

6-26-80

BB-1449
TXR-1481Government
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du Canada

MEMORANDUM

EPA
001481
NOTE DE SERVICE

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

FROM
DE
Pesticide Section,
Toxicological Evaluation Division.

SUBJECT
CHIEF

Audit & Validation of the Study: "Teratogenic
Study on Phaltan".

SECURITY CLASSIFICATION - DE SECURITE
OUR FILE - N. REFERENCE
YOUR FILE - V. REFERENCE
DATE June 26, 1980.

IBT No.: WCRF-139 (this number was found on
raw data; the final report
has no report number).

Dated February 15, 1966.

Common name: Folpet.

Trade name: Phaltan.

Petitioner: Chevron Chemical Co.
Ortho Division.

OVERALL COMMENTS:

The raw data available on microfiche were verified and compared with the results given in the final report. These raw data, with few inconsequential errors and discrepancies, were found to support basically the results given in the final report. In this context therefore the present study is valid.

When the scientific value of the present study is considered, its validity becomes strongly questionable. This is particularly true when the present standards of methodology and experimental design are taken into account.

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154
1

"Teratogenic Study on Phalitan"

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AUDIT:

1. Report No.: IBT No.: WCRF-139. (This number was found on raw data; the final report has no number. This number could be also J-139, according to some raw data).
Dated February 15, 1966.
2. Date of Study: Proposed starting date: July 12, 1965
(0 Day).
Proposed termination date: Aug. 9, 1965
(28th day of pregnancy)
3. Sponsor: Chevron Chemical Company
Ortho Division.
4. Protocol: Hand written protocol for the combined study on Phalitan, Captan and Difolatan using single dose of 75 mg/kg and Thalidomide (75 mg/kg) as positive control in addition to control group, is available on microfiche. It basically outlined the procedure given in the final report.
5. Test material: No information is available on microfiche regarding the test material.
6. Animal suitability: Dutch-Belted rabbits were apparently used. Their mating records, maternal body weight at 0 Day are available on raw data.
7. Raw data: Handwritten records, sufficient to compare with the results given in the final report.

VALIDATION OF EVALUATION:

1. Dates: Dates varied from group to group as follows

Group	0 Day	Euthanasia (28th Day)
Control	7-10-1965	8-7-1965
Thalidomide	7-16-1965	8-13-1965
Phalitan	7-12-1965	8-9-1965

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2

2. Protocol: "Proposed" Protocol was apparently followed.
3. Test material: No information available on microfiche.
4. Personnel: Report prepared by: Margaret Ives, Ph.D.
Chief Toxicologist.
- Report approved by: J. C. Calandra, Ph.D.,
Director.

Handwritten reports are initialled (illegible) and many are signed by Al "Wahli".

EXECUTION OF THE STUDY:

The information available on microfiche consists of a copy of each of the following final reports, having the same IBT report number: WCRF-139 - (i) "Teratogenic Study on Difolatan" (Dated Dec. 6, 1965; using Dutch Belted rabbits; (ii) "Teratogenic Study on Captan" (Dated Feb. 14, 1966; using Dutch Belted rabbits), (iii) "Teratogenic Study on Phaltan" (Dated Feb. 15, 1966; using Dutch Belted rabbits), "Rabbit Reproductive Study - Phaltan" (Dated Aug. 20, 1965; using Dutch Belted rabbits), "Rabbit Reproductive Study - Captan" (Dated Aug. 25, 1965; using Dutch Belted rabbits), "Rabbit Reproductive Study - Difolatan" (Dated Aug. 25, 1965; using Dutch Belted rabbits). Microfiche contains also some correspondence, financial statements, handwritten protocol and raw data for chicken reproduction study on captan (IBT No. WCRF-139)", and handwritten protocol and raw data for concurrent teratogenic studies on Captan, Tolpet and Captofol.

Raw data records covering body weights (Table I of the final report) progeny data (Table II) and observation of viable young during incubation (Table III) were verified and compared with the results given in the final report. The available raw data basically support the results given in the final report. Some minor discrepancies were found (same as in the sponsor's audit), but they are due mostly to rounding the second decimal in the body weight results.

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FEB 14 1966
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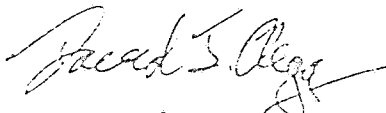
The annotations on some individual pathology records (e.g. does nos. 45, 47, 48) states: "extreme sepsis", "very moderate sepsis", "no sepsis". Evidence for the presence or absence of "sepsis" is not provided, since neither histopathological nor microbiological examinations or tests were apparently made. Judging from the use of the term "sepsis" as seen on raw data, one is inevitably inclined to question the professional competence of the person performing the autopsies.

OVERALL COMMENTS:

The raw data available on microfiche were verified and compared with the results given in the final report. These raw data, with inconsequential errors and discrepancies, were found to support basically the results given in the final report. In this context therefore the present study is valid.

When the scientific value of the present study is considered, its validity becomes strongly questionable. This is particularly true when the present standards of method and experimental design are taken into account.


N. Platonow.


D. J. Clegg.

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4