

P0117

2097-15

2/10/90

MAY 10 1990

Beecham Laboratories
501 Fifth Street
Bristol, Tennessee 37620

Dear Dr. Alan R. Wagner

Subject: Mycodex Aqua-Spray
EPA Reg. No. 2097-15
Application dated March 22, 1990

The proposed amendment to the registration of the product cited above under the Federal Insecticide Fungicide and Rodenticide Act removing the active ingredient, MGK R-11, is acceptable subject to the comments listed below. A stamped copy of the label is enclosed for your records.

- 1) Based on the current Confidential Statement of Formula (CSF) dated March 22, 1990 the product will not meet the label claim for the active ingredients. The percentage claimed in the ingredient statement for the active ingredients must be the same as the certified lower limit for the these ingredients listed in the CSF. A new CSF which agrees with the label declaration must be submitted or the label ingredients statement must be changed to agree with the current CSF.
- 2) This change in formulation is only acceptable as a basic formulation change not as an alternate formula. Submit a new CSF with the proper block checked.
- 3) Provide the upper and lower Certified Limits of the individually added inerts in the CSF.
- 4) Submit the product chemistry data for the new formulation including the flashpoint of the product.

55898:I:Tavano:CBI-01:KENCO:05/03/90:08/03/90:ka:SW:VO:DD:CT

CONCURRENCES							
SYMBOL	H7505c						
SURNAME	Tavano						
DATE	5/4/90						

- 5) Submit a 1 year storage stability study. The formulated product must be analyzed for its active ingredients at time zero and for one year of storage. The storage must be under warehouse conditions of temperature and humidity using containers similar to those which will be used in the trade. This study must be submitted within 15 months of the date of this letter.
- 6) Provide the chemical identity of the ingredient, Polyquaternium - 6. Include the Chemical Abstracts Number and a Material Safety Data Sheet.
- 7) Since your data matrix does not give a dielectrical breakdown voltage, you must add the following to the use directions:
"Do not use this product in or on electrical equipment due to the possibility of shock hazard."
- 8) The petroleum distillate may be declared as an inert ingredient.

Sincerely yours,



Phil Hutton
Product Manager (17)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

HUMAN: Harmful if swallowed or inhaled. Avoid breathing mist. Avoid contamination of food. Wash hands with soap and water after using.

ANIMAL: Avoid treatment of nursing kittens and puppies. If treatment is necessary spray on tips of fingers and rub into coat.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. DO NOT APPLY DIRECTLY TO WATER.

STORAGE AND DISPOSAL

Storage: Store in a cool, dry area.

Disposal: Do not reuse empty container. Wrap container and put in trash collection.

EPA EST. NO. 37425-PL-1

EPA REG. NO. 2897-15

95 6370-01
W99

Control No.

3054-34 **MYCODEX®** **aqua-spray** WITH PYRETHRINS

KILLS-GROOMS-DEODORIZES

KILLS FLEAS AND TICKS
ON DOGS AND CATS

ACTIVE INGREDIENTS

Pyrethrins	0.20%
Piperonyl butoxide technical	2.00%
Petroleum distillate	0.36%

INERT INGREDIENTS	96.94%
TOTAL	100.00%

SOLD EXCLUSIVELY THROUGH VETERINARIANS

CAUTION
KEEP OUT OF REACH OF CHILDREN
SEE SIDE PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS

Net Contents 16 R. oz. (473 mL)

Beecham
laboratories
DIV. OF BEECHAM INC. BOSTON, MASS. 02120

DIRECTIONS FOR USE

CATS and DOGS

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Cover animal's eyes with band and with a firm fast stroke, to get a proper spray mist, spray head, ears and chest and damp. With finger tips into face and around mouth, nose, and eyes. Then spray neck, middle and hind quarters, finishing legs last.

For best penetration of spray to the skin, direct spray against the natural lay of the hair. On long haired dogs, rub your hand against the lay of the hair, spraying the ruffled hair directly behind the hand. Make sure spray thoroughly wets ticks. Repeat treatment as needed. For improved appearance, wipe off excess with towel and comb or brush pet. Repeat grooming when dry.

PUPPIES and KITTENS

Treat same as cats and dogs except nursing puppies and kittens, spray only along back or on your finger tips and rub in with your finger tips.

PETS' SLEEPING QUARTERS

Spray around base boards, windows, door frames, wall cracks and focal area of floors. If mosquitoes, gnats, or flies are present, spray lightly into the air. Repeat as needed. The pet's bedding should be sprayed, making sure the area beneath the bedding is sprayed, too. After spray has dried, remove old bedding and replace with fresh bedding. Treat pets with one of our registered flea and tick control products before allowing them to enter treated area.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 10 1990

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
1974-1990, the EPA has
found that this product
meets the EPA Requirements

2097-15