

137  
MAY 22 1985

345/143984  
17/4

John E. McDaniel  
Burns-Biotec Laboratories, Inc.  
2000 Galloping Hill Road  
Kenilworth, NJ 07033

Dear Mr. McDaniel:

Subject: Amendment - Delete Two Drug Ingredients  
and Associated Label Claims  
Aurimite  
EPA Registration No. 6392-5  
Your Application Dated December 3, 1984

**BEST AVAILABLE COPY**

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is acceptable, provided that you make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

1. On the label ingredient statement please make the following changes:

[REDACTED]

b. [REDACTED]

- c. Please identify the first active as dioctyl sodium sulfosuccinate on the label. This is our commonly accepted name.

2. Add the following new precaution to the label "Discontinue use and consult a veterinarian if infection persists."

3. Please provide the flashpoint of a sample from your current formulation. Please confirm/correct the value as noted on the Confidential Statement of Formula (CSF).

Change the word "controlling" to "controlling" in the statement beginning "For use as an aid in..." which imply total eradication.

Submit five (5) copies of your revised final product label  
you release the product for shipment with the amended labeling.

A stamped copy of the label is enclosed for your records.

This acceptance removes the product from New Animal Drug status.

Sincerely yours,

George T. LaRocca  
Product Manager (15)  
Insecticide-Rodenticide Branch  
Registration Division (78-767)

Enclosure

cc: Director, Division of Surveillance

Silk-Screened Bottle, Front Panel

AURIMITE®

Active Ingredients: 1.952% docusate sodium, 1.952% benzocaine,  
0.04% pyrethrins, 0.49% piperonyl butoxide technical\*, 0.18%  
petroleum distillate. [REDACTED]

\*Equivalent to 0.392% of (butylcarbityl)(6-propylpiperonyl) ether  
and 0.098% of related compounds.

KEEP OUR OF REACH OF CHILDREN  
CAUTION  
See rear panel for additional precautions

EPA Est. 29909-CA-1

EPA Reg. No. 6392-5

1 FL OZ

Distributed by Burns-Biotec Laboratories, Inc., Kenilworth, NJ 07033

ACCEPTED  
with COMMENTS  
in EPA Letter Dated

MAY 22 1985

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
6392-5

Silk-Screened Bottle, Rear Panel

For use as an aid in eliminating ticks and mites in the ears of dogs and cats and for temporary relief from itching caused by such conditions.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Shake well before using. Apply 10 drops into ears twice daily until ticks and mites are eliminated.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid inhalation of vapors. Avoid contact with skin. Wash contaminated skin promptly with soap and water. Avoid contamination of food and water.

STORAGE AND DISPOSAL: Store in original bottle in locked storage areas. Do not reuse bottle. Rinse thoroughly before discarding trash.

5 of 7

Shelf Carton, Front Panel

AURIMITE

Active Ingredients: 1.952% docusate sodium, 1.952% benzocaine,  
0.04% pyrethrins, 0.49% piperonyl butoxide technical\*, 0.18%  
petroleum distillate.

\*Equivalent to 0.392% of (butylcarbityl)(6-propylpiperonyl) ether  
and 0.098% of related compounds.

KEEP OUT OF REACH OF CHILDREN  
CAUTION  
See rear panel for additional precautions

EPA Est. 29909-CA-1

EPA Reg. No. 6392-5

12 - 1 FL OZ BOTTLES

Distributed by Burns-Biotec Laboratories, Inc., Kenilworth, NJ 07033

6 of 7

Shelf Carton, Rear Panel

For use as an aid in eliminating ticks and mites in the ears of dogs and cats and for temporary relief from itching caused by such conditions.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Shake well before using. Apply 10 drops into ears twice daily until ticks and mites are eliminated.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid inhalation of vapors. Avoid contact with skin. Wash contaminated skin promptly with soap and water. Avoid contamination of food and water.

STORAGE AND DISPOSAL: Store in original bottle in locked storage areas. Do not reuse bottle. Rinse thoroughly before discarding in trash.

207  
Shelf Carton, Left Panel

AURIMITE®

Shelf Carton, Right Panel

AURIMITE®

Control No.

Shelf Carton, Top Flap

AURIMITE®