

37425-14

03-08-2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR - 8 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Jean Butler
Pet Chemicals
P.O Box 18993
Memphis, TN 38118-0993

Dear Ms. Butler:

Subject: Adams Ear Mite Lotion
EPA Reg. No. 37425-14
Submission dated 9-25-03

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.

Net contents must be expressed as fluid ounces, as this product is a liquid.

Delete from the Precautionary statements for humans the following precautions which detract from the First Aid statements:

In case of contact, immediately flush eyes with plenty of water. Obtain medical attention if irritation persists. If swallowed do not induce vomiting.

Delete from the animal precautionary statements the following: "Do not use on meat or mild (sic) producing animals." This detracts from the statement "Not for use on horses intended for slaughter." Further, the product is not labeled for use on animals other than dogs, cats, and horses.

Under Indications, the statement about broken skin/open wounds is preceded by the word "Caution". For this statement, use "Attention" or "Note". On pesticide products, Caution may only be used as a signal word in connection with the precautionary statements.

The claim "Do not put directly on broken skin or an open wound" appears to contradict the direction "Adams fly repellent lotion may be applied on a bandage." Clarify these directions so that they are not contradictory.

One copy of the finished labeling must be submitted prior to releasing the product for shipment. If you have questions, please call Ann Sibold at 703 305-6502.

Sincerely,

Ann Sibold
for Richard Gebken
Acting Product Manager 10
Insecticide Branch
Registration Division (7505C)

ACCEPTED
with COMMENTS
In EPA Letter Dated:
MAR - 8 2004

ADAMS EAR MITE LOTION

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
37425-14

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

[ALTERNATE BRAND NAMES]:

MITA-CLEAR™

THOROUGH CARE™ FLY REPELLENT LOTION

ADAMS™ FLY REPELLENT LOTION

PET-MITE™ EAR MITE LOTION

KILLS EAR MITES

FOR DOGS - PUPPIES - CATS - KITTENS

INSECTICIDE AND REPELLENT FOR USE ON HORSES

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:	<u>96.85%</u>
	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 _____ OZ

PRECAUTIONARY STATEMENTS

CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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 eyes. If in eyes, flush with water. Do not use on meat or milk producing animals. 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">• Immediately call a poison control center or doctor.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give any liquid to the person.• Do not give anything by mouth to an unconscious person.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.

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FIRST AID (Cont'd)	
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
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 1-877-757-4943 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.

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.

Caution: Do not put directly on broken skin or an open wound. Adams Fly Repellent lotion may be applied on a bandage.

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.

In case of Emergency or for Product Use Information call _____
(Distributors may elect to use their own phone numbers)

MANUFACTURED BY:
PET CHEMICALS
P.O. BOX 18993
MEMPHIS, TN 38118-0993

Netserver/Regulatory/SPI labels/37425-14amend(1-14-03)(EPA appr. 4-8-03)fp1(horse-amend-9-25-03)