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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TOX Chem No.: 586
TB Project No.: 9-2150
RD Record No.: 251,420

MEMORANDUM

SUBJECT: Naled (Dibrom) - Laboratory Data Audit
EPA ID No. 239-1633

FROM: Irving Mauer, Ph.D., Geneticist 11/02/89
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Health Effects Division (H7509C)

TO: William H. Miller/Dan Peacock, PM Team 16
Insecticide-Rodenticide Branch
Registration Division (H7505C)

THRU: Karl P. Baetcke, Ph.D., Chief 11/07/89
Toxicology Branch I - Insecticide, Rodenticide Support
Health Effects Division (H7509C)

Registrant: Chevron Chemical, Richmond, CA

Performing Laboratory: Bio-Research Laboratories (BRL)
Senneville, Quebec (Canada)

Request

Review the laboratory/data audit of the following long-term study in accordance with SOP 3050-4:

Dibrom: Chronic Oral Toxicity/ Carcinogenicity Study in Rats (Chevron S-1802); BRL Project No. 9394, Final Report dated June 7, 1984. (EPA MRID No. 00141784.)

Background

This chronic rat assay with Dibrom Technical was one of three FIFRA studies selected for audit at BRL according to the "neutral scheme" procedure of OCM/LDIAD as representative of long-term studies.

The study was originally reviewed and evaluated by the Toxicology Branch (TB) for compliance with FIFRA data requirements (DER attached to memorandum: Mauer to Miller, stamp-dated December 20, 1984, TB Document No. 004128, et seq.). It was initially judged CORE-SUPPLEMENTARY because of certain deficiencies,* but upgraded to CORE-MINIMUM upon receipt of additional data which resolved to the Agency's satisfaction all outstanding issues of the initial review (see memorandum: Mauer to Miller/Otaki, date-stamped June 28, 1985, TB Document No. 004521).

Data Audit

The laboratory/data audit of this study was conducted October 20 through 23, 1987 by a team consisting of Drs. Dexter S. Goldman, Ken K. Kanagalingam and Frances E. Liem of headquarters OCM/LDIAD, accompanied by Drs. Scot Eustis and Michael Jokinen of the National Toxicology Program (NIEHS/ Pathology).

With minor exceptions considered to have no impact on the integrity of the study, no major discrepancies between raw lab data or protocols and the final report were noted by the audit team in any of the specialties covered. No deficiencies in either GCP or QA compliance were noted. Although minor inconsistencies in pathological nomenclature with respect to some non-neoplastic lesions were found, these were not considered to be critical to the outcome of the study.

In summary, the minor deficiencies noted by the audit team were considered not to impact the scientific integrity of this chronic rat study.

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*1. A rationale for gavage administration;
2. Evidence that the HDT approached an MTD;
3. Individual clinical data;
4. Sufficient gross pathology; and
5. An explanation for increased mortality in controls (DER, TB Document No. 004128).

TB Conclusions

As indicated above, with additional information supplied after our initial evaluation, TB found the study adequate to satisfy regulatory data requirements for both chronic toxicity and carcinogenicity (CORE-MINIMUM). Accordingly, we concur with the favorable assessment of the audit report.