5-28-97

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 5/28/97

SUBJECT: **PP#6F4769/6H4775. Lambda-Cyhalothrin (Karate®) in/on Rice. Evaluation of Residue Data and Analytical Methodology.**

DP Barcode: D228792, D228931
Trade Name: Karate®
EPA Reg#: 10182-96
Class: Insecticide

Caswell: #271F
Chem#: ~~128867~~ 128897
PRAT Case#: 288001, 288031
40 CFR: §180.438, §185.3765, §186.3765, and §185.1310

MRID#'s: 440755-00, 440755-01, 440755-02, and 440755-03.

TO: Adam Heyward/George Larocca, PM Team 13
Insecticide Branch/RD (7505C)

FROM: José J. Morales, Charles Lewis, SanYvette Williams-Foy
PIRAT/RCAB/HED (7509C)

5/23/97

THRU: Michael S. Metzger, Chief
RCAB/HED (7509C)

INTRODUCTION

Zeneca Ag Products (formerly ICI Agricultural Products) is requesting the establishment of tolerances for the insecticide lambda-cyhalothrin and its epimer in/on rice grain at 1.0 ppm, rice straw at 1.8 ppm, and rice hulls at 5.0 ppm.

SUMMARY

Occupational exposure and aggregate risk estimates do not exceed HED's level of concern. This Section 3 registration should not pose an unacceptable aggregate risk to infants and children. Therefore, HED has no objection to the issuance of this Section 3 registration for the use of lambda-cyhalothrin and its epimer in/on rice. **Tolerances for the combined residues of lambda-cyhalothrin and its epimer in/on rice grain at 1.0 ppm, rice straw at 1.8 ppm and rice hulls at 5.0 ppm should be established to support this Section 3 registration.**

NOTE:

The following anticipated residue values should be used when conducting a DRES run:

rice grain - 0.34 ppm
polished rice - 0.00204 ppm
rice hulls - 2.108 ppm
rice bran - 0.0748 ppm

The registrant provided percent crop treated information to be used in the dietary risk assessment [7%, note from D. Brassard (BEAD), 5/15/97, attached]. This percent crop treated was evaluated by BEAD and found appropriate for the subject petition.

TOXICOLOGICAL ENDPOINTS

DIETARY

1) *Acute Toxicity.* No endpoint was selected by the TES (Toxicity Endpoint Selection) Committee (3/94). The TESC determined that this risk assessment was not required.

2) *Chronic Toxicity.* RfD = 0.001 mg/kg/day. This RfD was established by the RfD/Peer Review Committee (9/15/94) based on a 1-year oral study (MRID #40017902) in dogs with a NOEL of 0.1 mg/kg/day and an uncertainty factor (UF) of 100. The LEL of 0.5 mg/kg/day was based on clinical signs of neurotoxicity (convulsions, ataxia, muscle tremors) and a slight increase in liquid feces.

3) *Cancer Risk.* Lambda-cyhalothrin has been classified by HED's RfD/Peer Review Committee (9/15/94) as a Group "D" chemical, "not classifiable as to human carcinogenicity".

NON-DIETARY

1) *Short- and Intermediate-Term Risk*

Inhalation Exposure - 0.3 ug/l (0.05 mg/kg/day). For short- and intermediate-term margin of exposure (MOE) calculations, the TES Committee (3/94) recommended use of the NOEL of 0.3 ug/l (0.05 mg/kg/day) from the 21-day inhalation toxicity study (MRID #41387702) in rats. The LEL of 3.3 ug/l was based on decreased body weight gains and clinical signs of toxicity including paw flicking, tail erections and tiptoe gait.

Dermal Exposure - In the 21-day dermal toxicity study (Acc. #073203), the NOEL was > 1000 mg/kg/day (limit dose) and the TES committee did not select an endpoint.

2) *Chronic Risk.* There is no chronic occupational exposure scenario for this use.

3) *Cancer Risk.* Lambda-cyhalothrin has been classified by HED's RfD/Peer Review Committee (9/15/94) as a Group "D" chemical, "not classifiable as to human carcinogenicity".

4) *Dermal Penetration.* For short- and intermediate-term MOE calculations, a dermal toxicity study was used, so dermal penetration data were not required.

AGGREGATE EXPOSURES AND RISKS

1. From Food and Feed Uses:

Tolerances with an expiration date of November 15, 1997 are established in 40 CFR §180.438, 40 CFR §185.3765 and 40 CFR §186.3765 for residues of lambda-cyhalothrin (a 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer a 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl (Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate on several raw agricultural commodities (RACs) at levels ranging from 0.01 to 6.0 ppm. A food additive tolerance of 10.0 ppm in/on dried hops is established under 40 CFR §185.1310 as a result of FAP#0H5599 (57 FR 32440). Tolerances with expiration date of 11/15/97 are established under 40 CFR §185.3765 for corn grain flour at 0.15 ppm, sunflower oil at 0.30 ppm, and wheat bran at 0.20 ppm. Tolerances with expiration date of 11/15/97 are established under 40 CFR §186.3765 for sunflower hulls at 0.50 ppm and tomato pomace (dry or wet) at 6.0 ppm. Current time-limited tolerances for animal products are: meat of cattle, goats, hogs,

horses, and sheep-0.2 ppm; meat of poultry-0.01 ppm; meat byproducts (mbyp) of cattle, goats, hogs, horses & sheep-0.2 ppm; mbyp of poultry- 0.01 ppm; fat of cattle, goats, hogs, horses, and sheep-3.0 ppm; fat of poultry-0.01 ppm; milk fat 5.0 ppm (reflecting 0.2 ppm in whole milk); and eggs-0.01 ppm.

Lambda-cyhalothrin is not a List A, B, C or D reregistration chemical, and therefore is not subject to reregistration requirements.

Acute Risk. This risk assessment was not conducted because the TES Committee has not identified an acute dietary endpoint for lambda-cyhalothrin.

Chronic Risk. Chronic dietary exposure estimates (DRES) for lambda-cyhalothrin are summarized as Attachment 1 (S. Knizner, 5/27/97). This DRES analysis was conducted using anticipated residues and percent crop treated (7% for rice) for several, but not all, commodities. The existing lambda-cyhalothrin tolerances plus the proposed Section 3 use resulted in an Anticipated Residue Contribution (ARC) that is equivalent to the following percentages of the RfD:

	% of the RfD
U.S. Population - 48 States	22%
Nursing Infants (<1 year old)	**25%**
Non-Nursing Infants (<1 year old)	**70%**
Children (1-6 years old)	**50%**
Children (7-12 years old)	**33%**
Hispanics	24%
Non-hispanic Others	27%

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S population (48 states).

2. *From Drinking Water:*

EFED studies indicate lambda-cyhalothrin is moderately persistent and mobile in surface water, but not ground water. There is no established Maximum Contaminant Level (MCL) for residues of lambda-cyhalothrin in drinking water. No health advisory levels for lambda-cyhalothrin in drinking water have been established. There is no entry for lambda-cyhalothrin in the "Pesticides in Groundwater Database" (EPA 734-12-92-001, September 1992).

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for consumption of contaminated water, the ranges the Agency is continuing to examine are all well below the level that would cause lambda-cyhalothrin to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with lambda-cyhalothrin in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

3. *From Non-Dietary Uses:*

Lambda-cyhalothrin is currently registered for use on the following residential non-food sites: general pest control (crack/crevice/spot), termiticide, landscape, turf ornamentals, commercial ornamentals, golf course turf, and unoccupied agricultural premises (CBI submitted by Zeneca Inc. on 4/10/97 in support of PP#6F4769/6H4775).

The Agency lacks sufficient residential-related exposure data to complete a comprehensive residential risk assessment for many pesticides, including lambda-cyhalothrin. However, due to the following facts: 1) that lambda-cyhalothrin has a low vapor pressure (2×10^{-10} torr); 2) there are no acute toxicity endpoints identified; 3) no short- or intermediate-term dermal toxicity endpoint was identified; 4) high worker inhalation MOEs (which ranged from 1,000 to 6,800); and 5) the low percentage of the RfD that is occupied by the pending and registered uses of this chemical; in the best scientific judgement of PIRAT, non-dietary, non-occupational uses of lambda-cyhalothrin would not pose a risk that exceeds HED's level of concern.

4. Cumulative Exposure To Substances with Common Mechanism of Toxicity.

Lambda-cyhalothrin is a member of the synthetic pyrethroid class of pesticides. Some other members of this class of pesticides include permethrin, esfenvalerate, cypermethrin, cyfluthrin, fenpropathrin, flucythrinate, fluvalinate, tralomethrin, and tefluthrin.

Section 408(b)(2)(D)(v) of the Food Quality Protection Act requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether lambda-cyhalothrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, EPA has not assumed that lambda-cyhalothrin has a common mechanism of toxicity with other substances.

DETERMINATION OF SAFETY FOR U.S. POPULATION

1. Acute risk. This risk assessment was not conducted because the TES Committee has not identified an acute toxicity dietary endpoint for lambda-cyhalothrin.

2. Chronic risk. Using the exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, EPA has concluded that dietary exposure to lambda-cyhalothrin will utilize 22% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to lambda-cyhalothrin in drinking water and via residential uses, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to lambda-cyhalothrin residues.

DETERMINATION OF CANCER RISK

Lambda-cyhalothrin has been classified by HED's RfD/Peer Review Committee (9/15/94) as a Group "D" chemical, "not classifiable as to human carcinogenicity". Therefore, this risk assessment was not conducted.

ENDOCRINE DISRUPTER EFFECTS

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...". The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

DETERMINATION OF SAFETY FOR INFANTS AND CHILDREN

In assessing the potential for additional sensitivity of infants and children to residues of lambda-cyhalothrin, EPA considered data from developmental toxicity studies in rats and rabbits and a 3-generation reproductive toxicity study in rats. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during prenatal development. Reproduction studies provide information relating to pre- and post-natal effects from exposure to the pesticide, information on the reproductive capability of mating animals, and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the no observed effect level (NOEL)in the animal study appropriate to the particular risk assessment. This 100-fold uncertainty (safety) factor is designed to account for inter-species extrapolation and intra-species variability. EPA believes that reliable data support using the standard 100-fold factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard factor.

1. Developmental Toxicity Studies

a. Rats. From the developmental toxicity study (MRID #073206) in rats, the maternal (systemic) NOEL was 10 mg/kg/day. The maternal LEL of 15 mg/kg/day was based on decreased body weight gain and decreased food consumption. The developmental (fetal) NOEL was >15 mg/kg/day at the highest dose tested (HDT).

b. Rabbit. From the developmental toxicity study (MRID #073206) in rabbits, the maternal (systemic) NOEL was 10 mg/kg/day. The maternal LEL of 30 mg/kg/day was based on decreased body weight gain. The developmental (fetal) NOEL was ≥ 30 mg/kg/day (HDT).

2. *Reproductive Toxicity Studies*

Rats. From the 3-generation reproductive toxicity study (MRID #073207 and 073209) in rats, both the parental (systemic) and reproductive (pup) NOEL's were 1.5 mg/kg/day. Both the parental (systemic) and reproductive (pup) LEL's were 5 mg/kg/day. They were based on a significant decrease in parental body weight (systemic) or a significant decrease in pup body weight (reproductive). The developmental NOEL was 5 mg/kg/day (HDT).

3. *Pre- and Post-Natal Sensitivity*

The toxicology data base for lambda-cyhalothrin is complete with respect to current toxicological data requirements. There are no pre- or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 3-generation reproductive toxicity study in rats.

Based on the above, EPA concludes that reliable data support the use of the standard 100-fold margin of uncertainty factor and that an additional uncertainty factor is not warranted at this time.

4. *Acute risk*

This risk assessment was not conducted because the TES Committee has not identified an acute toxicity dietary endpoint for lambda-cyhalothrin.

5. *Chronic risk*

Using the exposure assumptions described above, EPA has concluded that the percent of the RfD that will be utilized by dietary exposure to residues of lambda-cyhalothrin ranges from 25 percent for nursing infants less than one year old, up to 70 percent for non-nursing infants less than 1 year old. Despite the potential for exposure to lambda-cyhalothrin in drinking water and via residential uses, EPA does not expect the aggregate exposure to exceed 100% of the RfD. Therefore, taking into account the completeness and reliability of the toxicity data and the conservative exposure assessment, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to lambda-cyhalothrin residues.

DETERMINATION OF SAFETY TO OCCUPATIONALLY EXPOSED WORKERS

1. Acute data for this formulation were available to PIRAT. The proposed work clothing and personal protective equipment (PPE) appearing on the Karate® label are in compliance with the Worker Protection Standard (WPS).

2. Acute data for the technical are available. The proposed restricted entry interval (REI) of 24 hours appearing on the Karate® label is in compliance with the WPS.

3. Occupational exposure assumptions and estimates of exposure are summarized in Tables 1 and 2, respectively. The current Section 3 label for Karate® (EPA Reg. No. 10182-96) requires applicators and other handlers to wear: coveralls over long-sleeved shirts and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, protective eyewear, chemical-resistant headgear for overhead exposure, chemical-resistant apron when cleaning equipment, mixing or loading and a respirator (dust/mist for outdoors, organic vapor for enclosed areas). Because TESC did not identify a dermal endpoint, PIRAT has estimated exposure from inhalation only, with workers wearing a dust/mist respirator (pilots are not expected to wear a respirator).

4. Using these exposure assumptions, HED has concluded that the inhalation MOEs resulting from the handling and application of lambda-cyhalothrin on rice will range from 1,000 for aerial equipment mixer/loaders to 6,800 for ground equipment applicators. These MOEs do not exceed HED's level of concern for occupationally exposed workers.

SUPPLEMENTAL INFORMATION

OCCUPATIONAL EXPOSURE

Table 1. Occupational Exposure Assumptions

PARAMETER	ASSUMPTION
Pesticide Handlers Exposure Database (PHED), Version 1.1, Unit of Exposure From Best Available Surrogate Exposure Table (BASET, 7/5/96)	Mixer/Loader (all liquid formulations, open mixing): Inhalation (80% correction for dust/mist respirator) = 0.242 µg/lb ai handled.
	Applicator - Ground (groundboom, open cab): Inhalation (80% correction for dust/mist respirator) = 0.14 µg/lb ai applied.
	Applicator - Air (liquid formulations, enclosed cockpit): Inhalation = 0.068 µg/lb ai applied.
Percent Absorption	Dermal: Not applicable, TES did not identify a dermal endpoint; Inhalation: 100% (based on tox study).

Table 1. Occupational Exposure Assumptions	
PARAMETER	**ASSUMPTION**
Application Type	Ground or Air
Minimum Finish Spray	Ground: 10 gal/A Air: 5 gal/A
Maximum Application Rate	0.04 lb ai/A
Maximum Applications Per Year	3
Duration of Exposure	Intermediate (one week to several months)
Acres Treated/Day (Y. NG,BEAD)	Ground: 92 acres Air: 366 acres
Average Farm Size (1992 Ag. Census)	Based on Poinsett county, AR = 324 acres
Worker Weight	70 kg (based on TOX endpoint)
Number of Farms Treated by PCO (Professional Chemical Operator)	Ground: 2; Air: 10 (OREB default values).

Table 2. Occupational Exposure and Risk Assessment[a]		
Worker	**Average Daily Dose[b]- Inhalation (ng/kg/day)**	**Short and Intermediate-Term Inhalation MOE[c]**
Ground Mixer/Loader	12.72	3,900
Ground Applicator	7.36	6,800
Aerial Mixer/Loader	50.61	1,000
Aerial Applicator	14.22	3,500

[a] MOEs are expressed to two significant figures.

[b] Average Daily Dose (ADD) = PHED unit exposure x % absorption x application rate x acres treated/day ÷ kg body weight.

[c] Short- and Intermediate-Term Occupational Exposure MOE = NOEL/ADD (where NOEL = 0.05 mg/kg/day).

DIETARY EXPOSURE

PRODUCT CHEMISTRY

The manufacturing process for lambda-cyhalothrin was submitted in support of PP#6F3318 (MRID# 401820-01) and discussed in S. Willett's memo of 9/29/87. There are no toxicological concerns for any of lambda-cyhalothrin impurities. Discussion about structure and isomers appears in M. Flood's memo of 9/19/91 (PP#7F3560/7H5543).

PROPOSED USE

The registered formulation of lambda-cyhalothrin proposed for use is Karate®. Karate® (EPA Reg. No. 10182-96) is an emulsifiable concentrate containing 13.1% of ai and 86.9% of inerts. This formulation contains 1 pound of active ingredient per gallon.

The following directions apply for rice: to control true armyworm, fall armyworm, yellow-stripped armyworm, rice water weevil, rice stink bug, grasshopper, leafhopper, oat birdcherry aphid, and green bug apply from 0.025 to 0.04 lbs ai/A. Apply as required by scouting at intervals of 5 to 7 days. Apply by air or ground equipment using sufficient water to obtain full coverage of foliage. When applying by air, apply in a minimum of 5 gallons of water per acre. Do not apply more than 0.12 lb ai/A/season. For control of rice water weevil in dry seeded rice, make a foliar application as indicated by scouting for the presence of adults, usually within a time-frame of 0 to 5 days after permanent flood establishment. Do not exceed 10 days from starting permanent flood until insecticide application. For control of rice water weevil in water seeded rice, make the first application after pinpoint flood when rice has emerged 0.5 inch above the waterline. Under conditions of prolonged migration into the field, scout the field for rice water weevil adults 3 to 5 days after the initial treatment and, if needed, apply a second application within 7 to 10 days. Do not release flood water within 4 days of an application. Do not apply more than 0.08 lb ai/A within 28 days of harvest or more than 0.04 lb ai/A within 21 days of harvest.

NATURE OF THE RESIDUE

Plants

Data on plant metabolism show that lambda-cyhalothrin is metabolized by cleavage of the ester linkage to form cyclopropane carboxylic acids and the corresponding phenoxybenzoic acid and/or 3-phenoxybenzyl alcohol (M. Flood's memo of 1/22/92, PP#7F3560/7H5543).

HED has decided that the plant metabolites need not appear in the tolerance expression at this time due to lack of toxicological concern and low concentrations found from residue studies (M. Flood's memo of 1/22/92, PP#7F3560/7H5543). The residue to be regulated is lambda-cyhalothrin and its epimer as specified in 40 CFR §180.438.

Animals

Studies of lambda-cyhalothrin metabolism in ruminants and poultry have been reviewed. In addition to the plant metabolites, lambda-cyhalothrin animal metabolites include 3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2-hydroxymethyl-2-methylcyclopropane-carboxylic acid (OH-CPA) and 4-hydroxy-3-phenoxybenzoic acid (4'-OH-3-PBAcid) (PP# 1F3992, M. Flood, 12/26/91).

Lambda-cyhalothrin is the major component of the residue, except for kidney and liver of ruminants and liver of poultry. In addition to the plant metabolites, 3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2-hydroxymethyl-2-methylcyclopropane-carboxylic acid (OH-CPA) and 4-hydroxy-3-phenoxybenzoic acid (4'-OH-3PBAcid) may be present in significant quantities. A residue transfer study in which cows were fed dietary levels of 8, 25 or 80 ppm lambda-cyhalothrin demonstrated that, at $\leq$ 8 ppm, OH-CPA levels in tissue would not exceed 0.01 ppm (See Reference in PP# 2F4109, 2F4114, 7F3560, and 1F3992, M. Flood, 8/31/92). As with plants, the residue to be regulated is lambda-cyhalothrin and its epimer.

HED has determined that animal metabolites do not need to appear in the tolerance expression at this time (PP# 1F3992, M. Flood, 12/26/91 and FAP#OH5599, M. Flood, 8/31/92).

ANALYTICAL METHODOLOGY

The analytical methodology used to determine the residues of lambda-cyhalothrin and its epimer in plant matrices is ICI Method 81, with minor modifications, which was first described in MRID# 400540-01. Briefly, samples were extracted with acetone:hexane 1:1 (v/v), coextracted lipids were removed by liquid-liquid chromatography, followed by a florisil column to remove endogenous materials. The final determination is made by capillary GC with electron capture detection. The limit of determination is 0.01 ppm. This method has undergone EPA Method Validation for soybeans (PP#6F3318/PP#7F3488, E. Greer memo of 9/30/87).

MULTIRESIDUE TESTING

The petitioner has determined recoveries of cyhalothrin and its metabolites PP890, and 3-PBAcid under FDA's multiresidue protocols (PP#7F3488, S. Willett's memo of 3/15/88; PP#7F3560/7H5543, M. Flood's memo of 9/19/91). As of 11/2/90, results have not been listed in FDA's summary.

RESIDUE DATA

Residue data reflecting the application of lambda-cyhalothrin to rice appear in the following report:

> "Lambda-cyhalothrin (ICIA0321): Residue Levels on Rice from Trials Conducted in the United States during 1995"; E. Roper, P. Francis, M. Kepler, J. Markle; 7/9/96; Study Number LCYH-95-MR-08; Report No. RR 96-056B. Performing Laboratory was Zeneca Ag Products, Western Research Center, Richmond, CA (MRID# 440755-02).

Sixteen field trials were conducted during 1995 in Arkansas (6), Louisiana (3), Missouri (1), Mississippi (2), Texas (2), and California (2). Four applications of lambda-cyhalothrin, as a broadcast foliar spray, were made at a rate of 0.04 lbs. ai/A (1X); the first application occurred 3 to 4 weeks after crop emergence. The second application was made 5 to 6 weeks after crop emergence. The final two applications were made 26 to 29 days and 20 to 21 days prior to harvest. After collection, samples were frozen and shipped to Zeneca, Inc., Environmental Chemistry Section, Western Research Center, Richmond, CA for analysis. PIRAT concludes that the residue data are adequate in quantity, quality and location to support the proposed tolerances on rice grain, rice hulls, and rice straw.

Residues of lambda-cyhalothrin were shown to be stable when stored at -18°C for up to 26 months in commodities like peach, pea, oil seed rape, wheat grain, sugarbeet root, cottonseed, apple, cabbage and potatoes (PP#0H5599, M. Flood's memo of 9/19/91). Studies have also been conducted on lambda-cyhalothrin and its epimer on cabbages, apples, and soil that have shown no significant decrease in residue levels or changes in isomer ratio after storage for 16 months at less than -15°C (PP#7F3560/7H5543, J. Morales memo of 12/13/94). Samples of rice grain and straw were analyzed for lambda-cyhalothrin residues up to almost 8 months after sampling. Maximum interval between extraction and analyses was 8 days.

Recovery data were obtained from untreated grain and straw samples fortified with lambda-cyhalothrin at the level of 0.007 ppm to 1.8 ppm. Recoveries ranging from 91% to 104% were obtained for grain; and from 77% to 95% for straw. Recovery data were obtained for lambda-cyhalothrin epimer in grain and straw at fortification levels ranging from 0.013 ppm to 3.2 ppm. Recoveries ranging from 78% to 101% were obtained for grain; and

from 84% to 114% for straw. Submitted chromatograms show well resolved peaks in support of this data.

Table 3 summarizes the amount of residues on rice grain resulting from 4 applications of lambda-cyhalothrin at the rate of 0.04 lbs. ai/A and a 21-day PHI.

Table 3. Lambda-cyhalothrin and its Epimer Residues on Rice Grain

Field Trial Location	ICIA0321 (ppm)[1]	R157836 (ppm)[2]
Shoffner, AR	0.46 0.47	0.05 0.06
Proctor, AR	0.56 0.79	0.06 0.09
Stuttgart, AR	0.42 0.37 0.39	0.04 0.04 0.04
Keiser, AR	0.31 0.35	0.03 0.04
Lodge Corner, AR	0.24 0.19	0.02 0.02
Georgetown, AR	0.25 0.26 0.29	0.02 0.02 0.03
Rosa, LA	0.14 0.11	0.02 0.01
Winnsboro, LA	0.16 0.20	0.02 0.02
St. Joseph, LA	0.18 0.17 0.20	0.02 0.02 0.03
Steele, MO	0.06 0.05	<0.01 <0.01
Leland, MS	0.32	0.04
Greenville, MS	0.18 0.20	0.02 0.03
Pattison, TX	0.13 0.15	0.01 0.01
Louise, TX	0.51 0.43	0.06 0.04

Table 3. Lambda-cyhalothrin and its Epimer Residues on Rice Grain		
Field Trial Location	ICIA0321 (ppm)[1]	R157836 (ppm)[2]
Richvale, CA	0.51 0.66	0.05 0.06
Biggs, CA	0.48	0.05

1. Lambda-cyhalothrin
2. Epimer of lambda-cyhalothrin

Table 4 summarizes the amount of residues on rice straw resulting from 4 applications of lambda-cyhalothrin at the rate of 0.04 lbs. ai/A and a 21-day PHI.

Table 4. Lambda-cyhalothrin and its Epimer Residues on Rice Straw		
Field Trial Location	ICIA0321 (ppm)[1]	R157836 (ppm)[2]
Shoffner, AR	1.2 1.4	0.10 0.14
Proctor, AR	1.2 1.2	0.16 0.16
Stuttgart, AR	0.52 0.47 0.46	0.04 0.03 0.03
Keiser, AR	0.49 0.41	0.13 0.03
Lodge Corner, AR	0.34 0.65	0.02 0.04
Georgetown, AR	0.42 0.36	0.04 0.04
Rosa, LA	0.34 0.45	0.03 0.04
Winnsboro, LA	0.23 0.22	0.02 0.02
St. Joseph, LA	0.15 0.15	0.03 0.03
Steele, MO	0.22 0.19	0.04 0.03
Leland, MS	0.49	0.06

Table 4. Lambda-cyhalothrin and its Epimer Residues on Rice Straw		
Field Trial Location	ICIA0321 (ppm)[1]	R157836 (ppm)[2]
Greenville, MS	0.23 0.20	0.01 <0.01
Pattison, TX	0.41 0.43	0.04 0.04
Louise, TX	1.4 0.81	0.22 0.12
Richvale, CA	0.85 0.65	0.09 0.06
Biggs, CA	0.87	0.11

1. Lambda-cyhalothrin
2. Epimer of lambda-cyhalothrin

As can be seen from Tables 3 and 4, the maximum residue on rice grain was 0.79 ppm for lambda-cyhalothrin, 0.09 ppm for lambda-cyhalothrin epimer; the maximum residue on rice straw was 1.4 ppm for lambda-cyhalothrin, 0.22 ppm for lambda-cyhalothrin epimer. All of the control samples were below the limit of detection. The petitioner is proposing a tolerance of 1.0 ppm on rice grain and of 1.8 ppm on rice straw. PIRAT considers that the submitted residue data supports the proposed tolerances for lambda-cyhalothrin and its epimer in/on rice grain and rice straw.

PROCESSING STUDIES

A rice processing study appears in the following report:

"Lambda-cyhalothrin (ICIA0321): Residue Levels on Rice and Processing Fractions From a Trial Conducted in the United States during 1995"; E. Roper, P. Francis, M. Kepler, J. Markle; 7/9/96; Study Number LCYH-95-PR-01; Report No. RR 96-055B. Performing Laboratory was Zeneca Ag Products, Western Research Center, Richmond, CA (MRID# 440755-01).

Two trials were conducted in MS and AR between June and September 1995. The AR trial was a back-up to the MS trial in the event of crop failure. The samples from the AR trial were neither processed nor analyzed. Lambda-cyhalothrin was applied as a broadcast foliar spray at the rate of 0.2 lbs ai/A (5X the label rate). The first application occurred 3 to 4 weeks after crop emergence. The second application was 5 to 6 weeks after emergence during flood. The last two applications were made 29 and 21 days prior to

harvest for a total of four applications. Samples were frozen within 1 hour of harvest at <-10°C. Processing of rice was conducted by the Texas A&M University Food Protein Research and Development Center, TX. Results are shown in Table 5.

Table 5. Lambda-cyhalothrin and its Epimer Residues on Rice and Processing Fractions

Commodity	ICIA0321 (ppm)[1]	R157836 (ppm)[2]
Grain	1.46	0.17
Grain	1.36	0.16
Polished Rice	<0.01	<0.01
Hulls	8.47	0.89
	9.18	1.00
Bran	0.30	0.04

1. Lambda-cyhalothrin
2. Epimer of lambda-cyhalothrin

As can be seen from Table 5, the average concentration factor for rice hulls is 6.2X, 0.006X for polished rice, and 0.22X for rice bran. As can be seen from Table 3, the highest average field trial (HAFT) residue for rice grain is 0.75 ppm. Applying the average concentration factor for rice hulls to the HAFT for rice grain results in 4.65 ppm. The petitioner is proposing a 5.0 ppm tolerance for residues of lambda-cyhalothrin and its epimer in/on rice hulls. PIRAT considers that the submitted processing study supports the proposed tolerance for lambda-cyhalothrin and its epimer in/on rice hulls. No concentration of lambda-cyhalothrin and its epimer occurred in polished rice and bran.

MEAT, MILK, POULTRY AND EGGS

The existing tolerances for meat, milk, poultry and eggs are based on the transfer of residues from a worse-case diet consisting of various animal feed items containing residues of lambda-cyhalothrin and its epimer [corn forage (6.0 ppm), sorghum grain (0.20 ppm), sorghum grain dust (1.5 ppm), wheat grain fractions (0.05 ppm), and wheat forage (2.0 ppm)]. No increase in the dietary burden of poultry and ruminants is expected from use on rice. Therefore, any secondary residues that might result in milk, meat, poultry and eggs would be covered by the existing tolerances on these commodities.

OTHER CONSIDERATIONS

Rotational Crop Restrictions

Studies submitted in support of lambda-cyhalothrin registration show that significant residues (<0.01 ppm) will not be present in crops rotated 30 days after application of parent lambda-cyhalothrin. No additional rotational crop data are needed to support current registered application rates (EFED review of 4/6/88).

International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) for residues of lambda-cyhalothrin and its epimer in/on rice. Therefore, international harmonization is not an issue for this Section 3 use.

Attachments:	Chronic DRES Run (S. Knizner, 5/27/97) D. Brassard memo of 5/21/97
cc with Attachments:	J. Morales, Charles Lewis, PIRAT, Caswell File (#271F), TOX (P. Hurley), OREB (#128867), CBTS (PP#6F4769/6H4775), DRES (B. Steinwand)
RDI:	PIRAT (5/21/97)