US ERA ARCHIVE DOCUMENT

Memorandum

Date:

October 1, 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

Registrant: BAYVET

Division of Cutter Laboratories

P.O. Box 390

Shawnee Mission, KS 66201

Active Ingredients:

| Fenthion (0,0-dimethyl 0-[3-methyl-4-(methylthio) | | |
|---|-----|-----|
| phenyl]phosphorothioate) | 7 | .6% |
| Petroleum Distillate | .56 | .7% |
| Xylene | .20 | .0% |
| Inert Ingredients: | | |

Background:

Product is registered for use (at a 1:8 dilution with water) as a pour-on for control of lice and horn flies. A previous review (January 14, 1981) noted that the registrant's correspondence of October 20, 1980 indicated adverse reactions had occurred in a number of incidents following (but not necessarily cause by) product use. In response to an Agency letter sent June 24, 1981, the registrant has reported on four such incidents.

Comments and Recommendations:

- 1. A host-parasite reaction seems to have occurred in the incidents resulting in 3 dead calves reported from the Manchester Veterinary Clinic. This type of reaction may also have occurred in the Corry, Pennsylvania incident resulting in 2 dead calves.
- 2. The report from Elmwood, Nebraska (3 animals staggering from the chute after treatment, the 4th dying 10 feet out from anaphylactic shock) may also have involved a host-parasite reaction. Application was in February, at which time warbles normally appear on backs of infested cattle in northern states. Sudden release of protein or waste products from considerable numbers of Hypoderma maggots may have led to the reactions seen.

- 3. It is unlikely that this product was responsible for the calf abortions reported from Burrton, Kansas.
- 4. The last accepted label (July 10, 1979) indicates the possibility of host-parasite reactions following use of this product.
- 5. IRB/TSS has no recommendations regarding label revisions for this product. The role, if any, that this product played in these incidents is unknown. Certainly other factors were involved. It is, however, encouraging to note that these were isolated incidents.

Report Summaries:

Record No. 44771: (Burrton, Kansas; dated 2-5-80). Product was used on 19 cows. One aborted on 2-4, another on 2-5; they were 6 weeks pre-parturient. No further abortions. Organ tissue from each calf was found to contain less than 0.02 ppm. Work at the Veterinary Diagnostic Laboratory at Kansas State University failed to find a cause for these abortions.

Record No. 44773: (Corry, Pennsylvania; dated 1/2/79). Product was used on about 25 different animals; 4 days after administration blindness became apparent (presumably in one animal), with subsequent loss of appetite, and, 3 days after symptoms appeared, the calf was dead. A second death followed at about 1 1/2-2 weeks after treatment, with identical symptoms. No fenthion was detected in tissues. No clear diagnosis could be made as to cause(s) of death.

Record No. 44774: (Elmwood, Nebraska; dated 2/27/80). Product was being used (probably in conjunction with other products and procedures; complaint sheet indicates ear tagging, vitamins etc.). First 3 cattle came staggering out of chute; 4th through chute died 10 feet out. Autopsy indicated anaphylactic shock.

Record No. 44775: (Manchester, Indiana; dated 2/23/79). Two separate instances reported in which two groups of cattle received LYSOFF treatment, along with Ralgro implantation. In one case, 8 days after treatment 2 calves had posterior paresis and ataxia. Calves died several days later. In the other case, two calves had similar symptoms at about 7 weeks after treatment. One recovered after treatment, the other died. In both cases clinical diagnosis was Warble granuloma with subsequent pressure and/or toxic necrosis of spinal cord.

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