121601
SHAUGHNESSEY NO.

3
REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 8/5/81 OUT 8/10/81

FILE OR REG. NO.

PETITION OR EXP. PERMIT NO. 524-EUP-56

DATE OF SUBMISSION 7/10/81

DATE RECEIVED BY HED 8/4/81

RD REQUESTED COMPLETION DATE 8/16/81

EEB ESTIMATED COMPLETION DATE

RD ACTION CODE/TYPE OF REVIEW 451/Protocol

TYPE PRODUCT(S): I, D, H, F, N, R, S Herbicide

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. R. Taylor (25)

PRODUCT NAME(S) Mon 097

COMPANY NAME Monsanto Company

SUBMISSION PURPOSE Registrant's Response to Previous EEB Review, Data Validations update, Data Request Review

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
121601	Acetamide	86.4

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Mon 097 (CP55097); acetochlor (No. 524-EUP-56)

EEB acknowledge reciept of one letter on August 5, 1981 from Monsanto Company dated July 10, 1981. The letter contains clarification on Avian Acute Oral LD50, 96 hour LC50 for bluegill sunfish, and rainbow trout, 48 hour LC50 for Daphnia magna and a request for determining need of an avian reproduction study.

1. Acute 96-hour LC50 Toxicity Study in Bluegill Sunfish, AB-79-078, ABC study number 24017, Accession number 99812.

Point (A): As would be expected, we have the capability to use any of the recommended procedures for statistical analysis of mortality data. When a report states or cites numerous techniques without specifying the exact one that was utilized, we run the data through our computer program. When only one partial mortality occurs and that partial mortality is low, then the reviewer has to decide if the statistics reflect a realistic LC50. The confidence limits of 0 to 1.8 were calculated by the computer (binomial analysis). This range represents the total test range of 0 to 100% mortality with only one partial mortality.

(B) If ABC had not had a 3°C increase in water temperature, the dissolved oxygen would more than likely have been above the required 40% saturation. In theory and based on previous laboratory experience, a three degree rise would have the following affect on 100% saturation: at 22°C, 100% saturation should be approximately 8.7 ppm ; at 25°C around 8.0 ppm. Therefore, if temperature control measures failed, the test could be significantly affected. The fish would be under a greater stress and could therefore indicat a lower LC50 value. This lower value could affect the registrant's product with unnessary label restrictions.

In relationship to the aeration question that ABC feels is contradictory, we will present the following rationales: First, we realize some chemical compounds, through their degradation, can reduce the DO level in the chamber. In these cases "flow through would be the preferred test"; second, when loading (grams bodyweight of fish per unit volume) is high, DO can be expected to drop faster. Since this test had a loading of 0.3* gms/liter, this would not appear to apply. However, quoting from Stephan's (1975) "For STATIC test with the species listed in Table 3, the loading in the test chambers must not exceed 0.8g/litter at or below the temperatures specified at the recommended

test temperatures and 0.4g/litter at higher temperatures". Thus the testing laboratory personnel should have realized that with the temperature variation that occurred on Day two that the test probably would not reach completion with enough DO. Aquatic test have been conducted with aeration and have been accepted for meeting requirements of registration. These studies did not use nominal starting concentrations but, instead, use analytically measured concentrations at the beginning and end of the study. They use the end of the study values for their concentration axis or values. They used the beginning values versus the ending values to depict the effect of aeration.

(*From ABC part "C" of letter July 10, 1981.)

(C) "the quality controls in the test are open to question as the loading per container was below the maximum."

First, the PM condensed and/or left out part of the sentence in the letter that was transmitted to Monsanto. We are quoting the original review statements:

"The quality controls in the test are open to question as the loading per container was 0.14g/L well below the 0.8g/L maximum." From the way the report was presented, we concluded that biomass loading was 0.14g/L. ABC indicates that the biomass loading was 0.3g/L. We understood from their report that they were using 15 liter of water per test vessel, placing five fish with mean weight of 0.41 grams per vessel. The closest that we come to their figure of 0.3g/L is 0.328g/L, with the following assumptions: 10 fish per vessel, 12.5 liters of water. In any event, if DO levels cannot be maintained, two or more vessels (Stephans, 1975) could be used. We feel that the power failure on Day 2 caused the recommended quality control to be violated, thus the test should have been re-ran as the controlled test which is required.

II. Acute 96 hour LC50 Toxicity Study in Rainbow Trout, AB-79-077, ABC Study Number 24016, ACC.# 99812

(A) We have no problem accepting one of the analysis techniques for mortality data, including the less preferred manual method. We object when a testing lab does not indicate specifically what analysis method is used. We would suggest to Monsanto that they should require their testing laboratories to state in the body of the report whether they used

a manual technique (graph), or computer program and identify the specific technique. The technique itself should then be referenced. The use of blanket and/or numerous citings of various dose-response mortality patterns analysis lends itself to speculation and invalidation of studies.

(B) See Range Finding Discussion in Conclusions

III Acute, 48-hour LC50 Toxicity Study in Daphnia magna, AB-79-079, ABC study number 24018, Acc. # 99812

(A) See II (A) Above.

(B) See Range Finding Discussion in Conclusions

IV Acute Oral LD50 Bobwhite Quail WL-80-003 project number 139-183, April 9, 1980, Acc. # 99812

This is a good example of what can happen to a study when various statistical techniques are referenced or if the specific technique that is cited is incorrect for the data. This study, due to the mortality pattern, does not lend itself to anlaysis by the probit techniques. Since laboratory personnel stated that they used the probit analysis for analyzing the data, we had no choice but to invalidate the study. The laboratory personnel would then have to demonstrate to us that they had the capability of analyzing the data with a valid technique for this type of mortality pattern. Otherwise, we would have to assume that they took an educated quess at the value, which is highly unacceptable, and very unscienfific.

Conclusions:

1. Range Finding Test: (a) the report that we recieved for Daphnia magna contain range finding dose levels of 0.1, 1.0, and 10 mg/L. None of these dose levels had any mortality. The laboratory report now indicates that the highest dose level was 100 mg/L. (B) with reference to the rainbow trout study, the laboratory's range finding data indicates that at 1.0 mg/L and, after 72 hours, all fish were dead. Instead of a progression up to 1.0 mg/L, they chose to use this as a center point. Thus, the results do not indicate an effect/no-effect range.

2. The following studies have been revalidated based on the information in this letter:

Test Type	Species	LD50/LC50	Status[1]
1. Avian Acute Oral LD50	Bobwhite Quail	1566 mg/kg (1315-1971)	Core
2. Acute 96-hour Warmwater Fish	Bluegill Sunfish		Invalid*
3. Acute 96-hour Cold Water Fish	Rainbow Trout	0.42 mg/l (0.35-0.52)	Core
4. 48-hr LC50 for Aquatic Invertebrates	Daphnia magna	14 mg/L (10-18)	Core

[1]Status - Core supports registration
*This study is being conducted again by the registrant.

3. Request for review of need to conduct Avian Reproduction Study (§ 163.71-4)

Based on EFB's review to date, we cannot assess the persistence of the pesticide or it's metabolites, and the bioacculnulation of the product or it metabolites. Without an Environmental Fate Profile of this product and it's degradates, we cannot address the "especially preceding or during the breeding season" section of 163.71-4. We, therefore, cannot request data until the results of the EUP and an Environmental Fate Profile are recieved.

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