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DATA ACCESSION NO(S). 404601-02

PRODUCT MANAGER NO. D. Edwards(12)

PRODUCT NAME(S) Dicofol (Kelthane)

COMPANY NAME Rohm and Haas Company

SUBMISSION PURPOSE Submission of data

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
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40042056



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

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Review of response to Data Call-in Notice of
September 29, 1987

FROM: Richard R. Stevens, Biologist *Richard R. Stevens*
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Hazard Evaluation Division (TS-769C)

THRU: Ray Matheny, Head *Ray Matheny 7/5/88*
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THRU: James Akerman, Chief *James Akerman 7/5/88*
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TO: Dennis Edwards, PM Team 12
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The Ecological Effects Branch (EEB) has reviewed additional information from Rohm and Haas in the form of supplements to two original studies in response to Agency comments (EEB Data Evaluations). These studies are:

1. Freshwater fish LC50 study.
2. Sheepshead minnow acute toxicity study.

An EEB review (L. Turner, 5/29/87) concluded that the freshwater fish study (rainbow trout, W. A. McAllister, et al., 1985, ABC Study No. 32806; Rohm and Haas Report No. 85RC-0016, Acc. No. 400420-56) is invalid and not repairable because the test material was not fully soluble and the test concentrations were not measured. The sheepshead minnow acute toxicity study (W. A. McAllister, et al., 1985, ABC Study No. TD 87M-1247; Rohm and Haas Report No. 85RC-0047, Acc. No. 400420-58) is invalid and not repairable because of the very poor fit of the dose-response line, which may have been due to using very small fish and fasting them for 48 hours before the test began.

The response from Rohm and Haas and ABC Laboratories on the rainbow trout study indicated the following:

"Although the surface film in all but the lowest test concentration probably indicated that the Kelthane was not in solution at the higher test levels, the test water contained the maximum practical concentration for the specific test conditions. That is, an effort was made to encompass the apparent water solubility of Kelthane (1 ppm) by evaluating the mortality pattern above and below solubility. As can be seen from the toxicity data and the resultant statistical calculations, there was a good fit to the dose-response line. This indicates that under the conditions tested the reported LC50's are valid."

EEB Response: Testing was performed around the solubility level (0.83 ppm in water). The presence of a surface film may mean that there was a solubility problem at the higher test levels and not all the material went into solution. As a result the actual LC50 value may be lower than the reported nominal concentrations. Measuring the concentrations would have answered our concerns in this case and is always a good idea when solubility is an issue. Without measured concentrations this study cannot be upgraded.

The response from Rohm and Haas and ABC Laboratories on the sheepshead minnow study can be summarized as follows:

1. Fish size was not felt to have impacted the erratic mortality response noted. Control and solvent control populations used for this test did not indicate starvation stress. Rather, the effect pattern was attributed to testing at the water solubility of Kelthane.
2. Water quality was suitable for testing.
3. The goodness of fit of the dose-response line was poor due to the nominal test concentrations bracketing the kelthane water solubility. Such mortality patterns are often noted when one tests near the solubility of a compound due to varying amounts of material in solution which elicit an erratic dose response. The test range used was necessary to obtain a statistical LC50. It should be noted that ABC used the EPA-supplied computer program, which gave an LC50 for this data set using the

probit, binomial and moving average tests. The EPA computer program was developed to statistically analyze data sets with a variety of dose responses, including erratic responses a mid-dose range, as was demonstrated by this study. Not all mortality patterns follow a distinct probit line..."

EEB Response: EEB accepts all the arguments from ABC presented above, especially the one regarding the fact that poor goodness of fit may be attributed to test concentrations bracketing solubility resulting in varying amounts of material in solution which can elicit an erratic dose response. As with the fish study above, measuring concentrations is always a good idea when solubility is an issue. Without measured concentrations this study cannot be upgraded.

In conclusion, EEB is not able to upgrade the two studies based on the data submitted. If the test material cannot be fully solubilized, then the test concentrations must be measured. Additionally, more statistically reliable results are likely to result from narrowing the concentration intervals in order to obtain more partial mortality concentrations.