GLYPHOSATE / TOX

8

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

TOX REV 2177

releasable

9/16/82

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

661A

MEMORANDUM

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. C-1021 entitled "Ninety-Day Subacute Oral Toxicity Study with CP67573 in Beagle Dogs" BTL-71-58. June 19, 1978. EPA Reg.#524-308. Glyphosate; CAS 661A

Recommendation:

As a result of the Toxicology Branch evaluation of this study utilizing microfiche of IBT records for the study and validations by the Canadians (dated 6/7/78) and the sponsor (Monsanto Company, dated 6/15/78), it is now considered unacceptable (core-invalid) for regulatory purposes. Microfiche records for the study do not contain diet preparation records; therefore critical raw data which would be supporting evidence that the dogs received CP67573 as intended, are missing. Additionally, other major deficiencies were noted during review of the microfiche (see Review section, deficiencies 1-4).

Background:

A Canadian validation report for this study dated 6/7/78 commented on several discrepancies and deficiencies of the study, including the lack of diet preparation records, but did not state a conclusion regarding its validity. In a "Validation Summary", dated March 1, 1982, published by the Canadian government, this study is listed under "Audit Results" as valid.

Review:

This evaluation is based upon review of microfiche of IBT records for the study and validations by the Canadians (dated 8/8/79) and the sponsor (Monsanto Company, dated 6/15/78).

No diet preparation records, such as a list of dates on which diets were prepared (with technician's signature or initials), were found in the raw data to support the final report statement that "fresh diets were prepared each week". Without this essential support to indicate that the rats received the test material, the study was not further critically reviewed; however the following additional deficiencies were noted while searching the microfiche (these items were among those discussed in the Canadian validation):

1) The only raw data for gross pathology examination consisted of 9 notations for 9 animals and 3 deaths listed as due to bleeding; these comments were on a sheet on which were tabulated the animal numbers by group and sex of sacrificed animals.

2) There were no raw data daily observation records.

3) There were no raw data food consumption values for the 13th week although values were reported.

4) Day 45 clinical studies raw data were for 5 rats/sex/group not 10, as the final report procedures stated.

Winnie Teeters 9/14/82

Winnie Teeters, Ph.D
Toxicology Branch
Hazard Evaluation Division (TS-769)

TS-769:th:TOX/HED:WTeeters:9-2-82:card 2