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

MEMORANDUM JUN 15 1982

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Franklin Gee, Product Manager #17
Registration Division (TS-767)

SUBJECT: EPA Reg. No 432-457 Inhalation Toxicity Studies for Resmethrin.

TOX Chem. No. 83E

Subchronic inhalation studies are required when it is determined that repeated exposures may approach levels where a toxic response may be realized based on the acute inhalation toxicity of the technical material or its formulations or if deemed necessary because of some other characteristic of the exposure to humans.

The proposed uses of CROSS-FIRE®, containing 3% resmethrin and 92.50% petroleum distillate, clearly represent situations of repeated and potentially toxic exposure. For example, the product will be used indoors in homes, stores, institutions, restaurants, food processing plants, warehouses, industrial installations, and horse stables in ULV mechanical misting sprayers and thermal foggers.

Thus, the following studies are required:

1. Acute inhalation LC50 for resmethrin technical.

2. Acute inhalation LC50 for the formulated product CROSS-FIRE®.

3. Ninety-day subchronic inhalation study with technical resmethrin. The highest dose level should elicit clear signs of toxicity. The overall assessment of this inhalation study should also include measurement of the effects on the nervous system (for example, assessment of motor coordination and other behavioral parameters).

4. Twenty-one day subchronic inhalation study with the product as formulated. The dose levels should be multiples of the highest anticipated exposure. This study may be waived if appropriate information on the inhalation hazard of petroleum distillate and inerts in this product are provided and determined to be sufficient to assess the inhalation hazard of these components of the formulated product.

Note: The requirement for subchronic inhalation studies for resmethrin was considered previously (see J. Doherty memo dated December 27, 1979, EPA Reg. No. 432-487, 432-547 and FAP 9H5205). The Penick Corporation submitted several studies conducted by the U. S. Army which were evaluated and found to be Supplementary and not acceptable to support the registration of resmethrin containing products. Specifically, the formulations tested were not substantially similar to CROSS FIRE®. In addition, the 90-day inhalation study with technical resmethrin was reported in summary form only. Also, it was conducted using only a single dose level of 250 ug/l and numerous parameters for toxicity were not evaluated.

Budd 6/14/82 DEP 6/15/82

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