MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 9688 - IC
Chemincio Lawn & Garden Insect Control

FROM: Olga Odiott
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C)

TO: George LaPace (PM 15)
Insecticide-Pesticide Branch
Registration Division (H75-05C)

APPLICANT: Chemincio Inc.
8494 Chapin Industrial Dr.
St. Louis, MO 63114

FORMULATION FROM LABEL:

Active Ingredient(s):
Permethrin

% by wt.
0.25%
0

Inert Ingredient(s): ........................................ 99.75%

Total 100.0%
BACKGROUND

Acute oral, acute dermal, acute eye, skin irritation and skin sensitization studies were submitted to support Req. No. 9688-1G. The studies were performed at Tox Monitor Lab. Inc. and Biologic Safety Research. MRID No. 415013-01 through 415013-05.

An acute inhalation study was not submitted.

RECOMMENDATION

RSB/PRS finds the studies acceptable to support this registration.

The skin sensitization study is considered core minimum data because the amount of test material used for the induction applications was half the amount specified by the Buehler's method.

An acute inhalation study is required for proper registration of this product.

LABELING

The signal word is Caution.

Revise the first sentence of the Precautionary statements to read as follows:

"Harmful if absorbed through skin. Causes moderate eye irritation."

Revise the Statements of Practical treatment as follows:

The "If on skin" and "If in eyes" statements should precede the other statements.

The "If on skin" statement should read as follows: "Wash with plenty of soap and water. Get medical attention."

Note:

Further label revisions may be necessary upon submittance of outstanding data.
DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§81-1)

Product Manager: (15) Reviewer: O. Odiott
MRID No.: 415013-03 Report Date: April 20, 1980
Testing Facility: Fox Monitor Lab, Inc Report No. 90-41-3
Author(s): Michael Kuklinski
Species: Sprague-Dawley rats
Age: 6-10 weeks Observation Days (Post
Weight: 200-300 gms Exposure): (14); other ( )
Source: Bio Lab, Inc. St. Paul, Minnesota
Test Material: Dawn & Harden Direct Contact
Quality Assurance (40 CFR §160.12): attached

Conclusion:

1. LD50 (mg/kg): Males = ______________; Females =
2. The estimated LD50 is > 5 gms/kg.
3. Tox. Category: Classification: [ ]

Procedure (Deviations From §81-1):

Results:

<table>
<thead>
<tr>
<th>DOSAGE (g/kg)</th>
<th>(NUMBER KILLED/NUMBER TESTED)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Males</td>
</tr>
<tr>
<td>5 gms/kg</td>
<td>0/5</td>
</tr>
</tbody>
</table>

Symptomology & Gross Necropsy Findings:

Animals appeared normal throughout the study.
No abnormalities observed at necropsy.

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

Product Manager: (15)  
MRID No.: 4(50)13-04  
Testing Laboratory: Tack Monitor Lab  
Author(s): Michael S., Radoslaw  
Species: New Zealand albino Rats  
Sex: Male & Female  
Wt.: 2-3 kg  
Test Material: Acute Dermal Agent Control  
Quality Assurance (40 CFR $160.12$): Attached

Summary:

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

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>2 gm/kg</td>
<td>Males</td>
</tr>
<tr>
<td>0/5</td>
<td>0/5</td>
</tr>
</tbody>
</table>

Symptomology & Gross Necropsy Findings:

Erythema and oedema were observed in all animals.  
1 day after treatment, symptoms cleared by day 2.  
No other symptoms observed.  
No abnormalities at gross necropsy.
DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: [15]  
MRID No.: 415013-01  
Testing Laboratory: Toxikon, Inc.  
Author(s): Michael Kukelwitzki  
Species: New Zealand White Rabbit  
Sex: Female  
Weight: 2.05 lbs  
Source: Scientific Small Animal Lab., Joliet, IL  
Dosage: 0.1 ml  
Test Material: Lawn & Duster, insect control  
Quality Assurance (40 CFR §160.12): Attached  

Summary:
Tox. Category: III  
Classification: Guideline

Procedure (Deviation From §81-4):

Results:

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>7</th>
<th>14</th>
<th>21</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cornea Opacity</td>
<td>0/6</td>
<td>2/6</td>
<td>1/6</td>
<td>1/6</td>
<td>0/6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iris</td>
<td>0/6</td>
<td>2/6</td>
<td>0/6</td>
<td>0/6</td>
<td>0/6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conjunctivae</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Redness</td>
<td>5/6</td>
<td>2/4</td>
<td>1/6</td>
<td>0/6</td>
<td>0/6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemosis</td>
<td>4/6</td>
<td>2/6</td>
<td>1/6</td>
<td>0/6</td>
<td>0/6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discharge</td>
<td>6/6</td>
<td>2/6</td>
<td>1/6</td>
<td>0/6</td>
<td>0/6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments:


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DATA REVIEW FOR SKIN IRRITATION TESTING ($81-5)

Product Manager: (15)            Reviewer: O. Odiott
MRID No.: 415013-02                Report Date: April 20, 1990
Testing Laboratory: Tex Houston Lab Inc.
Author(s): Michael Rykalinski
Species: New Zealand White Rabbit
Age: 8-10 weeks old
Sex: 
Weight: 2.09-2.342 gm
Dosage: 0.5 gm
Test Material: Smith & Harden

Quality Assurance (40 CFR §160.12): Attached

Summary:

The Primary Irritation Index =

Toxicity Category: IV

Classification: Guideline

Procedure (Deviations From §81-5):

Results:

Edema or erythema were not observed throughout the study.

Special Comments:
DATA REVIEW FOR SKIN SENSITIZATION TESTING (§81-6)

Product Manager: (15)  
MRID No.: 415010-05  
Testing Laboratory: Bioderm Safety Research  
Author(s): Michael Kubelski  
Species: Hartley albino guinea pig  
Sex: Male  
Weight: 243-325 gm  
Source: Harlan Sprague Dawley, Indianapolis, Ind.  
Test Material: Human & Animal Protein Control  
Positive Control Material: DNCB  
Quality Assurance (40 CFR §160.12): attached  
Method: Büechler’s

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

Procedure (Deviation From §81-6): 0.2 gm of test material was used for induction & challenge treatments instead of 0.4 gm as specified by the Büechler’s method

Results: Test group 10 was treated with the undiluted test material 3 times a week for 3 weeks for a total of 10 induction exposures. A challenge application was performed 2 weeks after the last induction.

Using the same schedule, 10 animals were treated with 0.19% DNCB in DMSO (positive control) and 6 animals served as negative control. The test group did not show irritation during induction or at challenge.

The positive control group showed sensitization.