MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 8329-61
ULV Mosquito Derriston 420

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

TO: George LaRocca
Insecticide-Rodenticide Branch
Registration Division (H75-05C)

APPLICANT: Clarke Outdoor Spraying Co.
159 W. Garden Avenue
Roselle, Illinois 60172

FORMULATION FROM LABEL:

Active Ingredient(s):
Permethrin 4.00 %
Pyrethrum Extract 20.00 %

Inert Ingredient(s): . . . . . . . . . . . . . . . . . . . .
36.00 %

Total 100.0 %

July 30, 1990
BACKGROUND

Acute oral, acute dermal, acute eye, acute inhalation, skin irritation and skin sensitization studies were submitted to support Reg. No. 8329-GI. The studies were conducted at Cosmopolitan Safety Evaluation. MRID No. 414933-02 through 414933-06. The acute inhalation study was not assigned a MRID number. It was assigned a MRID, you just didn't look.

RECOMMENDATION

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

The acute eye study was classified as core minimum data because the "discharge" criteria was not evaluated.

The skin sensitization study was classified as core minimum data because naive controls were not used.

LABELING

The signal word is Caution.

Delete the precautionary statements that appear beneath the Child hazard warning statements on the center panel of the label.

The Precautionary statements should read as follows:

"Harmful if absorbed through skin or inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."

The Statements of practical treatment should read as follows:

"If on skin: Wash with plenty of soap and water. Get medical attention.
If inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth to mouth. Get medical attention.
If swallowed: Call a Physician or Poison Control Center. Do not induce vomiting."
DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING ($81-1)

Product Manager: (15) 
Reviewer: O. Odiott 
MRID No.: 414933-02
Report Date: Jan. 10, 1990
Testing Facility: Commonwealth Health Evaluation 
Report No. 45073
Author(s): Geoffrey H. Johnston
Species: Salmonella - Daurby algae strain
Age: Young adult
Weight: 200-240 g
Observation Days (Post Exposure): (14); other
Source: Laboratory colony
Test Material: Biocid 4170 W-V (De Grace, 420)
Quality Assurance (40 CFR §160.12): Attached

Conclusion:

1. LD50 (mg/kg): Males = \[\text{value}\]; Females = \[\text{value}\]

2. The estimated LD50 is \[\text{value}\] mg/kg.

3. Tox. Category: \[IV\]; Classification: \[Guideline\]

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>5.0 g/kg</td>
<td>Males</td>
</tr>
<tr>
<td></td>
<td>0/5</td>
</tr>
</tbody>
</table>

Symptomology & Gross Necropsy Findings:

Physical examination: No abnormalities observed up to day 1 after treatment.

Animals appeared normal and gained weight throughout the rest of the test period. The one animal that died showed tremors and was found dead on day 2. At necropsy, no abnormalities were noted for the surviving animals. Mottled live and congested kidneys were observed in the animal that died.
DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING ($81-2$)

Product Manager: (15) Reviewer: O. Odiott
MRID No.: 414933-03 Report Date: 9 Jan. 1990
Testing Laboratory: Cosmetics, Enal, Hend. Report No. 3572
Author(s): Geoffrey K. Robbins
Species: New Zealand Albino Rabbit
Sex: Males: 5 females: 5 Wt.: 2.95 - 3.35 kg.
Test Material: Biomut 4+20 u/L (Detergent 430)
Quality Assurance (40 CFR $160.12$): Attached

Summary:

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

Procedure (Deviations From $81-2$):

________________________

________________________

Results:

Reported Mortality

<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>2.09 g/kg</td>
<td>0/5</td>
</tr>
</tbody>
</table>

Symptomology & Gross Necropsy Findings:

Very slight to well defined erythema and edema were observed up to 3 days after treatment. No other symptoms observed. No abnormalities observed at necropsy.
DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3)

Product Manager: (15) 41542801 Reviewer: O. Odjott
MRID No.: Not assigned Report Date: 23 Feb. 1990
Author(s): Geoffrey R. Robbins
Species: Sprague-Dawley rats
Sex: 15 males, 10 females Weight: 201-209 (♂), 255-269 (♀)
Source: Laboratory category
Test Material: Primary 4+20 ULV (Devon Int. 426)
Quality Assurance (40 CFR §150.12): Attached

Summary:
1. LC₅₀ (mg/kg): Males = ; Females = 
2. The estimated LC₅₀ is 73.0 mg/L
3. Mean Concentration:

Procedure (Deviations From §81-2):

Results:

<table>
<thead>
<tr>
<th>Exposure Concentration (mg/L)</th>
<th>Reported Mortality</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(NUMBER KILLED/NUMBER TESTED)</td>
<td>Males</td>
</tr>
<tr>
<td>------------------------------</td>
<td>---------------------</td>
<td>-------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0/5</td>
</tr>
<tr>
<td>3.9 mg/L</td>
<td></td>
<td>1/6</td>
</tr>
<tr>
<td>Maximum attainable C₁</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MHAD = 0.6 μ and 0.8 μ</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Symptomology & Gross Necropsy Findings:

Perineal staining, decreased fur, not and marked
Decreased locomotor activity. At necropsy, congested lungs with slight opacities observed in the 2 animals that died. Chromatineta and perineal staining was obtained in those animals also. The remaining animals appeared normal.
DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: (15)  
MRID No.: 414933-04  
Testing Laboratory: Cosmopolitan Safety Lab  
Report No.: D-2073  
Author(s): Geoffrey A. Richmond  
Species: Albino Rabbit — New Zealand Type  
Sex: 3 Male, 3 Female  
Source: Laboratory Colony  
Dosage: 0.1 ml  
Test Material: 4% 20403 (Deprotin 430)  
Quality Assurance (40 CFR §160.12): Attached  

Summary:
Tox. Category: III  
Classification: Core Minimum

Procedure (Deviation From §81-4): Discharge criteria was not evaluated.

Results:

<table>
<thead>
<tr>
<th></th>
<th>Observations (number &quot;positive&quot;/number tested)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hour</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Cornea Opacity</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0/6</td>
</tr>
<tr>
<td>Iris</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0/6</td>
</tr>
<tr>
<td>Conjunctivae Redness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0/6</td>
</tr>
<tr>
<td>Chemosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0/6</td>
</tr>
<tr>
<td>Discharge</td>
<td></td>
</tr>
</tbody>
</table>

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

Product Manager: (15)  
MRID No.: 414933-05  
Testing Laboratory: Company Safety Eval. Report No. E2073  
Author(s): Geoffrey R. Hackman  
Species: New Zealand albino rabbit  
Age: Young adult  
Sex: 4 females, 2 males  
Weight: 2.1 - 2.3 kg.  
Dosage: 0.5 ml  
Test Material: Biocid 4+20 UCV (Devostator 420)  
Quality Assurance (40 CFR §160.12): Attached

Summary:

The Primary Irritation Index = 0.8

Toxicity Category: IV

Classification: Indefinite

Procedure (Deviations From §81-5):

Results:

Very slight erythema on 4/6 animals, and
very light edema on 1/6 animals were observed at
72 hrs. Symptoms cleared by day 5.

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

Product Manager: (15)                             Reviewer: O. Odjott
MRID No.: 414933-06                             Report Date: 3 Jan. 1976
Author(s): Geoffrey L. Pederson
Species: Albino guinea pig
Sex: Male                                      Weight: 300-350 gm
Source: Camden Research Lab Animals, Maumee, New York
Test Material: Prioristat 4120 HLV (Deoestil 420)
Positive Control Material: 30% p-phenylenediamine in oint
Quality Assurance (40 CPR §150.11): Attached

Method: Büchler's

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

Procedure (Deviation From §81-6): Naive control groups were not included

Results: 10 guinea pigs were treated with the undiluted test material (0.5%)
each week for three weeks. Two weeks after the last induction period,
challenge was performed. Erythema was observed after the first induction period. Upon challenge
the same degree of erythema was observed. A positive control group was reported as periodically
tested under the same conditions, and as clearly
a sensitizing response.