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

APR 16 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTA

MEMORANDUM

SUBJECT: March 12, 1987 Letter from ICI Americas, Inc.

FROM: Michael Slimak, Chief
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

TO: George LaRocca
PM Team 15
Registration Division (TS-767C)

This is to confirm that the subject letter accurately reflects a phone call I had with Mr. James Wagner on February 25, 1987. A copy of the ICI letter will be retained in the appropriate EEB chemical file.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 12, 1987

Mr. George T. LaRocca
Product Management Team (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)
U.S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460

Dear Mr. LaRocca:

RE: Data Call-In Notice for
Ecological Effects Data for Permethrin and Cypermethrin
ICI Response Dated January 20, 1987
KARATE® Insecticide
EPA File Symbol 10182-OA
ICI Letter Dated February 23, 1987
Aquatic Laboratory Study Protocols

On February 19, 1987, ICI representatives met with the Agency to discuss laboratory protocols for the following studies:

- Fish life-cycle study (cypermethrin and KARATE)
- Acute toxicity test for mysid shrimp (permethrin and KARATE)

As a follow-up to our meeting at EPA, Dr. Michael Slimak in a phone conversation of February 25, 1987, with Mr. James Wagner, provided the following answers to our concerns:

1. Fish Life-Cycle Study

Dr. Slimak confirmed that we are correct that neither Guidelines nor SEP ask for (1) fish/egg residue levels, (2) depuration rates, (3) use of radiolabeled compound. However, the Agency now feels that it was an oversight not to have included these as requirements and, therefore, at some unspecified future time, the Guidelines/SEP may be revised to correct the oversight. For now, although the Agency would like a study to provide these data, a study will not be rejected for lack of it.

Until EPA change the Guideline/SEP, we are not obligated to use radiolabeled compound. If radiolabeled material is not used, we are aware that we must be able to provide data on the concentrations of active ingredient in the tanks.

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that the 48-hour observation period applies to adult brood females and the 24-hour requirement applies to the offspring. We believe our ICI Brixham Laboratory is currently following this procedure; however, if not, Dr. Slimak doubted the Agency would reject a study if the shrimp were older than 24 hours.

This letter is submitted to obtain your concurrence with our understanding of items discussed. Please advise if you have any comments.

Respectfully submitted,

Barbara Kaminski

Barbara J. Kaminski
Senior Pesticide Regulatory Specialist

BJK/pb
g6/030987pb30

cc: Dr. Michael W. Slimak (EPA, HED/EEB)

answer to this letter in memo from Slinak dated 4/16/87 + review by Stavola dated 2/23/87

ICI Americas Inc.

Agricultural Chemicals Division

FEDERAL EXPRESS

February 23, 1987

Mr. George T. LaRocca
Product Management 15
Insecticide-Rodenticide Branch
Registration Division (TS-767C)
U.S. Environmental Protection Agency
Crystal Mall 2, Room 204
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. LaRocca:

RE: KARATE® Insecticide
EPA File Symbol 10182-OA
Fish Life-Cycle Study Protocol

ICI has received EEB comments requesting a fish life-cycle study (Guideline Ref. No. 72-5) in support of the subject application. This is a new, previously unidentified data requirement for pyrethroids. ICI believes that this should be a condition of registration and in our response dated January 15, 1987 has indicated our willingness to conduct the study on that basis.

On May 1, 1986, ICI submitted a proposed protocol for a fish life-cycle study to be conducted in response to a Data Call-In Notice for Cypermethrin dated October 25, 1985. In a letter of January 20, 1987, ICI has agreed to all Agency-suggested revisions to the protocol with one exception, the request for residue and depuration studies using radiolabeled test material. If the Agency agrees that this is an acceptable protocol for cypermethrin, we would like to view this as a standardized ICI protocol for fish life-cycle studies.

We, therefore, respectfully request the Agency's approval of the cypermethrin protocol as an acceptable protocol for conducting the KARATE (PP321) fish life-cycle study.

Sincerely,

Barbara J. Kaminski
Senior Pesticide Regulatory Specialist

BJK:ly
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RECORD NO.

SHAUGHNESSEY NO. REVIEW NO.

EEB REVIEW

DATE: IN 2-3-87 OUT 2-17-87

FILE OR REG. NO 10182-18

PETITION OR EXP. NO.

DATE OF SUBMISSION 1-20-87

DATE RECEIVED BY HED 1-29-87

RD REQUESTED COMPLETION DATE 3-2-87

EEB ESTIMATED COMPLETION DATE 3-2-87

RD ACTION CODE/TYPE OF REVIEW 117

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

DATA ACCESSION NO(S).

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
Aquatic Biologist
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

THRU: Douglas J. Urban
Head - Section III
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

THRU: Michael W. Slimak
Chief
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

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.

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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.