

AUG 28 1986

Shaughnessy No.: 128897

Date Out of EAB: AUG 28 1986

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

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



Attached, please find the EAB review of...

Reg./File # : 10182-OA
Chemical Name: PP321
Type Product : Insecticide
Product Name : KARATE IEC
Company Name : ICI Americas Inc.
Purpose : Request for registration on cotton

Action Code(s): 100 EAB #(s) : 6164
Date Received: 11/12/85 TAIS Code: 56
Date Completed: AUG 28 1986 Total Reviewing Time: 4.0 days

Deferrals to: Ecological Effects Branch
Residue Chemistry Branch
Toxicology Branch

1. CHEMICAL: Common name:

None

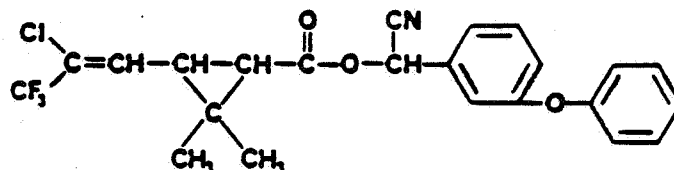
Chemical name:

(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, PP321

Structure:



Formulations:

1 lb/gal EC

2. TEST MATERIAL:

Study 1-hydrolysis:cyclopropane-labeled [¹⁴C] PP321, 95% pure.

Study 2-aerobic soil metabolism:cyclopropane-labeled [¹⁴C] PP321, 97.7% pure.

Study 3-mobility and adsorption/desorption:cyclopropane labeled [¹⁴C] PP563 (cyhalothrin)/PP321, 36.2% PP321.

Study 4-aerobic soil metabolism:benzene ring-labeled [¹⁴C] cypermethrin, 95% pure.

Study 5-leaching and adsorption/desorption:benzene ring-labeled [¹⁴C] cypermethrin (55:45, cis:trans)

Study 6-confined accumulation rotational crops:cyclopropane-labeled [¹⁴C] PP321 95% isomerically pure.

Study 7-leaching and adsorption/desorption:cyclopropane-labeled [¹⁴C] cyhalothrin 99.5 % pure.

Study 8-not applicable (soil comparisons).

Study 9-confined accumulation rotational crops:benzene ring labeled [¹⁴C] cypermethrin.

Study 10-fish residue accumulation:benzene ring-labeled [¹⁴C] cypermethrin.

Study 11-photodegradation in water:cyclopropane-labeled [¹⁴C]PP321 (radiochemical purity 98%, isomeric purity 95%, specific activity 1.93GBq/mM)

Study 12-photodegradation on soil:cyclopropane-labeled [¹⁴C]PP321 (radiochemical purity 98%, specific activity 1.93GBq/mM)

Study 13-field dissipation terrestrial:PP321(Karate, 1b/gal EC)

Study 14-anaerobic aquatic and aerobic aquatic metabolism:benzene ring-labeled [¹⁴C] cypermethrin (98% pure, specific activity 52.8 mCi/mM, 55:45 cis/trans isomers)

3. STUDY/ACTION TYPE:

Application for registration for use on cotton.

4. STUDY IDENTIFICATION:

The following studies have been 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.

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- 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 ^{14}C -PP321. RJ 0381B. ICI Americas Inc., Wilmington, DE. Acc. No. 073990. Reference 12J.
- 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.
- 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.
- 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.
- The following study was not reviewed because the data are not necessary to fulfill mobility data requirements:
- Weissler, M. and S.R. Hill. 1980. Cypermethrin: Leaching of formulated cypermethrin in soil columns. ICI Americas Inc., Wilmington, DE. RJ0137B. Acc. No. 073990. Reference 17J.

The following studies were not reviewed because they are literature reviews only:

Ellgehausen, H., J.A. Guth, and H.O. Esser. 1980. Factors determining the bioaccumulation potential of pesticides in the individual compartments of aquatic food chains. *Ecotoxicol. Environ. Safety* 4:134-157. ICI Americas Inc., Wilmington, DE. Acc. No. 073990. Reference 20J.

Macek, K., S. Petrocelli, and B.H. Sleight III. 1979. Considerations in assessing the potential for, and significance of, biomagnification of Chemical residues in aquatic food chains. In Aquatic Toxicology, ASTM STP 667 L.L. Marking and R.A. Kimerle, eds. American Society for Testing and Materials, pp. 251-268. ICI Americas Inc., Wilmington, DE. Acc. No. 073990 Reference 19J.

The following study was not reviewed because it is not pertinent to environmental fate data requirements:

Hall J.S. and J.P. Leahey. 1983. Cyhalothrin: Fate in River Water. ICI Americas Inc., Wilmington, DE. RJ 0320B. Acc. No. 073990. Reference 10J

The following studies were not reviewed because bioaccumulation studies done using cyhalothrin as the test substance cannot be used to register PP321:

Hammer, M.J. and I.R. Hill. 1985. Cyhalothrin: The accumulation of cyhalothrin and its degradation products by channel catfish and Daphnia magna in a soil/water system. ICI Americas Inc., Wilmington, DE. RJ 0427B. Acc. No. 073990. Reference 16J.

Leahey, J.P. and S. Parker. 1985. Cyhalothrin: Characterization of residue accumulated by carp continuously exposed to ¹⁴C-cyhalothrin. ICI Americas Inc., Wilmington, DE. RJ 0407B. Acc. No. 073990. Reference 15J.

Shigeoka, T. 1984. PP-321 (Cyhalothrin): Accumulation in fish (carp) in a flow-through water system. ICI Americas Inc., Wilmington, DE. Mites Report No. 58-367. Acc. No. 073990. Reference 14J.

The following studies were not reviewed because they contain data on pesticide accumulation in birds only:

Curl, E.A. and S.D. Milner. 1980. Cypermethrin: Accumulation and depletion of radioactive residues in the tissues of mallard duck and bobwhite quail following daily dosing. ICI Americas Inc., Wilmington, DE. RJ 0147B. Acc. No. 073990. Reference 24J.

Knight, S.W. and J.P. Leahey. 1984. PP321: Evaluation of the potential of accumulation by quail and mallard. ICI Americas Inc., Wilmington, DE. RJ 0384B Acc. No. 073990. Reference 23J.

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5. REVIEWED BY:

Arthur Schlosser
Chemist
EAB/HED/OPP

Signature: Arthur O. Schlosser

Date: August 27, 1986

6. APPROVED BY:

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

Signature: E. Regelman

Date: AUG-28 1986

7. CONCLUSIONS:

The hydrolysis data submitted are invalid because the test material was used at a rate higher than its water solubility.

The photodegradation study in water is scientifically invalid because the test material was used at a rate higher than its water solubility.

The photodegradation study on soil is scientifically invalid because the material balance was inadequate and only one sample (at 30 days) was taken for the sunlight-irradiated treated soil.

The aerobic soil metabolism data are acceptable and satisfy guideline requirements. Two studies were considered: one for the alcohol moiety and one for the acid moiety of the molecule.

The leaching and adsorption/desorption studies submitted partially satisfy data requirements. One of the studies was done on cyhalothrin but was accepted because all of the test material showed low mobility. Additional data are needed on a fourth soil type.

The field dissipation study submitted does not satisfy registration requirements because no analyses were made for the degradation products.

The confined accumulation study on rotational crops could not be validated because soil analyses data were not provided. In addition radioactive residues in plant material were not characterized.

The fish residue accumulation study submitted does not satisfy data requirements because it was done with cypermethrin and not PP321.

8. RECOMMENDATIONS:

We cannot concur with the proposed use of Karate on cotton. The following data developed according to EPA "Pesticide Assessment Guidelines Subpart N" are still required: 161-1 hydrolysis,

161-2 photodegradation in water, 161-3 photodegradation on soil, 162-2 anaerobic soil metabolism, 163-1 leaching or adsorption/desorption (data on rapid leaching on an additional soil type using one of the methods described in the guidelines), 164-1 terrestrial field dissipation, 165-1 confined rotational crop studies, 165-4 fish residue accumulation, 158-140 reentry protection and 158-142 spray drift. Data on rotational crop (field) studies, 165-2, may be needed based on the results of the rotational crop (confined) studies.

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 a constituent of cyhalothrin. Data on cyhalothrin have been submitted to the Agency with an application for an Experimental Use Permit for use in animal health (GRENADE Insecticide Petition for Temporary Tolerance to support experimental use on cattle; Pesticide Petition No. 5G3204; Ref. 53218-EUP-1 & 2; EPA Accession No. 073202-0732223; Submitted December 19, 1984). PP321 is one of the 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 up to 30 applications per season at 0.005-0.03 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 0.375 lb ai/A per season.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

See Dynamac T-1/T-2 review.

11. COMPLETION OF ONE-LINER:

Not completed at this time.

12. CBI APPENDIX:

All data discussed here are considered CBI by the registrant and must be treated as such.

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