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RECORD NO.

15

128897
SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

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

DATA ACCESSION NO(S). 400524-08, 400524-09

PRODUCT MANAGER NO. G. LaRocca (15)

PRODUCT NAME(S) Karate Insecticide (PP-321)

COMPANY NAME ICI Americas Inc.

SUBMISSION PURPOSE Submission of Data/Information to Support proposed Registration of Cotton Use

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
128897	PP321 or Karate	

(1)

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: (+)-α-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-.02	1.28-2.56	Apply as required by scouting, usually at 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-.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-.03	3.20-3.84	Under light bollworm/budworm infestation levels, 0.02 lb ai/A may be applied in conjunction 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, ICI Americas, Inc. has also applied for Section 3 registrations for use on soybeans and domestic use as well.

In 1985 over 10,684,600 acres of cotton were planted in the United States. Over 70 percent of cotton was grown in Texas, Mississippi, and California.

Cotton belongs to the mallon family and requires a long, frostfree 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 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 boll weevil, respectively. Application is more likely to start in late June.

101.2 Likelihood of Adverse Effects to Nontarget Organisms

Technical PP321 ranged from 92.8-98.0% a.i. for the studies in this hazard assessment.

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).

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 rat 90-day 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.

Acute Aquatic Organism Toxicity

Technical - 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} = 6.68 ng/L, 9.13 ng/L.

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.

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 may be highly toxic to marine invertebrates, with an EC_{50} > 0.59 mg/L. A sheepshead minnow early life stage study indicated a NOEL may be 0.25 ug/L and a LOEL may be 0.38 ug/L.

Environmental Fate and Residues

Limited environmental fate data were available to EEB. Radiolabeled PP321 was reported to have a half-life > 166 hours on loam soil irradiated with artificial light at 25 °C. PP321 dissipated from the upper 10 cm of silt loam (MS) and clay loam (IL) soils with half-lives of < 14 and 28 to 56 days, respectively, following application of radiolabeled PP321 at 142 to 146 g ai/ha.

Nonvalidated data indicate radiolabeled cyhalothrin was found to have a maximum bioconcentration factor 7X in edible tissues, 66X in nonedible tissues, and 19X in whole fish by day 14 of the 31-day exposure period. Radioactivity in the water increased from 0.28 ppb at day 0 to 0.95 ppb at day 32 of the exposure period (EAB review, July 28, 1987).

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. 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
Top 6 inches of water (direct application)	22 ppb

Aquatic Residues

Pertinent environmental fate data (i.e., hydrolysis, photodegradation) 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.

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

Risk Assessment

A. Effects on Terrestrial Organisms

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. No data were available with regard to the effects on avian reproduction from exposure to Karate.

Based on the maximum estimated residues on short rangegrass, 7 ppm is well below both the estimated triggers for restricted use classification (1/5 LC_{50} = 792 ppm) and endangered species (1/10 LC_{50} = 394 ppm). In addition, 7 ppm is well below the reported LOEL of 250 ppm for the rat 90 day feeding study.

The exposure is also expected to be well below the level of concern for mammalian species.

Therefore, Karate is not expected to pose an acute hazard to terrestrial organisms. This chemical is highly toxic to bees. The potential reproductive hazard to avian species from exposure to PP321 is unknown.

B. Effects on Aquatic Organisms

Karate is very highly toxic to freshwater fish, freshwater invertebrates, and marine/estuarine fish. This compound appears to be highly toxic to marine invertebrates.

The preliminary EEC of 201 pptr clearly exceeds the triggers for restricted use classification (1/10 LC_{50} values ranging from 0.668 to 24 pptr) and endangered species (1/20 LC_{50} with values ranging from 0.334 pptr to 12 pptr).

Of all the aquatic organism studies, it appears that the aquatic invertebrates are the most sensitive and the least sensitive is the marine invertebrate pacific oyster.

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 (crop) cotton cluster. Labeling to protect these species will be required pending concurrence from the Office of Endangered Species, Fish and Wildlife Service. See Adequacy of Labeling, Section 101.5, "Endangered Species Restrictions."

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 = > 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 invalid. The high percent mortality for the solvent control and the control causes serious concern. In addition, the measured concentrations fluctuated so that the actual concentration that caused mortality could not be accurately ascertained. The Guidelines Requirement Reference No. 72-3 is unfulfilled.

- 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 it appears 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. Due to major data discrepencies, This study is classified as "Supplemental"; therefore, this study does not fulfill 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 invalid. The major concerns are as follows:

- o The study author reported selecting the healthiest female daphnids on day 6 of the study, and reducing the number of daphnids from 50 to 30 in each test chamber.

- o The study design only included two test chambers per treatment level, instead of seven test chambers (with one daphnid each) and three test chambers (with five daphnids each). These discrepancies cause concern for the scientific soundness and therefore the study is classified as "Invalid." The Guidelines Requirement Reference No. 72-4 is unfulfilled.

- 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. However, there are significant data discrepancies, based on lack of raw data, that are outlined in the Data Evaluation Record. Specific concerns include the measured concentrations ranging from only 20 to 64 percent of the nominal; the light intensity and photoperiod varied considerably from the SEP guidelines. Therefore, this study is classified as Supplemental. The Guidelines Requirement Reference No. 72-4 is unfulfilled.

- 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).

In addition, a full fish life cycle protocol has been submitted and approved with required modifications in August 1987. This is to address the data gaps for Guidelines Requirement Reference No. 72-5.

ICI Americas, Inc., funded a mesocosm study to evaluate the effects of Karate on aquatic organisms. This study was conducted in 1986 and to date EEB has not received the results of this study.

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

§71-4 - Avian Reproduction - Both Upland Game Birds and1Waterfowl;

§72-3 - Acute LC_{50} Estuarine/Marine Organisms Including the Mollusc (Preferably Shell Deposition) Study and Shrimp Study;

§72-4 - Fish Early Life-Stage on Both Freshwater and Marine Fish Species;

§72-4 - Aquatic Invertebrate Life Cycle on Both Freshwater and Marine Species;

§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).

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 by cleaning of equipment or disposal of waste.

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

The following restrictions apply to use of this product after February 1, 1989:

> Before using this pesticide on cotton in the counties listed below, you must obtain the PESTICIDE USE BULLETIN FOR PROTECTION OF ENDANGERED SPECIES for the county in which the product is to be used. The Bulletin is available from your County Extension Agent, State Fish and Game Office, or your pesticide dealer. Use of this product in a manner inconsistent with the PESTICIDE USE BULLETIN FOR PROTECTION OF ENDANGERED SPECIES is a violation of Federal laws.

Labeling in Attachment II must be included in totality immediately following the above statements. This labeling is subject to change pending concurrence from the U.S. Fish and Wildlife Service.

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."

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 hazard to freshwater fish and invertebrates and marine invertebrates.

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).

Basic data requirements, which include three acute studies, seven chronic, and one simulated field study have not been satisfied. 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. The adverse effects would impact these organisms directly and indirectly via the food chain.

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

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Attachment A

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 OR SOYBEANS 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, SACRAMENTO, SOLANO, SUTTER, TEHEMA AND YOLO

FLORIDA

BROWARD, DADE, GLADES AND PALM BEACH

KETUCKY

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

OKALAHOMA

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, SEOUATCHIE, SMITH, SULLIVAN AND WAYNE.

TEXAS

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

UTAH

UTAH AND WASHINGTON

VIRGINIA

LEE, RUSSELL, SCOTT, SMYTH, TAZEWELL, WASHINGTON AND WISE"