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622-37

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 19 1991

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Mr. Alan Wagner  
SmithKline Beecham Animal Health  
PO Box 971039  
Miami, FL 33197

Dear Mr. Wagner:

Subject: Revised Labeling, Revised Confidential Statement of  
Formula, and Adverse Incidents  
Mitox Liquid  
EPA Registration No. 622-37  
Your letter dated January 17, 1991

The labeling 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 change listed below before you release the product for shipment bearing the amended labeling:

The statement "For Veterinary Use Only" must appear on the upper portion of the front panel.

Although we are approving the subject labels since they were in need of updating no further action (amendments, etc.) on this file will be taken until you indicate the status of this product as a new animal drug. As indicated in our last two letters (Nov. 20, 1990 and Sept. 19, 1990) this product as formulated and labelled would qualify as a new animal drug.

With respect to EPA data and labeling requirements we have the following comments:

1. We do not have any product chemistry data for your product. Please submit the product specific product chemistry data for your product or provide MRID Numbers (if data were submitted earlier).
2. Sulfacetamide, Neomycin Sulfate, and Tetracaine Hydrochloride are listed as active ingredients on the CSF. You must either provide their EPA Registration Numbers or all data as required for new actives must be submitted. Also, ~~you must~~ <sup>CONCURRENCE</sup> report the purity of all actives on the CSF.

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DATE	John Hellett 6-11-91				

3. In our letter dated September 19, 1990 we asked you to identify all efficacy, safety, and domestic animal safety data (by MRID number) submitted in support of registration. We have not received this information. As stated previously this should receive your immediate attention.
4. We acknowledge receipt of the subject product's adverse animal reaction summary sheet. Our files do not contain any additional adverse incidents. Upon receipt of the information requested in item 3 the Agency will conduct a review of all data including adverse incident information to determine the safety of this product to dogs/cats.
5. As indicated in our November 20, 1990 letter this product is subject to any data requirements levied by Registration Division and/or Reregistration Division as long as it is under EPA jurisdiction.

Sincerely,

George T. LaRocca  
Product Manager 15  
Insecticide-Rodenticide Branch  
Registration Division (H7505C)

enclosure

12 ml.

# Mitox Liquid

FOR USE ON DOGS AND CATS

An aid in the treatment of bacterial infections of the external ear canal associated with ear mite infestation.

### Active Ingredients

Neomycin base (as the sulfate) .....	0.5X
Carbaryl (1-Naphthyl N-ethylcarbamate)* .....	1.0X
Sulfacetamide .....	9.0X
Tetracaine hydrochloride .....	0.5X
Inert Ingredients .....	89.0X
	<u>100.0X</u>

\*Sevin

**CAUTION: KEEP OUT OF REACH OF CHILDREN. HARMFUL IF SWALLOWED. SHAKE WELL BEFORE USING.**

SmithKline Beecham Animal Health  
West Chester, PA 19380

RECEIVED  
 WITH COMPLIANCE  
 in EPA Labeling  
 JUN 19 1991  
 Under the  
 Federal Insecticide,  
 Fungicide, and  
 Rodenticide Act  
 622-37

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**PRECAUTIONARY STATEMENTS**  
**Hazards to Humans and Domestic Animals**

**CAUTION**

**HUMAN:** Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.

**Directions:** If severe accumulations of ceruminous material are present, clean ear before treatment with a ceruminolytic agent. Follow this cleaning with treatment with Mitox as directed. Fill lower section with Mitox and massage gently to distribute evenly. For infections, repeat as needed. For ear mites, continue treatments at 10 day intervals until controlled. Do not use on pregnant dogs or cats.

EPA Est. 37425-FL-1      EPA Reg. No. 622-37  
For Veterinary use Only

**STORAGE AND DISPOSAL**

**STORAGE:** Store in a cool, dry area away from heat and open flame. Do not contaminate water, food or feed by storage or disposal. Do not transfer contents to other containers.

**DISPOSAL:** Do not reuse container. Rinse thoroughly and wrap container in several layers of newspaper and discard in trash.