

US EPA ARCHIVE DOCUMENT

PO-837  
TYL-2586

MEMORANDUM NOTE DE SERVICE

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

FROM : Dr. D.B. Davies,  
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"

<u>NAME OF LABORATORY:</u>	INDUSTRIAL BIO-TEST LABORATORIES
<u>LABORATORY REPORT NUMBER:</u>	8531-09996
<u>REPORT DATE:</u>	MAY 9, 1977
<u>COMMON NAME OF COMPOUND:</u>	PROFENOFOS
<u>OTHER NAME(S):</u>	BROMOPROPYLATE, CURACRON, SELECRON, COMPANY CODE: CGA 15324
<u>FORM OF TEST MATERIAL:</u>	UNKNOWN
<u>PETITIONER:</u>	CIBA-GEIGY CORP.
<u>TYPE OF STUDY:</u>	SPECIAL TESTING: CHOLINESTERASE DET MINATION
<u>SPECIES:</u>	BEAGLE DOG
<u>FILE UNDER:</u>	PROFENOFOS
<u>RECOMMENDATION PER AUDIT/VALIDATION:</u>	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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