

APR 11 1990

PA 17

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Adams Veterinary Research Laboratories, Inc  
Subsidiary of Norden Laboratories  
P.O. Box 971039  
Miami, FL 33197

Dear Dr. Alan R. Wagner

Subject: Adams Flea Off Ear Mite Lotion  
EPA Reg. No. 37425-14  
Application dated March 8, 1990

The proposed amendment to the registration of the product cited above under the Federal Insecticide Fungicide and Rodenticide Act removing the active ingredient, NGK R-11, is acceptable subject to the comments listed below. A stamped copy of the draft label is enclosed for your records.

- 1) Based on the current Confidential Statement of Formula (CSF) dated March 8, 1990 the product will not meet the label claim for the active ingredients. The percentage claimed in the ingredient statement for the active ingredients must be the same as the certified lower limit for these ingredients listed in the CSF. A new CSF which agrees with the label declaration must be submitted or the label ingredients statement must be changed to agree with the current CSF.
- 2) This change in formulation is only acceptable as a basic formulation change not as an alternate formula. Submit a new CSF with the proper block checked.
- 3) Provide the upper and lower Certified Limits of the individually added inerts in the CSF.
- 4) Submit the product chemistry data for the new formulation including the flash point of the product.

55893:I:Tavano;CBI-13;KENCO:04/04/90;05/04/90;ka;sw;vo;dd;ka

CONCURRENCES

SYMBOL	H7505C						
SURNAME	Tavano						
DATE	4/7/90						

PL 20000

- 5) Submit a 1 year storage stability study. The formulated product must be analyzed for its active ingredients at time zero and for one year of storage. The storage must be under warehouse conditions of temperature and humidity using containers similar to those which will be used in the trade. This study must be submitted within 15 months of the date of this letter.
  
- 6) Provide the chemical identity of the ingredients listed below. Include Chemical Abstracts Numbers and Manufacturing Safety Data Sheets.

[REDACTED]  
[REDACTED]

- 7) Provide the chemical identity and percentages of all components of the ingredients listed below. Include Chemical abstracts Numbers for each component and a Manufacturing Safety Data Sheet.

[REDACTED]  
[REDACTED]

Sincerely yours,



Phil Hutton  
Product Manager (17)  
Insecticide-Rodenticide Branch  
Registration Division (H7505C)

# A<sup>®</sup> ADAMS<sup>™</sup> EAR MITE LOTION A<sup>®</sup>

## PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

### CAUTION

**HUMAN:** Harmful if swallowed. Avoid breathing vapors. Avoid contact with eyes. In case of contact immediately flush eyes with plenty of water. Obtain medical attention if irritation persists. If swallowed do not induce vomiting. Wash hands with soap and water after using.

**ANIMAL:** Avoid contact with the eyes. If in eyes flush with water. Do not use on meat or milk producing animals.

**ENVIRONMENTAL HAZARDS:** This product is toxic to fish. Do not add directly to water.

**PHYSICAL OR CHEMICAL HAZARDS:** None

**SHAKE WELL BEFORE USE**

### GENERAL DESCRIPTION

ADAMS EAR MITE LOTION combines the insecticidal properties of natural pyrethrin with the healing properties of Aloe Vera Gel and PABA (sunscreen). Together they provide your pet with both protection from insects and relief from the irritation they cause.

REPELLENT LOTION FOR EARS & SKIN

DOGS • PUPPIES • CATS • KITTENS

**KILLS**

AND TEMPORARILY REPELS

EAR MITES • FLIES • MOSQUITOES • GNATS

FLEAS • TICKS • CHIGGERS • LICE

### ACTIVE INGREDIENTS

Pyrethrin	0.15%
Piperonyl butoxide technical	1.50%
N-Octyl bicycloheptene dicarboximide	0.50%
Di-n-propyl sebacate/homocarbonate	1.00%
<b>INERT INGREDIENTS</b>	<b>98.85%</b>
<b>TOTAL</b>	<b>100.00%</b>

\*Equivalent to 1.20% of butylcarbityl (8-propylpiperonyl) ether and 0.30% related compounds.

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

SEE SIDE PANEL FOR PRECAUTIONARY STATEMENTS

NET CONTENTS 2 FL. OZ./59 ml

EPA Est. No. 37425 FL 1

EPA Reg. No. 37425 14

## DIRECTIONS

DOGS • PUPPIES

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.  
**TO KILL AND REPEL EAR MITES:** Apply ADAMS PAN-OTIC EAR CLEANER to the ear canal. Gently dry ear with a cotton ball. Apply 1/2 tsp of ADAMS EAR MITE LOTION to the ear canal daily for 7 to 10 days or as directed.  
**TO KILL TICKS:** Make sure the tick is fully attached to the animal. Apply ADAMS EAR MITE LOTION to the skin around the tick. **TO USE AS A REPELLENT:** Apply ADAMS EAR MITE LOTION to the inner surfaces of the outer ear.

### STORAGE AND DISPOSAL

**STORAGE:** Store in a cool, dry place. Do not store in open flame. Do not contaminate food or feed. Do not store in storage or disposal containers.

**DISPOSAL:** Do not reuse. Dispose of in a thoroughly and wrap contents in newspaper and discard in trash.

Sold Only Through Licensed Veterinarians  
Product No. 6830

**A ADAMS Veterinary-Strength Products**  
ADAMS VETERINARY RESEARCH LABORATORIES, INC./Subsidiary of Norden Laboratories, Miami, FL 33197, U.S.A.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated

4 - 9 1990

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

37425-14

**BEST AVAILABLE COPY**

# THOROUGH CARE



## INDICATIONS

For use on horses. Controls flies, gnats, mites, mosquitoes, chiggers, lice and ticks.

## PRECAUTIONARY STATEMENTS

### CAUTION

**HUMAN:** Harmful if swallowed. Avoid breathing vapors. Avoid contact with eyes. In case of contact, immediately flush eyes with plenty of water. Obtain medical attention if irritation persists. If swallowed, do not induce vomiting. Wash hands with soap and water after using.

**ANIMAL:** Avoid contact with the eyes. If in eyes, flush with water. Do not use on meat or milk producing animals.

**ENVIRONMENTAL HAZARDS:** This product is toxic to fish. Do not add directly to water.

**PHYSICAL OR CHEMICAL HAZARDS:** None

**CAUTION:** Do not put directly on broken skin or an open wound. ThoroughCare® Fly Repellent Lotion may be applied on a bandage.

## FLY REPELLENT LOTION

With Lanolin, Aloe Vera and Sunscreen

### ACTIVE INGREDIENTS

Pyrethrins ..... 0.15%  
\*Piperonyl butoxide, technical 1.50%  
N-Octyl bicycloheptene  
dicarboximide ..... 0.50%

Di-n-propyl isocinchomeronate 1.00%  
Inert Ingredients ..... 96.85%  
TOTAL ..... 100.00%

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

## KEEP OUT OF REACH OF CHILDREN

### CAUTION

See Side Panel for  
Precautionary Statements

EPA EST. NO. 37425-FL-1  
EPA REG. NO. 37425-14-622

Net Contents 12 fl. oz./355 ml

## DIRECTIONS FOR USE

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

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.

## 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:** Do not reuse container. Rinse thoroughly and wrap container in several layers of newspaper and discard in trash.

Sold Only Through  
Licensed Veterinarians

Manufactured for: Norden Laboratories, Inc.  
Lincoln, ME 04501

Product No. 8741

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAR - 9 1990

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

37425-14