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UNITED S TES ENVIRONMENTAL PROTECTION AGENCY 000208

000208

DATE: August 11, 1978

SUBJECT: Amended registration of EPA #7001-148, Dursban Insect Spray
Caswell No. 219AA

FROM: H.W. Spencer, Ph.D.
Toxicology Branch, HED (TS-769)

TO: Frank Sanders, PM #12
Registration Division (TS-767)

Registrant: Occidental Chemical Co.
PO Box 198
Lathrop, CA 95330

Conclusions: Recommendations:

1. The change in formulation of inerts has produced a reduction in irritative effects of the product as evidenced by the toxicity data submitted.

2. TOX Branch finds the formulated material to be in Tox. cate. III requiring the signal word "caution".

TOX Branch defers to the P.M. for completion of the labeling.

Summary of Newly Submitted Toxicity Data FE000856

Tox. Cat.	Route	Value (Score-1/120)	Animal
IV	Eye Irritation	Non-Irritating	rabbit
III	Dermal Irritation	(Score-1)	rabbit
III	Dermal Tox	LD_{50}>2 g/kg	rabbit
III	Oral	LD_{50} 1.16 g/kg	rat, female
III	Oral	LD_{50} 1.37 g/kg	rat, male
III	Dermal Irritation	moderate irritant (Score-3.34)	rabbit

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-Acute Eye Irritation:

Material tested: Zoecon #FX000856 6.7% concentration and New formulation [redacted]. Received by laboratory 12/22/77.

Animal tested: White New Zeland rabbits, (9) young adults, randomly chosen, unsexed for study.

Method: Both eyes were examined prior to use to ensure utility of eyes. Ears were marked and animals were allowed to acclimate to laboratory. 0.1 ml of the formulation, undiluted was placed into everted left lower lid and gently held to prevent loss of the test material. Three animals' eyes were washed for 1 minute with warm H_2O after 30 seconds.

Results: Scores at 24, 48, 72, 96 hr and 7, 14 days. Fluorescein was used at 72 hr and 7 days to aid reading of lesions.

Draize scoring was used. Only 1 animal of the 9 treated showed a (Score 1 for redness) only at 24 hr.

TOX Branch considers this study Core-minimum data. Tox Cat IV Non-Irritating

Study by Elars, Bioresearch Labs., Ft. Collins, Colo. Project No. 1370 dated 1/26/78.

-Dermal Toxicity:

Material tested: Zoecon compd #FZ000856 Lot #856 [redacted], dtd 1/20/78, received by Elars 1/26/78. New Formulation and 6.7% concentration [redacted].

Animal tested: 8 adult New Zealand rabbits 4/sex (4-5 lbs) housed in pairs and ear-marked.

Method: Fur was clipped and skin was abraded on 2 males and 2 females the others remained with skin intact.

A 4"x4" gauze several thicknesses covered the application area and was then covered with Saran wrap and wrapped with adhesive tape and conform tape for 24 hr.

Scoring was by the Draize method.

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Papillary response was checked at 24 hr. Observations were made daily. Gross and histopathological exam was made at 14 days where indicated.

Results: Weight loss was not evident erythema was seen (Score 1) in (3/4 abraded) and (4/4 intact) on day 2. Erythema subsided in one with abraded skin and appeared in 4/4 with intact skin.

TOX Branch noted no signs of toxicity were seen. Skin sloughed off by day 14 to reveal normal skin beneath.

No postmortem changes were note.

TOX Branch considers the data adequate to indicate Tox cat III and an LD_{50} >2 g/kg dermally

Study by Elars Bioresearch Labs, Ft. Collins, Colo. Project No. 1375, dated 2/24/78.

Acute Oral Toxicity

Material tested: Formulation FZ000856 Batch 20 Jan/78, clear liquid received 1/25/78 from Zoecon Corp.

Animal tested: S-D derived white rats. 5/sex/group

Method: The material was dosed by stomach tube to males (215-284g) or to females, (165-209g). The material was dosed at 0.54 g/kg, 0.81 g/kg, 1.22 g/kg, 1.87 g/kg or 2/84 g/kg since the S.G. was 0.812 ± 2%.

The animals were fasted for 24 hrs prior to dosage. Food and water were then admitted ad lib. Observation was up to 14 days.

Results:

Males ml/kg	dead/dosed	Females
0.67	0/5	1/5
1.0	0/5	1/5
1.5	1/5	2/5
2.3	5/5	5/5
3.5	5/5	5/5

LD_{50} 1.37 g/kg (95% C.L. 1.17-1.62g/kg)

LD_{50} 1.16 g/kg (95% C.L. 0.84-1.61 g/kg)

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