1-14-81

Memorandum

Date: January 14, 1981

Subject: EPA Reg. No. 11556-48 LYSOFF POUR-ON FOR LICE
Caswell #456F

From: B. T. Backus
IRB/TSS

To: Mr. George LaRocca
Product Manager 15

Applicant: BAYVET Division Cutter Laboratories
P.O. Box 390
Shawnee Mission, Kansas 66201

Active Ingredients:
Fenthion (O,O-dimethyl O-[3-methyl-4-(methylthio)phenyl] phosphorothioate).....7.6%
Petroleum Distillate.....56.7%
Xylene.....20.0%
Inert Ingredients:.....15.7%

Background:

Data for this product were previously reviewed June 16, 1980. At that time it was indicated the acute dermal study was not adequate to satisfy the previously imposed requirement, and it was recommended that a statement appear on the label regarding susceptibility of Brahmin cattle to this pesticide.

Comments and Recommendations:

1. The dermal LD50 study received 11-14-80 is acceptable.

2. In the cholinesterase inhibition study received 5-2-80 no Brahmin cattle were used. In retrospect, separate plasma and RBC cholinesterase values would have provided more information than whole blood values; however, even at the 5X dosage levels, despite considerable drops in whole blood cholinesterase activity levels, test subjects evidenced no symptoms.

3. We can accept this product and its uses without a statement as to particular susceptibility of Brahmin cattle. However, the correspondence of October 20, 1980 from BAYVET indicates some adverse reactions have occurred, and these should be reported to the Agency [see CFR40 162.8(b)(1) and (2)].

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Review:

The following study was conducted at the Bayvet Division of Cutter Laboratories, Inc. Pharmaceutical Research and Development Toxicology. Material tested was the registered product (LYSOFF™ Pour-On). Study is dated October 8, 1980, and was received at EPA November 14, 1980, and is in Acc. 243782.

1. Dermal LD50 Evaluation for LYSOFF™ 7.6% Pour-On in Rabbits

Procedure: Two groups of 5M, 5F NZ white rabbits, 1.72-2.26 kg, received a 24-hr occluded dermal exposure to 2000 or 4000 mg/kg of product, with subsequent 14-day observation.

Results:

Dosage Level Mg/Kg	Mortalities M	F
2000	*3/5	**1/5
4000	5/5	5/5

* one of these deaths probably due to mucoid enteritis
** animal which died had injured back and presumably died of complications

Dermal LD50 is given as more than 2000 mg/kg but less than 4000 mg/kg. Symptoms included diarrhea, lacrimation, muscle fasciculations, ataxia, decreased activity and incoordination. Necropsy of the males at 4000 mg/kg showed lung congestion in 3 animals, with no other significant gross lesions. Necropsy of the females at 4000 mg/kg showed gastrointestinal lesions in 2 and lung congestion in 3. Skin in treated areas had normal dermis and subcutis, with crust formation in the stratum corneum and thickening in the stratum spinosum.

Study Classification: Core Minimum Data (Lacking individual body weights; deaths occurred at even the lowest dosage level, and it is impossible to compute a dermal LD50 with 95% confidence limits; however, the Dermal LD50 appears to be above 2000 mg/kg. The study in Acc. 242427 - previously reviewed June 16, 1980 - indicates no deaths for 2M, 2F exposed to a level of 2000 mg/kg).

Product Classification: Tox. Cat. III

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