4-11-80 (12)

EE BRANCH REVIEW

DATE: IN 1/10/80 OUT 4/11/80

FILE OR REG. NO. 707-75

PETITION OR (EXP. PERMIT NO.) 8F2106

DATE DIV. RECEIVED

DATE OF SUBMISSION

DATE SUBMISSION ACCEPTED

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

DATA ACCESSION NO(S). 099034 (10/16/79) & 099192 (1/9/80)

PRODUCT MGR. NO. 25-Mountfort

PRODUCT NAME(S) Stampede 3E Herbicide

COMPANY NAME Rohm & Haas

SUBMISSION PURPOSE Data Review

CHEMICAL & FORMULATION Propanil: 3',4'-Dichloropropanilide

Propanil

101 Physical and Chemical Properties
(see previous review by J. S. Leitzke, 12/3/79)

102 Behavior in the Environment
(see previous review by J. S. Leitzke, 12/3/79

103 Toxicological Properties
(see previous review by J. S. Leitzke, 12/3/79, for Minimum Requirements, additional Fish Acute LC_{50}'s and Additional Laboratory Tests)

103.2.3 Fish Acute LC_{50}'s
(Note: The following is not a validation)

EG&G, Bionomics. 1979. Acute toxicity of STAM technical (TD-79-2040, TD-79-241, TD-79-242) to newly hatched fathead minnow fry (Pimephales promelas), September, 1979 (Accession No. 099034).

EG&G, Bionomics. 1979. Acute toxicity of STAM technical (TD-79-241, TD-79-288, TD-79-289, TD-79-290) to newly hatched fathead minnow fry (Pimephales promelas), December, 1979 (Accession No. 099192)

Results recalculated from given data on Stephan's program

TD-No.	Lot No.	(ppm AB) (% 2,5-DCA)	Recalculated 96-hr LC_{50} (ppm AI)	Goodness of Fit	as AB	as 2,5-DCA
79-242	Purified	(3.5 ppm)	7.6 (3.2-659)	0	.026 ppb	-------
	(upper)		[8.73 (7.65-10)	.307	.031 ppb]	
	(lower)		[11.44 (4.11-∞)	.108	.040 ppb]	
79-240	9287	(11 ppm)	3.78 (1.77-15.46)	.002	.042 ppb	26.46 ppb
	(upper)	(0.7%)	[5.13 (4.88-5.86)	.667	.056 ppb	35.91 ppb]
	(lower)		[3.45 (2.05-58)	.47	.038 ppb	25.15 ppb]
79-241	8771-1st	(2360 ppm)	.247 (0-∞)	0	.583 ppb	5.681 ppb
	(upper)	(2.3%)	[5.39 (2.48-132.5)	.963	12.7 ppb	123.97 ppb]
			Neg. Slope			
	(lower)		[.12 (0-∞)	0	.283 ppb	2.76 ppb]
79-241	8771-2nd	(2360 ppm)	.0637 (0-∞)	.006	.150 ppb	1.465 ppb
	(upper)	(2.3%)	[.289 (0-.42)	-	.682 ppb	6.647 ppb]
	(lower)		[.063 (.055-.072)	-	.149 ppb	1.449 ppb]
79-288	2580	(8 ppm) (0.2%)	7.28 (5.46-11.55)	.63	.058 ppb	14.56 ppb
79-290	2649	(54 ppm) (0.53%)	5.05 (3.82-6.34)	.63	.272 ppb	26.765 ppb
79-289	2709	(34 ppm) (0.36%)	6.43 (5.57-7.42)	.65	.218 ppb	23.148 ppb

#8771 - "Old" technical
#9287, 2580, 2649 & 2709 - "New" technical

Static bioassays were conducted on newly hatched fathead minnow fry (Pimephales promelas) (< 24-hr old) at 24-25°C in 2.0 l of water in 3.8 l jars. Major differences between the September and December tests were daily providing each replicate 200 ul brine shrimp in Sept. and 60 ul in Dec. and use of acetone as solvent in Sept. and triethylene glycol in Dec. All test concentrations were expressed as nominal ppm AI and were not actual, measured levels.

All tests in Sept. and the Dec. test on lot no. 8771 (the "old" technical) have very poor Goodness of Fit values (< 0.05). Such poor dose-response relationships can be caused by non-random distribution or significant non-homogeneity of test animals, poor dispensing of toxicant, adsorption of toxicant onto organic matter or glass jars and a variety of other reasons. (All bioassays used only one stock solution series; so a poorly prepared second stock solution could not have been the cause.) For whatever the reason, these bioassays had highly unusual dose-response curves in that as test concentrations decreased, mortality first decreased, jumped up to a higher level and then decreased again; the Sept. test on lot no. 8771 started with increasing mortality and then decreased. (See Figs. 1 & 2). Additional LC_{50}'s were calculated using the upper and lower parts of these curves, and the results are included in the table above. Goodness of Fit values for most of these recalculated LC_{50}'s are acceptable.

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104.4 Adequacy of Toxicity Data

One of the purposes of these tests was to try to prove that the "old" technical used in the Univ. Wisc.-Superior (UW-S) embryo-larvae study (#8771) is much more toxic than the "new" technical currently being produced from a newer, "cleaner" source of 3,4-DCA (#9287, 2580, 2649 and 2709). This does not appear to have been entirely successfully done. While the LC_{50}'s for the "new" technicals are generally similar to each other (range is 3.78 - 7.28 ppm), the LC_{50} calculated from the upper part of the "old" technical's first test (5.39 ppm) is also similar to these. (Of all the LC_{50}'s calculated from either test on the "old" technical, this one had the best Goodness of Fit, 0.963). This LC_{50} (5.39 ppm) is markedly dissimilar to the other values calculated from the first test (total range 0.247 ppm; lower part 0.12 ppm) as is the second test's upper part LC_{50} (0.289 ppm) to its other values (0.0637 and 0.063 ppm). The very poor dose-response relationships for these two bioassays and their general scientific unsoundness are well illustrated in Fig. 1. This is not the case with the bioassays on the Purified and lot No. 9287;

Fig. 1. Dose-Response Curve for Sept. + Dec. Tests on "Old" Technical (#8771).

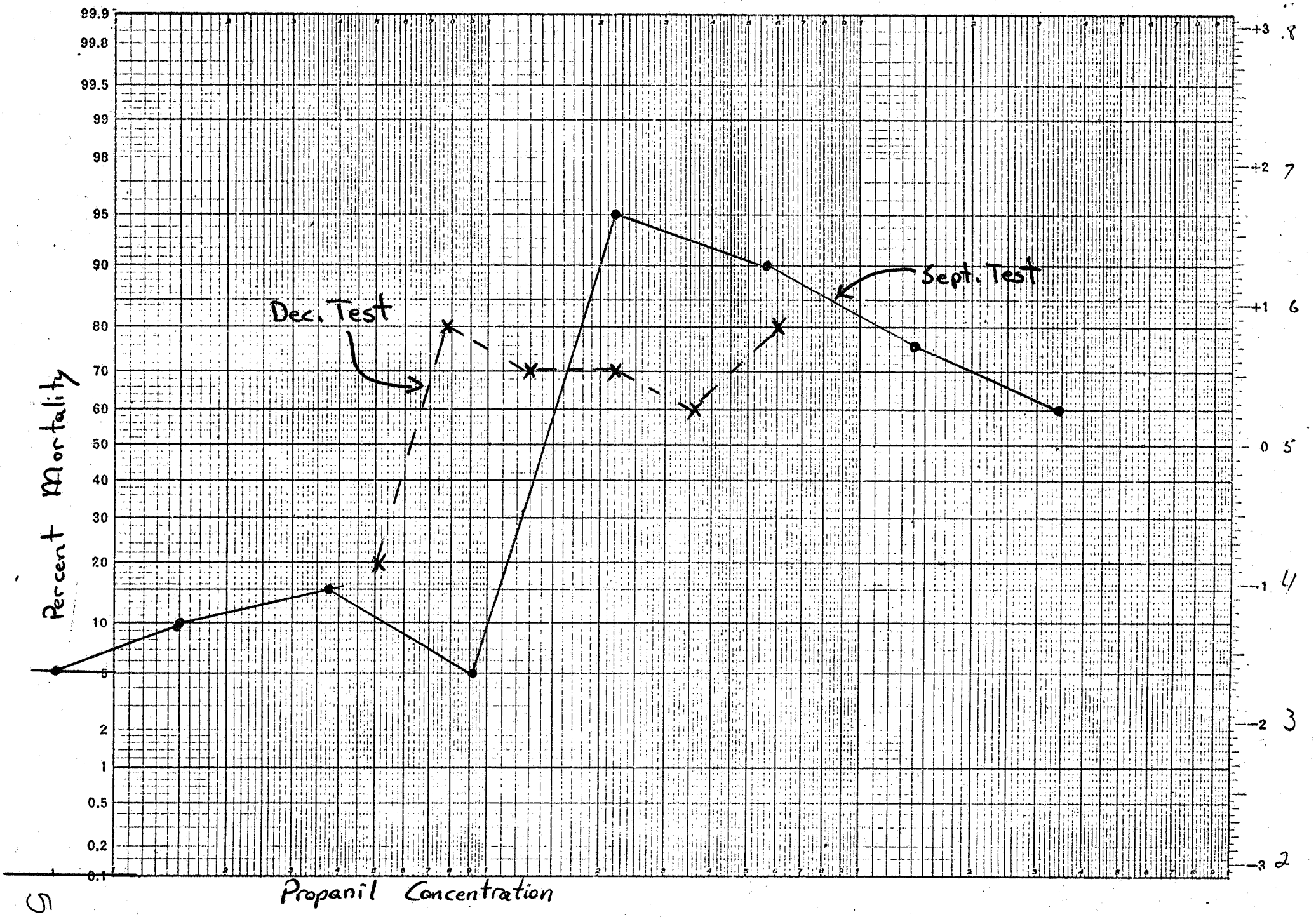
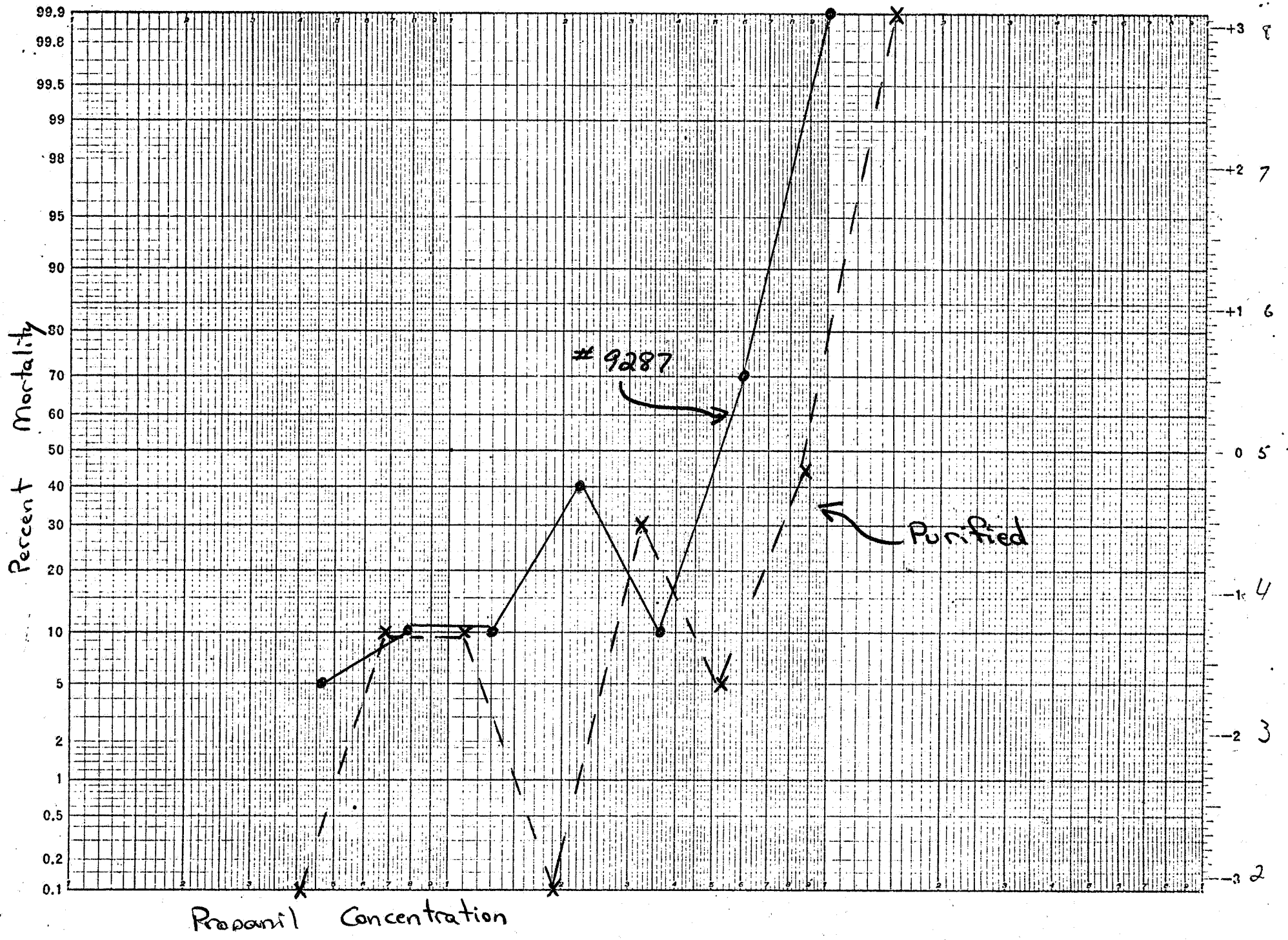


Fig. 2. Dose-Response Curve for the Sept. Tests on #9287 and Purified.



the LC_{50}'s for the total range and upper and lower parts of these are relatively similar to each other. The dose-response curves for these two bioassays (Fig. 2.) illustrate well there is one main curve in each test. In other words, despite poor Goodness of Fit values, these latter two bioassays are still relatively sound and their poor Fits may have been due to one or two non-random distributions of test organisms. The "old" technical biossays, however, are not scientifically sound enough to use them to adequately compare the "new" technicals to the "old".

Another purpose of these tests was to provide information to help identify the contaminant that is allegedly in the "old" technical but not in the "new." The chemical analyses done on each of the technicals indicate only a few major differences in make-up between "old" and "new" technicals. First is the different amounts of [redacted] as indicated in the table, with the "old" technical having considerably more than the new. Looking at this difference, one could think that any apparent difference in toxicity would be caused by the difference in total [redacted] is the primary toxic ingredient. If this were the case then the LC_{50}'s recalculated in terms [redacted] all the biossays should be roughly equivalent. This is not the case. As shown in the table, there are considerable differences between the "old" and "new" technicals and amongst the "new" technicals as well. Another major difference in the make-up is the amount of [redacted] as indicated on the table. Recalculation of the LC_{50}'s in terms [redacted] again shows little indication of the alleged contaminant. (Actually, the greater amount [redacted] the "old" technical is probably there because it did not react with the [redacted] to form as much [redacted] as is in the "new" technicals; these differences are presented on the chemical analysis sheets.) Neither total [redacted] be soley responsible for apparent toxicity differences between the technicals. Thus, these tests do not aid in adequately identifying the alleged contaminant.

A final purpose of these bioassays was to compare these results with those of the UW-S embryo larvae study. In order to do this adequately, tests methods should be as similar as possible. The submitted bioassays were static, used newly hatched fry and were in terms of nominal amounts of propanil. The UW-S study was flow-through, used exposed eggs and was in terms of measured propanil. Tests done in a static system can often give considerably different results than tests done as flow-through. Fry from continuously exposed eggs were much more sensitive than 24-48 hr old fry at the same levels (see Sect. 103.4.2 in previous review by J. S. Leitzke, 12/3/79). Delivery of toxicant into the test are not always as calculated, and use of measured levels can also

give different results from nominal levels. The effect criteria from the bioassays were also different. In the submitted bioassays, it was death at 96-hr. In the UW-S study, the most sensitive parameters were Mean Dry Weight and Mean Total Length at 54 days, both more sensitive than Fry Survival at 54 days, Mean Percent Hatch and Abnormal and Dead Hatchings. These differences preclude any attempt to compare the results of the two studies.

104.5 Additional Data Required

The previous review (J. S. Leitzke, 12/3/79) listed 4 data requirements in the 2nd option for chronic aquatic hazard determination which is being followed by the registrant. Following is a summary of the information submitted by the registrant to EEB to this date in fulfillment of the Data Requirements:

1) 96-hr LC_{50} on Rainbow Trout - No progress mentioned
2) Quality Control Bioassays - Submitted but do not adequately satisfy the purposes for these tests (see Sect. 104.4)
3) Chemical Analyses of Different Batches - Submitted and Adequate
4) Identification of Alleged Contaminant - No sufficient evidence from data provided.

Also noted in the previous review was the requirement of 2 Avian Dietary LC_{50}'s for terrestrial hazard determination. No progress was mentioned in fulfilling this Data Requirement.

107 Conclusions

This review concerns data submitted to fulfill the Data Requirements of the previous review (Sect. 107.5, J. S. Leitzke, 12/3/79). These requirements arose because of concern for potential terrestrial hazard and potential chronic aquatic hazard, the latter on the basis of an extrapolated 96-hr LC_{50} and the Univ. Wisc-Superior (UW-S) fish embryo-larvae study. The submitted data is referenced to EG&G Bionomics Sept. 1979 and Dec. 1979 under Accession. Nos. 099034 and 099192.

107.4 Data Adequacy Conclusions

The main purposes of the submitted fathead minnow (Pimephales promelas) fry static acute tests were to provide 1) a Quality Control on the recent technical batches and proof of different toxicity of "old" technical (used in the UW-S study) and "new" technicals, 2) information to identify the alleged contaminant in the "old" technical but not in the "new" and 3) a basis for comparing the results of these results with those of the UW-S study. In relation to these 3 main purposes:

1) While LC_{50}'s for the "new" technicals are generally similar to each other, the LC_{50} calculated from the upper part of the "old" technical's first test is also similar to these. (Additional LC_{50}'s were calculated from the upper and lower parts of the curves from both the first and second tests. In both cases the LC_{50}'s are dissimilar to each other). Poor Goodness of Fit values for the two bioassays on the "old" technical and their very poor dose-response curves indicate that these bioassays are not scientifically sound. Thus, the "old" technical's bioassays are not sound enough to compare results between "old" and "new" technicals.

2) Chemical analyses of the different technicals [redacted] compounds at higher levels in the "old" technical than in "new" [redacted] However, LC_{50}'s recalculated in terms of either of these alleged toxic ingredients are not equivalent between the various technicals. Thus, these tests do not aid in adequately identifying the alleged contaminant.

3) There are several major differences in the methods between the submitted bioassays and the UW-S study. The submitted tests were static, used newly hatched fry, were in terms of nominal concentrations and used death at 96-hr for an effect criterion. The UW-S test was flow-through, used exposed eggs, was in terms of measured levels and used Mean Dry Weight and Total Length at 54-days as most sensitive test parameter. These differences preclude any attempt to compare the results of the two studies.

107.5 Data Requirements

The previous review (J. S. Leitzke, 12/3/79) listed 4 data requirements in the 2nd option for chronic aquatic hazard determination which is being followed by the registrant. Following is a summary of the information submitted by the registrant to EEB to this date in fulfillment of the Data Requirement:

1) 96-hr LC_{50} on Rainbow Trout - No progress mentioned

2) Quality Control Bioassays - Submitted, but do not adequately satisfy the purposes for these tests (see Sect. 107.4); improvements could be made in soundness of bioassays themselves and their comparability to the UW-S study.

3) Chemical Analyses of Different Batches - Submitted and Adequate.

4) Identification of Alleged Contaminant - No sufficient evidence from data provided; might prove useful to test suspected contamination in a purified state.

Also noted in the previous review was the requirement of 2 Avian Dietary LC_{50}'s for terrestrial hazard determination. No progress was mentioned in fulfilling this Data Requirement.

107.6 Special Notes

The major thrust of the chronic aquatic hazard assessment was the calculated Maximum Acceptable Toxicant Concentrations (MATC) of the most sensitive coldwater species tested, the rainbow trout. While this was calculated from acute and chronic tests on the fathead minnow and applied to rainbow trout acute data, the registrant may wish to measure the MATC on trout directly. Species like the fathead minnow have been commonly used for chronic life-cycle tests because of availability and shorter life-cycles, not for their sensitivity. Because embryo-larvae tests are usually as sensitive as life-cycle tests, an embryo-larvae test on rainbow trout would provide data for a much clearer hazard assessment on propanil than is now possible.

107.7 Recommendations

The registrant has chosen to follow the 2nd option for chronic aquatic hazard determination. However, as noted in Sections 107.4 & 5 this has not been successful, and as noted in the previous review (J. S. Letizke, 12/3/79) the 1st option must now be followed. In general, under this option the registrant must show that actual levels of contamination are much lower and less hazardous than theoretically expected levels. In order to do this propanil must be used for one season on a large scale. With this in mind, Ecological Effects Branch does not object to a conditional registration of propanil on wheat subject to written agreement to the condition the registrant fulfill the following data requirements:

1. Two Avian Dietary 5(+3)-day LC_{50}'s on the technical;

2. Rainbow trout 96-hr LC_{50} on the technical;

3. Field residue monitoring study; the general protocol for this (as given in Sect. 107.5 of the previous review) calls for triplicate water and hydrosoil samples (for propanil, 3,4-DCA and TCAB) pre- and post-application for enough time to establish a decline curve; at least one of the experimental ponds must be immediately adjacent to and downwind of a large wheat field being treated; since propanil can be applied either aerially or on the ground, two sets of experimental ponds for these two uses must be sampled;

4. If the results of the above tests show that biologically significant levels exist, more tests may be required.

Again, to provide data for a much clearer hazard assessment, the registrant may wish to measure the MATC on rainbow trout directly in an embryo-larvae study.

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