WORKER HEALTH AND SAFETY BRANCH

ADDITIONAL DATA PACKAGE RECOMMENDATION SHEET

DATE: July 12, 1996

TO: P. Anderson, Registration Specialist

RE: PRODUCT NAME: Aatrex 4L
ACTIVE INGREDIENT(S): (40.8%) ATRAZINE
(2.2%) ATRAZINE related compounds
I.D. NUMBER: 161341-E
EPA REGISTRATION NUMBER: 100-497
DOCUMENT NUMBER(S): 220-451
COMPANY NAME: Ciba-Geigy

TITLE: "Submission of final report amendment to the dermal sensitization study in guinea pigs with Aatrex 4L - positive control data in support of record number 126886 in volume 220-193"

X This study is acceptable for use in future exposure assessment and mitigation evaluations.

X Archive data in Pest Management Division Library for future references.

COMMENTS:

The positive control study reported adequately addresses WH&S memorandum dated 5-10-96 (ID No. 143224-E, Document No. 220-193).

Data Required: No

ADDENDUM

1. Document No. 220-091, study titled, "Dermal sensitization study in female guinea pigs"

This sensitization study used the modified Buehler methodology. It deviated slightly from the Buehler protocol. An equal number of female and male guinea pigs was not used; only female guinea pigs were employed. The narration did not indicate if these female guinea pigs were nulliparous. The study deviated slightly from the EPA's Pesticide Assessment Guidelines 81-6. No 72 hour dermal scoring was reported for the challenge phase. Edema was not included in the observations or in the dermal scoring scale.

The neat test article (7.6% AI) was used for the exposure tests. The narration did not indicate if the test article was moistened for the exposure tests. The positive control was 0.05% (w/v) DNCB diluted with ethanol/water (20/80, v/v) solution. Negative (=Irritation) controls were employed.

The dermal scores were zero (0/10) for erythema @ 24 & 48 hours. The incidence was zero (0/10) as was the severity index.

The reported Dermal Sensitization data indicate the neat test article was not a sensitizer in the female animal model tested.

2. Document No. 220-404, ID No. 153751-E, study titled "Dermal sensitization study in guinea pigs"

This dermal sensitization study was assayed using the modified Buehler methodology. The study deviated slightly from the Buehler protocol. An equal number of female and male guinea pigs was not employed in the tests; only male guinea pigs were exposed. The study was consistent with the EPA's Pesticide Assessment Guidelines 81-6. No 72 hour dermal scoring was reported for the challenge phase.

The range finding test was evaluated using the neat test article (? % AI ?), and 50%, 10%, and 1% solutions (v/v) diluted with an ethanol/water mixture. The 50% (v/v) solution was used for the exposure tests. The positive control was DNCB: 0.06% (w/v) solution diluted with 50% ethanol. Negative (=Irritation) controls were employed.

The dermal scores were:

	Induction	**Challenge**		**Sensitization Index**	
		test article	control	test article	control
erythema					
24 hrs	1.3	2.0	1.5	1.5	--
48 hrs	1.2	1.3	1.1	1.1	--
edema					
24 hrs	0.7	1.7	1.1	2.4	--
48 hrs	0.9	1.1	0.5	1.2	--

NOTE: Day 10 scores were not used in the calculations.

The reported Dermal Sensitization data indicate the 50% test article was a skin sensitizer in the animal model tested.

Joshua L. Johnson
(Associate Pesticide Review Scientist)

J. Sanborn
(Toxicologist)

[original signed by J. Johnson & J. Sanborn]