MEMORANDUM


FROM: Henry Spencer, Ph.D. Section 7 Toxicology Branch Hazard Evaluation Division (TS-769)

TO: Robert Taylor, Product Manager #25 Herbicide Branch Registration Division (TS-767)

THRU: Albin B. Koczalski, Ph.D. Section Head, Section 7 Toxicology Branch Hazard Evaluation Division (TS-769)

Background:

A previously completed IBT study was found by the registrant to suggest an oncogenic response. However, as the study was subsequently questioned as to its validity, the registrant, Ciba-Geigy Limited, commissioned the present study.

Comments:

There was an apparent increased incidence of both adenocarcinomas and fibroadenomas of the mammary tissues in female rats as reported by the registrant. Although these effects occurred only at the 1000 ppm dosage level (HDT), and the report is of an interim nature, Toxicology Branch considers the interim findings sufficient to warrant the close scrutiny of any additional requests for tolerances until the full study has been submitted and reviewed.
The interim findings reported by the registrant with respect to mammary tumors in females were as follows.

<table>
<thead>
<tr>
<th>Pathologic Findings</th>
<th>Historic Control</th>
<th>Concurrent Control</th>
<th>10 ppm</th>
<th>70 ppm</th>
<th>500 ppm</th>
<th>1000 ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenocarcinoma</td>
<td>3/75</td>
<td>0/22</td>
<td>1/5</td>
<td>1/1</td>
<td>0/5</td>
<td>8/25</td>
</tr>
<tr>
<td>Fibroadenoma</td>
<td>3/75</td>
<td>0/22</td>
<td>0/5</td>
<td>1/1</td>
<td>1/5</td>
<td>3/25</td>
</tr>
</tbody>
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