MEMORANDUM


FROM: Sami Malak, Ph.D., Chemist Tolerance Petition Section III Residue Chemistry Branch Hazard Evaluation Division (TS-769C)

TO: George La Rocca, PM #15 Insecticide-Rodenticide Branch Registration Division (TS-767)

and

Toxicology Branch Hazard Evaluation Division (TS-769C)

THRU: P. V. Errico, Section Head Tolerance Petition Section III Residue Chemistry Branch Hazard Evaluation Division (TS-769C)

With this submission, dated 12/28/87, the petitioner, Coopers Animal Health, Inc. of Kansas City, Kansas requests amending the label (EPA Reg. 59-204) for the Atroban formulation by adding the following disposal statement to the product's Storage and Disposal:

"Disposal of Cattle Dip Solution: Spent cattle dip solutions may be applied to land areas set aside and dedicated to disposal of cattle dip solutions or to crop or pasture land areas. Permethrin is toxic to fish. Therefore, to minimize run off into surface water, land spreading should occur only
surface water run off and soil erosion in general will be held to a minimum."

The petitioner stated that the above cited amendment was prompted by USDA Animal and Health Inspection Service (APHIS) who currently are the sole users of this product in their tick eradication program in Puerto Rico. USDA/APHIS expressed the need for clearer instructions on the product label on how to dispose of spent cattle dip solutions.

The proposed disposal statement for the Atroban label, does not restrict disposal by USDA personnel only and the use of this product on livestock is not restricted to Puerto Rico only.

Atroban 42.5% EC, a product of Coopers Animal Health, Inc. of Kansas City, is an emulsifiable concentrate the active ingredient of which is permethrin (3-phenoxyphenyl) methyl(±)-cis, trans-3-(2,2-dichlorophenyl)-2,2-dimethylcyclopropane-carboxylate. Cis/trans ratio in the product is maximum 55% (±) cis and minimum, 45% (±) trans. The product contains 3.6 lbs ai/gallon (0.45 lb ai/pt).

For control of ticks, mites, lice, and mosquitoes on livestock, the registered use on the Atroban label (Reg. No. 59-204) allows for a biweekly dip or spray treatment to thoroughly wet the animal using a maximum of 0.2 lb ai/animal (2 qt of 0.054% solution). A biweekly surface application of the animal premises where flies rest is also permitted at 0.004 lb ai/750-1000 sq ft (0.5 oz of 0.128% solution). Atroban is not registered for use on crops.

As a comparison to a permethrin formulation with crop uses, references are made here to the Pounce 3.2 EC containing 38.4% permethrin. Pounce 3.2 EC, a product of FMC Corporation of Philadelphia, is registered for use on a variety of field crops, fruit trees, range grass, and ornamentals (Reg. No. 279-3014). The registered use allows a maximum of 0.25 lb ai/A/application to cropland for a maximum of 3.25 lb ai/A/crop season, and 0.4 lb ai/A/application to orchards for a maximum of 2.0 lb ai/A/crop season. The PHI’s range from zero to 60 days. Specific grazing/feeding restrictions, as well as plant back intervals in days (PBI) appear throughout the Pounce 3.2 EC label.

The proposed disposal of spent dip solutions containing permethrin to cropland may contribute to higher residue levels in/on the food/feed commodities of these crops. Thus, higher tolerances and the possibility of seizure of those commodities in commerce could be expected. For this reason, and in order to process this application, the registrant is advised to submit the following:
1. The confidential statement of formula for clearance of the inerts.

2. The frequency of disposing of spent dip solutions, permethrin concentrations in spent solutions, and the maximum amount of permethrin that will be disposed of to an acre of land per crop season.

3. The nature of cropland areas where spent dip solutions will be disposed of; i.e., fallow land, planted (what crop); and timing of disposing of spent dip solutions, does it coincide with crop harvest, prior to or, after crop harvest?; if prior to crop harvest, how many days from disposing of spent dip solutions to harvesting?; if after crop harvest, how many days may elapse from disposing of spent dip solutions to planting a rotational crop?.

4. The number of days from preparing dip solutions to disposing of them.

5. After the requested information is received and evaluated, we can then decide what and if any field residue data are needed.

Recommendations

We recommend against incorporating the disposal statement on the Atroban label as proposed until the registrant provides us with the information listed above under items 1 through 4.

Note to PM:

This memo discusses RCB issues pertaining to use of Atroban on field crops. Other issues such as efficacy, effects on wild life, soil residues, leaching to ground water, compliance with RCRA, etc. are of course not within the purview of RCB, but may impact this proposed label change request.

cc: Circu, RF, SF (permethrin or Atroban), Permethrin Reg No. 59-204, and S. Malak