

APR 23 1990

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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 and Tick Shampoo
EPA Reg. No. 37425-4
Application dated March 22, 1990

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

- 1) Based on the current Confidential Statement of Formula (CSF) dated March 22, 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 the 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 inserts in the CSF.
- 4) Submit the product chemistry data for the new formulation including the flashpoint of the product.

55894:I:Tavano:LCBI-07:KENCO:04/18/90:05/17/90:de:SW:EK:CL

CONCURRENCES

SYMBOL	H7505C							
SURNAME	Tavano							
DATE	4/20/90							

- 5) Submit a 1 year storage stability study. The formulated product must be analyzed for its active ingredients time at 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 [REDACTED]. Include the Chemical Abstracts Number and a Material Safety Data Sheet.
- 7) Provide the chemical identity and percentages of all components of the ingredients listed below. Include Chemical Abstracts Numbers for each component and a Material Safety Data Sheet.
 - a) [REDACTED]
 - b) [REDACTED]

Sincerely yours,

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

ADAMSTM A[®] FLEA AND TICK SHAMPOO A

PRECAUTIONARY STATEMENTS

**Hazards to Humans
and Domestic Animals**

CAUTION

HUMAN: Harmful if swallowed. Avoid contact with eyes. In case of contact, flush with water. Avoid contact with food and food serving areas. Wash thoroughly after using with soap and warm water.

ANIMAL: Do not use on puppies and kittens less than six weeks of age.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not add directly to water. Do not wash animal where runoff is likely to occur.

DIRECTIONS FOR USE

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

Thoroughly soak animal with warm water taking 2-3 minutes to wet hair. Apply ADAMS FLEA AND TICK SHAMPOO on head and ears and lather, then repeat procedure with

FOR DOGS - PUPPIES - CATS - KITTENS

KILLS

**FLEAS - LICE - TICKS
DEODORIZES**

Gnats - Mosquitoes - Flies

ACTIVE INGREDIENTS

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

**INERT INGREDIENTS

TOTAL 97.85%

*Equivalent to 1.20% of butylcarbityl (6-propyl piperonyl) ether and 30% of related compounds.

**Inert ingredients include a concentrated rich lathering shampoo enriched with coconut extract and lanolin. Removes loose dandruff, dirt and scales. Leaves the coat soft and shining.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Side Panel for Precautionary Statements

EPA Est. No. 37425-FL-1

EPA Reg. No. 37425-4

Net Contents 12 fl. oz./355 ml

Directions For Use (continued)

neck, chest, middle and hindquarters, finishing legs last. Let animal stand 3-5 minutes (this is an important part of grooming procedure), then rinse animal thoroughly.

For extremely dirty or scaly animals the above procedure may be repeated. ADAMS FLEA AND TICK SHAMPOO may be used every 7-10 days as directed by your veterinarian.

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 empty container. Rinse thoroughly and wrap container in several layers of newspaper and discard in trash.

Sold Only Through
Licensed Veterinarians

889 85-6845-01



ADAMS Veterinary-Strength ProductsTM

ADAMS VETERINARY RESEARCH LABORATORIES, INC.
Subsidiary of Norden Laboratories, Miami, FL 33197, U.S.A.

ACCEPTED
with COMMENTS
in EPA Letter Dated

24 1990

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

37425-4