212201
RECORD NO.

122897
SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 1- -88 OUT 3-17-88

FILE OR REG. NO 10182-OA

PETITION OR EXP. NO.

DATE OF SUBMISSION 12/9/87

DATE RECEIVED BY HED 1-15-88

RD REQUESTED COMPLETION DATE 5-3-88

EEB ESTIMATED COMPLETION DATE

RD ACTION CODE/TYPE OF REVIEW 101

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

DATA ACCESSION NO(S). 404363-01, 404363-02, 404363-03

PRODUCT MANAGER NO. G. Larocca(15)

PRODUCT NAME(S) Karate (PP321)

COMPANY NAME ICI Americas, Inc.

SUBMISSION PURPOSE Data submitted in support of registration

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
	Karate/PP321	

2050928

(1)

Revised Ecological Effects Branch Review

Karate (PP321)

100.0 Submission Purpose and Label Information

100.1 Submission Purpose and Pesticide Use

ICI Americas, Inc., is requesting a Section 3 Registration for Karate, also known as PP321, to be used on cotton. Karate is a synthetic pyrethroid insecticide that may be used for the control of a variety of insects on cotton by contact action.

100.2 Formulation Information

ACTIVE INGREDIENT:
(+)- -cyano-(3-phenoxyphenyl)methyl(±)-cis-3-(Z-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate 13.1%
INERT INGREDIENTS: 86.9%
TOTAL . . 100.0%

Karate contains 1 pound of active ingredient per gallon (1 lb ai/gal).

100.3 Application Methods, Directions, Rates

Recommended Applications

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling must be in possession of the user at the time of application.

Apply Karate 1E as shown in the following chart:

Cotton Spray Recommendations

Target Pests	Rate (lb ai/A)	Fluid oz/A	Remarks
Thrips, spp. Tobacco thrips Soybean thrips	0.01-0.02	1.28-2.56	Apply as required by scouting, usually intervals of 5 to 7 days. Timing and frequency of applications should be based upon insect populations reaching locally determined economic thresholds.

Cotton Spray Recommendations (cont'd)

Target Pests	Rate (lb ai/A)	Fluid oz/A	Remarks
Lygus bugs Pink bollworm Cabbage looper Cotton leaf perforator Cutworm spp. Saltmarsh caterpillar Cotton fleahopper	0.02-0.03	2.56-3.84	Apply with ground or air equipment using sufficient water to obtain full coverage of foliage.
Cotton bollworm Tobacco budworm Boll weevil Fall armyworm Beet armyworm	0.025-0.03	3.20-3.84	Under light bollworm/budworm infestation levels, 0.02 lb ai/A may be applied in conjuction with intense field monitoring. For boll weevil control spray on a 3-to 4-day schedule. Do not apply within 21 days of harvest. Do not apply more than 1.6 pt (0.2 lb ai/A season) Do not graze livestock in treated areas.

RATE CONVERSION CHART

Lb ai/A	Fl oz/A	Pt/A	Treated A/gal
0.01	1.28	0.08	100
0.02	2.56	0.16	50
0.025	3.20	0.20	40
0.03	3.84	0.24	33

100.4 Target Organisms

Karate is expected to control a wide variety of insect pests on cotton, which include the following: thrips (tobacco and soybean), lygus bugs, pink bollworm, cabbage looper, cotton leaf perforator, cutworm, saltmarsh caterpillar, cotton fleahopper, cotton bollworm, tobacco budworm, boll weevil, fall armyworm, and beet armyworm.

100.5 Precautionary Labeling

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not contaminate water by cleaning of equipment or disposal of wastes. Use with care when applying in areas adjacent to any body of water. Do not apply when weather conditions favor drift from treated areas. Do not apply directly to water.

101.0 Hazard Assessment

101.1 Discussion

Karate is a new synthetic pyrethroid with no registered uses. Experimental use permits have been granted for the following uses: cotton, alfalfa, corn, sorghum, lettuce, soybeans, sunflowers, wheat, and peanuts.

In addition to the application on cotton, ICI Americas, Inc. has applied for Section 3 registrations for use on soybeans and domestic use as well. EEB has also been informed that the registrant has applied for use on sweet corn, wheat and sunflowers, though we have not received a request for review for these proposed uses.

Cotton belongs to the mallow family and requires a long, frost free season. Typically, cotton is grown in areas where the mean temperature of the summer months is greater than 77 °F. Planting starts as early as February in Texas, and moves north across the cotton belt as the season advances. The bulk of the U.S. crop is planted during April but may may not be completed until mid-June, depending on the season. Most of the U.S. crop is harvested in October and November except in the Plains areas of Texas, which may be as late as December. The typical growing season is 175 days. The plant is herbaceous with a long tap root and attains a height of 2 to 5 or more feet. Most of the cotton grown in the United States is upland cotton with a staple length (fibers) of 1 inch or longer. Some extra-long staple 1-1/2 inches long cotton are grown in Texas, New Mexico, Arizona, and California.

Karate may be sprayed as early as 7 days after planting in order to control pests such as fall and beet armyworm and the cabbage and soybean loopers. Karate is expected to be applied as early as 21 and 45 days after planting to control the bollworm and the boll weevil, respectively. Application is more likely to start in late June.

101.2 Likelihood of Adverse Effects to Nontarget Organisms

Terrestrial Organisms Toxicity

Toxicity to Avian Species

The available data indicate technical grade PP321 (or Karate) is practically nontoxic to waterfowl on an acute oral basis (mallard LD_{50} > 3950 mg/kg).

Technical grade PP321 is practically nontoxic to upland game birds and slightly toxic to waterfowl on a subacute dietary basis (bobwhite LC_{50} > 5300 ppm, mallard LC_{50} = 3948 ppm).

Cyhalothrin, an active ingredient which is also currently unregistered, consists of two pairs of enantiomers. One of the two pairs is PP321 (Karate). A supplemental mallard duck reproduction study indicated the NOEL=5 ppm cyhalothrin and LOEL= 50 ppm cyhalothrin for eggs laid. The NOEL may even be less than 5 ppm cyhalothrin depending on the raw data that need to be submitted with regards to the terminal findings.

A supplemental bobwhite quail reproduction study indicated the NOEL $\leq$ 50 ppm for eggs laid, eggs set, viable embryos, live embryos, normal hatchlings, and 14-day survivors at $\leq$ 50 ppm cyhalothrin. The statistical analysis indicated the NOEL $\leq$ 50 ppm for eggs cracked as well. However, the study author reported percent eggs cracked to be as high as 17% in the control which indicates these results are unreliable. Additional data discrepencies need clarification.

Mammalian Toxicity

PP321 is moderately toxic to mammals on an acute oral basis (rat LD_{50} values ranging from 56 to 79 mg/kg). A 90-day rat feeding study indicated a NOEL of 50 ppm and a LOEL of 250 ppm. A chronic dog feeding study indicated a NOEL of 0.5 mg/kg/day. The LOEL was 3.5 mg/kg/day. Teratogenicity studies on cyhalothrin indicate NOELs for the rat and rabbit of 10 mg/kg/day.

Honey Bee Toxicity

Technical PP321 is highly toxic to honey bees with a reported contact LD_{50} of 0.038 ug/bee and an oral LD_{50} = 0.909 ug/bee. Formulated product (5.04% ai) is also highly toxic to honey bees with a reported contact LD_{50} = 0.098 ug/bee and a oral LD_{50} = 0.483 ug/bee.

Aquatic Organism Toxicity

Acute - Freshwater Organisms

PP321 is very highly toxic to both warmwater and coldwater fish (bluegill LC_{50} = 0.21 ug/L and rainbow trout LC_{50} = 0.24 ug/L). This chemical is very highly toxic to freshwater invertebrates as well, with a reported Daphnia magna LC_{50} = 0.36 ug/L and Gammarus pulex LC_{50}'s = 6.68 ng/L, 9.13 ng/L.

Chronic- Freshwater Organisms

A supplemental study conducted on Daphnia magna exposed to PP321 indicated the number of young and the number female reproductive days were affected at levels as low as 18.3 ng/l with the NOEL = 8.5 ng/l. A NOEL= 18.3 ng/l was indicated for the growth of the Daphnia magna and a LOEL= 37.2 ng/l. The study has major discrepenices that deviate from current methodology. Adult survival could not be accurately ascertained.

Formulated Product

Formulation testing with 12.92% PP321 ai, indicates the formulated product is also very highly toxic to fish and invertebrates, with LC_{50} values ranging from 0.09 ug/L to 3.4 ug/L. PP321 is formulated with inerts that cause concern for toxicity to aquatic organsims.

Acute- Marine/Estuarine Organisms

The available estuarine data indicate that technical PP321 is very highly toxic to the sheepshead minnow, with an LC_{50} value of 0.807 ug/L. An embryolarvae study on the Pacific oyster indicated technical PP321 is highly toxic to marine invertebrates, with an EC_{50} > 0.59 mg/L. A mysid acute toxicity study indicated the PP321 is very highly toxic to mysid shrimp with an LC_{50}= 4.9 ng/l.

Chronic- Marine/Estuarine Organisms

A fish early life-stage study was conducted on sheepshead minnow exposed to PP321. This scientifically sound study, which was classified as "core", indicated that the weight of Cyprinodon variegatus is affected at levels as low as 0.38 ug/l and the NOEL= 0.25 ug/l. The percent survival of embryos, larval survival from hatch and larval survival from initial indicated a NOEL $\geq$ 0.38 ug/l. Length also indicated a NOEL $\geq$ 0.38 ug/l.

A supplemental life-cycle study was conducted on Mysidopsis bahia, mysid shrimp, exposed to PP321. The study results indicate that the NOEL= 1.7 ng/l for both survival and dry weights. Reproductive sucess may have a NOEL= 0.22 ng/l and a LOEL= 0.46 ng/l. These results are inconclusive since raw data need to be submitted to complete the calculations. There are other discrepencies that also need clarification with regards to measured concentration data.

Environmental Fate and Residues

Limited environmental fate data were available to EEB. PP321 dissipated with a half-life of 14-28 days in sandy loam soils in North Carolina and California and 28-60 days in silt loam soil in Mississippi and silty clay loam soils in Illinois. It should be noted that no analysis was made for degradation products.

Cyclopropane-labeled ^{14}C Cyhalothrin (99.5 % pure) of which PP321 is a constituent was immnobile on loamy sand, clay loam and sandy loam soil TLC plates; 60-90 % of the recovered remained within 1-cm of the treated area.

A non-validated bioaccumulation study on carp exposed to radio-labeled cyhalothrin is reported to have a bioconcentration factor at least 4600 to 5000 in total fish(Art Schlosser, EAB, Personal communications 3-10-88). The water solubility is reported to be 4 ppb.

Radiolabeled PP321, at 0.46 ug ai/g, degraded with a half-life of < 30 days in sandy loam soil moistened to 40 percent of the moisture-holding capacity at zero suction and incubated at 20 °C (EAB review, April 11, 1986).

Terrestrial Residues

PP321 (Karate) can be applied at a maximum rate of 0.01 to 0.03 lb ai/A, as often as every 3 days, for up to 7 to 10 times per season, depending on the application rate. Using EEB's nomograph (Urban, D and N. Cook, Ecological Risk Assessment, EPA-540/9-85-001), the following terrestrial residues are expected based on a single application rate of 0.03 lb ai/A:

Substrate	Residues (ppm)
Short rangegrass	7
Long grass	3
Leaves and leafy crops	4
Forage (alfalfa and clover)	2
Pods containing seeds	4
Fruit	0.21

Soil (top 0.1 inch)	0.66 ppm
Top 6 inches of water (direct application)	22 ppb

A terrestrial estimated environmental concentration (TEEC) was also calculated using a computer model (designed by Richard Lee, EEB). The following assumptions were made: an initial residue of 4 ppm, which is best case(leaves and leafy crops), an application interval of 3 days(as stipulated on the label), number applications is 7 per season, and the foliar half-life of 23 days (see attachment A), the average residue is expected to be 15 ppm. The maximum residue is expected to be 22 ppm (See Attachment B). The TEEC was also calculated for residue on insects. The maximum residue was 11 ppm and the average residue was 7 ppm (See Attachment C).

Pertinent environmental fate data (i.e., hydrolysis, aqueous photodegradation, and areobic soil metabolism) were lacking in order to conduct a Simulator for Water Resources in Rural Basins Model (SWRRB) and the Exposure Analysis Monitoring Systems Model (EXAMS), to estimate the aquatic EEC. Even with the water solubility being so low, 4 ppb, the potential for runoff and drift is of serious concern. In the past, these data have been provided by other companies who applied for registration of synthetic pyrethroids.

EEB estimated a preliminary EEC (See Attachment D) indicating residues from aerial application may be as high as 201 pptr.

Risk Assessment

A. Effects on Terrestrial Organisms

Avian

Karate is practically nontoxic to waterfowl on an acute oral basis. The chemical is practically nontoxic to upland game birds and slightly toxic to waterfowl on a subacute dietary basis.

The submitted reproduction data on the mallard exposed to cyhalothrin showed adverse effects on number of eggs laid at levels of 50 ppm cyhalothrin, with the NOEL= 5 ppm cyhalothrin. Technical PP321 is expected to be even more toxic since it is the "biologically active constituent" of cyhalothrin. Therefore, the NOEL is probably less than 5 ppm.

The NOEL for the mallard is exceeded using the estimated residue on short rangegrass, 7 ppm, calculated by the nomograph. Karate is expected to be persistent, therefore, a TEEC was estimated, and the average and maximum residue of 15 and 22 ppm, respectively, clearly exceed the NOEL. In addition, the techncical NOEL is probably lower. It should be noted, that this compound, unlike most registered synthetic pyrethroids, may cause reproductive impairment to avian wildlife at levels of exposure.

Gulls and terns have been found to eat insects in cotton fields (Ann Stavola, personal communications, March 14, 1988). The TEEC's of 7 and 11 ppm for insects exceeds the mallard NOEL of 5 ppm. Other avian species such as doves, ring-necked pheasant, songbirds, and greater prairie chicken are found in cotton fields for feeding, loafing, cover, and broodrearing. Geese and ducks are reported to incidentally visit cotton fields in Oklahoma throughout the year (Gusey, W. F. and Z. Maturgo, Wildlife Utilization of Croplands Environmental Conservation Department, Shell Oil Company, Houston, TX, November 1972).

Using the most sensitive species (mallard) data with a NOEL of 5 ppm cyhalothrin (and is probably lower for technical) it appears that many species of avian wildlife may be adversely affected from exposure to this compound in cotton fields. Raw data are required on the two avian reproduction studies on cyhalothrin to complete the review. In addition, since it is apparent that the technical is expected to be more toxic than cyhalothrin, and the level of exposure exceeds the mallard NOEL for cyhalothrin, it is clear that an acceptable avian reproduction study on the mallard exposed to technical PP321 alone is required before the concerns for avian wildlife can be mitigated. Without these data, it appears that higher tier terrestrial testing or residue monitoring is needed. It should be noted if ICI does not sufficiently address the concerns identified in the bobwhite reproduction study on cyhalothrin(and study upgraded to core), then a reproduction study on the bobwhite exposed to technical PP321 will be required as well.

Based on the acute toxicity data, it appears that neither the restricted use nor the endangered species triggers are exceeded. But the exposures are expected to exceed the NOEL for avian reproduction, therefore, endangered species concerns for avian wildlife will be considered.

Mammalian

The exposure is expected to be well below the NOEL of 50 ppm reported for the rat 90-day-chronic feeding study. Therefore there is no concern for mammalian species.

Bees

This chemical is highly toxic to bees. There are additional studies conducted on bees exposed to PP321 that have not yet been completely evaluated by EEB.

B. Effects on Aquatic Organisms

Karate is very highly toxic to freshwater and marine/estuarine fish and invertebrates.

The preliminary estimated environmental concentration (EEC)of 201 pptr clearly exceeds the triggers for restricted use classification (1/10 LC_{50} values as low as 0.49 pptr) and endangered species (1/20 LC_{50} with values as low as 0.245 pptr).

The EEC exceeds the NOEL for mysid shrimp by as much as 913 times, and the level at which is expected to cause effects (LOEL) by as much as 436 times and LC_{50} by as much as 41 times. The EEC is approximately the same as the the NOEL and is below the LOEL and the LC_{50} values for marine fish.

The EEC exceeds the NOEL by 23 times, the LOEL by 10 times for Daphnia magna. The EEC is approximately the same as the LC_{50} values for freshwater fish (no chronic data were available for freshwater fish).

Endangered Species Consideration

Based on the available data on aquatic toxicity to both fish and invertebrates, the use of Karate (PP321) on cotton will pose a hazard to both freshwater and marine/estuarine endangered nontarget organisms.

Karate (PP321) has similar toxicities to permethrin and fenvalerate, which have been found to cause jeopardy to certain listed species within the cotton (crop) cluster. The U.S. Fish and Wildlife will be contacted to determine if there are any endangered avian wildlife in cotton fields that would be adversely affected from exposure to this pesticide.

101.4 Adequacy of Toxicity Data

The following data were included in this submission to support registration of Karate on cotton.

- Hill, R.W. (1985) PP321: Determination of Acute Toxicity to Sheepshead Minnow (Cyprinodon variegatus), submitted to ICI Americas, Inc. Prepared by Imperial Chemical Industries, PLC, Brixham Laboratory, Brixham, Devon. EPA Accession No. 073989.

The study is scientifically sound and with a 96-hour LC_{50} = 0.807 (0.672 and 0.967) ug/L (ppb) (measured concentration), PP321 is "very highly toxic" to the marine fish, sheepshead minnow Cyprinodon variegatus. The NOEL = $\geq$ 0.29 ug/L (ppb). The study fulfills the Guidelines Requirements Reference No. 72-3 for the acute toxicity determination for the marine fish with a representative 96.5% PP321 technical.

- Hamer, M.J.; Farrelly, E.; Hill, I.R. (1985) PP321: Toxicity to Gammarus pulex. Submitted by ICI Americas, Inc., prepared by ICI Plant Protection Division, Jealotts Hill Research Station, Bracknell, Berkshire. EPA Accession No. 073989.

These studies appear to be scientifically sound; however, there are major discrepancies that detracted from the studies. Consequently, the studies were classified as "Supplemental."

Test I reported an LC_{50} (95% confidence limits) value of 6.68 (4.9 to 9.2) ng/L (pptr). Test II reported an LC_{50} (95% confidence limits) value of 9.13 (7.13 to 11.98) ng/L (pptr).

These values indicate that PP321 is very highly toxic to the freshwater invertebrate Gammarus pulex. These studies do not fulfill Guidelines Requirements Reference No. 72-2 for acute freshwater invertebrate toxicity testing.

- Thompson, R.S. (1985) PP321: Determination of Acute Toxicity to Mysid Shrimp (Mysidopsis bahia). Submitted by ICI Americas, Inc. Prepared by Brixham Laboratories. EPA Accession No. 073989.

This study is scientifically sound and is classified as "core". The fluctuating measured concentrations cause concern, but are not expected to significantly detract from the study's scientific soundness. It is important for the study author to understand that this decision is made on a case-by-case basis, and the laboratory testing compounds such as these should be extremely cautious with the dilution of the test material. The concerns have been basically satisfied. Based on the results submitted, PP321 is very highly toxic to the mysid shrimp, with a reported LC_{50}= 4.9 ng/l (pptr). The Guidelines

Requirement Reference No. 72-3 is satisfied.

- Hill, R.W. (1985) PP321: Determination of the Acute Toxicity to Larvae of the Pacific Oyster (Crassostrea gigas). Submitted by ICI Americas, Inc. Prepared by Brixham Laboratory, Devon. Accession No. 073989.

Based on the submitted data the LC_{50} is > 1.0 mg/L (ppm), nominal concentration, and 0.59 mg/L, mean measured concentration, for oyster embryolarvae exposed to PP321. This indicates PP321 is highly toxic to the pacific oyster. This study is classified as "core"; therefore, this study fulfills Guidelines Requirement Reference No. 72-3.

- Hamer, M.J.; Farrelly, E.; Hill, I.R. (1985) PP321: 21-Day Daphnia magna Life Cycle Study. Submitted by ICI Americas, Inc. Prepared by ICI, Plant Protection Division, Jealotts Hill Research Station, Bracknell, Berkshire. EPA Accession No. 073989.

This study is classified as supplemental. The major concerns are as follows:

The deviations in the methodology detract from the study, so that the accurate percent survival and, therefore, an accurate adult survival NOEL is unobtainable. The fact that the number of test organisms were reduced from 50 to 30 causes serious concern. In addition, the study design should have had each daphnid in separate containers. This would increase the statistical power of the study as well as determine the no. of young per female. The recommended 1974 protocols in Subdivision E clearly required more replicates than were used in this study, which was conducted in 1985.

In addition, the study author reported in the recently submitted information that the culture contained males, which is an indication the the cultures were under stress.

- Hill, R.W.; Caunter, J.E.; Cumming, R.I. (1985) PP321: Determination of the Chronic Toxicity to Sheepshead Minnow (Cyprinodon variegatus) Embryos and Larvae. Submitted by ICI Americas, Inc. Prepared by Imperial Chemical Industries, PLC, Brixham Laboratory, Brixham, Devon. EPA Accession No. 073989.

This study is scientifically sound and is classified as "core" Additonal data were submitted that satisfied data discrepencies. The data indicate that the NOEL$\leq$ 0.25

ug/l and a LOEL of 0.38 ug/l for weight. The Guidelines Requirement Reference No. 72-4 is fulfilled.

- Thompson, R.S.; Williams, T.D. (1985) PP321: Toxicity to the Green Algae Selenastrum capricornutum. Submitted by Imperial Chemical Industries PLC. Prepared by Brixham Labortory, Brixham, Devon. EPA Accession No. 073989.

The study appears to be scientifically sound; however, there are major discrepancies that detract from the study. This study is classified as "Supplemental." Therefore, the Guidelines Requirement Reference No. 123-2, Tier II, Aquatic Plant Nontarget Phytotoxicity Test is not fulfilled. Based on available information, the EC_{50} appears to be > 310 ppb (mean measured concentration).

- Roberts, N.L. Fairley, C. Chanter, D.O., McAllister, A., and Almond, R.H.(1982). The Effect of the Dietary Inclusion of Cyhalothrin on Reproduction in the Mallard Duck. Prepared by Huntingdon Research Centre, Huntingdon, Cambridgeshire, PE 18 6ES and submitted by ICI Americas, Inc., EPA Acession No. 073989.

This study is classified as supplemental. There are data discrepencies that detract from the study. It appears the NOEL= 5 ppm cyhalothrin and the LOEL= 50 ppm cyhalothrin for eggs laid. The NOEL may even be less than 5 ppm cyhalothrin for ovary pathology, depending on the raw data that needs to be submitted with regards to the terminal findings.

- Roberts, N.L., Fairley, C., Chanter, D.O., McAllister, A. and Almond, R.H. (1982). The Effect of the Dietary Inclusion of Cyhalothrin on Reproduction in the Bobwhite Quail. Prepared by Huntingdon Research Centre, Huntingdon, England PE 186ES Submitted by ICI Americas, Inc. EPA Accession No. 073989.

Based on the submitted data, it appears that cyhalothrin does not cause reproductive impairment to bobwhite for the number of eggs laid, eggs set, viable embryos, live embryos, normal hatchlings, and 14-day survivors that the NOEL was $\leq$ 50 ppm cyhalothrin for eggs cracked, (and damaged) as well. However, the percent eggs cracked was reported to be as high as 17 percent for the control. Therefore, the results for this parameter are unreliable. The study appears to be scientifically sound, however, there are data discrepencies that cause concerns. at $\leq$ 50 ppm cyhalothrin. The statistical analysis indicated

- Thompson, R.S. 1987. PP321 (Lambda Cyhalothrin) Determination of Chronic Toxicity to mysid shrimp (Mysidopsis bahia). Prepared by: ICI PLC Brixham Laboratory. Submitted by ICI Americas, Inc. EPA Accession No. (Not available).

The study appears to be scientifically sound. However, based on the incomplete raw data, the reproductive success can not be calculated. There are discrepencies with regard to measured concentrations that require clarification as well. Therefore, the study is classified as supplemental. The current data indicate that the reproduction may be affected at 0.46 ng/l and the NOEL= 0.22 ng/l. Survival and dry weight were affected at 3.7 ng/l and the NOEL= 1.7 ng/l(measured concentration).

In addition, a full life cycle protocol was submitted and approved with required modifications in August 1987. Since then, the protocol has been resubmitted for review in February 1988, and is currently under review. This is to address the data gaps for Guidelines Requirement Reference No. 72-5.

ICI Americas, Inc., funded a mesocosm study which was conducted in 1986, to evaluate the effects of Karate on aquatic organisms. This study was just submitted for review in March 1988.

Based on the data submitted and reviewed, significant data gaps still exist. The following studies are required:

§71-4 - Avian Reproduction - Waterfowl, Technical PP321;

§72-4 - Invertebrate Life-cycle on Freshwater Species;

§72-5 - Fish Life Cycle Study

§72-6 - Aquatic Organism Accumulation Test;

§72-7 - Simulated or Actual Field Testing for Aquatic Organisms; and

§141-2 - Honey Bee Toxicity of Residues of Foliage (using formulated product).
This study is currently under EEB review.

The following studies require additional raw data to be submitted before a review can be completed:

§71-4 - Avian Reproduction- Cyhalothrin data on Mallard and Bobwhite; Note* If data discrepenices are not satisfied so that it can be upgraded to core, then bobwhite reproduction on technical PP321 is required.

§72-4 - Marine Invertebrate Life Cycle.

101.5 Adequacy of Labeling

The following labeling is required at the time of registration.

A. Outdoor Uses

This pesticide is extremely toxic to fish. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwaters.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

B. Manufacturing Use

This pesticide is extremely toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this products is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Endangered Species Restrictions

Pending receipt of a consultation for this chemical, and based on the current information from the U.S. Fish and Wildlife Service, the use of this chemical in the following counties may jeopardize endangered species. (Attachment E).

102.0 Classification

The Special Review Criteria, as well as the Restricted Use Criteria have been exceeded. Therefore, this pesticide is required to be classified as a "Restricted Use Pesticide." Decision as to Special Review will be made pending receipt and evaluation of the data in Section 101.4

103.0 Conclusions

Based on the current toxicity data and the current agricultural practices associated with cotton, EEB concludes that the use of this pesticide will undoubtedly pose a serious risk to freshwater and marine fish and invertebrates. In addition, it is apparent that this synthetic pyrethroid, unlike most registered synthetic pyrethroids, may pose a reproductive risk to avian wildlife at levels of exposure. No other registered synthetic pyrethroid has been found to cause a decrease in number of eggs laid at the level of expected exposure.

The prelimanry aquatic EEC exceeds the lowest reported aquatic NOEL by as much as 913 times, the level that causes adverse effects(LOEL) to aquatic organisms by as much as 436 times and exceeds the LC_{50} by as much as 41 times.

The preliminary EEC clearly exceeds the endangered species and restricted use classification triggers for all aquatic organisms. In addition, this preliminary EEC clearly exceeds the Special Review criteria (in this instance, 1/2 LC_{50}) for freshwater fish and invertebrates and marine invertebrates).

Basic data requirements, which includes three chronic studies and the raw data for additional three chronic studies must be submitted. EEB needs to review the simulated aquatic field study which was submitted in March 1988. In addition, essential environmental fate data are needed before an SWRRB/EXAMS Model can be conducted on this chemical.

Based on the use pattern of this compound, chronic exposure is evident. There are concerns not only for potential invertebrate and fish kills, but the potential adverse effects (via starvation) to the higher trophic levels in the food chain.

Based on all of the above information it is evident that the use of this pesticide would pose a serious risk to endangered and nonendangered nontarget aquatic organisms. This pesticide may pose a hazard to nonendangered avian wildlife as well. U.S. Fish and Wildlife Service will be

contacted to determine if this will pose a hazard to endangered avian wildlife in cotton fields. The adverse effects would impact the organisms directly and indirectly via the food chain.

Until essential data gaps are fulfilled and the results from the 1986 Karate mesocosm study are reviewed and show that there is no hazard to aquatic organisms and the concerns for avian wildlife have been mitigated, EEB strongly recommends that Karate not be registered for use on cotton.

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3/17/88

66	4.088955
67	3.967565
68	3.849779
69	3.73549
70	3.624593
71	3.516989
72	3.412579
73	3.311269
74	3.212967
75	3.117582
76	3.02503
77	2.935225
78	2.848086
79	2.763535

Attachment A

Maximum residue ---------- 6.825158
Average residue ---------- 3.898427

A PROGRAM FOR PESTICIDE FATE SIMULATION

DAILY ACCUMULATED PESTICIDE RESIDUES---MULTP. APPL.

Chemical name ----------	PP321
Initial concentration (ppm) -----	4
Half-life ----------	23 — foliar half-life
A number of application --------	3
Application interval ----------	24.5
Length of simulation (day) -----	79

DAY	RESIDUE (PPM)
0	4

1	
2	3.881251
3	3.766028
4	3.654225
5	3.545741
6	3.440477
7	3.338339
8	3.239233
9	3.143069
10	3.04976
11	2.959221
12	2.87137
13	2.786127
14	2.703415
15	2.623158
16	2.545283
17	2.46972
18	2.396401
19	2.325259
20	2.256228
21	2.189247
22	2.124254
23	2.061191
24	2
25	1.940626
26	5.823192
27	5.650317
28	5.482576
29	5.319813
30	5.161882
31	5.00864
32	4.859947
33	4.715668
34	4.575673
35	4.439834
36	4.308028
37	4.180134
38	4.056038
39	3.935625
40	3.818787
41	3.705418
42	3.595414
43	3.488676
44	3.385107
45	3.284613
46	3.187101
47	3.092485
48	3.000678
49	2.911596
50	6.825158
51	6.622539
52	6.425934
53	6.235166
54	6.050061
55	5.870451
56	5.696173
57	5.52707
58	5.362986
59	5.203774
60	5.049288
61	4.899389
	4.753939

66	4.088955
67	3.967565
68	3.849779
69	3.73549
70	3.624593
71	3.516989
72	3.412579
73	3.311269
74	3.212967
75	3.117582
76	3.02503
77	2.935225
78	2.848086
79	2.763535

Maximum residue ---------- 6.825158
Average residue ---------- 3.898427

A PROGRAM FOR PESTICIDE FATE SIMULATION

DAILY ACCUMULATED PESTICIDE RESIDUES---MULTP. APPL.

Attachment B
Residue on leaves and leafy crops

Chemical name ----------	PP321
Initial concentration (ppm) -----	4
Half-life ----------	23
A number of application --------	7
Application interval ----------	3
Length of simulation (day) -----	30

DAY	RESIDUE (PPM)
0	4
1	3.881251
2	3.766028
3	7.654225
4	7.426992
5	7.206505
6	10.99256
7	10.66623
8	

9	10.34957
10	14.04232
11	13.62545
12	13.22094
13	16.82845
14	16.32886
15	15.8441
16	19.37373
17	18.79858
18	18.2405
19	21.69899
20	21.05481
21	20.42975
22	19.82325
23	19.23475
24	18.66372
25	18.10965
26	17.57202
27	17.05036
28	16.54418
29	16.05303
30	15.57646
	15.11404

Maximum residue ---------- 21.69899
Average residue ---------- 14.4894

A PROGRAM FOR PESTICIDE FATE SIMULATION

DAILY ACCUMULATED PESTICIDE RESIDUES---MULTP. APPL.

A Hachmeat C

Expected Residues on Insects

Chemical name ----------	PP321
Initial concentration (ppm) -----	2
Half-life ----------	23
A number of application --------	7
Application interval ----------	3
Length of simulation (day) -----	30

DAY	RESIDUE (PPM)
0	2
1	1.940626
2	1.883014
3	3.827112
4	3.713496
5	3.603253
6	5.496282
7	5.333112
8	5.174787
9	7.021162
10	6.812723
11	6.610472
12	8.414224
13	8.16443
14	7.922051
15	9.686867
16	9.39929

21	9.911623
22	9.617374
23	9.331861
24	9.054823
25	8.786011
26	8.525178
27	8.272089
28	8.026514
29	7.788229
30	7.557018

Maximum residue ---------- 10.8495
Average residue ---------- 7.244698

A PROGRAM FOR PESTICIDE FATE SIMULATION

DAILY ACCUMULATED PESTICIDE RESIDUES---MULTP. APPL.

Chemical name ----------	PP321'
Initial concentration (ppm) -----	4
Half-life ----------	23
A number of application --------	7
Application interval ----------	3
Length of simulation (day) -----	30

DAY	RESIDUE (PPM)
0	4
1	3.881251
2	3.766028
3	7.654225
4	7.426992
5	7.206505
6	10.99256
7	10.66623
8	

Attachment D

EEC CALCULATION SHEET

I. FOR FOLIAR APPLICATION

Runoff

$$\frac{0.03 \text{ lb}}{\text{ai/A}} \times 0.01 \text{ (1\% runoff)} \times 10 \text{ A (from 10 A drainage basin)} = 0.003 \text{ lb (tot. runoff)}$$

EEC of 1 lb ai direct application to 1 A pond 6-feet deep = 61 ppb
Therefore, EEC = 61 ppb x 0.003 lb = 0.183 ppb
or 183 pptr

II. FOR AERIAL APPLICATION

A. Runoff

$$\frac{0.03 \text{ lb}}{\text{ai/A}} \times 0.6 \text{ (appl. efficiency)} \times 0.01 \text{ (1\% runoff)} \times 10 \text{ A (10 A drainage basin)} = 0.0018 \text{ lb (tot. runoff)}$$

B. Drift

$$\frac{0.03 \text{ lb}}{\text{ai/A}} \times 0.05 \text{ (5\% drift)} = 0.0015 \text{ lb (tot. drift)}$$

Total loading = 0.0018 lb + 0.0015 lb = 0.0033 lb

Therefore, EEC = 61 ppb x 0.0033 lb = 0.2013 ppb
or 201 pptr

ENDANGERED SPECIES LABELING FOR COTTON USE PRODUCTS
CONTAINING ONE OR MORE OF THE FOLLOWING ACTIVE INGREDIENTS:

Permethrin
Fenvalerate(pydrin)

ALABAMA

COLBERT, GREENE, JACKSON, LAMAR, LAUDERDALE, LIMESTONE, MADISON, MARSHALL, MORGAN, PICKENS, AND SUMTER

ARIZONA

GRAHAM, MARICOPA, MOHAVE, PIMA, PINAL AND SANTA CRUZ

ARKANSAS

BENTON, CLAY, CLARK, CROSS, LAWRENCE, LEE, POINSETTE, POLK, RANDOLPH, SHARP, AND ST. FRANCIS

CALIFORNIA

BUTTE, COLUSA, GLENN, IMPERIAL, KERN, MERCED, MODOC, RIVERSIDE, SACREMENTO, SOLANO, SUTTER, TEHEMA, AND YOLO

FLORIDA

BROWARD, DADE, GLADES, AND PALM BEACH

KENTUCKY

BALLARD, BUTLER, EDMUNDSON, GREEN, HART, JACKSON, LAUREL, LIVINGSTON, MARSHALL, McCRACKEN, McCEARY, PULASKI ROCKCASTLE, TAYLOR, WARREN, AND WAYNE

MISSISSIPPI

CLAIBORNE, COPIAH, HINDS, ITAWAMBA, LOWNDES, MONROE, AND NOXUBEE

NEVADA

CLARK

NEW MEXICO

EDGECOMBE, NASH, AND PITT

OHIO

PICKAWAY

OKLAHOMA

DELAWARE, MCCURTAIN AND PUSHAMATAHA

OREGON

LAKE

TENNESSEE

BEDFORD,BLOUNT, CLAIBORNE, DECATUR, FRANKLIN, HANCOCK, HARDIN, HICKMAN, KNOX, LAWRENCE, LINCOLN, LOUDON, MARSHALL, MAURY, MEIGS, MONROE, RHEA, ROANE, SCOTT, SEQUATCHIE, SMITH, SULLIVAN, AND WAYNE

TEXAS

BASTROP, BURLESONB, COMAL, HARRIS, HAYS, JEFF DAVIS, PECOS, AND REEVES

UTAH

UTAH AND WASHINGTON

VIRGINIA

LEE, RUSSELL, SCOTT, SMYTH, TAZEWLL, WASHINGTON AND WISE