



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

MEMORANDUM

17
JAN 16 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Ametryn. Company Response to Data-Call-In.

EPA No. 080801
Record No. 234874

Project No. 9-0484
Tox. Chem. No. 431

TO: Geraldine Werdig, PM #50
Registration Division (TS-767c)

FROM: John E. Whalan, D.A.B.T., Toxicologist
Section 1, Toxicology Branch I (IRS)
Health Effects Division (TS-769c)

THRU: Edwin R. Budd, Section Head
Section 1, Toxicology Branch I (IRS)
Health Effects Division (TS-769c)

John E. Whalan
12-15-88

Ed R. Budd
11/6/89

CIBA-GEIGY has requested waiving the toxicology data-call-in requirements for three categories, and offered justification to that effect. The following is a response to this petition.

81-7 Delayed Neurotoxicity - Hen

The Registrant stated that this study should not be required since this class of chemicals does not possess any known potential for causing neurological effects (i.e. cholinesterase inhibition). TB agrees since this study is only required for organophosphates.

82-5 90-Day Neurotoxicity

The Registrant stated that this study should not be required since this class of chemicals does not possess any known potential for causing neurological effects (i.e. cholinesterase inhibition). TB agrees since this study is only required for organophosphates which prove to have neurologic involvement in an acute delayed neurotoxicity study.

82-1 90-Day Feeding (Rodent and Nonrodent)

The Registrant claimed that the EPA already has chronic studies in dogs and rats in its files, and has certified them as meeting the five tests of acceptability noted in the data-call-in. Since both of these studies have sufficient interim sacrifice data to address dosing issues, there is no need to do any other 90-day studies.

The TB agrees that a subchronic study need not be performed if the information it would yield is adequately supplied by an acceptable chronic study. The adequacy of the only rat and dog chronic studies on file is key to this query, however:

24-Month Chronic Oral Toxicity of Ametryne 80W in Albino Rats
Industrial Bio-Test Laboratories, Inc., IBT No. E-4715;
sponsored by Geigy Chemical Company

Two-Year Chronic Oral Toxicity of Ametryne 80W in Beagle Dogs
Industrial Bio-Test Laboratories, Inc., IBT No. C-4716;
sponsored by Geigy Chemical Company

Both of these IBT studies were carefully scrutinized in 1982 and classified Invalid. If these are the studies meant to satisfy the subchronic and chronic data requirements, they are void and must be replaced by new studies.