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PRODUCT MANAGER NO. G. LaRocca (15)

PRODUCT NAME(S) Permethrin and Cypermethrin

COMPANY NAME ICI Americas Inc.

SUBMISSION PURPOSE Registrant Response to DCI Notice and Previous EEB Review of Aquatic Laboratory Toxicity Protocols

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

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MEMORANDUM

SUBJECT: Response by ICI Americas, Inc. to Ecological Effects Branch's Comments of July 3, 1986 Regarding Protocols for Fish Life Cycle Study and Mysid Acute and Chronic Toxicity Studies with Permethrin and Cypermethrin.

FROM: Ann Stavola
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THRU: Douglas J. Urban
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THRU: Michael W. Slimak
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TO: George LaRocca, PM-15
Insecticides-Rodenticides Branch
Registration Division (TS-767-C)

ICI Americas, Inc. has responded to the comments made by EEB on July 3, 1986 regarding the protocols for a fish life cycle study and mysid shrimp acute and chronic toxicity tests with permethrin and cypermethrin.

In this submission, dated January 20, 1987, the registrant contends that they did not receive EEB's analysis of the protocols until December 16, 1986, over 5 months after this branch's review. In order to meet the DCI deadlines for completion of the studies they stated they began these studies prior to receiving the comments. Therefore, three of the

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changes and additions to the protocols (two for the fish life cycle test and one for the acute testing of mysid shrimp) were not incorporated into the protocols. Furthermore, the registrant does not believe the changes EEB wants are necessary and provides rationales to support their viewpoint. EEB has determined that their arguments are not valid, and that without the protocol changes recommended by EEB, the fish life-cycle study and mysid acute toxicity study will probably not meet our guidelines requirements. When the data are submitted to EPA for review, we will evaluate it and make a final determination concerning its acceptability.

Mysid Acute Toxicity Study

The test organisms must be less than or equal to 24-hours-old at the start of the exposure.

The registrant argues that our SEP, Acute Toxicity Test for Estuarine and Marine Organisms, EPA-540/9-85-010, states the shrimp must be maintained in the test water for 48 hours prior to testing, and that given a 24-hr. period to collect the shrimp, the age at the start of the study would be up to 3 days.

The SEP is not a protocol, only a guidance document. It recommends several protocols, one of which is an EPA publication Bioassay Procedures for the Ocean Disposal Permit Program, EPA-600/9-78-010. On page 62, in the chapter "Methods for Acute Static Toxicity Tests with Mysid Shrimp," it states "Newly hatched juvenile mysids ($\leq$ 24-hr.-old) are used because of their uniform size and proven success in toxicity tests... To obtain juveniles, isolate several brooding females in a large beaker the day before the test, and harvest the young on the day of the test". The 48-hour acclimation period in the SEP refers to a holding period for the brooding females. This is also the procedure used for the acute toxicity tests with Daphnia in which the organisms must also be $\leq$ 24-hr.-old at the start of the test. To obtain immature daphnids at this age brooding females are reared in the dilution water at the test temperature. These are standard procedures which are accepted and followed by aquatic toxicologists. ICI's argument is not accepted.

Fish Full Life Cycle Study

Residue analyses must be conducted on fish not selected for spawning, unused eggs (embryos) and F_1 generation fry [User's Guide for Conducting Life-Cycle Chronic Toxicity Tests with Fathead Minnows (Pimephales promelas)], EPA-600/8-81-011.

These analyses may require the use of radiolabeled test material if analytical methods cannot measure the chemical below the effect levels.

The registrant argues that the residue analyses are not necessary since pyrethroids do not bioaccumulate at rates or for lengths of time that are hazardous to fish populations. EEB needs the residue data from a laboratory study to serve as a comparison with the residue data collected in field studies and monitoring programs and to provide a response curve of residue accumulation vs. concentration for different life stages. Therefore, ICI's argument is not accepted and the residue analyses are required. However, we no longer believe that a 14-day depuration study is necessary.

In addition, while we can recommend that a 96-hr. acute toxicity test on 2-week old fish hatched from the original eggs be performed, it is not a requirement. This aspect of the life cycle test is optional.

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