

US EPA ARCHIVE DOCUMENT

Amendment to DER
Bioaccumulation of cyhalothrin in carp

The Environmental Fate and Groundwater Branch (EFGWB) deferred the decision of the acceptability to use carp in lieu of bluegill as a test species in the bioaccumulation study to the Ecological Effects Branch (EEB).

EEB has reviewed the information that was submitted by ICI Americas, Inc. on 9/27/88. The data were interesting, but were inadequate to support the use of carp instead of bluegill as a test species.

However, after personal communications with Al Jarvinin, EPA Laboratory, Duluth, MN, 4/20/89, EEB believes that with the BCF of 4600 for carp, and the expected BCF from the fathead minnow fish life cycle study that will be submitted in June of this year (personal communications, John Tapp, ICI Americas, Inc., March 1989), that the expected bioaccumulation in fish from typical field exposures can be estimated and used for a risk assessment.

ICI Americas, Inc. should be aware that this decision is on a case by case basis, and that the classification of future bioaccumulation studies may jeopardized if the study is conducted using a test species other than the bluegill (Lepomis macrochirus) without approval from EFGWB/EEB prior to study initiation.

Adequacy of Study

- Classification- According to the Environmental Fate and Ground Water Review dated September 19, 1988, "all issues have been resolved except EFGWB needs EEB's input regarding the acceptability of using carp as a test species." Since it is apparent that test species was the only remaining concern, this study has been classified as CORE. The BCF for cyhalothrin is 4600.
- Rationale- The data discrepancies have been addressed by the study authors.
- Repairability- N/A

Reviewed by: Candace Brassard *Candace Brassard 4/25/89*
Ecological Effects Branch
Environmental Fate and Effects Division (H-7507-C)

Approved by: *Douglas J. Urban Ann Stavola 5/10/89*
Ecological Effects Branch
Environmental Fate and Effects Branch (H-7507-C)

cc: Environmental Fate and Groundwater Branch
Art Schlosser

Shaughnesy No.: 128897

Date Out of EAB: SEP 19 1988

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

From: Paul Mastradone, Acting Chief *PJM*
Environmental Chemistry Review Section #1
Environmental Fate and Ground Water Branch (TS-769C)

Thru: Paul F. Schuda, Chief *Paul F. Schuda*
Environmental Fate and Ground Water Branch (TS-769C)

Attached, please find the EAB review of ...

Reg./File #: 10182-0A

Chemical Name: PP321

Type Product: Insecticide

Company Name: ICI AMERICAS, Inc.

Purpose: Review Registrant's Response to EAB Review Dated 3/24/88

Date Received: 5/16/88

Action Code: 101

Date Completed: 08/24/88

EAB#(s): 80746

Monitoring Study Requested: _____

Total Reviewing Time: 2 days

Monitoring Study Voluntarily: _____

Deferrals To:

X

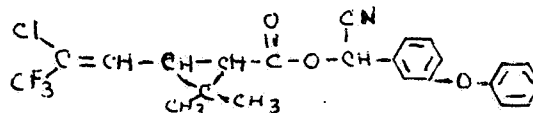
Ecological Effects Branch

Residue Chemistry Branch

Toxicology Branch

1. Chemical: PP321

Trade Name: Karate®



Chemical Name: (+)-alpha-cyano-(3-phenoxyphenyl)methyl(+)-cis-3)-Z-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate

2. Test Material: N/A

3. Study/Action Type: review registrant's response to EAB Review #80108, dated March 24, 1988

4. Study Identification: N/A

5. Reviewed By:

Patricia Ott
Chemist
Environmental Chemistry Review Section #1

Signature: *Pat Ott*
Date: 8/25/88

6. Approved By:

Paul Mastradone
Acting Chief
Environmental Chemistry Review Section #1

Signature: *Paul J Mastradone*
Date:

7. Conclusions:

Fish Bioaccumulation

The EAB reviewer (EAB #80108, dated 3/24/88) raised several concerns about the previously submitted study:

(1) Use of carp as the test species

The EAB reviewer deferred to EEB on the suitability of carp as a valid test species, and the registrant (ICI AMERICAS, Inc.) sent an explanation to EEB. A final determination on the fish bioaccumulation study will be made by EAB after EEB's opinion on this issue is received.

(2) Inconsistencies in reporting of BCF's

The registrant's BCF of 5000 was a rounded-off figure and the actual figure of 4600, obtained from their contractor's original data, is the actual BCF. The registrant's explanation is satisfactory.

(3) The registrant should supply BCF calculations

The registrant supplied calculations for the BCF of 4600 and this issue is satisfied.

Anaerobic Soil Metabolism

- (1) Anaerobic conditions may not have existed during the study

The registrant responded by indicating they followed the Subpart N Guidelines for an anaerobic soil metabolism study by incubating treated soil aerobically for 30 days, then flooding the soil. This issue is resolved.

- (2) Very little CO₂ was evolved when treated soil was immediately flooded, and anaerobic conditions may not have existed under flooded conditions.

Significant amounts of CO₂ were formed during aerobic soil metabolism or when the soil was flooded after a 30 day aerobic soil metabolic period. The registrant explained that this difference in CO₂ production occurred because the parent is much more rapidly degraded under aerobic conditions. This explanation is satisfactory.

- (3) Data on the anaerobic metabolism of the "alcohol" portion of the molecule have not been submitted or specifically referenced

The registrant indicated studies were cited in the registration application of PP321 on cotton, using ¹⁴C-benzyl-labelled cypermethrin, which described the metabolism of the alcohol half of the molecule, which is identical to that of PP321. In this submission, the registrant quoted from the Summary and Overview of EPA accession #073990. ¹⁴C-Benzyl-labelled cypermethrin rapidly degraded (half-life of <3 weeks). The major degradates produced were 3-phenoxybenzaldehyde and 3-phenoxybenzoic acid. After 25 weeks, ¹⁴CO₂ under aerobic and anaerobic conditions accounted for up to 70%. This response is acceptable.

- (4) An estimate of half-life under anaerobic conditions should be provided

In this submission, the registrant reported a half-life for PP321 after flooding of about 30 days. This is acceptable.

Reentry

RD needs to send a separate bean sheet to Dr. James Adams, who will then address the registrant's comments on reentry.

8. Recommendations:

Fish Bioaccumulation

All issues have been resolved except EFGWB (formerly EAB) needs EEB's input regarding the acceptability of using carp as a test species. It is recommended that RD send the registrant's rationale contained in this submission to EEB.

Anaerobic Soil Metabolism

All issues have been resolved. Therefore, this data requirement is satisfied.

Reentry

It is recommended that RD send a separate bean sheet to Dr. James Adams, who will then address the registrant's comments on reentry.

9. Background:

The only remaining data gap for the registration of PP321 on cotton is fish bioaccumulation. The previously submitted study used carp as a test species. EAB is waiting for EEB's opinion as to the suitability of this test species. In this submission, the registrant submitted a rationale for using carp.

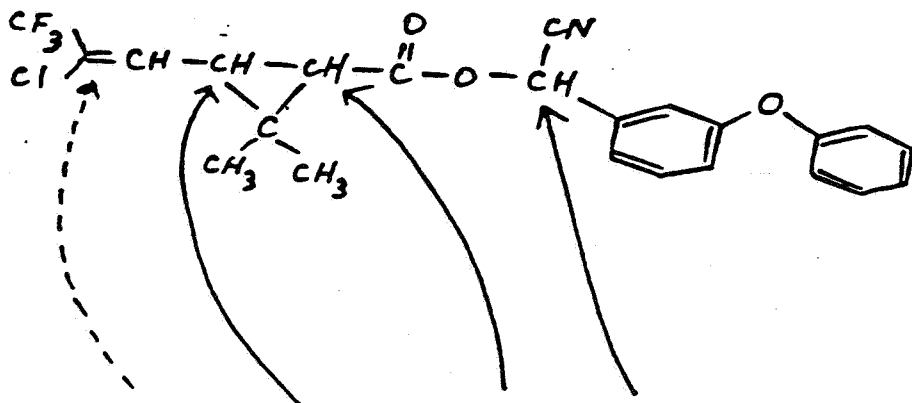
10. Review of Individual Studies: N/A

11. Completion of One-Liner: N/A

12. CBI Appendix: N/A

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C-3 C-1 C 3 asymmetric centers

$2^3 = 8$ optical isomers

2 geometric isomers

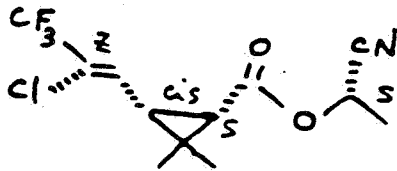
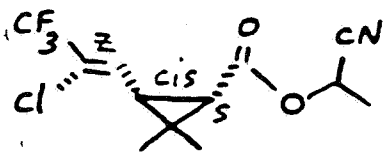
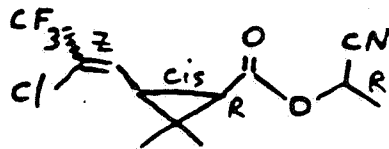
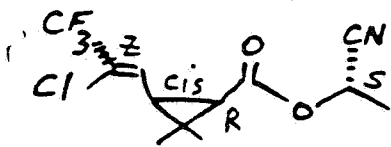
Z- & E- isomers

4 cis- &

4 trans- isomers

total 16 isomers theoretically possible

cyhalothrin consists of 4 cis Z isomers only



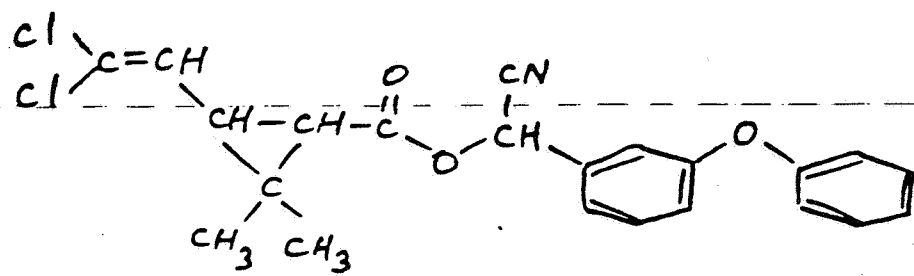
PP321 (pair B)

(pair A)

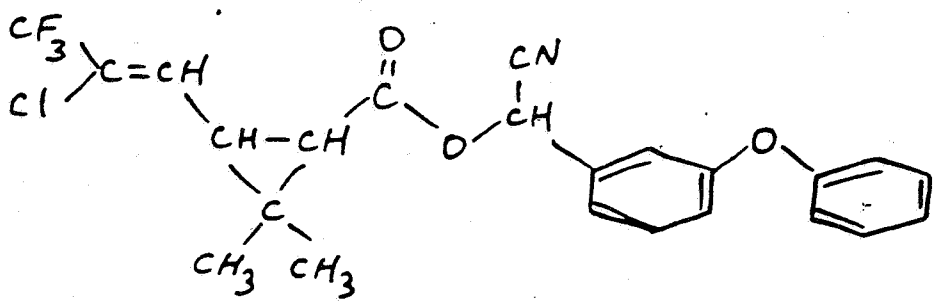
cyhalothrin

PP321 consists of 2 cis Z isomers only

ICI pyrethroid esters



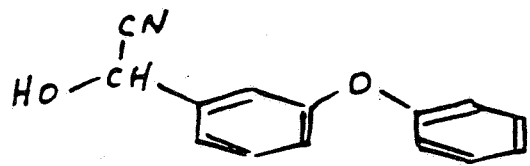
cypermethrin



cyhalothrin (x PP321)

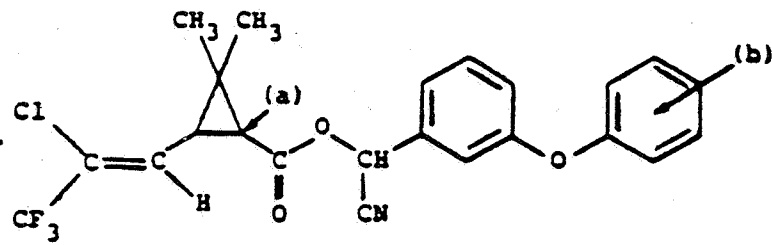
NOTE

Common alcohol



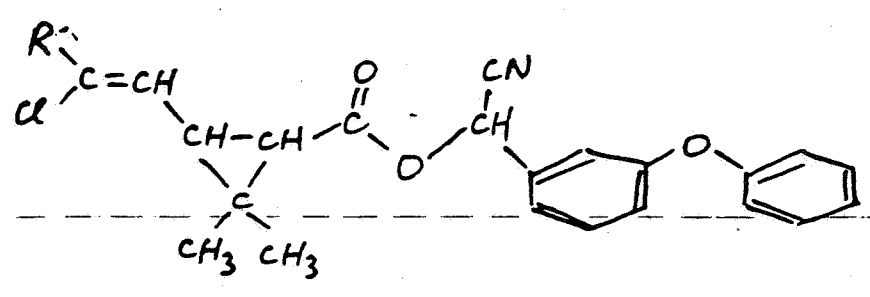
3-phenoxybenzal cyanhydrin

FIGURE 1 : Position of Radiolabelling in ^{14}C -PP321 Samples



- (a) position of radiolabelling in ^{14}C -cyclopropane labelled PP321
- (b) position of radiolabelling in ^{14}C -[U]-phenyl labelled PP321

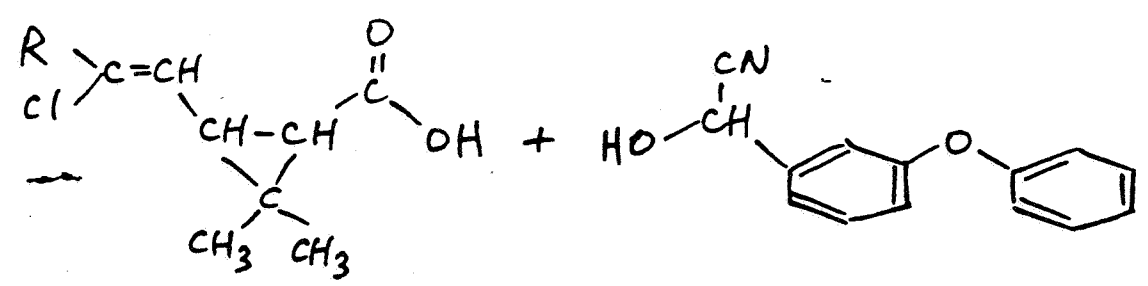
(4)



R = Cl \equiv cypermethrin

R = CF₃ \equiv cyhalothrin [PP321]

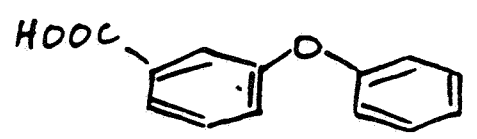
↓ ester cleavage



cyclopropane
carboxylic
acid

cyanhydrin

↓



3-phenoxybenzoic acid