BB-843
TXR-2334

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MEMORANDUM NOTE DE SERVICE

002334

SECURITY CLASSIFICATION - DE SÉCURITÉ	
OUR FILE - NOTRE RÉFÉRENCE	
YOUR FILE - VOTRE RÉFÉRENCE	
DATE	April 9, 1980.

TO / A: Mr. D. J. Clegg,
Head, Pesticide Section,
Toxicological Evaluation Division.

FROM / DE: Pesticide Section,
Toxicological Evaluation Division.

SUBJECT / OBJET: Validation of the Study: "Teratogenic Study with AC-92100 Technical in Albino Rats" IBT No. B-1374(B), Dated July 2, 1972.

Common Name: Terbufos

Trade name: Counter; AC-92100.

Petitioner: American Cyanamide Co., Princeton, N.J.

Overall Comments: Raw data on microfiche consist of hand written laboratory notes (mostly dated, but not signed, nor initialled) covering only principal animals. These raw data basically are the same as in the final report, except of incomplete data on skeletal development.

Test performed on principal animals and reported in the final report, was done at 2 different time periods: (i) 0.15 mg/kg: April 27-May 11, 1972. (ii) 0.075 mg/kg: June 6-20, 1972.

Controls' raw data are not available on microfiche. Information is not available either for test material, origin or animals, and proposed material.

Due to the above mentioned deficiencies and omissions, the present study is consequently not valid.

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"Teratogenic Study with AC-92100 Technical in Albino Rats"

A. AUDIT:

1. Report No.: IBT No.: B-1374(B)
Dated July 21, 1972.

2. Date of Study: Proposed dates are not available on microfiche.

3. Protocol: Proposed procedure is not available on microfiche.

4. Test material: Information not available on microfiche.

5. Animal suitability: Information not available on microfiche.

6. Raw data: Incomplete.

B. VALIDATION OF EVALUATION:

1. Dates: Started: April 27, 1972 (first dosing).
Terminated: June 6, 1972 (last sacrifice).

2. Protocol: Since proposed protocol is not available, comparison with final report cannot be made.

3. Test material: Information not available on microfiche.

4. Personnel: Report prepared by: Sandra Haley
Assistant Toxicologist
Rat Toxicity

Report approved by: James B. Plank
Senior Group Leader
Rat Toxicity

and

Paul L. Wright, Ph.D.
Section Head, Toxicology

and

M. L. Keplinger, Ph.D.
Manager, Toxicology

and

J. C. Calandra
President

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C. EXECUTION OF THE STUDY:

Raw data available on microfiche consist of hand written laboratory notes covering principal animals.

Test was performed on principal animals at 2 different time periods.

(i) April 27, 1972 - first dosing (on the 6th day of pregnancy) using 0.15 and 0.30 mg/kg levels. All animals given the 0.30 mg/kg died within 6 days. Animals given the lower dose, i.e. 0.15 mg/kg, survived and were killed in May 11, 1972.

(ii) Second part began in June 6, 1972, with dosing 20F on the 6th day of pregnancy with 0.075 mg/kg. All animals survived and were killed on June 20, 1972.

Data are not available on microfiche for controls for both parts of the study.

Raw data found on microfiche and covering parameters of principals are basically the same as in the final report, except of incomplete raw data on skeletal development.

It should be noted that the dose of 0.3 mg/kg producing mortality, in pregnant females, is substantially more toxic than the single oral acute LD_{50} dose of 9 (5.2-15.3) mg/kg in female rats, previously reported (see submission review for the same compound of November 3, 1976).

OVERALL COMMENTS: Raw data on microfiche consist of hand written laboratory notes (mostly dated, but not signed, nor initialled) covering only principal animals. These raw data basically are the same as in the final report, except of incomplete data on skeletal development. Test performed on principal animals and reported in the final report, was done at 2 different time periods: (i) 0.15 mg/kg: April 27-May 11, 1972. (ii) 0.075 mg/kg: June 6-20, 1972.

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Controls' raw data are not available on microfiche. Information is not available either for test material, origin of animals, and proposed material.

Due to the above mentioned deficiencies and omissions, the present study is consequently not valid.

N. Platonow.

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D. J. CLEGG

D. J. Clegg.

ORIGINAL SIGNÉ PAR

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