

PO-837
TNR-2536

Government of Canada : Gouvernement du Canada

MEMORANDUM

NOTE DE SERVICE

266AA

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

FROM : Dr. D.B. Davies,
DE Task Force for Re-assessment
of Chemical Safety

SECURITY - CLASSIFICATION - DE SECURITE

002536

OUR FILE - N° REFERENCE

YOUR FILE - N° REFERENCE

DATE

November 21, 1980

Amended March 18, 1981

SUBJECT
OBJET

AUDIT AND VALIATION OF THE IBT STUDY: "CHOLINESTERASE
ACTIVITY STUDY WITH CGA 15324 TECHNICAL IN BEAGLE DOGS"

NAME OF LABORATORY:

INDUSTRIAL BIO-TEST LABORATORIES

LABORATORY REPORT NUMBER:

8531-09996

REPORT DATE:

MAY 9, 1977

COMMON NAME OF COMPOUND:

PROFENOFOS

OTHER NAME(S):

BROMOPROPYLATE, CURACRON, SELECRON.
COMPANY CODE: CGA 15324

FORM OF TEST MATERIAL:

UNKNOWN

PETITIONER:

CIBA-GEIGY CORP.

TYPE OF STUDY:

SPECIAL TESTING: CHOLINESTERASE DET
MINATION

SPECIES:

BEAGLE DOG

FILE UNDER:

PROFENOFOS

RECOMMENDATION PER AUDIT/VALIDATION:

STUDY INVALID

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OVERALL COMMENTS

Pronounced discrepancies between stated and analytically determined dietary levels of test material serve to seriously undermine the validity of the present study. Residue analyses of diet samples (performed after termination of the study) indicated that the levels of test material fed were on average 5-times (and up to 78-times) higher than levels stated in the final report. Moreover, inadequate and non-uniform diet mixing procedures likely prevented homogeneous dispersion of the test material in the diet, which reduces the degree of confidence one can attach to the analytical results and presents the possibility that animals ingested widely fluctuating levels of the test material during the course of study. In short, the study is adjudged invalid since the actual levels of test material fed are unknown. In addition, some confusion exists regarding the identity and nature of the test material, although the bulk of evidence suggests a technical grade preparation was used.

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