



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

8/20/1990

AUG 20 1990

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Review of Additional Data Submitted for PP321.

FROM: James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H-7507-C)

TO: George La Rocca, PM 15
Insecticide and Rodenticide Branch
Registration Division (H-7505-C)

The Ecological Effects Branch has completed the review of the fathead minnow life cycle study and the mallard reproduction study that were submitted a condition of registration. The results are summarized as follows:

Lambda-cyhalothrin (Karate PP 321): Determination of chronic toxicity to fathead minnow (Pimephales promelas) full life cycle, 1989, performed by Imperial Chemical Industries PLC, Brixham Lab, UK. Study authors were J. F. Tapp, B. G. Maddock, B. J. Gillings. Submitted by ICI Americas, Inc. June 1990. MRID No. 415190-01.

Based on the data that was submitted, EEB is unable to ascertain if this study is scientifically sound. There are significant discrepancies that need to be addressed. The study authors should refer to section 14 A for a detailed listing of concerns.

Specifically, the study authors reported there were residue levels of lambda-cyhalothrin in the Dilution Water Control and the Solvent Control. The study authors should clarify if indeed these reported levels were from chemical contamination. In fact, in some cases, the levels in the controls overlapped the range of residues reported in the lowest treatment level.

There is also a concern that the level of quality assurance was inadequate, since there were inconsistencies with data reporting.

The study authors must address the discrepancies noted in section 14. A of the data evaluation record. If the study authors provide information to negate these concerns then the classification will be reconsidered.

Beavers, J.B., K.A. Hoxter and M.J. Jaber. 1989. PP321: A One-Generation Reproduction Study with the Mallard (Anas platyrhynchos). Prepared by Wildlife International Ltd., Easton, Maryland. Laboratory Project No. 123-143. Submitted by ICI Americas, Inc. MRID Number: 415121-01.

It appears this study is scientifically sound, however, there are discrepancies that need to be addressed by the study authors. Therefore, this study is classified as supplemental as it does not meet guideline requirements. The NOEL was determined to be 30 ppm. The study authors or the registrant should report the chemical properties of Hexaconazole, since the mallards used in this avian reproduction study were maintained in the same room as the Hexaconazole treated pens. This study design of using one control group for two studies is not recommended in the future.

The study authors should also report if the residue levels in the feed of 10-05-88 were indeed lambda-cyhalothrin or background contamination.

This study may be reclassified depending on the information submitted by the company.