



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

JUL 2 1990

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Touchdown - Sulfosate - EPA Registration Nos.
10182-276 and 10182-277 - PP#9F3796 - Sulfosate
in/on Corn - Supplement to MRID No. 41209905

Project No.: 0-1150
Record No.: 162 448
MRID No.: Supplement to
41209905

CASwell: 893C

FROM: William Dykstra, Reviewer
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Health Effects Division (H7509C)

William Dykstra 6/26/90

TO: Robert Taylor, PM 25
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THRU: Roger Gardner, Acting Section Head
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Roger Gardner 6-26-90

*KFB
6/26/90*

Requested Action

Review company supplement to coded histopathology report.

Conclusions and Recommendations

The supplemental information to the 2-year combined chronic toxicity/oncogenicity studies in rats and mice is not adequate to upgrade the core supplementary status of those studies. Additional data are required as detailed in this memorandum. Stated briefly, tissue masses could not be tracked with the submitted data.

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Review

1. New Data Submitted

VOLUME 1

Study Title

Supplement to MRID No. 41209905
Addendum to Final Report - Two year Chronic
Toxicity and Oncogenicity Dietary Study with
SC-0224 in Rats

2. Discussion

The January 5, 1988 review by W. Dykstra of the two 2-year chronic studies concluded the following:

"The 2-year rat feeding is considered a supplementary study. Evaluation of individual rat pathology sheets (Appendix N) did not provide a clear indication that tissue masses identified in the antemortem examination (Appendix I) and noted in the postmortem gross necropsy (Appendix L) were further evaluated microscopically. These deficiencies are required to be resolved." [End of quotation.]

"The 22-month mouse feeding study is considered a supplementary study. The tissue masses listed in Table I (clinical observations) and Table L (necropsy observations) were not clearly identified in the histopathology observations (Table N) as being histologically examined. This deficiency has to be resolved." [End of quotation.]

3. TB Conclusion

In the previous submission (MRID No. 412099-01), ICI stated that "in volumes 7 through 9, information will be submitted which we believe will greatly facilitate the tracking of tissue masses." [End of quotation.]

According to that submission:

"The following are being submitted for each study:

"1. Trail for individual clinical mass observations.

"2. Clarifications/annotations to trail.

"3. Necropsy detail report by animal with codes.

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"4. Histopathology detail report by animal with codes.

"Histopathology detail report by animal with codes.

"Necropsy and histopathology detail reports by animal were included in the original reports without codes. In the coded section to the extreme right of the enclosed printouts, lesion numbers are listed which will clarify our tracking system. The Trail for Individual Clinical Mass Observation is an ancillary table prepared for EPA convenience." [End of quotation.]

The only data received by TB at this time is item 4: Histopathological detail report by animal with codes for each study.

Additionally, the dictionary code, which was hand delivered, and the present addendum code provide codes only for the individual histopathological findings for each animal in the addenda. A check between the original histopathological report and the newly submitted histopathological addendum, by using the dictionary codes, shows that the original histopathological findings and the histopathological findings in the addenda are the same. Therefore, the coded information in the histopathological addenda can be verified.

However, items 1, 2, and 3 listed above of ICI's previous submission are required to be submitted to complete the evaluation of tracking the tissue masses. Following satisfactory tracking of the tissue masses, both the chronic rat and mouse studies can be upgraded to core-guideline.