

US EPA ARCHIVE DOCUMENT



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AUG 18 1986

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Company Response to Toxicology Branch Evaluation of
Acetochlor Two-Generation Reproduction Study in
Rats. EPA ID. No. 524-GUI; TOX PN #1409/1410
Caswell #003B

TO: Robert Taylor (25)
Registration Division (TS-767)

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Action Requested

Review and comment on the response by Monsanto regarding the Toxicology Branch evaluation of the two-generation reproduction study conducted in rats with acetochlor.

Recommendation

It is recommended that this study (#IR-80-053) be upgraded to Core-Minimum status. The NOEL for reproductive effects is 500 ppm, with an LEL of 1500 ppm based on findings of decreased weight gain in F2b pups. Although a NOEL for systemic toxicity was not determined in this study, other chronic toxicity data are available from which a systemic toxicity NOEL may be determined.

Discussion

The major deficiency(ies) which caused Toxicology Branch to originally classify the study as Core-Supplementary data was the perceived inconsistency with the 1982 guidelines. Although this study was submitted in 1983, and reviewed in 1985, the study was initiated in April 1980, and the final report was issued in December 1982. Therefore, the 1978 Proposed Guidelines are more appropriate to the review of this study.

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Regarding the apparent inconsistency with the proposed 1978 Guidelines, Toxicology Branch agrees that the study requirement for histopathology on 25 females/dose group cannot be correct, as those guidelines only require sufficient dams to achieve 20 litters/dose. Further, as was pointed out by the Registrant, other portions of those guidelines only require histopathology on 10 rats/sex/dose, as was done in the present study. This inconsistency was corrected in the 1982 FIFRA Pesticides Assessment Guidelines.

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