To: George La Rocca  
Product Manager #15  
Registration Division (TS-767C)

From: Emil Regelman, Supervisory Chemist  
Review Section #3  
Exposure Assessment Branch  
Hazard Evaluation Division (TS-769C)

Attached, please find the EAB review of...

Reg./File # : 10182-OA
Chemical Name: PP 321
Type Product: Insecticide
Product Name: Karate 1 EC
Company Name: ICI Americas Inc.
Purpose: Response to comments made on request for registration for use on cotton and review of additional data.

Date Received: 1/30/87
Date Completed: SEP 17 1987
ACTION CODE: 101
EAB # (s): 70233
Total Reviewing Time: 5.0 day

Monitoring study requested:  
Monitoring study voluntarily:  

Deferrals to:  
Ecological Effects Branch  
Residue Chemistry Branch  
Toxicology Branch
1. **CHEMICAL:**

   **Common name:**

   None

   **Chemical name:**

   \((R+S)-\text{alpha-Cyano-3-phenoxybenzyl}-(1R,1S)-\text{cis-3-(Z-2-chloro-}
   3,3,3\text{-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate. It is a 1:1 mix-
   ture of the (Z)-(1R,3R), S ester and (Z)-1S,3S), R ester.}

   **Trade name(s):**

   Karate, the active ingredient is PP321

   **Formulations:**

   1 l 1% gal EC

2. **TEST MATERIAL:**

   Study No. 1 - Cyclopropane-and phenyl-labeled \([^{14}\text{C}]\) PP321 (radiochemical purities 97-98%).
   Study No. 2 - Phenyl-labeled \([^{14}\text{C}]\)PP321 (radiochemical purity 99%).
   Study No. 3 - Cyclopropane-and phenyl-labeled \([^{14}\text{C}]\) PP321.
   Study No. 4 - Cyclopropane-labeled \([^{14}\text{C}]\) cyhalothrin PP563 (radiochemical purity 80.5%).
   Study No. 5 - Cyclopropane-labeled \([^{14}\text{C}]\) cyhalothrin (total radiochemical purity 96.6%).

3. **STUDY/ACTION TYPE:**

   Data review to support Section 3 registration for use on cotton.

4. **STUDY IDENTIFICATION:**


The following studies submitted previously were reviewed in response to registrant's comments:


5. REVIEWED BY:

Arthur Schlosser
Chemist
EAB/HED/OPP

Signature: [Signature]
Date: September 16, 1987

6. APPROVED BY:

Emil Regele
Supervisory Chemist
Review Section #3, EAB/HED/OPP

Signature: [Signature]
Date: SEP 17 1987

7. CONCLUSIONS:

Study No. 1-PP321 appears to be stable to sunlight on soil surfaces.

Study No. 2-This adsorption/desorption study is not acceptable because concentrations of PP321 in the test solutions exceeded its solubility in water.

Study No. 3-In this field soil dissipation study PP321 had half-lives of <14 and 28-56 day respectively in silt loam (MS) and clay loam (IL). Most of the test material remained in the top 5 cm of the soil during the test period.
Study No. 4-This fish accumulation study was found to be unacceptable because it was performed on cyhalothrin, the accumulation and de-puration of PP321 were not specifically addressed, and other experimental discrepancies concerning the composition and test concentrations of the test substance were found.

Study No. 5- This fish accumulation study was not of the required flow-thru type and was performed on cyhalothrin. It is not acceptable for satisfying guidelines but it does contain supplementary information.

See Discussion Section 10 and Dynamac Final Tasks 1 and 2 of July 28, 1987 for more complete information and responses to registrant's comments.

8. RECOMMENDATIONS: We cannot concur with the use of PP321 on cotton. The following data are required to support this use: (1) anaerobic soil metabolism (161-2). (2) leaching and adsorption/desorption (163-1). Additional data are needed on a fourth soil type containing <1% organic matter. This study should be done using the column leaching or soil TLC methods if a batch equilibrium study is not feasible. (3) confined rotational crop (165-1) using PP321 ring-labeled in the alcohol moiety of the molecule. (4) fish accumulation (164-4). (5) Reentry A field rotational crop study (165-2) may be needed if residues of significance are identified in the confined rotational crop study.

9. BACKGROUND:

A. Introduction

PP321 is a synthetic pyrethroid insecticide, described as (R+S)-alpha-cyano-3-phenox benzyl-(1R+1S)-cis-3-(Z-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate. It is a 1:1 mixture of the (Z)-(1R,3R), S ester and (Z)-(1S,3S), R ester. It does not yet have a common chemical name.

PP321 is one of two stereoisomer pairs that comprise cyhalothrin.

B. Directions for Use

PP321 is a broad spectrum contact insecticide developed for use on cotton. It is applied as needed usually at three to seven day intervals at 0.01-0.03 lb ai/A. The proposed formulation is a single active ingredient 1 lb/gal EC. It may be applied using ground equipment or aircraft. Do not apply more than 0.2 lb ai/A per season.
The following studies have been previously reviewed:


10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

Registrant's comments will be addressed in the order that they appear in the "Overview and Summary" Acc.# 400524-04 which should be consulted for the full text of comments and responses.

(1) Hydrolysis: EAB comment was that the test material was used at a rate higher than its water solubility.

The registrant cited experimental difficulties due to the extreme insolubility of the test substance (0.004 ppm). EAB has learned that Product Chemistry (RCB) has accepted the reported solubility. No further work will be needed; the data requirement will be considered satisfied.

(2) Photodegradation in Water: EAB comment was that the test material was used at a rate higher than its water solubility.

As for the hydrolysis study above no further work will be needed; the data requirement will be considered satisfied.

(3) Photodegradation on soil: EAB found the original study invalid because of material balance and other deficiencies.

The registrant submitted a new study (See Dynamac Final Report of July 28, 1987, Study No. 1). This study has been found acceptable and completely fulfills the guideline data requirement.

(4) Leaching and adsorption/desorption: EAB requested an additional study on a fourth soil type.

The registrant submitted adsorption/desorption studies which were not accepted because the test material was applied at nominal con-
centrations above its water solubility. A study on a fourth soil
type containing less than 1% organic matter is still needed. This
may be a column leaching or soil TLC study.

(5) Field Soil Dissipation: EAB rejected a previously submitted
study because no analyses were made for degradation products.

The registrant has submitted further field dissipation studies
(See Dynamac Final Report of July 28, 1987, Study No. 3). These
have been found acceptable and support the proposed use on
cotton.

(6) Rotational crops (confined): EAB could not validate the con-
 fined rotational crop study because soil analyses data were not
provided and residues in plant material were not identified.

The registrant responded that the aerobic soil metabolism study
which was found acceptable was carried out on the same soil and
at the same time as the confined rotational crop study. Therefore,
as indicated in the guidelines, the aerobic soil data can support
the rotational crop study as far as soil residues are concerned.
The registrant further claims that characterization of plant res-
ides should not be necessary since $^{14}$C residues found in test
plants were insignificant (<0.01 ppm) when corrected against con-
trols. See study No. 6, EAB# 6164, Aug. 28, 1986. This study was
carried out with cyclopropane-labeled $[^{14}$C]$^{32}$P in only. Additional
data are needed on the uptake of the alcohol moiety into rotated
crops using benzene ring-radiolabeled PP321 in a confined study.

(7) Fish accumulation: EAB commented that the study submitted
does not satisfy data requirements because it was done with
cypermethrin and not PP321.

The registrant responded that the EAB reviewer meant 'cyhalothrin'
rather than 'cypermethrin' and that since PP321 is one of the
two pairs of enantiomers which comprise cyhalothrin it would be
expected to behave similarly.
There appears to be some confusion in this matter in that 'cyper-
methrin' and not 'cyhalothrin' was meant in the EAB review.
See Study No. 10, Dynamac review of August 26, 1986, EAB# 6164.
No fish accumulation studies on cyhalothrin were included in this
review. Three studies concerning the fish accumulation of cy-
halothrin were not previously reviewed because they did not speci-
fically address accumulation of PP321. These studies are addressed
in the present review (see studies 4 and 5 of Dynamac review of
July 28, 1987). Study No. 5 (test material:cyhalothrin not PP321)
was not carried out in a flow thru system; it was considered to
provide supplemental data but it would not satisfy guidelines.
Study No. 4 (two studies combined) was done on cyhalothrin and
does not satisfy guidelines for the following reasons: (1) The
concentrations of cyhalothrin in the treated water were too
variable and may have accounted for less than 50% of total 14C in solution during the exposure period. (2) The bioaccumulation and depuration of PP321 were not specifically addressed or reported in this study. PP321 does not appear to have even been mentioned in the text of either study. (3) There appears to be some question about the composition of cyhalothrin that needs to be resolved. Recent ICI comments state that cyhalothrin contains two pairs of enantiomers while text in the studies state that it contains 16 isomers composed of eight enantiomeric pairs. (4) The water concentration used for the study (0.02 ppb) appears to have been unnecessarily low and the preferred fish test species (bluegill sunfish) was not used. A new study using PP321 as the test material is needed.

11. **COMPLETION OF ONE-LINER:** Not applicable.

12. **CBI APPENDIX:** Data submitted are claimed to be CBI and should be treated as such.