

US EPA ARCHIVE DOCUMENT



6-21-89

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

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

Strike 4-12 ULV
Magnum 44 ULV

FROM: William S. Woodrow WSW 6-20-89
Precautionary Review Section E 6/21/89
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):	% by wt.
Permethrin (3-Phenoxyphenyl) methyl (+) cis.	_____
trans-3-(2,2-dichloroethyl)-2,2-dimethyl-	_____
cyclopropane carboxylate	4.00
Technical Piperonyl Butoxide	12.00
Inert Ingredient(s):	84.00

Total 100.0%

(Magnum 44 ULV)

Active Ingredients:	_____
Permethrin (3-Phenoxyphenyl) methyl (+) cis + trans	_____
-3-(2,2-dichloroethyl)-2,2-dimethyl-	_____
cyclopropane carboxylate	4.00%
Technical Piperonyl Butoxide	4.00%
<u>INERT INGREDIENTS:</u>	92.00%

67561

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 (4% Permethrin & 12% Piperonyl Butoxide), and Magnum 44 ULV (4% 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.

LABELLING: (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: (15) Reviewer: Woodrow
 MRID No.: 408805-02 ~~W. Waller~~
 Testing Facility: Cosmopolitan Safety Eval. Report Date: 6-20-89
 Author(s): G.R. Robbins Report No. A1864
 Species: Rat, Sprague Dawley
 Age: young adult Observation Days (Post Exposure): (14); other ()
 Weight: M 240-340, F 200-300g
 Source: not given
 Test Material: Strike 412 (Permethrin 4%, PB 4%), liquid
 Quality Assurance (40 CFR §160.12): None

Conclusion:

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

Procedure (~~Deviations From §81-1~~): 5.0 g/kg administered to each of 5M & 5F by gavage. Animals observed for mortality and toxicity after day of dosing, 2x daily. To 4 days & necropsy. Body wt. end of 0, week 1.
 Results:

Reported Mortality

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

Symptomology & Gross Necropsy Findings:

Clinical signs: 1 hr, all rats showed yellow perianal staining. Day 1, 2 females had convulsions. Day 2 - rats normal, except 3/5 females showed rectal staining; all rats appeared normal thereafter. All rats gained weight. All organs and tissues appeared normal at necropsy.

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

Product Manager: (15)

Reviewer: Woodrow Waller

MRID No.: 408805-03

Report Date: 6-20-59

Testing Laboratory: Cosmopolitan Safety Eval.

Report No. B1864

Author(s): G. R. Robbins

Species: Rabbits, NZ type

Sex: 5M+5F

Wt.: ~~not stated~~ 2.5-3.5 kg

Test Material: Aliche 4-12 (49% Permethrin)

Quality Assurance (40 CFR §160.12): none

Summary:

- LD50 (mg/kg): Males = _____; Females = _____; Combined = _____;
- The estimated LD50 is $> 2.0 \text{ g/kg}$
- Tox. Category: III. Classification: Guidelines

Procedure (~~Deviations From §81-27~~): 2.0 g/kg applied to clipped, intact skin of 5M+5F rabbits. Areas protected by "wraps" - 24 hour contact. Rabbits observed 14 days for mortality and toxic signs. At 14 days, rabbits subjected to necropsies.

Results:

Reported Mortality

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

Symptomology & Gross Necropsy Findings:

No pharmacologic or toxic signs. Some slight irritation at application sites. Necropsies did not reveal any tissues or organ abnormalities.

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

Product Manager: (15) Reviewer: Woodrow
 MRID No.: 408805-05 Report Date: 6-20-89
 Testing Laboratory: Cosmopolitan Safety Eval. Report No. D1864
 Author(s): G. R. Robbins
 Species: Rabbits
 Sex: not given Weight: 2.0 - 3.5 kg
 Source: not given
 Dosage: 0.1ml
 Test Material: strike 4-12 (4% Permethrin), liquid
 Quality Assurance (40 CFR §160.12): none

Summary:

Tox. Category: III Classification: Gueddino

Procedure (Deviation From §81-4): 0.1ml test material to conj of each
of 6 rabbits (conjunctival sac). Eye lids held together 1 sec only;
test eye not washed. All eyes opened & scored for irritation
according to Drauz @ 1, 2, 4, 48, 72 hrs.

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	6/6	3/6	1/6	0/6				
Chemosis	3/6	0/6	0/6	0/6				
Discharge	-	-	-	-				

Comments: No iris or corneal involvement. 1/6 animals
1-0 score for redness irritation @ 48 hours; absent by
3 days.

Product Manager: (15) Reviewer: Woodrow M. Waller
 MRID No.: 408805-06 Report Date: 6-20-89
 Testing Laboratory: Cosmopolitan Safety Eval Report No. E1864
 Author(s): G. P. Robbins
 Species: Rabbit, N 2 type
 Age: not given
 Sex: not given
 Weight: 2.0-3.5 kg
 Dosage: 0.5ml
 Test Material: Alcike 4-12 (49% Permethrin), liquid
 Quality Assurance (40 CFR §160.12): None

Summary:

The Primary Irritation Index = 0.5

Toxicity Category: III

Classification: Guidelines

Procedure (~~Deviations From §81-5~~): 0.5ml test material introduced under 1" sq. gauze pad held by tape, to each of 6 clipped rabbit backs. Entire backs wrapped in plastic shielding. 4 hr control. Unwrapping removed, sites wiped, 30-barrier after cleaning @ 24, 48, 72 hrs sites scored for irritation according to Draize - (Max. score Results: possible = 8.0

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, & at 1, 3, 5 hrs post exposure, & 1x daily for 14 days
& necropsy necropsies. Body wts at 0, 2, 3, 4, 7 & 14 days.

Results - Nominal concentration = 15.63 mg/L

The actual aerosol concentration (determined gravimetrically

was:	Time	filter wt. gain	mg/L	mean
	30 min	50.3	5.03	} 5.1 mg/L
	2hr - 17 min	51.8	5.18	
	3hr - 17 min	50.5	5.05	

Particle size:

MM Dia = approx. 0.8 μ at both 1hr (5 min), & at

3hrs. Geometric std. deviation = ± 2.9 & ± 3.0

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 perineal staining, all animals wet on backs. Beginning day 2, all rats appeared normal. Body weight gain was comparable for treated & control rats.

Necropsies did not reveal any tissue or organ abnormalities.

No mortality.

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

Product Manager: (15) Reviewer: ^{Woodrow} ~~M. Waller~~
MRID No.: 408805-07 Report Date: 6-20-89
Testing Laboratory: Cosmopolitan Safety Eval. Report No. F1864
Author(s): G. R. Robbins
Species: Guinea pig
Sex: Male Weight: 300-500g
Source: Camm Res. Lab. Animals
Test Material: Strike 4-12 (4% Permethrin), liquid
Positive Control Material: Not named.
Quality Assurance (40 CFR §160.12): none

Method: Buehler

Summary:

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

Procedure (~~Deviation From §81-6~~): + control, "periodically a known sensitizer is tested under the same conditions"

Induction: 0.5ml test material applied to clipped right sides of 10 mg. p., under 20x20mm Webber cloth patch/adhesive

Results: Tape & tissue of g.p. wrapped & plaster wrap - 6hr contact. Wrappings removed, treated sites wiped. Each site examined and scored according to Draize @ 24 & 48 hrs, after wrap removal. This induction repeated 2 more times at weekly intervals (3 inductions total). Animals then rested 2 weeks before challenge.

Challenge: 2 weeks after last induction application, animals challenged @ 0.5ml as before (on right sides), and also on clipped left sides (virgin sites), 6hr contact.

Pre-challenge: 14 days after 1st challenge, animals again challenged on left sides, using a 2nd virgin test site. All challenge/rechallenge applications scored 24 & 48 hrs after patch removal.

Results: Challenge scores compared to an induction score; if an. challenge score "substantially" higher

than induction (as.) scores, considered a + sensitive -

+ criteria: 1) erythema score > 1 grade

2) edema score > 1 grade

3) size of diameter of erythema increased by more than 1 cm.

		24 hrs			48 hrs		
		induction challenge			re challenge		
Test	Et	1.0	1.6	1.3	1.0	1.4	1.2
Material	Ed	0.6	1.3	1.3	0.5	1.2	0.9
	D	2.7	3.2	3.4	2.6	3.1	3.3
Positive	Et	0.9	2.3		0.7	2.2	
Control	Ed	0.4	1.7		0.2	1.1	
	D	1.6	3.9		1.6	3.9	

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

It may be seen in the average erythema & edema scores at 24 & 48 hours, that challenge & re challenge scores were "substantially" greater than induction scores.

Strick 4-12 is a dermal sensitization - in guinea pigs.

670 Piperonyl Butoxide

Tox Chem No. 652 BB Permethrin File Last Updated _____ Current Date 6-20-89

Study/Lab/Study #/Date	Material	EPA Accession No.	Results: LD50, LC50, PIS, NOEL, LEL	TOX. Cat.	CORE Grade/Doc. No.
Acute oral LD50, Rat Cosmopolitan Safety Eval. # A1864. 5-15-88	Strike 4-12 ULV 4.0% Permethrin (2.0% Piperonyl Butoxide)	408805-02	LD50 > 5.0g/kg	IV	Guide-lines
Acute dermal LD50, Rabbit Cos. Safety Eval. # B1864 5-29-88	"	408805-03	LD50 > 2.0g/kg	III	Guide-lines
Acute inhalation LC50, Rat. Cos. Safety Eval. # C1864 6-10-88	"	408805-04	LC50 > 5.1 mg/L	IV	Guide-lines
Primary eye irrit. Rabbit Cos. Safety Eval. # D1864 4-2-88	"	408805-05	1/6 animals 1.0 score for adverse irritation at day 2, all clear by day 3	III	Guide-lines
Primary dermal irrit. Rabbit Cos. Safety Eval. # E1864 4-20-88	"	408805-06	A minimally irritating substance; no visible irritation by 72 hrs	III	Guide-lines
Dermal sensitization, guinea pig. Cos. Safety Eval. # F1864 6-17-88	"	408805-07	Ataxia 4-12 ULV did sensitize guinea pigs	-	Guide-lines