MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 3125-615, 3125-660, 3125-647
          Foliwa 3.6F, 
          
          Raxil 0.24F, 
          Raxil 2.4F

FROM: Olga Odiott
      Precautionary Review Section
      Registration Support Branch
      Registration Division (H75-05C)
      13/3, 1990

TO: Susan Levine
     (PM 21)
     Pesticide Information Branch
     Registration Division (H75-05C)

APPLICANT: Henry Corporation
           Agricultural Chemicals Division
           P.O. Box 4513
           Kansas City, Missouri 64130

FORMULATION FROM LABEL:

Active Ingredient(s):

\( \text{2,4-Dichlorophenoxyacetic acid} \) \( \text{2,4-D} \) \( \text{2,4- Dichloro-1,1-Dimethylalkane} \) \( \text{2,4-D} \) \( \text{2,4- Dichloro-1,1-Dimethylalkane} \)

Inert Ingredient(s): .................................................................

Total 100.0%

2380
BACKGROUND

Acute oral, acute dermal, primary eye irritation, skin irritation, skin sensitization and acute inhalation studies were submitted to support registration No. 3125-GOU, 3125-GOE and 3125-GOG (Policur 3.6 F, Raxil 0.26 F and Raxil 2.6 F, respectively). The studies were conducted on Policur 3.6 F. MRID No 412633-04 through 412633-09.

RECOMMENDATION

RSB/PRS finds the acute oral, acute dermal, primary eye irritation, skin irritation and skin sensitization studies acceptable to support registration of the three aforementioned formulations.

The acute inhalation study is considered supplementary data, therefore a new study must be submitted. The mass median aerodynamic diameter is higher than the 1.0 μ required by the Agency. A Memo by Dr. Stanley Gross on inhalation toxicity testing is included for registrant reference.

LABELING

Precautionary statements:

Delete the statement "Causes eye injury."

Statements of practical treatment

Revise the "If swallowed" and "If on skin" statements as follows:

If swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, or, if available, by administering syrup of ipecac. Do not induce vomiting or give anything by mouth to an unconscious person.

If on skin: Wash with plenty of soap and water. Get medical attention.
DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: (21)  
MRID No.: 412633-04  
Testing Laboratory: Hobay Corp.  
Author(s): J. P. Sheets  
Species: New Zealand White Rabbits  
Sex: 2 males, 4 females  
Weight:  
Source:  
Dosage: 0.1 ml  
Test Material: 
Quality Assurance (40 CFR §160.12): 

Summary:  
Tox. Category: T  
Classification: Guideline  

Procedure (Deviation From §81-4): 

Results:

<table>
<thead>
<tr>
<th>Observations</th>
<th>Hour</th>
<th>Days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1/12</td>
<td>2/12</td>
</tr>
<tr>
<td>Cornea Opacity</td>
<td>0/6</td>
<td>0/6</td>
</tr>
<tr>
<td>Iris</td>
<td>0/6</td>
<td>0/6</td>
</tr>
<tr>
<td>Conjunctivae Redness</td>
<td>0/6</td>
<td>0/6</td>
</tr>
<tr>
<td>Chemosis</td>
<td>0/6</td>
<td>0/6</td>
</tr>
<tr>
<td>Discharge</td>
<td>1/6</td>
<td>0/6</td>
</tr>
</tbody>
</table>

Comments: 

240
DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3)

Product Manager: [21] Reviewer: O. Odiott
MRID No.: 4100.33-05 Report Date: May 11, 1989
Testing Laboratory: Milby Report No. 9740
Author(s): R.J. Shutz, JG
Species: Sprague-Dawley rats
Sex: 18 males, 18 females; Weight: 1X7 - 269 g
Source: Sasco Inc. Omaha, Nebraska
Test Material: Polycar 7.6 Flammable
Quality Assurance (40 CFR §160.12): Attached

Summary:
1. LC50 (mg/kg): Males = _______ ; Combined = _______ ; Females = _______
2. The estimated LC50 is _______
3. Mean Concentration: _______
4. Tox. Category: ______. Classification: Supplementary

Procedure (Deviations From §81-2): MHAD species above 1.0 / L

Results:

<table>
<thead>
<tr>
<th>Exposure Concentration (mg/L)</th>
<th>Reported Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(NUMBER KILLED/NUMBER TESTED)</td>
</tr>
<tr>
<td></td>
<td>Males</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>39.09 (± 7.46) mg/L</td>
<td>0/6</td>
</tr>
<tr>
<td>MHAD: 6.8 ± .4</td>
<td></td>
</tr>
<tr>
<td>7.138 (± 1.370) mg/L</td>
<td>0/6</td>
</tr>
<tr>
<td>MHAD: 5.6 ± .4</td>
<td></td>
</tr>
</tbody>
</table>

Symptomology & Gross Necropsy Findings:

Nasal discharge, static and roughened ears were observed in females only. The pinnae cleared by day 2 post-exposure. Abnormalities were not observed at necropsy.
DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§81-1)

Product Manager: (21) Reviewer: O. Odiott
MRID No.: 412633-06 Report Date: May 14, 1989
Author(s): L.P. Shults
Species: Sprague-Dawley rats
Age: 7-10 weeks Old Observation Days (Post Exposition): (14); other ( )
Weight: 223 - 359 gm Source: Sprague-Dawley, male
Test Material: Foliar Spray Flammable
Quality Assurance (40 CFR §160.12): Attached

Conclusion:

1. LD50 (mg/kg): Males = 4154 mg/kg; Females = 3162 mg/kg; Combined =
2. The estimated LD50 is

Procedure (Deviations From §81-1):

Results:

<table>
<thead>
<tr>
<th>DOSAGE (mg/kg)</th>
<th>(NUMBER KILLED/NUMBER TESTED)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Males</td>
</tr>
<tr>
<td>1000 mg/kg</td>
<td>-</td>
</tr>
<tr>
<td>2000 mg/kg</td>
<td>0/5</td>
</tr>
<tr>
<td>3500 mg/kg</td>
<td>1/5</td>
</tr>
<tr>
<td>5000 mg/kg</td>
<td>4/5</td>
</tr>
</tbody>
</table>

Symptomology & Gross Necropsy Findings:

Weight loss.
Laminated urine after decreased water activity, salivation, and ataxic gait observed. Hyporeactivity, ileus, and tail bite were observed in some animals.

At necropsy, ventrum/inguinal/herbal strain were observed. Nerve and red strain were also observed.

Focal adhesion micriscopic lesions were found in the stomach, brown necrosis in non-palpable mucosa.
DATA REVIEW FOR SKIN IRRITATION TESTING ($81-5)

Product Manager: (21)                     Reviewer: O. Odiott
MRID No.: 41263-07                      Report Date: May 4, 1984
Testing Laboratory: Hobay Corp
Author(s): L. C. Shulte
Species: New Zealand White Rabbits
Age: 33 weeks
Sex: One female, five males
Weight: 0.5 ml
Dosage: 0.5 ml
Test Material: 30% flexible
Quality Assurance (40 CFR §160.12): Attached

Summary:

The Primary Irritation Index = 0.21

Toxicity Category: IV

Classification: Guideline

Procedure (Deviations From §81-5):

Results:

Edema was not observed. Very slight erythema noted in 3/6 animals. 1 hour after the exposure, brisk and in 1/6 animals 24 hours after exposure. All symptoms cleared by 40 hours.

Special Comments:
DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING ($81-2$)

Product Manager: (21)  
MRID No.: 412633-05  
Testing Laboratory: Ubecey Co., Inc.  
Author(s): L. P. Sheets  
Species: New Zealand White Rabbit  
Sex: 6 males, 6 females  
WT: 2.17 - 2.95 kg  
Test Material: folium 3.0 Flourelle  
Quality Assurance (40 CFR §150.12): attached

Summary:

1. LD$_{50}$ (mg/kg): Males = _______; Females = _______; Combined = _______;  
2. The estimated LD$_{50}$ is $>2,000$ mg/kg;  
3. Tox. Category: III. Classification: Guideline

Procedure (Deviations From $§81-2$):


Results:

<table>
<thead>
<tr>
<th>DOSAGE (mg/kg)</th>
<th>(NUMBER KILLED(NUMBER TESTED))</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000 mg/kg</td>
<td>Males</td>
</tr>
<tr>
<td></td>
<td>0/6</td>
</tr>
</tbody>
</table>

Symptomology & Gross Necropsy Findings:

Erythema was observed at the dose site for 1/12  
Animals white nasal discharge in 1/12 animals;  
No other symptoms observed. At necropsy,  
Gross lesions were not present.
DATA REVIEW FOR SKIN SENSITIZATION TESTING (§81-6).

Product Manager: (21)  
MRID No.: 412633-09  
Reviewer: O. Odioi  
Testing Laboratory: Hobay Corp.  
Date: Aug. 3, 1989  
Author(s): T.S. Shuh  
Report No. 940-05  
Species: Hanley albino guinea pigs  
Source: Sisco Inc., Madison, WI  
Weight: 2.8 - 3.5 kg  
Test Material: Folieum 3.0% liquid  
Positive Control Material: DNCB - 0.1% 10% 50% ethanol  
Quality Assurance (40 CFR §160.12):  
Method: Büchner's Close-Patch Technique  

Summary:  
1. This product is / is not a dermal sensitizer.  
2. Classification:  

Procedure (Deviation From §81-6):  

Results: Test substance was applied undiluted for a total of 3 induction periods. There were no signs of irritation in any animals. The positive control group was treated with DNCB and after the third induction period signs of irritation were observed. Upon challenge, no irritation was observed in the test group. Signs of sensitization were observed in the positive control group.