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

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CASWELL FILE

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM JUL 15 1982

TO: Robert J. Taylor  
Product Manager No. (25)  
Registration Division (TS-767)

THRU: Christine F. Chaisson, Ph.D. *C.F. Chaisson*  
Toxicology Branch  
Hazard Evaluation Division (TS-769)

SUBJECT: Protocols for a two year mouse oncogenicity study  
and a six-month dog study with R-50224.  
Corr. No. 22, Tox No. 721D.

According to meeting notes dated May 24, 1982, the two protocols mentioned above were considered acceptable. However, no rationale is presented in the submitted protocols for the use of a six month dog study rather than a one-year study.

The two protocols also fail to include a procedure and schedule for feed consumption determination. Although the test substance is to be added to the drinking water in the mouse study or administered to dogs via gavage, food consumption data would be a useful indicator of general health. These measurements would also be useful to the interpretation of body weight changes that might be observed. According to a memorandum summarizing the May 24, meeting (To: Robert Coberly, Toxicology Branch, From: Vickie Walters, Registration Division), the rationale for the method of administration and the lack of feed consumption data are to be included in the final report. In view of the general usefulness of food consumption data, proposed absence of such data is not advisable.

The procedures for determining stability of the test chemical in the drinking water are not defined precisely. There is no discussion of how frequently and over what period of time the water is to be sampled to determine stability of the solutions to be tested. In addition, no procedure for determining water consumption during the study is included.

All other aspects of the two protocols are consistent with accepted practices and require no further comments.

*Roger Gardner*

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*16/05/7/1/82*