MEMORANDUM

TO: G. Sprock, Registration Specialist

RE: PRODUCT NAME: Azinphos-methyl
ACTIVE INGREDIENT(S): AZINPHOS-METHYL
I.D. NUMBER: 169608-E
EPA REGISTRATION NUMBER: 3125-0-
DOCUMENT NUMBER(S): 154-296, 297, 298, 299, 300, 301.
COMPANY NAME: Bayer Corp.

DATE: July 14, 1998

Two (2) studies were included in Document Number 154-300.


   X This study is acceptable for use in future exposure assessment and mitigation evaluations.

   X Archive data in Pest Management Division Library for future references.

COMMENTS:

This Dermal Sensitization study was assayed using the Magnusson and Kligman Maximization protocol. Randomly, an equal number of male and female guinea pigs were employed for each exposure test. The methodology deviated slightly from the Maximization procedure. No 72 hour dermal scoring was reported for the challenge phase. Erythema scoring was not differentiated from the edema scoring for any of the tests. The study deviated slightly from the EPA’s Pesticide Assessment Guidelines 81-6.
The diluent used for the 1% and 12.5% test article solutions was not reported. The scoring for erythema and edema was not differentiated.

The Range Finding test was evaluated @ test article’s solutions (v/v) of 0.05%, 0.2%, 1%, 3%, 6%, 12.5% and 25%. The technical article (92.8%) was evaluated @ 1% for the intradermal induction phase and @ 12.5% for the topical induction and topical challenge phases. The testing treatments were:

I. Induction A. intradermal
   1. test article group
      a. Freund’s complete adjuvant in a 1:1 dilution of sterile physiological saline.
      b. 1% test article diluted with Cremophor EL 2% (v/v) in sterile physiological saline.
      c. 1% test article diluted in an equal volume of Freund’s complete adjuvant and Cremophor EL 2% (v/v) in sterile physiological saline.
   2. control
      a. Freund’s complete adjuvant.
      b. Cremophor EL 2% (v/v) in sterile physiological saline.
      c. a 1:1 solution of Freund’s complete adjuvant and Cremophor EL 2% (v/v) in sterile physiological saline.

B. topical
   1. test article group
      a. 12.5% test article plus Cremophor EL 2% (v/v) in sterile physiological saline.
   2. control
      a. Cremophor EL 2% (v/v) in sterile physiological saline

II. Challenge A. topical
   1. test article group
      a. 12.5% test article plus Cremophor EL 2% (v/v) in sterile physiological saline.
   2. control
      a. Cremophor EL 2% (v/v) in sterile physiological saline
No sensitization index (= degree of sensitization) could be computed because no induction scores were reported. However, a severity index was computed. (The severity index is the sum total of grades in a treatment group @ 24, 48, or 72 hours, divided by the number of animals in that treatment group). The dermal scores were:

<table>
<thead>
<tr>
<th></th>
<th>Induction Sensitization index</th>
<th>Challenge test severity article index</th>
<th>control</th>
</tr>
</thead>
<tbody>
<tr>
<td>edema/erythema</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24 hr</td>
<td>0.0</td>
<td>2.3</td>
<td>0.5</td>
</tr>
<tr>
<td>48 hr</td>
<td>0.0</td>
<td>2.0</td>
<td>0.1</td>
</tr>
</tbody>
</table>

Nineteen of the twenty animals’ test scores were used in the evaluation. Of the 19 test animals, 18 were observed with dermal scores of 1 or greater; 9 of these 18 test animals had scores of 3, the maximum score. The controls had scores of zero (5) and 1 (5).

The reported Dermal Sensitization study indicates the 12.5% test article is a sensitizer in the animal model tested.

Data Required: No


This study is acceptable for use in future exposure assessment and mitigation evaluations.

Archive data in Pest Management Division Library for future references.

COMMENTS:

This dermal sensitization study was evaluated using the Buehler methodology. The study deviated from the Buehler procedure. An equal number of female and male guinea pigs were not employed; only male
guinea pigs were used for each test. No 72 hour dermal scoring was reported for either the induction or the challenge phase of the tests. Edema scoring was not differentiated from the erythema scoring. The study deviated slightly from the EPA Pesticide Assessment Guidelines 81-6. No 72 hour dermal scoring was reported for either the induction or the challenge phase of the tests.

The Range Finding test was assayed using the neat test article (13.6% azinphos-methyl) and solutions (v/v) of 0.01%, 0.05%, 0.1%, 0.5%, 1%, 10%, and 25%. The 0.05% solution was used for the exposure tests. Negative controls were employed. The positive control was 0.05% (w/v) DNBCB solution in a 50% ethanol/sterile water mixture.

The dermal scores were:

<table>
<thead>
<tr>
<th></th>
<th>Induction</th>
<th>Sensitization index</th>
<th>Challenge</th>
</tr>
</thead>
<tbody>
<tr>
<td>erythema/ edema</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24 hr</td>
<td>0.3</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>48 hr</td>
<td>0.1</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

The reported Dermal Sensitization study indicate the 0.05% test article was not a sensitizer in the animal model tested.

Data Required: No

CONCLUSION

Although the formulated product (13.6% azinphos-methyl) when tested at 0.05% was not a sensitizer, the technical material (92.8%) when tested at 12.5% was a sensitizer in the animal model. Thus, the active ingredient, azinphos-methyl, is considered to be a sensitizer.