

PM-13

Reg # 8220-16

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Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0050. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number
218093

Application for Pesticide - Section I

1. Company/Product Number 8220-16	2. EPA Product Manager George La Rocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) EAR-RITE Insecticidal Ear Wash for Dogs	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Carter-Wallace, Inc. Lambert Kay Division P.O. Box 1418 Cranbury, NJ 08512-0187 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of final printed container and carton labeling (3 copies of each) for:

(a) EAR-RITE Insecticidal Ear Wash for Dogs in follow-up to acceptance of a labeling amendment per Agency letter of 10/30/90 and

(b) LASSIE Insecticidal Ear Wash for Dogs in follow-up to previous notification of the additional brand name.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Metal Plastic Glass Paper Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Dorothy A. S. Fields, Ph.D.	Title Executive Director, Regulatory Affairs Dept. Carter-Wallace, Inc.	Telephone No. (Include Area Code) (609) 655-6334
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) 1994
2. Signature <i>Richard K Fisher</i>	3. Title VP, Research and Development Lambert Kay Division	
4. Typed Name Richard K. Fisher, D.V.M.	5. Date 6/7/95	

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**PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND
DOMESTIC ANIMALS**

CAUTION

Harmful if swallowed. For external use on dogs only. Not for prolonged use. If condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult a veterinarian.

**PHYSICAL OR CHEMICAL
HAZARD**

Do not use, pour, spill or store near heat or open flame.

**STATEMENT OF PRACTICAL
TREATMENT**

IF SWALLOWED: Induce vomiting by touching finger to back of throat.

EAR MITE DIAGNOSIS

Dogs with ear mites will shake their heads and vigorously scratch their ears. Ear mites live in the ear canal where they cause a dark, reddish brown, waxy debris to be formed. The mites can usually be seen by placing a small amount of the debris on a black surface under a bright light. They will appear as small, moving white specks.

Ear-Rite®

**Insecticidal Ear Wash
for Dogs**

**Aids in
Wax Removal
Controls Ear Mites**

ACTIVE INGREDIENTS:

Piperonyl Butoxide, Technical* 0.50%
Pyrethrins 0.05%

INERT INGREDIENTS 99.45%
100.00%

*Equivalent to 0.4% (butylcarbityl) (6-propylpiperonyl) ether and 0.1% other related compounds.

KEEP OUT OF REACH OF CHILDREN

CAUTION: See side for additional precautionary statements.

4 FL.OZ. (118 mL)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Clean ears twice a month as an aid in reducing probability of ear mite infestation and wax accumulation. Instill 10 drops of EAR-RITE® Insecticidal Ear Wash into each ear. Gently massage base of ear for 3 to 5 minutes. Let soak for a few more minutes. Then let dog shake its head to remove as much micide as possible. Swab thoroughly with cotton.

STORAGE AND DISPOSAL

Store in a cool and dry place. Do not reuse empty container. Wrap container and discard in trash.

CARTER-WALLACE, INC.
LAMBERT KAY DIVISION
Granbury, N.J. 08512-0187

EPA Est. 8220-PJ-2


EPA Reg. No. 8220-16

Product No. 51106 BT-51105-12

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FOR DOGS
INSECTICIDAL EAR WASH
Ear-Rite
Lambert Kay



Lambert Kay
Ear-Rite[®]
INSECTICIDAL
EAR WASH
FOR DOGS

Aids in
Wax Removal
Controls Ear Mites

KEEP OUT OF REACH OF CHILDREN
CAUTION:
See side
for additional
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statements



4 FL. OZ.
(118 mL)


Lambert Kay
INSECTICIDAL EAR WASH
FOR DOGS
ACTIVE INGREDIENTS
INERT INGREDIENTS

PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND
DOMESTIC ANIMALS
CAUTION

PHYSICAL OR CHEMICAL
HAZARD

STATEMENT OF PRACTICAL
TREATMENT
IF SWALLOWED

EAR MITE DIAGNOSIS


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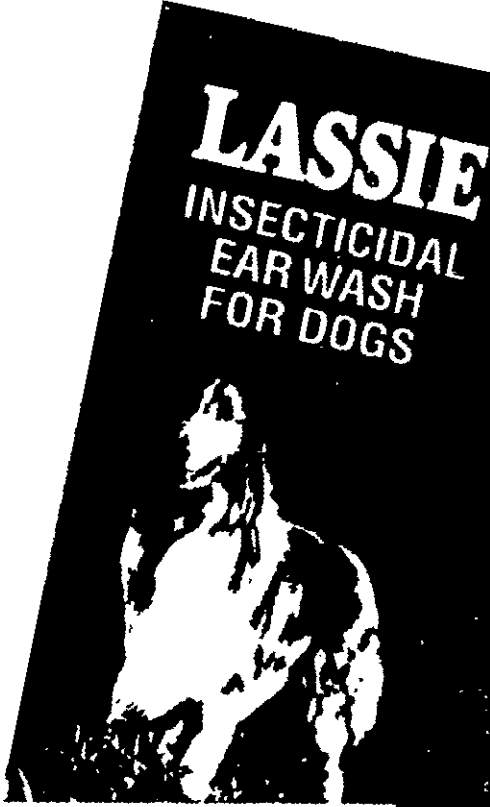

Lambert Kay
INSECTICIDAL EAR WASH
FOR DOGS
DIRECTIONS FOR USE
EAR RITE

STORAGE AND DISPOSAL



BEST COPY AVAILABLE

Copy 1 of 3
3



**Controls Ear Mites
Aids in Wax Removal**

LASSIE
INSECTICIDAL
EAR WASH FOR DOGS

ACTIVE INGREDIENTS
INERT INGREDIENTS

PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND
DOMESTIC ANIMALS

ENVIRONMENTAL CHEMICAL
HAZARD

STATEMENT OF PRACTICAL
TREATMENT

PERMITTED DRUGS

LASSIE
INSECTICIDAL
EAR WASH
FOR DOGS



**Controls Ear Mites
Aids in Wax Removal**

MADE IN U.S.A.

CAUTION

4 FL OZ (118 mL)



MADE IN U.S.A.

CAUTION

4 FL OZ (118 mL)

BEST COPY AVAILABLE

Copy 1 of 3

