

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

13 MAY 1992

Alan R. Wagner DVM, MS
SmithKline Beecham
P.O. Box 971039
Miami, FL 33197

Dear Dr. Wagner:

Subject: Submission of Efficacy Data; Label Revision
Adams Ear Mite Lotion
EPA Registration Number 37425-14
Submission dated April 17, 1992

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. Submit one (1) copy of the final printed label prior to releasing the product for shipment.

1. The proposed directions for use do not include a statement which indicates the frequency of product application, although such a statement does appear in the current directions. Reinstate clear instructions regarding frequency of reapplication for this use.
2. Revise the statement "Place the correct amount of ADAMS EAR MITE LOTION..." to read "Place a sufficient amount of ADAMS EAR MITE LOTION...".

The efficacy data which was submitted has been assigned the MRID number 422873-01. Please use this number in all future references to this data.

Sincerely,

Rym

Richard F. Mountfort
Product Manager (10)

CONCURRENT Insecticide-Rodenticide Branch
Registration Division

SYMBOL							
SURNAME							
DATE							

ADAMS EAR MITE LOTION

PRESENT DIRECTIONS FOR USE

TO KILL AND REPEL EAR MITES: Clean ear with ADAMS PAN-OTIC EAR CLEANER to remove build up wax and dirt. Gently dry ear with a cotton ball or soft cloth and apply a thin film of ADAMS EAR MITE LOTION. The lotion may be applied daily for 7 to 10 days or as directed by your veterinarian.

PROPOSED DIRECTIONS FOR USE

TO KILL EAR MITES: Clean ear with ADAMS PAN-OTIC EAR CLEANER to remove built up wax and dirt. Place the correct amount of ADAMS EAR 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.

ACCEPTED
with COMMENTS
In EPA Letter D-1005

15 MAY 1992

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
37495-14

ADAMS™ EAR MITE LOTION

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 (sunscreens). 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

Pyrethrins	0.15%
*Piperonyl butoxide, technical	1.50%
N-Octyl bicycloheptene dicarboximide	0.50%
Di-n-propyl isocinchomerate	1.00%
INERT INGREDIENTS	96.85%
TOTAL	100.00%

*Equivalent to 1.20% of butylcarbitol & propylparathion ester and 0.30% 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

Net Contents 2 fl. oz. 59 ml

DIRECTIONS

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

TO KILL AND REPEL EAR MITES: Use ADAMS PAN-OTIC EAR CLEANER to remove ear wax. Gently dry ear with a cotton ball or towel. Apply ADAMS EAR MITE LOTION daily for 7 to 10 days or as directed.

TO KILL TICKS: Make sure ticks are dead before use.
TO USE AS A REPELLENT: Spray inner surfaces of the outer ear and around the ear when animals enter infested area. Repeat as directed.

STORAGE AND

DISPOSAL: Store in a cool, dry, open flame. Do not contaminate.

DISPOSAL: Do not reuse empty container. Wash thoroughly and wrap container in newspaper. Do not discard in trash.

Sold Only Through Licensed Veterinarians

SmithKline Beecham Animal Health
West Chester, PA 19380

BEST AVAILABLE COPY