

MAY 3 1991

W. James Gardner
Director, Regulatory Affairs
Evsco Pharmaceuticals
P.O. Box 209 Harding Highway
Buena, NJ 08310

Dear Mr. Gardner:

Subject: Label Revision
Theradex Shampoo, EPA Reg. No. 3134-28
Submission dated October 3, 1990

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 comments listed below. Five copies of the finished labeling must be submitted prior to releasing the product for shipment.

Column 13b on your Confidential Statement of Formula should be revised to total 100 percent. Revise your CSF accordingly.

The percent composition of all components is still required for the inert ingredient, Alpine #6308. Have your supplier contact us directly concerning this information.

Sincerely,

RFM
Richard F. Mountfort
Product Manager (10)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

3735

theradex™



Shampoo for Veterinary Use Only

ACTIVE INGREDIENTS:

*Technical Piperonyl	
Butoxide	0.60%
Pyrethrins	0.06%

INERT INGREDIENTS: 99.34%

*Equivalent to 0.48% (butylcarbityl) (6-propylpiperonyl) ether and 0.12% related compounds

INDICATIONS: A cleansing shampoo which aids in restoring the natural lustre of the hair coat of dogs and cats. Kills fleas and lice.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply only as specified on this label. Wet animal completely with warm water. Apply enough theradex to obtain a good lathering of the entire body. Allow lather to remain in contact with skin for five minutes or longer before rinsing thoroughly with warm water. Use once or twice a week depending on the severity of condition.

WARNING: Keep Out of Reach of Children

Precautionary Statements

Hazards to Humans and Domestic Animals: WARNING:
 May cause eye injury. Harmful if swallowed. Do not get in eyes or on clothing. Wear goggles, safety glasses or face shield.
 If in eyes: Flush with plenty of water. Get medical attention if irritation persists.
 Wash hands thoroughly with soap and water after using. Avoid contact with animal's eyes, mouth or other mucous membranes. For external use only.

Storage and Disposal

Storage: Do not contaminate water, food, or feed by storage or disposal. Store in original container in a safe place away from heat.
Disposal: Do not reuse empty container. Wrap container and put in trash.

EPA Reg. No. 3134-28
EPA Est. No. 3134-NJ-1

ONE GALLON (3.785 liters)



EVSCO PHARMACEUTICALS

Affiliate of IGI, Inc. Buena, NJ (USA) 08310

Lot No.

Made in USA

ACCEPTED
 with COMMENTS
 in EPA Letter Dated
 MAY 31 1991

Use of this product is limited to the use specified on the label.
 For more information, contact the manufacturer.
 3134-28

NOTE: Draft label shown has been enlarged to approx. 158% of actual size.