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

DATA ACCESSION NO(S). 406417-01

PRODUCT MANAGER NO. G. LaRocca (15)

PRODUCT NAME(S) Cypermethrin products

COMPANY NAME ICI Americas, Inc.

SUBMISSION PURPOSE Submission of fish full life cycle study in response to DCI of 10/25/85

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

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

FEB 16 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: EEB's Review of the Cypermethrin Fish Full Life Cycle Study Conducted by ICI Americas, Inc. in Response to the Data Call-In Notice of October 25, 1985. (EPA Accession No. 406417-01).

TO: George LaRocca, PM-15
Insecticides-Rodenticides Branch
Registration Division, TS-767c

FROM: James Akerman, Chief for H.T. Craven 2/15/89
Ecological Effects Branch
Environmental Fate and Effects Division, TS-769c

EEB has completed its review of the fish full life cycle study conducted by ICI Americas, Inc. with the synthetic pyrethroid, cypermethrin. We concluded that the study is scientifically sound, but it does not meet Guideline requirements as not all the raw data were submitted for EEB to complete the analysis.

At the time the protocol was reviewed (May 16, 1986) EPA's "SEP for the Fish Full Life Cycle Toxicity Test" was not available. Therefore several parts of the procedure do not comply with those recommended in the SEP, although the basic design of the study is acceptable. However, EEB dose not endorse one specific protocol, so flexibility in the design of the study is allowed provided the scientific validity of the study is not compromised.

According to the SEP, eggs no older than 24 hours should be used to start the study. However, the protocol was approved allowing eggs up to 48 hours old to used. In actuality, all but one batch of eggs were 24 hours old. ASTM guidelines for early life stage tests with fathead minnows allow eggs up to 48 hours old to used. As all batches of eggs were pooled prior to random distribution to the embryo cups, we do not believe that using some eggs in this age class affected the outcome of the study.

The SEP also states that the study should begin with 50 embryos to each of 4 replicate larval chamber. This study only

had 40 embryos per each of 2 larval chambers. Using more eggs (200 vs. 80) might have reduced some of the variability seen in some responses--particularly those of the solvent controls. The SEP prefers that mature fish be paired--one male, one female--per spawning chamber to reduce antagonistic behavior between males. In this study the mature fish were kept together as a breeding group but the number of males were culled to maintain a maximum number of four mature males per tank. As we do not know if this latter arrangement contributed to any of the negative effects seen in the spawning fish--i.e., weight loss--we attributed all effects to exposure to cypermethrin.

The data indicated that replicate B of the solvent control (SC) had a high mortality when 16 of the F0 35 larvae in the replicate were dead by day 11 posthatch. This value did not change from day 11 through day 60. An examination of all water quality data for the dilution water and exposure water did not indicate there was anything unusual about the water quality in that replicate compared to the three other control replicates. Likewise, the water residue data did not indicate any cross-contamination of that chamber with cypermethrin. The concentration of the solvent (TEG) was 12.5 ug/L, which is an acceptable amount. It was decided to average the data from that replicate with the other solvent control replicates, but to keep these values separate from those of the dilution water control (DWC).

In order to verify the reported results of this study, one-way ANOVAs and Duncan's Multiple Range Test with the SAS program were used to analyze: number of F_0 larvae hatched; survival of F_0 fish at days 5, 30, and 60; and lengths of F_0 live fish at 30 and 60 days. Toxstat (ANOVA, Dunnett's test, William's test, and Tukey's test) was used to analyze 30-day and 60-day F_0 survival; weights and lengths of sacrificed F_0 fish at 60 days and 300 days; and egg production. In all analyses the replicates for each treatment and type of control were combined, but the results for the DWC and SC were kept separate. All concentrations reported are the mean measured concentrations.

Our statistical analyses indicated that the results reported for hatchability of F0 larvae, 30-day and 60-day survival of F0 larvae, lengths of the F0 larvae at 30 days and 60 days (the lengths for the fish that were transferred to spawning tanks were analyzed separately from those that were sacrificed), weights of the F0 larvae at 60 days and egg production were accurate.

In our analysis of the lengths and weights of F0 fish at 300 days we analyzed the males and females separately. This procedure allowed us to detect significant effects on growth of adult fish which the study authors did not detect. The LOEC for decreased weight and length of male fish was 0.051 ug/L. Except for the significant decrease in length at this concentration, the lengths of the other males increased slightly as the concentrations increased. This seems to indicate that a

stimulatory, or hormetic, response occurred. The response curve for male weights is similar to that of the male lengths, although the slight increases in weight with concentration are not statistically significant. The LOEC for decreased weight and length of female fish was 0.323 ug/L. A hormetic effect with increasing chemical concentration was not observed in the female fish.

A comparison of the egg production data with the growth data indicated that the lowest egg production (one egg by 14 females) occurred in the group with the smallest females whereas the greatest egg production (2300 eggs per female) occurred in the group with normal-sized females. These results indicate there may be a correlation between egg production and body weight of females. Reproduction may also be affected by sublethal stresses which were not measured in this study.

We counted additional fish as deformed in the groups at 0.077 and 0.154 ug/L, based on the data provided in Table 33. Our count of deformed fish is: 3 (DWC), 1 (SC), 2 (0.051 ug/L), 4 (0.077 ug/L), 5 (0.154 ug/L) and 5 (0.323 ug/L). Deformed fish, which were mainly males, were included among those that were allowed to spawn throughout the study. Mortality of adults is not dose related. Total mortalities of adult fish from control to highest concentration are: 1, 1, 1, 1, 2 and 1. The presence of deformed fish did not appear to have a negative effect on reproduction.

According to our analysis the following values are the acceptable NOEC and LOEC values for the several parameters measured during this study.

Parameter	NOEC	LOEC
Hatching of F_0 Larvae	> 0.653 ug/L	--
30-Day Survival of F_0 Larvae	0.077 ug/L	0.154 ug/L
60-Day Survival of F_0 Larvae	0.077 ug/L	0.154 ug/L
Length of 30-Day F_0 Larvae	> 0.323 ug/L	--
Length, Weight of 60-Day F_0 Larvae	> 0.323 ug/L	--
Length, Weight of 300-Day Male F_0 Fish	< 0.051 ug/L	0.051 ug/L
Length, Weight of 300-Day Female F_0 Fish	0.154 ug/L	0.323 ug/L
Egg Production	0.154 ug/L	0.323 ug/L

Analyses of the percent of F_1 embryos that hatched and survived could not be done as the raw data were not included. We need the data presented in a manner similar to that for the F_0 embryos: number of eggs exposed per cup for each concentration, cumulative number of larvae hatched and dead for each embryo cup; and number of days to hatch. Likewise, the raw data for the 28-day survival of the F_1 fish must be separated into mortality for each separate batch and not the mean mortality per replicate

concentration. Analyses of the effects of cypermethrin on length and weight will not be done until the raw data on hatchability and survivability are submitted.

At this time, we do not believe that the lower survivability seen in the solvent controls (56.2%) compared to the dilution water controls (78.7%) compromises the acceptability of the study since the survivability of the treatment groups is similar to that of DWC, and the SC fish have a similar response regarding growth as the DWC fish. However, acceptability of the F_1 phase of the study will be determined after the raw data are submitted and analyzed.

If there are any questions regarding our evaluation of this study please contact Ann Stavola at 557-1354.