

US EPA ARCHIVE DOCUMENT

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

002134

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Robert Taylor (25)
Registration Division (TS-767)

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

SUBJECT: Evaluation of IBT Study No. 651-00565 entitled "Two-
Year Chronic Oral Toxicity Study with CP 67573 in Beagle
Dogs." BTL-71-33. November 30, 1973. EPA Reg.#524-308;
Glyphosate; Accession No. 234133

Recommendation:

This study must be considered invalid because critical raw data are missing; diet preparation records which would be supporting evidence that the dogs received CP 67573 as intended are not present in study records. Furthermore, additional deficiencies were noted also.

Background:

A Canadian report dated June 19, 1978 for this study, although commenting on several aspects of the study (including lack of documentation for weekly preparation of diet according to the protocol) does not make a statement regarding validation of the study. However, in a "Validation Summary", dated March 1, 1982, published by the Canadians, this dog study is listed under "Audit Results" as valid.

On July 8, 1982, the Registration Division received "hard copy" of all IBT data used in the sponsor's (Monsanto Company) validation of the above titled chronic dog study with glyphosate (This material was compiled by R.W. Street on July 2, 1982).

The following evaluation is based upon this recently provided additional material.

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Review:

No diet preparation records, such as a list of dates on which diets were prepared (with technician's signature or initials), were present in the raw data to support the final report statement that diets were prepared weekly. Since this essential support indicating that the dogs received the test material as intended was missing, the study was not further critically evaluated; however, the following relevant points were noted while reviewing the data:

1. There is no assurance that all animals nor all required tissues of each animal were evaluated histologically since only positive findings were noted on individual pathology sheets in the raw data; 15/32 dogs had positive findings for one or more tissues or organs.

2. There is some question as to whether all dogs received a thorough gross examination since positive findings were recorded for only 2/32 dogs.

3. There is no assurance that daily clinical observations were made since there are comments on the dogs' condition for only eight days of the two-year study.

4. There were no raw data for reported urinary specific gravity values for the initial and 3-month periods.

5. There were no raw data pertaining to purity, storage, stability, or dietary analysis of the test material.

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