

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: August 2, 1979

SUBJECT: EPA Registration#1471-EUP-AI; EL-5219 EC; CASWELL#623A & 889

FROM: William Dykstra, Ph.D
Toxicology Branch (TS-769)

WMD 8/2/79 WSW

TO: Dan Dickson
Product Manager#25

ACTION REQUESTED: Herbicide for experimental use on soybeans and cotton.
RECOMMENDATIONS:

1. Trifluralin is an RPAR Chemical.
2. The EUP can be toxicologically supported.
3. The toxicity data submitted are acceptable as Core-Minimum Data and support the EUP.

Name of Product: EL-5219 EC

<u>Ingredient</u>	<u>Percent Weight</u>
Trifluralin, [REDACTED]	17.2
Oryzalin, [REDACTED]	17.2
[REDACTED]	
	100.0

Inerts cleared under 180.1001 (c) & (d).

Section F: Tolerances for trifluralin (40 CFR 180.207) and oryzalin (40 CFR 180.304) on cotton and soybeans have already been established.

This pre-packaged product will not result in any residue higher than the tolerance previously established.

Review: Acute Toxicity Studies of EL-5219, An emulsifiable concentrate formulation containing trifluralin [REDACTED] and oryzalin [REDACTED]

Study Numbers: R-0-456-78
R-0-457-78
B-E-206-78
B-D-210-78
R-H-155-78

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

(2)

1. Acute Rat Oral Toxicity of EL-5219 Studies R-0-457-78 & R-0-456-78.

Test Material: EL-5219; Lot#X-35110

A group of 5 male and 5 female Wistar rats, average weight 118 ± 1.3 gm, was fasted overnight. Each animal was given a single oral dose of 0.5 ml/kg BW of test material. Observation for 14 days.

Results: No deaths LD50 > 0.5 ml/kg (500 mg/kg)

Toxic Signs: No toxic signs

Body Weight: All animals gained weight.

Necropsy: Not reported

Classification: Core-Minimum Data; TOX Category III: CAUTION

2. Acute Rabbit Ocular Irritation Study of EL-5219 Study B-E-206-78.

Test Material: EL-5219

0.1 ml of test material was instilled into the conjunctival sac of one eye of each of six NZW rabbits (3M + 3F). Observation and scoring at 1, 2, 3, 7 and 14 days after exposure.

Results: Conjunctivitis persisted in 1/6 for 7 days. Corneal opacity in 1/6 for days 1, 2 and 3 which healed on day 7.

Classification: Core-Minimum Data; TOX Category II: WARNING

3. Acute Rabbit Dermal Toxicity and Irritation Study of EL-5219 Study B-D-210-78.

Test Material: EL-5219

A group of 3 male and 3 female NZW rabbits, 2.61 ± 10 kg BW; received 2.0 ml of test material on the intact (3 backs were abraded) skin sites of the fur clipped trunk under occlusion for 24 hours. Toxicity, including dermal irritation, was evaluated for 14 days.

Results: No deaths LD50 > 2.0 ml/kg (2.0 ~~gm~~ kg)

Toxic Signs: Slight erythema and edema developed within 24 hours of exposure. Normal healing occurred with epidermal dehydration and desquamation. At the conclusion of the 14 day observation period, all treatment sites were normal except for slight desquamation that was evident in 4 animals. No systemic toxicity was observed.

Body Weight: Normal body weight gain in all animals.

2
600

(3)

Necropsy: Not reported

Classification: Core-Minimum Data; TOX Category III: CAUTION

Primary Skin Irritation: TOX Category III: CAUTION:

4. Acute Rat Inhalation Toxicity Study of EL-5219 Study R-H-155-78.

Test Material: EL-5219

10M + 10F Wistar Rats were exposed (head only) for one hour to a mist atmosphere of EL-5219 at a nominal concentration of 38 ul/L (38 mg/L) of air. The Mist was generated from a DeVilbiss 841 Nebulizer into a 6 L spherical inhalation chamber at an airflow of 5.6L/minute. Observation was for 14 days.

Results: No deaths LC50 > 38 mg/L

Toxic Signs: Mild chromodacryorrhea and chromorhinorrhea were noted in all animals immediately following exposure. These conditions cleared within two hours. Mild hypoactivity, which was noted in all animals, persisted for 1 to 2 hours after exposure. Three rats had labored respiration that persisted for at least 4 hours after exposure. All animals appeared normal 24 hours after exposure and throughout the remainder of the study.

Body Weight: Body weight gains were normal.

Necropsy: Not reported

Classification: Core-Minimum Data; TOX Category IV: CAUTION

TOX/HED:th:RD Initial WWOODROW:8-1-79

22m
8/2/79
1/16

3
601