11-18-80

Government of Canada / Gouvernement du Canada

MEMORANDUM NOTE DE SERVICE

CASWELL FILE #159

SECURITY - CLASSIFICATION - DE SÉCURITÉ

TO / A: Dr. C.T. Miller,
Co-Ordinator,
Task Force for Re-assessment
of Chemical Safety

OUR FILE – N / RÉFÉRENCE

YOUR FILE – N / RÉFÉRENCE

FROM / DE: Dr. N. Platonow,
Task Force for Re-assessment
of Chemical Safety

DATE: November 18, 1980

See also audit of June 29, 1979

SUBJECT / OBJET: AUDIT AND VALIDATION OF THE STUDY: "RABBIT TERATOGENIC STUDY CAPTAN AND PHALTAN"

NAME OF LABORATORY:	IBT
STUDY NUMBER:	J-5420
FINAL REPORT DATE:	OCTOBER 17, 1967
TEST MATERIALS:	(1) CAPTAN (2) FOLPET
OTHER NAMES:	(1) ORTHOCIDE-406, SR-406 (2) PHALTAN
PETITIONER:	CHEVRON CHEMICAL CO. ORTHO DIVISION
TYPE OF STUDY:	TERATOGENIC
TEST SPECIES:	RABBIT
FILE UNDER:	(1) CAPTAN (2) FOLPET
ORIGINAL REPORT FILE UNDER:	CAPTAN AND ALSO UNDER FOLPET
RECOMMENDATION:	INVALID STUDY

OVERALL COMMENTS: The raw data, especially those dealing with skeletal and internal examinations of the progeny are either missing or are incomplete. Numerous discrepancies were noted between raw data and results given in the final report. Control data are completely unavailable. In view of the above, the present study is considered invalid.

NOTE: The present study was partially audited and validated. See Captan file: Memo by H. Cunningham, dated June 29, 1979, and entitled "Validation of Rabbit Teratogenic Study with Captan (IBT No. J-5420)".

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"Rabbit Teratogenic Study--Captan and Phaltan"

AUDIT:

1.	Report No.:	J-5420 Dated October 17, 1967
2.	Date of Study:	Dates of proposed start and termination are not available.
3.	Sponsor:	Chevron Chemical Company, Ortho Division.
4.	Protocol:	Proposed hand written protocol is available on microfiche.
5.	Test Material:	IBT internal memo of 6-15-1967, states that the test material is "on hand".
6.	Animal Suitability:	New Zealand rabbit of unknown origin and strain.
7.	Raw Data:	Hand written individual animal records, signed and dated. These records, however, are not complete.

VALIDATION OF EVALUATION:

1.	Dates:	Females were bred from 6-13-1967 to 7-4-1967; they were killed from 7-4-1967 to 8-2-1967.
2.	Protocol:	"Proposed" protocol was apparently followed.
3.	Test Material:	No information available on microfiche.
4.	Personnel:	Report prepared by: Gerald Kennedy, B.S. Staff Assistant and Greenie Jackson, M.S. Technical Supervisor Wedge's Creek Research Farm Report approved by: Ottis E. Fancher, Ph.D. Director and J. C. Calandra, M.D., Ph President

Hand written records are signed by Victor Hardie.

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EXECUTION OF THE STUDY:

The information available on microfiche consists of a copy of the final report, financial statements, hand written protocol, and incomplete raw data for individual animals.

Raw data are not available;for control animals; for the group given thalidomide at highest dose level, i.e. 50 mg/kg for male animals and breeding procedure; to indicate that dissection and skeletal examinations were performed; to show in what form the test materials were utilized.

The available raw data were compared with results found in the final report and the errors and discrepencies are shown in the attached corrected Tables II, IV, V and VI.

Some minor differences were noted between the corrected figures of the present memo and those in memo of H. Cunningham of June 29, 1979. This is apparently due to differences in interpretation of some of the raw data.

OVERALL COMMENTS:

The raw data, especially those dealing with skeletal and internal examinations of the progeny are either missing or are incomplet Numerous discrepencies were noted between raw data and results given in the final report. Control data are completely unavailable. In view of the above, the present study is considered invalid.

A. Platonow:

CE Mendoza
Carolyn F. Keller
Co-ordinator

_____Captan Review_____

Page _____ is not included in this copy.

Pages __4___ through __8___ are not included in this copy.

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