

Shaughnessy No. 128897

Date Out of EAB: SEP 17 1987

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

ACTION CODE: 101

Date Completed: SEP 17 1987

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 -alpha-Cyano-3-phenoxybenzyl-(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.

Trade name(s):

Karate, the active ingredient is PP321

Formulations:

1 lb/gal EC

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

3. STUDY/ACTION TYPE:

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

4. STUDY IDENTIFICATION:

Environmental Fate Data Overview and Summary for Resubmission for PP321 on Cotton, Jan. 15, 1987. Acc. No. 400524-04.

Parker, S. and J.P. Leahey. 1986. PP321: Photodegradation on a soil surface. Project No. RJ0537B. Submitted by ICI Americas Inc., Wilmington, DE. Acc. No. 400524-05.

Vickers, J.A. and D.W. Bewick. 1986. PP321: Adsorption and desorption in soil. Submitted by ICI Americas Inc., Wilmington, DE. Acc. No. 400524-06.

Bewick, D.W., D.W. Barlett, and P. Hendley. 1986. PP321: fate of radio-labeled material in soil under field conditions. Project No. RJ0529B. Prepared and submitted by ICI Americas Inc., Wilmington, DE. Acc. No. 400524-07.

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

? 1984. PP-563 (Cyhalothrin): Accumulation in fish (carp) in a flow-through water system. Protocol No. MITES/563/4. Prepared by Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, Japan, and submitted by ICI Japan Limited. Acc. No. 470082-032.

Hamer, M.J. and I.R. Hill. 1985. The accumulation of cyhalothrin and its degradation products by channel catfish and Daphnia magna in a soil/water system. RJ 0427B. Prepared and submitted by ICI Americas, Inc., Wilmington, DE. Acc. No. 470082-034.

Leahy, J.P. and S. Parker. 1985. Characterization of residues accumulated by carp continuously exposed to ¹⁴C-cyhalothrin. Report No. RJ0407B. Prepared and submitted by ICI Plant Protection Division, Berkshire, U.K. Acc. No. 470082-033.

5. REVIEWED BY:

Arthur Schlosser
Chemist
EAB/HED/OPP

Signature: Arthur O. Schlosser

Date: September 16, 1987

6. APPROVED BY:

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

Signature: Emil Regelman

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 depuration 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-phenoxybenzyl-(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:

Askew, P.D. and I.R. Hill. 1985. A comparison of the microflora and physicochemical properties of soils used in UK laboratory studies with those of USA soils. ICI Americas Inc., Wilmington, DE. RJ 0429B. Acc. No. 073990. Reference 22J.

Bharti, H., D.W. Bewick, and R.D. White. 1985. PP563 and PP321: Degradation in soil. RJ 0382B. ICI Americas Inc., Wilmington, DE. Reference 4J.

Collis, W.M.D. and J.P. Leahey. 1984. PP321: Hydrolysis in water at pH 5, 7, and 9. RJ 03388. ICI Americas Inc., Wilmington, DE. Reference 1J.

Curl, E.A., J.P. Leahey, and S.J. Lloyd. 1984a. PP321: Aqueous photolysis at pH 5. RJ 0362B. ICI Americas Inc., Wilmington, DE. Reference 2J.

Curl, E.A., J.P. Leahey, and S. Lloyd. 1984b. PP321: Photodegradation on a soil surface. RJ 0358B. ICI Americas Inc., Wilmington, DE. Reference 3J.

Hammer, M.J. and I.R. Hill. 1980. Cypermethrin: The accumulation of cypermethrin and its degradation products by channel catfish in a model soil/water system. RJ0153B. ICI Americas Inc., Wilmington, DE. Reference 18J.

Harvey, B.R., C.K.J. Zinner, R.D. White, and I.R. Hill. 1981. Cypermethrin: Degradation in soil in the laboratory. RJ 0162B. ICI Americas Inc., Wilmington, DE. Reference 5J.

Lloyd, S.J., E.A. Curl, and J.P. Leahey. 1984. Measurement of radioactive residues transferring into rotational crops grown in soil treated with ¹⁴C-PP321. RJ 0381B. ICI Americas Inc., Wilmington, DE. Acc. No. 073990. Reference 12J.

Rapley, J.H., D.J. Arnold, and J. Vincent. 1981. Cypermethrin: Degradation in river and pond water and sediments. RJ 0175B. ICI Americas Inc., Wilmington, DE. Reference 7J.

Rapley, J.H., D.J. Arnold, J. Vincent, and D. Moore. 1980. Cypermethrin: Degradation in river water and sediments. RJ 0119B. ICI Americas Inc., Wilmington, DE. Reference 6J.

Stevens, J.E.B. and D.W. Bewick. 1985. PP563 and PP321: Leaching of PP563 and PP321 and their degradation products in soil columns. RJ 04088. ICI Americas Inc., Wilmington, DE. Reference 8J.

Stevens, J.E.B. and I.R. Hill. 1980. Cypermethrin: Mobility of cypermethrin and its degradation products in soil columns. RJ 0166B. ICI Americas Inc., Wilmington, DE. Reference 9J.

Stevens, J.E.B. and N.J. Poole. 1981. Cyhalothrin: leaching on soil thick-layer chromatograms. RJ 0206B. ICI Americas Inc., Wilmington, DE. Acc. No. 073990. Reference 21J.

Ussary, J.P. 1985. PP321 Dissipation in U.S. soils-1983. TMU 1809. ICI Americas Inc., Wilmington, DE. Reference 11J.

Woods, T.M., D.W. Bewick, and J.P. Leahey. 1980. Cypermethrin: Rotational crop study. RJ 0161B. ICI Americas Inc., Wilmington, DE. Reference 13J.

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 confined 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 residues should not be necessary since ^{14}C residues found in test plants were insignificant (<0.01 ppm) when corrected against controls. See study No. 6, EAB# 6164, Aug. 23, 1986. This study was carried out with cyclopropane-labeled [^{14}C]PP321 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 'cypermethrin' 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 cyhalothrin were not previously reviewed because they did not specifically 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 ^{14}C 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.