MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 8329-GL 8329-GV

Strike 4-12 ULV
Magnum 44 ULV

FROM: William S. Woodrow WSW 6-20-89
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C)

TO: La Rocca / Heyward (PM 15)
Insecticide / Rodenticide Branch
Registration Division (TS-767C)

APPLICANT: Clarke Outdoor Spraying Co., Inc.
159 N. Garden Ave.
Roselle, IL 60172

FORMULATION FROM LABEL:

(Strike 4-12 ULV)
Active Ingredient(s):
- Permethrin (3-Phenoxyphenyl) methyl (+) cis.
- trans-3-(2,2-dichloroethenyl)-2,2-dimethyl-2-cyclopropane carboxylate
- Technical Piperonyl Butoxide

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

% by wt.

Total 100.0% 84.00

(Magnum 44 ULV)
Active Ingredients:
- Permethrin (3-Phenoxyphenyl) methyl (+) cis trans
- 3-(2,2-dichloroethenyl)-2,2-dimethyl-2-cyclopropane carboxylate
- Technical Piperonyl Butoxide

INERT INGREDIENTS:

4.00%
4.00%
92.00%
BACKGROUND:
The Clarke Spraying Co. submitted acute oral, acute dermal, acute inhalation, primary eye, and dermal irritation, and dermal sensitization studies to support two products: Strike 4-12 ULV (47% Permethrin & 12% Piperonyl Butoxide), and Magnum 44 ULV (44% Permethrin & 4% Piperonyl Butoxide). MRID Nos. used were 408805-02 through 408805-07.

RECOMMENDATION:

1) The acute toxicity studies submitted by Clarke Outdoor Spraying are acceptable to RSB/PRS, to support Strike 4-12 ULV (Reg. No. 8329-GU), however these data do not support Magnum 44 ULV. The acute toxicity studies currently submitted were conducted using Strike 4-12 ULV (12.00%, piperonyl butoxide).

2) Registration of the Magnum 44 ULV product will require submission of acute oral, dermal, inhalation, primary eye, and dermal irritation, and a dermal sensitization studies conducted using the Magnum 44 ULV formulation.

LABELING: (Strike 4-12 ULV)

1) The CAUTION label signal word is appropriate.
2) The Precautionary Statements are acceptable.

3) Add the following to the Statements of Practical Treatment:

   "If on skin: Wash with plenty of soap and water. Get medical attention.
   If in eyes: Flush with plenty of water.
   Call a physician."

   "
DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§81-1)

Product Manager: (16) Reviewer: Woodrow
MRID No.: 40880-02 Report Date: 6-20-89
Testing Facility: Cosmopolitan Safety Eval.
Author(s): G.E. Hoveman
Species: Rat, Sprague-Dawley
Age: Young adult
Weight: M = 240–340 g, F = 200–300 g
Exposure: (14); other ( )
Source: Not given
Test Material: Strike 412 (Permethrin 4%, PB 4%), Liquid
Quality Assurance (40 CFR §160.12): None

Conclusion:
1. LD50 (mg/kg): Males = _____; Females = _____; Combined = _____
2. The estimated LD50 is > 5.0 g/kg
3. Tox. Category: IV. Classification: Guidelines

Procedure (Deviation from §81-1): 5.0 g/kg administered to each of
5/7 male Sprague-Dawley. Animals observed for mortality and weight
weekly.

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>5.0/kg</td>
<td>%5</td>
</tr>
</tbody>
</table>

Symptomology & Gross Necropsy Findings:

Clinical signs: 1 hr, all not showed yellow feces and thirst.
Day 1, 7 females not conscious. Day 2–date normal except
3 females showed excited standing: all rats appeared normal
thereafter. All rats gained weight. All organs and tissues
appeared normal at necropsy.
DATA REVIEW FOR A² DERMAL TOXICITY TESTING

Product Manager: (15) Woodrow
MRID No.: 408805-03 Reviewer: W. Waller
Testing Laboratory: Cosmopolitan Safety Eval. Report Date: 6-20-59
Author(s): G. P. Robbins Report No. B-1864
Species: Rabbits, N 2 type
Sex: EM 150
Wt.: Not stated 2.5-3.5 kg
Test Material: Strike 4-12 (4% Permethrin)
Quality Assurance (40 CFR §160.12): None

Summary:
1. LD50 (mg/kg): Males = ; Females = ; Combined =
2. The estimated LD50 is >2.0 g/kg
3. Tox. Category: I
   Classification: Guidelines

Procedure:
Deviations From §212: 2.0 g/kg applied to clipped, intact skin of 5 M & 5 F rabbits. Doses prepared by "wraps"-24 hour contact. Rabbits observed 14 days for mortality and toxic signs. At 14 days, rabbits subjected to necropsy.

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>2.0 g/kg</td>
<td>0/5</td>
</tr>
</tbody>
</table>

Symptomology & Gross Necropsy Findings:
No pharmacologic or toxic signs. Some slight irritative at application point sites. Necropsies did not reveal any tissue or organ abnormalities.
DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3)

Product Manager: (15) Reviewer: W. Woodrow
MRID No.: 408805-04 Report Date: 6-20-79
Testing Laboratory: Cosmopolitan Safety Labs Report No. C1847
Author(s): G. B. Robbins
Species: Rat, Sprague-Dawley
Sex: Male
Source: Testing
Test Material: Strike 4-12 (4,92 Permethrin), Liquid
Quality Assurance (40 CFR §160.12): None

Summary:

1. LC50 (mg/kg): Males = ______ ; Females = ______

2. The estimated LC50 is > 5.1 mg/L

3. Mean Concentration:

4. Tox. Category: IV. Classification: Guideline

Procedure (Deviations from §81-2): 47.4 liter exposure chamber

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>
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<tr>
<td></td>
<td>Males</td>
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<td>______</td>
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<td>______</td>
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<td>______</td>
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</tbody>
</table>

Symptomology & Gross Necropsy Findings:

Analysis: "coarse" fur "superimposed" & "tissue. Areas: subcutaneous "fetuses contained activated charcoal. Samples collected at 1 liter/min. Particles size + geometric std deviation measured 7X using a cascade Impactor. Animals were observed for mortality & toxic effects."
DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: (15)
MRID No.: 408805-05
Testing Laboratory: Metropolitan Safety Eval.
Author(s): G. P. Robbins
Species: Rabbit
Sex: Male
Weight: 2.0 - 3.5 kg
Source: M. P. Matei
Dosage: 9 ml
Test Material: Strike 4-12 (4.7% Permethrin), liquid
Quality Assurance (40 CFR §160.12): none

Summary:
Tox. Category: III
Classification: Guideline

Procedure (Deviation From §81-4): 0.1 ml test material to eye of each of 6 rabbits (conjunctivae, cornea). Eyelids held together 1 second, treated eyes not washed. All eyes examined 1 week for irritation according to Osha @ 1, 2, 4, 8, 24, 48, 72, 1445.

Results:

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

Comments: No irritant corneal involvement. No excessive lacrimation. No evidence of redness irritation @ 48 hours; about dry in 3 days.
DATA REVIEW FOR SKIN IRRITATION-TESTING

Product Manager: (15)  
MRID No.: 40 8 850 0-06  
Testing Laboratory: Caspari Laboratory  
Author(s): G. R. Robbins  
Species: Rabbit, N 7 type  
Age: Not given  
Sex: Not given  
Weight: 2.0-3.0 kg  
Dosage: 0.5 mL  
Test Material: Aceta 4-127 4% Permethrin, liquid  
Quality Assurance (40 CFR §160.12): None  

Summary:

The Primary Irritation Index = 0.5  
Toxicity Category: III  
Classification: Suggested  

Procedure (Deviations From § 81-5): 0.5 mL test material introduced under 1 sq. gauze pad held by tape, to each of 6 clipped rabbits. Entire vehicle wrapped in plastic sealing 4 hr contact. Unwrapping removed after lamps 72 hrs. Result analyzed for irritation according to Design (Test Score).  
Results: Possible = 9.0  

At 45 min, 6/6 animals showed 1.0 for erythema, 3/6 showed edema.  
At 24 hrs, 3/6 showed 1.0 for erythema, no edema.  
At 48 hrs, 2/6 showed 1.0 for erythema.  
At 72 hrs, no visible irritation.  
A minimally irritating substance.  

Special Comments:
During exposure, 2 at 13, 6 hrs post exposure, 1 x daily for 14 days
2 days post exposure, Body Td at 2, 13, 4, 7, 14 days.
Results: Normal concentration = 15.63 mg/L

The actual second concentration (determined gravimetrically)
was: Time filter weight mg/L

<table>
<thead>
<tr>
<th>Time</th>
<th>Weight (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 min</td>
<td>50.3</td>
</tr>
<tr>
<td>2hr-7min</td>
<td>51.8</td>
</tr>
<tr>
<td>3hr-17min</td>
<td>50.5</td>
</tr>
</tbody>
</table>

Particle size:

MMAD = approx. 0.8µ. At both 1hr/min. At
3hrs. Geometric std. deviation = ± 2.9k ±3.0µ

Thus, the particles were in a respirable range.

Control rats appeared normal. Treated rats (exposed to test
material) showed reduced activity, 3/5 females showed
perioral ataxing, all animals died on backs. Beginning
day 2, all rats appeared normal. Body weight gain
was comparable for treated & control rats.

No鄞ous did not reveal any trouble at organ

no mortality.
DATA REVIEW FOR SKIN SENSITIZATION TESTING (§81-6)

Product Manager: (15)  
Reviewer: Harter
MRID No.: 403705-07  
Report Date: 6-20-89
Author(s): G.R. Balchini
Species: Guinea pig
Sex: Male  
Weight: 300-500g
Source: Cumm. Lab. Animals
Test Material: Attical 4.17 (4% Permethrin), liquid
Positive Control Material: Not named
Quality Assurance (40 CFR §160.12): None
Method: Buchler

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

Procedure (Deviation From §81-6): Tested, "Periodically a known sensitizer is tested under the same conditions."

Induction: 0.5ml test material applied to clipped right side of 10 gm guinea-pig. Under 20x20mm Webbed cloth patch/adhesive

Results: Tape + Trace of s.p. wrapped + plastic wrap. 6 hr contact. Wrapping removed, treated sites washed. Each site examined and scored according to Doury at 24, 48, 96 hrs. After wrap removal, this induction repeated 2 more times at weekly intervals (3 induction total). Animals then rested 2 weeks before challenge.

Challenge: 2 weeks after last induction application, animals challenged with same before (on right side) and also on clipped left sides (virgin sites) 6 hr contact.

Post-challenge: 14 days after last challenge, animals again challenged on left sides, using a 2nd virgin test site.

All challenge/pretreatment applications scored 24, 48, 96 hrs after patch removal.

Results: Challenge scores compared to an induction score, i.e. challenge score substantially lower.
than induction (w) scene, considered a + sensitivity.
Criteria: 1) erythema score > 1 grade
2) edema score > 1 grade
3) size of diameter of erythema exceeded by
   more than 1 cm.

<table>
<thead>
<tr>
<th></th>
<th>24 hrs</th>
<th>48 hrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Induction challenge &amp; challenge rechallenge</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>Et</th>
<th>1.0</th>
<th>1.6</th>
<th>1.3</th>
<th>1.0</th>
<th>1.4</th>
<th>1.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edema</td>
<td>Ed</td>
<td>0.6</td>
<td>1.3</td>
<td>1.3</td>
<td>0.5</td>
<td>1.2</td>
<td>0.9</td>
</tr>
<tr>
<td></td>
<td>D</td>
<td>2.7</td>
<td>3.2</td>
<td>3.4</td>
<td>2.6</td>
<td>3.1</td>
<td>3.3</td>
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<tr>
<td>Positive</td>
<td>Et</td>
<td>0.9</td>
<td>2.3</td>
<td></td>
<td>0.7</td>
<td>2.2</td>
<td></td>
</tr>
<tr>
<td>Central</td>
<td>Ed</td>
<td>0.4</td>
<td>1.7</td>
<td></td>
<td>0.2</td>
<td>1.1</td>
<td></td>
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<tr>
<td></td>
<td>D</td>
<td>1.6</td>
<td>3.9</td>
<td></td>
<td>1.6</td>
<td>3.9</td>
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</tr>
</tbody>
</table>

Et = erythema, Ed = edema, D = dia. of erythema wheel (cm)

It may be seen in the average erythema of
edema scores at 24 + 48 hours, that challenge of
a challenge score was "substantially" greater
than induction scores.

At 4-12, it is a deemed sensitive-challenged
presen...
<table>
<thead>
<tr>
<th>Study/Lab/Study #/Date</th>
<th>Material</th>
<th>EPA Accession No.</th>
<th>Results: LD₅₀, LC₅₀, PIS, NOEL, LEL</th>
<th>TOX Cat.</th>
<th>CORP Grade/Doc. No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral LD₅₀, Rat</td>
<td>Strike 4-12 ULV</td>
<td>408805-02</td>
<td>LD₅₀ &gt; 5.08 g/kg</td>
<td>1V</td>
<td>Guidelines</td>
</tr>
<tr>
<td>Cosmopolitan Safety Eval. # A 1864</td>
<td>5-15-88</td>
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<tr>
<td>Acute dermal LD₅₀, Rabbit</td>
<td></td>
<td>408805-03</td>
<td>LD₅₀ &gt; 2.09 g/kg</td>
<td>111</td>
<td>Guidelines</td>
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<td>Cos. Safety Eval. # B 1864</td>
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<td>G-29-88</td>
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<tr>
<td>Acute inhalation LC₅₀, Rat</td>
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<td>408805-04</td>
<td>LC₅₀ &gt; 5.1 mg/L</td>
<td>1V</td>
<td>Guidelines</td>
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<td>Cos. Safety Eval. # C 1864</td>
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<td>6-10-88</td>
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<tr>
<td>Primary epiderm, Rabbit</td>
<td></td>
<td>408805-05</td>
<td>Yeast skin 1.0 score for redness irritation at day 2, all clear by day 3</td>
<td>111</td>
<td>Guidelines</td>
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<td>Cos. Safety Eval. # D 1864</td>
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<td>4-22-88</td>
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<tr>
<td>Primary dermal, Rabbit</td>
<td></td>
<td>408805-06</td>
<td>A minimally irritating substance; no visible irritation by 72 hrs</td>
<td>111</td>
<td>Guidelines</td>
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<td>Cos. Safety Eval. # E 1864</td>
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<td>4-20-88</td>
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<tr>
<td>Desmal sensitization, guinea pigs</td>
<td></td>
<td>408805-07</td>
<td>Strike 4-12 ULV did sensitization guinea pigs</td>
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<td>Cos. Safety Eval. # F 1864</td>
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