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CASWELL FILE

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OFFICE OF  
PESTICIDES AND TOXIC  
SUBSTANCES

JUN 26 1992

MEMORANDUM

SUBJECT: Glofosinate-Ammonium (Ignite<sup>R</sup>; Hoe 039866): Review of the registrant's responses to 6 acute toxicity studies

Caswell No. 580I  
Submission No. S411557  
MRID Nos. 421733-01 to 07

HED Project No. 2-1407  
DP Barcode: D174445

TO: J. Miller / J. I. Mayes, PM Team 23  
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Introduction

In 1991, Tox. Branch II evaluated 6 acute toxicity studies conducted on the chemical Ignite 1SC Herbicide (Tox. Doc. No. 008640), and the studies and the core classifications are as follows:

<u>Studies</u>	<u>Core Classification</u>
1. Acute oral toxicity-rats (MRID No. 417961-02)	Supplementary
2. Acute dermal toxicity-rats (MRID No. 417961-03)	Supplementary

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|--|---------------|
| 3. Acute inhalation-rats<br>(MRID No. 418463-02)             | Unacceptable  |
| 4. Primary eye irritation-rabbits<br>(MRID No. 417961-04)    | Supplementary |
| 5. Primary dermal irritation-rabbits<br>(MRID No. 417961-05) | Supplementary |
| 6. Dermal sensitization-guinea pig<br>(MRID No. 417961-06)   | Supplementary |

The registrant, Hoechst Celanese Corp., has submitted the missing information and explanations for the deficiencies identified by the previous reviewer on the above studies.

### Discussion

The 5 acute toxicity studies had a discrepancy regarding the date that the Quality Assurance Statement was signed. There were two dates which appeared on the statement, and the Registrant submitted information to show that the more recent date was when the quality assurance statement was issued after the final report audit. The earlier date was the date of the original draft report, and it was used for tracking of the report during processing, copying, and distribution. The five studies which were identified to contain this discrepancy are upgraded to **minimum** from **supplementary**, and they are as follows:

- |  |         |
|--|---------|
| a. Acute oral toxicity-rats<br>(MRID No. 421733-02)  | Minimum |
| b. Acute dermal toxicity-rats<br>(MRID No. 421733-03)  | Minimum |
| c. Primary eye irritation-rabbit<br>(MRID No. 421733-05)<br>Based upon the current eye irritation classification Ignite 1SC Herbicide should be classified as <b>Category II</b> for eye irritation because the opacity was reversible within 14 days. | Minimum |
| d. Primary dermal irritation-rabbit<br>(MRID No. 421733-06)  | Minimum |
| e. Dermal sensitization-guinea pigs<br>(MRID No. 421733-07)  | Minimum |

The acute inhalation study in rats (MRID No. 418463-02) was found to have several deficiencies (Tox. Document No. 008640).

The registrant has satisfactorily addressed most of the deficiencies (MRID No. 421733-04). It was previously identified that the data of this study did not show a dose-related trend in mortality, and the highest mortality rate was 60%. In the opinion of this reviewer, better data could easily be obtained with another study performed with some care. However, an additional study would probably not provide us more useful information than what was obtained from this study which tested up to 4.2 mg/L. Although the current data were not ideal and were barely sufficient for estimating a  $LC_{50}$ , a toxicity category could be established for labeling purposes. Therefore, the study is upgraded to minimum. The  $LC_{50}$  was estimated to be 4.42 mg/L, and the toxicity category for acute inhalation is Category III.