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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM SEP 29 1982

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

THRU: Orville E. Paynter, Chief
Toxicology Branch
Hazard Evaluation Division (TS-769)

SUBJECT: Evaluation of IBT Study No. B-566 entitled "Three-
Generation Reproduction Study with CP 67573 in Albino
Rats". BTL-71-34; July 26, 1973; EPA Reg.#524-308;
Glyphosate; Caswell No.: 661A

Recommendation:

This study was recently (4-8-81) reassessed as invalid by Drs. C.T. Miller and P.S. Nawrot of the Canadian Government and Toxicology Branch concurs with their evaluation. Also, the sponsor, Monsanto Company, apparently recognizing the study's deficiencies, has replaced the study with a new one. However, in the Canadian listing of the status of IBT studies, dated March 1, 1982, which reflects their current official position, this study is listed as valid. This memo establishes that the Toxicology Branch considers this study unacceptable (core-invalid) for regulatory purposes.

Review:

The Miller and Nawrot report of 4-8-81 contained a note stating that the study was considered valid during the early stages of the development of validation procedures and that the study has now been replaced. Their "Overall Comments" on the study were as follows:

"Audit and validation of this study revealed that although some evidence existed that the test material was received, there is not real evidence that it was actually incorporated into the diet. There are no records available concerning the preparation or administration of diet. The sources of selection for some males and females for the F₂ parental generation can not be established. There is no raw data available to support the results on organ weights for the F₂ parental animals presented in the final report. Based on the above, the study should be considered invalid. In addition, the male and female weanlings were selected for future generations on the basis of their health and body weight (only healthy and heavier pups were selected). Dams which failed to conceive during the first mating period (first litter) were eliminated from the matings for the second litter. Both practices inevitably affected the outcome of the final results of this study. The study should be considered invalid".

Toxicology Branch concurs with this conclusion.

Winnie Teeters LDC 9/28/82
Winnie Teeters, Ph.D.
Toxicology Branch
Hazard Evaluation Division (TS-769)