

5-5-89
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SUBJECT: Request for Waiver of Fish Acute Testing Requirements for Bolstar

FROM: James W. Akerman
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

TO: D. Edwards, PM12
Registration Division (H7505C)

The Ecological Effects Branch (EEB) has reviewed Mobay Corporations request for a waiver of the fish acute toxicity testing requirement for their product Bolstar 6. This request is due partially to the inability of the registrant to determine the concentration of dissolved Bolstar (TGAI) that produces an acute LC_{50} on rainbow trout. Mobay has made numerous attempts to test the technical material but due to the very low solubility of the substance those efforts have failed. On 12-02-87, EEB allowed the registrant to substitute the formulated product for the TGAI in their acute testing. The registrant then referred to formulated product testing studies by Lamb (1975, MRID:45330). EEB reevaluated the Lamb studies and found three deficiencies preventing proper review. These deficiencies are 1) the source of fish, 2) the loading factor and 3) the physio-chemical measurements of the test solution.

Mobay has with their latest submission (3-29-89) concerning this waiver supplied the above information. EEB has reconsidered the Lamb (1975) studies with this new information and finds these studies sufficient to recommend the waiver of further fish acute toxicity studies. The Lamb (1975) formulated product testing will be accepted in lieu of fish acute toxicity testing on the technical material.

CONCURRENCES							
SYMBOL	H7507C	H7507C					
SURNAME	Gutenson	Cramer					
DATE	5/5/89	5/5/89					

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tion

DATA REVIEW NUMBER: (ES) 103.1.3 (I)

TEST: Fish Acute LC₅₀

SPECIES: Bluegill Sunfish

RESULTS (1) 96-Hour LC₅₀: 1.0 (.7-1.5)* ppm

(2) p, p' DDT Control 96-hour LC₅₀: 4.3 (3.2-5.8)*ppb

*95% confidence limits

CHEMICAL: Bolstar (Bay NTN 9306) 6 lb. a.i./gal. EC (64% a.i.)

TITLE Acute Toxicity of Bay NTN 9306 6 lb./gal. Emulsifiable
Concentrate to Bluegill, Channel Catfish, and
Rainbow Trout (Report No. 45330)

ACCESSION NO. 095559

STUDY DATE: October 11, 1975

RESEARCHER: D. W. Lamb and D. J. Roney, Chemagro Agric. Div.,
Mobay Chem. Corp.

REGISTRANT: Chemagro Agricultural Division, Mobay Chemical Corp.

VALIDATION CATEGORY: - Supplemental

CATEGORY REPAIRABILITY: No (See over)

ABSTRACT: The 96-hour LC₅₀ Bolstar 6 EC versus bluegill sunfish
was presented. ⁵⁰ The LC₅₀ was 1.0 (0.7-1.5) ppm as
per method of Weil (1952) ⁵⁰

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Additional Information/Comments

A. Additional Test Data

(I) Methodology/Protocol

- (a) Basically, study was performed as per the proposed Guidelines of 1978.
- (b) The following points are noted:
 - (i) A minimum of 5 concentrations was used.
 - (ii) The researcher indicates a geometric factor of 2.16 between concentrations.
 - (iii) Water was used as the stock solution solvent.
 - (iv) Fish were obtained from a commercial hatchery and acclimated for a minimum of 5 days.
 - (v) Fish were approximately 35 mm. in length and weighted 0.5 to 1.0 gm.
 - (vi) Bioassay water was reconstituted to provide a soft water with pH of 7.2
 - (vii) Ten fish per control and ten fish per concentration were used.
 - (viii) A p, p'¹DDT control was used; no solvent controls were used since water was the solvent.
 - (ix) Loading factor was less than 1 gm/liter.
 - (x) Temperature of water was 22°C.
 - (xi) Prior to introduction of the chemical and fish, bioassay water was saturated with dissolved oxygen.
 - (xii) During the 96-hour exposure, fish were not fed, water was not aerated, and mortality data were recorded at 24-hour intervals.
 - (xiii) Statistical methodology was that of Weil (1952).

(2) Additional Test Results

(a) Researcher's Comments/Conclusions

- (i) 96-hour LC_{50} for p,p' DDT (technical) controls was 4.3 (3.2-5.8) ppb.
- (ii) 96-hour LC_{50} for bluegill versus Bolstar 6 EC was 1.0 (0.7-1.5) ppm. [Dose levels used were 0.2, 0.5, 1.0, 2.2, and 4.7 ppm.]
- (iii) Mortality observed at 96-hours for Bolstar-treated fish was as follows: 0.2 ppm: 0/10 (no dead/no tested); 0.5 ppm: 0/10; 1.0 ppm: 7/10; 2.2 ppm: 8/10; 4.7 ppm: 10/10.
- (iv) The researcher indicates in a "synopsis" section preceding this report (but does not state it in this report) that fish studies were not conducted on the technical grade of Bolstar due to its very low solubility in water.

(b) Reviewer's Comments/Conclusions

- (i) The protocol followed by the researcher appears acceptable.
- (ii) The reviewer examined the 96-hour mortality data of bluegill exposed to p, p' DDT using the method of Weil (1952) and found the following:

- LC_{50} = 4.36 ppb
- 95% confidence limits = 3.22-5.89 ppb
- Geometric Dosing Factor: 2.17

These data correlate well with those of the researcher.

(iii) Bolstar Mortality Data/Finney Probit:

The reviewer examined the 48-, 72-, and 96-hour mortality data of bluegill exposed to Bolstar 6EC using the method

of Finney Probit and found the following:

(1) 48-hour data:

- LC_{10} : 0.936(0.317-2.766) * ppm
- LC_{50} : 11.976(1.469-97.631)* ppm
- LC_{90} : 153.203(1.817-12917.671)* ppm
- Slope: 1.158
- CHI^2 : 3.043

(2) 72-hour data:

- LC_{10} : 0.426 (0.224-0.809)* ppm
- LC_{50} : 1.350 (0.909-2.005)* ppm
- LC_{90} : 4.276 (2.149-8.509)* ppm
- Slope: 2.560
- CHI^2 : 6.247

(3) 96-hour data:

- LC_{10} : 0.509 (0.318-0.814)* ppm
- LC_{50} : 1.054 (0.779-1.427)* ppm
- LC_{90} : 2.185 (1.361-3.510)* ppm
- Slope : 4.051
- CHI^2 : 4.549

These data indicate a sharp increase in mortality from 48- to 96-hours ** with the 48-hour LC_{50} of 11.976 ppm declining to 1.054 ppm at 96-hours. This increase in toxicity may be due to two factors: the compound takes several days to get into solution or degradation of the parent compound occurs producing a more toxic degradate. Note that the 96-hour LC_{50} value correlates well with that of the researcher.

* 95 % confidence limits

** Note that zero mortality for all levels occurred at 24-hours.

(iv) Bolstar Mortality Data/Weil Method (1952)

The reviewer examined the 96-hour mortality data using the method of Weil (1952) and developed similar values to those of the researcher: 96-hour LC_{50} : 1.10 (0.80-1.51)* ppm. It is pointed out, however, that the geometric dosing factor, as discussed by Weil (1952), is to be a constant factor between concentration levels. In this study the dosing factor is not constant but varies between concentration levels: 2.5 between 0.2 and 0.5 ppm; 2 between 0.5 and 1.0 ppm; 2.2 between 1.0 and 2.2 ppm; 2.14 between 2.2 and 4.7 ppm. Therefore, the use of Weil methodology by the researcher to analyze the data is questionable. The reviewer does point out, though, that in this case the Weil method does not appear to be affected by the variation in dosing factor, for the results by the Weil method correlate well with those of Finney Probit.

B. Validation Category/Category Repairability

Although this study appears to be "scientifically sound", it is classified Supplemental because formulated product rather than technical grade product was tested. The reviewer notes the statement by the researcher that technical Bolstar was not used due to its low solubility in water. However, this in itself is not a valid reason for not performing the fish acute LC_{50} study with the technical chemical because other pesticides which have low solubility in water have been tested in this manner. Further, the available data indicate that the technical material is considerably more toxic than the 6EC if the technical material gets in solution. **

Relative to Category Repairability, the reviewer recommends that the warmwater fish acute LC_{50} using technical Bolstar be performed using the "Basic Flow-Through Acute Toxicity Test Method", as per Stephan, C.E., 1975. In this manner, the concentration of toxicant in the test chambers will be measured and, therefore, Bolstar's solubility question will be partly answered. Based upon this, the reviewer does not believe that this study (with Bolstar 6EC) can be reclassified as Core data.

* 95% confidence limits.

** EPA, Animal Biology Laboratory Data, October, 1977.

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C. Additional Information Needed

The following information is required to complete assessment of this study as Supplemental:

- (1) The photoperiod used during the study.
- (2) The name of the hatchery from which bluegill were obtained.
- (3) The loading factor for the bluegill study.
- (4) The dissolved oxygen concentration during the study.