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8220-16

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3455528681

APR 16 1998

Ms. Dorothy Fields
Carter-Wallace, Inc.
Lambert Kay Division
PO Box 1418
Cranbury, NJ 08512-0187

Dear Ms. Fields:

Subject: Labeling; Change in Alternate/Basic Formulation
Ear-Rite Insecticidal Ear Wash for Dogs
EPA Registration No. 8220-16
Your Application Dated August 11, 1997

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable provided that you make the labeling changes indicated below prior to release for shipment of product bearing the amended labeling:

1. Delete the phrase "With Aloe Vera to Help Soothe Irritated Ears." As stated in our August 12, 1997 letter, this claim is drug related and unacceptable. You may state that your product contains aloe vera but you cannot make any drug related claims associated with it's presence.
2. Revise the statement to read as follows: "Contains Pyrethrins, a Botanically Derived Insecticide."
3. Revise the Precautionary Statements as follows: "Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling."
4. Under First Aid delete the "IF SWALLOWED" statement since your product is toxicity category IV for acute oral.

The Confidential Statements of Formula dated August 11, 1997 for the basic and alternate formulations have been reviewed and are acceptable.

Submit two copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

Sincerely,

George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505C)

EAR-RITE Insecticidal Ear Wash
for Dogs, EPA Reg. No. 8220-16

Application for Labeling Amendment
OPP ID No. 247860

Side Panel
Carton Labeling

EAR-RITE® INSECTICIDAL EAR WASH FOR DOGS

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS**

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

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

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. 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. Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing or medicated 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

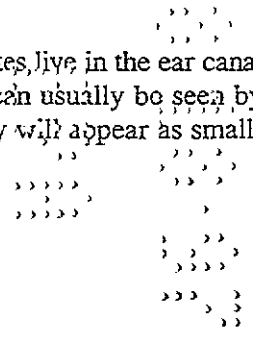
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

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.



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APR 16 1998

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Lambert Kay Division
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EAR-RITE Insecticidal Ear Wash
for Dogs, EPA Reg. No. 8220-16

2/7

Application for Labeling Amendment
OPP ID No. 247860

Front and Back Panels
Carton Labeling

EAR-RITE® INSECTICIDAL EAR WASH FOR DOGS

Aids in Wax Removal

Controls Ear Mites

Contains a Botanically Derived Insecticide

With Aloe Vera to Help Soothe Irritated Ears

KEEP OUT OF REACH OF CHILDREN
CAUTION: See other cautions and ingredient
statement on side panel

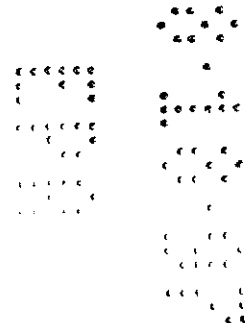
4 FL. OZ. (118 mL)

ACCEPTED
with COMMENTS
in EPA Letter Dated

APR 16 1998

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

8220-16



Copy 2 of 5

EAR-RITE Insecticidal Ear Wash
for Dogs, EPA Reg. No. 8220-16

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Application for Labeling Amendment
OPP ID No. 247860

Side Panel
Carton Labeling

EAR-RITE® INSECTICIDAL EAR WASH FOR DOGS

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS**

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

PRECAUTIONARY STATEMENTS HAZARD TO HUMANS AND DOMESTIC ANIMALS CAUTION

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FIRST AID

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4/7

EAR-RITE Insecticidal Ear Wash
for Dogs, EPA Reg. No. 8220-16

Application for Labeling Amendment
OPP ID No. 247860

Side Panel
Carton Labeling

EAR-RITE® INSECTICIDAL EAR WASH FOR DOGS

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 miticide as possible. Swab thoroughly with cotton. Do not repeat treatment for 2 weeks.

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry area.

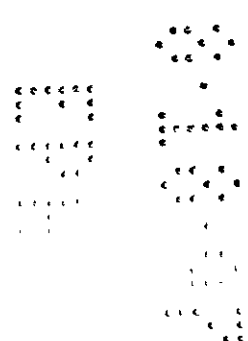
DISPOSAL: Securely wrap original container in several layers of newspaper and discard in trash.

For information call 1-800-690-6455 (8:30 AM - 4:30 PM Eastern Time, Monday - Friday).

Carter-Wallace, Inc.
Lambert Kay Division
Cranbury, N.J. 08512-0187

EPA Reg. No. 8220-16
EPA Est. 8220-NJ-1

Product No.
CT-



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EAR-RITE Insecticidal Ear Wash
for Dogs, EPA Reg. No. 8220-16

Application for Labeling Amendment
OPP ID No. 247860

Front Panel
Bottle Label

EAR-RITE® INSECTICIDAL EAR WASH FOR DOGS

Aids in Wax Removal

Controls Ear Mites

Contains a Botanically Derived Insecticide

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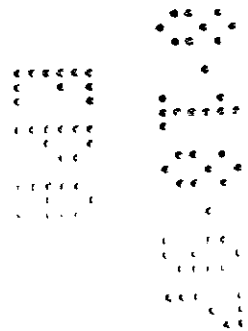
INERT INGREDIENTS 99.45%
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*Equivalent to 0.4% (butylcarbityl)
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KEEP OUT OF REACH OF CHILDREN

CAUTION: See other cautions on side panel.

4 FL. OZ. (118 mL)



EAR-RITE Insecticidal Ear Wash
for Dogs, EPA Reg. No. 8220-16

4/7

Application for Labeling Amendment
OPP ID No. 247860

Side Panel
Bottle Label

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS**

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

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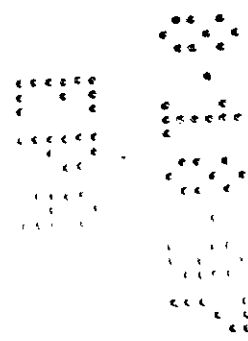
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EAR-RITE Insecticidal Ear Wash
for Dogs, EPA Reg. No. 8220-16

7/7

Application for Labeling Amendment
OPP ID No. 247860

Side Panel
Bottle Label

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Lambert Kay Division
Cranbury, N.J. 08512-0187

EPA Reg. No. 8220-16
EPA Est. 8220-NJ-1

Product No.
BT-

