

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

22 SEP 1995

Richard K. Fisher, D.V.M.  
Carter-Wallace, Inc.  
Lambert Kay Division  
P.O. Box 1418  
Cranbury, NJ 08512-0187

Dear Dr. Fisher:

Subject: Submission of Upgraded Data and Revised Labeling  
X-O-TROL Flea & Tick Spray for Dogs  
EPA Registration Number 8220-60  
Submission Dated August 15, 1995

The Agency has completed its review of the additional information submitted to upgrade a previously-provided dermal sensitization study to acceptable. The Agency has concluded that the study is now acceptable and that the product is not a dermal sensitizer. A copy of the Agency's review is enclosed for your records.

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 comment listed below:

- Create a new paragraph in the directions for use section for the instructions that begin with the statement "Hold bottle upright and point nozzle . . .". These instructions should be included a paragraph that is distinct and separate from the sentence "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

Submit three copies of finished printed labeling prior to releasing product for shipment.

If you have any questions or comments, please contact me at (703) 305-6788.

Sincerely,

RPK

Richard P. Keigwin, Jr.  
Product Manager 10

Insecticide-Rodenticide Branch  
CONCURRENCES  
Registration Division (7505C)

SYMBOL							
SURNAME							
DATE							

ACCEPTED  
with COMMENTS  
In EPA Letter Dated

22 SEP 1995

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

8220-60

**KILLS FLEAS!  
FLEA EGGS...  
FOR 127 DAYS**  
ON YOUR PET AND ON SURFACES  
YOUR PET CONTACTS

INSECT  
GROWTH  
REGULATOR

**X-O-TROL®**  
FLEA & TICK  
SPRAY FOR DOGS

ACTIVE INGREDIENTS:

Pyrethrins ..... 0.0500%  
Piperonyl Butoxide, Technical ..... 0.5000%  
Permethrin ..... 0.2000%  
Fenoxycarb: ethyl(2-(4-phenoxyphenoxy)-ethyl)carbamate... 0.0625%

INERT INGREDIENTS: ..... 99.1875%

\*Equivalent to 0.40% butylcarbityl (6-propylpiperonyl) ether  
and 0.10% related compounds. \*\*3-(phenoxyphenyl)methyl (+/-) cis,trans-  
3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate.  
Cis:trans ratio: min. 35% (+/-) cis and max. 65% (+/-) trans.

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional  
precautionary statements.

1 PINT (473 mL)



Lambert Kay™

LB 36123 026

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

Avoid contact with eyes, skin or clothing. Caution: May be irritating to skin. May cause injury and harmful if absorbed through skin or inhaled. Avoid breathing spray mist. Wash hands and water after handling. Remove contaminated clothing before reuse. Do not use on children under 3 months of age. Do not spray in eyes, in mouth, or on the face. Do not use this or any other pesticide on cats or dogs.

**PHYSICAL OR CHEMICAL HAZARD**

Do not use or store near heat or open flame.

**STATEMENT OF PRACTICAL CONCERNS**

**If in Eyes:** Flush eyes with plenty of water. If irritation persists. **If on Skin:** Wash with water. Get medical attention. **If Swallowed:** Call Poison Control Center. Drink 1 or 2 glasses of water. Do not induce vomiting by touching back of throat with finger. If conscious, do not give anything by mouth and do not use emetics. **If Inhaled:** Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Hold bottle upright. Spray in the desired direction of spray. Spray the dog from a distance of 12 to 18 inches.

Start spraying at the tail moving the dispenser toward the head. Be sure that the dog's entire body is covered including under the body. While spraying fluff the hair so that the spray penetrates to the skin. Make sure spray wets thoroughly. Avoid spraying eyes, in face or on genitalia. Repeat as necessary.

**STORAGE AND DISPOSAL**

**Storage:** Store in a cool area away from heat and open flame. Keep from freezing.

**Disposal:** Do not reuse empty container. Wrap original container in several layers of newspaper and discard in trash.

Distributed by Carter-Wallace, Inc.,  
Lambert Kay Division, Cranbury, NJ 08512-0187

EPA Reg No. 8220-60 EPA Est. 8220-NJ-2  
Product No. 36123 LB-36123-03B