

US EPA ARCHIVE DOCUMENT



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

NOV 28 1989

MEMORANDUM

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Screen of an Ametryn Chronic Feeding Study in Dogs.

EPA No. 80801-04  
Record No. 253683

Project No. 0-0022  
Tox. Chem. No. 431

TO: Thomas Luminello, PM #50  
Registration Division (H7505C)

FROM: John E. Whalan, D.A.B.T., Toxicologist  
Section 1, Toxicology Branch I (IRS)  
Health Effects Division (H7509C)

*John Whalan*  
11-9-89

THROUGH: Roger L. Gardner, Acting Section Head  
Section 1, Toxicology Branch I (IRS)  
Health Effects Division (H7509C)

*R.L.G.*  
11-24-89

Ametryn was recently selected to be a pilot chemical in the FIFRA 88 review process. A Chronic Feeding Study in Dogs (Ciba-Geigy, Project No. 842118, July 20, 1987) was screened for acceptability at that time. The study was found to be unacceptable by HED Acceptance Criteria.

The report did not mention the purity of the test article, or provide stability information. There were five dosed groups. The two highest dose groups had sufficient mortality to warrant decreasing the doses. This should not be a problem since there were still three dose groups that had no mortality. Neither lactic dehydrogenase (LDH) nor urine volume were measured. ALT and GGT were performed in place of LDH. Urine volume is not strictly required. Organ weights were not measured for lung and spleen. The histopathology tables were limited to the dogs sacrificed terminally, and lesion severities were not included in the summary tables. This study received Quality Assurance review.

The purity of the test article, and the stability of the test article in feed must be reported. The lung and spleen weights should have been measured. Because of these inadequacies, the Registrant should be required to initiate a new study unless these issues can be resolved.

1  
1