



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

July 30, 1990

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 8329-GI
ULV Mosquito Derivator 420

FROM: Olga Odiott *O. Odiott* *E 8/3/90*
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C)

TO: George La Rocca (PM 15)
Insecticide-Rodenticide Branch
Registration Division (H75-05C)

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

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
<u>Permethrin</u>	<u>4.00%</u>
<u>Pyrethrul Butoxide, Technical</u>	<u>20.00%</u>
Inert Ingredient(s):	<u>76.00%</u>
Total	100.0%

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

RSB/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: Cosmopolitan Safety Evaluation Report No. A5073
 Author(s): Geoffrey R. Robbins
 Species: Spontaneous-Dawley albino rats
 Age: Young adult Observation Days (Post
 Weight: 200-214 (♀) 260-270 (♂) gm Exposure): (14); other ()
 Source: Laboratory colony
 Test Material: Biomist 4 + 20 UV (Devestater 420)
 Quality Assurance (40 CFR §160.12): attached

Conclusion:

1. LD₅₀ (mg/kg): Males = _____; Females = _____; Combined = _____
2. The estimated LD₅₀ is 75.0 g/kg
3. Tox. Category: IV. Classification: Fluoride

Procedure (Deviations From §81-1): _____

Results:

Reported Mortality

DOSAGE (/kg)	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
<u>5.0 g/kg</u>	<u>0/5</u>	<u>1/5</u>	<u>1/10</u>

Symptomology & Gross Necropsy Findings:

^{abdominal}
Perineal staining was 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 liver and congested intestines were observed in the animal that died.

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

Product Manager: (15)
 MRID No.: 414933-03
 Testing Laboratory: Cosmopolitan Safety Eval.
 Author(s): Geoffrey R. Robbins
 Species: New Zealand albino rabbit
 Sex: 5 males, 5 females Wt.: 2.95 - 3.25 kg.
 Test Material: Bionist 4+20 ULV (Devasfaber 420)
 Quality Assurance (40 CFR §160.12): attached

Reviewer: O. Odiott
 Report Date: 9 Jan. 1990
 Report No. B 2072

Summary:

- LD₅₀ (mg/kg): Males = ; Females = ; Combined = ;
- The estimated LD₅₀ is 22.0g/kg.
- Tox. Category: III. Classification: Guideline.

Procedure (Deviations From §81-2):

Results:

DOSAGE (/kg)	Reported Mortality		
	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
2.0g/kg.	0/5	0/5	0/10

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. Odiott
 MRID No.: not assigned Report Date: 23 Feb. 1990
 Testing Laboratory: Cosmopolitan Safety Evaluation Report No. C2073
 Author(s): Geoffrey R. Robbins
 Species: Sprague-Dawley rats
 Sex: 10 males & 10 females Weight: 201-209 (♀); 255-267 (♂) gm
 Source: Laboratory colony
 Test Material: Biomist 4 + 20 ULV (Devasater 420)
 Quality Assurance (40 CFR §160.12): attached.

Summary:

- LC₅₀ (mg/kg): Males = _____; Females = _____; Combined = _____
- The estimated LC₅₀ is 73.0 mg/l
- Mean Concentration: _____
- Tox. Category: III. Classification: Guideline

Procedure (Deviations From §81-2): _____

Results:

Exposure Concentration (mg/L)	Reported Mortality		
	(NUMBER KILLED/NUMBER TESTED) Males	Females	Combined
3.0 mg/l	0/5	0/5	0/10
* 3.9 mg/l	1/5	1/5	2/10
* maximum attainable []			
MHAD = 0.6 μ ± 0.8 μ			
respectively			

Symptomology & Gross Necropsy Findings:

Perineal staining, dorsal fur matted and matted;
 decreased locomotor activity. At necropsy; congested
 lungs with slight opaque areas over all lobes was
 observed in the 2 animals that died. Chromaturia
 and perineal staining was observed in these animals also.
 The remaining animals appeared normal.

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: (15) Reviewer: O. Odiott
 MRID No.: 414933-04 Report Date: 22 Dec 1989
 Testing Laboratory: CosmoPharm Safety Eval. Report No. D2073
 Author(s): Geoffrey R. Robbins
 Species: Albino Rabbit - New Zealand type.
 Sex: 3 males, 3 females Weight: 2.0 - 2.1 kg.
 Source: Laboratory Colony
 Dosage: 0.1 ml.
 Test Material: Biomist 4+20ULLV (Derastator 420)
 Quality Assurance (40 CFR §160.12): Attached.

Summary:

Tox. Category: IV Classification: Core minimum
 Procedure (Deviation From §81-4): Discharge criteria was
not evaluated.

Results:

	Observations (number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Cornea Opacity	0/6	0/6	0/6	0/6	—			
Iris	0/6	0/6	0/6	0/6	—			
Conjunctivae Redness	0/6	0/6	0/6	0/6	—			
Chemosis	0/6	0/6	0/6	0/6	—			
Discharge	—	—	—	—				

Comments: _____

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

Product Manager: (15)
MRID No.: 414933-05
Testing Laboratory: Cosmopoint Safety Eval.
Author(s): Geoffrey R. Robbins
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: Biomist 420 UUV (Derostator 420)
Quality Assurance (40 CFR §160.12): attached.

Reviewer: O. Odiott
Report Date: 28 Dec. 1989
Report No. E2073

Summary:

The Primary Irritation Index = 0.8

Toxicity Category: IV

Classification: Guideline

Procedure (Deviations From §81-5):

Results:

Very slight erythema on 4/6 animals, and very slight 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)
MRID No.: 414933-06
Testing Laboratory: Cosmopolitan Safety Eval.
Author(s): Geoffrey R. Robbins
Species: albino guinea pig
Sex: male
Weight: 326-356 gm
Source: Camm Research Lab Animals, Wayne, New Jersey
Test Material: Biomist 4+20 ULV (Derostat 420)
Positive Control Material: 20% p-phenylenediamine in saline
Quality Assurance (40 CFR §160.12): 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 (0.5ml) once a 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 showing
a sensitizing response.