

US EPA ARCHIVE DOCUMENT

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Residue Chemistry Review

Comments:

Subject: PP No. 5F04588, Lambda-Cyhalothrin (KarateR) on alfalfa, leaf lettuce, and the head and stem Brassica crop subgroup. Evaluation of Residue Data and Analytical Methodology. Chemical No. 128897. D219683. CBTS No. 16293. MRID No. 43781001, 43781002, 43781003, and 43781004, Case No. 287003.

Document

Class:

Product

Chem:

Residue

Chem:

860.1200 Directions for use
860.1380 Storage stability data
860.1480 Meat/milk/poultry/eggs
860.1500 Crop field trials
860.1550 Proposed tolerances

Biochemicals:

DP Barcode: D219683

MRIDs: 43781001, 43781002, 43781003, 43781004

PC Codes: 128897 lambda-Cyhalothrin

Commodities: Alfalfa; Lettuce, Leaf; Broccoli; Cauliflower; Cabbage; Broccoli, Chinese; Brussels sprouts; Cabbage, Chinese; Kohlrabi; Cattle, Meat; Goat, Meat; Hog, Meat; Horse, Meat; Sheep, Meat; Poultry, Meat; Cattle, Liver; Goat, Liver; Hog, Liver; Horse, Liver; Sheep, Liver; Cattle, Kidney; Goat, Kidney; Hog, Kidney; Horse, Kidney; Sheep, Kidney; Poultry, MBYP; Cattle, Fat; Goat, fat; Hog, Fat; Horse, Fat; Sheep, Fat; Poultry, fat; Milk, fat; Egg

Administrative #: 5F04588

Reviewers: Linda Kutney

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MEMORANDUM

SUBJECT: PP No. 5F04588, Lambda-Cyhalothrin (Karate^R) on alfalfa, leaf lettuce, and the head and stem Brassica crop subgroup. Evaluation of Residue Data and Analytical Methodology. Chemical No. 128897. D219683. CBTS No. 16293. MRID No. 43781001, 43781002, 43781003, and 43781004, Case No. 287003.

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THROUGH: Elizabeth Haeberer, Acting Branch Chief
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TO: Debbie McCall, Acting Section Head
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Zeneca Ag Products (formerly ICI Agricultural Products) is requesting the establishment of tolerances for the insecticide lambda-cyhalothrin on alfalfa, leaf lettuce, and the head and stem Brassica crop subgroup. The requested tolerances for lambda-cyhalothrin and its epimer are:

Alfalfa, forage	3.0 ppm
Alfalfa, hay	4.0 ppm
Lettuce, leaf	2.0 ppm
and	
head and stem Brassica crop subgroup (broccoli; broccoli, Chinese; Brussels sprouts; cabbage; cabbage, Chinese (napa); cabbage, Chinese mustard; cauliflower; caval broccolo; and kohlrabi)	0.4 ppm

Tolerances with an expiration date of November 15, 1997 are established in 40 CFR §180.438, 40 CFR 185.3765 and 40 CFR 186.3765 for residues of lambda-cyhalothrin (a 1:1 mixture of (S)- α -cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-

2,2-dimethylcyclopropanecarboxylate and (R)- α -cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer a 1:1 mixture of (S)- α -cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)- α -cyano-3-phenoxybenzyl (Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate on several raw agricultural commodities (RACs) at levels ranging from 0.01 to 6.0 ppm, including the time-limited tolerances established under 40 CFR 180.438 for Brassica members, broccoli and cabbage at 0.4 ppm, and for head lettuce at 2.0 ppm. A time-limited food additive tolerance of 10.0 ppm in/on dried hops is established under 40 CFR §185.1310. Current time-limited tolerances for animal products are: meat of cattle, goats, hogs, horses, and sheep-0.2 ppm; meat of poultry-0.01 ppm; meat byproducts (mbyp) of cattle, goats, hogs, horses & sheep-0.2 ppm; mbyp of poultry- 0.01 ppm; fat of cattle, goats, hogs, horses, and sheep-3.0 ppm; fat of poultry-0.01 ppm; milk fat 5.0 ppm (reflecting 0.2 ppm in whole milk); and eggs-0.01 ppm.

CBTS understands that the existing tolerances on broccoli, cabbage, and animal commodities were established as time-limited tolerances because of environmental and ecological concerns.

No registration standard has been issued for lambda-cyhalothrin.

CBTS has recommended for several section 18 uses of lambda-cyhalothrin on crops such as rice, wheat and sorghum.

CONCLUSIONS

1. The manufacturing process of technical grade lambda-cyhalothrin has been adequately described. CBTS does not foresee any residue problems from impurities in the technical.
- 2a. CBTS suggests that a revised Section B/label be submitted which includes the following restriction: "Do not tank mix with any pesticidal product which does not have a registered use."
- 2b. Section B gives the maximum pounds ai per acre per season to be used on alfalfa. A revised KARATE[®] label should also be submitted which states the maximum pounds ai per acre per season to be used on alfalfa, as has been done in Section B.
3. The nature of the residue in plants and animals is adequately understood. The residue to be regulated is lambda-cyhalothrin and its epimer.
- 4a. 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 plants.

- 4b. ICI Method 86 has been validated as an adequate enforcement method by EPA for determination of parent lambda-cyhalothrin and its epimer in/on animal tissues and milk.
- 4c. Analytical reference standards are available from the Pesticide and Industrial Chemical Repository, RTP, NC.
- 4d. Multiresidue method data have been submitted to FDA for evaluation.
- 5a. Storage stability data are adequate for alfalfa, lettuce, and the head and stem Brassica crop subgroup.
- 5b. *The submitted residue data do not support the proposed tolerances on alfalfa. The petitioner should submit a revised section F which proposes tolerances of 5.0 in alfalfa forage and 6.0 ppm in alfalfa hay.*
- 5c. The submitted residue data are adequate in quantity, quality and geographic representation to support the proposed tolerance of 2.0 ppm lambda-cyhalothrin and its epimer on leaf lettuce.
- 5d. The referenced residue data are adequate in quantity, quality and geographic representation to support the proposed tolerance of 0.4 ppm lambda-cyhalothrin and its epimer on the head and stem Brassica crop subgroup 5A.
- 6a. Alfalfa forage, hay, meal and silage are animal feed items for beef and dairy cattle. Alfalfa meal is a feed item for poultry and swine. No feed items are involved with the proposed uses on leaf lettuce and the head and stem Brassica crop subgroup.
- 6b. Established time-limited tolerances for animal commodities are adequate to cover the proposed uses, with the exception of poultry fat.
- 6c. *The current time-limited tolerance for poultry fat for lambda-cyhalothrin of 0.01 ppm may be exceeded. An updated tolerance of 0.03 ppm for "poultry, fat" should be proposed in a revised Section F for lambda-cyhalothrin and its epimer.*
- 6d. *The Petitioner must submit a revised Section F which proposes a tolerance of 2.0 ppm for "aspirated grain fractions."*
- 7. An International Residue Limit Status sheet is attached to this review. Since no Codex, Mexican or Canadian tolerances are established for lambda-cyhalothrin on/in alfalfa, lettuce

and the Brassica crop group, no compatibility problems exist. However, there are some CODEX limits for lambda-cyhalothrin (sum of isomers) on other crops, and a Mexican expression exists for the parent, presumed.

RECOMMENDATIONS

TOX considerations permitting and provided a revised Section B/label is submitted as described in Conclusion 2a above, CBTS can recommend for the proposed tolerances for lambda-cyhalothrin and its epimer at 2.0 ppm on leaf lettuce and 0.4 ppm on the head and stem Brassica crop subgroup. A DRES run may be initiated at this time.

CBTS recommends against a tolerance on alfalfa forage and hay for the reasons stated in conclusions 2a, 2b, 5b, 6b, 6c, and 6d, above. However, provided revised Sections B and F are submitted to address these conclusions, CBTS can recommend for tolerances of 5.0 ppm on alfalfa forage, 6.0 ppm in alfalfa hay, 0.03 ppm in poultry fat, and 2.0 ppm in aspirated grain fractions, TOX considerations permitting. These levels can be included in the DRES run.

CBTS understands that the existing tolerances on broccoli, cabbage, and animal commodities were established as time-limited tolerances because of environmental and ecological concerns.

DETAILED CONSIDERATIONS

PRODUCT CHEMISTRY

MANUFACTURE

No additional product chemistry data were submitted with this registration. The manufacturing process of technical grade lambda-cyhalothrin has been adequately described in a previous review. CBTS does not foresee any residue problems from impurities in the technical. (PP# 5E4431, S. Willett, 6/3/96).

Conclusion

The manufacturing process of technical grade lambda-cyhalothrin has been adequately described. CBTS does not foresee any residue problems from impurities in the technical.

FORMULATION

The formulation to be used is KARATE® Insecticide, an emulsifiable concentrate containing 1 pound ai of lambda-cyhalothrin per gallon (equivalent to 13.1 % ai lambda-cyhalothrin) and 86.9% inert ingredients.

RESIDUE CHEMISTRY

PROPOSED USE

The table below, entitled "Proposed Use Summary," lists directions for lambda-cyhalothrin use on leaf lettuce, alfalfa, and the head and stem Brassica crop subgroup. The petitioner and EPA define the head and stem Brassica crop subgroup as including broccoli; Chinese broccoli; Brussels sprouts; cabbage; Chinese (napa) cabbage; Chinese mustard cabbage; cauliflower; cavalo broccolo; and kohlrabi. The Agency defines representative crops for the head and stem Brassica crop subgroup as including broccoli or cauliflower and cabbage. Time-limited tolerances have already been established under 40 CFR 180.438 for broccoli and cabbage at 0.4 ppm. A time-limited tolerance also is in place under 40 CFR 180.438 for head lettuce at 2.0 ppm.

PROPOSED LABEL SUMMARY

DIRECTIONS/COMMENTS	USE RATES/TREATMENT SCHEDULE*	PHI	SEASONAL MAXIMUM
LETTUCE, HEAD AND LEAF			
Apply as required by scouting, usually at intervals of 5 or more days. Timing and frequency of applications should be based upon insect populations reaching locally determined economic thresholds.	0.015 - 0.025 LB AI/A (equivalent to 1.92-3.20 fl oz/A)	1 day	Do not apply more than 0.3 lb ai (2.4 pint) per acre/season.
Apply with ground or air equipment using sufficient water to obtain full coverage of foliage. When applying by air, apply in a minimum of 2 gallons of water per acre.	0.020 - 0.030 LB AI/A (equivalent to 2.56-3.84 fl oz/A)		
Do not apply within 1 day of harvest.			
Do not apply more than 0.3 lb ai (2.4 pints) per acre per season.			
ALFALFA, ALFALFA GROWN FOR SEED			
Use higher recommended dosage for increased pest pressure or for increased residual pest control.	0.015 - 0.025 LB AI/A equivalent to (1.92-3.20 fl oz/A)	1 day Forage	Do not apply more than 0.12 lb ai/A per season-NOTE THIS RESTRICTION IS ON THE PROPOSED DIRECTIONS FOR USE, BUT NOT IN THE KARATE® LABEL BOOKLET.
Apply a minimum of 2 gallons of finished spray per acre by aircraft or 10 gallons of water with ground equipment. Use higher gallonage, 5-10 gallons by air, or 20 by ground, finished spray per acre when foliage is dense and/or when pest populations are high.	0.020 - 0.030 LB AI/A equivalent to (2.56-3.84 fl oz/A)	7 days-Hay	
Do not apply more than 0.03 lb ai/A per cutting. Do not apply within 1 day of harvest for forage or within 7 days of harvest for hay.			
HEAD AND STEM BRASSICA CROP SUBGROUP			
Apply as required by scouting, usually at intervals of 5 or more days. Timing and frequency of applications should be based upon insect populations reaching locally determined economic thresholds.	0.015 - 0.025 LB AI/A equivalent to (1.92-3.20 fl oz/A)	1 day	Do not apply more than 0.24 lb ai/A (1.92 pts/A) per season
Apply with ground or air equipment using sufficient water to obtain full coverage of foliage. When applying by air, apply in a minimum of 2 gallons of water per acre.	0.020 - 0.030 LB AI/A equivalent to (2.56-3.84 fl oz/A)		
Do not apply within 1 day of harvest.			
Do not apply more than 0.24 lb ai (1.92 pints) per acre per season.			

* NOTE: RATES TO BE USED ARE DEPENDENT ON THE TYPE AND INTENSITY OF TARGET PESTS TO BE CONTROLLED (LISTED IN ACTUAL LABEL). Also note that the Registrant certifies that the proposed directions for use are identical to those approved under the registrations for broccoli and cabbage, and under the registration for head lettuce.

CBTS suggests that a revised Section B/label be submitted which includes the following restriction with use directions: "Do not tank mix with any pesticidal product which does not have a registered use."

Section B gives the maximum pounds ai per acre per season to be used on alfalfa. A revised KARATE® label should also be submitted which states the maximum pounds ai per acre per season to be used on alfalfa, as has been done in Section B.

NATURE OF THE RESIDUE-PLANTS

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 (Lambda-cyhalothrin SF, G. Kramer, 2/9/96).

Conclusion

Based on metabolism studies conducted on cotton, cabbage, soybeans and wheat; the nature of the residue in plants is adequately understood. The residue to be regulated is lambda-cyhalothrin and its epimer.

NATURE OF RESIDUE - ANIMALS

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

Lambda-cyhalothrin is the major component of the residue, except for kidney and liver of ruminants and liver of poultry. In addition to the plant metabolites, 3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2-hydroxymethyl-2-methylcyclopropane-carboxylic acid (OH-CPA) and 4-hydroxy-3-phenoxybenzoic acid (4'-OH-3PBAcid) may be present in significant quantities. A residue

transfer study in which cows were fed dietary levels of 8, 25 or 80 ppm lambda-cyhalothrin demonstrated that, at < 8 ppm, OH-CPA levels in tissue would not exceed 0.01 ppm (See Reference in PP# 2F4109, 2F4114, 7F3560, and 1F3992, M. Flood, 8/31/92). As with plants, the residue to be regulated is lambda-cyhalothrin and its epimer.

HED has determined that animal metabolites do not need to appear in the tolerance expression at this time (PP# 1F3992, M. Flood, 12/26/91 and FAP#OH5599, M. Flood, 8/31/92). CBTS will not require further animal metabolism data to support new uses for lambda-cyhalothrin on alfalfa, lettuce or the Brassica crop group.

Conclusion

The nature of the residue in animals is adequately understood; the residue to be regulated is lambda-cyhalothrin, per se, and its epimer.

ANALYTICAL METHODS

ICI Method 81 (MRID# 40054001) was used to determine the residues of lambda-cyhalothrin and its epimer in plant matrices. ICI Method 81 has undergone an EPA method validation for soybeans (PP# 6F3318, PP# 7F3488, E. Greer, 9/30/87) and was found to be adequate for enforcement purposes (PP# 6F3318, S. Brooks, 10/30/87).

ICI Method 81 involves acetone:hexane 1:1 (v/v) extraction, followed by liquid-liquid chromatography to remove lipids and florisil column cleanup. Quantification uses capillary GC with electron capture detection. The limit of detection and quantification was 0.01 ppm for lambda-cyhalothrin and its enantiomer (PP# 7F3488, J. Morales, 11/17/92).

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 tissue with 50% acetone:hexane. The aqueous fraction is removed and the organic layer dried with sodium sulfate, and then cleaned using Florisil column chromatography. Determination is accomplished using packed column gas chromatography and a ⁶³Ni electron capture detector. The limit of determination 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 C₁₈ 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 C₁₈ 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 electron capture detector. 4'-OH-3-PBAcid is quantitated using HPLC with electrochemical detection. The limit of determination is 0.01 ppm. (PP# 7F3488, J. Morales, 11/17/92).

Analytical reference standards are available from the Pesticide and Industrial Chemical Repository, RTP, NC. (Section 18# 93TX0028, J. Stokes, 8/6/93).

Multiresidue method data have been submitted to FDA for evaluation (Section 18# 93TX0028, J. Stokes, 8/6/93).

Conclusions

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 plants.

ICI Method 86 has been validated as an adequate enforcement method by EPA for determination of parent lambda-cyhalothrin and its epimer in/on animal tissues and milk.

Analytical reference standards are available from the Pesticide and Industrial Chemical Repository, RTP, NC.

Multiresidue method data have been submitted to FDA for evaluation.

STORAGE STABILITY:**Alfalfa**

Alfalfa forage and hay were fortified with lambda-cyhalothrin, its enantiomer, and its metabolites and stored frozen at <-15C. ICI method 81 was used to obtain the results summarized in the following tables. Storage time to extraction generally increases for each commodity, as one reads towards the bottom of the table. In all cases, between 2-22 days were needed to proceed from extraction to final analysis.

STORAGE STABILITY RESULTS FOR LAMBDA-CYHALOTHRIN AND ITS ENANTIOMER					
ALFALFA FORAGE SAMPLES					
ID NO F7-...	SAMPLE TO EXTRACTION (DAYS)	FORTIFICATION (PPM) R157836 CYHALOTHRIN	FORTIFICATION (PPM) ICIA0321 ENANTIOMER	% RECOVERY R157836 CYHALOTHRIN	% RECOVERY ICIA0321 ENANTIOMER
63-1	248-259	0.52-2.59	0.39-1.97	90-102	89-104
62-1	247-261	0.26-2.59	0.2-1.97	96-113	97-114
61-1	287-316	0.26-2.59	0.2-1.97	91-111	91-111
31-1	390	0.57	0.43	94	98
07-1	448	0.57	0.43	116	115
01-1	454	0.28	0.22	96	97
33-1	956	0.57	0.43	101	98
ALFALFA HAY SAMPLES					
ID NO F7-...	SAMPLE TO EXTRACTION (DAYS)	FORTIFICATION (PPM) R157836 CYHALOTHRIN	FORTIFICATION (PPM) ICIA0321 ENANTIOMER	% RECOVERY R157836 CYHALOTHRIN	% RECOVERY ICIA0321 ENANTIOMER
62-14	287-300	0.26-2.59	0.2-1.97	92-108	92-100
63-14	309	2.59	1.97	108	114
09-5	325	0.028	0.022	92	92
61-14	335-338	0.014-2.59	0.011-1.97	94-120	93-129
06-5	429	0.028	0.022	104	82
01-5	438	2.84	2.16	115	112

STORAGE STABILITY RESULTS FOR METABOLITES OF LAMBDA-CYHALOTHRIN							
ID NO F7..	SAMPLE TO EXTRACTION (DAYS)	FORTIFICATION (PPM) PP890	FORTIFICATION (PPM) 3PB ACID	FORTIFICATION (PPM) 3PB ALCOHOL	% RECOVERY PP890	% RECOVERY 3PB ACID	% RECOVERY 3PB ALCOHOL
3 ALFALFA FORAGE SAMPLES							
31-1	662	0.02	0.02		76	112	
01-1	784	0.05 0.01	0.01	0.05	105 82	109	102
ALFALFA HAY SAMPLES							
01-5	776	0.1 0.25		0.25 0.5	67 87		77 94
34-5	809	0.5		0.5	87		94

Alfalfa forage and hay samples were stored frozen at <-15 C for 126-956 days from sampling to extraction and an additional 2-22 days from extraction to analysis. The sample storage conditions and timeframes were similar to the fortified samples. Recoveries reported for alfalfa samples were acceptable (ranging from 90-123% for lambda-cyhalothrin, 82-129% for its enantiomer, and 67-105% for PP890, 109-112% for 3PB Acid and 77-102% for 3PB Alcohol metabolites).

Conclusion

Storage stability data for alfalfa are adequate.

Leaf Lettuce

Leaf lettuce was fortified with lambda-cyhalothrin, its enantiomer, and its metabolites at 0.01 to 0.57 mg/kg (ppm), and stored frozen at <-15 C for about 24 months (557-706 days) before extraction and an additional 1-7 days from extraction to analysis. These results are summarized in the following table.

STORAGE STABILITY RESULTS FOR LAMBDA-CYHALOTHRIN AND ITS METABOLITES ON LEAF LETTUCE

ID NO F7-	SAMPLE TO EXTRACTION (DAYS)	FORTIFICATION (PPM)	FORTIFICATION (PPM)	FORTIFICATION (PPM)	FORTIFICATION (PPM)	FORTIFICATION (PPM)	% RECOVERY	% RECOVERY	% RECOVERY	% RECOVERY	% RECOVERY
		R157836 CYHALOTHRIN	ICIA0321 ENANTIOMER	PP890	3PB ACID	3PB ALC	R157836 CYHALOTHRIN	ICIA0321 ENANTIOMER	PP890	3PB ACID	3PB ALCOHOL
LEAF LETTUCE SAMPLES											
81-1	557			0.01 0.20	0.01	0.21			123 106	106	75
85-1	601	0.57	0.43				81	81			
86-2	655	0.28	0.22				78	73			
88-2	673	0.28	0.22				91	87			
87-1	706	0.57	0.43				93	93			

Leaf lettuce samples were stored frozen at <-15 C for 503-720 days from sampling to extraction and an additional 1-7 days from extraction to analysis. The sample storage conditions and timeframes were similar to the fortified samples. Recoveries reported for leaf lettuce were acceptable (ranging from 73-123%).
Conclusion

Storage stability data for leaf lettuce are adequate.

Brassica Vegetables

Storage stability data for lambda-cyhalothrin have been previously reviewed. Storage stability data for lambda-cyhalothrin indicate that residues are stable in peach, pea, oilseed rape, wheat grain, sugarbeet root, cottonseed, apple, cabbage and potato when stored at -18 C for periods up to 26 months (PP# 1F3952/1H5607, M. Flood, 9/19/91). Data for lambda-cyhalothrin also cover the epimer.

Conclusion

Storage stability data are adequate for head and stem Brassica crops.

CROP FIELD TRIALS

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Residues of lambda-cyhalothrin and its enantiomer and metabolites in/on alfalfa forage and hay, and leaf lettuce are summarized in the following tables. Preliminary data reported prior to the final study, i.e., the "pilot" study, are also summarized.

Zeneca Agricultural Products (previously ICI Americas) of Wilmington, Delaware, conducted the field trials submitted in support of the current petition.

Alfalfa

Sixteen field trials were conducted on alfalfa forage and hay in twelve States between March and November, 1990. The field trials were conducted using ground and aerial applications in AZ, CA, IA, ID, KS, MI, MN, MT, NE, NY, SD, and WI, representing EPA Regions 1, 5, 7, 8, 9, 10, and 11.

Samples of alfalfa forage and hay were analyzed, using ICI (now Zeneca) analytical method 81, for residues of parent lambda-cyhalothrin, its epimer, and two metabolites, observing a 1 day PHI for forage and a 7 day PHI for hay. Samples were stored for up to 978 days. Maximum combined residues in forage (at the proposed 1 day PHI) were 5.0 ppm, and in alfalfa hay (at the proposed 7 day PHI) were 6.0 ppm.

The pilot program (study 0321-90-MR-08) used ground application of lambda-cyhalothrin (KARATE®) on alfalfa in IA, CA, AND ID for four times (in CA and IA) and three times (ID) at the 0.03 lb ai/A rate, for a seasonal total of 0.12 lb ai/A or 0.09 lb ai/A. The maximum label rate proposed for alfalfa in the proposed directions for use is 0.12 lb ai/A/season. The alfalfa was cut after 1, 7-8, and 14 days to determine the amount of lambda-cyhalothrin in/on alfalfa. This maximum label rate for alfalfa should be added to the KARATE® label, too. (MRID 437810-02).

LAMBDA-CYHALOTHRIN IN ALFALFA FORAGE & HAY DATA FROM THE PILOT STUDY CONDUCTED IN IA, CA, AND ID					
CROP	SPRAY	# TRIALS	PHI	RANGE (ppm)	MEAN (PPM)
Lambda-Cyhalothrin					
FORAGE	GROUND	12	1	0.62-3.8	1.6
HAY		12	7	0.22-3.4	1.8
FORAGE	AERIAL	4	1	0.78-3.8	1.9
HAY		4	7	0.32-4.9	2.2
Lambda-Cyhalothrin Enantiomer					

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LAMBDA-CYHALOTHRIN IN ALFALFA FORAGE & HAY DATA FROM THE PILOT STUDY CONDUCTED IN IA, CA, AND ID

CROP	SPRAY	# TRIALS	PHI	RANGE (ppm)	MEAN (PPM)
FORAGE	GROUND	12	1	0.07-0.44	0.24
HAY		12	7	0.07-0.44	0.25
FORAGE	AERIAL	4	1	0.06-0.97	0.41
HAY		4	7	0.06-0.98	0.42

MAXIMUM RESIDUES OF LAMBDA-CYHALOTHRIN, ITS ENANTIOMER, PP890 AND 3-PB ACID IN ALFALFA FORAGE & HAY. DATA FROM THE PILOT STUDY, 0321-90-MR-08, CONDUCTED IN IA, CA, AZ, AND ID

CROP	LAMBDA-CYHALOTHRIN	ENANTIOMER	PP890	3-PB ACID	PHI
FORAGE	3.8	0.97	0.08	0.07	1
HAY	4.9	0.98	0.34	0.32	7 TO 8

The full-scale ground application residue study (0321-90-MR-01) and an aerial application study (0321-90-MR-04) involved application of lambda-cyhalothrin (KARATE®) one time on alfalfa just prior to cutting, at the 0.03 lb ai/A rate. The alfalfa was then cut after 1, 7, and 14 days to determine the amount of lambda-cyhalothrin in/on alfalfa. (A seasonal total of 0.12 lb ai/A was the maximum label rate proposed for alfalfa and this maximum label rate for alfalfa should be added to the KARATE® label, too. (MRID 437810-02).

LAMBDA-CYHALOTHRIN & ENANTIOMER (PPM) AFTER GROUND APPLICATION TO ALFALFA

CROP	PHI	LAMBDA-CYHALOTHRIN RESIDUES	CYHALOTHRIN MEAN	ENANTIOMER RESIDUES	ENANTIOMER MEAN
FORAGE	1	1.41, 1.65, 2.09, 2.67	2.0	0.17, 0.21, 0.26, 0.26	0.22
	7	0.60, 1.01, 1.32, 1.57	1.1	0.09, 0.17, 0.20, 0.21	0.17
	14	0.19, 0.28, 0.40, 0.63	0.38	0.04, 0.04, 0.07, 0.12	0.07
HAY	1	2.75, 3.58, 5.02, 5.55	4.2	0.26, 0.36, 0.43, 0.50	0.39
	7	1.70, 2.21, 2.64, 2.84	2.3	0.25, 0.28, 0.35, 0.37	0.31
	14	0.54, 0.68	0.61	0.08, 0.10	0.09
FORAGE	1	1.38, 1.80, 2.21, 3.77	2.3	0.19, 0.20, 0.23, 0.39	0.25
	7-8	0.67, 0.86, 0.97, 1.44	0.98	0.08, 0.12, 0.14, 0.18	0.13
	14	0.27, 0.28, 0.40, 0.90	0.46	0.04, 0.05, 0.06, 0.13	0.07
HAY	1	1.62, 3.73, 4.28, 9.42	4.8	0.21, 0.43, 0.45, 0.92	0.50
	7-8	1.25, 1.88, 2.10, 2.85	2.0	0.20, 0.28, 0.30, 0.34	0.28
	14	0.40, 0.48, 0.70, 1.31	0.72	0.07, 0.07, 0.10, 0.16	0.10

LAMBDA-CYHALOTHRIN & ENANTIOMER (PPM) AFTER GROUND APPLICATION TO ALFALFA					
CROP	PHI	LAMBDA-CYHALOTHRIN RESIDUES	CYHALOTHRIN MEAN	ENANTIOMER RESIDUES	ENANTIOMER MEAN
FORAGE	1	0.62, 0.71, 1.63	0.99	0.07, 0.16, 0.16	0.13
	7	0.43, 0.67, 0.76	0.62	0.06, 0.10, 0.12	0.09
	13-14	0.36, 0.37, 0.38	0.37	0.06, 0.06, 0.06	0.06
HAY	1	2.63, 4.42, 5.06	4.0	0.22, 0.43, 0.50	0.38
	7	1.48, 1.80, 2.20	1.8	0.18, 0.22, 0.27	0.22
	13-14	1.19, 1.28, 1.53	1.3	0.14, 0.17, 0.20	0.17

DATA FROM APPLICATION STUDY 032-90-MR-08 PERFORMED IN CUTLER, CA; INCONIUM, IA; AND EAGER, ID

MAXIMUM LAMBDA-CYHALOTHRIN & ENANTIOMER (PPM) AFTER GROUND APPLICATION TO ALFALFA					
CROP	STATE	PHI	LAMBDA CYHALOTHRIN	ENANTIOMER	TOTAL RESIDUE: LAMBDA CYHALOTHRIN + ENANTIOMER
FORAGE	IA	1	3.77	0.39	4.16
	CA	7	1.57	0.21	1.78
	IA	14	0.90	0.13	1.03
HAY	IA	1	9.42	0.92	10.34
	IA	7	2.85	0.34	3.19
	ID	13-14	1.53	0.20	1.73

DATA FROM APPLICATION STUDY 032-90-MR-08 PERFORMED IN CUTLER, CA; INCONIUM, IA; AND EAGER, ID

LAMBDA-CYHALOTHRIN & METABOLITES (PPM) AFTER ALFALFA GROUND APPLICATION				
ALFALFA FORAGE (PHI= 1 DAY) FROM GROUND APPLICATION STUDY				
STATE	LAMBDA-CYHALOTHRIN ICIA0321	ENANTIOMER R157836	PP890 3-PHENOXYBENZYL ALCOHOL	3-PBA 3PHENOXYBENZYL ACID
KS	0.81	0.10	0.03	0.02
MI	1.0	0.13	NA	NA
MN	1.9	0.26	0.06	0.04
MT	1.0, 1.1	0.13, 0.14	NA	NA
NY	2.2, 2.3	0.31, 0.44	0.07	0.04
SD	1.4, 1.7	0.22, 0.26	NA	NA
WI	1.6, 1.6	0.20, 0.28	NA	NA
CA	2.0, 2.0	0.21, 0.26	0.07, 0.07	0.04, 0.04
NE	1.2, 1.2, 1.2, 1.3	0.17, 0.17, 0.21, 0.22	NA	NA
MAX	2.3	0.44	0.07	0.04
ALFALFA HAY (PHI= 7 DAYS) FROM GROUND APPLICATION STUDY				
KS	1.5	0.24	0.34	0.29
MI	1.2	0.19	NA	NA
MN	0.22, 0.23	0.07, 0.08	0.24	0.22
MT	1.9, 2.5	0.28, 0.35	NA	NA
NY	1.6	0.26	0.20	0.14
SD	2.0, 2.3	0.33, 0.38	NA	NA
WI	1.1	0.16	NA	NA
CA	3.4	0.44	0.31, 0.34	0.29, 0.30
NE	1.0	0.17	NA	NA
MAX	3.4	0.44	0.34	0.30

NA = NOT ANALYZED, DATA ARE FROM STUDY 0321-90-MR1

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LAMBDA-CYHALOTHRIN & METABOLITES (PPM) AFTER ALFALFA AERIAL APPLICATION*				
STATE	LAMBDA-CYHALOTHRIN ICIA0321	ENANTIOMER R157836	PP890	3-PB ACID
ALFALFA FORAGE (PHI= 1 DAY) FROM AERIAL APPLICATION STUDY*				
AZ	1.9	0.41	0.04	0.05
CA	1.0	0.21	NA	NA
SD	0.78, 0.83	0.06, 0.07	NA	NA
WI	3.6, 4.6	0.91, 0.97	0.04	0.06
MAX	3.8	0.97 TOTAL MAX. LAMBDA- CYHALOTHRIN AND ENANTIOMER = 4.8 PPM	0.04	0.06
ALFALFA HAY (PHI= 7 DAYS) FROM AERIAL APPLICATION STUDY*				
AZ	0.32	0.06	0.09, 0.13	0.12, 0.14
CA	2.2	0.38	NA	NA
SD	1.5	0.28	NA	NA
WI	4.6, 4.9	0.97, 0.98	0.30	0.32
MAX	4.9	0.98 TOTAL MAX. LAMBDA- CYHALOTHRIN AND ENANTIOMER = 5.8 PPM	0.30	0.32

* NA = NOT ANALYZED, DATA FROM AERIAL APPLICATION STUDY, 03221-90-MR-04

Although the quantity, quality and geographic representation appear to be adequate, the submitted residue data do NOT support the proposed tolerances on alfalfa forage of 3.0 ppm and alfalfa hay of 4.0 ppm.

The maximum total residue for lambda-cyhalothrin and enantiomer observed in/on alfalfa forage, at the proposed 1 day PHI, was 4.8 ppm. The maximum total residue for lambda-cyhalothrin and enantiomer observed in/on alfalfa hay, at the proposed 7 day PHI, was 5.9 ppm. Both values exceed the requested tolerances for combined residues of lambda-cyhalothrin and enantiomer of 3.0 ppm for alfalfa forage and 4.0 ppm for alfalfa hay.

Conclusion

The submitted residue data do not support the proposed tolerances on alfalfa. The petitioner should submit a revised section F which proposes tolerances of 5.0 in alfalfa forage and 6.0 ppm in alfalfa hay.

Leaf Lettuce

Eight field trials on leaf lettuce were conducted in eight States in 1990. Field trials were conducted on leaf lettuce in AZ, CA, CO, FL, MI, NY, TX and WA, representing EPA geographical Regions 1, 3, 5, 6-7, 9, 10, 11-12. Ten applications of lambda-cyhalothrin were made to leaf lettuce at the 0.03 lb ai/A rate, for a seasonal total of 0.3 lb ai/A, the proposed maximum use rate. The interval between applications varied, but a PHI of 1 day was observed, in accordance with the proposed label. Residues were reported on leaf lettuce with the outer leaves of the leaf intact and with the outer leaves removed. (MRID 437810-01).

Samples of leaf lettuce were analyzed using ICI Method 81 for residues of parent lambda-cyhalothrin and its epimer. In addition samples were analyzed for two metabolites. Samples were stored frozen at < -20 C for a period of up to 727 days. Maximum combined residues of lambda-cyhalothrin and epimer in forage (at the proposed 1 day PHI) were 1.8 ppm with the leaves intact and 0.9 ppm with the leaves removed. Based on these data, lambda-cyhalothrin residues should not exceed 2.0 ppm in leaf lettuce.

LAMBDA-CYHALOTHRIN & ENANTIOMER (PPM) AFTER GROUND APPLICATION TO LEAF LETTUCE *				
STATE	ICIA0321 CYHALOTHRIN	R157836 ENANTIOMER	PP890 3PB-ALCOHOL	3-PBA 3PB-ACID
RESIDUES PRESENT WITH OUTER LEAVES OF LEAF LETTUCE INTACT				
AZ	1.3	0.12	0.23	0.15
CA	1.2, 0.94	0.11, 0.08	NA	NA
CO	1.7	0.12	0.52	0.15
FL	0.69	0.08	NA	NA
MI	0.78	0.06	0.24	0.14
NY	1.3	0.12	0.31	0.16
TX	0.52	0.05	NA	NA
WA	0.24, 0.36	0.03, 0.03	NA	NA

LAMBDA-CYHALOTHRIN & ENANTIOMER (PPM) AFTER GROUND APPLICATION TO LEAF LETTUCE *				
MAX	1.7	0.12	0.52	0.16
RESIDUES PRESENT WITH OUTER LEAVES OF LEAF LETTUCE REMOVED				
STATE	ICIA0321 CYHALOTHRIN	R157836 ENANTIOMER	PP890 3PB-ALCOHOL	3-PBA 3PB-ACID
AZ	0.40, 0.54	0.06, 0.08	NA	MA
CA	0.65	0.06	NA	NA
CO	0.72	0.09	NA	NA
FL	0.52, 0.38	0.07, 0.08	NA	NA
MI	NA	NA	NA	NA
NY	0.83	0.09	NA	NA
TX	0.46	0.05	NA	NA
WA	0.34	0.03	NA	NA
MAX	0.83	0.09	NA	NA

NA = NOT ANALYZED

Conclusion

The submitted residue data are adequate in quantity, quality and geographic representation to support the proposed tolerance of 2.0 ppm lambda-cyhalothrin and its epimer on leaf lettuce.

Head and Stem Brassica Crop Subgroup

No additional residue crop field data were provided for the head and stem Brassica crop subgroup in the current submission. Reference was made to the existing time-limited tolerances of 0.4 ppm for lambda-cyhalothrin and its epimer in/on the Brassica crops, cabbage and broccoli.

Requested tolerances for residues of lambda-cyhalothrin and its epimer were 0.4 ppm for the head and stem Brassica crop subgroup.

CBTS could recommend for a crop subgroup 5A tolerance for the head and stem Brassica crop subgroup. (NOTE: This is not a tolerance for the leafy Brassica greens crop subgroup 5B and not for the entire Brassica crop group).

Conclusion

The referenced residue data are adequate in quantity, quality and geographic representation to support the proposed tolerance of 0.4 ppm lambda-cyhalothrin and its epimer on the head and stem Brassica crop subgroup 5A.

MEAT, MILK, POULTRY, AND EGGS:

Alfalfa forage, hay, meal and silage are animal feed items for beef and dairy cattle. Alfalfa meal is a feed item for poultry and swine. No feed items are involved with the proposed uses on leaf lettuce and the head and stem Brassica crop subgroup.

The current time-limited tolerances for lambda-cyhalothrin and its epimer are as follows, according to the EPA's August, 1996, version of the "Tolerance Index System." The published tolerances in the 1995 40CFR 180.438, included below in *italics*, are out-of-date, since they were established 7/5/95 (i.e., four days after publication of the CFR).

meat of cattle, goats, hogs, horses, and sheep-
0.2 ppm
(*listed in 1995 40CFR180.438 as 0.01 ppm*)

meat of poultry 0.01 ppm
(*not listed in 1995 40CFR180.438*)

mbyp of cattle, goats, hogs, horses & sheep- 0.2 ppm
(*listed in 1995 40CFR180.438 as 0.01 ppm*)

mbyp of poultry- 0.01 ppm
(*not listed in 1995 40CFR180.438*)

fat of cattle, goats, hogs, horses, and sheep- 3.0 ppm
(*listed in 1995 40CFR180.438 as 0.02 ppm for all but hog fat, which was incorrectly listed in the 40CFR as 0.01 ppm*)

fat of poultry-0.01 ppm
(*not listed in 1995 40CFR180.438*)

milk fat 5.0 ppm (reflecting 0.2 ppm in whole milk) -
(*listed in 1995 40CFR180.438 as 0.25 ppm, reflecting 0.01 ppm in whole milk*)

eggs 0.01 ppm
(*not listed in 1995 40CFR180.438*)

Secondary Residue Calculations, Feeding Levels

Secondary dietary burdens for animal commodities were calculated using a realistic worst case diet and required alfalfa tolerances, as follows:

$$\Sigma (\% \text{ component in diet} \times \text{ppm}) / (\% \text{ Dry Matter}) = \text{ppm animal dietary burden}$$

CALCULATED REALISTIC WORST CASE SECONDARY DIETARY BURDENS FOR ANIMAL COMMODITIES			
% CROP IN DIET	TOLERANCE (PPM)	% DRY MATTER (DM)	DIETARY BURDEN (PPM)
BEEF CATTLE			
70% ALFALFA FORAGE	5.0	35%	10.00
20% ASPIRATED GRAIN FRACTIONS*	2.0	85%	0.47
10% CORN GRAIN FLOUR	0.15	85%	0.02
TOTAL BURDEN FOR BEEF CATTLE			10.5 PPM = TOTAL BURDEN FOR BEEF CATTLE
DAIRY CATTLE			
60% ALFALFA FORAGE	5.0	35%	8.57
20% SORGHUM GRAIN DUST	2.0	85%	0.47
20% CORN GRAIN FLOUR	0.15	85%	0.04
TOTAL BURDEN FOR DAIRY CATTLE			9.1 PPM = TOTAL BURDEN FOR DAIRY CATTLE
POULTRY			
10% ALFALFA MEAL	6.0	89%	0.67
80% SORGHUM GRAIN	0.2	86%	0.19

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CALCULATED REALISTIC WORST CASE SECONDARY DIETARY BURDENS FOR ANIMAL COMMODITIES			
% CROP IN DIET	TOLERANCE (PPM)	% DRY MATTER (DM)	DIETARY BURDEN (PPM)
10% CORN GRAIN	0.05	88%	0.01
TOTAL BURDEN FOR POULTRY			0.9 PPM = TOTAL BURDEN FOR POULTRY
SWINE			
10% ALFALFA MEAL	6.0 (AS FOR HAY)	89%	0.67
20% WHEAT GRAIN DUST	2.0	85%	0.47
70% SORGHUM GRAIN	0.2	86%	0.16
TOTAL BURDEN FOR SWINE			1.3 PPM = TOTAL BURDEN FOR SWINE

THE TOLERANCES IN THE 40 CFR SHOULD BE REVISED TO INCLUDE "ASPIRATED GRAIN FRACTIONS," AT 2.0 PPM LAMBDA-CYHALOTHRIN AND ITS EPIMER. THE TERM "GRAIN DUST" IS NOT USED. THE TOLERANCE FOR ASPIRATED GRAIN FRACTIONS INCLUDES A MIXTURE OF ALL ASPIRATED GRAINS FOR WHICH THE PESTICIDE HAS A TOLERANCE, AND SHOULD BE ESTABLISHED AT THE HIGHEST CURRENT TOLERANCE SET FOR ANY "GRAIN DUST," I.E., 2.0 PPM.

Average residues in poultry reflecting a 1 ppm feeding level for lambda-cyhalothrin (from PP# 7F3488, MRID #400279-14) were as follows (Dodd, 5/3/94):

	ppm
eggs	<0.005
liver	<0.005
muscle	<0.005
fat	0.025 (average of subcutaneous and abdominal fat)

Average residues in meat and milk of cattle reflecting a 1 ppm feeding level for lambda-cyhalothrin (from PP# 6F3318, Acc. #073982) were as follows (Dodd, 5/3/94):

	ppm
milk	0.02
muscle	0.01
fat	0.17 (average of subcutaneous and peritoneal)

liver 0.02
kidney 0.01

Residues reflecting calculated dietary burdens of 10.5 ppm for beef cattle; 9.1 ppm for dairy cattle; 0.9 ppm for poultry; and 1.3 ppm for swine were extrapolated from the data reflecting 1 ppm in the diet. From the data above, the maximum calculated residues expected for meat and milk are as follows (*cattle feeding residues used for goats, horses and sheep*):

meat of cattle, goats, hogs, horses, and sheep-
0.10 ppm
(current tolerance is 0.2 ppm)

meat of poultry-
<0.005 ppm
(current tolerance is 0.01 ppm)

liver of cattle, goats, hogs, horses, and sheep-
0.2 ppm
(current tolerance is 0.2 ppm)

kidney of cattle, goats, hogs, horses, and sheep-
0.10 ppm
(current tolerance is 0.2 ppm)

meat of poultry
<0.005 ppm
(current tolerance is 0.01 ppm)

fat of cattle, goats, hogs, horses, and sheep-
1.8 ppm
(current tolerance is 3.0 ppm)

fat of poultry
~~0.0225 ppm~~
(current tolerance is 0.01 ppm)

milk fat (reflecting 0.20 ppm in whole milk)-
5.00 ppm
(assuming milk is 4% fat and lambda-cyhalothrin is concentrated primarily in the fat of milk)
(current tolerance is 5.0 ppm for milk fat, reflecting 0.2 ppm in whole milk)

eggs-
<0.005 ppm
(current tolerance is 0.01 ppm)

Conclusions

Alfalfa forage, hay, meal and silage are animal feed items for beef and dairy cattle. Alfalfa meal is a feed item for poultry and swine. No feed items are involved with the proposed uses on leaf lettuce and the head and stem Brassica crop subgroup.

Established time-limited tolerances for animal commodities are adequate, *with the exception of poultry fat.*

The current time-limited tolerance for poultry fat for lambda-cyhalothrin of 0.01 ppm may be exceeded. An updated tolerance of 0.03 ppm for "poultry, fat" should be proposed in a revised Section F for lambda-cyhalothrin and its epimer.

The Petitioner must submit a revised Section F which proposes a tolerance of 2.0 ppm for "aspirated grain fractions."

OTHER CONSIDERATIONS

An International Residue Limit Status sheet is attached to this review. Since no Codex, Mexican or Canadian tolerances are established for lambda-cyhalothrin on/in alfalfa, lettuce and the Brassica crop group, there are no current compatibility problems. However, there are some CODEX limits for lambda-cyhalothrin (sum of isomers), and a Mexican expression exists for the parent, presumed.

ATTACHMENT 1: International Residue Limit Status Sheet

cc (with attachment 1): RF, L. Kutney, E. Haeberer, Adam Heyward (RD); George LaRocca (RD), Circu, PP# 4F04588
CM2:305-5351:RM804D/801:7509C:LLKutney:llk-8/14/96
RDI: TPT2: 8/14/96; N. Dodd:8/14/96;Loranger:8/19/96;E. Haeberer:8/26/96;