

270-345

05/13/2009

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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

May 13, 2009

**Ms. Lorri Chavez, Director of Regulatory Affairs**  
**Farnam Companies, Inc.**  
**dba Central Life Sciences**  
**301 West Osborn Road**  
**Phoenix, AZ 85013-3928**

**Subject:** Amended Re-registration Label  
**Product Name:** Adams Ear Mite Lotion  
**OPP Decision:** 356441  
**EPA Reg. No.:** 270-345

Dear Ms. Chavez;

The Agency in accordance with the Federal Fungicide and Rodenticide Act as Amended (FIFRA) has completed reviewing all of the information submitted with your application to support the reregistration of the aforementioned product in connection with the MGK<sup>®</sup> 326 RED, and have concluded that your submission is acceptable with the following label revision provisions:

1. Delete the marketing claim sub-statement “, AND SUNSCREEN”<sup>1</sup>
2. Revise the **FIRST AID** statements by placing them in the following order:
  1. “IF INHALED: . . .”
  2. “IF IN EYES: . . . .”
  3. “IF SWALLOWED: . . . .”
  4. “IF ON SKIN OR CLOTHING: . . . .”
3. Revise the **HAZARD TO HUMANS AND DOMESTIC ANIMALS** statement as follows:

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<sup>1</sup> This is an implied safety claim 40 CFR 156.10.

**“CAUTION**

Harmful if inhaled. Causes moderate eye irritation. Avoid contact with eyes or clothing. Avoid breathing vapor. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wear long-sleeved shirt, long pants, shoes, and socks.”

The ‘ANIMALS’ statement may be retained as is.

4. Revise the **ENVIRONMENTAL HAZARDS** statement as follows:

“This pesticide is toxic to fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.”

5. Revise the **DIRECTIONS FOR USE** statement as follows:

Revise the text “Not for use on horses intended for slaughter” to read “Do not use on horses or foals intended for slaughter.”

Also, revise the text “Note: Do not put directly on broken skin or an open wound” to read “Do not apply over cuts, wounds, or irritated skin.”

Also, add the following text: “Do not apply near eyes and mouth. Apply sparingly around ears. Do not apply more than one (1) time per day.”

Also, revise the “To Kill Ear Mites:” sub-statement in lines 1-4 as follows: “Place a small amount of Pet-Mite Lotion into each ear, applying only enough lotion to coat the surface of the ear canal. Gently massage the base of the ear. Leave lotion in ear for a few minutes and carefully wipe the excess lotion from the ear with cotton. Repeat once more once more after 7 days.”

(This revision is necessary so as not to contradict the ‘apply sparingly around ears statement’ required by the MGK® 326 RED.)

6. Revise the **STORAGE AND DISPOSAL** statement as follows:

**“STORAGE AND DISPOSAL:**

Do not contaminate water, food, or feed by storage and disposal.

Storage: Store in a cool, dry place inaccessible to children and pets. Always store pesticides in the original container. If a leaky container must be contained within another, mark the outer container to identify the contents. Store pesticides away from food, pet food, seed, fertilizers, and veterinary supplies.

Disposal: Nonrefillable container. Do not reuse or refill this container. If Empty: Place in trash or offer for recycling if available. If partly filled: call your local solid waste

agency disposal instructions. Never place unused product down any indoor or outdoor drain.”

The Agency is in the process of developing and improving the current Efficacy Assessment Guidelines. The Agency intends to defer the determination of any related efficacy data requirements supporting the claims that may appear on this label until these Efficacy Assessment Guidelines are complete. When the guidelines are finalized, the Agency expects to issue a Data Call-In to address the revised guidelines to all registrants with registrations for products that have not previously submitted efficacy data sufficiently consistent with the revised guidelines.

NOTE: This product is not being re-registered under FIFRA Sec. 4(g) at this time.

Farnam Companies, Inc. should note that a notice of availability of EPA’s reregistration eligibility decision (RED) document for products containing piperonyl butoxide was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42385-42386). EPA’s RED for products containing pyrethrins was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42387-42389). EPA’s RED for products containing MGK® 264 was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42381-42383). As a result, additional data and/or labeling changes may be required for products containing piperonyl butoxide, pyrethrins, and/or MGK® 264.

You must submit two copies of the final printed label revised in accordance with the comments listed above before the product is released for shipment under this label. If you have any questions, you may contact Clayton Myers at (703) 347-8874 or [myers.clayton@epa.gov](mailto:myers.clayton@epa.gov).

A copy of your label stamped “Accepted with Comments” is enclosed for your records.

Sincerely,



Richard J. Gebken, Product Manager (10)  
Registration Division, Insecticide Branch

Attachment

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### ADAMS EAR MITE LOTION

- KILLS EAR MITES
- FOR DOGS, PUPPIES, CATS, KITTENS
- INSECTICIDE AND REPELLENT FOR USE ON HORSES
- WITH LANOLIN, ALOE VERA, AND SUNSCREEN

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated**  
**MAY 13 2009**  
 Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act,  
 as amended, for the pesticide  
 registered under EPA Reg. No.  
270-345

#### ACTIVE INGREDIENTS:

Pyrethrins .....	0.15%
*Piperonyl Butoxide, technical.....	1.50%
N-Octyl bicycloheptene dicarboximide .....	0.50%
Di-n-propyl isocinchomeronate .....	1.00%
OTHER INGREDIENTS .....	96.85%
TOTAL .....	100.00%

\*Equivalent to 1.20% of butylcarbityl (6-propylpiperonyl) ether and 0.30% related compounds.

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**  
 See Side Panel for Precautionary Statements  
 See Back of Card for Precautions and Directions for Use

Net Contents \_\_\_\_\_ fl oz

EPA Reg. No. 270-345  
 EPA Est. No. 11715-TN-1

**READ ENTIRE LABEL BEFORE EACH USE**  
**FOR USE ON DOGS, CATS, AND HORSES ONLY**

**PRECAUTIONARY STATEMENTS**  
**CAUTION**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**HUMANS:** Harmful if swallowed. Avoid breathing vapors. Avoid contact with eyes. Wash hands with soap and water after using.

**ANIMALS:** Avoid contact with eyes. If in eyes, flush with water. 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.

FIRST AID	
IF SWALLOWED	<ul style="list-style-type: none"> <li>• Immediately call a poison control center or doctor.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give <b>any</b> liquid to the person.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
IF INHALED:	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
IF IN EYES:	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-234-2269 for emergency medical treatment information.	

### ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not add directly to water.

### DIRECTIONS FOR USE

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

To Kill Ear Mites: Clean ear with Pet-Otic®. Place a sufficient amount of Pet-Mite Lotion into each ear to thoroughly coat the surface of the ear canal. Gently massage the base of the ear. Leave lotion in ear for a few minutes and carefully wipe the excess lotion from the ear with cotton. Do not reapply for 7 days. Lotion to be applied twice at 7 day intervals.

Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals, or animals on medication. Do not use on puppies and kittens under 12 weeks.

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## INDICATIONS

FOR USE ON HORSES – Not for use on horses intended for slaughter. Controls flies, gnats, mites, mosquitoes, chiggers, lice and ticks. Before application, remove dirt or debris by brushing or washing with a mild detergent. When areas are completely dry, apply a light film to affected areas, massaging into the skin daily for 2 to 3 days. Then apply every 3 to 5 days as needed. To kill ticks, cover the tick with the lotion and let stand a few minutes before removing tick.

NOTE: Do not put directly on broken skin or an open wound.

### STORAGE AND DISPOSAL

**STORAGE:** Store in a cool, dry area away from heat and open flame. Do not contaminate water, food, or feed by storage or disposal. Do not transfer contents to other containers.

**DISPOSAL: If empty:** Do not reuse this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Manufactured by:

Pet Chemicals

P.O. Box 18993

Memphis, TN 38118-0993