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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM DEC 13 1982

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Marilyn Mautz (16)
Registration Division (TS-767)

THRU: Orville E. Paynter, Ph.D.
Chief, Toxicology Branch
Hazard Evaluation Division (TS-769)

SUBJECT: Re-evaluation of Validated IBT Study of Curacron; Acute Delayed Neurotoxicity in Chickens, Study#8580-10426
CASWELL#266AA

Registrant: Ciba-Geigy Corp.
Agricultural Division
Greensboro, North Carolina 27409

Background Information:

This study has been validated by HPB Canada and classified as "Valid with reservations". The Canadian validation has necessitated a reevaluation of the study.

Recommendation:

It is recommended that as a result of our evaluation, this study be classified as Core Minimum Data. As per the review of 11/2/78 from D. Ritter, no delayed neurotoxicity was noted in birds treated with this chemical at dose levels up to an including 52 mg/kg. The requirement noted in the memo of May 13, 1982 that Ciba-Geigy "provide an acceptable (neurotoxicity) study by 6/1/83" has now been satisfied.

Review of Data:

Acute Delayed Neurotoxicity, Chickens. IBT No. 8580-10426. June 6, 1977. Submitted by Ciba-Geigy.

(This study was validated by Dr. Davies of HPB Canada on August 4, 1981 and classified as "Valid with reservations" on the basis of the following deficiencies:

minor toxicit

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Government of Canada / Gouvernement du Canada

MEMORANDUM **NOTE DE SERVICE**

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. D.B. Davies,
Task Force for Re-assessment
of Chemical Safety

DATE: November 18, 1980
Revised: June 16, 1981
" Aug. 4, 1981

SUBJECT / OBJET: AUDIT AND VALIDATION OF THE IBT STUDY:

NAME OF LABORATORY:	Industrial Bio-Test Laboratories
LABORATORY REPORT NO.:	IBT No. 8580-10426
REPORT DATE:	June 6, 1977
COMMON NAME OF COMPOUND:	Profenofos
OTHER NAME(S):	Curacron, Selecron; Company Code: CGA-15324
FORM OF TEST MATERIAL:	Stated to be a 38" emulsifiable concentrate (see Test Material Section)
PETITIONER :	CIBA-Geigy Corporation
TYPE OF STUDY:	Acute Delayed Neurotoxicity
SPECIES, BREED AND STRAIN:	Hen
FILE UNDER:	PROFENOFOS
RECOMMENDATION:	Valid*

OVERALL COMMENTS

The present study is adjudged valid with reservations. The findings presented in the final report are substantiated by the raw data. Raw data were generally complete and were recorded in an acceptable fashion with all records signed, dated and witnessed. However, although the study is adjudged valid from the audit standpoint, it should be considered unacceptable as an investigation to examine the delayed neurotoxic potential of profenofos per se. In this regard, the following reservations concerning experimental design and conduct serve to undermine the scientific integrity of the investigation:

1) The preliminary acute toxicity study was poorly contrived. The calculated LD50 is of questionable accuracy since it was derived on the basis of mortality data generated from two independent dosing regimens. The inaccuracy of the LD50 is demonstrated by the observation that 85% mortality was witnessed among birds dosed at the calculated LD50 level in the subsequent neurotoxicity study. The preliminary study is acceptable only as a pilot study to provide dosage information for the neurotoxicity study.