



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCESOPP OFFICIAL RECORD  
HEALTH EFFECTS DIVISION  
SCIENTIFIC DATA REVIEWS  
EPA SERIES 361

## MEMORANDUM

DATE: 6/27/02

SUBJECT: PP#0F6092. Request for the Use of Lambda-Cyhalothrin in/on Canola, Pome Fruits, Stone Fruits, Tree Nuts, Almond Hulls, and Tobacco including Apple and Peach Cooking Studies. Evaluation of Analytical Method and Magnitude of the Residue Data.

DP Barcode: D262858, D276160

Submission#: S574546

Chemical#: 128897

Class: Insecticide

PRAT Case#: 292497

Caswell#: NA

CAS#: 91465-0806

MRID: 4 5 0 0 7 0 0 1 - 1 1 ,  
45032401,  
45443101 -05Trade Name: KARATE®  
WARRIOR® TEPA Reg#: 10182-96  
10182-434

CFR: §180.438

TO: Arnold Layne/ William Sproat PM 3  
Registration Division (7505C)

FROM: William D. Cutchin, Chemist *William D. Cutchin*  
Science Information Management Branch  
Health Effects Division (7509C)

THRU: Richard Loranger, Branch Senior Scientist *R. Loranger*  
Registration Action Branch 2  
Health Effects Division (7509C)

Following is the review of a petition from Zeneca Ag Products requesting establishment of permanent tolerances for residues of the insecticide lambda-cyhalothrin on the following commodities:

Canola seed .....	0.15 ppm
Pome fruit crop group .....	0.30 ppm
Apple pomace, wet .....	2.50 ppm
Stone fruit crop group .....	0.50 ppm
Tree nut crop group .....	0.05 ppm
Almond hulls .....	1.5 ppm

The review was performed by the Life Sciences Division of Oak Ridge National Laboratory under the supervision of SIMB and RAB2. The data assessment has undergone secondary review within the branch and has been revised to reflect current HED and OPP policy. If any additional input is needed, please advise.

#### Executive Summary of Residue Chemistry Deficiencies

- The petitioner should submit a revised Section F proposing a tolerance on canola at 1.0 ppm and canola oil at 2.0 ppm.

cc: RAB2 Reading File, PP#0F6092

RESIDUE CHEMISTRY REVIEW

**LAMBDA-CYHALOTHRIN (ICIA0321)**

[1:1 mixture of (S)- $\alpha$ -cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)- $\alpha$ -cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate]

**MRIDs 45007001, 45007002, 45007003, 45007004, 45007005, 45007006, 45007007, 45007008, 45007009, 45007010, 45007011, 45032401, 45443101, 45443102, 45443103, 45443104, 45443105**

DP Barcode: D262858, D276160      Trade Name: Karate®/Warrior T®

Petition #: 0F6092 (canola, stone fruits, pome fruit, tree nuts, tobacco)

PC Code: 128897 (cyhalothrin 128867)      EPA Reg. No.: 10182-96

Submission #: S574546      CAS#: 91465-08-6

Prepared for  
Health Effects Division, Office of Pesticide Programs  
U.S. Environmental Protection Agency  
1921 Jefferson Davis Highway  
Arlington, VA 22202

Prepared by  
Chemical Hazard Evaluation Group  
Toxicology and Risk Analysis Section, Life Sciences Division  
Oak Ridge National Laboratory  
Oak Ridge, TN 37831  
Task Order No. 01-121

Disclaimer

This review may have been altered by the Health Effects Division subsequent to the contractor's signatures above.

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Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Dept. of Energy under contract DE-AC05-00OR22725.

PERMANENT TOLERANCE PETITION FOR LAMBDA-CYHALOTHRIN IN/ON:

CANOLA SEED; POME FRUIT CROP GROUP; APPLE POMACE, WET; STONE FRUIT CROP GROUP; TREE NUT CROP GROUP, NUTMEAT; ALMOND HULLS (PP# 0F6092)

DP Barcode D262858, D276160; Shaughnessy No. 128897 (cyhalothrin 128867)

INTRODUCTION

Zeneca Ag Products has submitted a petition for the establishment of permanent tolerances for residues of the pyrethroid insecticide lambda-cyhalothrin, in/on canola, pome fruits and wet apple pomace, stone fruits, tree nuts, and almond hulls. Data has also been submitted from three tobacco field trials conducted in 1996 and 1997 in EPA Region 2 to satisfy OPPTS 860.1000 guideline requirements for use of lambda-cyhalothrin on tobacco (a tolerance or exemption of a tolerance is not required). Specifically, the petitioner has proposed to establish tolerances for lambda- cyhalothrin, a 1:1 mixture of (S)- $\alpha$ -cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2- dimethylcyclopropanecarboxylate and (R)- $\alpha$ -cyano-3-phenoxybenzyl- (Z)-(1S,3S)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer expressed as epimer of lambda-cyhalothrin, a 1:1 mixture of (S)- $\alpha$ -cyano-3- phenoxybenzyl- (Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop -1-enyl)-2,2-dimethylcyclopropane-carboxylate and (R)- $\alpha$ -cyano-3-phenoxybenzyl-(Z)-(1R,3R) -3-(2-chloro-3,3,3- trifluoroprop-1- enyl)-2,2-dimethyleyclopropanecarboxylate as indicated in/on the following commodities:

Canola seed .....	0.15 ppm
Pome fruit crop group .....	0.30 ppm
Apple pomace, wet .....	2.50 ppm
Stone fruit crop group .....	0.50 ppm
Tree nut crop group, nutmeat .....	0.05 ppm
Almond hulls .....	1.5 ppm

Lambda-cyhalothrin is a synthetic pyrethroid insecticide and acaricide used to control a wide range of pests (including aphids, adult Japanese beetles, grasshoppers, and butterfly larvae) in a variety of applications. It may also be used for structural pest management and in public health applications to control insects such as mosquitoes, cockroaches, ticks, and flies, which may act as disease vectors. Another use is as SABER® Pour-On Insecticide, which is applied down the backline of beef cattle for control of lice and horn flies. Lambda-cyhalothrin is compatible with most other insecticides and fungicides. For some of its uses, it is applied to soil before crops emerge.

Currently established tolerances for residues of lambda-cyhalothrin are listed under 40 CFR §180.438 and include permanent tolerances on plants ranging from 0.01 ppm on soybeans to 6.0 ppm on alfalfa hay, corn forage, and tomato pomace (dry or wet). Tolerances are also

established on animal commodities ranging from 0.01 ppm in eggs, poultry meat, and poultry meat by-products (mbyp) to 5.0 ppm in milk fat (reflecting 0.2 ppm in whole milk). A temporary tolerance for canola (0.1 ppm) is listed as expired as of 12/31/00.

The following volumes of residue chemistry data were submitted with this petition: MRID 45007001 thru -11, 45032401, and 45443101 thru -05. Their citations are provided near the end of this document.

## CONCLUSIONS

### OPPTS 830 Series GLNs: Product Properties

1. Product chemistry data for lambda-cyhalothrin were reviewed in 1992. There are no toxicological concerns for any of the lambda-cyhalothrin impurities. CBTS recommended that the IUPAC names for lambda-cyhalothrin and its epimer (rather than the Chemical Abstract names) appear in the regulation. Three formulations of lambda-cyhalothrin were used on the crops tested in this petition. The stone fruit and pome fruit crop field trials were conducted using the capsule suspension KARATE/WARRIOR 2.09CS (formulation number WF2471; 2.13 lbs ai/gal; EPA Reg. No. not stated). For the canola and tobacco studies, the emulsifiable concentrate KARATE 1EC (formulation number GFU383C; 1 lb ai/gal; EPA Reg No. 10182-96) was employed. Tree nuts received the capsule suspension WARRIOR T (formulation number WF2616; 1 lb ai/gal; EPA Reg No. 10182-434).

### OPPTS GLN 860.1200: Proposed Uses

- 2a. The proposed directions are adequate for use of the lambda-cyhalothrin on canola. The product label indicates that up to three applications of 0.015-0.030 lb ai/A up to a total of 0.090 lb ai/A/season are permitted. Apply as required by scouting at 5 day intervals with a PHI of 7 days.
- 2b. The proposed directions for use of the lambda-cyhalothrin on pome fruits (including apples and pears) are adequate. The first application is to be made as required by scouting. The maximum application rate per treatment is 0.04 lb ai/A applied up to five times at 5 day spray intervals for a maximum of 0.2 lb ai/A/season with a PHI of 21 days.
- 2c. The proposed directions for use of the lambda-cyhalothrin on stone fruits (including cherries, peaches, and plums) are adequate. The first application is to be made as required by scouting. The application rate per treatment is 0.02-0.04 lb ai/A applied up to five times (total of 0.2 lb ai/A/season) with re-treatment intervals of 5 days and a PHI of 14 days.
- 2d. The proposed directions for use of the lambda-cyhalothrin on tree nuts are adequate. The first application is to be made as required by scouting. The application rate per treatment is

0.02-0.04 lb ai/A applied up to four times (total of 0.16 lb ai/A/season) with re-treatment intervals of 5 days and a PHI of 14 days.

- 2e. The proposed directions for use of the lambda-cyhalothrin on tobacco are adequate. The first application is to be made as required by scouting. The application rate per treatment is 0.015-0.03 lb ai/A applied up to four times (total of 0.09 lb ai/A/season) with re-treatment intervals of 7 days and a PHI of 40 days.

#### OPPTS GLN 860.1300: Nature of the Residue - Plants

- 3a. No new nature of the residue studies were submitted with this application. Based on metabolism studies conducted on cotton, cabbage, soybeans and wheat, the nature of the residue in plants is adequately understood. Lambda-cyhalothrin is metabolized by cleavage of the ester linkage to form cyclopropanecarboxylic acids and the corresponding phenoxybenzoic acids or alcohols. In most cases the parent compound is the principal constituent of the residue. However, in the cabbage metabolism study the cis- and trans-cyclopropanecarboxylic acids were the major constituents. 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. The residue to be regulated is lambda-cyhalothrin and its epimer R157836.

#### OPPTS GLN 860.1300: Nature of the Residue - Livestock

- 3b. No new nature of the residue studies were submitted with this application. Studies of lambda-cyhalothrin metabolism in ruminants and poultry have been previously reviewed. Lambda-cyhalothrin is the major component of the residue, except for kidney and liver of ruminants and liver of poultry, where, 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. As with plants, the residue to be regulated is lambda-cyhalothrin and its epimer R157836. HED has determined that animal metabolites do not need to appear in the tolerance expression at this time. CBTS decided earlier not to require further animal metabolism data to support uses for lambda-cyhalothrin on alfalfa, lettuce or the Brassica crop group.

#### OPPTS GLN 860.1340: Analytical Methods - Plants

- 4a. Adequate enforcement methods are available for determination of lambda-cyhalothrin residues in all plant commodities. ICI Method 81 is used to determine the residues of lambda-cyhalothrin and its epimer in plant matrices. ICI Method 81, which is also called PPRAM 81, has undergone an EPA method validation for soybeans and was found to be

adequate for enforcement purposes. This method involves acetone:hexane 1:1 (v/v) extraction, followed by liquid-liquid chromatography to remove lipids and florisil column cleanup. Quantification uses capillary gas chromatography (GC) with electron capture detection (ECD). The limit of quantification (LOQ) is 0.01 ppm for both lambda-cyhalothrin and its enantiomer. ICI Method 81 has been validated as an adequate enforcement method by EPA for determination of parent lambda-cyhalothrin and its epimer in/on plants.

- 4b. In analytical studies of all crops in this petition, the procedure used was based on methods PPRAM 81 and PPRAM 70. This procedure quantified both lambda-cyhalothrin and its epimer R157836, and the LOQ was 0.01 ppm for both residues in all matrices except apple juice, which had an LOQ of 0.001 ppm for both residues and an LOD of 0.0004 ppm for lambda-cyhalothrin and 0.0002 ppm for R157836. LODs were not mentioned for any other commodities in this petition besides apple juice. In the sample preparation based on the PPRAM 81/PPRAM 70 methods, lambda-cyhalothrin and R157836 are extracted from the sample with a 1:1 (v/v) acetone:hexane mixture. The acetone is removed by partitioning with deionized water. An acetonitrile liquid-liquid column cleanup is used to remove extracted lipids, and Florisil adsorption chromatography is used to remove interfering endogenous materials. Quantification is accomplished by either packed column isothermal GC/ECD (gas chromatography with electron capture detection) with an external standard or by programmed temperature capillary GC/ECD (for apple juice).
- 4c. The petitioner submitted concurrent recovery studies for all crops under consideration for the present petition. Recoveries of lambda-cyhalothrin and its epimer R157836 were within the acceptable range of 70-120% for all matrices with the exception of three at the lowest fortification level in the apple and peach cooking studies (3 of 92 recoveries), and all control samples were below the LOQ. Limited but adequate sample chromatograms were provided for the method recoveries by the analytical laboratories for all commodities on which it was used.

#### OPPTS GLN 860.1340: Analytical Methods - Animals

- 4d. Adequate enforcement methods are available for determination of lambda-cyhalothrin residues in animal commodities. ICI Method 86 is used to determine residues of lambda-cyhalothrin in animal matrices. Parent lambda-cyhalothrin is extracted from milk or animal tissue with 50% acetone:hexane. The aqueous fraction is removed and the organic layer dried with sodium sulfate. Cleanup uses Florisil column chromatography. Determination of residue is accomplished using packed column GC and a <sup>63</sup>Ni ECD. The LOQ is 0.01 ppm. ICI Method 86 has been validated by EPA as an adequate enforcement method for determination of parent lambda-cyhalothrin and its epimer in/on animal tissues and milk.
- 4e. ICI Method 96 is used to determine lambda-cyhalothrin metabolites in meat, milk, poultry and eggs. Samples are extracted with acetonitrile:hydrochloric acid or methanol, the extract

is diluted with water, and parent lambda-cyhalothrin is removed on a C<sub>18</sub>-bonded silica cartridge. The eluate is evaporated and refluxed for 4 hours with concentrated hydrochloric acid. The hydrolysate is then partitioned into dichloromethane. For 3-PBAcid and/or 4'-OH-3-PBAcid analyses, the extracts are evaporated, reconstituted in 50% methanol and passed through a C<sub>18</sub> column. The eluate is evaporated and redissolved in dichloromethane. 3-PBAcid is methylated with diazomethane prior to GCMS with selected ion monitoring (SIM). CPA is benzylated with benzyl bromide and purified on a Florisil column prior to GC with an ECD. 4'-OH-3-PBAcid is quantitated using HPLC with electrochemical detection. The LOQ is 0.01 ppm.

#### OPPTS GLN 860.1360: Multiresidue Method

- 4f. The petitioner has determined recoveries of cyhalothrin and its metabolites PP890 and 3-PBAcid under FDA's multiresidue protocols. As of 11/01, these results had not been listed in FDA's Pestrak Data Files. On the basis of the recoveries made, this requirement is considered to have been met.

#### OPPTS GLN 860.1380: Storage Stability Data - Plants

- 5a. No new freezer storage stability studies were submitted with this application. Previous freezer storage stability data demonstrated that residues of lambda-cyhalothrin and its epimer are stable in peach, pea, oilseed rape, wheat grain, sugar beet roots, cottonseed, apple, cabbage and potato when stored at -18 °C for periods up to 26 months. Storage stability data were also reviewed earlier and found to be adequate for alfalfa and lettuce. Alfalfa forage and hay samples were stable stored frozen at <-15 °C for ≤956 days from sampling to extraction and an additional 2-22 days from extraction to analysis. Leaf lettuce samples were stable frozen at <-15 °C for ≤720 days from sampling to extraction and an additional 1-7 days from extraction to analysis. Additionally, certain processed commodities (flour, starch, apple dry pomace, refined oil, and soapstock) were stable frozen at <-15 °C for up to 32 months. The existing storage stability database for lambda-cyhalothrin is considered adequate to support the residue data for the numerous crops presented in this petition.

#### OPPTS GLN 860.1380: Storage Stability Data - Animal Commodities

- 5b. No new studies were submitted with this application. The existing animal commodity storage stability data is considered adequate for the purposes of this petition.

#### OPPTS GLN 860.1480: Meat/Milk/Poultry/Eggs

- 6a. Ruminant feed items associated with this petition are canola meal, wet apple pomace, and almond hulls. The maximum theoretical dietary burden resulting from these proposed new uses is 2.84 ppm for beef cattle (65% of diet) and 1.59 ppm (45% of diet) for dairy cattle. The worst-case scenario dietary burden based on commodities with established lambda-



cyhalothrin tolerances is 10.0 and 10.9 ppm for beef and dairy cattle, respectively (a diet of corn forage and alfalfa hay). Substitution of canola meal, wet apple pomace, and/or almond hulls for either corn forage or alfalfa hay does not increase the dietary burden for beef or dairy cattle. Therefore, the established tolerances for ruminant commodities (milk, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep) are adequate to cover the proposed new uses.

- 6b. The only poultry feed item associated with this petition is canola meal, which represents up to 15% of a poultry diet, and results in a dietary burden of 0.15 ppm. The worst-case scenario dietary burden for poultry based on commodities with established lambda-cyhalothrin tolerances is 1.4 ppm (diet of rice grain or hulls or sorghum grain). Substitution of canola meal for rice grain or hulls or sorghum grain does not increase the dietary burden for poultry. Therefore the established tolerances for poultry commodities (eggs, fat, meat, and meat byproducts) are adequate to cover the proposed new uses.
- 6c. The only swine feed item associated with this petition is canola meal, which represents up to 15% of a swine diet, and results in a dietary burden of 0.15 ppm. The worst-case scenario dietary burden for swine based on commodities with established lambda-cyhalothrin tolerances is 0.72 ppm (diet of rice grain or hulls or sorghum grain). Substitution of canola meal for rice grain or hulls or sorghum grain does not increase the dietary burden for swine. Therefore, the established tolerances for swine commodities (fat, meat, and meat byproducts) are adequate to cover the proposed new uses.

#### OPPTS GLN 860.1500: Crop Field Trials

- 7a. Zeneca Ag Products has submitted data from 6 canola field trials conducted in Canada in 1998 to permit use of lambda-cyhalothrin on canola grown in Canada. The lambda-cyhalothrin was applied as the 120EC (emulsifiable concentrate) formulation KARATE Insecticide (1 lb ai/gal). Canola was treated three times with a broadcast foliar spray of 0.009 lb ai/A (total of 0.027 lb ai/A/season; 1X maximal application rate for the Canadian petition). Several applications were too low or too high (0.66X -1.11X). The first application was 18-19 days prior to harvest, and the second and third treatments were at 5-7 day intervals. The PHI was 6-7 days (versus 7 days proposed). Residue levels of lambda-cyhalothrin in/on canola were <0.01–0.13 ppm and residues of its epimer R157836 were <0.01 ppm for all but three samples (0.01 ppm each).
- 7b. Zeneca Ag Products has submitted data from 10 canola field trials conducted in Canada in 2000 to permit use of lambda-cyhalothrin on canola grown in Canada. The lambda-cyhalothrin was applied as Warrior T Insecticide (1 lb ai/gal, capsule suspension). Canola was treated three times with a broadcast foliar spray of either 0.009 lb ai/A (total of 0.027 lb ai/A/season; 1X maximal application rate for the Canadian petition) or 0.030 lb ai/A (total of 0.090 lb ai/A/season; 1X maximal application rate for the U.S. petition). The first application was 19-21 days prior to harvest, and the second and third treatments were at 5-7

day intervals. The PHI was 7-9 days. Residue levels of lambda-cyhalothrin in/on canola were <0.01–0.69 ppm and residues of its epimer R157836 were <0.01–0.06 ppm. The results of these Canadian field trials, storage stability, and method validation data indicate that the proposed tolerance of 0.15 ppm on canola is too low. **The registrant should submit a revised Section F proposing a tolerance for lambda-cyhalothrin and its epimer R157836 on canola at 1.0 ppm.**

- 7c. Zeneca Ag Products has submitted data from 7 canola field trials conducted in the U.S. in 1999 in support of their petition to permit use of lambda-cyhalothrin on canola. Canola was treated three times with a broadcast foliar spray of 0.03 lb ai/A (total of 0.09 lb ai/A/season; 1X maximal application rate). For each trial, the first application was 17-21 days prior to harvest, and the second and third treatments were at 5-7 day intervals. The PHI was 5-7 days. Residue levels of lambda-cyhalothrin in/on canola were <0.01–0.07 ppm and residues of its epimer R157836 were <0.01 ppm for all but three samples, for a total of ~0.02–0.12 ppm. All untreated control samples were below the LOQ of 0.01 ppm for both residues. Although the results of these field trials, the storage stability, and method validation data support the proposed tolerance of 0.15 ppm for use of lambda-cyhalothrin on canola, the Canadian trials described above indicate that a 1.0 ppm tolerance is necessary.
- 7d. Zeneca Ag Products has submitted data from 12 field trials on apples and 6 field trials on pears conducted in 1997 to support its proposed permanent tolerance of 0.30 ppm lambda-cyhalothrin on the pome fruit crop group. The lambda-cyhalothrin capsule suspension KARATE/WARRIOR® 2.09 CS (2.09 lbs ai/gal) was applied 5 times as a foliar broadcast spray at 0.04 lb ai/A for an annual total of 0.20 lb ai/A (proposed 1x seasonal rate). The first application was dormant to pre-bloom; the second spray was applied 35-42 days before harvest, and the remaining three applications occurred at 5-7 day intervals; both low and high volume sprays were used. The PHI was 20-21 days (versus 21 days proposed). Residue levels of lambda-cyhalothrin on apples were 0.02–0.23 ppm and R157836 levels were <0.01–0.02 ppm. Residue levels on pears were 0.04–0.10 ppm and for R157836 were <0.01 ppm. The geographic diversity, number of submitted field trials, and storage stability data are adequate and support the requested permanent tolerance of 0.30 ppm for the use of lambda-cyhalothrin on pome fruits.
- 7e. Zeneca Ag Products submitted data from 12 field trials on peaches, 9 field trials on sweet cherries, and 9 field trials on plums conducted in 1997 to support its proposed lambda-cyhalothrin permanent tolerance of 0.50 ppm on the stone fruit crop group. The lambda-cyhalothrin capsule suspension KARATE/WARRIOR 2.09 CS (2.09 lbs ai/gal) was applied 5 times as a foliar broadcast spray at 0.04 lb ai/A for an annual total of 0.20 lb ai/A (proposed 1x seasonal rate). The retreatment intervals were 4–10 days and the PHI was 13-14 days (versus 14 days proposed). Residue levels of lambda-cyhalothrin in/on peaches were 0.01–0.38 ppm, and R157836 residues were <0.01–0.03 ppm. Residue levels of lambda-cyhalothrin in/on plums were 0.01–0.10 ppm, and R157836 residues were <0.01–0.01 ppm. Residues of lambda-cyhalothrin in/on sweet cherries were 0.04–0.18 ppm, and of R157836

were <0.01–0.02 ppm. The geographic diversity, number of submitted field trials, and storage stability data are adequate and support the requested permanent tolerance of 0.50 ppm for the use of lambda-cyhalothrin on stone fruits.

- 7f. Zeneca Ag Products submitted data from 5 field trials on almonds and 5 field trials on pecans conducted in 1998 to support its proposed lambda-cyhalothrin permanent tolerance of 0.05 ppm on the tree nut crop group nutmeat and 1.5 ppm on almond hulls. Lambda-cyhalothrin, formulated as the capsule suspension KARATE/WARRIOR 1 CS (1 lb ai/gal), was applied four times as a foliar broadcast spray at a rate of 0.04 lb ai/A, for a total of 0.16 lb ai/A/season ( $\pm 7.5\%$  of the proposed 1x seasonal rate). The first application was at the dormant to pre-bloom growth stage, the second was 24–28 days prior to harvest, and the 3<sup>rd</sup> and 4<sup>th</sup> applications were at 5–8 day intervals. The PHI was 13–14 days (versus 14 days proposed). Residue levels of lambda-cyhalothrin and its epimer R157836 in/on almond and pecan nutmeat were all <0.01 ppm but on almond hulls were 0.20–1.1 ppm for lambda-cyhalothrin and 0.02–0.08 ppm for R157836. The geographic diversity, number of field trials and storage stability and method validation data support the proposed lambda-cyhalothrin tolerance of 0.05 ppm in/on almond nutmeat and 1.5 ppm in/on almond hulls.
- 7g. Zeneca Ag Products submitted data from three tobacco field trial conducted in 1996 and 1997 in EPA Region 2 to satisfy OPPTS 860.1000 guideline requirements for use of lambda-cyhalothrin on tobacco (a tolerance or exemption of a tolerance is not required). Lambda-cyhalothrin, formulated as the emulsifiable concentrate KARATE 1EC, was applied foliarly either two or three times at a rate of  $0.03 \pm 10\%$  lb ai/A, for a total of 0.06 lb (0.67X) or 0.09 lb (1X) ai/A/season. The first application was within one day after transplanting and the second and third (if needed) were two and four weeks later, respectively. The PHI ranged from 40–108 days (versus 40 days proposed). A portion of the leaves from each harvest was air-dried or flue-cured. Residue levels of lambda-cyhalothrin and its epimer R157836 on treated tobacco leaves were <0.01–0.03 ppm and < 0.01 ppm (the LOQ), respectively, for almost all samples irrespective of their level of dryness. The submitted data satisfy the OPPTS 860.1000 guideline requirements, and indicate that further studies (metabolism, pyrolysis) are not needed because all residues were <0.1 ppm and metabolism studies were available on other plants.
- 7h. Residue decline studies were conducted only for peaches and tobacco. The limited data indicate that residues decline with time (residues in most samples were near or below the LOQ). The failure to provide residue decline studies on the other crops is not considered a serious limitation because lambda-cyhalothrin is known to be non-systemic.

#### OPPTS GLN 860.1520: Processed Food/Feed

- 8a. There are no processed commodities of regulatory interest for pears, cherries, peaches, pecans, and almonds, and processing studies are not relevant to their petitions. Processing studies are also not relevant for the registration of lambda-cyhalothrin use on tobacco.

- 8b. A processing field trial was conducted in Granger, WA to determine the amount of lambda-cyhalothrin and its epimer R157836 in/on apples and its processed commodity wet apple pomace and fresh juice. Lambda-cyhalothrin (formulation KARATE/WARRIOR 2.09 CS, 2.09 lb ai/gal capsule suspension) was applied 5 times by broadcast foliar spray to apple trees at 0.04 ai/A for a total of 0.2 lb ai/A/season. The first application was at the dormant stage and the 2<sup>nd</sup> application was 39 days prior to harvest, followed by 3<sup>rd</sup>, 4<sup>th</sup>, and 5<sup>th</sup> applications at 5-7 days. The PHI was 21 days. Residues of lambda-cyhalothrin + R157836 concentrated 8.06X in wet apple pomace but were reduced significantly in apple juice. Multiplying the HAFT for the RAC apples (0.21 ppm) by the 8.06X concentration factor yields 1.7 ppm, which supports the proposed tolerance of 2.5 ppm on wet apple pomace. For risk assessment purposes, a residue value of 0.001 ppm can be used for juice based on this study.
- 8c. A cooking study was conducted to determine the amount of lambda-cyhalothrin and its epimer R157836 in/on remaining in apple commodities when prepared for cooking and processed into applesauce. The total applied was reported to be equivalent to 0.2 lb ai/A, which is the maximum seasonal application rate. Residues of lambda-cyhalothrin and R157836 in apples after washing declined slightly ranging for an average concentration factor of 0.84X. Residues of lambda-cyhalothrin and R157836 in apples after peeling, cooking, and canning declined significantly for an average concentration factor of 0.08X.
- 8d. A processing field trial was conducted in Chico, CA to determine the amount of lambda-cyhalothrin in plums and its processed commodity prunes. Lambda-cyhalothrin (formulation KARATE/WARRIOR 2.09 CS) was applied 5 times by broadcast foliar spray with a 5-day retreatment interval and a PHI of 14 days. The application rate was 0.04 lb ai/A for a total of 0.2 lb ai/A/season (1X use rate). The total residues (lambda-cyhalothrin + R157836) were concentrated 1.4X in prunes. Multiplying the HAFT of 0.105 ppm for plum by the 1.4X concentration factor yields 0.15 ppm, which is below the proposed tolerance of 0.50 ppm for stone fruits. Therefore, a separate tolerance for prunes is not necessary.
- 8e. A processing study was conducted on canola seed processed commodities (meal and refined oil). Three foliar broadcast applications were applied at the rate of 0.09 lb ai/A, for a total application of 0.27 lb ai/A/season or 3X the field trial application rate. The first application was made at 21 days prior to harvest. The second and third applications were made at 7 day intervals. Mature canola seeds were harvested by combine 7 days after last application. The results of the processing study indicates no concentration of residues in meal but up to 5X for R157836 in refined oil. For tolerance purposes RAB2 concludes that the appropriate oil concentration factor is 2.3X (total oil residues of 0.30 ppm divided by 0.13 ppm in seed). Multiplying the HAFT of 0.75 ppm for canola RAC by 2.3X concentration factor yields 1.7 ppm, which is above the proposed tolerance of 0.15 ppm and the suggested tolerance of 1.0 ppm for canola. Therefore, a separate tolerance for canola refined oil is required. **The registrant should submit a revised Section F requesting a tolerance of 2.0 ppm for residues lambda-cyhalothrin and R157836 in canola refined oil.**

- 8f. A canning study was conducted to determine the amount of lambda-cyhalothrin and its epimer R157836 remaining in peach commodities when prepared for canning and processed into canned peaches. The total applied was reported to be equivalent to 0.2 and 0.39 lb ai/A, which is 1 and 2X the maximum seasonal application rate. Residues in peaches after peeling declined significantly to <0.01-0.02 for lambda-cyhalothrin and <0.01-0.01 ppm for R157836 for an average concentration factor of 0.04X. Residues in peaches after canning declined significantly to <0.01-0.04 for lambda-cyhalothrin and <0.01-0.01 ppm for R157836 for an average concentration factor of 0.04X.

#### OPPTS GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

- 9a. No new rotational crop studies were submitted with this petition. Rotational studies are potentially relevant for only canola and tobacco since pome fruits, stone fruits, and tree nuts are perennials. Previous studies showed that significant residues (>LOQ of 0.01 ppm) will not be present in crops rotated 30 days after application of parent lambda-cyhalothrin. The submitted label (which does not include crops under consideration for the present petition) has no restrictions on replanting of crops.

#### Other Considerations:

10. Current status sheets available to HED indicate that a Codex maximum residue level (MRL) of 0.2 ppm has been established for pome fruits for cyhalothrin, which is inconsistent with the proposed U.S. lambda-cyhalothrin tolerance of 0.3 ppm for pome fruits (Crop Group 11). It is unclear if harmonization can be achieved because residues up to 0.25 ppm were found in the U.S. trials for apples. Codex MRLs were not established for the other crops presently under consideration [canola seed, stone fruits (Crop Group 12), tree nuts (Crop Group 14), and tobacco]. Neither Canadian nor Mexican MRLs are established for lambda-cyhalothrin for any crops for which tolerances are being presently recommended.

#### RECOMMENDATIONS

Pending receipt of the revised Section F and the upcoming human health risk assessment for lambda-cyhalothrin, the following permanent tolerances expressed as residues of lambda-cyhalothrin, a 1:1 mixture of (S)- $\alpha$ -cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)- $\alpha$ -cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer expressed as epimer of lambda-cyhalothrin, a 1:1 mixture of (S)- $\alpha$ -cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)- $\alpha$ -cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate, should be established:

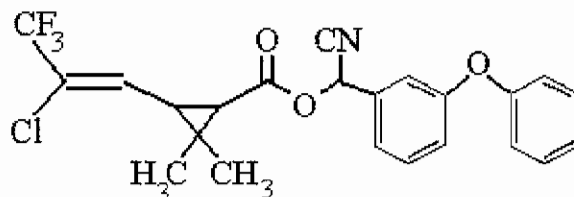
Pome fruit crop group ..... 0.30 ppm

Apple pomace, wet .....	2.50 ppm
Stone fruit crop group .....	0.50 ppm
Tree nut crop group, nutmeat (Group 14) .....	0.05 ppm
Almond hulls .....	1.5 ppm
Canola seed .....	1.0 ppm
Canola oil .....	2.0 ppm

### **DETAILED CONSIDERATIONS**

#### **OPPTS 830 Series GLNs: Product Properties**

The chemical structure of lambda-cyhalothrin is as follows:



Product chemistry data for lambda-cyhalothrin were reviewed earlier and are summarized as follows (PP#7F3488, DP Barcode: D177185, J. J. Morales, 11/12/92). 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 lambda-cyhalothrin impurities. Discussion about structure and isomers appears in M. Flood's memo of 9/19/91 (PP#7F3560/7H5543). CBTS concluded that the manufacturing process of technical grade lambda-cyhalothrin has been adequately described and did not foresee any residue problems from impurities in the technical grade product. ICIA0321 (lambda-cyhalothrin) Technical (EPA Reg. No. 10182-131) contains a minimum 81% ai. Although deficiencies pertaining to the written confirmation from the Chemical Abstract Service were resolved, CBTS recommended that the IUPAC names for lambda-cyhalothrin and its epimer (rather than the Chemical Abstract names) appear in the regulation, since in their opinion, a practicing chemist can more readily relate the IUPAC names to the structure (M. Flood memo, 9/19/91, PP#7F3560/7H5543 and M. Flood memo 3/23/92, FAP#OH5599).

Three formulations of lambda-cyhalothrin were used on the crops tested in this petition. For the stone fruit and pome fruit crop groups, the lambda-cyhalothrin capsule suspension KARATE/WARRIOR 2.09CS (formulation WF2471, equivalent to Karate Z, EPA Reg. No. 10182-414; 2.09 lbs ai/Gal of product; ) was used. For the canola and tobacco trials, an emulsifiable concentrate (formulation GFU383C, KARATE 1EC; 1 lb ai/gal of product; % ai and EPA Reg. No. not specified) was employed. The capsule suspension KARATE/WARRIOR 1CS (formulation WF2616; 1 lb ai/gal of product; % ai and EPA Reg. No. not specified) was

used for the tree nut crop group. Zeneca has three US registered products that contain 1 lb ai/gal of product: Karate Insecticide (emulsifiable concentrate, 13.1% ai, EPA Reg. No. 10182-96),; Warrior 1EC (emulsifiable concentrate, 12.6% ai, EPA Reg. No. 10182-395); and Warrior T with Zeon Technology (capsule suspension, 11.4% ai, EPA Reg. No. 10182-434).

### **OPPTS GLN 860.1200: Proposed Uses**

#### Canola

The proposed directions for use of the lambda-cyhalothrin formulation WARRIOR T Insecticide (EPA Reg. No. 10182-434 1 lb ai/gal) on canola are adequate. Up to three applications can be made at 0.015- 0.030 lb ai/A for a maximum of 0.090 lb ai/A/season. The first application is made as required by scouting and then at 5 day intervals with a PHI of 7 days. Apply by ground or air equipment using sufficient water to ensure adequate coverage with a minimum of 2 gpa by air.

#### Pome Fruit Crop Group

The proposed directions for use of the lambda-cyhalothrin formulation WARRIOR T Insecticide (EPA Reg. No. 10182-434 1 lb ai/gal) on pome fruits (which include apples and pears) are adequate. The first application is to be made as required by scouting. The maximum application rate per treatment is 0.04 lb ai/A applied up to five times at 5 day spray intervals for a maximum of 0.2 lb ai/A/season. The PHI is 21 days. Apply with ground or air equipment with sufficient water to obtain full coverage. Use a minimum of 5 gpa by air.

#### Stone Fruit Crop Group

The proposed directions for use of the lambda-cyhalothrin formulation WARRIOR T Insecticide (EPA Reg. No. 10182-434 1 lb ai/gal) on stone fruits (which include cherries, peaches, and plums) are adequate. The first application is to be made as required by scouting. The maximum application rate per treatment is 0.04 lb ai/A applied up to five times (total of 0.2 lb ai/A/season) with re-treatment intervals of 5 days and a PHI of 14 days. Apply with ground or air equipment with sufficient water to obtain full coverage. Use a minimum of 5 gpa by air. Do not apply more than 0.16 lb ai/A post bloom.

#### Tree Nuts Crop Group

The proposed directions for use of the lambda-cyhalothrin formulation WARRIOR T Insecticide (EPA Reg. No. 10182-434 1 lb ai/gal) on tree nuts are adequate. The first application is to be made as required by scouting. The maximum application rate per treatment is 0.04 lb ai/A applied up to four times (total of 0.16 lb ai/A/season) with re-treatment intervals of 5 days and a PHI of 14 days. Apply with ground or air equipment with sufficient water to obtain full coverage. Use a minimum of 5 gpa by air. Do not apply more than 0.12 lb ai/A post bloom.

Tobacco

The proposed directions for use of the lambda-cyhalothrin formulation WARRIOR T Insecticide (EPA Reg. No. 10182-434 1 lb ai/gal) on tobacco are adequate. The first application is to be made as required by scouting. The maximum application rate per treatment is 0.03 lb ai/A applied up to three times (total of 0.09 lb ai/A/season) with re-treatment intervals of 7 days and a PHI of 40 days. Apply with ground or air equipment with sufficient water to obtain full coverage. Use a minimum of 2 gpa by air.

**OPPTS GLN 860.1300: Nature of the Residue - Plants**

No new studies were submitted with this application. Based on metabolism studies conducted on cotton, cabbage, soybeans and wheat, the nature of the residue in plants is adequately understood (PP#7F3560/7H5543, M. Flood, 1/22/92). Lambda-cyhalothrin is metabolized by cleavage of the ester linkage to form cyclopropanecarboxylic acids and the corresponding phenoxybenzoic acids or alcohols. In most cases the parent compound is the principal constituent of the residue. However, in the cabbage metabolism study the cis- and trans- cyclopropanecarboxylic acids were the major constituents. 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 (Lambda-cyhalothrin SF, Memo from P. Hurley to M. Flood, 1/3/92). The residue to be regulated is lambda-cyhalothrin and its epimer R157836 (Lambda-cyhalothrin SF, G. Kramer, 2/9/96) (see PP#5F04588, DP Barcode: D219683, L. Kutney, 8/26/96).

**OPPTS GLN 860.1300: Nature of the Residue - Livestock**

No new studies were submitted with this application. Studies of lambda-cyhalothrin metabolism in ruminants and poultry have been reviewed. Lambda-cyhalothrin is the major component of the residue in animals, except for kidney and liver of ruminants and liver of poultry, where, 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 R157836. 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). CBTS decided earlier not to require further animal metabolism data to support uses for lambda-cyhalothrin on alfalfa, lettuce or the Brassica crop group (summarized in PP#5F04588, DP Barcode: D219683, L. Kutney, 8/26/96).



**OPPTS GLN 860.1340: Analytical Methods - Plants**

Adequate enforcement methods are available for determination of lambda-cyhalothrin residues in plant commodities. ICI Method 81 (MRID#40054001) has been validated as an adequate enforcement method by EPA for determination of parent lambda-cyhalothrin and its epimer in/on plant matrices (PP#5F04588, DP Barcode: D219683, L. Kutney, 8/26/96). This method involves acetone:hexane 1:1 (v/v) extraction, followed by liquid-liquid chromatography to remove lipids and florisil column cleanup. Quantification is by GC/ECD and the method LOQ is 0.01 ppm for both lambda-cyhalothrin and its enantiomer R157836.

The analytical procedure used for all the commodities in this petition was based on methods PPRAM 81 [Sapiets, A. (1984) *Determination of Residues of Cyhalothrin in Crops: A Gas-Liquid Chromatography Method Using an Internal Standard*; ICI Plant Protection Division Report PPRAM81] and PPRAM 70 [Sapiets, A. (1983) *The Determination of Residues of PP321 in Crops: A Gas-Liquid Chromatography Method Using an Internal Standard*; ICI Plant Protection Division Report PPRAM70]. The LOQ was 0.01 ppm for both residues in all matrices except apple juice. For apple juice, a published method (Keith, L. H., C. Warren, J. Deegan, R. A. Libby and G. Wentler (1983) *Principles of Environmental Analysis*, Anal. Chem. 55, 2210–2218) was used to determine an LOQ of 0.001 ppm for both residues and an LOD of 0.0004 ppm for lambda-cyhalothrin and 0.0002 ppm for R157836. With the exception of the LOD for apple juice there was no mention of the LOD for any other commodities in this petition.

For the sample preparation based on the PPRAM 81/PPRAM 70 methods, lambda-cyhalothrin and R157836 are extracted from the sample with a 1:1 (v/v) acetone:hexane mixture. After removing the acetone by partitioning with water, lipids are removed from the extract on an acetonitrile liquid-liquid column. Further cleanup of the extract is accomplished by elution from a Florisil column with diethyl ether/hexane. The eluate from the Florisil column is evaporated to dryness and recovered in a known volume of hexane for analysis by gas chromatography. Quantification is accomplished by either packed column isothermal GC/ECD with an external standard or by programmed temperature capillary GC/ECD (for apple juice). Limited sample chromatograms and calibration information were provided by the analytical laboratory (Zeneca Ag Products at Richmond, CA), but the method is considered well enough established to make the procedure acceptable for all commodities on which it was used. Cyhalothrin (Reference No. N1391) is employed as the external analytical reference standard. This reference standard contains 36.2 % (w/w) lambda-cyhalothrin and 54.1 % (w/w) R157836.

**Method Validation/Concurrent Recoveries**

The petitioner submitted concurrent recovery studies for all crops, with the results (uncorrected) for lambda-cyhalothrin and its epimer R157836 as shown in Table 1. Samples were fortified with 0.003-1.2 ppm lambda cyhalothrin and 0.007-2.3 ppm R157836, which in most cases bracketed the residues found in the magnitude of the residue testing. In the cases where it did not (lambda cyhalothrin in apple, pear, and plum field trials), sufficient data was provided by

similar crops or from the epimer R157836. All tested samples had adequate recoveries, 70-120%, of both lambda-cyhalothrin and R157836 for all matrices with the exception of three at the lowest fortification level in the apple and peach cooking studies (3 of 92 recoveries). Control matrices showing interferences for lambda-cyhalothrin, R157836, or both, were below the LOQ of 0.01 ppm. No corrections to data based on background in the control samples or fortification recoveries were made for any residue found in the samples.

<b>TABLE 1: Validation recoveries of lambda-cyhalothrin and R157836 from samples of various matrices fortified with lambda-cyhalothrin.</b>						
<b>Matrix</b>	<b>Lambda-cyhalothrin</b>			<b>R157836</b>		
	<b>Fortification (ppm)</b>	<b>% Recovery</b>		<b>Fortification (ppm)</b>	<b>% Recovery</b>	
		<b>Value</b>	<b>Crop mean <math>\pm</math>SD</b>		<b>Value</b>	<b>Crop mean <math>\pm</math>SD</b>
Canola -Canada '98	0.007	101	$97 \pm 8.2$	0.013	100	$96 \pm 6.7$
	0.010	98		0.020	93	
	0.017	94		0.033	98	
	0.102	85		0.198	86	
	0.153	107		0.297	103	
Canola -Canada '00	0.007	114	$98 \pm 8.0$	0.013	108	$96 \pm 8.3$
	0.007	97		0.013	85	
	0.007	94		0.013	85	
	0.07	103		0.13	103	
	0.07	100		0.13	101	
	0.07	107		0.13	103	
	0.07	106		0.13	105	
	0.07	93		0.13	92	
	0.07	90		0.13	92	
	0.70	87		1.3	85	
	0.70	91		1.3	92	
Canola -USA	0.003	92,93	$83 \pm 12$	0.007	92,94	$84 \pm 11$
	0.034	70		0.066	70	
	0.17	76		0.33	79	
Processing Study						
Seed	0.17	82,89	$95 \pm 8$	0.33	79,79	$85 \pm 7$
Meal	0.0034	104		0.00659	84	
Refined Oil	0.034	101		0.0659	96	
Apple	0.008	96	$102 \pm 6.8$	0.012	108	$107 \pm 4.2$
	0.020	99		0.030	107	
	0.020	103		0.030	103	
	0.040	100		0.060	103	
	0.100	114		0.150	114	
Apple (processing)	0.100	118	—	0.150	118	—
Wet pomace	0.602	104	—	0.899	104	—
Apple juice	0.007	100	$100 \pm 2$	0.012	100	$95 \pm 3$
	0.007	102		0.013	94	
	0.007	102		0.013	94	
	0.007	98		0.013	94	
	0.008	98		0.013	93	

TABLE 1: Validation recoveries of lambda-cyhalothrin and R157836 from samples of various matrices fortified with lambda-cyhalothrin.						
Matrix	Lambda-cyhalothrin			R157836		
	Fortification (ppm)	% Recovery		Fortification (ppm)	% Recovery	
		Value	Crop mean $\pm$ SD		Value	Crop mean $\pm$ SD
Apples (Cooking)	0.23	73	$93 \pm 22$	0.44	85	$96 \pm 14$
	0.23	71		0.44	94	
	0.68	81		1.3	92	
	0.68	75		1.3	83	
	0.68	76		1.3	82	
	0.17	120		0.033	103	
	0.17	95		0.033	94	
	0.0056	115		0.011	118	
Cooked Apples	0.0056	139	$98 \pm 7$	0.011	122	$99 \pm 4$
	0.017	88		0.033	84	
	0.008	88		0.012	96	
	0.040	98		0.060	98	
Applesauce	0.068	100	$107 \pm 13$	0.120	105	$110 \pm 9$
	0.080	105		0.132	97	
	0.008	94		0.012	105	
	0.080	106		0.120	106	
Pear	0.201	120	$104 \pm 11$	0.300	120	$107 \pm 6$
	0.008	84		0.012	115	
	0.008	110		0.060	103	
	0.040	104		0.120	99	
Cherry	0.201	109	$83 \pm 16$	0.300	109	$92 \pm 16$
	0.401	112		0.599	111	
	0.017	72		0.033	71	
	0.017	48		0.033	75	
Peach	0.017	89	$106 \pm 5$	0.033	100	$103 \pm 2$
	0.017	89		0.033	83	
	0.017	88		0.033	97	
	0.23	67		0.44	91	
Peach (Canning)	0.23	86	$110 \pm 5$	0.44	93	$109 \pm 2$
	0.56	72		1.1	70	
	0.68	87		1.3	88	
	0.0056	78		0.011	97	
Peeled Peach	0.0056	99	$103 \pm 2$	0.011	110	$102 \pm 2$
	0.017	84		0.033	95	
	0.0056	124		0.011	137	
	0.017	89		0.033	91	
Canned Peach	0.017	72	$103 \pm 2$	0.033	78	$103 \pm 2$
	0.008	111		0.012	103	
	0.020	105		0.030	104	
	0.040	101		0.060	101	
Plum	0.008	110	—	0.012	109	—
Plums (processing)	0.080	111	—	0.120	102	—
Prunes						

TABLE 1: Validation recoveries of lambda-cyhalothrin and R157836 from samples of various matrices fortified with lambda-cyhalothrin.						
Matrix	Lambda-cyhalothrin			R157836		
	Fortification (ppm)	% Recovery		Fortification (ppm)	% Recovery	
		Value	Crop mean $\pm$ SD		Value	Crop mean $\pm$ SD
Almond hulls	0.007	95	91 $\pm$ 11	0.013	91	90 $\pm$ 11
	0.34	100		0.66	100	
	0.68	90		1.3	91	
	1.2	77		2.3	76	
Almond nutmeat	0.007	95	93 $\pm$ 7.8	0.013	102	102 $\pm$ 6.4
	0.007	99		0.013	108	
	0.007	85		0.013	95	
Pecan	0.007	86	93 $\pm$ 7.6	0.013	100	98 $\pm$ 3.5
	0.007	100		0.013	100	
	0.007	92		0.013	94	
Tobacco, green	0.007	90	97 $\pm$ 9.9 <sup>1</sup>	0.012	92	88 $\pm$ 3.8 <sup>1</sup>
	0.008	108		0.013	86	
	0.037	92		0.063	85	
Tobacco, cured	0.007	87	89 $\pm$ 2.9 <sup>1</sup>	0.013	79	81 $\pm$ 5.3 <sup>1</sup>
	0.040	92		0.060	87	
	0.073	87		0.127	77	

Data obtained as follows: canola, p. 18, MRID 45032401, p. 43, MRID 45443101, p. 54 MRID 45443103, p. 20 MRID 45443102; apple, p. 18, MRID 45007001; apple processing study, p. 19, MRID 45007002; apple cooking study, p. 52, MRID 45443104; pear, p. 18, MRID 45007003; cherry pp. 46-47, MRID 45007004; peach, pp. 58-61, MRID 45007005 and p. 56, MRID 45443105; plum, pp. 46-48, MRID 45007006; plum processing, pp. 16 and 26, MRID 45007007; almond hulls and nutmeat, p. 19, MRID 45007008; pecan, p. 17, MRID 45007009; tobacco, pp. 15-16, MRID 45007010.

The LOQ was 0.01 ppm for lambda-cyhalothrin and its epimer R157836.

<sup>1</sup>Calculated by reviewer.

#### **OPPTS GLN 860.1340: Analytical Methods - Animals**

Adequate enforcement methods are available for determination of lambda-cyhalothrin residues in animal commodities. ICI Method 86 is used to determine residues of lambda-cyhalothrin in animal matrices (PP#6F3318, M. Firestone, 1/22/86). Parent lambda-cyhalothrin is extracted from milk or animal tissues with 50% acetone:hexane. The aqueous fraction is removed and the organic layer dried with sodium sulfate. Clean-up is accomplished using Florisil column chromatography. Determination is accomplished using packed column gas chromatography and a <sup>63</sup>Ni electron capture detector. The LOQ is 0.01 ppm (PP#7F3488, J. Morales, 11/17/92). ICI Method 86 has been validated by EPA as an adequate enforcement method for determination of parent lambda-cyhalothrin and its epimer in/on animal tissues and milk (PP#6F3318, PP#7F3488, E. Greer, 9/30/87 and PP#6F3318, S. Brooks, 10/30/87).

ICI Method 96, (MRID# 41793501) is used to determine lambda-cyhalothrin metabolites in meat, milk, poultry and eggs. Samples are extracted with acetonitrile:hydrochloric acid or

methanol, the extract is diluted with water, and parent lambda-cyhalothrin is removed on a C<sub>18</sub>-bonded silica cartridge. The eluate is evaporated and refluxed for 4 hours with concentrated hydrochloric acid. The hydrolysate is then partitioned into dichloromethane. For 3-PBAcid and/or 4'-OH-3-PBAcid analyses, the extracts are evaporated, reconstituted in 50% methanol and passed through a C<sub>18</sub> column. The eluate is evaporated and redissolved in dichloromethane. 3-PBAcid is methylated with diazomethane prior to GCMS with selected ion monitoring (SIM). CPA is benzylated with benzyl bromide and purified on a Florisil column prior to GC with an electron capture detector. 4'-OH-3-PBAcid is quantitated using HPLC with electrochemical detection. The LOQ is 0.01 ppm (PP#7F3488, J. Morales, 11/17/92; summarized in PP#5F04588, DP Barcode: D219683, L. Kutney, 8/26/96).

#### **OPPTS GLN 860.1360: Multiresidue Method**

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 11/01, the results had not been listed in FDA Pestrak Files (<http://vm.cfsan.fda.gov/~frf/pestdata.html>). On the basis of the recoveries made, the multiresidue requirement was considered to have been met (PP#5E4431, 43421701, S.H. Willett, 6/3/96).

#### **OPPTS GLN 860.1380: Storage Stability Data - Plants**

No new freezer storage stability studies were submitted with this application. Storage stability data for lambda-cyhalothrin have been previously reviewed. Storage stability data for lambda-cyhalothrin and its epimer indicate that residues are stable in peach, pea, oilseed rape, wheat grain, sugar beet roots, cottonseed, apple, cabbage and potato when stored at -18 °C for periods up to 26 months (PP#1F3952/1H5607, M. Flood, 9/19/91). Storage stability (<-15 °C) data were also previously found to be adequate for alfalfa (up to 956 days) and lettuce (up to 720 days) (PP#5F04588; DP code D219683, L. Kutney, 8/26/96). Cabbage, apples, and soil were also shown to be stable frozen for up to 16 months (ICI Plant Protection Division Report No. M4773B, 1988, Burke, S and A. Sapiets). Processed commodities (flour, starch, apple dry pomace, refined oil, and soapstock) were stable frozen at <-15 °C for up to 32 months (Zeneca Ag Products Report No. RR 93-080B, 1993, C.L. Eckstein).

In the presently submitted studies, crops and their maximum frozen storage period were: canola (339 days), apples (253 days), apple juice (557 days), apple pomace, wet (214 days), pear (598 days), cherry (244 days), peach (275 days), plum and prune (228 days), unshelled almonds and almond hulls (202-269 days), pecans (151-197 days) and tobacco (143-217 days). Therefore, the existing storage stability database is adequate to support the residue data for the crops under consideration for the present petition.

**OPPTS GLN 860.1380: Storage Stability Data - Animals**

No new studies were submitted with this application, and the reviewer was unable to find any information on earlier such studies. Additional information is not required for this action.

**OPPTS GLN 860.1500: Crop Field Trials****Canola - Canada 1998**

Zeneca Ag Products has submitted data from 6 canola field trials conducted in Canada in 1998 to obtain an amendment to the registration for lambda-cyhalothrin use on canola in Canada. Zeneca also wished to support the petition for a lambda-cyhalothrin tolerance on canola grown in the United States. The lambda-cyhalothrin was applied as the 120EC (emulsifiable concentrate) formulation KARATE Insecticide (GFU383C; 1 lb ai/gal). Field trials were conducted in three Canadian provinces at 6 sites: Alberta (Airdrie, Claresholm), Manitoba (Oak Bluff, Arborg), and Saskatchewan (Neuhorst, Waldheim). The results are reported in:

MRID 45032401. Miller, M.M. and R. McDonnell (1999) Lambda-cyhalothrin: residue levels on canola from trials conducted in Canada during 1998. Zeneca Ag Products, Richmond, CA. Report No. RR 99-059B. November 3, 1999. Unpublished.

Canola plants were grown under typical Canadian climatic conditions and agricultural practices. Each trial included four plots: plot 1 was an untreated control; plots 2 and 3 were treated three times with a broadcast foliar spray of 0.009 lb ai/A (total of 0.027 lb ai/A/season; 1X maximal application rate for the Canadian petition); and plot 4 was treated three times with 0.030 lb ai/A (total of 0.090 lb ai/A/season; 1X maximal application rate for the U.S. petition). Exceptions to the treatment rates, as shown in Table 2, were the two Alberta trials (plots 2 and 3: 0.010 lb ai/A, 1.11X Canadian rate; plot 4: 0.020 lb ai/A, 0.66X U.S. rate) and one Saskatchewan trial (plots 2 and 3: 0.008 lb ai/A, 0.89X Canadian rate; plot 4: 0.028 lb ai/A, 0.93X U.S. rate). For each trial, the first application was 18-19 days prior to harvest, and the second and third treatments were at 5-7 day intervals. The PHI was 6-7 days. The insecticide was applied three times as a foliar broadcast spray in approximately 10.7 gal/A using a CO<sub>2</sub>-pressurized hand-held boom. One sample was collected from plots 1, 2 and 3, and two samples from plot 4 using a combine and followed by manual sieving to remove excess chaff. Samples were frozen within 3 hours of collection and kept frozen during shipment to the analytical laboratory (Western Research Center, Zeneca Ag Products, Richmond, CA) and thereafter until analysis (-18 ± 5 °C). Samples were ground to homogeneity with dry ice using a Retsch Centrifugal Mill and/or Hobart VC25 chopper, extracted, and analyzed for lambda-cyhalothrin and its epimer R157836 using methods based on PPRAM 70 and PPRAM 81. Samples were analyzed within 34 days of extraction. The method LOQ was 0.01 ppm.

Residue levels of lambda-cyhalothrin in/on canola were <0.01–0.13 ppm and residues of its epimer R157836 were <0.01 ppm for all but three samples, for a total of ~0.02-0.14 ppm. All

untreated control samples were below the LOQ of 0.01 ppm for both residues. The results of the 1998 field trials conducted in Canada and the storage stability and method validation data support the proposed tolerance of 0.15 ppm for use of lambda-cyhalothrin on canola imported from Canada. Field trial data for canola are summarized in Table 2. A residue decline trial was not conducted. Residue decline studies with tobacco and peaches indicated that residues do not increase with time.

#### Canola - Canada 2000

Zeneca Ag Products through its subsidiary Syngenta Crop Protection, Inc. has submitted data from 10 canola field trials conducted in Canada in 2000 to support the registration for lambda-cyhalothrin use on canola in Canada. The lambda-cyhalothrin was applied as the WARRIOR T Insecticide(1 lb ai/gal, capsule suspension, WF2773) formulation. Field trials were conducted in three Canadian provinces at 10 sites: Alberta (Leduc, Wetaskiwin, Lecombe), Manitoba (Brookdale, Brandon (2)), and Saskatchewan (Dundurn, Rosthern, Wakaw, Saskatoon). The results are reported in:

MRID 45443102. Schwab, D., Anderson, C., Niekamp, J. (20019) Lambda-Cyhalothrin: Residue Levels on Canola from Trials Conducted in Canada during 2000. Syngenta Crop Protection, Inc., Richmond, CA. Report No. RR 00-075B. June 1, 2001. Unpublished.

Canola plants were grown under typical Canadian climatic conditions and agricultural practices. Each trial included four plots: plot 1 was an untreated control; plots 2 and 3 were treated three times with a broadcast foliar spray of 0.009 lb ai/A (total of 0.027 lb ai/A/season; 1X maximal application rate for the Canadian petition); and plot 4 was treated three times with 0.030 lb ai/A (total of 0.090 lb ai/A/season; 1X maximal application rate for the U.S. petition). For each trial, the first application was 19-21 days prior to harvest, and the second and third treatments were at 5-7 day intervals. The PHI was 6-9 days. The insecticide was applied three times as a foliar broadcast spray in approximately 8-13 gal/A using commercial equipment or simulated commercial sprayers. One 0.5 lb sample was collected from each plot by hand or combine. Samples were frozen within 4.5 hours of collection and kept frozen during shipment to the analytical laboratory (ABC Laboratories, Inc., Columbia, MO) and thereafter until analysis ( $-18 \pm 10$  °C). Samples were ground to homogeneity with dry ice using a Robot Coupe Vertical Batch Processor and/or Stephan Cutter/Mixer chopper, extracted, and analyzed for lambda-cyhalothrin and its epimer R157836 using methods based on PPRAM 70 and CCRL-MTH-022. Samples were analyzed within 25 days of extraction. The method LOQ was 0.01 ppm.

Residue levels of lambda-cyhalothrin in/on canola were <0.01–0.69 ppm and residues of its epimer R157836 were <0.01-0.06 ppm. All untreated control samples were below the LOQ of 0.01 ppm for both residues. The results of the 2000 field trials conducted in Canada and the storage stability and method validation data indicate the proposed tolerance of 0.15 ppm for use of lambda-cyhalothrin on canola imported from Canada is too low. Field trial data for canola are summarized in Table 2.

Canola - USA

Zeneca Ag Products has submitted data from 7 canola field trials conducted in the US in 1999 to obtain an amendment to the registration for domestic use of lambda-cyhalothrin on canola. The lambda-cyhalothrin was applied as the 120EC (emulsifiable concentrate) formulation KARATE Insecticide (GFU383C; 1 lb ai/gal). Field trials were conducted in six states at 7 sites: Georgia and North Carolina (Region 2), Minnesota and North Dakota (Region 5), and Idaho (2-trials) and Washington (Region 11). The results are reported in:

MRID 45443101. Miller, M.M. (2000) Lambda-Cyhalothrin: Residue Levels on Canola from Trials Conducted in the United States during 1999. Zeneca Ag Products, Richmond, CA. Report No. RR 00-038B. June 6, 2000. Unpublished.

Canola plants were grown under typical regional climatic conditions and agricultural practices. Each trial included two plots: plot 1 was an untreated control; plot 2 was treated three times with a broadcast foliar spray of 0.03 lb ai/A (total of 0.09 lb ai/A/season; 1X maximal application rate). For each trial, the first application was 17-21 days prior to harvest, and the second and third treatments were at 5-7 day intervals. The PHI was 5-7 days. The insecticide was applied three times as a foliar broadcast spray in approximately 9-19 gal/A using a CO<sub>2</sub>-pressurized hand-held boom or tractor mounted boom. One sample was collected from plot 1 and duplicate samples were from collected plot 2 using a combine and followed by sieving to remove excess chaff. With the exception of the Bonners Ferry, WA trial, samples were frozen within 2.5 hours of collection. The Bonners Ferry, WA samples were retained on dry ice for 36 hours. All samples were shipped frozen or on dry ice to the processing facility (Western Research Center, Zeneca Ag Products, Richmond, CA) and thereafter until analysis ( $-18 \pm 5$  °C). Samples were ground to homogeneity with dry ice using a Retsch Centrifugal Mill and/or Hobart VC25 chopper. Frozen samples were shipped to the Central California Research Laboratory, Inc. (CCRL), Fresno, CA for analysis. Samples were extracted, and analyzed for lambda-cyhalothrin and its epimer R157836 using methods based on PPRAM 70 and PPRAM 81. Samples were analyzed within 5-7 months from the time of collection. The method LOQ was 0.01 ppm.

Residue levels of lambda-cyhalothrin in/on canola were <0.01–0.07 ppm and residues of its epimer R157836 were <0.01 ppm for all but three samples, for a total of ~0.02-0.12 ppm. All untreated control samples were below the LOQ of 0.01 ppm for both residues. The results of the U.S. field trials, the storage stability, and method validation data support the proposed tolerance of 0.15 ppm for use of lambda-cyhalothrin on canola. Field trial data for canola are summarized in Table 2.



TABLE 2: Residues of lambda-cyhalothrin and its epimer R157836 in/on canola following 3 broadcast foliar applications of KARATE at a rate of 0.009-0.030 lb ai/A for a seasonal total of 0.027-0.090 lb ai/A.						
Test location in Canada	Plot no.	Application rate (lb ai/A) [total/season]	PHI (days)	Residue levels (ppm) (uncorrected) <sup>1</sup>		
				lambda-cyhalothrin	R157836	Total <sup>2</sup>
Canada 1998						
Airdrie, Alberta	2, 3 4, 4	0.010 [0.030] 0.020 [0.059]	7	0.06, 0.07 0.13, 0.11, 0.12	<0.01, <0.01 0.01, 0.01, 0.01	<0.07, <0.08 0.14, 0.12, 0.13
Claresholm, Alberta	2, 3 4, 4	0.010 [0.030] 0.020 [0.059]	7	0.03, <0.01 0.02, 0.02, 0.02	<0.01, <0.01 <0.01, <0.01, <0.01	<0.04, <0.02 <0.03, <0.03, <0.03
Oak Bluff, Manitoba	2, 3 4, 4	0.009 [0.027] 0.030 [0.090]	6	<0.01, <0.01 0.01, 0.01, 0.01	<0.01, <0.01 <0.01, <0.01, <0.01	<0.02, <0.02 <0.02, <0.02, <0.02
Arborg, Manitoba	2, 3 4, 4	0.009 [0.027] 0.030 [0.090]	7	<0.01, <0.01 <0.01, <0.01, <0.01	<0.01, <0.01 <0.01, <0.01, <0.01	<0.02, <0.02 <0.02, <0.02, <0.02
Neuhorst, Saskatchewan	2, 3 4, 4	0.008 [0.024] 0.028 [0.084]	7	<0.01, <0.01 0.02, 0.02, 0.02	<0.01, <0.01 <0.01, <0.01, <0.01	<0.02, <0.02 <0.03, <0.03, <0.03
Waldheim, Saskatchewan	2, 3 4, 4	0.009 [0.027] 0.030 [0.090]	7	<0.01, <0.01 0.02, 0.01	<0.01, <0.01 <0.01, <0.01	<0.02, <0.02 0.03, 0.02
Canada 2000						
Dunden, Saskatchewan	2 3 4	0.009 [0.027] 0.009 [0.027] 0.030 [0.090]	7	0.08, 0.07 0.03 0.09	<0.01, <0.01 <0.01 <0.01	0.09, 0.08 0.04 0.10
Leduc, Alberta	2, 3 4	0.009 [0.027] 0.030 [0.090]	7	0.04, 0.04 0.14	<0.01, <0.01 0.01	0.05, 0.05 0.15
Wetaskiwin, Alberta	2, 3 4	0.009 [0.027] 0.030 [0.090]	7	0.02, 0.08 0.19	<0.01, <0.01 0.02	0.03, 0.09 0.21
Labombe, Alberta	2, 3 4	0.009 [0.027] 0.030 [0.090]	7	0.04, 0.03 0.09	<0.01, <0.01 <0.01	0.04, 0.03 0.10
Rosthern, Saskatchewan	2 3 4	0.009 [0.027] 0.009 [0.027] 0.030 [0.090]	7	0.03, 0.03 0.02 0.08	<0.01, <0.01 <0.01 <0.01	0.04, 0.04 0.03 0.09
Wakaw, Saskatchewan	2, 3 4	0.009 [0.027] 0.030 [0.090]	7	0.10, 0.06 0.14	<0.01, <0.01 0.01	0.11, 0.07 0.15
Saskatoon, Saskatchewan	2 3 4	0.009 [0.027] 0.009 [0.027] 0.030 [0.090]	7	0.07, 0.08 0.07 0.49	<0.01 <0.01 0.03	0.08, 0.09 0.08 0.52
Brookdale, Manitoba	2, 3 4	0.009 [0.027] 0.030 [0.090]	7	0.11, 0.07 0.54	0.01, 0.01 0.05	0.12, 0.07 0.59

TABLE 2: Residues of lambda-cyhalothrin and its epimer R157836 in/on canola following 3 broadcast foliar applications of KARATE at a rate of 0.009-0.030 lb ai/A for a seasonal total of 0.027-0.090 lb ai/A.						
Test location in Canada	Plot no.	Application rate (lb ai/A) [total/season]	PHI (days)	Residue levels (ppm) (uncorrected) <sup>1</sup>		
				lambda-cyhalothrin	R157836	Total <sup>2</sup>
Brandon, Manitoba	2	0.009 [0.027]	9	0.15, 0.20	0.01, 0.02	0.16, 0.22
	3	0.009 [0.027]		0.20	0.02	0.22
	4	0.030 [0.090]		0.69	0.06	0.75
Brandon (2), Manitoba	2, 3	0.009 [0.027]	7	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
	4	0.030 [0.090]		0.03	<0.01	0.04
US 1999						
Girard, Georgia	2	0.030 [0.090]	5	<0.01, 0.01 <0.01	<0.01, <0.01 <0.01	<0.02, 0.02 < 0.02
Whitakers, North Carolina	2	0.030 [0.090]	7	<0.01 <0.01	<0.01 <0.01	<0.02 < 0.02
Campbell, Minnesota	2	0.030 [0.090]	7	<0.01 <0.01, <0.01	<0.01 <0.01, <0.01	<0.02 < 0.02, <0.02
West Fargo, North Dakota	2	0.030 [0.090]	7	<0.01 <0.01	<0.01 <0.01	<0.02 < 0.02
Walla Walla, Washington	2	0.030 [0.090]	7	0.05, 0.05 0.04	<0.01 <0.01, 0.01	0.06, 0.06 0.05, 0.05
Dayton, Idaho	2	0.030 [0.090]	7	0.04, 0.05 0.07	0.04, 0.04 0.05	0.08, 0.09 0.12
Bonnars Ferry, Idaho	2	0.030 [0.090]	7	0.02 0.01	<0.01 <0.01	0.03 0.02

Data from pp. 10-11, 14, and 19-20 of MRID 45032401, pp 13 of MRID 45443101, and pp. 8 of MRID 45443102. The LOQ was 0.01 ppm for lambda-cyhalothrin and its epimer R157836.

<sup>1</sup>One sample was collected from plots 2 and 3 and two samples were collected from plot 4. Duplicate analyses were performed on some plot 4 samples.

<sup>2</sup>Calculated by reviewer.

**Conclusions:** The results of the Canadian and domestic field trials, storage stability, and method validation data indicate that the proposed tolerance of 0.15 ppm on canola is too low for the proposed U.S. use pattern. **The registrant should submit a revised Section F proposing a tolerance for lambda-cyhalothrin and its epimer R157836 on canola at 1.0 ppm.**

## Pome fruit

Zeneca Ag Products has submitted data from 18 field trials on apples (12 trials) and pears (6 trials) as representative crops to support a permanent tolerance for lambda-cyhalothrin on pome fruit (Crop Group 11). Lambda-cyhalothrin was applied as the capsule suspension formulation KARATE/WARRIOR 2.09 CS (2.09 lb ai/gal).

**Apples.** Data from 12 apple field trials were submitted by the petitioner. The field trials were conducted in 1997 in EPA Region 1 (NY, 2 trials; PA 1 trial), Region 2 (NC), Region 5 (MI, 2 trials), Region 9 (CO), Region 10 (CA), and Region 11 (4 trials). The results are reported in:

MRID 45007001. Spiller, C.J. and Kahn, B.B.(1999) Lambda-cyhalothrin: Residue levels on apples from trials conducted in the United States during 1997. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR98-068B. April 7, 1999.

Each trial consisted of one untreated control plot and one or two treated plots. The lambda-cyhalothrin formulation KARATE/WARRIOR 2.09 CS was diluted in water and applied to the trees five times as a foliar broadcast spray of 0.04 lb ai/A, for a total of 0.20 lb ai/A/season (1X proposed rate). The trees received either low volume applications (50-73 gpa) or high volume applications (219-243 gpa) with tractor-driven air blast spray equipment. The first application was applied dormant to pre-bloom, the second was applied 35-42 days before harvest, and the third through fifth applications were made at 5-7 day intervals. The PHI was 20-21 days (versus 21 days proposed). One sample (24 apples;  $\geq 5$  lbs) was taken from each control plot and 2 independent samples were collected from each treated plot. Within 3 hours of collection, samples were frozen (-18 °C) and maintained frozen during transport to the analytical laboratory (Western Research Center, Richmond, CA) and prior to preparation and analysis. Homogeneous samples were prepared by chopping the whole fruit in a Hobart VCM chopper with dry ice. Samples were analyzed for lambda-cyhalothrin and R157836 using methods based on PPRAM 81 (ICI Method 81) and PPRAM 70.

Results for the field trials on apples are shown in Table 3. Residue levels of lambda-cyhalothrin were 0.02-0.23 ppm and of R157836 were <0.01-0.02 ppm, for a total of ~0.03-0.25 ppm. The highest residues (total of 0.15-0.25 ppm) were found in the two field trials in Lawsonville, NC. All untreated control samples were below the LOQ of 0.01 ppm. The number of field trials and the residue, storage stability, and method validation data support the proposed lambda-cyhalothrin tolerance of 0.30 ppm on the pome fruit crop group. Geographic distribution of the 12 field trials followed OPPTS guidelines for apples as part of a crop group: three trials were conducted in EPA Crop Region 1, one trial in each of Regions 2, 9, and 10, two trials in Region 5, and four trials in Region 11.

TABLE 3: Residues of lambda-cyhalothrin and its epimer R157836 in/on apples following 5 foliar applications of KARATE/WARRIOR 2.09 CS at a rate of 0.04lb ai/A for a seasonal total of 0.20 lb ai/A.						
Test location: Nearest city, state (EPA crop region)	Spray volume (gpa)	Apple variety	PHI (days)	Residue levels (ppm) (uncorrected)		
				lambda- cyhalothrin	epimer R157836	Total <sup>1</sup>
Sodus Township, NY (1)	Low (60)	Northern Spy	20	0.06	< 0.01	< 0.07
			20	0.06	< 0.01	< 0.07
Dundee, NY (1)	Low (60)	McIntosh	20	0.09	< 0.01	0.10
			20	0.08	< 0.01	0.09
Conklin, MI (5)	Low (55-61)	Empire	20	0.10	0.01	0.11
			20	0.10	0.01	0.11
Hereford, PA (1)	High (219-238)	Red Delicious	21	0.09	< 0.01	0.10
			21	0.10	< 0.01	0.11
Hart, MI (5)	High (220-228)	McIntosh	20	0.07	< 0.01	0.08
			20	0.09	< 0.01	0.10
Ephrata, WA (11)	High (223-226)	Classic	21	0.10	< 0.01	0.11
			21	0.08	< 0.01	0.09
White Salmon, WA (11)	High (238-243)	Red Delicious	21	0.07	< 0.01	0.08
			21	0.06	< 0.01	0.07
Lawsonville, NC (2)	Low (59-63)	Red Delicious	21	0.22, 0.23 <sup>2</sup>	0.02, 0.02 <sup>2</sup>	0.24, 0.25 <sup>2</sup>
	High (224-233)		21	0.14	0.01	0.15
Eckert, CO (9)	Low (60)	Red Delicious	21	0.03	< 0.01	0.04
	High (224-228)		21	0.05	< 0.01	0.06
Visalia, CA (10)	Low (59-60)	Golden Delicious	20	0.11	0.01	0.12
	High (232-235)		20	0.06	< 0.01	0.07
Yakima, WA (11)	Low (69-73)	Red Delicious	21	0.04	< 0.01	0.05
			21	0.02	< 0.01	0.03
Granger, WA (11)	Low (50)	Rome	21	0.10	< 0.01	0.11
			21	0.06	< 0.01	0.07

Data from pp 19-20 and 23-24 of MRID 45007001.

The LOQ is 0.01 ppm for both lambda-cyhalothrin and R157836.

<sup>1</sup>Total residues were calculated by the reviewer.

<sup>2</sup>Duplicate analyses were conducted of one sample.

**Pears.** Data from 6 pear field trials were submitted by the petitioner. The field trials were conducted in 1997 in EPA Region 1 (NY), Region 10 (two trials in CA), and Region 11 (two trials in WA, one in OR). The results are reported in:

MRID 45007003. Spiller, C.J. and Kahn, B.B.(1999) Lambda-cyhalothrin: Residue levels on pears from trials conducted in the United States during 1997. Zeneca Ag

Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610.  
Report No. RR98-072B. May 6, 1999.

Each trial consisted of one untreated control plot and one or two treated plots. The lambda-cyhalothrin formulation KARATE/WARRIOR 2.09CS, was diluted in water and applied to the trees 5 times as a foliar broadcast spray of 0.04 lb ai/A, for a total of 0.20 lb ai/A/season (1X proposed rate). The trees received either low volume applications (50-66 gpa) or high volume applications (136-240 gpa) with tractor-driven air blast spray equipment. The first application was at the dormant to pre-bloom stage, the second was 38-41 days before harvest, and the third through fifth applications followed at 5-7 day intervals. The PHI was 20-21 days (versus 21 days proposed). Pear samples (24 pears;  $\geq 5$  lbs) were collected from the plots, frozen within one hour, shipped to the processing site, homogenized, and analyzed for lambda-cyhalothrin in the same way as apples.

Results for the field trials on pears are shown in Table 4. Residue levels of lambda-cyhalothrin and R157836 on pears were, respectively, 0.04-0.10 ppm, and  $<0.01$  ppm for a total of 0.05-0.11 ppm. All untreated control samples were below the LOQ of 0.01 ppm. Geographic distribution of the 6 field trials followed OPPTS guidelines for pears as part of a crop group: one trial was conducted in EPA Crop Region 1, two trials were in Region 10, and three were in Region 11. The number of field trials and the residue, storage stability, and method validation data support the proposed lambda-cyhalothrin tolerance of 0.30 ppm on the pome fruit crop group.

<b>TABLE 4: Residues of lambda-cyhalothrin and its epimer R157836 in/on pears following 5 foliar applications of KARATE/WARRIOR 2.09CS at a rate of 0.04 lb ai/A for a seasonal total of 0.20 lb ai/A.</b>						
<b>Test location: Nearest city, state (EPA crop region)</b>	<b>Spray volume (gpa)</b>	<b>Crop variety</b>	<b>PHI (days)</b>	<b>Residue levels (ppm) (uncorrected)</b>		
				<b>lambda- cyhalothrin</b>	<b>epimer R157836</b>	<b>Total<sup>1</sup></b>
Visalia, CA (8)	Low (58-66)	Monterrey	20	0.05	$< 0.01$	0.06
			20	0.06	$< 0.01$	0.07
White Salmon, WA (11)	Low (55-60)	Bartlett	20	0.08	$< 0.01$	0.09
			20	0.09, 0.10 <sup>2</sup>	$< 0.01$ , $< 0.01$ <sup>2</sup>	0.10, 0.11 <sup>2</sup>
Buena, WA (11)	Low (50)	Bartlett	20	0.09	$< 0.01$	0.10
			20	0.09	$< 0.01$	0.10
Fairfield, CA (10)	High (136-240)	Bartlett	20	0.04	$< 0.01$	0.05
			20	0.05	$< 0.01$	0.06
Hood river, OR (11)	High (214-223)	Bosc	21	0.09	$< 0.01$	0.10
			21	0.09, 0.10 <sup>2</sup>	$< 0.01$ , $< 0.01$ <sup>2</sup>	0.10, 0.11 <sup>2</sup>
Sodus Township, NY (1)	Low (60-61)	Bartlett	20	0.05	$< 0.01$	0.06
	High (220-222)		20	0.07	$< 0.01$	0.08

Data from pp. 18 and 21 of MRID 45007003.

The LOQ is 0.01 ppm for both lambda-cyhalothrin and R157836.

<sup>1</sup>Total residues were calculated by the reviewer.

<sup>2</sup>Duplicate analyses were conducted of one sample.

**Conclusions:** The petitioner has requested a permanent tolerance of 0.30 ppm for use of the lambda-cyhalothrin on pome fruit (Crop Group 11). In the submitted field trials, residue levels of lambda-cyhalothrin + R157836 in/or apples were ~0.03-0.25 ppm and on pears were ~0.05-0.11 ppm. The number of field trials and their geographic distribution were adequate for apples and pears, which are the representative crops for the pome fruit crop group (Group 11). The residue, storage stability, and method validation data support the proposed lambda-cyhalothrin tolerance of 0.30 ppm on the pome fruit crop group. Residue decline trials were not conducted but decline studies with tobacco and peaches indicated that residues do not increase with time.

### Stone Fruit

Zeneca Ag Products has submitted data from 9 field trials on sweet cherries, 12 field trials on peaches (including a residue decline study), 9 field trials on plums, and one plum processing study to support a permanent tolerance for lambda-cyhalothrin on stone fruit (Crop Group 12). The trials were conducted in 1997 using the lambda-cyhalothrin capsule suspension formulation KARATE/WARRIOR 2.09CS (2.09 lb ai/gal).

All trials included one untreated control plot and one or two treated plots. Lambda-cyhalothrin (formulated as a capsule suspension, KARATE/WARRIOR 2.09CS, WF2471) was applied 5 times as a foliar broadcast spray using either a backpack mist sprayer or a tractor-driven air blast sprayer at the rate of 0.04 lb ai/A, for a seasonal total application of 0.2 lb ai/A (1X proposed rate). The re-treatment interval was 4–10 days and the PHI was 13-14 days (versus 14 days proposed). The first application was made during the dormant to pre-bloom stage; the second application was made 28-35 days prior to harvest; the 3<sup>rd</sup>, 4<sup>th</sup>, and 5<sup>th</sup> applications were made at 4-10 day intervals after the second application. Spray was made by diluting the formulated product with water was applied using either low volume (50-73 gpa) or high volume (121-249 gpa) sprays. A single sample was collected from untreated plots; two samples were collected from treated plots in trials where there was only one treated plot; one sample was collected from each treated plot in trials that had two treated plots. The fruit was stored in a freezer within 4.5 hours after collection, and was shipped frozen to the analytical laboratory at Zeneca, Inc. (Richmond, CA) where it was stored at  $-18 \pm 5$  °C until extraction and analysis. The samples were homogenized by blending the entire fruit (with pits removed) in a Hobart VCM-40 chopper with dry ice. Within 1-4 days of extraction, the samples were analyzed for lambda-cyhalothrin and its epimer R157836 by the GC/ECD method (based on PPRAM81/PPRAM70) described in Section OPPTS GLN 860.1340: Analytical Methods - Plants.

**Cherries.** Data from 9 sweet cherry field trials were submitted by the petitioner. The field trials were conducted in 1997 in EPA Region 5 (4 trials in MI), Region 10 (two trials in CA), and Region 11 (one trial in WA, two in OR). The results are reported in:

MRID 45007004. Spillner, C. J., B. V. Thomas, and B. B. Kahn (1999) Lambda-cyhalothrin: Residue levels in sweet cherries from trials conducted in the United States in 1997. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 98-060B. January 14, 1999. Unpublished.

The results from the field trials of sweet cherries are summarized in Table 5. Samples for sweet cherries weighed at least 3 lbs. Residue levels of lambda-cyhalothrin in/on sweet cherries were 0.04–0.18 ppm, and residue levels of R157836 were <0.01–0.02 ppm for a total of ~0.05–0.20 ppm. The highest residues occurred in the two trials in Oregon. All control samples were below the LOQ of 0.01 ppm for lambda-cyhalothrin and for R157836. Geographic distribution of the 9 field trials followed OPPTS guidelines for sweet cherries as part of a crop group (2 trials were required in each of Regions 5, 10, and 11). The number of field trials and the residue, storage stability, and method validation data support the proposed lambda-cyhalothrin tolerance of 0.50 ppm for the stone fruit crop group (Group 12).

Table 5: Residues of lambda-cyhalothrin and R157836 in/on sweet cherries treated with 5 foliar applications of KARATE/WARRIOR 2.09CS at a rate of 0.04 lb ai/A (0.20 lb ai/A/season).						
Test Location: city, state (EPA Region)	Application Volume (gpa)	Crop variety	PHI (days)	Residue Levels (ppm) (uncorrected)		
				Lambda- Cyhalothrin	R157836	Total <sup>1</sup>
Hart, MI (5)	Low (63-66)	Ulster	13	0.07	<0.01	0.08
			13	0.04	<0.01	0.05
Coopersville, MI (5)	Low (68-71)	Heidel- fingen	13	0.07	<0.01	0.08
			13	0.05	<0.01	0.06
Hughson, CA (10)	Low (70-71)	Bing	14	0.11	0.01	0.12
			14	0.11	0.01	0.12
Yakima, WA (11)	Low (70-71)	Bing	14	0.08	<0.01	0.09
			14	0.09	<0.01	0.10
Hart, MI (5)	High (230-237)	Gold	13	0.16	0.01	0.17
			13	0.16	0.01	0.17
Ada, MI (5)	High (217-231)	Sam's	13	0.14	0.01	0.15
			13	0.12	<0.01	0.13
Fairfield, CA (10)	High (121-233) <sup>2</sup>	Bing	13	0.05	<0.01	0.06
			13	0.05	<0.01	0.06
Parkdale, OR (11)	Low (57-68)	Lambert	13	0.12	0.01	0.13
			13	0.18	0.02	0.20
Salem, OR (12)	Low (56-60 )	Van	13	0.15,	0.02	0.17
	High (203-221)		13	0.17, 0.18 <sup>3</sup>	0.02, 0.02 <sup>3</sup>	0.19, 0.20 <sup>3</sup>

Data from pp. 7-9, 12, 19, 32-34, 46 and 47 of MRID 45007004.

The LOQ was 0.01 ppm for both lambda-cyhalothrin and R157836.

<sup>1</sup>Total residues were calculated by the reviewer.

<sup>2</sup>The first application was made at 121 gpa and the 4 subsequent applications were 233 gpa.

<sup>3</sup>Duplicate analyses were conducted of one sample.

**Peaches.** Data from 12 peach field trials were submitted by the petitioner. The field trials were conducted in 1997 in EPA Region 1 (two in PA), Region 2 (two in GA, one in SC, NC), Region 5 (MI), Region 6 (TX), and Region 10 (three in CA, one in AZ). The results are reported in:

MRID 45007005. Spillner, C. J., R. J. Bussey, and B. B. Kahn (1998) Lambda-cyhalothrin: Residue levels on peaches from trials conducted in the United States during 1997. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 98-062B. December 14, 1998. Unpublished.

The results from the 12 peach field trials are summarized in Table 6. Samples for peaches consisted  $\geq$  24 peaches (4-11.5 lbs) taken by hand from at least four trees. Residue levels of lambda-cyhalothrin in/on peaches were 0.01–0.38 ppm, and residue levels of R157836 were <0.01–0.03 ppm for a total of ~0.02-0.41 ppm. All control samples were below the LOQ of 0.01 ppm for lambda-cyhalothrin and for R157836. Geographic distribution of the 12 field trials followed OPPTS guidelines for peaches as part of a crop group (3 trials were required in Regions 2 and 10, and one trial in Regions 1, 5, and 6). The number of field trials and the residue, storage stability, and method validation data support the proposed lambda-cyhalothrin tolerance of 0.50 ppm for the stone fruit crop group (Group 12).

Table 6: Residues of lambda-cyhalothrin and R157836 in/on peaches treated with 5 foliar applications of KARATE/WARRIOR 2.09CS at a rate of 0.04 lb ai/A (0.20 lb ai/A/season).						
Test Location: city, state (EPA Region)	Application Volume (gpa)	Variety	PHI (days)	Residue Levels (ppm) (uncorrected)		
				Lambda- Cyhalothrin	R157836	Total <sup>1</sup>
Hereford, PA (1)	Low (72-73)	Glo- haven	14	0.06	<0.01	0.07
			14	0.08	<0.01	0.09
Winterville, GA (2)	Low (58)	Winblo	13	0.11	<0.01	0.12
			13	0.07	<0.01	0.08
Visalia, CA (10)	Low (58-61)	O'Henry	14	0.13	<0.01	0.14
			14	0.10	<0.01	0.11
Madera, CA (10)	Low (62-73)	Suncrest	14	0.04	<0.01	0.05
			14	0.05	<0.01	0.06
Orefield, PA (1)	High (236-241)	Red Haven	14	0.11	<0.01	0.12
			14	0.11	<0.01	0.12
Chula, GA (2)	High (213-247)	June Gold	14	0.18	0.02	0.20
			14	0.20	0.02	0.22
York, SC (2)	High (226-236)	Sun- haven	13	0.10	<0.01	0.11
			13	0.27, 0.38 <sup>2</sup>	0.02, 0.03 <sup>2</sup>	0.29, 0.41 <sup>2</sup>



Marysville, CA (10)	High (225)	Loadel	14	0.08	<0.01	0.09
			14	0.14	0.01	0.15
Conklin, MI (5)	Low (63-68) High (225-249)	Red Haven	14	0.09	<0.01	0.10
			14	0.09	<0.01	0.10
Wharton, TX <sup>3</sup> (6)	Low (75) High (200)	June Gold	14	0.06	<0.01	0.07
			14	0.04	<0.01	0.05
Hingley, AZ (10)	High (203-214)	Desert Gold	13	0.01	<0.01	0.02
			13	0.02	<0.01	0.03
Taylorsville, NC (2)	Low (60-62)	Georgia Bells	13	0.14	0.01	0.15
			13	0.09	<0.01	0.10

Data from pp. 7, 9, 20, 21, 24, 39-43, and 58-61 of MRID 45007005.

The LOQ was 0.01 ppm for both lambda-cyhalothrin and R157836.

<sup>1</sup>Total residues were calculated by the reviewer.

<sup>2</sup>Duplicate analyses were conducted of one sample.

<sup>3</sup>The Wharton, TX trial employed 5 application of 0.05 lb ai/A for a seasonal total of 0.25 lb ai/A (1.2X rate).

A residue decline trial for peaches was conducted at Hereford, PA. The results of this decline study are shown in Table 7. The average of the sum of the residues of lambda-cyhalothrin and R157836 for duplicate samples at PHI of 7 days is 0.125 ppm. The average of the sum of the residues for PHIs of 10, 14, 17 and 20 days are 0.07, 0.08, 0.075 and 0.065 ppm, respectively. These results indicate a possible decline in the residues for PHI >7 days; however, the residues are essentially constant for PHIs ranging from 10 to 20 days. The PHI for stone fruits should be greater than 10 days; 14 days is consistent with the field trials.

Table 7: Residue decline of lambda-cyhalothrin in/on Peaches (Glo-haven variety) treated with five foliar applications of KARATE/WARRIOR 2.09CS at a rate of 0.04 lb ai/A (0.20 lb ai/A/season).					
Test Location: city, state (EPA Region)	Spray Volume (gpa)	PHI (days)	Residue Levels (ppm) (uncorrected)		
			Lambda- Cyhalothrin	R157836	Total <sup>1</sup>
Hereford, PA (1)	Low (72-73)	7	0.14	0.01	0.15
		7	0.09	<0.01	0.10
		10	0.09	<0.01	0.10
		10	0.03	<0.01	0.04
		14	0.06	<0.01	0.07
		14	0.08	<0.01	0.09
		17	0.06	<0.01	0.07
		17	0.07	<0.01	0.08
		20	0.06	<0.01	0.07
		20	0.05	<0.01	0.06

Data from pp. 20, 58 and 60 of MRID 45007005.

The LOQ was 0.01 ppm for both lambda-cyhalothrin and R157836.

<sup>1</sup>Total residues were calculated by the reviewer.

**Plums.** Data from 9 plum field trials were submitted by the petitioner. The field trials were conducted in 1997 in EPA Region 5 (2 trials in MI), Region 10 (five trials in CA), and Region 11 (WA). The results are reported in:

MRID 45007006. Spillner, C. J., B. V. Thomas, and B. B. Kahn (1998) Lambda-cyhalothrin: Residue levels in plums from trials conducted in the United States in 1997. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 98-053B. December 10, 1998. Unpublished.

The results from the field trials for plums are summarized in Table 8. Samples consisted  $\geq 24$  plums (5-12.5 lbs) taken by hand from at least four trees. Residue levels of lambda-cyhalothrin in/on plums were 0.01–0.10 ppm and residue levels of R157836 were  $<0.01$ –0.01 ppm for a total of  $\sim 0.02$ –0.11 ppm. The highest residues were in Grand Rapids, MI. All control samples were below the LOQ of 0.01 ppm for lambda-cyhalothrin and for R157836. Geographic distribution of the 9 field trials followed OPPTS guidelines for plums as part of a crop group (4 trials were required in Region 10 and one in Regions 5 and 12). The number of field trials and the residue, storage stability, and method validation data support the proposed lambda-cyhalothrin tolerance of 0.50 ppm for the stone fruit crop group (Group 12).

<b>Table 8: Residues of lambda-cyhalothrin and R157836 in/on plums treated with 5 foliar applications of WF2471 [2.09 ai/gal in a capsule suspension] at the rate of 0.04 lb ai/A for a seasonal total of 0.2 lb ai/A.</b>						
<b>Test Location: city, state (EPA Region)</b>	<b>Spray volume (gpa)</b>	<b>Crop variety</b>	<b>PHI (days)</b>	<b>Residue Levels (ppm)</b>		
				<b>Lambda- Cyhalothrin</b>	<b>R157836</b>	<b>Total<sup>1</sup></b>
Mears, MI (5)	Low (60-64)	Stanley	13	0.05	$<0.01$	0.06
			13	0.07	$<0.01$	0.08
Visalia, CA (10)	Low (59-62)	Santa Rosa	13	0.02	$<0.01$	0.03
			13	0.02	$<0.01$	0.03
Sultana, CA (10)	Low (60-63)	Nubiana	13	0.01	$<0.01$	0.02
			13	0.01	$<0.01$	0.02
Grand Rapids, MI (5)	High (227-241)	Stanley	13	0.09	$<0.01$	0.10
			13	0.10	0.01	0.11
Orosi, CA (10)	High (208-213)	Friar	13	$<0.01$	$<0.01$	0.02
			13	$<0.01$	$<0.01$	0.02
Chico, CA (10)	High (206-218)	French	14	0.03	$<0.01$	0.04
			14	0.03	$<0.01$	0.04
Forest Grove, OR (12)	Low (60-70)	Italian	14	0.02	$<0.01$	0.03
	High (212-242)		14	0.02	$<0.01$	0.03
Fairfield, CA (10)	Low (59-65)	French Prune	14	0.03	$<0.01$	0.04
			14	0.04	$<0.01$	0.05

Toppenish, WA (11)	Low (50) High (200)	Friar	13 13	0.01 <0.01, <0.01 <sup>2</sup>	<0.01 <0.01, <0.01 <sup>2</sup>	0.02 0.02, 0.02 <sup>2</sup>
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Data from pp. 7, 9, 20, 24, 31-34 and 46-48 of MRID 45007006.

The LOQ was 0.01 ppm for both lambda-cyhalothrin and R157836.

<sup>1</sup>Total residues were calculated by the reviewer.

<sup>2</sup>Duplicate analyses were conducted of one sample.

**Conclusions:** The petitioner has requested a permanent tolerance of 0.50 ppm for use of lambda-cyhalothrin applied as the capsule suspension formulation KARATE/WARRIOR® 2.09 CS (WF2471, 2.09 lbs ai/gal) on stone fruits (Crop Group 12). In the submitted field trials, total residue levels (lambda-cyhalothrin + R157836) in/on sweet cherries were ~0.05-0.20 ppm, on peaches were ~0.02-0.41 ppm, and on plums were ~0.02-0.11 ppm. The number of field trials and their geographic distribution were adequate for cherries, peaches, and plums, which are the representative crops for the stone fruit crop group (Group 12). The residue, storage stability, and method validation data support the proposed lambda-cyhalothrin tolerance of 0.50 ppm on the stone fruit crop group. A residue decline study for peaches showed that residues do not increase with time, and supports a PHI of 14 days.

### Tree Nuts

**Almonds.** Zeneca Ag Products submitted data from 5 almond field trials in 1998 to support the petition for a lambda-cyhalothrin tolerance on tree nuts (Crop Group 14). The trials were conducted at 5 locations in California (Visalia, Chico, Dunnigan, Esparto, and Hughson) in EPA Region 10. The almond trees were grown under typical U.S. climatic conditions and agricultural practices. The results are reported in:

MRID 45007008. Miller, M.M. and J.C. Aston (1999) Lambda-cyhalothrin: residue levels on almonds from trials conducted in the United States during 1998. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 99-032B. July 6, 1999. Unpublished.

Each trial consisted of one untreated control plot and one treated plot. Lambda-cyhalothrin, formulated as the capsule suspension KARATE/WARRIOR 1 CS (WF2616; 1 lb ai/gal), was diluted in water and applied to the trees four times as a foliar broadcast spray of 0.04 lb ai/A, for a total of 0.16 lb ai/A/season ( $\pm$  5% of the 1X proposed rate). The trees received either 4 low volume applications (33-50 gpa; 3 trials) or one low volume application followed by 3 high volume applications (203-250 gpa; 2 trials). The spray was applied using a back pack mist blower spray or tractor-driven air blast equipment. The first application was at the dormant to pre-bloom growth stage, the second was 24-28 days prior to harvest, and the 3<sup>rd</sup> and 4<sup>th</sup> were at 5-8 day intervals. The PHI was 13-14 days (versus 14 days proposed). One sample ( $\geq$  2.5 lbs hulls and  $\geq$  5.0 lbs unshelled almonds) was collected by hand from each control plot and two independent samples were collected from each treated plot.

Samples were frozen within 4 hours of collection and kept frozen during shipment to the analytical laboratory (Western Research Center, Zeneca Ag Products, Richmond, CA) and thereafter until analysis ( $-18 \pm 5^\circ\text{C}$ ). The unshelled almonds were separated into almond nutmeat and shells. The almond nutmeat and collected almond hulls were each (separately) ground to homogeneity with dry ice using a Hobart VCM chopper. The ground samples were extracted and analyzed on the same day (most samples) or within 1-8 days of extraction for lambda-cyhalothrin and its epimer R157836. Analysis and extraction was by methods based on PPRAM 70 and PPRAM 81, adapted for use with an external standard. The method LOQ was 0.01 ppm (0.007 ppm for lambda-cyhalothrin and 0.013 ppm for R157836).

Residue levels of lambda-cyhalothrin and its epimer R157836 in/on almond nutmeat were all  $<0.01$  ppm. Residues on almond hulls ranged from 0.20-1.1 ppm for lambda-cyhalothrin and 0.02-0.08 ppm for R157836 for a total of 0.31-1.18 ppm. No differences were seen in residues from low volume compared to high volume applications. All untreated control samples were below the LOQ of 0.01 ppm for lambda-cyhalothrin and for R157836. Geographic distribution of the 5 almond field trials followed OPPTS guidelines (5 trials were required in Region 10). The number of field trials and the residue, storage stability, and method validation data support the proposed lambda-cyhalothrin tolerance of 0.05 ppm in/on tree nuts and 1.5 ppm in/on almond hulls. A residue decline trial was not conducted. The field trial data for almonds are summarized in Table 9.

TABLE 9: Residues of lambda-cyhalothrin and its epimer R157836 in/on almond nutmeat and almond hulls after 4 foliar applications of KARATE/WARRIOR 1 CS at 0.04 lb ai/A (0.16 lb ai/A/season ± 5%).					
Test location (all are EPA Region 10)	Spray volume (gpa)	PHI (days)	Residue levels (ppm) (uncorrected)		
			lambda-cyhalothrin	R157836	Total <sup>1</sup>
Almond nutmeat					
Visalia, CA	Low (33-45)	13	<0.01	<0.01	<0.02
		13	<0.01	<0.01	<0.02
Chico, CA	Low (43-48)	14	<0.01	<0.01	<0.02
		14	<0.01	<0.01	<0.02
Dunnigan, CA	Low (45)	14	<0.01	<0.01	<0.02
		14	<0.01	<0.01	<0.02
Esparto, CA	High (35, 235-250) <sup>2</sup>	14	<0.01	<0.01	<0.02
		14	<0.01	<0.01	<0.02
Hughson, CA	High (50, 203-204) <sup>2</sup>	14	<0.01	<0.01	<0.02
		14	<0.01	<0.01	<0.02
Almond hulls <sup>3</sup>					
Visalia, CA	Low (33-45)	13	0.38	0.03	0.41
		13	0.30, 0.29, 0.30	0.02, 0.02, 0.02	0.32, 0.31, 0.32

TABLE 9: Residues of lambda-cyhalothrin and its epimer R157836 in/on almond nutmeat and almond hulls after 4 foliar applications of KARATE/WARRIOR 1 CS at 0.04 lb ai/A (0.16 lb ai/A/season $\pm$ 5%).					
Test location (all are EPA Region 10)	Spray volume (gpa)	PHI (days)	Residue levels (ppm) (uncorrected)		
			lambda-cyhalothrin	R157836	Total <sup>1</sup>
Chico, CA	Low (43-48)	14	0.29	0.02	0.31
		14	0.34	0.03	0.37
Dunnigan, CA	Low (45)	14	0.28	0.03	0.031
		14	0.29, 0.29	0.03, 0.03	0.32, 0.32
Esparto, CA	High (35, 235-250) <sup>2</sup>	14	0.45	0.04	0.49
		14	0.48	0.04	0.52
Hughson, CA	High (50, 203-204) <sup>2</sup>	14	0.91	0.08	0.99
		14	0.9, 1.1	0.07, 0.08	0.97, 1.18

Data from pp. 20-21 of MRID 45007008.

The LOQ was 0.01 ppm for lambda-cyhalothrin and its epimer R157836

<sup>1</sup>Total residues were calculated by the reviewer.

<sup>2</sup>The first application was low volume, followed by 3 high-volume applications.

<sup>3</sup>Multiple analyses were conducted of samples with more than one value.

**Pecans.** Zeneca Ag Products submitted data from 5 pecan field trials in 1998 to support the petition for a lambda-cyhalothrin tolerance on tree nuts (Crop Group 14). The trials were conducted in EPA Region 2 (AL, GA), Region 4 (MS), Region 6 (Boling, TX) and Region 8 (Lockney, TX). The pecan trees were grown under typical U.S. climatic conditions and agricultural practices. The results are reported in:

MRID 45007009. Miller, M.M. and J.C. Aston (1999) Lambda-cyhalothrin: residue levels on pecans from trials conducted in the United States during 1998. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 99-028B. July 1, 1999. Unpublished.

Each trial consisted of one untreated control plot and one or two treated plots. Lambda-cyhalothrin, formulated as the capsule suspension KARATE/WARRIOR 1 CS (WF2616; 1 lb ai/gal), was diluted in water and applied to the trees four times as a foliar broadcast spray of 0.04 lb ai/A, for a total of 0.16 lb ai/A/season ( $\pm$  7.5% of the 1X proposed rate). The trees received either 4 low volume applications (22-50 gpa; 3 trials) or one low volume application followed by 3 high volume applications (194-245 gpa; 2 trials). The first application was at the dormant to pre-bloom growth stage, the second was 24-28 days prior to harvest, and the 3<sup>rd</sup> and 4<sup>th</sup> were at 5-8 day intervals. The PHI was 13-14 days (versus 14 days proposed). One sample ( $\geq$ 5.0 lbs mature pecans) was collected by hand from each control plot and each treated plot in TX and MS, and two independent samples were collected from each treated plot in AL and GA. Pecan samples ( $\geq$ 5.0 lbs mature pecans) were collected from the plots, frozen within 6 hours, shipped to the processing site where unshelled pecans were separated into nutmeat and shells, the shells

were discarded, and the nutmeat was homogenized and analyzed for lambda-cyhalothrin in the same way as almonds.

Residue levels of lambda-cyhalothrin and its epimer R157836 in/on pecan nutmeat from both untreated (control) and treated samples were all below the LOQ of 0.01 ppm for a total of ~0.02 ppm. No differences were seen in residues from low volume compared to high volume applications. Geographic distribution of the 5 pecan field trials followed OPPTS guidelines (2 trials were required in Region 2 and one trial in Regions 4, 6, and 8). The number of field trials and the residue, storage stability, and method validation data support the proposed lambda-cyhalothrin tolerance of 0.05 ppm in/on tree nuts (nutmeat). A residue decline trial was not conducted. The field trial data for pecans are summarized in Table 10.

<b>TABLE 10: Residues of lambda-cyhalothrin and its epimer R157836 in/on pecan nutmeat following 4 foliar applications of KARATE/WARRIOR 1 CS at 0.04 lb ai/A (0.16 lb ai/A/season <math>\pm</math> 7.5%).</b>					
<b>Test location (EPA Region)</b>	<b>Spray volume (gpa)</b>	<b>PHI (days)</b>	<b>Residue levels (ppm)<sup>1</sup> (uncorrected)</b>		
			<b>lambda-cyhalothrin</b>	<b>R157836</b>	<b>Total</b>
Lafayette, AL <sup>1</sup> (2)	Low (22-40)	13	<0.01	<0.01	<0.02
		13	<0.01	<0.01	<0.02
Camilla, GA <sup>1</sup> (2)	High (35, 203-238) <sup>2</sup>	13	<0.01	<0.01	<0.02
		13	<0.01	<0.01	<0.02
Greenville, MS (4)	Low (37-47)	14	<0.01	<0.01	<0.02
	High (37, 200-203) <sup>2</sup>	14	<0.01	<0.01	<0.02
Boling, TX (6)	Low (40-50)	14	<0.01	<0.01	<0.02
	High (40, 200-206) <sup>2</sup>	14	<0.01	<0.01	<0.02
Lockney, TX (8)	Low (39-45)	14	<0.01	<0.01	<0.02
	High (39, 194-245) <sup>2</sup>	14	<0.01	<0.01	<0.02

Data from p. 18 of MRID 45007009.

The LOQ was 0.01 ppm for lambda-cyhalothrin and its epimer R157836

<sup>1</sup>Two samples were collected from each treated plot for the AL and GA trials.

<sup>2</sup>The first application was low volume, followed by 3 high-volume applications.

**Conclusions:** The petitioner has requested a permanent tolerance of 0.05 ppm in/on tree nuts (nutmeat) (Crop Group 14) and 1.5 ppm in/on almond hulls for the use of lambda-cyhalothrin as the capsule suspension formulation KARATE/WARRIOR® 1 CS (WF26161, 1 lb ai/gal). In the submitted field trials, residue levels of lambda-cyhalothrin and R157836 in/on almond and pecan nutmeat from both untreated (control) and treated samples were all below the LOQ of 0.01 ppm for a total of ~0.02 ppm. Residues on almond hulls ranged from 0.20-1.1 ppm for lambda-cyhalothrin and 0.02-0.08 ppm for R157836, for a total of 0.31-1.18 ppm. The number of field trials and their geographic distribution were adequate for almonds and pecans, which are the representative crops for the tree nut crop group (Group 14). The residue, storage stability, and

method validation data support the proposed lambda-cyhalothrin tolerance of 0.05 ppm in/on tree nuts (nutmeat) (Crop Group 14) and 1.5 ppm in/on almond hulls.

### Tobacco

Zeneca Ag Products submitted data from one tobacco field trial conducted in 1997 (in KY) and two trials conducted in 1996 (in NC) to satisfy OPPTS 860.1000 guideline requirements for use of lambda-cyhalothrin on tobacco (a tolerance or exemption of a tolerance is not required). The tobacco variety for the KY trial was 14 X L8 ("burly") and for the NC trials was K-326. The trials were conducted in EPA Region 2 under typical U.S. climatic conditions and agricultural practices. The results are reported in:

MRID 45007010. Spillner, C.J. B. Kahn, and J.L. Marth (1999) Lambda-cyhalothrin: residue levels on tobacco from a trial conducted in the United States during 1997. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 98-057B. January 7, 1999. Unpublished.

MRID 45007011. Markle, J.C., P.D. Francis, and C.J. Spillner (1998) Lambda-cyhalothrin (ICIA0321): residue levels on flue-cured tobacco from trials conducted in the United States during 1996. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 97-038B. August 26, 1998. Unpublished.

Each trial consisted of three plots: one untreated control plot and two plots treated with lambda-cyhalothrin, formulated as the emulsifiable concentrate KARATE 1EC (formulation number GFU383C; 1 lb ai/gal). Of the two treated plots, one received two applications and the other 3 applications of lambda-cyhalothrin at a rate of  $0.03 \pm 10\%$  lb ai/A, for a total of 0.06 lb (0.67X) or 0.09 lb (1X) ai/A/season. The insecticide was applied as a broadcast foliar spray in a volume of 11-15 gpa using a CO<sub>2</sub> pressurized backpack sprayer. The first application was on the same day (KY trial) or the next day (NC trials) after transplanting. The second and third applications (if needed) were made two and four weeks, respectively, after transplanting. The PHI for the KY trial was 70-84 days and for the two NC trials was 40-108 days for the first through the third priming. Samples ( $\geq 2.5$  lbs green leaves) were collected by hand from each plot: one from the control plot and one (NC trials) or two (KY trial) samples from each treated plot. A portion of the leaves from each harvest (or priming) were either air-dried (KY trial;  $\geq 2.0$  lb dried) or flue cured (NC trials;  $\geq 1.7$  lb cured).

Samples were frozen within 7 hours of collection and kept frozen during shipment to the analytical laboratory (Western Research Center, Zeneca Ag Products, Richmond, CA) and thereafter until analysis ( $-18 \pm 5^\circ\text{C}$ ). The samples were ground to homogeneity with dry ice using a Hobart VCM-40 chopper. The ground samples were extracted and analyzed within four days for lambda-cyhalothrin and its epimer R157836. Analysis and extraction was by methods based on PPRAM 70 and PPRAM 81, adapted for use with an external standard.

Residue levels of lambda-cyhalothrin and its epimer R157836 in/on tobacco leaves were almost all below the LOQ of 0.01 ppm, for both untreated (control) and treated samples. The exception was the treated samples collected after the first priming in Fremont NC, for which the total residues were 0.04 ppm. No differences were seen in residue levels of green and cured leaves. Residue levels appeared to decline with time, although most residues were below the LOQ. The geographic location and number of field trials, storage stability, and method validation data provided satisfy OPPTS 860.1000 guideline requirements for use of lambda-cyhalothrin on tobacco (a tolerance or exemption of a tolerance is not required). Further studies (metabolism, pyrolysis) are not warranted because the total toxic residue (based on metabolism studies in other plants) was below 0.1 ppm. The field trial data for tobacco are summarized in Table 11.

<b>TABLE 11: Residues (uncorrected) of lambda-cyhalothrin and its epimer R157836 in/on tobacco following 2 or 3 foliar applications of KARATE 1EC at 0.03 lb ai/A (0.06 or 0.09 lb ai/A/season <math>\pm</math> 10%).</b>								
No. applications	PHI, days (priming order)	lambda-cyhalothrin	R157836	Total	PHI, days (priming order)	lambda-cyhalothrin	R157836	Total
	1997 trial in Springfield, KY [EPA Crop Region 2]							
	Green leaves, residue levels (ppm)				Air-dried leaves, residue levels (ppm)			
2	84	<0.01	<0.01	<0.02	84	<0.01	<0.01	<0.02
2	84	<0.01	<0.01	<0.02	84	<0.01	<0.01	<0.02
3	70	<0.01	<0.01	<0.02	70	<0.01	<0.01	<0.02
3	70	<0.01	<0.01	<0.02	70	<0.01	<0.01	<0.02
	1996 trial in Fremont, NC [EPA Crop Region 2]							
	Green leaves, residue levels (ppm)				Flue-cured leaves, residue levels (ppm)			
2	55 (1 <sup>st</sup> )	<0.01	<0.01	<0.02	63 (1 <sup>st</sup> )	<0.01	<0.01	<0.02
2	68 (2 <sup>nd</sup> )	<0.01	<0.01	<0.02	75 (2 <sup>nd</sup> )	<0.01	<0.01	<0.02
2	81 (3 <sup>rd</sup> )	<0.01	<0.01	<0.02	91 (3 <sup>rd</sup> )	<0.01	<0.01	<0.02
3	40 (1 <sup>st</sup> )	0.03	<0.01	<0.04	48 (1 <sup>st</sup> ) <sup>1</sup>	0.03; 0.03	0.01; 0.01	0.04; 0.04
3	53 (2 <sup>nd</sup> )	<0.01	<0.01	<0.02	60 (2 <sup>nd</sup> )	<0.01	<0.01	<0.02
3	66 (3 <sup>rd</sup> )	<0.01	<0.01	<0.02	76 (3 <sup>rd</sup> ) <sup>1</sup>	<0.01; <0.01	<0.01; <0.01	<0.02; <0.02
	1996 trial in Browns Summit, NC [EPA Crop Region 2]							
	Green leaves, residue levels (ppm)				Flue-cured leaves, residue levels (ppm)			
2	65 (1 <sup>st</sup> )	<0.01	<0.01	<0.02	76 (1 <sup>st</sup> )	<0.01	<0.01	<0.02
2	91 (2 <sup>nd</sup> )	<0.01	<0.01	<0.02	99 (2 <sup>nd</sup> )	<0.01	<0.01	<0.02
2	101 (3 <sup>rd</sup> )	<0.01	<0.01	<0.02	108 (3 <sup>rd</sup> )	<0.01	<0.01	<0.02
3	52 (1 <sup>st</sup> )	<0.01	<0.01	<0.02	63 (1 <sup>st</sup> )	<0.01	<0.01	<0.02
3	78 (2 <sup>nd</sup> )	<0.01	<0.01	<0.02	86 (2 <sup>nd</sup> )	<0.01	<0.01	<0.02
3	88 (3 <sup>rd</sup> )	<0.01	<0.01	<0.02	95 (3 <sup>rd</sup> )	<0.01	<0.01	<0.02



Data from p. 17, MRID 45007010 and pp. 21-22, MRID 45007011.

The LOQ was 0.01 ppm for lambda-cyhalothrin and its epimer R157836.

<sup>1</sup>Two analyses were conducted of one sample.

### **OPPTS GLN 860.1520: Processed Food/Feed**

There are no processed commodities of regulatory interest for pears, cherries, peaches, pecans, and almonds, and processing studies are not relevant to their petitions. Processing studies are also not relevant for the registration of lambda-cyhalothrin use on tobacco.

#### Apple

##### *Juice and Pomace Study*

Zeneca Ag Products has submitted data from an apple processing study conducted in Washington State in 1997. The processed commodities of regulatory interest for apples are wet pomace and fresh juice. The study is part of a petition to obtain a permanent tolerance of Crop group 11, pome fruit. The results are reported in:

MRID 45007002. Spillner C., and R. Hampton (1999) Lambda-cyhalothrin processing study on apples from a trial conducted in Washington during 1997. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 99-010B. July 26, 1999. Unpublished.

Two plots of apples were established, one untreated and the other treated with lambda-cyhalothrin as the formulation KARATE/WARRIOR® 2.09 CS (2.09 lb ai/gal capsule suspension, KARATE Z). Lambda-cyhalothrin was applied 5 times by broadcast foliar spray to apple trees at 0.04 ai/A for a total of 0.2 lb ai/A/season. The first application was at the dormant stage and the 2<sup>nd</sup> application was 39 days prior to harvest, followed by 3<sup>rd</sup>, 4<sup>th</sup>, and 5<sup>th</sup> applications at 5-7 day intervals. The PHI was 21 days. Applications were made with a tractor-driven air-blast sprayer in sprayer-solution volumes of 50 gpa. Samples (70 lbs of mature apples) were harvested by hand and sent at ambient temperature Englar Food Laboratories, Inc., Moses Lake WA. The apples arrived the day after harvesting and were refrigerated at  $5 \pm 5^{\circ}\text{C}$  for 9 days and then processed simulating commercial practices. Subsamples were frozen until shipment for analysis to Zeneca Ag Products, Western Research Center in Richmond, CA. The processing began by washing the apples and removing any debris, after which the apples were crushed by a hammermill to a homogenous pulp and heated with steam to 40-50 °C. An enzyme treatment was added to the pulp for about 2 minutes. After settling, the pulp was pressed using a hydraulic apple press and the apple juice was collected and strained. The wet pomace and fresh juice were then shipped frozen to the analytical laboratory at Zeneca, Inc. (Richmond, CA). Upon receipt, the samples were placed in storage at  $-18 \pm 5^{\circ}\text{C}$  until processing.

Samples of fresh fruit and wet pomace were prepared by chopping in a Hobart VCM-25 chopper with dry ice to obtain finely ground, homogenous samples. Juice samples required no additional preparation. Samples were then again frozen until extraction. The sampling-to-extraction interval ranged from 214-557 days and extraction occurred within 3 days. Samples were analyzed for lambda-cyhalothrin and its epimer R157836 using methods PPRAM81/PPRAM70 described in Section OPPTS GLN 860.1340: Analytical Methods - Plants.

All untreated control samples were below the LOQ of 0.01 ppm for lambda-cyhalothrin and R157836. Residues on treated apples were 0.08-0.09 ppm for lambda-cyhalothrin and <0.01 ppm for R157836 for a total of ~0.09-0.10 ppm. Residues in apple juice were all below the LOQ (0.001 ppm). Residues in apple pomace were 0.68-0.69 for lambda-cyhalothrin and 0.06 ppm for R157836, for a total of 0.74-0.75 ppm, and representing approximately an 8-fold concentration for the total residues relative to the RAC. Multiplying the HFT for the RAC apples (0.21 ppm) by the 8.06X concentration factor yields 1.7 ppm, which supports the proposed tolerance of 2.5 ppm on wet apple pomace. The processing study was conducted in a geographically appropriate area and is supported by adequate storage stability and method validation data. The results from the processing study on apples are shown in Table 12.

### *Cooking Study*

Zeneca Ag Products has submitted data from a laboratory apple processing study conducted at their Western Research Center, Richmond, California in 1999. The processed commodities of regulatory interest for apples are wet pomace and fresh juice. The study is part of a petition to obtain a permanent tolerance of Crop group 11, pome fruit. The results are reported in:

MRID 45443104. Kleinschmidt, M., and Miller M. (2001) Lambda-Cyhalothrin: Reduction in Residue Levels on Apples from Trials Conducted in the United States during 1999. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 00-096B. January 31, 2001. Unpublished.

Two of 75 lb samples of marketable apples, Granny Smith and Rome, were obtained from a farmer near the Western Research Center, Richmond, CA. The varieties were chosen because they are typical of those chosen to produce applesauce. The subset of each variety of apples were treated with WF2616 (1 lb ai/gal) capsule suspension diluted in local water. Lambda-cyhalothrin was applied 2 times in a spray chamber. Apples were placed in a tray pedicel-end up and so as not to be in contact with one another then sprayed. After a 15 min. air drying period, the apples were rotated as to be pedicel-end down and then resprayed. The apples were air dried for 2 hrs. The total applied was reported to be equivalent to 0.2 lb ai/A, which is the maximum seasonal application rate. A 3 lb sample of the untreated apples and duplicate 3 lb samples of the treated apples were collected into labeled bags and placed over blue-ice. The remainder of the apples were boxed at ambient temperature. Both cooled and ambient containers were transferred within

3 hrs of treatment to the processing and analytical facility, The National Food Laboratory, Inc., Dublin, California.

Each apple sample was washed, peeled and sliced, cooked, and canned yielding commercially canned applesauce. Samples were taken during the processing: before and after washing (whole fruit), after peeling (peeled, quartered fruit), after cooking (cooked fruit), and after canning (applesauce). Samples were stored frozen,  $<-12^{\circ}\text{C}$ , until analysis. The sampling-to-extraction interval was no longer than 279 days. Samples were prepared for analysis by chopping with dry ice to obtain finely ground, homogenous samples. Sample extracts were stored frozen and analyzed within 7 days. Samples were analyzed for lambda-cyhalothrin and its epimer R157836 using methods adapted from PPRAM81/PPRAM70 described in Section OPPTS GLN 860.1340: Analytical Methods - Plants.

All untreated control samples were below the LOQ of 0.01 ppm for lambda-cyhalothrin and R157836. Residues on treated apples before washing were 0.14-0.32 ppm for lambda-cyhalothrin and 0.01-0.02 ppm for R157836. Residues in apples after washing declined slightly ranging from 0.18-0.32 ppm for lambda-cyhalothrin and 0.02-0.03 ppm for R157836 for an average concentration factor of 0.84X. Residues in apples after peeling, cooking, and canning declined significantly to  $<0.01$ -0.03 for lambda-cyhalothrin and  $<0.01$  ppm for R157836 for an average concentration factor of 0.08X. The processing study was supported by adequate storage stability and method validation data. The results from the processing study on apples are shown in Table 12.

TABLE 12: Residues (uncorrected) of lambda-cyhalothrin and its epimer R157836 in/on apples and processed apple commodities.				
Commodity	Lambda-cyhalothrin (ppm)	R157836 (ppm)	Total [mean]	Concentration factor
Residues following 5 broadcast foliar applications of KARATE/WARRIOR® 2.09 CS at the rate of 0.04lb ai/A for a seasonal total of 0.20 lb ai/A. The PHI was 20-21 days.				
Apples	0.08; 0.09	<0.01; <0.01	<0.09, <0.10 [0.095]	—
Wet Pomace	0.68; 0.69	0.06; 0.06	0.74; 0.75 [0.745]	8.06
Juice	<0.001; <0.001; <0.001; <0.001	<0.001; <0.001; <0.001; <0.001	<0.002, <0.002, <0.002, <0.002 [0.002]	0.11
Residues following 2 spray applications for a total of 0.20 lb ai/A. *				
After Spray	0.20, 0.14, 0.24 0.23, 0.22, 0.30	0.02, 0.01, 0.02 0.02, 0.02, 0.02	0.22, 0.14, 0.26 0.25, 0.24, 0.32	—
Before Wash	0.28, 0.26, 0.24 0.30, 0.30, 0.32	0.02, 0.02, 0.02 0.02, 0.02, 0.02	0.30, 0.28, 0.26 0.32, 0.32, 0.32	—
After Wash	0.18, 0.24, 0.24 0.26, 0.32, 0.18	0.02, 0.02, 0.02 0.03, 0.02, 0.02	0.20, 0.26, 0.26 0.29, 0.34, 0.20	0.84
After Peeling	<0.01, <0.01, <0.01 0.02, 0.02, 0.02	<0.01, <0.01, <0.01 <0.01, <0.01, <0.01	<0.02, <0.02, <0.02 0.03, 0.03, 0.03	0.08
After Cooking	<0.01, <0.01, <0.01 0.02, 0.03, 0.03	<0.01, <0.01, <0.01 <0.01, <0.01, <0.01	<0.02, <0.02, <0.02 0.03, 0.04, 0.04	0.10
Applesauce	<0.01, <0.01, <0.01 <0.01, <0.01, <0.01	<0.01, <0.01, <0.01 <0.01, <0.01, <0.01	<0.02, <0.02, <0.02 <0.02, <0.02, <0.02	0.07

Data from p 19, MRID 45007002 and p 53-54 MRID 45443104.

The LOQ for lambda-cyhalothrin and R157836 is 0.01 ppm for all apple commodities except for juice at 0.001 ppm.

All untreated control samples were below the LOQ of 0.01 ppm for lambda-cyhalothrin and R157836.

\* Results for both Granny Smith and Rome apples.

### Plum

Zeneca Ag Products has submitted data from a processing study on plums/prunes conducted in the United States in 1997. The results are reported in:

MRID 45007007. Spillner, C. J., B. V. Thomas, and B. B. Kahn (1998) Lambda-cyhalothrin: processing study on plums from a trial conducted in California during 1997. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 98-061B. December 10, 1998. Unpublished

One crop of plums was raised in Chico, CA, in 1997 for the processing study. Two plots were established, one untreated and the other treated with the lambda-cyhalothrin formulation KARATE/WARRIOR 2.09CS (2.09 lb/gal). Five foliar broadcast applications were applied at the rate of 0.04 lb ai/A, for a total application of 0.2 lb ai/A/season or 1X the field trial

application rate. The first application was made at the dormant to pre-bloom stage. The second application was made at 29 days prior to harvest, with subsequent treatments (3<sup>rd</sup>, 4<sup>th</sup> and 5<sup>th</sup>) at 5-day intervals. The fifth application was made 14 days prior to harvest. Spray volumes (diluted in water) for the trial were 206–218 gpa. Seventy-five pounds of mature plums were harvested by hand from at least four trees in each plot. These samples were stored in refrigerators for 4-5 days before being shipped (cooled with blue ice) by overnight carrier to Englar Food Laboratories, Inc. (Moses Lake, WA) for processing. Just prior to processing a minimum of five pounds of RAC plums from each sample were collected, packaged and placed in a freezer until shipment to the analytical laboratory (Zeneca Ag Products, Western Research Center, Richmond, CA). Plums were processed by first washing for 5 minutes in cold water and removing any debris, then placing them in a laboratory air dryer set at 68-79 °C for 25 hours. The plums were dried to a moisture content of 23-27% (commercial standard for prunes is 19-29% moisture). The cooled prunes were packaged and stored in a freezer until shipment to the analytical laboratory (Zeneca Ag Products). The analytical laboratory received the samples frozen and stored them at  $-18 \pm 5$  °C except during the time when preparation and analysis was performed. Samples of plums and prunes were chopped in a Hobart VCM 25 with dry ice until completely homogeneous. Samples were analyzed for lambda-cyhalothrin and its epimer R157836 using method based on PPRAM81/PPRAM70 described in Section OPPTS GLN 860.1340: Analytical Methods - Plants. The period of storage prior to extraction and analysis was 223–228 days.

All untreated control samples were below the LOQ of 0.01 ppm for lambda-cyhalothrin and R157836. Residues on treated plums were 0.04 ppm for lambda-cyhalothrin and <0.01 ppm for R157836. Prune residues were 0.06 ppm for lambda-cyhalothrin and <0.01 ppm for R157836, representing approximately a 1.4-fold concentration relative to the RAC for the total residues. Multiplying the HAFT of 0.105 ppm for plum by the 1.4X concentration factor yields 0.15 ppm, which is below the proposed tolerance of 0.50 ppm for stone fruits. Therefore, a separate tolerance for prunes is not necessary. This study suffers from the drawback that it was not conducted at an exaggerated application rate and only one sample was evaluated of the RAC and prunes. However, it is unlikely that significant concentration of residues (i.e., to the 0.50 ppm crop group tolerance) would have occurred in prunes (total residues of ~0.07 ppm) since total residues for the RAC were 0.02-0.11 ppm in the 9 magnitude of residue field trials. The processing study was conducted in a geographically appropriate area and is supported by adequate storage stability and method validation data; the results are summarized in Table 13.

TABLE 13: Residues (uncorrected) of lambda-cyhalothrin and its epimer R157836 in/on plums and their processed commodity prunes following 5 broadcast foliar applications of KARATE/WARRIOR® 2.09 CS at the rate of 0.04lb ai/A for a seasonal total of 0.20 lb ai/A. The PHI was 14 days.				
Commodity	Lambda-cyhalothrin (ppm)	R157836 (ppm)	Total	Concentration factor
Plums	0.04	<0.01	0.05	—
Prunes	0.06	<0.01	0.07	1.4

Data from pp. 7, 16, 19, 21, and 26 of MRID 45007007.  
The LOQ for lambda-cyhalothrin and R157836 was 0.01 ppm.

### Canola

Zeneca Ag Products has submitted data from a processing study on canola conducted in the United States in 1999. The results are reported in:

MRID 45443103. Miller, M., (2000) Lambda-Cyhalothrin: Residue Levels on Processed Commodities of Canola from a Trial Conducted in the United States during 1999. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 00-037B. May 30, 2000. Unpublished.

One field trial in Idaho was conducted in 1999 for the processing study. Two plots were established, one untreated and the other treated with the lambda-cyhalothrin formulation KARATE 1 EC (1 lb ai/gal). Three foliar broadcast applications were applied at the rate of 0.09 lb ai/A, for a total application of 0.27 lb ai/A/season or 3X the field trial application rate. The first application was made at 21 days prior to harvest. The second and third applications were made at 7 day intervals. Spray volumes (diluted in water) for the trial were 10 gpa. Mature canola seeds were harvested by combine 7 days after last application, collected, sieved, and fifty pound samples bagged for processing. Samples were shipped at ambient temperature to the processing facility, Food Protein Research & Development Center, Texas A&M University, Bryan, Texas. Samples were then stored frozen, < -12 °C, until processed. Canola processing simulated industrial processes as closely as possible except that, for compliance and monitoring purposes, samples were processed in batch mode rather than continuous mode as in commercial operation. Fractions collected during processing were stored frozen until shipment. Treated and untreated seed, processed canola meal, and refined oil were shipped frozen to Zeneca Ag Products Western Research Center, Richmond, California, stored frozen and then shipped to the analytical laboratory, Central California Research Laboratory, Fresno, California. Samples were analyzed for lambda-cyhalothrin and its epimer R157836 using method based on PPRAM81/PPRAM70 described in Section OPPTS GLN 860.1340: Analytical Methods - Plants. The maximum storage interval prior to extraction and analysis was 184 days which is within the period of demonstrated storage stability. Sample extracts were stored a maximum of 1 day before analysis.

All untreated samples were below the LOQ of 0.01 ppm for lambda-cyhalothrin and R157836. Residues on treated canola seed were 0.08 - 0.12 ppm for lambda-cyhalothrin and 0.02 - 0.03 ppm for R157836. Canola meal residues were <0.01 ppm for both lambda-cyhalothrin and R157836. Canola refined oil residues were 0.20 ppm for lambda-cyhalothrin and 0.10 ppm for R157836. The results of the processing study indicates no concentration of residues in meal and approximately a 1.7 - 2.5X concentration of lambda-cyhalothrin and 3.3 - 5X for R157836. For tolerance purposes RAB2 concludes that the appropriate oil concentration factor is 2.3X (total oil residues of 0.30 ppm divided by 0.13 ppm in seed). Multiplying the HAFT of 0.75 ppm for

canola RAC by 2.3X concentration factor yields 1.7 ppm, which is above the proposed tolerance of 0.15 ppm and the suggested tolerance of 1.0 ppm for canola. Therefore, a separate tolerance for canola refined oil is required. **The registrant should submit a revised Section F requesting a tolerance of 2.0 ppm for residues lambda-cyhalothrin and R157836 in canola refined oil.** The processing study was conducted in a geographically appropriate area and is supported by adequate storage stability and method validation data; the results are summarized in Table 14.

TABLE 14: Residues (uncorrected) of lambda-cyhalothrin and its epimer R157836 in/on canola processed commodities following 3 broadcast foliar applications of KARATE 1 EC at the rate of 0.09 lb ai/A for a seasonal total of 0.27 lb ai/A. The PHI was 7 days.					
Canola Commodity	Lambda-cyhalothrin (ppm)	R157836 (ppm)	Total	Concentration Factor	
				Parent	R157836
Seed	0.12,0.12,0.08	0.03,0.03,0.02	0.14	—	—
Meal	<0.01,<0.01	<0.01,<0.01	<0.01	0.08 - 0.13	0.33 - 0.5
Refined Oil	0.20,0.20	0.10,0.10	0.30	1.7 - 2.5	3.3 - 5

Data from pp. 13 of MRID 45443103.

The LOQ for lambda-cyhalothrin and R157836 was 0.01 ppm.

### Peaches

Zeneca Ag Products has submitted data from a processing study on peaches conducted in the United States in 1999. The results are reported in:

MRID 45443105. Kleinschmidt, M., Miller, M., (2001) Lambda-Cyhalothrin: Reduction of Residue Levels on Peaches from Trials Conducted in California during 1999. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 00-097B. January 29, 2001. Unpublished.

Two of 75 lb samples of marketable peaches, Cling and Freestone, were obtained from a local processor near the Western Research Center, Richmond, CA. The varieties were chosen because they are typical of those chosen to produce applesauce. The subset of each variety of apples were treated with WF2616 (1 lb ai/gal) capsule suspension diluted in local water. Lambda-cyhalothrin was applied 2 times in a spray chamber. Peaches were placed in a tray pedicel-end up and so as not to be in contact with one another then sprayed. After a 15 min. air drying period, the peaches were rotated as to be pedicel-end down and then resprayed. The peaches were allowed to dry after the last treatment. The total applied was reported to be equivalent to 0.2 lb ai/A for the Freestone peaches, which is 1X the maximum seasonal application rate and 0.39 lb ai/A for the Cling peaches, which is the 2X maximum seasonal application rate. A 3 lb sample of the untreated peaches and duplicate 3 lb samples of the treated peaches were collected into labeled

bags and place over blue-ice. The remainder of the peaches were boxed at ambient temperature. Both cooled and ambient containers were transferred on the same day as treatment to the processing and analytical facility, The National Food Laboratory, Inc., Dublin, California.

Each apple sample was washed, lye peeled, and canned yielding commercially canned peaches. All processed were done according to commercial practices except lye peel which was adapted to small batches by halving, pitting, and spraying the lye onto the peaches by hand before placement onto the steamer conveyor belt. Samples were taken during the processing: before and after washing (whole fruit), after peeling (halved fruit), and after canning (canned, cooked halved fruit). Samples were stored frozen,  $<-12^{\circ}\text{C}$ , until analysis. The sampling-to-extraction interval was no longer than 272 days. Samples were prepared for analysis by chopping with dry ice to obtain finely ground, homogenous samples. Sample extracts were stored frozen and analyzed within 72 days. Samples were analyzed for lambda-cyhalothrin and its epimer R157836 using methods adapted from PPRAM81/PPRAM70 described in Section OPPTS GLN 860.1340: Analytical Methods - Plants.

All untreated control samples were below the LOQ of 0.01 ppm for lambda-cyhalothrin and R157836. Residues on treated peaches before washing were 0.16-1.05 ppm for lambda-cyhalothrin and 0.02-0.06 ppm for R157836. Residues in peaches after washing declined ranging from 0.13-0.57 ppm for lambda-cyhalothrin and 0.01-0.06 ppm for R157836 for an average concentration factor of 0.76X. Residues in peaches after peeling declined significantly to  $<0.01$ -0.02 for lambda-cyhalothrin and  $<0.01$ -0.01 ppm for R157836 for an average concentration factor of 0.04X. Residues in peaches after canning declined significantly to  $<0.01$ -0.04 for lambda-cyhalothrin and  $<0.01$ -0.01 ppm for R157836 for an average concentration factor of 0.04X. The processing study was supported by adequate storage stability and method validation data. The results from the processing study on apples are shown in Table 15.



TABLE 15: Residues (uncorrected) of lambda-cyhalothrin and its epimer R157836 in/on peaches and processed peaches commodities.				
Commodity	Lambda-cyhalothrin (ppm)	R157836 (ppm)	Total	Concentration factor
<b>Residues on Freestone peaches following 2 spray applications for a total of 0.20 lb ai/A.</b>				
After Spray	0.27,1.05,0.22,0.16	0.02,0.03,0.03,0.02	0.29,1.08,0.25,0.18	—
Before Wash	0.24,0.23,0.16	0.02,0.02,0.02	0.26,0.25,0.18	—
After Wash	0.26,0.26,0.15,0.13	0.02,0.03,0.02,0.01	0.28,0.29,0.17,0.14	0.96
After Peeling	<0.01,<0.01,<0.01	<0.01,<0.01,<0.01	<0.02,<0.02,<0.02	0.04
After Canning	<0.01,<0.01,<0.01	<0.01,<0.01,<0.01	<0.02,<0.02,<0.02	0.04
<b>Residues on Cling peaches following 2 spray applications for a total of 0.39 lb ai/A.</b>				
After Spray	0.45,0.73,0.70,0.44	0.03,0.05,0.04,0.06	0.48,0.78,0.74,0.50	—
Before Wash	0.82,0.77,0.57,0.47	0.05,0.05,0.06,0.05	0.87,0.82,0.63,0.52	—
After Wash	0.26,0.46,0.37	0.03,0.04,0.04	0.29,0.50,0.41	0.56
After Peeling	<0.01,0.02,0.02	<0.01,0.01,0.01	<0.02,0.03,0.03	0.04
After Canning	0.04,0.02,0.01	0.01,0.01,<0.01	0.05,0.03,0.02	0.04

Data from pp. 14-15 and pp. 17-18 MRID 45443105.

The LOQ for lambda-cyhalothrin and R157836 is 0.01 ppm.

All untreated control samples were below the LOQ of 0.01 ppm for lambda-cyhalothrin and R157836.

#### **OPPTS GLN 860.1480: Meat/Milk/Poultry/Eggs**

##### **Ruminants**

Feed items associated with this petition that apply to ruminants are canola meal, wet apple pomace, and almond hulls. These commodities respectively represent up to 15, 40, and 10% of a beef cattle diet and 15, 20, and 10% of a dairy cattle diet. As shown in Table 16, the maximum theoretical dietary burden resulting from these proposed new uses is 2.84 ppm for beef cattle (65% of diet) and 1.59 ppm (45% of diet) for dairy cattle. Also shown in Table 16, is the worst-case scenario dietary burden based on commodities with established lambda-cyhalothrin tolerances (total of 10.0 and 10.9 ppm for beef and dairy cattle, respectively, from a diet of corn forage and alfalfa hay). Substitution of canola meal, wet apple pomace, and/or almond hulls for either corn forage or alfalfa hay does not increase the dietary burden for beef or dairy cattle. Therefore, the established tolerances for ruminant commodities (milk, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep) are adequate to cover the potential transfer of secondary residues resulting from the proposed new uses.

TABLE 16. Maximum theoretical dietary burdens of residues of lambda-cyhalothrin and its epimer R157836 to cattle for commodities associated with this and previous petitions.						
Commodity	Dry matter (%)	Proposed or established tolerance (ppm)	Beef cattle		Dairy cattle	
			% of diet	Burden (ppm)	% of diet	Burden (ppm)
MTDB based on commodities associated with this petition.						
Canola meal	88	1.0	15	0.17	15	0.17
Apple pomace, wet	40	2.50	40	2.500	20	1.250
Almond hulls	90	1.5	10	0.167	10	0.167
Total			65	2.84	45	1.59
MTDB based on commodities associated with previous petitions.						
Corn forage	40	6.0	40	6.000	50	7.500
Alfalfa hay	89	6.0	60 <sup>1</sup>	4.045	50 <sup>1</sup>	3.371
Total			100	10.0	100	10.9

Burden = (Residue (ppm) x % Diet)/% dry matter

<sup>1</sup>Alfalfa hay represents ≤70% of a beef cattle diet and ≤60% of a dairy cattle diet; it represented 60% and 50% of this theoretical diet for beef and dairy cattle, respectively.

### Poultry

The only poultry feed item associated with this petition is canola meal, which represents up to 15% of a poultry diet, and results in a dietary burden of 0.15 ppm. As shown in Table 17, the worst-case scenario dietary burden for poultry based on commodities with established lambda-cyhalothrin tolerances is 1.4 ppm. Substitution of canola meal for either rice grain or hulls, or sorghum grain does not increase the dietary burden for poultry. Therefore the established tolerances for poultry commodities (eggs, fat, meat, and meat byproducts) are adequate to cover the potential transfer of residues resulting from the proposed new uses.

<b>TABLE 17. Maximum theoretical dietary burdens of residues of lambda-cyhalothrin and its epimer R157836 to poultry for commodities associated with this and previous petitions.</b>			
<b>Commodity</b>	<b>Proposed or established tolerance (ppm)</b>	<b>% of poultry diet</b>	<b>Burden (ppm)</b>
<b>MTDB based on commodities associated with this petition.</b>			
Canola meal	1.0	15	0.15
<b>MTDB based on commodities associated with previous petitions.</b>			
Rice grain	1.0	60	0.600
Rice hulls	5.0	15	0.750
Sorghum, grain	0.2	25 <sup>1</sup>	0.050
<b>Total</b>		100	1.400

Burden in poultry = (Residue in ppm x Fraction of diet)

<sup>1</sup>Sorghum grain can represent up to 80% of a poultry diet; it represented 25% of this theoretical diet.

### Swine

The only swine feed item associated with this petition is canola meal, which represents up to 15% of a swine diet, and results in a dietary burden of 0.15 ppm. As shown in Table 18, the worst-case scenario dietary burden for swine based on commodities with established lambda-cyhalothrin tolerances is 0.72 ppm. Substitution of canola meal for either rice grain or hulls, or sorghum grain does not increase the dietary burden for swine. Therefore the established tolerances for swine commodities (fat, meat, and meat byproducts) are adequate to cover the potential transfer of residues resulting from the proposed new uses.

<b>TABLE 18. Maximum theoretical dietary burdens of residues of lambda-cyhalothrin and its epimer R157836 to swine for commodities associated with this and previous petitions.</b>			
<b>Commodity</b>	<b>Proposed or established tolerance (ppm)</b>	<b>% of swine diet</b>	<b>Burden (ppm)</b>
<b>MTDB based on commodity associated with this petition.</b>			
Canola meal	1.0	15	0.15
<b>MTDB based on commodities associated with previous petitions.</b>			
Rice grain	1.0	65	0.650
Sorghum, grain	0.2	35 <sup>1</sup>	0.070
<b>Total</b>		100	0.720

Burden in swine = (Residue in ppm x Fraction of diet)

<sup>1</sup>Sorghum grain can represent up to 90% of a swine diet; it represented 35% of this theoretical diet.

### **OPPTS GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops**

No new studies were submitted with this petition. Rotational studies are potentially relevant for only canola and tobacco since pome fruits, stone fruits, and tree nuts are perennials. Previous studies showed that significant residues (exceeding the LOQ of 0.01 ppm) will not be present in crops rotated 30 days after application of parent lambda-cyhalothrin. According to the EFED review of 4/6/88, no additional rotational crop data were needed to support registered application rates at that time (PP#6F4769 & PP#6H4775, DP Barcodes: D228792 & D228931, J.J. Morales et al., 5/28/97). The submitted label (which does not include crops under consideration for the present petition) has no restriction on replanting of crops for which lambda-cyhalothrin as the formulation KARATE is used. Restrictions would not be expected because lambda-cyhalothrin is non-systemic and has a rather short half-life of 10–14 days (NV920006, DP Barcode: D185478, G. Jeffrey Herndon, 10/8/92).

### **International Residue**

Current status sheets available to HED indicate that a Codex maximum residue level (MRL) of 0.2 ppm has been established for pome fruits for cyhalothrin, which is inconsistent with the proposed U.S. lambda-cyhalothrin tolerance of 0.3 ppm for pome fruits (Crop Group 11). It is unclear if harmonization can be achieved because residues up to 0.25 ppm were found in the U.S. trials for apples. Codex MRLs were not established for the other crops presently under consideration [canola seed, stone fruits (Crop Group 12), tree nuts (Crop Group 14), and tobacco]. Neither Canadian nor Mexican MRLs are established for lambda-cyhalothrin for any crops for which tolerances are being presently recommended.

Attachment 1: Citations of studies reviewed by ORNL for DP Barcode D262858.

Attachment 2: International Residue Status Sheet

**Attachment 1.****CITATIONS**

The following reports were reviewed by ORNL for lambda-Cyhalothrin (DP Barcode: D262858):

- 1) MRID 45007001. Spiller, C.J. and Kahn, B.B.(1999) Lambda-cyhalothrin: residue levels on apples from trials conducted in the United States during 1997. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR98-068B. April 7, 1999.
- 2) MRID 45007002. Spillner C., and R. Hampton (1999) Lambda-cyhalothrin: processing study on apples from a trial conducted in Washington during 1997. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 99-010B. July 26, 1999. Unpublished.
- 3) MRID 45007003. Spiller, C.J. and Kahn, B.B.(1999) Lambda-cyhalothrin: residue levels on pears from trials conducted in the United States during 1997. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR98-072B. May 6, 1999.
- 4) MRID 45007004. Spillner, C. J., B. V. Thomas, and B. B. Kahn (1999) Lambda-cyhalothrin: residue levels in sweet cherries from trials conducted in the United States in 1997. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 98-060B. January 14, 1999. Unpublished.
- 5) MRID 45007005. Spillner, C. J., R. J. Bussey, and B. B. Kahn (1998) Lambda-cyhalothrin: Residue levels on peaches from trials conducted in the United States during 1997. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 98-062B. December 14, 1998. Unpublished
- 6) MRID 45007006. Spillner, C. J., B. V. Thomas, and B. B. Kahn (1998) Lambda-cyhalothrin: Residue levels in plums from trials conducted in the United States in 1997. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 98-053B. December 10, 1998. Unpublished.
- 7) MRID 45007007. Spillner, C. J., B. V. Thomas, and B. B. Kahn (1998) Lambda-cyhalothrin: processing study on plums from a trial conducted in California during 1997. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 98-061B. December 10, 1998. Unpublished.
- 8) MRID 45007008. Miller, M.M. and J.C. Aston (1999) Lambda-cyhalothrin: residue levels on almonds from trials conducted in the United States during 1998. Zeneca Ag

- Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 99-032B. July 6, 1999. Unpublished.
- 9) MRID 45007009. Miller, M.M. and J.C. Aston (1999) Lambda-cyhalothrin: residue levels on pecans from trials conducted in the United States during 1998. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 99-028B. July 1, 1999. Unpublished.
  - 10) MRID 45007010. Spillner, C.J. B. Kahn, and J.L. Marth (1999) Lambda-cyhalothrin: residue levels on tobacco from a trial conducted in the United States during 1997. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 98-057B. January 7, 1999. Unpublished.
  - 11) MRID 45007011. Markle, J.C., P.D. Francis, and C.J. Spillner (1998) Lambda-cyhalothrin (ICIA0321): residue levels on flue-cured tobacco from trials conducted in the United States during 1996. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 97-038B. August 26, 1998. Unpublished
  - 12) MRID 45032401. Miller, M.M. and R. McDonnell (1999) Lambda-cyhalothrin: residue levels on canola from trials conducted in Canada during 1998. Zeneca Ag Products, Richmond, CA.. Report No. RR 99-059B. November 3, 1999. Unpublished.
  - 13) MRID 45443101. Miller, M.M. (2000) Lambda-Cyhalothrin: Residue Levels on Canola from Trials Conducted in the United States during 1999. Zeneca Ag Products, Richmond, CA. Report No. RR 00-038B. June 6, 2000. Unpublished.
  - 14) MRID 45443102. Schwab, D., Anderson, C., Niekamp, J. (2001) Lambda-Cyhalothrin: Residue Levels on Canola from Trials Conducted in Canada during 2000. Syngenta Crop Protection, Inc., Richmond, CA. Report No. RR 00-075B. June 1, 2001. Unpublished.
  - 15) MRID 45443103. Miller, M., (2000) Lambda-Cyhalothrin: Residue Levels on Processed Commodities of Canola from a Trial Conducted in the United States during 1999. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 00-037B. May 30, 2000. Unpublished.
  - 16) MRID 45443104. Kleinschmidt, M., and Miller M. (2001) Lambda-Cyhalothrin: Reduction in Residue Levels on Apples from Trials Conducted in the United States during 1999. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 00-096B. January 31, 2001. Unpublished.

- 17) MRID 45443105. Kleinschmidt, M., Miller, M., (2001) Lambda-Cyhalothrin: Reduction of Residue Levels on Peaches from Trials Conducted in California during 1999. Zeneca Ag Products, Western Research Center, 1200 South 47<sup>th</sup> Street, Richmond, CA 94804-4610. Report No. RR 00-097B. January 29, 2001. Unpublished.

**Attachment 2.**

INTERNATIONAL RESIDUE LIMIT STATUS			
Chemical Name: lambda-cyhalothrin [1:1 mixture of (S)- $\alpha$ -cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)- $\alpha$ -cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate]	Common Name: lambda-cyhalothrin	<input checked="" type="checkbox"/> Proposed tolerance <input type="checkbox"/> Reevaluated tolerance <input type="checkbox"/> Other	Date: October 2, 2001
<b>Codex Status (Maximum Residue Limits)</b>		<b>U. S. Tolerances</b>	
<input type="checkbox"/> No Codex proposal step 6 or above <input type="checkbox"/> No Codex proposal step 6 or above for the crops requested		Petition Number: 0F6092 DP Barcode: D262858 Other Identifier: PC Code 128897 (formerly 128867)	
Residue definition (step 8/CXL): <i>MRLs exist for cyhalothrin, but not for lambda-cyhalothrin. Residue definition is sum of all isomers.</i>		Reviewer/Branch: Bill Cutchin/RAB2	
		Residue definition: (*see footnote)	
Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm) <b>PROPOSED</b>
pome fruits	0.2	Canola seed	0.15
		Canola meal	0.30
		Canola oil	0.40
		Pome fruit (Crop Group 11)	0.30
		Apple pomace, wet	2.50
		Stone fruit (Crop Group 12)	0.50
		Tree nuts, nutmeat (Crop Gp. 14)	0.05
		Almond hulls	1.5
<b>Limits for Canada</b>		<b>Limits for Mexico</b>	
<input type="checkbox"/> No Limits <input checked="" type="checkbox"/> No Limits for the crops requested		<input type="checkbox"/> No Limits <input checked="" type="checkbox"/> No Limits for the crops requested	
Residue definition: cyhalothrin-lambda		Residue definition: lamda cvalotrina (cvalotrina)	
Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)



Notes/Special Instructions: S.Funk, 10/02/01.

Rev. 1998

\*Residues of lambda-cyhalothrin, a 1:1 mixture of (S)- $\alpha$ -cyano-3-phenoxybenzyl- (Z)-(1R,3R)-3- (2-chloro-3,3,3- trifluoroprop-1-enyl) -2,2-dimethylcyclopropane-carboxylate and (R)- $\alpha$ -cyano-3-phenoxybenzyl-(Z)- (1S,3S)-3- (2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropane-carboxylate and its epimer expressed as epimer of lambda- cyhalothrin, a 1:1 mixture of (S)- $\alpha$ -cyano-3-phenoxybenzyl- (Z)- (1S,3S)-3- (2-chloro-3,3,3-trifluoroprop-1-enyl)- 2,2-dimethylcyclopropanecarboxylate and (R)- $\alpha$ -cyano-3-phenoxy- benzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate



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047757

**Chemical:** ALPHA-CYANO-3-PHENOXYBENZYL-3-(2-CHLORO-

**PC Code:** 128897

**HED File Code** 11000 Chemistry Reviews

**Memo Date:** 06/27/2002

**File ID:** DPD262858

**Accession Number:** 412-03-0018

**HED Records Reference Center**  
11/12/2002