UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FILE COPY

NOV 28 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA File No. 50534-RNO. Dermal use of fenvalerate (Pydrin, Ectrin WDL) on sheep and goats.

FROM: Richard Loranger, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

R. Loranger

THRU: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Adam Heyward, PM # 17
Insecticide Rodenticide Branch
Registration Division (TS-767)

In response to our 9/13/84 memo and the conference held on the same date, SDS Biotech has submitted a revised label for the insecticide fenvalerate [Ectrin WDL; cyano(3-phenoxyphenyl)methyl-4-chloro-alpha-(1-methylethyl)benzene acetate; Pydrin] to be used on sheep and goats.

The following revisions have been made on the Ectrin Insecticide Water Dispersible Liquid label.

1. The repeat interval has been increased from 14 to 30 days and a maximum of 2 applications imposed in both the spring and fall pest seasons. This eliminates our concern with applications every 2 weeks throughout the year.

2. The rate for the pour-on treatment has been doubled so that all 3 modes of application (spray, pour-on, ULV spray) result in 227-236 mg ai per animal by our calculation (247 mg according to SDS).

3. Premise applications have been withdrawn since fly development is nil in dry sheep/goat feces and almost no market animals are housed in closed quarters.

4. A pre-slaughter interval of 30 days has been imposed.

The registrant should be informed that we do not consider PSI's longer than 1-2 days practical. A revised label incorporating such a preslaughter interval is required.

We also note that dip and sprinkler treatments are included on the label at the same concentration for sprays. It is our judgement that separate data reflecting these two modes of application are needed. The "dip" and "sprinkler" terms should be deleted.

To determine whether the existing tolerances of 1.5 ppm for fenvalerate in sheep and goat meat, fat and meat by-products are adequate we must consider total residues resulting from consumption of treated feeds and the dermal applications. For feed items our information indicates that 50% of the lamb diet can be corn silage as well as 50% dry apple pomace. We have contacted 4 sheep experts (R. Kott, Montana State Univ,; M. Calhoun, Texas A &M; L. McNeal, Utah State Univ.; R. Jordan, Univ. of Minnesota) and FDA feed experts (George Graber, Bill Price, 443-4438) concerning possible use of corn silage and apple pomace simultaneously in lambs being prepared for slaughter. They all indicated that these feed items are used for roughage and, in the unlikely event both were being fed, would not in combination comprise more than 50% of the diet. Therefore, the maximum amount of fenvalerate in the sheep diet will be on the same order (20-25 ppm) as that of cattle. As discussed in the K. Arne review of PP# 1F2430 (3/3/82) the 1.5 ppm tolerances are based on 20 ppm in the diet and one feeding study showing up to 0.8 ppm fenvalerate in fat following consumption of 10.9 ppm Pydrin. Therefore, the existing tolerance will allow for only trace residues from the proposed dermal use. As discussed below, this is the likely situation for sheep and goats.

The available dermal cattle studies are discussed in the 7/26/82 and 8/16/83 reviews concerning the requested use of Ectrin. These studies demonstrated that the major source of residues from the dermal sprays is licking or grooming resulting in oral ingestion. For example, the control cow in one trial had fat and cream residues of the same magnitude as the 10 treated cows. The control was allowed to roam in the same pasture in that case permitting grooming/licking of treated cows. In a second experiment the control was kept separate from treated animals. The latter had up to 1.1 ppm fenvalerate in milk fat and traces (0.02-0.03 ppm) in fat tissue. All control samples of milk and fat contained no detectable residues (<0.01 ppm). In a third study the control was again kept separate from treated animals, but the latter were also restrained to prevent licking themselves or each other. These sprayed cows had <0.01 ppm fenvalerate in non-fatty tissues, 0.01-0.03 ppm in fat and a maximum 0.17 ppm in milk fat (versus 1.1 ppm for unrestrained treated cows). All samples from the control were again not detectable.

From the above data we conclude that only traces (<0.05 ppm) of fenvalerate will result in livestock tissues from dermal sprays provided animal grooming/licking is minimal. We consulted the 4 sheep experts noted above regarding the extent of grooming in sheep and goats. The response in all cases was similar concerning such behavior in these animals - "virtually none at all", "negligible", "very minimal" compared to cattle. If they are poorly fed, they might start eating their own wool. This would be very unlikely for

lambs being prepared for slaughter. We conclude that residues in goat and sheep tissues from the dermal sprays will be under 0.1 ppm. The established tolerances of 1.5 ppm for sheep and goat meat, fat and meat by-products will be adequate to cover combined residues from ingestion of treated feeds and the dermal treatments. Milk is not an issue here since the use is restricted to non-lactating goats.

Conclusions and Recommendation

1. We do not consider pre-slaughter intervals (PSI) longer than 1-2 days practical for dermal treatment of livestock. A revised label containing such a PSI is required.

2. The "dip" and "sprinkler" treatments should be deleted from the label since separate residue data supporting such uses are required.

3. The established tolerances for meat, fat and meat by-products of goats and sheep will cover residues of fenvalerate from the proposed dermal use plus registered uses on feed items (even with the 1-2 day PSI we are requiring).

Provided the label changes noted in Conclusions 1 and 2 are made we have no objections to the dermal uses of Ectrin WDL on sheep and goats (non-lactating).

The registrant should be informed that we will not accept dermal uses on cattle without an increase in the existing tolerances for meat, fat, meat by-products, and milk. The data to this point indicate the tissue tolerances will have to be increased from 1.5 to 2.0 ppm while the milkfat tolerance will need to go from 7.0 to 10.0 ppm (reflecting 0.4 ppm in whole milk). A petition proposing these tolerances will be required to register the dermal uses on cattle. It should be noted that even higher tolerances than those listed above may be needed if some of the numerous pending tolerances for fenvalerate on feed items are established in the future (for example, 75 ppm tolerance for dry grape pomace).

cc: R.F.Circu, S.F., Pydrin and amended use: Loranger
RDI: ARR: 11/23/84: RDS:11/26/84
TS-769:RL:bj:Rm-810:CM#2: X557-7324: 11/26/84