



3-6-98

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

March 6, 1998

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: EPA Reg. No.: 241-GAA AC 303,630
INSECTICIDE-MITICIDE TECHNICAL
DP Barcode: D241971
Case No: 044966

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505C)

Byron T. Backus
6 MARCH 1998
JCR

To: Ann Sibold, PM 03
Insecticide Branch
Registration Division (7505C)

Registrant: American Cyanamid Company

FORMULATION (LABEL DECLARATION)

Active Ingredient(s):

129093 Chlorfenapyr..... % by wt.

Inert Ingredient(s):.....93.0%

.....7.0%

Note: this study was conducted on a metabolite of Chlorfenapyr

BACKGROUND: The registrant has submitted an oral LD50 study (with rats) on a compound identified as AC 303267, a soil metabolite of chlorfenapyr. This study is in MRID 444526-20, and was conducted at the Agricultural Products Research Division of American Cyanamid.

RECOMMENDATION: The oral LD50 study is acceptable. The metabolite AC 303267 has an oral LD50 value > 5000 mg/kg in rats, and is in toxicity category IV by the oral exposure route.

LABELING: As this oral LD50 study was conducted on a metabolite of an active ingredient, rather than an actual component of a product, no labeling recommendations are made.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§81-1, 870.1100)

Product Manager: 03

MRID No.: 44452620

Reviewer: Byron T. Backus, Ph.D.

Study Completion Date: November 20, 1997

Study No.: T-1003

Testing Facility: American Cyanamid Company Agricultural Research Division

Author(s): Lowe, C.A. & Bradley, D.

Quality Assurance (40 CFR §160.12): Included (p. 4)

Test Material: AC 303267

Species: Rat; Albino, Sprague-Dawley-derived (CrI:CD®BR(SD)BR)

Age: Males: 9-10 weeks; Females: 9-12 weeks

Weights: M: 274-343 g; F: 185-260 g.

Source: Charles River Laboratories

Conclusion:

1. LD₅₀:

Males >5000 mg/kg (1/5 died at this dose)

Females >5000 mg/kg (no deaths at this dose)

Combined >5000 mg/kg (1/10 died at this dose)

2. The estimated LD₅₀ is >5000 mg/kg

3. Tox. Category: IV

Classification: Acceptable

Procedure (Including deviations from §81-1): "The test substance was ground to a fine powder with a mortar and pestle and then mixed with 0.5% carboxymethyl cellulose (CMC) and...(water) to achieve a uniform weight/volume dispersion of the test substance in the diluent. The test dispersions were prepared on the day of dosing and stirred continuously during dosing using a stir bar and stir plate... The test substance was administered by oral intubation... Individual doses were calculated based on fasted body weights." The concentration of test material was varied by dosage level, so each animal received 10 mL/kg of a 5%, 10% or 50% concentration.

Results:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
500	0/5	0/5	0/10
1000	0/5	0/5	0/10
5000	1/5	0/5	0/10

Observations: One male in the 5000 mg/kg group died on day 4. "There were no clinical signs noted during the study period." From information on p. 17 the animal was found dead, with no indications prior to this of any symptoms.

Gross Necropsy: "Gross pathological changes in the decedent were limited to a discolored liver and hemorrhagic and discolored lungs. There were no gross pathological findings observed in animals which were sacrificed at the termination of the study."

ACUTE TOX ONE-LINERS

1. PC CODE: 129093 [Metabolite of]
2. CURRENT DATE: March 6, 1998
3. TEST MATERIAL: AC 303267 [Metabolite of Chlorfenapyr]: 98.1%

Study/Species/Lab Study #/Date	MRID No.	Results	Tox. Cat.	Core Grade
Oral LD50/rat/American Cyanamid/T-1003/20-NOV- 1997	44452620	1/10 rats died following dosage at 5000 mg/kg; LD50 > 5000 mg/kg	IV	A

Core Grade Key: **A = Acceptable**