to determine a fivefold MOS over the use level. Zoecon responded by deleting cats from the label and submitting a dog cholinesterase study in 1989. We reviewed this study in 1990 and found it supplementary. To date we have not received a response to the supplementary status of the earlier study nor an indication on how this data gap will be satisfied. A fivefold safety factor must be demonstrated to maintain the registration of this product.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

Sincerely yours,

George T. LaRocca  
Product Manager 13  
Insecticide Branch  
Registration Division (7505C)

Enclosure

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Available Through Veterinarians

**VET-KEM®**  
**KEMOLATE EMULSIFIABLE LIQUID**

**Use Only On Dogs**

**DO NOT USE ON CATS**

For the control of fleas, ticks, and sarcoptic mange

Gives control of sarcoptic mange on dogs with one dip treatment

Gives 16 days residual control of fleas and Brown Dog ticks

Each ounce of product makes 1 gallon [128 oz]

1 bottle makes 4 gallons

Proven Effective Control

Kills fleas and ticks

**ACTIVE INGREDIENT:**

Phosmet (CAS #732-11-6)..... 11.75%

**OTHER INGREDIENTS:\***..... 88.25%

Total: 100.00%

\* Contains aromatic petroleum solvent

Protect from temperatures below 20° F

**KEEP OUT OF REACH OF CHILDREN**

**WARNING**

**READ ALL DIRECTIONS AND PRECAUTIONS BEFORE USING.**

See side panel for Note to Physician and Veterinarian

NET CONTENTS

ACCEPTED  
with COMMENTS  
in EPA Letter Dated

MAR 31 1998

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

2724-169

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**READ ENTIRE LABEL BEFORE EACH USE  
USE ONLY ON DOGS**

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **DO NOT USE ON CATS.**

**Fleas and ticks:** Mix 1 oz (2 Tbsp) Kemolate with 1 gallon water. Sponge on solution until skin is wet. For maximum residual control, allow to dry on animal. Allow animal to dry before handling. Do not reapply product for 7 days.

Do not use on dogs under 12 weeks. The solution may be stored or used for 30 days.

**Assure containers are disposed of properly or thoroughly closed following use.**

Sarcoptic mange on dogs is characterized by loss of hair, thickened skin, and intense itching caused by the mite *Sarcoptes scabiei*, var. *canis*. Mix 1 oz (2 Tbsp) Kemolate with 1 gallon water. Sponge on dog until skin is wet and allow to shake dry. Do not rinse. If no improvement is seen within 14 days, consult your veterinarian. If mange mites reinfest your dog, retreatment may be necessary.

**STORAGE and DISPOSAL:** Do not contaminate water, food, or feed by storage or disposal. **Storage:** Store in original container away from children. **Disposal:** Do not reuse container. Rinse thoroughly before discarding in trash.

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS: WARNING**

May be fatal if swallowed. Harmful if absorbed through skin. Causes eye and skin irritation. Avoid contact with eyes, skin, or clothing. Avoid breathing vapor. Use only in well ventilated areas. Applicators must wear protective eyewear, long-sleeved shirt, long pants, elbow-length waterproof gloves, waterproof apron, and unlined waterproof boots. Wash all contaminated clothing with soap and hot water before reuse. Wash thoroughly with soap and water before eating, drinking, or using tobacco. Not intended for human use.

**HAZARDS TO DOMESTIC ANIMALS: WARNING**

May be fatal if swallowed. Do not get in eyes. Do not use this product on animals simultaneously or within 30 a few days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. However, flea and tick collars may be immediately replaced. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. 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. Improper dilution of this product could cause serious injury to dogs. Do not use on cats.

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**FIRST AID:** If **swallowed**, call a physician/veterinarian or Poison Control Center immediately. Do not induce vomiting. Do not give anything by mouth to an unconscious person. Avoid alcohol. If **in eyes**, rinse immediately with plenty of water. Call physician/veterinarian immediately. If **on skin**, wash promptly with soap and water. Remove contaminated clothing. If **inhaled**, remove individual to fresh air. Apply artificial respiration if necessary.

**NOTE TO PHYSICIAN AND VETERINARIANS:** Kemolate [Brand Name] is an organophosphorous insecticide and cholinesterase inhibitor. Atropine is antidotal. 2-PAM is also antidotal and may be administered with atropine. If ingested do not induce vomiting. May present aspiration hazard. Usual symptoms of poisoning in animals include salivation, labored breathing, gastrointestinal disturbance, tremors, staggering, and pin-point pupils.

**PHYSICAL OR CHEMICAL HAZARDS:** Do not use or store near heat or open flame. Protect from temperatures below 20° F.

For more information and in case of emergency call [phone number].

Vet-Kem® is a registered trademark of Wellmark International.

Seller makes no warranty, express 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  
Bensenville, IL 60106

EPA Reg. No. 2724-169  
Made in USA

EPA Est. No.